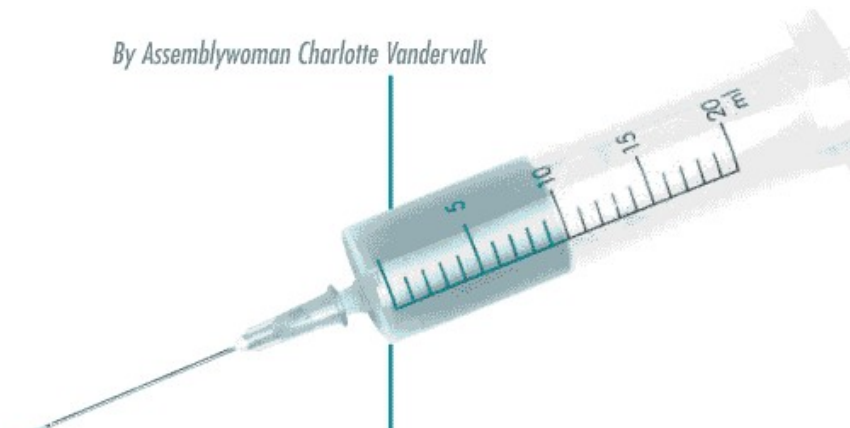


By Assemblywoman Charlotte Vandervalk



IMMUNIZATIONS: PROTECTING AN AT-RISK POPULATION

New Jersey mandates that our school children receive more immunizations than any other state in the U.S. Most of the time, these immunizations are uneventful, as they are usually administered to “healthy persons who have substantial expectations for the safety of the vaccines.”¹ However, the doctors at the National Immunization Program, Centers for Disease Control and Prevention (CDC) admit that “while their benefits far outweigh their risks and costs, no vaccine is perfectly safe.”² The CDC also acknowledges that a certain segment of the population is adversely affected by vaccinations. Yet, for New Jersey parents who fear that their child might be in that minority population, the state offers limited options for exemptions from the mandatory vaccination program. It is an all-or-nothing approach that perilously ignores the potential danger to at-risk children and their families.

Many feel that this all-or-nothing approach is a good thing. They feel that the safety of immunizations has been assured by testing before licensure. However, when the at-risk population is statistically so small, it is entirely possible that serious adverse effects might not present themselves in prelicensure testing. The CDC recognizes this problem and noted in a summary of the adverse events reported to the federal Vaccine Adverse Event Reporting System (VAERS) that “some adverse events are unlikely to be detected in pre-licensure clinical trials because of their low frequency,

the limited numbers of enrolled subjects and other study limitations.”³ The CDC concluded that “adverse events after vaccinations occur but are generally rare.”⁴

When VAERS was implemented in 1990, strategies were developed to attribute certain adverse reactions to certain vaccinations based upon the interval between the vaccine and the reaction. “For seizures following the DTP vaccine, events were included if they occurred within three days of vaccination; this was to differentiate them from seizures caused by the measles-mumps-rubella (MMR) vaccine, which tend to occur after six days following vaccination. For seizures following the MMR vaccine, events were included if they occurred between 6 and 30 days of vaccination.”⁵

Data from surveillance studies on VAERS reporting show that “during 1991 – 2001, reports of deaths ranged from 1.4 percent to 2.3 percent, and reports of life-threatening illness ranged from 1.4 percent to 2.8 percent of all adverse event reports.”⁶ These studies may, however, be limited because in many cases – especially deaths – the event is categorized as some other condition, such as sudden infant death syndrome (SIDS), and is never reported to VAERS.

MONETARY COMPENSATION FOR INJURIES

Because of the potential liability from these adverse reactions, the federal government established a National Vaccine

Injury Compensation Program (NVICP) as a no-fault compensation alternative, and the federal government holds harmless the vaccine manufacturers, those providers who administer vaccines and the governments that mandate them. The NVICP compensates for specific adverse events that can be attributable to vaccinations and, to date (from FY1990 to 2009), has paid out \$939,064,953.83 in petitioners' award amounts. Also, to date, 994 deaths have been reported to the NVICP.⁷ Acknowledged under-reporting of vaccine-associated adverse events (VAAEs) could indicate that far more awards could be given if all the adverse effects cases were accurately reported.

The Hannah Poling case is perhaps the most well-known award given by the NVICP. It was determined that Hannah had an underlying mitochondrial disorder that caused her to react adversely to her vaccinations. The case was settled out-of-court, and Hannah's father, a neurology resident at Johns Hopkins Hospital, noted that "there was no debate that vaccines had risks. They're not safe for everybody, and one person for whom they proved unsafe happened to be my daughter."⁸ (More than 5,000 families are currently awaiting results from a special federal vaccine court hearing the same issue.)

The World Health Organization agrees with Poling's observation regarding the inherent risk of vaccines for some children and has noted that "it is incontestable that a small number of individuals are harmed by vaccines...what is known with certainty about the causality and pathogenesis of VAAEs is quite limited."⁹

Herein is the dilemma. We do not know what causes these severe reactions in this limited, at-risk population. Just who are these people for whom vaccines will not be safe? In most cases, we don't know until the reaction occurs. This is problematic for parents faced with state-imposed vaccination mandates, especially when directives from our governmental health agencies continue to evolve as research in this area progresses.

MERCURY STILL IN SOME VACCINES

Thimerosal is an illustrative example of the problem. Thimerosal is an ethylmercury (49.55 percent mercury by weight) preservative used in many vaccines. "In July 1999, the Public Health Service agencies, the American Academy of Pediatrics and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines

as a precautionary measure. Since 2001, with the exception of some influenza vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines."¹⁰ This precautionary approach was dropped in April 2002, when the FDA's Advisory Committee on Immunization Practices (ACIP) encouraged providers to vaccinate with trivalent influenza vaccine (TIV) all healthy children 6 to 23 months of age. In 2003, the ACIP moved from encouraging this thimerosal-containing vaccine to recommending it. While a 2005 FDA review of VAERS data on inactivated influenza vaccinations among children less than two years of age supported immunization, the FDA also noted that the review provided only generally reassuring, although limited, data regarding the safety of TIV among children in this age range and called for continued surveillance for seizures and other clinically significant adverse effects.¹¹

Thimerosal is still being used in flu vaccines, and New Jersey is now the first state in the nation to mandate annual flu and pneumonia shots for those in preschool. For the majority of the children, these immunizations will be medically uneventful, but not for all. However, given the medically acknowledged at-risk segment of the population and our state's standing as having the highest per-capita population of developmentally delayed children in the country, is it any wonder that parents are upset?

Most medical decisions are made with informed consent. A school nurse or teacher cannot give an aspirin to a child without parental approval. The CDC advises that "anyone who takes a vaccine should be fully informed about both the benefits and the risks of vaccination."¹² Yet the fact that our vaccination program for school children is mandatory makes

informed consent superfluous. Parents can be informed of the risks, but have no legal right to say no if they feel the risks are too great. It would appear that the federal government, with the creation of the NVICP and the VAERS, has consciously accepted the responsibility for that small segment of the population adversely affected by immunization and has determined

that financial compensation is the only option. Yet, a monetary award cannot truly compensate for a lifelong disability or for the emotional and physical stress that can accompany such a condition for both the child and the family.

MEDICAL EXEMPTIONS TOSSED OUT

New Jersey law allows for religious and medical exemptions from immunizations. The medical exemption must be



“IF WE CANNOT EASILY IDENTIFY CHILDREN WITH METABOLIC DISORDERS OR THOSE WHO ARE IMMUNOCOMPROMISED IN SOME WAY, HOW CAN THE STATE MANDATE, OVER PARENTAL OBJECTION, THAT VACCINATIONS BE ADMINISTERED WITHOUT ALLOWING FOR SOME TYPE OF CONSCIENTIOUS EXEMPTION? ”

based upon certain guidelines from the CDC and the American Academy of Pediatrics (AAP). However, oftentimes this medical exemption, signed by a physician, is tossed out by local authorities who overrule the physician.

Recently, a parent contacted my office after her daughter had been hospitalized with paralysis following an immunization. The parent was extremely upset and worried because the school district had rejected the medical exemption letter from the family doctor and was now requiring that her son receive the same vaccination. The son was traumatized, and the parent could not face the anguish and expense of another potential hospitalization. The daughter's severe reaction might help her to obtain a medical exemption for that specific immunization for a limited period of time in the future, but her reaction does not exempt her or her siblings from further immunization requirements.

Present medical exemption guidelines are also inadequate because it is not yet standard practice to evaluate the metabolic health of newborns before immunizations begin. We have to wait until the child is harmed to discover that – for that child – that vaccination is not safe. Without advance knowledge of a child's evolving neurologic health, can a physician administer a vaccination confident that he or she is not violating the oath to do no harm? The physician is left to accept the safety of immunizations for *all* children and administer the vaccine to *all* children unless it has been clinically shown for the specific child that it is contraindicated. How many doctors have accepted this general standard only to discover after the fact, as in the case of Hannah Poling, that the child had an underlying condition that placed the child at a high risk? We must find a way to identify these at-risk children before they are immunized.

It would seem reasonable to seek to identify any commonalities among those in this at-risk population so that preimmunization testing could be done. In addition, accommodations must be made for those who have already been identified as being in a high-risk category for an adverse event after routine immunizations, such as “immunocompromised individuals and those with a previous history of anaphylaxis after a previous vaccine administration. ...Another possible high-risk group is that of individuals with metabolic disorders. However, a detailed analysis of the published English-language medical literature revealed little or no information regarding special considerations for

immunization of patients with inborn errors.”¹³

If we cannot easily identify children with metabolic disorders or those who are immunocompromised in some way, how can the state mandate, over parental objection, that vaccinations be administered without allowing for some type of conscientious exemption? As a result of the new additional vaccinations mandated by the New Jersey Public Health Council, some parents who believe that their children are at risk have actually chosen to move to neighboring Pennsylvania – a state where a physician's signed exemption does not get overruled, and a state that has not experienced widespread epidemics as a result of those exemptions.

OTHER STATES OFFER CHOICE

Eighteen states (Arkansas, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Texas, Utah, Vermont, Washington and Wisconsin) allow some type of philosophical or conscientious exemption from vaccinations. These 18 states contain over 50 percent of the U.S. population, meaning that half of the people in the country already have immunization choice. States such as California and Texas

maintain this choice even though their states feature highly mobile populations. The few disease outbreaks in those states are generally clustered among the unimmunized. In 2005, a report stated that “currently, the rate of religious and philosophical exemption to mandatory childhood vaccination is very small. Nationally, the rate of exemption is only 0.64 percent, and

prior to 2000, the rate of exemption did not exceed 2.5 percent in any one state. **These numbers have led the National Vaccine Advisory Committee to conclude that religious and philosophical exemptions do not pose a threat to public health.**”¹⁴


UNTIL SCIENCE ADVANCES, PARENTS NEED CHOICE

New Jersey has an obligation to protect the rights of the minority population that is at risk for severe adverse reactions to vaccinations. Until such time as these children can be readily identified, the state should allow religious, medical and conscientious exemptions from mandatory immunizations as called for in my Assembly Bill #260. Under A-260, a student with a conscientious exemption would not be permitted to attend school during a disease outbreak or threatened



outbreak. Also, the commissioner could suspend the conscientious exemption in an emergency, and a school administrator, taking into consideration the spread of a communicable disease, could prohibit the attendance of a student with a conscientious exemption and specify the amount of time the student must remain away from the school.

Only in this way can the state protect the majority without violating the rights of this minority until more is known about the underlying conditions that define this minority group. Efforts need to be undertaken to focus on prevaccination testing so that this at-risk population can be identified *before* the immunization schedule begins and *before* any potential harm can occur. Until such time as science discovers what makes these children more at-risk than others, their parents should be allowed the right to protect their children through a conscientious objection.

Assemblywoman Vandervalk is currently serving her seventh term in the Assembly. Many of her legislative efforts have been targeted toward protecting the health of New Jersey's citizens. She is a member of the Assembly's Consumer Affairs Committee and Housing and Local Government Committee. 

¹ Zhou, W., Pool, V., Iskander, J. K., English-Bullard, E., & VAERS Working Group. (2003). Surveillance for safety after immunization: Vaccine Adverse Event Reporting System (VAERS)—United States, 1991-2001. *Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report*. www.cdc.gov/MMWR/PREVIEW/MMWRHTML/ss5201a1.htm.

² Rosenthal, S., & Chen R. (1995). The reporting sensitivities of two passive surveillance systems for vaccine adverse events. *American Journal of Public Health*, 85, 1706-1709. www.ajph.org/cgi/reprint/85/12/1706.

³ Zhou, W., Pool, V., Iskander, J. K., English-Bullard, E., & VAERS Working Group. (2003). 1.

⁴ Zhou, W., Pool, V., Iskander, J. K., English-Bullard, E., & VAERS Working Group. (2003). 1.

⁵ Rosenthal, S., & Chen R. (1995). 1707.

⁶ Zhou, W., Pool, V., Iskander, J. K., English-Bullard, E., & VAERS Working Group. (2003). 7.

⁷ U.S. Department of Health and Human Services. (2009). *National vaccine injury compensation program*. http://www.hrsa.gov/Vaccinecompensation/statistics_report.htm.

⁸ Harris, G. (2008, March 8). Deal in an autism case fuels debate on vaccine, *The New York Times*.

www.nytimes.com/2008/03/08/us/08vaccine.html.

⁹ Ward, B. J. (2000). Vaccine adverse events in the new millennium: Is there reason for concern? *Bulletin of the World Health Organization*, 78(s), 205-215. [www.who.int/bulletin/archives/78\(2\)205.pdf](http://www.who.int/bulletin/archives/78(2)205.pdf).

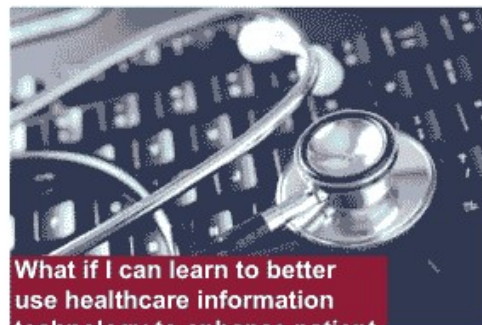
¹⁰ Department of Health and Human Services, Centers for Disease Control and Prevention. (2008, June 23). *Mercury and vaccines—Thimerosal*. www.cdc.gov/vaccinesafety/concerns/thimerosal.htm.

¹¹ McMahon, A. W., Iskander, J., Haber, P., Chang, S., Woo, E. F., Braun, M. M., et al. (2005, February). Adverse events after inactivated influenza vaccination among children less than 2 years of age: Analysis of reports from the vaccine adverse event reporting system, 1990 - 2003, *Pediatrics*, 115(2), 453-460.

¹² Department of Health and Human Services, Centers for Disease Control and Prevention. (2008, July 22). *Vaccine safety and adverse events*. www.cdc.gov/vaccines/vac-gen/safety.

¹³ Department of Health and Human Services, Centers for Disease Control and Prevention. (2008, July 22).

¹⁴ May, T., & Silverman, R. D. (2005). Free-riding, fairness and the rights of minority groups in exemption from mandatory childhood vaccination. *Human Vaccines*, 1(1), 12-15. <http://www.landesbioscience.com/journals/vaccines/article/maHV1-1.pdf>.



What if I can learn to better use healthcare information technology to enhance patient care and improve outcomes?

You can.

STEVENS

Institute of Technology

Wesley J. Howe School of Technology Management

Learn more today.

Visit <http://howe.stevens.edu/hith> or contact Carol V. Brown, Ph.D., program director, by phone (201-216-5581) or email (hitm@stevens.edu).