Governor’s Task Force on Autism Spectrum Disorders

Task Force Requests to the Florida Department of Health
September 10, 2008

Dear Task Force Members,

Florida Department of Health would like to thank Governor Charlie Crist and the members of the Autism Task Force for giving us the opportunity to respond to your questions and provide you with information about immunizations. The health and safety of our children, as well as all Floridians, are top priorities of the Department of Health.

Immunizations prevent serious diseases and their associated complications. The Department of Health continually monitors all information and reports relating to immunizations and wants to ensure their safety for all Floridians. The United States currently has the safest, most effective vaccine supply in history. Years of testing are required by law before a vaccine can be licensed. Once in use, vaccines are continually monitored for safety and their effectiveness.

The Department has researched your questions and provided individual summaries and associated data in the attached notebook.

I hope the information provided offers clarity regarding the importance and safety of immunizations. We value partnerships with community advocates, such as you, and hope that together we can protect, promote, and improve the health of our children.

Sincerely,

Jean L. Kline, R.N., B.S.N., M.P.H.
Deputy Secretary for Health – Public Health Programs
State Public Health Nursing Director
Task Force Requests to the Florida Department of Health
Re: Immunizations and Related Data

1. Develop a side-by-side chart of CDC and Florida vaccinations schedule and recommendations and highlight differences.

2. List of vaccinations generally, then broken down by fatal and non-fatal illnesses

3. List of vaccine-preventable illnesses, incidence and outcome (number of cases and number of deaths)

4. A list of all vaccines and the years they were introduced into the schedule of Florida.

5. Pre and post 1980 vaccine schedules (comparison, list of all vaccinations received since 1980 and when added to the vaccine schedule)

6. Investigate other states’ opt-outs for non fatal vaccinations that have been added in the last 20 years.

7. Question which vaccines given to children under age of two still have thimerosal? Flu shot still has thimerosal? Did DOH mandate that all vaccines have none? How long has this been in place? (2003)?

8. Data on numbers of vaccine preventable diseases for the 18 states with philosophical exemptions.

9. State breakdown of school entry immunization exemptions, broken down by type and uptake rate.

10. DOH/DOE the number of unvaccinated people in Florida, and incidence. Funding epidemiological study.

11. Risk of waiting until 24 or 30 months to introduce immunizations.
Millions of people have benefited from vaccines for more than two centuries. The history of vaccines and immunization began in the 1790s with Edward Jenner’s creation of the world’s first vaccine for smallpox. Before the existence of vaccines, diseases such as smallpox, measles, rubella, diphtheria, polio, and pertussis (whooping cough) were common childhood killers and left many survivors disabled for life. Fortunately, in Florida and the United States, these devastating diseases have been almost eliminated due to the widespread use of safe, effective, and affordable vaccines. In fact, smallpox, a disease that has caused countless suffering and death for centuries, was eradicated worldwide through vigorous vaccination programs. There is little else in medicine that can compare to this achievement. With concerted effort, other diseases, such as polio and measles (a disease that infects approximately thirty million children per year, killing approximately 750,000 of them), can similarly be eradicated.

Public health professionals and the World Health Organization (WHO) rank immunizations in the top ten health achievements of the past century. Immunization is as important as the development of safe drinking water and public sanitation practices. Vaccines protect infants, children, and adults from the unnecessary harm and premature death caused by a number of severe communicable diseases. Vaccination is the single most effective communicable disease prevention strategy. Vaccines are also among the most cost-effective medical interventions available, providing huge savings in direct medical care costs, as well as indirect costs such as lost time from work and school. Unlike other areas of health care, widespread immunization has effectively leveled racial-ethnic disparities in this country.

Florida’s child care and school entry immunization requirements ensure that students are protected against communicable diseases in settings where such diseases are easily transmitted. When most children are immunized, even vulnerable children, who are not able to be immunized due to medical reasons, are protected. This concept, known as “herd immunity,” is the key to the low levels of vaccine-preventable diseases in Florida, nationally and in most developed countries. Herd immunity occurs when a large proportion of the population (85–98% depending on the disease) receives vaccine against a disease. Such high immunization coverage rates protect susceptible individuals in a group because, due to immunity in most of the group, transmission of disease cannot be sustained.

The fact that early childhood immunization and child care/school entry immunization requirements lead to herd immunity, is an important reason for their effectiveness in reducing the spread of communicable diseases. The huge reductions now seen in most of the vaccine-preventable diseases did not occur until states implemented school and child care immunization
entry requirements. Without herd immunity, those who are too young to be immunized, and/or have medical or religious contraindications to immunization, and/or have diseases that cause immunodeficiency, would all be at much greater risk for infections and their sequelae. That is, when fewer children are immunized, then children who cannot be immunized are much more vulnerable to getting infected with a disease—a disease that can be prevented when most people are immunized.

Section 1003.22 of the Florida Statutes requires immunization for school entry and attendance, and allows for medical (temporary and permanent) or religious exemption from immunizations. The Florida child care and school entry immunization requirements cover public and private schools, childcare facilities, and family childcare homes. They are in accordance with the recommendations from the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association. These organizations set the standard of care and practice that health care providers, health plans, and insurance companies follow with respect to providing immunizations.

Florida Statutes require specific immunizations for infants and children who attend child care, family childcare homes, pre-kindergarten and school. Immunization entry requirements for school and child care settings relate to factors such as whether the disease is communicable in child care and school settings, whether the vaccine has been on the market long enough to assess for previously undetected side effects, and whether the vaccine is covered by insurance and health plans.

Immunization safety is of utmost concern to parents, health care providers, the public health community, legislators and vaccine manufacturers. Vaccines undergo rigorous and lengthy testing for both safety and efficacy prior to approval by the Food and Drug Administration (FDA). Today’s vaccines are much more pure than those produced decades ago. This increased purity has the effect that the total number of antigens (from the vaccines themselves and from other substances in the vaccine preparation) introduced to the body is much less, even as the number of recommended vaccines has increased.

Concerns about vaccine safety have been addressed since the time when vaccines were first introduced. Public health authorities and governmental bodies must balance the right to immunize for the “common good” with individual rights and concerns. The U.S. Supreme Court, in 1905, ruled in Jacobson v. Massachusetts that the need to protect the public health through compulsory smallpox vaccination outweighed the individual’s right to privacy. This justification is consistently applied to child care and school entry immunization requirements, with allowances for religious beliefs and medical conditions.

Recently, some parents and vaccine safety advocacy groups have raised questions about a purported link between Autism Spectrum Disorders (ASD) and vaccines. Factors such as the preservative thimerosal (previously used in diphtheria, tetanus, pertussis, Haemophilus influenzae type b, and hepatitis B vaccines); the MMR (measles, mumps, rubella) vaccine; and the number, timing and spacing of vaccines have all been suggested at one time or another as causing or triggering ASD.

Because of these concerns, the medical and public health communities have sought to rigorously examine the scientific evidence for or against an association between vaccines and ASD. Authoritative evidence-based recommendations for or against medical screenings and
interventions increasingly set the standard of care. The evidence must come from convincing scientific studies—i.e., methodologically rigorous, of high statistical power and subjected to critical peer review prior to publication. Thus, medical interventions where harms outweigh benefits are quickly abandoned, while those demonstrating that the benefits outweigh harms are adopted and promoted.

The scientific studies addressing vaccine safety are too numerous to describe here but the Department of Health has compiled a bibliography (included in the Supporting Documents Section) of many of the pertinent studies. Similarly, a critique of the quality of the various studies is beyond the scope of this document. However, in summary, the reviews of the scientific literature by recognized medical and public health authorities, such as the prestigious Institute of Medicine (IOM), indicate that vaccines are not associated with ASD. The IOM is part of the United States National Academy of Sciences, a nongovernmental, not-for-profit organization chartered to provide national advice on issues relating to biomedical science, medicine, and health. It uses a volunteer workforce of scientists and has a formal peer review process. Thus, it works outside the framework of the U.S. federal government to provide independent guidance and analysis. In their report “Immunization Safety Review: Vaccines and Autism,” the IOM Immunization Safety Review Committee stated “…the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism. The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism. The committee further finds that potential biological mechanisms for vaccine-induced autism that have been generated to date are theoretical only.” Similarly, the WHO’s Global Advisory Committee on Vaccine Safety reviewed the evidence and released a July 2006 statement concluding that “there is no evidence of toxicity in infants, children or adults exposed to thimerosal (containing ethyl mercury) in vaccines.”

Despite the many scientific studies that demonstrated no causal connection between thimerosal and ASD, in July 1999, U.S. Public Health Service agencies and the American Academy of Pediatrics recommended that thimerosal be removed from vaccines as a precautionary measure aimed at reducing any additional exposure to mercury. Today, all vaccines recommended for use in infants and young children are available in forms that have no or only trace amounts of thimerosal. The term “trace” in this context means 1 microgram (1 millionth of a gram) of mercury per dose or less. To put this into context, according to an FDA survey of commercial seafood, a 6 oz can of albacore tuna contains, on average, 60 micrograms of mercury.

Methyl mercury, from sources such as seafood and coal plant emissions, is a well known toxicant. It is not readily eliminated by the human body and therefore accumulates and poses health risks. On the other hand, ethyl mercury (from thimerosal) is more rapidly metabolized and eliminated so poses much less risk. Referring again to the WHO’s 2006 statement, “…the pharmacokinetic profile of ethyl mercury is substantially different from that of methyl mercury. The half-life of ethyl mercury is short (less than one week) compared to methyl mercury (1.5 months), making exposure to ethyl mercury in blood comparatively brief. Further, ethyl mercury is actively excreted via the gut, unlike methyl mercury that accumulates in the body.”

A robust immunization program has tremendous benefit to individual and public health. Calls for opposing immunizations and/or school entry vaccination requirements, or for providing easier and more numerous ways to obtain exemptions for required vaccinations, are resulting in growing numbers of individuals not properly immunized. This, in turn, is leading to increases in outbreaks of vaccine preventable disease such as measles and pertussis. This is occurring not just in the United States but in a number of developed countries such as the Netherlands, Great Britain,
Switzerland, France and Israel. In fact, Great Britain has recently had to rescind its 1980’s declaration that measles was no longer endemic (that is, children in Great Britain can now contract measles even if no new cases are brought in from the outside). Thus, children and adults in developed nations are increasingly suffering from significant illness, disability and death due to vaccine-preventable diseases. With the ease and volume of international travel today, Florida is highly vulnerable to the importation of such diseases, especially if the number of children immunized, and herd immunity levels, decline.

The suggestion that immunizations might lead to developmental disorders is troubling to parents. It is important that Florida’s parents have access to and clear explanations of the recent findings published in medical journals that confirm that there is no causal link between vaccines and autism or other neurological conditions. The Florida Department of Health supports efforts by the CDC and others to identify the biological and environmental causes of autism and other developmental disabilities. The Florida Department of Health monitors all issues pertaining to immunizations and stays abreast of all vaccine research in order to stop vaccine-preventable diseases without compromising the health and safety of children and adults. The Florida Department of Health and the CDC place a high priority on vaccine safety and the integrity and credibility of vaccine safety research.
Questions and Answers on Immunizations
The best way to protect each of our children is to protect all of our children.

Why do we immunize our children?

- To protect them from disease, disability, and death.
  In the pre-vaccine era, diseases that are now vaccine-preventable were major causes of life-long disability as well as death.
- To save on health care costs, including out-of-pocket expenses by the family.
- To protect other children who are not immune from our children if our children develop one of the vaccine-preventable diseases.
  — This includes children for whom vaccines are not safe, who are too young to be immunized, in whom the vaccine did not work, or who are not immunized for other reasons.

Why do we keep immunizing children when the diseases are gone?

- The reason we have so few cases in the US is that our immunization levels are so high.
- All the vaccine-preventable diseases (except smallpox) still occur in the rest of the world, at rates higher than in the US, and most still occur in the US at low levels, especially in underimmunized populations.
- Any of these diseases can be reintroduced into any community in the US at any time. Florida receives very large numbers of visitors, from all over the world.

How do vaccines protect children who have not been immunized?

- If almost all children in a population are immune to a disease, a child who does develop the disease will be surrounded by immune children, and the spread of infection will stop.
- With slightly lower immune rates, the outbreak may not stop by itself, but public health prevention activities such as isolating cases and giving antibiotics, vaccines or immune globulin to contacts can stop the outbreak.

How effective are vaccines?

- The vaccines in common use against vaccine-preventable diseases are all highly effective. Some are close to 100% effective, some as low as 85%.
- Only vaccines that have been determined to be effective at preventing spread of the disease in the population are used in the United States. Before a vaccine is recommended for widespread use, a careful assessment is made by a national expert panel, based on the best available science. The panel assesses the seriousness of the disease if it is not prevented, the vaccine’s effectiveness in preventing the disease, and the frequency and consequences of adverse reactions to the vaccine. A vaccine is recommended to be included in the national immunization schedule when, on balance, the benefit to the whole community of routine immunization with that vaccine is much greater than the risks.
Why do we require immunization for attendance in child care or public school?

- Most vaccine-preventable diseases spread easily where children are gathered together. Getting the immunization coverage rate close to 100% can stop outbreaks from spreading if the disease is introduced.

- High immunization coverage protects the few children who are not immune to the disease.
  —Non-immune children at child care or school include those who have medical reasons why vaccines are not safe for them, those in whom the vaccine did not work, those with religious exemptions to immunization, and those too young to have received certain vaccines.

- A few children are not protected against some of the diseases they were immunized against. Going to child care or school with other immunized children protects these children.

Is it fair to require children to be immunized to attend child care or school?

- High immunization levels protect both the immunized children and the few who are not immune.

- Child care and school immunization laws have been shown to be a very effective way to achieve and maintain very high immunization coverage levels.

- In effect, society has made an agreement: I agree to immunize my child if you agree to immunize yours. All the children benefit from their own protection against serious diseases, and also from being surrounded by immune children.

- Some children experience side effects to vaccine doses they receive. Most are mild, a few rare ones are not. No vaccine is totally free of side effects, though all have improved over the years as researchers have helped manufacturers to refine their manufacturing processes.

- All children benefit from the vaccines, including the doses they have received themselves and the ones other children have received, but only a few develop severe side-effects.
  —Compensation mechanisms are in place for injured children and their families—the National Vaccine Injury Compensation Program, and compensation lawsuits.

Why do we have religious exemptions to immunization requirements?

- Almost all states have such exemptions.

- Having religious exemptions strikes a balance among respect for the genuine convictions of some families, the desire for all children to have access to public schools, and the desire to protect all residents of our communities from infectious diseases.

- As long as the proportion of children in a school who receive religious exemptions is very low, it is still possible to attain high overall coverage and protect all the children in the school.

- If there are cases of one of the vaccine-preventable diseases in a childcare center or school, all unimmunized children will be excluded for the duration of the outbreak. Children with either medical or religious exemptions will be excluded. Taking this step reduces, but does not eliminate, the hazard to the other children of allowing some children to attend schools without being immunized.
Develop a side-by-side chart of CDC and Florida vaccinations schedule and recommendations and highlight differences

The Florida Department of Health adopts, coordinates, and recommends the routine Childhood and Adolescent Immunization Schedules in accordance with the recommendations of the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

- The ACIP Recommended Immunization Schedules are recognized as a standard of practice by physicians, healthcare providers, state immunization programs and other entities involved in immunizations.
- There are no differences between the CDC recommended immunization schedule and that of Florida.
- Immunization schedules are updated each year for healthcare providers to refer to and share with parents when planning the medical preventive care of their infants and children.
- While many immunizations are licensed and recommended by CDC for routine medical care, it is important to note that NOT all of the routinely recommended immunizations are required for entry/attendance in Florida schools. It is important to distinguish the difference between which immunizations are recommended for routine medical care and which are required for school.
- Immunization requirements for school are set by grade level in contrast to age groups listed on the recommended schedule. This uniform requirement facilitates all children having the most protection as medically possible for many diseases that can be transmitted in the classroom.

—One example is the diphtheria-tetanus-pertussis-containing vaccine (Dtap): While the 5th dose of Dtap is recommended for children 4 to 6 years of age, the 5th dose is required for entry into Kindergarten. Traditionally, children entering Kindergarten are 5 to 6 years of age. A copy of the routine recommended schedule is included in this section.

The following table details the recommended immunizations in contrast to those required for school.

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Routine CDC/ACIP Immunization Recommendations</th>
<th>Florida Child Care and School Immunization Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria-Tetanus-Pertussis (DTaP)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hepatitis A (HepA)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B (HepB)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Haemophilus influenza type b (Hib)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Influenza (Flu)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Meningococcal (MCV4)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Measles-Mumps-Rubella (MMR)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pneumococcal (PCV)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Poliovirus (IPV)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Tetanus-Diphtheria (Td)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Varicella</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
The following table further illustrates the number of vaccines available for prevention of certain communicable diseases in contrast to the vaccines that are required for child care and school and the year the requirement was introduced.

<table>
<thead>
<tr>
<th>CDC Recommended Immunization Schedule for Persons Aged 0–19 Years</th>
<th>Year Immunization Requirements First Initiated for Florida Schools K to 12 and Child Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UNITED STATES, 2008</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Birth</strong></td>
<td><strong>2 mos</strong></td>
</tr>
<tr>
<td>DTaP</td>
<td></td>
</tr>
<tr>
<td>Flu</td>
<td>Annual</td>
</tr>
<tr>
<td>Hep A</td>
<td></td>
</tr>
<tr>
<td>Hep B</td>
<td>X</td>
</tr>
<tr>
<td>Hib</td>
<td>X</td>
</tr>
<tr>
<td>HPV</td>
<td></td>
</tr>
<tr>
<td>Meningitis</td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td></td>
</tr>
<tr>
<td>MR</td>
<td></td>
</tr>
<tr>
<td>Pneumo</td>
<td>X</td>
</tr>
<tr>
<td>Polio</td>
<td>X</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>X</td>
</tr>
<tr>
<td>Td</td>
<td></td>
</tr>
</tbody>
</table>

Florida recommends immunizations in accordance with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics and the American Academy of Family Physicians. All ACIP routinely recommended immunizations are not mandated for entry/attendance in Florida schools. MR: Measles & Rubella (Phased out with licensure of the MMR). MMR: Measles, Mumps & Rubella. NR: Not Required.
List of vaccinations generally, then broken down by fatal and non-fatal illnesses

List of vaccine-preventable illnesses, incidence and outcome (number of cases and number of deaths)

While some vaccine-preventable diseases are of short duration and without serious complications, the viruses and bacteria that cause these diseases can all result in serious complications, long-term disabilities, and even death.

Varicella (chickenpox) is one example: Most children and adults experience an uncomfortable inconvenience with a low-grade fever and rash and no serious complications from varicella. However, a small percent of children and adults experience complications such as secondary skin infections, pneumonia, meningitis, encephalitis, and possible death.

Varicella vaccine was licensed in 1995. When a new vaccine is introduced it is often slow to be fully utilized, this was the case with varicella vaccine. To note: during 1998, Florida reported six deaths from acute varicella. Two of the adult deaths were linked to children in the home and one child was exposed in the classroom. In contrast, one death was reported in Florida in 2006 from varicella.

The following tables provide a brief description of the diseases and case information pre and post immunization for the U.S. and Florida.

### Historical Comparison of Vaccine-Preventable Disease Cases and Deaths with Vaccine Licensure from 1900 to 2006. (U.S.: Estimated Annual Averages.)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Pre-Vaccines</th>
<th>Post-Vaccines (2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases/Year</td>
<td>Deaths/Year</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>20,000</td>
<td>2,160</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>1,822</td>
</tr>
<tr>
<td>H. influenzae (Hib)</td>
<td>20,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>117,333</td>
<td>137</td>
</tr>
<tr>
<td>Hepatitis B (Acute)</td>
<td>66,232</td>
<td>237</td>
</tr>
<tr>
<td>Invasive Pneumonia</td>
<td>63,067</td>
<td>6,500</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>440</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>39</td>
</tr>
<tr>
<td>Pertussis</td>
<td>200,752</td>
<td>4,034</td>
</tr>
<tr>
<td>Polio (Acute)</td>
<td>19,794</td>
<td>1,393</td>
</tr>
<tr>
<td>Polio (Paralytic)</td>
<td>16,316</td>
<td>1,879</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>17</td>
</tr>
<tr>
<td>Smallpox</td>
<td>29,005</td>
<td>337</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>472</td>
</tr>
<tr>
<td>Varicella (chickenpox)</td>
<td>4,085,120</td>
<td>105</td>
</tr>
<tr>
<td>Total</td>
<td>5,399,558</td>
<td>20,572</td>
</tr>
</tbody>
</table>
Another vaccine success story relates to the prevention of Haemophilus influenzae type B (Hib) disease. Prior to the introduction of an effective vaccine to prevent this disease, Hib was the leading cause of meningitis among children younger than 5 years of age with about two-thirds of all cases occurring in children less than 18 months of age.

The following graph demonstrates the decrease in Hib disease for children less than 5 following the licensure of Hib vaccine.
The state of Florida has experienced a large population boom since the early 1900s. In fact, the population in 2007 (18,762,014 residents) was more than 11 times the population of 1934 (1,585,596 residents). This drastic change in population makes it difficult to make fair comparisons of the burden of vaccine-preventable diseases over time, as a larger population would be expected to have a larger number of cases, all else being equal. To address this, we have used the 2007 population (18,762,014 residents) to estimate the number of cases that would have been reported for each year, had the population size been comparable to the 2007 population. This “standardized” estimate was calculated by dividing the 2007 population by the population for a given historical year to get a population ratio. The number of cases reported for that given year was multiplied by the population ratio. For example, the 2007 population (18,762,014 residents) was 10.1 times the population in 1939 (1,853,660 residents). The number of cases reported in 1939 was multiplied by 10.1 to estimate the number of cases that would have been reported in 1939 if the 1939 population was equal to the 2007 population.

The following table (Table 1) presents a summary of these standardized estimates of select vaccine-preventable disease cases occurring in census years for 1940 to 2000. These standardized estimations are represented in the charts on the following pages as a dashed line. The actual number of cases reported for each year is represented in the charts as a solid line. Note that as the population size approaches the 2007 population, the dashed line and the solid line converge.

This drastic change in population makes it difficult to make fair comparisons of the burden of vaccine-preventable diseases over time, as a larger population would be expected to have a larger number of cases, all else being equal.

<table>
<thead>
<tr>
<th>Rates from</th>
<th>Diphtheria</th>
<th>Measles</th>
<th>Mumps</th>
<th>Whooping cough</th>
<th>Polio</th>
<th>Rubella</th>
<th>Smallpox</th>
<th>Tetanus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1940</td>
<td>2,185</td>
<td>22,581</td>
<td>2,596</td>
<td>3,752</td>
<td>323</td>
<td>1,479</td>
<td>69</td>
<td>167</td>
</tr>
<tr>
<td>1950</td>
<td>645</td>
<td>16,620</td>
<td>9,657</td>
<td>3,133</td>
<td>3,133</td>
<td>299</td>
<td>0</td>
<td>286</td>
</tr>
<tr>
<td>1960</td>
<td>274</td>
<td>15,362</td>
<td>16,476</td>
<td>1,587</td>
<td>244</td>
<td>3,130</td>
<td>0</td>
<td>105</td>
</tr>
<tr>
<td>1970</td>
<td>38</td>
<td>4,160</td>
<td>8,309</td>
<td>260</td>
<td>0</td>
<td>9,828</td>
<td>0</td>
<td>44</td>
</tr>
<tr>
<td>1980</td>
<td>0</td>
<td>826</td>
<td>373</td>
<td>130</td>
<td>0</td>
<td>208</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>1990</td>
<td>1</td>
<td>855</td>
<td>281</td>
<td>84</td>
<td>0</td>
<td>24</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>2000</td>
<td>0</td>
<td>2</td>
<td>8</td>
<td>78</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
Reported and Standardized* Diphtheria Cases in Florida, 1934–2007

Reported and Standardized* H. influenzae Meningitis Cases in Florida, 1982–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,782,014. See the paragraph preceding these charts for a more detailed description of these calculations.


*Number of cases that would have occurred in Florida each year if Florida had a population of 18,782,014. See the paragraph preceding these charts for a more detailed description of these calculations.
Reported and Standardized* Measles Cases in Florida, 1934–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.

Reported and Standardized* Mumps Cases in Florida, 1935–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.
Reported and Standardized* Pertussis Cases in Florida, 1934–2007

Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.

Reported and Standardized* Polio Cases in Florida, 1934–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.
Reported and Standardized* Rubella Cases in Florida, 1937–2007

Reported and Standardized* Smallpox Cases in Florida, 1934–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 16,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.
Reported and Standardized* Tetanus Cases in Florida, 1935–2007

*Number of cases that would have occurred in Florida each year if Florida had a population of 18,762,014. See the paragraph preceding these charts for a more detailed description of these calculations.
Vaccine-Preventable Diseases

We have also taken this opportunity to provide descriptions of the vaccine-preventable diseases.

**Measles**

Measles is a highly contagious disease that is transmitted by respiratory droplets and airborne spread. Symptoms include rash, high fever, cough, runny nose, and red, watery eyes (lasts about a week). The disease can result in severe complications, including pneumonia, encephalitis, seizures, and death. Although measles is no longer a common disease in the United States, it remains widespread in most countries of the world, including some countries in Europe. Current outbreaks in the United States highlight the ongoing risk of measles importations from other countries by people who travel.

Measles causes ear infections in nearly one out of every 10 children who get it. As many as one out of 20 children with measles gets pneumonia, and about one child in every 1,000 who get measles will develop encephalitis. (This is an inflammation of the brain that can lead to convulsions, and can leave your child deaf or mentally retarded.) For every 1,000 children who get measles, one or two will die from it. Measles can also make a pregnant woman have a miscarriage, give birth prematurely, or have a low-birth-weight baby.

Before the measles vaccine became available, there were approximately 450,000 measles cases and an average of 450 measles-associated deaths were reported each year. Widespread use of measles vaccine has led to a greater than 99% reduction in measles cases in the U.S. compared with the pre-vaccine era.

**Mumps**

Mumps is an acute viral illness that is spread through direct contact with respiratory secretions or saliva. Symptoms include fever, headache, muscle aches, tiredness, and swelling of salivary glands. Severe complications are rare. However, mumps can cause encephalitis, meningitis, inflammation of the testicles (orchitis), ovaries and/or breasts (oophoritis and mastitis), spontaneous abortion, and deafness (which is usually permanent).
Rubella

Rubella is an acute viral disease that causes fever and rash and is spread by contact with an infected person, through coughing and sneezing. Complications include birth defects if the pregnant woman has rubella. An infant with congenital rubella syndrome may have the following: deafness, cataracts, heart defects, mental retardation, and liver and spleen damage (at least a 20% chance of damage to the fetus if a woman is infected early in pregnancy).

Tetanus

Tetanus is a disease of the nervous system caused by bacteria that enters the body through a break in the skin (not just a rusty nail). Symptoms include lockjaw, stiffness in the neck and abdomen; difficulty swallowing followed by severe muscle spasms, seizure-like activity, and severe autonomic nervous system disorders. Death occurs in about 10–20% of cases.

H Flu: Haemophilus influenzae type b (Hib) (Invasive)

H Flu is a disease which is most serious for children under age one. It is spread by coughing and sneezing. Symptoms are serious and include: meningitis, pneumonia, epiglotitis (a severe throat infection), skin infections, and arthritis. Children who survive Hib meningitis may develop permanent neurological disability, including brain damage, hearing loss, and mental retardation. 5% to 10% cases of Hib meningitis are at risk of dying.
Chickenpox (Varicella)

A disease caused by infection with the varicella zoster virus, which is spread by coughing and sneezing (highly contagious) and by direct contact. Symptoms include rash with blister-like lesions and fever. Serious complications from chickenpox include bacterial infections which can involve many sites of the body including the skin, tissues under the skin, bone, lungs (pneumonia), joints, and blood. Other serious complications are due directly to infection with the varicella-zoster virus and include viral pneumonia, bleeding problems, and infection of the brain (encephalitis). Many people are not aware that before a vaccine was available approximately 10,600 persons were hospitalized and 100 to 150 died as a result of chickenpox in the U.S. every year.

Pneumococcal disease

Pneumococcal disease is a leading cause of serious illness in children and adults throughout the world leading to ear infections, pneumonia, bacteremia (an infection in the bloodstream), and meningitis. It is one of the most common causes of death in America from a vaccine-preventable disease. Children less than 5 years old in childcare programs are at 2 to 3 times more likely to experience invasive pneumococcal infections than children in home care.

Whooping Cough (Pertussis)

Pertussis can be a serious illness, particularly for babies and young children. More than 50% of babies with reported cases of pertussis must be hospitalized. Coughing can be so severe that it is hard for babies to eat, drink or breathe.

- Babies may bleed behind the eyes and in the brain from coughing.
- The most common complication is bacterial pneumonia. About 1 child in 10 with pertussis also gets pneumonia, and about 1 in every 50 will have convulsions.
- Brain damage occurs in 1 out of every 250 children who get pertussis.
- Pertussis causes about 10–20 deaths each year in the United States.
Hepatitis B

Hepatitis B is a serious disease caused by a virus that attacks the liver and can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. It is contracted when someone is exposed to blood from an infected person. Infants are at risk if their mother is infected prior to or during birth; other risks include occupational exposure through needlesticks, having sex with an infected person, and by sharing drugs, needles, or "works" when injecting drugs.

Polio

Polio is an infectious disease caused by a virus that lives in the throat and intestinal tract. It is most often spread through person-to-person contact with the stool of an infected person and may also be spread through oral/nasal secretions.

Polio was one of the most dreaded childhood diseases of the 20th Century in the United States. There were usually about 13,000 to 20,000 cases of paralytic polio reported each year in the US before the introduction of Salk inactivated polio vaccine (IPV) in 1955. Polio peaked in 1952 when there were more than 21,000 reported cases. The number of cases of polio decreased dramatically following introduction of the vaccine and the development of a national vaccination program. In 1965, only 61 cases of paralytic polio were reported compared to 2,525 cases reported cases just five years earlier in 1960.

The last cases of naturally occurring paralytic polio in the United States were in 1979, when an outbreak occurred among the Amish in several Midwestern states. From 1980 through 1999, there were 152 confirmed cases of paralytic polio cases reported. Of the 152 cases, eight cases were acquired outside the United States and imported. The last imported case caused by wild poliovirus into the United States was reported in 1993.

Sources: http://www.cdc.gov/vaccines/vpd-vac/vpd-list.htm
http://phil.cdc.gov/phil/home.asp
http://www.vaccineinformation.org/photos/
Florida adopts the same Routine Childhood and Adolescent Immunization Schedules as published by the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP).

- The schedules contain recommended immunizations, ages and spacing to assist healthcare providers plan preventive healthcare with parents for their children.
- Immunizations are provided as a standard of care by the healthcare provider irrespective of school entry requirements.
- Vaccination is one of a small group of medical interventions with direct and simultaneous benefits to individuals and communities. The more vaccinated individuals there are in a community, the greater the protection against disease. This is called herd immunity.
- School immunization laws were first established to control outbreaks of smallpox and are now used to avoid epidemics of vaccine-preventable contagious diseases, such as measles and pertussis (whooping cough) that can be spread in the close contact of the classroom.
- It is important to note that not all of the immunizations on the routine schedule are required for child care and schools in Florida. There is often confusion between what is recommended as part of medical care and what is required for school.

The table below illustrates the increased number of vaccines since 1980 that are available to prevent a greater number of communicable diseases and the complications that may develop.

<table>
<thead>
<tr>
<th>Vaccines in the Routine Childhood and Adolescent Schedule Pre and Post 1980</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>*Diphtheria-Tetanus-Pertussis (DTaP)</td>
</tr>
<tr>
<td>*Haemophilus influenzae type b (Hib)</td>
</tr>
<tr>
<td>*Hepatitis B</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV)</td>
</tr>
<tr>
<td>Influenza (Flu)</td>
</tr>
<tr>
<td>*Measles-Mumps-Rubella (MMR)</td>
</tr>
<tr>
<td>Meningococcal (MCV4)</td>
</tr>
<tr>
<td>*Pneumococcal (PCV)</td>
</tr>
<tr>
<td>*Polio</td>
</tr>
<tr>
<td>Rotavirus</td>
</tr>
<tr>
<td>*Varicella</td>
</tr>
</tbody>
</table>

* Immunizations required by Florida for school and/or child care
Investigate other states’ opt-outs for non-fatal vaccinations that have been added in the last 20 years.

While there are no states to date that have laws in place for an “Opt-Out” for a specific vaccine, 18 states have laws allowing philosophical exemption for immunizations. In contrast, 47 states provide exemptions for religious beliefs and one state provides for religious exemption from immunizations in child care and pre-K only.

- Florida provides exemptions from immunization for religious beliefs and medical reasons as identified by the child’s healthcare provider.
- Public health balances its responsibility to provide appropriate immunization exemptions while also protecting the susceptible, un-immunized students from exposure in the classroom. If this balance is lost, the possible outcome would be pockets of diseases that should be prevented by vaccine. While most people do not suffer severe complications, all vaccine-preventable-diseases may result in a fatal outcome.

The immunization coverage rate for the MMR vaccine is high in Florida and nationally as well. However, public health remains vigilant to any significant drop in these coverage rates in order to protect children and adults from measles, mumps and rubella. Florida has experienced small outbreaks in communities that have low or no immunization coverage rates.

Great Britain has experienced a rise in measles and mumps case reduction because fewer parents are immunizing their children.

- Immunization rates in England dropped and the number of measles and mumps cases rose significantly following a publication in The Lancet of a 1998 paper and the subsequent media coverage that suggested an association with the combination measles, mumps and rubella vaccine—MMR—and the development of autism.
- 2007 saw the highest number of measles cases recorded in England and Wales since the current method of monitoring the disease was introduced in 1995.
- The Lancet article was withdrawn following further scientific review.
- Low vaccine uptake over the past decade means there is now a large group of children who either haven’t been vaccinated or who have received just one dose. These children are susceptible to not only measles but to mumps and rubella as well.
- While immunization levels were reduced from 92% to 85%, measles cases increased from 112 to 958 for the years 1995 to 2007.
- Fearing the vaccine more than the disease: the graphs on the following page reflect the decrease in the percent of 2-year-olds in England who received at least one dose of MMR, and the rise in the cases of measles and mumps reported. Source: Health Protection Agency, United Kingdom.
Public confidence in England for the MMR vaccine is now high with more than 8 out of 10 children receiving one dose of MMR by their second birthday. While the percentage of children being vaccinated is rising again, England has had to declare measles and mumps endemic again as it will take years to reverse the disease trend.
Which vaccines given to children under the age of two still have thimerosal? Flu shot has thimerosal? Did DOH mandate that all vaccines have none? How long has this been in place?

Which vaccines given to children under the age of two still have thimerosal? Flu shot has thimerosal? Routinely recommended childhood vaccines have not contained thimerosal as a preservative since 2001. All vaccines for children under the age of two are available without thimerosal. Table 1, produced by the U.S Food and Drug Administration, lists all vaccines routinely recommended for children 6 years of age and younger. This table illustrates the absence of thimerosal as a preservative in childhood vaccines.

- According to data, there is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, 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.

- There are licensed flu vaccines available for infants 6 months and older that are thimerosal free.

How long has this been in place?

- As a precautionary measure, the U.S. Public Health Service (including the FDA, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), and the American Academy of Pediatrics issued two Joint Statements, urging vaccine manufacturers to reduce or eliminate thimerosal in vaccines as soon as possible (CDC 1999 and CDC 2000). The U.S. Public Health Service agencies have collaborated with various investigators to initiate further studies to better understand any possible health effects from exposure to thimerosal in vaccines.

- At present, all routinely recommended vaccines for U.S. infants are available only as thimerosal-free formulations or contain only trace amounts of thimerosal (≤1 micrograms mercury per dose), with the exception of inactivated influenza vaccine. Inactivated influenza vaccine for pediatric use is available in a thimerosal-preservative containing formulation and in formulations that contain either no thimerosal or only a trace of thimerosal, but the latter is in more limited supply (see Table 1). All pediatric vaccines in the routine infant immunization schedule are manufactured without thimerosal as a preservative. As of January 14, 2003, the final lots of vaccines containing thimerosal as a preservative expired. These changes have been accomplished by reformulating products as more expensive single dose vials that do not contain a preservative.

Did DOH mandate that all vaccines have none? There is no DOH mandate regarding thimerosal in vaccines. Bills were introduced by the legislators during the last few sessions and were not passed. The Florida Department of Health provides and recommends thimerosal-free vaccine for children.

Thimerosal. Thimerosal is a mercury-containing organic compound. Since the 1930s (Powell, 1931), it has been widely used as a preservative in a number of biological and drug products, including many vaccines, to help prevent potentially life threatening contamination with harmful microbes. It has been used to kill bacteria and prevent contamination in antiseptic ointments,
creams, jellies, and sprays used by consumers and in hospitals, including nasal sprays, eye drops, contact lens solutions, immunoglobulins, vaccines, antivenins, and tattoo inks. Thimerosal does not reduce the potency of the vaccines that it protects (Baker 2008).

Thimerosal is metabolized or degraded to ethylmercury and thiosalicylate. Ethylmercury is an organomercurial that should be distinguished from methylmercury, a substance that has been the focus of considerable study.

<table>
<thead>
<tr>
<th>Ethylmercury is not methylmercury—Significant Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methyl Mercury</strong></td>
</tr>
<tr>
<td><strong>Health risk</strong></td>
</tr>
<tr>
<td>Toxic chemical; scientific evidence of health risk</td>
</tr>
<tr>
<td><strong>Sources</strong></td>
</tr>
<tr>
<td>Toxic chemical found in the environment and food:</td>
</tr>
<tr>
<td>• Coal power plant emissions in air and water</td>
</tr>
<tr>
<td>• Seafood</td>
</tr>
<tr>
<td><strong>Amount</strong></td>
</tr>
<tr>
<td>60 µg in one 6 oz can of albacore tuna</td>
</tr>
<tr>
<td><strong>Metabolism</strong></td>
</tr>
<tr>
<td>Accumulates in body</td>
</tr>
<tr>
<td><strong>Exposure (half-life)</strong></td>
</tr>
<tr>
<td>1.5 months</td>
</tr>
</tbody>
</table>
Table 1. Thimerosal Content of Vaccines Routinely Recommended for Children 6 Years of Age and Younger (FDA website http://www.fda.gov/cber/vaccine/thimerosal.htm—accessed 8/1/2008)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Tradename (Manufacturer)</th>
<th>Thimerosal Status</th>
<th>Approval Date for Thimerosal Free or Thimerosal/Preservative Free (Trace Thimerosal)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP</td>
<td>Infanrix (GlaxoSmithKline Biologicals)</td>
<td>Free</td>
<td>Never contained more than a trace of thimerosal, approval date for thimerosal-free formulation 9/29/2000</td>
</tr>
<tr>
<td>Daptacel (Sanofi Pasteur, Ltd)</td>
<td>Free</td>
<td></td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Tripedia (Sanofi Pasteur, Inc)</td>
<td>Trace (≤0.3 µg Hg/0.5mL dose)</td>
<td>03/07/01</td>
<td>Never contained more than a trace of Thimerosal, approval date for thimerosal-free formulation 1/29/2007</td>
</tr>
<tr>
<td>DTaP-HepB-IPV</td>
<td>Pediarix (GlaxoSmithKline Biologicals)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Pneumococcal conjugate</td>
<td>Prevnar (Wyeth Pharmaceuticals Inc)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Inactivated Poliovirus</td>
<td>IPOL (Sanofi Pasteur, SA)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Varicella (chickenpox)</td>
<td>Varivax (Merck &amp; Co, Inc)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Mumps, measles &amp; rubella</td>
<td>M-M-R-II (Merck &amp; Co, Inc)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Recombivax HB (Merck &amp; Co, Inc)</td>
<td>Free</td>
<td>08/27/99</td>
</tr>
<tr>
<td></td>
<td>Engerix B (GlaxoSmithKline Biologicals)</td>
<td>Free</td>
<td>03/28/00, approval date for thimerosal-free formulation 1/30/2007</td>
</tr>
<tr>
<td>Haemophilus influenzae type b conjugate (Hib)</td>
<td>ActHIB (Sanofi Pasteur, SA)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td></td>
<td>OmniHIB (GlaxoSmithKline)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td></td>
<td>PedvaxHIB (Merck &amp; Co, Inc)</td>
<td>Free</td>
<td>08/99</td>
</tr>
<tr>
<td></td>
<td>HibTITER, single dose (Wyeth Pharmaceuticals, Inc.)1</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Hib/Hepatitis B combination</td>
<td>Comvax (Merck &amp; Co, Inc)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
<tr>
<td>Influenza</td>
<td>Fluzone (Sanofi Pasteur, Inc)</td>
<td>0.01% (12.5 µg/0.25 mL dose, 25 µg/0.5 mL dose)2</td>
<td>12/23/2004</td>
</tr>
<tr>
<td></td>
<td>Fluzone (Sanofi Pasteur, Inc)3 (no thimerosal)</td>
<td>Free</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluvinin (Novartis Vaccines and Diagnostics Ltd)</td>
<td>0.01% (25 µg/0.5 mL dose)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluvinin (Novartis Vaccines and Diagnostics Ltd)</td>
<td>Trace (&lt;1ug Hg/0.5mL dose)</td>
<td>09/28/01</td>
</tr>
<tr>
<td></td>
<td>Preservative Free</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza, live</td>
<td>FluMist (MedImmune Vaccines, Inc)</td>
<td>Free</td>
<td>Never contained Thimerosal</td>
</tr>
</tbody>
</table>

* Since this update, Rotavirus Vaccine was licensed, that is thimerosal free.
** Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 mL dose or 25 µg of Hg per 0.5 mL dose.
*** The term “trace” has been taken in this context to mean 1 microgram of mercury per dose or less.
1 HibTITER was also manufactured in thimerosal-preservative containing multidose vials but these were no longer available after 2002.
2 Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.
3 A trace thimerosal containing formulation of Fluzone was approved on 9/14/02 and has been replaced with the formulation without thimerosal.
References


Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, Clarkson T, “Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal,” Environmental Health Perspectives Volume 113, Number 8, August 2005.

Federal Register, January 19, 1979, 44: 3990.
Federal Register, November 19, 1999, 64: 63323-63324.


Internet resources

http://www.fda.gov/cber/vaccine/thimerosal.htm
http://www.cdc.gov/flu/about/qa/thimerosal.htm
http://www.immunizationinfo.org/thimerosal_mercury_detail.cfv?id=136
http://www.immunizationinfo.org/thimerosal_mercury_detail.cfv?id=3
http://iaomt.org/testfoundation/thimcontent.htm
The Task Force wanted data on numbers of vaccine preventable diseases for the 18 states with philosophical exemptions.

Vaccine-preventable disease levels have been successfully reduced in the U.S. with the advent of immunizations. However, these diseases still exist and can once again become common—and deadly—if vaccination coverage does not continue at high levels. Even though most infants and toddlers have received all recommended vaccines by age 2, many under-immunized children remain, leaving the potential for outbreaks of disease.

The following table reflects the numbers of vaccine-preventable diseases for the 18 states with philosophical exemptions for immunizations. This data was provided by the Centers for Disease Control and Prevention (CDC). Florida data has been added to correspond with the data from the 18 states with philosophical exemptions.

- It is not possible to draw any conclusions about the effect of philosophical exemptions on disease rates from these data alone. Incidence rates (cases per 100,000 children per year) would have to be compared between states with and without philosophical exemptions.
- Such a comparison must take account of other factors in addition to the size of the population of children, such as introductions of disease from outside the U.S., and socio-economic factors.
- Experience has shown that, while reported case numbers may be low one year, introduction of a disease into a susceptible community can escalate into an outbreak very quickly.
- The CDC’s Morbidity and Mortality Weekly Report (MMWR) reported in its August 23, 2008, issue about the US measles experience for the first half of 2008. They state: “The number of measles cases reported during January 1–July 31, 2008, is the highest year-to-date since 1996. This increase was not the result of a greater number of imported cases, but was the result of greater viral transmission after importation into the United States, leading to a greater number of importation-associated cases. These importation-associated cases have occurred largely among school-aged children who were eligible for vaccination but whose parents chose not to have them vaccinated.”
- A 2006 paper published in the Journal of the American Medical Association (Omer SB, Pan WKY, Halsey NA et al: “Non-medical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence,” JAMA 2006, 296:1757–1763) showed that pertussis (whooping cough) incidence was 50% higher in states with easier availability of non-medical exemptions to school immunization requirements, and with available personal belief exemptions.
- A 2000 paper in the same journal (Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE: “Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization,” JAMA 2000, 284:3145–3150) showed that in Colorado, which has had a philosophical exemption since 1977, the risk of measles and pertussis is elevated 22-fold and 6-fold, respectively, in exemptors compared to vaccinated children. They also showed that the rate of measles in vaccinated children was higher in counties with high proportions of exemptors.
### 2006 Comparison of Vaccine-Preventable Disease Cases, Among States with Philosophical Exemptions for Immunizations, Florida and U.S.

<table>
<thead>
<tr>
<th>2006</th>
<th>Measles*</th>
<th>Mumps**</th>
<th>Rubella*</th>
<th>Tetanus*</th>
<th>Pertussis**</th>
<th>Hep B-acute*</th>
<th>Polio (paralytic)*</th>
<th>Diphtheria**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>0</td>
<td>40</td>
<td>0</td>
<td>1</td>
<td>508</td>
<td>u</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Arkansas</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>112</td>
<td>87</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>California</td>
<td>6</td>
<td>31</td>
<td>1</td>
<td>11</td>
<td>1,749</td>
<td>427</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Colorado</td>
<td>1</td>
<td>51</td>
<td>0</td>
<td>0</td>
<td>710</td>
<td>34</td>
<td>0</td>
<td>0</td>
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<td>Idaho</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>88</td>
<td>15</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Louisiana</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>24</td>
<td>63</td>
<td>0</td>
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<td>Maine</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>174</td>
<td>26</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Michigan</td>
<td>1</td>
<td>84</td>
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<td>3</td>
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<td>320</td>
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</tr>
<tr>
<td>New Mexico</td>
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<td>0</td>
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</tr>
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<td>14</td>
<td>0</td>
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<tr>
<td>Ohio</td>
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<td>3</td>
<td>644</td>
<td>123</td>
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<td>0</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>1</td>
<td>64</td>
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<td>58</td>
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<td>1</td>
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<td>Vermont</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>110</td>
<td>4</td>
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<td>2</td>
<td>42</td>
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<td>0</td>
<td>377</td>
<td>74</td>
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<tr>
<td>Wisconsin</td>
<td>0</td>
<td>842</td>
<td>0</td>
<td>0</td>
<td>221</td>
<td>33</td>
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<tr>
<td>Total of states above</td>
<td>11</td>
<td>1,423</td>
<td>2</td>
<td>26</td>
<td>7,656</td>
<td>2,039</td>
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<td>0</td>
</tr>
<tr>
<td>Florida</td>
<td>4</td>
<td>15</td>
<td>1</td>
<td>2</td>
<td>228</td>
<td>420</td>
<td>0</td>
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<tr>
<td>U.S. Total</td>
<td>55</td>
<td>6,584</td>
<td>11</td>
<td>41</td>
<td>15,632</td>
<td>4,713</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Confirmed Cases  **Confirmed and Probable Cases
Provide a state breakdown of school entry immunization exemptions, broken down by type and uptake rate.

All fifty states have medical exemptions to vaccines, such as a serious allergy to a vaccine component. Forty-eight states, including Florida, provide for religious exemptions. Additionally, there are 18 states that have philosophical exemptions for school entry. Two additional states have a philosophical exemption for child care entry only.

- Vaccines are recommended by the Centers for Disease Control and Prevention (CDC) and professional societies, such as the American Academy of Pediatrics. These organizations make science based recommendations; states set requirements, usually when children enter child-care centers and elementary schools as entry requirements. These requirements help prevent the spread of communicable diseases in these group settings.

- School immunization requirements have largely contributed to a significant drop in diseases and the complications that can be prevented by immunizations. Before the measles vaccine, measles caused 100,000 American children to be hospitalized and 3,000 to die every year. In the early 1970s, public health officials found that states with vaccine mandates had rates of measles that were 50 percent lower than states without mandates.

- Florida balances the need to protect the health of students in the classroom while respecting those with a religious opposition to immunizations. During an outbreak, any child who does not have protection against that specific disease is excluded from school. This includes children who have either medical or religious exemptions.

- The finding that lower immunization rates caused higher rates of disease shouldn’t be surprising. In 1991 a massive epidemic of measles in Philadelphia centered on a group that chose not to immunize their children; as a consequence nine children died from measles. And in 2005, a 17-year-old unvaccinated girl who unknowingly brought measles back with her from Romania attended a church gathering of 500 people in Indiana and caused the largest outbreak of measles in the United States in ten years; this outbreak was limited to children whose parents had chosen not to vaccinate them. These events showed that for contagious diseases like measles and pertussis, it’s hard for unvaccinated children to successfully hide among herds of vaccinated children.

The following table reflects school entry exemptions and school population data for the states with a philosophical exemption.
<table>
<thead>
<tr>
<th>State</th>
<th>Kindergarten</th>
<th></th>
<th></th>
<th></th>
<th>Middle School</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Children Enrolled</td>
<td>Children Surveyed</td>
<td>Medical</td>
<td>Religious</td>
<td>Philosophical</td>
<td>Children Enrolled</td>
<td>Children Surveyed</td>
<td>Medical</td>
</tr>
<tr>
<td>Arizona</td>
<td>90,719</td>
<td>89,915</td>
<td>166</td>
<td>0.2%</td>
<td>*</td>
<td>1,822</td>
<td>2.0%</td>
<td>87,089</td>
</tr>
<tr>
<td>Arkansas</td>
<td>36,790</td>
<td>36,790</td>
<td>16</td>
<td>0.0%</td>
<td>36</td>
<td>0.1%</td>
<td>123</td>
<td>0.3%</td>
</tr>
<tr>
<td>California</td>
<td>503,160</td>
<td>503,160</td>
<td>827</td>
<td>0.2%</td>
<td>*</td>
<td>*7,108</td>
<td>1.4%</td>
<td>NA</td>
</tr>
<tr>
<td>Colorado</td>
<td>64,468</td>
<td>956</td>
<td>*</td>
<td>0.1%</td>
<td>55</td>
<td>5.6%</td>
<td></td>
<td>62,420</td>
</tr>
<tr>
<td>Idaho</td>
<td>21,663</td>
<td>21,663</td>
<td>65</td>
<td>0.3%</td>
<td>77</td>
<td>0.4%</td>
<td>538</td>
<td>2.5%</td>
</tr>
<tr>
<td>Louisiana</td>
<td>148,538</td>
<td>148,538</td>
<td>20</td>
<td>0.0%</td>
<td>*</td>
<td>*</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Maine</td>
<td>14,751</td>
<td>13,826</td>
<td>62</td>
<td>0.4%</td>
<td>15</td>
<td>0.1%</td>
<td>373</td>
<td>2.7%</td>
</tr>
<tr>
<td>Michigan</td>
<td>134,898</td>
<td>134,898</td>
<td>969</td>
<td>0.7%</td>
<td>499</td>
<td>0.4%</td>
<td>3,549</td>
<td>2.6%</td>
</tr>
<tr>
<td>Minnesota</td>
<td>67,337</td>
<td>67,337</td>
<td>382</td>
<td>0.6%</td>
<td>*</td>
<td>*3,919</td>
<td>5.8%</td>
<td>66,804</td>
</tr>
<tr>
<td>New Mexico</td>
<td>28,067</td>
<td>27,845</td>
<td>49</td>
<td>0.2%</td>
<td>*243</td>
<td>0.9%</td>
<td>*</td>
<td>27,220</td>
</tr>
<tr>
<td>North Dakota</td>
<td>7,641</td>
<td>7,092</td>
<td>11</td>
<td>0.2%</td>
<td>11</td>
<td>0.2%</td>
<td>46</td>
<td>0.6%</td>
</tr>
<tr>
<td>Ohio</td>
<td>150,212</td>
<td>148,112</td>
<td>392</td>
<td>0.3%</td>
<td>*</td>
<td>*1,232</td>
<td>0.8%</td>
<td>NA</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>49,348</td>
<td>48,220</td>
<td>81</td>
<td>0.2%</td>
<td>104</td>
<td>0.2%</td>
<td>194</td>
<td>0.4%</td>
</tr>
<tr>
<td>Texas</td>
<td>352,969</td>
<td>344,176</td>
<td>2,260</td>
<td>0.7%</td>
<td>*</td>
<td>*6,478</td>
<td>1.9%</td>
<td>331,513</td>
</tr>
<tr>
<td>Utah</td>
<td>47,486</td>
<td>46,062</td>
<td>93</td>
<td>0.2%</td>
<td>16</td>
<td>0.0%</td>
<td>1,176</td>
<td>2.6%</td>
</tr>
<tr>
<td>Vermont</td>
<td>6,838</td>
<td>6,838</td>
<td>20</td>
<td>0.3%</td>
<td>5</td>
<td>0.1%</td>
<td>164</td>
<td>2.4%</td>
</tr>
<tr>
<td>Washington</td>
<td>77,218</td>
<td>75,288</td>
<td>213</td>
<td>0.3%</td>
<td>106</td>
<td>0.1%</td>
<td>3,077</td>
<td>4.1%</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>71,298</td>
<td>1,560</td>
<td>5</td>
<td>0.3%</td>
<td>2</td>
<td>0.1%</td>
<td>25</td>
<td>1.6%</td>
</tr>
<tr>
<td>Florida</td>
<td>226,536</td>
<td>226,536</td>
<td>478</td>
<td>0.2%</td>
<td>1,249</td>
<td>0.6%</td>
<td>–</td>
<td>216,892</td>
</tr>
</tbody>
</table>

* Religious and Philosophical exemptions included together.

Information was obtained from the Centers for Disease Control and Prevention’s 2006-2007 School Entry Immunization Assessment Report—this report may be viewed at the following web address: http://www2.cdc.gov/nip/schoolsurv/rptgmenu.asp

Florida does not have an exemption for philosophical reasons.
DOH/DOE: The number of unvaccinated people in Florida and incidence. Funding an epidemiological study.

Data is not available to provide the number of unvaccinated people in Florida. Reporting of all immunizations administered in Florida into the centralized immunization registry is voluntary and not mandated by law.

The following provides a description and considerations for designing a study of vaccine exposure and autism spectrum disorders.

Summary

This document reviews options available for an epidemiologic study to address the question, “Is the rate of autism or autism spectrum disorders (ASDs) significantly lower in Florida children who have received no doses of any vaccine, than in children who have received one or more doses of vaccine?”

The smaller the difference one wants to detect in a study, the larger the needed number of study subjects is. Also, sample size has to be very large for a study where both the exposure (no vaccines) and the disease (autism) are uncommon. Such a study requires an adequate number of subjects who have both the exposure and the disease. Autism spectrum disorders taken together have a cumulative incidence of 5 to 10 children per 1000 by age 8, and receiving no vaccines is quite rare, at 1% or less of all children at age 2 to 3 years old. A study would likely have to include most or all autistic children in the state. There is no central registry of all these children, or of the vaccine status of all children.

The best option is an alternative cohort study design, in which immunization histories are obtained for all autistic children in a certain age range in a defined geographic area, and the size of the population of children with no or some doses of vaccine received by that age living in that area is estimated from immunization surveys. If a wide enough age range of children is included, and if significant data access issues can be resolved, it might be possible to do such a study in the geographic area covered by the CDC-sponsored University of Miami ASD prevalence project.

Because of the large sample sizes needed for any of these studies, they are likely to be expensive to carry out. While an exact dollar amount cannot be estimated without knowing precisely which question is to be answered, and thus what the details of the study design would be, it would be wise to assume such a study would take at least two years to complete.
Study questions

One interested party has described the study question as whether autism ever occurs in children who have received no vaccines. Since autism was first described as a syndrome in the early 20th century, before vaccines came into use, receipt of vaccines is not a necessary precursor to or cause of autism or autism spectrum disorders.

So perhaps the question can be reformulated as, “Is the rate of autism or autism spectrum disorders (ASDs) significantly lower in children who have received no doses of any vaccine, than in children who have received one or more doses of vaccine?”

A closely related question would be, “Is the rate of autism or ASDs greater in children in proportion to the number of doses of vaccines received?” While this latter question would have to be refined in an actual study design, the question would be whether children who have received 4 different injections have a higher rate than those who have received 3 injections, which in turn is higher than in those who have received 2, 1, or 0 injections. The measurement of vaccine exposure in such a study would also have to be refined to take account of the number of different antigens contained in each vaccine dose received.

The material that follows is based on answering the original question, about ASD risk associated with no vaccine versus any vaccine. Different questions may be of interest, for example comparisons of ASD risk in relation to the age at first dose of vaccine, or number of doses of vaccine or number of antigens received by a certain age, or the maximum number of antigens administered on any one visit. Addressing these would involve similar study designs and sample size considerations as those described here, but the details would be different. In particular, the needed level of detail about exact immunization histories needed for these alternative questions may not be available in the statewide 2-year-old survey and thus the best option mentioned above may not be feasible.

Study design options

In general, epidemiologic studies fall into three categories: cohort studies, case-control studies, and cross-sectional studies. All are designed to see if there is an association, not due to chance, between particular exposures and particular disease outcomes.

In cohort studies, people are enrolled based on whether they do or do not have a particular exposure or characteristic of interest, and then are followed over time to determine whether they develop the outcomes of interest. If there is an association between the exposure and the disease, there will be an increased rate of the disease in those with the exposure compared to the rate in those not exposed. Subjects must be enrolled as exposed or unexposed without any knowledge of their eventual outcome. Cohort studies can be prospective, where subjects are enrolled now and followed into the future, or historical, where subjects are enrolled retrospectively, often many years after the fact, and then followed until the present.

In case-control studies, people are enrolled based on whether or not they have a particular disease, and are then studied to determine whether they had certain exposures of interest in the past. If there is an association between the exposure and the disease, the proportion of those with the disease who have the exposure will be higher than the proportion among those without the
disease. Subjects must be enrolled as cases or controls without knowing whether they had the exposure of interest.

In cross-sectional studies, people are enrolled from a population without knowing whether they are exposed or not, and without knowing whether they have the disease of interest or not. This approach is commonly used in a random sample questionnaire survey of people from a population, for example the population of people who partook of a meal that was followed by a gastroenteritis outbreak, or the population of a town with a suspected waterborne disease outbreak.

Cohort studies are particularly useful with reasonably common diseases, and can be used to study multiple outcomes. They usually take a long time to complete, unless done as historical cohort studies. If the study is historical, the investigator usually has much less control over how exposure was measured or assessed. Cohort studies are very inefficient for rare diseases, because large numbers of subjects have to be enrolled to be reasonably sure an adequate number of cases will occur for study. Case-control studies are particularly useful with rare diseases, but again retrospective exposure assessment can be limiting. Case-control studies also require large sample sizes if the exposure is also rare.

Baseline data for Florida

Data from the Florida DOH annual random sample of two-year-old immunization levels show that quite consistently, from year to year, about 1% of Florida children aged 2 to 2.9 years old have received no doses of vaccine. A federal telephone survey carried out nationally each year suggests that the Florida percentage is much lower, with around 0.3% of children having no vaccine doses on board at age 2 to 2.9 years. That same federal study shows that children with no vaccines fall into three quite diverse groups: children with low-education, low-income parents who do not have access to health care services; children with high-education, high-income parents, who have access to health care services but do not immunize their children for religious or philosophical reasons; and children with medical contraindications to vaccination.

While we do not have exactly comparable data available at school entry, the percentage with no vaccines on board cannot be lower for any birth cohort than it was at age 2 to 2.9 years old.

The expected prevalence of autism and ASD by age 8 years, using the methods of the CDC-sponsored autism surveillance sites, is about 5 to 10 children per 1000, or 0.5 to 1%. If the percentage with no immunizations is 1%, then for each one-year birth cohort of 220,000 live births, there would be about 2200 unimmunized children at age 2. The expected number of autistic children (that is, children with a diagnosis of an autism spectrum disorder) by age 8 in that cohort of 2200 children would be 11 to 22. If we were to combine 5 one-year birth cohorts, the expected number would be 55 to 110 autistic children by age 8. These children would amount to approximately 0.5 to 1.0% of all autistic children in Florida, if there was no protective effect of non-vaccination.

These calculations would have to be refined to account for children who move in or out of Florida between birth and age 8 years. Also, by age 8 some of the children with no doses of vaccine at age 2 to 2.9 years will have received one or more doses of vaccine, perhaps for attendance at daycare or school. For purposes of this proposed study, the investigators would need to be clear about what they would consider to be a child not exposed to vaccines: never exposed before autism diagnosis, or not exposed prior to a particular age.
Cohort study options

A straightforward cohort study would involve identifying all the totally unimmunized children who had been born in Florida in a certain time period, verifying they have received no doses of vaccine by age 2 or 3, and then determining if they have developed autism by some specified age. A similar cohort of immunized children would also be followed up. This is not practical, as there is no central registry of children at this age who have not received any vaccines.

An alternative approach to a cohort study might be to gain access to a complete list of Florida-born autistic children in Florida, such as might be the result of applying the methods of the current Miami-Dade county prevalence study to the entire state. The entire population of live-born infants for a five-year study period could be considered to be the cohort of interest. We would then ascertain the complete immunization history of all these autistic children, and thus identify all those who have never received doses of any vaccine, only a few doses, or a full complement of vaccines. The denominators for these two incidence rates would be the estimated number of children who had zero and any doses of vaccine by age 3, from the annual Florida immunization survey.

We can then estimate incidence rates in the birth cohort, for those who have received no doses of vaccine by age 3 and those who have received one or more doses of any vaccine by age 3.

One weakness of this approach is that we have two conflicting estimates for the percentage of Florida children aged 2 to 2.9 years old, one from a Florida Department of Health survey and one from a national survey with many Florida respondents. One would have to decide which of these to rely on. The fact that the immunization histories of the autistic children would have been derived from a different methodology than either of the surveys would also be a methodologic issue.

Another weakness is that there is currently no state-wide autism registry using the CDC/University of Miami methods. If this study were to be done with just Miami-Dade County subjects in the CDC-funded University of Miami prevalence study, it would have only about 15% as large a sample size as a statewide study. This reduction in sample size would result in about a ten-fold reduction in statistical power to detect a two-fold difference in incidence between the two groups.

It is important to do a study of this type in a setting where the probability of inclusion in the study is the same for all persons with the same condition (ASD here). Including data from the health and special education information systems of many different school systems is not advisable, without the kind of quality control that is included in the CDC-sponsored prevalence study area projects.

Study size would likely be further reduced by exclusion from the numerator and denominator of the rates of some or all of the children who had medical contraindications to some or all vaccines. Such children might be at increased risk of developing ASDs or other neurodevelopmental conditions, and thus would not be a good population to include in the proposed study.

Any study of this type would need to account for numerous potential confounders of the relationship between vaccine receipt and ASDs, since healthy children who receive no vaccines are different in many ways from those who do receive vaccines.

One way to recruit children who have received no doses of any vaccine would be from religious communities who object to immunization. In some states, such communities are highly visible and localized and it would be relatively easy to recruit families systematically from such communities. In Florida, however, families with such beliefs can be found in all parts of the state in relatively
small numbers. The impression of county health department staff is that the parental decision to request a religious exemption at school entry is highly individual, even among families who belong to religious communities that have objections to immunizations.

At school entry, approximately 0.6% of children entering kindergarten (in 2007, this was 1,362 children) are enrolled with religious exemptions, as well as 0.4% of children in seventh grade (925 children). DOH does not know the identities of these children. Children attending school on religious exemptions may have received some doses of vaccine. It would probably be worth determining how many children could be recruited for an epidemiologic study in Florida through religious congregations and religiously-oriented schools, and how many of those would be totally unimmunized. If the number is sufficient, such children could serve as the basis for a cohort study.

Case-control study options

In a case-control study, we would select a group of autistic children (cases), and a group of non-autistic children (controls) of the same age, and determine their immunization histories. A project of this type could be done by sampling the case subjects from the records of one or more large autism treatment centers or school systems, and selecting control subjects at random from the same communities from which the cases came.

Sample size issues are also important here, however. It would take approximately 7,000 subjects (2,000 cases and 5,000 controls) to have an 88% certainty of being able to detect an odds ratio of 2.0 (that is, the odds of disease are twice as high in the exposed as in the non-exposed), for the association between “any vaccine receipt” and ASD. In Florida, in each one-year birth cohort about 1,100 to 2,200 autism cases are expected. If five one-year birth cohorts are included in the study, about 5,500 to 11,000 children would be available for study, so from 10 to 40% of all autistic children in the state would have to be included as cases in the study.

Cross-sectional study options

In a cross-sectional design, we would enroll children in the study in some region of the state, for example at school entry, without knowing either their immunization or their autism diagnosis status. The assumption here is that all children who reach school-entry age are registered for school, even if they are moderately or profoundly disabled. The biggest challenge of a study of this type would be assuring uniform diagnostic criteria for ASDs across multiple schools and school districts.

School personnel already ascertain immunization status at the moment of school entry, which in principle should allow identification of children with no doses of any vaccine. This may or not be recorded unambiguously for children seeking enrollment under medical or religious exemptions; this would have to be explored further. Also, if the desire is to identify children who had received no doses by a particular cut-off age like 2 or 3 years, then full immunization histories would have to be obtained for all children, to find those who had received at least some vaccines between age 3 and school entry but none before.

Sample size considerations would argue strongly against this study design. Unless a very large fraction of the state or the whole state was included in the project, the number of subjects enrolled for the study who turned out to be autistic would be too small to allow for adequate study power to detect a small increase in risk.
What is the risk of waiting until 24 to 30 months to introduce immunizations?

In general, infants are our most vulnerable population to infectious diseases. Their ability to fight off potential deadly diseases has not fully developed in comparison to older children and adults. Any delay in providing this necessary prevention increases the risk of their contracting these life-threatening diseases and developing severe complications or death.

- Many of the diseases vaccines protect against are very dangerous to infants. Newborns, babies, and toddlers can all be exposed to diseases from parents, other adults, brothers and sisters, at child care, on a plane, or even at the grocery store. International travel is easier than ever—an infant can be exposed to diseases from other countries without a parent knowing.

- Infants and children stand to benefit the most from vaccines, as they are the most vulnerable to disease and the least likely to have been previously exposed to infection and acquired natural immunity.

- Waiting until a child is 24 to 30 months of age to be immunized exposes the young infant to serious and possibly deadly diseases that can be prevented.

- Many people think that they don’t have to vaccinate their children because the risk of vaccine-preventable diseases is so low. However, lapsing immunization rates are the reason why epidemics begin—both in this country and abroad. It has happened in our time, and can happen again if children fail to be vaccinated.

  —Between 1989 and 1991, lapsing rates of MMR vaccinations among preschoolers in the US led to a sharp jump in the number of measles cases. 55,000 people became sick and 120 died.

  —From January 1 through April 25, 2008, CDC received a total of 64 reports of confirmed measles cases in nine states—the highest number for the same time period since 2001.

  —Of the 64 people infected by the measles virus, only 1 had documentation of prior vaccination. Among the other 63 case-patients were 14 infants who were too young to be vaccinated.

  —Many of the cases among US children occurred in children whose parents claimed exemption from vaccination due to religious or personal beliefs, or in children too young to be vaccinated. Disease transmission occurred in a variety of community and healthcare settings, including homes, childcare centers, schools, hospitals, emergency rooms, and doctors’ offices.

- For almost all of the diseases that are vaccine-preventable, incidence and mortality rates were very high in infants and toddlers before vaccines were introduced. The major exceptions would be hepatitis A and B, and even there, transmission from mother to unborn baby was an important route of transmission. Even polio, which we sometimes think of as a disease of school-age children because of the epidemics in that age group in the early 1950s, was originally named “infantile paralysis.”

- During 1997–2000, out of 28,187 reported cases of pertussis (whooping cough), one quarter were in children under age 6 months. Almost 81% of the hospitalizations, 57% of the pneumonias, 58% of the encephalopathies, and over 93% of the deaths were in children under 6 months old. (CDC. Pertussis—United States, 1997–2000. MMWR 2002; 51:73–76).

- Most children are protected from measles by antibodies passively transferred from their mother until they are about a year old. Incidence of the infection then rises rapidly after the first birthday. This is why measles vaccine is recommended to be given at the first birthday, and even earlier during outbreaks. Waiting until children are 2 years old to give measles vaccine would allow development of a very large pool of un-immunized and unprotected children aged 12 to 24 months—about 200,000 at any one time in Florida alone—who could easily maintain an extensive measles epidemic. Among 67,032 measles cases occurring in the United States in 1987–2000, 43% were under 5 years old. Among these children, 41.4% had one or more complications, 26% were hospitalized, and 0.3% died (97 children). Complication rates were much lower in people aged 5 to 9 years (18.1%), and 10 to 19 years (12.8%), and then were higher in adults aged 20 to 29 (29%) and aged 30 and over (34.1%).
“In the 1920s, more than 125,000 diphtheria cases, with 10,000 deaths, were reported annually in the US, with the highest fatality rates among the very young and the elderly.” (Nelson Textbook of Pediatrics, 18th Edition, Saunders, 2007, page 1153).

The following chart reflects the decline in the disease rate of measles, mumps and rubella in Florida with the date of vaccine licensure.

While the risk of infants and children coming into contact with vaccine-preventable diseases is lower since the advent of immunizations, the best way to keep that risk down is to keep those vaccinations up. Any decline in immunization—either on a community, national or even an individual basis—can open up a window on vaccine-preventable diseases that immunizations have done such a great job keeping closed.

Before the Haemophilus influenzae type b (Hib) vaccine was introduced, mortality rates from meningitis due to that organism in the early 1980s were 5 times as high in children under one year of age as in children one to four years old. (Schoendorf KC, Kiely JL, Adams WG, Wenger JD, “National trends in Haemophilus influenza meningitis mortality and hospitalization among children,” 1980 through 1991).

The problem is even a low risk of contact with vaccine-preventable diseases places unvaccinated infants and children at-risk. The only disease that has been completely wiped out in the world is smallpox (which is why smallpox is the only vaccine that is no longer needed). The rest of the diseases that children are immunized against still make occasional appearances and may pose a risk to anyone who isn’t fully vaccinated.

Experts frequently say that the diseases that are uncommon in the U.S. are only a plane ride away. That’s because outbreaks in this country often begin when an unvaccinated person travels to a country where vaccination isn’t routine, and where diseases like polio, diphtheria, or measles still occur. The traveler then picks up the disease, and brings it home—a dangerous souvenir that can then be passed around to anyone who isn’t vaccinated or hasn’t yet been fully vaccinated (including those who are at greater risk, such as infants and pregnant women). Foreign visitors can also bring diseases into the country.

Why immunize infants? Today’s low risks could potentially grow into high risks. If enough parents stop immunizing their children, diseases that have been under control for years can actually make comebacks, causing epidemics.
The following Florida Statutes and Administrative Codes assure provision of immunizations for eligible children and details immunization requirements for childcare and school.

**Medicaid and Insurance Benefits for Eligible Children**

Section 409.815, F.S., lists Medicaid benefits and also lists benchmark benefits (KidCare) which include preventive health services including services recommended in the “Guidelines for Health Supervision of Children and Youth” as developed by the American Academy of Pediatrics and immunizations and injections.

Medicaid policy for the Child Health Check-up (EPSDT is a mandatory Medicaid service) lists the periodicity of visits and addresses the content of care, including routine immunizations. In addition under OBRA 89, states must provide all medically necessary services identified during and EPSDT screen (known as child health check up in Florida) without regard to whether those services are included in the state’s Medicaid state plan.

Section 627.6579, F.S., addresses requirements for commercial insurance regarding child health supervision and also includes routine immunizations.

**Mandated School Immunizations**

The following is a summary of required school immunizations, which are detailed in the “Immunization Guidelines—Florida Schools, Child Care Facilities and Family Day Care Homes,” which are referenced in Rule 64D-3.046, Florida Administrative Code.

Requirements: Prior to entry, attendance or transfer to preschools, schools (K-12), licensed childcare facilities, and family daycare homes, each child shall have on file a Florida Certification of Immunization, DH 680, documenting the following:

**PUBLIC/NON-PUBLIC SCHOOLS K-12 (CHILDREN ENTERING, ATTENDING, OR TRANSFERRING TO FLORIDA SCHOOLS):**

- Four or five doses of diphtheria, tetanus, and pertussis vaccine; three or four doses of polio vaccine; two doses of measles, mumps, and rubella vaccine; two or three doses of hepatitis B vaccine; one dose of varicella vaccine (kindergarten effective school year 2001/2002, then each year an additional grade); two doses of varicella vaccine (kindergarten effective school year 2008/2009, then each year an additional grade)

**PUBLIC/NON-PUBLIC SCHOOLS SEVENTH GRADE:**

- One dose tetanus diphtheria (TD) vaccine; Effective with the 2009/2010 school year, one dose of tetanus-diphtheria-pertussis vaccine (Tdap)

**PUBLIC/NON-PUBLIC PRE-K (AGE-APPROPRIATE DOSES AS INDICATED):**

- Diphtheria, tetanus, and pertussis vaccine; polio vaccine; measles, mumps and rubella vaccine; hepatitis B vaccine; varicella vaccine (effective school year 2001/2002); Haemophilus influenzae type b (Hib) vaccine

**LICENSED CHILDCARE FACILITIES AND FAMILY DAYCARE HOMES:**

- Children entering or attending licensed childcare facilities and family daycare homes shall have received as many of the following age-appropriate immunizations as are medically indicated in accordance with the current Recommended Childhood Immunization Schedule: diphtheria, tetanus, and pertussis vaccine; polio vaccine; measles, mumps and rubella vaccine; varicella vaccine; Haemophilus influenzae type b (Hib) vaccine; Pneumococcal Conjugate vaccine

**AUTHORITY:** K-12: section 1003.22, Florida Statutes, and Rule 64D-3.046, Florida Administrative Code

**LICENSED CHILDCARE FACILITIES, FAMILY DAYCARE HOMES AND SPECIALIZED CHILDCARE FACILITIES FOR THE CARE OF MILDLY-ILL CHILDREN:** sections 402.305 & 402.313, Florida Statutes, and Rules 65C-22.006 and 65C-25.002 and 25.008, Florida Administrative Code


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