ISSUE REPORT

CLOSING THE VACCINATION GAP: A Shot in the Arm for Childhood Immunization Programs



AUGUST 2004

PREVENTING EPIDEMICS. PROTECTING PEOPLE.



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The opinions expressed in this report do not necessarily reflect the views of the individuals or organizations.

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wenty percent of preschool children, aged 19-35 months,¹ do not receive all routine vaccinations to protect against a range of common childhood diseases. While the Centers for Disease Control and Prevention (CDC) announced a significant increase in vaccination rates from 2002 to 2003, each year an estimated 2.1 million preschool children are still not fully immunized.² Leaving a single child unprotected is one too many.

Preschoolers are particularly vulnerable to a host of childhood diseases and therefore, are most in need of comprehensive, preventive vaccinations. However, this is the age group with the lowest immunization rates. The gap in rates is particularly concentrated in poor and minority communities.

From a variety of perspectives, including medical and financial, the public benefits when all children are vaccinated. High vaccination rates are important safeguards against the spread of epidemics. Numerous cost-benefit analyses show that vaccination against the most common childhood diseases delivers large returns on investment — saving \$18.40 in medical costs and indirect costs, such as disability, for every \$1 spent on immunization.³ In this report, Trust for America's Health (TFAH) and Every Child By Two (ECBT):

- I. Discuss the importance of childhood immunizations,
- **2.** Examine immunization rates,
- **3.** Discuss factors contributing to the gap in vaccination rates for pre-school children, and
- Recommend improvements to U.S. vaccination policy.

Ensuring that all children have access to the full series of immunizations in a timely manner is achievable. Closing the vaccination gap should be high on our list of national health priorities.

"THERE ARE ACTUAL, ACHIEVABLE MEASURES THAT COULD BE TAKEN TO **IMMEDIATELY IMPROVE** PRESCHOOLER IMMUNIZATION RATES IN THE U.S. **PRESCHOOLERS ARE** PARTICULARLY VULNERABLE TO A HOST OF CHILDHOOD ILLNESSES. NO CHILD IN AMERICA SHOULD HAVE TO GET SICK FROM A VACCINE PREVENTABLE DISEASE. It'S TIME FOR US TO **REDOUBLE EFFORTS TO** PROTECT THE 20 PERCENT OF PRESCHOOLERS WHO ARE ROUTINELY NOT BEING IMMUNIZED ON TIME."

 ROSALYNN CARTER,
Former First Lady of the United States, President and Cofounder of Every Child By Two

HOW IMMUNIZATION COVERAGE IS MEASURED

The current, common measure of full immunization coverage is referred to as the 4:3:1:3:3 standard. This is gauged by measuring the percentage of children between 19 and 35 months of age who have received the following battery of immunizations: four or more doses of diphtheria-tetanus-pertussis vaccine (DTaP); three or more doses of inactivated polio vaccine (IPV); one or more dose of measles, mumps, rubella vaccine (MMR); three or more doses of Haemophilus influenzae type B vaccine (Hib); and three or more doses of Hepatitis B vaccine (HepB).

The 4:3:1:3:3 standard has been tracked for five years.⁴ In 1999, the national coverage rate was 73.2 percent. After remaining relatively stable for four years, the rate jumped from 74.8 percent in 2002 to 79.4 percent in 2003 (See Chart).⁵ Although the 2003 coverage rate represents an all- time high, 20 percent of children still do not receive all needed vaccines on time.

YEARLY IMMUNIZATION RATE PERCENTAGE FOR THE 4:3:1:3:3 STANDARD 1999-20036

Importance of Childhood Immunization

ver the course of the twentieth century and into the twenty-first, vaccines have been developed to reduce the incidence of devastating vaccine-preventable diseases. Immunization policy in the U.S. currently focuses mainly on children, as vaccine-preventable diseases can strike young children who are most susceptible to their consequences. Laws requiring that children be immunized prior to entering school, which were initiated among the states during the Carter Administration, have pushed immunization coverage rates to near universal percentages among school-aged children (95 percent for school-aged children.)⁷

WHY ARE PRESCHOOL-AGED VACCINATIONS SO CRITICAL?

Although newborns receive antibodies from their mothers and therefore enjoy short-term immunity to many diseases, such immunity often lasts only a month and generally expires within a year. Moreover, mothers pass no protection to certain vaccine-preventable diseases, such as whooping cough.⁸

Thus, to prevent large segments of the population from disease exposure, vaccination must occur at an early age. It is particularly crucial to immunize young children since their bodies are still developing, leaving them often incapable of fighting many diseases. Yet over 20 percent of pre-school children do not receive all needed vaccines, leaving them vulnerable to many vaccine-preventable diseases, including:

Polio: Polio virus causes acute paralysis that can lead to permanent physical disability and

Immunization is one of the most successful public health achievements of the 20th Century. Due to systematic programs, smallpox has been eliminated worldwide, and cases of polio, measles, pertussis, diphtheria, and Hib are at all-time lows. The burden of other diseases has been significantly reduced. even death. Most permanent disabilities caused by polio occur in children.⁹

Measles: During recent measles outbreaks, half of the fatalities were in children under five years of age.¹⁰

Diphtheria: Diphtheria results in death primarily in the very young and the elderly.¹¹

Hepatitis B: Infants and children who become infected with hepatitis B virus are at highest risk of developing lifelong infection, which often leads to death from liver disease (cirrhosis) and liver cancer. Approximately 25 percent of children who become infected with life-long hepatitis B virus would be expected to die of related liver disease as adults.¹²

Mumps: Mumps is a major cause of deafness in children.¹³

According to one study, the standard childhood immunization series prevents approximately 10.5 million cases of infectious illness a year and 33,000 deaths in the United States.¹⁴ Another report published by the World Health Organization, UNICEF and the World Bank found that three million lives are saved worldwide each year through childhood immunizations — a number that could be doubled with increased funding.¹⁵

IMMUNIZATION SUCCESSES THROUGH THE YEARS

Smallpox: Varying strains of smallpox disease have been identified, each extremely infectious and leading to skin lesions, permanent scarring, and serious illness. Depending on the strain, fatality rates run as high as 25 percent to less than one percent.16 Smallpox is immunization's greatest success story to date, as this dreaded disease has been eradicated. As of the early twentieth century, tens of thousands of smallpox cases were reported in the U.S. each year.¹⁷ The last case of smallpox in the U.S. was reported in 1949, and routine vaccination of American children ended in 1971. The last case of smallpox in the world occurred in Somalia in 1977.18 In 1980, scientists officially declared that vaccines had been successful at eradicating smallpox worldwide.

Polio: Before polio vaccine was available, the U.S. had 50,000 polio cases a year, including 13,000 to 20,000 cases of paralytic polio. These annual epidemics of polio often left thousands of victims - mostly children permanently in braces, crutches, wheelchairs, and with iron lungs.¹⁹ Immunization has eliminated the disease in the U.S. and Western Hemisphere, and the World Health Organization had set a goal of eradicating polio worldwide by the end of 2004. However, Nigeria's northern State of Kano suspended polio immunization in August 2003 amid rumors that the vaccine was contaminated with HIV and that it caused infertility. Consequently, polio cases reemerged in Nigeria and other previously polio-free countries. Polio immunization has restarted in Kano and the WHO now estimates that polio can be eradicated by the end of 2005.20

Measles: Measles is one of the most infectious diseases in the world; more than 90 percent of people who are not vaccinated will get measles if they are exposed to the virus. In the U.S., roughly one in five who develop the disease require hospitalization for one or more complications.²¹ Before 1963, more than three million cases of measles and 500 deaths from measles were reported each year. More than 90 percent of children had measles by age 15.²² Widespread introduction of vaccine has resulted in a reduction of measles incidence from 894,134 cases in 1941 to 89 cases in 1998 and 44 cases in 2002.^{23, 24}

Pertussis: Pertussis (also known as whooping cough) can be a severe illness, resulting in prolonged coughing spells that can last for many weeks or even months. In children, the disease often leads to vomiting and can interfere with efforts to eat, drink, and breathe; children often suffer dehydration and lost weight, and infants are prone to pneumonia, brain damage, seizures, and mental retardation.25 Before pertussis immunization was available, nearly all children developed whooping cough. The CDC reports that following the introduction of immunization in the mid-1940s, pertussis incidence declined more than 99 percent by 1970 and to an alltime low of 1,010 cases by 1976. However, since then, an increase in incidence of the disease has been documented, with more than 10,000 cases reported in 2003 and outbreaks occurring every three to four years. Furthermore, some researchers have estimated that only one-third of pertussis cases in the U.S. are actually reported. ²⁶

Diphtheria: Diphtheria is a serious bacterial disease that frequently causes heart and nerve problems. The death rate is five percent to 10 percent, with higher death rates (up to 20 percent) in the very young and the elderly. In the 1920s, prior to regular immunization, there were 100,000 to 200,000 American cases of diphtheria each year and 13,000 people died from the disease.²⁷ Since the introduction of immunization, diphtheria has dramatically declined from a high of 206,939 reported cases in 1921 to one in 2002. ^{28, 29}

Haemophilus Influenzae type B (Hib): Before Hib vaccination, Haemophilus influenzae type B caused serious infections in 20,000 children each year, producing meningitis (12,000 cases) and pneumonia (7,500 cases), bacteria in the blood, and inflammation of the epiglottis.³⁰ Hib meningitis killed 600 children each year, and left many survivors with deafness, seizures, or mental retardation. Since introduction of conjugate Hib vaccine in December 1987, the incidence of Hib has declined by 98 percent.³¹ The number of cases of serious Hib disease in children under five years of age reported in 2002 was 331.³² Rubella: While rubella is usually mild in children and adults, up to 90 percent of infants born to mothers infected with rubella during the first trimester of pregnancy will develop congenital rubella syndrome (CRS), resulting in heart defects, cataracts, mental retardation, and deafness. Expectant mothers are now routinely tested for rubella antibodies during pregnancy. From 1964-1965, before routine rubella immunization, there was an epidemic of 12.5 million cases that resulted in an estimated 20,000 infants born with CRS; 2,100 neonatal deaths; and 11,250 miscarriages. Of the 20,000 infants born with CRS, 11,600 were deaf, 3,580 were blind, and 1,800 has mental retardation. Due to the widespread use of rubella vaccine, only 18 cases of rubella and one case of CRS were reported in 2002.33

Hepatitis B: National studies show that about 12.5 million Americans have been infected with hepatitis B virus at some point in their lifetime. Over 10 percent of these individuals develop chronic infection, increasing chances for chronic liver disease, cirrhosis, and liver cancer. An estimated 20 to 30 percent of such cases stem from infection during childhood. Approximately 5,000 people die each year from hepatitis B-related liver disease resulting from chronic hepatitis B. However, with the recent advent of vaccine, the number of new infections per year has declined from an average of 450,000 in the 1980s to 7,996 in 2002.³⁴ The greatest decline has occurred among children and adolescents due to routine hepatitis B vaccination.35

Tetanus: Tetanus, commonly known as Lockjaw, is a severe disease that causes stiffness and spasms of the muscles and is often fatal. The larynx (throat) can close causing breathing and eating difficulties, muscles spasms can cause fractures (breaks) of the spine and long bones. Some people go into a coma, and die. Approximately 30 percent of reported cases end in death. From 1922-1926, there were an estimated 1,314 cases of tetanus per year in the U.S.³⁶ In 2002, as a result of extensive immunization, only 25 cases of tetanus were reported.³⁷ **Mumps:** While usually a mild disease, mumps can produce swelling of the brain, nerves and spinal cord which in some cases leads to paralysis, seizures, and fluid in the brain. Moreover, in children, it is a major cause of deafness. Prior to immunization, the U.S. suffered approximately 200,000 cases per year. After vaccine licensure in 1967, reports of mumps decreased rapidly, but brief resurgences, such as an epidemic in 1987 that led to a reported 12,848 cases occurred. Since then, a second dose of mumps vaccine was added to the standard childhood MMR series and as a result, annual cases are now in the hundreds rather than the thousands.³⁸

Varicella: Although generally mild, varicella (chickenpox) virus can lead to severe illness causing complications such as secondary bacterial infections, severe loss of fluids (dehydration), pneumonia, central nervous system irregularities, and shingles. The virus is highly contagious and thus virtually all unimmunized individuals contract varicella if exposed to the virus, usually prior to adulthood. Before immunization, the U.S. reported an estimated four million cases a year, leading to approximately 11,000 hospitalizations and 100 deaths. A new chickenpox vaccine was licensed in 1995, and incidence of the disease is now declining.³⁹

Chickenpox can be particularly dangerous to a developing fetus. Pregnant women who have never had chickenpox are at risk of contracting chickenpox during pregnancy. A small percentage of women who get chickenpox in the first or second trimester can have babies with birth defects known as "congenital varicella syndrome." In addition, chickenpox may be more severe in pregnant women than in others putting the woman at risk of severe complications. Vaccinating close contacts of a susceptible pregnant woman is the most effective way to protect her from disease.⁴⁰

Influenza: Influenza is a serious disease. In an average year, the flu causes 36,000 deaths and 114,000 hospitalizations in the United States. While the majority of deaths resulting from flu occur in the elderly, rates of infection are highest among children and hospitalization rates among children zero-to-one year old are similar to those of the elderly.

BENEFITS OF IMMUNIZATIONS: ECONOMIC SAVINGS

In addition to saving lives and improving the quality of life, immunization generates significant economic benefits. According to an extensive cost-benefit analysis by the CDC, every dollar spent on immunization saves \$6.30 in direct medical costs, with an aggregate savings of \$10.5 billion. When including indirect costs to society — a measurement of losses due to missed work, death and disability as well as direct medical costs — the CDC notes that every dollar spent on immunization saves \$18.40, producing societal aggregate savings of \$42 billion.⁴¹ Various cost-benefit analyses produce similar measurements.⁴²

The DTaP vaccine is particularly cost effective. Each dollar spent on DTaP produces \$8.50 of direct medical cost savings and \$24 of societal savings.⁴³ More importantly, diphtheria immunizations alone prevent almost 13,000 deaths per year.

Other vaccines also produce a positive cost-benefit outcome:

- Hib produces \$1.40 in direct and \$2 in societal savings
- Hepatitis B produces \$0.50 in direct savings in both infants and adolescents, \$1.30 in direct prenatal savings, \$2.20 in societal savings in adolescents, \$3.10 in societal savings in infants, and \$14.50 in societal savings in prenatal cases
- Inactive polio vaccine produces \$3.03 in direct and \$5.45 in societal savings
- MMR produces \$10.30 in direct savings and \$13.50 in societal savings for each dollar spent
- Varicella produces \$0.90 in direct and \$5.40 in societal savings.⁴⁴

BENEFITS OF IMMUNIZATION: "HERD IMMUNITY"

Immunization protects not only the individual receiving the vaccine, but the whole community as well. By eliminating potential carriers of disease, immunization can protect even those who are not immunized because their chances of encountering the disease are limited. This is referred to as "herd immunity." This is especially important for those who cannot be immunized, including:

Those who are too young to be vaccinated (e.g., children less than a year old who are not yet vaccinated for measles virus because the mother's antibodies, which are transmitted to the newborn, may render the vaccine ineffective. Because antibody levels vary among infants, many remain susceptible to measles virus prior to receiving the vaccine at age one);

- Those who cannot be vaccinated for medical reasons (e.g., children and adults with weakened immune systems); and
- Those for whom the vaccine proves ineffective, meaning they do not develop an adequate response to vaccination.

Immunization Rates

WORKING TO SAVE KIDS

66 Early in the Administration, Mrs. Carter called Me. She and the President had dined with Senator Dale Bumpers and his wife the night before. "Betty has some ideas about immunizing children and I would like for you to see her." I called Mrs. Bumpers that day and she came to my office on February 18, 1977. She explained how "when Dale was governor of Arkansas, we organized everything from the National Guard to the churches and schools to get children immunized. If you get everyone going, it will work," she said. 45 As a result of this meeting a nationwide effort to raise immunization rates ensued. 29

- Joseph A. Califano, Jr., Former Secretary of Health, Education and Welfare

Ninety-five percent of school-aged children are fully covered as a result of laws mandating immunization prior to school entry.46 These laws arose in the late 1970s and early 1980s as part of a major, nationwide effort by the Carter Administration to bolster low immunization rates in children.⁴⁷ By the 2001-2002 school year, all 50 states, the District of Columbia, and Puerto Rico had adopted school entry requirements, covering kindergarten through 12th grade and day care centers. In forty-eight states, Head Start programs adopted school entry requirements. However, the exact requirements for all these groups vary by state.48 Moreover, faith-based and home daycare centers are not universally required to screen for immunization, leaving this population potentially vulnerable to disease outbreaks.49

In contrast, 20 percent of preschool children are not fully immunized. CDC data indicate that 79.4 percent of children between 19 and 35 months of age received all vaccines recommended for universal administration.⁵⁰ Although this rate is an all-time high, there are disparities among the states and cities that reveal a crack in the system designed to protect young children from vaccine-preventable diseases. The 15 percent gap in coverage rates between school-aged children and preschoolers is concerning, particularly since toddlers are at a critical age developmentally when diseases hit hardest.⁵¹

Coverage rates vary significantly from state to state, from a high of 94 percent in Connecticut to a low of 67.5 percent among toddlers in Colorado. Twenty-six states have immunization rates below 80 percent.⁵² (See Table on Page 10) "The CDC'S ANNOUNCE-MENT OF THE HIGHEST IMMUNIZATIONS RATES FOR INFANTS AND TODDLERS IS GREAT NEWS. THE EVEN BETTER NEWS IS THAT WE KNOW WHAT IT WOULD TAKE TO REACH THE LAST 20 PERCENT OF PRESCHOOLERS. HOPEFULLY, THE LATEST PROGRESS WILL REINVIGORATE ALL OF US TO STRIVE FOR FULL CHILDHOOD VACCINATION RATES IN AMERICA."

- BETTY BUMPERS, Former First Lady of Arkansas, Cofounder of Every Child By Two

19-35 Months of Age by State				
	4:3:1:3:3 Series		4:3:1:3:3 Series	
Alabama	80.4	Montana	80.0	
Alaska	79.7	Nebraska	80.4	
Arizona	76.9	Nevada	75.7	
Arkansas	76.5	New Hampshire	86.5	
California	77.4	New Jersey	75.0	
Colorado	67.5	New Mexico	75.2	
Connecticut	94.0	New York	78.6	
Delaware	76.3	North Carolina	86.7	
District of Columbia	76.2	North Dakota	80.4	
Florida	81.0	Ohio	82.3	
Georgia	76.6	Oklahoma	70.5	
Hawaii	82.0	Oregon	76.5	
Idaho	78.1	Pennsylvania	86.2	
Illinois	82.9	Rhode Island	85.2	
Indiana	79.0	South Carolina	84.3	
lowa	81.1	South Dakota	80.9	
Kansas	75.7	Tennessee	78.8	
Kentucky	81.0	Texas	74.8	
Louisiana	69.9	Utah	78.8	
Maine	78.6	Vermont	83.6	
Maryland	81.3	Virginia	84.0	
Massachusetts	90.7	Washington	75.3	
Michigan	81.5	West Virginia	74.6	
Minnesota	83.9	Wisconsin	81.2	
Mississippi	83.6	Wyoming	75.8	
Missouri	83.3	US Average	79.4	

Estimated Vaccination Coverage Rate for Children 19-35 Months of Age by State

4:3:1:3:3 Four or more doses of DTP, three or more doses of poliovirus vaccine, one or more doses of any MCV, three or more doses of Hib, and three or more doses of HepB

Source: CDC, U.S. National Immunization Survey, 2003

Vaccinations in Urban Areas and Among Minority Communities

Some urban settings have significantly low immunization rates. According to CDC data collected for a select group of cities and counties, Houston, Texas reports the lowest immunization coverage rate at 69.2 percent. Detroit is close behind with a rate of 69.6 percent. The immunization rate is much higher in Boston, 88.8 percent and Santa Clara County, California, 83.6 percent.^a (See Table)

City/County	Immunization Coverage Rate (Percent)		
Highest Rates			
Boston	88.8		
Santa Clara County, CA	83.6		
Franklin County, OH	81.8		
Lowest Rates			
Dallas	70.2		
Detroit	69.6		
Houston	69.2		
Source: CDC, U.S. National Immunization Survey, 2003			

Certain groups also suffer disproportionately low rates of coverage. Immunization rates for the African-American community are the lowest according to CDC figures. For white children, the immunization rate is 82.5 percent, while for African-American children, it is 73 percent.⁵⁴ Many experts believe that rates in the African-American community

Disease Outbreaks

About 2.1 million children are left unprotected every year, leading to outbreaks of disease. For example, from 1989-1991, a measles epidemic resulted in 55,000 reported cases, 11,000 hospitalizations, and 123 deaths; this afflicted primarily preschool children in low income inner city neighborhoods.58 The resurgence was attributed to low immunization rates, inadequate access to care, missed opportunities to administer vaccines, and inaccurately high estimates of protection on the part of parents and providers.⁵⁹ Research showed that the epidemic was spawned primarily by communities in which only 50 percent of preschoolaged children had received the vaccine.60

In 2003, more than 10,000 pertussis cases were reported. More recently, parts of the Midwest have been experiencing pertussis outbreaks this year. As of mid-July 2004, Wisconsin reported more than 800 cases of pertussis.⁶¹ The city of Chicago has experienced 107 confirmed cases of the disease as of early July.⁶² These resurgences have been occurring more

may actually be far lower than official numbers.⁵⁵ However, significant progress has been made; for example, in 1970 African-American and minority children had measles immunization rates 20 percent lower than white children.⁵⁶ Among all races, underimmunization is generally concentrated among the impoverished.⁵⁷

frequently in recent years throughout the country, and some researchers have estimated that only one-third of pertussis cases in the U.S. are actually reported.

Influenza is another virus that results in significant disease burden each year. Influenza (flu) is a serious disease, and people of all ages can get infected. In an average year, the flu causes 36,000 deaths and 114,000 hospitalizations in the United States. While the majority of deaths resulting from flu occur in the elderly, rates of infection and hospitalization rates are highest among children. During the 2003-2004 flu season, over 150 children died from influenza and many more were hospitalized as a result of complications. At its October 2003 meeting, the Advisory Committee on Immunizations Practices (ACIP) voted to expand its influenza recommendation to include annual vaccination of all children 6-23 months of age. The ACIP also recommends that close contacts of children 0-23 months of age be vaccinated annually against influenza.

RECOMMENDED COVERAGE

Each year the Advisory Committee on Immunization Practices (ACIP) meets to discuss additions and edits to the recommended childhood and adolescent immunization schedule. The schedule is then approved by ACIP, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).



Factors Contributing to the 20% Vaccination Gap

Several factors are contributing to the fact that 20 percent of American preschoolers are not receiving all needed immunizations. These factors can be broadly described as:

- Systemic issues including underfunded immunization programs
- Underutilized and unevenly supported immunization registry systems among the states
- **Public misperception** about the importance of timely vaccination and vaccine safety

Systemic Issues

Efforts to immunize children involve a set of complex and separate financial arrangements among federal, state, and local health agencies, as well as collaborations with public and private health care providers. State governments have the responsibility for meeting the health needs of residents who are not served or are underserved by the private health care sector. Each state invests in immunization programs, but no state has sufficient resources to ensure all children are immunized. The federal government thus assists states by providing funds for vaccine purchase and infrastructure support.⁶³

Federal assistance is provided primarily through two sources: Section 317 of the Public Health Service Act, administered by the National Immunization Program within the CDC, and the Vaccines for Children (VFC) program, administered jointly by the CDC and the Centers for Medicare and Medicaid Services (CMS).64,65 The Section 317 program provides funds for state immunization operational costs and many of the vaccines provided in public health clinics. The VFC program aims to improve vaccine availability to children nationwide by providing vaccines free-of-charge to Medicaid-eligible, uninsured, underinsured, American Indian, or Alaska Native children through both public and private providers. ⁶⁶ In FY 2004, funding for Section 317 grants was \$418 million and \$1.2 billion for VFC.

Vaccine Delivery. Over half of immunizations are paid for by the government,⁶⁷ but about 70 percent of vaccines are administered in private settings.⁶⁸ The VFC program and the Medicaid program provide publicly-funded vaccines primarily through private delivery.⁶⁹ Alarmingly, the IOM has found that the private contribution to this partnership may be weakening.⁷⁰

Most public and private health insurance includes vaccine benefits, but the scope of these benefits varies widely by insurance type and by vaccine. To address this issue, state and federal governments have required certain types of insurance coverage for some vaccines. However, the regulatory effort is uneven and difficult to administer.⁷¹

Of growing concern is the plight of underinsured children — those whose families have health care insurance that excludes vaccine coverage, or that charges high deductibles or copayments. These children, largely from working families, are not eligible to receive federally-funded VFC vaccines unless they travel to a Federally Qualified Health Center (FQHC), federally-designed comprehensive health organizations serving predominantly underserved population. Relying on FQHC limits access to many underserved children due to location or accessibility. Underinsured children are not permitted to receive vaccines at a public health clinic, even if they visit that clinic for all of their other medical needs. Legislation, the Children's Vaccine Access Act of 2004, has been introduced in Congress to remedy this, but has not been passed.

Requirements under the VFC program also affect financing for some vaccines. The VFC statute sets a limit, or cap, on prices that the federal government pays for certain vaccines (e.g. tetanus and diphtheria (Td) vaccine) that were in use prior to 1993. The price caps are so low, however, that these vaccines were removed from the VFC program in 1998 when no vendor would bid on a contract to sell the vaccines to the federal government. Consequently, these vaccines are unavailable for purchase under the program.

Vaccine Supply. Closely related to vaccine financing and delivery is supply. The vaccine supply system has experienced major changes in recent decades and many believe that the current system may be in jeopardy. In the last 30 years, over 25 companies produced vaccines. However, currently only five companies produce all vaccines recommended for routine use by children (and adults).⁷² Although vaccines are important disease prevention tools and have significant societal value, they often generate lower revenues than pharmaceuticals. Vaccines must compete with other more lucrative products in a manufacturer's portfolio.⁷³

In addition, the process of developing and manufacturing vaccines is complex, expensive, and lengthy. Research and development can take more than five years and there is a long lead time for manufacturing a single lot of vaccines up to a year. In addition, the U.S. Food and Drug Administration's (FDA) process for reviewing vaccines is more complex than for pharmaceuticals. Moreover, vaccine manufacturing is more uncertain than most other pharmaceutical products. For example, the composition of the influenza virus vaccines changes nearly every year.⁷⁴

Vaccine supply has also been plagued by recent shortages that were unprecedented in scope and severity. While temporary production problems appear to have eased, the disruption remains.75 potential for Shortages, such as the one during 2001-2002 for DTaP, MMR, varicella, and pneumococcal conjugate vaccines can lead to deferral in immunization. Reasons for the recent shortages include one vaccine manufacturer's decision to cease production of DTaP and manufacturing problems at production facilities. In addition, an unexpectedly rapid uptake/demand for the new pneumococcal conjugate vaccine was accompanied by sporadic manufacturing problems. Changes in recommendations regarding vaccines, including the decision to eliminate the use of thimerosal as a preservative and an expanded age recommendation for flu vaccine among adults, also led to vaccine shortages.

More recent vaccine supply issues have also occurred – a shortage of influenza vaccine during 2003-2004. The severe start to the flu season, and the deaths of five young children in Colorado spurred public demand for vaccine and shortages in some parts of the U.S. ensued. In addition, shortages of pneumococcal conjugate vaccine in early 2004 developed due to production problems of the sole manufacturer.

Inadequate Immunization Program Funding and Vaccine Cost Increases.

Between 1999 and 2003, the cost to immunize one child rose from \$186 to \$472 per child, as new vaccines have been added to the recommended schedule. Moreover, the cost of vaccines is projected to rise substantially over the next several years. The current cost of the recommended vaccine series for children through age six is estimated to rise as high as \$1,200 per child by 2020, due in large part to the development of new, more expensive vaccines.⁷⁶

The projected three-fold increase in immunization costs coincides with substantial pressure on federal and state budgets. Currently, approximately 56 percent of childhood vaccine is purchased with public dollars, including federal, state and local funds; the remaining vaccine is purchased in the private sector.⁷⁷

Federal appropriations have not kept pace with the cost of vaccines. As the chart shows, the cost of immunizing one child was estimated at \$472 in 2004. However, the federal appropriation for the immunization of a child is only \$220, far short of the total cost.



States have reduced funding for immunizations, while at the same time vaccine costs continue to rise. The Institute of Medicine (IOM) found that in response to state budget cuts, most reduced the scale of effort of their immunization activities, commonly reducing outreach, education efforts, and vaccine delivery arrangements with contractors. Half of the states have reported that budget cuts affected staffing, requiring them to reduce immunization program personnel, consolidate positions, or leave vacancies unfilled.⁷⁸

IOM's "Calling The Shots" report states that, "immunization financing was explicitly structured to be a federal-state partnership...federal policymakers never expected federal funds to be sufficient to cover the full cost of vaccine purchase and delivery for disadvantaged groups... and federal funds are provided to supplement, not supplant, state investments in immunization programs." Various opinions regarding state versus federal roles in the purchase of vaccines exist among the vaccine advocacy community. However, all clearly agree that decreased state investments paired with insufficient federal funding must be remedied in order to insure an equitable distribution of vaccines among all U.S. children.

Immunization Information Systems (Registries)

Immunization Information Systems, also known as immunization registries, are confidential, computerized information systems that collect vaccination data about children within a geographic area.⁷⁹ Children are typically entered into a registry at birth (often through a linkage with electronic birth records) or at first contact with the health care system (parents may decline such participation). A registry can provide a single source for all community immunization data, if a registry includes all children in a given geographic area and all providers follow through with reporting of immunization information.

Registries allow health care providers to consult a unified immunization record. With such records, health care providers may ensure that a child's immunizations are upto-date, send reminders when immunization is due or missed, and prevent duplicative immunization. In addition, the registries can identify high risk, under-immunized populations, thus helping to prevent disease outbreaks while focusing public health outreach dollars in areas of most need. Vaccine distribution is streamlined, and community and state coverage rates can be tracked for public health purposes. Registries can also help providers better track the immunizations they provide, resulting in more accurate (often increased) reimbursement from participating health plans.

Approximately 11,000 children are born in the U.S. every day, each in need of the full series of immunizations by age two. Frequent changes to the immunization schedule due to the advent of new and/or newly combined vaccines results in confusion among both the provider community and parents. Keeping track of immunizations through registries helps alleviate this confusion, resulting in more efficient, timely, and cost-effective vaccination. For example, 21 percent of 19-35 month olds receive at least one extra dose of unneeded vaccine at a total cost of \$15 million. In addition, 22 percent of American children see two or more providers in their first year of life and three percent visit three or more providers.⁸⁰ Each change in providers necessitates a manual record pull and review at a total annual cost of approximately \$16 million.⁸¹

Every state has either a functioning registry, or a registry under development. Several states have more than one registry with plans to connect systems in the future. An estimated \$300 million under the federal immunization grant program (section 317 of the Public Health Services Act) has been awarded in support of registries since 1994. While many registries are partially supported via state and private funds (including significant funding from the Robert Wood Johnson Foundation), the source of the majority of funds utilized to develop and maintain registries has been the federal government through the immunization grant program. Since these funds are discretionary (subject to the annual federal budget process) and since state grantees have autonomy in determining how to use allocated infrastructure funding, registries throughout the country are at different stages in development and recruitment of providers.

Nationwide, only an estimated 43 percent of children under age six have one or more of their immunizations recorded in a registry. Approximately 75 percent of public providers are using the registries, but only 31 percent of the private providers participate.⁸² Although in the long run registries can save immunization programs, providers, schools, and other stakeholders significant funds, recruitment to the private provider community and connections to schools require outreach dollars. Unfortunately, immunization programs faced with level or decreased funding often place registries at the bottom of their list of funding priorities.

Public Misperceptions

A major concern of many public health officials is that immunization may be taken for granted. Studies show that recipients often undervalue vaccines and that both parents and physicians often do not recall the scourges once caused by now vaccine-preventable diseases. Moreover, there have been media reports sensationalizing unfounded allegations regarding vaccine safety. In addition, numerous Web sites, alternative medicine practitioners, anti-vaccine advocates and several public officials that dispute the safety of various vaccines have caused public alarm. Various rumors and theories, many without merit, also have frightened some away from immunization.83

Parents' views about vaccination can range from absolute support to outright objection. A poll of pediatricians and family physicians found that three out of four have encountered a parent that refused child vaccination during the previous year.⁸⁴ Many of those who refuse immunization are misinformed and/or poorly educated about vaccines and their side-effects. One major national survey found that one in four parents mistakenly believes that too many vaccines can weaken a child's immune system.⁸⁵

According to a recent study, "attitudes, beliefs, and behaviors indicative of vaccine safety concerns contribute substantially to underimmunization in the United States." Study researchers concluded that children from non-Hispanic white, higher-income families who were under-immunized with two or more vaccines missed these essential vaccinations because their parents have refused to immunize them out of fear over vaccine safety and mistrust of their doctors. Although the study found that vaccine safety concerns were significantly more common among parents of underimmunized children, many parents of fully immunized children had similar attitudes and beliefs. This should be of great concern because it may result in drop in the high childhood vaccination levels that the U.S. is currently experiencing.⁸⁶

The Institute of Medicine's (IOM) Immunization Safety Review (ISR) Committee released its final report in May 2004 examining the hypothesis that vaccines, specifically the measles-mumps-rubella (MMR) vaccine and thimerosal-containing vaccines, are causally associated with autism. Following a thorough review of the available research on this subject, the committee concluded that, "the body of epidemiological evidence favors a rejection of a causal relationship between the MMR vaccine and autism...and that the body of epidemiological evidence favors a rejection of a causal relationship between thimerosal-containing vaccines and autism." The committee also recommended that funding for autism research be redirected towards efforts that will result in more promising outcomes.87

In fact, vaccines are very safe. While minor side-effects from vaccines may develop, serious adverse events are extremely rare and some are so rare that risk cannot be accurately assessed. Most vaccine adverse events are minor and temporary, such as a sore arm or mild fever and can often be controlled by taking acetaminophen before or after vaccination. There are so few vaccine-related deaths that it is impossible to assess the risk statistically; the Institute of Medicine in its 1994 report states that the risk of death from vaccines is "extraordinarily low."⁸⁸

Recommendations: Improving Immunization Coverage

In 2003 the Institute of Medicine's (IOM) Committee on the Evaluation of Vaccine Purchase Financing in the U.S. issued a report, Financing Vaccines in the 21st Century: Assuring Access and Availability. The Committee determined that the federal government should pay for immunizations that meet a standard of societal benefit. It concluded that the current public-private financing of both childhood and adult immunizations is fragmented, unequal, and inadequate. Members of the Committee believe that the present system requires that providers track patient eligibility for too many federal programs and insurance plans, forcing them to refer patients outside their practice and therefore causing too many missed immunizations. The IOM recommended a far-reaching plan to modernize the vaccine supply and delivery system in the U.S. The plan involved an insurance mandate, combined with a government subsidy and voucher plan for the uninsured to receive recommended vaccines.

The vaccine insurance mandate would require all private and public health plans, including Medicare, Medicaid, and the State Children's Health Insurance Program, to cover all vaccines recommended by the Advisory Committee on Immunization Practices. To fund the cost of vaccines and administration fees, the IOM proposed a new federal subsidy. To ensure delivery of all recommended vaccines to the uninsured, the plan includes a government voucher. The value of the voucher would be based on the subsidy amount and could be used to obtain vaccines from the provider of choice.

Stakeholders, who recently met to provide formal feedback regarding the findings of the report, clearly concurred with many of the conclusions which spurred the IOM's recommendations including:

- The importance of vaccines for both children and adults and the need to increase vaccination coverage rates of adults;
- Vaccines are undervalued by society as a whole;
- There is an urgent need to assure access to vaccines and eliminate financial barriers;
- There must be adequate reimbursement of vaccines and administration costs to providers;
- Regulatory harmonization is of paramount importance; and
- Liability protection must be strengthened to insure manufacturing stability.

However, none of the stakeholders seemed to feel that the extensive changes recommended by the IOM were either necessary or feasible.

TFAH and Every Child By Two recommend several immediate steps that should be taken to improve immunization coverage rates and stabilize our nation's vaccine production and delivery system. The following four alternative strategies would address many of the concerns brought to light by the IOM committee.

I) Increased Funding for Vaccines and Vaccine Infrastructure Activities

If the nation is to meet our Healthy People 2010 goals of vaccinating 90 percent of children and adults, adequate funding resources must be provided to the CDC, states, and localities to ensure that those in need of immunizations receive them. Therefore, TFAH and Every Child by Two support a FY 2005 appropriation for the CDC's National Immunization Program (NIP) of \$824 million. This is a \$180 million increase above current appropriations level. The \$824 million includes \$298 million for the Section 317 Grants for vaccine purchases for children, \$68 million for the State Grants for vaccine purchase for adults, \$228 million for State Grants for operations and infrastructure activities, including immunization registries, \$79 million for the NIP prevention, safety, and administrative activities, and \$151 million for Global Immunization Activities.

Although immunization registries are often considered a lower budget priority as states strive to purchase and administer vaccines, they are one of the most effective tools available today to improve immunization rates. Creating a fully operational system of immunization registries in each state could help increase the vaccination rate by identifying the remaining 20 percent of preschool-aged children who need vaccines, allowing program staff to pinpoint valuable outreach dollars. Approximately \$50 million annually is now being spent on registries, from a myriad of sources including federal grants, state funding, and charitable donations.

The cost of immunization registries is estimated at \$124 million annually, according to the CDC. Despite that price tag, registries could save over \$270 million annually by avoiding various costs, such as manually pulling medical records in provider offices for school or daycare entry, duplicative vaccinations, and school system review of immunization records.⁸⁹ By facilitating more efficient program functions such as vaccine administration and distribution, registries have the potential of saving even more public funds.

The importance of registries led the National Vaccine Advisory Committee (NVAC) to launch the Initiative on Immunization registries in 1998 to facilitate development of a nationwide network of community- and statebased immunization registries.90 NVAC has noted that, "the barriers to creating a national system of state-based registries are mainly political and financial rather than technical."91 Despite the benefits of fully operational registries, health departments and political leaders often have difficulty prioritizing the allocation of funds for the development and maintenance of these systems because many related benefits will be incurred mainly in the future. Support among state policymakers and health agencies is critical to insure the completion and ongoing usage of these critical public health tools which have the potential of interacting with future electronic medical records.

"Neglecting to vaccinate 2.1 million preschool kids on time each year is simply unacceptable. This is not a lost cause. We could make real change, real fast by taking some real simple steps."

- SHELLEY A. HEARNE, DRPH, Executive Director of Trust for America's Health

2) Changes to Vaccines for Children (VFC) and State Children's Health Insurance Programs (SCHIP)

Bi-partisan legislation has been introduced in Congress to improve the VFC program in several ways. Two key provisions increase access to immunization for underinsured children and eliminate the price caps on certain vaccines that the federal government purchases from manufacturers. The Children's Vaccine Access Act would permit underinsured children to receive immunizations at public health clinics, not just Federally Qualified Health Centers (FQHCs). This would greatly increase the number of settings underinsured children could go to receive vaccines.

Another important provision of the bill is the elimination of the price cap on certain vaccines that were in use prior to 1993 when the VFC statute was enacted. The price caps have resulted in certain manufacturers of Td vaccines containing tetanus and diphtheria toxiods to refuse to bid on CDC purchase contracts. Consequently, these vaccines are not available under VFC.

The Bush Administration supports these two measures, and included similar provisions its FY 2005 budget proposal for the CDC. Congress should enact these important measures to increase immunization access for the uninsured and to enhance vaccine supply.

In addition, children currently served by the State Children's Health Insurance Programs (SCHIP) within states that designed their SCHIP programs separate from Medicaid –

3) Vaccine Insurance Mandate

TFAH and Every Child By Two support efforts to require all health plans to fully cover ACIP-recommended immunizations without copayments and deductibles. Many vaccines have tremendous societal benefit — they prevent disease and save lives. In addition, the economic savings are irrefutable. Requiring health plans to fully cover ACIP-recommended vaccines would eliminate the financial barriers faced by the

4) Education and Awareness Measures

To combat misperceptions about vaccines and improve communication between providers and parents, education and awareness efforts must be explored. A systematic educational effort addressing common misconceptions is needed to ensure informed decision making about immunizations.⁹² Health care providers including physicians, nurses, and other primary care practitioners have a unique opportunity to educate parents because parents see them as the most important source of information about immunizations.

The CDC has run a nationwide media campaign for the past seven years to reach parents and educate them about the importance of immunizations.⁹³ Despite the campaign, however, 20 percent of preschoolers continue to miss at least one recommended vaccine. The CDC should continue to work closely with primary care providers organi"non-Medicaid expansion SCHIPs" – do not qualify for VFC vaccine, which is entitled to Medicaid children. Modifications to the program to make all children insured under SCHIP eligible for VFC have been presented many times. Bi-partisan legislation was introduced in 2001 in to address this issue. The legislation has been reintroduced in the 108th Congress as part of a larger bill, the Hispanic Health Improvement Act of 2003. TFAH and Every Child by Two strongly support the provision to permit all children under SCHIP to qualify for VFC vaccine.

underinsured, working families of this nation who consistently fall through the cracks of our healthcare system. The IOM recommended such a mandate. However, TFAH and Every Child By Two recommend a stakeholder conference be convened to build consensus toward an appropriate and workable financing mechanism, as many stakeholders disagreed with the IOM's proposal for funding the mandate.

zations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the National Association of Pediatric Nurse Practitioners and other providers to increase awareness among parents and legal guardians about the importance of immunization and to develop materials to debunk unfounded allegations regarding the safety of vaccines. In addition, primary care providers should be encouraged to utilize all child health care encounters, including wellness and acute care visits, to screen and, when indicated, immunize children.

Finally, respected community leaders should be encouraged to vocally support immunization activities while refuting unfounded claims about vaccine safety. The public should be encouraged to base their medical decisions on science, not antivaccine rhetoric.

Appendix: Case Studies

CASE STUDY: PROJECT RESCATANDO SALUD

One outreach program that has been helping to improve immunization rates among Latinos in the Los Angeles County area is "Rescatando Salud." This project between the Los Angeles County Immunization Program, the Esperanza Community Housing Corporation, and the St. John's Family Childcare Center trains local women as community health promoters (or promotoras) who conduct home visits.

Rescatando Salud serves a community that is largely Latino and is considered a pocket of need based on its population size, lack of medical services, low-income levels, low immunization coverage rates, and the high measles morbidity that occurred during the 1990 measles outbreak. Promotoras educate approximately 350 Latino parents a month through home visits. Data gathered from the Young Child Immunization Survey in August 2000 show that immunization rates and health knowledge within the local community have increased significantly since the start of Rescatando Salud. The program has been so successful that it is currently being replicated in the Los Angeles African-American community.

CASE STUDY: COLORADO

According to 2003 CDC data, Colorado has the lowest immunization coverage rate of any state. Only 67.5 percent of 19 to 35 month old children are fully vaccinated. The national average is much higher — 79.4 percent. Despite the low rate, Colorado experienced a significant jump in immunization rates from the 2002 level of 62.7 percent. The state attributes the gain to aggressive efforts to obtain and provide additional financial resources for immunization.

Given the state's low immunization rate compared to the rest of the nation, the Denver Post examined immunization delivery in the state.⁹⁴ The analysis found the following factors affected vaccination coverage rates:

Registries: Unlike many others, Colorado has no statewide registry system to track the immunization history of each member of the state. Immunization advocates identify registries as critical in a society in which families move, change jobs, change health insurance, and become uninsured with great frequency. Statistics within the state provide evidence of the effectiveness of registries. For example, Denver Health and Kaiser Permanente each have systems, and significantly outperform the state in terms of immunization coverage rates.⁹⁵

Shortages: National vaccine shortages were particularly acute in Colorado, especially the Four Corners region, and the state is still catching up, according to the Colorado Children's Immunization Coalition.⁹⁶

Funding: While the Vaccines for Children program provides federal assistance, state contributions to the program dropped from \$500,000 to zero in 2002.⁹⁷ Colorado has since taken several steps to increase funding and improve immunization rates. For example, in January 2004, the state health director ordered that \$388,355 in federal grant funds be redirected to provide immunization program enhancements for 15 local health agencies across Colorado. Governor Bill Owens earmarked \$500,000 in one-time federal funds to immunization. These funds were part of the money the state received under the Jobs and Growth Tax Relief Reconciliation Act of 2003. The Colorado legislature has also restored \$500,000 in state funding to the Immunization Program.⁹⁸

Systemic Issues: An August 2004 study suggests that state Medicaid eligibility, administrative, and reimbursement policies have contributed to decreased access to needed services for children, including immunizations.⁹⁹ The lack of access may be one reason why Medicaid patients have a significantly higher rate of certain illnesses in Colorado, including vaccine-preventable diseases. In addition, the state's comparatively low rates of physician reimbursement for Medicaid patients mean fewer doctors accept the health insurance for the very poor, which leads to many children lacking a "medical home."¹⁰⁰

Public Perception: While the state has roughly the same average number of parents objecting to immunization as other states, certain geographic areas have extremely vocal parents that do not want their children immunized.

CASE STUDY: ROCHESTER, NEW YORK

Another case study shows how a targeted community-wide effort can greatly improve pediatric immunization rates. During a recent National Immunization Conference sponsored by the CDC, Dr. Peter G. Szilagyi, Professor of Pediatrics at the University of Rochester, described how Rochester, New York turned its immunization rates around, reducing and perhaps eliminating racial and socioeconomic disparities within the community.

In 1993, the immunization rate for Rochester's large, impoverished and primarily African-American and Latino inner-city population was measured at 55 percent, which compared to 73 percent in the suburbs. A concerted effort at improvement succeeded dramatically. By 1999, the same population had an immunization rate of 84 percent -- well above the national average and 10 percent greater than the rest of New York state even after excluding New York City.

The program for improvement began in 1993 with a randomized, controlled trial by the

University of Rochester designed to establish whether a reminder-recall-outreach intervention based in primary care offices could raise immunization rates. The pediatricians who cared for the greatest numbers of urban children were enlisted and asked to track vaccinations and place reminder phone calls to parents who fell behind schedule. Home vaccination visits were conducted for the children furthest behind. The results were extremely impressive and also provided increased compliance with other preventive services, such as lead and anemia screening.

As a follow-up, the local health department and then the hospitals and insurers took responsibility for costs and greatly expanded the project. By 1999, the program closed the urban-suburban gap from the 18 percent differential in 1993 to a mere four percent. Moreover, the gap between whites and Latinos fell from 15 percent to one percent, and gap between whites and African-Americans fell from 13 percent to seven percent.

Endnotes

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- 80 "National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19— 35 Months - United States, 1998," <u>Morbidity</u> <u>and Mortality Weekly Report</u>: 49 (22 September 2000): 9.

⁶⁹ Ibid.

- 81 Development of Community and State-Based <u>Immunization Registries</u> (Washington, D.C.: National Vaccine Advisory Committee, 12 January 1999): 10.
- 82 "Immunization Registry Progress United States, January - December 2002," <u>Morbidity and Mortality Weekly Report</u>: 53 (28 May 2004): 431-433 <<u>http://www.cdc.gov/mmwr/preview/</u> mmwrhtml/mm5320a3.htm> 7 June 2004.
- 83 Recent research has debunked many fears that vaccines can cause certain childhood disorders: — Autism: In 1998 a British doctor urged a follow-up of his earlier observation that the MMR vaccine might, in rare cases, cause such behavioral problems as autism by triggering an intestinal disorder like Crohn's disease. He had based his conjecture on a small group of cases —12 children. Since then, several large-scale investigations in the U.S., England, and Finland have shown that neither Crohn's disease nor autism occurs more often following immunization.

• Brain damage: In children six months to five years old, a fever can trigger brief seizures marked by jerking or stiffness. Two vaccines - the MMR and the diphtheria-tetanus-pertussis (DTP) commonly cause fever and thus, in a small number of cases, seizures. These fever - related incidents occur in one in 3,000 children vaccinated against MMR and one in 1,700 kids inoculated with the old, whole-cell DTP vaccine. (The rate is markedly lower with the newer, "acellular" DTaP vaccine: one in 14,000 children.) In the vast majority of cases, convulsions caused by fever in young children do no lasting harm - although they can be frightening to parents. In about 1 in a million cases, though, these seizures are followed by epilepsy, coma, or mental impairment. In such instances, some researchers suspect, the fever simply unmasked an underlying condition: If the vaccine-related fever hadn't triggered the onset of the disorder, another fever would have done so. There hasn't been enough research to know for sure whether this is true, and in rare instances, seizures are not fever induced.

• **SIDS** (sudden infant death syndrome): Antivaccine groups also claimed that whole-cell DTP increased the risk of SIDS, but large studies have found that immunized infants actually have a slightly lower risk.

• Allergies: In the 1990s one hypothesis explaining the rise in the rates of allergic diseases, such as hay fever, asthma, and eczema, was that better hygiene was shielding children from the germs they needed to "educate" their immune system to distinguish harmless substances like pollen and dust from more harmful bacteria and viruses. Some scientists wondered whether vaccines might contribute to that by preventing kids from contracting "normal" childhood diseases. A recent study of immunization rates at 91 medical centers in 38 countries put such concerns to rest, showing no association between vaccination and the incidence of allergic diseases in children ages six to seven. In a separate study of children ages 13 to 14, those with the highest immunization rates actually had lower rates of allergic conditions.

• Juvenile diabetes: In 1997, an immunologist theorized that the timing of the flu vaccine might have an influence on the occurrence of Type 1 diabetes. But a 2001 study conducted by the Centers for Disease Control and Prevention (CDC) compared infants who developed diabetes with those who did not found no link between the time the vaccine was given and the disease.

• Weakened immunity: One of the charges leveled most frequently by anti-vaccine activists is that too many immunizations can overwhelm a young child's developing immune system. This theory is currently being investigated by the Immunization Safety Review Committee, created by the CDC and the Institute of Medicine of the National Academies of Science. But pediatric immunologist Richard Johnston, M.D., at the University of Colorado School of Medicine says that taken together, the purified antigens (compounds that stimulate an immune response, which protects against the real disease) in all of the recommended childhood vaccines represent a mere drop in the ocean compared to what small children are exposed to in their daily lives. And many studies have found that when several vaccines are combined into one shot - standard practice - no major adverse side effects have been detected.

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- 85 Ibid
- 86 Deborah A. Gust, Tara W. Strine, Maurice Emmanuel, Philip Smith, "Underimmunization Among Children: Effects of Vaccine Safety Concerns on Immunization Status." <u>Pediatrics</u>. 114. (1 July 2004).
- 87 <u>Immunization Safety Review: Vaccines and Autism</u>, (Washington, D.C.: Institute of Medicine, 2004). http://www.iom.edu/report.asp?id=20155> 29 July 2004.

- 88 Of all deaths reported to VAERS between 1990 and 1992, only one is believed to be even possibly associated with a vaccine. <http://www.cdc.gov/nip/publications/6mi shome.htm> 29 July 2004.
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- 100 Karen Auge, "State Vaccinations Lag: Colorado Ranks Last Nationwide in Childhood Inoculations," <u>Denver Post</u>, 1 August 2003.



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