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ISSUE BRIEF

Adult Immunization: Shots to Save Lives

AN ISSUE BRIEF FROM TRUST FOR AMERICA'S HEALTH, THE INFECTIOUS DISEASES SOCIETY OF AMERICA, AND THE ROBERT WOOD JOHNSON FOUNDATION

The 2009 novel H1N1 flu outbreak has been a serious reminder that there is no strong mechanism in place for vaccinating adults in the United States. Public health departments are struggling with how to reach adults in communities around the country to encourage them to get vaccinated against H1N1, the seasonal flu, and, in some cases, pneumonia in a short period of time, without any real infrastructure in place.

It is unfortunate, but not surprising, that between 40,000 and 50,000 adults die annually from vaccine preventable diseases in the United States. Millions of American adults go without routine and recommended vaccinations because our medical system is not set up to ensure adults receive regular preventive health care. The result is thousands of deaths from seasonal influenza, invasive pneumococcal disease, the effects of hepatitis B, and other infectious diseases that could have been prevented each year if more adults were vaccinated.[1] The U.S. Centers for Disease Control and Prevention (CDC) has estimated the direct health care burden of adult vaccine-preventable diseases at about $10 billion annually.[2]

CDC recommends that adults should be vaccinated against a range of diseases, including chickenpox, diphtheria, hepatitis A and B, human papillomavirus, influenza, measles, meningococcal disease (meningitis), mumps, pertussis (whooping cough), pneumococcal disease (pneumonia), rubella, shingles, and tetanus.[3] Recommendations for some specific vaccines vary depending on an individual's risk factors and age.

Despite the recommendation of medical experts about the effectiveness and safety of these adult vaccines, immunization rates remain low. Currently, there is no real system or structure in place to ensure adults have access to or receive the vaccines they need unless they are part of institutions that have vaccine requirements, such as being enrolled in colleges or universities, serving in the military, or working in health care settings. Significant numbers of adults do not have regular well care exams and switch doctors and health plans often, which makes it extremely difficult to set up ways for people to know what vaccines they need and for doctors to track and recommend vaccines to patients.

In addition, lack of health insurance coverage and high costs can be an obstacle. Private medical insurance does not always pay for adult vaccinations, and many patients can not afford vaccines, some of which are expensive. Even governmental program support is inconsistent. Medicaid coverage varies among states, and the Medicare process for vaccine payment is often bureaucratic and cumbersome, and not all recommended adult vaccines are covered under Medicare Part B, resulting in out-of-pocket costs that can be prohibitive for some older Americans.

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According to the National Immunization Survey released by CDC in 2007:[4]

- Only 2.1 percent of eligible adults (18 to 64 years old) had the tetanus, diphtheria, and whooping cough vaccine in the previous two years;
- Just under two percent of older patients (60 and over) had the shingles vaccine;
- Only 10 percent of eligible adult women (18 to 26 year olds) had the human papillomavirus (HPV) vaccine;
- Only 36.1 percent of all adults are vaccinated annually for the seasonal flu. Seniors, ages 65 and older, are considered most at risk for complications from the flu, and the CDC recommends all seniors receive a flu shot and the pneumonia vaccine. Yet only 69 percent of seniors, ages 65 and older, had the flu vaccine in 2008. Only 58 percent of Medicare beneficiaries received flu vaccines; and
- Only 66.9 percent had the pneumococcal vaccine, which is far short of the CDC's goal of a 90 percent vaccination rate for seniors.[5]

The consequences are severe in terms of deaths and illnesses that could have been prevented. For instance, each year, approximately 36,000 Americans die of the seasonal flu, 5,000 die from pneumonia, and more than one million adults get shingles, an extremely painful condition that causes a blistering skin rash.[6, 7] In addition, approximately 20 million Americans ages 15 to 49 are currently infected with HPV and are at risk for cervical cancer, and more than 800,000 to 1.4 million Americans are estimated to have chronic viral hepatitis B infection.[8, 9]

According to the National Center for Immunization and Respiratory Diseases, vaccine-preventable diseases kill more Americans every year than traffic accidents, breast cancer, or HIV/AIDS.[10]

Leading scientific and medical organizations, including CDC and the Infectious Diseases Society of America (IDSA), have called for the development of a strong adult immunization program to help prevent these unnecessary deaths and illnesses. Concerns about the need for an adult vaccine strategy have intensified with the novel H1N1 experience, and awareness of the importance of vaccines as a response to many biological terrorism threats, such as smallpox or anthrax continues to grow.

This paper reviews reasons why adult vaccination rates are so low and outlines a series of recommendations for actions needed to develop and implement an effective strategy to make sure American adults have the opportunity to receive the vaccines recommended by medical experts.

VACCINE SUCCESSES

There is considerable evidence that immunizations are effective:

- In the United States, mass vaccination has eliminated polio;
- Smallpox has been eradicated worldwide through widespread immunization;
- Among U.S. children, the recommended immunization series prevents approximately 10.5 million cases of infectious illness a year and 33,000 deaths;[11]
- An economic evaluation of the impact of seven vaccines -- diphtheria, tetanus, and pertussis (DPT), tetanus and diphtheria (Td), *Haemophilus influenzae* type b (Hib), polio, hepatitis B, and varicella (chicken pox), and measles, mumps, and rubella (MMR), routinely given to children found that these seven vaccines prevent more than 14 million cases of disease and more than 33,500 deaths during the lifetime of children born in any given year in the United States, and annually save $10 billion in direct medical costs and more than $40 billion in indirect societal costs.[12] With widespread childhood hepatitis B vaccinations, experts predict there will be a dramatic decline in liver cancer cases among the next generation of adults; and
- A report issued by the World Health Organization (WHO), UNICEF and the World Bank found that three million lives are saved worldwide each year through childhood immunizations, a number that could even be higher with more funding.[13]

ROUTINE PREVENTABLE DISEASES WITH ADULT VACCINES AVAILABLE TO PREVENT THEM[14]

Adults need vaccinations for new diseases and "booster" shots for diseases that they were vaccinated against as children, because their immunity may wane over time. In addition, new vaccines are being developed against old diseases, and adults can benefit from these vaccines as they become available.

Vaccinations against diseases, such as pneumococcal and influenza, are especially important for people at high risk, including those suffering from chronic illnesses such as heart disease, pulmonary disease, diabetes, alcoholism or chronic liver disease (cirrhosis), and for health care professionals and caregivers. Also, Americans who travel to certain foreign countries may need vaccines to protect against diseases that exist in those regions but are not prevalent in the United States.

Vaccines go through rigorous review and testing for effectiveness and safety by the U.S. Food and Drug Administration (FDA) before they are released to the market. The safety of vaccines is tracked through a monitoring system to keep track of potential patterns of adverse side effects.

The Vaccine Adverse Event Reporting System (VAERS) is a joint CDC and FDA program that works with manufacturers, health care providers, and members of the public to report possible adverse events that people experience following vaccinations.[15] In addition, the Vaccine Safety Datalink (VSD) project is a collaboration between CDC's Immunization Safety Office (ISO) and eight large managed-care organizations to monitor safety and answer scientific questions about vaccine side effects.[16]

> "There's a legitimate concern in the public about vaccine safety because vaccines are given to healthy people. For that reason, there is a very high level of responsibility to ensure that they are safe and do not cause harm."
>
> - Edward A. Belongia, MD, Marshfield Clinic Research Foundation

- **Diphtheria:** Diphtheria is a serious bacterial disease that frequently causes heart and nerve problems. Without treatment, 40 to 50 percent of infected persons die, with the highest death rates occurring in the very young and the elderly. Diphtheria has largely been eradicated in the United States and other industrialized nations through widespread vaccination. There were only five reported cases of diphtheria between 2000 and 2007 in the United States.[17]
- **Hepatitis A:** Each year in the United States, hepatitis A infection sickens 125,000 to 200,000 people, resulting in 70 to 100 deaths. Hepatitis A disease tends to occur in outbreaks sometimes attributed to many people having eaten from the same infected food source or transmission from person to person in family settings.
- **Hepatitis B:** National studies show that about 12.5 million Americans have been infected with hepatitis B virus at some point in their lifetimes. More than 10 percent of infected individuals develop chronic infection, increasing chances for chronic liver disease, cirrhosis and liver cancer. Hepatitis B-related liver disease kills about 5,000 people and costs $700 million annually in health care and productivity-related costs.
- **Human Papillomavirus (HPV):** Approximately 20 million Americans currently are infected with HPV, and another 6.2 million people become newly infected each year. At least 50 percent of sexually active men and women acquire genital HPV infection at some point in their lives. HPV can lead to cervical cancer. The HPV vaccine includes protection against the two HPV strains that cause 70 percent of all cervical cancers.
- **Influenza:** Many illnesses are called "flu." These include respiratory as well as gastrointestinal disorders and can be caused by a variety of infectious agents. Influenza is a specific respiratory infection caused by influenza viruses. Influenza vaccine protects against influenza, not the other disorders. In an average year, influenza causes approximately 36,000 deaths and 200,000 hospitalizations in the United States.

- **Pertussis:** Also known as whooping cough, pertussis is highly contagious and can result in prolonged coughing spells that may last for many weeks or even months. Approximately 50 out of every 10,000 people who develop pertussis die from the disease. Since the 1980s, the number of reported pertussis cases has steadily increased, especially among adolescents and adults.[18] In 2004, a total of 25,827 cases of pertussis were reported to the CDC, the highest number since 1959. Of these, 7,008, or 27 percent, occurred among those between age 19 and 64. Young infants who die from pertussis often catch the infection from an adult or adolescent.

- **Pneumococcal disease:** The pneumococcal bacterium is spread by coughing and sneezing. It is the most common cause of pneumonia, inflammation of the coverings of the brain and spinal cord (meningitis), bloodstream infection (sepsis), ear infections and sinus infections (sinusitis) in children under two years of age. The elderly are especially susceptible to this infection. In 2006, there were approximately 41,000 cases of invasive pneumococcal disease, resulting in 5,000 U.S. deaths.

- **Tetanus:** Commonly known as lockjaw, tetanus is a severe disease that causes stiffness and spasms of the muscles, with approximately 30 percent of reported cases ending in death. Tetanus bacteria grow in soil and are an ongoing threat. In the United States, mortality due to tetanus has declined at a constant rate due to the widespread use of tetanus toxoid–containing vaccines since the late 1940s. According to CDC, in 2005, a total of 27 tetanus cases and 2 deaths were reported to the national tetanus surveillance system.[19]

- **Zoster (Shingles)[20]:** Zoster (shingles) is a very painful nerve infection caused by the same virus as chickenpox and is often accompanied by a localized skin rash with blisters. Anyone who has had chickenpox can develop shingles because the virus remains in the nerve cells of the body after the chickenpox infection clears and can emerge years later to cause shingles. The disease most commonly occurs in people 50 years and older, and those with compromised immune systems. There are approximately one million zoster cases annually; one in three Americans will get shingles in their lifetime; frequently shingles and post-herpetic neuralgia increase with age.

ADDITIONAL CHILDHOOD VACCINE-PREVENTABLE DISEASES

In addition to the adult immunizations, there are also a number of other immunizations that are recommended during childhood, including:

- ***Haemophilus influenzae type b (Hib):*** Prior to the vaccine, Hib meningitis killed 600 children each year, and caused seizures among many survivors as well as permanent deafness, and mental retardation. Since the vaccine's introduction in 1987, the incidence of serious Hib bacteria infection has declined by 98 percent in the United States.

- **Measles:** As a result of widespread vaccination, measles is no longer endemic in the United States. However, because measles is still widespread in many countries, the United States is at risk of "importation" of the disease, and if high immunity is not maintained in adults and children, there is a risk of re-establishment of endemic transmission. Measles is highly contagious. In the first half of 2008, CDC received reports of 131 measles cases from 15 states and the District of Columbia -- the highest year-to-date number since 1996.[21] More than 90 percent of those infected had not been vaccinated or their vaccination status was unknown. In the United States, roughly one in five people who develop measles require hospitalization for one or more complications from the disease.

- **Meningococcal disease:** Meningococcal disease is a serious bacterial illness, and is a leading cause of bacterial meningitis in children two through 18 years old in the United States. About 1,000 - 2,600 people get meningococcal disease each year in the United States and 10-15 percent of these people die. Young college students living in dormitories and military recruits living in barracks are especially vulnerable.

- **Mumps:** Prior to the mumps vaccine, the United States suffered approximately 200,000 cases of mumps per year with 20 to 30 deaths. Since a second dose of mumps vaccine was added to the standard childhood immunization series, annual cases are now in the hundreds rather than the thousands.

- **Rotavirus:** Rotavirus is a disease of the digestive tract caused by any one of three strains of rotavirus. Infection causes acute gastroenteritis (vomiting and diarrhea), and humans of all ages are susceptible to rotavirus infection. According to CDC, each year rotavirus is responsible for more than 400,000 doctor visits; more than 200,000 emergency room visits; 55,000 to 70,000 hospitalizations; and between 20 and 60 deaths in the United States.

- **Rubella:** Before the rubella vaccine was introduced, widespread outbreaks mostly affected children in the 5-9 year age group. Between 1962 and 1965, rubella infections during pregnancy were estimated to have caused 30,000 still births and 20,000 children to be born impaired or disabled.

- **Varicella/Chickenpox:** Although generally mild, varicella (chickenpox) is a highly contagious virus that can lead to severe illness with complications such as secondary bacterial infections, severe dehydration, pneumonia, central nervous system deficits/disease and shingles. Chickenpox has been reduced by 80 percent in the United States since the introduction of the vaccine.[22]

FUTURE POSSIBLE VACCINATIONS

A number of additional vaccinations are in the research and development phase. Scientists hope that many additional vaccines are on the horizon for both infectious and chronic diseases. Most of the current vaccinations in wide use are focused on infectious diseases, but there are a number of potentially promising vaccines aimed at chronic disease issues and factors that contribute to chronic disease or behavior health, including smoking, drug use, and obesity. A smoking vaccine is currently in clinical trials.[23]

CDC'S IMMUNIZATION RECOMMENDATIONS TO HEALTH CARE WORKERS[24]

INFLUENZA: Health care personnel need an influenza vaccination every year. Unvaccinated health care workers can spread influenza to patients and are a key cause of influenza outbreaks among patients and long-term care residents. The vaccine does not cause influenza.

HEPATITIS B: Five to 10 percent of acute hepatitis B infections lead to chronic infection, and these lead to liver damage (cirrhosis), liver cancer, or death. Hepatitis B vaccine should be given to protect individuals who are in contact with blood, body fluids, or used needles.

MEASLES/MUMPS/RUBELLA (MMR): Health care workers who are not already immune to MMR should be vaccinated. Even mild or undetectable rubella disease can cause birth defects.

TETANUS/DIPHTHERIA/PERTUSSIS (Td/Tdap): Health workers need a booster every 10 years for Td (tetanus-diphtheria) vaccine, and Tdap should replace a single dose of Td for adults who have not received a dose of Tdap previously. Persons may receive Tdap if it has been at least two years since the last Td vaccination. Health workers who are injured and/or who have direct patient contact should be especially vigilant about booster shots.

VARICELLA (CHICKENPOX): Varicella can be transmitted in hospitals by patients, staff, and visitors. Health workers who are not already immune should be vaccinated.

VACCINES FOR TRAVELERS[25]

Recommended: U.S. authorities recommend certain vaccines to protect travelers from illnesses present in other parts of the world and to prevent the importation of infectious diseases across international borders. The vaccinations travelers need depend on several factors, including destination, whether the individual will be spending time in rural areas, the season of the year, age, health status, and previous immunizations. The CDC recommends travelers visit its destinations page at http://wwwn.cdc.gov/travel/destinations/list.aspx to learn which vaccines they may need for specific countries.

Required: The only immunization required by international health regulations is yellow fever vaccination for travel to certain countries in sub-Saharan Africa and tropical South America. Saudi Arabia requires meningococcal vaccination during the Hajj (the annual Muslim pilgrimage to Mecca) and documentation of polio vaccination must be presented for children 15 years of age and younger.

VACCINES DURING PREGNANCY

> "Chickenpox can make you very sick if you are an adult. Adults are 25 times more likely to have a severe case of chickenpox than children. The disease can result in death. In pregnant women, it can cause birth defects."
>
> --Anne Gershon, MD, Columbia University College of Physicians, Department of Pediatrics.

Pregnant women have a higher risk of complications from influenza compared with the general population. Women who may become pregnant should consult with their health care providers to ensure they are current on routinely recommended vaccines. It is recommended that women who become pregnant should receive the inactivated seasonal flu shot and women should receive the Tdap vaccine before they become pregnant.[26] In addition, the MMR vaccine can prevent birth defects due to infection with rubella during pregnancy. Anyone receiving either the MMR or varicella (chickenpox) vaccine should wait four weeks before becoming pregnant. If a woman is already pregnant, she should wait until after delivery to get either of these vaccines.

The H1N1 outbreak demonstrated the need for pregnant women to receive flu vaccinations, as they suffered higher rates of severe reactions than the general population.[27]

I. PNEUMOCOCCAL AND SEASONAL INFLUENZA VACCINATIONS

To illustrate the low rates of adult vaccinations, TFAH conducted an analysis of the number of seniors who have been vaccinated against pneumonia and adults who have been vaccinated against the seasonal flu in each state. These represent the two most successful campaigns for adult immunizations, yet the number of adults who get vaccinated is still relatively low.

Pneumonia Vaccinations for Seniors

CDC has recommended that all seniors, ages 65 and older, should be vaccinated against pneumonia, and HHS has set a national goal of immunizing 90 percent of seniors by the year 2010. This shot is only required once in a lifetime for most people. As of 2008, only 66.9 percent of seniors have received the vaccine.[28] Vaccination rates range from a low of 55.4 percent in the District of Columbia and a high of 73.2 percent in Oregon.

CDC also recommends that anyone over the age of two with underlying health problems (such as asthma, heart disease, lung disease, sickle cell disease, diabetes, alcoholism, cirrhosis, and other chronic diseases), with a disease that lowers the body's resistance to infection (such as Hodgkin's disease, or HIV/AIDS), who smoke, or who are taking any drug or treatment that lowers the body's resistance to infection (such as long-term steroids or radiation therapy), should get immunized against pneumonia.

People with flu, particularly seniors, are at risk for developing pneumonia as a complication. Pneumonia can be lethal, particularly in older adults. Together with flu, pneumonia is the eighth leading cause of death in the United States.

Pneumococcal Vaccination Rates for Adults Aged 65+			
	Percent Vaccinated	**Percent NOT Vaccinated**	**Rank: 1 = Lowest Vaccination Rate**
Alabama	64.0% (+/- 1.8)	36.0%	8
Alaska	64.0% (+/- 4.4)	36.0%	8
Arizona	68.2% (+/- 2.3)	31.8%	30
Arkansas	64.2% (+/- 1.5)	35.8%	12
California	61.0% (+/- 1.9)	39.0%	3
Colorado	72.6% (+/- 1.3)	27.4%	50
Connecticut	66.6% (+/- 1.4)	33.4%	22
Delaware	70.0% (+/- 2.1)	30.0%	38
D.C.	54.4% (+/- 2.3)	45.6%	1
Florida	62.4% (+/- 1.3)	37.6%	4
Georgia	64.0% (+/- 1.6)	36.0%	8
Hawaii	67.9% (+/- 1.8)	32.1%	27
Idaho	64.7% (+/- 1.8)	35.3%	14
Illinois	59.6% (+/- 1.7)	40.4%	2
Indiana	66.9% (+/- 1.7)	33.1%	24
Iowa	70.1% (+/- 1.5)	29.9%	40
Kansas	68.5% (+/- 1.2)	31.5%	32
Kentucky	65.2% (+/- 1.6)	34.8%	16
Louisiana	66.3% (+/- 1.7)	33.7%	21
Maine	70.5% (+/- 1.7)	29.5%	43
Maryland	66.1% (+/- 1.6)	33.9%	19
Massachusetts	69.6% (+/- 1.1)	30.4%	36
Michigan	65.8% (+/- 1.4)	34.2%	18
Minnesota	70.8% (+/- 1.7)	29.2%	45
Mississippi	66.8% (+/- 1.4)	33.2%	23
Missouri	67.3% (+/- 1.9)	32.7%	26
Montana	71.2% (+/- 1.5)	28.8%	47
Nebraska	70.2% (+/- 1.3)	29.8%	41
Nevada	66.1% (+/- 2.4)	33.9%	19
New Hampshire	71.2% (+/- 1.5)	28.8%	47
New Jersey	63.5% (+/- 1.4)	36.5%	6
New Mexico	64.6% (+/- 1.6)	35.4%	13
New York	63.3% (+/- 1.6)	36.7%	5
North Carolina	68.8% (+/- 1.0)	31.2%	33
North Dakota	69.4% (+/- 1.7)	30.6%	35
Ohio	68.4% (+/- 1.7)	31.6%	31
Oklahoma	71.1% (+/- 1.3)	28.9%	46
Oregon	73.2% (+/- 1.5)	26.8%	51
Pennsylvania	69.7% (+/- 1.4)	30.3%	37
Rhode Island	71.8% (+/- 1.6)	28.2%	49
South Carolina	64.0% (+/- 1.4)	36.0%	8
South Dakota	64.7% (+/- 1.4)	35.3%	14
Tennessee	65.4% (+/- 1.9)	34.6%	17
Texas	63.7% (+/- 1.6)	36.3%	7
Utah	68.0% (+/- 1.9)	32.0%	28
Vermont	69.0% (+/- 1.4)	31.0%	34
Virginia	68.1% (+/- 2.0)	31.9%	29
Washington	70.0% (+/- 0.8)	30.0%	38
West Virginia	66.9% (+/- 1.8)	33.1%	24
Wisconsin	70.5% (+/- 1.8)	29.5%	43
Wyoming	70.3% (+/- 1.5)	29.7%	42
U.S. Total	**66.9%**	**33.1%**	**N/A**

Source: Behavioral Risk Factor Surveillance System.

Seasonal Flu Vaccinations for Adults

The annual vaccine for seasonal flu is the largest existing program for adult vaccinations in the United States. However, only a fraction of adults receive this vaccine. In some states, the rates of adult vaccinations for the flu is as low as 25.5 percent (Nevada), and even in the state with the highest vaccination rate, South Dakota at 49.2 percent, less than half of the state's population has been vaccinated. Seasonal flu vaccines have been largely recommended for individuals above the age of 50, since they are most at risk for health complications related to the flu. Even with targeted efforts to vaccinate individuals above the age of 65, the rates of annual flu vaccinations for seniors is as low as 61.3 percent in D.C and no state exceeds 80 percent. The highest rate is 77.9 percent in Colorado.

SEASONAL FLU VACCINATION RATES FOR ADULTS, 2008

State	18-49 Year Olds	50-64 Year Olds	65 Years and Over	Total
Alabama	26.3% (+/- 2.8)	41.8% (+/- 2.8)	68.7% (+/- 2.7)	37.9% (+/- 1.9)
Alaska	26.7% (+/- 3.5)	43.0% (+/- 4.9)	68.5% (+/- 6.3)	35.2% (+/- 2.8)
Arizona	22.2% (+/- 3.6)	39.4% (+/- 4.6)	71.4% (+/- 3.2)	34.8% (+/- 2.6)
Arkansas	27.7% (+/- 2.7)	44.9% (+/- 2.8)	70.5% (+/- 2.5)	40.1% (+/- 1.8)
California	18.4% (+/- 1.5)	39.5% (+/- 2.2)	70.0% (+/- 2.2)	30.8% (+/- 1.1)
Colorado	28.9% (+/- 1.6)	48.6% (+/- 1.9)	77.9% (+/- 1.7)	40.4% (+/- 1.2)
Connecticut	28.3% (+/- 2.6)	45.7% (+/- 3.0)	74.6% (+/- 2.4)	41.1% (+/- 1.8)
Delaware	26.1% (+/- 3.0)	46.7% (+/- 3.9)	69.6% (+/- 3.5)	38.8% (+/- 2.2)
D.C.	30.3% (+/- 2.8)	44.2% (+/- 3.3)	61.3% (+/- 3.5)	38.2% (+/- 2.0)
Florida	17.7% (+/- 2.5)	32.4% (+/- 2.8)	63.5% (+/- 2.5)	31.4% (+/- 1.7)
Georgia	21.8% (+/- 2.3)	38.6% (+/- 2.8)	65.2% (+/- 2.9)	31.8% (+/- 1.7)
Hawaii	31.9% (+/- 2.5)	47.4% (+/- 2.8)	77.1% (+/- 2.5)	44.2% (+/- 1.7)
Idaho	20.8% (+/- 2.3)	39.5% (+/- 2.8)	68.4% (+/- 2.9)	33.0% (+/- 1.7)
Illinois	20.8% (+/- 2.2)	38.6% (+/- 3.0)	63.2% (+/- 2.9)	31.9% (+/- 1.7)
Indiana	21.5% (+/- 2.6)	39.9% (+/- 3.1)	68.6% (+/- 3.1)	34.1% (+/- 1.9)
Iowa	32.7% (+/- 2.4)	48.2% (+/- 2.7)	76.5% (+/- 2.2)	44.8% (+/- 1.7)
Kansas	26.9% (+/- 2.0)	43.5% (+/- 2.1)	72.0% (+/- 1.9)	38.9% (+/- 1.4)
Kentucky	25.8% (+/-2.5)	43.6% (+/- 2.6)	73.6% (+/- 2.3)	38.6% (+/- 1.7)
Louisiana	27.5% (+/- 2.3)	43.6% (+/- 2.6)	68.0% (+/- 2.8)	38.2% (+/- 1.6)
Maine	25.0% (+/- 2.1)	47.3% (+/- 2.3)	74.6% (+/- 2.2)	40.6% (+/- 1.5)
Maryland	26.8% (+/- 2.0)	46.3% (+/- 2.4)	69.8% (+/- 2.5)	38.5% (+/- 1.4)
Massachusetts	28.5% (+/- 1.6)	45.8% (+/- 1.8)	72.0% (+/- 1.7)	40.5% (+/- 1.1)
Michigan	23.0% (+/- 1.8)	41.8% (+/- 2.1)	70.0% (+/- 2.0)	35.7% (+/- 1.3)
Minnesota	36.8% (+/- 2.9)	50.4% (+/- 2.9)	76.4% (+/- 2.6)	46.6% (+/- 2.0)
Mississippi	24.7% (+/- 2.2)	38.4% (+/- 2.3)	67.5% (+/- 2.2)	35.5% (+/- 1.5)
Missouri	26.5% (+/- 2.8)	45.1% (+/- 3.3)	71.3% (+/- 2.8)	39.2% (+/- 2.0)
Montana	25.3% (+/- 2.6)	40.9% (+/- 2.5)	69.3% (+/- 2.4)	37.8% (+/- 1.7)
Nebraska	33.0% (+/- 2.4)	51.3% (+/- 2.3)	75.7% (+/- 1.8)	45.2% (+/- 1.6)
Nevada	15.4% (+/- 2.3)	29.6% (+/- 3.5)	57.1% (+/- 3.9)	25.5% (+/- 1.8)
New Hampshire	28.9% (+/- 2.2)	49.4% (+/- 2.5)	78.1% (+/- 2.1)	42.6% (+/- 1.6)
New Jersey	22.9% (+/- 1.9)	39.9% (+/- 2.2)	65.9% (+/- 2.2)	34.8% (+/- 1.3)
New Mexico	28.0% (+/- 2.6)	42.3% (+/- 2.8)	69.7% (+/- 2.6)	38.6% (+/- 1.8)
New York	24.8% (+/- 2.1)	43.9% (+/- 2.6)	70.9% (+/- 2.4)	37.6% (+/- 1.5)
North Carolina	28.4% (+/- 1.7)	47.3% (+/- 1.9)	73.0% (+/- 1.6)	40.4% (+/- 1.2)
North Dakota	30.0% (+/- 2.8)	45.4% (+/- 2.7)	73.2% (+/- 2.4)	42.1% (+/- 1.9)
Ohio	24.2% (+/- 1.9)	42.0% (+/- 2.0)	70.3% (+/- 1.8)	37.1% (+/- 1.3)
Oklahoma	27.8% (+/- 2.0)	51.3% (+/- 2.4)	73.2% (+/- 2.1)	41.8% (+/- 1.4)
Oregon	20.7% (+/- 2.3)	43.2% (+/- 2.7)	70.1% (+/- 2.6)	35.3% (+/- 1.7)
Pennsylvania	23.7% (+/- 2.0)	43.2% (+/- 2.3)	71.7% (+/- 2.0)	38.3% (+/- 1.4)
Rhode Island	28.1% (+/- 2.8)	49.9% (+/- 3.0)	74.0% (+/- 2.6)	42.0% (+/- 2.0)
South Carolina	23.6% (+/- 2.3)	42.9% (+/- 2.7)	68.0% (+/- 2.4)	36.3% (+/- 1.6)
South Dakota	37.8% (+/- 2.7)	53.6% (+/- 2.6)	76.3% (+/- 2.1)	49.2% (+/- 1.8)
Tennessee	29.0% (+/- 3.2)	42.7% (+/- 3.1)	70.8% (+/- 2.8)	39.5% (+/- 2.1)
Texas	24.8% (+/- 1.9)	42.1% (+/- 2.5)	71.1% (+/- 2.2)	35.4% (+/- 1.5)
Utah	30.7% (+/- 2.4)	48.6% (+/- 3.2)	73.3% (+/- 3.0)	39.8% (+/- 1.8)
Vermont	26.1% (+/- 2.1)	46.9% (+/- 2.2)	73.4% (+/- 2.2)	40.2% (+/- 1.5)
Virginia	29.3% (+/- 3.3)	48.0% (+/- 3.6)	73.1% (+/- 3.1)	40.7% (+/- 2.4)
Washington	26.3% (+/- 1.3)	44.2% (+/- 1.4)	71.4% (+/- 1.4)	38.0% (+/- 0.9)
West Virginia	23.5% (+/- 2.4)	46.5% (+/- 2.9)	71.1% (+/- 2.8)	39.1% (+/- 1.8)
Wisconsin	28.9% (+/- 2.8)	44.4% (+/- 3.2)	73.0% (+/- 3.0)	40.5% (+/- 2.0)
Wyoming	27.7% (+/- 2.0)	44.8% (+/- 2.1)	70.7% (+/- 2.1)	39.5% (+/- 1.4)
National Totals	**24.1% (+/- 0.5)**	**42.0% (+/- 0.5)**	**69.5% (+/- 0.5)**	**36.1% (+/- 0.7)**

Source: Behavioral Risk Factor Surveillance System. More information on the methodology for this analysis is available in Appendix D.

II. BARRIERS TO ADULT IMMUNIZATION

Several barriers keep the numbers of adult vaccinations low.

- **LIMITED ACCESS:** Most adults are outside of institutionalized settings, like the military, where vaccinations can be required;
- **LIMITED CARE AND INSURANCE COVERAGE:** Primary and preventive care for adults is limited, particularly for the uninsured or underinsured;
- **LIMITED FINANCING FOR IMMUNIZATIONS:** Many adults have medical insurance that does not pay for vaccines and their administration, so out-of-pocket costs may be prohibitive;
- **MISUNDERSTANDING AND MISINFORMATION:** Many adults are misinformed about the safety and effectiveness of vaccines; and
- **LIMITED REARCH AND DEVELOPMENT:** Vaccine research, development, and production have been limited in the United States for decades.

A. LIMITED ACCESS: FEW REQUIREMENTS FOR ADULT VACCINATIONS EXIST

The United States has developed successful childhood vaccination campaigns. To protect children from vaccine-preventable diseases, states have enacted laws that require immunization for the entry of children into the school system and into child care facilities. In addition, a Vaccines for Children (VFC) program was created to pay for vaccines for all children. According to data from the 2006-2007 school year, approximately three-quarters of the states already have reached the national Healthy People 2010 target of at least 95 percent coverage for all vaccines recommended for children in kindergarten.[29] The high nationwide coverage underscores the value of school-entry requirements in boosting vaccination coverage.

Creating a program to reach all adults is more complicated. For adults, there are no institutions, such as schools, which could facilitate a broad immunization requirement, although certain establishments like universities or the military require some immunizations for adults who are affiliated with these institutions. For example, many colleges require new students to prove they have been immunized against MMR, meningococcal disease and hepatitis B. Military personnel must also have certain vaccinations, and, depending on deployment, receive additional immunizations to protect against such bio-terror threats as smallpox and anthrax. Nursing homes that receive Medicare payments are required to offer seasonal influenza and pneumococcal vaccinations to their residents, but residents are not required to accept them. Also, the requirement to offer the shots in nursing homes does not extend to the facility's health workers, staff, or visitors. Some hospitals and other health care facilities require an immunization review for specific vaccinations upon admission of a patient or for new employees.

B. LIMITED CARE AND INSURANCE COVERAGE: ADULT CARE DOES NOT STRESS PRIMARY CARE OR PREVENTION

The American health care system for adults is geared more toward treating illness than ensuring wellness. Many adults rarely see a primary care physician or only go to a doctor when they are sick or are managing chronic conditions. And, many adults receive most of their medical care from sub-specialists who do not consider immunizations their responsibility. In addition, many doctors are unaware of specific immunization guidelines for adults, and many adult patients are unaware that they need vaccinations. And, a significant number of adults – an estimated 44 million Americans – lack access to primary health care altogether.[30]

Since vaccinations have not traditionally been provided regularly as part of adult care, basic systems are not well established for doctors to provide them.

> "I get a card from my veterinarian when it's time to bring my dog and cat in for their shots. Why don't I get a card from my doctor when it's time for me to get mine?"
>
> --Gregory A. Poland, MD, Director, Mayo Clinic Vaccine Group.

> "Many doctors are not vaccine-savvy with respect to adults, and we need to educate them. Practices should have 'standing orders,' so that every patient who comes in is screened and asked questions about immunization -- and then receives the vaccines if they are needed."
>
> --William Schaffner, MD, Vanderbilt University School of Medicine, Department of Preventive Medicine

One problem for doctors is the difficulty in storing adult vaccines in their offices. Different vaccines have different temperature storage requirements such as refrigeration or use of a freezer, and even a short power loss can ruin an entire inventory. Many small physician practices do not have the facilities for backup power. Also, the administration fee provided by some payors does not include the cost of purchasing refrigerators/freezers and other storage costs. And, even if a doctor's office stores vaccine, it is hard to predict how much vaccine they will need or use, since most adult vaccines are recommended over a period of 50 to 70 years, as compared to vaccines for children, which are mostly administered during the first six years of life. There is no guarantee that the adults in any one practice will generate enough demand for a particular vaccine, so vaccines may have to be discarded once their "use by" date expires, resulting in unreimbursed costs.

In addition, many health care workers themselves do not get regularly recommended vaccinations. A 2003 immunization survey conducted by CDC, for example, showed seasonal influenza vaccination coverage of only 40 percent among health care workers.[31] Experts say that immunizations are especially important for health care workers, since they can transmit infections to their ill and immune-compromised patients and vice versa. This is considered an especially important issue in hospitals and nursing homes, where many patients are elderly and at increased risk for influenza and pneumococcal disease. Vaccination of health care personnel can reduce staff illnesses, absenteeism, and the likelihood of sickness and death among patients.

Studies have consistently shown several additional reasons why health care workers do not get influenza vaccinations. The most frequent reason unvaccinated workers gave for not getting the flu shot was that they thought that they did not need it.[32] Some expressed concern about vaccine side effects, including the erroneous belief that vaccine can cause the flu. Others perceived themselves to be at low risk for catching the virus or felt that getting vaccinated was an inconvenience.

In addition, despite the scientific evidence to the contrary, some doctors and medical providers have unsubstantiated personal concerns about vaccinations that cause them to dissuade patients from receiving vaccines or they pass along misinformation to their patients about vaccinations. For instance, there were reports that a number of health providers counseled their patients not to get the novel Influenza H1N1 vaccine in spite of the scientific evidence of the safety and effectiveness of the vaccine. Many public health experts recommend that increased education about vaccinations should be included as part of nursing, medical, and other health professional educational curricula.

> "Health care workers often [mistakenly] think they're immune. They've been working in this setting for a long time, have been around sick people, and [wrongly] think they have natural defenses."
>
> -- Pascale Wortley, MD, MPH, Chief, Health Services Research and Evaluation Branch, National Center for Immunization and Respiratory Diseases, CDC.

In an effort to increase the number of adults being vaccinated, a number of medical groups, including the American College of Physicians and the IDSA, are trying to increase awareness within medical school curricula and among certain specialties, such as gynecology, which have regularized patient contact. So, for instance, when women go for mammograms or Pap tests, they could also have access to vaccinations.

In addition, flu vaccination campaigns are making vaccines regularly available to individuals in alternative sites outside of the medical care setting, such as through drug stores and supermarkets. During the novel Influenza H1N1 vaccination campaigns, a number of non-traditional sites were also used with success, including airports, zoos, social service agencies, and baseball parks. Alternative sites could also be explored for other vaccinations beyond influenza.

KEEPING TRACK OF VACCINATIONS

Effective tracking of adult immunization is important to help people avoid getting redundant or unnecessary vaccinations. Registries can maintain patient confidentiality while serving as good health records for individuals and as a means to track population vaccination trends.[33] Forty-nine states have some form of childhood vaccination registry in effect. Approximately 20 percent of adults over 19 years of age have at least some immunization information in an immunization registry. The wider use of electronic medical records in the years ahead could make tracking vaccinations easier for individuals and providers.

C. LIMITED FINANCING FOR VACCINES: LACK OF INSURANCE COVERAGE LIMITS VACCINATIONS

One major obstacle to adult vaccinations is cost. A number of insurance programs, including some state Medicaid programs, do not cover the actual costs for doctors to administer vaccines. Many private insurers require patient co-payments for vaccinations.[34] Government programs cover approximately nine percent of adults younger than 65 years of age. While federal funds from Section 317 of the Public Health Service Act given to states can be used to help support adult vaccinations in public health clinic settings, most of these funds are used to support childhood immunization programs.[35] The Section 317 program is a discretionary federal grant program to all states, 6 cities, territories and protectorates, which provides vaccines to underinsured children and adolescents not served by the VFC program, and as funding permits to uninsured and underinsured adults.[36]

In addition, Medicare coverage for vaccinations for adults ages 65 and older is fragmented. Medicare Part B pays for influenza, pneumococcal, and hepatitis B vaccines, and covers other vaccines only when they are related to an injury – tetanus, for example, or other direct exposure to a disease.[37] As of 2006, Medicare Part D pays for all current and future vaccines not covered by Part B; however recipients confront obstacles in obtaining vaccines through Medicare Part D, since the system is designed to reimburse pharmacies rather than physicians.

Finally, the costs of several of the new adult vaccines are relatively expensive and can be a disincentive to vaccinating adults. Zostavax®, the approved vaccine against shingles, is one of the most expensive vaccines on the market, as is Gardasil®, an HPV vaccine. (The cost of Zostavax® can be as high as $200 or more for a single shot; Gardasil®, costs up to $175 or more per dose and three doses are needed per individual.)

D. MISUNDERSTANDING AND MISINFORMATION: MISPERCEPTIONS AND MYTHS KEEP SOME ADULTS FROM GETTING VACCINATED

Scientific research has shown that 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 a pain reliever before or after vaccination. There are so few vaccine-related deaths that it is impossible to assess the risk statistically.[38]

The benefits of vaccines greatly outweigh the potential adverse effects. Diseases such as measles, mumps, and rubella have essentially been eradicated from the United States and Europe in the past 40 years due to widespread vaccination efforts.[39] Many adults in the United States or Europe have never even known anyone with a case of measles, mumps, or rubella, yet these diseases continue to plague other parts of the world where vaccination campaigns and consistently available resources do not exist. Due to unsubstantiated fear over vaccinations and a complacent attitude towards diseases adults have not encountered in modern times, some adults have chosen not to vaccinate their children and/or themselves, and in turn rates of certain vaccine-preventable diseases have increased in recent years, highlighting the importance of continued efforts to vaccinate.[40]

With the current outbreak of 2009 novel H1N1 influenza, many questions regarding the safety of vaccines, specifically the H1N1 vaccines, have been brought to the forefront of discussions. Two months after the first doses of the H1N1 vaccine became available to the public an extensive review of adverse effects indicated that the vaccine is safe.[41] No side effects beyond those typical of the seasonal flu vaccine were reported, and a very small number of serious adverse events have been reported.

The importance of vaccinations cannot be overstated. According to the CDC:

Perhaps the greatest success story in public health is the reduction of infectious disease resulting from the use of vaccines. Routine immunization has eradicated smallpox from the globe and led to the near elimination of wild polio virus. Vaccines have reduced some preventable infectious diseases to an all-time low, and now few people experience the devastating effects of measles, pertussis, and other illnesses.[42]

When used in conjunction with education and other public health measures, vaccinations can continue to increase the quality and length of life across the world.

Despite the evidence of safety and effectiveness of vaccines, many adults are unaware that they need certain vaccinations or are misinformed about vaccines.

According to the findings of a 2007 public opinion survey by the National Foundation on Infectious Diseases, many adults did not know that adult vaccinations were available that could protect them from diseases for which they could be at risk.[43] Forty percent of respondents reported that they did not think they needed vaccines because they were vaccinated as a child, 34 percent were not concerned about catching diseases that can be prevented by vaccines, 32 percent were not concerned about spreading an illness to friends, family, and co-workers, 25 percent thought diseases prevented by vaccines are not serious or life-threatening, and 18 percent said they thought vaccines were not necessary for adults.

Despite the scientific evidence, a number of respondents expressed concern about vaccine safety or efficacy. Thirty-five percent had heard or read that vaccines are not safe, 25 percent reported that they thought a vaccine made them sick, and 14 percent felt that vaccines do not work.

About one-fourth of respondents expressed concern about cost. Twenty-seven percent thought insurance would not cover vaccines, 26 percent thought vaccines are too expensive, and 22 percent said they would not get vaccinated if they had to pay for it.

Adult vaccination rates are particularly low for minority groups. Researchers have found that African Americans were significantly less likely than whites to have positive attitudes toward influenza vaccination.[44] According to 2008 data, 69 percent of older non-Hispanic whites received the seasonal influenza vaccination, compared to only 53 percent and 51 percent of older African Americans and Hispanics, respectively.[45] The gap for pneumococcal vaccination coverage was even greater; vaccination rates were 61 percent for non-Hispanic whites, compared to 45 percent for African Americans and 29 percent for Hispanics. Researchers are trying to better understand the reasons behind these disparities. Numerous studies have shown that economics, education, and discrimination all are factors.[46] This study suggested that negative attitudes about vaccinations among African Americans had much more influence over vaccination decisions than recommendations from health care providers.

Even some members of the medical community express personal concern about vaccinations, despite the scientific evidence of safety and efficacy, which sometimes causes them to pass along misinformation to patients or even refuse to vaccinate patients. Public health experts recommend greater efforts be made to help provide increased education about the safety of vaccines to medical providers who may have concerns, particularly to encourage providers to provide the most up-to-date information to their patients.

E. RESEARCH AND DEVELOPMENT: RAMPING UP DISCOVERIES AND ADVANCES

Vaccine research and development can be expensive for pharmaceutical companies, and it is often difficult for manufacturers to obtain the development support needed to push a new vaccine toward profitability. Studies have shown that each new product reaching the market can take up to a decade of development, and a financial investment of up to $1 billion.[47] In addition, the fact that the market for adult vaccines can be limited, since vaccination rates are so low, has discouraged many U.S. manufacturers from major investment in vaccine development.

In recent years, Congress has enacted legislation that makes it easier and faster for the HHS to fund the development and procurement of new medical countermeasures against bioterrorism and some naturally-occurring emerging infectious threats. Through the Biomedical Advanced Research and Development Authority (BARDA), the government has created measures to guarantee that they will pay manufacturers for vaccines and drugs produced for the Strategic National Stockpile (SNS), once development is complete.[48] Unfortunately, since its creation, BARDA has not been adequately funded to allow the program to achieve its mission. In fiscal year (FY) 2010, BARDA received $305 million from Congress. Organizations such as the Center for Biosecurity recommended BARDA receive $1.7 billion in FY 2010 to successfully carry out its mission and responsibilities.[49] Furthermore, Congress has authorized the HHS Secretary to permit emergency use of critical products through a streamlined, but temporary FDA licensure procedure.[50] This emergency authority eases some of the regulatory burden of getting a new vaccine into the market. In December 2009, HHS Secretary Kathleen Sebelius announced she was ordering a major review of policies for developing medical countermeasures against public health threats.[51]

FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating and licensing vaccines in the United States. Typically, the development of a new vaccine follows an approval process similar to the one used for drugs. Human studies are conducted in three phases, the first, a small trial to look at safety and to see if there is an immune response; the second, to assess dosage; and the third and largest to document efficacy.

Today, many experimental vaccines are in public and private sector vaccine development pipelines, aimed at routine use in healthy pediatric and adult populations, travelers, the military, and potential emerging biological threats.[52]

Recent years have seen the introduction of several important new vaccines, including those against zoster (shingles) and HPV, as well as improved versions of existing vaccines, such as the meningococcal conjugate vaccine and a pertussis vaccine that is effective in adolescents and adults (included in Tdap vaccine). Work is underway on vaccines for cytomegalovirus (CMV), a common virus that can be passed by a pregnant woman to her fetus, resulting in severe hearing, mental or movement impairments; and group B Streptococcus, a bacterium that can cause life-threatening infections in newborns and illness among pregnant women, the elderly and those ill with other conditions.

Scientists are always working on new vaccines, as well as trying to improve upon existing vaccines. Efforts to develop a single vaccine that would protect against all influenza viruses are underway, as is an extensive global program to design and test candidate vaccines against HIV, which causes AIDS, and for which there currently is no vaccine available. Also of global importance are new vaccines that could protect against Ebola and Marburg viruses, which cause hemorrhagic fever; against malaria, a parasitic illness transmitted by mosquitoes that causes one million deaths every year, mostly in infants, young children and pregnant women, and most of them in Africa; and against tuberculosis (TB), which kills approximately 2 million people worldwide annually. Scientists are also tackling non-infectious conditions and are trying to develop new vaccines that could prevent various types of cancer as well as brain diseases that might result in substance abuse, such as cocaine, nicotine, and methamphetamine addictions.

III. COORDINATION BETWEEN THE FEDERAL GOVERNMENT AND STATE AND LOCAL HEALTH DEPARTMENTS

While the federal government sets the guidelines and many policies related to vaccinations, it is the state and local health departments that manage both routine vaccination efforts on a regular basis and emergency vaccinations in the event of a new disease outbreak or bioterrorism event. In addition, each state has vaccination laws and requirements, which the federal government supports by setting policies and providing funding.[53]

The federal Advisory Committee on Immunization Practices (ACIP) determines which vaccines to recommend and approves the vaccines, and then state and local health departments organize, administer, and maintain vaccine campaigns and registries.[54] Most health departments around the country hold their own vaccination clinics and educate the public about the importance of keeping up to date on immunizations.[55]

On a routine basis, public health departments often administer childhood and adult vaccinations in public-private partnerships with health care providers. For instance, health departments maintain clinics where children can come for the vaccines they need for school as an alternative to receiving the vaccinations from their private pediatricians. In addition, health departments administer adult vaccinations through clinics and often maintain flu vaccination clinics. Being able to receive vaccinations through health departments is particularly important to have for individuals and families who are uninsured or underinsured.

For example, in an effort to improve preteen vaccination rates, California implemented Preteen Vaccine Week in 2009.[56] Through kits and planning materials, educational materials, public service announcements, and adolescent health conferences, California raised awareness about the ACIP recommendations for preteens. Health departments are using many avenues such as schools, community centers, and local media to improve vaccination rates in their communities.

Another function of many state and local health departments is to collect vaccination data and maintain immunization registries. These registries are often used to help ensure children and adolescents keep up-to-date with immunizations.

In 1998, in an effort to facilitate community- and state-based immunization registry development, the federal National Vaccine Advisory Committee (NVAC) launched the Initiative on Immunization Registries to facilitate local and state based immunization registries in the United States. One of the national health objectives for 2010 is to increase to 95 percent the proportion of children under 6 years of age who are part of a fully operational Immunization Information System (IIS).[57] IIS are confidential, computerized information systems that can record vaccination data about all children within a certain geographic area.[58] State- and locally-based immunization registries are critical to effective documentation of vaccination coverage; they enable implementation of vaccination strategies, and they decrease resources needed to measure, achieve, and maintain increased levels of vaccination coverage.[59]

As health information technology advances in the United States, many experts believe the inclusion of registry-like information in electronic health records may facilitate public health department access to this information and make monitoring immunizations by providers easier as well.

State and local health departments also play an important role in immunizing Americans during new outbreaks and crises, such as bioterrorism events. The federal government maintains the SNS, which includes countermeasures and vaccines for emergencies, but state and local health departments are responsible for the management and administration of vaccinations in their jurisdictions. State and local health departments plan and train to: 1) receive SNS assets from the federal government; 2) distribute, or move, those assets from the storage facility to the point-of-dispensing (POD); and 3) dispense, provide, or administer the medical countermeasure to the affected persons. According to the CDC, "preparedness to receive, stage, store, and distribute SNS material is essential to saving lives at risk during a public health emergency."[60]

During the novel Influenza H1N1 outbreak, the federal government purchased the vaccine and distributed it to designated vaccination sites in states through public-private partnerships, so some vaccine went to the health departments, some went to private health care providers, and some went to other health care entities, such as pharmacies, as determined by the state or territorial health department. Each state is responsible for conducting its own vaccination campaign. For instance, in Virginia, the state

and local government and health departments are using advertisements on buses and in movie theaters, television and radio ads, temporary tattoos, t-shirts and stickers as part of their media campaign to encourage residents to get vaccinated.[61] Other states are using local health departments to directly administer vaccinations. In Jackson County, Ohio, the local health department set up vaccination sites throughout the county including a weekday and weekend clinic at the health department as well as school-based clinics.[62]

IV. CONCLUSION AND RECOMMENDATIONS

> "We've had significant improvement in getting children immunized...but it's an embarrassment that we have done so poorly with adults."
>
> --Congressman Henry A. Waxman, Chairman of the House Energy and Commerce Committee

Each year, hundreds of thousands of American adults are hospitalized and tens of thousands die from diseases that could have been prevented by vaccination. CDC estimates that the cost of the health burden to society from vaccine preventable diseases is approximately $10 billion annually. Initiating improvements in the nation's ability to immunize adults will prevent disease, mitigate suffering, and reduce health care costs.

TFAH and IDSA recommend a number of actions be taken to increase adult immunization rates for vaccine-preventable illnesses. Many are based on IDSA's 2007 statement, Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States: Policy Principles of the Infectious Disease Society of America.[63] These recommendations reflect the views of TFAH and IDSA and do not necessarily reflect the views of those consulted on this paper or those who served as peer reviewers.

1. INCREASE DEMAND FOR ADULT VACCINES

- If adult immunization coverage is to increase, public and provider awareness must be improved.
  - With respect to public awareness, CDC should receive additional resources to create and manage a broad public education campaign targeted at improving adult immunization rates, with active participation by and collaboration with state and local public health departments. Federal officials, in partnership with medical societies and public health departments, also must conduct an assertive campaign to combat the rise in "vaccine hesitancy." Targeted information that is culturally-appropriate should be made available to high-risk groups and racial and ethnic minority populations. State and territories should receive adequate resources to tailor immunization campaigns and approaches to their own unique and diverse populations at local levels.
  - Professional medical societies (e.g., obstetrics/gynecology and internal medicine) should support ongoing education of their members about the importance of adult immunization. Medical and nursing schools should expand curricula on vaccine-preventable diseases in adults.
- With respect to providers, it should become a standard practice to review patients' immunization histories and offer vaccinations at appropriate medical encounters. Providers should consider routine preventive heath care visits, such as cancer screenings and pre-natal visits, as an opportunity to discuss the patient's immunization needs. Providers and other parties should work to establish purchasing cooperatives to lower costs and risks to individual providers. Hospitals and medical practices should promote the use of standing orders for vaccinations.
- Providers should take advantage of advances in electronic medical records or immunization registries to improve information-sharing about patients' vaccination histories across different providers and to generate reminders to providers and patients about recommended vaccinations. Federal standards for meaningful use of health information technology (IT), which will accompany health IT grants to providers as part of the American Recovery and Reinvestment Act (ARRA), should also include vaccine notification and tracking.

- All health care workers should play an increased role in reducing transmission of disease and set an example by complying with the immunization recommendations from ACIP to protect themselves, their staffs, and their patients. This includes receiving an annual influenza vaccination to protect themselves and their patients. IDSA supports "universal immunization of health care workers against seasonal and 2009 H1N1 influenza by health care institutions (inpatient and outpatient) through mandatory vaccination programs as those programs are likely to be the most effective means to protect patients against the transmission of seasonal and H1N1 influenza by [health care workers]."[64]
- Mirroring the patient immunization offer mandates at nursing homes, more hospitals and health facilities should develop policies to offer vaccinations to eligible adult inpatients and outpatients. There should be adequate payment to hospitals for vaccine acquisition, storage, and administration. The Joint Commission should establish criteria for assessing influenza, pertussis, and hepatitis B immunization rates in health care workers as a measure of institutional compliance and performance.

2. EXPAND EXISTING FEDERAL IMMUNIZATION PROGRAMS AND CREATE A "VACCINES FOR UNINSURED ADULTS PROGRAM"

- Congress should increase funding for the Section 317 Program. In March 2009, CDC provided Congress with a professional judgment estimate that the Section 317 Program would require $1.6 billion in FY 2010 to fully protect children who rely on this program and to extend the program to increase adult immunization rates as well. FY 2010 funding for the program is only $496.8 million. Congress allocated an additional $300 million to the program as part of the ARRA, with those funds to be expended in FY 2009 and 2010, so that funding should be built into the FY 2011 baseline. In addition, operations funding should be provided to cover physician's expenses in administering the vaccines, which is not currently covered by the 317 Program. TFAH and IDSA recommend at least $800 million in funding for the 317 Program in FY 2011.
- Congress should build on the innovations that result from the one-time $300 million in supplemental funding from ARRA and provide a distinct funding stream to be used by states in enhancing their outreach efforts to adults in the FY 2011 budget.
- Congress should be commended for including a mandate for full coverage of all ACIP-recommended immunizations for all insured Americans as part of the pending health reform legislation. Regardless of the outcome of that debate, steps must be taken to provide funds to cover immunizations for those who will remain uninsured and to cover costs of immunizations during the time of transition where benefits are being extended post-reform. A Vaccines for Uninsured Adults (VFUA) Program that would help ensure that adult vaccines become a routine entitlement, similar to the VFC Program, should be created. Important legislation was introduced in the 110th Congress to establish such a program *(see Vaccines for the Uninsured proposal text box)*.
- Congress and HHS should act to ensure that Medicare beneficiaries receive coverage for all preventive vaccines under Medicare Part B instead of covering most vaccines under Part D. Part B procedures are straightforward and already cover influenza, pneumococcal and hepatitis B vaccines. Health reform legislation passed by the U.S. House of Representatives in 2009 includes a provision that would transfer Medicare-covered vaccines from Part D to Part B. Legislation was also introduced in the 110th Congress to transfer all Medicare-covered vaccines from Part D to Part B *(see Vaccines for the Uninsured proposal text box)*.
- The Centers for Medicare and Medicaid Services (CMS) should require institutions, as a condition of participating in the Medicare program, to offer annual influenza vaccination to all health care personnel, report annual vaccination rates, and undertake vigorous promotional campaigns to increase vaccine acceptance. Mandatory policies for institutions receiving Medicare payments should be considered.
- Congress should increase funding to permit CDC to increase its capacity to measure adult immunization coverage rates and support enhanced development, interoperable functionality, and use of state and regional immunization registries and/or take advantage of advances in electronic medical health records.

- Congress should provide the National Institutes of Health (NIH), CDC and FDA with increased support for vaccine-safety surveillance and research.
- HHS agencies (CDC, the Agency for Healthcare Research and Quality, CMS, HRSA), the Department of Defense, the Department of Veterans Affairs, and the Federal Bureau of Prisons should conduct assessments of barriers to adult immunization within their own programs, collect data regularly about immunization rates and practices within their settings, conduct research to evaluate and eliminate barriers to immunization, and receive the resources to accomplish these goals.
- Medicare and Medicaid vaccine administration fees must be increased to cover providers' actual cost of administration.

VACCINES FOR THE UNINSURED PROPOSAL

In the 110th Congress, Representative Henry A. Waxman, (D-CA), chair of the House Energy and Commerce Committee, sponsored legislation to strengthen adult and adolescent immunization. One bill, H.R. 4933, would have established a Vaccines for Uninsured Adults program, modeled after the successful Vaccines For Children program. The measure proposed creating an entitlement program for all low income adults to receive free vaccines, and for physicians to receive a fee for providing the immunizations. The bill also proposed authorizing programs to educate the public about the importance of adult immunization and permit grants to states to strengthen state adult immunization efforts. In addition, the legislation would require CMS, through increased research, to find more effective ways to encourage adults and, specifically, health care workers to get immunized. The measure would authorize $800 million annually for the first five years to implement these changes. Another bill, H.R. 4992 in the 110th Congress, focused on helping older Americans by moving vaccine coverage from Medicare Part D to Medicare Part B, thereby removing obstacles to vaccine delivery and providing administration fees to doctors for vaccinating patients.

3. STRENGTHEN PRIVATE INSURANCE COVERAGE OF ADULT VACCINES

- Private payers should provide coverage for all ACIP-recommended adult vaccines and consider administration fees provided by Medicare Part B to be the minimal standard. If a federal mandate does not occur as part of health reform, states should require full coverage of ACIP-recommended vaccines.
- The National Committee on Quality Assurance should work toward including every adult vaccine recommended by ACIP in the Health Plan Employer Data and Information Set (HEDIS), a set of measures that reflect quality of care in managed care and other health care settings.

4. SUPPORT ADDITIONAL RESEARCH INTO ADULT VACCINES

- Research supported by BARDA, NIH, CDC, FDA, and other federal agencies must be funded sufficiently to support the development of new adult vaccines, as well as improvements in existing vaccines. Effectiveness, safety and cost-benefit should be considered.
- Congress should appropriate $1.7 billion for FY 2011 in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA's advanced research and development mission.
- Health services research should be funded to study public and provider acceptance of vaccines, safety concerns among the public, and racial, ethnic, and economic disparities in immunization rates, and to implement and evaluate interventions designed to eliminate unnecessary concerns and disparities.
- Congress should provide incentives that support vaccine development and production by industry within the United States to help assure adequate supplies of vaccine, especially in times of crisis. Steps should be taken to stabilize the vaccine market by assuring that vaccines will be purchased once produced. The announced intent of governments to guarantee purchases of fixed amounts of vaccines has helped to stabilize production in some cases and encourage continued research and development.

5. INCREASE RESOURCES FOR STATE AND LOCAL HEALTH DEPARTMENTS' VACCINATION CAMPAIGNS

- Sufficient resources must be provided to state and local health departments to conduct successful vaccination campaigns. Such campaigns should reach out to adults to inform them about the availability, benefits, and safety of vaccines, as well as maintain vaccination clinics to administer vaccines to the general public, but particularly the uninsured and underinsured. Sufficient funding is an ongoing challenge. In 2009, the National Association of County and City Health Officials surveyed a sample of local health departments (LHDs) nationwide to measure the impact of current economic conditions on LHDs' budgets, workforce, and programs. The report found that LHDs had begun to eliminate or reduce vital programs and staff. In the first half of 2009, approximately 8,000 staff positions in LHDs were lost due to layoffs or attrition. An additional 12,000 LHD employees were subjected to reduced hours or mandatory furloughs. The response efforts to the novel Influenza H1N1 outbreak would not have been possible without one-time and limited federal funding and the shifting of staff resources from other programs.
- Ongoing support must be provided to ensure that state and LHDs have continuous capacity to support vaccination and public health programs that help support vaccine efforts. Often vaccination campaigns are funded as "just-in-time" or one-time campaigns instead of an ongoing continued service.

APPENDIX A: COMMUNITIES TAKING ACTION: SUCCESS STORIES AND INNOVATIONS

Vax and Vote

In an effort to increase the rates of those receiving flu shots, the Robert Wood Johnson Foundation (RWJF), together with Sickness Prevention Achieved through Regional Collaboration (SPARC), created the Vote and Vax initiative to provide flu vaccination clinics at or near polling centers across the country.

The program first started in 2004, and has helped to provide thousands of vaccinations to at-risk Americans. In recent years the efforts have been expanded, and in November 2008 Vote and Vax delivered 21,434 flu shots at 331 locations in 42 states and the District of Columbia.[65] Almost half of those vaccinated reported that they had either not received a flu shot the previous year or would not have been vaccinated but for the Vote and Vax program.

Colorado: A Decade of Targeting Adults

Colorado places a special emphasis on adult immunization. For the past 10 years, the goal of the state's Influenza and Adult Immunization Coalition has been to decrease vaccine-preventable diseases through collaborative efforts in education and immunization.

Located within the state department of public health, the program uses, among other things, community outreach, media, and provider education to spread the message. The state does not run immunization clinics, but provides vaccines to community clinics, such as church-based or mobile clinics, that deliver immunizations to underserved populations, such as the homeless.

Coalition officials meet monthly with community clinics, pharmacies (which under state law can administer shots), vaccine manufacturers, and local public health agencies, among others, to coordinate efforts. They also work with a local television station, which sponsors health fairs, to distribute posters and brochures that encourage immunization.

"Originally we were mostly concerned with flu and pneumococcal vaccination," says Margaret Huffman, ND, RN, the provider services unit manager for Colorado's immunization program. "Since the introduction of the zoster vaccine, HPV and the Tdap recommendations, we highlight all the immunizations that adults should be considering."[66]

The program uses money from Section 317 to fund its activities. Its greatest success has been with the state's elderly. "We really do well with our seniors," Huffman says. "We are one of the top states with flu and pneumococcal vaccines. We don't do as well with our younger adults, but we are working on it."[67]

Howard County, Maryland: Drive-through Flu Shots

Howard County, Maryland has a convenient and relatively quick way to deliver seasonal flu shots: a drive-through clinic. People don't leave their cars – they just roll up their sleeves, roll down their windows, and stick out their arms.

"It is just as easy as getting fast food, and a lot better for you," says Peter Beilenson, MD, the county's health officer.[68]

During the three years the drive-through has been operating, the biggest challenges have been logistics and traffic control. Beilenson says the process has gotten better and faster each year. This past fall, the county delivered shots to 4,000 people in five hours from a large parking lot that surrounds a local warehouse. The shots are free, paid for by the county health department.

"We set the clinic up in a huge circular driveway, with police directing traffic,'' says Beilenson, the former Baltimore City Health Commissioner. "People fill out consent forms while waiting in line, and then move on. We have about 10 or 12 lanes. People literally just drive by and hold out their arms. It's extremely simple, and we can get a massive number of people through."[69]

This is not the only such drive-through operation in the country. The Department of Veterans Affairs, for example, also sponsors local drive-through immunization clinics in various locations around the country.

Public health experts recommend generally that a post-immunization waiting period be incorporated into drive-through clinic plans, to provide protection against the possibility some people may feel dizzy after receiving an immunization.

Immunize LA Families

Immunize LA Families, part of the South Los Angeles Health Projects, successfully uses the federally funded Women, Infants and Children (WIC) nutrition program as a place to reach families in order to encourage pediatric immunization. It now plans to do the same with influenza vaccination among adult pregnant women who use WIC services.

"WIC is one place where you can reach women and children, and we have one of the biggest WIC programs in the country,'' says Steve Baranov, Vice President for Community Health at the Los Angeles Biomedical Research Institute, Harbor-UCLA Medical Center, and Executive Director of South Los Angeles Health Projects. "We enroll 20,000 pregnant women every year. Now, let's see if we can get them to go get immunizations."[70]

Immunize LA Families also hopes to initiate adult immunization outreach activities in churches, senior citizen centers and other sites, with support from the Racial and Ethnic Approaches to Community Health (REACH) program, created by CDC to support community coalitions that work to eliminate racial and ethnic health disparities. At present, Immunize LA Families receives less than $500,000 a year from CDC's REACH program. "If we could double our budget, we could do much more," Baranov says.[71]

APPENDIX B

Joint Statement of Medical Societies Regarding Adult Vaccination by Physicians

Summary:
In an effort to emphasize the importance of adult vaccination against an increasing number of vaccine-preventable diseases, primary care and many subspecialty physicians should take an active role in the discussion and review of their adult patients' vaccination status and in the administration of recommended vaccines. Increased consumer demand for quality care, and guidelines and/or recommendations from the CDC and professional societies provide additional impetus for a renewed and stronger emphasis on provision of vaccines.

The Potential Role of Subspecialists:
Primary care is the most convenient and appropriate setting for delivery of vaccines to most adult patients, since it serves as their "medical home." However, many patients with chronic disease also have a "medical home" with a subspecialist. For example, infectious disease physicians often provide primary and preventive care services for patients with HIV infection. Other subspecialists also may serve as the preferred source of care for their patients with chronic disease, providing an opportunity to serve as a source of vaccination administration or referral.

It is proposed that:
(1) Primary and subspecialty physicians should conduct immunization review at appropriate adult medical visits to educate patients about the benefits of vaccination and to assess whether the patient's vaccination status is current, referring to the Advisory Committee on Immunization Practices Adult Immunization Schedule.

(2) When appropriate, physicians should provide or refer patients for recommended immunizations.

(3) Physicians who administer vaccines should ensure appropriate documentation in the medical record. In addition, documentation of vaccination in other settings, patient refusal, and any contraindications is advisable. The use of immunization registries and electronic data systems facilitates access to accurate and complete immunization data.

(4) Physicians who refer patients for vaccination also should review and document the vaccination status of their patients whenever possible.

(5) Consistent with the CDC Advisory Committee on Immunization Practices and multiple subspecialty organizations, physicians and their staff should be immunized consistent with CDC recommendations, with particular attention to annual influenza immunization.

Signed:

American College of Physicians

Infectious Diseases Society of America

Society of Hospital Medicine

American Association of Clinical Endocrinologists

American Association for the Study of Liver Diseases

Society of General Internal Medicine

American Society of Hematology

Society for Adolescent Medicine

American College of Chest Physicians

American College of Allergy, Asthma and Immunology

American Gastroenterological Association

The Endocrine Society

The American Academy of Allergy, Asthma and Immunology

American College of Gastroenterology

American Society of Clinical Oncology

American Society of Nephrology

American College of Cardiology

American Thoracic Society

The Society for Healthcare Epidemiology of America

APPENDIX C: TYPES OF VACCINES AND VACCINE PRODUCTION

Current Vaccines[72]

There are many different kinds of vaccines. **Live, attenuated vaccines** contain a version of the living microbe that has been weakened in the lab so it does not cause disease. This kind of vaccine is the closest thing to a natural infection; thus, it can elicit strong cellular and antibody responses and produce lifelong immunity with only one or two doses. Not everyone can safely receive this kind of vaccine. People with weakened immune systems, for example, should not receive live vaccines. These vaccines need to be refrigerated or frozen to keep their strength. Vaccines against measles, mumps, chickenpox and shingles are live attenuated vaccines.

Inactivated vaccines are those made by killing the disease-causing organism with chemicals, heat, or radiation. These are more stable than live vaccines and may be safer. However, most of these vaccines stimulate a weaker immune system response than do live vaccines, requiring several additional doses, or booster shots, to maintain immunity.

Subunit vaccines include only those parts (antigens) that best stimulate the immune system, rather than the entire microbe. The chances of adverse effects from these vaccines are generally lower than with other types. Once scientists identify which antigens are the most important in inducing infection, they may be able to either grow the microbe in the laboratory and use chemicals to break it apart, or manufacture the antigen molecules from the microbe using recombinant DNA technology. Vaccines produced this way are called **recombinant subunit vaccines.** The vaccine for hepatitis B is a recombinant subunit vaccine. **Polysaccharide vaccines** are a type of subunit vaccine. They are made from pieces of the polysaccharide capsule that surrounds certain bacteria. Polysaccharide vaccines are generally less effective than live attenuated vaccines and inactivated vaccines that are based on protein. They also are not very effective in infants and children under two years of age. The pneumococcal vaccine for adults is a polysaccharide vaccine. Conjugate vaccines are another type of subunit vaccine. They are made by joining the polysaccharide capsule that surrounds the bacterium to a protein carrier. This makes the vaccine effective in infants and young children. Examples include *Haemophilus influenzae* type b (Hib) and pneumococcal vaccines for children.

Toxoid vaccines are used to prevent illness caused by poisons developed by some bacteria. Scientists inactivate these toxins by treating them with formalin, a solution of formaldehyde and sterilized water. Such "detoxified" toxins, called toxoids, are safe for use in vaccines. When the immune system receives a vaccine containing a toxoid, it develops antibodies to fight off the natural toxin. The immune system produces antibodies that lock onto and block the toxin. Vaccines against diphtheria and tetanus are examples of toxoid vaccines.

Chemicals commonly used in the production of vaccines include a suspending fluid (sterile water, saline, or fluids containing protein); preservatives and stabilizers (for example, albumin, phenols, and glycine); and adjuvants, or enhancers, which help improve the vaccine's effectiveness. Vaccines also may contain very small amounts of the culture material used to grow the virus or bacteria used in the vaccine, such as chicken egg protein.

Vaccines of the Future[73]

DNA vaccines are still in experimental stages. DNA vaccines use the genes that code for those all-important antigens. Researchers have found that when the genes for a microbe's antigens are introduced into the body, some cells will take up that DNA. The DNA then instructs those cells to make the antigen molecules. The cells secrete the antigens and display them on their surfaces. In other words, the body's own cells become vaccine-making factories, creating the antigens necessary to stimulate the immune system.

Recombinant vector vaccines are experimental vaccines similar to DNA vaccines, but they use an attenuated virus or bacterium to introduce microbial DNA to cells of the body. "Vector" refers to the virus or bacterium used as the carrier.

APPENDIX D: METHODOLOGY FOR PNEUMONIA AND SEASONAL INFLUENZA VACCINATIONS

Data for this analysis was obtained from the Behavioral Risk Factor Surveillance System (BRFSS) dataset (publicly available on the web at cdc.gov/brfss).[74] To conduct the analyses, TFAH contracted with Edward N. Okeke, PhD, MBBS, MPH at the Department of Health Management and Policy at the University of Michigan School of Public Health.

To account for the complex nature of the survey design and obtain estimates accurately representative at the state level, we used sample weights provided by the CDC in the dataset. The main purpose of weighting is to reduce bias in population estimates by up-weighting population sub-groups that are under represented and down-weighting those that are over represented in the sample. Also estimation of variance, which indicates precision and is used in calculating confidence intervals, needs to take into account the fact that the elements in the sample will generally not be statistically independent as a result of the multistage sampling design.

We specified the sampling plan to STATA[75] using the svyset command and the following set of weights: sample weight variable (FINALWT), first-stage stratification variable (STSTR), and primary sampling unit variable (PSU). Omission of the stratification variable in STATA implies no stratification of PSUs prior to first-stage sampling. Omission of the primary sampling unit variable implies one-stage sampling of elements and no clustering of sampled elements. Omission of the sample weight implies equally weighted sample elements. Mean proportions for each variable were estimated using the svy: proportion command.

For pneumococcal vaccination, the individual is asked whether he/she has ever received a pneumonia shot. In all cases we exclude observations with missing data as well as observations where the individual either refused to answer, or replied, "Don't know." This never amounted to more than 5 percent of the observations.

For the seasonal influenza analysis, the variable of interest was the FLUSHOT variable.[76] Researchers weighted data from 2008 using sample weights provided by the CDC in the dataset and dropped observations where either the survey participant answered, "don't know" or refused to answer. These accounted for less than 0.5 percent of all observations. Researchers then calculated influenza vaccination rates for three different population samples – individuals aged 18-49, individuals aged 50-64, and individuals 65 and older – for each state. The research team reported 2008 influenza vaccination rates for each sub-sample, along with standard errors and 95 percent confidence intervals. Respective sample sizes for each sub-sample were 151,903, 130,713, and 121,459.

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GLOSSARY OF ACRONYMS

ACIP: Advisory Committee on Immunization Practices

AHRQ: Agency for Healthcare Research and Quality

ARRA: American Recovery and Reinvestment Act

BARDA: Biomedical Advanced Research and Development Authority

BRFSS: Behavioral Risk Factor Surveillance System

CBER: Center for Biologics Evaluation and Research

CDC: U.S. Centers for Disease Control and Prevention

CMS: Centers for Medicare and Medicaid Services

Dtap: Diphtheria, tetanus and pertussis

FDA: U.S. Food and Drug Administration

HEDIS: Health Plan Employer Data and Information Set

HHS: U.S. Department of Health and Human Services

Hib: Haemophilus influenzae type b

HPV: Human Papillomavirus

HRSA: Health Resources and Services Administration

IDSA: Infectious Diseases Society of America

IIS: Immunization Information System

ISO: Immunization Safety Office

LHD: Local Health Department

MMR: Measles, mumps, and rubella

NIH: National Institutes of Health

NVAC: National Vaccine Advisory Committee

PHSSEF: Public Health and Social Services Emergency Fund

REACH: Racial and Ethnic Approaches to Community Health

RWJF: Robert Wood Johnson Foundation

SNS: Strategic National Stockpile

SPARC: Sickness Prevention Achieved through Regional Collaboration

TB: Tuberculosis

Td/Tdap: Tetanus, diphtheria, and pertussis

TFAH: Trust for America's Health

VAERS: Vaccine Adverse Event Reporting System

VFC: Vaccines for Children

VFUA: Vaccines for Uninsured Adults

VSD: Vaccine Safety Datalink

WHO: World Health Organization

WIC: Women, Infants and Children

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