

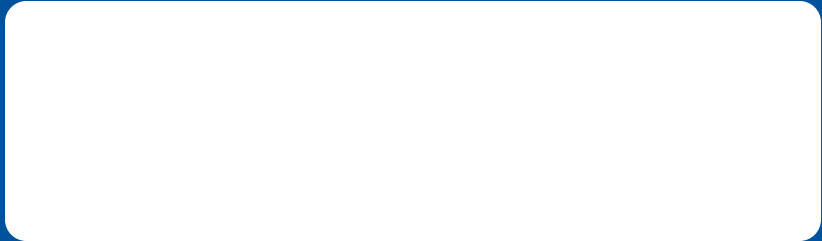


**National  
Foundation for  
Infectious  
Diseases**

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RESEARCH PREVENTION EDUCATION

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# Increasing Influenza Immunization Rates in Infants and Children: Putting Recommendations Into Practice

STRATEGIES TO HELP PEDIATRIC AND FAMILY PRACTICES  
IMPLEMENT IMMUNIZATION RECOMMENDATIONS



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This publication was made possible by an unrestricted educational grant to the National Foundation for Infectious Diseases by Aventis Pasteur.

Issued: April 2003



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# About the National Foundation for Infectious Diseases

The National Foundation for Infectious Diseases (NFID) is a non-profit tax-exempt 501(c)(3) organization founded in 1973 and dedicated to encouraging and sponsoring public and professional education about infectious diseases, supporting research and training in infectious diseases, and aiding in the prevention and treatment of infectious diseases.

NFID carries out its mission by educating the public; educating health-care providers; supporting research and training in infectious diseases; building coalitions; and honoring scientific and public health achievement, legislative contributions, and philanthropy in infectious diseases.



# Executive Summary

THE NATIONAL FOUNDATION FOR INFECTIOUS DISEASES (NFID) convened a panel of experts on November 1, 2002 to discuss ways to increase influenza vaccination rates among high-risk and healthy children. The impetus for the roundtable meeting was a change in influenza recommendations from the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP). While these groups continue to strongly recommend vaccination of children aged 6 months and older with certain medical conditions, they now also encourage vaccination of all healthy children aged 6 to 23 months "when feasible." This change resulted from data showing that influenza-related hospitalization rates in otherwise healthy children were comparable to hospitalization rates for influenza in people 65 years of age and older.

The NFID panel, which included experts in immunization, pediatrics, infectious diseases, and public health, reviewed data on influenza disease burden and epidemiology, efficacy and safety of the influenza vaccine, and barriers to pediatric influenza immunization and ways to overcome them. The goal was to recommend models and infrastructures that practices could implement before and during influenza season to increase vaccination rates.

## Low Pediatric Influenza Vaccination Rates

The long-standing recommendation to provide influenza vaccine to all children with an underlying risk factor has not changed; however, vaccination rates of high-risk children in these groups remain low. In children with asthma, the most prevalent condition conferring high risk, influenza vaccination rates are only 10 to 31 percent in any given year. These low rates may be due to lack of awareness among parents and healthcare providers of the potential complications of influenza.

Particularly troubling, given these low vaccination rates, is the annual number of excess influenza-related hospitalizations in children. The rates in high-risk children under 1 (1900 per

100,000) and from 1 to 2 years of age (800 per 100,000) are considerably higher than in persons 65 years of age and older (228 per 100,000).

Unlike other vaccines, influenza vaccine should optimally be administered during October and November, as influenza generally peaks from late December through early March. Therefore, timing is an additional factor complicating administration of influenza vaccine. Reaching and vaccinating both at-risk and healthy children aged 6 to 23 months during this time frame presents a formidable challenge. Finally, practical barriers to increased immunization, such as the need to identify, remind, and recall eligible children, further complicate the process.

## Barriers to Increased Influenza Immunization Can Be Overcome

Once healthcare providers and parents appreciate the rationale for the ACIP and AAP guidelines for vaccination of high-risk children and their encouragement to vaccinate all children aged 6 to 23 months, barriers to implementation of the pediatric influenza vaccination plan will need to be overcome. The consensus panel defined these barriers and proposed ways they could be overcome with disease education, improved practice models, and vaccination infrastructure.

## Working Models and Infrastructures Exist Across the Country

Multiple strategies must be implemented at the practice level to increase influenza vaccination rates. Further, different combinations of strategies need to be implemented based on individual practice needs. Therefore, recommendations from the panel include a list of proven strategies that providers may adapt for their own practices. These recommendations include:

- **Reminder/recall notices**, such as computerized models, auto-dialers, reminders from providers during well and sick child visits, etc. Reminders can be targeted (i.e., sent to parents of high-risk children) or general (i.e., sent to the entire practice population, negating the need to allocate resources to identifying specific patients).
- **Practice assessment**. What providers believe is happening in their practices rarely matches reality once charts are examined carefully. One simple way to assess progress over time is to chart the number of influenza vaccine doses administered each year.
- **Use of standing orders**. Frequently used in emergency rooms and the inpatient setting during influenza season, standing orders can help increase vaccination rates in other practice settings.
- **Establishment of “influenza clinics.”** Setting aside specific hours within the practice for effectively managed clinics can result not only in increased rates of vaccination but decreased costs of administration.
- **Mass influenza immunization programs**. Mass influenza immunization programs at clinics and large practices that include pediatric, adult, and geriatric patients have resulted in delivery of thousands of influenza vaccines in single-day sessions.
- **Methods and materials for parent education**. All healthcare providers should prioritize in-office parent education and give parents take-home material, when available, that will help them understand the importance of pediatric influenza immunization.
- **Methods and materials for educating office staff (nurses, non-medical personnel)** should focus on the importance of influenza vaccine and the need to educate and inform parents at every opportunity. The office staff should also be immunized to prevent spread of influenza to children presenting to the clinic.

On the following pages is a more comprehensive review of the panel’s discussion of the current CDC and AAP influenza vaccination recommendations for high-risk and healthy children as well as available data on the efficacy and safety of the inactivated influenza vaccine and its underutilization among children. The report also covers the panel’s discussion of existing barriers to pediatric influenza immunization, and, more importantly, suggestions about useful approaches and model programs that healthcare providers can use in their own practices to achieve higher childhood vaccination rates.



# Introduction

DESPITE LONG-STANDING RECOMMENDATIONS to provide influenza immunization to all high-risk children, few receive the vaccination in any given year.<sup>1</sup> For example, only 10 to 31 percent of children with asthma are vaccinated each year. Administering influenza vaccine to chronically ill children—who are at high risk for complications of influenza—is clearly a difficult task in pediatric and family practices because most practices do not have an infrastructure in place that allows them to specifically identify and vaccinate these children during the influenza season. On November 1, 2002, the National Foundation for Infectious Diseases (NFID) convened a panel of experts to discuss the importance of influenza vaccination and ways to increase influenza vaccination rates among high-risk and healthy children. This consensus report presents strategies that have been shown to increase immunization rates and suggests ways to implement them in a variety of pediatric practices.

Strategies to increase immunization rates are particularly important given recent recommendations that have increased the number of children targeted for influenza immunization. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) revised their recommendations for influenza vaccination in infants and young children for the 2002-2003 influenza season.<sup>2,3</sup> In the past, recommendations targeted children over 6 months of age with at least one risk factor, but indicated that influenza vaccine *could* be given to any child over 6 months of age, regardless of risk factors, to reduce the impact of influenza. The new recommendations continue to target high-risk children, but now they *encourage* influenza vaccination of all healthy children aged 6 to 23 months *when feasible* (see sidebar).

## CDC Pediatric Influenza Vaccination Schedule<sup>2</sup>

### Flu shots are recommended in October for the following targeted high-risk children and adolescents:

- Children with chronic pulmonary disorders, including asthma and cystic fibrosis
- Children who have diabetes, heart, kidney or liver disease, or certain blood disorders such as sickle cell disease
- Children under 9 years of age who are receiving influenza vaccine for the first time, because they will need a booster dose one month after the initial dose
- Persons aged 6 months to 18 years who are receiving long-term aspirin therapy

### Other targeted groups include:

- Healthy children aged 6 to 23 months, who are encouraged to get influenza vaccine when feasible
- Household contacts of high-risk and healthy children in categories listed above

This change resulted from an increasing awareness of the impact influenza infections have on otherwise healthy infants.<sup>2,3</sup> Data suggest that healthy children under 2 years of age have hospitalization rates associated with influenza that are comparable to those in people 65 years of age and older. This has led many experts to consider whether all children between 6 months and 2 years of age should receive yearly influenza vaccinations. While at this time ACIP and AAP do not “recommend” vaccination in this group, both organizations “encourage, when feasible,” administering influenza vaccine to these infants and children; the CDC has indicated that a full recommendation could be made within one to three years.<sup>2</sup>

Since influenza immunization occurs in less than one-third of all high-risk children, it is clear that universal immunization of children aged 6 to 23 months will prove to be a challenge. To address the challenge of providing influenza vaccine not only to children with known risk factors, but also to all children aged 6 to 23 months, the NFID convened a consensus panel of experts in immunization, pediatrics, infectious diseases, and public health. This group reviewed data on influenza disease burden and epidemiology, efficacy and safety of the influenza vaccine, and barriers to immunization and ways to overcome them. They also heard reports from several providers in different practice settings who achieve very high influenza vaccination rates in pediatric populations. The panel’s goal was to define models and methods providers can use nationwide to improve influenza vaccination rates among children.

The panel focused on a key phrase regarding delivery of influenza vaccine that appears in the ACIP and AAP recommendations: “when feasible, influenza vaccine should be given to children 6 to 23 months of age.” The issue of feasibility also applies to delivery of influenza vaccine to high-risk children. There are many elements that determine feasibility, including vaccine efficacy and safety, vaccine supply, and logistical issues. This last element is unique to influenza immunization since the vaccine must be given at a specific time of year.

Other elements were also discussed. Parental participation and acceptance of the need for the vaccine is essential. Reimbursement is an important factor. Liability could be an issue; at present, influenza virus vaccines are not included in the Vaccine Injury Compensation Program (VICP). This will change when ACIP develops a full recommendation in the future.

All of these issues are addressed in detail in Part I of this report. Once physicians and parents agree to meet the goal of administering influenza vaccine to all high-risk children and to those aged 6 to 23 months, questions will arise about how to achieve this goal. Part II presents strategies to effectively increase immunization rates in various populations and suggests ways to implement them in a variety of pediatric practices.

# Part I

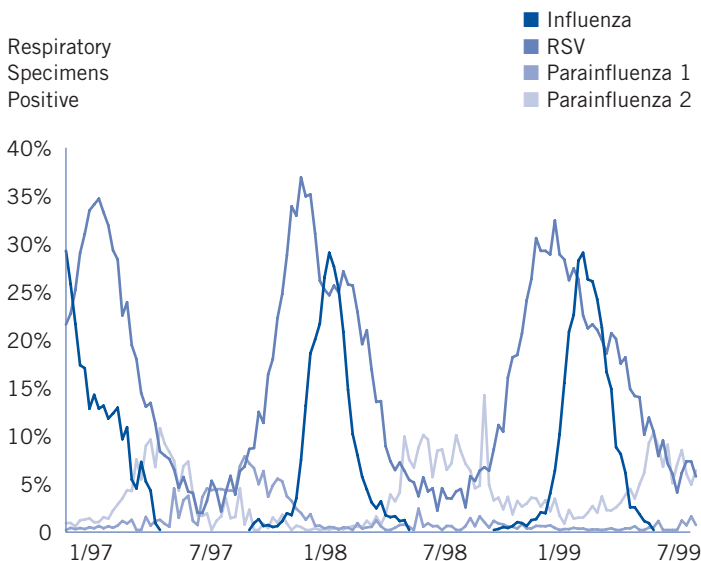
## The Importance of Influenza Vaccination in Healthy and High-Risk Children

### INFLUENZA: EPIDEMIOLOGY AND DISEASE BURDEN IN YOUNG CHILDREN

Influenza has distinct seasonal peaks in morbidity in adults. In children, distinct seasonal peaks are more difficult to recognize because of the significance of other respiratory viruses, particularly respiratory syncytial virus (RSV), in contributing to childhood morbidity.<sup>4,5</sup> While a distinct peak in influenza isolates is seen each winter, a broader peak of RSV occurs most years in temperate climates, overlapping the influenza peak (**Figure 1**). Further complicating understanding the true burden of influenza infection is the tremendous variability of influenza infections from season to season. To get a clear picture, a number of studies encompassing different influenza seasons must be examined.

**Figure 1:**

#### Seasonal Occurrence of Influenza\*, RSV†, and Parainfluenza‡ Viruses in All Age Groups in the U.S., 1997–1999



\*WHO Collaborating Laboratories Surveillance System, 1996-1999.<sup>5</sup>

†CDC National Respiratory Enteric Viruses Surveillance System, 1996-1999.<sup>4</sup>

RSV=respiratory syncytial virus.

NB: Influenza data collected only from October to May each year. Thus, a gap appears in the influenza curve and the relative contribution of influenza may not be to scale compared with other viruses included in the graph.

A large 20-year study conducted from 1957 to 1976 documented culture-positive influenza infection in children hospitalized with lower respiratory tract disease.<sup>6</sup> During peak months of influenza season, 11 to 36 percent of all hospitalized children younger than 72 months of age had influenza virus infection, depending on the year. Another hospital-based study reported the proportion of patients with chronic conditions who were hospitalized with viral infections.<sup>7</sup> The chronic conditions in children in this study were mostly respiratory and the majority had asthma. In children younger than 60 months of age, influenza was responsible for 10 to 12 percent of hospitalizations; overall rates of influenza infection ranged from 10 to 25 percent across all ages.

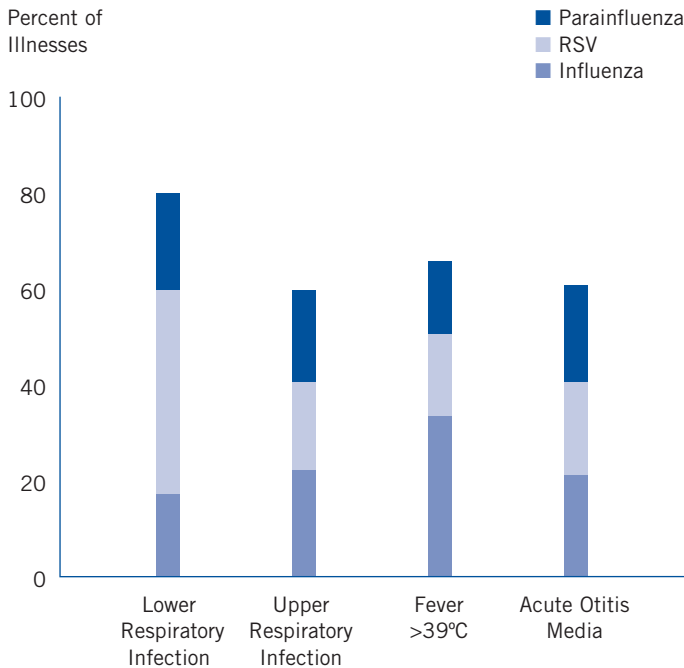
In a population-based study published in 1997, children up to 5 years of age were followed in a clinic over a 20-year period.<sup>8</sup> This study showed similar results, with influenza virus accounting for about 15 percent of lower respiratory tract illnesses (**Figure 2**). Another interesting point highlighted by this study was the number of febrile illnesses caused by influenza virus in this young age group. These febrile illnesses may or may not have been accompanied by respiratory symptoms.

A large 19-year ecologic study included more than two million children under 5 years of age enrolled in Tennessee Medicaid.<sup>9,10</sup> This study included only healthy children—those without high-risk conditions, not institutionalized or disabled, and not of low birth weight. Unlike others detailed above, the outcomes of this study were not based on laboratory diagnosis; rather, the study compared rates of hospitalization with acute respiratory diseases during summer, peri-influenza, and influenza seasons.

Overall, the study showed that hospitalization rates for acute respiratory illnesses decrease as children get older, with rates highest in children under 12 months of age. Within each age group, the highest hospitalization rates were during influenza season, followed by the peri-influenza season and then summer. Hospitalizations for acute respiratory disease approximately doubled from summer to

Figure 2:

## Impact of Respiratory Viruses on Illness in Children Aged <5 Years: 20-Year Population-Based Study



Reed et al.<sup>8</sup>

the RSV season. During influenza season, hospitalization rates increased another 25 percent. This 25 percent increase was considered “excess” morbidity owing to influenza.<sup>9</sup>

This study also examined outpatient visits. Low-risk children aged 1 to 3 years had an average of 10 to 12 outpatient visits per 100 children attributable to influenza infection. This was consistent with reported influenza attack rates of 20 to 30 percent in children (meaning 20 to 30 of every 100 children were infected with influenza), resulting in about 30 to 50 percent of infected children requiring doctor visits. Some received antibiotic therapy; the study did not assess whether antibiotic use was appropriate.<sup>9</sup>

There are several limitations of this study. Investigators made every attempt to extract relevant results in light of other viruses, however, RSV, other winter viruses, or newly recognized viruses, such as metapneumovirus, could have confounded the data. On

the other hand, the impact of influenza in very young children might have been underestimated because the study only examined acute respiratory illnesses, and influenza can cause other types of hospitalizations, such as fever and sepsis syndromes. Finally, the study ended in 1993, before widespread use of pneumococcal conjugate vaccines, which may prevent bacterial complications of influenza.

A companion 25-year study tracked culture-proven influenza in a much smaller cohort of children, who were followed more closely.<sup>11</sup> The study included 1,665 healthy children up to 5 years of age. Outcome measures were culture-positive or laboratory-proven influenza, outpatient visits, lower respiratory tract infection (LRTI), otitis media, and hospitalizations.

Approximately 9 percent of children under 12 months of age and 11 percent of those aged 1 to 2 years had symptomatic influenza illness. Incidence of acute otitis media (AOM) was about 5 percent in the youngest age group and about 6 percent in the older children; about 1 percent of children had LRTI. There were no hospitalizations in children over 2 years of age, but in children younger than 2, the rate was approximately 3.5 hospitalizations per 1,000 children. Three children had bacterial super-infections (two had *S. pneumoniae* infections and one had *H. influenzae* type b infection) that may have been prevented by the conjugate vaccines now in use. Two children had croup, one had pneumonia, and one had a sepsis-like syndrome. Children were hospitalized from one to 10 days and those with bacterial complications had the longest stays.<sup>11</sup>

A recently published study focused on the clinical course of children hospitalized with croup at one large medical center in Finland.<sup>12</sup> While parainfluenza virus was the most common cause of croup in this study, croup associated with influenza virus was found to be significantly more severe than croup associated with parainfluenza virus. Of croup patients with influenza infection, 62 percent received steroids, 24 percent required supplemental oxygen, 28 percent were admitted to the intensive care unit (ICU), and 66 percent also had pneumonia.

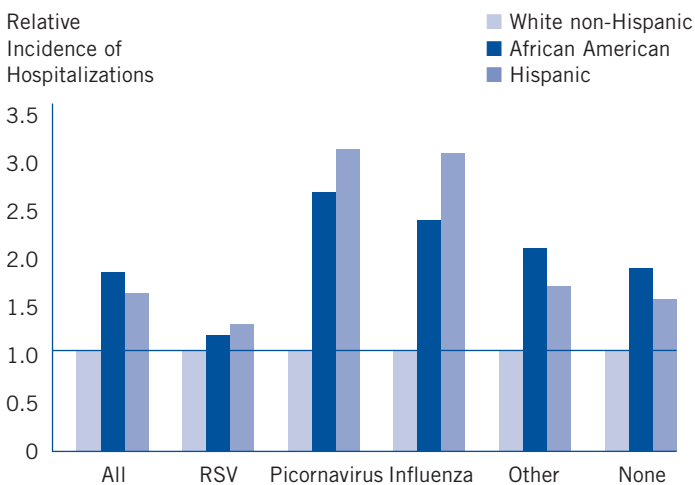
## New Vaccine Surveillance Network

The New Vaccine Surveillance Network is a recently launched, small CDC network that includes sites in Rochester, NY, and Nashville, TN.<sup>13</sup> The network conducts population-based surveillance of the burden of acute respiratory infections in children that are potentially vaccine preventable, provides data for policy decision making, and evaluates the impact of vaccines.

Children enrolled in the surveillance network are under 5 years of age and have had acute respiratory infection or febrile inpatient admissions. Admissions between Sunday and Wednesday are tracked and data are extrapolated to the entire week. Parents or guardians are provided informed consent and annual audits are performed to identify missed admissions. Data collected include demographic information, admission diagnosis, clinical and risk factor data, hospital course, chest X-ray results, and discharge diagnosis. Nasal and throat swabs are obtained for culture and polymerase chain reaction (PCR) testing.

**Figure 3:**

### Relative Incidence\* of Acute Respiratory Illness Hospitalizations in U.S. Children Aged <5 Years



All white/non-white differences statistically significant except RSV

\*Incidence compared with reference group (white non-Hispanics)

RSV= respiratory syncytial virus

B Schwartz.<sup>13</sup>

During the first year of surveillance, viral respiratory pathogens were not identified in 36 percent of the hospitalized children. About 60 percent of RSV and 40 percent of parainfluenza and influenza infections were detected by PCR only (i.e., patients were culture-negative). Overall, African Americans had a 78 percent higher rate of admission, and Hispanics had a 57 percent higher rate of admission compared with whites (**Figure 3**). The rate of influenza hospitalizations among African Americans was about two and a half times greater, and in Hispanics about three times greater, than in whites. This difference is significant for all pathogens except RSV. Differences in hospitalization rates by ethnic and racial group may be due, in part, to real differences in disease incidence or severity or may reflect different healthcare utilization and criteria for hospitalization.

Most of the children admitted with influenza infection were under 5 months of age. The most common admission diagnosis was fever related (i.e., fever, febrile seizure, febrile neonate, sepsis). Additional admitting diagnoses included pneumonia, asthma, bronchiolitis, otitis media, and croup. Discharge diagnoses for those with influenza included a significantly higher proportion with fever or sepsis compared with those with infection caused by other respiratory pathogens. In general, the hospital course for children with influenza infection was uncomplicated. The median duration of hospitalization was two days, few patients required supplemental oxygen, and none were cared for in ICUs.

Findings from this first year of surveillance are limited because of the relatively small population included and the absence of epidemic influenza disease in that particular year. Further data are being collected through ongoing surveillance for febrile and respiratory disease hospitalizations.

## SAFETY, EFFICACY, AND USE OF INACTIVATED INFLUENZA VACCINE IN CHILDREN

Influenza vaccines have proved efficacious and effective across a broad range of age groups, but are there adequate safety and efficacy data to support extending the influenza vaccination program to healthy children? The CDC recently convened a task force to address this question. The task force reviewed studies conducted in children using split virus trivalent inactivated vaccines (TIV) of contemporary antigenic content. Studies of inactivated vaccines not licensed for use in the U.S. were excluded because they are not directly comparable to U.S. vaccines. Only vaccines produced after 1981 were included, since earlier vaccines had reduced or very low antigenic content or contained whole virus. Although several trials compared the effectiveness of TIV with nasally administered live, cold-adapted influenza vaccine (CAV), TIV is the main focus of this section, since it is the only influenza vaccine currently licensed for use in children in the U.S.

The Houston Family Study was a randomized, double-blind, placebo-controlled study that included 189 children aged 3 to 18 years.<sup>14</sup> Children were given TIV, CAV, or placebo in a single dose. During the initial influenza season, only influenza B circulated. Because the CAV contained only influenza A strains, this study was only capable of assessing the efficacy of TIV.

There were no significant differences between TIV and placebo in the rates of local tenderness at the injection site and between CAV and placebo in incidence of rhinorrhea or nasal congestion. Both vaccines were very well tolerated. Immune responses were measured by hemagglutinin inhibition assays (HAI). Although the youngest children had lower antibody responses to TIV, fourfold rises in HAI were seen in approximately 50 to 60 percent of children for both H3N2 and H1N1 strains.

Efficacy rates for TIV versus placebo varied depending on the definition of illness. For the prevention of culture-confirmed disease, vaccine efficacy was slightly less in the younger children, but for the prevention of febrile illness, a more severe presentation of influenza infection, vaccine efficacy was greater in the younger children than in the older ones. This study concluded that for TIV, antibody titers improved with age; 40 to 60 percent of children 6 years of age and younger and 80 to 100 percent of children over 6 years of age had fourfold rises in HAI antibody to influenza B after a single TIV dose. Overall vaccine efficacy of TIV for prevention of influenza B infection was 62 percent and efficacy for febrile illness was 76 percent.

In the following year, the same study enrolled 192 children.<sup>15</sup> The circulating strain was an H1N1 strain with an antigenic drift. Again, the vaccine was immunogenic, both for younger and older children. TIV had improved immunogenicity in older children while CAV had improved immunogenicity in younger children. However, overall TIV efficacy for prevention of culture confirmed H1N1 infection was 62 percent while CAV efficacy was 51 percent.

A large randomized, placebo-controlled trial funded by the National Institutes of Health (NIH) was conducted at Vanderbilt University from 1985 to 1990.<sup>16</sup> The study enrolled 5,210 subjects aged 1 to 65 years, a number of whom participated for several years, and randomized subjects to TIV, bivalent CAV, or placebo. Pediatric data were extracted from this study and recently published.<sup>17</sup> Year one of the study was a pilot year, with a total of 300 people enrolled across all ages immunized. In the five years of the trial, 791 healthy children aged 1 to 16 years were enrolled; each child participated in the trial between two and five years.

Although local induration and pain were noted with the TIV injection, the vaccine was well tolerated in all age groups. As expected, the percentage of patients seropositive to vaccine strain antigens prior to receipt of the vaccine was much lower in younger children. Also,

fewer subjects were seropositive for H1N1 than for H3N2. A higher percentage of older seronegative children had a fourfold rise in HAI titer following a single dose of TIV than younger seronegative children. In children already seropositive, CAV was less immunogenic than TIV with fewer CAV recipients achieving fourfold HAI titer rises than TIV recipients. For prevention of culture-positive influenza disease, TIV efficacy was 91 percent for H1N1 and 77 percent for H3N2; CAV efficacy was 95 percent for H1N1 and 68 percent for H3N2. These differences were not statistically significant.

In summary, although the frequency of local reactions increased somewhat with age, this large study demonstrated that TIV is safe and effective—50 to 60 percent of children under 6 years of age and 75 to 100 percent of children over 6 years of age had a fourfold increase in HAI antibody response after one TIV dose. Ideally, young children should receive two doses; however, in many young children a single dose was immunogenic. When other definitions of illness are included, TIV also appears to be efficacious for prevention of clinical illness and seroconversion. The studies also support the protective efficacy of TIV against all three strains of influenza virus even in years with appreciable antigenic drift.

### Daycare Center Studies

Several influenza vaccine efficacy studies have focused on use of inactivated influenza vaccine in daycare centers. Viral respiratory pathogens may disseminate from daycare attendees to family members and other outside contacts; such contacts often include high-risk individuals, such as elderly grandparents and younger siblings.

Heikkinen et al randomized 187 daycare attendees aged 1 to 3 years to receive two doses of TIV and 187 remained unvaccinated.<sup>18</sup> This study reported no safety data. Influenza was cultured from five of the vaccinees and 29 of the control subjects (vaccine efficacy was 83 percent). It is important to note that these data are representative of a typical influenza outbreak in children with a 15 percent attack rate. TIV was also associated with an 83 per-

cent reduction in influenza-associated AOM with an overall reduction in AOM morbidity of 36 percent.

A study by Clements and colleagues included 186 daycare attendees aged 6 to 30 months, randomized to either two doses of TIV or placebo.<sup>19</sup> No safety data were reported. Children were examined biweekly by otoscopy; influenza vaccine was found to be protective against AOM during this influenza season.

Hurwitz and colleagues randomized 127 daycare attendees to either two doses of TIV or hepatitis A vaccine.<sup>20,21</sup> Adverse events were assessed and both vaccines were well tolerated. Children with detectable pre-season titers had higher post-immunization responses to TIV. TIV was 31 percent effective in preventing culture-confirmed H3N2 infection, 45 percent effective in preventing culture-confirmed influenza B infection, and 45 percent effective overall. No significant differences were noted between the two vaccine groups in total respiratory illness, episodes of otitis media, physician visits, antibiotic use, or days absent from school. Interestingly, unvaccinated household contacts of vaccinated children had 42 percent fewer febrile respiratory episodes compared with unvaccinated household contacts of unvaccinated children.

Finally, an unpublished study was presented at a recent CDC ACIP meeting [David Greenberg, MD; October 17, 2002]. The subjects, healthy infants aged 6 to 24 months were randomized to receive either TIV or placebo; 525 children received TIV and 261 children received placebo. Half of the doses were administered in children aged 6 to 12 months. There were no severe adverse events related to either TIV or placebo. Post-vaccination titers of greater than 40 or fourfold rises in HAI antibody titer against all three vaccine strains were noted in 90 percent of TIV recipients. In the 1999-2000 influenza season, the vaccine reduced the rates of culture-confirmed influenza illness by 66 percent. In the 2000-2001 influenza season, there was no reduction in the rate of culture-positive influenza. However, the latter influenza season was mild; H1N1 was the predominant influenza

strain, a few influenza B viruses circulated, and the proportion of death attributed to pneumonia and influenza did not exceed the epidemic threshold nationally.

### Study in High-Risk Children

Sugaya and colleagues studied 137 children with mild to severe asthma; 82 received TIV during an H3N2 epidemic year with marked antigenic drift.<sup>22</sup> Sera were obtained, the children were evaluated, and influenza cultures were obtained. H3N2 was isolated from 62 percent of the controls and 20 of the vaccinees, resulting in an efficacy rate of 68 percent. Vaccine efficacy was 54 percent in children under 7 years of age and 78 percent in children over 7 years. Influenza B was isolated in nearly half of the unvaccinated children and in only 27 percent of the vaccinees (efficacy rate of 44 percent). Again, efficacy was greater in the older age groups. Remarkable in this study was the high attack rate of influenza in this population. In older asthmatic children, TIV was effective against H3N2 disease but was slightly more effective against influenza B. The safety profiles appear good and, overall, results are comparable to those seen in healthy children.

In summary, approximately 1,000 doses of TIV have been administered in clinical trials to children aged 6 to 23 months. Vaccine has been well tolerated, but these relatively small numbers provide insufficient power to assess the probability of uncommon adverse events. The safety profile of TIV in much larger numbers of adults has been consistently acceptable.

## RECOMMENDATIONS FOR INFLUENZA VACCINATION OF CHILDREN

ACIP and AAP recommendations for immunizing high-risk children over 6 months of age, using the killed, inactivated vaccine, encompass a variety of groups. These groups include those with chronic pulmonary disease, congenital heart disease, hemoglobinopathies, immunosuppression, and/or those receiving immunosuppressive therapy.<sup>2,3</sup> Children treated or hospitalized within the past year for a chronic metabolic or renal disease are also targeted for vaccination, as are children who have been receiving long-term aspirin therapy for Kawasaki syndrome or juvenile rheumatoid arthritis.

Vaccination is also recommended for any person in close contact with children in these groups and for those who will be in close contact with infants from birth to 6 months of age during influenza season. Children younger than 6 months of age are not eligible for influenza immunization, making it important to vaccinate people in close contact with them to protect the infants by replacing their risk of exposure.

New, beginning with the 2002–2003 influenza season, is an ACIP encouragement to vaccinate all children aged 6 to 23 months, because of substantially increased risk of influenza-related hospitalization. In addition, ACIP passed a resolution supporting coverage for vaccines in this age group under the Vaccines for Children (VFC) program; this will be implemented for the 2003–2004 season. AAP concurs and issued a policy statement in December 2002 that encouraged for the first time that healthy children aged 6 to 23 months be immunized for influenza to the extent logistically and economically feasible.

### Population Estimates: Children Recommended or Encouraged for Influenza Vaccination

Based on 2000 Census data and the 2000 National Health Interview Survey (NHIS), there are an estimated eight million high-risk children aged 6 months to 18 years, including those



**Table 1:**

## Prevalence of High-Risk Conditions in U.S. Children Aged 6 Months to 18 Years

Condition	Prevalence (%)	Number
Asthma: Ever	12.7	8,918,000
Asthma: In past 12 months	5.7	3,994,000
Heart disease	1.3	930,000
Diabetes mellitus	0.3	190,000
Sickle cell disease	0.2	162,000
Cystic fibrosis	0.01	7,000
<b>*Total (ever asthma)</b>	<b>14.2</b>	<b>10,024,000</b>
<b>*Total (recent asthma)</b>	<b>7.4</b>	<b>5,192,000</b>

\*Totals do not reflect that more than one condition was present in some children.

Erhart et al.<sup>25</sup>

who will become at least 6 months of age during the influenza season.<sup>23,24</sup> The NHIS defined high-risk children by self-reports of asthma. Asthma was reported in two categories: an attack at any time or an attack within the last 12 months. The presence of other high-risk conditions, including heart disease, cystic fibrosis, diabetes mellitus, and sickle cell disease, was also assessed.

There is a substantial difference in the proportion of children who may be defined as high risk based on how recently they experienced asthma (**Table 1**).<sup>25</sup> In fact, there are more than twice as many parental reports of children who have ever had an episode of asthma than of those who have had an attack in the past year. Between 7 and 14 percent of children aged 6 months to 18 years are defined as high risk; that equates to five to 10 million children in the U.S.

In addition, healthy children aged 6 to 23 months, for whom vaccination is encouraged, number about 5.6 million.<sup>26</sup> Including the midrange of high-risk children, in aggregate, over 13.5 million children are recommended or encouraged to receive influenza vaccination each year.

Finally, those who are close contacts of high-risk children also should be vaccinated. Depending on the definition of high risk (e.g., children who have had an asthma attack within the past 12 months versus those who have ever had an attack) and whether all children under 2 years of age are included in this group, the estimated number of healthy pediatric contacts who should be vaccinated ranges between 24 and 27 million.<sup>25,26</sup>

There are no national data on influenza vaccine coverage rates in children. Discussions are ongoing about collecting influenza vaccination data through the National Immunization Survey (NIS), which is the primary approach for capturing vaccination coverage data in young children. However, at present, NIS does not collect data about influenza; there are also no estimates available from the NHIS or the Behavior Risk Factor Surveillance Survey. Therefore, available data are derived from specific studies.

In one study of vaccination coverage among high-risk (asthmatic) children in managed care organizations in 1995-1996, only 9 percent received influenza vaccination (**Table 2**).<sup>27</sup> The diagnosis

**Table 2:**

## Influenza Vaccination Rates in U.S. Children With Asthma in Managed Care Organizations, 1995–1996

	Percent Receiving Influenza Vaccine	Odds Ratio
TOTAL	9.0	
AGE		
1 to 3 years	7.0	1 (referent group)
4 to 6 years	9.8	2.7 (1.9-4.0)
BETA-AGONIST PRESCRIPTIONS		
0	5.1	1 (referent group)
1	13.9	2.6 (2.4-2.8)
2	21.1	3.8 (3.4-4.1)
≥3	34.0	5.2 (4.7-5.7)
HOSPITALIZATIONS/ER VISITS		
0	8.6	1 (referent group)
≥1	29.7	1.5 (1.4-1.8)

Kramarz et al.<sup>27</sup>

of asthma was defined based on ICD coding or asthma medication prescriptions. Higher vaccination rates were seen in older children, with rates nearing 10 percent in those aged 4 to 6 years. Those with more severe disease, measured by the number of yearly prescriptions for beta-agonists, had higher immunization rates, as did those who had a hospitalization or an emergency room visit during the previous year.

The study also reported substantial missed opportunities for vaccination. Sixty-one percent of asthmatic children made outpatient visits between September 1 and December 30. Among children making a visit, influenza vaccination was provided to 40 percent of those who visited allergy clinics, 10 percent of those who visited pediatric clinics, and just 3 to 9 percent of those who visited general medicine or family practice clinics.

There are several other studies that measured influenza vaccination rates among high-risk children who attend subspecialty clinics. Chung and colleagues showed 32 percent coverage among children who had moderate to severe asthma and who were seen at an allergy-immunology clinic.<sup>28</sup> Another study reported 79 percent coverage in a cystic fibrosis clinic.<sup>29</sup> One of the commonalities throughout these studies is that children who had more respiratory disease visits and more severe illness were vaccinated at higher rates.

Finally, an unpublished study of high-risk children in Rochester, NY, included analysis of an insurance database for five managed care plans from 1998 to 2001.<sup>30</sup> The study included children aged 6 to 23 months, who were continuously enrolled during the influenza season, and were defined as being at high risk based on an ICD-code diagnosis matching a high-risk category, or by two or more asthma-related visits in 12 months. Over 20 percent of all high-risk patients, including over 20 percent of asthmatics, were vaccinated. In the three most recent seasons, there was no trend toward increasing vaccination coverage.

## FEASIBILITY OF UNIVERSAL INFANT AND TODDLER INFLUENZA VACCINATION

The seasonal nature of influenza dictates a specific window of opportunity for influenza vaccination. In addition, children under 9 years of age receiving influenza vaccine for the first time require two doses separated by 30 days. In these children, the first dose must be given in October to have time to deliver the second dose before December, since influenza activity typically peaks in January or February. Thus, the process of providing influenza vaccine is a challenge unlike others faced by pediatricians and family physicians.

The University of Rochester and the CDC recently completed three studies on the feasibility of universal influenza vaccination in certain age groups. The studies were concerned with the effects of universal influenza vaccination on staffing time; tracking and recalling patients; and provider attitudes, beliefs, and concerns. The studies also asked providers their thoughts on parental concerns—a complicated issue because it affects provider actions.

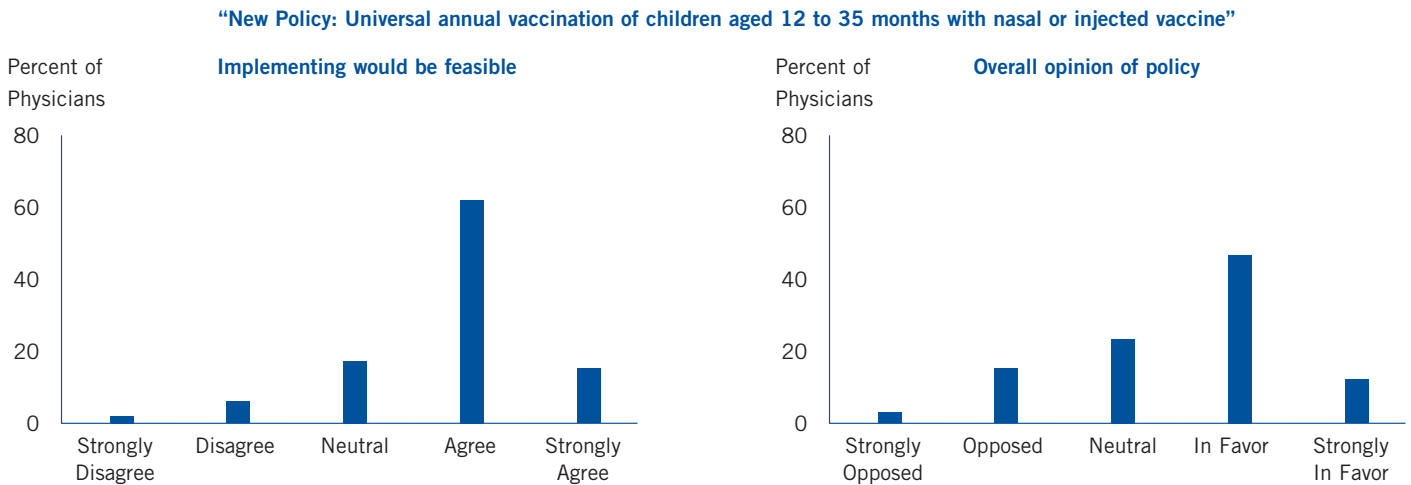
### National Influenza Vaccination Survey

Information collected from physician focus groups in Rochester was used to develop the National Influenza Vaccination Survey, mailed in February 2001 to a random sample of U.S. pediatricians and family practitioners obtained from the American Medical Association masterfile. Three follow-up surveys were mailed, and there was one telephone follow-up. The overall response rate was 62 percent (N=458), with a higher rate in pediatricians (80 percent, N=306) than in family practitioners. Demographic characteristics of responders were similar to those of nonresponders.

The survey provided physicians with a rationale about the ACIP, AAP, and American Academy of Family Practitioner (AAFP) plans to consider universal influenza vaccination recommendations, but focused on children aged 12 to 35 months. At the time the survey was initiated, investigators believed that this older group, not those aged 6 to 23 months, would be included in universal

Figure 4:

## National Influenza Vaccination Survey Results



influenza recommendations. Availability of a nasal vaccine was assumed as were insurance and coverage under the VFC program.

Only 8 percent of physicians said it would not be feasible to implement a universal influenza immunization policy in their practices (**Figure 4**). The vast majority (76 percent) agreed or strongly agreed they could implement the policy. The overall opinion of the universal influenza vaccination policy was also mostly favorable, although 18 percent were opposed or strongly opposed to it. Some physicians (15 percent) felt that adding the influenza vaccine would deter or delay other vaccines, but the majority (66 percent) did not; 20 percent had no opinion.

Physicians identified up-front vaccine costs as the largest barrier to implementing universal influenza vaccination. Additional barriers included inability to identify and recall children needing the vaccine, time needed to discuss safety, and, in a small percentage of physicians, the need for extra visits and additional staff. Physicians anticipated similar barriers from families—costs, a crowded vaccine schedule, safety, and the need for extra visits—but also expected family barriers to include a sense that influenza infection is not severe enough to warrant vaccination.

Most physicians indicated they would consider all visits as immunization visits, but data show this is not the case in practice—physicians most often deliver vaccinations during routine visits only. Physicians felt the best location for vaccination administration was their own practice, but they thought it acceptable for public health clinics, and about 25 percent even thought it was acceptable for daycare centers, to administer the vaccine.

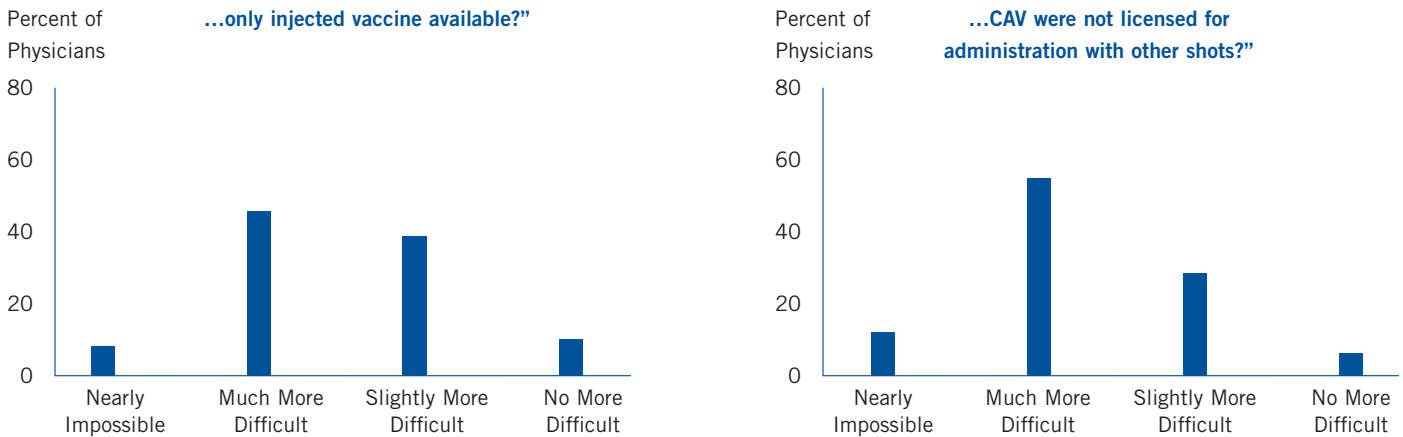
Physicians were asked if the policy would be more difficult to implement if only the injected vaccine were available; slightly over half indicated it would be more difficult or nearly impossible and the remainder said it would be slightly or no more difficult (**Figure 5**). If the candidate CAV were not licensed for administration with other vaccinations, 66 percent of physicians believe implementation would be much more difficult or nearly impossible, while 34 percent believe it would be only slightly or no more difficult.

The initial part of the survey focused on children aged 12 to 35 months. When asked if it would be feasible to implement the policy in children aged 6 to 12 months, a higher percentage of pediatricians and family physicians were concerned about vaccinating this age group. They thought it would be less feasible and more thought it would deter other vaccinations.

Figure 5:

## National Influenza Vaccination Survey Results

“How much more difficult will implementation be if...



Family physicians were more likely to oppose universal influenza vaccination. They cited practical barriers, including inability to remind, and were more concerned about safety. More family physicians thought parents would be upset about the requirement for universal vaccination or would not agree to influenza vaccination. Family physician practices have variable patient populations; some include a high percentage of young adults and young children while others include mostly people over age 65. However, the percentage of family practices that include children under 2 years of age is relatively small.

### Time and Motion Study

The time and motion study goal was to assess the time and staff effort currently used to provide pediatric influenza vaccination. It included seven practices in an upstate New York county and examined current strategies for influenza immunization in high-risk children. Study sites included three suburban practices and four inner city practices that together serve a quarter of all the children in the county.

The median amount of time for influenza vaccination visits was 16 minutes (Table 3). Of the 16 minutes, only two minutes was actual vaccination time, with the remainder spent checking in, or waiting in a waiting or exam room. Suburban practices were much more

efficient—their median time was about 10 minutes—while in urban practices it was twice as long. In both cases, physicians or nurse practitioners had to be present at only a small percentage of visits.

Extrapolating study results to an entire practice, the authors found that if the median time for delivering each vaccine is 10 minutes, vaccinating 100 children would require four half days of examination room time, 12 hours of nursing time, and 10 minutes of physician time. The study concluded that influenza vaccination can consume substantial time. This was not a large issue when only

Table 3:

### Time and Motion Study: Median Wait Time

Location	Component	Time (minutes)		
		25th	Median	75th
Waiting Room	Check-in/waiting	4.0	6.0	8.8
Exam Room	Nurse examination*	0	.1	.1
	MD examination†	0	.1	.1
	Vaccinating	1.1	2.0	4.0
	Wait time	3.5	8.0	12.5
	<i>Total time in exam room</i>	<i>4.6</i>	<i>10.2</i>	<i>16.7</i>
<b>Total</b>		<b>8.6</b>	<b>16.2</b>	<b>25.5</b>

\*Nurse examination in 20% of visits

†MD examination in 9% of visits

high-risk children were targeted, because they represent a small percentage of patients in most practices. When all children must be vaccinated, it will have a greater impact on individual practices. More efficient ways to deliver influenza vaccine must be found if universal immunization recommendations are to be met.

## Insurance Database Analysis

The insurance database analysis estimated the proportion of influenza vaccine-eligible children already seen in primary care practices and the additional visits needed if universal influenza vaccination for infants and toddlers were adopted. The insurance database included over 8,000 children. Providers were located in six counties in the Rochester area in upstate New York; most were pediatricians, a small percentage was family physicians, and an even smaller percentage was hospital clinics. About a third of the practices were urban, 40 percent were suburban, and 30 percent were rural. Most of the children were enrolled in commercial insurance plans and 14 percent were enrolled in Medicaid managed care.

Children aged 6 to 23 months who visited the doctor between October and December of three separate influenza seasons were included in the analysis (**Table 4**). However, since the influenza vaccination season can vary depending on supply and other factors, investigators also examined the number of children seen during the “maximum five-month window” for vaccination from September

**Table 4:**

### Insurance Database Analysis: Percentage of Children Aged 6-23 Months Needing Additional Visits for Universal Influenza Immunization

Vaccination Window (months)	Only Well-Child Visits		All Visits Used	
	1 Visit (%)	2 Visits (%)	1 Visit (%)	2 Visits (%)
5 (September–January)	20	16	14	5
4 (October–January)	29	24	22	7
<b>3 (October–December)</b>	<b>39</b>	<b>35</b>	<b>33</b>	<b>12</b>
2 (October–November)	32	57	44	25
2 (November–December)	35	54	44	23

to January, during the four-month window from October to January, and during the “minimum two-month window” for vaccination from October to November or November to December. In actuality, most influenza vaccinations are given in three months: October, November, and December, and then vaccination stops, even though influenza virus continues to circulate.

If a three-month window exists and only well-child visits are used to provide influenza vaccine, 39 percent of children would require one additional visit and 35 percent would need two additional visits for universal influenza vaccination coverage. If all visits were used for vaccinations, 33 percent of children would need one additional visit, but just 12 percent would need two additional visits. As with delivery of all childhood vaccines, using all visits as opportunities to vaccinate will have a significant impact on the number of visits required and on immunization rates.

In general, investigators found that children on Medicaid would require more additional visits, as these children do not visit the doctor as frequently as privately insured children. Also, children seen in pediatric offices would require fewer additional visits than those seen in other types of practices, as they tend to make more frequent visits anyway.

Based on these three studies, investigators concluded that practices would require more efficient strategies to accommodate the extra visits that will be necessary to increase influenza vaccination rates.

In summary, investigators concluded that:

- Most physicians agree that universal influenza vaccination is feasible but there are some barriers, including cost, safety, and reminder/recall.
- Current practices for influenza vaccination are inefficient and “vaccination only” clinics or “vaccination only” hours need to be explored.
- Substantial extra visits would be required even if all current visits were used as opportunities for vaccination.

# Part II

## Models for Increasing Pediatric Vaccination Rates

### LESSONS LEARNED FROM ADULT MODELS

Strategies that effectively increase adult immunization rates are also generally effective in pediatric populations. It is essential that providers have adequate knowledge about the disease and the vaccine that prevents influenza, but without going beyond this, immunization rates will not improve. Providers must also:

- **Understand the impact of their recommendations in overcoming negative patient attitudes.** Studies show that physician recommendations have an appreciable impact on patient behaviors.
- **Get organized and take seriously the task of providing immunizations.** An organizational and administrative strategy, along with institutionalizing delivery of immunizations, is the single most important factor in delivering vaccines. Strategies that have proved effective should be adopted whenever possible.
- **Evaluate and provide feedback.** The importance of audit and feedback cannot be ignored. Without some measure, providers do not realize the need to improve performance.

A meta-analysis from the Rand Corporation and others involved with evidence-based review examined controlled clinical trials of interventions that increase adult immunization rates (Figure 6).<sup>31</sup>

The review showed that most interventions have an impact on multiple targets. Organizational change (e.g., standing orders, development of walk-in clinics, etc.) was singled out as the most potent predictor of improved immunization rates. But other interventions were also significantly associated with increased rates.

Another review examined strategies that improve vaccination rates for children, adolescents, and adults.<sup>32</sup> This review was completed by the Task Force on Community Preventive Services and summarized in *Morbidity and Mortality Weekly Report (MMWR)*. Various types of studies were included in this analysis, including observational studies as well as clinical trials. The review identified effective strategies that increase demand, enhance access, and address provider barriers. Standing orders for adults were identified as being among the most effective strategies, but in most situations, the best strategies were actually multifactorial.

Finally, a survey of children hospitalized with fever or with respiratory symptoms during the 1999-2000 influenza season showed that the positive predictors for immunization were provider recommendation (which had the largest impact), past history of influenza-like illness, and having family members with a positive past vaccination history.<sup>33</sup> The negative predictors included lack of knowledge, lack of provider recommendation, and simply forgetting to get the vaccine.

**Figure 6:**  
Interventions that Increase Use of Adult Immunizations

Intervention	Targets of Intervention			
	Patient	Provider	Organization	Community
Reminders	×	×		
Feedback		×		
Education	×	×	×	
Financial incentives	×	×	×	
Regulatory intervention	×	×	×	
Organizational change			×	
Media campaign	×	×		×

Intervention	Odds Ratio
Organizational change	16.0
Provider reminder	3.8
Patient financial incentive	3.4
Provider education	3.2
Patient reminder	2.5
Patient education	1.3

Stone et al.<sup>31</sup>

**Table 5:**

### Effect of Patient Attitude and Provider Recommendation on Influenza and Pneumococcal Vaccination Rates

	Patient Attitude			
	Influenza Vaccine		Pneumococcal Vaccine	
	Positive	Negative	Positive	Negative
Rates with a provider recommendation	87.1%	82%	85.3%	85.1%
Rates without a provider recommendation	82%	27%	46.9%	15.8%

Nichol et al.<sup>34</sup>

Results from other studies and surveys provide data on specific interventions. A cross-sectional survey of high-risk veterans reported on the effect of provider recommendations on uptake of influenza and pneumococcal vaccines (Table 5).<sup>34</sup> If the provider recommended a vaccine, immunization rates were high, even among patients who had negative personal attitudes toward the vaccine. However, lack of a provider recommendation coupled with a patient's negative attitude toward a vaccine resulted in extremely low vaccination rates in these high-risk patients—27 percent for influenza and 16 percent for pneumococcal vaccine.

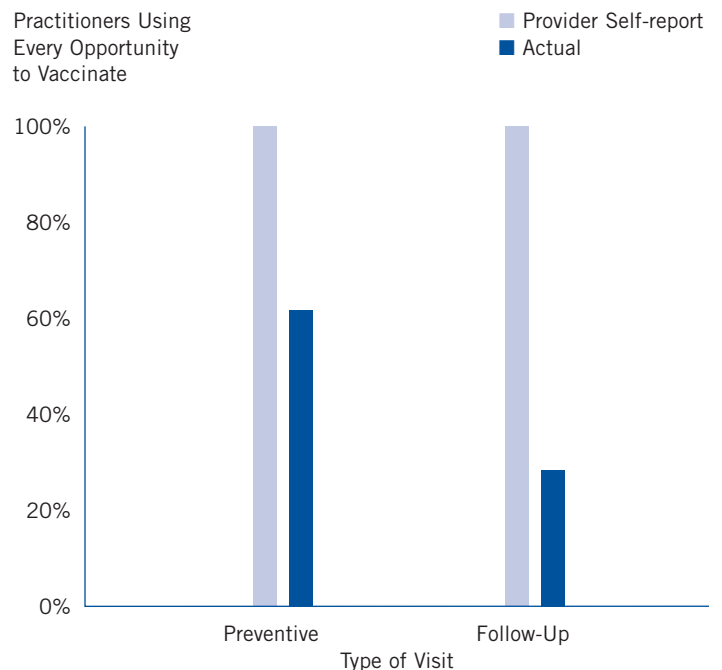
Standing orders, in particular, have a strong impact on vaccination rates.<sup>35</sup> A physician must be involved in developing the policies and protocols that will be approved, but the most effective standing orders do not require a physician's signature for each patient; rather, they empower the appropriate nurses. In some states, LPNs and RNs can perform assessments according to the protocol and administer the indicated vaccine. In the case of influenza vaccination, standing orders might need to be issued just once for each influenza season. Standing orders and protocols already exist for many other interventions. For example, in emergency rooms, nurses may debride a wound and provide tetanus vaccine before a physician sees a patient.

Another essential component of almost any effective immunization program is a reminder and recall system. A study by Szilagyi and colleagues showed that while some reminder and recall systems are more effective than others, most have a significant positive impact on immunization rates.<sup>36</sup> In another study, use of a two-stage computer reminder followed six weeks later with an autodial telephone message resulted in increased influenza vaccination rates in high-risk children from 5 to 32 percent.<sup>37</sup>

A systematic review by Bordley and colleagues included 15 audit and feedback studies conducted between 1966 and 1997.<sup>38</sup> Five of the studies were conducted in children. In general, the literature is quite consistent in suggesting that audit and feedback, either alone or in combination, may improve immunization rates. Perception versus performance was reported in a recent pediatric immunization study (Figure 7).<sup>39</sup> One hundred percent of practitioners said they took advantage of every opportunity to

**Figure 7:**

### Perception vs. Performance for Pediatric Immunizations



Prislin et al.<sup>39</sup>

vaccinate during well-child or follow-up visits. In actuality, only 60 percent used every well-child visit as an opportunity to vaccinate and just over 20 percent used every follow-up visit. Without some measure of effectiveness, many practitioners do not realize the need to improve.

The same study, which included 28 pediatric providers in 10 urban clinics, confirms the high percentage of missed opportunities to vaccinate.<sup>39</sup> Providers missed about 50 percent of all opportunities to immunize. They missed nearly 40 percent of opportunities during well-child visits, 72 percent of opportunities during follow-up visits, and 88 percent of opportunities during acute-care visits. Having a vested interest in, and positive attitudes toward, immunizations correlated with fewer missed opportunities. Enthusiastic, impassioned providers had fewer missed opportunities.

There are a number of studies demonstrating that physicians do not employ effective strategies to improve vaccination rates. A national survey on this topic included generalists and medical subspecialty physicians who care for adults.<sup>40</sup> Very few used many of these kinds of strategies and, surprisingly, 15 to 25 percent did not even strongly recommend immunizations.

In another national survey of physicians' influenza vaccination practices, 43 percent of physicians reported stopping influenza vaccination before January 1 and just 27 percent continued vaccinating into February and beyond.<sup>41</sup> Over 40 percent were neutral or hesitant to vaccinate after the onset of influenza activity locally. More than 90 percent did not use any sort of reminder/recall system, instead relying—in whole or in part—on high-risk patients coming into the office for immunizations.

## PRIVATE PRACTICE MODEL

Anders Nelson, MD, is a primary care pediatrician with a 5,000-child practice in Clarks Summit, Pennsylvania. His office handles 12,000 visits each year. Dr. Nelson considers his primary job teaching parents and children how to care for themselves and remain healthy. His goal is to minimize the number of sick children seen in his office. One way he does this is by maximizing delivery of influenza vaccine within his practice each year.

Dr. Nelson's office comprises himself, two nurses, one receptionist, and is not computerized; billing is completed through an external service. Although Dr. Nelson's methods are "grass roots," he employs multiple strategies to increase influenza vaccination rates. He presented his experiences to the panel.

**Parent Education.** As reported in several studies, the effect of the physician, nurse practitioner, or other healthcare provider's opinion about vaccination seems to have the largest impact on patient behaviors in Dr. Nelson's practice. Healthcare professionals must educate parents about the benefits of influenza vaccination with an emphasis on safety. Dr. Nelson is comfortable that side effects are not a big issue, and he communicates this to parents, for whom safety is a primary concern. He discusses with parents the adverse event profile of the influenza vaccine.

**Patient Identification and Reminder/Recall.** Since Dr. Nelson believes in universal vaccination, he "identifies" every patient 6 months of age and older as one who would benefit from influenza vaccination. He and his staff not only educate families all year long, but also remind them at each visit that their children will need influenza vaccination each fall. Parents are told to call the office around mid-September to schedule an appointment for the vaccination clinic. While large practices may have the infrastructure to offer walk-in clinics, this would overwhelm a smaller practice. In Dr. Nelson's office, every visit is scheduled.



**Increasing Access/Vaccine Scheduling and Administration.** During the last influenza season, Dr. Nelson held clinics from 8:00 a.m. to 12:30 p.m. on eight consecutive Fridays. Children were scheduled one per minute (i.e., five appointments at 8:00, five at 8:05, etc.). The practice has three exam rooms—one nurse works in each of two rooms and Dr. Nelson sees patients for other types of visits in the third room.

Upon arrival, parents are asked to review a poster set up by the receptionist's window that communicates contraindications to influenza vaccination (severe allergy to eggs or severe allergic reaction to a prior dose). Fliers are also available about informed consent. Parents sign in—they fill in the child's first and last name; month, day, and year of birth, which are needed for billing; and sign the form.

The receptionist assigns patients to one of the two rooms. The clinic is somewhat "militarily oriented," but each family is in the examination room alone. Some appointments are made for a single vaccination, but many families arrive with two to three children. The process is very efficient, with 30 children scheduled in 30 minutes; average wait times are short, with most people out within five minutes. After each family receives influenza vaccine, the nurse walks out with them to check off a spot on the sign-in sheet confirming vaccine administration.

During those eight four-hour clinics, 872 influenza vaccine doses were administered. During the clinic held on September 28, 2001, 163 children were vaccinated in 255 minutes, which is 1.6 minutes per vaccinee. Influenza vaccinations continue to be offered during all other office visits in Dr. Nelson's practice and large numbers of children in his practice continue to be vaccinated outside clinic hours. In total, the practice vaccinated 2,165 children in 2001.

Because vaccine clinics are the most efficient way of delivering the influenza vaccine, Dr. Nelson continues to refine the process in search of methods that provide optimal benefits to the practice and his patients. During the 2002-2003 influenza season, Dr. Nelson held vaccine clinics twice a day on Monday, Tuesday, Thursday, and Friday for 12 weeks. The sessions were held from 8:00 a.m. to 8:30 a.m. and 3:30 p.m. to 4:00 p.m. on each of the four days.

**Removing Barriers.** There is no office visit charge for influenza vaccination-only visits. Removing this barrier had a large impact on vaccine uptake in Dr. Nelson's office. Because of the structure of the influenza vaccination clinics and the large number of children seen in a relatively short time, insurance payment for the vaccine and administration fee provide sufficient reimbursement.

Dr. Nelson points out that while these clinics may not be financial windfalls, they are financially feasible. In his practice, he reports that the large volume of influenza vaccination-only visits means that even small reimbursements add up.

**Provider Commitment.** Provider commitment and belief in immunization is key to success no matter the type of practice. Dr. Nelson's clinics are profitable, but, he says, *"Even if I only broke even, I would still do what I'm doing, because I'm not going to see as many sick kids. I don't want to see my kids in my office sick, I don't want to prescribe an antibiotic when they get a secondary ear infection or pneumonia. I don't want to see them in the hospital with a significant pneumonia. So, if I can prevent any of that, it's worth every penny."*

## PUBLIC HEALTH CLINIC / PRIVATE PRACTICE MODEL

Mountain Park Health Center is a large, federally funded, full-service public health clinic in Phoenix, Arizona. The pediatrics department comprises eight pediatricians, one public health nurse, and eight medical assistants. Residents and nurse practitioners rotate through the department on a monthly basis. To maximize delivery of influenza vaccines each fall, the pediatrics department capitalizes on the center's strong infrastructure, taking advantage of an existing walk-in clinic, extensive computer systems and networks of programmers, and Internet connections to state immunization registries. As with all successful immunization efforts, Mountain Park employs a multifaceted approach.

**Professional Education.** The three key physicians in the pediatric department espouse "public health attitudes," fully supporting all types of immunizations and devoting considerable time to educating staff about the importance of vaccination, including influenza immunization. They endorse and support ACIP and AAP recommendations and make sure everyone has an opportunity to read and understand the guidelines. The public health nurse is responsible for training everyone authorized to administer vaccines, including medical assistants, on proper vaccination technique. Medical assistants are responsible for most of the influenza vaccinations administered through the walk-in clinic.

**Parent Education.** Every provider in the department is expected to educate parents about all necessary vaccines, including influenza vaccine, at every visit. Parents require constant reminders that, unlike many other vaccines, influenza vaccine can only be given at a certain time of the year, and must be given every year to provide protection. Influenza education brochures are available and offered to parents, but a large percentage of parents in this clinic have low literacy levels, limiting overall effectiveness of the brochures. As an alternate means of communicating with parents, the clinic has developed simple posters that it displays through-

out the year to capture parents' attention when they are in other departments within the facility. Another key component of parent education is providing immunization aftercare instructions, which every provider does.

**Patient Identification.** High-risk patients are identified throughout the year during well and sick visits. They are also identified through internal software systems that allow for patient sorting by a variety of methods, including diagnostic codes. This allows for quick identification of high-risk children not already flagged for influenza vaccination during normal visits. The clinic also provides influenza vaccine to any healthy child over 6 months of age at the parents' request. The physicians believe not all conditions that place a child at high risk may be identified in the first two years of life.



**Immunization Tracking.** A record of every influenza dose is downloaded into the Arizona State Immunization Information System (ASIIS) the day it is administered. The system provides two printouts: one for the parent and one for the provider. The printouts include information on the vaccinations just administered and the date the next vaccinations are due. During health fairs or influenza clinics, the patient's chart is not pulled. During these sessions, a roster is used and parents sign a permit; the vaccination printouts are added to the patient's chart at the next well or sick child visit.

**Outreach.** Providers remind parents about influenza vaccination all year long. In addition, postcards are mailed every August. Children needing to come in for the first dose are directed to make an appointment, while those who have received influenza vaccine in prior years are directed to the walk-in clinic. During influenza season the walk-in clinic is available for extended hours and standing orders are in effect.

As influenza season progresses, the public health nurse reviews computerized files to identify high-risk patients not yet immunized. She makes telephone follow-up calls to increase coverage rates. Patients identified include those treated for asthma, allergies, and pneumonia, as well as those receiving palivizumab.

**Increased Access.** Influenza vaccine is administered in a variety of settings. Influenza vaccine is administered during well and sick visits; privately insured patients are generally vaccinated in this setting. The walk-in clinic, where no physician appointment is necessary, is available to all children who have had an influenza vaccine in prior years. Finally, mass immunization programs are offered on several Saturdays during influenza season. A mass immunization program is discussed in detail in the next section.

## MANAGED CARE IMMUNIZATION CLINIC MODEL

Kaiser Permanente Colorado (KPC) has been providing influenza vaccination clinics each year for the past decade. Over these 10 years, the managed care organization has fine-tuned its efforts to make the clinics more efficient and effective for both members and staff. The program is large—80,000 doses were administered in 2001. About 40 percent of the doses were administered in influenza clinics and 30 to 40 percent were administered during specific immunization walk-in weeks. The remaining 20 to 30 percent were administered during routine visits.

For the first clinic of the 2002-2003 season, 89,000 reminders were mailed, 11,000 to parents of children aged 6 months to 17 years. About 3,300 children, or 30 percent of those who received reminders, attended the clinic. More clinics are scheduled and thousands of influenza vaccines are administered daily at KPC's facilities. In addition to vaccinating other high-risk populations, the KPC goal for the 2002-2003 season is to administer vaccine in 40 to 50 percent of all healthy children aged 6 to 23 months.

At KPC, the staff meets every month throughout the year to prepare for these clinics, which is necessary due to the size of the program. While this is a substantially larger program than most, the same principles for success apply. To achieve success, KPC employs a multifaceted approach.

**Provider Education.** An Immunization Taskforce makes policy recommendations to all providers. The taskforce includes the chiefs of pediatrics and family medicine, pediatricians, nurses, pharmacists, employee health staff, and programmers. Committee decisions regarding influenza vaccination are communicated to providers throughout the summer.

**Patient Identification.** The importance of identifying and reaching out to children is paramount. Lists of ICD codes are used to identify high-risk members through the internal database. KPC has also encouraged local business partnerships to use ICD codes to identify

high-risk patients. One possible application of this is that small practices may be able to ask insurers in their area to help in identifying high-risk children in their practices by scanning the insurance databases for children with certain medical conditions.

**Reminders.** Reminders and educational outreach materials are mailed two to three weeks before scheduled clinics. KPC's reminder mailings include informed consent forms. The mailing



is usually an 8½" x 11" card folded in half; the outside does not contain any personal data or any indication that the recipient is in a high-risk category. Instead, it includes messages such as, "It's flu season," or, "Many people

with certain conditions need to get their flu shot." When the member opens the mailing, the person's name is displayed along with a statement that says, "According to our records we would recommend that you receive a flu shot this year."

Members are asked to sign the consent, which includes their name and identification number. They are instructed to "bring this with you to get your free flu shot," easing workflow during the clinics and creating an efficient paper trail. Forms are collected and data entered for tracking purposes. This year, mailings were sent to families with children under 2 years of age describing the new encouragement for vaccination in this age group.

Posters are placed in exam rooms beginning in August, except for obstetrics, where they are posted in June. The goal for obstetrics patients is to educate family members of infants who will be under 6 months of age during influenza season about their need to be vaccinated. Obstetricians are encouraged to talk to expectant families throughout the summer about why they need to be vaccinated to protect their newborns.

An influenza hotline is available throughout the influenza season. The recorded message is changed weekly and includes clinic dates and locations. The hotline is helpful in reducing the volume of calls operators must handle. KPC has learned that even if nothing substantial changes in the message, it is important that at least the beginning changes each week: "You've reached the influenza clinic hotline; this is information for the week of October 26th."

**Removing Barriers and Expanding Access.** A financial barrier, co-payment, is currently waived for vaccine-only visits. This could change, particularly for members under 65 years of age, as cost-sharing plans for insurers and members evolve. Patient access is enhanced by clinics held on Saturdays, which are very convenient for families with young children. There are some families who cannot come in on Saturdays, because of religious or work reasons, so additional clinics are held during the week.

For children under 9 years of age receiving the influenza vaccination for the first time, two doses, one month apart, are indicated. To facilitate this schedule, KPC schedules two vaccine clinics at least 28 days apart.

**Vaccination Scheduling and Administration.** Due to the large size of the KPC program, they have dealt with, and continue to overcome, logistical and planning obstacles each year.

*Standing orders* are required for the influenza vaccine clinic.

While the signed consent form may not be a legal requirement in most states, KPC employs it in cases where members will not have direct contact with a doctor in the administration of the vaccine. The signed informed consent is kept for one year. Electronic records of the influenza vaccine administration are available well beyond that period.

*Aftercare instructions* are given to every patient post-vaccination. For infants, toddlers, and children who need a second vaccine, instructions include the date of the next clinic at least one month in the future. Aftercare instructions also alert families to potential

side effects in an effort to circumvent phone calls in the days following mass immunization.

*A standardized injection site* for influenza vaccination is used. For example, a specific location on the child's right thigh might be identified and used for all influenza vaccines, while any other vaccine must be injected into the left thigh. This is helpful for getting a clear picture of whether local reactions are attributable to the influenza vaccine.

*Private areas are used for injections.* While it may be difficult to move large numbers of patients through standard exam rooms quickly, large open rooms create other problems. Crying children are distracting and disturbing to other children waiting to be vaccinated, making it more difficult to immunize them. Providers should devote time to considering traffic flow within their clinic settings while being mindful of the need to vaccinate in a closed room if at all possible.

*Morning bottlenecks* have been a problem in past years, as many KPC members tend to arrive as soon as the clinic opens; this is more common among seniors. In a typical six-hour day, half of the total daily doses are given within the first two hours. KPC is considering preempting the morning rush by including information about morning crowding in future mailings.

*Different-sized syringes are used for different doses.* Because children under 3 years of age get a half-dose, in a situation where hundreds or even thousands of injections are administered in a day, there is always an opportunity for making mistakes. To minimize the possibility of mistakes, doses are drawn in different-sized syringes. Half-doses are drawn up in 1-cc syringes and a large sticker is placed on each one; full doses are drawn up in 3-cc syringes.

*Drive-through vaccination is provided at scheduled times.* During the 2002-2003 season, KPC administered thousands of influenza immunizations in this way, with four lines of traffic coming



through the organization's parking lot. Nurses stood outside and gave injections in the arm as people drove through. It is a very popular method with members, it generally takes no more than eight to 10 minutes, and it cuts down on traffic inside the facility. This service is not offered to young children due to the need to inject them in the standard site (e.g., thigh) instead of the arm.

*Refrigerators are swept* before each year's influenza vaccination clinics begin, to be sure all expiration dates are checked.

*Vehicular traffic control is a concern* for large programs, depending on the layout of surrounding streets. KPC vaccine clinics have been so successful that they have caused traffic jams at 8:00 a.m. on Saturdays. Local law enforcement is consulted about traffic control in any area where KPC feels it may be an issue.

*Unique, brightly colored shirts* worn by those administering vaccines can be helpful in large areas. Patients can then be directed to "See the woman in the red T-shirt."

**Potential problems** are always a concern. KPC has tackled many.

*Weather* can create a number of problems. If snow is an issue, the facility must be prepared to clear driveways, parking lots, and sidewalks before and during clinic hours.

*Physicians are not always present* in the clinic while influenza vaccination is taking place. KPC determined that a physician does not need to be in the facility during the clinics. However, anaphylaxis instructions are available and staff is expected to call 911 in the case of an emergency. KPC is comfortable with this set-up, as influenza vaccines have long been given routinely by nursing professionals at many locations, including the local Walgreen's, K-Mart, or Kroeger supermarket, without a physician on-site.

## INFORMATICS STRATEGIES

Medical Informatics is the science and art of information management applied to the needs of healthcare workers and patients. Computers and telecommunications have already met many administrative needs in clinical settings. However, despite proven usefulness, information technology has been relatively underutilized for clinical purposes.

Because the annual window for influenza vaccination can be as short as two months and the group of patients targeted for influenza vaccination is changing, identification and recall of patients in need of influenza vaccine can be difficult and complex. While multiple strategies for reaching and vaccinating children are essential, computer-based solutions are becoming increasingly important for practicing clinicians and health systems.

Any clinical information system containing patient demographic information and either previous immunization history or medical diagnoses can be used to identify and recall patients. Several types of computer-based systems are available; the simplest are practice management systems that track billing codes. Somewhat more complex are computerized, practice-based immunization tracking systems and immunization registries. Finally, electronic medical records promise to be the comprehensive tool for identification of all patients requiring influenza vaccine.

Regardless of the system used, the quality of patient identification and recall procedures is dependent upon the quality of the data in the system. For example, date of birth, used to identify patients eligible for vaccine based on age, is usually recorded accurately for all patients; however, data about previous years' influenza vaccine administration or patient history of asthma may not be available.

## Practice Management Systems

Nearly all clinical settings use a computer-based Practice Management System (PMS) and nearly all have the ability to generate lists of patients based on specified selection criteria (e.g., age, or previous billing codes for influenza vaccine or for a condition or disease conferring high-risk status). For example, a report can list all patients within a specified age range and those who received influenza vaccine in the past two years, or who have a diagnosis of asthma. This list can be used for manual telephone reminders or reminder letter generation at the beginning of the influenza season. A PMS that automatically generates letters further simplifies the process.

## Immunization Tracking Systems

Since any PMS relies on data entry by clerical staff, a limitation of these systems is that important data may be missing. A better way to track immunizations and allow for patient recall is to use an immunization tracking system available to clinicians at the point of care.<sup>42</sup> One example is the Automated Record for Child Health (ARCH) created at Boston Medical Center. Nurses used ARCH in the medication room while preparing immunizations for administration. The software prepared pre-printed labels to speed documentation, used an inventory of lot numbers to speed data entry, and allowed nurses to see a patient's immunization records easily from anywhere in the clinic. Finally, the easy printing of school and camp forms saved nurses from having to handwrite immunization data on these forms. Evaluation of the system showed that nurses found it easy to use, doses missing from the database were dramatically reduced from 38 percent to zero, and in the first year of use, the system relieved nurses from handwriting 100,000 dates.

Once in place, the system was then used to support six dedicated influenza clinics (scheduled on Friday afternoons) to increase pediatric influenza vaccination rates. The system identified any child who had received influenza vaccine in the last two years.

Address labels were printed and postcards were sent asking parents to call for an appointment. Overall, the system was simple to use, effective in reaching children who needed influenza vaccine, and helpful in alleviating the documentation burden pediatric practices normally face.

## Immunization Registries

State-based immunization registries offer immunization tracking on a statewide level and are likely to improve monitoring of influenza vaccine histories for families that change practices within a state. These systems have the added benefit of being supported outside the office setting by state health departments and thereby save practices from having to perform database administration. While just a few years ago it seemed that recording these data would be a distant goal, recent data show that in 14 states, 67 to 100 percent of children under 6 years of age have two or more immunizations recorded in a public registry. While none of the immunization registries currently in use is perfect, they are all evolving. A rating system available from the CDC discusses various registries and their capabilities.<sup>43</sup>

A major challenge to successful implementation of state-based immunization registries is the transfer of existing data from clinical settings to the registries. Evolving standards for data exchange promise to simplify this process over time.

## Electronic Medical Records

Only 5 to 10 percent of all clinicians, and fewer pediatric clinicians, use an electronic medical record (EMR) at the point-of-care, however, the use of EMRs in both groups is steadily increasing across the U.S. While expense and implementation difficulties may delay widespread use of EMRs for several more years, many clinical sites have successfully used these systems to identify patients who could benefit from influenza vaccine. The treating clinician is in the best position to record accurate diagnoses, immunizations administered, and additional risk factors. A well-designed EMR can interpret data while the patient is on-site and remind the clinician to administer influenza vaccine. Finally, because treating clinicians input information directly, data will be of the highest quality and will generate more effective reminder lists.

While no computer-based clinical information system is perfect, all child health providers should be encouraged to explore implementation of some type of computer-based immunization tracking system. Ideally it should be a point-of-care system that allows nurses or doctors to enter data at the time immunizations are administered. Minimally, any system should be easy to use, support reminder/recall efforts, and offer the ability to print forms. Systems that also allow tracking and reporting based on date of birth and presence of other medical conditions are even better. Immunization tracking should be considered an “essential technology” for the pediatric clinician as these systems can enhance delivery of all immunizations including influenza vaccine.

# Conclusion

PANELISTS AGREED THAT MOST PEDIATRIC AND FAMILY PRACTICES do not have an infrastructure in place that allows them to optimally reach and vaccinate children during the influenza season. The new ACIP and AAP encouragement to vaccinate all children aged 6 to 23 months, along with any child 6 months of age and older who has one or more risk factors, further complicates the challenge.

To make positive strides in influenza vaccination rates, providers must use multifaceted approaches combining proven strategies that increase immunization rates. Some strategies may be common to all practices (e.g., provider commitment). Others will be useful in all practices, but may be implemented quite differently depending on individual practice capabilities (e.g., reminder/recall). Finally, there are some strategies that may work only in certain types of practices (e.g., mass immunization clinics). Success will involve different strategies in different settings.

→ **Provider commitment** is the single most important element in increasing pediatric influenza immunization rates. Provider recommendations regarding vaccination have a significant impact on patient behavior. No combination of strategies will work unless this element is firmly in place.

→ **Parent education** is an integral component. Parents must understand the burden of influenza infection in young children to become partners in the effort to increase vaccination rates. Information should be provided to parents well before the ideal vaccination time. Some practices have noted that after one or two influenza seasons, parents begin to proactively seek out vaccine in subsequent influenza seasons.

→ **Patient identification** is handled differently in various practices. Patients may be identified at well and sick visits, through computer-based billing or immunization tracking systems, or by prescriptions given (e.g., asthma-related medications). Some practices may identify every child as a candidate for influenza immunization while others locate those with certain

risk factors and all those aged 6 to 23 months. Different methods of patient identification may be necessary based on the extent of the practice's resources for reminder/recall.

→ **Reminder/recall** can be accomplished in a variety of ways. While computerized systems that identify patients, print labels, and provide postcards are optimal, these integrated systems are not available to most practices. Other methods for reminder/recall of patients targeted for influenza vaccination include in-person reminders throughout the year, live and computer-generated phone calls shortly before and during influenza season, posters displayed in the office, and use of a recorded phone message on an influenza "hotline."

Finally, some practices may wish to identify all patients over 6 months of age as candidates for influenza vaccination, negating the need for patient identification strategies. In this case, every member of the practice receives a reminder notice. Each practice must examine its resources to determine the best method for identification and reminder/recall.



→ **Missed opportunities** must be minimized. For routine childhood vaccinations, missed opportunities may have less of an impact because many children make several visits throughout the year, so that within 15 months they are up-to-date, even though there were missed opportunities to vaccinate. That cannot work for influenza vaccination because of the short window of opportunity for vaccination. Standing orders may be helpful in reducing missed opportunities as they empower nurses and other healthcare professionals to provide influenza vaccine even in the absence of the physician.

→ **Barriers must be removed** to the greatest extent possible. Many practices have waived co-payments for influenza-vaccination-only visits. Providing necessary documentation by mail before the scheduled appointment can reduce in-office waiting time—a benefit to patients and providers alike. When scheduling vaccine-only clinics, practices must consider providing a variety of times (e.g., Saturdays and early morning or evening week-day hours) to give working parents options.

→ **Access can be increased** by a variety of methods. Small offices may consider 30-minute influenza vaccine clinics, while larger practices may find half-day clinics optimal. The largest groups, like Kaiser Permanente Colorado, may find mass immunization clinics the most efficient.

→ **Audit and feedback** can be accomplished no matter the practice size. Audit can be as simple as measuring yearly doses of influenza vaccination administered. Practices can work toward the ideal methods, but can make simple changes immediately.

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