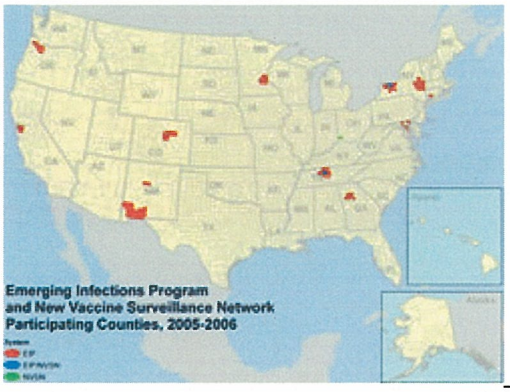
What types of vaccine effectiveness studies are being conducted by CDC now?



(/flu/images/professionals/map_eip_nvsn_counties.jpg) Map: Emerging Infections Program and New Vaccine Surveillance Network Participating Counties, 2005-2006

Because of the changing nature of influenza viruses and the vaccine, annual assessment of the effectiveness of influenza vaccines is important. Vaccine effectiveness studies can look at various target populations (*e.g.*, children, the elderly), and determine how well the vaccine prevents against different outcomes (*e.g.*, hospitalization, illness, death, and laboratory-confirmed infection). CDC is currently conducting studies that have only a laboratory-confirmed outcome. The findings of these studies are then used to enhance vaccine recommendations or support the need for new methods of vaccine production.

In 2004, a 3-year CDC-funded pilot study with the Marshfield Clinic Research Foundation was initiated to develop an assessment system of the vaccine's effectiveness across all groups for whom influenza vaccine is targeted. This study is in its final year.

Through CDC's Emerging Infections Program Network and the New Vaccine Surveillance Network, other vaccine effectiveness studies are being conducted during the 2006-07 influenza season among children 6-59 months of age. These studies will assess the effectiveness of the vaccine in preventing laboratory-confirmed influenza hospitalizations.

Influenza Vaccine Effectiveness Studies Currently Being Conducted by CDC

Table 1. Marshfield Clinic Studies

Study Design	Cohort and case-control
Seasons	2004-05, 2005-06, 2006-07
Setting	Clinic population in north-central WI
Age	All ACIP-recommended groups
Cases	Patients with acute respiratory illness (ARI) symptoms and influenza positive by culture or RT-PCR
Cohort Controls	Cohort of adults and children for whom ACIP recommended annual influenza vaccination. Age-matched persons with ARI symptoms in same healthcare system.

Vaccination data	Obtained from regional electronic vaccine registry and patient report
Source of other data	Electronic medical record and interview of adult or parent/guardian
Other patient characteristics included in analyses	Age, gender, race, high- risk condition, use of health care

Table 2. Emerging Infections Program Studies

Study Design	Case-control
Seasons	2005-06, 2006-07
Setting	Hospitals in 8 (05-06) and 9 (06-07) states
Age	6-23 mo (05-06), 6-59 mo (06-07)
Cases	Children hospitalized with laboratory confirmed influenza test. Testing done as ordered by clinicians.
Controls	Age- and zip-code matched children not hospitalized with influenza
Vaccination data	Obtained from health care providers and parent report
Source of other data	Medical chart review, interview of parent/guardian
Other patient characteristics included in analyses	Age, gender, race, insurance status, high- risk conditions, socioeconomic status

Table 3. New Vaccine Surveillance Network Studies

Study Design	Case-control
Seasons	2003-04, 2004-05, 2005-06, 2006-07
Setting	Hospitals, Emergency Departments, and outpatient clinics in 3 counties (TN, NY, OH)
Age	6-59 months
Cases	Children prospectively enrolled with fever or ARI who test positive for influenza by culture or RT-PCR
Controls	Children prospectively enrolled with fever or ARI who test negative for influenza by culture and RT-PCR
Vaccination data	Obtained from health care providers
Source of other data	Medical chart review, interview of parent/guardian
Other patient characteristics included in analyses	Date enrolled, age, gender, race, insurance status, high-risk conditions, socioeconomic status and other risk factors.

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State of Alaska Epidemiology **Bulletin**

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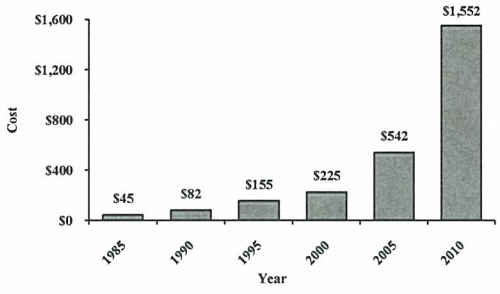
Only Pediatric/Adolescent Vaccines to be Supplied by State Beginning in 2011

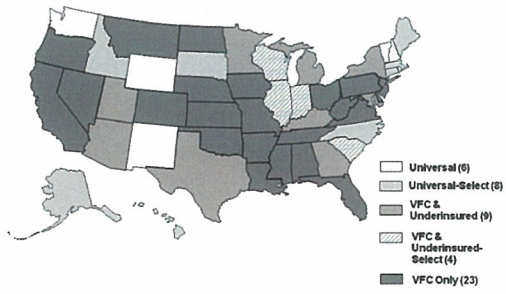
For over 30 years the Alaska Immunization Program maintained a "universal" vaccine program, distributing at no cost all Advisory Committee on Immunization Practices (ACIP)-recommended pediatric and selected adult vaccines to public and private providers in Alaska. This vaccine distribution has been supported almost entirely with two sources of federal funding. The *Vaccines for Children (VFC) Program* pays for vaccines for children who meet certain federal criteria. *Section 317 of the U.S. Public Health Service Act (317)* covers the cost of vaccines for the approximately one-third of Alaska children who are not VFC-eligible, as well as adult vaccines. As a federal entitlement program, VFC funding increases to support newly recommended vaccines for children; however, 317 funding has not kept pace with rapidly rising vaccine costs, which have risen almost seven-fold in the last 10 years (Figure 1).

Figure 1: Alaska Immunization Program Estimated Cost to Purchase Recommended Vaccines for One Child from their Year of Birth through Age 18 Years, for Selected Years from 1985 through 2010



has made it increasingly challenging for Alaska to maintain its vaccine distribution policy; however, these challenges are not unique to Alaska. Almost one-half (23/50) of U.S. states supply vaccines only for VFC-eligible children, i.e., vaccines are not supplied for children who do not meet program eligibility criteria or for adults. Other state vaccine supply policies include *universal purchase* (all vaccines for all children), *universal purchase select* (vaccines for all children except selected expensive vaccines available for VFC-eligibles only), and *VFC and underinsured* and *VFC and underinsured select* (varying levels of coverage for underinsured children) (Figure 2).

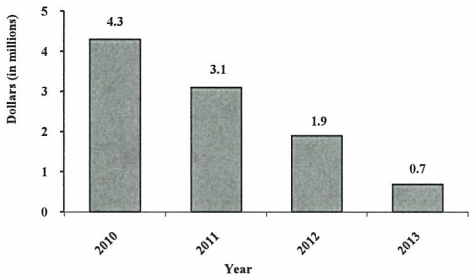
Figure 2: Public Purchase Pediatric Vaccine Supply Policy — United States, July 2010[1]



Alaska's vaccine purchases are supported almost entirely with funding from the U.S. Centers for Disease Control and Prevention (CDC). In 2008, CDC informed Alaska that the state had been "significantly overfunded" relative to other state and local immunization programs for many years, and the agency could no longer support Alaska's universal immunization program. CDC agreed to maintain 317 funding at ~$4.3 million through 2010, with the understanding that funding would decrease in subsequent years.

To meet the challenges presented by increased vaccine costs and reduced funding, Alaska has taken incremental steps to reduce vaccine expenditures while trying to maintain maximum availability of pediatric vaccines. In 2007, the Immunization Program discontinued shipments of adult influenza vaccine to private providers. In January 2009, the state limited the provision of human papillomavirus (HPV) and meningococcal conjugate vaccines to children who met the federal eligibility requirements of the Vaccines for Children (VFC) Program.[2] These program modifications helped trim vaccine costs by more than $2 million per year. However, CDC has notified Alaska that, beginning in 2011, the state's 317 vaccine dollars will be reduced by ~$1.2 million for each of the next 3 years, at which time Alaska's funding will be proportionate to that received by other immunization programs in the United States (Figure 3). Therefore, a change in Alaska's vaccine supply policy is necessary (Box).

Figure 3: Projected 317 Vaccine Funding for Alaska, 2010–2013



Box. The Alaska Immunization Program's 2011 Vaccine Supply Policy

Due to the increased cost of vaccines and federal 317 funding cuts, the following Alaska Immunization Program vaccine supply policy will become effective on **January 1, 2011**:

- All ACIP-recommended pediatric vaccines except HPV and MCV4 will continue to be supplied for all children through age 18 years. HPV and MCV4 will continue to be available for VFC-eligible children only.
- **Adult vaccines that historically have been provided by the Alaska Immunization Program (i.e., influenza, pneumococcal, tetanus/diphtheria) will no longer be supplied to public or private sector providers.**

Alternate Resources Available for Adult Vaccines

Private insurance policies and Medicare frequently support the cost of adult vaccines. Resource information related to Medicare billing and other potential funding sources is posted on the Section of Epidemiology website.[3] Manufacturer contact information for vaccine ordering also is included.

Conclusion

Although the Alaska Immunization Program regrets this policy change for adult vaccines, we are pleased that we can continue to provide pediatric vaccines at the current level throughout 2011. As the state's 317 funding levels continue to decrease over the next 3 years, this pediatric policy may need to be reconsidered. We will also continue to monitor the implementation of the Patient Protection and Affordable Care Act to determine its potential impact on vaccine funding in the future. To the greatest extent possible, we will continue our commitment to eliminate vaccine-preventable diseases in Alaska's children.

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(Contributed by Laurel Wood, MPA, Immunization Program Manager, Section of Epidemiology)