

Deployment of Combination Vaccines and STI vaccines

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Overview

- **Process of deploying a new pediatric vaccine in the Vaccines for Children (VFC) program**
- **Combination vaccines**
- **Introduction of prior STI vaccines**

How a Vaccine Comes to Market

- **Clinical Trials**
- **US Food and Drug Administration (FDA) Licensure**
- **Post Licensure Studies**

National Recommendations

- **Advisory Committee on Immunization Practices (ACIP)**
 - 15-member expert committee which provides advice and guidance to the federal government on use of vaccines for effective control of vaccine preventable diseases
 - Meets three times annually
- **AAP, AAFP, ACOG Recommendations**
 - Often harmonized with ACIP

AAP=American Academy of Pediatrics

AAFP=American Academy of Family Physicians

ACOG=The American College of Obstetricians and Gynecologists



ACIP Recommendations

- **For what population is the vaccine recommended?**
 - Universally at a certain age
 - For high-risk persons
- **Recommended schedule**
 - Route and dose
 - Frequency--3-dose series, one dose, boosters...
 - Minimum ages and intervals

Factors to Consider—Disease

- **Epidemiology of Disease**
 - Significant morbidity and mortality caused by the disease
 - Age-specific risks of infection/disease
 - Numbers and percent of population affected
 - Subpopulations at higher risk
- **Costs of the disease**
 - Direct--Hospitalizations, emergency department visits, medical office visits, medications and other treatment
 - Indirect—time lost from work

Factors to Consider—Vaccine

- **Vaccine specific information**
 - Age-specific risk of adverse events due to vaccine
 - Ability of a person of a certain age to respond to vaccine
- **Is the vaccine highly efficacious?**
 - Is the vaccine immunogenic (in that population)?
 - Does it prevent disease in recipients of the vaccine?
 - Does it prevent spread of disease to others?
- **How long does the vaccine protect the recipient?**
- **Co-administration with other recommended vaccines?
(safety and immunogenicity issues)**

Cost Effectiveness

- **Disease burden**
- **Vaccine efficacy**
- **Vaccine coverage rates**
- **Direct health costs**
- **Indirect societal costs**
- **What costs are prevented due to immunization**
- **Costs of immunization**

Other Issues

- **Vaccine administration, storage and handling**
 - Easy to administer
 - Not easily damaged by cold or heat
 - Clear, easy to read labels
- **Costs from physician perspective**
 - Costs of vaccine
 - Other related costs (inventory, ordering, storage, temperature monitoring, materials, staff time (discuss with parent and for administration), etc.)
 - Reimbursement for both vaccine and administration

Vaccines for Children

- **ACIP votes on whether or not to include a new pediatric vaccine in the Vaccines for Children (VFC) program**
 - Covers recommended vaccines through age 18 for eligible clients
 - Uninsured
 - Medi-Cal eligible
 - Native American or Alaska Native
 - Underinsured if immunized at a Federally Qualified Health Center (FQHC) or Rural Health Center

<http://www.eziz.org>

VFC Resolution

- **VFC resolution (who is eligible under VFC, schedule, and contraindications and precautions)**
- **Federal VFC Contract with manufacturer**
 - Negotiation of contract
- **Vaccine available from VFC program**
 - California sends a letter to all VFC providers when a new vaccine becomes available through the program

Combination Vaccines

- **Multiple antigens into a single preparation**
 - Different antigens from different organisms in one vaccine
 - MMR, DTaP
 - DTaP-IPV, hepatitis B-hepatitis A
 - Multiple strains of an infection that cause the same disease
 - Trivalent Polio
 - Multiple serotypes of the same organism
 - Streptococcus pneumoniae (pneumococcus)
 - Influenza

Why Combination Vaccines?

Number of Diseases Prevented in the Routine Childhood and Adolescent Immunization Schedule

1985

Measles
Rubella
Mumps
Diphtheria
Tetanus
Pertussis
Polio

7

1995

Measles
Rubella
Mumps
Diphtheria
Tetanus
Pertussis
Polio
Hib (infant)
HepB
Varicella

10

2006

Measles
Rubella
Mumps
Diphtheria
Tetanus
Pertussis
Polio
Hib (infant)
HepB
Varicella
Pneumococcal disease
Influenza
Meningococcal disease
HepA
Rotavirus
HPV

16

Examples of Recently Licensed Multipurpose Vaccines

- **First combinations (DTP, MMR)**
- **Pediarix® (DTaP-IPV-hepatitis B)—2002**
 - 2 months, 4 months, 6 months
- **Pentacel® (DTaP-IPV/Hib)—2008**
 - 2 months, 4 months, 6 months, 15-18 months
- **Kinrix® (DTaP, IPV)—2008**
 - 4-6 years

Combination Vaccines

- **Non-inferiority to monovalent or combination products licensed previously**
 - Immunogenicity
 - Safety

Benefits

- Fewer injections for child while getting protection against multiple vaccine preventable diseases
- May improve timeliness of immunization coverage
- Reduced cost for storage and administration of separate vaccines

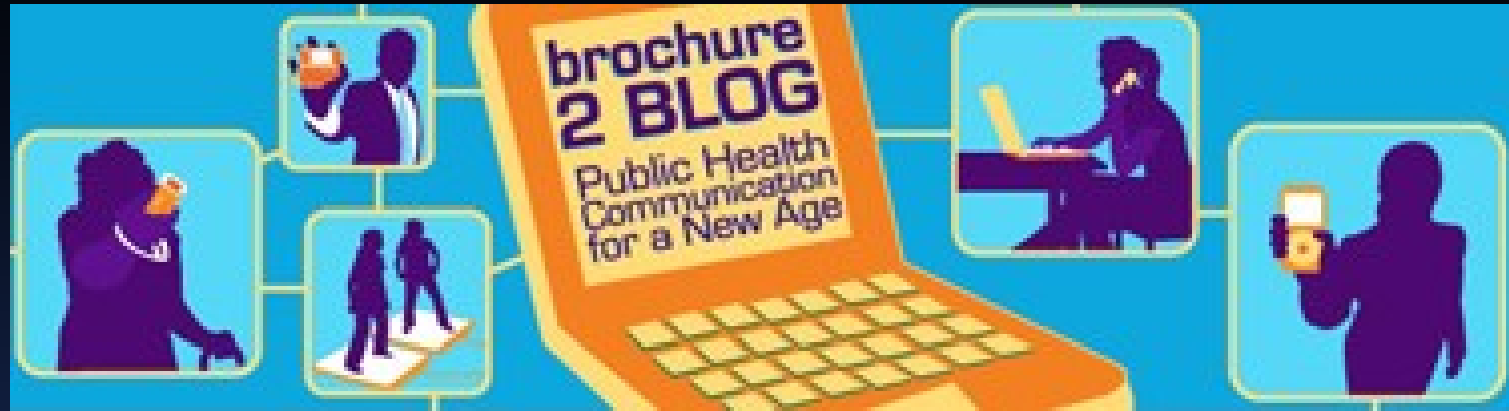
Combination Vaccine Concerns

- **Confusion between combination vaccines**
 - Different combination vaccines with different but overlapping groups of antigens
 - E.g., two pentavalent vaccines (DTaP-IPV-Hep B, DTaP-IPV/Hib)
- **Extra dose of one antigen**
 - E.g., hepatitis B (birth dose and 3 doses Pediarix®)
- **Reimbursement concerns**
 - Vaccine and administration reimbursement
- **Accurate recordkeeping could be an issue**

Concerns about Combination Vaccines

- **Some parents want to delay and spread out current immunizations**
 - E.g., MMR as separate measles, mumps and rubella





Webinar

YouTube

Blogging

Podcast

E-mail

MySpace

Text Message

Wiki

**Immunization
Registry**

Internet

Second Life



Post Licensure Safety

- **Vaccine Adverse Event Reporting System (VAERS)**
 - Accepts reports from the public and providers on adverse events associated with vaccines licensed in the United States (online, phone)
 - Data is reviewed to monitor safety of licensed vaccines
- **Phase IV studies by the manufacturer**
- **Vaccine Safety Datalink**
 - Investigates possible associations that might be identified during VAERS or Phase IV studies
- **Clinical Immunization Safety Assessment (CISA) Network**
 - Conducts clinical research and addresses vaccine safety questions

Disease Surveillance

- **Some with state reporting requirements**
- **National surveillance system**
 - Sentinel sites

MMRV Recommendations

- **Licensed in 2005 for use among healthy children 12 months – 12 years**
- **Postlicensure studies**
 - Clustering of seizures 7-10 days after MMRV (VSD)
 - Preliminary adj OR = 2.3 (95% CI: 1.6-3.20)
 - rate of febrile seizure=9/20,000 vaccine recipients
 - One additional febrile seizure per 2,000
- **ACIP removed their previous preference for administering combination MMRV vaccine over separate MMR and varicella vaccines (2008)**

Recommended Schedules and Combination Vaccines

- The Recommended Childhood and Adolescent Immunization Schedule and the Recommended Adult Immunization Schedule are revised annually.
- Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of the series.

Recommended Immunization Schedules for Persons Aged 0 Through 18 Years
--- United States, 2009

Challenges with New Vaccines for Adolescent or Adult Populations

- **Low rate of adolescent and adult preventive care**
- **Multi-dose series more difficult in adolescent population**
- **Vaccine cost is a barrier for uninsured adults**

Challenges with New STI Vaccines

- **May be controversial if targeting young adolescents**
 - If vaccine is preventive, then need to promote immunization at an early age
 - Concerns about duration of immunity if it is a new vaccine
 - Denial by parents that their child could be sexually active before adulthood
 - Concerns immunization may promote promiscuity

HPV Vaccine Workgroup

- **Department of Health Services**
 - Immunization Branch
 - STD Control Branch
 - Cancer Control Branch
 - Office of Women's Health
 - Other programs: MCAH/Office of Family Planning, Office of AIDS, Department of Education
 - Joint planning anticipating release of HPV vaccine
 - Consistent messages
 - Development of educational materials
 - Website (www.hpvvaccineca.org)

HPV Vaccine

- **Controversy over HPV vaccine mandates introduced throughout the country**
- **California legislation introduced in December 2006**
- **Media concerns around vaccine safety**
 - Common with any new vaccine
 - A lot of press concerns with HPV vaccine
- **Issues around consent for immunization with adolescents**

THANK YOU!

