

## Concepts in Vaccine Practice



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Chief, Division of Pediatric Infectious Diseases  
Director, Pediatric Clinical Trials Unit  
University of Louisville School of Medicine

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### Disclosures

I have the following financial relationships with the manufacturers of commercial products and/or provider of commercial services discussed in this CME activity:

Research support from: GlaxoSmithKline, Merck, Novartis, Pfizer, Sanofi Pasteur

Consultant for: GlaxoSmithKline, Merck, Novartis, Pfizer, Sanofi Pasteur



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### Objectives

- Understand how vaccines are developed and recommended
- Gain insight into practical aspects of vaccinating patients in the office setting
- Incorporate general rules for vaccinating that can guide everyday implementation of vaccine programs



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**Anticipated Changes in Practice**

- Decrease in vaccine administration errors
- Improved immunization rates
- Timely adoption of new recommendations




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**Concepts in Vaccine Practice**

- Development, policy, and recommendations
- Financing
- Monitoring delivery and safety
- Federal requirements for vaccinators
- Rules by which to vaccinate
- Administration errors
- Pearls
- Contraindications and precautions




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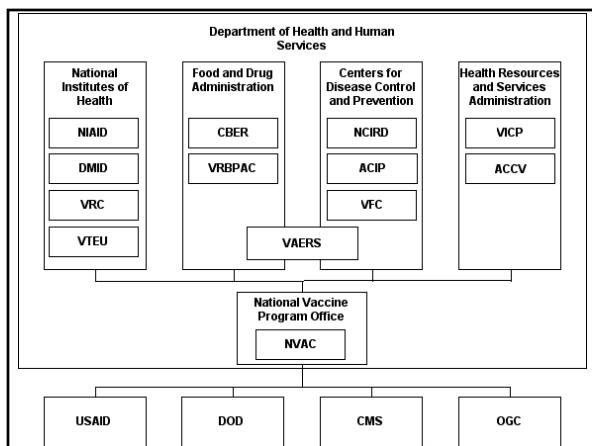
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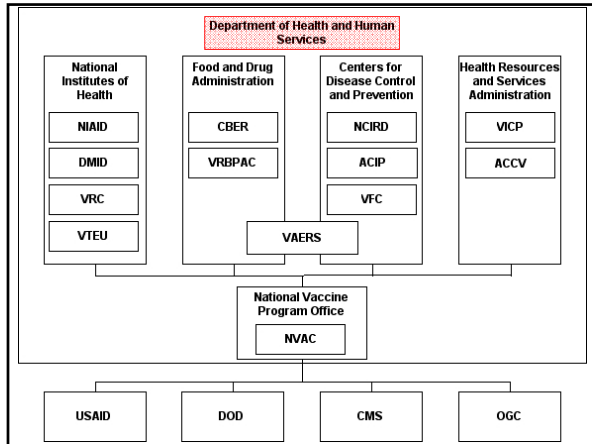
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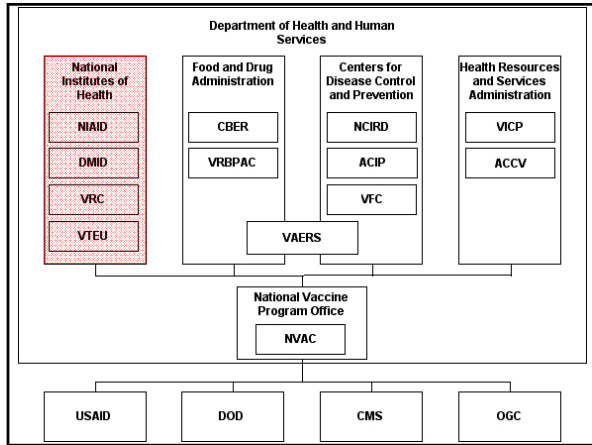
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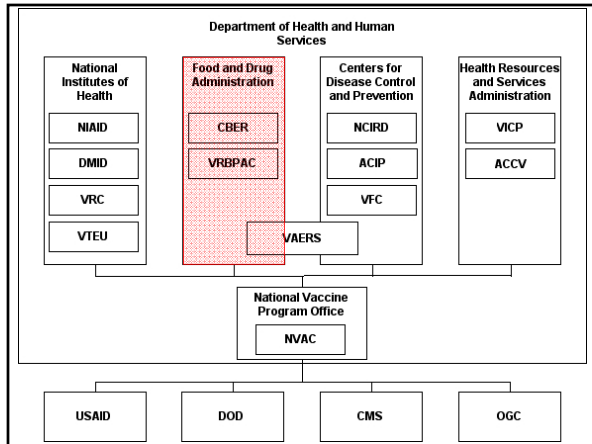
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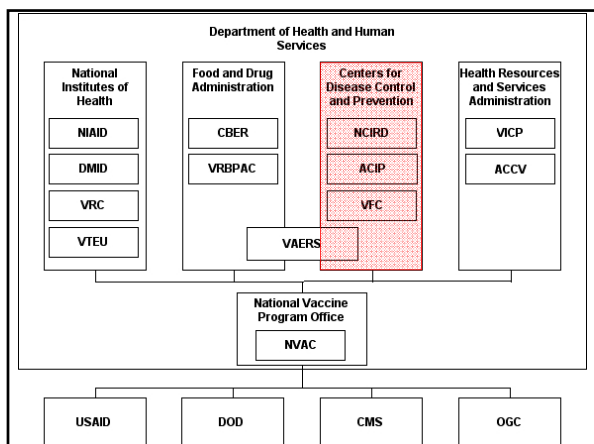
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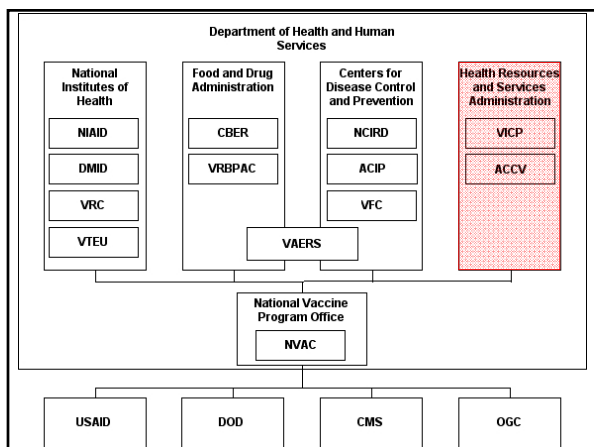
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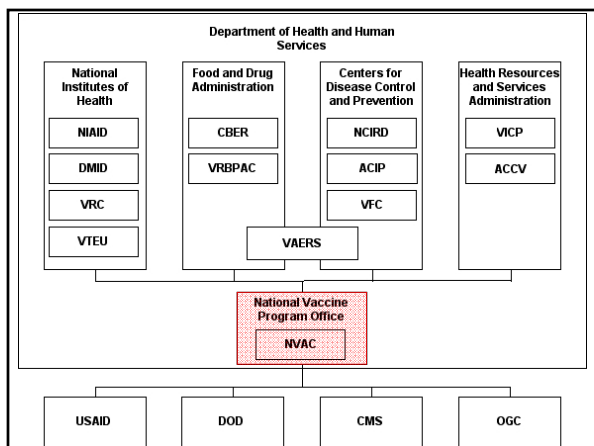
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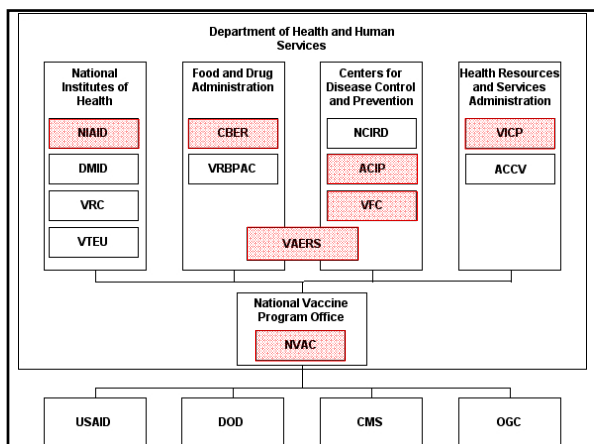
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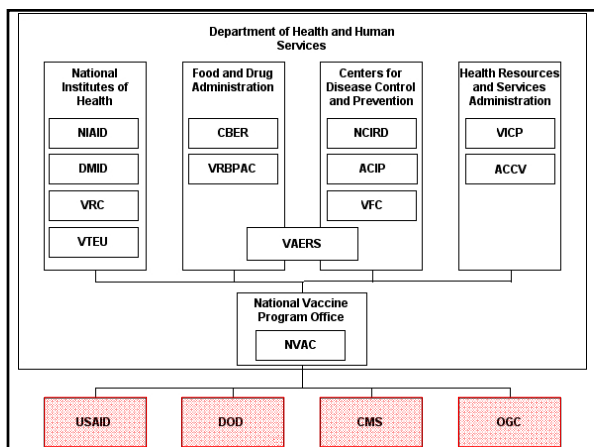
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**Economic Evaluation**

- Comparative evaluation of alternative lines of action that includes effects as well as costs
- Vaccines that produce health benefits and cost savings are inherently cost-effective
- Vaccines that produce health benefits but do not save costs: decision to use depends on willingness to pay

Ess. Clin Infect Dis 2002;35:294

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### Quality-Adjusted Life Years

- Each year in perfect health = 1.0
- Death = 0
- Years lived in less than full health = 0 to 1
- Weighting based on survey responses

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### Quality-Adjusted Life Years

- How is the weight assigned?
- More weight given to adverse physical outcomes?
- Health states worse than death?
- Prohibitive cost per QALY saved?
- Effect of a patient's health on caregivers?

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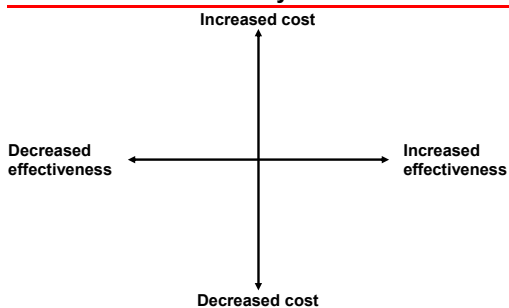
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### Cost-Effectiveness Analysis



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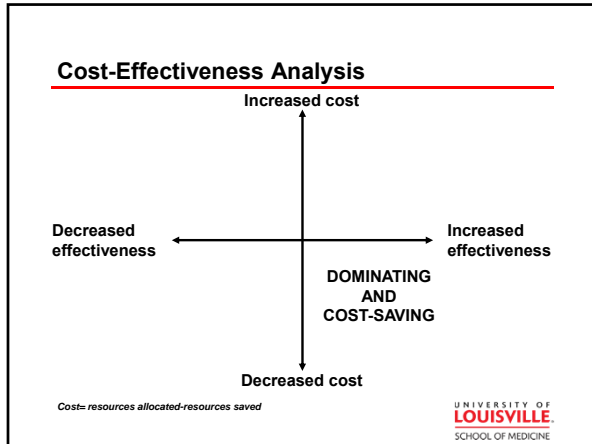
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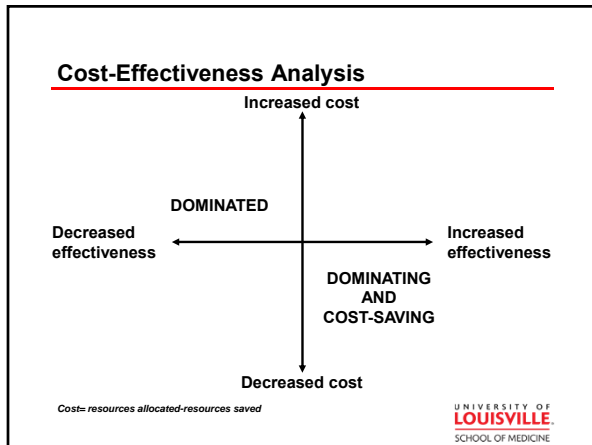
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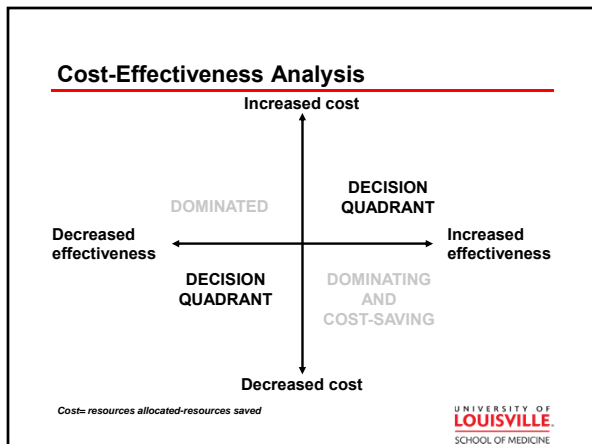
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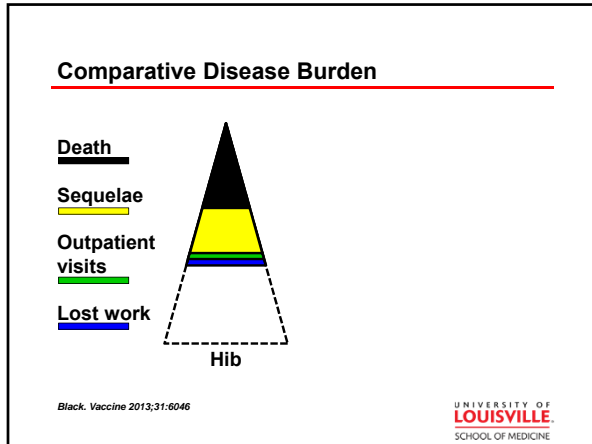
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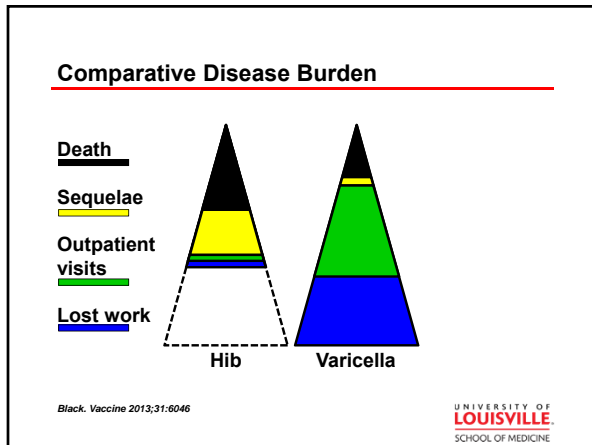
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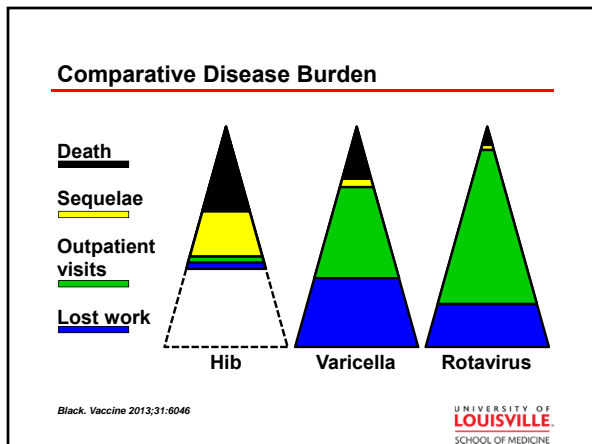
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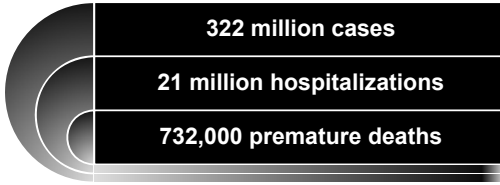
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**Impact of Routine Childhood Immunizations**  
**U.S., 1994-2013**



Whitney. MMWR 2014;63:352-55  
 Cohort=78.6 million children. Analysis includes all vaccines except influenza and HepA. Costs adjusted to 2013 dollars; future disease costs discounted 3% annually.

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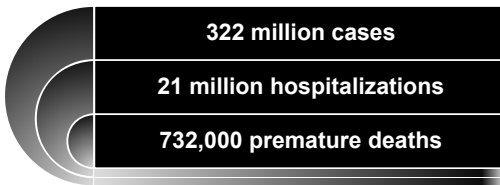
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**Impact of Routine Childhood Immunizations**  
**U.S., 1994-2013**



**—Net savings—**  
**Payers' perspective: \$295 billion**  
**Societal perspective: \$1.38 trillion**

Whitney. MMWR 2014;63:352-55  
 Cohort=78.6 million children. Analysis includes all vaccines except influenza and HepA. Costs adjusted to 2013 dollars; future disease costs discounted 3% annually.

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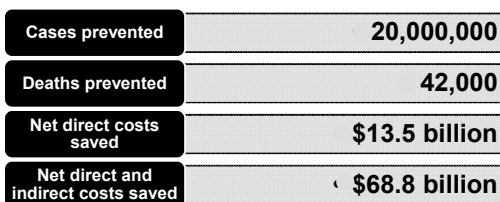
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**Impact of Routine Childhood Immunizations**  
**U.S. birth cohort, 2009**



Zhou. Pediatrics 2014;133:577-85  
 Cohort=4.3 million children followed until death. Influenza vaccine excluded. Costs adjusted to 2009 dollars; future costs discounted 3% annually.

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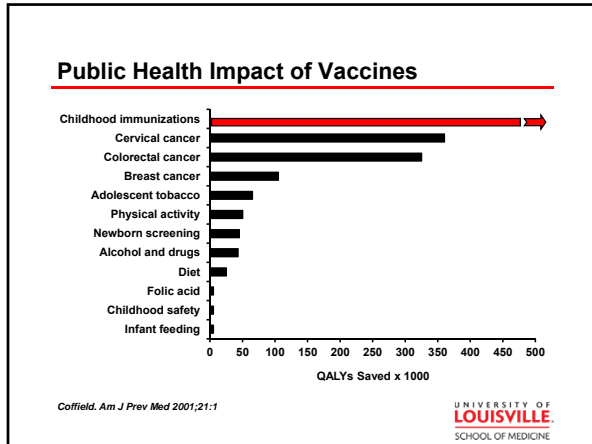
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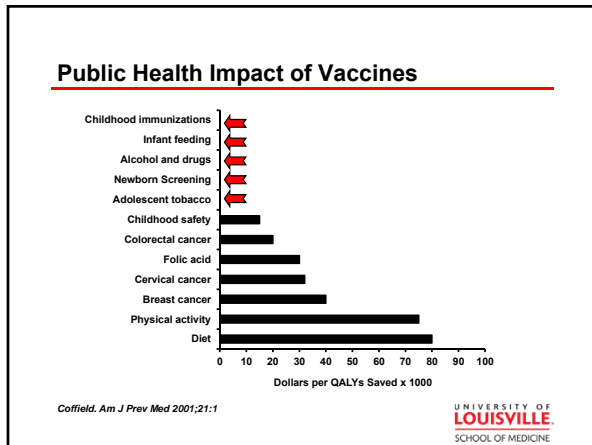
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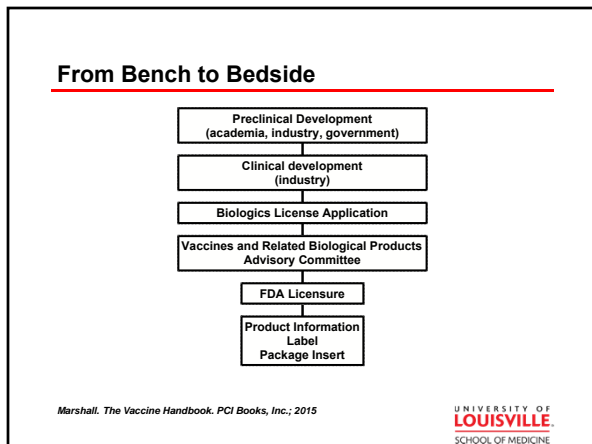
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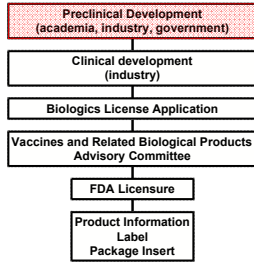
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### From Bench to Bedside



Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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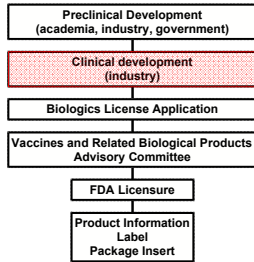
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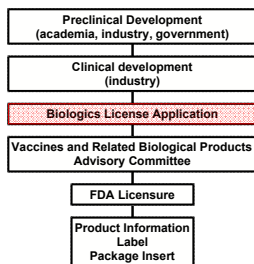
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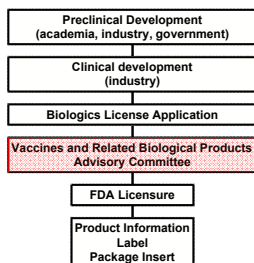
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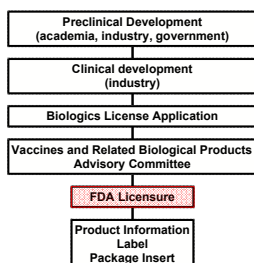
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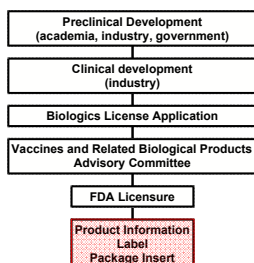
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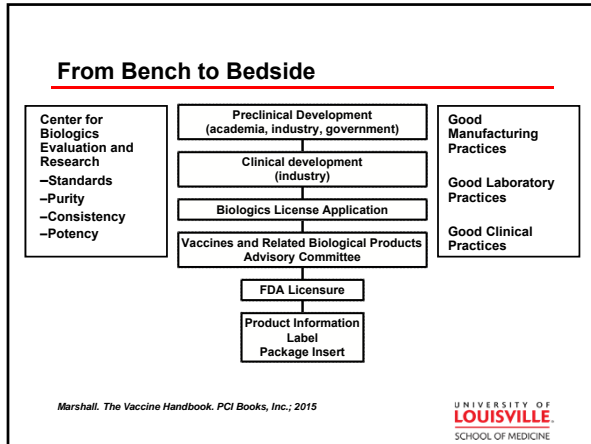
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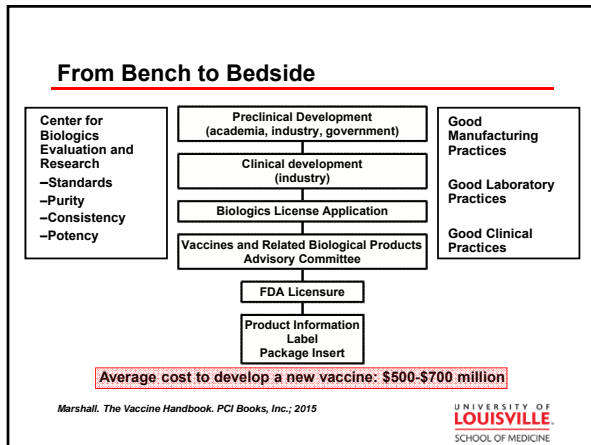
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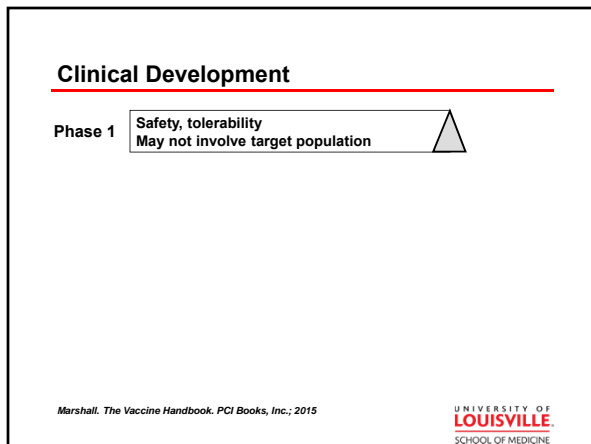
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### Clinical Development

|         |  |           |
|---------|--|-----------|
| Phase 1 | Safety, tolerability<br>May not involve target population        | ▲         |
| Phase 2 | Safety, immunogenicity, dosing<br>Performed in target population | ▲<br>100s |

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### Clinical Development

|         |   |            |
|---------|---|------------|
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| Phase 3 | Safety, immunogenicity, longevity of immune response, concomitant use, efficacy | ▲<br>1000s |

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### Clinical Development

|         |   |               |
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| Phase 2 | Safety, immunogenicity, dosing<br>Performed in target population                | ▲<br>100s     |
| Phase 3 | Safety, immunogenicity, longevity of immune response, concomitant use, efficacy | ▲<br>1000s    |
| Phase 4 | Post-licensure<br>Safety  | ▲<br>100,000s |

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**Recommendations for Use**

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ACIP (CDC)  
AAP  
AAFP

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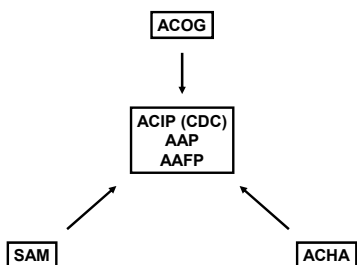
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**Recommendations for Use**

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**Considerations**

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- Characteristics of the product
- Principles of active and passive immunization
- Epidemiology and burden of disease
- Safety
- Cost analysis of preventive measures
- Published and unpublished studies
- Expert opinion

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**ACIP Actions**

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- Routine recommendation
  - Every person in specified age group
  - PCV13 at 2, 4, 6, 12-15 months

Adapted from Rodewald. ACIP Meeting, October 2009



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**ACIP Actions**

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- Routine recommendation
  - Every person in specified age group
  - PCV13 at 2, 4, 6, 12-15 months
- Catch-up recommendation
  - Defined cohorts and time periods
  - Second dose of VAR for all who had 1 dose

Adapted from Rodewald. ACIP Meeting, October 2009



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**ACIP Actions**

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- Routine recommendation
  - Every person in specified age group
  - PCV13 at 2, 4, 6, 12-15 months
- Catch-up recommendation
  - Defined cohorts and time periods
  - Second dose of VAR for all who had 1 dose
- Risk-based recommendation
  - Risk factors for disease or complications
  - PPSV23 for adult smokers

Adapted from Rodewald. ACIP Meeting, October 2009



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**ACIP Actions**

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- Permissive statement
  - Allow use but no recommendation
  - HPV4 for males (2010)

Adapted from Rodewald. ACIP Meeting, October 2009



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**ACIP Actions**

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- Permissive statement
  - Allow use but no recommendation
  - HPV4 for males (2010)
- Recommendations against
  - Specify when vaccine should not be used
  - Routine MCV4 for healthy 2 to 10-year-olds

Adapted from Rodewald. ACIP Meeting, October 2009



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**2010: Evidence-Based System**

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- GRADE
  - Grading of recommendations
  - Assessment
  - Development
  - Evaluation
- A: apply to all persons in age- or risk-based groups (*recommend, recommend against, should, should not*)
- B: individual decision making (*may, suggest*)
- (C: no recommendation or unresolved)

Ahmed. Vaccine 2011;29:9171



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**2010: Evidence-Based System**

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- Evidence Rank 1
  - Randomized controlled trials
  - Overwhelming observational evidence
- Evidence Rank 4
  - Clinical experience
  - Controlled or observational studies with major limitations

Ahmed, Vaccine 2011;29:9171



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**Notes**

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- Provisional recommendations no longer posted



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**Notes**

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- Provisional recommendations no longer posted
- Recommendations “harmonized” since 1995



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**Notes**

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- Provisional recommendations no longer posted
- Recommendations "harmonized" since 1995
- Differences between AAP and ACIP may exist



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**Notes**

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- Provisional recommendations no longer posted
- Recommendations "harmonized" since 1995
- Differences between AAP and ACIP may exist
- Insurance coverage may await publication



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**Notes**

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- Provisional recommendations no longer posted
- Recommendations "harmonized" since 1995
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- Insurance coverage may await publication
- Separate ACIP vote determines coverage by VFC



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**Notes**

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- Insurance coverage may await publication
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- All vaccination mandates are local




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**Notes**

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- Provisional recommendations no longer posted
- Recommendations “harmonized” since 1995
- Differences between AAP and ACIP may exist
- Insurance coverage may await publication
- Separate ACIP vote determines coverage by VFC
- All vaccination mandates are local
- Package Insert
  - Legal document
  - Determines how vaccine can be marketed




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**Labels vs Recommendations**

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| Vaccine | Label         | Recommendation |
|---------|---------------|----------------|
| MMR     | ≥12 mo of age |                |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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**Labels vs Recommendations**

| Vaccine | Label         | Recommendation                          |
|---------|---------------|---|
| MMR     | ≥12 mo of age | 6-12 mo of age for international travel |

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**Labels vs Recommendations**

| Vaccine | Label         | Recommendation                          |
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| MMR     | ≥12 mo of age | 6-12 mo of age for international travel |
| RAB     | 5-dose series |   |

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**Labels vs Recommendations**

| Vaccine | Label         | Recommendation                          |
|---------|---------------|---|
| MMR     | ≥12 mo of age | 6-12 mo of age for international travel |
| RAB     | 5-dose series | 4-dose series                           |

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**Labels vs Recommendations**

| Vaccine | Label                     | Recommendation                          |
|---------|---------------------------|---|
| MMR     | ≥12 mo of age             | 6-12 mo of age for international travel |
| RAB     | 5-dose series             | 4-dose series                           |
| RV1     | Last dose ≤24 wk of age   |   |
| RV5     | First dose 6-12 wk of age |   |

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| Vaccine | Label                     | Recommendation                          |
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| MMR     | ≥12 mo of age             | 6-12 mo of age for international travel |
| RAB     | 5-dose series             | 4-dose series                           |
| RV1     | Last dose ≤24 wk of age   | First dose 6-14 wks, 0 days of age      |
| RV5     | First dose 6-12 wk of age | Last dose <8 mo, 0 days of age          |

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**Labels vs Recommendations**

| Vaccine | Label                               | Recommendation                          |
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| MMR     | ≥12 mo of age                       | 6-12 mo of age for international travel |
| RAB     | 5-dose series                       | 4-dose series                           |
| RV1     | Last dose ≤24 wk of age             | First dose 6-14 wks, 0 days of age      |
| RV5     | First dose 6-12 wk of age           | Last dose <8 mo, 0 days of age          |
| Tdap    | 5-yr interval since last DTaP or Td |   |

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**Summary of Adult Immunization Study Budget Items - 2015**  
Key: Yellow = Vaccine; Purple = Personnel; Grey = Other

**Table 1: Personnel and other budget items - by activity and organization**

| Activity  | Organization | 2015      | 2016      | 2017      |
|-----------|--------------|-----------|-----------|-----------|
| Vaccine   | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
| Personnel | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
| Other     | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |

**Table 2: Vaccine budget items - by activity and organization**

| Activity  | Organization | 2015      | 2016      | 2017      |
|-----------|--------------|-----------|-----------|-----------|
| Vaccine   | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
| Personnel | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
| Other     | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |
|           | NIH          | 1,000,000 | 1,000,000 | 1,000,000 |

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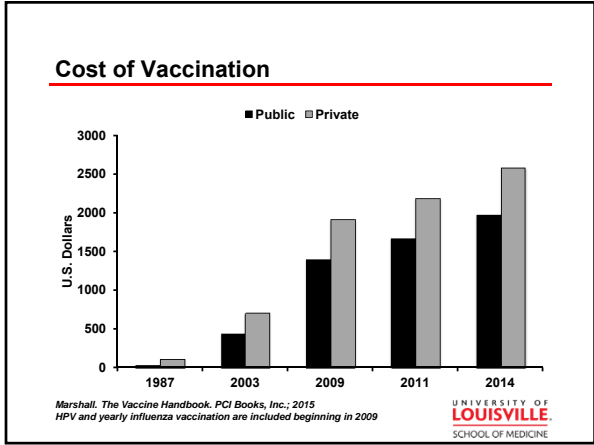
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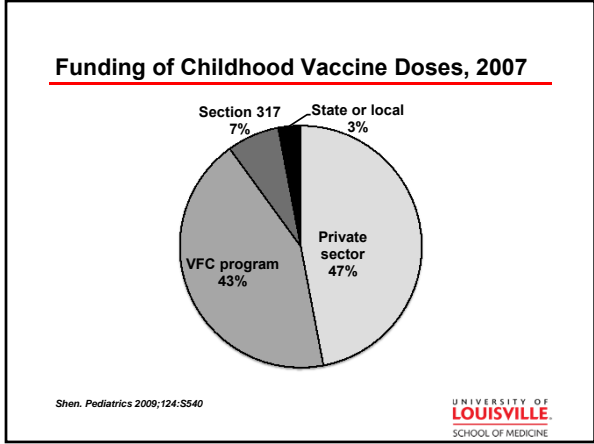
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**Public Financing**

| Attribute | 317 Funds                          | VFC       |
|-----------|------------------------------------|-----------|
| Source    | Annual discretionary appropriation | Mandatory |

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**Public Financing**

| Attribute   | 317 Funds                          | VFC  |
|-------------|------------------------------------|--|
| Source      | Annual discretionary appropriation | Mandatory  |
| Eligibility | No restrictions                    | Medicaid-eligible<br>Uninsured<br>Native American<br>Alaska native<br>Underinsured |

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**Public Financing**

| Attribute   | 317 Funds                          | VFC  |
|-------------|------------------------------------|--|
| Source      | Annual discretionary appropriation | Mandatory  |
| Eligibility | No restrictions                    | Medicaid-eligible<br>Uninsured<br>Native American<br>Alaska native<br>Underinsured |
| Stability   | Significant fluctuations           | Stable funding stream  |

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### Public Financing

| Attribute   | 317 Funds                          | VFC  |
|-------------|------------------------------------|--|
| Source      | Annual discretionary appropriation | Mandatory  |
| Eligibility | No restrictions                    | Medicaid-eligible<br>Uninsured<br>Native American<br>Alaska native<br><b>Underinsured†</b> |
| Stability   | Significant fluctuations           | Stable funding stream  |

†Must receive vaccine at Federally Qualified Health Centers or Rural Health Clinics




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### Actions Required Under VFC Resolutions

| Action  | ACIP Recommendation |                                  |
|---|---------------------|----------------------------------|
|   | Affirmative         | Permissive                       |
| Provider expected to offer vaccine to VFC-eligible children     | Yes                 | No                               |
| Provider may offer vaccine to VFC-eligible children             | Yes                 | Yes                              |
| Provider expected to vaccinate VFC-eligible children on request | Yes                 | Yes, if available; if not, refer |
| Program expected to promote recommendation                      | Yes                 | No                               |
| Uptake is a measure of performance                              | Yes                 | No                               |

Rodewald. ACIP Meeting, October 2009




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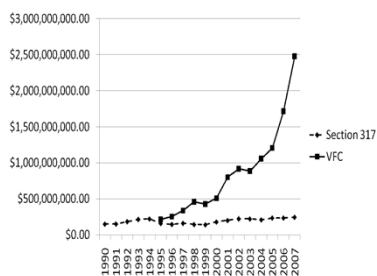
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### Public Financing



Lance Rodewald, NCIRD, CDC




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**Monitoring Delivery: NHIS**

**National Health Interview Survey**

- Conducted since 1957
- Current target: 35,000 households containing 87,500 persons

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Monitoring Delivery: BRFSS**

**Behavioral Risk Factor Surveillance System**

- Conducted since 1984
- State-level, random digit-dialing survey of noninstitutionalized civilians ≥18 years of age
- Covers 350,000 adults each year
- Useful for influenza vaccine and PPSV23

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Monitoring Delivery: HEDIS**

**Health Plan Employer Data and Information Set**

- National Committee for Quality Assurance
- Managed health care plan performance measures

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Monitoring Delivery: Miscellaneous**

- School surveys
- Special area and population surveys
- Geographic
- Medicaid participants
- Nursing home residents

Marshall. The Vaccine Handbook. PCI Books, Inc., 2015




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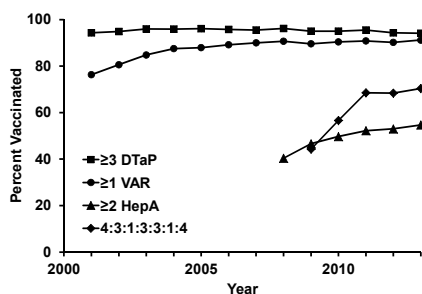
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**Coverage Rates: 19-35 Months of Age**



CDC. MMWR 2014;63:741.




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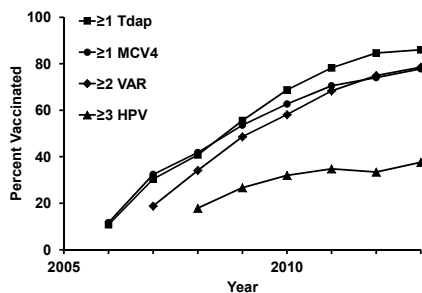
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**Coverage Rates: 13-17 Years of Age**



CDC. MMWR 2014;63:625.




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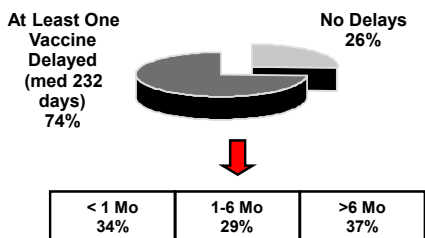
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### Timeliness of Immunizations by 24-35 Mo



Luman. JAMA 2005;293:1204 (N=14,810; 2003 NIS data, 24-35 mo)

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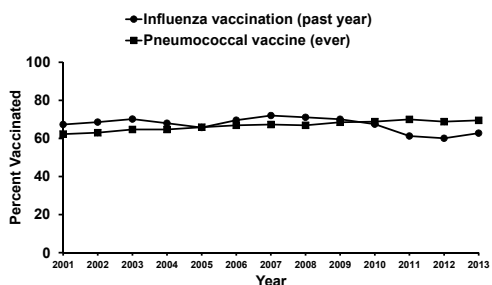
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### Coverage Rates: ≥65 Years of Age



National Center for Chronic Disease Prevention and Health Promotion. <http://apps.nccd.cdc.gov/brfss/index.asp> (BRFSS)

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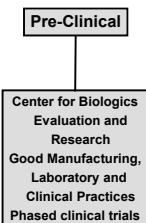
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### Monitoring Safety



Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015

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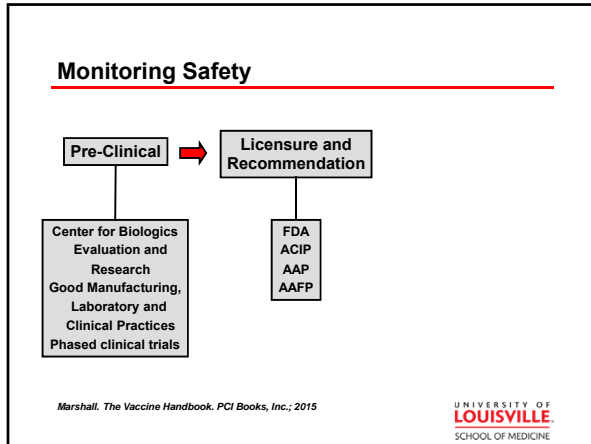
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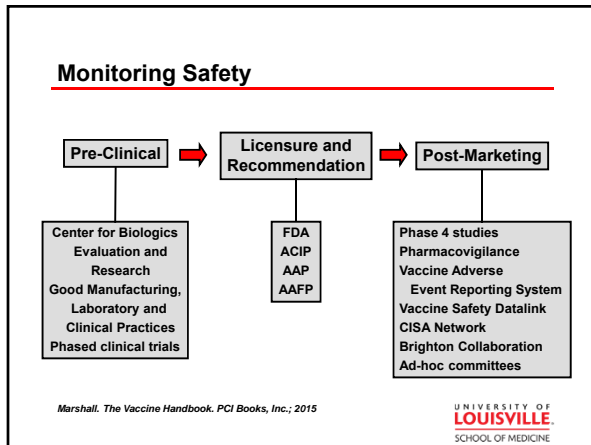
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- ### Federal Requirements—VIS
- Give a current, take-home copy of the relevant VIS to the parent, legal representative, or adult recipient before each dose of each vaccine
  - Use the VIS published by the CDC
  - Mandatory for vaccines covered under the VICP
  - Mandatory for vaccines purchased under federal contract
  - Encouraged for all other vaccines
- Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015
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**Federal Requirements—VIS**

- Provide VIS for each component of combination vaccines if there is no VIS for the combination
- Use visual or oral supplements for illiterate or blind patients
- Translations are available

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Federal Requirements—VIS**

- Permanent medical record or office log
  - Name of the VIS, publication date, and date it was given to the recipient
    - Patient signature is not required
    - VIS is not considered informed consent
  - Name and title of person administering vaccine
  - Address where the permanent record is kept
  - Date of administration
  - Manufacturer
  - Lot number

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Federal Requirements—VAERS**

- Report any event listed by the manufacturer as a contraindication to subsequent doses of the vaccine
- Report any event listed in the Reportable Events Table that occurs within the specified time period after vaccination

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Federal Requirements—OSHA**

- Adhere to the Bloodborne Pathogens Standard

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—1**

- Any vaccines can be given at the same time
- Separate sites must be used
- Exceptions
  - VAR and smallpox vaccine
  - MCV4-D and PCV13 in asplenic children

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015  
Tse. Vaccine 2012;30:2024-31



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**Rules by Which to Vaccinate—1**

- Any vaccines can be given at the same time
- Separate sites must be used
- Exceptions
  - VAR and smallpox vaccine
  - MCV4-D and PCV13 in asplenic children

*ZOS label warns against concomitant administration with PPSV23 (impaired response to ZOS), but ACIP recommendation allows concomitant use.*

*Increased risk of febrile seizures with concomitant use of IIV and PCV13. Magnitude of risk is <1 in 1,000 vaccinated. ACIP recommendation allows concomitant use.*

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015  
Tse. Vaccine 2012;30:2024-31



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**Rules by Which to Vaccinate—2**

- Separate live vaccines by at least 28 days (if not given at the same time)
- Exceptions
  - YFV may be given at any time after single-antigen measles vaccine
  - Live oral vaccines (RV, Ty21a, adenovirus) may be given at any time in relation to any other live vaccines
  - LAIV is not an exception

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—3**

- Different inactivated vaccines may be given at any time with respect to each other
- Exception: MCV4-D and PCV13 in asplenic children

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—4**

- Doses of the same vaccine must be separated by minimum intervals
- Exceptions
  - The 4-day grace period (not applicable to RAB)
  - Early, accelerated, or compressed schedules
- A minimum interval is a minimum interval except when it's not
  - DTaP doses 3 and 4: 6 mo, but 4 is OK
  - VAR doses 1 and 2: 3 mo, but 28 days is OK

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—5**

- All vaccines have a minimum age
- Exceptions
  - HepB
  - RAB

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—6**

- Do not restart a vaccine series if the recommended dosing interval is exceeded
- Exception: Oral typhoid Ty21a

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—7**

- Similar vaccines made by different manufacturers are interchangeable
- Exception
  - Preference for using the same brand of DTaP, HPV, and RV for the entire series
  - Preference for using same brand of MCV for series in high-risk infants 2-23 months of age
  - Do not defer vaccination if the same brand is not available

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—8**

- There is no harm in vaccinating a person who has already had the disease or the vaccine (in fact, there is reason to vaccinate when disease can be caused by multiple serotypes)
- Exceptions
  - Too many doses of PPSV23, tetanus toxoid, or diphtheria toxoid can cause increased reactogenicity
  - Anthrax vaccine is more reactogenic in persons who have had anthrax

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—9**

- Defer MMR and VAR after administration of antibody-containing blood products
- Exceptions
  - Do not defer MMR and VAR in postpartum women who receive antibody-containing blood products during pregnancy, including anti-Rho(D) globulin
  - LAIV, Ty21a, RV, YFV, ZOS, and adenovirus may be given

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Rules by Which to Vaccinate—10**

- Live vaccines may be used in households with immune compromised persons
- Exceptions
  - Smallpox
  - LAIV if profoundly immunosuppressed

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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### Use of Live Vaccines in Households of Immunosuppressed Individuals

| Vaccine  | Recommendation  |
|----------|---|
| LAIV     | Contraindicated if profoundly immunosuppressed        |
| MMR      | May be used   |
| RV       | May be used   |
| Smallpox | Contraindicated                                       |
| Ty21a    | May be used   |
| VAR      | May be used (avoid contact if lesions develop)        |
| YFV      | May be used   |
| ZOS      | May be used (standard precautions if lesions develop) |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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### Administration Errors

| Vaccine                         | Error               | Corrective Action |
|---------------------------------|---------------------|-------------------|
| Live                            | Expired or damaged  |                   |
|                                 | Less than full dose |                   |
|                                 | More than full dose |                   |
| Inactivated                     | Expired or damaged  |                   |
|                                 | Less than full dose |                   |
|                                 | More than full dose |                   |
| VAR, ZOS, MMR, MMRV, YFV, MPSV4 | Given IM            |                   |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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### Administration Errors

| Vaccine                         | Error               | Corrective Action               |
|---------------------------------|---------------------|---------------------------------|
| Live                            | Expired or damaged  | Redose same day or 4 wk later   |
|                                 | Less than full dose | Redose same day or 4 wk later   |
|                                 | More than full dose | None                            |
| Inactivated                     | Expired or damaged  | Redose when error is discovered |
|                                 | Less than full dose | Redose when error is discovered |
|                                 | More than full dose | None                            |
| VAR, ZOS, MMR, MMRV, YFV, MPSV4 | Given IM            | None                            |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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### Administration Errors

| Vaccine | Error                 | Corrective Action |
|---------|-----------------------|-------------------|
| HepB    | Given SQ              |                   |
| MCV4    | Given SQ              |                   |
| DTaP    | Adolescent or adult   |                   |
| Tdap    | Infant primary series |                   |
|         | Dose 4 or 5           |                   |
|         | Child 7-9 yr          |                   |
| PPSV23  | Child <2 yr           |                   |
| VAR     | Adult ≥60 yr          |                   |
| ZOS     | Child                 |                   |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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### Administration Errors

| Vaccine | Error                 | Corrective Action                   |
|---------|-----------------------|-------------------------------------|
| HepB    | Given SQ              | Give IM when error is discovered    |
| MCV4    | Given SQ              | None                                |
| DTaP    | Adolescent or adult   | None                                |
| Tdap    | Infant primary series | Give DTaP when error is discovered  |
|         | Dose 4 or 5           | None                                |
|         | Child 7-9 yr          | None                                |
| PPSV23  | Child <2 yr           | Give PCV13 when error is discovered |
| VAR     | Adult ≥60 yr          | Give ZOS same day or 4 wk later     |
| ZOS     | Child                 | None                                |

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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### ISMP National Vaccine Error Reporting Program



Please consider the following items when completing this online reporting form:

- Answer the questions as best you can.
- Tell us the story of what went wrong, any causes or contributing factors, how the event was discovered or intercepted, and the outcome of the patient(s) involved.
- Share your recommendations for error prevention.
- Provide any associated materials (e.g., product photographs, containers, labels, de-identified prescription order scans) that help support the information being submitted.

ISMP guarantees confidentiality of information received. ISMP is a federally certified patient safety organization (PSO), providing legal protection and confidentiality for submitted patient safety data and error reports. [Click here](#) to learn more about legal protection of patient safety information submitted to ISMP.

The report information will be forwarded, in confidence, to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). When applicable, the report information will be forwarded to product vendors to inform them about vaccine labeling, packaging, and nomenclature issues that may foster errors by their design. Your name and contact information will not be shared unless you grant permission.

If you are reporting an unpreventable adverse reaction to a vaccine product, please visit VAERS (<http://vaers.hhs.gov>).

Please do NOT submit any provider or patient identifiable information when submitting reports to ISMP.

Institute for Safe Medication Practices. <http://verp.ismp.org>

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**Other Pearls—Serology**

- Pre-vaccination
  - Adults without personal history of chickenpox
  - Consider in internationally adopted children
- Post-vaccination
  - HepB: high-risk health care workers; dialysis patients; persons with HIV infection
  - RAB: pre-exposure prophylaxis for laboratory workers
  - Some cases of invalid dosing

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Other Pearls**

- Physical examination not required for vaccination
- Gloves not routinely needed
- Do not change needles after withdrawing from vial
- Swipe rubber stopper with alcohol
- Do not aspirate back on the syringe
- Separate injections in the same area by  $\geq 1$  inch
- Do not prefill syringes (exception: mass influenza immunization campaigns where only 1 vaccine type is being used)
- Do not use partial or fractional doses of vaccine

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Contraindications**

- Increases likelihood of a serious adverse event
- Vaccine should not be given
- Permanent contraindications for all vaccines: severe allergy to vaccine or component

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Precautions**

- Might increase risk of a serious adverse event
- Could compromise immunogenicity
- Could be mistaken for a vaccine reaction
- Default position: defer vaccination
  - Risk of deferral: susceptibility to disease
  - Risk of vaccination: largely theoretical
- Considerations: epidemiology of disease, patient's circumstances, missed opportunities

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Notable Contraindications**

- DTaP
  - Encephalopathy within 7 days of pertussis-containing vaccine
  - Progressive neurological disorder (until stabilized)
- Severe allergy to vaccine or components
  - Baker's yeast: HepB, HPV
  - Eggs: LAIV, IIV, YFV
  - Gelatin or neomycin: MMR, VAR

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Notable Contraindications**

- Pregnancy: LAIV, MMR, smallpox, VAR, ZOS
- Immune impairment
  - Any: smallpox, Ty21a, YFV
  - Severe : LAIV, MMR, VAR, ZOS
- Aspirin or salicylate therapy: LAIV
- Untreated active TB: MMR, VAR, ZOS

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015



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**Screening Questions**

- Is the patient sick today?
- Does the patient have severe allergies to medicines, foods, drugs, or vaccines?
- Has the patient had serious reactions to previous vaccinations?
- Has the patient had a seizure or brain or neurological problems?
- Does the patient have asthma or another chronic medical condition?

IAC. <http://www.immunize.org/catg.d/p4060.pdf> (accessed 11/06/12)



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**Screening Questions**

- Has a health care provider diagnosed wheezing or asthma in the past year (children 2-4 years of age)?
- Does the patient have cancer, leukemia, a blood disorder, HIV infection, AIDS, tuberculosis, or any problem with the immune system?
- In the last 3 months, has the patient received any treatments that might weaken his or her immune system, such as steroids, cancer chemotherapy, or radiation?

IAC. <http://www.immunize.org/catg.d/p4060.pdf> (accessed 11/06/12)



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**Screening Questions**

- Are there any family members who have problems with their immune system?
- Has the patient received blood transfusions or immune globulin in the past year?
- Is the patient pregnant or is there a chance she could become pregnant in the next 3 months?
- Has the patient received any other vaccines in the last 4 weeks?

IAC. <http://www.immunize.org/catg.d/p4060.pdf> (accessed 11/06/12)



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**Erroneous Contraindications**

- Mild acute illness with or without fever
- Mild respiratory illness (including OM)
- Mild gastroenteritis
- Antibiotic or antiviral therapy
- Low-grade fever, redness, pain, swelling after previous dose
- Prematurity (delay HepB in infants <2000 gm whose mothers are HBsAg-negative)
- Pregnant, unimmunized, or immunosuppressed household contact (except pre-event smallpox)

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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**Erroneous Contraindications**

- Breastfeeding (except pre-event smallpox)
- Convalescent phase of illness
- Exposure to an infectious disease
- Positive TST without active disease
- Simultaneous TST
- Allergy to penicillin, duck meat or feathers, or environmental allergens
- Fainting after previous dose
- Seizures, SIDS, allergies, vaccine reactions in family members

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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**Erroneous Contraindications**

- Malnutrition
- Stable neurological condition (eg, CP, seizures, developmental delay)
- Allergy shots
- Extensive limb swelling after DTP, DTaP, or Td that is not an Arthus-type reaction
- Brachial neuritis after previous dose of tetanus toxoid-containing vaccine
- Autoimmune disease
- History of the vaccine-preventable disease

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015




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**Precaution Scenarios**

- 2-month-old experiences 4 hours of inconsolable crying after DTaP
- Should he get the second dose at 4 months of age?
- Analysis
  - Risk of recurrence: low
  - Consequences of recurrence: temporary
  - Risk of disease: high

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015

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**Precaution Scenarios**

- 6-month-old with moderate febrile illness
- Should he get the 6-month shots?
- Analysis
  - Risk of vaccine reaction: low
  - Consequences of reaction: attribution
  - Risk of disease: high
  - Risk of missed opportunity: high

Marshall. The Vaccine Handbook. PCI Books, Inc.; 2015

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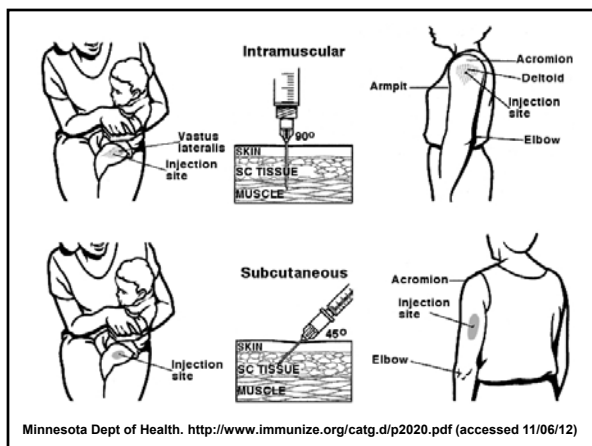
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