

Implementing New Vaccines to Protect Adolescents

Public Health Law Conference
Atlanta, GA
June 14, 2006

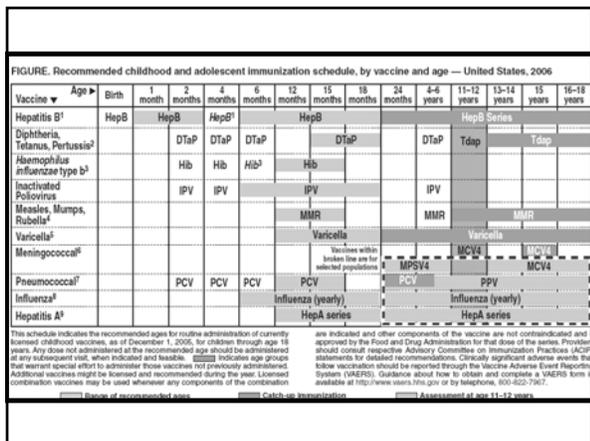
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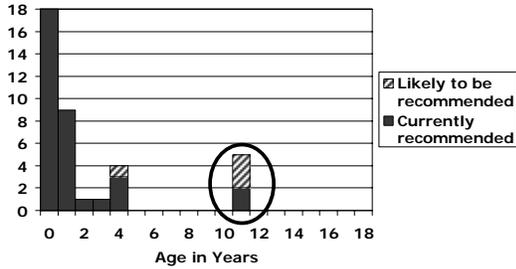


Questions

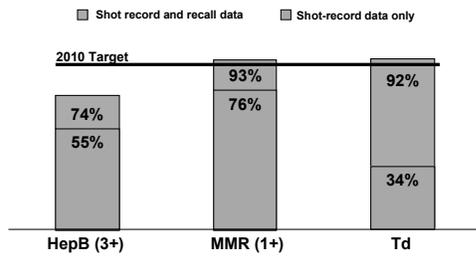
- Why an adolescent platform?
- What are barriers to vaccinating adolescents?
- Impact and potential role of school laws?



Vaccinations From Birth to 18 Years of Age: 2006



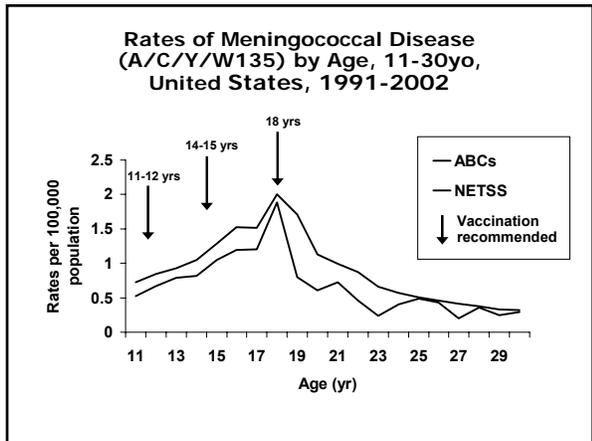
14-27. Universally Recommended Vaccination Coverage Among Children 13-15 Years, 2001



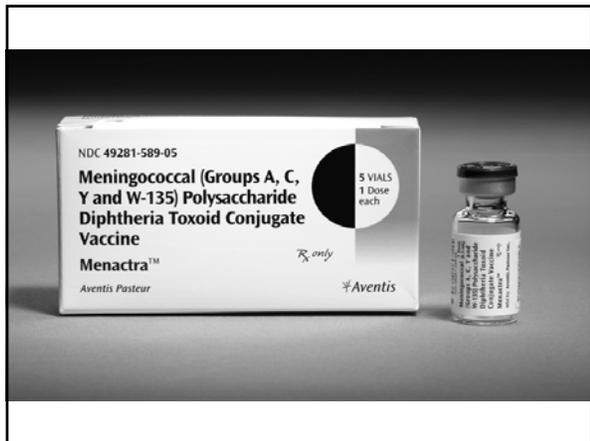
Source: National Health Interview Survey (NHIS), CDC, NCHS.

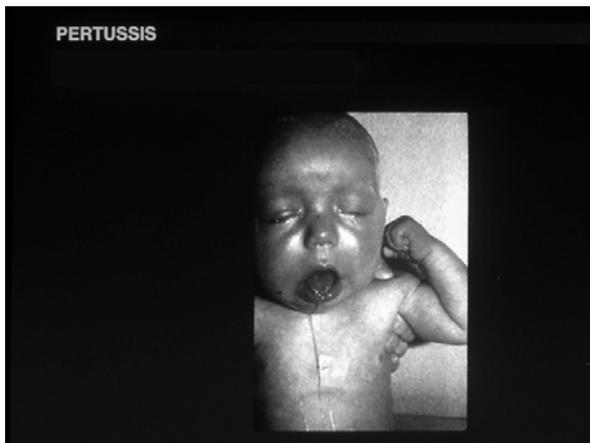
Three new vaccines for adolescents in less than two years

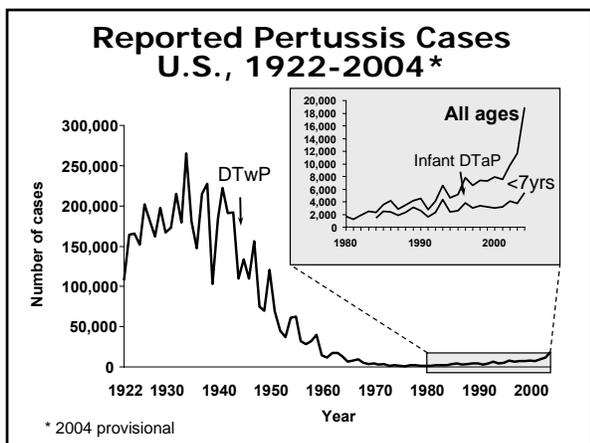








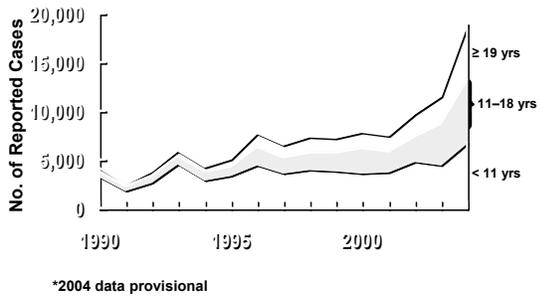




The Pertussis Paradox

- In 2004, pertussis vaccination levels among children 19-35 months of age were the highest ever recorded
- In 2004, the largest number of pertussis cases (25,827) was reported since 1959

Reported Pertussis by Age, United States - 1980-2004*



The New War on Pertussis

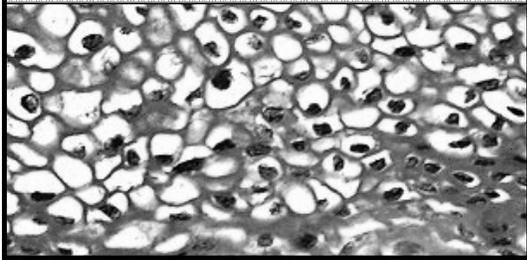
- Phase I – vaccination of adolescents
- Phase II – vaccination of adults

Adolescent Pertussis Vaccination Objectives

- **Primary**
 - Protect adolescents

- **Secondary**
 - Reduce *B. pertussis* reservoir
 - Potentially reduce incidence of pertussis in other age groups

Oncogenic human papillomavirus (HPV) and cervical cancer



HPV Infection

- HPV is very a prevalent sexually transmitted infection.
- First genital HPV infection is usually acquired around the time of sexual debut. Infection with multiple types not uncommon.
- Infection is usually transient and not associated with symptoms.
- Persistent infection with high risk types is the most important risk factor for cervical cancer precursors and cervical cancer
- HPV 16 more likely to persist than other types

Clinical Impact of HPV Infection in the US

Annual estimates

- Abnormal Pap tests - 2.8 million
- Cervical cancer - 10,520 cases; 3900 deaths
- Genital warts - 0.5 to 1 million

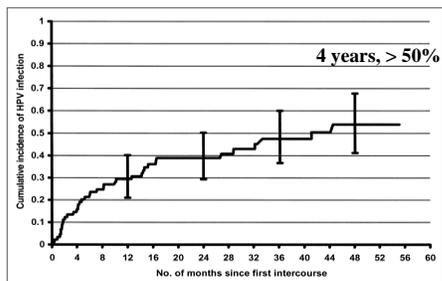
Chesson: Perspectives on sexual and reproductive health, 2004:36
American Cancer Society

HPV Prevalence Population Estimates, U.S.

- 20 million people are infected
- 15% of persons age 15-49 currently infected
- 6.2 million new infections each year
- > 50% of sexually active men & women acquire genital HPV infection

Cates, STD 1999; Weinstock, Perspectives on Sexual and Reproductive Health 2004; Koutsky Am J Med 1997

Cumulative Incidence of HPV Infection among Female College Students, by Time Since Sexual Debut



Winer et al. Am J Epidemiol 2003;157

HPV Vaccine Phase II Trials Prevention of Persistent Infection

Manufacturer Vaccine	Vaccine		Placebo		VE (95% CI)
	N	cases	N	cases	
Merck HPV 16	768	0	765	41	100% (90,100)
GSK HPV 16/18	366	0	355	16	100% (77,100)

Koutsky et al. NEJM 2002, 347
Harper et al. Lancet 2004, 364

Efficacy - Phase III Trial Quadrivalent HPV Vaccine HPV 16/18 Related Cervical Cancer Precursors

Endpoint	Vaccine (N=5301)	Placebo (N=5258)	Efficacy	(97.5% CI)
HPV 16/18 related CIN 2/3	0	21	100%	(76,100)

Mean 17 Months of Follow-Up in Per Protocol Population
Merck, unpublished data, ACIP presentation, February 2006

Rationale: Routine Vaccination of Females at 11-12 Years

- **Routine**
 - Prevalent infection, targeting 'high risk' groups not possible
- **11-12 years**
 - More females vaccinated prior to sexual debut than at older ages
 - Implementation advantages; consistent with young adolescent health care visit
 - Although duration of protection not known, no evidence of waning immunity; ongoing studies will monitor duration

Selected Steps From Recommendation to Implementation

- Communicate with programs, providers, and public
- Secure federal contract for vaccine
- States
 - Develop vaccine financing and management plans
 - Educate vaccine providers
- Implement vaccination coverage monitoring system to evaluate programs and vaccine

States' School Immunization Laws and Regulations

They certainly are effective, but



Measles in 6 States Strictly Enforcing School Laws vs. Other States*

	Measles incidence †		
	1975-76	1977	1978 ‡
6 states	47.0	40.6	2.7
Other states	50.4	90.3	35.2

* MMWR 1978; 27:303-4
 † per 100,000 < 18 years
 ‡ 1st 31 weeks

Table 6. Differences in state immunization laws and enforcement in areas with high and low incidence of measles ^a

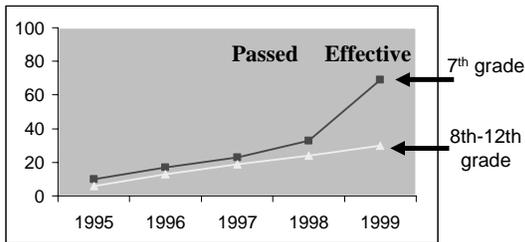
	Low	High
Number of areas	13	10
Statewide laws	12 (92%)	9 (90%)
Mean duration of existence	6.4 yr	6.8 yr
Covers school entry	12 (92%)	9 (90%)
Covers all grades ^b	6 (46%)	0 (0%)
School exclusion ^b enforced	10 (77%)	0 (0%)

^aAm J Public Health 1981; 71: 270-4.

^bSignificant difference $p < 0.025$.

From: Orenstein WA and Hinman AR. Vaccine 1999; 17(S3):S19-S24.

Hepatitis B Coverage Following 7th Grade School Entry Requirement, San Diego*



*Using parent-held vaccination record

Adapted from Averhoff F, Linton L, Paddecord KM, Edwards C, Wang W, Fishbein D. A middle school immunization law rapidly and substantially increases immunization coverage among adolescents. Am J Public Health 2004 94:978-84

Effect of State Middle School Vaccination Requirements on Coverage in 9th Grade, Kansas City (Missouri and Kansas), 2002

	Kansas City		P
	Missouri	Kansas	
MMR #2*	81%	97%	NS
Tetanus†	48%	27%	NS
Hepatitis B‡	73%	19%	<0.01

* Both states have K entry requirements (KS effective 1992; MO effective 1994)

† Both states have requirements for 10 years after the last dose (KS effective 1991; MO effective 1993)

‡ Only Missouri has requirement (7th grade, effective 1999)

Adapted from Wilson TR, Fishbein DB, Ellis PA, Edlavitch SA. J Adolescent Health, 2005;37:511-16.

School Laws Utility

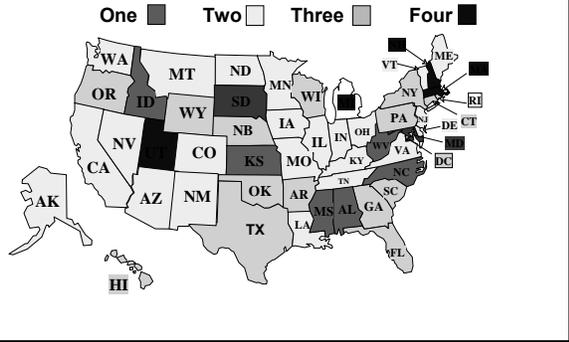
- Powerful incentive
- Useful as last resort for stragglers
- Used to prevent school outbreaks
- Concerns
 - Opening school laws has some risk
 - Financial implications
 - Non-universal vaccines

Conclusions

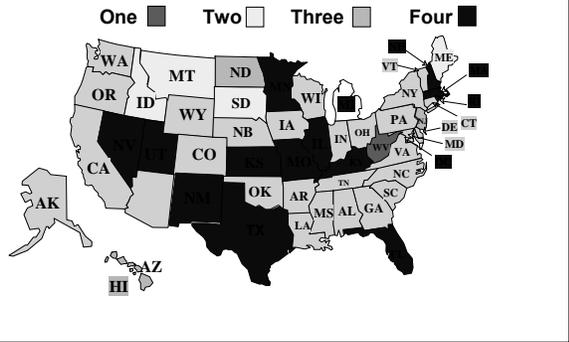
- Child and adolescent vaccination is a great investment for society
- Adolescent vaccination is a leading edge of immunization programs, but implementation of adolescent vaccines will be challenging
- School vaccination requirements are effective, but should be used cautiously

THANK YOU

Number of vaccines recommended for 11-12 year olds required in 5th, 6th, or 7th grades

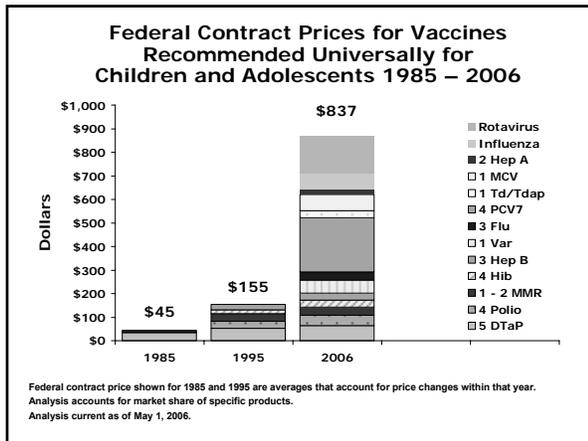


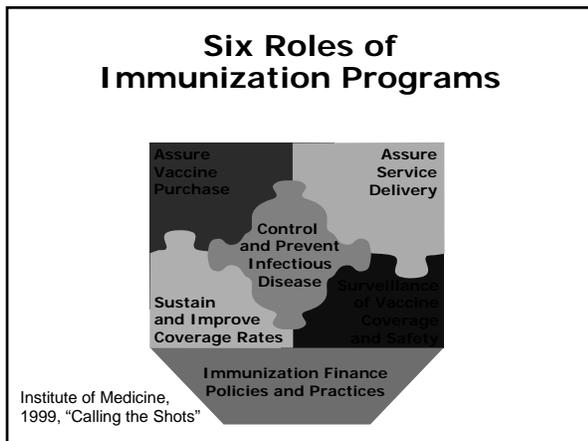
Number of vaccines recommended for 11-12 year olds required in any grades



Stresses and Challenges

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION





Assuring Service Delivery

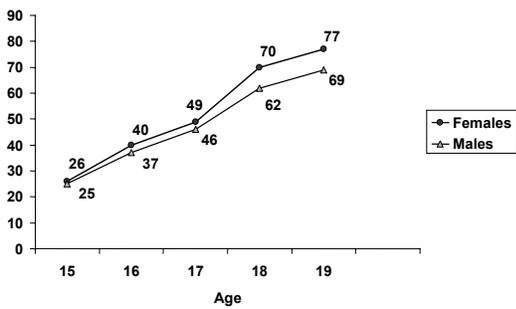
- **CDC works with / through state and urban area immunization programs**
 - Section 317 and VFC cover the U.S.
 - Operations funding provided

- **States work through their VFC providers, public and private**

How Does Public Health Reach Children

- **VFC program has 45,000 provider sites**
 - 75% of sites are private providers
 - 25% are public sector sites
- **Collectively, VFC providers vaccinate 90% of children**
 - VFC vaccine for VFC-eligible children
 - Private purchase vaccine for other children

Percentage of Adolescents Who Have Had Vaginal Sex, by Gender and Age National Survey of Family Growth (NSFG), 2002



Mosher et al., 2005; Vital and Health Statistics: No. 362

HPV Vaccine and Cervical Cancer Screening

- **Even with 100% coverage, current generation HPV vaccines will not eliminate need for cervical cancer screening in the US**
- **Types other than HPV 16 and 18 cause ~30% of cervical cancers**
