HPV Vaccine:

A Case Study of Initial Success and Future Challenges

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CENTERS FOR DISEASE CONTROL AND PREVENTION

Outline

- HPV, Cervical Cancer, Vaccine Background
- Keys aspects of implementation to date
- Current and future challenges
  - Addressing health disparities!!!

Background

- HPV the most common STD
  - 26.8% prevalence among US females aged 14-59 years
- HPV and Cervical Cancer
  - 70% of all cervical cancers caused by HPV types16 and 18
- Prophylactic HPV vaccine (Gardasil)
  - Highly efficacious against types 6,11,16,18
  - FDA approved in June 2006
  - 3 doses over 6 month period
  - $360 cost for series

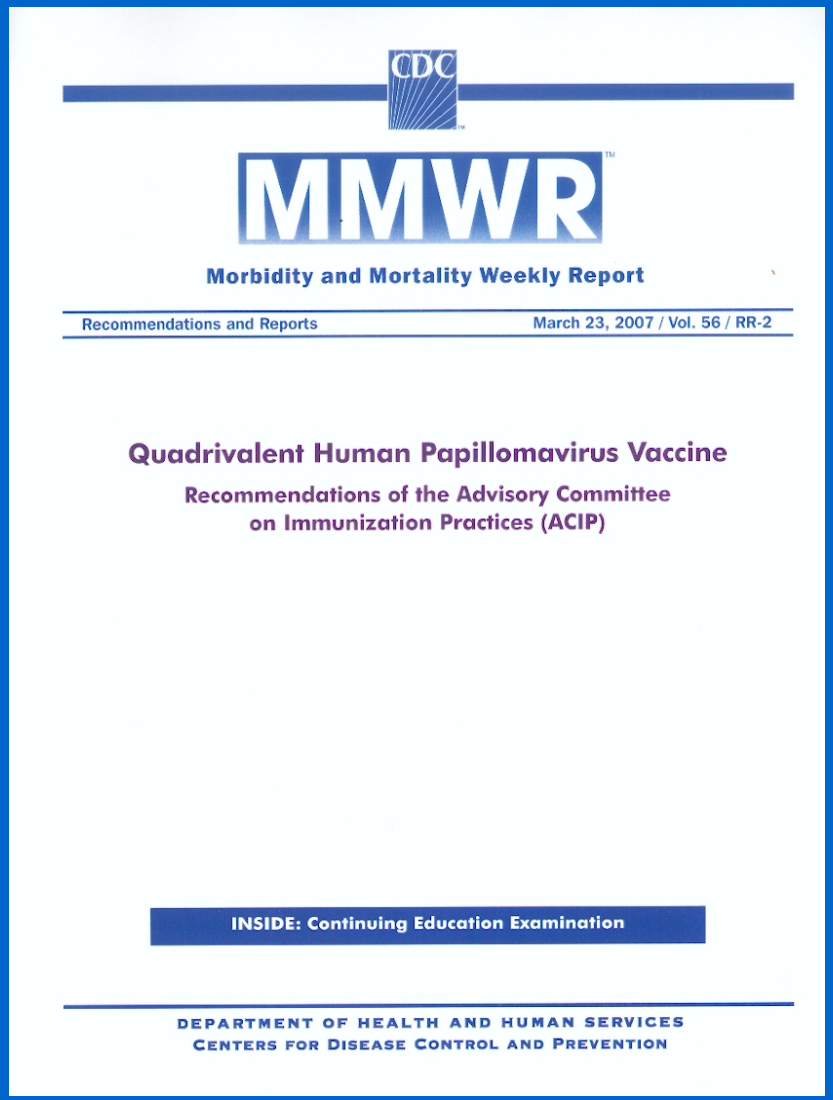
Dunne et al., 2007. *JAMA* 297(8): 813;
Bosch et al., 2003. *J Natl Cancer Inst Monogr* 31: 3; Koutsky et al.,2002. *NEJM* 347: 1645;
www.fda.gov/cber/label/HPV060806LB.pdf;

Keys Aspects of Implementation to Date

- ACIP Recommendations
- VFC Financing
- Delivery
- Public Awareness and Acceptance

ACIP Recommendations

- 15-member federal advisory committee (CDC coordinated)
- Liaisons from major medical associations and government agencies
- Purpose:
  - Develops and publishes recommendations for vaccine use
  - authority to add vaccines to the Vaccine for Children (VFC) program



Recommendations for Quadrivalent HPV Vaccine

Routine vaccination
Females age 11-12 years

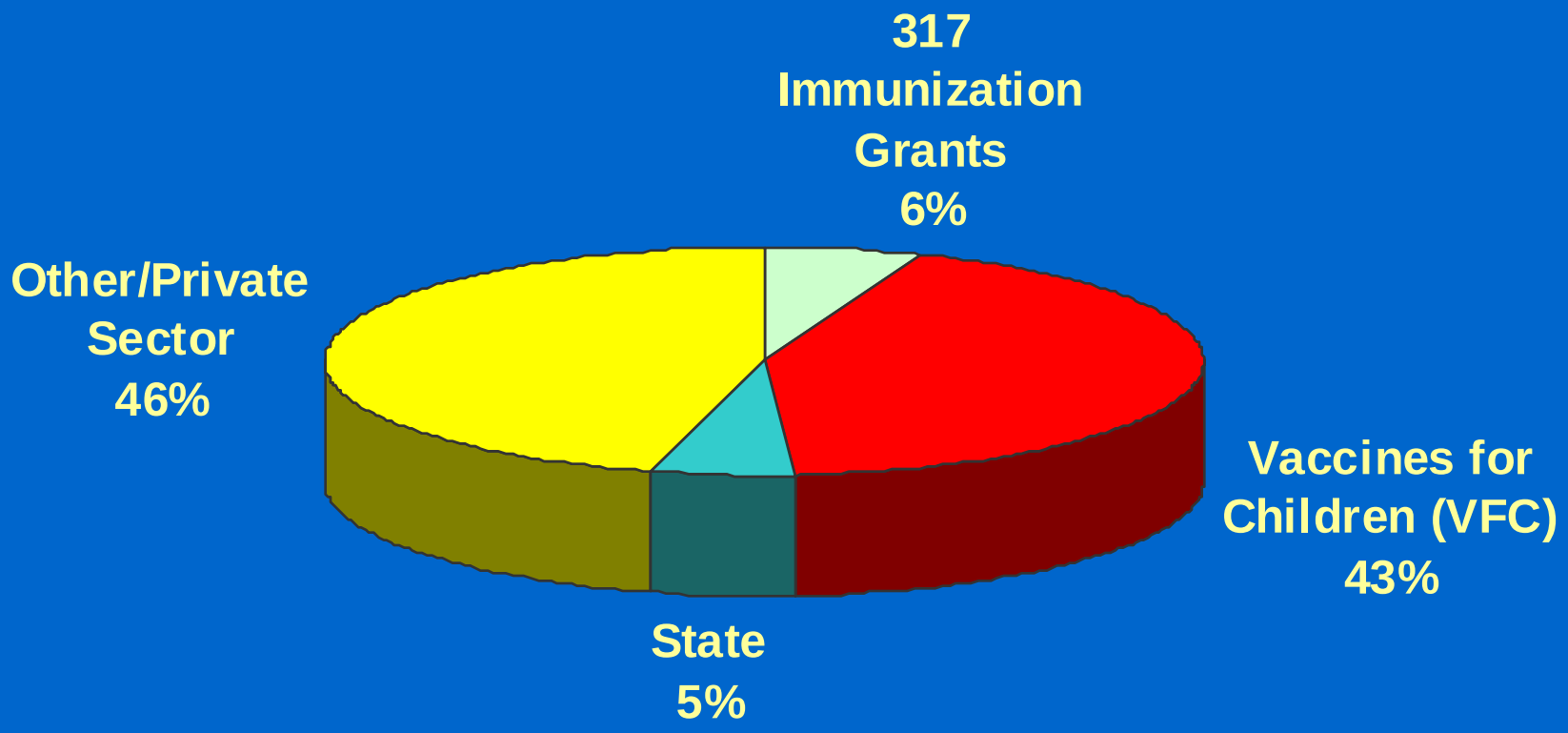
Catch-up
Females age 13-26 years

VFC Financing

- Provides free vaccine to eligible children <19 yrs
- ACIP vote determines funding
- Federal government contracts with manufacturer
- Government supplies vaccine to VFC enrolled providers
- Limitations of VFC
  - Coverage restricted
  - Cost of stocking vaccine

Childhood Vaccine Doses Distributed by Funding Source

Calendar Year 2005



Source: Vaccine manufacturers Biologics Surveillance Data 2005

Note: Does not include influenza vaccine

Delivery

- ~7.5 M doses distributed through June 2007
- By April 2007 – all states purchased vaccine for public sector
- Vaccine is primarily being delivered in traditional primary care settings; alternative settings are being explored

Successful States' Experiences

In New Hampshire, Soft Sell Eases Vaccine Fears

CONCORD, N.H. — A vaccine for a sexually transmitted virus that causes cervical cancer may be creating controversy across the country, but in New Hampshire physicians say so many people want it that they cannot satisfy the demand.

New York Times, May 2007

- NH estimated 25% uptake in first year
- SD one-year initiative to vaccinate all 11-18 year old

Markowitz, ISSTDR July 2007, Seattle WA

Public Awareness/Acceptance

Pre-licensure data

- HPV awareness and knowledge low
- Acceptability generally high among all groups (providers, parents, adolescents)
- Education may increase acceptability
  - Davis et al., 2004 showed increased acceptability post education, especially among “undecided”
  - Dempsey et al., 2006 showed no increased acceptability post education

California Statewide Survey of parents

Vaccine acceptance group	%
Likely to vaccinate by age 13	74.5
Likely to vaccinate by age 16 but not 13	5.5
Unlikely to vaccinate by age 13 or 16	18.3

J Adolescent Health 2007;40:108

Media coverage of HPV Vx

- Content analyses of online news stories (n=250)
  - Between June-Sept. 2006
  - Coverage more likely to be neutral (52.4%) or positive (33.2%) than negative (14.4%)
  - “Concerns” over cost and increased sexual risk often cited (but varied pre- and post-ACIP recommendations)

Habel M et al. unpublished data

Challenges for Development of HPV Vaccine Programs

- Adolescent health care access
- Consent
- Safety concerns/low perceived risk
- Multiple vaccines (?)
- Will those most at risk get the HPV vaccine?

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Racial/Ethnic disparities in HPV rates women age 14-59 (n=1921)

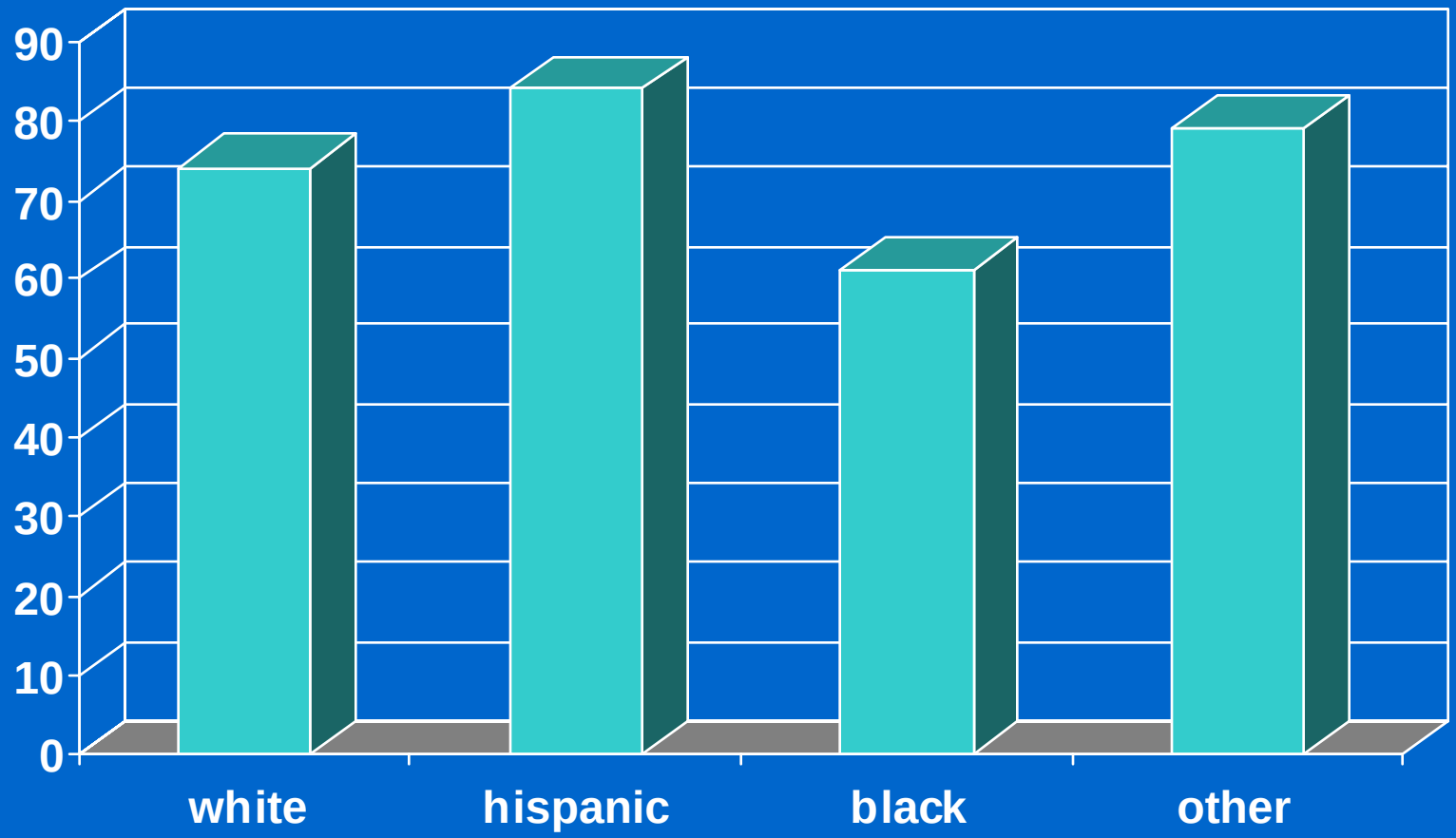
Race/Ethnicity	Prevalence, %
Non-Hispanic White	24.2
Non-Hispanic Black	39.2
Mexican-American	24.3

Dunne et al., 2007. *JAMA* 297(8): 813

HPV Vaccine Acceptability among underserved populations

- Pre-licensure data showed intent to vaccinate not related to race or ethnicity
- Methodological issues:
  - Lack of published research focusing specifically on underserved populations
  - Clinic setting
  - Hypothetical and different socio-political context

California Statewide Survey of Parents
% likely to vaccinate daughter before age 13



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Pediatrician Intent to Vaccinate 10-12 Year Old Females by Clinic Clientele

% Black/African-American patients	Will likely recommend	Will not likely recommend/ not sure
0-24%	45%	55%
25%-100%	58%	42%

P<.01

Daley et al., unpublished data

Access/Utilization of Immunization Health Care

- Lower rates for African Americans, Hispanics across all life stages
- NIS (2000) data on complete immunization series for children:
  - Whites (79%)
  - Hispanic (73%)
  - African American (71%)

MMWR, 2001; 50: p. 637

Barriers to immunization

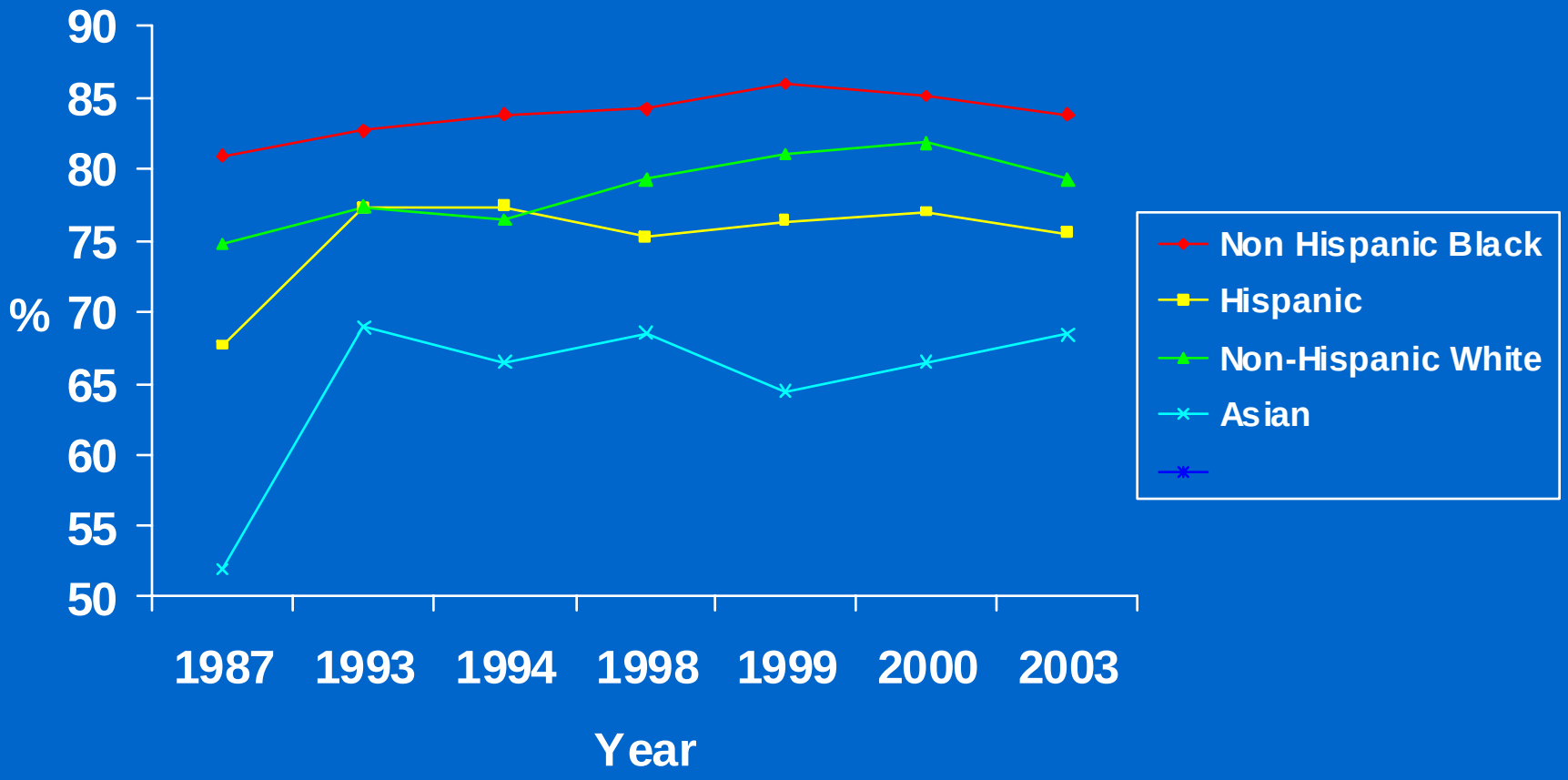
- Structural
  - Lack of insurance
  - No usual primary care setting
  - Other access issues (work, transportation)
- Individual
  - Language
  - Knowledge
  - Distrust
  - Dissatisfaction

HPV Vx Acceptability among African American Women and Latina Immigrants

- Differences among minority women
  - African American women
    - Skepticism re: effectiveness
    - Concerns about side effects
    - Motivated by education, affordability, knowing others who were vaccinated
  - Latina women
    - Motivated by multiple sources
      - Doctors
      - Television
      - Churches
      - Other women

Scarinci et al., 2007 *J of Women's Health* 16(8): 1224

Rates of Pap Test in past 3 years, women 18+: NHIS 2005



Percentage of women reporting Pap Test in last year: NSFG (1995)

Race/Ethnicity

Hispanic	52.3%
Non-Hispanic White	63.3%
Non-Hispanic Black	67.6%

Hewitt et al., 2002: *AJPH*; 92(4):666

Pap Test Rates among U.S. women: NHIS (2000)

- Lower Pap Test rates associated with:
  - Lack of usual source of care
  - Low family income
  - Low education attainment
  - Being unmarried
  - Being age 65 and older

Hewitt et al., 2004: *Prev Med*, 39: 270.

Access/Utilization of Reproductive Health Care

- Varies by race/ethnicity:
  - White women more likely to use private provider
  - African American women more likely to use public family planning or hospital-based clinic
  - Hispanic women more likely to have no usual source of reproductive health care

Conclusions

- Great deal of interest/attention on HPV vaccine(s)
- Some success in HPV Vx uptake
- Addressing underserved populations:
  - Monitor uptake and impact of HPV Vx
  - Develop appropriate strategies to address concerns
  - Address access/utilization issues
    - improving access and utilization of services in other settings where immunizations could be provided (reproductive health care??)