Varicella Vaccination Program

Progress and Challenges

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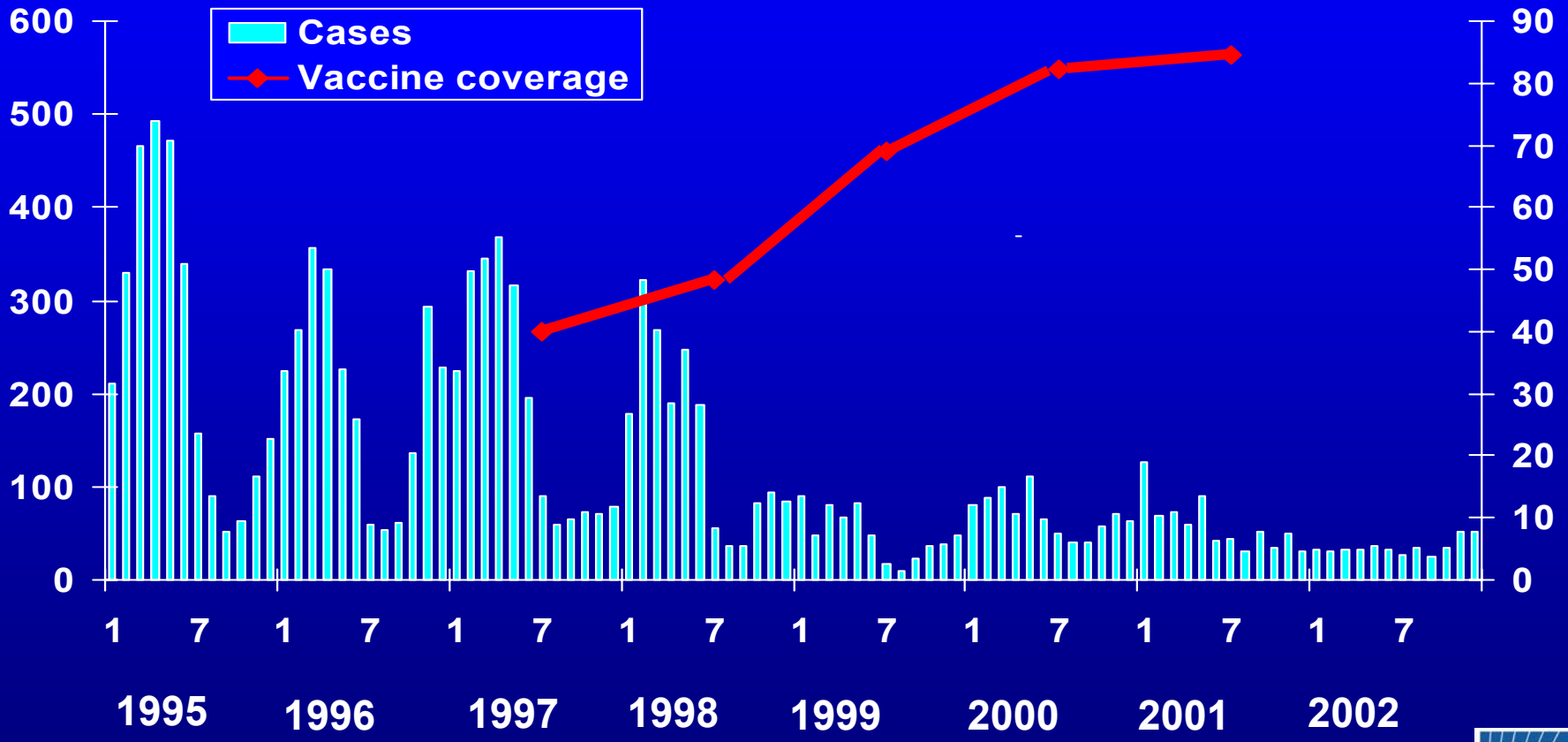
National Immunization Conference, Chicago, March 18, 2003

CDC Immunization

Progress

- Vaccine impact on mortality and morbidity
  - Decline in varicella cases
  - Decline in varicella hospitalizations
  - Decline in varicella deaths
- Vaccine
  - Coverage including child care and school requirements
  - Safety
  - Effectiveness

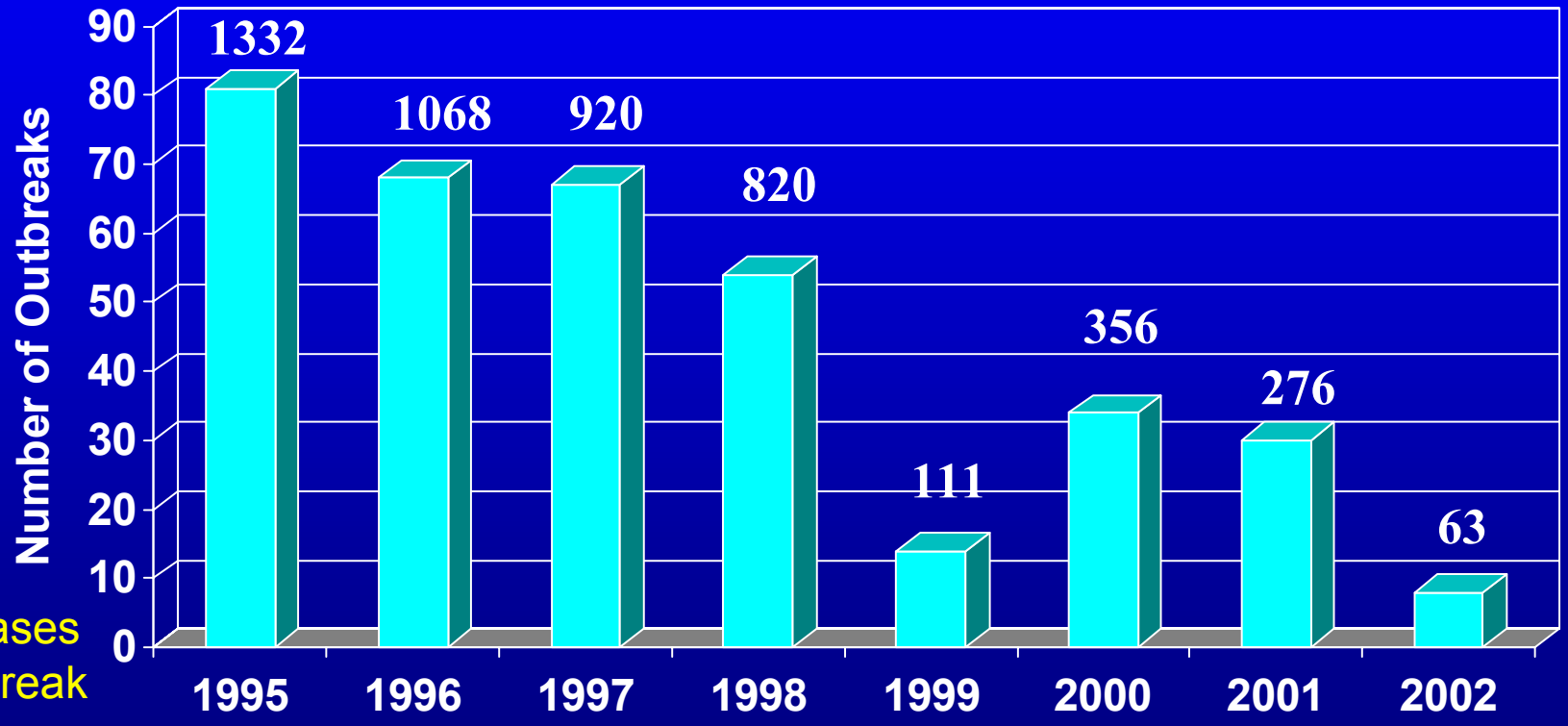
Monthly Varicella Cases and Vaccine Coverage
Antelope Valley, CA, 1995 – 2002



Reduction (%) of Varicella Cases by Age
Varicella Active Surveillance Sites, Jan-Sept 1995 to 2002

Age group	Antelope Valley, CA	West Philadelphia
< 1	91	78
1-4	94	87
5-9	78	91
10-14	71	89
15-19	82	77
20+	79	46
Total	89	87

Varicella Outbreaks and Number of Outbreak-related Cases Antelope Valley, CA, 1995-2002



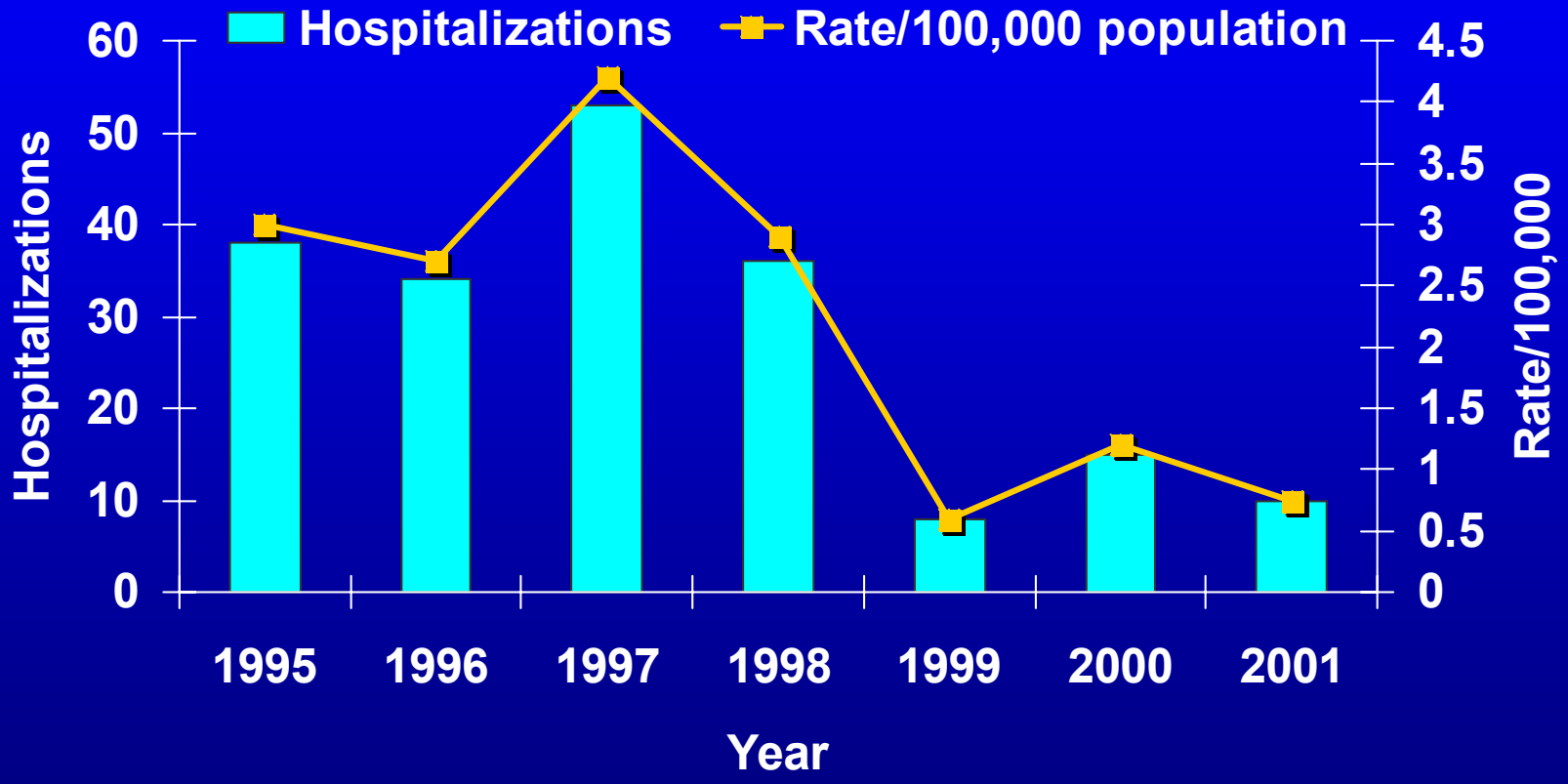
6 cases
utbreak

8 cases
/outbrea

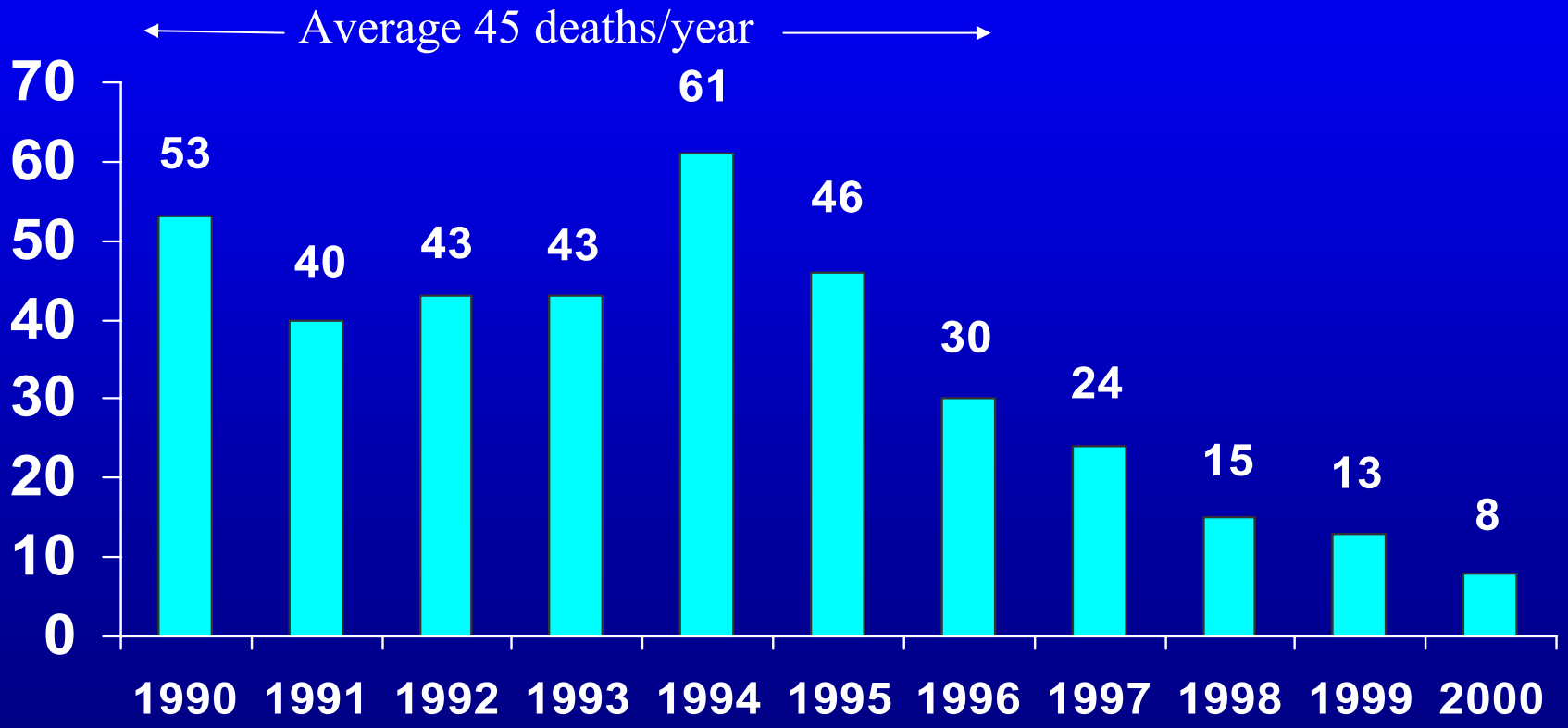
Reduction in Varicella Cases Reported to National Notifiable Disease Surveillance System USA, 4 States, 1993-1995 and 2002

	Reduction in varicella cases in 2002 compared to average cases 1993-95	Vaccine coverage 2001
Texas	85 %	84%
Michigan	84 %	77%
West Virginia	72 %	82%
Illinois	65%	57%

Varicella Hospitalizations, 1995-2001
3 Active Surveillance Areas



Varicella Deaths among Children and Adolescents < 20 years, U.S., 1990-2000

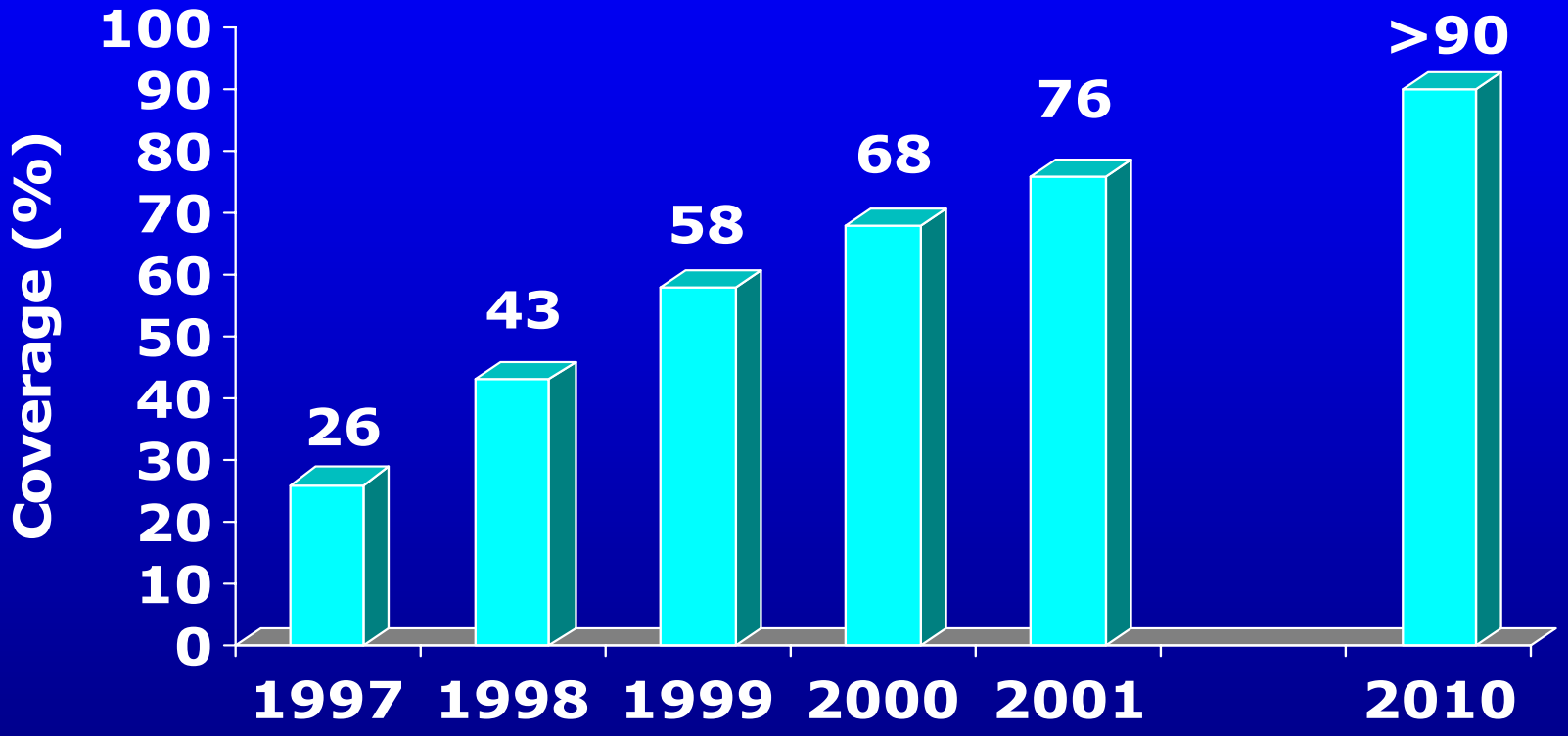


Varicella Deaths Reported in 2002

- 9 year old healthy, unvaccinated child
  - Invasive Group A *Streptococcus* sepsis
  - Exposed in after-school child care and/or school setting to unvaccinated children
- 37 year old healthy, unvaccinated male
  - Pneumonia and other complications
  - Exposure from unvaccinated 9 year old daughter

Vaccine Coverage, Safety and Effectiveness

Varicella Vaccine Coverage, U.S. Children 19-35 Months National Immunization Survey



State range
53% - 90%

CDC Immunization

State Requirements for Varicella Vaccine for Child Care or School Entry

By January 2003

- 35 states had implemented child care or school requirements
  - 30 states – childcare and school
  - 3 states – childcare only
  - 2 states – school only

Varicella Vaccine Safety*

- Serious adverse events very rare
  - 2.9 reported per 100,000 doses
- Deaths: most have definite or plausible other explanations or insufficient information to determine causality
- Herpes zoster in healthy vaccinees but rate < natural disease
- Secondary transmission from healthy vaccinees extremely rare

Vise RP et al JAMA, 2000. Sharrar R et al Vaccine 2000, Black S et al PIDJ 1999

The New England Journal of Medicine

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OUTBREAK OF VARICELLA AT A DAY-CARE CENTER DESPITE VACCINATION

KARIN GALIL, M.D., M.P.H., BRENT LEE, M.D., M.P.H., TARA STRINE, M.P.H., CLAIRE CARRAHER, R.N., ANDREW L. BAUGHMAN, PH.D., M.P.H., MELINDA EATON, D.V.M., JOSE MONTERO, M.D., AND JANE SEWARD, M.B., B.S., M.P.H.

VARICELLA VACCINE — ARE TWO DOSES BETTER THAN ONE?

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Varicella Outbreak in Day Care Center New Hampshire, 2001

- Overall vaccine effectiveness = 44.0% (95% CI 6.9 – 66.4)

- Effectiveness for prevention of moderate or severe disease = 86.0% (95% CI 38.7– 96.8%)

*Galil K et al. N Engl J Med. 2002;347:1909-15

Post-licensure Varicella Vaccine Effectiveness

Study	Vaccine Effectiveness		Study method Setting/Design
	All disease	Mod/severe dz	
Outbreaks N=15	71%-100%	93-100%	Outbreak investigations Child care centers, schools
Galil, NEJM, 2002	44% (-6, 67%)	86%	Child care center
Outbreak MD	59% (-1, 84%)	75%	School
Clements, PIDJ, 1999	83% (67-90%)	100%	CCC prospective cohort
Vazquez, NEJM, 2001	85% (78-90%)	97%	Case control, clinical practice
Seward, (Prel. 2003)	79% (70-85%)	93% (84 -97%)	SAR in households, VASP site

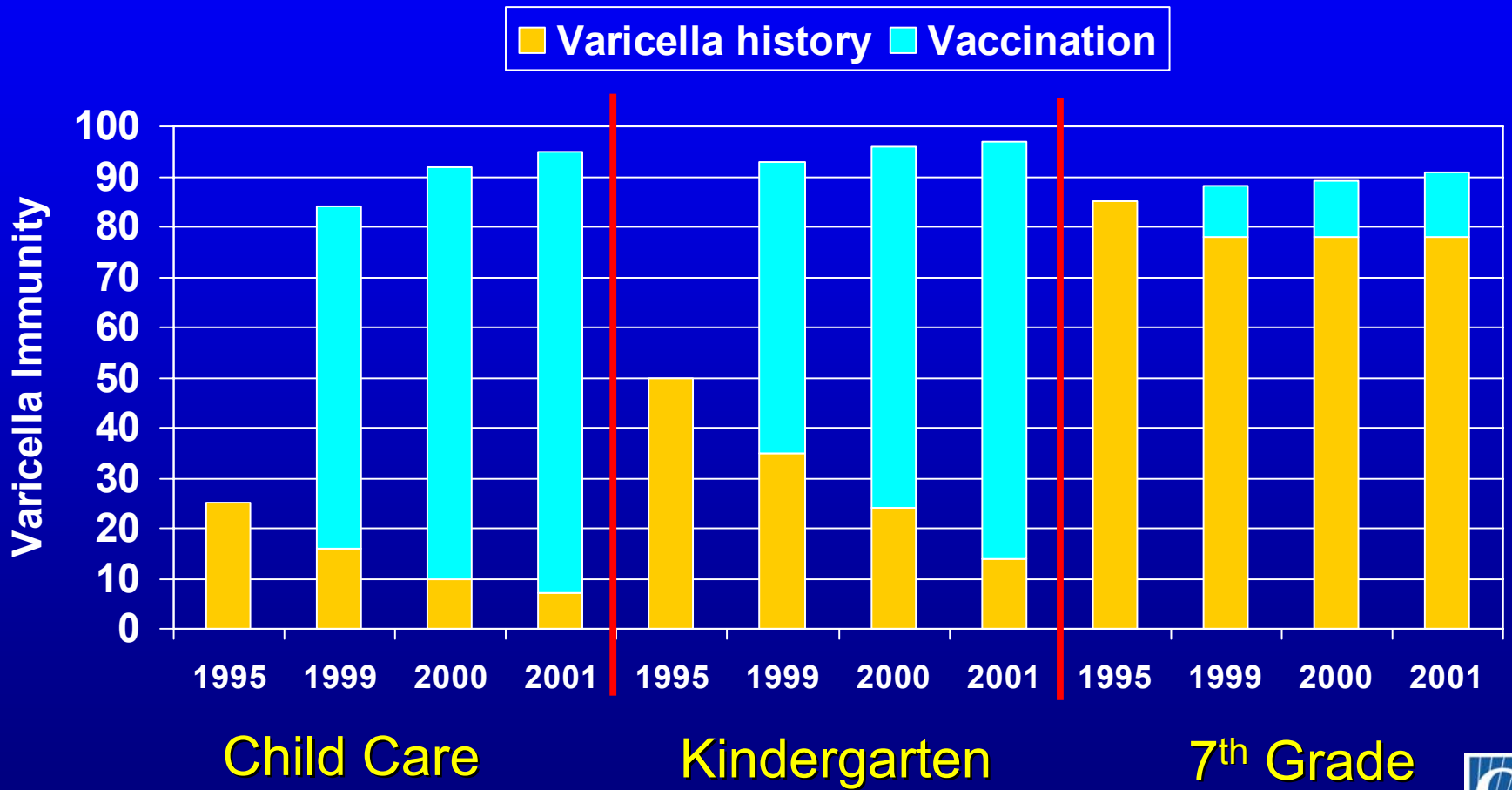
Challenges

- Implementing school requirements especially for older children
- Vaccine effectiveness and risk factors for vaccine failure
- Understanding breakthrough disease
- Predictions for an increase in herpes zoster (modeling)

Importance of School Requirements

- Change in varicella epidemiology
- Decline in exposure
- Potential for increasing proportion of susceptible older children, adolescents and adults

Monitoring Varicella Immunity and Immunization Levels, Massachusetts



Communicating Ballanced Perspective on Vaccine Effectiveness

- One low vaccine effectiveness estimate
- Many normal effectiveness estimates using a variety of study methods
- Excellent protection against moderate and severe disease
- Dramatic disease decline

Risk Factors for Vaccine Failure

- Age (likelihood of exposure)
- Asthma/Reactive airway disease and/or steroids
- Younger age at vaccination
- Longer time since vaccination
- Varicella and MMR vaccine interval < 28 days

Next Steps

- Findings to date do not indicate a need for policy change
- Study phase IV data, vaccinated cohort of 90,000 children
- Independent effects of risk factors

Breakthrough Disease

- Varicella in person vaccinated > 42 days before rash onset
- Milder than natural disease
- Does not appear to increase with time since vaccination
- Transmission occurs in family and outbreak settings
- Continue to study clinical and public health significance

Concerns with Childhood Varicella Vaccination Program

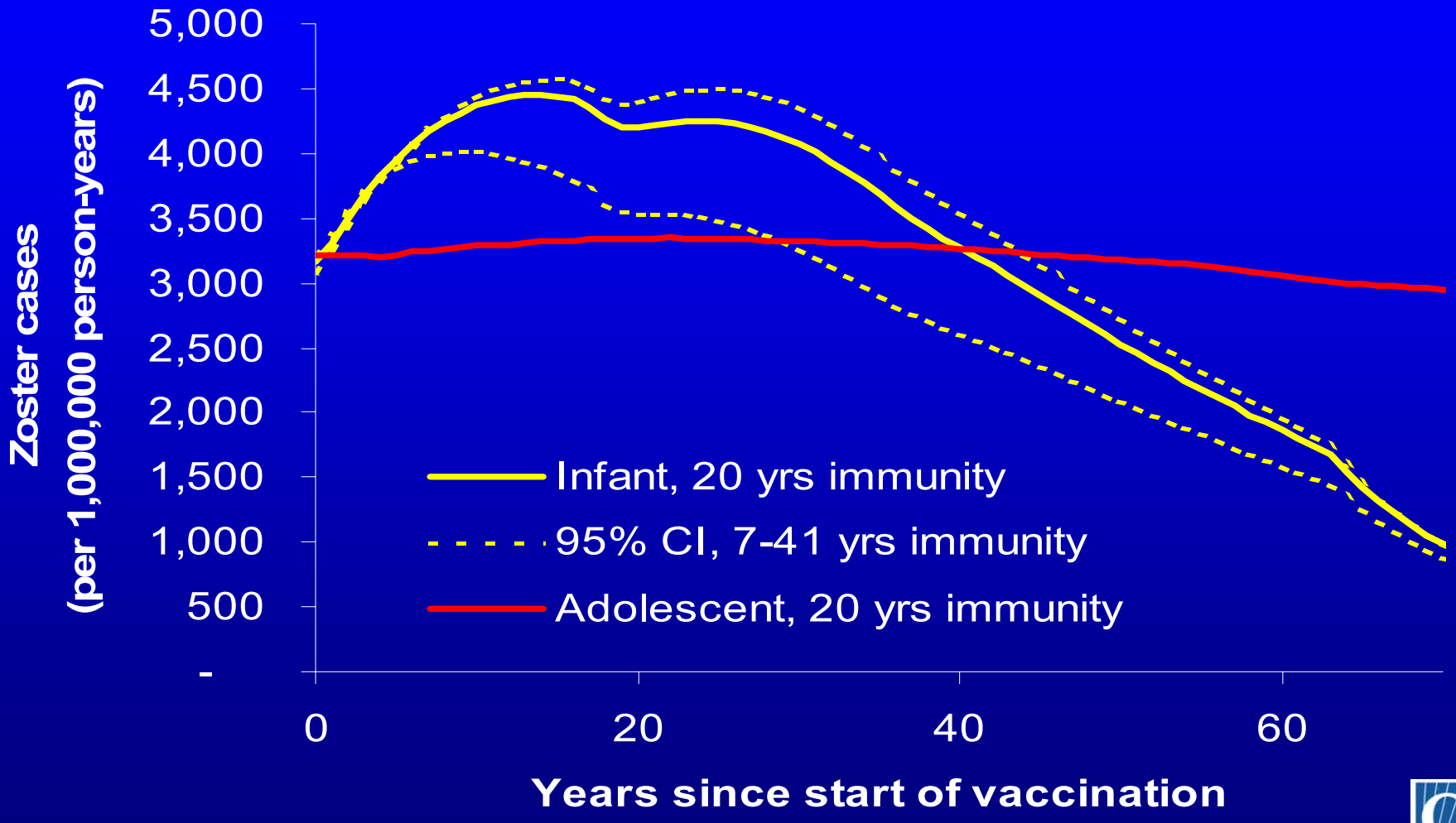
Exposure to VZV virus may boost immune response, preventing or postponing development of zoster

Hope-Simpson, 1965

Varicella and Herpes Zoster

- Does exposure to varicella help maintain immunity and modify risk of herpes zoster?
- Immunity to herpes viruses complex
  - Role of internal boosting?
  - Role of external boosting?
  - Duration of protection from boosts?
- Inactivated varicella vaccine decreased risk of herpes zoster in bone marrow transplant patients
- Adult vaccine trial for prevention/modification of H. zoster

Predicted Impact of Varicella Vaccination on Herpes Zoster



Herpes Zoster Surveillance in the United States

Varicella and Herpes Zoster Disease Trends

Varicella active surveillance sites

- Philadelphia: zoster cases reportable since 1995
- 2 sites: investigations of zoster cases < 20 years

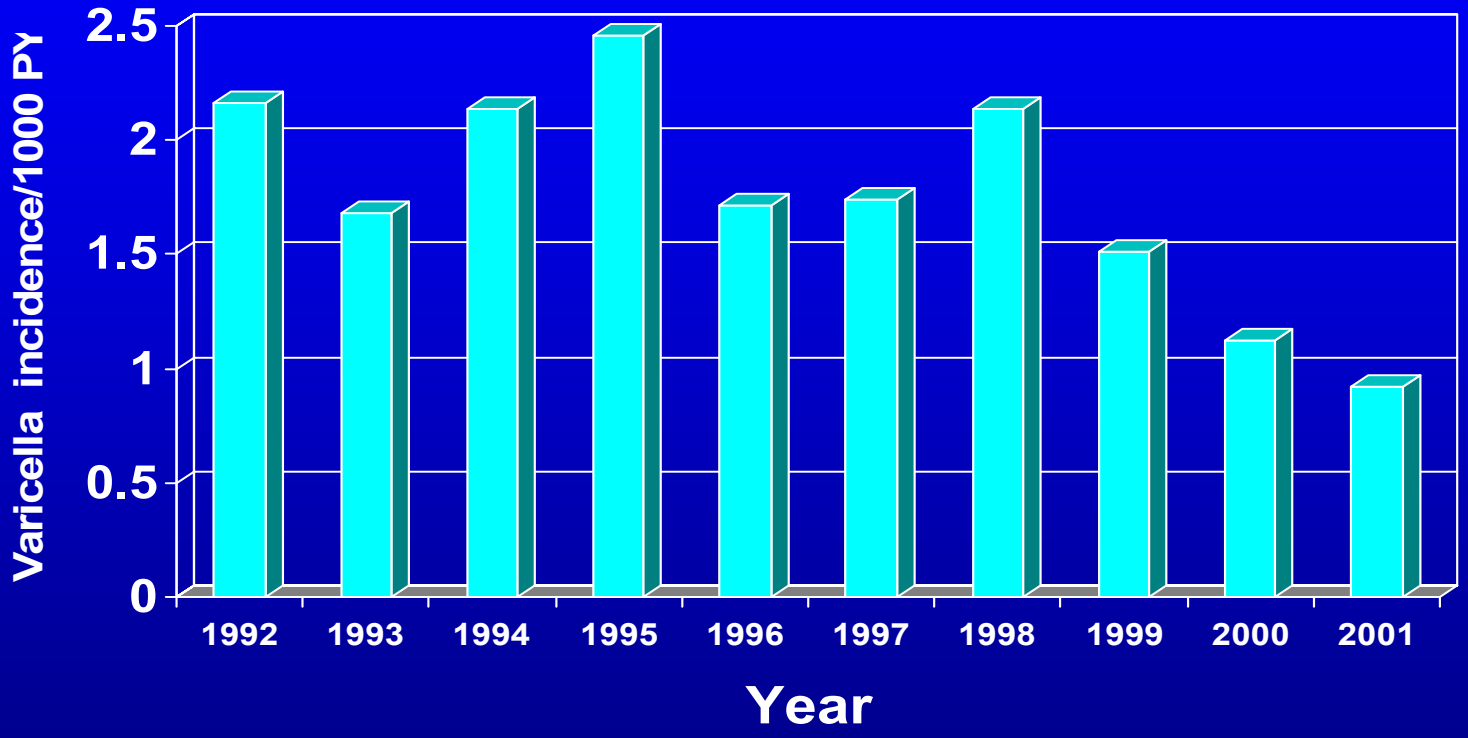
Massachusetts

- State-wide surveillance using survey methods since 1998 (BRFSS)

Seattle – Health Maintenance Organization

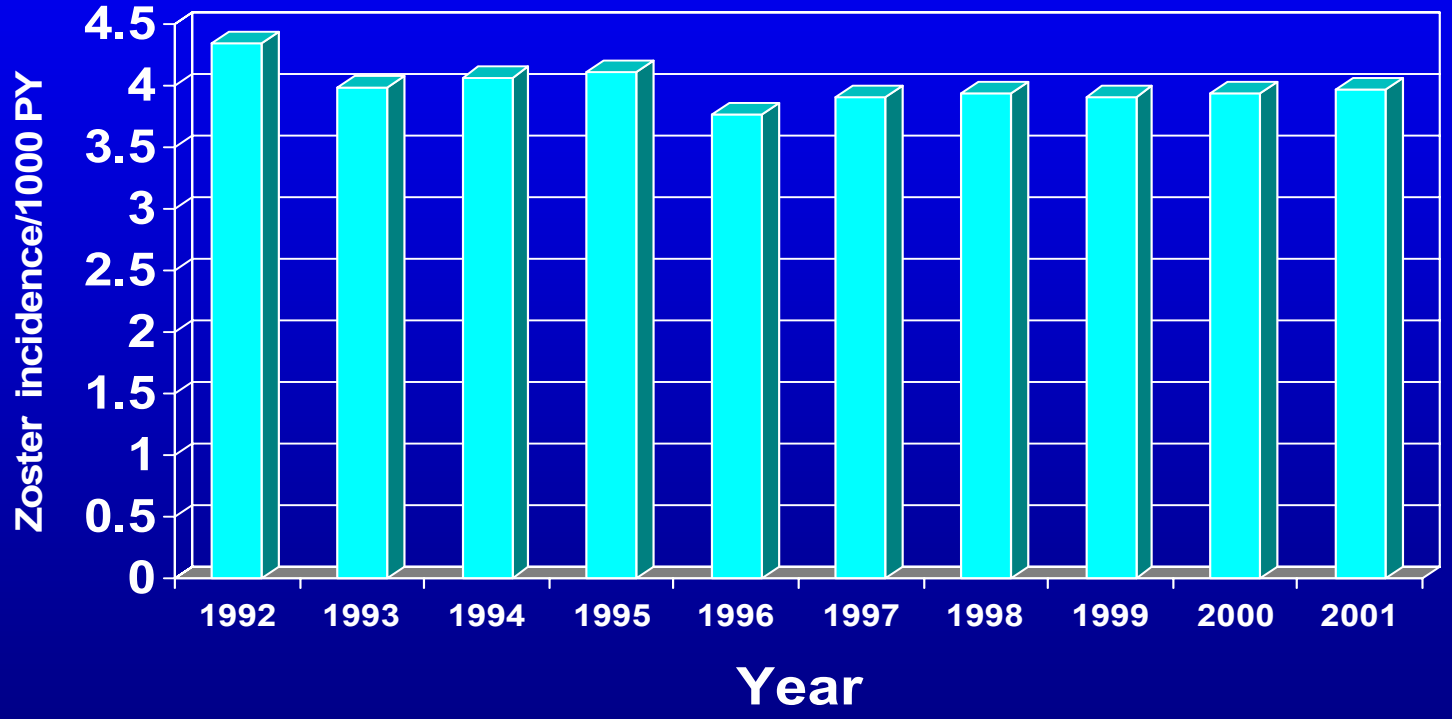
- Medical encounter and telephone consultation records since 1992

Age Adjusted Varicella Incidence
Group Health Cooperative, Seattle, 1992-200



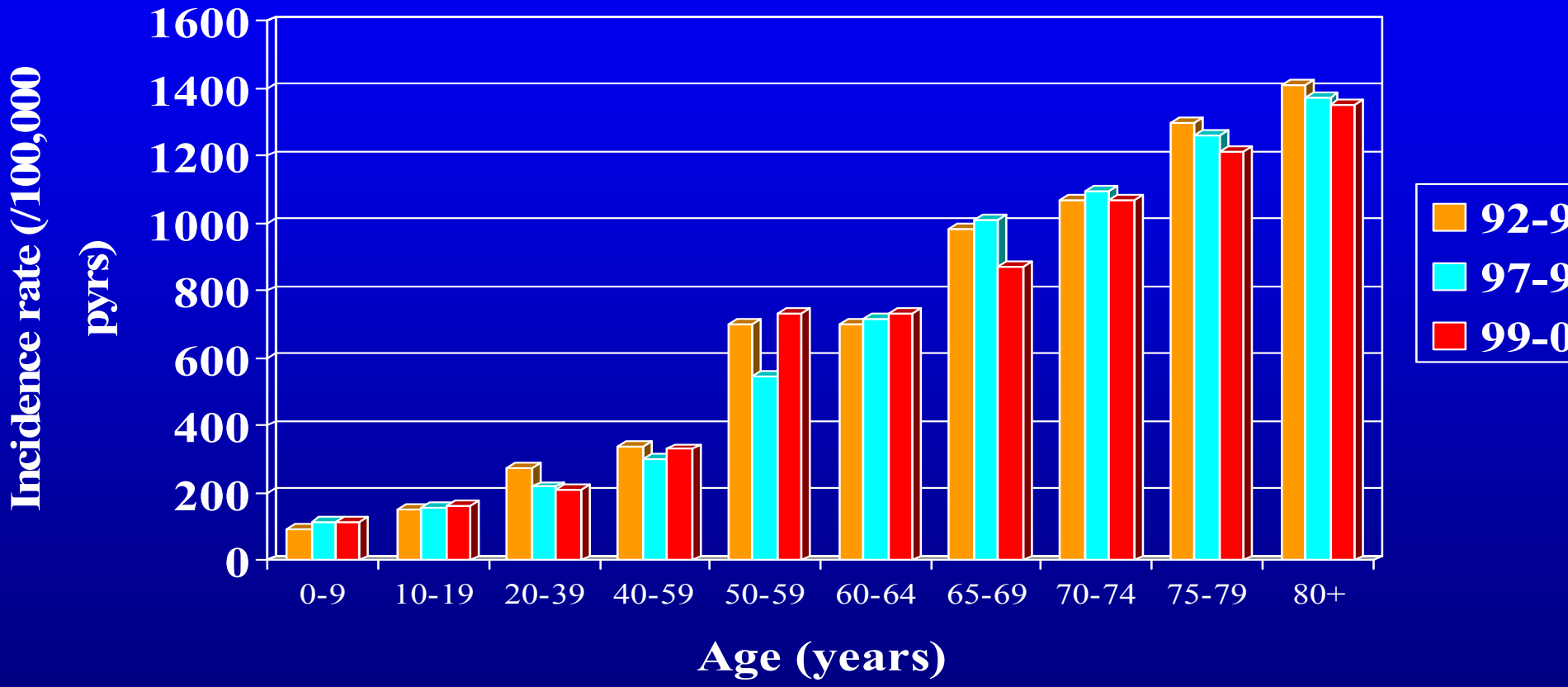
* Age adjusted to 1995 GHC population

*Age Adjusted H. Zoster Incidence GHC, Seattle, 1992-2001



* Age adjusted to 1995 GHC population

Incidence Rate of H. Zoster by Age and Year, GHC, Seattle,1992-2001



Summary

- Varicella vaccine is safe and effective
- Decline in varicella cases, hospitalizations and deaths
- Reduced disease transmission
- Importance of school requirements
- Importance of national monitoring for herpes zoster as well as varicella

Collaborators

- State, City and County Health Departments
- Project staff – varicella active surveillance project
  - LA County: T. Maupin, L. Mascola, R. Civen
  - Philadelphia: B. Watson, D. Perelli, C. Heath
  - Travis County, TX: L. Tabony, J. Pelosi
- John Edmunds (UK)
- GHC, Seattle: L. Jackson, K. Bohkle
- Mass. BRFSS: S. Lett, K. Yih, D. Brooks
- CDC
  - NIP/ESD/VVPDB: Varicella staff, EISO and fellows

    A. Jumaan, P. Garguillo, R. Harpaz. L. Zimmerman, J. Zhang, M. Marin & H. Nguyen
  - Staff who assisted with outbreaks
  - NIP/ESD/VSB: Vaccine safety staff, EISO
  - NIP/DMD: NIS
  - NCID: National VZV lab
    - S. Schmid, V. Loparev
  - NCHS: mortality data
- FDA: R. Wise, P. Krause, others (vaccine safety)