

# Evaluation of Tetravalent Meningococcal Conjugate Vaccine Effectiveness: Project Status Report

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## Meningococcal Disease

- ❑ Caused by the bacterium *Neisseria meningitidis*
- ❑ Typically presents as meningitis or bacteremia
- ❑ Case-fatality rate is 10-15%, and as many as 20% of survivors have permanent sequelae, including:
  - brain damage
  - loss of limb
  - deafness
  - lifelong learning disabilities

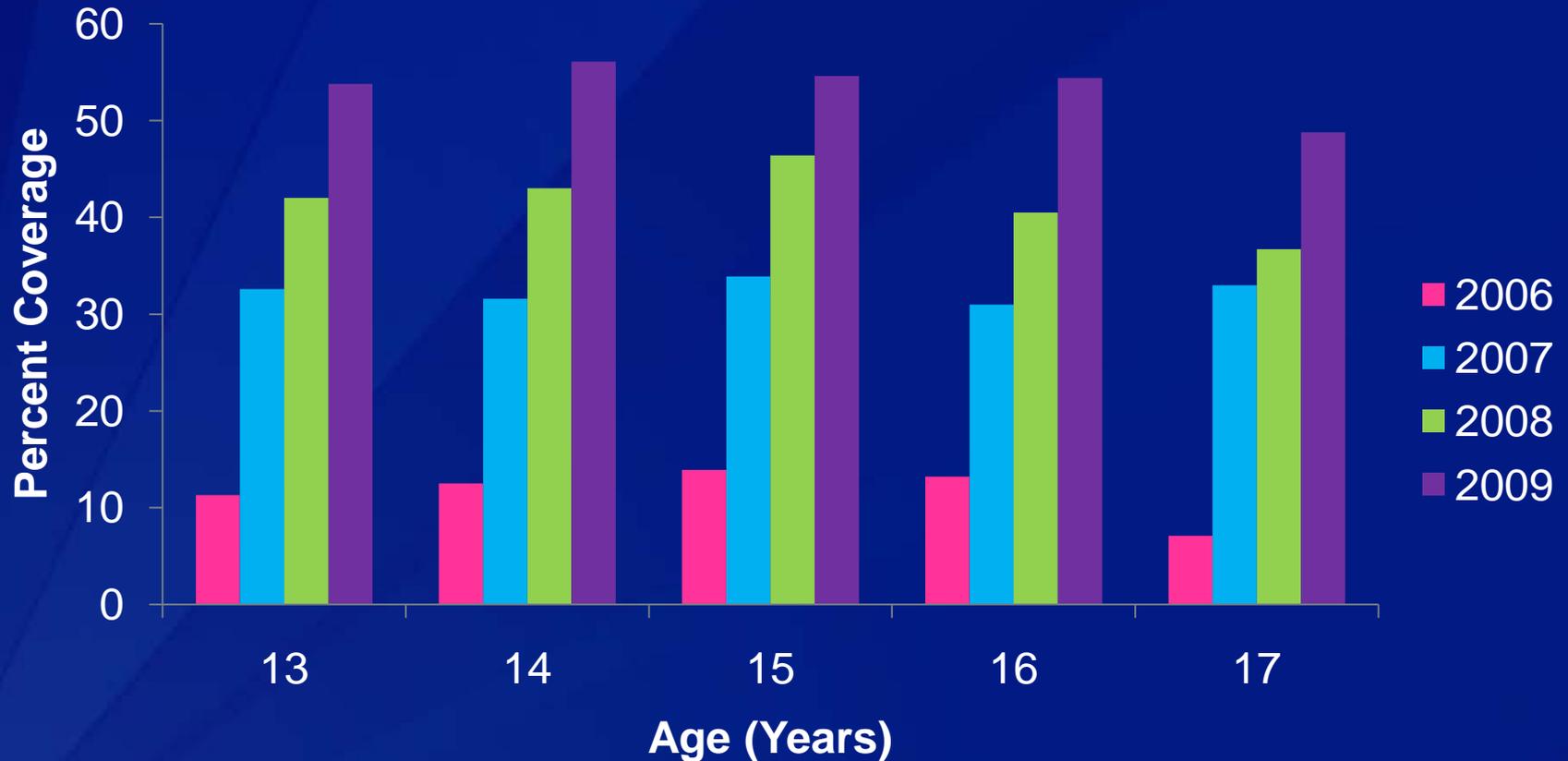


# Quadrivalent Meningococcal Conjugate Vaccine: MCV4

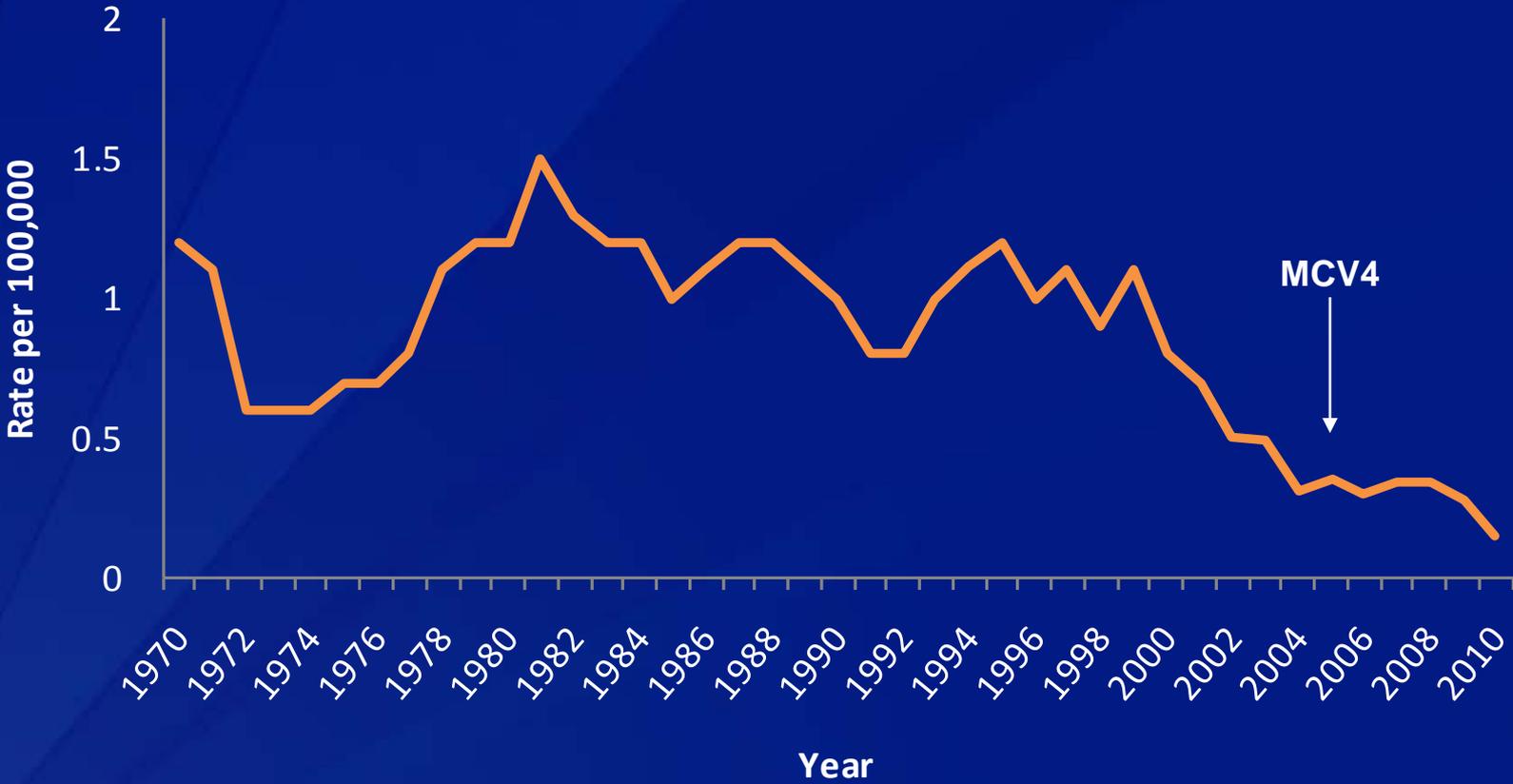
- ❑ Protects against serogroups A, C, Y, W135
- ❑ Licensed for use in persons 2-55 years old
- ❑ ACIP recommendations:
  - Routine use in 11-18 year olds with booster dose at 16 years
  - Persons at increased risk of disease\*

\*2-dose primary series administered 2 months apart for persons aged 2 through 54 years with persistent complement component deficiency (e.g., C5--C9, properdin, factor H, or factor D) and functional or anatomic asplenia, and for adolescents with human immunodeficiency virus (HIV) infection

# Coverage of Meningococcal Vaccination among 13-17 year-olds, NIS-Teen, 2006-2009

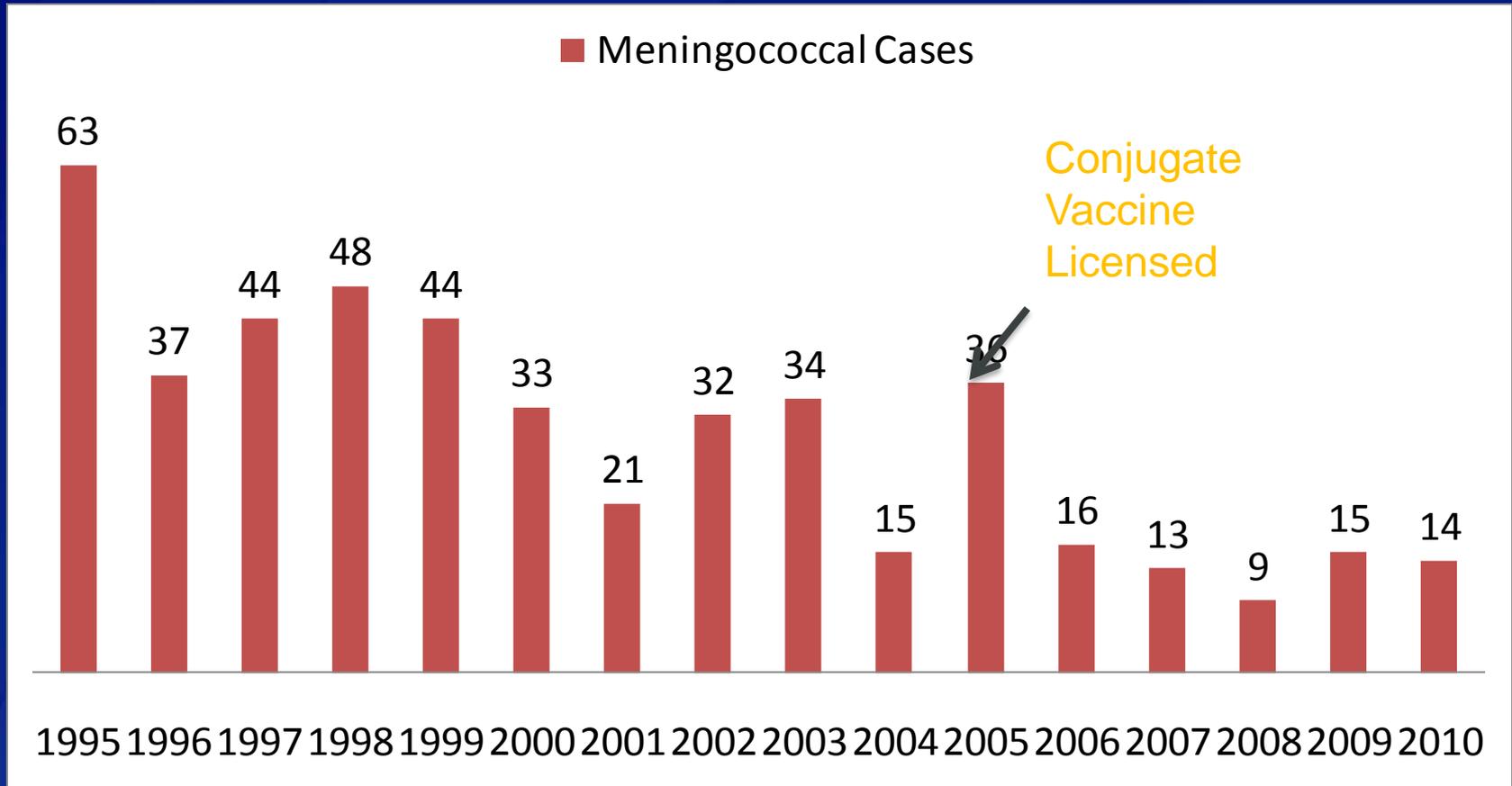


# Meningococcal Disease Incidence, United States

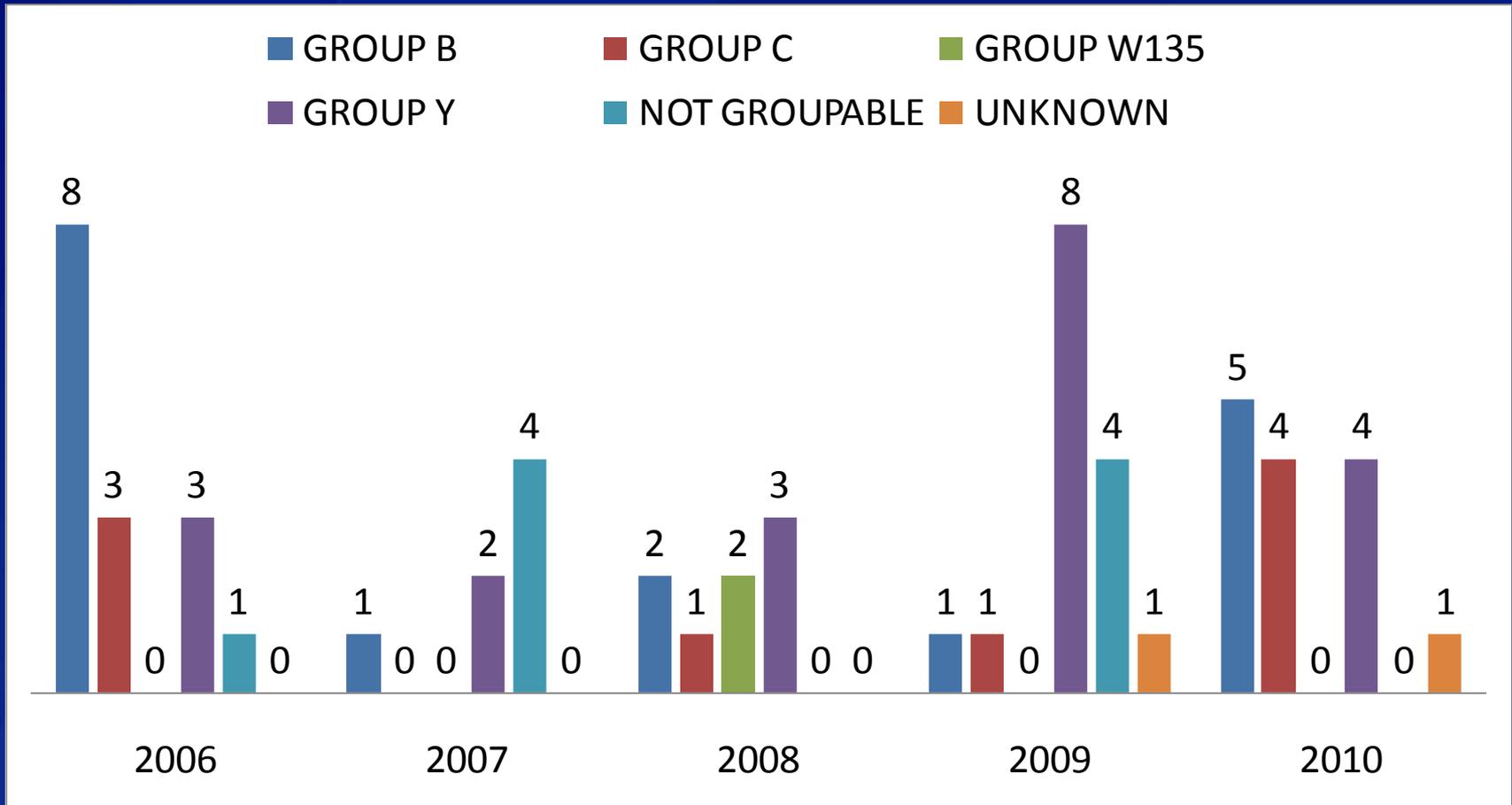


1921-1996 NNDSS data, 1997-2010 ABCs data estimated to U.S. population (2010 data provisional)

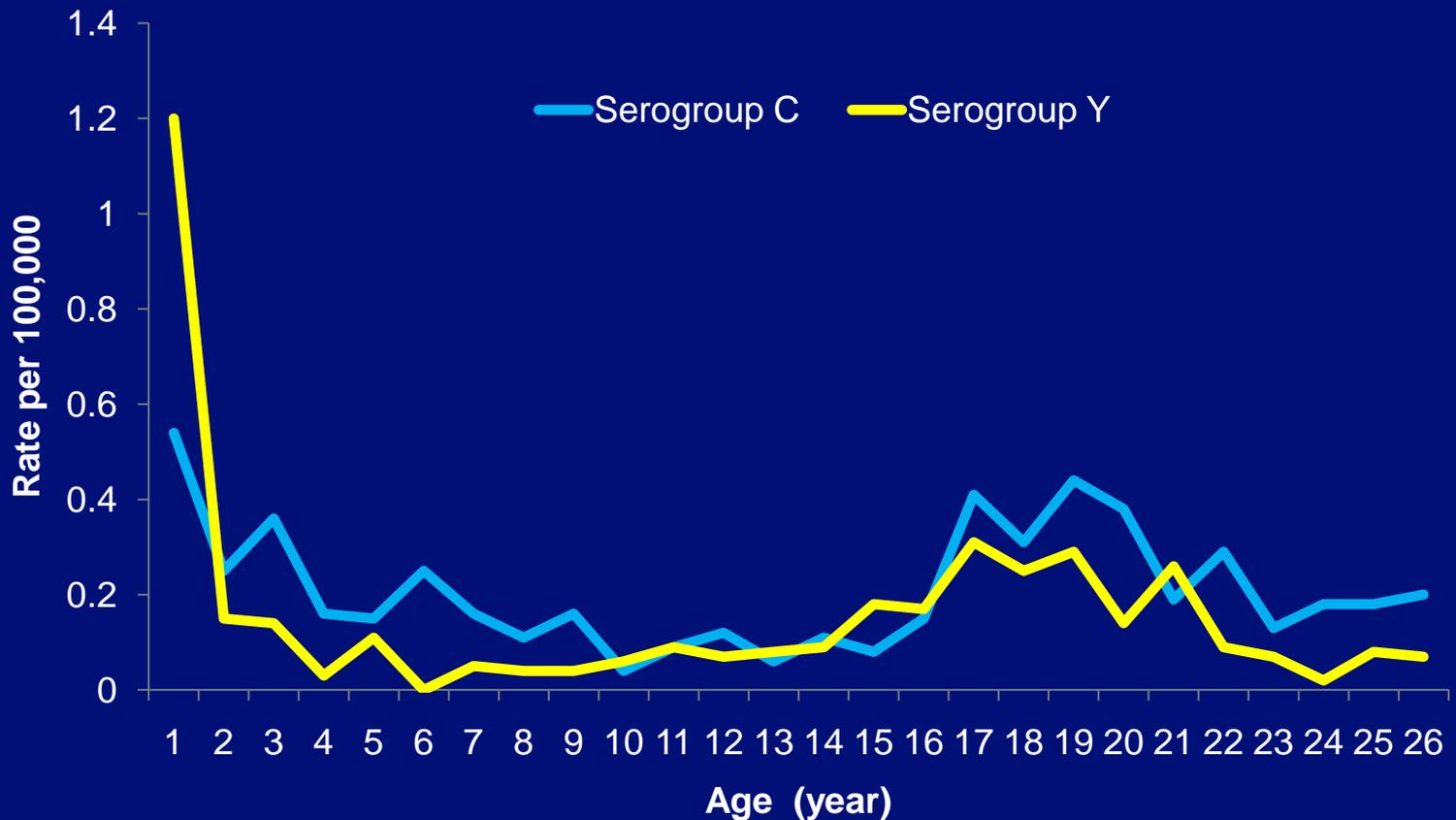
# Meningococcal Infections in AZ



# *N. Meningitidis* Serogroup Breakdown: 2006 – 2010



# Rates of Meningococcal Disease (C and Y) by Age, 1999-2008



\*Active Bacterial Core surveillance (ABCs), estimated to the US population

# Rates of Serogroup C,Y,W-135 Meningococcal Disease\*

Year	Incidence per 100,000 (95% confidence interval)	
	11-19 year olds	≥20 year olds
2004 and 2005	0.23 (0.15, 0.35)	0.16 (0.13, 0.20)
2006 and 2007	0.27 (0.18, 0.40)	0.22 (0.18, 0.26)
2008 and 2009	0.14 (0.08, 0.24)	0.21 (0.18, 0.26)

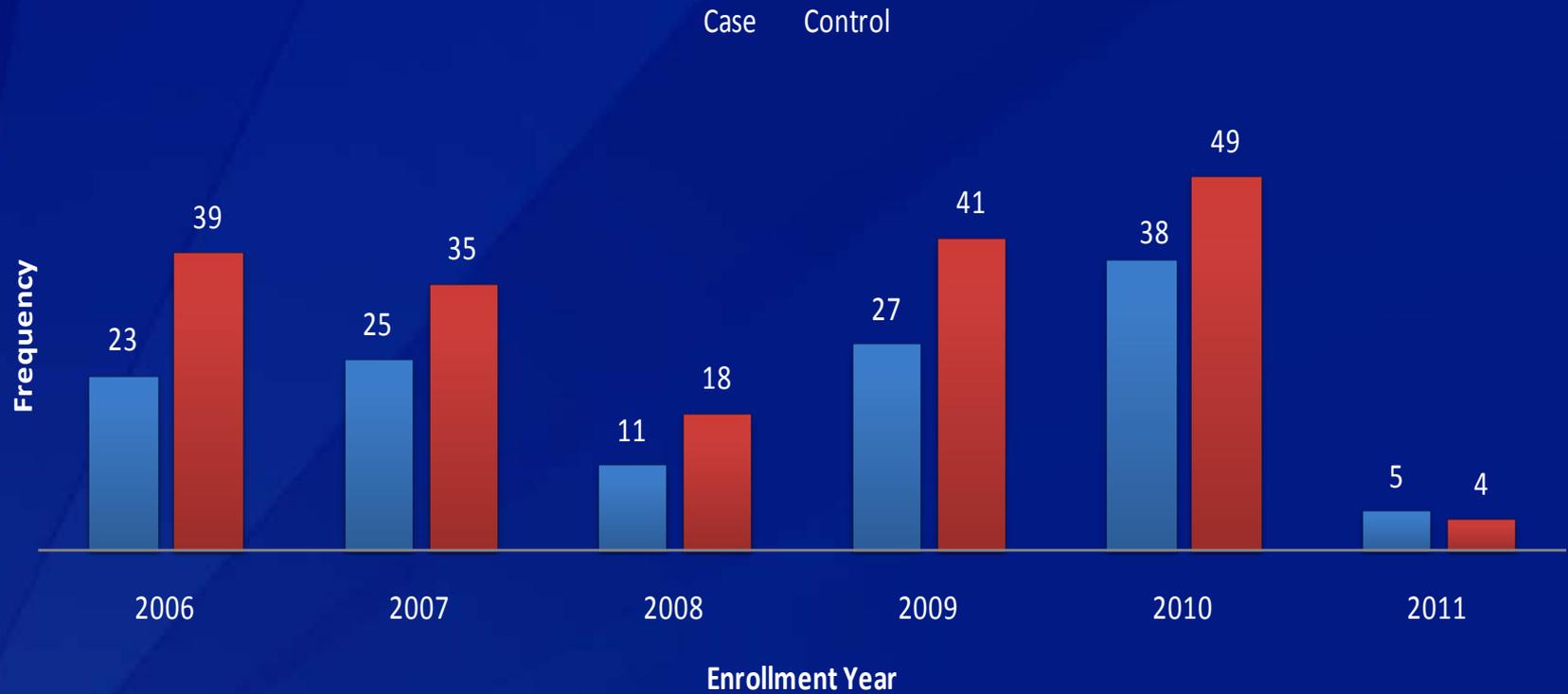
\*Active Bacterial Core surveillance, estimated to the US population

## **MCV4 Post-licensure Evaluation**

- ❑ **Menactra (MCV4) licensed in the US in 2005**
  - Menveo licensed in February 2010
- ❑ **Enrollment started in January 2006**
- ❑ **Matched case-control study**
  - Residents of ABCs or MeningNet sites
  - At least 11 years old and born on or after January 1, 1986
  - 4 controls per case
  - Matched by age and geographic area

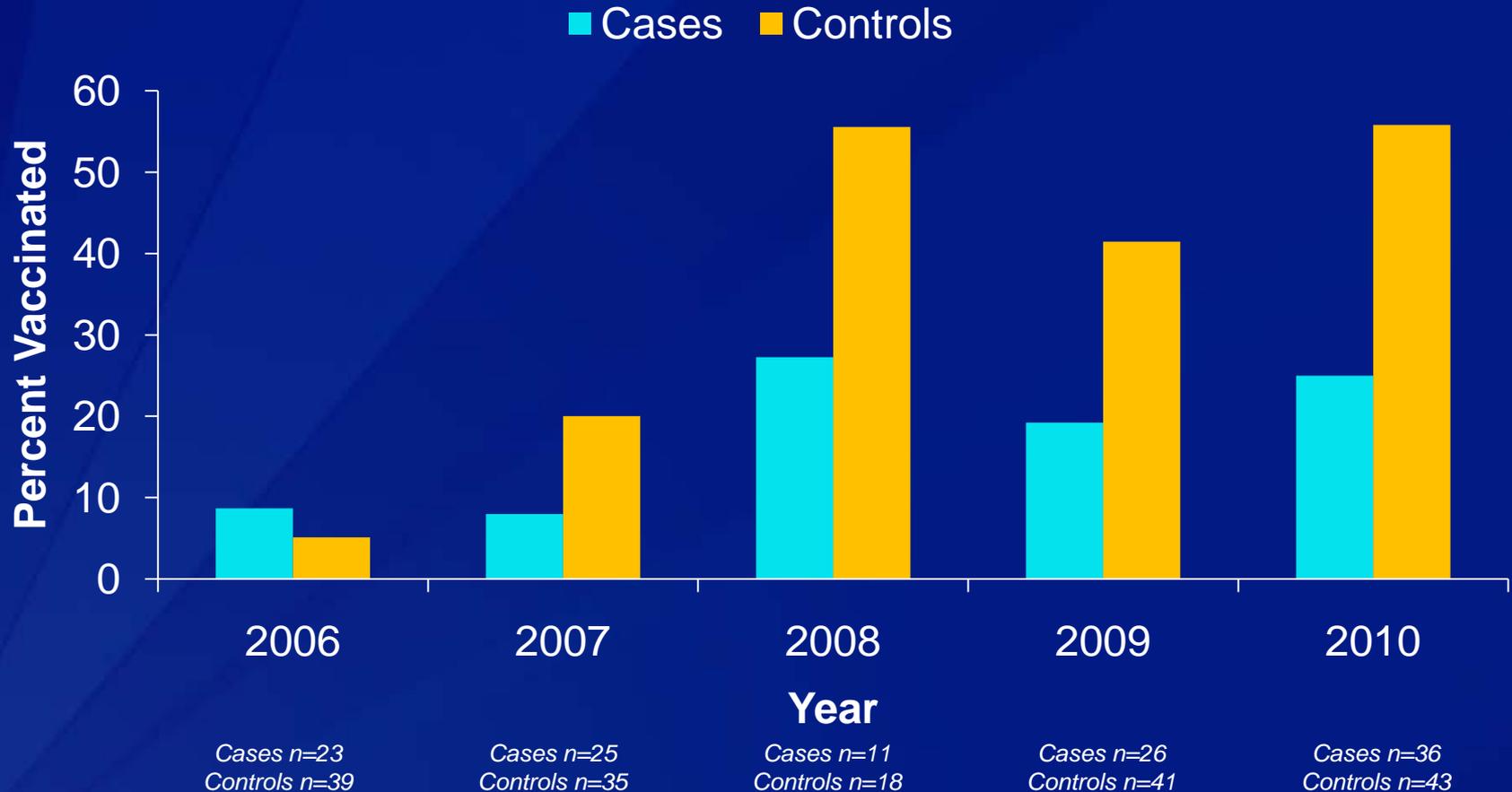


# Case and Control Enrollment



Analysis results based on paperwork received by March 23, 2010.

# Proportion of Cases and Controls Vaccinated with MenACWY<sub>D</sub> by Year



Based on paperwork received by March 11, 2011; unknown vaccination status excluded

# Preliminary VE, Menactra Effectiveness, (0-5 years)

All Enrolled Cases Controlling for:	VE (95% CI)
All Serogroups (C, Y, and W135)	74% (36-90%)

Analysis results based on paperwork received by March 23, 2010.

Controls for smoking status and underlying condition status

PRELIMINARY RESULTS, SUBJECT TO CHANGE. PLEASE DO NOT DISTRIBUTE

## Preliminary Menactra VE Estimates, Duration of Protection\*

Cases*	VE (95% CI) All cases (n=128)	VE (95% CI) Cases with no underlying illness (n=113)
Vaccinated <1 year	>99% (0,100%)	>99% (0, 100%)
Vaccinated 1 to 2 years	80% (-3,96%)	89% (8, 99%)
Vaccinated 2 to 5 years	50% (-49, 83%)	60% (-30, 88%)

Analysis results based on paperwork received by March 23, 2010.

Controls for smoking status and underlying condition status

PRELIMINARY RESULTS, SUBJECT TO CHANGE. PLEASE DO NOT DISTRIBUTE

## Arizona Results

- ❑ **Since 2009, 5 cases eligible for study**
  - 4 serogroup Y, 1 serogroup C
  - 1 vaccinated, 3 not vaccinated, 1 unknown
- ❑ **12 controls enrolled**
  - 7 vaccinated

## What is the Future of the MCV4 Study?

- ❑ **Continue enrollment through 2012**
  - Serogroup specific VE estimates
  - VE estimates for persons with underlying medical conditions
  - Effectiveness of new vaccine (Menveo)
  
- ❑ **Continue to monitor for cases of breakthrough disease in persons vaccinated with MCV4**

# It's Their Turn!

## Pre-teens and Teens Need Vaccines Too!



### Why does Arizona require that my child receive the meningitis and whooping cough vaccines?

The Arizona Department of Health Services (ADHS) wants to make sure your child is protected against serious diseases. Students 11 years and older entering 6th - 9th grades must be vaccinated with MCV4 to protect against meningococcal disease (meningitis) and Tdap to protect against pertussis (whooping cough), diphtheria, and tetanus. Tdap vaccine is only required if 5 years have passed since the child's last dose of tetanus/diphtheria containing vaccine. MCV4 is also recommended for 10th - 12th graders. These requirements support the Centers for Disease Control and Prevention's (CDC) recommendation that children 11 years and older receive MCV4 and Tdap vaccines.

### Are these diseases really harmful to my child?

Yes. Meningococcal infection can be very serious, even deadly. The disease can spread quickly, sometimes causing death in 48 hours or less. Even with antibiotic treatment, adolescents die in about 10% of cases. About 20% of survivors will have long-term disability, such as loss of a limb, deafness, nervous system problems, or brain damage.

Whooping cough (pertussis) causes coughing fits that can be so severe that adolescents can miss school or be unable to participate in sports or other social activities. Parents may also have to miss work to take care of a sick child.

### I thought my child was already vaccinated against whooping cough (pertussis)...

Protection from some childhood vaccines can wear off. The immunity from childhood vaccination against pertussis does not last into the adolescent years. A booster shot will help your child to continue to be protected against pertussis.

### What other vaccines are recommended for adolescents?

In addition to the Tdap and MCV4 vaccines, the CDC recommends that adolescent girls receive human papilloma virus (HPV) vaccine to protect them against cervical cancer. Influenza (flu) vaccine is also recommended for all adolescents. Ask your doctor about vaccinations your child may have missed at an earlier age such as:

- Measles, Mumps, Rubella (MMR)
- Chickenpox (Varicella)
- Polio (IPV)
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Flu (Influenza)
- Pneumococcal (PPV)

### Are the vaccines safe?

Yes, vaccines are safe and effective. Before any vaccine is available to the public, it must be extensively studied and the FDA must approve it as safe and effective. These vaccines are also recommended by the American Academy of Pediatrics, the American Academy of Family Physicians, and the Society for Adolescent Medicine.

### How much do these vaccines cost?

For families with health insurance, all or most of the cost is usually covered. Children age 18 and younger may be eligible to get the vaccines free through the Vaccines for Children program (VFC) if they are Medicaid eligible, uninsured, American Indian or Alaska Native. Parents can find a VFC provider by contacting their local health department.

### For More Information

Please visit [www.azdhs.gov/phs/immun](http://www.azdhs.gov/phs/immun) or call your local health department.

# It's My Turn!

2 b



healthy



Tell your parents that students 11 years and older entering 6th-9th grades should be vaccinated against serious diseases.

Why?

It could save YOUR life!  
And your friends' lives too!

**Protect your children from serious diseases.**

Students 11 years and older in 6th - 9th grades must be vaccinated against meningitis and whooping cough. Students entering 10th-12th grade should also be vaccinated.

Schedule an appointment with your child's healthcare provider.

For more information, visit [www.azdhs.gov/phs/immun](http://www.azdhs.gov/phs/immun) or call your local health department.



# Thank You

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**602-364-3817**

**For more information please contact Centers for Disease Control and Prevention**

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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