

# Overview of Current Vaccination Policies and Recommendations in Healthcare Personnel: U.S. Centers for Disease Control and Prevention

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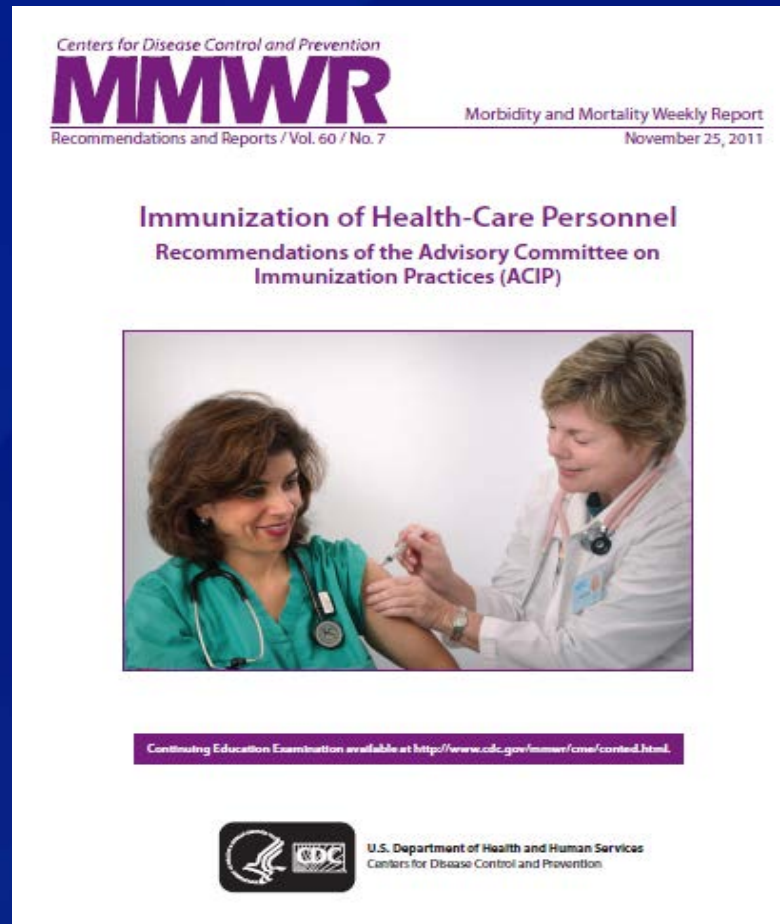
Viral Hepatitis Prevention Board  
November 15, 2012

National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention

Division of Viral Hepatitis



# Recommendations for Immunization of Healthcare Personnel (HCP)<sup>1</sup>



<sup>1</sup>Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). November 25, 2011/60(RR07);1-45.

# Vaccines Recommended for HCP

<b>Disease</b>	<b>Primary schedule and booster</b>	<b>Indication(s)</b>
Hepatitis B	3 doses: First two doses 4 weeks apart, 3 <sup>rd</sup> dose 5 months after second	HCP at risk for blood or body fluid exposure
Influenza	Annual	All HCP
Measles	2 doses: $\geq 28$ days apart	All HCP who lack presumptive evidence of immunity; consider for those born before 1957
Mumps	2 doses: $\geq 28$ days apart	All HCP who lack presumptive evidence of immunity; consider for those born before 1957
Rubella	1 dose (most HCP receive 2 doses of MMR)	All HCP who lack presumptive evidence of immunity (birth before 1957 NOT acceptable evidence of immunity for women who could become pregnant)
Pertussis	1 dose (with Tdap; Td every 10 years)	All HCP
Varicella	2 doses administered 4-8 weeks apart if $\geq 13$ years old	HCP who lack evidence of immunity

# Vaccines Recommended for HCP in Certain Circumstances

Disease	Primary schedule and booster	Indication(s)
Meningococcal	<p>Quadrivalent conjugate vaccine for HCP ages 19-54 years; quadrivalent polysaccharide vaccine for HCP ages <math>\geq 55</math> years</p> <p>1 dose; booster dose in 5 years if HCP remains at increased risk</p>	Microbiologists who might routinely be exposed to <i>N. meningitidis</i>
Typhoid fever	<p>IM vaccine: 1 dose, booster every 2 years</p> <p>Oral vaccine: 4 doses on alternate days; manufacturer recommends revaccination with the entire 4-dose series every 5 years</p>	Workers in microbiology labs who frequently work with <i>Salmonella Typhi</i>
Polio (IPV)	2 doses 4-8 weeks apart, 3 <sup>rd</sup> dose 6-12 months after second dose	HCP who have close contact with patients who might be excreting polioviruses

# Proof of Immunity for HCP

Vaccine	Birth before 1957	MD Dx	+ Serology	Self Report	Documented Vaccination
Hepatitis B	No		$\geq 10$ mIU/mL <sup>4</sup>	No	✓
Influenza	No	No	No	No	✓
Measles	✓ <sup>1</sup>	Yes <sup>3</sup>	✓	No	✓
Mumps	✓ <sup>1</sup>	Yes <sup>3</sup>	✓	No	✓
Rubella	✓ <sup>1,2</sup>	No	✓	No	✓
Pertussis	No	No	No	No	✓
Varicella	No	Yes	✓	No	✓

<sup>1</sup>Consider immunization of HCP born before 1957, recommend during an outbreak

<sup>2</sup>All HCP of childbearing potential should be immunized

<sup>3</sup>Requires lab confirmation

<sup>4</sup>Obtain 1-2 months post last vaccine dose

Weber DJ, Schaffner W. ICHE 2011

# HepB Vaccination

- **≥3-dose series for all HCP with risk for blood and body fluid exposure (since 1982)**
  - Generally administered at 0, 1, and 6 months

Single-antigen vaccines <sup>1</sup>				Combination vaccine <sup>1</sup>	
Recombivax HB <sup>®</sup>		Engerix-B <sup>®</sup>		Twinrix <sup>®</sup>	
Dose	Volume	Dose	Volume	Dose	Volume
10 µg	1 mL	20 µg	1 mL	20 µg	1 mL

<sup>1</sup>A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), Part II: Immunization of Adults. December 8, 2006/55(RR16);1-33.

# Post-Vaccination Serologic Testing (PVS)

- ❑ **Post-vaccination serologic testing (antibody to hepatitis B surface antigen [anti-HBs]) 1-2 months after last dose recommended for all HCP at high risk for blood and body fluid exposure (since ~1997)**
  - HCP with anti-HBs  $\geq 10$  mIU/mL:
    - No post-exposure prophylaxis for hepatitis B necessary, regardless of source patient's hepatitis B surface antigen (HBsAg) status
  - HCP with anti-HBs  $< 10$  mIU/mL:
    - Revaccinate (1-3 doses), followed by PVS 1-2 months after last dose

# Vaccine Non-Responders (anti-HBs <10 mIU/mL)

- ❑ **>6 total doses HepB vaccine not recommended**
- ❑ **Vaccine non-responders (after 6 doses) should be tested to determine infection status**
  - Hepatitis B surface antigen (HBsAg)
  - Antibody to hepatitis B core antigen (anti-HBc)
- ❑ **Infected HCP (HBsAg-positive) who perform exposure-prone procedures should seek counsel from a review panel regarding the procedures they can safely perform; they should not be excluded from work<sup>1</sup>**

<sup>1</sup>Updated CDC Recommendations for the Management of Hepatitis B Virus-Infected Health-Care Providers and Students. July 6, 2012/61(RR03);1-12.



# Post-Exposure Prophylaxis

## Source patient HBsAg status<sup>1</sup>

HCP vaccination and response status↓	<u>Positive</u>	<u>Negative</u>
Unvaccinated	HBIG x1, initiate vaccination	Initiate vaccination
Previously vaccinated		
Known responder	No treatment	No treatment
Known non-responder		
After 3 doses	HBIG x1, initiate revaccination	No treatment
After 6 doses	HBIG x2 (separated by 1 month)	No treatment

<sup>1</sup>If source patient has unknown HBsAg status but high-risk, HCP managed as if source patient HBsAg-positive

# Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard

- ❑ States what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials
  - Offer HepB vaccine
  - Post-exposure evaluation/prophylaxis (immediately available)
- ❑ Unpaid trainees and volunteers not covered
- ❑ Effective since 1992

At no cost to worker

<sup>1</sup>[http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=INTERPRETATIONS&p\\_id=21010](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21010)

# Decline in Hepatitis B Infections among HCP

## □ Hepatitis B infections among HCP:

- 1983: 17,000 cases estimated<sup>1</sup>
- 2010: 263 cases estimated<sup>2</sup>

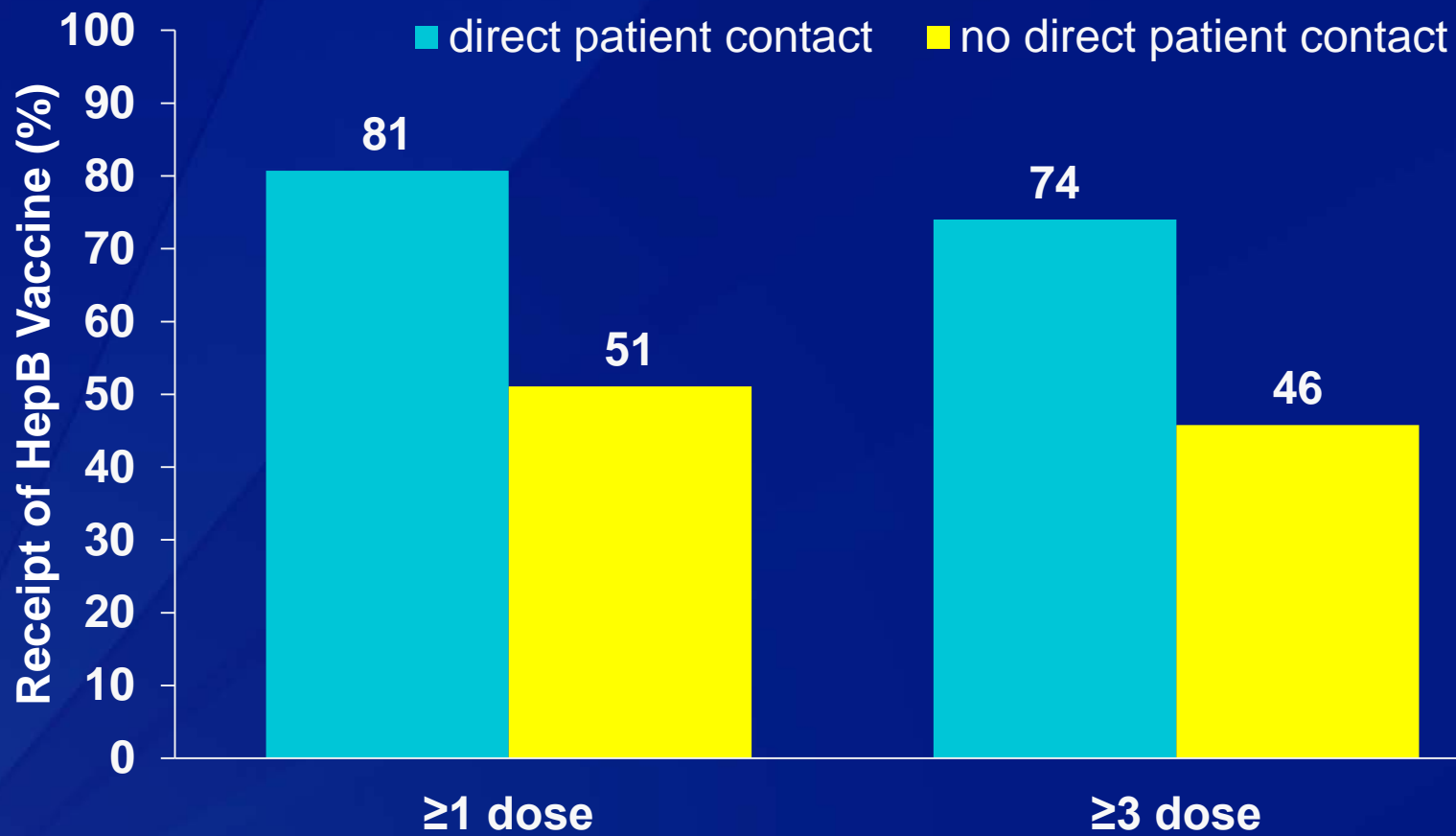
## □ Decline attributed to:

- HepB vaccination
- Improvements in infection control

<sup>1</sup>Beltrami 2000

<sup>2</sup>Surveillance data, considering that occupational history was assessed for 43.6% of cases and using a correction factor of 10.5 to account for underreporting and asymptomatic infection

# Proportion of HCP who Received HepB Vaccine by Patient Contact Status — NHIS, 2010



NHIS=National Health Interview Survey, provided by K. Byrd

# Risk and Reporting of Occupational Blood and Body Fluid Exposures

	Non-Trainee	Trainee
<b>Risk (annual)</b>		
Percutaneous injury <sup>1</sup>	10%	18%
Mucosal exposure <sup>2</sup>	13%	22%
<b>Proportion of exposures reported to occupational health</b>		
Percutaneous injury <sup>1</sup>	54%	54%
Mucosal exposure <sup>2</sup>	17%	17%

<sup>1</sup>Needlesticks, cuts, or bites

<sup>2</sup>Blood or body fluid contact with mucus membranes or non-intact skin

# Acute Hepatitis B Surveillance — NNDSS, 2005-2010

- ❑ 203 cases among HCP<sup>1</sup> reported to CDC
- ❑ HepB vaccination determined through routine surveillance question: “Has this patient ever received the three dose series of Hepatitis B vaccine?”

- Yes: 39 (19.2%)
- Unknown: 49 (24.1%)
- No: 115 (56.7%)



**Additional  
information  
67/88 (76%)**

NNDSS=National Notifiable Diseases Surveillance System

<sup>1</sup>Occupational history assessed for a subset of cases (e.g., 46.0% and 43.6% of cases for 2009 and 2010, respectively).

# 203 Cases of Acute Hepatitis B among HCP Reported to CDC, 2005-2010

- ❑ Mean age: 41.7 years, range: 18-69 years (n=203)
- ❑ Male: 40.4% (82/203)
- ❑ Accidental stick with needle/sharp object: 16.7% (28/168)<sup>1</sup>
- ❑ Other hepatitis B risk factor: 59.6% (121/203)<sup>2</sup>

<sup>1</sup>During 6 weeks – 6 months prior to illness; information on post-exposure prophylaxis not available

<sup>2</sup>Other risk factors consist of: contact with hepatitis case, receipt of dialysis, blood transfusion, men who have sex with men, injection drug use, multiple sexual partners, surgery, acupuncture, or tattoo

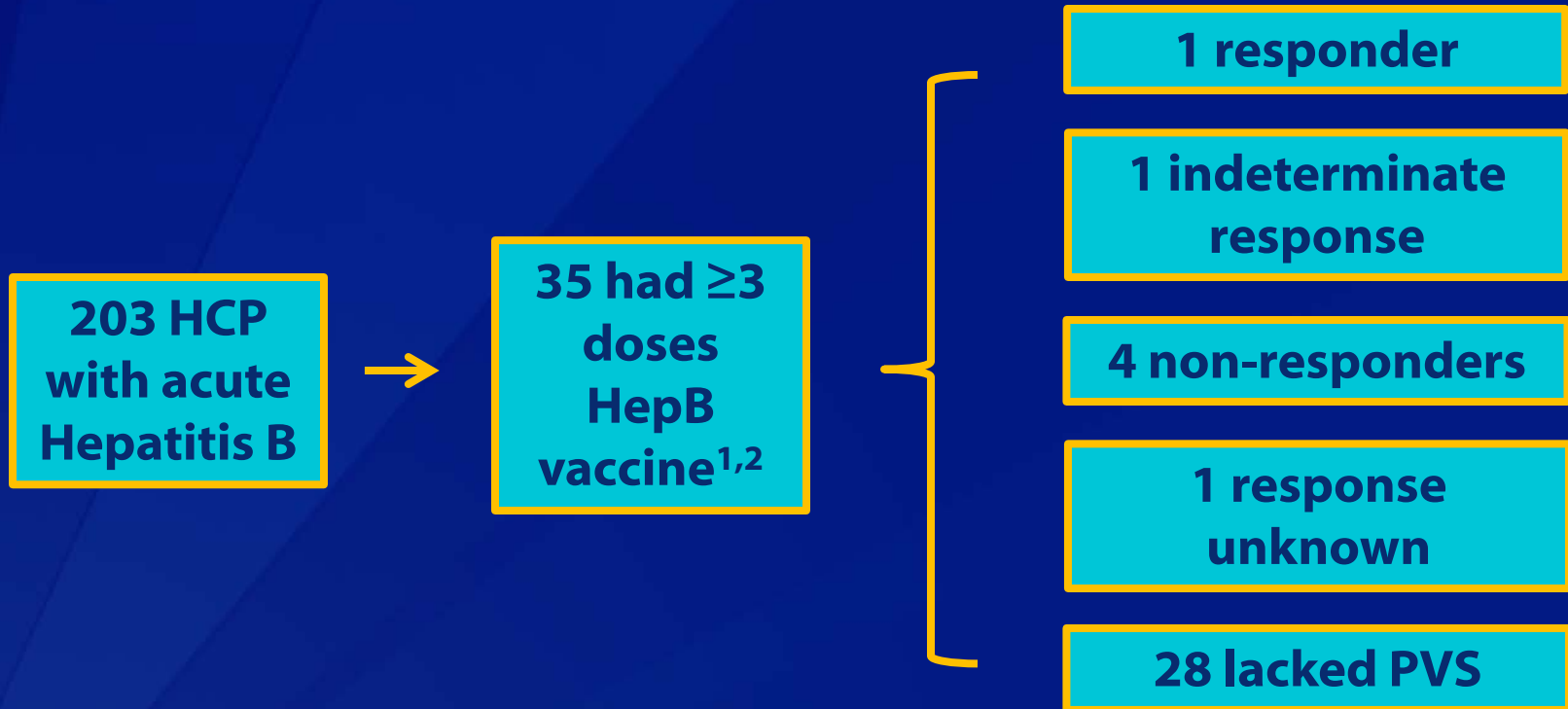
## 203 Cases of Acute Hepatitis B among HCP Reported to CDC, 2005-2010, cont.

- ❑ Hospitalized: 40.8% (75/184)
- ❑ Developed chronic infection: 37.5% (6/16)
- ❑ Died: 0% (0/151)
  
- ❑ Vaccinated: 19.2% (35/182)<sup>1</sup>

<sup>1</sup>Follow-up not attempted for 115 cases initially reported to have not received HepB vaccination series



# Vaccination and PVS Testing Status among HCP with Acute Hepatitis B



<sup>1</sup>7 with complete documentation of dates of vaccination; minimum dosing intervals heeded for 7 with complete documentation

<sup>2</sup>4 of 8 with information developed chronic infection

# Previously Vaccinated HCP

- ❑ **Increasing proportion of HCP have received HepB vaccine series in remote past**
  - 1991: Routine infant HepB vaccination (2011:  $\geq 91\%$  coverage for children aged 19-35 months<sup>1</sup>)
  - 1999: Catch-up vaccination 0-18 yrs (2010-11: 90% coverage for adolescents aged 17 years<sup>2</sup>)
- ❑ **PVS testing not recommended after routine infant or child HepB vaccination**
  - Approximately 95% of infants have serologic evidence of protection after vaccination

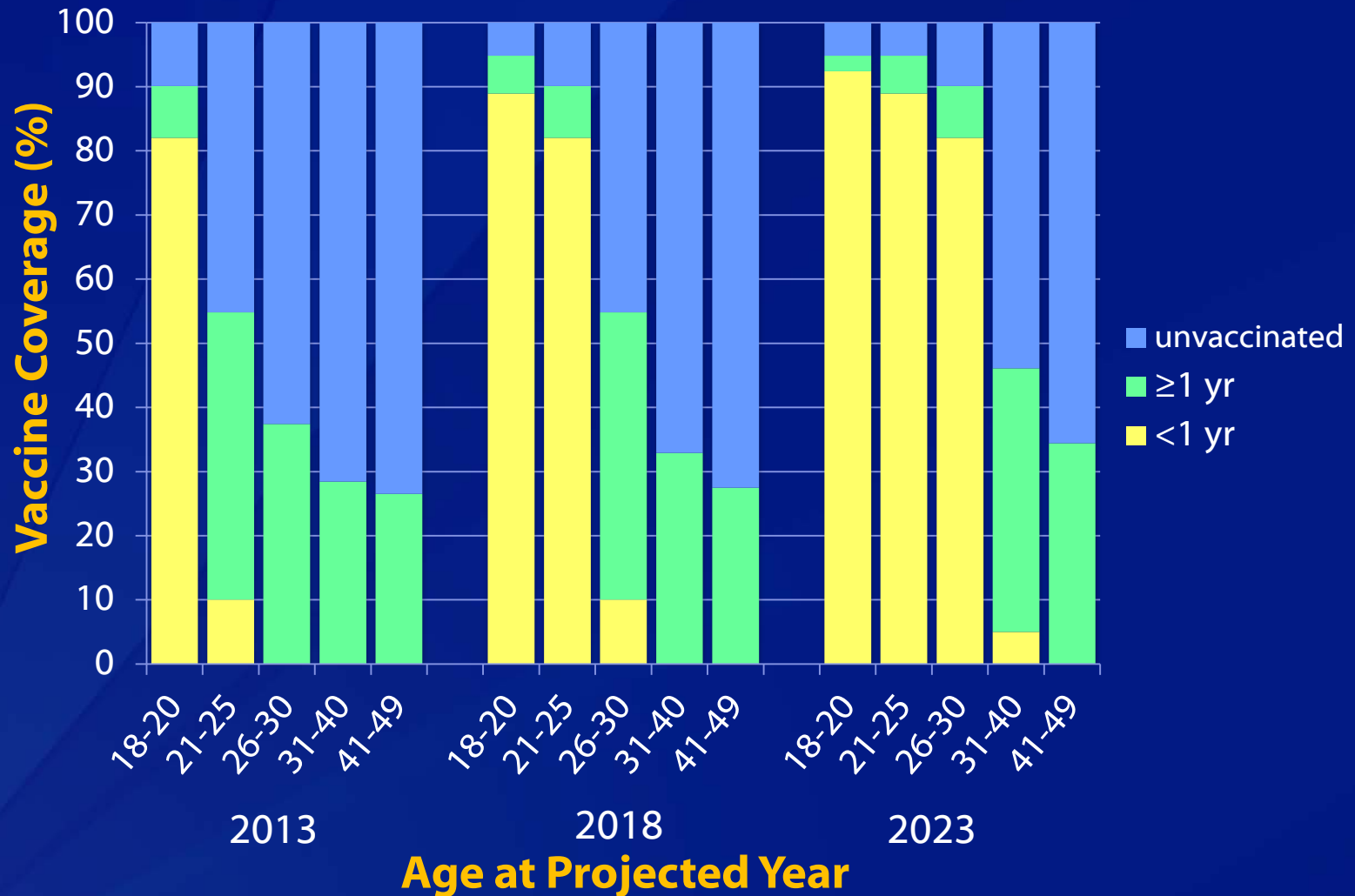
<sup>1</sup>National Immunization Survey,  $\geq 3$  dose

<sup>2</sup>National Immunization Survey – Teen,  $\geq 3$  dose

# Age of HCP at Time of HepB Vaccination

- ❑ **Over time, more HCP will have been vaccinated at <1 year of age, instead of  $\geq 1$  year of age**
  - Years after vaccination, persons vaccinated at <1 year of age more often have anti-HBs <10 mIU/mL (compared to persons vaccinated at  $\geq 1$  year of age)

# Projected HepB Vaccination Coverage ( $\geq 3$ doses) by Age at First Dose and Age Group in General U.S. Population<sup>1</sup>



<sup>1</sup>Lu, Vaccine 2011. National Health Immunization Survey 2009, National Immunization Survey - Teen 2010, National Immunization Survey 1994-2010, prepared by M. Reilly

# Testing for Anti-HBs and Protection

- ❑ **Anti-HBs after HepB vaccine series wanes over time**
  - Even when anti-HBs decreases to  $<10$  mIU/mL, breakthrough HBV infection uncommon in immunocompetent vaccine responders<sup>1</sup>
- ❑ **Anti-HBs  $<10$  mIU/mL at a time distant from vaccine completion does not distinguish:**
  - Initial responders
  - Non-responders (susceptible to infection after 6 doses of vaccine)

<sup>1</sup>Leuridan, CID 2011

# ACIP Hepatitis Work Group Considered Approaches for Ensuring Protection for HCP Vaccinated in the Distant Past

- ❑ No pre-exposure management (post-exposure evaluation for all recognized and reported exposures)
- ❑ Pre-exposure anti-HBs, followed by revaccination if necessary<sup>1</sup>
- ❑ Pre-exposure challenge dose of vaccine, followed by anti-HBs and revaccination if necessary<sup>1</sup>

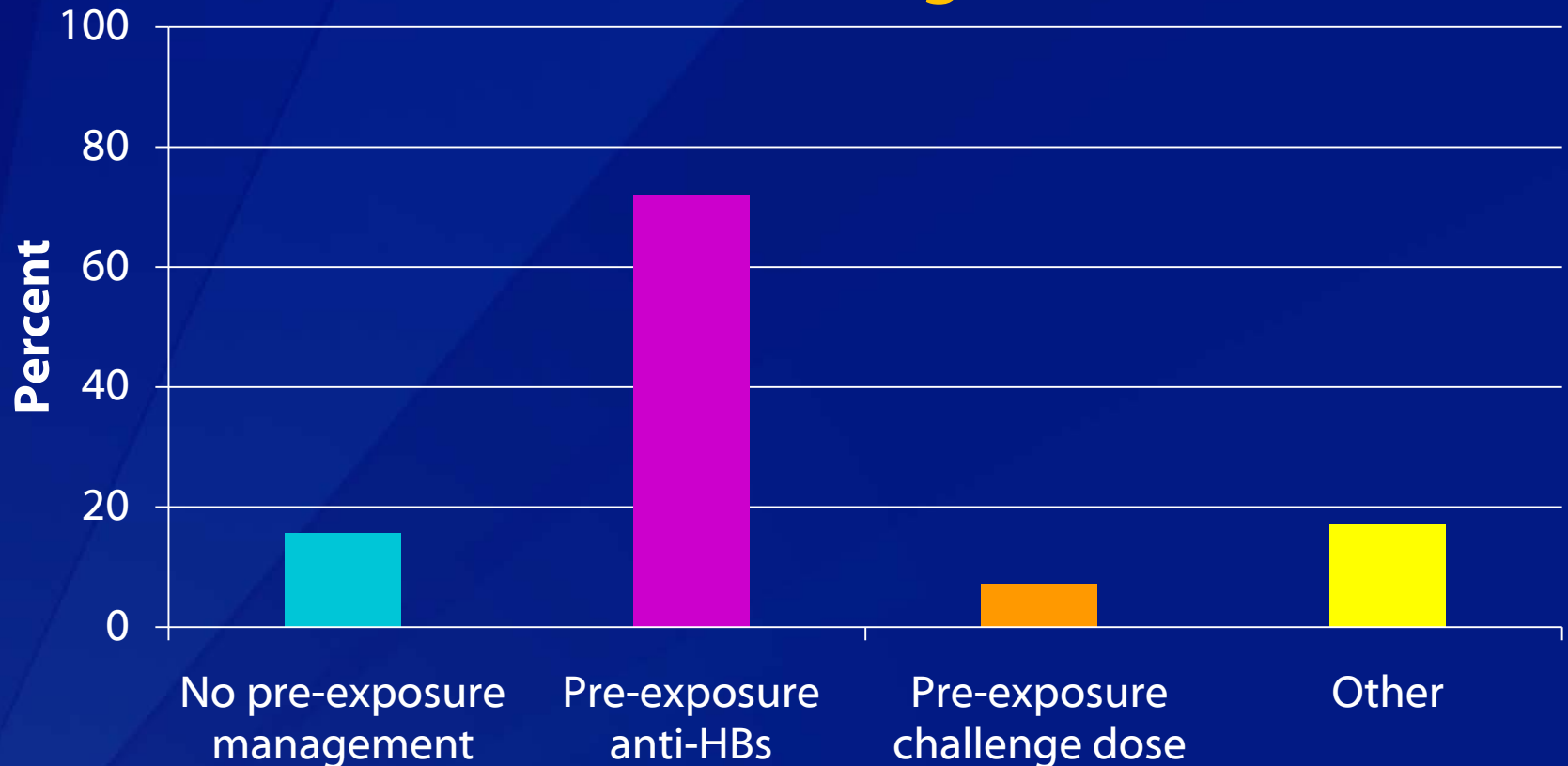
<sup>1</sup>Up to 3 additional doses (6 doses total) of vaccine administered pre-exposure; anti-HBs measured after last dose

# Incremental Cost-Effectiveness Ratios (ICERs), US\$ (Assumes 95% Protection)

	No pre-exposure management		Pre-exposure anti-HBs		Pre-exposure challenge dose	
	<u>1<sup>st</sup> year</u>	<u>10 years</u>	<u>1<sup>st</sup> year</u>	<u>10 years</u>	<u>1<sup>st</sup> year</u>	<u>10 years</u>
ICER						
Non-trainees	1,610,998	1,114,364	3,149,183	796,140	6,352,660	1,161,710
Trainees	2,270,801	917,859	4,542,467	893,619	4,507,834	889,668
HBV infections (per 100,000)						
Non-trainees	1.7	--	0.4	--	0.4	--
Trainees	3.0	--	0.7	--	0.7	--

□ ICERs <\$50,000 generally considered cost-effective

# Proportion of Healthcare Institutions Using Various Approaches for Managing Vaccinated HCP Lacking PVS Testing<sup>1</sup>



<sup>1</sup>153 responding institutions (response rate 39.3%); institutions predominantly acute care hospitals



# Information Considered for Identifying Preferred Approach

- ❑ Changing epidemiology of hepatitis B
- ❑ HCP risk of blood and body fluid exposure
- ❑ HCP rates of reporting blood and body fluid exposures
- ❑ Probability of HBsAg-positive source patient
- ❑ Efficacy of hepatitis B immune globulin (HBIG) for post-exposure prophylaxis
- ❑ HCP HepB vaccine coverage
- ❑ Evidence of serologic and clinical protection after vaccination with HepB primary series
- ❑ Evidence of serologic protection after “challenge” dose of HepB vaccine
- ❑ Long-term HepB vaccine protection
- ❑ Acute hepatitis B among HCP
- ❑ Current practices survey

# Work Group's Preferred Approaches for Ensuring Protection for HCP Vaccinated in the Distant Past

- ❑ No pre-exposure management (post-exposure evaluation for all recognized and reported exposures)
- ❑ Pre-exposure anti-HBs, followed by revaccination if necessary<sup>1</sup>

<sup>1</sup>Up to 3 additional doses (6 doses total) of vaccine administered pre-exposure; anti-HBs measured after last dose

# Comparison of Approaches

## No pre-exposure management

- ❑ No protection for unrecognized and unreported exposures
- ❑ More infections
- ❑ Less work now, more work on exposure
- ❑ Lower initial incremental cost-effectiveness ratios

## Pre-exposure anti-HBs

- ❑ Protection for unrecognized and unreported exposures
- ❑ Fewer infections
- ❑ More work now, less work on exposure
- ❑ Lower 10-year incremental cost-effectiveness ratios

# Institutional Characteristics that May Favor An Approach

## No pre-exposure management

- ❑ High staff turnover (e.g., long-term care facilities)

## Pre-exposure anti-HBs

- ❑ Frequent blood and body fluid exposures among HCP
- ❑ High prevalence of HBsAg-positive source patients
- ❑ Post-exposure prophylaxis not readily available (e.g., home healthcare staff)

**Discussion or Questions?**

# ACIP Hepatitis Work Group

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# Acknowledgements

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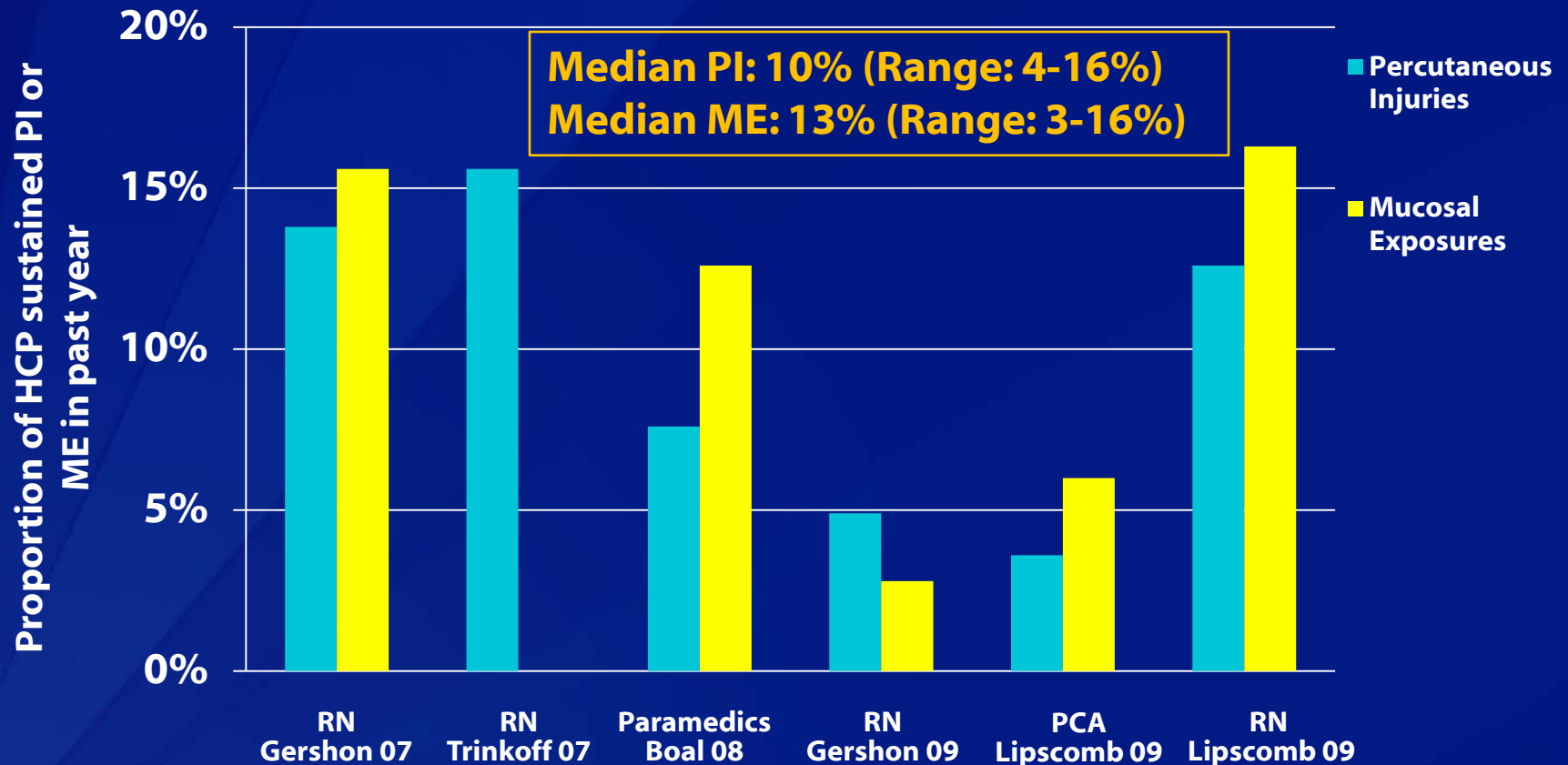
### **Research Triangle Institute, Int.**

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# **Additional Slides**

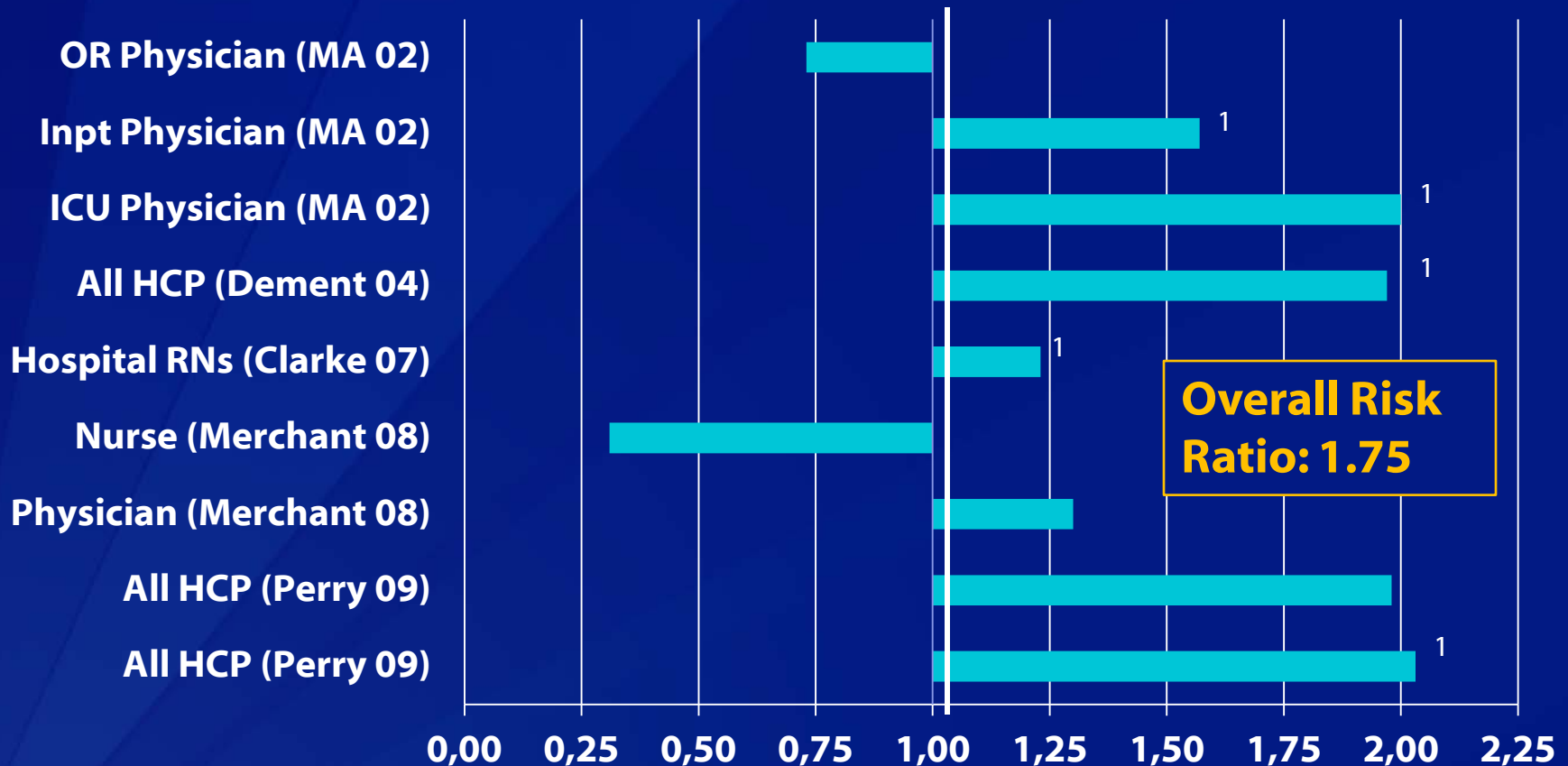


# Annual Proportion of BBF Exposures to HCP (Non-trainees) by Exposure Type, 2002-present



RN=registered nurses (non-hospital based, home healthcare)  
PCA=patient care assistants

# Risk Ratio for BBF Exposure: Trainees vs. Non-trainees



RN=registered nurses, OR=operating room, Inpt=inpatient, ICU=intensive care unit

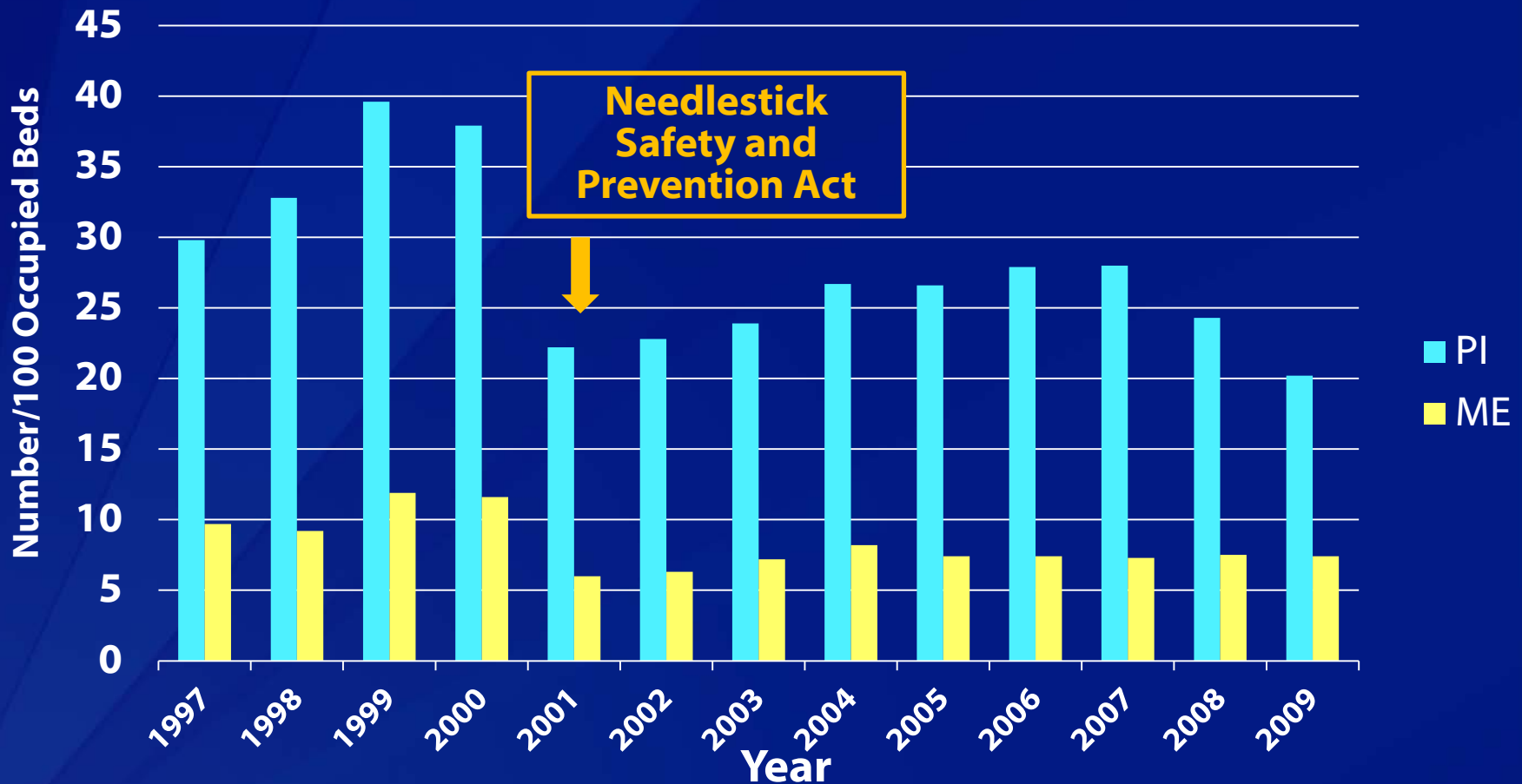
<sup>1</sup>Percutaneous injuries only

# Needlestick Safety and Prevention Act

- ❑ **Directed OSHA to revise Occupational Exposure to Bloodborne Pathogens Standard**
- ❑ **Established in greater detail requirements that employers identify and use effective and safer medical devices<sup>1</sup>**
  - **Effective since 2001**

<sup>1</sup><http://www.osha.gov/SLTC/bloodbornepathogens/standards.html>

# Rates of Percutaneous Injuries (PI)<sup>1</sup> and Mucosal Exposures (ME)<sup>2</sup> — EPINet, 1997-2009<sup>3</sup>



EPINet=Exposure Prevention Information Network

<sup>1</sup>PI=Needlestick, cut, or bite

<sup>2</sup>ME (termed "blood and body fluid exposures" by EPINet)=Contact with mucous membranes or non-intact skin

<sup>3</sup><http://www.healthsystem.virginia.edu/pub/epinet/rates.html>

# Prevalence of Chronic Hepatitis B among Selected Populations

Population	Prevalence	Source
US population (overall)	0.3%	Wasley 2010
Alaska Natives	1% - 2%	Personal communication <sup>1</sup>
Inmates	1% - 4%	MMWR 2003/52 (RR01)
Injection drug users	3%	MMWR 2006/55 (RR16)
US immigrants	4% - 11%	Mitchell 2011
HIV-positive persons	6% - 14%	MMWR 2006/55 (RR16)
API in NYC	12% - 24%	Wang 2011

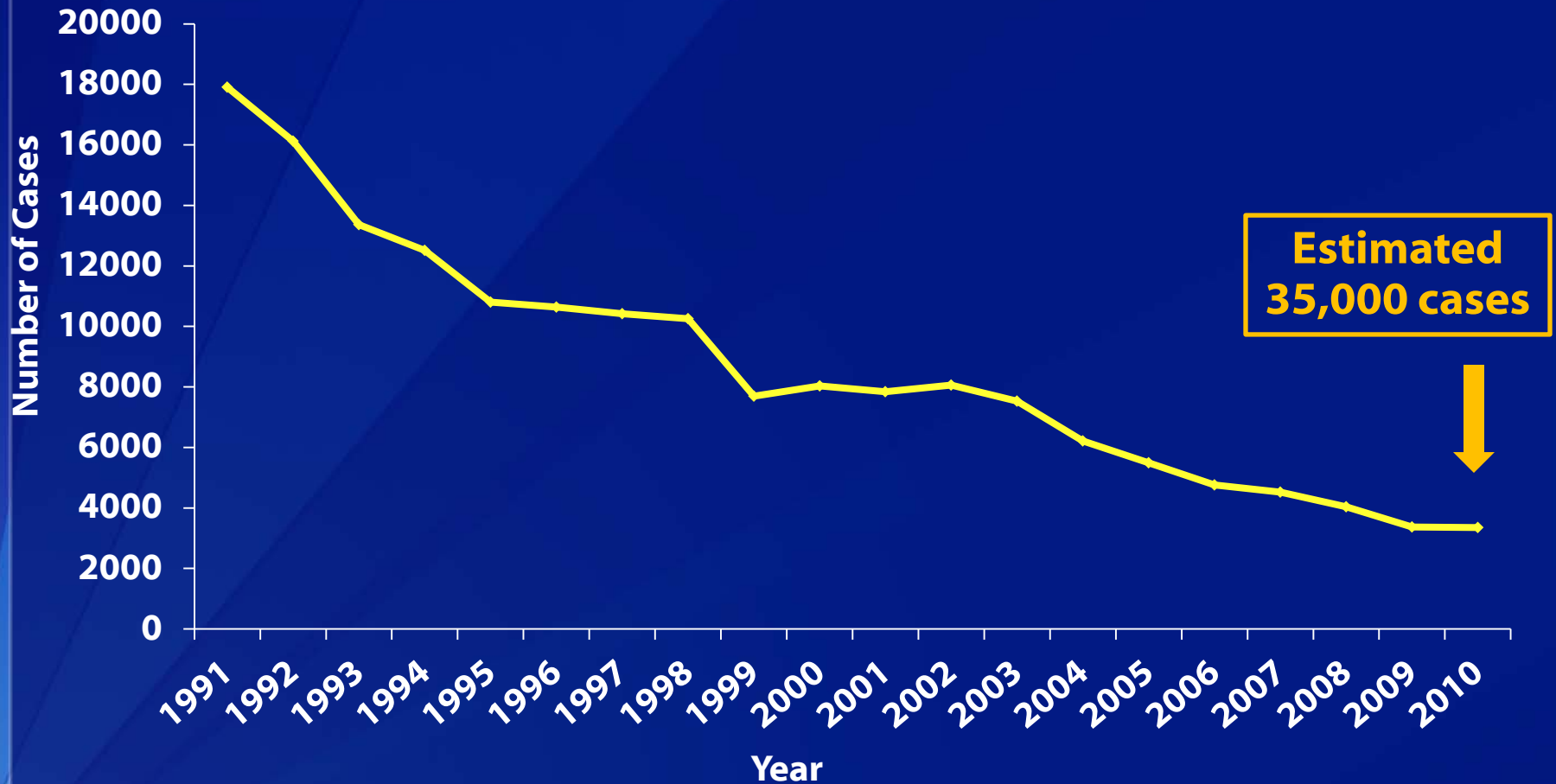
□ 0.9%<sup>2</sup> of source patients HBsAg-positive

API=Asian Pacific Islanders

<sup>1</sup>Brian McMahon and Brenna Simons, Alaska Native Tribal Health Consortium

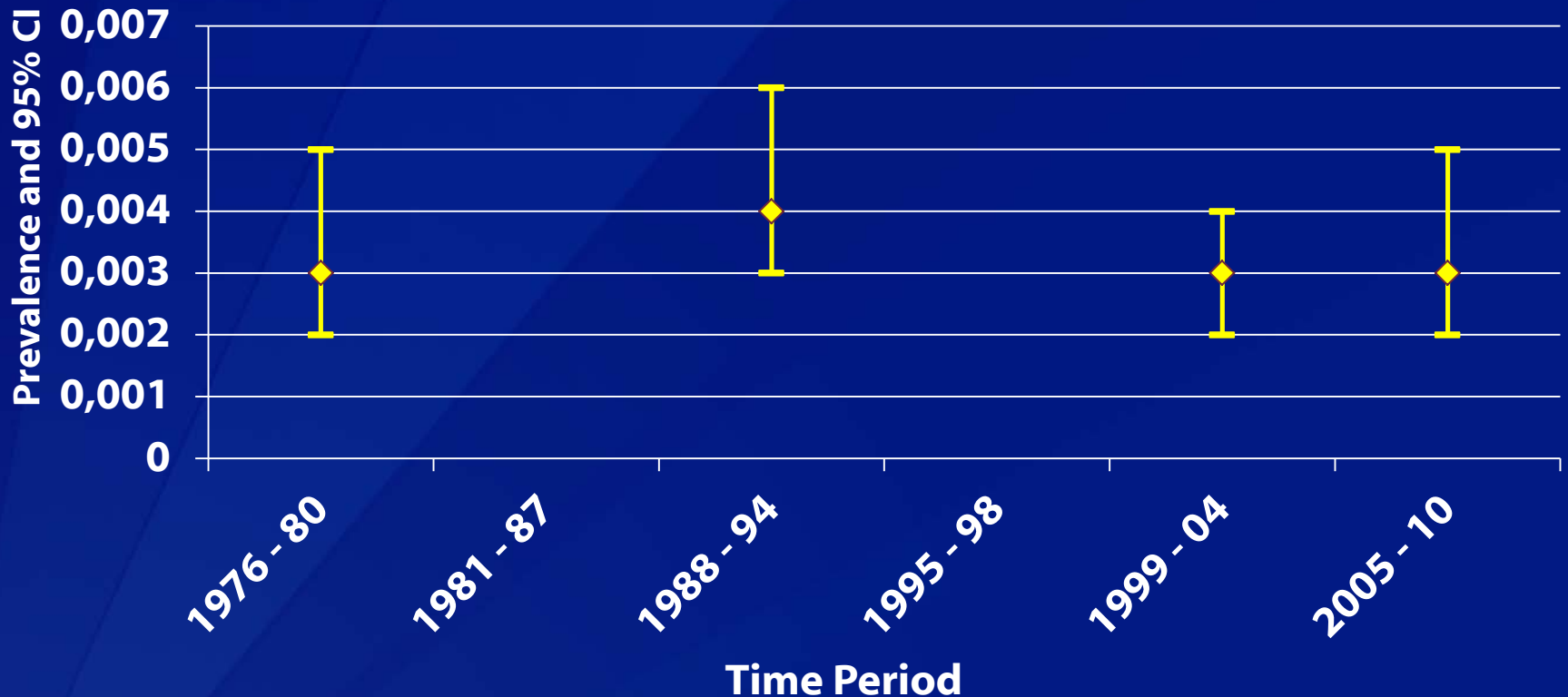
<sup>2</sup>Representing 7,170 exposures from three healthcare institutions

# Number of Reported Acute Hepatitis B Cases (U.S.) — NNDSS, 1991–2010



NNDSS=National Notifiable Diseases Surveillance System

# Weighted Prevalence of Chronic Hepatitis B<sup>1</sup> (U.S.) — NHANES, 1976–2010



Estimated 800,000 to 1.4 million persons with chronic Hepatitis B in U.S.

NHANES=National Health and Nutrition Examination Survey

<sup>1</sup>Chronic Hepatitis B defined as the presence of both hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc), prepared by H. Roberts

# Other Hepatitis B Risk Factors

Risk Factor <sup>1</sup>	Reported to CDC (N=203)	History of ≥3 doses HepB vaccine <sup>2</sup> (N=35)
Contact with Hepatitis case	36/155 (23.2%)	4/25 (16.0%)
Dialysis patient	1/171 (0.6%)	1/24 (4.2%)
Blood transfusion	9/191 (4.7%)	2/35 (5.7%)
MSM	10/39 (25.6%)	1/2 (50%)
Injection drug use	11/192 (5.7%)	1/34 (2.9%)
Multiple sex partners	52/141 (36.9%)	9/22 (40.9%)
Surgery	46/192 (24.0%)	7/35 (20.0%)
Acupuncture	7/144 (4.9%)	1/25 (4.0%)
Tattoo	38/189 (20.1%)	8/35 (22.9%)
<b>Any of above</b>	<b>121/203 (59.6%)</b>	<b>18/35 (51.4%)</b>

<sup>1</sup>During 6 weeks – 6 months prior to illness except blood transfusion

<sup>2</sup>Excludes 4 misclassified cases

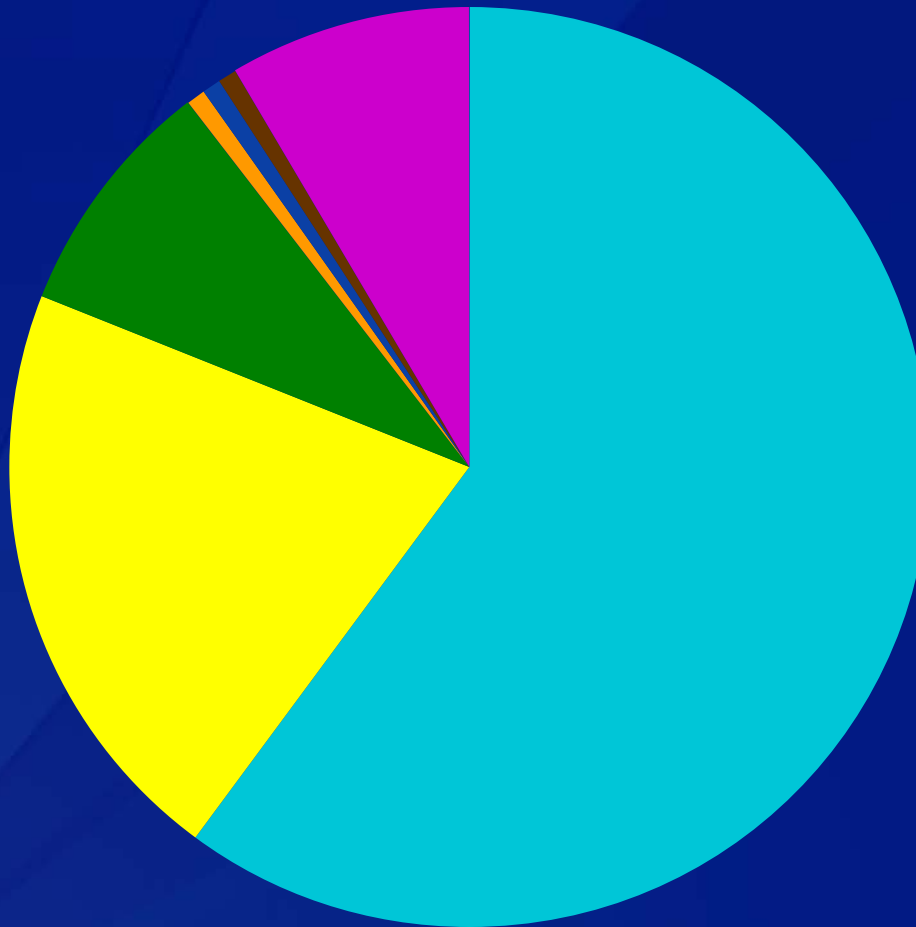


# Current Practices Survey

- ❑ **Administered electronically to 580 listserv subscribers in California**
  - Predominantly infection control and employee health staff
- ❑ **One survey to be completed per institution**
- ❑ **Assessed current practices for ensuring healthcare personnel (HCP) protection against Hepatitis B Virus (HBV)**
- ❑ **153 responses**
  - 39.3% response rate<sup>1</sup>

<sup>1</sup>Based on denominator of 389 acute care hospitals

# Institution Classification



- Nongovernment Not-for-Profit Community Hospital
- Investor-Owned (For-Profit) Community Hospital
- State and Local Government Community Hospital
- Federal Government Hospital
- Nonfederal Long Term Care Hospital
- Hospital Unit of Institution
- Other

# Institution Characteristics

- ❑ **Number of licensed beds: 8-1801  
(median=202)**
  - 151 (98.7%) have adult beds
  - 78 (51.0%) have pediatric beds
- ❑ **Proportion teaching hospital: 24.2%**
- ❑ **Number of HCP with reasonably anticipated risk for blood or body fluid exposure: 35-15,421  
(median=1000)**