



# Healthcare Infection Control Practices Advisory Committee Meeting

June 15-16, 2009

GCC

Atlanta Georgia

**SAFER • HEALTHIER • PEOPLE™**



# DHQP Updates: Prevention and Response Branch

June, 2009 HICPAC

L. Clifford McDonald, MD

**SAFER • HEALTHIER • PEOPLE™**



# Outline

- Injection safety: linking with CMS and Safe Injection Practices Coalition
- Working with AHRQ to address gaps in HICPAC recommendations
- Ongoing investigations of novel H1N1



# Injection Safety: CDC Perspective...



- Shift in healthcare delivery from acute care settings, such as hospitals, to ambulatory care, long term care and free standing specialty care sites
  - Infection control oversight often lacking
  
- Outbreaks of hepatitis B and C virus and other infections are increasingly recognized in these alternate settings
  - Health departments are facing challenges in evaluating infection control breaches and investigating healthcare associated infections



# Ambulatory Surgery Centers Infection Control Surveys



- 14.9 million procedures took place in ASCs in 2006
- Average survey interval = 8.5 years
- Surveys did not address basic infection control practices
- CDC tools adapted for Nevada
  - Sixty-four percent of the 28 ASCs subjected to a federal survey had condition-level, i.e. serious, noncompliance with the Medicare ASC health and safety standards
- CMS expanded via pilot conducted in OK, NC, and MD
  - 68 randomly selected ASCs
  - Infection control problems were common, ranging from failure to clean equipment between patients, to routine use of flash sterilization of surgical instruments, to re-use of single-dose vials of medication or infusates for multiple patients

# Infection Control Survey Tool is being adopted in nationally as part of new ASC Conditions for Coverage, with support from stimulus package



## PART 2 – INFECTION CONTROL & RELATED PRACTICES

### Instructions:

- Circle the applicable response, as well as information on the manner in which information was obtained
- Unless otherwise indicated, a “No” response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).
- If N/A is circled, please explain why there is no associated observation, or why the question is not applicable

### I. Hand Hygiene

#### Additional Instructions:

- **Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).** Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute

# Injection Safety Campaign



**ONE NEEDLE,  
ONE SYRINGE,  
ONLY ONE TIME.**



Safe Injection Practices Coalition

[www.ONEandONLYcampaign.org](http://www.ONEandONLYcampaign.org)



# "MRSA II" AHRQ/CDC Projects



- Reduction in *Clostridium difficile* infections in regional collaboratives of in-patient healthcare settings
- Reducing the Overuse of Antibiotics by PCP Treating Patients in Ambulatory and Long-term Care Settings
- Improving the Measurement of Surgical Site Infection Risk Stratification and Outcome Detection
- Produce Rapid National, Regional, and State-level Estimates of HAIs to Evaluate the Impact of Inter-agency HAI Initiatives
- Reduction of Infections Caused by KPC-producing Organisms Through Application of Recently Developed CDC/HICPAC Recommendations



# REDUCE MRSA: Randomized Evaluation of Decolonization vs. Universal Clearance to Eliminate MRSA



- Identifies a more cost-efficient and effective alternative to MRSA prevention
- Large, simple, cluster-randomized trial comparing *clinical effectiveness* of:
  - Targeted approach based on screening patients for MRSA colonization to guide use of decolonization regimens
  - More uniform approach (topical chlorhexidine bathing) applied to all patients admitted to the ICU
- Established collaborative relationship and in-kind contribution from 160-facility Hospital Corporation of America (HCA)
- Concept and protocol development with CDC Prevention Epicenters investigators

# SAUL Study

## Standardizing Antibiotic Use in Long-term Care

- Optimizing antibiotic use could reduce adverse events and limit the emergence of drug-resistance bacteria
- Assess current antibiotic practices in a group of LTCFs and apply a published standard to determine appropriateness
  - Utilizes the Loeb et al. “minimum criteria”
  - Validate the use of these criteria
- Develop and pilot new approaches to improve antibiotic use in a subset of LTCFs



# Prevention of BSI in Hemodialysis

- To evaluate true rates of BSI in dialysis patients
  - Establish consensus about preventive measures
  - Pilot study to evaluate antimicrobial locks
- Dialysis collaborative
  - Use “collaborative” approach among motivated outpatient dialysis facilities
  - Evaluate implementation and effect of surveillance combined with best practices to prevent BSI

# Innovation in Hand Hygiene Adherence Measurement

- Current gold standard: direct observation
  - Costly and subjective
  - Technology promising but unvalidated
- Cooperative Agreement (U. Maryland)
  - Radio Frequency Identification (RFID) tagged to hand gel dispensers and employee badges
  - Goal: validate for monitoring, optimize feedback
- Interagency Agreement (U. Iowa)
  - Low-cost wireless technology (motes)
  - Goal: validate, study impact of data feedback, attitudes re e-monitoring





# Healthcare personnel (HCP) with confirmed novel H1N1 infection, United States 2009

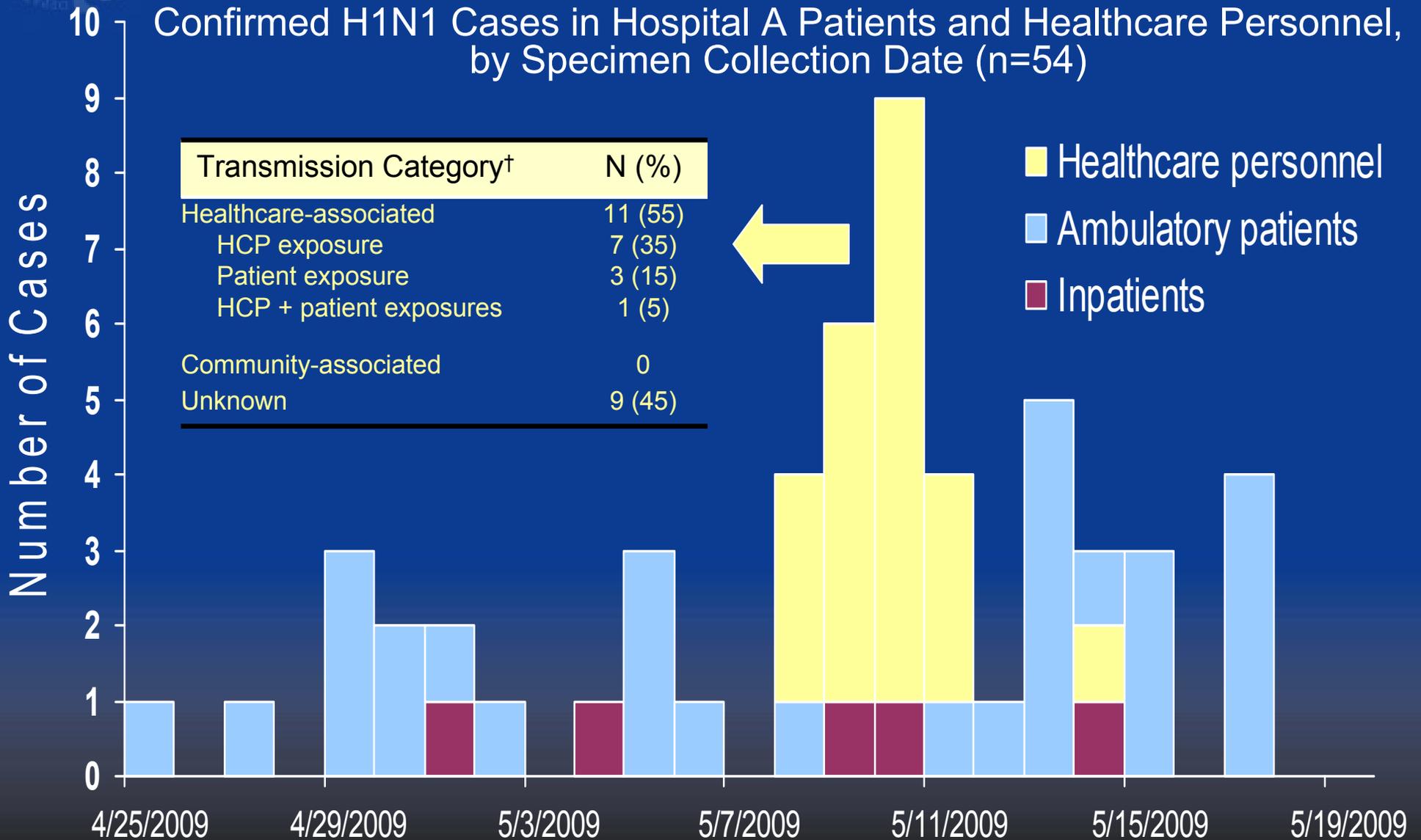
- Reports of infected HCP solicited from May 4 to May 15, 2009
  - 77 HCP reported
  - From 23 states
- Case reports analyzed from first 26 reports
  - Most likely acquisition setting
    - Community 42%
    - Healthcare 50%
      - No HCW with possible or probable Patient to provider transmission used all recommended PPE
      - 3/12 reported using respiratory protection for all encounters

# Assessing healthcare worker exposures to novel H1N1, Ohio, April 2009



- **Background: Surgical resident confirmed case (CC)**
  - 4/23-26: At conference in Arizona
  - 4/27-28: Treated patients while symptomatic
  - 4/28-29: Overnight admission to hospital
  - Facility identifies 166 exposed HCW; 113 receive Tamiflu prophylaxis
  - Low community transmission (1 other confirmed case in OH)
- **Cross-sectional study: Assess protective and risk factors for transmission among healthcare personnel (N=166)**
  - Conducted sero-survey with acute and convalescent blood draws
  - Administered exposure/risk factors and risk perception questionnaires
- **Enrolled 136 participants (102 with acute and conv sera)**
  - 50% did NOT receive seasonal influenza vaccination
    - Of these, 32% were more likely to accept this year because of H1N1 outbreak
  - 37% talked to and 27% worked in OR with CC (22% can't recall)
  - 29% (n=40) recall CC coughing
    - Of these, 40% neither masked and 3% both always masked
  - 66% believe that they are at higher risk of H1N1 infection as HCWs

# Cluster of novel H1N1 at Hospital A– Chicago, 2009



†Based on HCP report of exposures in the 7 days prior to illness onset



# Acknowledgements

- **Injection Safety/CMS**
  - Joe Perz
  - Melissa Schaffer
- **Addressing Gaps**
  - John Jernigan
  - Alex Kallen
  - Priti Patel
  - Kate Ellingson
- **H1N1 Investigations**
  - Alex Kallen
  - Matt Wise
  - Carol Rao
  - Kate Ellingson
  - Mike Jhung
  - Shelly Magill



## Preventing Healthcare Associated Infections

An overview of the historic HHS and CDC investments for HAI prevention through the Economic Recovery Act

Division of Healthcare Quality Promotion  
National Center for Preparedness, Detection and Control  
of Infectious Diseases

**SAFER • HEALTHIER • PEOPLE™**



# Economic Recovery Act

- Funds to HHS to implement HHS Action Plan
- 50\$ M—all funding to states
- HHS HAI Action Plan Steering Committee
  - \$40 M to CDC for state health departments
  - \$10 M to CMS for state survey agencies



# ARRA for HAIs: Mechanism

- Epidemiology and Laboratory Capacity (ELC) Program
  - The purpose of the program is to assist eligible public health agencies improve surveillance for, and response to, infectious diseases by
    - (1) strengthening epidemiologic capacity;
    - (2) enhancing laboratory practice;
    - (3) improving information systems; and
    - (4) developing and implementing prevention and control strategies.
- The focus of the activities is on infectious diseases and drug-resistant infections
- Current funding by CCID programs to all 50 states, DC, PR



# Economic Stimulus Funding ELC Activities (\$35.8 M)



- A: State HAI program
  - State HAI plan and State HAI coordinator
  - Multidisciplinary committee for State HAI program
  - Report to CDC on progress in HAI prevention
- B: Expand NHSN
  - NHSN state coordinator
  - Training for hospitals in state and NHSN expansion
  - NHSN reporting on HHS targets
  - Validation studies in hospitals in state
- C: State Prevention Collaboratives
  - Training for hospitals in state
  - Linkage to other HHS and private sector initiatives
    - AHRQ, CMS
  - Reductions in HHS Prevention targets



# Economic Stimulus Funding EIP Activities (\$4M)

## – Activities:

- Population surveillance in 10 states
- Give a picture of healthcare associated infections throughout the community
  - MRSA
- Developmental work
  - Validation methods
  - Translating MRSA and Clostridium difficile population metrics into metrics that can be used by all states
  - Non-hospital settings: nursing homes, ambulatory clinics, home healthcare

Monday Jun 15, 2009

Print Download Reader Text A+ A-



SEARCH

[Home](#) | [Overview](#) | [Programs](#) | [Plans & Reports](#) | [Grants & Contracts](#) | [Announcements](#) | [Contacts](#)

# Recovery Money

## Funding Available for Health Care Jobs in Needy Communities

\$200 Million in Recovery Act funds are expected to support 3,300 clinicians in health centers, rural health clinics, and other health care facilities that care for the uninsured and underserved people. In exchange for two years service with the National Health Services Corp, clinicians will receive loan repayments of up to \$50,000.

- [National Health Service Corps](#)
- [Number of jobs by State](#)
- [Locate Vacancies](#)
- [Apply for the program](#)

[Where Your Money Is Going](#)[Roadmap to Recovery: Increasing Access to Health Care for People across the Country](#)[Recovery.Gov](#)

Select Program:  Go

[Inspector General Financial and Activity Reports, Inspector General Recovery Plans, and Government Accountability Office Findings.](#)

## CDC: Infectious Diseases Recovery Plan

Last updated: 2009-05-15

### Table of Contents

Click on each of the links below to read the part of the Plan relating to each topic.

- [Objectives](#) | [Measures](#) | [Schedule and Milestones](#) | [Projects and Activities](#) | [Review Process](#) | [Cost and Performance Plan](#) | [Energy Efficiency Spending Plans](#) | [Program Plan Award Types](#)

### Fraud, Waste and Abuse

Report misuse of Recovery funds to [Inspectors General Hotlines](#) and find [Whistleblower Information](#).

### State, Local, Tribal and Territorial Information

Link to [State Recovery Sites](#) and [Tribal News](#) to learn about recovery progress in your area.

### Agency Sites and Information

Track Agency progress with [Financial and Activity Reports](#), read the [Agency Recovery Plans](#), and visit [Agency Recovery Sites](#).

## Objectives

### Program Purpose

To improve and support state health departments' capacity for rapid scale of HAI prevention, dissemination of HHS evidence-based practices within hospitals, targeted monitoring and investigation of the changing epidemiology of HAIs per new prevention collaboratives, and improve State Survey Agency (SA) inspection capability of Ambulatory Surgery Centers nationwide, enabling SAs to identify and correct infection control deficiencies in ambulatory surgical centers.

### Public Benefits

Healthcare-associated infections occur in all settings of care. It has been estimated that in 2002, 1.7 million infections and 99,000 associated deaths occurred in hospitals alone. The financial burden attributable to these infections is staggering with an estimated \$33 billion in added healthcare costs (2009; 1-2 ). Recent research efforts supported by the CDC and the Agency for Healthcare Research Quality (AHRQ) have shown that implementation of CDC HAI prevention recommendations can reduce some healthcare-associated infections by as



# Clinical and Environmental Microbiology Branch -Updates-

Matt Arduino, MS, DrPH



# Updates

- Research on Nontuberculous mycobacteria on healthcare water distribution Systems
- Influenza Research Activities

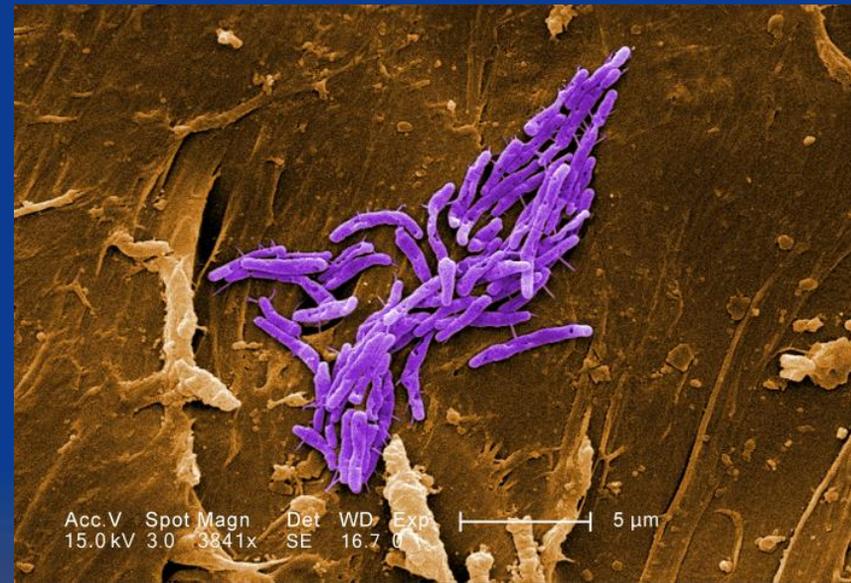


# Nontuberculous Mycobacteria

## ■ Pennsylvania Skilled Nursing Facility Intervention Study

- Facility with patients on vents
- 5 patients with AFB+ bronchoscopies (*M. chelonae* complex)
- Water contaminated with many rapid growers as well as ice-machine; facility conducted hyper-chlorination and installation of point of use filters

## ■ Legionella monochloramine Study



*Mycobacterium fortuitum* microcolony; SEM Image: Janice Carr



# Twenty four week evaluation of point-of-use filters in a long term care facility



Table 1. Species isolated from a long term care facility and a nearby location

Water Sample Location	Species
Facility Nurse Station Sinks	<i>Mycobacterium fortuitum</i> / <i>M. peregrinum</i> complex <i>M. chelonae</i> <i>M. mucogenicum</i>
City Water Main Supply, Facility Basement	<i>Mycobacterium fortuitum</i> / <i>M. peregrinum</i> complex <i>M. chelonae</i>
Service Station, One Block South	<i>M. mucogenicum</i>



# RGM in premise plumbing of a SNF, demonstrating efficacy of POU filters



Estimated Concentration of NTMs (log<sub>10</sub> CFU/ liter)

<u>Sample Site</u>	<u>Water</u>	<u>4 Wks</u>	<u>8 Wks</u>	<u>12 Wks</u>	<u>16 Wks</u>	<u>20 Wks</u>	<u>24 Wks</u>
Unit 2 Nurse Station Sink	Unfiltered	<2.60 <sup>c</sup>	3.82	3.96	<2.60	3.93	3.11
	Filtered <sup>a</sup>	ND <sup>d</sup>	ND	ND	ND	ND	ND
	Filtered <sup>b</sup>	ND	ND	ND	ND	ND	ND
Unit 3 Nurse Station Sink	Unfiltered	4.36	4.61	4.29	4.75	4.01	3.87
	Filtered <sup>a</sup>	ND	ND	ND	ND	ND	ND
	Filtered <sup>b</sup>	ND	ND	ND	ND	ND	ND
Unit 4 Nurse Station Sink	Unfiltered	2.89	2.92	3.05	<2.60	3.68	3.36
	Filtered <sup>a</sup>	ND	ND	ND	ND	ND	ND
	Filtered <sup>b</sup>	ND	ND	ND	ND	ND	ND
Inlet City Water Main Supply	Unfiltered	<2.60	<2.60	<2.60	<2.60	2.75	<2.60
Service Station, One Block South	Unfiltered	<2.60	2.64	ND	<2.60	2.85	ND

■ Rapidly growing mycobacteria (RGM) were isolated from this sample; <sup>a</sup>Filtered water sample obtained after the POU filter had been in use for 14 days; <sup>b</sup>Filtered water sample obtained immediately after installation of a new POU filter; <sup>c</sup>RGM counts were present, but not statistically significant; <sup>d</sup>ND = None Detected; detection limit was 3 CFU/ liter



# Efficacy of a point-of-entry monochloramine generator in a hospital hot water system



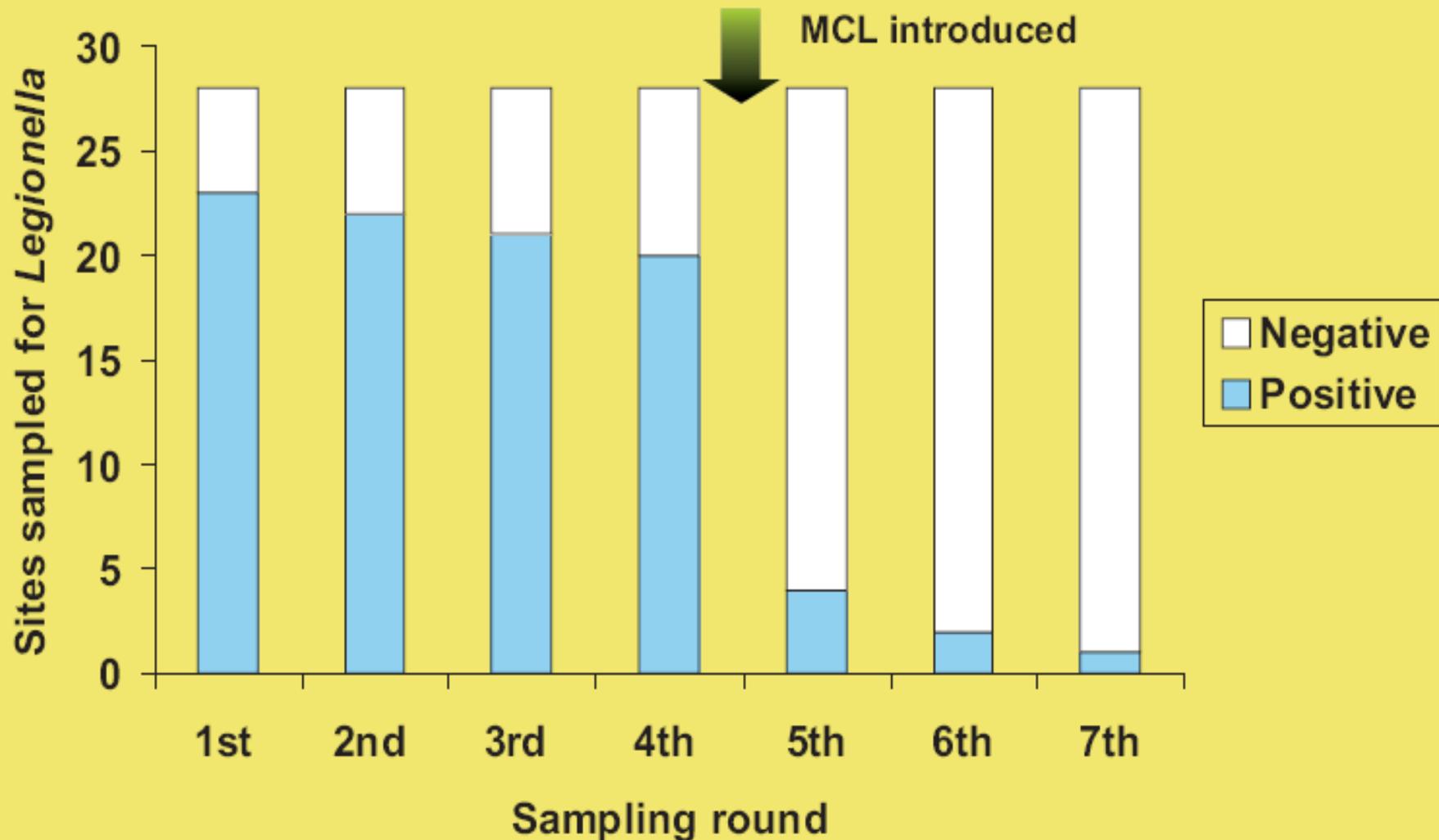
- Collaboration between DHQP, DBD, California DOH, and the hospital
- Hospital has seven floors of patient rooms; receives potable water carrying a free chlorine residual
- Evaluated *Legionella*, mycobacteria, and free-living amoeba in hot water and biofilm before and after monochloramine generation



# Mean Chlorine, Monochloramine (MCL), and pH measurements pre- and post-MCL introduction

Measurement	Pre-MCL (mean)	Post-MCL (mean)
Chlorine	0.2 mg/L	0.4 mg/L
MCL	0 mg/L	1.3 mg/L
pH	7.4	7.0

Figure 1. *Legionella* culture results pre- and post-MCL introduction\*



\**Legionella* isolates were predominantly *L. pneumophila* serogroup 1



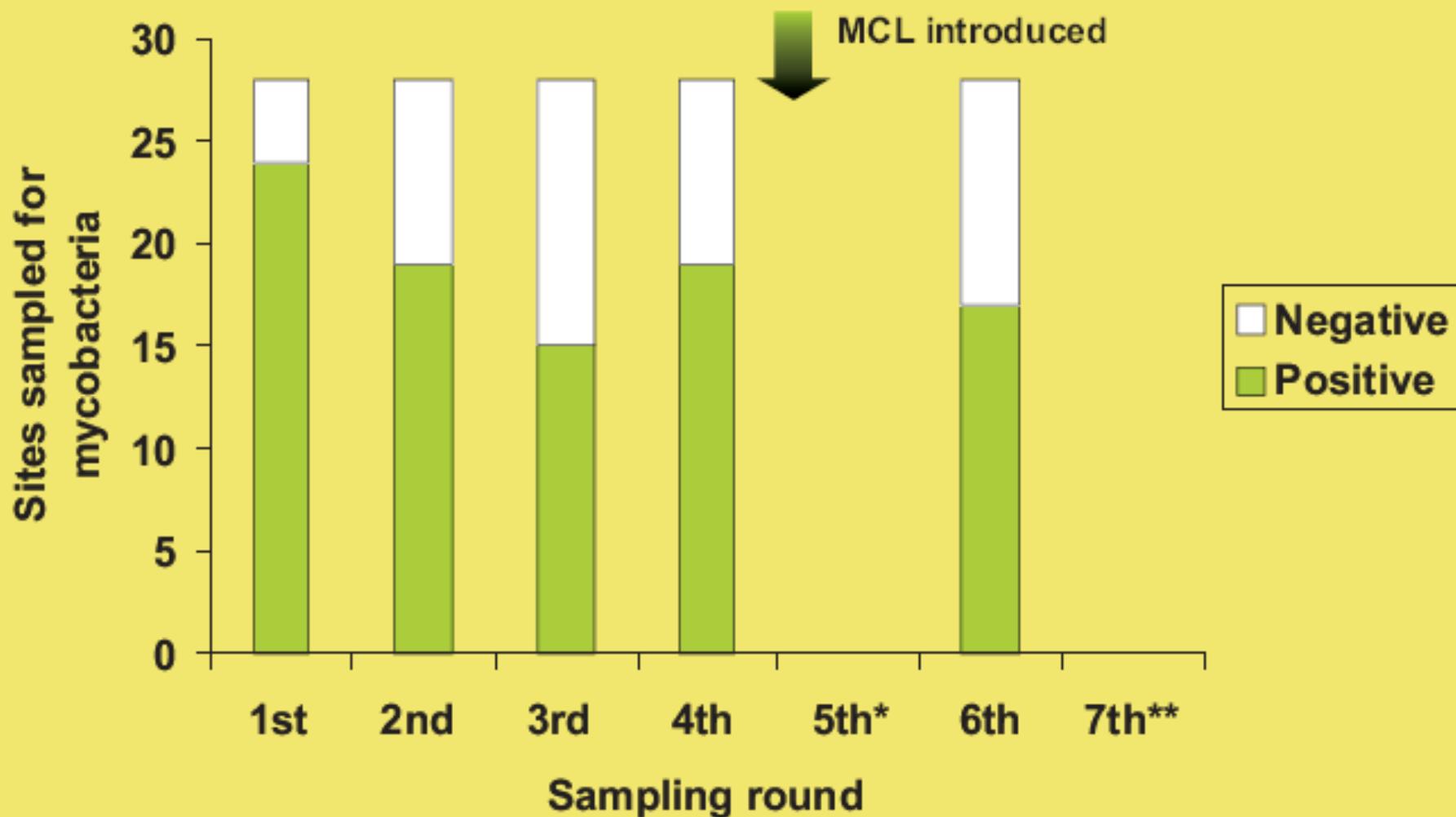
# Presence of mycobacteria in hospital hot water and biofilm

## Percent (%) positive AFB (acid fast bacteria)



Sample	Pre-Monochloramine Samples				Post-Monochloramine Samples		
	1	2	3	4	5	6	7
All Samples	61.8	41.8	32.7	50.0	48.1	74.1	64.3
Sinks	58.8	45.2	32.5	57.1	47.5	86.8	63.6
Showers	65.0	33.3	35.7	33.3	50.0	50.0	66.7
Water	71.4	46.4	32.1	50.0	59.3	85.2	60.7
Biofilm	48.1	37.0	33.3	50.0	33.3	63.0	67.9
Sites	82.1	67.9	53.6	67.9	66.7	89.3	85.7

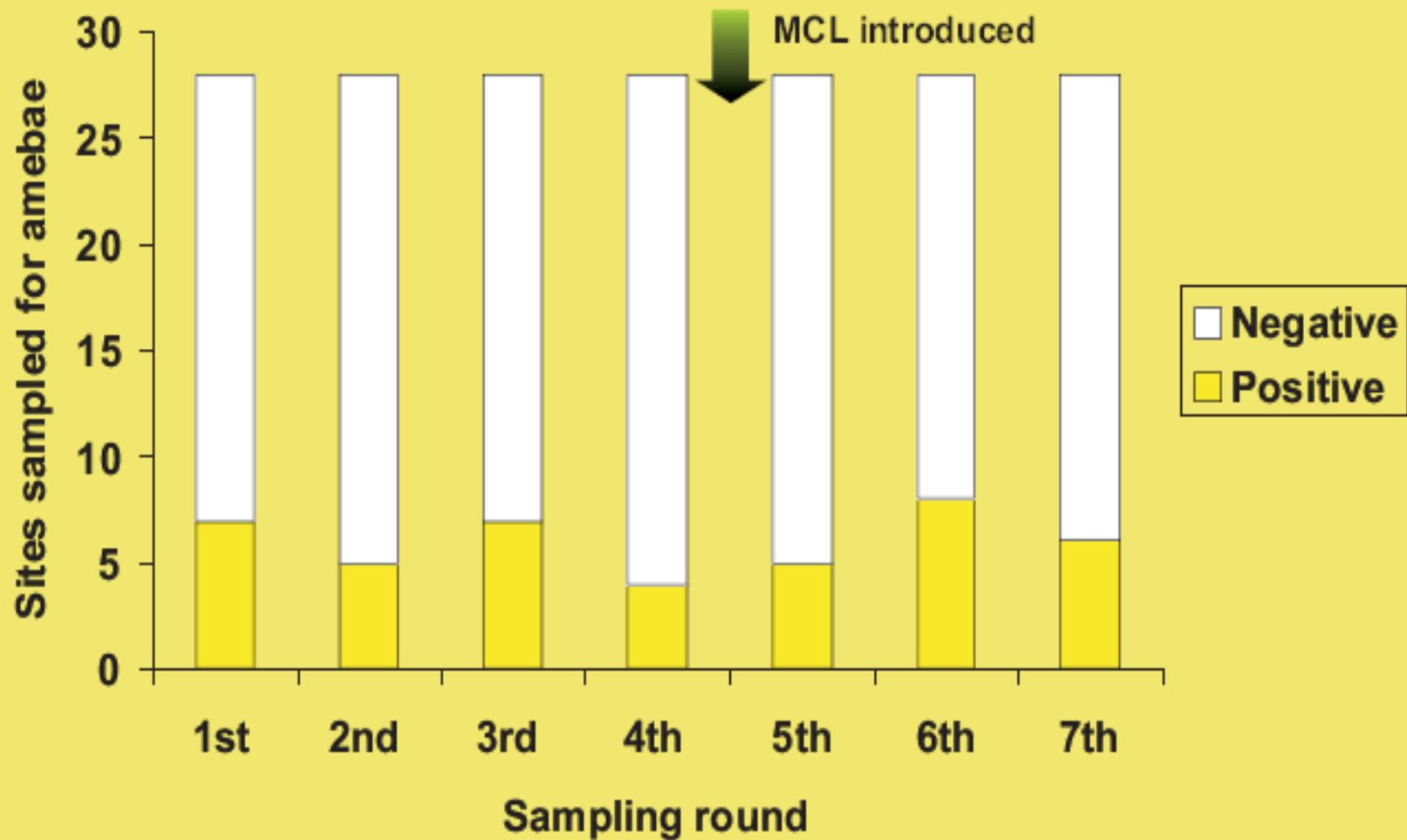
Figure 2. Mycobacteria culture results pre- and post-MCL introduction



\*Not performed

\*\*Results pending

Figure 3. Amebae culture results pre- and post-MCL introduction





# Efficacy of a point-of-entry monochloramine generator in a hospital hot water system

- Addition of MCL into a hospital potable water system rapidly reduced *Legionella* colonization.
- Mycobacteria and amebae colonization did not change significantly.
- On-site MCL introduction may be a promising option for lowering risk of healthcare-associated LD.

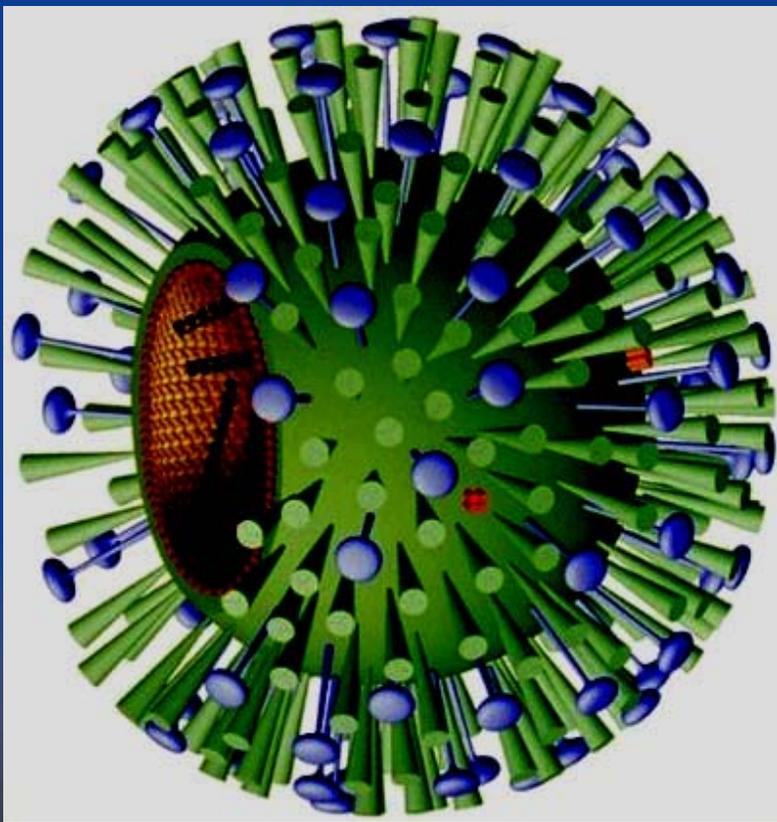


# Influenza Research Activities

- 1. Evaluation of environmental persistence of influenza viruses on environmental surfaces and fomites at various temperatures and humidity.
- 2. Evaluate contamination of N95 respirators (viral persistence and contamination of exterior surfaces)
- 3. Evaluate methods for decontaminating N95s for reuse by healthcare personnel
- 4. Evaluate Sequence for Donning and Removing Personal Protective Equipment (PPE) developed during SARS to determine risk of autoinoculation
- 5. Evaluate the persistence of influenza virus in aerosols



# Influenza Infectivity Study Proposal



Leslie M.V. Rios, Ph.D.  
ORISE Fellow

Division of Healthcare Quality Promotion  
Project Officer Dr. Michael Bell  
Project Coordinator Dr. Judith Noble-Wang



# Specific Aims

- Perform infectivity-persistence experiments of several Influenza virus strains at various temperatures and relative humidity (RH) on surfaces in the presence of blood and respiratory secretions
- Improve infection control guidelines for healthcare workers and hospitals



# Possible Variables

- Strain (4)
  - AH1, AH3, B1, B2
- RH (3)
  - 20%, 40%, 60%
- Temperature (2)
  - 18°C, 25°C
- Time (12 ±)
  - 0hr, 1h, 2h, 3h, 4h, 5h, 6h, 1d, 2d, 3d, 4d, 5d. .
- Fluids (3)
  - Respiratory mucus analog, Whole blood, Media control
- Surfaces (7)
  - Non-Porous: Stainless Steel, Glass, Laminate
  - Porous: Folders, Tissue, Polyester, Cotton



# Methods – Cell Culture

- MDCK Cells
- Serial dilutions in 96-well plates
  - Monitor for 7d for CPE
- Immunostaining
- Calculate  $TCID_{50}$





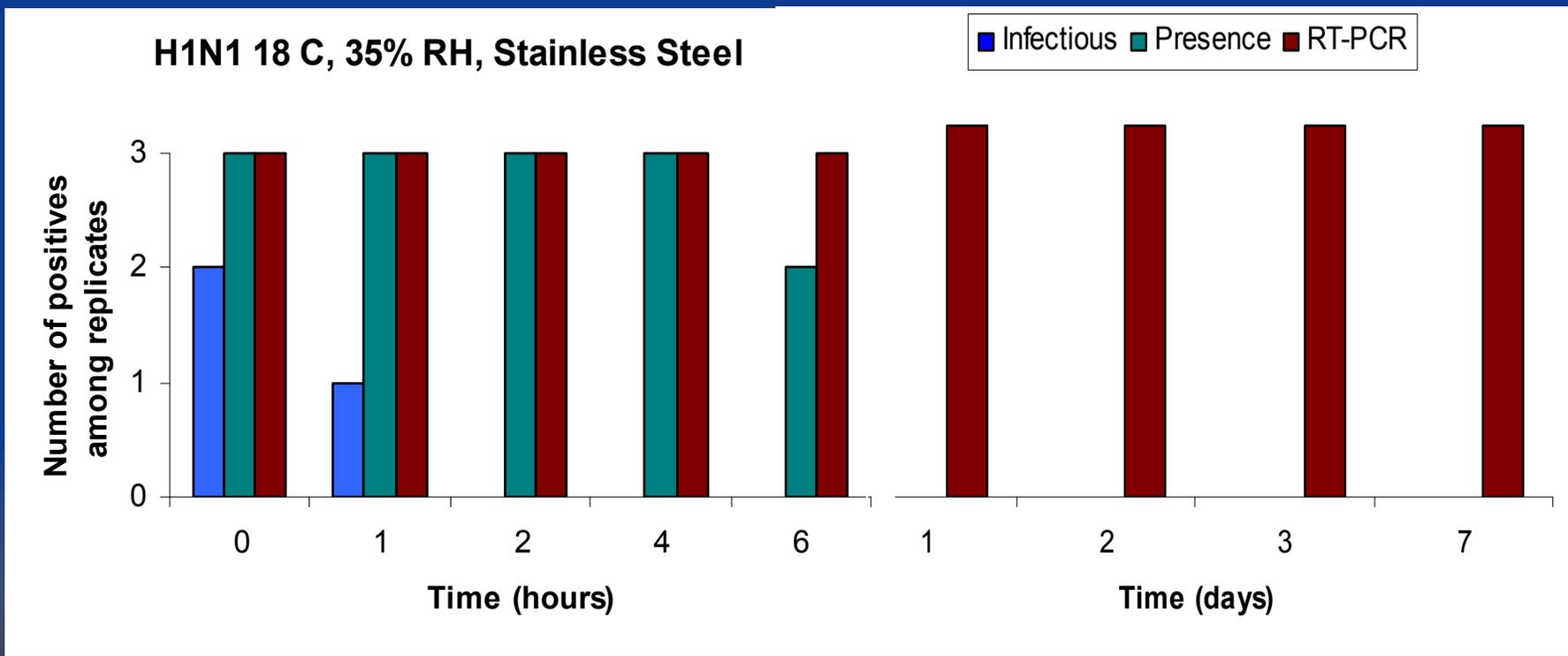
# Methods – Real Time RT-PCR

- Test persistence of viral RNA
- Plot detection limits over time
- Influenza A and B primers
- 96-well plate format

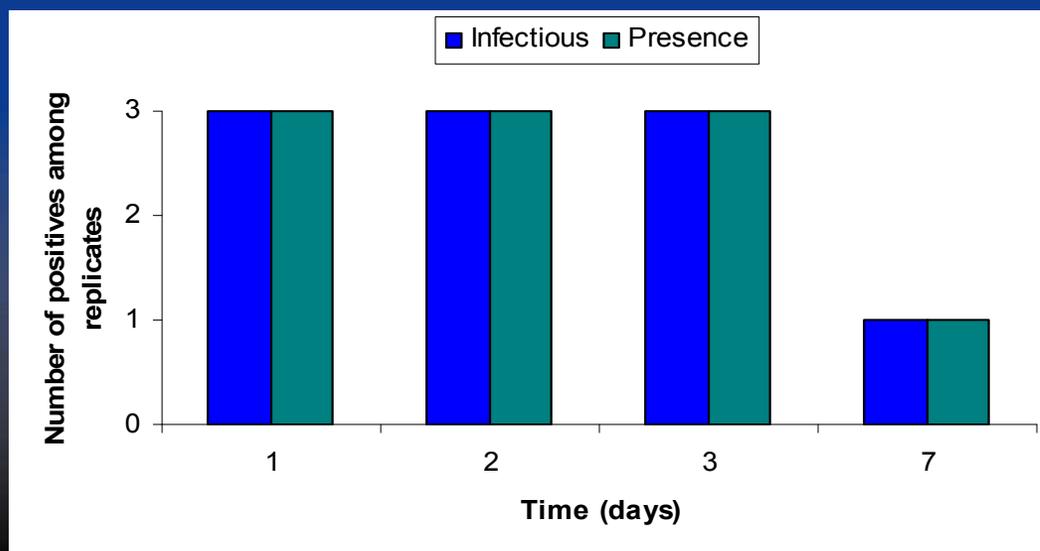
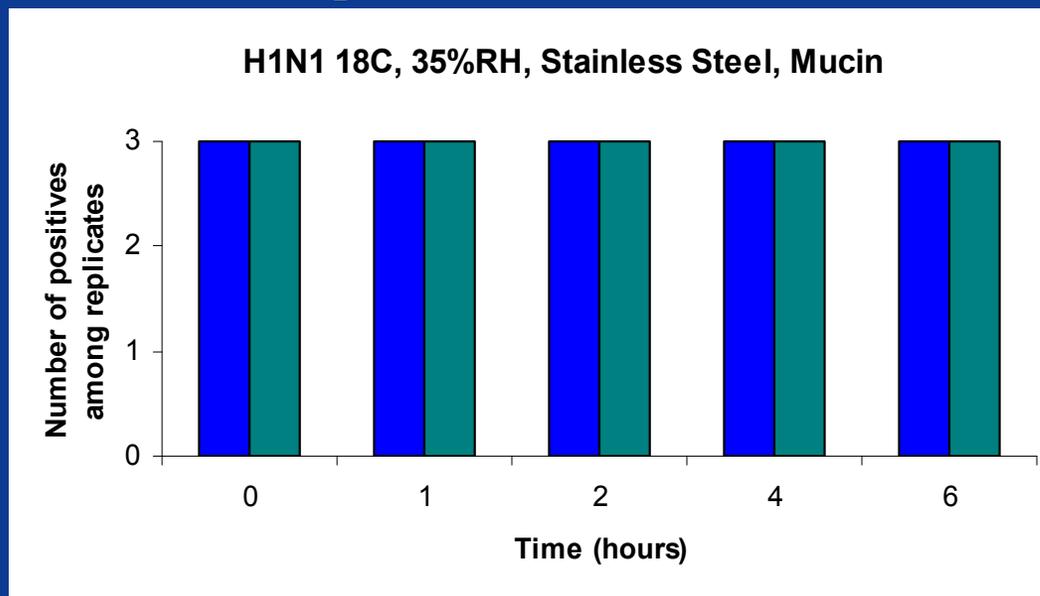




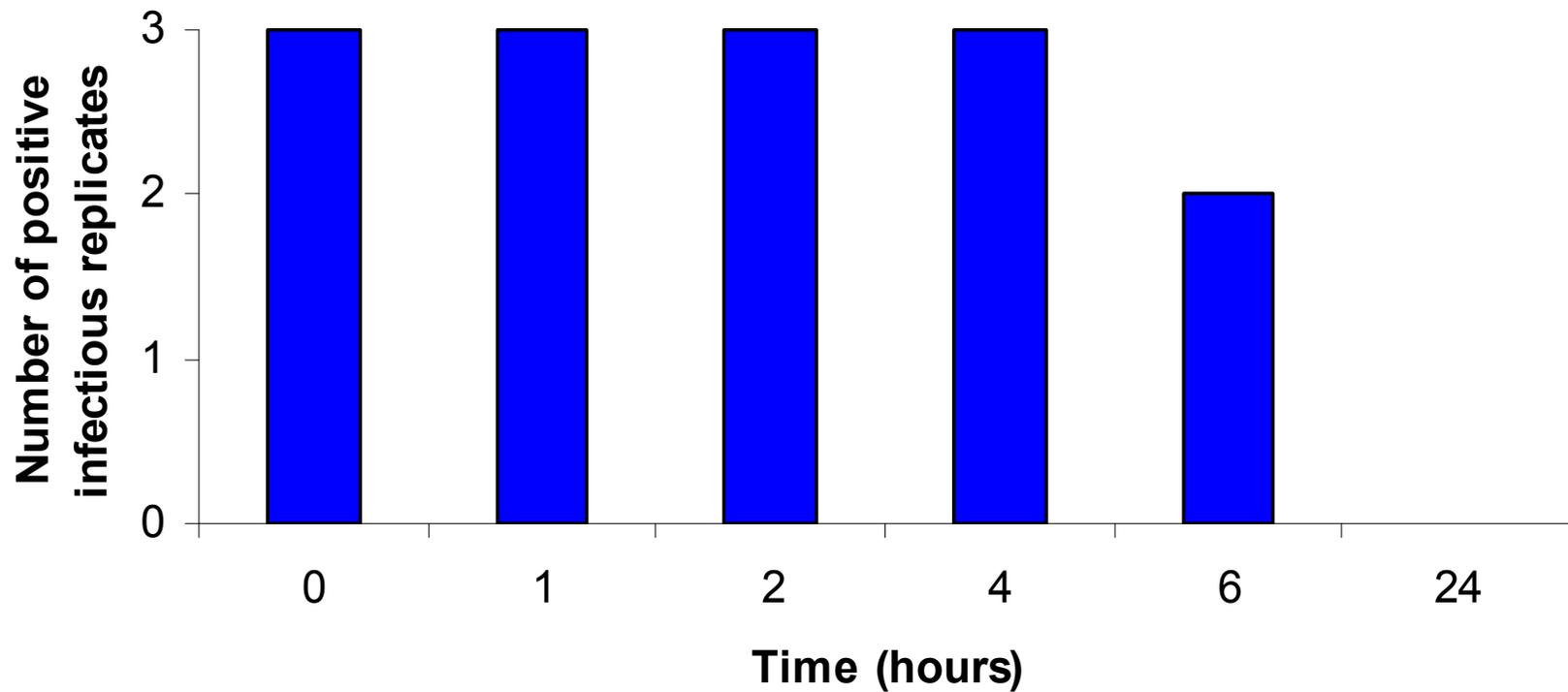
# Results



# Persistence of infectious H1N1 suspended in mucin



# H1N1 suspended in blood on smooth non porous surface, 18°C, 35% RH



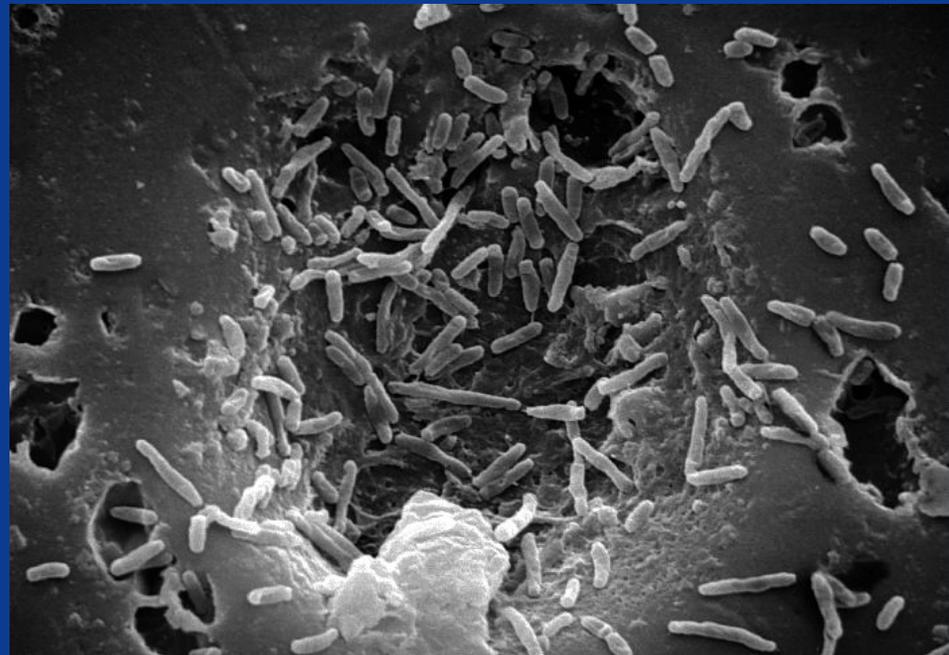
# Acknowledgements

## ■ NTM

- Margaret Williams
- Joseph Carpenter
- Joan Shields
- Catherin Armbruster
- Kristin Perry

## ■ Influenza Studies

- Leslie Rios





# Novel Influenza A (H1N1) Infection Control Working Group

David A. Pegues, MD

HICPAC

June 15, 2009



# Working Group

## Members:

- David Pegues, HICPAC
- Russ Olmsted, HICPAC
- Jeff Engel, HICPAC
- Barbara Soule, HICPAC
- Bill Borwegen, Occupational Health and Safety Director, SEIU
- Katherine Cox, Asst. Dir., Research & Collective Bargaining Services, AFSCME
- Bill Kojola, Industrial Hygienist, AFLCIO

## Listening in:

- Jack Longmire, OSHA
- Patty Bray, OSHA
- Frank Hearl, NIOSH
  
- Phone conference held Tuesday 6/8/09



# Agenda

- Review influenza epidemiology
  - Duration of infectivity
  - Transmission in community and healthcare facilities
  - Role of the environment
  
- Discuss influenza transmission studies
  - Animal models
  - Human volunteers
  - Epidemiologic and laboratory studies
  
- Discuss current infection control recommendations for novel H1N1 (swine flu) and seasonal influenza
  
- Make infection control recommendation for healthcare facilities for H1N1 (swine flu)



# Interim Guidance for Infection Control for Care of Patients with Novel Influenza A (H1N1) Infection in Healthcare Setting

- Respiratory hygiene and cough etiquette
- Patient placement
  - Private room
  - AIR for procedure likely to generate aerosols
- Isolation precautions
  - Standard and Contact Precautions + eye protection
  - Respiratory protection:
    - Fit-tested N95 mask or better for all persons entering the room
    - Ill persons should wear a surgical mask when outside the patient room



# Isolation Precautions for Seasonal Influenza (HICPAC, 2007)

- Respiratory hygiene/cough etiquette
- Patient placement
  - Private room; cohort, if necessary
- Isolation precautions
  - Standard and Droplet Precautions
  - Respiratory protection:
    - Surgical mask when entering patient room (5 days except in immunocompromised persons)
    - Ill persons should wear a surgical mask when patient transport is necessary



# Transmission Studies

## Direct Contact

- Direct (person to person)
- Indirect (fomite)
- Hand washing—Ryan et al, Am J Prevent Med, 1982
  - Reduced total respiratory illnesses
- Fomites—Bean et al, J Infect Dis, 1982
  - Survival up to 24-48 h on nonporous surfaces
  - Transfer to hands up to 24 h



# Transmission Studies Droplet

- Large respiratory droplets  $>10 \mu\text{m}$
- UVA—Saldado et al, Lancet Infect Dis, 2002
  - Rare hospital transmission of influenza
- U Rochester pediatric ward—Bridges et al, Clin Infect Dis, 2003
  - Transmission to adjacent cribs more readily than across room or hall



# Transmission Studies Airborne, 1

- Droplet nuclei  $<5 \mu\text{m}$
- Animal studies
  - Ferret—Andrews, 1941
  - Mouse—Schulman, Nature, 1962  
and Am J Pub Health,  
1968
  - Guinea pig—Mubareka et al, J  
Infect Dis, 2009
    - Airborne transmission of H3N2 is  
efficient
    - Fomite transmission of H3N2 is  
inefficient



# Transmission Studies Airborne, 2

- Human observational studies
  - VAMC TB wards—Blumfeld et al, J Clin Invest, 1959
    - ILI attack rate in UV light vs. non-UV ward: 19% vs. 2%
  - Airliner, Alaska—Moser et al, Am J Epidemiol, 1979
    - 72% attack rate
- Aerosols in UWVa Emergency Department
  - NIOSH, 2009 (unpublished)
  - 53% of virus detected by RT-PCR was in the aerosol fraction  $<4 \mu\text{m}$



# Influenza Transmission Conclusions

- Potential for influenza transmission via contact, droplet, and airborne routes has been demonstrated.
- The relative contribution of these three routes in healthcare-associated influenza transmission has not been established.
- The contribution of respiratory protection to prevention of healthcare-associated influenza transmission in the hierarchy of control measures has not been defined.
- Respiratory protection must be placed in the context of other infection control and administrative measures to limit the occupational transmission of H1N1 (swine flu) in healthcare facilities.



# PPE for Healthcare Workers to Limit the Transmission of Pandemic Influenza

- Recommendation for routine use of respirators
  - IOM, Preparing for an influenza pandemic, PPE for healthcare workers, 2007
  - NIOSH, PPE for healthcare workers, 5 year action plan, 2008
- Recommendation against routine use of respirators
  - Cochrane Review, Interventions for the interruption or reduced transmission of the spread of respiratory viruses, 2009



# Position 1

- NIOSH-certified fit-tested respirators currently should remain the standard for respiratory protection for health care workers caring for patients infected with H1N1 (swine flu)
  - Virus: lack of preexisting immunity and vaccine and potential for increased virulence are concerns
  - Respiratory protection: performance of respiratory vs. surgical mask against aerosol challenge
- Cost and availability of N95 masks and need for fit testing should not be barriers
- Utilize surveillance triggers for implementing respiratory protection
- Priorities
  - Ensure HCW safety, education and compliance with use of PPE
  - Investigate transmission of H1N1 (swine flu) in healthcare facilities
  - Promote further research on aerobiology of influenza and PPE detailed in 2007 IOM report through NIOSH



# Position 2

- Isolation precautions for seasonal influenza (Standard and Droplet) currently are sufficient to limit the transmission of H1N1 (swine flu) in healthcare facilities.
  - Clinical superiority of N95 masks vs. surgical mask in preventing influenza infection from patient to healthcare worker has not been demonstrated
  - Respiratory protection will not impact transmission of influenza among HCWs in the community and will have a limited impact in healthcare facilities
  - Currently, the epidemiology and virulence of H1N1 (swine flu) is consistent with that of seasonal influenza
  - Need to align influenza isolation precautions
- Priorities:
  - Ensure HCW education and compliance with use of PPE
  - Investigate transmission of H1N1 (swine flu) in healthcare facilities
  - Promote further research of influenza transmission in healthcare facilities and efficacy of PPE



# Questions to be Addressed by Working Group

- Final recommendations on novel influenza A (H1N1) isolation precautions
- Clinical and epidemiologic thresholds to modify isolation precautions
- Exclusion of high-risk groups from direct patient care (e.g., pregnant, immunocompromised)
- PPE in non-acute care settings (e.g., ambulatory care, hemodialysis facilities, long-term care facilities)
- Potential impact of antiviral susceptibility and vaccination on these recommendations



# Proposed Changes of MMR Vaccine 'Evidence of Immunity' Requirements for Healthcare Personnel

**Kathleen Gallagher, Amy Parker, Joe Perz, Mike Bell, Jane Seward**

**June 15, 2009  
HICPAC Meeting**

**SAFER • HEALTHIER • PEOPLE™**





# Outline

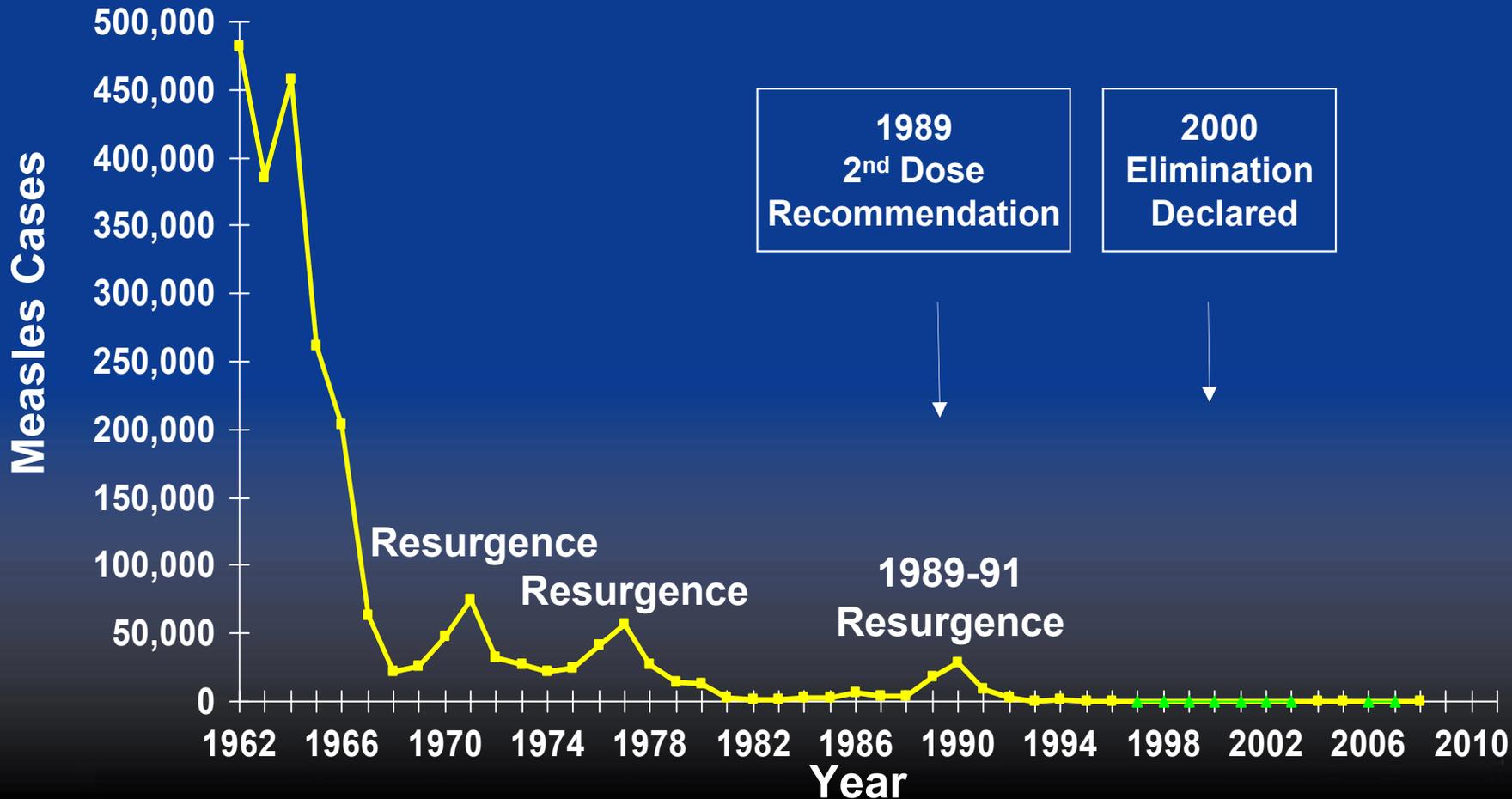
- Provide background on epidemiology of measles, mumps, and rubella and current MMR vaccine and proof of immunity recommendations
- Describe activities/process since last HICPAC meeting
- Discuss currently proposed changes & rationales



# Measles Epidemiology, US, 1962-2008



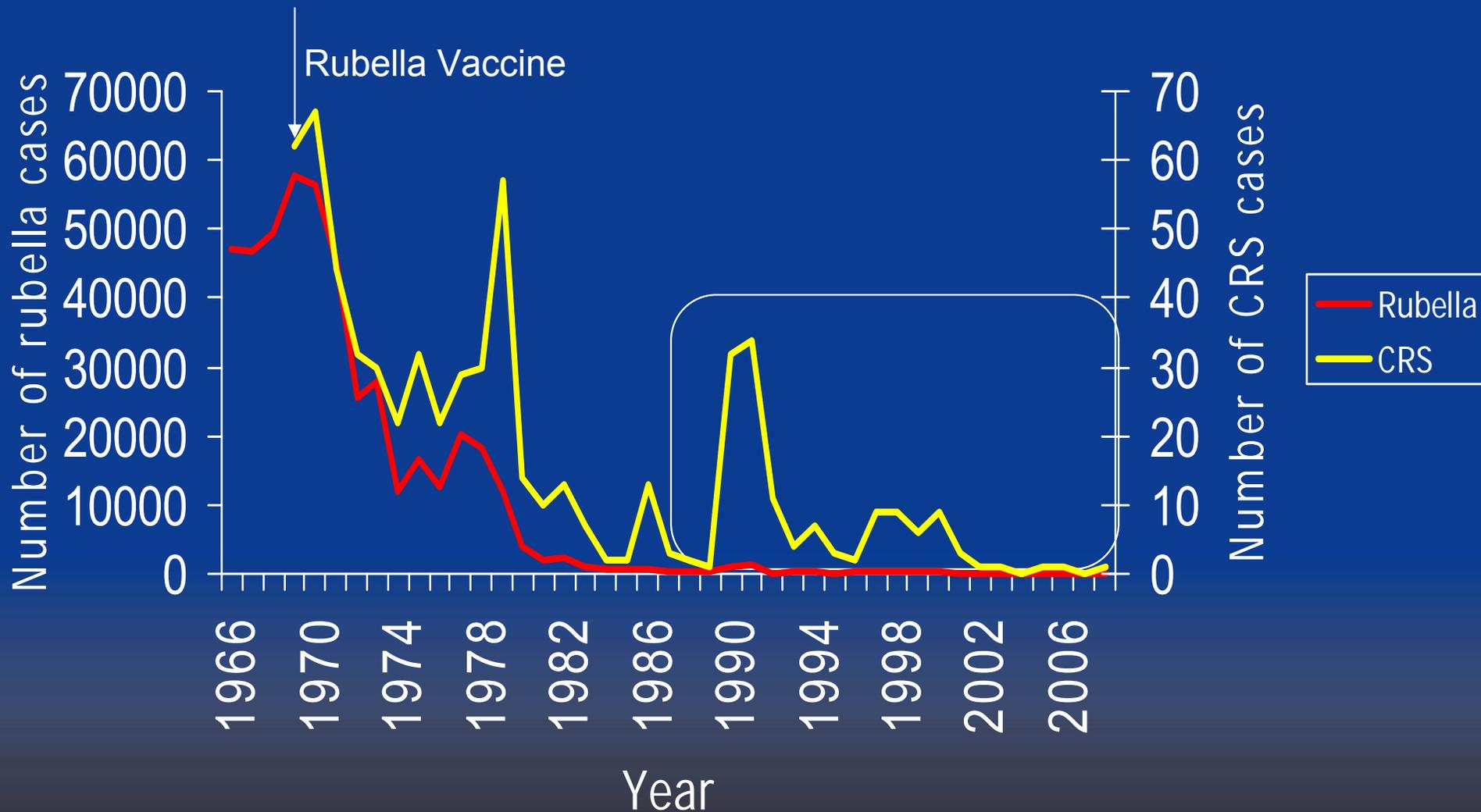
**1963  
Vaccine Licensed  
1<sup>st</sup> Dose  
Recommendation**



\*2008 data through December 5

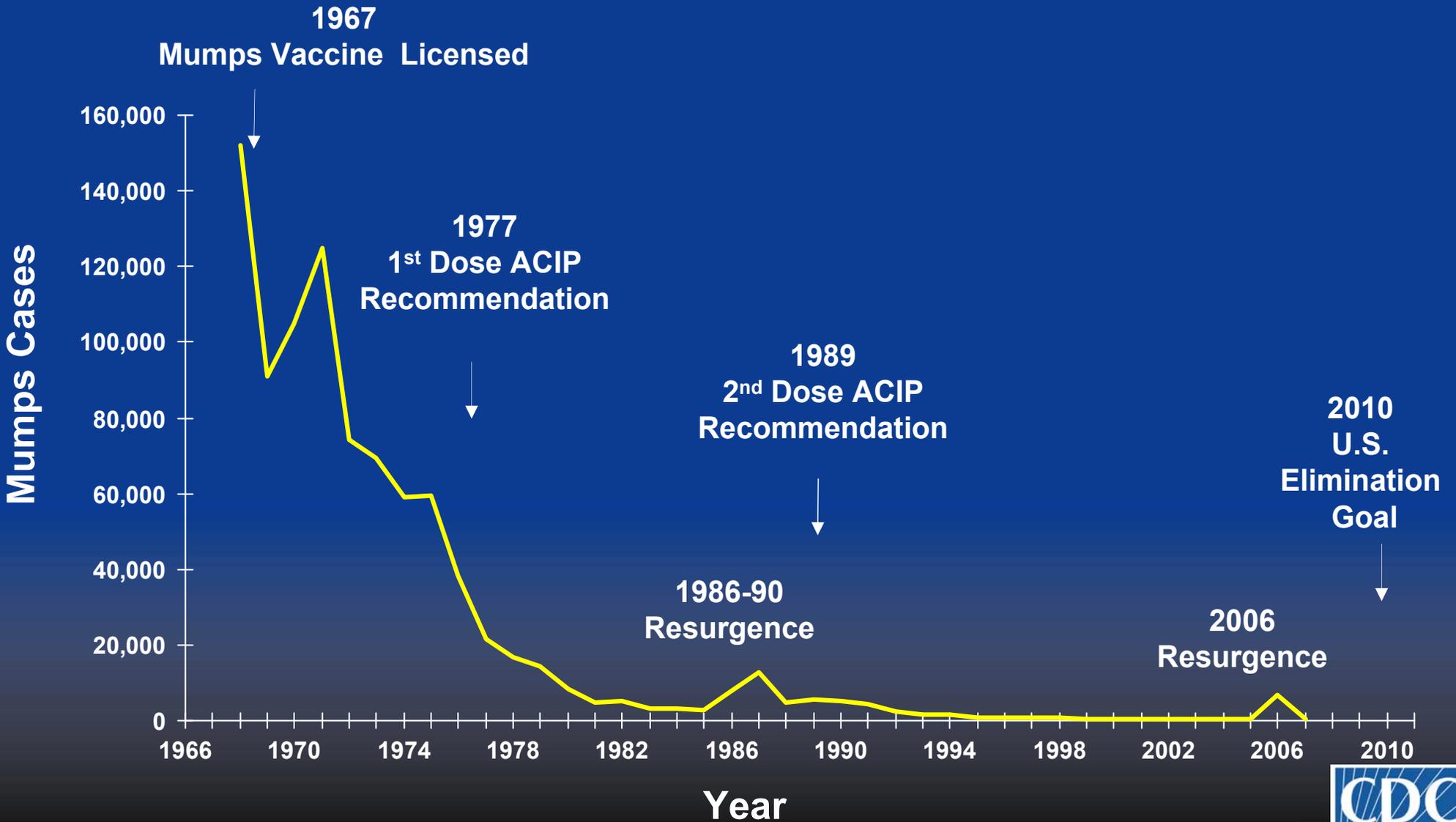


# Reported Rubella and CRS United States, 1966-2008

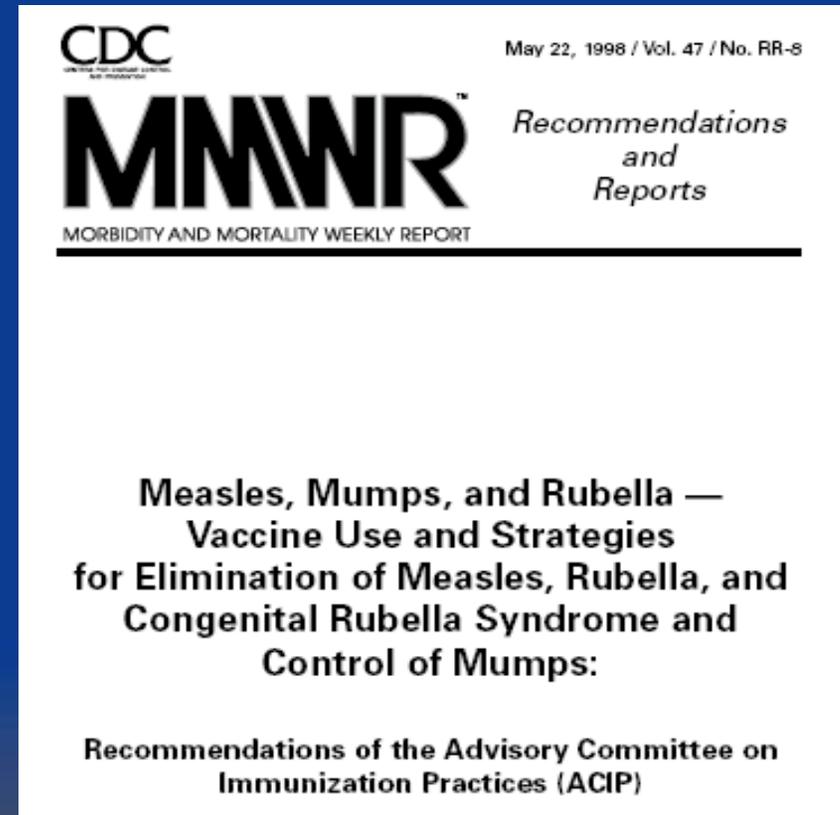
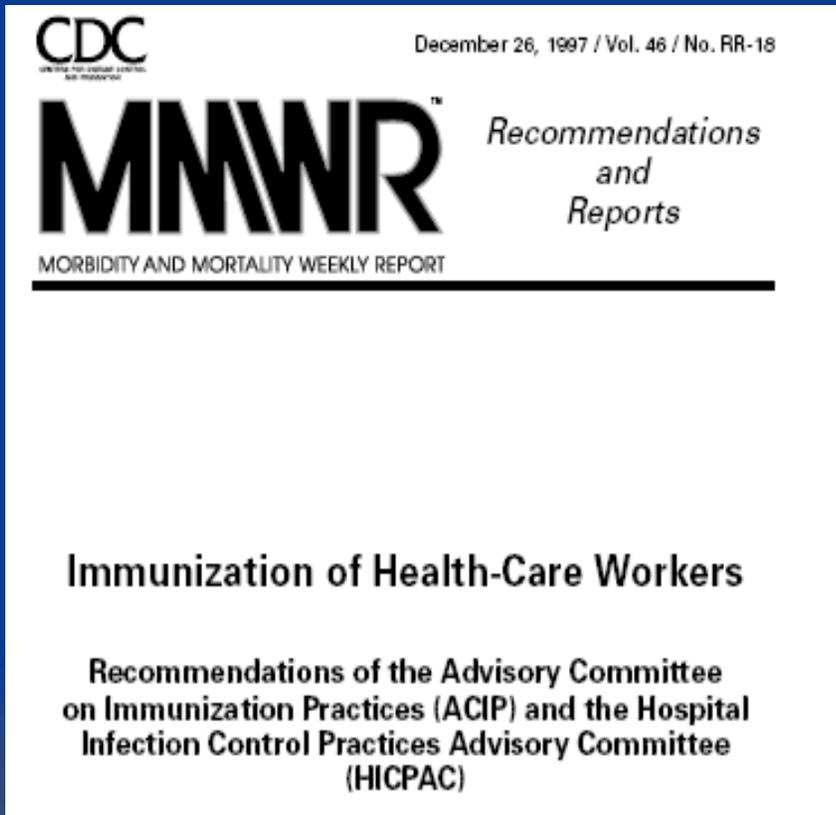




# Mumps Epidemiology, US, 1967-2008



# 1997 ACIP/ HICPAC and 1998 ACIP MMR Recommendations





# Measles and Mumps in Healthcare Facilities

- **Exposures to measles and mumps in HCFs**
  - Virtually all measles cases will visit at least one health care facility during their infectious period
  - 2006 mumps outbreak in the US resulted in numerous health care related exposures
    - Kansas hospital spent \$56,000 containing a mumps outbreak
- **Nosocomial transmission**
  - 1986-1987 nosocomial transmission of mumps in 2 ERs and 2 LTC facilities in Tennessee
  - During 2001- 08, 27(5%) reported measles cases were transmitted in healthcare settings
    - In 2008, 11% of cases
  - Considerable economic costs and public health effort to contain (~\$100,000 to \$400,000)





# Current Routine MMR Vaccine Recommendations for HCP\*



- MMR vaccine policy recommendations:
  - Measles (1998)<sup>1</sup> & Mumps (2006)<sup>2</sup>: 2 doses<sup>+</sup>
  - Rubella (1998)<sup>1</sup>: 1 dose
  
- “Persons who work within medical facilities should be immune to measles and rubella... vaccine should be considered for all personnel, including those born before 1957, who have no proof of immunity”
  
- “health-care facilities should consider recommending MMR vaccine(s) to unvaccinated workers born before 1957”<sup>1</sup>

\* Without other evidence of immunity

<sup>+</sup>MMR is the vaccine of choice when protection against any of these three diseases is required on or after the first birthday, unless any of its component vaccines is contraindicated.

1. CDC MMWR 1997;46{RR-18}:1-42. 2. CDC. MMWR. 1998;47{RR-8}:1-57

2. CDC. MMWR Notice to Readers. 2006;55(22):629-630



# Current ACIP MMR Vaccine 'Presumptive Evidence of Immunity' Requirements for HCP<sup>1,2</sup>

1. Documentation of administration of appropriate vaccination against measles, mumps, and rubella (i.e., administration on or after the first birthday of two doses of live measles and mumps vaccine separated by greater than or equal to 28 days and one dose of live rubella vaccine)
2. Laboratory evidence of immunity
3. Documentation of physician diagnosed disease (measles & mumps)
4. Born before 1957\*+

\*May vary depending on current state or local requirements.

+ Health-care facilities should consider recommending a dose of MMR vaccine for unvaccinated workers born before 1957 who are at risk for occupational exposure to measles and who do not have a history of measles disease or laboratory evidence of measles immunity.

# ACIP Recommendations for MMR Vaccine during *Outbreaks*

- **Measles and rubella outbreaks--** “during outbreaks, health-care facilities also should strongly consider recommending a dose of MMR vaccine to unvaccinated health-care workers born before 1957 who do not have serologic evidence of measles or rubella immunity or a history of measles disease.”<sup>1</sup>
- **Mumps outbreaks--** “During an outbreak, health-care facilities should strongly consider recommending 2 doses of a live mumps virus vaccine to unvaccinated workers born before 1957 who do not have evidence of mumps immunity”<sup>2</sup>

1. CDC. *MMWR* 1998;47{RR-8}:1-57

2. CDC. *MMWR* Notice to Readers. 2006;55(22):629-630





# Changes Proposed at February HICPAC Meeting

- **Currently, healthcare personnel are considered immune if they have one or more of the following:**
  - 1) **Appropriate vaccination against measles, mumps, and rubella (i.e., administration on or after the first birthday of two doses of live measles and mumps vaccine separated by greater than or equal to 28 days and at least one dose of live rubella vaccine)**
  - 2) **Laboratory evidence of immunity or laboratory-confirmation of disease**
  - 3) **Documentation of physician diagnosed disease (measles & mumps)**
  - 4) **Born before 1957**





# Since the Last HICPAC

- Discussed and incorporated feedback received at February's HICPAC and ACIP Meetings
  - Not uniform support for removal of birth before 1957 as proof of immunity
- Obtained additional feedback and consensus from ACIP Adult Working Group (with some invitees from HICPAC)
- Revised proposed changes to the recommendations
- Will be presented at ACIP meeting on June 24<sup>th</sup> for vote



ACIP/HCW 'Evidence of Immunity' Requirements for Healthcare Personnel for MMR Vaccine: PROPOSED LANGUAGE

TABLE 1. Acceptable presumptive evidence of immunity to measles, rubella, and mumps

	Routine	Persons who work in health-care facilities*	International travelers	Students at post-high school educational institutions
Measles	<p>(1) documentation of adequate vaccination+: preschool-aged children and adults not at high risk: 1 dose - school-aged children (grades K-12): 2 doses&amp;,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed measles</del></p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+**,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>
Rubella	<p>(1) documented administration of one dose of live rubella virus, vaccine+,or</p> <p>(2) laboratory evidence of immunity, or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f (except women in this age group who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>
Mumps	<p>(1) documented administration of one dose of live mumps virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of two doses of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity, or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed mumps</del></p>	<p>(1) documented administration of one dose of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of one dose of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>



ACIP/HCW 'Evidence of Immunity' Requirements for Healthcare Personnel for MMR Vaccine: PROPOSED LANGUAGE

TABLE 1. Acceptable presumptive evidence of immunity to measles, rubella, and mumps

	Routine	Persons who work in health-care facilities*
Measles	<p>(1) documentation of adequate vaccination+: preschool-aged children and adults not at high risk: 1 dose - school-aged children (grades K-12): 2 doses&amp;,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed measles</del></p>
Rubella	<p>(1) documented administration of one dose of live rubella virus, vaccine+,or</p> <p>(2) laboratory evidence of immunity, or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f (except women in this age group who could become pregnant++)</p>
Mumps	<p>(1) documented administration of one dose of live mumps virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of two doses of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity, or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f</p> <p><del>4) documentation of physician diagnosed mumps</del></p>

**Proposed change #1: Addition of laboratory confirmation of disease**





# Rationale for Including 'Laboratory Confirmation of Disease'



- Include for completeness. Cases are rare and naturally acquired immunity is robust and long lasting
- Reasonable to conclude that persons who have laboratory evidence of disease are immune
- For surveillance purposes, we rely on laboratory confirmation of disease (especially, measles and rubella)
- Varicella is already including 'laboratory confirmation of disease'<sup>1</sup>

1. CDC. *Prevention of Varicella. Recommendations of ACIP. MMWR. 2007;56{RR-4}:1-37*

ACIP/HCW 'Evidence of Immunity' Requirements for Healthcare Personnel for MMR Vaccine: PROPOSED LANGUAGE

TABLE 1. Acceptable presumptive evidence of immunity to measles, rubella, and mumps

	Routine	Persons who work in health-care facilities*
Measles	<p>(1) documentation of adequate vaccination+: preschool-aged children and adults not at high risk: 1 dose - school-aged children (grades K-12): 2 doses&amp;,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>3) born before 1957@f</p> <p><del>4) documentation of physician diagnosed measles</del></p>
Rubella	<p>(1) documented administration of one dose of live rubella virus, vaccine+,or</p> <p>(2) laboratory evidence of immunity, or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f (except women in this age group who could become pregnant++)</p>
Mumps	<p>(1) documented administration of one dose of live mumps virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of two dose of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity, or laborator confirmation of disease, or</p> <p>(3) born before 1957@f</p> <p><del>4) documentation of physician diagnosed mumps</del></p>

**Proposed change #2: Delete documentation of physician diagnosed disease as adequate evidence of immunity for measles and mumps**





# Rationale for Eliminating 'Documentation of Physician Diagnosed Measles or Mumps'

- Potentially susceptible persons may be working in healthcare settings, because current recommendations are not being adhered to as intended
- It may not be feasible to contact childhood physicians to obtain documentation of disease history
- Accuracy of clinical diagnosis has declined, especially with vaccine-modified disease (mumps)

ACIP/HCW 'Evidence of Immunity' for Healthcare Personnel for MMR Vaccine: PROPOSED LANGUAGE

TABLE 1. Acceptable presumptive evidence of immunity to measles, rubella, and mumps

	Routine	Persons who work in health-care facilities*	
Measles	<p>(1) documentation of adequate vaccination+: preschool-aged children and adults not at high risk: 1 dose - school-aged children (grades K-12): 2 doses&amp;,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed measles</del></p>	h
Rubella	<p>(1) documented administration of one dose of live rubella virus, vaccine+,or</p> <p>(2) laboratory evidence of immunity, or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f (except women in this age group who could become pregnant++)</p>	ci
Mumps	<p>(1) documented administration of one dose of live mumps virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of two dose of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity, or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed mumps</del></p>	

**@ Footnote for ROUTINE circumstances:**  
**For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should strongly consider recommending two doses of MMR vaccine (for measles and mumps) and one dose of MMR vaccine (for rubella), respectively.**



ACIP/HCW 'Evidence of Immunity' Requirements for Healthcare Personnel for MMR Vaccine: PROPOSED LANGUAGE

TABLE 1. Acceptable presumptive evidence of immunity to measles, rubella, and mumps

	Routine	Persons who work in health-care facilities*
Measles	<p>(1) documentation of adequate vaccination+; preschool-aged children and adults not at high risk: 1 dose - school-aged children (grades K-12): 2 doses&amp;,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed measles</p>	<p>(1) documented administration of 2 doses of live measles virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed measles</del></p>
Rubella	<p>(1) documented administration of one dose of live rubella virus, vaccine+,or</p> <p>(2) laboratory evidence of immunity, or</p> <p>(3) born before 1957 (except women of childbearing age who could become pregnant++)</p>	<p>(1) documented administration of one dose of live rubella virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f (except women in this age group who could become pregnant++)</p>
Mumps	<p>(1) documented administration of one dose of live mumps virus vaccine+,or</p> <p>(2) laboratory evidence of immunity,or</p> <p>(3) born before 1957,or</p> <p>(4) documentation of physician-diagnosed mumps</p>	<p>(1) documented administration of two doses of live mumps virus vaccine+</p> <p>(2) laboratory evidence of immunity, or laboratory confirmation of disease, or</p> <p>(3) born before 1957@f</p> <p><del>4) documentation of physician-diagnosed mumps</del></p>

**£ Footnote for OUTBREAKS**

**For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella.**



# Rationale for Strengthening Footnotes for HCP Born before 1957



- It allows HCP born before 1957 to still be considered immune
- Allows facilities that have already been routinely screening or vaccinating these individuals (or that plan to) to have ACIP/HICPAC support to continue these practices
- Recommends aggressive vaccination of HCP when outbreaks occur





# Implementation



- These policies could be implemented with other annual routine disease-prevention measures (e.g., influenza vaccination, TB skin testing)
- Implementation could be started soon and phased in within a few years



# Conclusions



- Current policy was established more than a decade ago and needs to be updated
- In the era of measles and rubella elimination, the goal is 100% immunity in high risk populations. The tolerance for any cases or exposures has decreased.
- HCP are at high risk for exposure so it is important to protect them preemptively.
  - Measles exposures/outbreaks are likely to continue in healthcare facilities
  - Future mumps exposures in HCFs are likely
- Current permissive recommendations are confusing.
- Determining who is presumed immune & who to vaccinate during an outbreak can be costly & disruptive.
- Some facilities already have policies in place that are consistent with the proposed changes.





# Expanded Pneumovax Recommendation

Alexis Elward M.D., M.P.H.

HICPAC

June 15, 2009

**SAFER • HEALTHIER • PEOPLE™**



# Background

- Pandemic Influenza predisposes individuals to secondary bacterial pneumonia
- *Streptococcus pneumoniae* identified in approximately 50% of secondary bacterial pneumonia infections and 20% of deaths during previous pandemics
- Pneumococcal vaccines not available



# Pneumovax

- Pneumovax (PPV 23) currently recommended for:
  - Age  $\geq$  65 years
  - Chronic medical condition predisposing pneumonia
  - Functional or anatomic asplenia
  - Immunocompromised with high risk of pneumonia
  - Asthma
  - Smokers
- Serotypes in PPV23:
  - 1,2,3,4,5,6B,7F,8,9N,9V,10A,11A,12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F



# Proposal

- ACIP is considering expanding recommendation for PPV 23 to critical infrastructure personnel targeted for prepandemic influenza vaccine
- Advantages
  - Relatively young healthy population likely to respond robustly to vaccine
  - Programmatic efficiency with concomitant administration influenza vaccine
  - Maintain critical response functions during a pandemic



# Estimating the Burden

20 million personnel\*

x

Influenza attack rate

x

% due to 23 pneumococcal serotypes  
included in PPV23

=

Expected cases of PPV23-type pneumococcal  
pneumonia attributable to influenza

\*Assuming population similar to overall population, 6.73 million of these have an indication under existing ACIP recommendations



# Assumptions

- Based whenever possible upon the published literature and current pandemic plan.
- Working group considered best, worst and base case scenarios
- Factored in interventions not available during previous pandemics:
  - Antiviral prophylaxis and treatment
  - Non-pharmaceutical interventions
  - Pre-pandemic influenza vaccine
  - Decreased incidence pneumococcal pneumonia as a result of routine childhood use of pneumococcal conjugate vaccine (PCV7)



# Programmatic Assumptions

- Pre-pandemic program implemented at time pandemic is declared
- Target 20 million critical infrastructure personnel—healthcare workers (HCW), electrical and water workers
- Assumed that all critical personnel were between ages 20 and 64
- Two doses of prepandemic vaccine
- Simultaneous administration of PPV23 with first dose of influenza vaccine



# Assumptions: Influenza Epidemiology

- Attack rates similar to previous pandemics in the absence of any 20<sup>th</sup> century interventions
- Attack rates may be reduced through the use of anti-viral prophylaxis, non-pharmaceutical interventions and pre-pandemic influenza vaccine
- Overall reductions in attack rates proportional to the effectiveness of interventions and the proportion of the population that receives them



# Estimating Secondary Bacterial Pneumonia Attack Rates

- 15% of individuals with pandemic influenza infection will go on to develop secondary bacterial pneumonia
- 50% of these cases will be caused by pneumococcus
- 78% of the pneumococcus would be one of the PPV23 serotypes



# Estimates: Results

- All assumptions entered into software package allowing thousands of simulations of various combinations
- Most estimates <100,000 cases
- Most likely estimate was 35,000 cases in the population of 20 million
- Vaccine effectiveness assumed over a broad range from 20-80%



# Number Needed to Vaccinate

Age Group, Years	Assumed PPV23 Vaccine Effectiveness		
	20	50	80
20-49	3,749	1,499	937
50-64	5,644	2,258	1,411

Assumes 31,903 total cases pneumococcal pneumonia, 75-80% caused by PPV23 serotypes



# Preventable Burden of PPV23-type Pneumonia

- In the absence of all influenza interventions
- 5,000-20,000 cases
- 700-3,000 hospitalizations
- 300-1,100 deaths
- Estimate of prepandemic influenza vaccine effectiveness is most important driver



# Economic Analysis

- Single pandemic occurrence, one year
- Analytic horizon included remaining life expectancy of people in target populations
- Cost Effectiveness Analysis used
- Cost-Effectiveness Ratios (CER)



# Cost Effectiveness Ratios

$$\frac{\text{(Vaccine cost + administration cost) - (cost of illness averted by vaccination)}}{\text{Number of outcomes of interest}}$$



# Health Outcomes

- Cases
- Number of hospitalizations
- Deaths
- Life-years saved (LYS)
- Discounted LYS

# Cost Inputs



Cost Category	Age	Base	Lower	Upper
Hospitalized pneumonia				
	15 to <45	\$9,148	\$7,319	\$10,978
	45 to <65	\$10,389	\$8,311	\$12,467
Outpatient				
	20-64	\$272	\$217	\$326
Program cost				
	Vaccine	\$18	\$15	\$20
	Administration	\$12	--	\$20
	Wastage	0.05	0	0.1



# Costs

- Cost of Program: \$608,295,000
- Medical Costs Saved: \$19,657,861
- Net Cost: \$588,637,139



# Summary Measures

Health Outcome	CE Ratio	95% CL
PPV23 pneumonia cases prevented	\$46,449	(\$4,860-\$65,098)
Hospitalizations prevented	\$322,204	(\$51,301-\$685,553)
Deaths prevented	\$840,741	(\$135,875-1,771,196)
Years of Life Saved	\$21,577	(\$3,376-\$47,758)
<b>Discounted Years of Life Saved</b>	<b>\$37,320</b>	<b>(\$5,865-80,359)</b>



# Factoring in Other Interventions:

- Zero effectiveness of neuraminidase inhibitors: \$28,954/Discounted LYS
- Zero effectiveness of pre-pandemic influenza vaccine: \$8,395/Discounted LYS
- All non PPV-23 completely ineffective: \$2,396/Discounted LYS



# Working Group Conclusions

- Rate-based model can be used to estimate burden of pneumococcal pneumonia during an influenza pandemic
- 35,000 cases of secondary pneumococcal pneumonia among 20 million critical infrastructure personnel
- Use of polysaccharide vaccine could have substantial public health benefits
- Increased benefit if influenza interventions ineffective or unavailable
- Cost Effective



# HICPAC Comments

- May be prudent to begin PPV23 vaccination sooner given uncertainties in novel H1N1 vaccine supply and timing
- Is there any surveillance data on frequency of secondary bacterial pneumonia among those with influenza?
  - Data are being collected
- Data from CDC ABC surveillance on risk to HCW without underlying conditions?
  - No data
- Sensitivity should be shown for religious preference
  - Vaccine would be voluntary
- Employee reluctance and fears will need to be addressed



# Update: Guideline for the Prevention and Management of Norovirus Outbreaks in Healthcare Settings

Tara MacCannell, MSc, PhDcand  
Kurt Stevenson, MD, MPH  
Craig Umscheid, MD, MSCE

HICPAC Meeting

June 15, 2009



# Norovirus Guideline Working Group

- Core Working Group
  - Tara MacCannell, DHQP, CDC
  - Kurt Stevenson, Ohio State, HICPAC
  - Craig Umscheid, CEP, UPHS
  - Rajender Agarwal, CEP, UPHS
  - Ingi Lee, CEP, UPHS
  - Gretchen Kuntz, CEP, UPHS
  
- External Review
  - Cliff McDonald, DHQP, CDC
  - Aron Hall, NCIRD, CDC
  - John Boyce, Hospital of St. Raphael, New Haven, CT
  
- Internal Review
  - Keith Ramsey, HICPAC
  - Elexis Elward, HICPAC

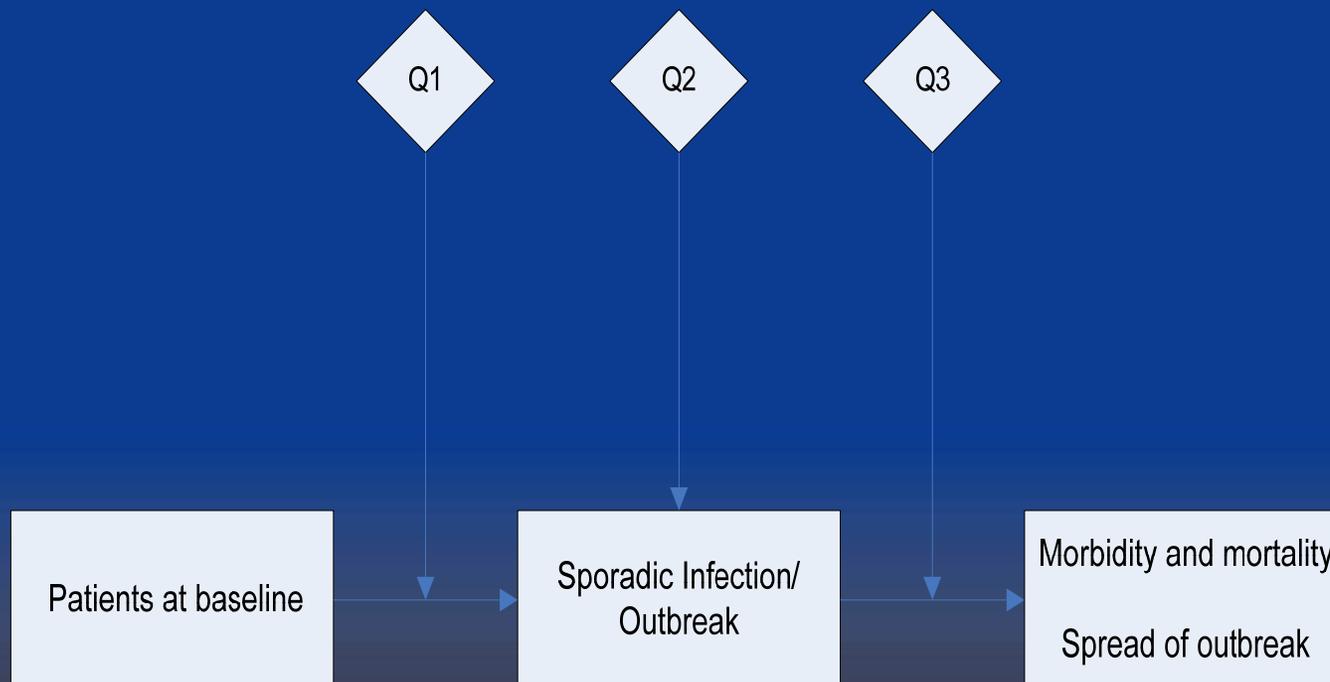


# Key Questions

1. What patient, virus or environmental characteristics increase or decrease the risk of Norovirus infection in healthcare settings?
2. What are the best methods to identify a Norovirus occurrence or outbreak in healthcare settings?
3. What interventions best prevent or contain Norovirus outbreaks in healthcare settings?



# Analytic Framework for Key Questions

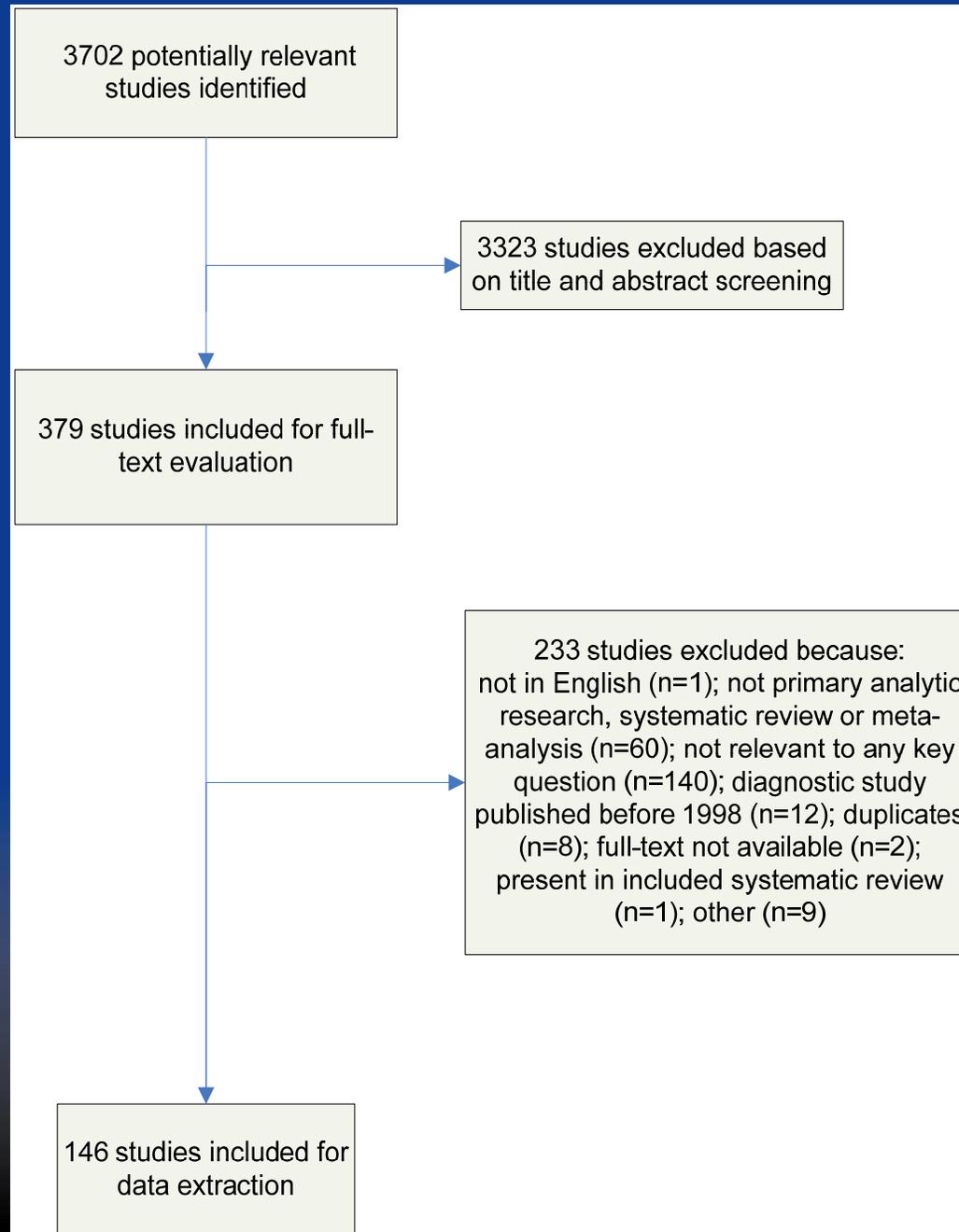




# General Guideline Development Process



# Flow of final search results



# Recent Steps...

- Complete evidence summaries for Q1-3
- Complete recs for Q1-3
- Peer review
- Publication

Timeframe: June '09

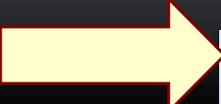
GUIDELINE SEARCH

DEVELOPMENT OF KEY QUESTIONS  
Review of relevant guidelines; vetting with clinical experts

LITERATURE SEARCH  
Databases identified; search strategy developed;  
references stored; duplicates resolved

ABSTRACT AND FULL-TEXT SCREENING  
To identify studies which were a) relevant to one or more  
key questions b) primary research, systematic review or  
meta-analysis and c) written in English

DATA EXTRACTION AND SYNTHESIS  
Data extracted; study quality assessed; evidence and  
GRADE tables developed.



FORMULATING RECOMMENDATIONS  
Evidence summaries; draft recommendations.





# Q1 Recommendations for Discussion

- 1.A.2.a Consider monitoring for signs of dehydration or renal dysfunction in those with symptomatic Norovirus infection and co-morbid conditions, especially those with underlying renal or cardiovascular disease, immunosuppression, or renal transplants, and institute appropriate medical therapy (**Category II**) (Key Question 1A)
- 1.A.2.b Consider longer periods of isolation or cohorting for complex medical patients, especially those with cardiovascular, autoimmune, or renal disorders, as they can experience protracted episodes of diarrhea (**Category II**) (Key Question 1A)



# Q1 Supporting Evidence

- ...Adult patients with symptomatic Norovirus who received immunosuppressive therapy or presented with underlying trauma were at risk for a greater than 10% rise in their serum creatinine.
- Norovirus-infected patients with cardiovascular disease or renal transplant patients were at greater risk for decreases in their potassium levels by greater than 20%.
- Observational, univariate study data also supported an increased duration of diarrhea (longer than two days) among hospitalized patients with cardiovascular, autoimmune, or renal disorders...



## Q2 Recommendations for Discussion

- 2.B In consultation with state or local laboratory policies, we suggest that healthcare facilities submit an appropriate, but limited, number of stool samples (e.g. 6 samples) from the cohort of symptomatic patients during the initial stage of a suspected Norovirus outbreak. **(Category II)**  
(Key Question 2B)



# Q2 Supporting Evidence

## Specimen Collection

- ...There was low quality evidence from three diagnostic studies regarding the minimum number of stool samples from symptomatic patients required to confirm a Norovirus outbreak.
- Using enzyme-linked immunoassays (ELISA), one Norovirus-positive sample obtained from 2-6 submitted samples was the minimum to identify an outbreak.



# Q2 Supporting Evidence

- Using a reverse transcriptase polymerase chain reaction (RT-PCR) method demonstrated that one positive specimen from 2-4 submitted stool specimens had sensitivities greater than 84%. If 5-11 stool samples were submitted, and 2 were confirmed as positive, this had a sensitivity of greater than 92%.
- When at least one stool specimen was submitted for identification, PCR testing confirmed Norovirus as the causative agent in a larger proportion of outbreaks than those using electron microscopy or ELISA methods...



# Q3 Recommendations for Discussion

- 3.A.1 Consider extending the duration of Contact Precautions for children <1 year old, even after resolution of symptoms seems to be apparent, as there is the potential for continued viral shedding and environmental contamination. We suggest extending Contact Precautions to a maximum of five days after the resolution of symptoms. **(Category II)** (Key Question 3A)
- 3.C.4.b Place patients in pediatric facilities on Contact Precautions with a provision to extend the duration of isolation if there is laboratory evidence that viral shedding persists after the resolution of symptoms



# Q3 Supporting Evidence

## Viral Shedding

- One observational study suggested that children under the age of six months may be at increased risk of prolonged viral shedding (greater than two weeks) even after the resolution of symptoms. Other findings suggest that infants under the age of one can shed very high levels of virus when compared with all other age groups.
- We also found high quality evidence demonstrating viral shedding in asymptomatic subjects, and low quality evidence demonstrating that shedding can persist for up to 22 days following infection, or 5 days after the resolution of symptoms.



# Q3 Recommendations for Discussion

- 3.B.2 Routine collecting and processing of environmental swabs during a Norovirus outbreak is not required. **(Category II)**



# Q3 Supporting Evidence

- A single systematic review evaluated 5 outbreaks with environmental sampling data. Three of those outbreaks confirmed environmental contamination with Norovirus.
- Two outbreaks that collected 47 environmental samples were unable to detect Norovirus. Of the over 200 swabs examined from the outbreaks in this review, 36% identified Norovirus contamination from fomites such as curtains, carpets, cushions, commodes and toilets, furnishings and equipment within 3-4 feet of the patient, handrails, faucets, telephones, and door handles.



## Q3 Recommendations for Discussion

- 3.C.1.b.1 Consider FDA-approved alcohol-based hand sanitizers as an adjunct method of hand hygiene during outbreaks of Norovirus when hands are not visibly soiled or have not been in contact with blood or body fluids. **(Category II)** (Key Question 3C)
- 3.C.1.b.2 Ethanol-based hand sanitizers are preferred as an adjunct method of hand hygiene compared to other alcohol or non-alcohol products during Norovirus outbreaks. **(Category II)** (Key Question 3C)



# Q3 Supporting Evidence

## Alcohol-based hand sanitizers

- We found very low quality evidence to suggest that hand hygiene with alcohol-based hand sanitizers may reduce the likelihood of symptomatic Norovirus infection.
- In lab settings, even with 95% ethanol products, the maximum mean log<sub>10</sub> reduction was 2.17. Evidence to evaluate the efficacy of alcohol-based hand disinfectants consisted of basic science studies using FCV as a surrogate for Norovirus.



# Q3 Supporting Evidence

- Moderate quality evidence supported ethanol as a superior active ingredient in alcohol-based hand disinfectants compared to propanol.
- The use of hand sanitizers with mixtures of ethanol and propanol have shown effectiveness against FCV compared to products with single active ingredients (70% ethanol or propanol) under controlled conditions.



## Q3 Recommendations for Discussion

- 3.C.11 We suggest that transfer of patients to skilled nursing facilities occur after a minimum of 48 hours has elapsed after symptom resolution from Norovirus infection, unless it is medically necessary to expedite these activities. (**Category II**) (Key Question 3C)



# Q3 Supporting Evidence

## Patient Transfers and Discharges

- We found very low quality evidence examining the benefit of delayed discharge or transfer for patients with symptomatic Norovirus infection.
  - Transfer of patients after symptom resolution was supported in one study, but discouraged in three others unless medically necessary.
  - Discharge home was supported once a patient's symptoms had resolved for a minimum of 48 hours.
  - For transfers to long term care or assisted living, patients were held for five days after symptom resolution



# Priority Recommendations

- 2.A.1 In the absence of clinical laboratory diagnostics or a delay in obtaining laboratory findings, use Kaplan's clinical and epidemiologic criteria as a tool to raise the index of suspicion of a Norovirus outbreak to help institute the appropriate infection control measures in a timely fashion. **(Category IB) (Key Question 2A)**
- 3.C.1.b.1 Consider FDA-approved alcohol-based hand sanitizers as an adjunct method of hand hygiene during outbreaks of Norovirus when hands are not visibly soiled or have not been in contact with blood or body fluids. **(Category II) (Key Question 3C)**



# Priority Recommendations

- 3.C.3 Facilities should develop policies that address provisions for staff leave among those who become symptomatic with Norovirus. All affected staff members should be excluded from work for a minimum of 48 hours after the resolution of symptoms. Once staff return to work, strict adherence to hand hygiene must be maintained. **(Category IC) (Key Question 3C)**
- 3.C.5.a Establish protocols for staff cohorting in the event of a Norovirus outbreak, where staff care for one patient cohort on their ward (e.g. exposed/symptomatic, exposed/asymptomatic, or unexposed). **(Category IC) (Key Question 3C)**



# Priority Recommendations

- 3.C.9.b Notify appropriate local and state health departments if an outbreak of Norovirus is confirmed. **(Category IC) (Key Question 3C)**



# Noteworthy Category II Recommendations

- 3.C.11 We suggest that transfer of patients to skilled nursing facilities occur after a minimum of 48 hours has elapsed after symptom resolution from Norovirus infection, unless it is medically necessary to expedite these activities. **(Category II)**
- 3.C.12.b.1 Consider increasing the frequency of cleaning and disinfection of patient care areas and high-touch surfaces during Norovirus outbreaks. Ward level cleaning may be increased up to twice daily, with high-touch surfaces cleaned and disinfected up to three times daily. **(Category II)**



# Areas for Future Research

- Assess the benefit of using the Kaplan criteria as an early detection tool for Norovirus outbreaks in healthcare settings, and to examine whether the Kaplan criteria are more predictive for select strains of Norovirus.
- Correlations between prolonged shedding of Norovirus after symptoms have subsided and the likelihood of secondary transmission of Norovirus infection
- Identification of an ideal animal model for surrogate testing of Norovirus properties and pathogenesis. Translate laboratory findings into practical infection prevention strategies.



# Areas for Future Research

- Evaluate the contribution of Norovirus-contaminated water sources in healthcare settings.
- Quantify the effectiveness of cleaning and disinfecting agents against Norovirus.
- Effectiveness and reliability of fogging, UV irradiation, and ozone mists to reduce Norovirus environmental contamination.
- The utility of medications that may attenuate the duration and severity of Norovirus illness



# Areas for Future Research

- Evaluate the effectiveness of FDA-approved hand sanitizers against Norovirus, and the role of non-alcohol based products
- Develop methods to evaluate Norovirus persistence in the environment with a focus on enduring infectivity
- The role of asymptomatic shedding (among recovered persons and carriers) in secondary transmission
- Duration of protective immunity and other protective host factors



# Improving the Quality of Evidence

- Primary analytic research
  - Use of controls in both clinical and laboratory settings
  - Comparisons between surrogate and human Norovirus strains
  - Consider healthcare-focused risk factors
- Statistically powered studies
- Evaluate clinically relevant outcomes
  - Studies focused on infection control interventions and associated outcomes

# Q2 Summary Table: Norovirus Diagnostics



**TABLE 3. TEST CHARACTERISTICS FOR NOROVIRUS IN FECAL SPECIMENS**

Diagnostic method	Reference standard	Quantity and type of evidence	Findings*				
			Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Detection limit
Kaplan criteria	Clinical microbiologic testing	1 DIAG <sup>16</sup>	68	99	97	82	NA
EIA/ELISA	PCR	10 DIAG <sup>10,11,12,13,14,15,16,17,18,19</sup>	31 – 90	65 – 100	52 – 100	56-97	NA
EM	PCR	2 DIAG <sup>20,21</sup>	24 – 58	98-99	88-94	71-91	NA
PCR	EM	8 DIAG <sup>10,11,12,13,14,15,16,17,18,19</sup>	56	83	19	97	<10 to > 10 <sup>7</sup> copies
NASBA	PCR	1 DIAG <sup>22</sup>	100	50	-	-	NA

\* Range from studies that reported test characteristics

# Q3 Summary Table: Prevention Strategies

## MEASURES FOR PREVENTION AND CONTROL OF NOROVIRUS OUTBREAKS IN THE PUBLISHED LITERATURE

### 1. HAND HYGIENE

- Wash hands with liquid soap and water (scrub for 15 seconds and rinse with water) and dry with a disposable paper towel
- Wash hands after going to the bathroom and prior to each meal
- Implement mandatory hand disinfection with a product containing 95% alcohol
- Make alcohol based handrubs available by every bedside
- Implement hygiene measures without waiting for virological confirmation
- Keep fingernails short and scrub with soap and nailbrush while washing hands if work involves handling food

### 2. PROTECTIVE APPAREL

- Wear gloves, mask and apron for contact with an affected patient or environment
- Encourage visitors to use protective apparel for contact with an affected patient

### 3. ISOLATION/COHORTING OF AFFECTED PATIENTS

- Cohort nurse or isolate symptomatic patients

### 4. STAFF POLICIES

- Exclude affected staff from work until symptom free for 48 hours
- Exclude non-essential personnel from an affected ward
- Prohibit staff working in affected areas from working in unaffected areas for 48 hours

### 5. WARD POLICIES

- Close the ward to new admission

### 6. VISITOR POLICIES

- Restrict visitors to 1-2 per patient and prohibit children from visiting
- Screen visitors for gastroenteritis and prohibit them from visiting if symptomatic

### 7. DISINFECTION

- Increase the frequency of routine ward, bathroom or toilet cleaning
- Disinfect vomitus immediately with concentrated hypochlorite
- Steam clean carpets
- Disinfect hard surfaces with 0.1% hypochlorite after cleaning
- Discard fabrics and furniture that cannot be disinfected
- Bathroom surfaces and high touch surfaces are specific areas of decontamination

### 8. EDUCATION OF HEALTHCARE WORKERS

- Educate healthcare workers (possible topics include identification of Norovirus, spread of gastroenteritis, cleaning and disinfection procedures, isolation, transfers and discharge)
- Educate family members of patients

### 9. SURVEILLANCE

- Perform active surveillance after defining the surveillance period and establishing the case definition
- Perform contact tracing among staff
- Review admission records of patients

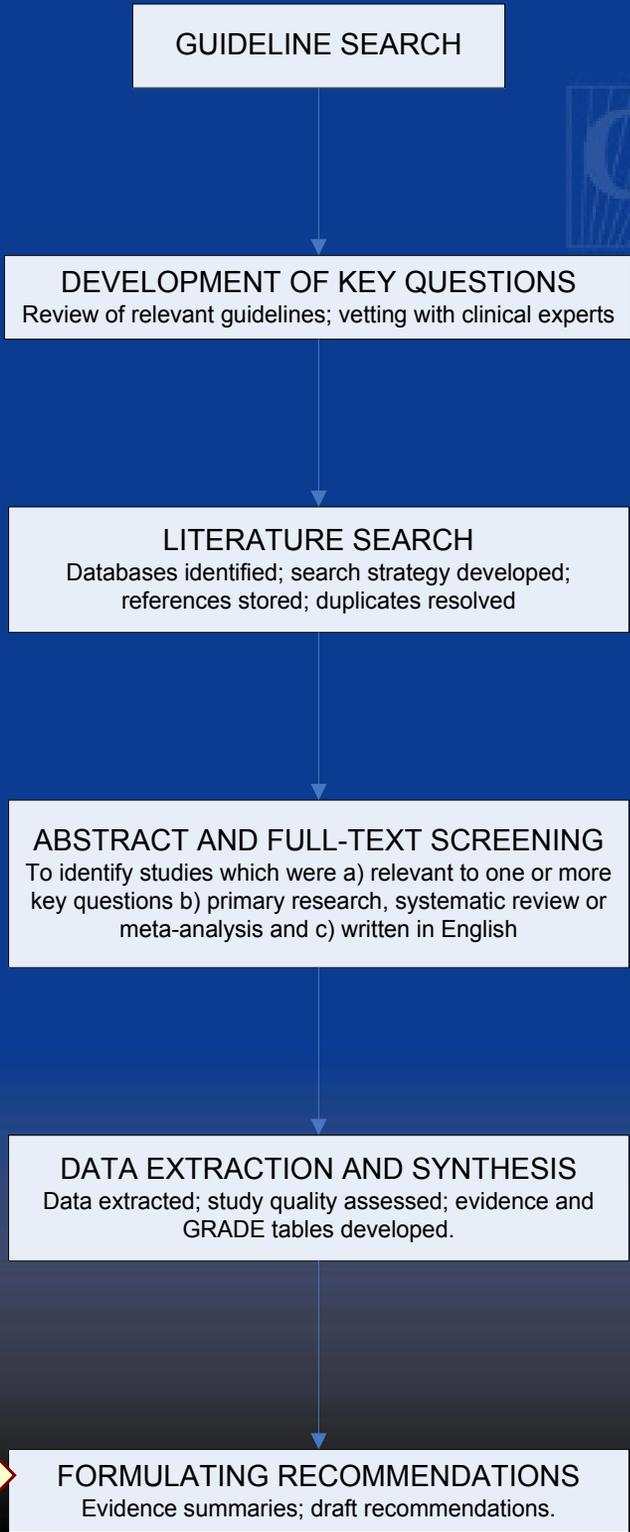
### 10. STANDARD PRECAUTIONS

- Standard precautions must be followed at all times



# Final Steps...

- Expert Review
- Complete Background and Implementation and Audit Sections
- HICPAC Review
- CDC Clearance
- Posting on Federal Register
- Final Revisions
- Publication
- Support GRADE process
- Timeframe:** Prior to Winter 2009-2010





# Infection Prevention and Control in Healthcare Personnel

Tammy Lundstrom, Mike Bell, Mark Russi

June 16, 2009  
HICPAC Meeting

**SAFER • HEALTHIER • PEOPLE™**



# Progress

- Two discussion re: sections of document needing update
- Identifying external experts to participate in guideline development



# Core Working Group Members

- HICPAC Tammy Lundstrom
- DHQP-CDC TBD
- CEP, UPHS TBD





# Sections needing update

- Data management and confidentiality
- Bloodborne pathogens (SHEA Guideline)
- GI infections (norovirus)
- Measles
- Mumps
- Pertussis
- Rabies
- Scabies



# Sections needing updating

- Staphylococcus aureus infection and carriage
- Tuberculosis (BCG, XDR-TB, BAMT)
- Varicella
- Influenza
- Pregnant HCP
- Latex allergy (shorten)
- Vaccine/prophylaxis/treatment tables



# Additional Sections?

- How to handle white powder
- Trainee travel (appendix)
- Interface of Occupational Medicine and MDROs
- SARS
- Anthrax
- Smallpox



# Additional Thoughts

- Reference updated ACIP guidelines for immunization of HCP
- Expand section on communicable disease reporting
- Revise OSHA section (300 log)



# Next Steps

- Fully identify working group members
- Fully identify external experts
- Search medical databases and web sites for relevant guidelines and narrative reviews
- Draft research questions to present to November HICPAC meeting



# Pediatric Guideline Update

Alexis Elward M.D., M.P.H.

HICPAC

June 16, 2009

**SAFER • HEALTHIER • PEOPLE™**



# Pediatric Infection Prevention

- Diseases: High volume /or high morbidity hospital-acquired infections
  - Central line-associated bloodstream infections (CLABSI)
  - Surgical Site Infections (SSI)
  - Methicillin Resistant *Staphylococcus aureus* (MRSA) colonization and infection
  - Viral infections in immunocompromised hosts
  
- Patients
  - Family centered care
    - Parents visiting while ill
    - Parents colonized with antibiotic resistant organisms
  - Developmentally appropriate, child centered care
    - Pet Therapy
    - Social interactions for the chronically ill child on isolation precautions
    - Child Life



# Pediatric Infection Prevention: Gap Summary

- Denominators
- Attributable Mortality
- Preventability of CLABSI in select pediatric subpopulations
- Benchmarks for pediatric SSI
- Risk stratification for pediatric SSI
- MRSA colonization (NICU)
- Family and patient education
- Viral infections (NICU)



# Stakeholder Feedback

- Society for Healthcare Epidemiology of America (SHEA) Pediatric Special Interest Group (PSIG)
  - N=40 Pediatric Infectious Diseases physicians and Pediatric Infection Preventionists
- Children's Hospitals Neonatal Consortium
  - Child Health Corporation of America subgroup
  - Mission: obtain best comparative neonatal data for children's hospitals
- Society for Pediatric Research 2009 symposium on NICU Infection Prevention



# Stakeholder Feedback: PSIG of SHEA

- Evidence to develop a pediatric guideline for addressing topics is lacking
  - Possible exception: NICU
- Consensus **against** developing a white paper based solely on expert opinion for family and patient centered care issues
- Formal gap analysis for research prioritization recommended

# PSIG Survey: Research Priorities

- PSIG surveyed by Charlie Huskins MD
- Rank topics 1-5 in order of importance
  - Most important =1
- Results: n=22 responses (response rate)

Topic	Mean Score
MDRO	2.32
Viral respiratory infections	3.41
CLABSI	3.41
Other device-related infections*	5.1
Fungal infections	5.5
SSI	5.59
VAP	6
Other‡	

\*Ventriculoperitoneal shunts, peritoneal dialysis catheters, Gastrostomy tubes<sup>†</sup> Diarrheal disease other than *Clostridium difficile*, special populations (NICU, Cystic fibrosis, transplant, cardiothoracic surgery), nosocomial influenza



# Stakeholder Feedback: CHNC

- Surveyed leadership of CHNC
- Enthusiasm for infection prevention guideline specific to NICU
- Priority topics: BSI prevention in patients with intestinal pathology



# NICU Guideline

- Pediatric Academic Societies Symposium May 2009
  - Compendium of Strategies to Prevent Healthcare-Associated Infections in the NICU
- Topics
  - Central Line Associated Bloodstream Infections
  - Methicillin resistant *Staphylococcus aureus*



# NICU Infection Prevention Questions

- What are the best strategies to prevent CLABSI in NICU patients?
  - Safety and efficacy of chlorhexidine in infants < age 2 months
  - Impact of silver coated catheters on CLABSI rates
  - Efficacy of closed flush medication systems
  - Efficacy of two person tubing changes using sterile garb
- What are the most effective methods of preventing MRSA colonization among NICU patients?
  - Risk of vertical transmission MRSA
- What are the most effective methods of preventing invasive Candidal infection among NICU patients?
  - Fluconazole v. Nystatin prophylaxis



# NICU Infection Prevention: Search Results

Topic	N of studies	N of interventions
CLABSI	46	4
MRSA	60	13
Candida	79	10

Only topic with randomized controlled trials is Candida



# Discussion

- Which documents appropriate and value added to be written under auspices of HICPAC?
  - Formal gap analysis, review of literature published subsequent to latest HICPAC guideline on the topic
  - NICU Infection Prevention guideline
- Writing plan