

Immunization Fast Track 2009

Medical Society of the State of New York
Supported by an educational grant from the New York State Department of Health

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Faculty

Disclosure

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Course Objectives

This one-hour seminar provides physicians and other healthcare personnel with updated information on the following immunization topics:

- Outlook for the 2008-2009 influenza season;
- Importance of influenza vaccine for health care personnel;
- New vaccines & new recommendations;
- Vaccine safety, with a closer look at HPV vaccine and MMR; and
- Continued importance of child and adult vaccination in reducing rates of vaccine-preventable diseases.

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2008-2009 Influenza Season Update

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2008-2009 Influenza Season Update

- The FDA approved six seasonal influenza vaccines that contain three new strains disease experts expect to be circulating.
- The six vaccines and their manufacturers are:

Afluria	CSL Limited
Fluarix	GlaxoSmithKline Biologicals
Flulaval	GlaxoSmithKline Biologicals
FluMist	MedImmune
Fluvirin	Novartis Vaccine
Fluzone	Sanofi Pasteur, Inc.

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2008-2009 Influenza Season Update

• FDA's Vaccines and Related Biological Products Advisory Committee, the World Health Organization and the Centers for Disease Control and Prevention recommend that vaccines to be used in the 2008-2009 influenza season in the US contain the following three strains:

- an A/Brisbane/59/2007 (H1N1)-like virus
- an A/Brisbane/10/2007 (H3N2)-like virus
- a B/Florida/4/2006-like virus

• Manufacturers have produced ~146 million doses of influenza vaccine including ~50 million doses of preservative-free vaccine.

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2008-2009 Influenza Season Update

• As supply is sufficient, CDC does NOT expect to recommend prioritization for high-risk groups only

• Target groups for vaccination

- Children aged 6 months through 19 years
- People 50 years of age and older
- Pregnant women
- People with chronic pulmonary (including asthma), cardiovascular (except HTN), renal, hepatic, hematologic or metabolic (including DM) conditions.
- People who have compromised respiratory functions
- Residents of nursing homes or other long term care facilities
- Health care personnel
- People who live with or care for those at high risk for complications from the flu

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2008-2009 Influenza Season Update

• What's new this season?

- Annual vaccination of all children aged 5-18 years is now recommended
 - Children aged 6 through 59 months continue to be a primary focus
- LAIV (Flumist) can now be used in healthy persons aged 2 through 49 years
- Oseltamivir or zanamavir continue to be recommended antivirals for treatment of influenza

MMWR Vol. 57, July 17, 2008

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Continued Importance of Immunizing Health Care Personnel (HCP)

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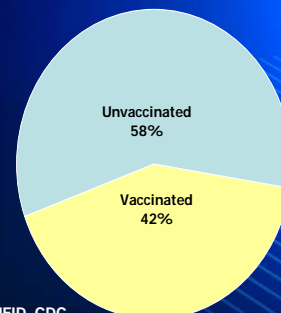
Vaccines routinely recommended for HCP

- Influenza
- Hepatitis B
- Measles/mumps/rubella (MMR)
- Varicella
- Tetanus/diphtheria/pertussis (Td/Tdap)
- Others (may be indicated, depends on circumstances)
 - ◀ Hepatitis A, Meningococcal, Typhoid, Smallpox

Immunization Action Coalition, July 2007
MMWR 46:RR-18, 1997

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Average Annual Influenza Vaccination Rates in HCP



Unvaccinated HCP can be a key cause of influenza outbreaks in health care settings.

HCP vaccination is associated with reduced absenteeism and fewer patient deaths.

NFID, CDC

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Why is influenza vaccine recommended for all HCP?

- Influenza causes death and disability
- Patients seen in the health care setting are at high risk of influenza death
- Unvaccinated HCP are susceptible, have high attack rates (often asymptomatic) and often work despite illness
- Influenza vaccine is safe and prevents influenza in healthy adults
- Vaccinated HCP miss less work and are less likely to transmit influenza to patients

MMWR Vol. 55 (RR-2), February 24, 2006

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Factors Influencing Decisions of Health Care Personnel to Receive Vaccine

Vaccinees (%)		Non-Vaccinees (%)	
Don't want to get sick	83	Concern re: side effects	36
Protect Patients	62	Not in Target Group	15
Convenience	68	Disagree with recommend	10
Free	58	Inconvenience	10
National Recommend	25	No high-risk patient contact	6
Physician Recommend	8	Dislike needles	5
		Forgot	5

Odds ratio for very strongly recommending to elderly if HCP vaccinated = 1.91

Nichol KL. *JCHE* 1997; 18:189

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There IS Professional Consensus

Multiple groups recommend & support HCP influenza vaccination:

- Advisory Committee on Immunization Practices (ACIP) and Healthcare Infection Control Practices Advisory Committee (HICPAC)
- The Joint Commission
- American College of Physicians
 - "An ethical obligation"
- Association for Professionals in Infection Control and Epidemiology (APIC)
 - "HCP have an obligation..."
- Infectious Disease Society of America (IDSA)

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Keys to Increasing HCP Vaccination Rates

- Provide vaccination at convenient times and locations
- Remove cost barriers
- Educate health care workers
 - HCP influenza vaccination is a PATIENT SAFETY ISSUE
 - Influenza virus is easily transmitted between HCP and patients, putting already ill patients at risk for influenza illness and its complications
 - CDC recommends annual vaccination for all HCP
 - Dispel the myths & misconceptions about influenza vaccination
 - Inactivated vaccine (TIV) cannot cause influenza

NYS Department of Health Immunization Program, 2007

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MYTH

FACT

You can get the flu from vaccine

The vaccine is made from killed or inactivated parts of the virus. They cannot cause disease.

The flu is no big deal

The flu is a major cause of hospitalization and death.

The side effects are worse than the flu

Mild side effects such as soreness, redness, aches and headaches are common. Serious side effects are very rare.

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NYS Department of Health Immunization Program, 2007

MYTH

FACT

Not everyone can receive flu vaccine

The only reason not to get the flu vaccine is if you have an allergy to egg or a previous dose of the vaccine.

Only older people need the flu vaccine

Everyone can benefit from the flu vaccine. In fact, elderly have less protection from vaccine; therefore, HCP vaccination is essential to provide them additional disease protection.

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NYS Department of Health Immunization Program, 2007

MYTH	FACT
You can only get the flu vaccine before December	Influenza peaks in February and sometimes later. You can get your flu shot through March and still benefit.

NYS Department of Health Immunization Program, 2007

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New Vaccines and New Recommendations

Pneumococcal Vaccine (PPSV23)

- Recommended for all adults ≥65 years AND
- Persons aged 2 through 64 years with chronic CV disease, chronic pulmonary disease, DM, chronic liver diseases, chronic renal disease, asplenia, immunosuppression, cochlear implants, CSF leaks

Now recommended for asthmatics and smokers 18 years and older!!!

Presented at ACIP 6/08 & 10/08, pending formal publication

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Pneumococcal Vaccine (PPSV23) Revaccination Recommendations

TABLE 2. Recommendations for the use of pneumococcal vaccine

Groups for which vaccination is recommended	Strength of recommendation*	Revaccination†
Immunocompetent persons[§]		
Persons aged ≥65 years	A	Second dose of vaccine if patient received vaccine ≥5 years previously and were aged <65 years at the time of vaccination.
Persons aged 2-64 years with chronic cardiovascular disease, [¶] chronic pulmonary disease, ^{**} or diabetes mellitus	A	Not recommended.
Persons aged 2-64 years with alcoholism, chronic liver disease, ^{††} or occupational fluid risk	B	Not recommended.
Persons aged 2-64 years with functional or anatomic asplenia [‡]	A	If patient is aged >10 years: single revaccination 25 years after previous dose. If patient is aged <10 years: consider revaccination 3 years after previous dose.
Persons aged 2-64 years living in special environments or social settings ^{§§}	C	Not recommended.
Immunocompromised persons[§]		
Immunocompromised persons aged ≥2 years, including those with HIV infection, leukemia, lymphoma, Hodgkin disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids), and those who have received an organ or bone marrow transplant.	C	Single revaccination if ≥5 years have elapsed since receipt of first dose. If patient is aged <10 years: consider revaccination 3 years after previous dose.

ACIP clarified revaccination interval of FIVE years! (10/08)

New Vaccines

- Monovalent rotavirus vaccine (Rotarix)**
 - 2-dose schedule at 2 and 4 months
 - Live, oral vaccine
 - Attempt to complete entire series with same product

ACIP Provisional Recommendations, June 2008

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New Combination Vaccines

- DTaP-IPV-Hib (Pentacel)**
 - Indicated for primary series in kids aged 2 through 18 months
- DTaP-IPV (Kinrix)**
 - Indicated for booster dose in kids aged 4 through 6 years

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Coming Soon...

- Possible extension of age indication for Boostrix (to match Adacel)
 - GSK filed with FDA for approval to expand use to adults (19-64 years old)
- Possible extension of age & gender indication for Gardasil
 - Merck filed with FDA for approval to expand use to adult women (27-45 years old) and males
- Bivalent HPV vaccine (Cervarix)
 - Licensure currently under FDA review

Presented at ACIP 6/08 & 10/08

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Update on Vaccine Safety

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“Vaccines are victims of their own success”

- Effective vaccine programs have achieved a significant decrease in vaccine-preventable diseases (VPDs)
- Increased focus by parents on the “presumed risks of the vaccine than on the known risks of the rare infection”
- “Parents more often describe vaccines with respect to their side effects and symptom-producing impact than as preventive agents”

Developmental and Behavioral Pediatrics 2005; 26(6):441-451

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Changes that have fostered the anti-vaccine movement

- ↑ number of vaccines recommended in childhood
- ↑ number of vaccines mandated by state law
- VPDs at an all time low, thus unfamiliar to young physicians and parents
- End of medical paternalism, physicians and patients both want patients to be more involved in their own medical care
- ↑ information technology, more “tech savvy” parents
- Social networking of small groups facilitated via internet
- Controversy and news of bad outcomes disproportionately represented by media

Pediatrics 2008;122(1):149-153

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Sources of Vaccine Information Used by Parents

- CDC focus group research with first time mothers
- Sources of information used by parents
 - Their child’s physician
 - Family members and friends with children
 - The internet

CDC, 2008

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What Parents are Reading...

- A Google search on “vaccine ingredients” shows:
 - Heavy metals like mercury and aluminum
 - Pus from sores of diseased animals
 - Horse Serum
 - Calf Serum
 - Fecal Matter
 - Urine
 - Macerated Cancer Cells
 - Sweepings from diseased children
- Jenny McCarthy
 - 
 - Speaks out publicly against vaccines. Her son was diagnosed with autism at age 2.

<http://www.mercola.com/article/vaccines/ingredients.htm>

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Childhood Immunizations Questions and Concerns

- All mothers had at least some questions or concerns about infant immunization including:
 - How often does my baby need shots?
 - What are the side effects (short-term and long-term) of vaccination?
 - Fever was the most commonly mentioned short-term side effect
 - Autism and unknown complications were the most commonly mentioned long-term side effect
 - Is it safe for a child to receive multiple vaccinations during a single visit?
 - What are the vaccine ingredients and are they safe?
 - How effective are the vaccinations?
 - Are vaccinations necessary?

CDC, 2008

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The Physician Perspective

- CDC qualitative research
 - Of the physicians (family medicine and pediatrics) surveyed, n=23
 - All reported that autism was an issue – seems to be increasing
 - Parental concerns include
 - MMR & autism
 - Too many shots
 - Vaccine ingredients
 - Parents use internet as source of information

CDC, 2008

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MMR Vaccine & Autism Concerns

- In 2000, CDC and the National Institutes of Health asked the Institute of Medicine (IOM) to put together an independent expert committee (the Immunization Safety Review Committee) to review evidence about whether vaccines cause certain health problems.
- The committee studied evidence about:
 - the theory that MMR vaccine causes autism
 - the theory that vaccines with thimerosal cause neurodevelopment disorders, including autism, ADHD, and speech or language delay.

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MMR Vaccine & Autism Concerns

- In its report of October 1, 2001, the IOM's Immunization Safety Review Committee concluded that the evidence was inadequate to either accept or reject a causal relationship. Additional studies were needed.
- The Committee did conclude that the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders was biologically plausible and believed that the effort to remove thimerosal from vaccines was "a prudent measure..."

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MMR Vaccine & Autism Concerns

- In 2004, the IOM's Immunization Safety Review Committee issued its final report incorporating new epidemiological evidence.
- The committee concluded that:
 - there is no causal relationship between thimerosal-containing vaccines and autism
 - the benefits of vaccination are proven
 - the hypothesis of susceptible populations is presently speculative
 - the widespread rejection of vaccines would lead to increases in incidences of serious infectious diseases

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Overview of MMR Vaccine

- Measles is a highly contagious vaccine-preventable disease and the most deadly of all childhood rash/fever illnesses. It is spread by droplets or direct contact with nasal or throat secretions of infected persons.
- Measles can be prevented by the combination vaccine MMR (measles, mumps and rubella).
- Children should be given the first dose of MMR vaccine soon after the first birthday (12 to 15 months of age). The second dose is recommended at age 4-6 years, before the start of kindergarten.

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Effectiveness of MMR Vaccine

- Unvaccinated persons are at risk for measles
- Sizeable measles outbreaks can occur in communities with a high number of unvaccinated persons
- More than 95% of the people who receive a single dose of MMR will develop immunity to all three viruses. A second vaccine dose gives immunity to almost all of those who did not respond to the first dose.

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Measles Outbreaks United States~2008

- Pre-vaccine era:
 - 3-4 million cases annually
 - 400-500 died
 - 48,000 hospitalized
 - 1,000 developed chronic disability from measles encephalitis

CDC, presented at ACIP 6/08

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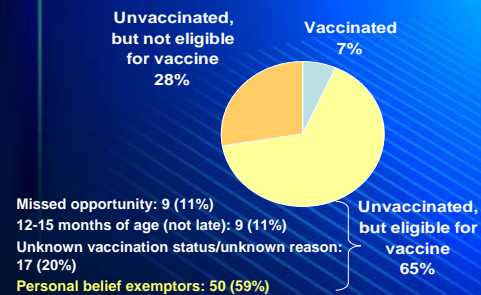
Measles Outbreaks United States~2008

- 106 (86%) of cases were import-associated
- 116 (94%) were in US residents
- 11 (69%) of 16 were importations from WHO European region
 - 2800 cases in European countries
 - >1000 cases in Israel

CDC, presented at ACIP 6/08

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Measles Cases by vaccination status, N = 123



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Measles Outbreaks United States~2008

- Import-associated cases are on the rise in the US
- Most cases are occurring in unvaccinated US residents
- Primary reason for lack of vaccinations is personal belief exemptions
- Until better global control is achieved, cases will continue to be imported into the US and outbreaks will occur as long as there are communities of unvaccinated people

CDC, presented at ACIP 6/08

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Measles Epidemic A Real Possibility

- Measles again endemic in Europe
 - Sub-optimal MMR vaccine coverage
- England and Wales
 - 2007-2008: 1,726 measles cases
 - More than in previous 10 years combined
 - Spreading throughout the UK (beyond London)
- Other countries with similar outbreaks
 - Switzerland, Austria, Italy, Israel, Japan....



BBC News, 2008: guardian.co.uk

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HPV Vaccine Safety Concerns

- Consumers, parents and the media have raised questions regarding the safety of the quadrivalent HPV vaccine Gardasil
 - Vaccine Safety is continually assessed via
 - Vaccine Adverse Event Reporting System (VAERS)
 - Vaccine Safety Datalink (VSD)
 - Clinical Immunization Safety Assessment (CISA)
 - Merck post-licensure monitoring
- FDA and CDC continue to find that Gardasil is a safe and effective vaccine
- Monitoring continues, as with all other vaccines

CDC VAERS Report, October 21, 2008

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HPV Vaccine Overview

Gardasil® (Merck)

- Quadrivalent vaccine against HPV types 16, 18, 6, 11
 - Types 16, 18 cause 70% of cervical cancers
 - Types 6, 11 cause 90% of genital warts
- FDA approved for use in females 9-26 years of age
- Prophylactic, not therapeutic
- Not a live vaccine
 - Virus-like particles (VLP)
- Highly effective
 - Clinical trials showed 100% effectiveness in HPV-naïve
- Dosing schedule 0, 2, and 6 months
 - NOTE Minimum interval of 24 weeks between doses 1 and 3

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HPV Vaccine Recommendations

- Recommended for all females aged 11-12 years
 - Females as young as 9 years of age can be vaccinated
 - Catch-up vaccination is recommended for females aged 13-26 years not previously vaccinated
- Vaccine is most effective if administered before sexual debut
 - Vaccine may be less effective in sexually active women
 - HPV testing prior to initiating vaccine is not recommended
- Vaccine is not a treatment for current HPV infection, genital warts, or cervical intraepithelial neoplasia
- Continued cervical cancer screening is essential

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Who Should Not Receive the HPV Vaccine?

- Not currently recommended (awaiting more evidence)
 - Females who are currently pregnant
 - Women over age 26 years
 - Males
- Contraindicated
 - Females with an allergic reaction to yeast or any other vaccine component

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HPV Vaccine Safety

- Over 20 million doses distributed & monitored via passive surveillance
 - >375,000 doses monitored via active surveillance
- 96% of reported adverse events are **non-serious**
 - Vomiting/syncope/fever/nausea/pain at injection site
- Serious Adverse Events reported rarely (~6%)
 - No concerning pattern among serious events
 - No apparent causal relationship established for
 - Guillain-Barre Syndrome
 - Venous thromboembolism
 - Death
- Many events reported have high baseline rates in absence of vaccination (e.g. syncope)

CDC VAERS Report, October 21, 2008

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HPV Vaccine Outcomes Data

- CDC assessing the burden of HPV-associated cancers in the US
 - Provide baseline data about HPV-associated cancers
 - Critical for monitoring the impact of HPV vaccine on the incidence of HPV-associated cancers and pre-cancers
- 1998-2003: HPV-associated cancer incidence 10.6 per 100,000
 - Top sites: cervix, oral cavity, oropharynx, anus, vulva, penis and vagina
 - Lower education and higher poverty associated with increased risk for HPV-associated cancers of cervix, penis and vagina

ABHACUS: http://www.cdc.gov/cancer/hpv/what_cdc_is_doing/

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Adult Immunization: Renewing the Focus

Adult Immunization Rates

- Adult immunization rates are low nationally
 - Health insurance is barrier
 - Reasons for not getting vaccinated
 - Not needed
 - Not aware
 - Side effects
 - Cost

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Adult Immunization Rates

2007 National Immunization Survey

- | | |
|----------------------------|--------------------------|
| – Influenza (06-07 season) | – Hepatitis A (≥2 doses) |
| • 42.2% age 50-64 | • 12.1% age 18-49 |
| • 68.8% age 65+ | – Hepatitis B (≥3 doses) |
| – Pneumococcal | • 23.4% age 18-49 |
| • 65.6% age 65+ | – Tdap (in past 2 years) |
| – Zoster | • 2.1% age 18-64 |
| • 1.9% age 60+ | – Td (in past 10 years) |
| | • 57.2% age 18-49 |

CDC/NCIRD, 2008

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Improving Adult Immunization Rates

- Thinking outside of the box
 - Healthcare Personnel
 - Influenza, Tdap
 - Partner with home care agencies
 - Community advocacy
 - Pharmacists
 - Influenza, Pneumococcal
 - Pregnant women
 - Influenza, Postpartum Tdap

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Facts about Adult Immunization

1. About 50,000 US adults die from vaccine-preventable diseases or their complications each year.
2. An average of 36,000 vaccine-preventable deaths each year are attributed to influenza; 90% of these deaths are in persons 65 years of age or older.
3. Each year in the US, pneumococcal disease accounts for nearly 40,000 cases of bacteremia and several thousand cases of meningitis.

NFID, August 2008

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Facts about Adult Immunization

4. In the US, an estimated 1.25 million people are chronically infected with the hepatitis B virus (HBV). HBV is 100 times more infectious than the HIV virus.
5. Before hepatitis A vaccine became available in the US, about 270,000 persons were infected with hepatitis A virus (HAV) each year. HAV is the most common vaccine-preventable disease acquired during travel.
6. Almost one-third of reported pertussis cases are in adults.
7. Unimmunized persons of any age can get measles, but those born after 1956 who do not have proof of immunity are particularly at risk and should be immunized.

NFID, August 2008

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Summary

- 2008-2009 influenza season
 - Vaccine recommended for all children 6 months through 18 years of age
 - All HCP should be vaccinated against influenza
- Pneumococcal vaccine now recommended for adult smokers and asthmatics
- Reassurance regarding vaccine safety remains a critical component of patient/parent counseling
- As vaccination rates decrease, there is a corresponding increase in vaccine-preventable diseases

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Questions?

- Please fill out the evaluation form
- Pick up your CME Certificate

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