

# Influenza

## Monica Mehta, PharmD, Long Island University

### A Webber Training Teleclass

# INFLUENZA

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- ### Presentation Objectives
- Briefly review influenza
    - History and epidemiology
    - Structure and classification
    - Pathogenesis
    - Diagnosis of influenza
  - Discuss management of influenza with antiviral agents
  - Describe influenza vaccination
    - Including influenza survey-based study at a hospital in Bronx, New York

- ### Seasonal Influenza Overview
- Infection caused by influenza type A or B
  - Acute, usually self-limited, febrile illness
  - Outbreaks generally occur annually in winter
    - Rates 10-40% over 5-6 week period
    - Mortality ~35,000 per year in US due to pulmonary complications
  - Clinical manifestations include fever, malaise, and cough
  - Anti-viral agents may reduce severity and duration
  - Vaccination is the best way to prevent influenza

- ### History of Influenza
- Cause of recurrent epidemics/pandemics every 1-3 years over last 400 years
  - Greatest known pandemic in 1819
    - Three waves of influenza
    - 21 million deaths worldwide (most deaths d/t secondary bacterial PNA)
  - At present, influenza vaccination, antibiotics, and antiviral agents have decreased mortality rates

### History of Influenza Epidemics & Pandemics

| Year                   | Population   | ~Deaths per 1,000                           | Influenza A subtype |
|------------------------|--|---|---------------------|
| 1675, 1782, 1837, 1847 | London   | 1 - 10                                      | Unknown             |
| 1890                   | UK   | 1-2.5                                       |                     |
| 1918-1919              | Worldwide<br>India<br>Western Samoa<br>Alaska<br>New Zealand whites<br>New Zealand Maori | 2-25<br>70<br>200<br>up to 600<br>5.5<br>42 | H1N1                |
| 1957                   | Worldwide  | 0.7   | H2N2                |
| 1968-1969              | Worldwide  | 0.3   | H3N2                |
| Seasonal influenza     | Developed countries  | 0.03-0.3                                    | H3N2, H1N1          |

Mathews J, et al. *Influenza and Other Resp Virus*:3:143-189.

- ### Epidemiology
- Worldwide influenza deaths 250K-500K annually
  - US deaths average ~36K annually (1990-1999)
    - 90% deaths occur in ≥ 65 year olds
    - Deaths in oldest elderly (≥ 85 year olds) are 16x higher compared to persons aged 65 - 69 years
  - US hospitalizations ~226K annually
    - Rates of infection highest among children
  - Overall rates have been increasing (due to growing predominance of influenza A and aging population)

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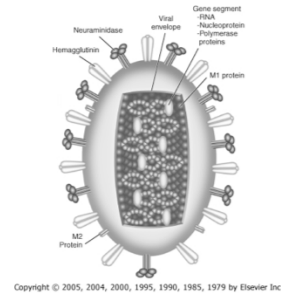
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#### Morbidity & Mortality

- Gateway to more serious ailments
  - Pneumonia, COPD exacerbation
- Causes of death
  - Complications of pneumonia and superimposed bacterial infections
  - Exacerbations of respiratory, cardiac, and renal conditions

#### Influenza Cell Structure

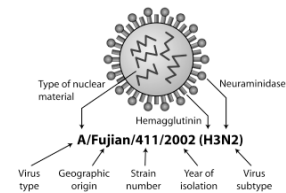


#### Influenza Classification

- Three types: Influenza A, B, & C
- Influenza A and B are the two types of influenza viruses that cause epidemic human disease
  - Influenza type C infections cause a mild illness

#### Influenza Classification

- Standard nomenclature = influenza type + place of initial isolation + strain designation + year of isolation
  - E.g. A/Puerto Rico/8/34 = Influenza A virus isolated from a patient in Puerto Rico in 1934



#### Influenza Classification

- Influenza A viruses are categorized into subtypes on the basis of two surface antigens
  - Hemagglutinin (H) – mediates entry of virus into the cell
  - Neuraminidase (N) – cleaves and releases newly formed viral particles
- Influenza A has 16 H subtypes and 9 N subtypes
  - Significant diversity among different viruses types
    - Genetic, structure, host range, epidemiology, clinical manifestations

#### Antigenic Drift

- Antigenic variants develop due to point mutations during replication
- Frequent emergence of variants through antigenic drift is the virological basis for seasonal epidemics
- Antigenic drift: Influenza A > B
- Reason for the usual incorporation of one or more new strains in each year's vaccine

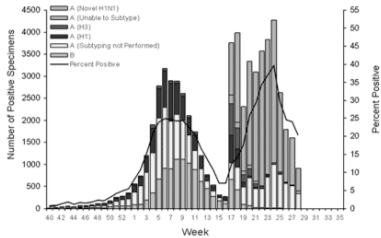
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#### Antigenic Characterization of Influenza Positive Tests

Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, 2008-09



#### Clinical Manifestations

- Symptoms are abrupt in onset and vary considerably from person to person
- Systemic symptoms (predominate early)
  - Fever, chills, HA, myalgia, malaise, anorexia
    - Myalgias = back, calf, possibly eye muscles
    - Fever 100-104° F typically
  - Severity related to fever
  - Systemic symptoms persist ~3 days
- Respiratory symptoms
  - Dry cough, severe pharyngeal pain, nasal obstruction & discharge, hoarseness, cough

#### People at High Risk for Complications From Influenza

- ≥ 65 years old or residents of LTCF
- People w/ long-term health problems (asthma, renal disease, DM, anemia, CVD)
- People w/ certain muscle or nerve disorders (seizures, severe cerebral palsy)
- People w/ weakened immune system (HIV, long-term steroids, chemotherapy)
- People 6 months - 18 years of age on long-term ASA (they can develop Reye Syndrome if they got influenza)
- Women who will be pregnant during influenza season
- All children 6-59 months of age

#### Diagnosing Influenza - Tests

- Diagnostic tests should be combined with clinical suspicion
- Three main testing modalities:
  1. RT-PCR
    - Highest sensitivity; used as a confirmatory test
  2. Immunofluorescence (fluorescent antibody staining)
    - Performance depends on laboratory expertise
  3. Rapid Diagnosis
    - Based on immunologic detection of viral antigen in respiratory secretions
    - Results in 30 minutes
    - Sensitivity 40-80%

#### Antiviral Agents

- Neuraminidase Inhibitors
  - Oseltamivir (Tamiflu)
    - Oral
  - Zanamivir (Relenza)
    - Inhaler
- Amantadines
  - Amantadine
  - Rimantadine



#### Who should be considered for Antiviral Therapy?

- Unvaccinated infants (12-24 months)
- Asthma or other chronic pulmonary diseases (e.g. CF)
- Significant cardiac disease
- Immunosuppressed
- HIV-infected
- Requiring long-term ASA (e.g. rheumatoid arthritis)
- Sickle cell anemia
- Chronic renal disease
- Cancer
- Chronic metabolic disease (e.g. DM)
- Neuromuscular disorders, seizure disorders, or cognitive dysfunction
- Adults > 65 years old
- Residents of long-term care institutions or nursing homes

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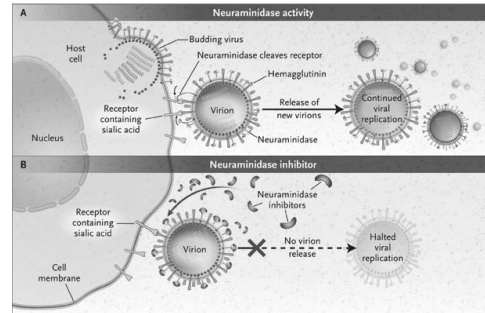
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#### Antiviral Usage

- Neuraminidase Inhibitors = primary agents
- Initiate within 2 days of illness onset
- Benefits of treatment
  - Shown to decrease the duration of influenza by one day compared with placebo
  - May prevent complications (pneumonia) or exacerbation of chronic disease
  - May decrease mortality
  - Data on viral shedding is mixed
- Chemoprophylaxis may be used in patients exposed to influenza
  - Especially in high risk patients
- Resistance rapidly emerging

#### Neuraminidase Inhibitors Mechanism



#### Neuraminidase Inhibitors: Indications

- Active against Influenza A and B
- Approved for use in adults and children
  - Zanamivir approved for treatment of persons age 7 years and older; prophylaxis in age 5 and older
  - Oseltamivir approved for treatment and prophylaxis of persons age 1 and older

#### Neuraminidase Inhibitors: PK

- Zanamivir
  - Dry powder for inhalation; not orally bioavailable
  - 10-20% of the active compound reaches the lungs and the rest is deposited in the oropharynx
  - 5-15% is absorbed and excreted in the urine
- Oseltamivir
  - Capsule or powder for liquid; Readily absorbed from GI
  - Converted by hepatic esterases to active form
  - Widely distributed in body
  - T1/2 = 6-10 hours; excreted primarily via kidneys (dose adjust in renal failure)

#### Amantadines

- Mechanism:
  - Inhibition of M2 ion channel activity of susceptible viruses (M2 channels play a role in replication)
  - Interfere with viral uncoating inside the cell
- Inhibitory for most influenza A, but not for influenza B
- Widespread high levels of resistance among influenza A (H3N2)
- Rimantadine is preferred over amantadine because of a more favorable adverse effect profile

#### Antivirals: Dosing in Influenza A & B

| Antiviral Agent                        | Adult Dosing  |
|--|---|
| Zanamivir (treatment)                  | 10mg (2 inhalations) BID                            |
| Zanamivir (prophylaxis)                | 10mg (2 inhalations) daily                          |
| Oseltamivir (treatment)                | 75mg PO BID   |
| Oseltamivir (prophylaxis)              | 75mg PO daily                                       |
| Amantadine & Rimantadine (treatment)   | 100mg PO BID (100mg daily in elderly over 65 years) |
| Amantadine & Rimantadine (prophylaxis) | 100mg PO BID (100mg daily in elderly over 65 years) |

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#### Antivirals – Treatment Duration

- Treatment: 5 days
- Prophylaxis: 5 – 10 days after last known exposure
  - May be longer in hospitals and long-term care facilities; minimum of 14 days

#### Adverse Effects

| Amantadines                              | Oseltamivir                                       | Zanamivir         |
|--|---|-------------------|
| CNS side effects (higher in amantadine)* | Nausea & Vomiting                                 | Bronchospasm**    |
| Nausea, Anorexia                         | Transient neuropsychiatric events (e.g. delirium) | Nausea & Diarrhea |
|  |   | Nasal symptoms    |

\*CNS side effects include nervousness, anxiety, insomnia, difficulty concentrating, and lightheadedness

\*\*Zanamivir is contraindicated in patients with underlying respiratory disease

#### Management of Influenza: Antiviral Resistance

|                             | Isolates tested (n) | Isolates tested (n), Resistant Viruses, Number (%) |           | Isolates Tested (n) | Resistant Viruses, Number (%) |
|-----------------------------|---------------------|--|-----------|---------------------|-------------------------------|
|                             |                     | Oseltamivir  | Zanamivir |                     |                               |
| Seasonal Influenza A (H1N1) | 1,099               | 1,094 (99.5%)                                      | 0 (0)     | 1,100               | 6 (0.5%)                      |
| Influenza A (H3N2)          | 213                 | 0 (0)  | 0 (0)     | 216                 | 216 (100%)                    |
| Influenza B                 | 620                 | 0 (0)  | 0 (0)     | N/A*                | N/A*                          |
| Novel Influenza A (H1N1)    | 274                 | 0 (0)  | 0 (0)     | 312                 | 312 (100%)                    |

FluView, 2008-2009 Influenza Season Week 28 ending July 18, 2009 CDC. 27

#### Influenza Vaccination

- Most effective means to prevent flu
- 70-90% effective in healthy adults <65 years old when vaccine and virus are antigenically similar
- 50-77% when antigenically dissimilar
- 90% effective in preventing influenza-related hospitalization

#### Influenza Vaccination Indications

- Persons aged 50 years and older
- Adults and children who have any condition that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration
- Residents of nursing homes and other chronic-care facilities
- Health-care workers
- Healthy household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza

Not a complete list (see [www.cdc.gov](http://www.cdc.gov) for all indications)

#### Other Means of Prevention

- Isolation precautions, negative pressure rooms, & good hand/respiratory hygiene
  - Offers modest benefit
  - Not been studied adequately to determine if they reduce transmission

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## CDC/ACIP Recommendations

- 1981: All HCW should be vaccinated
  - Who are HCW?
- Vaccination goals: reduce transmission, staff illness & absenteeism, morbidity & mortality among high risk persons
- JCAHO: must offer
  - But cannot enforce (violation of employee rights)

## Inactivated Influenza Vaccine

- Sterile suspension prepared from influenza viruses propagated in embryonated chicken eggs
- Standardized for particular season
- The 2009–2010 trivalent influenza vaccines will contain:
  - A/Brisbane/59/2007 (H1N1)-like antigen
  - A/Brisbane/10/2007 (H3N2)-like antigen
  - B/Brisbane/60/2008-like antigen
- Dose = 0.5ml in prefilled syringe given IM (preferably in deltoid)

## Pharmacology

- Effectiveness depends on age, immunocompetence, and degree of similarity between the vaccine and infecting virus
- Majority develop high post-vaccination hemagglutination-inhibition antibody titers
- These antibody titers are protective against illness caused by strains similar to those in the vaccine

## Pharmacology

- Antibody against one virus type or subtype confers little or no protection against another virus
- Antibody to one antigenic variant may not protect against a new antigenic variant

## Contraindications

- Contraindications: known hypersensitivity, reaction to egg/chicken proteins
- Delay in active neurologic d/o (ok when stable)
- Delay in febrile or acute disease (ok when stable)
- Warnings: Guillain-Barre syndrome within 6 weeks of prior vaccine, bleeding disorders (hemophilia, thrombocytopenia, on anticoagulant) - monitor for hematoma, latex allergy
- Pregnancy category C (but risk of influenza complications is increased during pregnancy)

## Guillain-Barre Syndrome

- 1976 swine influenza vaccine was associated with increased frequency of GBS (1 case in 100,000)
- GBS has an annual incidence of 10-20 cases in 1 million adults
- No evidence indicates an increase fatality from GBS among people vaccinated
- Potential benefits outweigh estimated risk of vaccine-associated GBS

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#### Fluarix Adverse Events

| Adverse Event            | Fluarix (n=760) | Placebo (n=192) |
|--------------------------|-----------------|-----------------|
| Local pain               | 54.7            | 12              |
| Local redness            | 17.5            | 10.4            |
| Local swelling           | 9.3             | 5.7             |
| Muscle aches             | 23              | 12              |
| Fatigue                  | 19.7            | 17.7            |
| Headache                 | 19.3            | 21.4            |
| Arthralgia               | 6.4             | 6.3             |
| Shivering                | 3.3             | 2.6             |
| Fever (>100.4-degrees F) | 1.7             | 1.6             |

#### Other Adverse Events

- Unsolicited adverse events (AE) from Study Fluarix-US-001
- AE  $\geq$  1% of recipients - Fluarix (placebo):
  - RTI 3.9% (2.6%), nasopharyngitis 2.5% (1.6%), nasal congestion 2.2% (2.1%), diarrhea 1.6% (0%), influenza-like illness 1.6% (0.5%), vomiting 1.4% (0%), dysmenorrhea 1.3% (1%)

#### Timing of Vaccination

- Influenza seasons vary in timing and duration
- >80% US outbreaks occurred in January or later
- Vaccination should begin soon after vaccine becomes available and continue throughout the season
- Vaccination campaigns for HCW should ideally begin mid-October and continued through December

#### Key in Education to HCW

- CDC: "Inactivated influenza vaccine contains killed viruses, and thus cannot produce signs or symptoms of influenza virus infection."

#### Vaccination Rates

- Per CDC, average national vaccination rate of HCW was 40.1% (2003) & 42% (2006)
- Individual institutions 2% to 60% in 2004
- Of those surveyed at Bronx-Lebanon Hospital Center (BLHC), 56.5% were vaccinated during 2006-2007 influenza season

#### Vaccination Goals

- National Health Objective has a goal of 60% immunization rate by 2010 to provide protective immunity
- Vaccination rate of 80% desired to confer herd immunity
  - 98% measles vaccination rate would potentially eradicate the measles virus

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#### Factors Influencing Vaccination Rate

- Prior Vaccination
  - Kimura study: statistically significant correlation b/w getting vaccinated and being vaccinated previously ( $p < 0.001$ )
- Motivation
- Knowledge & Attitude
  - Belief that vaccine is "safe, valuable, and wise" correlated with accepting vaccine

#### Steps To Increase Vaccination Rates

- Educational campaign + formalized "vaccine day"
- Strongly developed leadership role
- Mobile vaccine carts
- Providing vaccination % to directors/chiefs half way through season
- Declination forms

#### Influenza Vaccination Survey-Based Study

- Mehta M, Pastor CA, Shah B. Achieving optimal influenza vaccination rates: a survey-based study of healthcare workers in an urban hospital. *J Hosp Infect.* 2008;70:76-79.

#### Purpose of Survey

- During employee health screenings, many HCW declined influenza vaccine
  - "Do not believe in vaccines"
  - "Vaccines have made my friends very sick"
  - "The vaccine may decrease spermatogenesis"
- How pervasive are these beliefs?

#### What We Hoped to Learn...

- Which groups of HCW refused the influenza vaccine?
- Why did they refuse?
- Is refusal linked to other factors?
  - Job position, frequency of pt contact
  - Perceived reason for vaccination
  - Knowledge of influenza & CDC recommendations

#### Bronx-Lebanon Hospital Center

- BLHC is a 858-bed, non-profit, community teaching medical center located in south central Bronx
- Two major divisions + ambulatory sites
  - Major focus of survey = Grand Concourse division
- Total of ~3,500 healthcare workers (HCW)



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#### Hypotheses

- Influenza vaccine acceptance linked with two parameters in particular
  - Knowledge of influenza
  - Motivation for getting vaccinated

#### First Wave: The Survey

- Eight questions
- Three categories of questions
  - General information of employee
  - Influenza vaccination
  - Knowledge
- IRB approved

#### Methods

- Cross-sectional design
- Survey team distributed and collected surveys by hand over ~2-weeks
- Distribution of survey
  - Attended grand rounds (IM, Peds, FM)
  - Attended meetings (housekeeping, pharmacy)
  - Floor to floor (nurses, PCTs)
  - Departmental managers (respiratory therapy, dietary)

#### Methods

- Survey was purely optional and anonymous
- Employees were offered a survey with no or minimal explanation
- Raffle w/ prizes served two functions (increased overall participation, decreased participation bias)
- Data entered into SPSS (statistical package for the social sciences)

#### Results

- 570 surveys collected
- Overall vaccination rate (2006-2007 flu season) 56.5%
- Top two reasons for not receiving vaccine
  - "I feel I do not need" (31.8%)
  - "I am afraid of getting sick from vaccine" (23%)

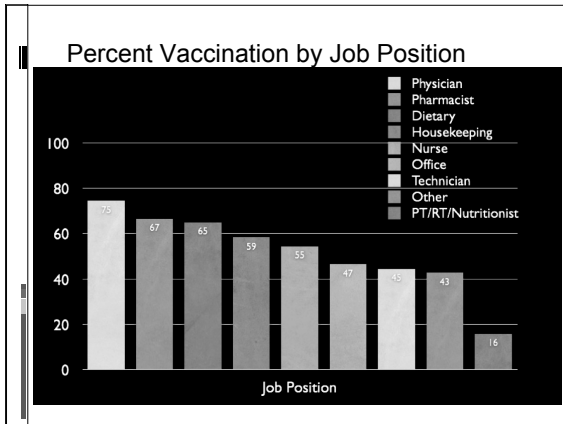
#### Respondent Demographics: Job Position

| Position                | Frequency | Percent |
|-------------------------|-----------|---------|
| Physician               | 166       | 29.2%   |
| Nurse, PA, NP           | 114       | 20%     |
| Technician              | 83        | 14.6%   |
| Pharmacist              | 12        | 2.1%    |
| Housekeeper/Maintenance | 41        | 7.2%    |
| PT/RT/Nutritionist      | 24        | 4.2%    |
| Dietary                 | 23        | 4%      |
| Office/Administrator    | 70        | 12.3%   |
| Other                   | 36        | 6.2%    |
| Total                   | 569       | 100%    |

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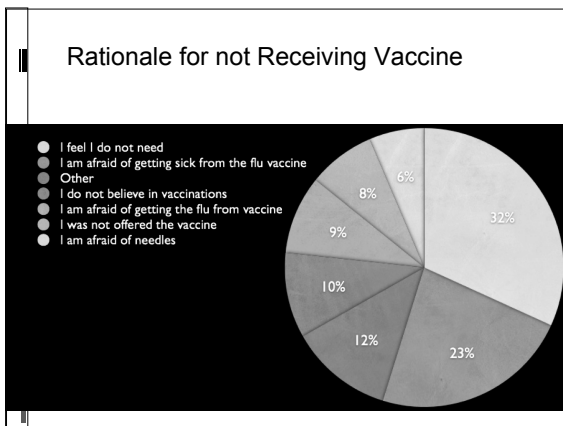
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#### Job Position

- Significant differences between groups when data was collapsed
  - Physicians\* vs. Non-physicians\* (p=0.001)
  - Technicians vs. Non-technicians\* (p=0.02)
  - Therapists (PT/RT/nutritionists) vs. Non-therapists\* (p=0.001)

\* Group with higher vaccination rate



#### Significant Findings: Knowledge

- Survey "knowledge" questions:
  - What is your best estimate regarding the number of deaths that occur each year due to the flu in the US?
  - Do you believe that the CDC recommends that health care workers receive the flu shot?
  - How often do you think the flu vaccine should be administered?

#### Significant Findings: Knowledge

- Knowledge score correlated with getting vaccinated
  - 3 "knowledge" questions
  - Participants vaccinated = 2.35/3 correct
  - Participants not vaccinated = 2.17/3 correct
    - Statistically significant (p = 0.003)

#### Significant Findings: Knowledge

- However, no relationship between getting all 3 knowledge questions correct and being vaccinated.
- Why might this be?
  - Other reasons...

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#### Significant Findings: Motivation

- Survey “motivation” question:
  - Why are flu vaccines for health care workers encouraged? (choose one):
    - To minimize sick days and loss of productivity
    - Because healthcare workers can get exposed to the flu by sick patients
    - Because sick patients are exposed to the flu by healthcare workers
    - To set an example to other workers

#### Significant Findings: Motivation

- HCW who received the vaccine were 3x more likely than those who did not receive the vaccine to indicate that:
  - “influenza vaccines are encouraged because sick patients are exposed to influenza by healthcare workers.”
- Statistically significant (p = 0.001)

#### Second Wave: Additional Players

- Managers were interviewed using a structured tool
- To assess:
  - Involvement of Management
    - Positive or Negative Reinforcement
    - Distribution of literature
  - Access: Mobile cart

#### Additional Players

|  | Vaccination Rate | Mobile Cart | Management involvement | Formal medical education |
|--|------------------|-------------|------------------------|--------------------------|
| Physicians                               | 74.7%            | Y           | Y                      | Y                        |
| Pharmacists                              | 66.7%            | Y           | N                      | Y                        |
| Dietary                                  | 65.2%            | Y           | Y                      | N                        |
| Housekeeping                             | 58.5%            | N           | Y                      | N                        |
| Nursing                                  | 54.6%            | Y           | N                      | Y                        |
| PT                                       | 16%              | N           | N                      | Y                        |
| RT                                       |                  | N           | N                      | Y                        |
| Laboratory (as part of technician group) | 44.6%            | N           | N                      | N                        |

#### Study Limitations

- Skewed representation: largest % of participants = physicians (29.2%); second largest = nurses (20%); third largest = technicians (14.6%)
- No to little data collected from night shifts and outpatient clinics
- Only two questions to test internal validity
- Possibility of > 1 survey/person
- Assumption that surveys reflect truth
- Other unknown factors (e.g. declination form)

#### Live Attenuated Influenza Vaccine

- Flumist™
- Contains live, attenuated virus and can cause mild symptoms related to influenza
- Intranasal administration
- Approved ONLY for use among healthy, non-pregnant, persons age 2 - 49 years
- Including HCW (per CDC)
- Advantages: broad mucosal & systemic response in children, ease of use, & increased acceptability

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#### Vaccine Comparison

| Trivalent inactivated influenza vaccine  | Live attenuated influenza vaccine (FluMist®)   |
|--|--|
| Inactivated virus (therefore, cannot produce s/sx of influenza)  | Live, attenuated virus (has potential to produce s/sx of influenza, e.g. runny nose, sore throat and congestion) |
| Intramuscular administration   | Intranasal administration  |
| Less expensive   | More expensive   |
| Approved for use among persons > 6 months, including those who are healthy and with chronic medical problems.  | Approved only for use among healthy persons age 2 to 49 years.   |
| Efficacy: conflicting and limiting data (some studies showing greater efficacy with LAIV compared to TIV and others showing no significant difference) |  |

#### Mandatory Vaccination for HCW in New York State 2009-2010

- On 8/13/09, an emergency regulation went into effect, requiring all personnel of healthcare settings receive seasonal annual influenza vaccine
  - Purposes: 1) protect health and safety of vulnerable patients, 2) maintain a healthy workforce
  - Must be vaccinated by 11/30/09 of each year
  - Unless medical contraindication or NY State determines that there is a shortage

New York State Department of Health. Accessed 9/1/09.

#### Mandatory Regulation Applies to...

- Hospitals, diagnostic/treatment centers, home health care agencies, long-term care, hospice
- Personnel who have direct contact with patients or whose activities are such that they pose a risk of transmission of influenza to patients
  - Including students & volunteers

New York State Department of Health. Accessed 9/1/09.

#### 2009 Novel H1N1 Influenza

- Previously called "swine flu"
  - Was initially believed many of the genes were similar to an influenza virus that normally occurs in pigs
- Most cases have occurred in people between the ages of 5 - 24-years-old
- Treatment: neuraminidase inhibitors (zanamivir, oseltamivir) only
  - Novel H1N1 is resistant to amantadines
- Infection control and prevention practices are critical

CDC. Accessed 7/27/09.

#### 2009 Novel H1N1 Influenza Vaccine

- The seasonal flu vaccine is unlikely to provide protection against novel H1N1 influenza
- A novel H1N1 vaccine
  - Currently in production
  - May be ready in the fall
  - Should be given in addition to seasonal vaccine

CDC. Accessed 9/1/09.

#### Recommendations on Recipients of Novel H1N1 Vaccine

- Pregnant women
- Household contacts and caregivers for children < 6 months
- Healthcare and EMS personnel
- All people 6 months to 24 years of age
- People aged 25 - 64 years who have health conditions associated are high risk
  - Current studies indicate that the risk for infection among persons age > 65 is less vs. younger age groups

CDC. Accessed 9/1/09.

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# Influenza

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