Objectives

By the end of this presentation, the listener will:

1. Be able to describe the effectiveness of Tamiflu as a treatment in various age groups.
2. List myths related to vaccines and explain why these beliefs are false.
To Tamiflu® or Not?

Influenza

- Pandemics:
  - 1918 Pandemic (Spanish flu): H1N1
  - 1957 Pandemic (Asian flu): H2N2
  - 1968 Pandemic (Hong Kong flu): H3N2
  - 2009 Pandemic (Swine flu): H1N1
  - Next Pandemic ??????

- Virology
  - Orthomyxoviridae
  - 3 types: A, B, C
The Influenza Virus

*Influenza type B virus has a different ion channel protein (NB)*

†Influenza type C virus has a single HEF protein for both functions

World Health Organization
Influenza Nomenclature

*Influenza type B does not occur as subtypes.*
Drug Arsenal

- M2 Ion Channel Inhibitors (A only)
  - Amantadine (Symmetrel®)
  - Rimantidine (Flumadine®)
- Neuraminidase Inhibitors (A and B)
  - Zanamavir (Relenza®)
  - Oseltamavir (Tamiflu®)
  - Peramivir (Rapivab™)

Oral Antivirals For Influenza

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<thead>
<tr>
<th>Antiviral</th>
<th>Trade Name</th>
<th>Influenza Type</th>
<th>Approved Ages</th>
<th>Side Effects</th>
<th>Cost/5d*</th>
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<tr>
<td>Amantadine</td>
<td>Symmetrel®</td>
<td>A</td>
<td>Px: ≥ 1yo; Tx: ≥ 1yo</td>
<td>CNS, anxiety</td>
<td>~ $10</td>
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<td>Rimantidine</td>
<td>Flumadine®</td>
<td>A</td>
<td>Px: ≥ 1yo; Tx: ≥ 12yo</td>
<td>CNS, anxiety</td>
<td>~ $15-20</td>
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<td>Zanamavir</td>
<td>Relenza®</td>
<td>A &amp; B</td>
<td>Px: ≥ 5yo; Tx: ≥ 7yo</td>
<td>Bronchospasm</td>
<td>~ $40-45</td>
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<td>Oseltamavir</td>
<td>Tamiflu®</td>
<td>A &amp; B</td>
<td>Px: ≥ 3mo; Tx: ≥ 1yo</td>
<td>Nausea/vomiting</td>
<td>~$100-150</td>
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*average adult patient, normal renal function
IV Antiviral for Influenza

- Peramivir (Rapivab™)
  - Neuraminidase inhibitor
  - First used in 2009-10 for emergency use
  - FDA approved December 2014
  - Used to treat severely ill or those with oseltamivir resistant strains
    - Approved for 18yo and older
    - Dosing down to neonates
  - $950 for a 1-day course

*average adult patient, normal renal function

Does Oseltamivir Work?

- The Controversy
  - Around for a long time
  - 2014 Cochrane Collaboration (April and December) and BMJ:
    - Reviewed randomized, placebo-controlled clinical trial data (most from 1990s)
    - Followed by a series of opinion pieces and articles that generated hype suggesting NAI’s do not work
Does Oseltamivir Work?

• What was found:
  – April 2014 review:
    • Treatment within the first 24-48 hrs can reduce symptom duration by ~ 1 day
    • Prophylaxis can reduce the risk of development of symptomatic influenza
      – *high risk contacts
  – December 2014 Review
    • Same efficacy results
  – Both reviews:
    • Included children and adults
    • Side effects highlighted

Oseltamivir Side Effects

• *Nausea and vomiting
  – Cochrane: 1.60 risk ratio when compared to placebo
  – 2001 (Whitley) Study:
    • N/V: 14.3% of children receiving oseltamivir compared with 8.5% receiving placebo
    • Diarrhea: higher in placebo (10.5%) compared with oseltamivir recipients (8.8%)

• Other possible:
  – Headache
  – Neuropsychiatric symptoms (confusion)
  – Renal impairment

Does Oseltamivir Work?

- What we do NOT know (for sure):
  - Effectiveness in severely ill patients - however:
    - Observational studies suggest may decrease morbidity and mortality
    - Survival advantage for those infected with H5N1
  - Effectiveness on patients with pneumonia
  - Effectiveness of risk of hospitalization in children

CDC Recommendations for the Use of Oseltamivir for the Treatment of Influenza

- Clinical trials and observational data show that early antiviral treatment can shorten the duration of fever and illness symptoms, and may reduce the risk of complications from influenza (e.g., otitis media in young children, pneumonia, and respiratory failure).
- Early treatment of hospitalized patients can reduce death.
- In hospitalized children, early antiviral treatment has been shown to shorten the duration of hospitalization.
- Clinical benefit is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset.
- Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who:
  - is hospitalized;
  - has severe, complicated, or progressive illness; or
  - is at higher risk for influenza complications.

Persons at higher risk for influenza complications recommended for antiviral treatment include:

- children aged younger than 2 years;
- adults aged 65 years and older;
- persons with chronic pulmonary (including asthma), cardiovascular (except hypertension alone), renal, hepatic, hematological (including sickle cell disease), and metabolic disorders (including diabetes mellitus), or neurologic and neurodevelopmental conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle, such as cerebral palsy, epilepsy [seizure disorders], stroke, intellectual disability [mental retardation], moderate to severe developmental delay, muscular dystrophy, or spinal cord injury);
- persons with immunosuppression, including that caused by medications or by HIV infection;
- women who are pregnant or postpartum (within 2 weeks after delivery);
- persons aged younger than 19 years who are receiving long-term aspirin therapy;
- American Indians/Alaska Natives;
- persons who are morbidly obese (i.e., body mass index is equal to or greater than 40); and
- residents of nursing homes and other chronic care facilities.
Influenza Vaccine

- Who?
  - **Everyone** ≥ 6 mos old

- When?
  - As soon as it is available
  - First outbreaks often October
  - Takes 2 weeks to develop antibodies

- What?
  - TIV/QIV for ≥ 6 mos old

Available Influenza Vaccines For Children

• Inactivated vaccines
  – All ages > 6mos
  – TIV (trivalent: 2 A strains, 1 B strain)
  – QIV (quadrivalent: 2 A strains, 1 B strains)

• Live intranasal vaccine (quadrivalent only)
  – Ages 2-49 yo
  (Contraindications: egg allergy, pregnant, immunocompromised, ages 2-4yo with asthma)

But if it was only that easy...
Vaccine Myths

Parents Have Increasing Doubts About Vaccines

Gust et al Pediatr 2008;122 (4):718
Permanent Medical Exemptions & Personal Beliefs Exemptions, Kindergarten Students, California

Refused pertussis vaccination
22.8 times increased risk of pertussis

Refused varicella vaccination
8.6 times increased risk of varicella
How did we get here?

• Real vaccine risks
  – 1950-1980s: whole cell DTP vaccine
  – 1976: Guillain-Barre from influenza vaccine
  – 1980s: OPV causing paralysis despite no cases of polio
  – 1990s: intussusception from rotavirus vaccine

How have we dealt with those risks?

• Move to DTaP vaccine
• Monitoring of occurrence of GBS after influenza vaccine
• Move from OPV to IPV vaccine
• Withdrawal of first rotavirus vaccine
The 1-2 Punch with Respect to Vaccine Safety

- 1998-99: Wakefield
- Then
- Thimerosal

Factors that have increased concern

- Distrust
  - Industry
  - Government
  - Doctors
- Uncertainty
- Rapid increase in the number of vaccines
- Rapid increase in the number of autism cases
- Internet/Media/Celebrities
The Things You Hear...

- Vaccines aren’t safe
- Vaccines cause autism
  - MMR
  - Thimerosal
  - Other vaccine ingredients
- Too many vaccines overwhelm the immune system
- Diseases no longer exist—or aren’t that dangerous
- Natural immunity is better
- Individual rights vs. public health needs
“Vaccines are Unsafe”

Vaccines are Safe

• Hundreds of millions of vaccines are given every year in U.S. with no problem
• Billions of vaccines are given in the world every year with no problem
• Vaccine safety infrastructure is large
  » VAERS
  » VSD
  » CISA
  » FDA
  » CDC
Sample Sizes Needed During Clinical Trials to Detect Increases in Rates of Rare Vaccine Adverse Events

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<tr>
<th>Rates of Event (%)</th>
<th>Sample Size*</th>
<th>No. Potentially Affected Annually¹</th>
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<td>0.1 vs. 0.2</td>
<td>50,000</td>
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<td>0.1 vs. 0.3</td>
<td>17,500</td>
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<td>0.01 vs. 0.02</td>
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<td>0.01 vs. 0.03</td>
<td>175,000</td>
<td>800</td>
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* Two-arm, power=80%, alpha (2 sided)=5%
¹ If the entire birth cohort (approx. 4 million children) received the vaccine each year


Vaccine Adverse Events Reporting System (VAERS)

- National post-licensure safety surveillance system jointly operated by CDC and FDA
- Spontaneous reporting system in existence since 1990
  - reports submitted by clinicians, manufacturers, patients/parents and others
- Subject to well-described limitations of passive surveillance
- Advantages
  - covers US population
  - permits monitoring for known adverse events
  - detects signals for previously unrecognized/rare adverse events
  - generates hypothesis
- Limitations
  - risk of underreporting or over reporting
  - incomplete data
  - lack of availability of denominator data

Adapted from Children's Hospital of Richmond at VCU
Other Vaccine “Safety Nets”

• Vaccine Safety Datalink (VSD)

   – Examples of VSD Studies:
     • Risk of seizures following pertussis and MMR vaccines
     • Risk of inflammatory bowel disease after measles-containing vaccines
     • Febrile seizures after MMRV and influenza vaccines
     • Guillain-Barre syndrome after H1N1 influenza vaccine
Other Vaccine “Safety Nets”

- Institute of Medicine Safety Reviews
  - MMR Vaccine and Autism
  - Multiple Immunizations and Immune Dysfunction
  - Vaccines and SIDS
  - Thimerosal and Neurodevelopmental Disorders
  - HBV Vaccine and Demyelination
  - Vaccines and autism
  - Influenza vaccine and neurological complications

- Clinical Immunization Safety Assessment Network (CISA)
  - 6 centers established to review vaccine safety
    • Northern CA Kaiser, Columbia, Johns Hopkins, Vanderbilt, Stanford, Boston University
  - Investigate immunologic, pathologic and genetic mechanisms of possible vaccine related adverse events
  - Provide consultation to providers regarding vaccine adverse events
“Vaccines can cause autism”

Vaccines and Autism

- MMR
- Thimerosal
- Aluminum
- Formaldehyde
Wakefield, 1998

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Lennell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Background
We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Introduction
We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some

Wakefield

- Findings never reproduced
- Wakefield had serious financial conflicts
- Co-authors withdraw from paper
- Paper retracted from Lancet
- Hearings held by British Health Authorities
- Wakefield sanctioned and license revoked
- The details of "an elaborate fraud" published in the British Medical Journal
In the wake of Wakefield

Vaccines and Autism

- What we know:
  - Wakefield retraction
  - Danish study
  - California study
  - Recent studies
  - Causes of autism
  - Heritability
  - Early recognition
  - Changes that had to occur in utero
Danish Study

Danish Cohort Study

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<th>The Past</th>
<th>The Present</th>
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<td>MMR</td>
<td>Autism: 283 ASD: 345</td>
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<td>1,647,504 person-yr</td>
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<tr>
<td>No MMR</td>
<td>Autism: 53 ASD: 77</td>
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<td>462,300 person-yr</td>
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Children born between 01/01/91 and 12/31/98
Population of Denmark

Madsen, K. Engh J Med 2012;347:497

Relative risk:
Autism: 0.92 (0.88-1.24)
ASD: 0.83 (0.65-1.07)

UK Study

Autism and MMR: United Kingdom

Cases per 100,000 Boys 2/5 Yrs


Kaye JA. BMJ 2001;323:460

19
California Study

Autism and MMR: California

- Highly heritable (more than breast cancer)
- Behavioral changes of autism often present before 1 year of age
- Autism associated with an increase in the number of neurons (i.e. insult occurs in utero)
- Ongoing studies specifically looking at risk of vaccines: none identified
- Autism hasn’t gone away despite thimerosal being taken out of vaccines
- Rates of autism may not be any different now than they were 40 years ago

Arch Gen Psychiatry 2011;68:459-465
J Peds 2011, April 19 epub
Thimerosal

Notice to Readers

Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service

The Food and Drug Administration (FDA) Modernization Act of 1997 called for FDA to review and assess the risk of all mercury-containing food and drugs. In line with this review, U.S. vaccine manufacturers responded to a December 1998 and April 1999 FDA request to provide more detailed information about the thimerosal content of their preparations that include this compound as a preservative. Thimerosal has been used as an additive to biologics and vaccines since the 1930s because it is very effective in killing bacteria used in several vaccines and in preventing bacterial contamination, particularly in opened multidose containers. Some but not all of the vaccines recommended routinely for children in the United States contain thimerosal.

MMWR 1999; 48 (26):564-566

Thimerosal

- Mercury content of recommended vaccines reviewed
- Recommendation to reduce mercury exposure
- Delay in Hepatitis B vaccination of newborns to minimize mercury exposure
- Once MMR couldn’t be targeted as a cause of autism, thimerosal became an attractive target
Thimerosal

• Thimerosal and Neuropsychological Function
  – 1047 children 7-10 years of age
  – Formal neuropsychological testing
  – Correlated outcome with thimerosal exposure
  – No evidence for a link between thimerosal exposure and neuropsychological functioning

Thompson WW, NEJM 2007;357:1281

Thimerosal

• 2008 California Study

Schechter R, Arch Gen Psych 2008:65:19-24
Aluminum

- Aluminum in vaccines
  - adjuvant
  - maximum amount 0.85 mg/dose
- Aluminum exposure
  - deodorant
  - food
    - adults average 7-9 mg/day
    » 200 mg in antacids
    - breast milk
    » 0.04 mg/L
    - formula
    » 0.225 mg/L

Aluminum Exposure in the First 6 Months of Life
“Too many vaccines overwhelm the immune system”

Do Too Many Vaccines Overwhelm the Immune System?

• Your immune system responds to hundreds of things every day
• There is no evidence that children get more infections right after they are immunized
• Clinical trials test multiple vaccines
• Increased vaccine purity
## Vaccine Antigen Make-Up

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<td>Polio 15</td>
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<td>Measles 10</td>
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Is natural immunity better?

- For some infections natural immunity is “better” because it lasts longer
- Natural immunity is not complete
  - Whooping cough, rotavirus
  - Multiple types of some disease agents (Pneumococcus, influenza)
- Natural immunity is only better if you survive the illness without serious consequences
- Natural immunity comes at a price
  - deafness, brain damage, hospitalization, pneumonia, paralysis, permanent scars
- You are taking a chance with letting your child develop natural immunity

Diseases **ARE** That Bad

- Prior to the availability of pneumococcal vaccine there were 200 deaths/year from this disease
- Out of the 5 cases of Hib reported last year in Minnesota, one died
- At least 10% of people with meningococcal disease die
- Over 400 children died in the U.S. from H1N1 influenza
- San Diego measles outbreak-out of 12 cases, one hospitalized
You can’t hide in the herd

- Herd immunity is very important
  - Elimination of H. flu disease
  - Decrease in influenza and pneumococcal disease in elderly because of pediatric immunization
  - Drop in Hepatitis A disease in California
- But, you can’t hide in the herd, especially if your herd thinks like you do
- Everyone else is NOT immunized
- It depends on what herd you are in- a partially immunized herd is a dangerous herd
- 5 cases of Hib reported this week in Minnesota suggesting that herd immunity is waning
- You will be thrown out of the herd (quarantined) if an outbreak occurs

“It’s a parent’s right to not vaccinate their child”
Parents’ Choice vs. the “Greater Good”

- Not vaccinating puts your child at risk
- Not vaccinating your child also puts others at risk
  - 3 innocent bystanders infected during San Diego measles outbreak
- Personal beliefs about immunization are affecting people who do not share those beliefs

What about alternative vaccine schedules?

The Sears Schedule
The Sears Schedule

- Based on the premise that it is better to spread out vaccines
- Based on Dr. Sears’ opinion about what diseases are dangerous and what diseases a child is likely to encounter
- Based on the assumption that aluminum in vaccines causes a problem
- Based on the premise that as long as enough people don’t follow the schedule, herd immunity will be maintained

Problems with Alternative Vaccination Schedules

- There is no scientific basis for them
- They leave children at risk for disease
- They leave our community at risk for outbreaks, including among those who are immunized
- They increase healthcare costs
Problems with Alternative Vaccination Schedules

• By delaying immunizations parents leave their children at risk.
  – The unimmunized are at increased risk to develop disease and expose others
    • All of the measles cases in San Diego in 2008 were unimmunized
    • 3 of them were too young to be immunized and were exposed in a doctor’s office
  – Unimmunized children are at increased risk for pertussis, mumps, chickenpox in schools

How can you respond?

• Listen carefully to concerns
  – Encourage questions
  – Empathize: acknowledge that there are many conflicting messages in the media
• Discuss known risks and benefits
  – Risks to unimmunized child
• Concerns about specific vaccines
  – Discuss
  – Administer other vaccines
• Multiple injection concerns
  – Last resort: modify schedule
• Revisit discussion in future visits
• Document
• Maximize benefits to their child
  – Not a public health discussion
  – Vaccines provide protection
  – Risk of disease for omitted vaccines
• Use personal stories
  • *Provide appropriate resources*
    – e.g., CDC, AAP, NNII, CHOP
Source of Information

Encourage Sound Sources

- Majority of sites found on an Internet search of “Vaccines” are anti-vaccine sites
- NNII site provides tips on how to evaluate the credibility of Web sites
  http://www.immunizationinfo.org
- How to identify a credible web site
  - Scientific studies cited and are current
  - Lack of financial conflict of interest
  - Experience in field
  - Lack of anecdotes
Thank you!