

# Exemptions, Legal Issues, and VAERS Reporting

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# Disclosures

- **William Atkinson has no financial conflict or interest with the manufacturer of any product named during this presentation**
- **The speaker will not discuss the use of any vaccine in a manner not approved by the Food and Drug Administration (FDA)**
- **The speaker not discuss vaccines not currently licensed by the FDA**

# Causes of Parent/Guardian Vaccine Hesitancy

- **Risk versus Benefit**
  - **risk: side effects, against personal, religious, or political beliefs**
  - **benefit: protection from vaccine-preventable diseases**

# Causes of Parent/Guardian Vaccine Hesitancy

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- “Lifestyle” issues
- Political issues
- Fear of side effects

# Homeopathy

- **Conceived by a German physician in the late 1700s**
- **Originally involved the “law of similars“**
  - **symptoms of disease can be cured by extremely small amounts of substances that produce similar symptoms in healthy people when administered in large amounts**
- **Products are extremely diluted and generally contain no active ingredient**

# Causes of Parent/Guardian Vaccine Hesitancy

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- “Lifestyle” issues
- Political issues
- Fear of side effects

# Causes of Parent/Guardian Vaccine Hesitancy

- “Lifestyle” issues
- Political issues
- Fear of side effects
  - real or imagined
  - no vaccine has ever been shown to cause autism, SIDS, or any other chronic condition

# Importance of Vaccine Safety

- **Decreases in disease risks and increased attention on vaccine risks**
- **Public confidence in vaccine safety is critical**
  - **higher standard of safety is expected of vaccines**
  - **vaccinees generally healthy (vs. ill for drugs)**
  - **lower risk tolerance = need to search for rare reactions**

# Importance of Vaccine Safety

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- **Vaccinations universally recommended or mandated**
- **Ongoing safety monitoring needed for the development of sound policies and recommendations**

# What is “Safe”?

- **SAFE = No Harm from the vaccine?**
  - no vaccine is 100% safe
- **SAFE = No Harm from the disease?**
  - no vaccine is 100% effective
- **Remind parents that to do nothing is to take a risk**

# How Do We Know Vaccines Are Safe?

- **Pre-licensure clinical trials, particularly placebo-controlled studies**
- **Post-licensure monitoring**
  - **Vaccine Adverse Event Reporting System (VAERS)**
  - **Vaccine Safety Datalink (VSD)**
  - **Clinical Immunization Safety Assessment (CISA) Network**

# Pre-Licensure Vaccine Safety Studies

- Laboratory
- Animals
- Humans



# Prelicensure Human Studies

- Phases I, II, III trials
- Phase III trials usually include a control group who receive a placebo
- Common reactions are identified
- Most Phase III trials include 2,000 to 5,000 participants
- Largest recent Phase III trial was REST – more than 68,000 children



**The largest vaccine trial in history was the Francis Field Trial of inactivated polio vaccine (1954-1955) involving 1.8 million children**

# Postlicensure Surveillance

- Identify rare reactions
- Monitor increases in known reactions
- Identify risk factors for reactions
- Identify vaccine lots with increased rates of reactions
- Identify “signals” – reports of adverse events more numerous than would be expected

# Vaccine Adverse Event Reporting System (VAERS)

- Jointly administered by CDC and FDA
- National reporting system
- Passive - depends on healthcare providers and others to report
- Anyone can report
- Receives ~30,000 reports per year
  - 10%-15% classified as serious (resulting in permanent disability, hospitalization, life-threatening illnesses or death)

<http://vaers.hhs.gov/>

# Vaccine Adverse Event Reporting System (VAERS)

- **Detects:**
  - new or rare events
  - increases in rates of known events
  - patient risk factors
- **VAERS cannot establish causality**
  - additional studies required to confirm VAERS signals and causality

# Vaccine Adverse Event Reporting System (VAERS)

- Healthcare providers are required by law to report to VAERS
  - any conditions on the Reportable Events Table
  - vaccine adverse events that are listed in the manufacturer's package insert

**VAERS Table of Reportable Events Following Vaccination\***

| <b>Vaccine/Toxoid</b>   | <b>Event and interval from vaccination</b>   |
|---|--|
| Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV | <ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Brachial neuritis (28 days)</li> <li>C. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>              |
| Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, P, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV        | <ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Encephalopathy or encephalitis (7 days)</li> <li>C. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>  |
| Measles, mumps and rubella in any combination; MMR, MR, M, MMRV, R                                      | <ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Encephalopathy or encephalitis (15 days)</li> <li>C. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul> |
| Rubella in any combination; MMR, MMRV, MR, R  | <ul style="list-style-type: none"> <li>A. Chronic arthritis (42 days)</li> <li>B. Any acute complications or sequelae (including death) of above event (interval - not applicable)</li> <li>C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>  |

<http://vaers.hhs.gov/>

# Vaccine Adverse Event Reporting System (VAERS)

- **What else should be reported?**
  - any clinically significant or unexpected event following vaccination
  - even if uncertain that the vaccine caused the event
  - for any vaccine
- **How to report**
  - paper (mail), fax, online

# *Post hoc ergo propter hoc*

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**“After this therefore because of this”**

**Temporal association does not  
prove causation**

**Just because one event follows  
another does not mean that the first  
caused the second**

# Elements Needed To Assess Causation of Vaccine Adverse Events

|                   | <u>Disease</u> | <u>No disease</u> |
|-------------------|----------------|-------------------|
| <u>Vaccine</u>    | a              | b                 |
| <u>No vaccine</u> | c              | d                 |

Rate in "vaccine" group =  $\frac{a}{a + b}$

Rate in "no vaccine" group =  $\frac{c}{c + d}$

If the rate in "vaccine" group is higher than the rate in the "no vaccine" group then vaccines may be the cause

# Does Vaccination Increase the Risk of Autism Spectrum Disorder (ASD)?

## VAERS Data

|                   | <u>ASD</u> | <u>No ASD</u> |
|-------------------|------------|---------------|
| <u>Vaccine</u>    | 345        | ?             |
| <u>No vaccine</u> | ?          | ?             |

$$\frac{\text{Risk in "vaccine" group}}{\text{Risk in "no vaccine" group}} = \frac{?}{?}$$

$$\text{Relative Risk} = ?$$

# Postlicensure Vaccine Safety Activities

- **Phase IV Trials**
  - ~10,000 participants
  - better but still limited
- **Large Linked Databases**
- **Clinical Evaluation Network**

# Vaccine Safety Datalink (VSD)

- Large linked database
- Links vaccination and health records
- Population under “active surveillance”
  - 9 HMOs
  - >2.5% (8 million) of U.S. population
- Can generate rates and relative risk because of the availability of unvaccinated population

# Participating VSD HealthCare Organizations



# Does Vaccination Increase the Risk of Autism Spectrum Disorder (ASD)?

## VSD Data

|                   | <u>ASD</u> | <u>No ASD</u> |
|-------------------|------------|---------------|
| <u>Vaccine</u>    | 345        | 440,310       |
| <u>No vaccine</u> | 77         | 96,571        |

Risk in “vaccine” group = 7.83/10,000

Risk in “no vaccine” group = 7.96/10,000

**Relative Risk = 0.98**

Madsen et al. *N Eng J Med* 2002;347:1477-82

# Clinical Immunization Safety Assessment (CISA) Project

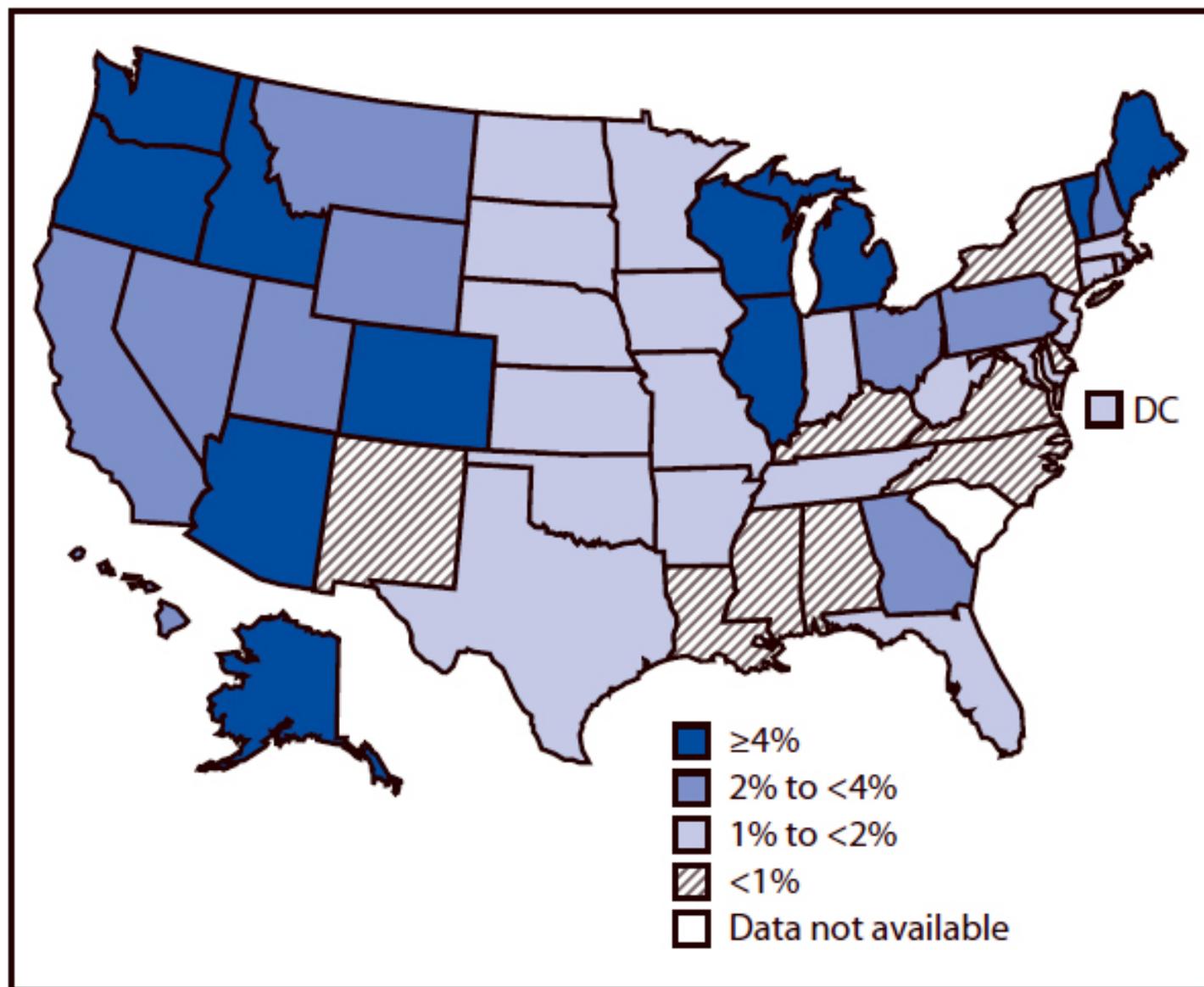
- Improve understanding of vaccine safety issues at individual level
- Evaluate individuals who experience adverse health events
- Gain better understanding of events
- Develop protocols for health care providers

# Exemptions to Vaccination

# Exemptions to Vaccination at Kindergarten Entry, 2012-2013 School Year

|                    | U.S. Median                   | MO                            |
|--------------------|-------------------------------|-------------------------------|
| <b>Medical</b>     | <b>0.3%</b>                   | <b>0.3%</b>                   |
| <b>Non-medical</b> | <b>1.5%</b>                   | <b>1.5%</b>                   |
| <b>Total</b>       | <b>1.8%</b><br><b>(+0.1%)</b> | <b>1.8%</b><br><b>(-0.6%)</b> |

**FIGURE.** Estimated percentage of children enrolled in kindergarten who have been exempted from receiving one or more vaccines\*  
— United States, 2012–13 school year



# Missouri Revised Statutes, Chapter 167, Section 167.181

- 2. It is unlawful for any student to attend school unless he has been immunized as required under the rules and regulations of the department of health and senior services... It is unlawful for any parent or guardian to refuse or neglect to have his child immunized as required by this section, unless the child is properly exempted.
- 3. This section shall not apply to any child if one parent or guardian objects in writing to his school administrator against the immunization of the child, **because of religious beliefs or medical contraindications**. In cases where any such objection is for reasons of medical contraindications, a statement from a duly licensed physician must also be provided to the school administrator.

# Children With Personal Belief Exemption

- 9-fold higher risk of varicella (Colorado, 1998-2008)
- 23-fold higher risk of pertussis (Colorado, 1996-2007)
- Introduce vaccine-preventable diseases (particularly measles) into school settings
- Expose children with medical exemptions to infection

# Personal Belief Exemptions

- **Permitting personal belief exemptions and easily granting exemptions are associated with higher and increasing nonmedical U.S. exemption rates**
- **State policies granting personal belief exemptions and states that easily grant exemptions are associated with increased pertussis incidence**

# Causes of Parent/Guardian Vaccine Hesitancy

- “Lifestyle” issues
- Political issues
- Fear of side effects
  - real or imagined
  - no vaccine has ever been shown to cause autism, SIDS, or any other chronic condition

# Autism and Vaccines

- **Multiple population-based studies have examined the rate of autism among vaccinated and unvaccinated children**
- **Available evidence does not indicate that autism is more common among children who receive MMR or thimerosal-containing vaccines than among children who do not receive vaccines**

[Autism Speaks™](#)[Be Informed](#)[Get Involved](#)[Walk Events](#)[Community](#)[Science](#)

# Autism Speaks™

[Science News](#)[News Archive](#)[CAN News Archive](#) [SEARCH](#)[Overview](#)[Science News](#)

## An Interview with Dr. Geri Dawson, Chief Science Officer, Autism Speaks, about the linking and autism

“... given what the scientific literature tells us today, there is no evidence that thimerosal or the MMR vaccine cause autism. Evidence does not support the theory that vaccines are causing an autism epidemic.”

- Dr. Geri Dawson, July 30, 2009



Gerri Dawson  
Chief Science Officer  
Autism Speaks

[Donate](#)[Store](#)[Resources](#)

What if  
you  
don't  
immunize  
your  
child  
?

IAC publication  
number p4017

# Reducing Personal Belief Exemptions

- Engage the parent and answer their questions if possible
- Be sure the parent understands that unvaccinated students will be excluded from school in the event of an outbreak
- Provide the parent with information
  - MO DHHS Parent/Guardian Exemption fact sheet
  - IAC “What If” fact sheet
- Suggest reliable websites for further information (some are listed on IAC “What If” fact sheet)

# Providers Can Change Minds

- **28% of parents doubtful about benefits and safety of certain vaccines**
- **Doubtful parents delayed or refused their child's vaccination**
- **Most parents who changed their minds about delaying or refusing vaccination cited information from their physician as the main reason for the change**

# Benefit and Risk Communication

- **Opportunities for questions should be provided before each vaccination**
- **Vaccine Information Statements (VISs)**
  - **must be provided before each dose of vaccine**
  - **public and private providers**
  - **available in multiple languages**

# Your Source for VISs www.immunize.org

[immunize.org](http://immunize.org) | [vaccineinformation.org](http://vaccineinformation.org) | [hepprograms.org](http://hepprograms.org) | [izcoalitions.org](http://izcoalitions.org)

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Vaccination Information for Healthcare Professionals

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### VISs

- ▶ [IAC Home](#)
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- ▶ [VISs by Language](#)
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- ▶ [Alternative Formats](#)
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## Vaccine Information Statements

### VISs by language

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|                           |                                |                             |                                |                            |
|---------------------------|--------------------------------|-----------------------------|--------------------------------|----------------------------|
| <a href="#">English</a>   | <a href="#">Chinese</a>        | <a href="#">Ilokano</a>     | <a href="#">Polish</a>         | <a href="#">Somali</a>     |
| <a href="#">Amharic</a>   | <a href="#">Croatian</a>       | <a href="#">Italian</a>     | <a href="#">Portuguese</a>     | <a href="#">Spanish</a>    |
| <a href="#">Arabic</a>    | <a href="#">Farsi</a>          | <a href="#">Japanese</a>    | <a href="#">Punjabi</a>        | <a href="#">Tagalog</a>    |
| <a href="#">Armenian</a>  | <a href="#">French</a>         | <a href="#">Karen</a>       | <a href="#">Romanian</a>       | <a href="#">Thai</a>       |
| <a href="#">Bengali</a>   | <a href="#">German</a>         | <a href="#">Korean</a>      | <a href="#">Russian</a>        | <a href="#">Turkish</a>    |
| <a href="#">Bosnian</a>   | <a href="#">Haitian Creole</a> | <a href="#">Laotian</a>     | <a href="#">Samoan</a>         | <a href="#">Urdu</a>       |
| <a href="#">Burmese</a>   | <a href="#">Hindi</a>          | <a href="#">Marshallese</a> | <a href="#">Serbo-Croatian</a> | <a href="#">Vietnamese</a> |
| <a href="#">Cambodian</a> | <a href="#">Hmong</a>          |                             |                                |                            |

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# How to Have a Successful Dialogue with Parents

- Take time to listen
- Solicit and welcome questions
- Keep the conversation going
- Balance science with anecdotal information
- Acknowledge benefits and risks

# How to Have a Successful Dialogue with Parents

- **Respect parents' authority**
- **Reduce the stress of shots**
- **Document parents' questions and concerns**
- **Follow up**
- **Don't give up**

### Welcome

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## Welcome to IAC



### About Us

The Immunization Action Coalition, a 501(c)(3) non-profit organization, is the nation's premier source of child, teen, and adult immunization information for health professionals and their patients.

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New IAC initiative to  
Give birth to the end  
of Hep B

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The Small Acts that Help to Keep  
Families Healthy Word of Mom

## Provider Resources for Vaccine Conversations with Parents



### Conversations Home

#### Talking to Parents about Vaccines

Understanding Vaccines and Vaccine Safety

Vaccine-preventable Diseases

About Vaccine Conversations with Parents

Provider Resources Web Tools

### Related Links

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[NIIW Educational Resources](#)

[For Parents: Vaccines for Your Children](#)

[Vaccines Home](#) > [Conversations Home](#)

 Recommend 5  Tweet 10  Share

## Talking to Parents about Vaccines Talking with Parents about Vaccines for Infants

### For health care professionals



Offers communication strategies for successful vaccine conversations with parents and caregivers.

- [Color for office printing](#)  
 [295 KB, 4 pages]
- [Black & white for office printing](#)  
 [308 KB, 4 pages]

**Printed size:** 8-1/2"x 11", 4 pages

**Commercial printer files** available [upon request](#)

## If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities

### For parents and caregivers



Outlines possible risks for parents who choose to delay or decline a vaccine; offers steps for parents to take to protect their child, family and others.

- [Color for office printing](#)

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 Centers for Disease Control and Prevention  
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Atlanta, GA 30333  
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(800-232-4636)  
TTY: (888) 232-6348  
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## Vaccine Education Center



### » Vaccine Education Center

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[A Look at Each Vaccine](#)

[Vaccine Schedule](#)

[Vaccine Safety](#)

[Vaccines: Practical Considerations](#)

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### Vaccine Mobile App

The Vaccine Education Center is pleased to announce the availability of its newest resource, "Vaccines on the Go: What You Should Know" — a free mobile app for iPhones.

[Learn more and download the app today»](#)

### Contact Us

We would like to hear from you. Please use our online form to contact us with questions or comments.

[» Contact Us Online](#)

## Welcome to the Vaccine Education Center

The Children's Hospital of Philadelphia's Vaccine Education Center provides complete, up-to-date and reliable information about vaccines to parents and healthcare professionals.

|  |  |
|--|--|
| <a href="#">A Look at Each Vaccine</a>   | <a href="#">VEC-Produced Materials</a> |
| <a href="#">Vaccine Safety</a>           | <a href="#">Vaccine Schedule</a>       |
| <a href="#">Practical Considerations</a> | <a href="#">Vaccine Science</a>        |

### Vaccine Mobile App



Always have vaccine information at your fingertips.

# Thank You



# Resources

- **CDC Vaccines and Immunization Website**
  - [www.cdc.gov/vaccines/](http://www.cdc.gov/vaccines/)
- **Immunization Action Coalition**
  - [www.immunize.org](http://www.immunize.org)
- **Vaccine Education Center at the Children's Hospital of Philadelphia**
  - [www.chop.edu/service/vaccine-education-center/home.html](http://www.chop.edu/service/vaccine-education-center/home.html)