Vaccine Safety Concerns and How to Respond to Vaccine-Hesitant Parents

June 12, 2012
11:00am – 12:30pm (CT)

Moderator: Nidhi M. Nakra, MPH – The Immunization Partnership

Speakers:
Dr. Julie Boom, MD – Texas Children’s Hospital
Alison Singer – Autism Science Foundation
Rachel Cunningham, MPH – Texas Children’s Hospital
Objectives

At the end of the webinar, participants will be able to:

• Describe three concerns or common misconceptions about vaccines

• Identify strategies that professionals can use to reassure vaccine-hesitant parents

• Understand the impact and benefits of storytelling to illustrate the benefits and risks of vaccination
Current Issues and Concerns Around Vaccine Safety

Julie A. Boom, M.D.
Director, Immunization Project
Associate Professor, Academic General Pediatrics
Baylor College of Medicine

June 12, 2012
Vaccine Safety Concerns and How to Respond to Vaccine-Hesitant Parents Webinar
Concern #1: What is the science? Do vaccines cause autism?
Review of alleged linkage

- 1998 - Wakefield published a case report of 12 children with IBD and regressive developmental delay
- Hypothesis: MMR caused bowel dysfunction, which resulted in neurodevelopmental disorders
- 2004 - 10 of Wakefield’s original 13 authors published a formal retraction
- 2010 - Lancet retracts study
- 2011 - BMJ investigation labels Wakefield’s study “an elaborate fraud” and Wakefield’s medical license is revoked

Why MMR? A victim of timing...
The body of evidence against an MMR-autism link


Looking at all the studies investigating a link between MMR and autism:

Institute of Medicine reviewed the body of literature and found that the evidence favors the rejection of a casual relationship between the MMR vaccine and autism.

Concern #2: Is thimerosal, a mercury derivative, harmful?
What is Thimerosal?

- Thimerosal has been used as a preservative in vaccines since 1930; only known risk is hypersensitivity
- Thimerosal is 49.6% by weight ethyl mercury
- Ethylmercury has a short half-life and does not cross the blood brain barrier due to its molecular size
"Although the names may sound the same, methylmercury and ethylmercury are very different. An analogy is the difference between methyl alcohol and ethyl alcohol: Methyl alcohol is antifreeze, and ethyl alcohol is a Bud light."

Dr. Ari Brown

Evidence mercury doesn’t cause autism

• In 1971, methyl mercury poisoning from fumigated grain caused pregnant women to deliver babies with epilepsy and mental retardation; not autism

• Denmark stopped using thimerosal in 1991; autism rates have risen since that time

• Symptoms of mercury poisoning and autism are different

• Exclusively breastfed babies will ingest more than 2 times the quantity that was ever in vaccines and 15 times that contained in the influenza vaccine

Evidence that mercury doesn’t cause autism


Looking at all the studies between thimerosal and autism:

Institute of Medicine reviewed the body of literature and found that the evidence favors rejection of causal relationship between thimerosal-containing vaccines and autism

Concern #3: Do vaccines overwhelm the immune system? And do we give too many too soon?
**FIGURE 1: Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012** (for those who fall behind or start late, see the catch-up schedule [Figure 3])

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<tr>
<th>Vaccine</th>
<th>Age</th>
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<th>1 month</th>
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<th>4 months</th>
<th>6 months</th>
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<td>Influenza (Yearly)</td>
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<td>Measles, mumps, rubella⁸</td>
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*Range of recommended ages for all children*  
*Range of recommended ages for certain high-risk groups*  
*Range of recommended ages for certain children and certain high-risk groups*  

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http://www.cdc.gov/vaccines/recs/schedules/default.htm
Our immune systems encounter challenges everyday:

“...an upper respiratory viral infection exposes a child to 4-10 antigens, and a case of strep throat 25-50.”

http://www.nap.edu/catalog.php?record_id=2138
Children are exposed to fewer vaccine antigens today than in the past . . .

Concern #5: Do vaccines cause other chronic diseases?
To date, there are no scientific studies validating the link between vaccination and any of the following:

- Diabetes
- Allergies and Asthma
- Sudden Infant Death Syndrome
- Multiple Sclerosis (after Hepatitis B vaccine)

http://www.nap.edu/catalog.php?record_id=2138
Evidence that vaccines don’t cause chronic diseases


Concern #6: Are vaccine ingredients safe?
Yes, but what are the ingredients and why are they there?

• What?
  – Ingredients include antibiotics, gelatin, aluminum, egg protein, formaldehyde.

• Why?
  – Antibiotics prevent vaccine contamination
  – Gelatin acts as a stabilizing agent
  – Aluminum is an adjuvant which stimulates immune response
  – Formaldehyde and egg protein are used in vaccine production

Vaccine refusals and exemptions
A common issue for pediatricians

- 85% of pediatricians annually encounter parents who refuse some vaccines
- 54% of pediatricians report encountering a parent who refused all vaccines
- 62% of pediatricians report an increase in parental concerns and refusals in last 10 years*
- More than 30% of pediatricians have dismissed families for refusing vaccines

Trends in delay or refusal of vaccines

- Between 2003-2008, % parents who refused or delayed vaccines increased from 22-39%
- The children of these parents were significantly less likely to be UTD at 19 months of age
- Approximately 1 in 8 parents has refused at least 1 recommended vaccine

Freed GL. et al.  *Pediatrics* 125, 654-659 (2009)
Trends in delay or refusal of vaccines

• Increasing number of states with personal belief exemptions (n=20)

• Mean exemption rates increasing at a rate of 5-6% per year in these states

Vaccine Exemptions in Texas

TX passes law allowing philosophical exemptions to vaccines for school entry.

Texas Department of State Health Services.
Julie A. Boom, M.D.

jboom@bcm.edu

(832) 822-3441
Q & A Session
Responding to Vaccine-Hesitant Parents

Alison Singer
Autism Science Foundation

The Immunization Partnership Webinar
June 12, 2012
Disclosures

• Nothing to disclose

• Neither Autism Science Foundation nor Alison Singer receive funding from pharmaceutical companies or vaccine manufacturers
New 4-step Framework for Communicating Science: Making the CASE for Vaccines

• **C**orroborate: Acknowledge the parents’ concern and find some point on which you can agree. Set the tone for a respectful, successful talk.

• **A**bout Me: Describe what you have done to build your knowledge base and expertise

• **S**cience: Describe what the science says

• **E**xplain/Advise: Give your advice to patient, based on the science
Top Three Parent Concerns about Vaccines

• Vaccines Cause Autism

• The diseases are not so bad (better to fight them naturally)

• Too Many Too Soon (let’s slow down the schedule)
I heard on tv that vaccines cause autism

• **Corroborate:** There’s certainly been a lot of coverage on television about vaccines and autism so I can understand why you have questions.

• **About Me:** I always want to make sure I’m up to date on the latest information so that I can do what’s best for my patients, so I’ve researched this thoroughly. In fact, I just returned from a professional conference…

• **Science:** The scientific evidence does not support a causal link. The CDC, the AAP, the NIH, the IOM (etc) all reviewed the data and all reached the same conclusion. Dozens of studies have been done. None show a link. In fact, the latest autism science indicates…

• **Explain/Advise:** Vaccines are critical to maintaining health and wellbeing. They prevent diseases that cause real harm. Choosing not to vaccinate does not protect children for autism, but does leave them open to diseases. Kids need these vaccines.
Measles isn’t so bad. I had chicken pox and I was fine.

- **Corroborate**: I can understand why you might feel that way. Hey, I had chicken pox myself.

- **About Me**: The vaccine program has been so successful and a lot of the diseases that we feared, like polio, are no longer a concern. Until last year, I had never seen a case of HIB or measles, but now these diseases are making a comeback. My colleague in San Diego was telling me about what’s going on in CA regarding the whooping cough epidemic. In my practice…..

- **Science**: These diseases have come back in areas where vaccination rates are low. Last year, 5 children died of HIB. Five cases of mumps have been diagnosed in NYC. 9 California babies died this year of pertussis.

- **Explain**: We care about our patients and don’t want to practice substandard care. All our patients need to be vaccinated. My children are fully vaccinated.
I want to spread out the shots so they won’t overwhelm my child’s immune system

- **Corroborate**: Kids today certainly get more shots than kids did years ago
- **About Me**: Our practice follows the CDC schedule because it is carefully designed to protect children at the time they are most vulnerable to disease. I recently returned from a meeting, or I served on a committee that reviewed the schedule…
- **Science**: Although kids get more shots today, they actually receive fewer antigens than when they got fewer shots, because technology has enabled us to make vaccines that have only the part of the cell that induces immune response. Plus, the immunological challenge from a vaccine is nothing compared to what kids fight off every day. An ear infection is a bigger immunological challenge. “Drop in the ocean”
- **Explain**: We want all the kids in our practice to be immunized so that they have the greatest chance for a long, healthy life. My own children are fully vaccinated.
New 4-step Framework for Communicating Science: Making the CASE for Vaccines

- **Corroborate**: Acknowledge the parents’ concern and find some point on which you can agree. This sets the right tone

- **About Me**: Describe what you have done to build your knowledge base and expertise

- **Science**: Describe what the science says

- **Explain/Advise**: Give advice to patient, based on the science
What do we need?

• Need to be able to respond to parents who say:

  “You can’t tell me vaccines don’t cause autism unless you can tell me what does cause autism”
Welcome to Autism 101
Autism Spectrum Disorders

- Autism Spectrum Disorders (ASDs) are a group of developmental disabilities.
  - Classic Autism
  - PDD-NOS
  - Aspergers Syndrome
  - Rett Syndrome
  - Childhood Disintegrative Disorder

- Impairment in 3 domains
  - Social (interest in people, joint attention, imaginative play)
  - Communication (language, speech)
  - Behavior (repetitive behaviors, tantrums, aggression)
What is autism?

social

language

behavior
What exactly is Autism?

- Sleep Disturbances
- Anxiety
- ADHD Symptoms
- Asperger’s Syndrome
- Depression
- Self-injurious Behavior
- Compulsive & Repetitive Behavior
- Sensory Integration Difficulties
- Cognitive Impairment
- Aggression
- Severe Functional Impairment
- Social Anxiety
- Depression
- Sleep Disturbances

Eric London 09
What do we know?

• 1 in 88 children diagnosed with an autism spectrum disorder (CDC)
• Early Intervention Works!
• Autism is a genetically based disorder
• Gene/Environment Interaction
What have we learned about cause?

• 15%-20% of autism attributable to specific genetic causes
  – Genetically-defined autisms

• Brain Imaging Studies and Genetics converging on neural synapses
  – “Synaptopathy”
  – Formation and Function
What have we learned about cause?

- 15% of autism attributable to specific genetic causes
  - Genetically-defined autisms

- Brain Imaging Studies and Genetics converging on neural synapses
  - “Synaptopathy”
  - Formation and Function

- Synaptic Protein Discoveries Leads to Novel Therapeutics
  - Animal Models of Autism
  - Clinical Trials in Humans for Fragile X, Phelan McDermid Syndrome

- Heritability vs De Novo mutation (older fathers, older mothers increase risk)
Copy Number Variation
Copy Number Variation
What do we know about cause?

• Several environmental factors have been implicated
  – Valproic Acid taken during pregnancy
  – Rubella exposure during pregnancy
  – Fertility drugs
  – Anti-depressants taken during pregnancy
  – Pet Shampoo
  – Ultrasound has been ruled out

• Environmental Factors currently being studied
  – IOM identified over 80 toxicants worthy of study

• Pre term infants at increased risk
What do we know about cause

- Differences in brain structure seen in 2\textsuperscript{nd} semester fetus\textsuperscript{1}

- There is an overproduction of brain cells in the frontal lobe, creating patches of functional abnormality. “Failure to prune”

- Have discovered genes responsible for “disregulation” or failure to govern and sort the number of cells generated.

- This new knowledge is essential to developing early biomarkers of risk to autism

What have we learned about treatment?

• Applied Behavior Analysis Therapy
  – Early Start Denver Model
  – New models for 9 months old, 6 months old, 3 months old?
• Speech Therapy
• Occupational Therapy
• Physical Therapy
• Social Skills Training
• FDA approved pharmacological interventions (Risperdal, Abilify)
• Ongoing FDA trials of OxytArboclofen and IGF1
• Clinical trials of Oxytocin
Other Treatments (Non Evidence based)

- Music Therapy (AIT)
- Horseback Riding
- Dolphin Therapy
- Special Diet (Gluten/Casein Free)
- Vitamin Supplements
- Secretin Injections
- Prism Glasses
- Anti-fungal agents
- Bleach enema

- Chelation
- Giant Magnets
- Raw camel milk
- Hyperbaric Oxygen
- Holding Therapy
- Nicotine Patch
- Marijuana (and not for the parent)
- Snake Oil (yes, actual snake oil)
Autism Science Foundation’s Mission

- Support autism research by providing funding and other support to scientists and organizations conducting, facilitating, publicizing and disseminating high quality autism research.

- Support families by reinforcing message that no science (over two dozen studies) indicates a causal link between autism and vaccines.

- Founded by parents and scientists, working together.
• Web  www.autismsciencefoundation.org
• Blog  www.autismsciencefoundation.wordpress.com
• Facebook  Autism Science Foundation
• Twitter  @AutismScienceFd
• YouTube  AutismScienceFdn
Q & A Session
“Give people a fact or an idea and you enlighten their minds; give them a story and you touch their souls.”

-Hassidic proverb
Storytelling as a communication strategy

• Shares experiences and engages listener
  • Perceived similarities and a sense of camaraderie
  • Resonates as a fellow parent

• Imparts values and makes meaning of experiences
  • Allows listener to receive knowledge from storyteller’s experience
  • Historical significance

• Addresses behavior
  • Different from case studies
  • Reduces resistance to behavior change

Houston TK et al. *Annals of Internal Medicine*. 2011;154:77-84
Health risk communication and narratives

• Risk perception and behavior change

• De Wit et al. – narrative communication increased perceived risk of HBV among MSM

• Ricketts et al. – personal stories in safety messages about unintentional injuries was more effective in improving behaviors

• Additional studies:

  • Taylor et al reported that 6 of 7 studies comparing narratives to statistics found narratives to be more persuasive

  • Baesler et al reported that 13 of 19 studies comparing narratives to statistics found narratives to be more persuasive

Ricketts M et al. *Social Science & Medicine*. 2010; 70:1441-1449
Hinyard L et al. *Health Education Behavior*. 2007; 34: 777-792
Immunization education and storytelling

“Anti-vaccine groups...have shared the heartbreak when they learned that their children were autistic and tied vaccines to it. People, logical or not, do not forget this kind of emotional prowess.”

“The power of anecdotal experiences supplemented by visual imagery should not be underestimated.”

Parikh RK. Pediatrics. 2008;121(3):621-622
Jenny McCarthy’s story

"Right before Evan’s MMR shot, I said to the doctor, 'I have a very bad feeling about this shot. This is the autism shot, isn't it?' And he said, 'No, that is ridiculous. It is a mother's desperate attempt to blame something,' and he swore at me, and then the nurse gave him the shot. "And I remember going, 'Oh, God, no!' And soon thereafter I noticed a change. The soul was gone from his eyes."

Oprah finished with a statement from the CDC, which said there was no science to support the connection between vaccines and autism.

Jenny’s response: “At home, Evan is my science.”
VACCINE-PREVENTABLE DISEASE
The Forgotten Story

Updated Edition

How Important are Vaccines?
Ask for W. Illsbees.

Meningitis

Meningitis is a life-threatening disease that can cause permanent damage or death if not treated. It is caused by a type of bacteria that enters the bloodstream and spreads to the brain. Symptoms can include high fever, headache, stiff neck, and vomiting. Early treatment with antibiotics is crucial to prevent permanent disability or death. Immunizations are available to prevent meningitis.

Breanne Palmer
Seasonal Flu

When Gay and Breanne Palmer traveled to Mexico for Christmas vacation with their sons, Tristan and Benjamin, Breanne contracted influenza. After she was diagnosed, she canceled their trip to Mexico. When she began vomiting and developed fever, there were only two things that could help: Pneumovax and FluVax. As the disease spread, the virus was attacking Breanne's brain and her lungs, making her unable to breathe. Her blood pressure dropped dramatically. But the doctors said she was going to die.

When all parents of healthy children will remember the suck, each one major in preventing deadly and preventable childhood disease, which is only if we don't act... or what they do. Texas Children's Hospital summarized that if children speak up to understand through 15 years old, no cancer should be diagnosed. Talk to your child's physician about which vaccines are right for your child.
76% of respondents reported using the book in direct conversation with parents about immunizations.

95% of respondents reported having a parent(s) change their mind about immunizations as a result of reading *Vaccine-Preventable Disease: The Forgotten Story*. 
Type of immunization information

- Other written: 20%
- Verbal: 32%
- Written and Verbal: 77%
- Neither: 0%
“It allows parents to see themselves in possible scenarios that actually happened to real parents…”

“Helpful adjunct to provide to nursing employees to help them deal with parent refusals... parents will say "how do you know?" I may not personally know the heartache, but the individuals in the book do.”

“This book put real patients with the diseases in front of the parents.”

“It’s another voice speaking to them. It helps them to see what the consequences could be without vaccinating.”

“True stories about families of all back grounds.”

“The pictures and stories make a greater impact than scientific literature.”

“The book shifts the discussion from the hypothetical to reality.

“Personal stories have a far greater impact than statistics.”

“Real people. Real stories.”

“It tells it like it is.”
Questions?

Rachel M. Cunningham
Texas Children’s Hospital
rmcunnin@texaschildrens.org
(832)-824-2010
Q & A Session
Thank you for participating!

Resources:

The Immunization Partnership
www.immunizeUSA.org

Texas Children’s Hospital
www.vaccines.texaschildrens.org

Autism Science Foundation
www.autismsciencefoundation.org
Please join us for our next webinar:
“Tools for Effectively Engaging Coalition Members and Stakeholders”
with Fran Butterfoss

Thursday, July 19th, 2012
11:00am – 12:30pm CT

Register at www.immunizeusa.org/en/cev/78

Immunize. Prevent What’s Preventable.
Please complete the online evaluation.

For more information on The Immunization Partnership, visit [www.immunizeUSA.org](http://www.immunizeUSA.org) or contact:

- Nidhi M. Nakra, MPH, [nnakra@immunizeUSA.org](mailto:nnakra@immunizeUSA.org)
- Linnea Nasman, [Lnasman@immunizeUSA.org](mailto:Lnasman@immunizeUSA.org)