A Passion for Prevention

CRIC Symposium September 28, 2016

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Disclosures

- I accept no honorarium for providing vaccine talks
- Organizations may choose to donate to Children's instead
- I am an Executive Board member of the National Foundation for Infectious Diseases
- I am a past voting member and current liaison member for the Advisory Committee on Immunization Practices at the CDC
- I am a member of the MN Advisory Committee on Immunization Practices at the MDH
- I have no financial conflicts of interest to disclose

Objectives

At the completion of this session the learner will be able to:

- 1. Describe the value of immunization in disease prevented and deaths averted.
- 2. Gain new skills in talking about the importance of vaccines in keeping children and the community safe
- 3. Describe our duty to first do no harm



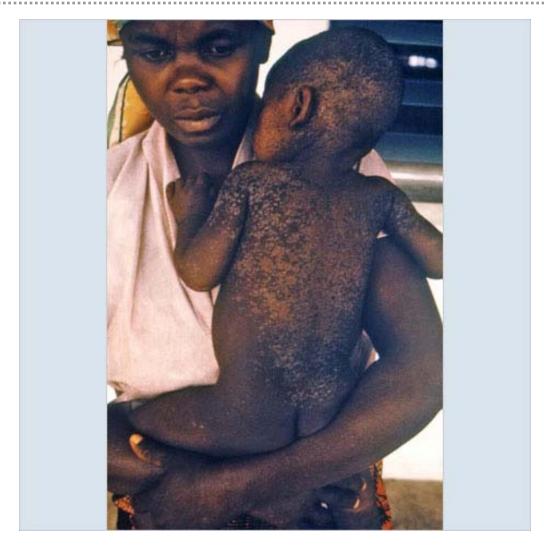
| Vaccines Work! Immunization Action Coalition 12/14 DISEASE | PRE-VACCINE ERA ESTIMATED ANNUAL MORBIDITY* | MOST RECENT REPORTS OR ESTIMATES [†] OF U.S. CASES | PERCENT DECREASE |
|------------------------------------------------------------|---------------------------------------------------|-------------------------------------------------------------|---------------------|
| Diphtheria | 21,053 | 0† | 100% |
| H. influenzae (invasive, <5 years of age) | 20,000 | 31‡ | >99% |
| Hepatitis A | 117,333 | 2,890§ | 98% |
| Hepatitis B (acute) | 66,232 | 18,800§ | 72% |
| Measles | 530,217 | 187† | >99% |
| Mumps | 162,344 | 584 [†] | >99% |
| Pertussis | 200,752 | 28,639† | 86% |
| Pneumococcal disease (invasive, <5 years of age) | 16,069 | 1,900# | 88% |
| Polio (paralytic) | 16,316 | 1† | >99% |
| Rotavirus (hospitalizations, <3 years of age) | 62,500** | 12,500 ^{††} | 80% |
| Rubella | 47,745 | 9† | >99% |
| Congenital Rubella Syndrome | 152 |]† | 99% |
| Smallpox | 29,005 | 0† | 100% |
| Tetanus | 580 | 26 [†] | 96% |
| Varicella | 4,085,120 | 167,490 ^{§§} | 96% |

Vaccine Adverse Events are Extremely Rare

- CDC analyzed 67 different vaccine research studies. April, 2015
 - For kids born in the last decade, 322 million illnesses prevented,
 21 million hospitalizations prevented and 732,000 deaths
 prevented over the course of their lifetimes
- NO evidence vaccines cause autism
- Pediatrics Maglione, M and Gidengil, C. 2015
 - Risk of anaphylaxis 1-1.3 in 1,000,000 doses
- Risk in perspective~
 - Car accidents = 38,000 deaths in children under 4 yrs in 2012 and
 523 deaths



2016: What makes vaccines a "tough topic"? How did we get here?





We went from scrambling for life-saving vaccines

to this...







The Vaccine Book: Making the Right Decision for Your Child Dr. Robert Sears

- Spreads out the approved CDC/AAP schedule
- No more than 2 vaccines at a time
- Offers a "selective" individualized schedule
- Not approved
- Causes delay
- Takes unnecessary risk
- Hard to keep track of
- Now risks loss of MD license for medical
 81© 2016 negligence





Sources & perceived credibility of vaccine safety information

Freed et al, Pediatrics Vol 127 Supplement 1, May 2011

- Parents report "a lot or some" trust for receiving vaccine safety information:
- 98% trust their doctor
- 96% trust others in health care
- 84% trust government experts
- 92% trust family/friends
- 73% trust parents who believe their child was harmed by a vaccine
- 26% trust celebrities
- Jan, 2009. On-line survey, rep sample 2521 parents of kids < 17 years old (N = 1552)



The Spectrum of Vaccine Acceptance or Refusal

Opel, NFID Clinical Vaccinology Course Spring, 2014

| PRO Vaccine | | Anti-Vaccine |
|----------------------------------------|-------------------------------------------------------|-------------------------------------------|
| Acceptors | Vaccine- hesitant | Rejector |
| Agree with or do not question vaccines | Are unsure about, delay, or choose only some vaccines | Completely reject vaccines |
| Child fully immunized | Child under-immunized | Child un-immunized |
| Believe vaccines are safe | Concerned vaccine side effects outweigh benefits | Very concerned about vaccine side effects |
| Believe vaccines work | Concerned vaccines might not prevent disease | Doubt vaccines work |
| High trust in provider | Desires a trustworthy provider | Low or no trust |
| Interest in vaccine info from provider | Interest in vaccine info from provider | No interest in vaccine info |
| ~70-90% | ~10-30% | <1% |

The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits

Opel et al. Pediatrics, Nov 4, 2013 (Also see Human Vaccines 2011 and Opel et al. Vaccine 2011)

- Presumptive ("We need to do some shots today") vs.
 Participatory conversations ("What do you want to do about shots?")
- Clinicians positively influence parental immunization decisionmaking
- The start of your immunization conversation will impact the outcome
- Pursue the recommendations as you would other life-saving medical conversations

Douglas J. Opel, MD, MPH Assistant Professor of Pediatrics University of Washington School of Medicine Seattle Children's Hospital



HOW the provider initiates the plan makes a difference

(N=111) Opel et al. Pediatrics 2013

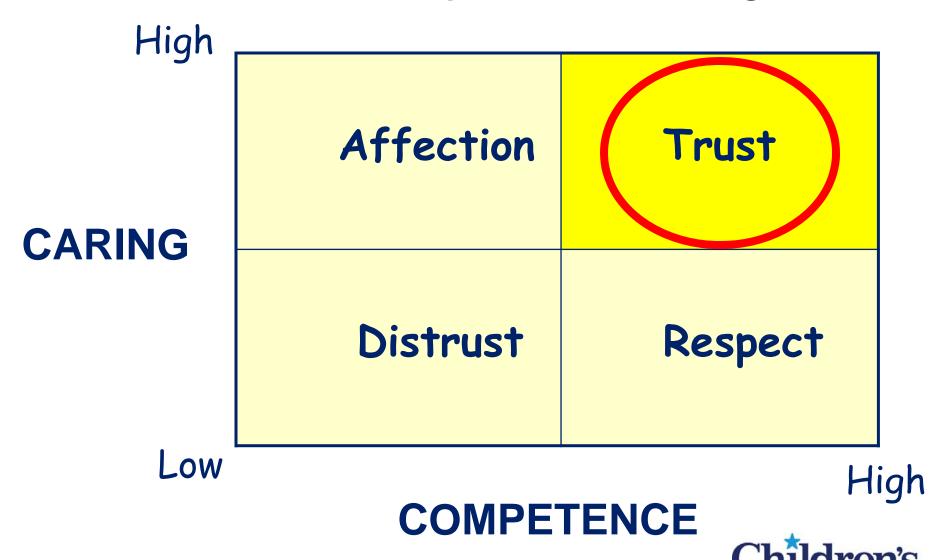
- Presumptive
- "It's time to start one year "How do you feel about old vaccines...we're going vaccination?" to be doing 2 live vaccines today; the MMR and chicken pox shots"
- Participatory

- Parent accepts 75%
- Resists 26%

- Parent accepts 4%
- Provides own plan 13%
- Resists 83%



Trust = Competence + Caring



13 | © 2016 Paling J. BMJ 2003; 327:745-748. Alaszewski A, Horlick-Jones T. BMJ 2003; 327:728-731

Vaccine Opposition is Rare

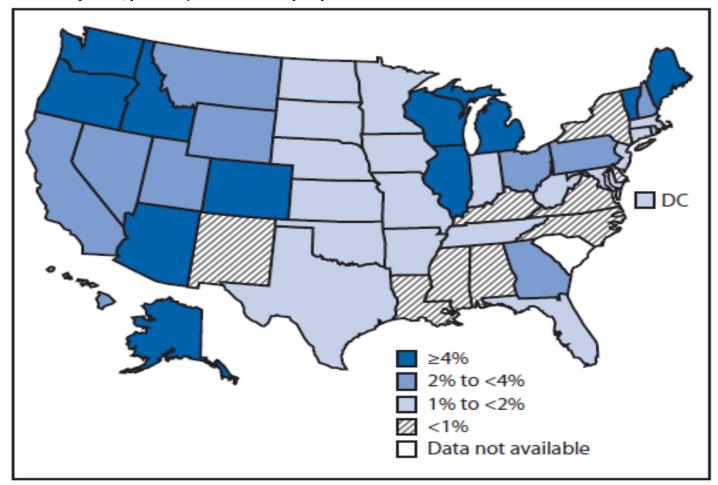
- "Believers"-Vaccine Aware >90 % rates for longstanding vaccines in toddlers
 - The vast majority of American parents vaccinate according to the recommended schedule
- Vaccine Hesitant <10%
 - A small but growing number of parents are confused and reluctant about vaccination
- Vaccine Opposed (Zero vaccines) <1% none
 - An even smaller, but well-organized and very vocal group of parents are anti-vaccination for a various reasons.

MMWR National and State Vaccination Coverage. US children 19-35 months, 2012 / 62(36);733-757 Sept 13, 2013



% of kindergartners exempting from 1 or more vaccine 2012-2013 school year

MMWR weekly August 2, 2013/62 (30):607-612





Hazards of exemptions

- Among the 222 US measles cases in 2011, 76% were not vaccinated for NON-medical reasons.
- MN had most cases (24) even with 96% MMR vaccine rate.
- Europe had >30,000 cases with 8 deaths.





Effective communication keys

- Listen First
- Ask what they are most concerned about
- Be prepared to speak to each concern
- www.cdc.gov/vaccines/spec-grps/hcp/conversations.htm
- Use science, but not science jargon
- Share anecdotes, but not exclusively
- Establish common ground: you both share concern for child safety



Assess origins of concerns: reasons parents give not to immunize



- -Contraindications
- -Precautions



- -Side effects
- -Medical accidents

• Philosophical

- —Individual rights
- -Alternative health



- -Not health care consumer
- Human or animal tissue in vaccines
- "Good health is achieved through seeking God"



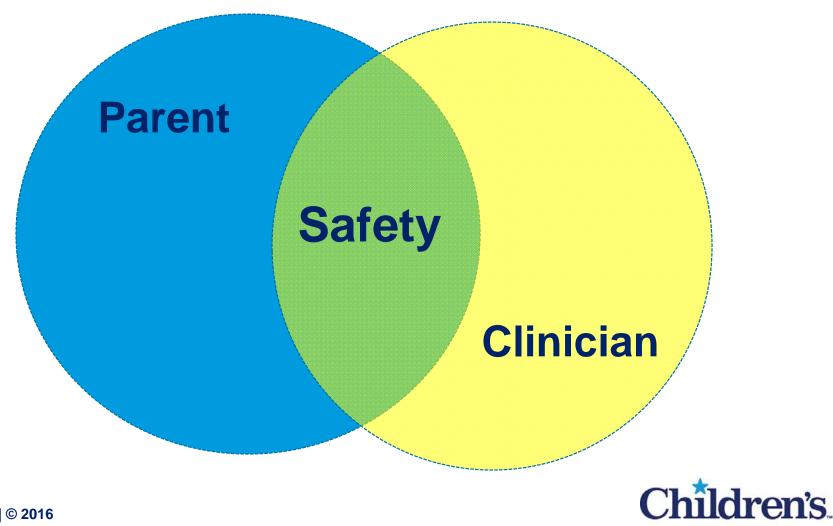
CASE model of communication

http://www2.aap.org/cisp/pediatricians/riskcommunicationvideos.html

- Corroborate. Acknowledge the parent's concern. Find a point of agreement that sets respectful tone
- About me. Talk about what you have done to build your knowledge base on the topic. Share your experiences.
- **Science.** Share what the evidence says about safety.
- Explain/Advise. The call to action to choose to vaccinate



Shared goals in safety



What is safe?

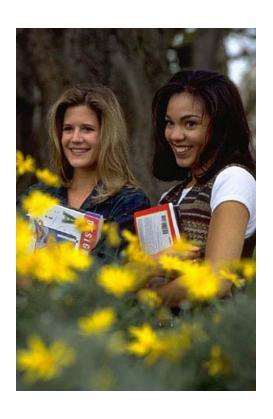
- SAFE = No Harm from the vaccine?
 No vaccine is 100% safe
- SAFE = No Harm from the disease?
 No vaccine is 100% effective
- Students may define safety as "absent negative effects"
- Have we communicated realistic expectations?
- To do nothing is to take a risk (like skipping your seat belt)
- "The risk of disease far outweighs the risk of vaccine"



Interventions with young people
Understanding attitudes toward adolescent vaccination and the decision-making dynamic among adolescents,

Understanding attitudes toward adolescent vaccination and the decision-making dynamic among adolescents, parents and providers. C Gowda, et all. BMC Public Health 2012, 12:509 dol:10.1186/1471-2458-12-509 July 7,2012

- Reminder Recall systems
- Information in advance of the visit
- Use of technology-email notices
- Story telling rather than directives
- Use of Social Media-Tweet flu season facts
- Use of Rewards, recognition, competition
- Mass flu vaccine clinics
- Giveaways
- Food!





Avoiding vaccines is to take a risk

- By choosing <u>not</u> to vaccinate one takes on the risk of disease, so both vaccinating and not vaccinating carry risks
- Use the car seat analogy of choosing not to strap in
- The unvaccinated against measles are 35 times more likely than the immunized to catch the disease.

Salmon DA, Haver M, et al. Health consequences of religious and philosophical exemptions from immunization laws. *JAMA* 1999;282L 47-53



Influenza

- Universal recommendation!
- All persons 6months of age and older should get an annual influenza vaccine
- One dose only for 9 and over so good for teens



Flu Vaccines-Do they work?

- Not a single answer
- Depends on age and type of vaccine given
- Intra-season efficacy initially 62% then 56% all ages 2013 and 0 in 2014-15 due to mismatch, 3% LAIV in 2015-16, compared to 63% IIV
- 9% in the elderly
- Measured just 3000 people during January 2013 for reduced clinic visits
- 76% for keeping elderly out of the hospital
- Overall mid-season efficacy is 56% -66%



Lines for vaccines H1N1 2009





Influenza Took the lives of 154 US Children in 2012-2013 Season

- 90% were unvaccinated
- 50% were normal, healthy children
- Children with neurodevelopmental disabilities, especially those who have difficulty handling secretions, were hard hit

• CDC.gov/flu



Effectiveness of Influenza vaccine against life-threatening PCR confirmed influenza illness in US children, 2010-2012

Ferdinands, et al Journal of Infectious Disease March 26, 2014

- 44 cases, 172 PICU controls, 93 community controls
- Influenza vaccination is associated with 74% reduction in the risk of life-threatening influenza illness in children
- Receipt of one dose of vaccine among children for whom 2 doses were recommended was <u>not</u> protective
- First ever study in children looking at flu vaccine and critical care



SBAR example-your elevator speech

- <u>Situation</u> Influenza is a dangerous disease. And flu vaccine is our best tool to prevent it.
- Background We can pass the flu 1 day before we even know we are sick. Getting the flu may mean being out of work for a week or more. Flu vaccine does not cause the flu. Pts die of influenza. We can transmit it to them.
- **Assessment** Influenza is a vaccine preventable disease that can be severe for your patients, you, & your family. Flu vaccines are safe and effective to avoid the flu.
- Recommendations Get vaccinated every year in the fall before the flu season begins and strongly encourage everyone 6 months of age and over to get vaccinated.
- IHI Patient Safety Communication Method 29 | © 2016

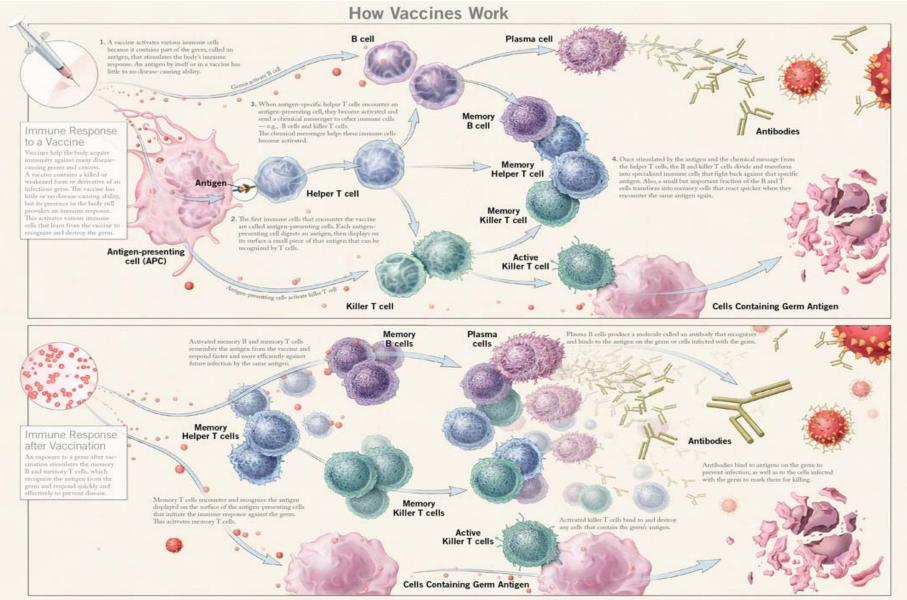


Emphasize ongoing safety monitoring

- Many ways that vaccines are monitored on an ongoing basis:
- Vaccine Safety Datalink (large HMO data analysis)
- VAERS (Vaccine Adverse Event Reporting System through the CDC & FDA, relies on providers) http://vaers.hhs.gov/
- CISA centers (6 centers for immunization safety assessments)
- Ongoing <u>post-marketing</u> surveillance by manufacturers



Studying the Science~ The power of human immunity



Will vaccines overwhelm my baby's immune system? They are powerfully prepared for vaccines





- The immune system has the capacity to respond to extremely large numbers of antigens; possibly 10,000 or more
- 2 billion CD4 T lymphocytes can be replenished daily
- T and B lymphocytes are abundant in a "lock and key" ability to deal with antigens individually; therefore no "immune system overload"
- All 14 vaccine combined hold ~150 immunological proteins
- The "thimble of water in an ocean" analogy



Example of why we keep fostering champions Hib epiglotittis at Children's of Minnesota in 2012

- 4 year old, unvaccinated girl, 14 intubation attempts
- nearly died
- Ventilated in the PICU for days
- Mom said:



"All I heard about vaccines were that they cause autism. I didn't want that so I didn't vaccinate. If I knew this could happen I would never have skipped vaccines. I wish someone would have told me instead of saying 'OK' when I refused the Hib vaccine."

She survived and was started on her catch-up schedule prior to discharge from the PICU.



AAP new policy statement on vaccine refusal Pediatrics on line 8/29/16

- In a member survey from 2006-2013:
 - Concerns about vaccines have shifted
 - Refusal increased >10% from 75% to 87% ('not necessary')
 - Pediatricians perceive the reasons parents delayed vaccines (pain and immune system overload) differed from the reasons they refused vaccines (considered vaccines unnecessary).
 - However, some reasons for vaccine refusal significantly declined in frequency, including the concern about autism and/or thimerosal (74 percent in 2006 versus 64 percent in 2013).
 - Pediatricians "always" dismissing patients for continued vaccine refusal doubled to nearly 12 percent.



AAP policy statement on vaccine refusal Pediatrics on line 8/29/16 "Countering Vaccine Hesitancy"

- States should enact day care and school laws with medical exemptions only. Eliminate all non-medical exemptions.
- If after counseling efforts are exhausted, parents decline immunizations, pediatricians may request that they sign a vaccine refusal form and/or seek care from a different health care provider.
- AAP advises pediatricians to:
 - have compassionate dialogues with parents to clear up misconceptions around vaccines,
 - provide accurate information about the safety and importance of vaccines, and
 - strive over time to help parents make the decision to vaccinate their child.



How do you handle vaccine refusers in your clinic?







Public Policy for the greater good







Ethical principles impacting vaccine discussion

- First do no harm--non-maleficence
- Utility—greatest benefit and least harm
- Duty to protect- both parental and clinician duty
- Autonomy—individual decision making without coersion
- Beneficence- advance the common good
- Justice—be fair and treat like cases alike



Measles

More than 1000 cases in Swansee Wales, 2013 Millions of children susceptible

www.gaurdian.co.uk accessed 6/8/13M





Morbidity and Mortality Weekly Report (MMWR)

MMWR

















Notes from the Field: Measles Outbreak --- Hennepin County, Minnesota, February--March 2011

Weekly

April 8, 2011 / 60(13);421

On March 2, 2011, the Minnesota Department of Health (MDH) confirmed measles in a Hennepin County resident aged 9 months. As of April 1, investigation of contacts and heightened surveillance had revealed a total of 13 epidemiologically linked cases in Hennepin County residents. Of those cases, 11 were laboratory confirmed, and two were in household contacts of confirmed cases and met the clinical case definition for measles.

The patients included children aged 4 months--4 years and one adult aged 51 years; seven of the 13 were of Somali decent. Eight patients were hospitalized. Vaccination status was known for 11 patients: five were too young to have been vaccinated, and six (all of Somali descent) had not been vaccinated because of parental concerns about the safety of the measles, mumps, and rubella (MMR) vaccine. The most recent rash onset was March 28. An additional, unrelated case of measles was confirmed in a Hennepin County resident aged 34 years who was exposed in Orlando, Florida, sometime during March 1--10.

The investigation determined that the index patient was a U.S.-born child of Somali descent, aged 30 months, who developed a rash February 15, 14 days after returning from a trip to Kenya. The patient attended a drop-in child care center 1 day before rash onset; measles developed in three contacts at the center and in one household contact. Secondary and tertiary exposures occurred in two congregate living facilities for homeless persons (four patients), an emergency department (two patients), and households (two patients). A virus isolate from the index patient was genotyped at CDC as B3, which is endemic in sub-Saharan Africa.

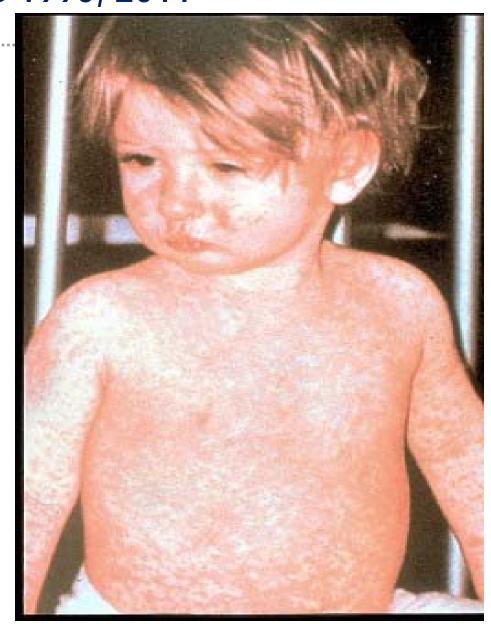
Outbreak control efforts have included following up with potentially exposed persons, providing immune globulin to persons without evidence of immunity, and recommending that persons without evidence of immunity who have been exposed to measles not leave their residence while potentially infectious (21 days). Multiple vaccination clinics have been held or scheduled at community venues and in the congregate living facilities.

In the United States, MMR vaccine normally is given as a 2-dose series, with the first dose at age 12--15 months and a second dose at age 4--6 years.* However, this series may be accelerated during outbreaks. In response to the current outbreak, MDH has recommended that children aged 6--11 months living in selected congregate living facilities receive a dose of MMR vaccine, and that older children and adults in these facilities receive vaccine if they are susceptible and have had less than 2 doses of MMR vaccine. MDH also has recommended an accelerated vaccination schedule (a total of 2 doses of MMR vaccine separated by at least 28



Resurgence of measles 1990, 2011

- Mostly imported and spread in under-immunized pockets
- In 2011, MN had most cases in US since mid 1990's
- No deaths, but multiple hospitalization with pneumonia
- Health care settings a common site of transmission
- Remember: Rash +3 C's
 - -Cough
 - Conjuntivitis
 - -Coryza



Measles worldwide today

CDC & WHO measles websites

- 20 million new cases a year
- 146,000 deaths every year (2.6 million in 1980)
- 400 deaths every day
- 17 deaths per hour



 Measles vaccine prevented 15.6 million deaths between 2000-2013



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Special Article

An Outbreak of Measles in an Undervaccinated Community

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+ Author Affiliations

ABSTRACT

Measles is readily spread to susceptible individuals, but is no longer endemic in the United States. In March 2011, measles was confirmed in a Minnesota child without travel abroad. This was the first identified case-patient of an outbreak. An investigation was initiated to determine the source, prevent transmission, and examine measles-mumps-rubella (MMR) vaccine coverage in the affected community. Investigation and response included case-patient follows up nost exposure prophylaxic voluntary isolation and quarantine and

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Published online June 9, 2014 PEDIATRICS Vol. 134 No. 1 July 1, 2014 pp. e220 -e228 (doi: 10.1542/peds.2013-4260)

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Measles Cases at Children's Hospitals and Clinics of Minnesota 2011

I didn't want to wake him up to vaccinate him...and now all I want him to do is wake up...

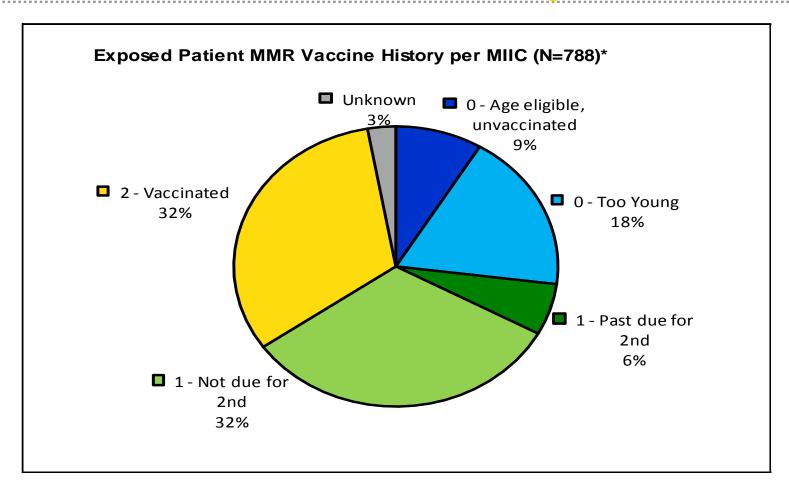


August, 2011 Children's Measles Index Case Summary

- Unvaccinated, US born 12 month-old
- Recently returned from a three-month stay in Kenya
- Offered early MMR prior to travel but family declined
- Modified measles clinical presentation with prolonged prodrome (9 days)
- Non-classic rash first noted on trunk prior to hospitalization
- Developed pneumonitis and required ventilator support for 15 days
- Hospitalized for 27 days



Exposed Patient Follow-up MMR Vaccine History





"When you protect your child, you protect my child" -Ben's Mom





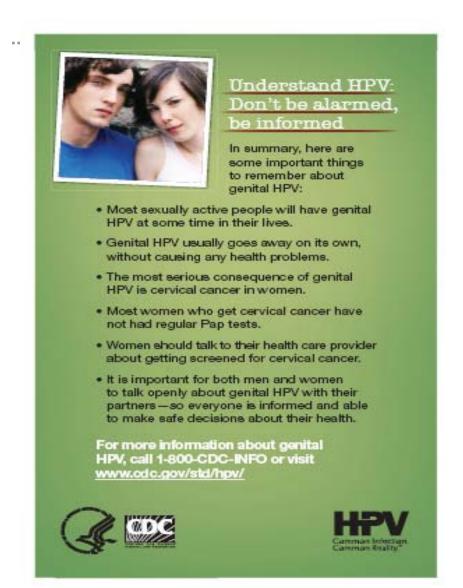


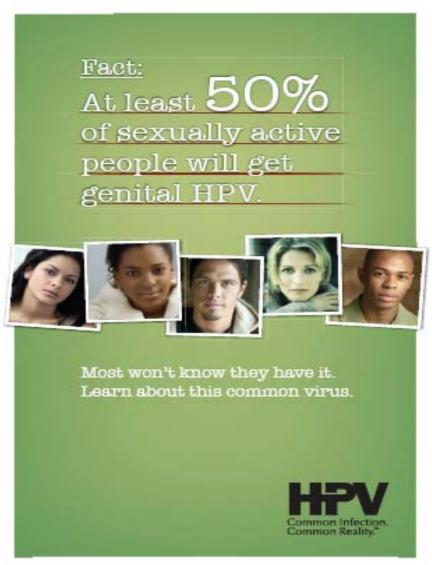
HPV and Institute of Medicine

- Institute of Medicine Consensus Report Adverse Effects of Vaccines: Evidence and Causality 8.25.11
- Anaphylaxis : exceedingly rare possibility
- Syncope: have patients sit for vaccines, wait and be observed for 15 minutes or more
- Pain/Sting at injection site: Warn about this temporary and manageable fact



Many HPV Resource Materials at CDC.GOV/vaccines





Giving a strong vaccine recommendation

Some Do's

- Listen first
- Start with the shared goal
- Be evidence based
- Emphasize disease risk
- Show photos of diseases
- Share your clinical experiences
- Share your personal story
- Make more time
- Be prepared to speak to each concern
- Use analogies
- www.cdc.gov/vaccines/specgrps/hcp/conversations.htm

Some Don'ts

- Flood with statistics
- Review the myths
- Use jargon
- Get preachy
- Lecture
- Shame or blame
- Compress risk
- Oversell efficacy
- Give up



The importance of recognition

- Measure and report vaccine rates
- Be the change you want to see
- Goal is clear
- Competition is healthy
- Know where you stand among your peers
- Winners" have a meaningful thank you recognition
- Celebrate successes



We are one world

Accessed from Twitter 9.216









52 | © **2016**

Malaysia-vaccine refusals up, "homeopathy" instead 27 cases of diphtheria, 5 deaths









Keep up the good work Vaccine hesitancy cannot be ignored





Prevention trumps treatment every time





This is what prevention looks like! Thank you for all you do!!









- Protect your enthusiasm from the negativity and fear of others. Never decide to do nothing just because you can only do a little. Do what you can. You would be surprised at what "little" acts have done for our world.
 - Steve Maraboli, Author of *Unapologetically You:* Reflections on Life and the Human Experience



Questions?





Vaccine communication resources

 Provide current resources for timely information

• WEBSITES:

- <u>www.immunizationinfo.org</u> (NNii)
- www.dovaccinescausethat.com/
- www.immunize.org (Immunization Action Coalition)
- <u>www.cdc.gov/vaccinesafety/</u>
- <u>www.vaccines.gov/conversations</u>
- <u>www.fda.gov/cber/safety/</u>
- www.ecbt.org/
- <u>www.vaccinateyourbaby.org/</u>
- www.vaccine.chop.edu
- www.voicesforvaccines.org

-BROCHURE;

Reliable Vaccine Resources:A guide for parents.Children's website.

-HOTLINES:

-CDC Immunization Hotline 1-800-232-2522

-BOOKS:

- -Vaccines: What Every Parent Should Know by Paul Offit and Louis Bell 2007
- -Do Vaccines Cause That?!

 By Martin Myers, MD and
 Diego Pineda, MS 2008

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