

Vaccine Refusal issues for the Primary Care Physician

Friday, June 17, 2011
Madrid II ~ 2:10pm - 2:55pm

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Objectives

- Review the background of immunizations in historical and legal contexts
- Examine current laws and exemptions
- Explore types of beliefs about vaccines and sources of misinformation
- Discuss concerns about specific vaccinations
- Consider the consequences of vaccine refusal

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Vaccine Refusal

Kyle J. Schauf, MD
Great Plains Family Medicine

Oklahoma Academy of Family Physicians Scientific Assembly
Friday, June 16th, 2011
Tulsa, OK

Disclosures

- No relationships to disclose

Objectives

- Review the background of immunizations in historical and legal contexts
- Examine current laws and exemptions
- Explore types of beliefs about vaccines and sources of misinformation
- Discuss concerns about specific vaccinations
- Consider the consequences of vaccine refusal
- Investigate strategies for counseling parents about vaccine safety

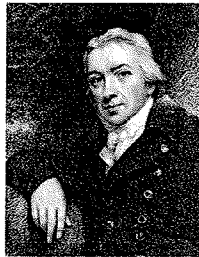
Immunization Basic Review

- Immunity is the presence of antibodies to a disease within our system
- Active immunity
 - Can take weeks to develop, but lasts long
 - Natural immunity
 - Antibodies develop from having the disease
 - Vaccine-induced immunity
 - Antibodies develop from exposure to killed/weakened form of disease
- Passive immunity
 - Occurs when antibodies are given to an individual
 - Immediate immunity, only lasts a short time¹

1 CDC Immunology types: <http://www.cdc.gov/vaccines/imz/manufacturing/types.htm>

History of Immunization Laws

- Dr. Edward Jenner of Gloucestershire, England
 - 1770's: Milkmaids bragged they would never get smallpox since they had cowpox
 - 1796: Took pus from cowpox sore and injected an eight year-old boy with it, then exposed him to smallpox!



2 Sam AM. Medical History: The history of vaccines and immunization. www.challenge-healthaffairs.org 3 (2009): 104-111


History of Immunization Laws

- First school mandate 1818 in Germany
- King of Württemberg decree
 - "every child must be vaccinated before it has completed its third year, under a penalty annually levied on its parents so long as the omission continues ... No person to be received into any school, college, or charitable institution ... who has not been vaccinated."²

3 Lecture 20: 2011 Immunization updates and challenges: Current Problems in Pediatric & Adolescent Health Care. 10/11/10 20:10 Mar

History of Immunization Laws

- Boston, MA 1827
 - First U.S. school mandate
 - Teachers were asked to have students submit proof they had been vaccinated
- Massachusetts 1855
 - First state to enact compulsory school vaccination law
 - Accompanied efforts to make school attendance mandatory³



3 Lantieri JD et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 40(3): 28-38. 2010 Mar


History of Immunization Laws

- Anti-vaccine sentiment starts almost as soon as vaccinations do
 - Other physicians work to discredit Jenner's theory
 - Local school boards oppose mandatory vaccinations
 - Some members of the public opposed vaccinations because it upset God's will for the blessed and the damned³

3 Lantieri JD et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 40(3): 28-38. 2010 Mar

History of Immunization Laws

- Cambridge, MA 1902
 - Smallpox outbreak starts
 - Health officials required everyone to be vaccinated or pay a \$5 fine
 - Reverend Henning Jacobson refused to be vaccinated or pay the fine⁴




"Compulsory vaccination is unreasonable, arbitrary and oppressive, and, therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best, and that the execution of such a law against one who objects to vaccination, no matter for what reason, is nothing short of an assault upon his person."

4 [http://www.wcpaia.org/publications/100_years_of_smallpox_100-115](http://www.wcpaia.org/publications/100_years_of_smallpox_1902-2002)
3 Lantieri JD et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 40(3): 28-38. 2010 Mar

History of Immunization Laws

- *Jacobson v. Massachusetts*, 1902
 - Took case all the way to Supreme Court, lost 7-2
 - Cited need for common good to sometimes interfere with personal liberty
 - Served as precedent for 1922 Supreme Court ruling upholding constitutionality of compulsory vaccination for school entry³



"Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will"

3 Laidra JD et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 40(5): 31-38. 2010 Mar


History of Immunization Laws

- Religious Exemptions
 - Mississippi case
 - Plaintiffs unsuccessfully argued compulsory vaccination violated religious freedom clause of 1st Amendment
 - Held that rights of schoolchildren to safe & healthy environment outweighed religious objections of parents
 - Despite this, religious exemptions still granted in 48 states³
 - Mississippi and West Virginia do not allow
 - Allowed to exist to avoid appearance of state coercion and allow sustainability of compulsory vaccination for school entry
- All states allow medical exemptions
 - Anaphylaxis, other adverse reactions
- Twenty-one states allow philosophical objections⁵

3 Laidra JD et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 40(5): 31-38. 2010 Mar
5 Omer SB, et al. Vaccination, individual exemptions, and the risk of vaccine-preventable diseases. J Epidemiol / Med Biol Rev. 1986;11: 245-8

History of Immunization Laws

- Oklahoma Law
 - Allows both religious and philosophical objections
 - Parent simply has to sign form / write letter
 - Okla. Stat. Ann. tit. 70, § 1210.191, 192



4 <http://www.ostfg.org/Issues/evr/wh/Health/SchoolImmunizationExemptionLaws.html> 12/16/09 Default.aspx

History of Immunization Laws

- Enforcement of immunization mandates
 - Often lax, especially when there is no outbreak
 - Parents get around the laws
 - Removal from public school and/or homeschooling
- All 50 states had immunization mandates for school entry by 1980
- However, each state has different processes and requirements for which vaccines are mandated³

3. Laitinen JT, et al. Immunization updates and challenges: Current Problems in Pediatric & Adolescent Health Care. 2011; 38:18-2000 Mar

History of Immunization Laws

- Example: Measles in the '60's and '70's
 - First U.S. vaccine in 1963
 - Estimated that infant/school age immunizations would lead to eradication by 1967
 - Did not happen
 - Only 17 states had school vaccine laws including measles
 - Enforcement lax in these states
 - Texarkana, TX 1970-71
 - City lies over Arkansas-Texas state line
 - TX did not require measles vaccine, AR did
 - 95% of measles cases from TX

3. Laitinen JT, et al. Immunization updates and challenges: Current Problems in Pediatric & Adolescent Health Care. 2011; 38:18-2000 Mar

Age 0-6 Vaccine Schedule⁶

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2011
 For those who fall behind or start late: see the catch-up schedule

Vaccine	Age	1	2	4	6	12	15	18	19-23	23	4-6
		month	months	months	months	months	months	months	months	years	years
Rotavirus	HeptB	2	4								
Poliovirus	IPV		2	4							
Diphtheria, Tetanus, Pertussis*	DTaP		2	4							
Tetanus, Diphtheria, Pertussis (Tdap)	Td					11-12	15	18			
Hepatitis B	HB	1	2	6							
MMR	MMR		12	18							
MMRV	MMRV		12	18							
MM2	MM2										
MM3	MM3										
MM4	MM4										
MM5	MM5										
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6. http://www.cdc.gov/vaccines/imz/downloads/0-6-vaccine-schedule.html

Anti-Immunization Resources

- Birth of the modern American anti-vaccine movement was on April 19th, 1982⁶⁶
 - Washington, D.C. NBC affiliate aired 1-hour special “DPT: Vaccine Roulette”
 - Featured six children with neurologic injuries purported to have happened after DPT inoculation
 - Three physicians contributed, Pediatric Red Book cited
 - Re-aired nationally on *Today* – uproar ensues
 - Group of five parents form Dissatisfied Parents Together (DPT)
 - With expansion, later re-named National Vaccine Information Center (NVIC)

66. OZAT. Daily stories how the anti-vaccine movement started in 82. Basic Books, 2011. ix.

Anti-Immunization Resources⁶⁶⁻⁶⁷

- Spate of lawsuits against vaccine manufacturers filed, millions of dollars in damages awarded
- By 1986, vaccine supply was in danger
 - No American manufacturer of DPT
 - Only one manufacturer of measles, polio each
- Led to creation of Vaccine Injury Compensation Program (VICIP) and Vaccine Adverse Events Reporting System (VAERS) by U.S. Congress
- System challenged in 2010 case *Bruesewitz v. Wyeth*
 - Supreme Court ruled vaccine manufacturers could not be sued individually outside the established system

66. OZAT. Daily stories how the anti-vaccine movement started in 82. Basic Books, 2011. ix.
67. <http://www.fda.gov/oc/ohrt/vaccineinjurycompensation.html>; <http://www.vaers.hhs.gov/>

Celebrities⁶⁶



Dr. Mehmet Oz & Oprah Winfrey



Larry King



Don Imus



Bill Maher




Jim Carrey

66. OZAT. Daily stories how the anti-vaccine movement started in 82. Basic Books, 2011.

Jenny McCarthy

- Son born in 2002, diagnosed with autism
- Believes vaccines given to her child caused his autism
- Started anti-vaccination campaign in 2007 - GenerationRescue.org
- Appeared on multiple television programs promoting campaign to parents
- Sister website, FourteenStudies.org



Why Parents Refuse Vaccines

- Religious Beliefs^{3,66}
 - Subverts religious freedom and God's will
 - Christian Scientists, Amish, Dutch Reform
 - Muslim fundamentalists in various countries see polio vaccine as Western sterilization plot
 - Some vaccines derived from cell lines taken from fetal tissue from elective abortions in 1960s
 - Rubella, hepatitis A, rabies, varicella
 - Catholic Church says use is permissible due to consequences of not vaccinating (including spontaneous abortions), but should work to derive from other cell lines
- Philosophical Beliefs
 - Vaccination is not a natural process

1. Evans JB, et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 10(3): 38-50, 2010 Mar. 66. GDS # 6064-03/09. http://dx.doi.org/10.1016/j.cpr.2010.01.001

Why Parents Refuse Vaccines

- Libertarian Influences³
 - View that government should not be able to compel medical treatment or violations of bodily integrity at any time
 - Constitutes criminal assault
 - Settled in court cases discussed earlier

1. Evans JB, et al. Immunization updates and challenges. Current Problems in Pediatric & Adolescent Health Care. 10(3): 38-50, 2010 Mar.

Why Parents Refuse Vaccines

- Risk vs. Benefit Calculation
 - Individuals read, watch news, etc. and formulates risk vs. benefit for themselves/children
 - Trapped in the prisoner's dilemma
 - Rationality of choice conditional on choices made by all other parents at the same time
 - Cannot know others' choices when they make their own choice
 - If everyone chooses to vaccinate their child, then why risk vaccinating mine?
 - If too many parents don't vaccinate, my child may be at risk!

1 Lecture 10: Use of Immunization updates and challenge - Chapter Performance Feedback & Addressing Health Care 4/13/11 10:36:20 AM

Why Parents Refuse Vaccines^{16,17,19,21,23-25}


- Concerns about safety and side effects
 - 60-70% of exemptions based on this
 - Additives and preservatives
 - Sometimes based in fact, but myths perpetuate even after problem is corrected
 - i.e. Rotashield (old Rotavirus vaccine) and intussusception
- Might overwhelm immune system
- Belief that vaccines don't work
- Concerns about medical contraindications
 - Immunosuppressed, hypersensitivities in past, pregnancy

Why Parents Refuse Vaccines^{16,17,19,21,23-25}

- Belief that child is not at risk and/or disease is not dangerous
 - Consequence of vaccine success
 - Forgotten severe sequelae of diseases
- Natural infection better protects than vaccines
- Cost


16. Pedrickson GD, Davis TC, Anon-JE, et al. Outbreak of immunization refusal: provider and parent perspectives. *Fam Med* 2004; 36: 429.
17. Finkel GL, Clark SF, Bisho SF, Estabro JM. Parental vaccine safety concerns: The experience of pediatricians and family physicians. *Am J Prev Med* 2004; 29: 14.
19. Salzman BA, MacLean LR, Omer SB, et al. Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study. *Arch Pediatr Adolesc Med* 2004; 158: 879.
21. Lawrence GL, Hill SF, McHughy CR, McHughy FB. Reasons for incomplete immunization among Australian children: A national survey of parents. *Aust J Physiother* 2004; 51: 385.
23. Borch L, Pringle L, et al. How to deal with vaccine hesitant parents. *Pediatrics* 2004; 114: 2014.
24. Olick EG, Maheshwari DM, Maslow JN. Do parents understand immunization? A national telephone survey. *Pediatrics* 2000; 106: 1097.
25. Smith A, Lewandowski E. Vaccine refusal: issues for the primary care physician. *Clin Pediatr* 1993; 32: 319.

Types of "Believers"



Immunization Advocates¹⁵

- 33% of surveyed parents
- Believe immunizations are:
 - Necessary
 - Safe
 - Important
- Good relationship with child's health care provider




[Return to Believer Types](#)

15 Gurt, DA, DeLong, N, Kennedy, A, Schwanz, B. Parents with doubts about vaccines: what's common and unique why. Pediatrics 2008; 122:118

Go Along to Get Alongs¹⁵

- 26% of surveyed parents
- Agree that immunizations are:
 - Necessary
 - Safe
- No strong feelings one way or the other




[Return to Believer Types](#)

15 Gurt, DA, DeLong, N, Kennedy, A, Schwanz, B. Parents with doubts about vaccines: what's common and unique why. Pediatrics 2008; 122:118

Health Advocates¹⁵

- 25% of surveyed parents
- Agree that immunizations are necessary
- Less convinced about their safety




[Return to Believer Types](#)

15 Gott, DA, Darling, SC, Kennedy, A, Schwartz, B. Parents with doubts about vaccines: what vaccines and reasons why. Pediatrics 2008; 122:1148

Fence-Sitters¹⁵

- 13% of surveyed parents
- Slightly agree that immunizations are necessary and safe
- Tend to have neutral relationship with child's health care provider




[Return to Believer Types](#)

15 Gott, DA, Darling, SC, Kennedy, A, Schwartz, B. Parents with doubts about vaccines: what vaccines and reasons why. Pediatrics 2008; 122:1148

Worrieds¹⁵

- 3% of surveyed parents
- May slightly agree that immunizations are necessary
- Strongly disagree that immunizations are safe
- Skeptical that provider has child's best interests at heart



[Return to Believer Types](#)

15 Gott, DA, Darling, SC, Kennedy, A, Schwartz, B. Parents with doubts about vaccines: what vaccines and reasons why. Pediatrics 2008; 122:1148

Specific Vaccine Concerns

- Pertussis
- Rotavirus
- Human papillomavirus
- Meningococcal disease
- Influenza
- Measles, mumps, & rubella
- Thimerosal
- *Haemophilus influenzae* type b (Hib)
- Hepatitis B

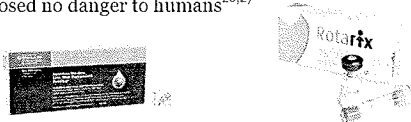
Pertussis

- Prior to vaccine in 1940s, 300K cases/year, 7K deaths
- Original pertussis vaccine was a whole-cell vaccine
- Known to be reactogenic, but still rarely so³
 - Most serious reactions were seizures and hypotonic-hyporesponsive episodes
 - Causal link to neurological damage never definitely proven
- Acellular pertussis vaccine introduced 1991⁶⁶
 - Uses fewer antigens to induce immunity, but still effective
- Whole-cell vaccine not available in U.S. since 2002

3. Kretzschmar M, et al. Immunisation updates and challenges. *Current Problems in Pediatric & Adolescent Health Care*. 10(3): 18-28, 2010 Mar.
66. Miller B, Wadsworth J, Demarest J, Rowe B (1991) "Pertussis vaccine and whooping cough in risk factors in acute neurological illness and death in young children". *Dev Biol Stand* 6: 379-84

Rotavirus Vaccines

- Pentavalent vaccine (Rotateq)
- Monovalent vaccine (Rotarix)
 - Use suspended March 2010 after traces of porcine circovirus found in vaccine
 - Use resumed in May 2010 after virus was found in Rotateq as well, and after determination that the virus posed no danger to humans^{26,27}



26. U.S. Food and Drug Administration. Components of rotavirus virus detected in Rotarix vaccine: no known safety risk. Available at: www.fda.gov/2010/03/2010-03-17-rotavirus-components-detected-in-rotarix-vaccine (Accessed on March 22, 2010).

27. U.S. Food and Drug Administration. Update on recovery orders for the use of rotavirus vaccines. Available at: www.fda.gov/2010/02/2010-02-18-rotavirus-vaccines (Approved on March 17, 2010).

Rotavirus Vaccines

- Tetravalent vaccine (Rotashield)^{28-31,66}
 - Licensed in 1998
 - Withdrawn from market one year later
 - Twenty-two times greater risk of intussusception within 5-7 days of vaccination, 1 excess case for every 10-12K infants vaccinated
 - Rates of intussusception for Rotateq and Rotarix no higher than placebo controls
 - Hypothesized to be due to differences of strains
 - Proved that VAERS worked as intended
- Kawasaki disease – no causal relationship found^{32,33}

²⁸ Rotavirus infection in immunocompetent children - United States, January-December 1999. *American Academy of Pediatrics Committee on Infectious Diseases. Pediatrics* 1999; 103:184.
²⁹ Murphy, T.J., Gargallo, P.V., Muesel, M.S. Intussusception among children given an oral rotavirus vaccine. *N Engl J Med* 2001; 344:954.
³⁰ DeBoer, E.T. The vaccine safety data link project. *Pharmacoepidemiol Ther* 2005; 30:493.
³¹ Wardle, M.L., East, S.E., Crawford, S.L. et al. Rotavirus vaccine-related hospitalizations: intussusception is a major event. *J Virol* 2006; 80:1274.
³² Oka, T. Dealing with the vaccine safety movement. *Health Aff (Millwood)* 2001; 20:1008.
³³ Rotavirus vaccination and intussusception in Botswana. Available at: www.fda.gov/oc/ohrt/vaccine/safety.htm. [Accessed October 18, 2007].
³⁴ Rotavirus Vaccine, Live, Oral Oral Suspension prescribing information. GlaxoSmithKline, Research Triangle Park, NC 2008.

Human Papillomavirus Vaccine

- Quadrivalent (Gardasil), Bivalent (Cervarix)
 - Gardasil adds protection against genital warts
- Concerns
 - Encourages sexual activity (Texas example)
 - Syncope
 - Higher risk of post-vaccination syncope in age group (11-26)
 - Recommend 15 minute waiting period after vaccination
 - Venous thromboembolism
 - 31 cases between 2006-08, 4 deaths
 - 90% had other risk factors, ongoing monitoring
- Other deaths after HPV vaccine found to have been in those with other risk factors / conditions⁶⁶

³⁴ Koopff, A.V., Atkinson, W.L., Maresca, E.K., Fickling, L.K. General recommendations on vaccination - recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2009; 58:33.
³⁵ Onda, R.A., Karpis, K., Wilcox, C. et al. Rotavirus and adenovirus vaccine for quadrivalent human papillomavirus quadrivalent vaccine. *JAMA* 2009; 301:179.
³⁶ Oka, T. Dealing with the vaccine safety movement. *Health Aff (Millwood)* 2001; 20:1008.

Meningococcal Disease Vaccine

- Quadrivalent vaccine MCV4 (Menactra)³⁶
 - Wider use than older monovalent vaccine (Menomune)
 - Approved for use in 2005
 - Indicated for ages 11-18, and those with risk factors
 - Covers 4/5 major serogroups of *N. meningitidis*
- Association with Guillain-Barré Syndrome (GBS)
 - 15 cases between 2005-2006 led to advisory by FDA and CDC (no deaths, all recovered)³⁷
 - No change in recommendation³⁸
 - 10-14% mortality among those with meningococcal meningitis
 - 11-19% morbidity among survivors

³⁶ Menomune. Meningococcal polysaccharide vaccine. Med Lett Drugs Ther 2003; 45:20.
³⁷ Madon, M.S., Har, Paves, A.V., Owen, R. et al. Impact of meningococcal serogroup C conjugate vaccines on carriage and herd immunity. *J Infect Dis* 2006; 194:1114.
³⁸ Dalrymple, M.E., Andrews, N.J., Threlk, C. et al. Herd immunity from meningococcal serogroup C conjugate vaccination in England: database analysis. *BMJ* 2003; 327:383.

H1N1 Influenza Vaccine

- Concerns about inadequate testing, lack of protection³⁹
 - Immunogenicity demonstrated, but no studies on efficacy
 - Developed in same manner as seasonal flu vaccine
- Concerns about GBS⁴⁰
 - Stem from 1976 swine flu vaccine
 - 7-fold risk increase (1 per 100 K)
 - Low infection rate of that particular influenza
 - Program halted
 - Risk of GBS in current H1N1 vaccine similar to regular seasonal influenza vaccine (extremely low)

39. Bradley JS, Baramba H, Baruch A. Also potential concerns over safety of 2009 H1N1 flu vaccine. *N Engl J Med* 2009; 361: 1000-1001.
40. Miller F, Senz J, Makris Y, Bellizzi F. Vaccines and Guillain-Barre syndrome. *BMJ* 2009; 339: 979.

H1N1 Influenza Vaccine⁴¹

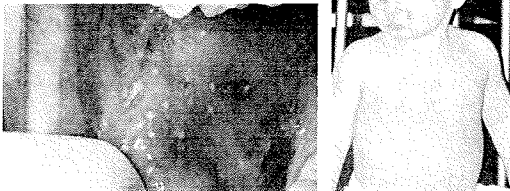
- Included in 2010 seasonal flu vaccine (not separate)
 - H1N1 strain
 - H3N2 strain
 - Influenza B strain
- Recommended for all persons age 6 months and above without contraindication



41. <http://www.cdc.gov/H1N1v2/>

Measles

- Prior to vaccine, 4 million children infected, 100K hospitalized, and 500 deaths / year⁶⁶



66. <http://www.cdc.gov/nczod/diseases/zoonotic/d104/measles.htm> Last visited 2011

MMR and Autism Spectrum Disorders (ASD)

- Temporal association = causal association
 - Apparent increase in ASD rates
 - California reported 210% increase in 1987-1998⁴²
 - 10 per 10 K in late 1990s vs. 4-5 per 10K in previous decades⁴³
 - Increase in number of childhood vaccines
 - Hib, varicella, Hep B, pneumococcal, 2nd dose MMR
- Systematic reviews of autism epidemiologic studies⁴³⁻⁴⁵
 - All concluded increased prevalence was due to
 - Changes in diagnostic criteria
 - Increased awareness

42. Department of Developmental Services. Changes in the population of persons with autism and pervasive developmental disorders in California's developmental services system, 1987-1998. A Report to the Legislature. California Health and Human Services, March 4, 1999.
43. Reichman, E. Epidemiology of pervasive developmental disorders. *Paediatr Res* 2006; 57: 293.
44. Wake, L, Frazier, D. The epidemiology of autistic spectrum disorders: is the prevalence rising? *Med J Austral Dis Health Res Rev* 2002; 8: 351.
45. Szatmari, P. The association of diagnostic subtypes to the growing administrative prevalence of autism in US special schools. *Paediatrics* 2006; 117: 1618.

MMR and ASD

- The Wakefield paper in *The Lancet*, 1998⁴⁶
 - 12 children with abdominal pain, diarrhea, loss of acquired skills with prior normal development
 - 9 diagnosed with autism / ASD
 - 8 with intestinal lymphoid nodular hyperplasia
 - 6 had onset of symptoms with recent MMR vaccine
- Hypothesized that inflammation from colitis left intestine more permeable to encephalopathic proteins which traveled to brain and caused autism
- Did not directly link the two

46. Wakefield, AJ, Murch, SH, Anthony, A, et al. Intestinal lymphoid nodular hyperplasia, colonic ulceration, and pervasive developmental disorder in children. *Lancet* 1998; 351: 637.


MMR & ASD^{26-28,66}

- Study was retracted in 2010
 - Children not consecutively referred / selection bias
 - No IRB approval
- Other problems
 - Small number of patients
 - No control group
 - Behavioral symptoms preceded GI symptoms in ALL cases
 - Ileal / colonic lymphoid hyperplasia is a normal variant in this age group
 - Stooling patterns of ASD kids compared - normal
- 90% of kids in U.K. had MMR vaccine at time of study
 - Autism usually diagnosed at same time
 - Temporal = causal
- 80% of all reports of autism from vaccines reported to VAERS from personal injury lawyers

26. Stratton, K, Wilson, CE, McCreesh, M (Eds). Immunization Safety Review: Mumps-Mumps-Gonorrhea's Attack and Return. National Academy Press, Washington, DC, 2001.
27. CDC, PA. Vaccines and Autism. Immunization Action Coalition. www.immunize.org (<http://www.immunize.org/safety/2006g.htm>) (Accessed on January 18, 2006).
28. Andrews, B, Stern, C, Gidding, J, Enns, A. The early development of young children with autistic spectrum disorder. *Arch Dis Child* 2006; 91: 417.
66. Oller P. Do only doctors know the truth? *Autism* 2006; 10: 201.

MMR & ASD

- Other hypotheses⁵⁰
 - Persistent intestinal measles virus
 - Severely flawed study (no blinding, timing of MMR)
 - Well-designed studies failed to reproduce results
 - Persistent measles infection / immune response
 - Several case control studies also disprove



50. Decker JE, Dwyer DE, Teshia MM. Autism and chronic disease: Is there evidence for a causal link? *Am J Orthod*. 20 May 2009.

MMR and Varicella

- 2010 Guideline Revision⁵⁶
 - Advisory Committee on Immunization Practices
 - MMRV vaccine (ProQuad) linked to slightly higher risk of febrile seizures in children ages 12-47 months
 - Advises physicians to discuss risks / benefits with patients
 - No preference for combination or separate MMR and varicella vaccines

56. Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention. *MMRV Vaccine*. 2010. 1-10. 2010. Apr.

Thimerosal

- Sodium ethylmercury thiosalicylate
- Previously used as preservative in vaccines⁵¹
 - Hep B, Hib, Tdap
 - Was never in MMR, polio, or pneumococcal vaccines
 - Influenza only now, at non-toxic level
- Controversy in 1999
 - Hypothesized that cumulative doses of vaccines with thimerosal could reach toxic levels⁵²
 - No adverse effects ever reported⁵³
 - Newborn Hep B shots delayed as precaution⁵⁴
 - Thimerosal-free vaccines available by 2000⁵⁵
 - Led to lower rates of Hep B vaccination even after thimerosal-free vaccines available

51. Decker JE, Dwyer DE, Teshia MM. Autism and chronic disease: Is there evidence for a causal link? *Am J Orthod*. 2009; 22:602-604.
52. Fombonne E, Smith R, Evans D. Preschool mercury exposure and later child immunization: cause for concern? *Neurotoxicology*. 2004; 25:601-604.
53. Lieberman, JM. Methylmercury contamination in fish: An Ounce of Prevention. *Communicating the Benefits and Risks of Vaccines to Patients: Infectious Diseases in Children*. Blackwell Publishing, Philadelphia, NJ 2003; 148.
54. Joint statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS). *Pediatrics*. 1999; 104: 928.
55. Statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS). *Advisory Committee on Immunization Practices*. Public Health Service. MMRV: Much More Than MMR. Page 2000. 19-22.

Thimerosal and ASD⁵¹

- Hypothesized that mercury poisoning leads to autism
 - Cannot excrete mercury as well, builds up
- Lack of evidence / faulty associations
 - Evidence-based, peer-reviewed literature shows no basis for high levels of mercury
 - Evidence that chelation therapy helps autism is lacking as well
 - Clinical presentations not similar, despite claims
 - Thimerosal does not cross blood-brain barrier
 - Six well-designed epidemiologic studies show no link
 - Compared U.S. data with other countries as well

51. Teneta JE, Hughes TK, Ticehurst MM. Autism and chronic disease: Little evidence for thimerosal as a contributing factor. J Child Psychol. 2005.

Haemophilus influenzae type b⁶⁶

- Prior to vaccine, caused 20K cases/year of pneumonia, meningitis, and blood infections, 1K deaths/year and brain damage in more
- Researcher Bart Classen did study claiming vaccine caused diabetes
 - Supported by head of National Vaccine Information Center, Barbara Loe Fisher
- More research occurred – found that risk was the same between vaccinated and unvaccinated
- His study also found to have major methodical flaws

66. Miller P. Deadly disease: How 40,000 children may have died from a flu shot. Newsweek. 2004.

Hepatitis B⁶⁶

- Before vaccine, 16,000 children / year infected
- Infected infants have greater chance of developing cancer
- Vaccine believed to cause SIDS, multiple sclerosis
 - Both claims debunked by many studies
- Disease has been nearly eliminated in children since introduction of vaccine in 1991



66. Miller P. Deadly disease: How 40,000 children may have died from a flu shot. Newsweek. 2004.

Consequences of Refusal

- Individual Risk⁵¹
 - Varicella – 9x more likely to contract
 - Measles – 22-35x more likely to contract
 - Pertussis – 6-23x more likely to contract
- Lack of herd immunity a problem for thousands who cannot be vaccinated (e.g. immunologically compromised)⁶⁶
- More outbreaks
 - 123 cases of measles in Jan.-July 2008 in U.S.⁵⁷
 - 91% in under/unvaccinated
 - 2/3 of these had refused for religious/philosophical reasons
 - Five cases of invasive Hib in Minnesota in 2008⁵⁸
 - Three had refused vaccination, one died of Hib meningitis

51. Deutz JE, Dwyer EK, Tomlin MM. Autism and vaccine disease: Little evidence for states as a contributing factor. *Up To Date*. 4 June 2009.
55. Dwyer JE. Daily scores from the anti-vaccine movement (2007-2008). *State Books*. 2008.
57. *Pediatrics*. 2008;122(1):100-104. MMWR Morbidity and Mortality Report 2008. 57: 83.
58. *Minnesota Department of Health*. *2008 Annual Report on Communicable Diseases - Minnesota*. 2008. MMWR Morbidity and Mortality Report 2009. 58: 13.

Consequences of Refusal

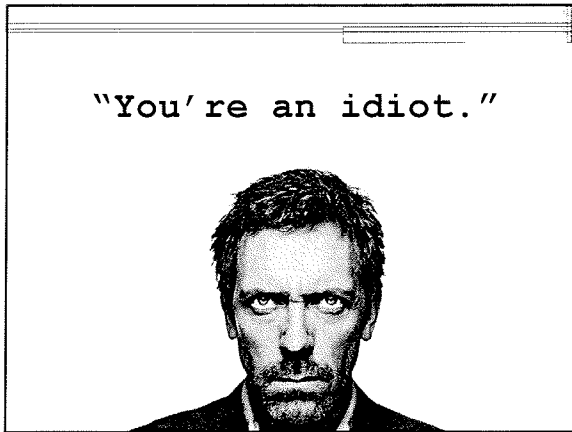
- More outbreaks
 - 2010 California pertussis outbreak⁵⁹
 - Largest outbreak in 50 years
 - Estimated 6,431 cases as of 11-02-2010
 - Many others often go undiagnosed
 - Ten deaths of infants under 3 months
 - CA Dept. of Health recommending booster immunizations
- Other community consequences⁵¹
 - Vaccinated individuals can contract disease from under/unvaccinated
 - Direct correlation of areas of infection and exemption rates for that area

59. <http://www.cdph.ca.gov/Programs/OPA/Pages/NR100201.aspx>
51. Deutz JE, Dwyer EK, Tomlin MM. Autism and vaccine disease: Little evidence for states as a contributing factor. *Up To Date*. 4 June 2009.

Approach to Parents

- Refusers evoke strong emotions in providers⁶⁰
 - Issues of trust
 - Medicolegal concerns
- As many as 4/10 pediatricians now refuse to see families who choose not to vaccinate their children⁶⁶
- Avoid this...

60. Apatow A, Laskowski E. Vaccination and issues for the primary care physician. *The Pediatrician*. 2006. 13: 398.
66. Dwyer JE. Daily scores from the anti-vaccine movement (2007-2008). *State Books*. 2008.



Approach to Parents

- Establish dialogue⁶¹
 - Dialogue more important than outcome at any one visit
 - Acknowledge
 - Shared goal – child's well-being
 - Large volume of information on vaccines' risks & benefits
 - Offer to help them gather information so they can make an informed decision

61. Myles MJ, Orentlicher DA, Mansour SK. Outbreaks versus misinformation. EBEP Audio 2009. 4:1

Approach to Parents

- Identify concerns^{23,62}
 - Identify source of concerns – media, Internet, friends/family
 - Heart-wrenching anecdotes vs. faceless statistics
 - Worries about suffering
 - Worry about possible harm of vaccine more than harm of disease

23. Hersh C, Redding GJ. How to talk to a vaccine-hesitant parent. Pediatrics 2008; 122:1091-1095.
62. O'Brien MA, BA. Responding to parents' concerns about immunization of children. Pediatrics 2007; 119:1428

Vaccine-Hesitant Parents

- Large percentage³ of our vaccine believers (41%)
- Types⁶³:
 - Uninformed but educable
 - Friends/family anti-vaccine, but want to counter this
 - Misinformed but correctable
 - Received anti-vaccine info, unaware of medically accurate info
 - Well-read and open-minded
 - Explored both sides, but want provider's opinion
 - Convinced and contented
 - Strongly anti-vaccination, but will listen (often to satisfy)
 - May moderate beliefs over time
 - Committed and missionary
 - Strongly anti-vaccination, want to convince the provider
- First three types will respond to information & dialogue

3. Laitin JB et al. Immunization systems and challenges. *Current Problems in Pediatric & Adolescent Health Care*. 2010; 38: 38-58. 2010 Mar.
63. Fox M, Warner SK. Why parents refuse immunizations. *Current Pediatric* 2008; 17:15

Approach to Parents

- Target education
 - May need information from variety of sources
 - 1/3 of parents want more information¹⁹
 - Physician one of the most influential among VHPs³
 - Information sources should^{16,64,65}
 - Be unbiased
 - Avoid scare tactics
 - Aggressive pro- (or anti-) vaccination messages
 - School requirements
 - Be non-judgmental

19. Salzman EA, Moshier JE, Omer SB, et al. Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study. *Arch Pediatr Adolesc Med* 2003; 157: 430-436
3. Laitin JB et al. Immunization systems and challenges. *Current Problems in Pediatric & Adolescent Health Care*. 2010; 38: 38-58. 2010 Mar.
64. Omer SA, Meltzer MI, Miller M, et al. Developing better immunization materials for concerned mothers. *Health Educ Res* 2008; 23: 499-509
65. Hall LN, Emswiler G, Coombs RW, et al. Improving vaccine communication: a strategy to increase vaccination. *Pediatrics* 1993; 100: 103-109


Topics to Cover⁶⁰

- Vaccine limitations
 - Acknowledge that they are not 100% risk free nor 100% effective; frame in terms of benefits
- Adverse reactions
 - Usually minor
 - Local skin reaction, transient low-grade fever
 - Serious risks vs. risks from disease
 - Measles encephalitis / sclerosing panencephalitis risk 1000x greater from natural infection than vaccine
- Misconceptions
 - Autism, overwhelming immune system
- Pain

60. Lyman A, Linnick E. Vaccine refusal: issues for the primary care physician. *Clin Pediatr* 1991; 30: 415-419

Approach to Parents

- Maintain relationship⁶²
 - AAP Bioethics Committee advises against discontinuing care for families who refuse or delay vaccines
 - Decision to vaccinate ultimately lies with parents
 - OK to tolerate decisions not likely to harm child
 - Must be re-examined during disease outbreak
 - Allows for continued discussion / dialogue
 - May still be unavoidable
 - Distrust of provider
 - Poor communication



62. Berkema, DS. Responding to parental refusal of immunizations of children. Pediatrics 2009; 113: 1128

Approach to Parents


- Alternative schedules⁶²
 - Most cited example is that of Dr. Robert Sears⁶⁶
 - Not founded in science
 - Increase duration of exposure to preventable diseases
 - Increase risk of noncompliance
 - Unreasonable at times
 - Use of separate components of MMR – not available in U.S.
- Parents should inform provider of unvaccinated status
- Document discussion of risks/benefits

62. Berkema, DS. Responding to parental refusal of immunizations of children. Pediatrics 2009; 113: 1128
66. Sears, R. *Drugs for children: how the alternative movement started us all*. Boca Raton: 2001

Conclusions and Summary

- Vaccine debate is as old as vaccines are
 - However, there is more information more readily available today
- Anti-vaccination movement prominence grows
- Misinformation about vaccines has real harm
- Healthy skepticism about vaccines (especially new ones) is acceptable, as long as information is sought to clarify
- Many different types of parents
- Tailored approach that explains risks/benefits in non-threatening manner works best

Questions?



Questions?

