



Forum on Vaccines: Addressing All Sides of the Issue

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Disclosure

- I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this forum.
 - I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.
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State of Children's Health I

The screenshot shows the Harvard School of Public Health website. At the top left is the Harvard crest and the text "HARVARD School of Public Health". To the right are navigation links: "people | calendar | myhsp | email |" and a search bar with a "go" button. Below this is a horizontal menu with links: "About HSPH", "Academics", "Admissions", "Research", "Faculty", "Student Life", "News", "Alumni", and "Make a Gift". The breadcrumb trail reads "home > news at hsp | press releases > 2007 releases". On the right side of the breadcrumb trail are "Share" and "Email" icons. A left sidebar contains a "Menu" section with links: "Press Release Home", "2008 Releases", "2007 Releases" (highlighted), "2006 Releases", "Press Release Archives", "News", and "Office of Communications". Below the menu is an "RSS Feeds" section with a link for "Harvard School of Public Health Press Releases". The main content area features the title "Press Releases 2007 Releases" and a sub-header "Chronic Conditions in Children Will Pose Future Health and Welfare Challenges". Below the sub-header is a summary: "Investigators describe probable causes, forecast impact on health, welfare system". The release date is "Tuesday, June 26, 2007". The main text begins with "Boston - The increased incidence of chronic conditions among American children predicts serious strains on health care and social welfare systems in the future, caution investigators from Massachusetts General Hospital (MGH) and Harvard School of Public Health (HSPH). In a commentary in the June 27 Journal of the American Medical Association - an issue devoted to pediatric chronic disease - the authors explain how rates of obesity, asthma and attention-deficit hyperactivity disorder (ADHD) have increased over the past three decades, review factors that may underlie those increases and examine future implications."

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Press Releases 2007 Releases

Chronic Conditions in Children Will Pose Future Health and Welfare Challenges

Investigators describe probable causes, forecast impact on health, welfare system

For immediate release: Tuesday, June 26, 2007

Boston - The increased incidence of chronic conditions among American children predicts serious strains on health care and social welfare systems in the future, caution investigators from Massachusetts General Hospital (MGH) and Harvard School of Public Health (HSPH). In a commentary in the June 27 Journal of the American Medical Association - an issue devoted to pediatric chronic disease - the authors explain how rates of obesity, asthma and attention-deficit hyperactivity disorder (ADHD) have increased over the past three decades, review factors that may underlie those increases and examine future implications.

State of Children's Health II

- **OVERALL:** In a 2007 UNICEF survey, the U.S. and Britain ranked last among 21 affluent countries assessed on the welfare of children.
- **CANCER:** is the leading cause of death by disease in children. The age-adjusted annual incidence of cancer in children increased from 129 to 166 cases per million children between 1975 and 2002. (EPA)
- **OBESITY:** One in three adolescents are overweight or at risk of becoming overweight. One in six youths aged 6 to 19 years are overweight, a 45% increase in the past 10 years alone. (CDC)
- **DIABETES:** Affects one in every 400 to 500 children. Of those children newly diagnosed with diabetes, the percentage with type 2 ("adult-onset") has risen from less than 5% to nearly 50% in a 10-year period. (CDC/NIH)
- **ASTHMA:** is the most prevalent chronic disease affecting American children, leading to 15 million missed days of school per year. From 1980 to 2004, the percentage of children with asthma has more than doubled, from 3.6% to 8.5%. (EPA)
- **ALLERGIES:** Approximately 34 percent of American children suffer from allergies, with 12 percent suffering from respiratory allergies, 9 percent from hay fever, and 13 percent from other allergies. The rate of food allergies is increasing as well. (CDC)
- **NEURODEVELOPMENTAL DISABILITIES:** One in six children is diagnosed with a neurodevelopmental disability, including 1/12 with ADHD. (CDC)
- **AUTISM:** affects 1/150 children in the U.S., 1/100 children in N.J., 1/60 boys in N.J. (CDC)

Vaccines: Real World Issues

- Parents/families trying to decide what is best for their children
 - Most want to vaccinate but are concerned about safety and desire flexibility
 - Primary care pediatricians are on the front lines trying to balance families' concerns and state/federal/professional society recommendations/mandates
 - How to weigh/who should weigh risks vs. benefits in the public health debate of our times?
 - What about informed consent?
 - What about policy based on science?
-

Press Release

Most U.S. Parents are Vaccinating According to New CDC Survey Vaccine Coverage Rates for Children Remain High

Embargoed Until 12 p.m. ET: September 4, 2008
Contact: CDC Division of Media Relations, Phone: 404-639-3286

- The vast majority of the nation's parents are having their children get recommended vaccinations, according to 2007 vaccine coverage estimates released today by the Centers for Disease Control and Prevention (CDC).
- Childhood immunization rates remain at or near record levels, with at least 90 percent coverage for all but one of the individual vaccines in the recommended series for young children, said the CDC's 2007 National Immunization Survey (NIS).
- More than 77 percent of children were fully vaccinated with all vaccines in the series of recommended vaccines, and there were no differences in coverage among any racial or ethnic group for the complete series. Importantly, less than 1 percent of children had received no vaccines by age 19 months to 35 months.

NJ Vaccine Mandates: Points of View

- "It's a great day for public health in New Jersey." – former Deputy Health Commissioner Dr. Eddy Bresnitz
 - "It is not right for the government and unelected councils to dictate what we put into our children." - Sue Collins, co-founder of the New Jersey Alliance for Informed Choice in Vaccination
-

Influenza Vaccine

- New Jersey: Only state in U.S. to mandate flu vaccine in any age of population
 - Mandated for preschool/daycare entry up to age 5 for fall/winter 2008
 - How did it happen?
 - Does the best available evidence support the mandate?
-

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Published online September 8, 2008

PEDIATRICS (doi:10.1542/peds.2008-2449)

POLICY STATEMENT

Prevention of Influenza: Recommendations for Influenza Immunization of Children, 2008–2009

Committee on Infectious Diseases

- “The benefits of protecting children against the **known risks of influenza** far outweigh the hypothetical risks associated with the minute amounts of thimerosal in some currently available forms of influenza vaccine...”

“Known Risks”: Flu mortality statistics

National Vital
Statistics Reports



Volume 56, Number 10

<http://www.cdc.gov/nchs/deaths.htm>

April 24, 2008

Deaths: Final Data for 2005

Table 10. Number of deaths from 113 selected causes by age: United States, 2005—Con.

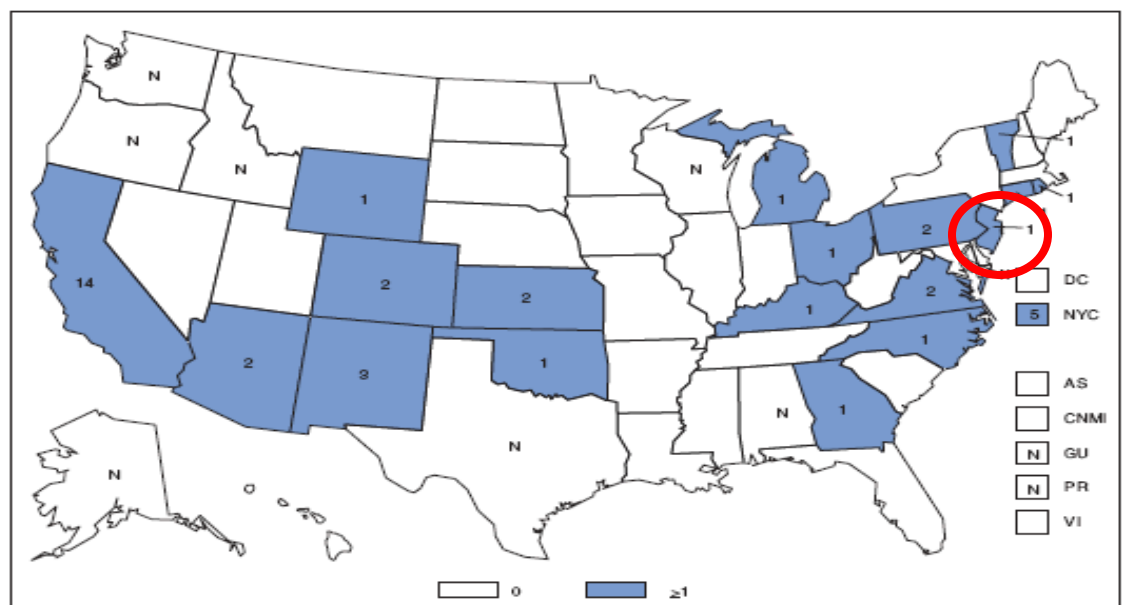
[The asterisks (*) preceding the cause-of-death codes indicate that they are not part of the *International Classification of Diseases, Tenth Revision* (ICD-10); see "Technical Notes"]

Cause of death (based on ICD-10, 1992)	All ages	Under 1 year	1-4 years	5-14 years	15-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85 years and over
Influenza and pneumonia (J10-J18)	63,001	265	110	106	172	354	934	2,183	3,422	6,623	18,563	30,267
Influenza (J10-J11)	1,812	19	19	20	12	11	19	45	66	137	482	982
Pneumonia (J12-J18)	61,189	246	91	86	160	343	915	2,138	3,356	6,486	18,081	29,285

Question: “36,000 deaths”?

Pediatric Flu-Associated Mortality

INFLUENZA-ASSOCIATED PEDIATRIC MORTALITY. Number of reported cases — United States and U.S. territories, 2006



Initial reporting for this condition began in week 40 (week ending October 9, 2004) of the 2004–05 influenza season. During 2006, a total of 43 influenza-associated pediatric deaths were reported to CDC by 18 states and New York City, with California reporting 14 deaths.

NOTE: 2.2 million children <18 in NJ (2006-07)

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- “The benefits of protecting children against the known risks of influenza far outweigh the hypothetical risks associated with the **minute amounts of thimerosal** in some currently available forms of influenza vaccine...”

“Minute Amounts”?

- “Notably, since the last formal FDA review of thimerosal use in biologics in 1976, two important things have changed regarding vaccines: there have been advances in the understanding of the human health effects of low-level exposure to mercury, and there has been an increase in the number of vaccines recommended for routine use in children. In their recent review, the FDA found that, depending on which formulation an infant received for each of his or her recommended vaccines, the infant could potentially be exposed on an immunization day to total levels of mercury that would exceed the Environmental Protection Agency (EPA) guideline of 0.1 micrograms of methylmercury per kilogram of infant body weight per day.”

SOURCE: The National Network for Immunization Information (NNii) is an affiliation of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, the American Academy of Pediatrics, the American Nurses Association, the American Academy of Family Physicians, the National Association of Pediatric Nurse Practitioners, the American College of Obstetricians and Gynecologists, the University of Texas Medical Branch, the Society for Adolescent medicine and the American Medical Association.

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

- “...because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible.”

Flu Vaccine Additives: Not Just Thimerosal

Influenza (Afluria)	Beta-Propiolactone, Calcium Chloride, Neomycin, Ovalbumin, Polymyxin B, Potassium Chloride, Potassium Phosphate, Sodium Phosphate, Sodium Taurodeoxycholate.
Influenza (Fluarix)	Egg Albumin (Ovalbumin), Egg Protein, Formaldehyde or Formalin, Gentamicin, Hydrocortisone, Octoxynol-10, α -Tocopheryl Hydrogen Succinate, Polysorbate 80, Sodium Deoxycholate, Sodium Phosphate, Thimerosal*
Influenza (Flulaval)	Egg Albumin (Ovalbumin), Egg Protein, Formaldehyde or Formalin, Sodium Deoxycholate, Phosphate Buffers, Thimerosal
Influenza (Fluvirin)	Beta-Propiolactone, Egg Protein, Neomycin, Polymyxin B, Polyoxyethylene 9-10 Nonyl Phenol (Triton N-101, Octoxynol 9), Thimerosal (multidose containers), Thimerosal* (single-dose syringes)
Influenza (Fluzone)	Egg Protein, Formaldehyde or Formalin, Gelatin, Octoxinol-9 (Triton X-100), Thimerosal (multidose containers)
Influenza (FluMist)	Chick Kidney Cells, Egg Protein, Gentamicin Sulfate, Monosodium Glutamate, Sucrose Phosphate Glutamate Buffer

Source: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

The multiple antigen argument

- What are we talking about?
 - Vaccine antigens and additives
 - Vaccine antigens vs. wildtype/natural exposures
 - Combinations
-

Supply and Demand

- Fluzone (T-free): estim 10 million doses, per manufacturer (0.25 vs. 0.5?)
 - FluMist (T-free): estim 12 million doses, per manufacturer (selected kids > 2)
 - Children in U.S. <18: 75 million
 - 0-5: 25 million
 - 6-11: 25 million
 - 12-17: 25 million
-

Science and Policy I

- Hambidge SJ, Glanz JM, France EK, McClure D, Xu S, Yamasaki K, Jackson L, Mullooly JP, Zangwill KM, Marcy SM, Black SB, Lewis EM, Shinefield HR, Belongia E, Nordin J, Chen RT, Shay DK, Davis RL, DeStefano F; Vaccine Safety Datalink Team: Safety of trivalent inactivated influenza vaccine in children 6 to 23 months old. JAMA. 2006 Oct 25;296(16):1990-7.

“It is also important to note that there is scant data on the efficacy and effectiveness of influenza vaccine in young children.”

And another message from our sponsor...

- **Financial Disclosures:** Dr France reports having received vaccine study funding from Sanofi Pasteur and MedImmune. Dr Yamasaki reports being a coinvestigator in clinical trials for MedImmune (FluMist) and Adventis (Tdap). Dr Jackson reports having received grant support from GlaxoSmithKline, having received grant support from and working as a consultant for Sanofi Pasteur and Chiron (now Novartis), and serving on the speakers' bureau for Sanofi Pasteur. Drs Mullooly and Nordin report having received grant support from Sanofi Pasteur. Dr Marcy reports working as a consultant for Sanofi Pasteur, Merck, GlaxoSmithKline, MedImmune, and Abbott and serving on the speakers' bureau for Sanofi Pasteur and GlaxoSmithKline. Dr Black and Mr Lewis report having received grant support from Sanofi Pasteur, Chiron, and MedImmune. Dr Shinefield reports having received grant support from and serving on the speakers' bureau for Sanofi Pasteur.
- **The authors report that there was no industry involvement in any aspect of this study.**

Science and Policy II

- Szilagyi PG, et al: Influenza vaccine effectiveness among children 6 to 59 months of age during 2 influenza seasons: a case-cohort study. Arch Pediatr Adolesc Med. 2008 Oct;162(10):943-51.

“In 2 seasons with suboptimal antigenic match between vaccines and circulating strains, we could not demonstrate VE in preventing influenza-related inpatient/ED or outpatient visits in children younger than 5 years. Further study is needed during years with good vaccine match.”

Science and Policy III

- Jefferson T, et al: Vaccines for preventing influenza in healthy children. Cochrane Database Syst Rev. 2008 Apr 16;(2):CD004879.

“It was surprising to find only one study of inactivated vaccine in children under two years, given current recommendations to vaccinate healthy children from six months old in the USA and Canada. If immunisation in children is to be recommended as a public health policy, large-scale studies assessing important outcomes and directly comparing vaccine types are urgently required.”

Mandate Part II: The Pneumococcal Vaccine Story

- Prevnar and the 7 serotypes
 - Cases of Invasive S. Pneumo. In Children <5 y: 73 (NJ 2006)
 - Cases of Invasive Drug-Resistant S. Pneumo. In all ages: 0 (NJ 2006)
-

Prevnar: A Cautionary Tale

Worrisome Infection Eludes a Leading Children's Vaccine

By LAURA BEL
Published: October 13, 2008

A highly drug-resistant germ has become a common cause of [meningitis](#), [pneumonia](#) and other life-threatening conditions in young children. The culprit — a strain of strep bacteria — can conquer almost all [antibiotics](#) in [pediatrics](#), and has dodged a vaccine otherwise credited with causing the number of serious infections in children to plummet.

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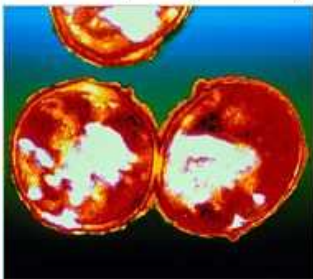
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THE SECRET LIFE OF BEES

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Infection with one type of strep bacteria is steadily rising.

Since 2000, American toddlers have been immunized against *Streptococcus pneumoniae*, or pneumococcus, an organism that preys largely on children younger than 5 and the elderly. [Pneumococcal meningitis](#) can be fatal, and survivors are often left with [deafness](#) and other lifelong neurological problems.

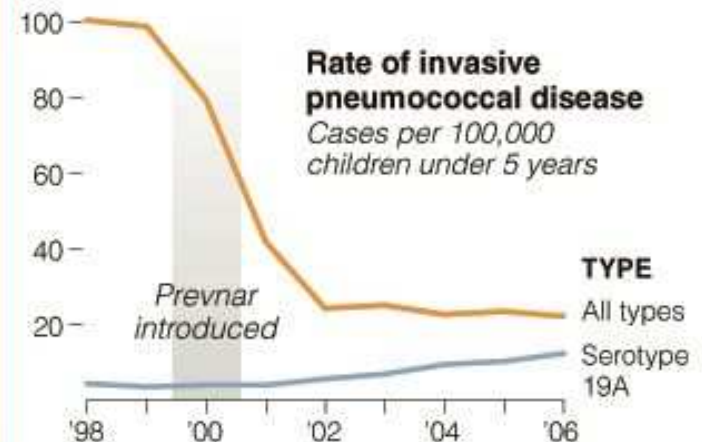
And by most measures, the vaccine has worked: by 2002, rates of infection from these bacteria had dropped as much as 80 percent in some places. But progress has now stalled, and infection with a particular type of pneumococcus, Serotype 19A, is steadily rising.

The New York Times

October 14, 2008

A Qualified Success

Infection rates from the pneumococcus bacteria, which can cause meningitis and pneumonia, have dropped substantially since the Prevnar vaccine was introduced in 2000. But infections from a particular type of the bacteria, Serotype 19A, have increased fourfold among young children and the elderly.



Responses?

- “It’s very much a concern,” said Dr. Bernard Beall, a pneumococcal expert at the federal Centers for Disease Control and Prevention... The pneumococcus has shown an extraordinary ability to evolve to our strategies.”
 - “Nature abhors a vacuum,” said Dr. Steven Black of Cincinnati Children’s Hospital. Indeed, almost all pneumococcal infections among American children today are caused by versions not covered by the vaccine, and 19A is leading the way. “People hoped against hope it wouldn’t happen,” he said.
-

Other safety concerns

- VAERS and its limitations (e.g., acute vs. chronic AE's)
 - Vaccine-associated paralytic polio
 - Rotavirus vaccine and intussusception
 - MMRV and seizures
 - Aluminum
-

Aluminum

- American Academy of Pediatrics, Committee on Nutrition: Aluminum toxicity in infants and children. *Pediatrics*. 1996 Mar;97(3):413-6
“Although aluminum is the most abundant metal in the earth’s crust and is ubiquitous in its distribution, it has no known useful biological function... Aluminum is now being implicated as interfering with a variety of cellular and metabolic processes in the nervous system and in other tissues.”
 - From CHOP’s Vaccine Information Center:
Aluminum is used in vaccines as an adjuvant. An adjuvant is a vaccine component that boosts the immune response to the vaccine. The adjuvant effects of aluminum were discovered in 1926. Aluminum adjuvants are used in vaccines such as hepatitis A, hepatitis B, diphtheria-tetanus-containing vaccines, Haemophilus influenzae type b, and pneumococcal vaccines, but they are not used in the live, viral vaccines, such as measles, mumps, rubella, varicella, or rotavirus.
-

“Is Aluminum the New Thimerosal?”

- Dr. Robert Sears:
http://www.mothering.com/articles/growing_child/vaccines/aluminum-new-thimerosal.html
- “Safe” injectable amount based on ASPEN guidelines = 25 mcg/day max per FDA
 - DTaP: 170-625 mcg, depending on manufacturer
 - Hepatitis A: 250 mcg
 - Hepatitis B: 250 mcg
 - HIB (PedVaxHib only): 225 mcg
 - HPV (Gardasil): 225 mcg
 - Pediarix (DTaP-Hepatitis B-Polio combination): 850 mcg
 - Pentacel (DTaP-HIB-Polio combination): 330 mcg
 - Pneumococcal (Prevnar): 125 mcg
 - Note: also found in breast milk, formula and other daily environmental exposures
 - What is a safe amount of aluminum (or mercury.... or lead....)? How about all together? How about in a 5 pound baby vs. a 200 pound adult?

Neurotoxicity of Additives

- Toimela T, Tahti H: Mitochondrial viability and apoptosis induced by aluminum, mercuric mercury and methylmercury in cell lines of neural origin. Arch Toxicol. 2004 Oct;78(10):565-74.

“All the metals tested induced apoptosis... The study emphasized the toxicity of methylmercury** to neural cells and showed that aluminum alters various cellular activities.”*

**cell death*

***thimerosal is ethylmercury*

Of Timing and Titters

- Hannah Poling: Canary in the Coal Mine?
 - Does timing matter? (DTaP study)
 - What about titers? (Holly's Law)
 - Flexibility: Weighing Safety, Efficacy and Individuality
 - Examples: Hep-B, MMR, Varicella vaccines
-

Example: DTP timing and AE

- McDonald KL, et al: Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma. J Allergy Clin Immunol. 2008 Mar;121(3):626-31.
 - “Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months...The mechanism for this phenomenon requires further research.”
 - Note: this Canadian study of a 1995 cohort evaluated predominantly whole-cell DTP vaccine, not the current DTaP vaccine used in the U.S.
-

The Case for Individuality I

1: [Lancet Neurol.](#) 2006 Jun;5(6):488-92.

Comment in:

[Lancet Neurol.](#) 2006 Jun;5(6):465-6.

[Lancet Neurol.](#) 2007 Jan;6(1):14-6.

De-novo mutations of the sodium channel gene SCN1A in alleged vaccine encephalopathy: a retrospective study.

[Berkovic SE](#), [Harkin L](#), [McMahon JM](#), [Pelekanos JT](#), [Zuberi SM](#), [Wirrell EC](#), [Gill DS](#), [Iona X](#), [Mulley JC](#), [Scheffer IE](#).

Epilepsy Research Centre and Department of Medicine, University of Melbourne, Austin Health, Heidelberg West, Victoria, Australia. s.berkovic@unimelb.edu.au

- **INTERPRETATION:** Cases of alleged vaccine encephalopathy could in fact be a genetically determined epileptic encephalopathy that arose de novo. These findings have important clinical implications for diagnosis and management of encephalopathy and, if confirmed in other cohorts, major societal implications for the general acceptance of vaccination.

The Case for Individuality II

1: [Expert Opin Biol Ther.](#) 2008 Nov;8(11):1659-1667.

Personalized vaccines: the emerging field of vaccinomics.

[Poland GA](#), [Ovsyannikova IG](#), [Jacobson RM](#).

1Director, Mayo Vaccine Research Group, Director, Program in Translational Immunovirology and Biodefense, Professor of Medicine and Infectious Diseases Mayo Clinic College of Medicine, Mayo Clinic, 611C Guggenheim Building, 200 First Street, SW, Rochester, MN 55905, USA +1 507 284 4968 ; +1 507 266 4716 ; poland.gregory@mayo.edu , 2Mayo Clinic College of Medicine, Mayo Vaccine Research Group, Program in Translational Immunovirology and Biodefense, Mayo Clinic, Rochester, Minnesota, USA, 3Mayo Clinic College of Medicine, Department of Medicine, Mayo Clinic, Rochester, Minnesota, USA, 4Mayo Clinic College of Medicine, Department of Pediatric and Adolescent Medicine Mayo Clinic, Rochester, Minnesota, USA.

The next 'golden age' in vaccinology will be ushered in by the new science of vaccinomics. In turn, this will inform and allow the development of personalized vaccines, based on our increasing understanding of immune response phenotype: genotype information. Rapid advances in developing such data are already occurring for hepatitis B, influenza, measles, mumps, rubella, anthrax and smallpox vaccines. In addition, newly available data suggest that some vaccine-related adverse events may also be genetically determined and, therefore, predictable. This paper reviews the basis and logic of personalized vaccines, and describes recent advances in the field.

PMID: 18847302 [PubMed - as supplied by publisher]

AAP on Vaccine Discussions

- In general, pediatricians should avoid discharging patients from their practices solely because a parent refuses to immunize his or her child.
- Families with doubts about immunization should still have access to good medical care, and maintaining the relationship in the face of disagreement conveys respect and at the same time allows the child access to medical care.

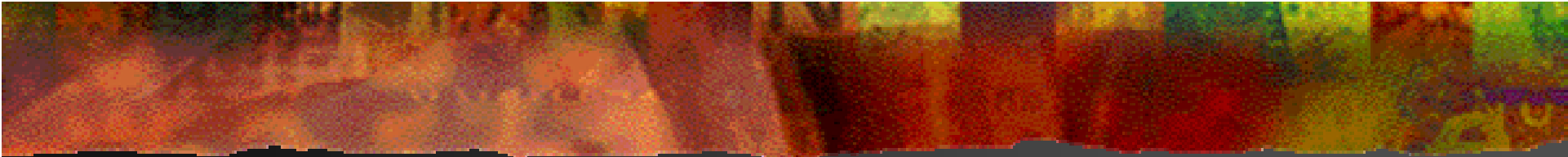
Diekema DS; American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. Pediatrics. 2005 May;115(5):1428-31.

CDC on Vaccine Discussions

- Excluding patients from your practice whose parents decline immunizations is not deemed the best public health strategy.
- Explore whether the parent is willing to allow his/her child to receive certain vaccines, to be immunized on an alternative schedule, or delay vaccination and “catch-up” if the parent changes his/her mind.
- Keep the lines of communication open with parents who choose to defer or who refuse vaccination by expressing your desire to talk more about vaccines during future visits.

Where do we go from here?

- Vaccine policy and procedure
 - What is in the best interest of public health?
 - How is this debated and decided?
 - One size fits all?
 - All or none?
-



Forum on Vaccines: Addressing All Sides of the Issue

Lawrence D. Rosen, MD FAAP

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Hackensack University Medical Center

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