Common Immunization Myths and Misconceptions:

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PATH: A Catalyst for Global Health; Sections of Emerging Disease and Influenza Consultant, Grant Funding

XenoPort Pharmaceuticals, my wife works as a pharmaceutical representative
Disclosures:

Patents:


Background

Parents, patients, and healthcare professionals all have misconceptions about vaccination

• More parents and patients are questioning the safety and effectiveness of vaccines. Your responses to them require knowledge, tact, and time.

• Healthcare providers can miss opportunities to vaccinate by believing false contraindications and following unnecessary rules.
Objectives

This presentation will provide:

• Information that addresses common concerns or misconceptions about vaccination.

• Concerns and misconceptions of patients, parents, and healthcare professionals will be reviewed.

• Links to related evidence-based resources —some are intended as background information for healthcare professionals and others for patients/parents.
Patient Myths
MYTH: Thimerosal Causes Autism

• The form of mercury found in thimerosal is ethylmercury (EM), not methylmercury (MM). MM is the form that has been shown to damage the nervous system. There is more Mercury in can of tuna than in all infant vaccines combined.

• Despite no evidence of harm, thimerosal was taken out of vaccines as a precaution and “because it can be” (due to single-dose vials)

• Since 2001, with the exception of a influenza vaccine product, thimerosal has not been used as a preservative in any routinely recommended childhood vaccines.
MYTH: Thimerosal Causes Autism

- Multiple studies have shown that thimerosal in vaccines does not cause autism when comparing children who received thimerosal containing vaccines and those who received vaccines not containing thimerosal.
- Studies of three countries compared the incidence of autism before and after thimerosal was removed from vaccines (in 1992 in Europe and 2001 in the U.S.). There was no decrease in autism with the switch to thimerosal-free vaccines.
References

• CDC’s Vaccine Safety Concerns web page
  www.cdc.gov/vaccinesafety/concerns

• IAC’s collection of thimerosal-related resources
  www.immunize.org/thimerosal

• NNii’s Mercury in Vaccines web page
  www.immunizationinfo.org/issues/thimerosalmercury

• Institute of Medicine reports on thimerosal
  www.nap.edu/books/030909237X/html and
  http://books.nap.edu/catalog/10208.html
MYTH: Ingredients in Vaccines Are Harmful

Aluminum

• Aluminum was used in some vaccines as an adjuvant—an ingredient that improves the immune response. They have been used for this purpose for more than 70 years.

• Aluminum is the most common metal found in nature. It is in the air and in food and drink. Infants get more aluminum through breast milk or formula than vaccines.

• Most of the aluminum taken into the body is quickly eliminated.
MYTH: Ingredients in Vaccines Are Harmful – cont’d

Formaldehyde

• Formaldehyde is used to detoxify diphtheria and tetanus toxins or to inactivate a virus.

• The tiny amount (35-100 µg) is left over from these steps.

• Formaldehyde is also found in products like paper towels, mascara, and carpeting.

• Humans normally have formaldehyde in their blood streams as result of normal metabolism, at levels higher than is found in vaccines (135-180 µg/L).
MYTH: Ingredients in Vaccines Are Harmful

Miscellaneous
- Antibiotics are present in some vaccines to prevent bacterial contamination when the vaccine is made.
- Additives such as include gelatin, albumin, sucrose, lactose, inorganic salts and sugars help the vaccine stay effective while being stored.

### Vaccine Excipient & Media Summary

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contains</th>
<th>Source: Manufacturer’s P.I. Dated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>sucrose, D-mannose, D-fructose, dextrose, potassium phosphate, plasdone C, anhydrase lactose, micro</td>
<td>March 2011</td>
</tr>
<tr>
<td></td>
<td>crystalline cellulose, polacrin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetic, castor oil, FD&amp;C Yellow #6, aluminum lake dye, human serum albumin, fetal bovine serum, sodium bicarbonate, human-diploid fibroblast cell cultures (WI-38), Dulbecco’s Modified Eagle’s Medium, monosodium glutamate</td>
<td></td>
</tr>
<tr>
<td>Anthrax (Biotrax)</td>
<td>aluminum hydroxide, benzethonium chloride, formaldehyde, amino acids, vitamins, inorganic salts and sugars</td>
<td>May 2012</td>
</tr>
<tr>
<td>BCG (Tice)</td>
<td>glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactate</td>
<td>February 2009</td>
</tr>
<tr>
<td>DT (Sanofi)</td>
<td>aluminum potassium sulfate, peptone, bovine extract, formaldehyde, thimerosal (trace), modified Miseluer and Miller medium, ammonium sulfate</td>
<td>December 2005</td>
</tr>
<tr>
<td>DTaP (Daptacel)</td>
<td>aluminum phosphate, formaldehyde, glutaraldehyde, 2-Phenoxyethanol, Stainer-Scholte medium, modified Miselu-Miller casamino acid medium (without beef heart infusion), dimethy-1-beta-cycloextrin, ammonium sulfate</td>
<td>October 2013</td>
</tr>
<tr>
<td>DTaP (Infanrix)</td>
<td>formaldehyde, glutaraldehyde, aluminum hydroxide, polysorbate 80, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium</td>
<td>November 2013</td>
</tr>
<tr>
<td>DTaP-IPV (Kinrix)</td>
<td>formaldehyde, glutaraldehyde, aluminum hydroxide, Vero (monkey kidney) cells, calf serum, lactalbumin hydrolysatate, polysorbate 80, neomycin sulfate, polyoxymyxin B, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium</td>
<td>November 2013</td>
</tr>
<tr>
<td>DTaP-HepB-IPV (Pediatix)</td>
<td>formaldehyde, glutaraldehyde, aluminum hydroxide, aluminum phosphate, lactalbumin hydrolysatate, polysorbate 80, neomycin sulfate, polyoxymyxin B, yeast protein, calf serum, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium, Vero (monkey kidney) cells</td>
<td>November 2013</td>
</tr>
<tr>
<td>DTaP-IPV/Hib (Pentacel)</td>
<td>aluminum phosphate, polysorbate 80, formaldehyde, sucrose, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polyoxymyxin B sulfate, Mueller’s Growth Medium, Mueller-Miller casamino acid medium (without beef heart infusion), Stainer-Scholte medium (modified by the addition of casamino acids and dimethyl-beta-cycloextrin), MRC-5 (human diploid) cells, CMRL 1969 medium (supplemented with calf serum), ammonium sulfate, and medium 199</td>
<td>October 2013</td>
</tr>
<tr>
<td>Hib (ActHIB)</td>
<td>ammonium sulfate, formalin, sucrose, Modified Mueller and Miller medium</td>
<td>January 2014</td>
</tr>
<tr>
<td>Hib (Hibexis)</td>
<td>formaldehyde, lactose, semi-synthetic medium</td>
<td>March 2012</td>
</tr>
<tr>
<td>Hib (PedvaxHIB)</td>
<td>aluminum hydrophosphate sulfate, ethanol, enzymes, phenol, detergent, complete fermentation medium</td>
<td>December 2010</td>
</tr>
</tbody>
</table>
References

• VEC’s “Aluminum in Vaccines: What you should know”
  www.chop.edu/export/download/pdfs/articles/vaccineeducation-center/aluminum.pdf

• IAC’s “Adjuvants and Ingredients” web section
  www.immunize.org/concerns/adjuvants.asp

• NNii’s “Aluminum Adjuvants in Vaccines”
  www.immunizationinfo.org/issues/vaccinecomponents/aluminum-adjuvants-vaccines

• AAP’s “Questions and Answers about Vaccine Ingredients”
  www2.aap.org/immunization/families/faq/vaccineingredien
References cont’d

CDC’s “Vaccine Excipient & Media Summary, by Excipient”

CDC’s “Vaccine Excipient & Media Summary, by Vaccine”

IAC’s Package Inserts web section
www.immunize.org/packageinserts
MYTH: Disease Rates Have Dropped Due to Factors Other Than Vaccination

- Better living conditions have had an impact on disease rates. BUT, the only real decrease in a VPD has occurred after the introduction of a vaccine to prevent it. Cf., polio
- Hib (1987) and varicella (1995), were introduced during times of modern hygiene.
- When U.K., Sweden, Japan, and Italy stopped using DTP vaccine, their pertussis rates jumped dramatically.
- Recent outbreaks of measles, pertussis, and varicella in the U.S. have been traced to pockets of unvaccinated children. When vaccination rates go down, disease rates go up.

**Figure 3**

Pertussis annual incidence rates in infants aged <1 year by state of residence, 1940-2007.

Source: National Epidemiological Surveillance Network.
Measles—United States, 1950-2001

Cases (thousands)

Vaccine Licensed

Estimated Incidence* of Invasive Hib Disease, 1987-2000

*Rate per 100,000 children <5 years of age
References

• CDC’s “Some Common Misconceptions About Vaccination and How to Respond to Them”
  www.cdc.gov/vaccines/vac-gen/6mishome.htm

• CDC’s “What Would Happen If We Stopped Vaccinations?” www.cdc.gov/vaccines/vacgen/whatififstop.htm

• IAC’s “Personal belief exemptions for vaccination put people at risk. Examine the evidence for yourself”
  www.immunize.org/catg.d/p2069.pdf

• NNii’s “Vaccine Effectiveness”
  www.immunizationinfo.org/parents/why-immunize
MYTH: Vaccines Are Not Effective

• Anti-vaccine websites often set up a straw man argument—claiming that experts say that vaccines are 100% effective, and then showing this is not true. No one claims that vaccines are 100% effective, no drug or medical procedure always works.

• Most childhood vaccines are effective when properly administered and all doses are received according to the recommended schedule. ( >80%, depending on vaccine)
MYTH: PPSV Vaccine Is Not Effective

An ~ 40,000 cases of invasive pneumococcal disease occurred annually. Case-fatality rates are high, in meningitis (~30%) or bacteremia (~20%).

PPSV is not a general “pneumonia vaccine” as people often think; i.e., it does not provide protection against all types of pneumonia (viral and bacterial). PPSV is 60–70% effective in preventing serious invasive pneumococcal disease.
References – PPSV

IAC’s PPSV web section
www.immunize.org/pneumococcal-ppsv

ACIP’s “Prevention of Pneumococcal Disease,”
April 4, 1997
MYTH: Influenza Vaccines Are Not Effective

• At least two factors play important roles in determining the likelihood that influenza vaccine will protect a person from influenza illness:

  1) characteristics of the person being vaccinated (such as their age and health), and

  2) the similarity or "match" between the influenza virus types in the vaccine and those spreading in the community.
MYTH: Influenza Vaccines Are Not Effective

Many vaccinated people think they “got the flu” from the vaccine when in reality, they had a cold or another viral infection.

Although, Live influenza has RARE secondary contact spread

Flu vaccines will not protect against infection and illness caused by other viruses that can also cause influenza-like symptoms.
References: Influenza Vaccines Are Not Effective

IAC’s Influenza web section
www.immunize.org/influenza

Flu Vaccine Effectiveness: Q&As for Health Professionals
www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm

Vaccine Effectiveness—How Well Does the Flu Vaccine Work? Q&As for the Public
www.cdc.gov/flu/about/qa/vaccineeffect.htm

Public health groups say flu vaccine is best tool, despite limitations
Influenza Vaccine Causes Guillain-Barre Syndrome

Risk estimates (with 95% confidence intervals) of Guillain-Barré syndrome following influenza vaccines select studies,

Influenza Vaccine Causes Guillain-Barre Syndrome

Cumulative risk of Guillain-Barré syndrome (GBS) among the 2009 pH1N1 vaccinated and unvaccinated groups by day and all ages, Emerging Infections Program, United States, 15 October 2009–31 May 2010.

**MYTH:** The vaccine wasn't properly tested and hasn't been proven to prevent HPV-related cancers.

**FACT:** In initial clinical trials, the vaccine was given to 20,000 women aged 16–26 years in 33 countries. It showed the vaccine is effective in preventing pre-cancerous abnormalities in cervical cells caused by high-risk HPV types 16 and 18.

Clinical trials of > 4,000 males aged 16–26 years showed the vaccine was 90% effective in preventing genital warts and abnormalities associated with penile cancer, and 78% effective in preventing anal disease, caused by HPV types 6, 11, 16 and 18.
**Myths: About HPV and the vaccine**

- **MYTH:** Having the vaccine at a young age leads to promiscuity.

- **FACT:** There is no evidence that boys and girls who receive the vaccine have sex earlier than those who do not have the vaccine, and nor do they have more sexual partners once they became sexually active.
Myths: About HPV and the vaccine

- **MYTH**: The HPV vaccine causes more serious side effects than other vaccines.

- **FACT**: >187 million doses of the vaccine have been given in more than 130 countries and all adverse reactions are monitored and investigated.

  - All vaccines can have side effects. Common side effects are pain, redness and/or swelling at the site of injection.

  - Very rarely, more serious side effects such as anaphylactic (allergic) reaction can occur, usually if you are allergic to an ingredient in the vaccine such as yeast.
Myths: About HPV and the vaccine

- **MYTH:** The vaccine can give you the virus and cause cancer.

- **FACT:** The vaccine is produced in either recombinant yeast or baculovirus, therefore **cannot** cause cancer or any other HPV-related diseases.
References: HPV vaccine

- The **World Health Organization** directs and coordinates health across the United Nations. It provides leadership on global health matters and evidence-based policy.

- The **Food and Drug Administration** is the regulatory authority for medicines in the USA.

- The **US Center for Disease Control and Prevention** is a world-leading authority on protecting populations from disease and disease control. Their website has comprehensive information about **HPV** and the **vaccine**.

- The **Society of Obstetricians and Gynaecologists of Canada** has put together this website, which provides a wealth of information for teens, adults, parents, teachers and health professionals about **HPV** and the **vaccine**.
Good Resources for Patients

• IAC’s Talking About Vaccines
  www.immunize.org/concerns
• VEC’s handouts on hepatitis A, meningococcal, HPV, influenza, shingles, and Tdap
  www.chop.edu/service/vaccine-educationcenter/order-educational-materials
• National Foundation for Infectious Diseases
  www.adultvaccination.org
• National Network for Immunization Information
  www.immunizationinfo.org
• CDC’s web section for adults
  www.cdc.gov/vaccines/spec-grps/adults.htm
Good Resources for Patients

• IAC’s “Vaccinations for Preteens and Teens, Age 11–19 Years”  www.immunize.org/catg.d/p4020.pdf

• IAC’s “Vaccinations for Adults”  
  www.immunize.org/catg.d/p4030.pdf

• IAC’s website for the public  
  www.vaccineinformation.org

• VEC’s “Vaccines and Adults: A Lifetime of Health”  
  www.chop.edu/export/download/pdfs/articles/vaccineeducation-center/vaccines-adults.pdf

• VEC’s “Vaccines and Teens: The Busy Social Years”  
Provider Myths
Provider Myths

- Vaccination contraindications and precautions are complicated, and the many new vaccines and their recommendations can cause confusion that leads to misconceptions.

- Providers who are concerned about vaccinating properly frequently err on the side of caution.

- Unfortunately, misconceptions can lead to missed opportunities to vaccinate.
Provider Myths

MYTH
Vaccines can’t be given to people who are sick.

FACT
Mild acute illness with or without fever is not a contraindication to vaccination. Neither is antibiotic treatment, recent exposure to an infectious disease, or convalescing from an illness.
Provider Myths

MYTH
Providers need to check vital signs before vaccinating.

FACT
ACIP does not recommend routinely checking temperature or other vital signs before vaccination. Mild illness is not a reason to withhold vaccination and requiring extra steps can be a barrier to immunization.
Provider Myth

MYTH
Certain vaccines can’t be given together.

FACT
All routine vaccines can be given simultaneously (at the same visit, not in the same syringe).

If 2 live virus vaccines are not given at the same visit, then they need to be separated by at least 4 weeks.

Inactivated vaccines can be given at the same time, or any time before or after, another inactivated or live vaccine.
Provider Myths

MYTH
Vaccines can’t be given to breastfeeding women.

FACT
All vaccines can be given to breastfeeding women except smallpox vaccine (yes, even live vaccines, even nasal-spray vaccines!).
MYTH
Live virus vaccines (zoster, varicella, MMR, and LAIV) should not be given to contacts of pregnant women or to contacts of immunocompromised people.

FACT
False. The only concern is when a person develops a varicella-like rash after receiving varicella or zoster vaccine. Then the vaccinee should avoid close contact with the unvaccinated infant or immunocompromised person.

True: Live polio vaccine was associated with VAPP.
Provider Myths

MYTH
Pregnant women should never get vaccines.

FACT
Pregnant women should not receive LIVE vaccines. Influenza and Tdap are recommended in pregnancy.

HPV vaccine has not been sufficiently studied so should not be administered during pregnancy at this time.
**MYTH**

Tdap can’t be given if a person has received Td in the last 5 years.

**FACT**

There is no "minimum interval" one needs to wait between receiving Td and Tdap. If necessary, it can be given the same day.
References: Provide Myths

- IAC’s “ACIP Recommendations” web section
  www.immunize.org/acip
- IAC’s “Ask the Experts” web section with CDC experts
  www.immunize.org/askexperts
- IAC’s Vaccine Information Statement (VIS) web section
  www.immunize.org/vis
- IAC’s Immunization Education Materials web section
  www.immunize.org/handouts
- IAC’s Pharmacist and Immunization web section
  www.immunize.org/pharmacists
Background Resources

• ACIP's “General Recommendations on Immunization”
  www.cdc.gov/mmwr/PDF/rr/rr5515.pdf
• CDC's “Pink Book”
  www.cdc.gov/vaccines/pubs/pinkbook/index.html
• CDC’s “Guide to Vaccine Contraindications and Precautions”
  www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm
• CDC’s “Immunization & Pregnancy”
Parent Myths
MYTH: MMR causes Autism

Co-occurring Conditions and Change in Diagnosis in Autism Spectrum Disorders

AUTHORS: Heather A. Close, BS,a Li-Ching Lee, PhD, ScM,a Christopher N. Kaufmann, MHS,a and Andrew W. Zimmerman, MDa

*aCenter for Autism and Developmental Disabilities Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland; and bLurie Family Autism Center, Massachusetts General Hospital for Children, Lexington, Massachusetts

KEY WORDS
autism spectrum disorder, co-occurring conditions, diagnosis change

ABBREVIATIONS
aOR—adjusted odds ratio
ASD—autism spectrum disorder
CI—confidence interval

WHAT’S KNOWN ON THIS SUBJECT: Mixed prevalence rates of co-occurring psychiatric and neurodevelopmental conditions have been reported in children diagnosed with an autism spectrum disorder (ASD). ASD diagnoses remain fairly stable within a continuum, but some do not meet criteria for an ASD diagnosis years after initial diagnosis.

WHAT THIS STUDY ADDS: Co-occurring neurodevelopmental and psychiatric conditions may explain, in part, why the diagnosis of an ASD may change with age.
MYTH: MMR causes Autism

Genetics in Medicine (2009) 11, 111–117; doi:10.1097/GIM.0b013e31818fd762

The prevalence of PTEN mutations in a clinical pediatric cohort with autism spectrum disorders, developmental delay, and macrocephaly

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1Center for Molecular and Human Genetics, The Research Institute at Nationwide Children's Hospital, Columbus, Ohio
2Departments of Pediatrics, Columbus, Ohio
3Pathology, The Ohio State University, Columbus, Ohio
Mitochondrial dysfunction in autism spectrum disorders: a systematic review and meta-analysis

D A Rossignol, R E Frye

Molecular Psychiatry 2012, 17 (3): 290-314

A comprehensive literature search was performed to collate evidence of mitochondrial dysfunction in autism spectrum disorders (ASDs) with two primary objectives. First, features of mitochondrial dysfunction in the general population of children with ASD were identified. Second, characteristics of mitochondrial dysfunction in children with ASD and concomitant mitochondrial disease (MD) were compared with published literature of two general populations: ASD children without MD, and non-ASD children with MD. The prevalence of MD in the general population of ASD was 5.0% (95% confidence interval 3.2, 6.9%), much higher than found in the general population (≈ 0.01%). The prevalence of abnormal biomarker values of mitochondrial dysfunction was high in ASD, much higher than the prevalence of MD. Variances and mean values of many mitochondrial biomarkers (lactate, pyruvate, carnitine and ubiquinone) were significantly different between ASD and controls. Some markers correlated with ASD severity. Neuroimaging, in vitro and post-mortem brain studies were consistent with an elevated prevalence of mitochondrial dysfunction in ASD. Taken together, these findings suggest children with ASD have a spectrum of mitochondrial dysfunction of differing severity. Eighteen publications representing a total of 112 children with ASD and MD (ASD/MD) were identified. The prevalence of developmental regression (52%), seizures (41%), motor delay (51%), gastrointestinal abnormalities (74%), female gender (39%), and elevated lactate (78%) and pyruvate (45%) was significantly higher in ASD/MD compared with the general ASD population. The prevalence of many of these abnormalities was similar to the general population of children with MD, suggesting that ASD/MD represents a distinct subgroup of children with MD. Most ASD/MD cases (79%) were not associated with genetic abnormalities, raising the possibility of secondary mitochondrial dysfunction. Treatment studies for ASD/MD were limited, although improvements were noted in some studies with carnitine, co-enzyme Q10 and B-vitamins. Many studies suffered from limitations, including small sample sizes, referral or publication biases, and variability in protocols for selecting children for MD workup, collecting mitochondrial biomarkers and defining MD. Overall, this evidence supports the notion that mitochondrial dysfunction is associated with ASD. Additional studies are needed to further define the role of mitochondrial dysfunction in ASD.
Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays

abstract

Global developmental delay and intellectual disability are relatively common pediatric conditions. This report describes the recommended clinical genetics diagnostic approach. The report is based on a review of published reports, most consisting of medium to large case series of diagnostic tests used, and the proposal of those that led to a diagnosis in such patients. Chromosomal microarray is designated as a first-line test and replaces the standard karyotype and fluorescent in situ hybridization subtelomere tests for the child with intellectual disability of unknown etiology. Fragile X testing remains an important first-line test. The importance of considering testing for inborn errors of metabolism in this population is supported by a recent systematic review of the literature and several case series recently published. The role of brain MRI remains important in certain patients. There is also a discussion of the emerging literature on the use of whole-exome sequencing as a diagnostic test in this population. Finally, the importance of intentional comanagement among families, the medical home, and the clinical genetics specialty clinic is discussed. Pediatrics 2014;134:e903–e918
Inborn error metabolic screening in individuals with nonsyndromic autism spectrum disorders

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Correspondence to Rafael Artuch at Clinical Biochemistry Department, Hospital Sant Joan de Déu, Passapèt Sant Joan d’Déu, 2. 08025 Esplugues, Barcelona, Spain.
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AIM To perform metabolic testing on 406 patients (age range 3-22y [mean 8.71, SD 4.15], 343 males and 63 females) with nonsyndromic autism spectrum disorders (ASD) to assess the diagnostic yield. In addition, we reviewed our hospital’s clinical database of 8500 patients who had undergone metabolic testing to be identified for inborn errors of metabolism (IEM), and described the characteristics of those with IEM and nonsyndromic ASD.

METHOD Neuropsychological evaluation included the Social Communication Questionnaire and Child Behavior Checklist. For metabolic testing/screening, urine samples were analyzed for the diagnosis of central creatine deficiency syndromes, purine and pyrimidine disorders, amino acid metabolism defects, mucopolysaccharidoses, and organic acidurias.

RESULTS The 406 recruited participants fulfilled the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria of ASD. No biochemical evidence of a metabolic disorder was detected in any of the 406 patients studied. Concerning the retrospective evaluation from the 8500 who had metabolic testing, 484 individuals had a diagnosis of an IEM (394 without the diagnosis of ASD and 70 with ASD diagnosis). Only one individual with IEM had a diagnosis of nonsyndromic ASD at the time of the metabolic study; the metabolic testing had revealed diagnosis of urea cycle disorder.

INTERPRETATION Metabolic testing should be considered in the work-up of individuals with syndromic ASD, but metabolic testing is not cost-effective for individuals with nonsyndromic ASD.
MYTH: MMR causes Autism

Andrew Wakefield et al, 1998 started this concern based on 12 children preselected for study.

12 of 13 authors of this study have retracted the study’s interpretation.

On 2/2/10, The Lancet retracted the paper citing the ruling of the U.K.’s General Medical Council that the primary author’s conduct regarding this research was “dishonest” “irresponsible” and had shown a “callous disregard for the suffering of children involved.”

01/2011, the BMJ published articles showing Wakefield’s work was deliberate fraud.
The findings were summarized as:

- There was no relationship between vaccination and autism
- There was no relationship between vaccination and Autism Spectrum Disorder
- There was no relationship between autism and the MMR vaccine
References: MYTH: MMR causes Autism

• IAC’s “MMR vaccine does not cause autism. Examine the evidence!”
  www.immunize.org/catg.d/p4026.pdf
• IAC’s “Clear Answers & Smart Advice about Your Baby’s Shots” by Ari Brown, MD, FAAP
  www.immunize.org/catg.d/p2068.pdf
• CDC’s “MMR Vaccine”
  www.cdc.gov/vaccinesafety/Vaccines/MMR/index.html
• The Fraud Behind the MMR Scare (IAC web section)
  www.immunize.org/bmj-deer-mmr-wakefield
• IOM Report: “MMR Vaccine and Autism”
  www.nap.edu/catalog.php?record_id=10101
References: MYTH: MMR causes Autism

• IAC’s “Evidence Shows Vaccines Unrelated to Autism”
  www.immunize.org/catg.d/p4028.pdf

• IAC’s “Decisions in the Omnibus Autism Proceeding”
  www.immunize.org/catg.d/p4029.pdf

• VEC’s “Vaccines and Autism: What you should know”
  www.chop.edu/export/download/pdfs/articles/vaccineeducation-center/autism.pdf

• “Vaccines and Autism: A Tale of Shifting Hypotheses” by Paul Offit, MD and Jeffery Gerber, MD
  www.journals.uchicago.edu/doi/pdf/10.1086/596476
References: MYTH: MMR causes Autism

- "Fitness to Practice Panel Hearing" report from the U.K.’s General Medical Council regarding Dr. Andrew Wakefield
  www.neurodiversity.com/wakefield_gmc_ruling.pdf

- The Lancet retraction
  http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/abstract

“How a zealot’s word led us astray on autism” by Arthur Caplan, PhD
www.msnbc.msn.com/id/35218819/ns/healthhealth_Care
Pertussis immunisation and serious acute neurological illnesses in children

David Miller
Nicola Madge
Judith Diamond
Jane Wadsworth
Euan Ross

Academic Department of Public Health, St Mary’s Hospital Medical School, University of London, London W2 1PG

David Miller, professor Nicola Madge, senior research fellow
Judith Diamond, research statistician
Jane Wadsworth, senior lecturer in medical statistics

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Euan Ross, professor

Correspondence to: Professor Miller.

BMJ 1993;307:1171-6

(95% confidence interval 1.6 to 6.9) of the number of cases associated with the vaccine was extremely small and statistically it was possible that other agents or predisposition factors could not be excluded.

Diphtheria, tetanus, and pertussis are all preventable and are now a rare cause of serious illness in children. The role of the vaccine as a prime or concomitant factor in the protection against severe acute neurological illnesses is still unclear. Some cases may have these illnesses cannot be determined in all cases. The balance of possible risk benefits from pertussis immunisation and use of the vaccine.

A childhood encephalopathy study was conducted in 1976 after reports questioning the safety of the vaccine had led to serious loss of confidence in the immunisation programme and a dramatic fall in immunisation rates for this vaccine. The study was designed to examine the causes and outcome of serious neurological illnesses in young children considered to have had encephalopathy after vaccination with diphtheria, tetanus, and pertussis vaccine in the previous seven days. Despite three years of active

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DPT vaccine is Dangerous

- Cody et al compared adverse reactions of DPT and DT vaccination.
- Persistent crying was common with DPT.
- Seizures followed 0.06% and hypotensive-hyporesponsive state followed 0.06% of DPT vaccinations.
- These complications did not follow immunization with the Swedish acellular pertussis vaccine.
- Follow-up studies of children in the Cody series who experienced seizures or the hypotensive/hyporesponsive state following DPT did not disclose any sequelae.
- Because vaccine-induced encephalopathy is so rare, a case-control study is appropriate. The only retrospective case-control study conducted calculated the risk of permanent brain damage following DPT as:
  - 1:310,000 doses, 95% confidence interval 1:50,000 to 1:18,000,000.
MYTH: Giving an infant multiple vaccines can overwhelm the immune system

• Babies are exposed to immunological challenges at the time of birth. As babies pass through the birth canal and breathe, they are immediately colonized with trillions of bacteria. Healthy babies constantly make antibodies against these bacteria and viruses.

• Though children receive more vaccines than in the past, today’s vaccines contain fewer antigens than previous vaccines.

  ▪ Smallpox vaccine alone contained 200 proteins; the 11 currently recommended routine vaccines contain fewer than 130 immunologic components.
References

• VEC’s “Too Many Vaccines? What you should know”
  www.chop.edu/export/download/pdfs/articles/vaccineeducation-center/too-many-vaccines.pdf

• FAQs about Multiple Vaccinations and the Immune System
  www.cdc.gov/vaccinesafety/Vaccines/multiplevaccines.html
MYTH: It’s better to space out vaccines using an alternative schedule

• Delaying vaccines increases the time children will be susceptible to diseases.
  ▪ SSPE and other complications of measles occur if infection is in the first 18 months of life. In 2011, there were more than 1200 cases reported in the US. Most among children <5 years of age
  ▪ There is no evidence that spreading out the schedule decreases the risk of adverse reactions.

• Requiring many extra appointments for vaccinations increases the stress for the child and may lead to a fear of visits to the clinic.
References

• “The Problem With Dr Bob’s Alternative Vaccine Schedule” by Paul Offit, MD, and Charlotte Moser

• AAP’s “Adhering to Vaccine Schedule is Best Way to Protect Children from Disease”
  www.immunize.org/aap/fisher.pdf

• VEC’s “Too Many Vaccines? What you should know”
  www.chop.edu/export/download/pdfs/articles/vaccineeducation-center/too-many-vaccines.pdf

• IOM Report: “Multiple Immunizations and Immune Dysfunction”
  www.nap.edu/catalog.php?record_id=10306

• “Parental Refusal of Pertussis Vaccination Is Associated with an Increased Risk of Pertussis Infection in Children”
  (Glanz et al, Pediatrics, June 2009)
  http://pediatrics.aappublications.org/content/123/6/1446.abstract
MYTH: Natural infection is better than immunization

• Natural infection, in many diseases does cause better immunity than vaccination.

• However, the price paid for natural disease can include paralysis, permanent brain damage, liver failure, liver cancer, deafness, blindness, pneumonia, or death.
References

- “Natural Infection vs. Immunization” by Paul Offit, MD
  www.chop.edu/service/vaccine-education-center/hottopicsnatural-infection-vs-immunization.html

- NNii’s “Exposure Parties”
  www.immunizationinfo.org/exposure_parties.cfm

- Photos of people with vaccine-preventable diseases
  www.immunize.org/photos

- Real-life accounts of people who have suffered or died from vaccine-preventable diseases
  www.immunize.org/reports
MYTH: Abortions Are Required to Produce Vaccines

- Production of varicella, rubella, rabies, adenovirus, and hepatitis A vaccines involves growing viruses in human cell culture.

- Two human cell lines provide these cultures; they were developed from two legally aborted fetuses in the 1960s. With known Congenital Rubella Syndrome

- The donor fetuses were not aborted for the purpose of obtaining these cells.

- The same cell lines have been used for 35 years — no new fetal tissue is required. WI-38 and MRC-5
References

- IAC’s web page about ethical and religious objections to vaccination
  www.immunize.org/concerns/religious.asp

- NNii’s “Human Fetal Links with Some Vaccines”
  www.immunizationinfo.org/issues/vaccinecomponents/human-fetal-links-some-vaccines
Religious Objections

- There is no direct command or directive in the Old or New Testaments or Holy Quran that says, "Do not vaccinate yourself or your children."

- However, there are scriptures and principles from which some religious groups derive that unspoken directive.
Religious Objections

- The Bible teaches that there are clean and unclean animals and that God's people are not to put the unclean into their bodies (Deuteronomy 14).

- Bible teaches that "Ye shall not eat of anything that dieth of itself"; (Deuteronomy 14:21) and "that flesh with the life thereof, which is the blood thereof, shall ye not eat". (Genesis 9:4)

- “Vaccines are often made of, or embodies, fetuses or eggs of said unclean creatures. The process of creating the vaccine often causes said creatures to die in the process. Many vaccines are made in or of the blood of diseased animals.”
Religious Objections

We must be very careful with pharmaceutical drugs. Pharmacy comes from the Greek word *pharmakeia* means witchcraft, sorcery. These are the main meanings:

- a) the use or administering of drugs
- b) poisoning
- c) sorcery, magical arts, often found in connection with idolatry.

Some pharmaceuticals are created from aborted fetal tissue or chemicals. It is prudent to research any/all prescriptions that any physician prescribes for you. My daughter was prescribed Enbrel for her rheumatoid arthritis. I was told it was a disease modifying drug that would target her immune system and teach it not to attack itself. What they did NOT tell me is that IT is CREATED using aborted fetal tissue. As soon as she learned that, she went off the medication. You cannot trust THEM (whoever THEY are) to give you all of the information, you must search it out for yourself.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Biologic</th>
<th>Expression System</th>
<th>Company</th>
<th>2010 Worldwide Sales in Millions</th>
<th>Approved Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Enbrel</td>
<td>CHO</td>
<td>Amgen</td>
<td>6,808</td>
<td>RA. ankylosing spondylitis, psoriasis, PA, juvenile rheumatoid arthritis</td>
</tr>
<tr>
<td>2</td>
<td>Humira</td>
<td>CHO</td>
<td>Abbott</td>
<td>6,548</td>
<td>RA. ankylosing spondylitis, juvenile rheumatoid arthritis, Crohn’s disease, PA. psoriasis</td>
</tr>
<tr>
<td>3</td>
<td>Remicade</td>
<td>Murine Myeloma</td>
<td>Johnson &amp; Johnson</td>
<td>6,478</td>
<td>Psoriasis, ulcerative Myeloma colitis, ankylosing spondylitis, Crohn’s disease, PA. RA</td>
</tr>
<tr>
<td>4</td>
<td>Avastin</td>
<td>CHO</td>
<td>Roche</td>
<td>6,193</td>
<td>Colorectal cancer, breast cancer, brain cancer, renal cell cancer, non-small cell lung cancer</td>
</tr>
<tr>
<td>5</td>
<td>Rituxin</td>
<td>CHO</td>
<td>Biogen-Idec</td>
<td>6,088</td>
<td>Non-Hodgkin’s lymphoma, RA, chronic lymphocytic leukemia</td>
</tr>
</tbody>
</table>

Data Source: Public Biotech 2010 – the numbers. Nature Biotechnology
Religious Objections

We should obey God rather than man – (Acts 5:29) Congressional Records (2000 – 2003) have shown that the pharmaceutical companies are more concerned with profit than they are with safety and have knowingly used toxins in the manufacturing of vaccines regardless of the risks.

In the Bible there have been times in history when evil government and government employees have attempted, through force or color of law, to intimidate, harm or destroy the children of God’s people. (Exodus 1 and 2 and Matthew 2). Therefore, if a parent feels that vaccines are not safe, it is their responsibility to defend our children from and individual or government who is attempting to subject our children to those vaccine risks.

- Parents are to care for and be responsible for their children. (1 Tim 5:8) Parents, not the government, make decisions for their children. The Comprehensive Child Health Immunizations Act of 1993 made known the fact that there are risks to vaccinations by stating "Vaccine information should be simplified to ensure that parents understand the benefits and risks".
MYTH: VAERS Data Prove that Vaccines Are Dangerous

VAERS data cannot “prove” anything

• Anyone can report anything and are encouraged to do so!
• Reports include many non-serious reactions.
• The number of reported adverse events is influenced by publicity.
• VAERS is properly used to detect early warning signals and generate hypotheses.
References

• Vaccine Adverse Events Reporting System (VAERS)
  www.vaers.hhs.gov

• CDC’s “Why it's Important to Monitor Vaccine Safety”
  www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html

• NNii’s “Monitoring Vaccine Safety”
  www.immunizationinfo.org/parents/why-immunize/monitoring-vaccine-safety

• NNii’s “Vaccine Safety: Cause or Coincidence?”
  www.immunizationinfo.org/issues/vaccine-safety/cause-orcoincidence

• WHO’s “Causality assessment of adverse events following immunization”
  www.who.int/vaccine_safety/causality/en
Good Resources for Providers Talking to Parents

- IAC’s Responding to Vaccine Concerns web section
  www.immunize.org/concerns

- IAC’s Talking with Parents web section
  www.immunize.org/concerns/comm_talk.asp

- Vaccine Education Center (at the Children’s Hospital of Philadelphia)
  www.vaccine.chop.edu

- AAP’s immunization website
  www.aap.org/immunization

- National Network for Immunization Information
  www.immunizationinfo.org
Good Resources for Parents

• IAC’s handouts for communicating with parents
  www.immunize.org/handouts/discussing-vaccines-parents.asp

• IAC’s website for the public
  www.vaccineinformation.org

• CDC’s web section about provider resources for parents
  www.cdc.gov/vaccines/spec-grps/hcp/conversations.htm

• CDC’s “Parents Guide to Childhood Immunization”
  www.cdc.gov/vaccines/pubs/parents-guide

• Vaccine Education Center (at CHOP)
  www.vaccine.chop.edu

• Every Child By Two’s websites: www.ecbt.org and
  www.vaccinateyourbaby.org

• National Network for Immunization Information
  www.immunizationinfo.org
Mandatory VaccinationViolates Civil Rights

• Massachusetts enacted the first mandatory vaccination law in the U.S. in 1809. (Smallpox)

• Vaccination laws have been found to be constitutional in U.S. courts. Seminal case was *Jacobson v. Massachusetts* in 1905.

• All states offer medical exemptions, 47 allow religious exemptions, and 20 allow philosophical exemptions. 22 allow school entrance without vaccination.

• Many states mandate that Parents need to be aware that if they don’t vaccinate their children, they are putting them, and their contacts, at risk of serious disease.
Child’s Right to Be Vaccinated

Three states, California, West Virginia, Mississippi eliminated philosophical exemption to vaccines

Mississippi in the late 1970s a case called Brown v. Stone.

Asked, “Is it your right not to be vaccinated?” Based on the second clause of the 14th Amendment—which states that all citizens of the United States should have equal protection under the law. The decision was for only medical exemptions.

California asked: “Is it your right to catch and transmit a potentially fatal infection?”

If parents have anti-vaccine beliefs, that doesn’t mean that children shouldn’t be protected. Essentially it became a civil rights issue.

Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States

A Review of Measles and Pertussis

Varun K. Phadke, MD¹; Robert A. Bednarczyk, MS, PhD²,³; Daniel A. Salmon, MPH, PhD⁴; Saad B. Omer, MBBS, MPH, PhD²,³,⁵,⁶

Conclusions and Relevance A substantial proportion of the US measles cases in the era after elimination were intentionally unvaccinated. The phenomenon of vaccine refusal was associated with an increased risk for measles among people who refuse vaccines and among fully vaccinated individuals. Although pertussis resurgence has been attributed to waning immunity and other factors, vaccine refusal was still associated with an
References

• IAC’s “What if you don’t immunize your child?”
  www.immunize.org/catg.d/p4017.pdf

• IAC’s “Decision to Not Vaccinate My Child” (declination form)
  www.immunize.org/catg.d/p4059.pdf

• “Personal belief exemptions for vaccination put people at risk”
  www.immunize.org/catg.d/p2069.pdf

• AAP’s “Refusal to Vaccinate” form

• All Star Pediatric’s sample vaccine policy statement
  www.immunize.org/aap/pediatrics_vaccine_letter.pdf

• VaccineEthics.org – University of Pennsylvania
  www.vaccineethics.org/issue_briefs/requirements.php
Don’t Worry About Every Possible Question

• Be able to recommend good websites and handouts for patients/parents.

• Be aware of major vaccine-critical groups and individuals and become familiar with their websites.

• Be ready to answer the most common questions — many concerns haven’t changed in over 200 years!

• Remember, it’s acceptable to say you’ll look into a question and get back to the patient with more information.

• It’s worth your time — people respect the opinion of their healthcare providers.
The National Childhood Vaccine Injury Act (NCVIA) of 1986

National Vaccine Injury Compensation Program

Vaccines save lives by preventing disease.

Most people who get vaccines have no serious problems. Vaccines, like any medicines, can cause side effects, but most are very rare and very mild. Some health problems that follow vaccinations are not caused by vaccines.

In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction. In these instances, the National Vaccine Injury Compensation Program (VICP) may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine. Even in cases in which such a finding is not made, petitioners may receive compensation through a settlement.

How It Works

Revisions to the Vaccine Injury Table were released in a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on July 28, 2015. The public comment period is now closed.