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webinar series

Kenneth Haller, MD

Scheduling and Spacing of Pediatric Immunizations with an Emphasis on Pneumococcal and Rotavirus Vaccines

June 19, 2014

This webinar is designed to help the participant:

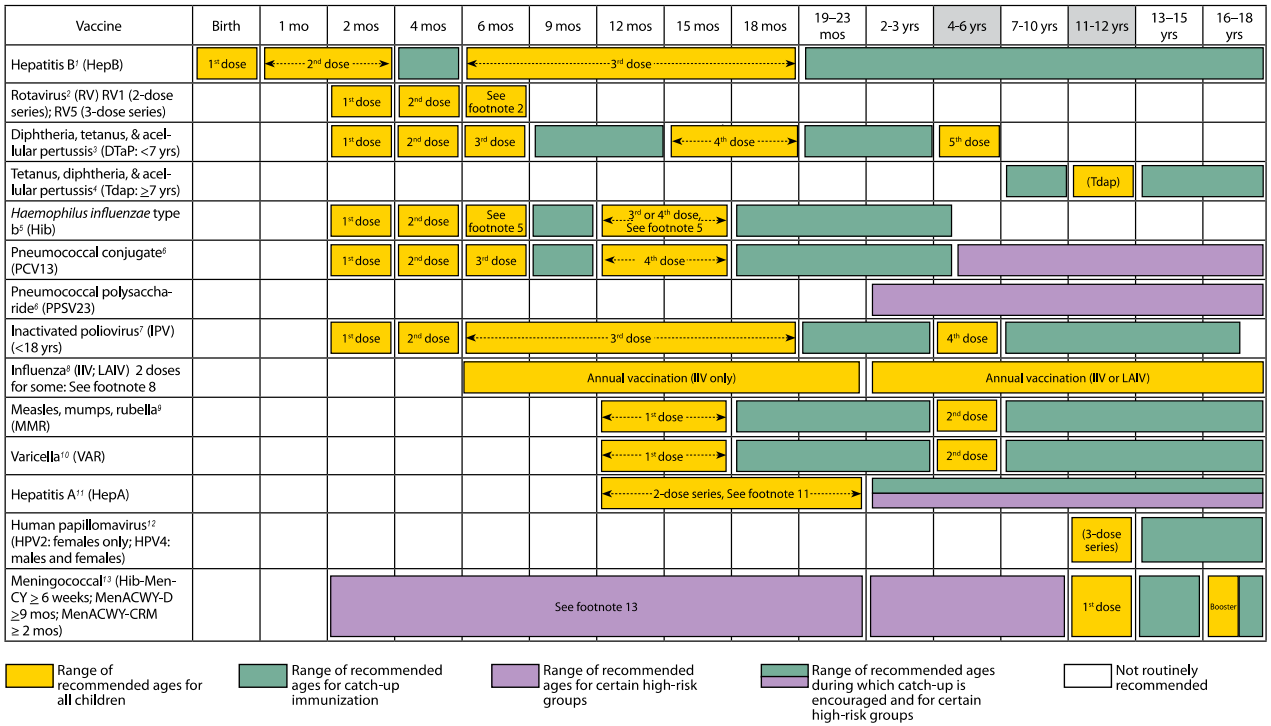
- Assure that vaccinations are given on time.
- Give catch up vaccines as efficiently as possible.
- Understand schedules specifically for pneumococcal and rotavirus vaccines.
- Address parental fears of vaccination.

I have no relevant financial disclosures.

- Kenneth Haller, MD

The Immunization Schedule

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2014.
(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).
These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2014. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http//www.cdc.gov/vaccines/acip), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Scheduling and Spacing: 3 Rules

1. There are minimum ages at which vaccines can be administered.
2. There are minimum intervals between successive doses of the same vaccine.
3. As children get older, some vaccines or boosters can be dropped.

Catchup Schedule

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States, 2014.

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[2]	6 weeks	4 weeks	4 weeks[2]		
Diphtheria, tetanus, & acellular pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[5]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12 through 14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[5] if current age is younger than 12 months and first dose administered at < 7 months old 8 weeks and age 12 months through 59 months (as final dose)[5] if current age is younger than 12 months and first dose administered between 7 through 11 months (regardless of Hib vaccine [PRP-T or PRP-OMP] used for first dose); OR if current age is 12 through 59 months and first dose administered at younger than age 12 months; OR first 2 doses were PRP-OMP and administered at younger than 12 months. No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 (PRP-T) doses before age 12 months and started the primary series before age 7 months	
Pneumococcal[6]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[7]	6 weeks	4 weeks[7]	4 weeks[7]	6 months[7] minimum age 4 years for final dose	
Meningococcal[13]	6 weeks	8 weeks[13]	See footnote 13	See footnote 13	
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months			
Hepatitis A[11]	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, & acellular pertussis[4]	7 years[4]	4 weeks	4 weeks if first dose of DTaP/DT administered at younger than age 12 months 6 months if first dose of DTaP/DT administered at age 12 months or older and then no further doses needed for catch-up	6 months if first dose of DTaP/DT administered at younger than age 12 months	
Human papillomavirus[12]	9 years	Routine dosing intervals are recommended[12]			
Hepatitis A[11]	12 months	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks[7]	6 months[7]	
Meningococcal[13]	6 weeks	8 weeks[13]			
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

FAQs: Why these vaccines for kids?

- These microorganisms are – or have been – common in the population.
- They cause terrible disease in kids.
- Researchers have developed vaccines for them.

Microorganism	Bad disease	Common in kids	Got a vaccine
Pneumococcus	YES	YES	YES
Rotavirus	YES	YES	YES
Anthrax	YES	NO	YES
RSV	YES	YES	NO

FAQs: Why this schedule/spacing?

- Based on how vaccines were tested and approved.
- Fits the need to get kids immunized as early and safely as possible.
- Represents a consensus of representatives from:
  - Advisory Committee on Immunization Practices
  - American Academy of Pediatrics
  - American Academy of Family Physicians

FAQs: Who enforces this?

- State and local jurisdictions through regulations on entry to daycare and school.
- Public Health perspective vs. Medical perspective.
- If vaccines are given at the wrong time (usually too early), kids may not be able to attend daycare or school.

Types of Vaccine Exemptions

- ***Medical exemption:*** children should be exempted if they have a contraindicating medical condition, temporary or permanent.
  - ➢ All states
- ***Religious exemption:*** parents may exempt their children from vaccination if it contradicts their sincere religious beliefs.
  - ➢ 48 states, Missouri YES (ONLY applies to grades K-12)
- ***Philosophical exemption:*** parents may exempt their children for any reason, not restricted to purely religious or spiritual beliefs, e.g., "moral, philosophical or other personal beliefs" (ME), or simply the parent(s) beliefs (CA).
  - ➢ 19 states, Missouri has a Parent/Guardian Exemption

Vaccines Required for Child Care and Preschool Attendance in Missouri

Vaccines Required	3 Months	5 Months	7 Months	≥ 19 Months
DTaP/DT	1	2	3	4+
IPV (Polio)	1	2	2	3+
Hib*	1	1+	2+	3+
Hepatitis B	1+	2	2+	3+
PCV* (Pneumococcal)	1	2	3	4+
MMR	--	--	--	1
Varicella	--	--	--	1

+ If a child has been immunized using the ACIP timing recommendations, he/she may have received more than the required doses for child care.

* Hib & PCV: The number of doses a child needs to complete the series depends on the age the child begins the series.

Pneumococcus and Rotavirus

- Both cause serious disease in children.
- Disease is worst in younger children.
- Vaccines have been effective in reducing incidence of hospitalization and death for both.
- Both have specific schedule requirements.

Pneumococcal Disease in Children

- Most common clinical presentation: Bacteremia without known site of infection.
- S. pneumoniae leading cause of bacterial meningitis among children <5 years of age.
- Common cause of acute otitis media.

Annual US Burden of Pneumococcal Disease in Children before Vaccine Use

- Bacteremia - 13,000 cases
- Meningitis - 700 cases
- Death - 200 cases
- Otitis media - 5,000,000 cases

Pneumococcal Conjugate Vaccine

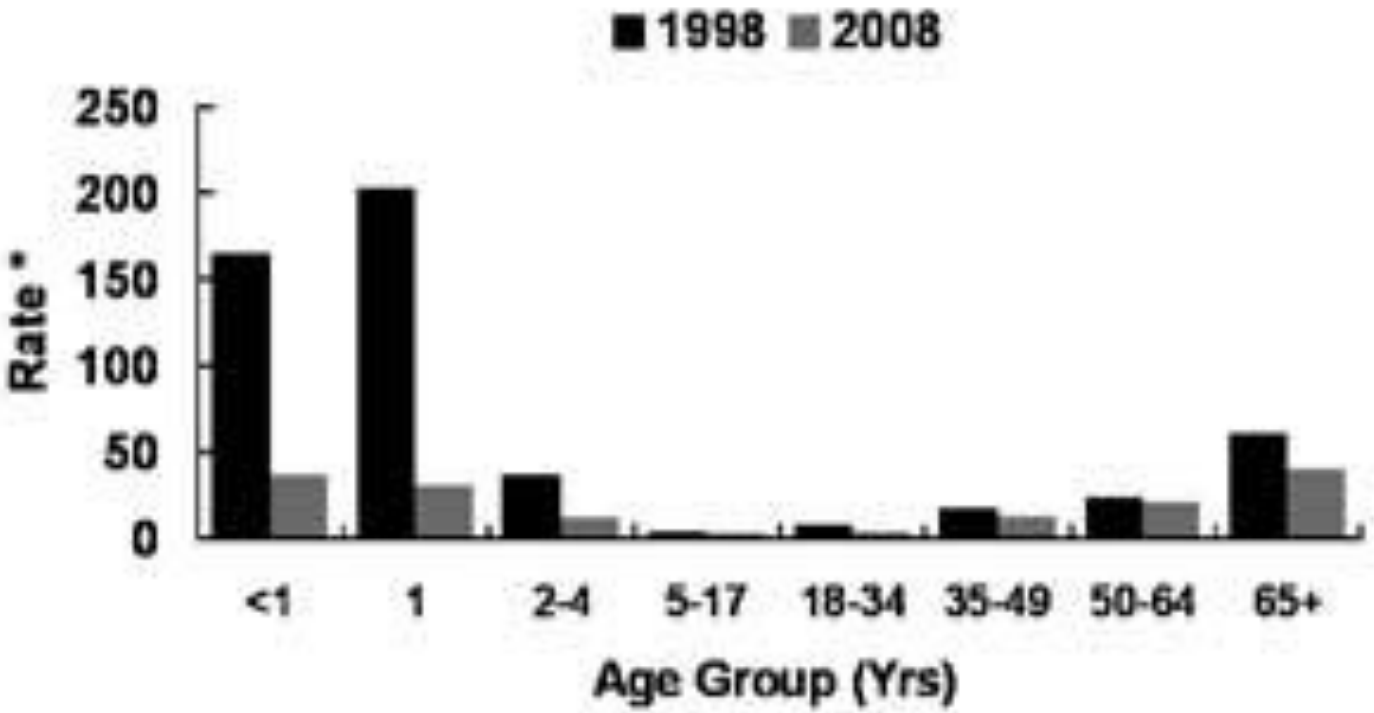
- Highly immunogenic in infants and young children, including those with high-risk medical conditions.
- >90% effective against invasive disease.
- Less effective against pneumonia and acute otitis media.
- 2000 - 7-valent polysaccharide conjugate vaccine licensed (PCV7).
- 2010 - 13-valent PCV licensed.

Direct Benefit of Vaccination: Invasive Pneumococcal Disease (IPD) Among Children < 5 Years Old

Pneumococcal Dz/100,000	1998-99	2008
All IPD	100	21
Vaccine serotypes	80	0.2

Source: Active Bacterial Core Surveillance/EP Network

Direct Benefit of Vaccination: Invasive Pneumococcal Disease (IPD) Among All Populations



IPD in MO in children < 5 years old by District, 2012

Central	1
Eastern	11
Northwest	9
Southeast	3
Southwest	10
TOTAL	**34**

Pneumococcal Conjugate Vaccine (PCV) Recommendations

- Routine vaccination of children 2 through 59 months of age.
- Primary doses at 2, 4, 6 months of age.
- First dose as early as 6 weeks.
- Booster dose at 12-15 months of age.
- Unvaccinated children 7 months of age or older require fewer doses.
  - MMWR 2010;59(RR-11):1-19

PCV Schedule for Unvaccinated Older Children

Age at first dose	Primary Series	Booster
7-11 months	2 doses*	YES
12-23 months	2 doses**	NO
24-59 months, healthy	1 dose	NO
24-71 months, medical conditions	2 dose**	NO

* separated by at least 4 weeks
** separated by at least 8 weeks
MMWR 2010;59(RR-11):1-19

Rotavirus Disease in Children

- Leading cause of severe diarrhea among infants and young children.
- Peak in the winter and spring months.
- Pre-vaccine, almost all U.S. children were infected with rotavirus before their 5th birthday, with annual incidence of:
  - > 400,000 doctor visits
  - > 200,000 ED visits
  - 55,000-70,000 hospitalizations
  - 20-60 deaths

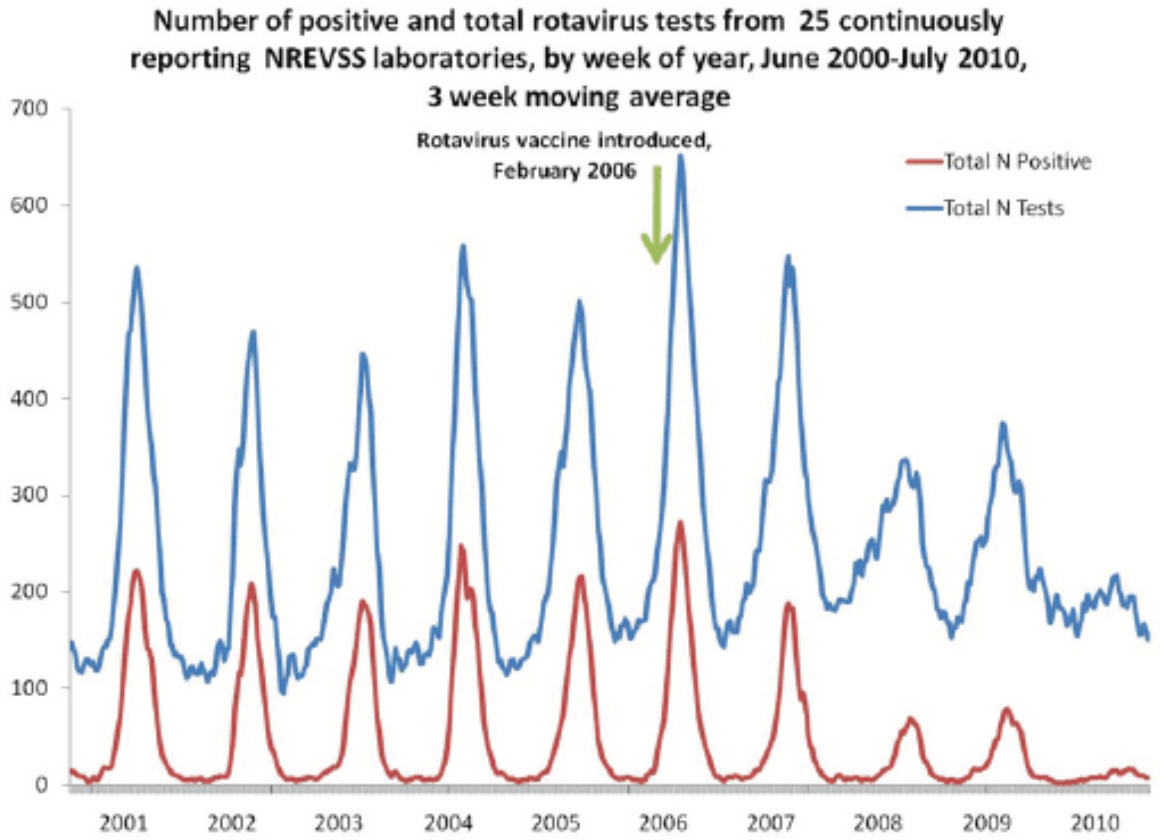
Rotavirus Vaccine: First Attempt

- RotaShield introduced 1999.
- Intussusception noted in trials but not statistically significant.
- Cases of intussusception reported to Vaccine Adverse Event Reporting System (VAERS).
- Risk increased 20 to 30 times over the expected risk for children of this age group within 2 weeks following the first dose of RotaShield vaccine.
- Rotashield withdrawn from market.

New Rotavirus Vaccines Introduced

- RotaTeq introduced 2006.
- Rotarix introduced 2008.
- International studies have suggested mild increase of intussusception after vaccination.
- However, US studies so far have found no increase in risk of intussusception after vaccination.
- Each year, the vaccine prevents an estimated 40,000 to 50,000 hospitalizations among U.S. infants and young children.

Direct Benefit of Vaccination: Rotavirus Testing and Disease



Rotavirus incidence trends from 2001-2010 using passively reported laboratory rotavirus test data from the National Respiratory and Enteric Virus Surveillance System (NREVSS).

Rotavirus Vaccine Recommendations

- RotaTeq: 3 doses at ages 2 months, 4 months, and 6 months.
- Rotarix: 2 doses at ages 2 months and 4 months.
- Minimum age: 6 weeks of age.
- Minimum spacing: 4 weeks.
- If different vaccines are given at 2 & 4 months, a third dose should be given.
- First dose should be given by 14 weeks, 6 days.
- Last dose should be given by 29 weeks, 6 days.

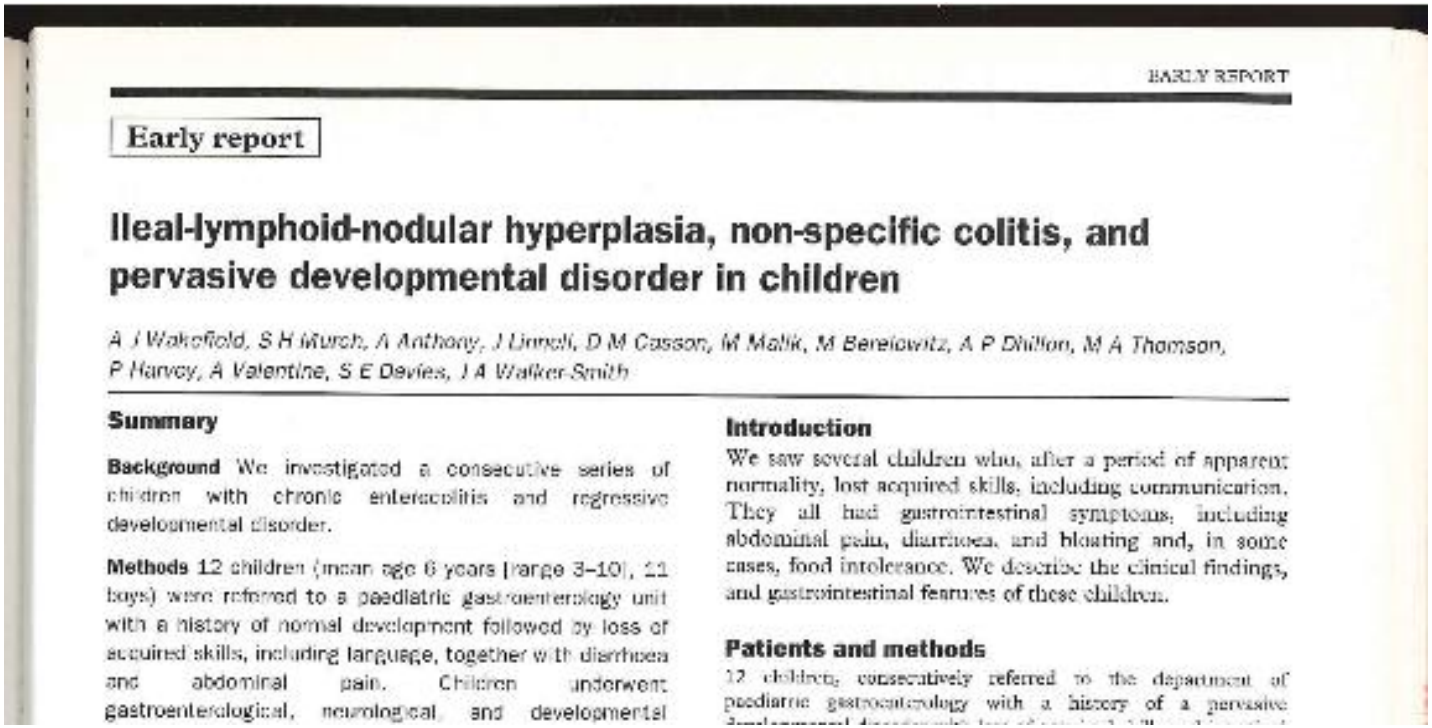
Rotavirus Vaccine Contraindications

- Severe (life-threatening) allergic reaction to a dose of rotavirus vaccine.
- Severe (life threatening) allergy to any component of rotavirus vaccine.
- Any severe allergies, including a severe allergy to latex.
- Severe combined immunodeficiency (SCID).
- History of intussusception.
- Consider abstaining from vaccination for babies with:
  - HIV/AIDS, or any other immunodeficiency syndrome.
  - Treatment with drugs such as long-term steroids.
  - Cancer, or cancer treatment with x-rays or drugs.

Addressing Parental Fear of Vaccines

The Lancet, Vol 351, February 28, 1998

The Wakefield Paper



Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

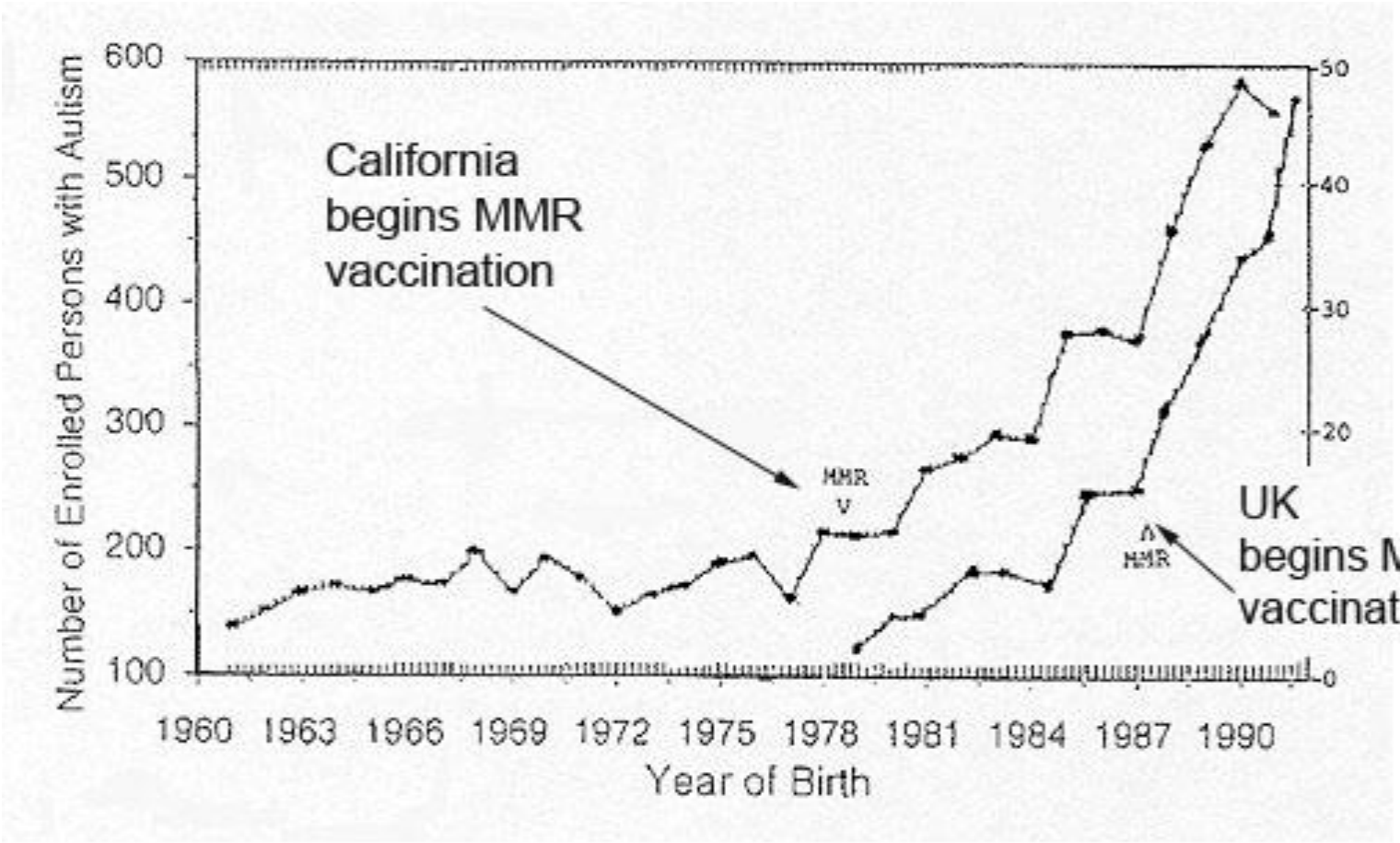
12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive

Addressing Parental Fear of Vaccines

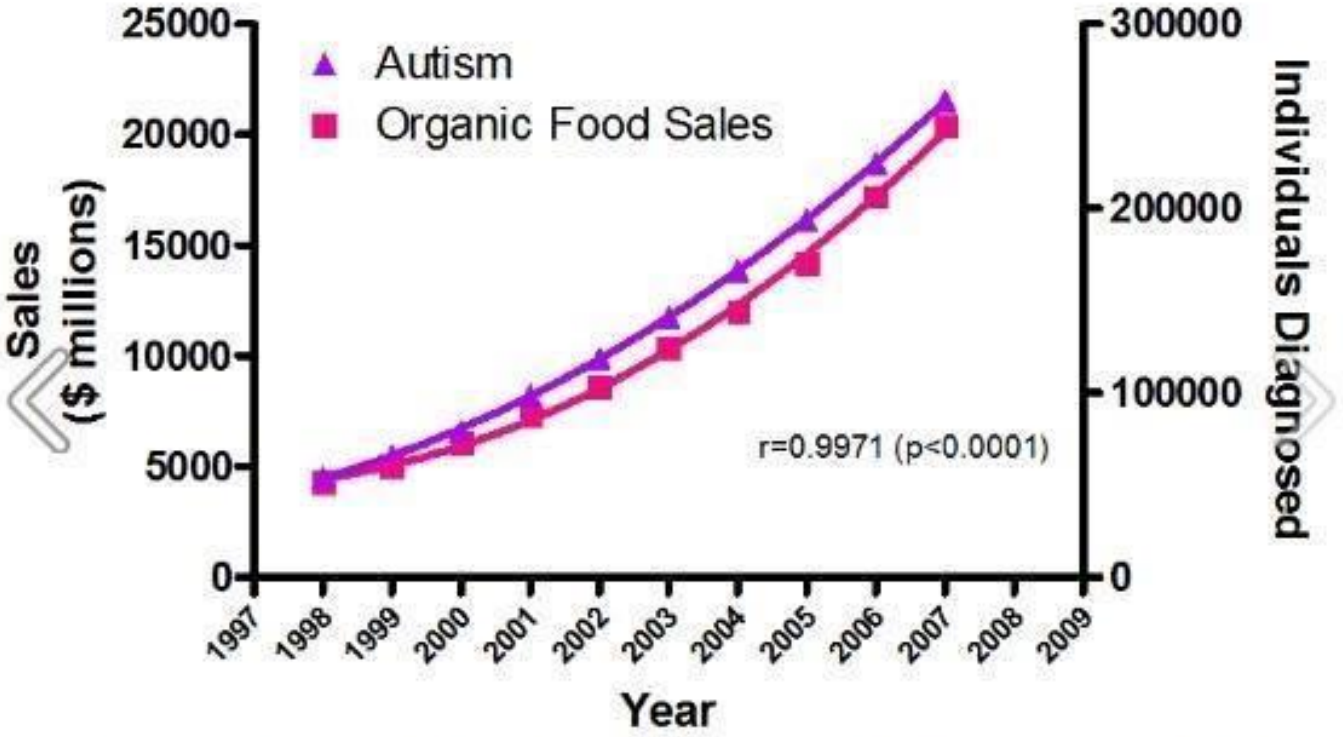
The Panic Virus, Seth Mnookin, 2011

"It's remarkable how static the makeup, rhetoric, and tactics of vaccine opponents have remained over the past 150 years. Then, as now, anti-vaccination forces fed on anxiety about the individual's fate in industrialized societies; then, as now, they appealed to knee-jerk populism by conjuring up an imaginary elite with an insatiable hunger for control; then, as now, they preached the superiority of subjective beliefs over objective proofs, of knowledge acquired by personal experience rather than through scientific rigor."

Poor risk assessment: Association vs. Causality



Poor risk assessment: Association vs. Causality



Sources: Organic Trade Association, 2011 Organic Industry Survey; U.S. Department of Education, Office of Special Education Programs, Data Analysis System (DANS), OMB# 1820-0043: "Children with Disabilities Receiving Special Education Under Part B of the Individuals with Disabilities Education Act

Anti-vaccine advocates: Compassionate messages

- Andrew Wakefield: “What happens to me doesn’t matter. What happens to these children does matter.”
- Jenny McCarthy, actress, anti-vaccination stalwart, and president of Generation Rescue: “Whether you’re in need at 3PM or 3AM, you have come to the right place. We are here for you, together resolving our heartaches and celebrating our victories.”
- J. B. Handley, co-founder of Generation Rescue: “To our community, Andrew Wakefield is Nelson Mandela and Jesus Christ rolled up into one… He’s a symbol of how all of us feel.”

Pro-vaccine physicians: Annoyance with/Accusation of parents

- *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All,* Dr. Paul Offit, ID specialist at CHOP, co-developer of a rotavirus vaccine: "There's a war going on out there… On one side are parents… On the other side are doctors… Caught in the middle are children…"
- *The Ladue News*, a local pediatrician, 2009: "I tell parents that there is absolutely no data to support [a vaccine-autism link, and failure to vaccinate children is] foolish and dangerous. Immunization is safe and effective with minimal minor side effects. There is a small but real chance of complications, including fatal complications, with both the chicken pox vaccine, which can lead to pneumonia, encephalitis and hepatitis, and the influenza vaccine, which can develop into pneumonia or other secondary bacterial infections."

Addressing Parental Fear of Vaccines

- Assume parents love their kids.
- Ask parents about the basis for their fears.
- Honor and value emotions.
- Acknowledge that parental fear is real and even healthy.
- Avoid contradiction and the conjunction “but.”
- Agree, and use the conjunction “and.”
- Share your stories.
- Help parents recognize the appropriate target for fear.
- Provide a fertile ground in which trust can grow.

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June 19, 2014

Questions?

Criticisms?

Comments?