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Parental Vaccine Refusal: What can we Do?

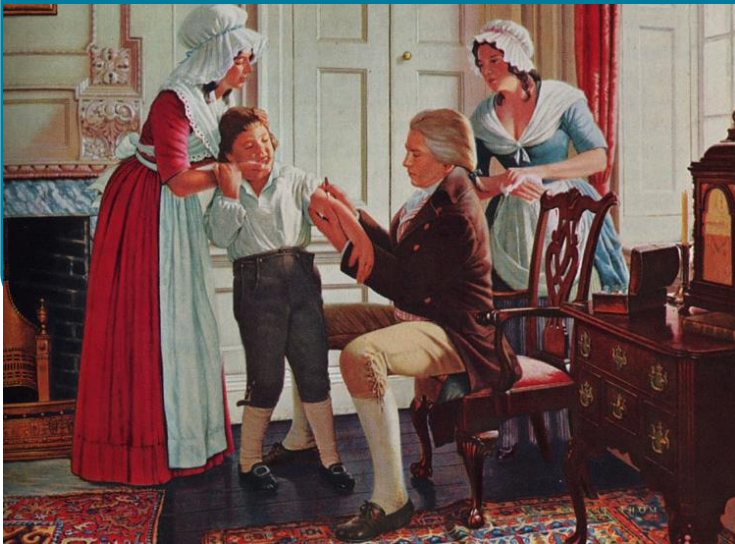
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Seattle Children's Hospital



Estimated Impact of Selected Vaccines in the U.S. since Introduction

Vaccine	Year Introduced	Cases Averted with 95% Coverage	Deaths Averted with 95% Coverage
Polio	1963	2,547,045	413,692
Measles	1970	34,137,129	28,329
Mumps	1967	10,792,317	2,593
Rubella	1969	3,073,981	1,095 633,000 fetal deaths
Varicella	1996	133,691,807	3,436
Hepatitis A	1996	3,674,988	4,291

Olshansky and Hayflick,
AIMS Public Health 2017;
4(2):127-138



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Yet the Problem of Vaccine-Hesitancy Remains

- Historically, there have always been individuals and groups that oppose vaccination for a variety of reasons
- Herd Immunity requires 90-95% of population vaccinated
- If this cannot be achieved willingly, either need to consider coercive measures or accept limited ability to contain disease spread



Under-Vaccination Cannot be Easily or Simply Characterized

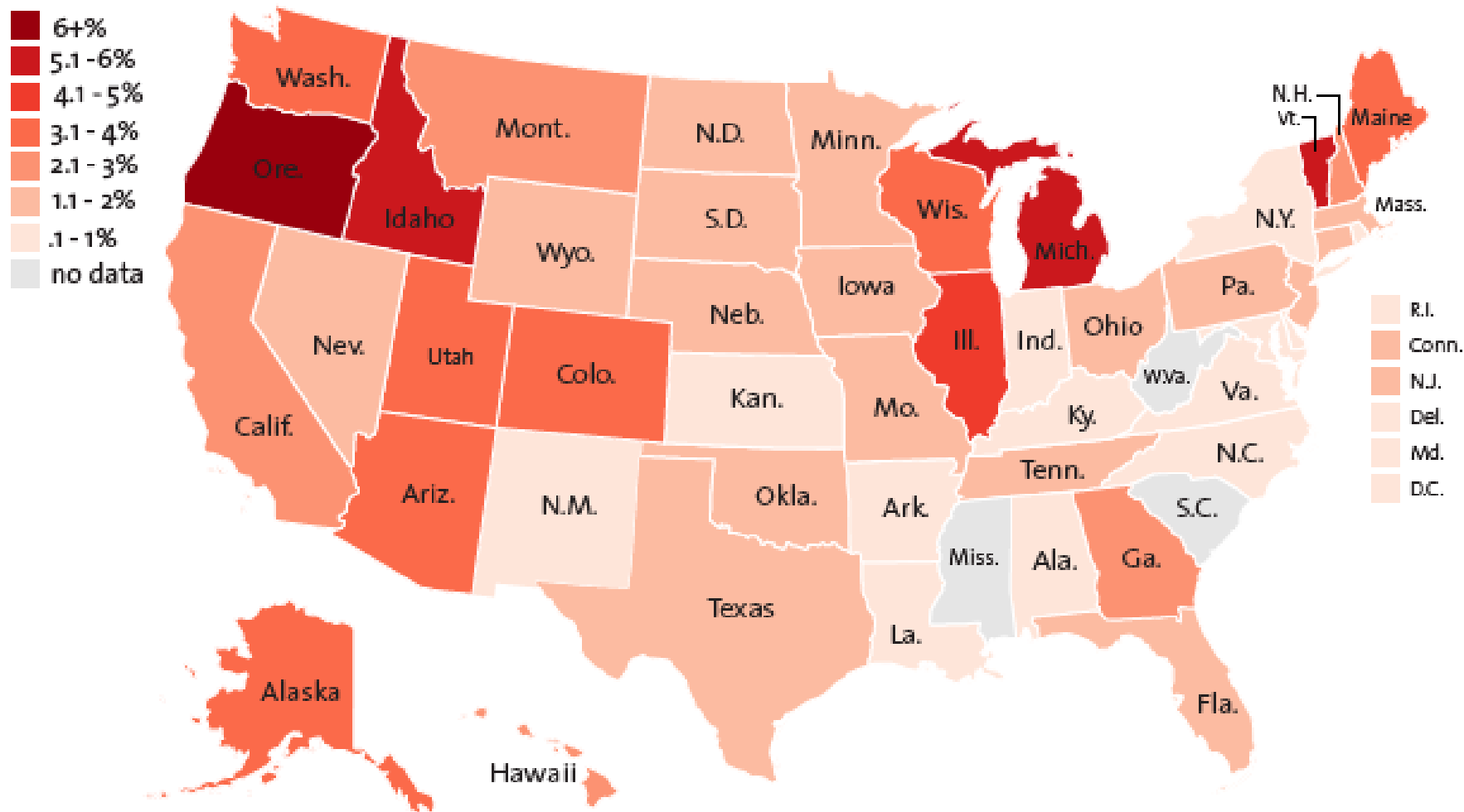


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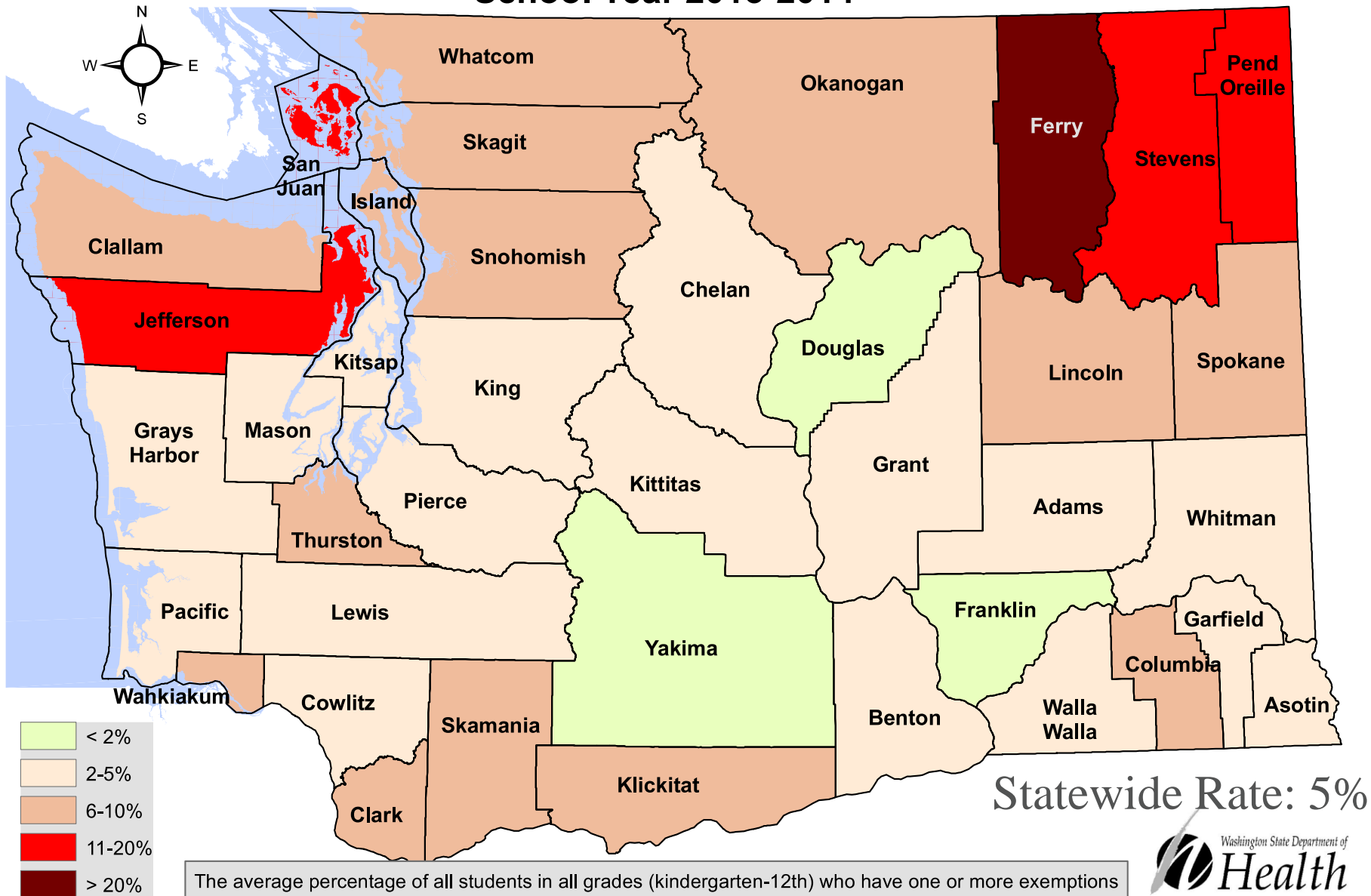
Rate of Nonmedical Vaccine Exemptions By State

Percentage of kindergartners with nonmedical exemptions, 2012-13 school year



Note: Children with exemptions may still be vaccinated.
Source: Centers for Disease Control

WA State All Grades Immunization Exemption Rates by County School Year 2013-2014



The average percentage of all students in all grades (kindergarten-12th) who have one or more exemptions to school-entry required vaccines as reported by public and private schools in each county.
WA State Department of Health Office of Immunization Child Profile, Created with ArcMap 10.0



DOH 348-450
June 2014

For people with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

SCHOOL	MMR VACCINE EXEMPTION	TOTAL ENROLLMENT	SCHOOL DISTRICT
Arrowhead Elementary	3.9%	413	Northshore School District
Kenmore Middle School	3.3%	708	Northshore School District
Inglemoor High School	2.6%	1,745	Northshore School District
Kenmore Elementary	1.6%	500	Northshore School District
Moorlands Elementary	1.0%	614	Northshore School District

Note: Schools with fewer than 10 students were excluded. Schools that hadn't reported their vaccination data to the Department of Health were also excluded.

Source: Washington Department of Health (2017-18)

EMILY M. ENG / THE SEATTLE TIMES



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SCHOOL	MMR VACCINE EXEMPTION	TOTAL ENROLLMENT	SCHOOL DISTRICT
Toppenish High School	0.5%	971	Toppenish School District
Garfield Elementary School	0.2%	415	Toppenish School District
Toppenish Middle School	0.2%	895	Toppenish School District
Kirkwood Elementary School	0.2%	549	Toppenish School District
Eagle High School	0%	145	Toppenish School District
Lincoln Elementary School	0%	398	Toppenish School District
Valley View Elementary	0%	472	Toppenish School District

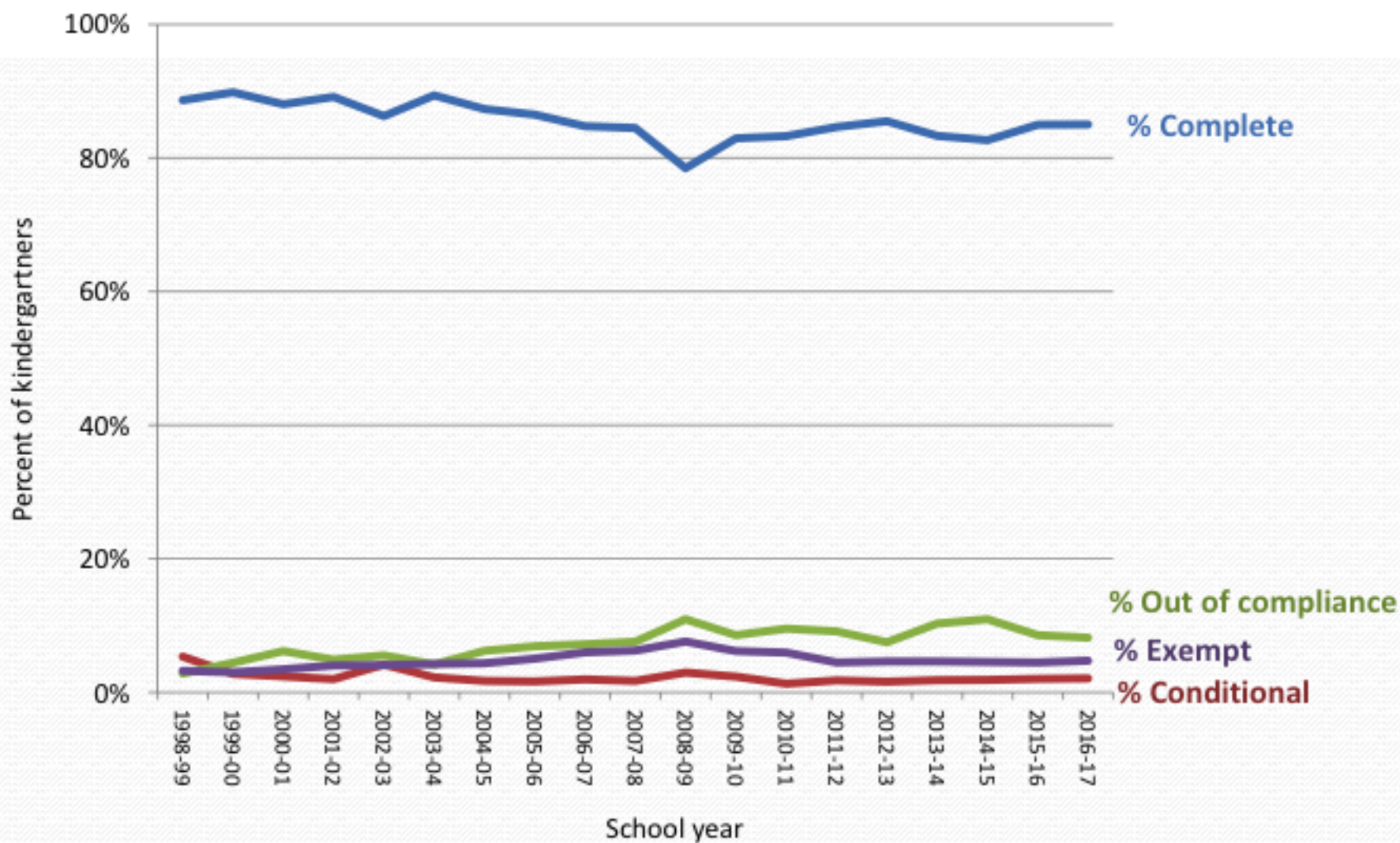


SCHOOL	MMR VACCINE EXEMPTION	TOTAL ENROLLMENT	SCHOOL DISTRICT
Family Link	30.5%	59	Vashon Island School District
Student Link	20.6%	34	Vashon Island School District
Mcmurray Middle School	9.3%	387	Vashon Island School District
Chautauqua Elementary	8.5%	598	Vashon Island School District
Vashon Island High School	8.4%	547	Vashon Island School District
The Harbor School	6.1%	82	Private
Vashon Special Education School	0%	12	Vashon Island School District



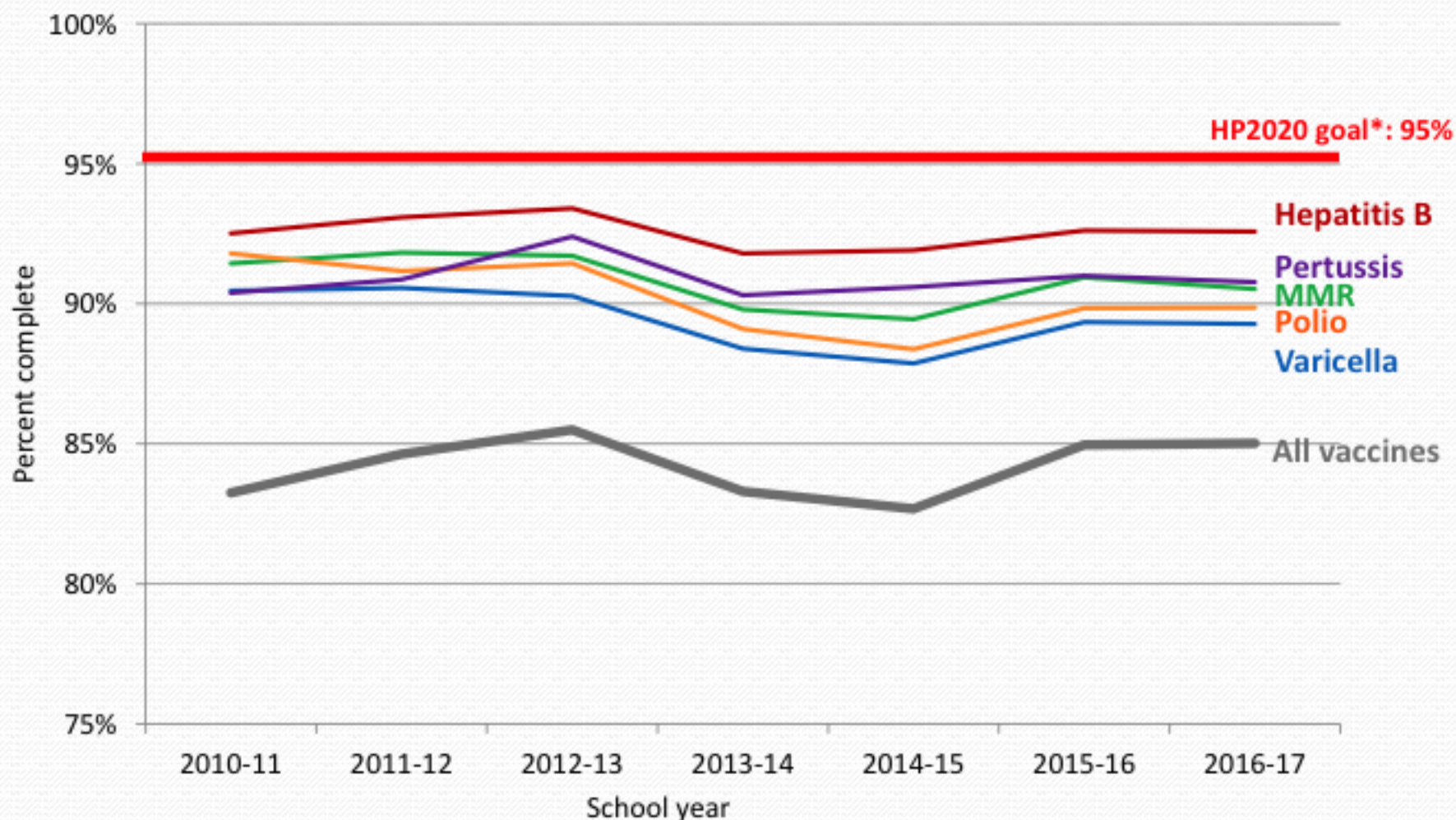
Immunization status of kindergartners, 1998 – 2017

The percentage of kindergartners complete for required immunizations was the same as last school year. Students with completed immunizations are better protected from getting and spreading vaccine-preventable diseases.



Kindergartners complete for required immunizations, 2010-2017

The percentage of kindergartners complete for required immunizations stayed the same as last school year. Students with completed immunizations are better protected from getting and spreading vaccine-preventable diseases.





SEEK FIRST TO UNDERSTAND

Families who are reluctant to vaccinate their children are a heterogeneous group

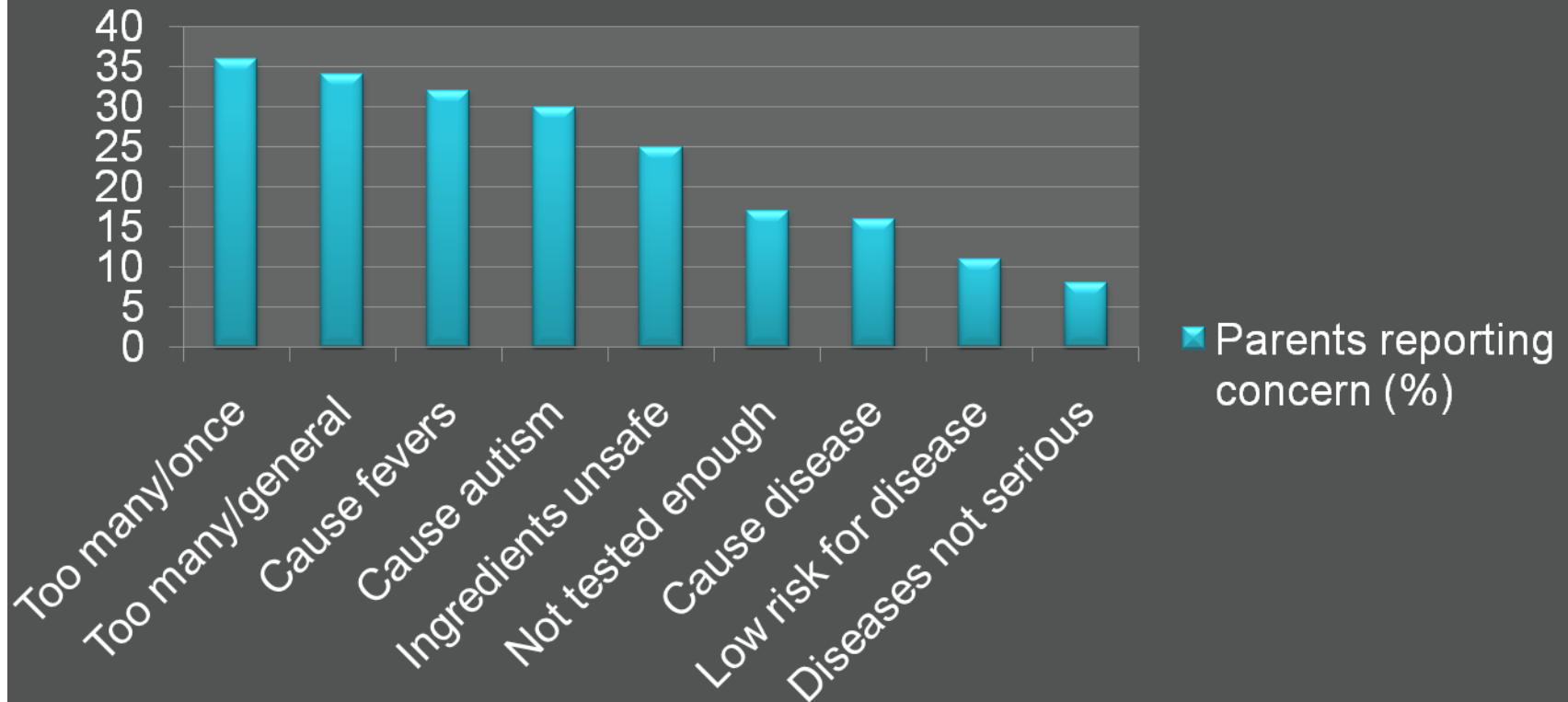


Parental Refusals 2009

- 11.5% of parents had refused a vaccine
- Among those who refused a vaccine, the vaccines refused:
 - HPV 56.4%
 - Mening 31.8%
 - Varicella 32.3%
 - MMR 17.7%

Parental Concerns about Vaccines

Vaccine Concerns Reported by Parents of Children Age 6 or Younger, 2010



Parental Hesitancy: Contributors

- Beliefs (not supported by reasonable evidence): Vaccine effects on immune system, opposition to injection of foreign material, concern about vaccine components
- Unsupported links between vaccines and harms: Autism and Measles Vaccine
- Lost memory of vaccine-preventable infectious diseases
- Flawed risk assessment and Scientific Illiteracy
- Internet and Media and Celebrities as source of “truth”
- Increasing number of vaccines



Parental Vaccine Concerns 2009

- 90% of parents feel vaccines are a good way to protect their children from disease
- 88% generally follow their physicians recommendation
- 54% are concerned about adverse effects
- 23% believe vaccines cause autism in healthy children
- 31% believe parents should have the right to refuse vaccines that are required for school for any reason
- 11% don't feel children need vaccines for diseases that are not common anymore.



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An even bigger problem may exist

- Increasing Requests to Spread out or Alter the Recommended Vaccine Schedule
- 93% of physicians report at least one request to alter the vaccine schedule in a given month
- Younger children lose protection of vaccines
- Most of our data doesn't capture this

Who is Refusing Vaccines?



Acceptors	Vaccine-hesitant	Rejectors
Agree with or do not question vaccines	Are unsure about, delay, or choose only some vaccines	Completely reject vaccines
Children fully immunized	Children under-immunized	Children un-immunized
High trust in provider	Desire a trustworthy provider	Low trust in provider
Interest in vaccine information from child's provider	Interest in vaccine information from child's provider	No interest in vaccine information
70%	30%	<1%



Improving Childhood Vaccination

Remove obstacles to vaccination



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Improving Childhood Vaccination

Rapidly and forcefully refute
unsubstantiated claims made publicly



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Social Media: The Epidemic of “Fake News”



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Anti-vaccine Messengers

BMJ PLoS How useful is a lifetime CR-10? Early research: Health researchers Managing genetic information: articles. Rules for ultrasound of unborn women. **SAVE THE CHILDREN. END APPEAL.**

HOW THE CASE AGAINST THE VACCINE WAS BUILT



MMR SCARE

HOW THE CASE AGAINST THE MMR VACCINE WAS FIXED

In the first part of a special *BMJ* series, **Brian Deer** exposes the bogus data behind claims that launched a worldwide scare over the measles, mumps, and rubella vaccine, and reveals how the appearance of a link with autism was manufactured at a London medical school

When I broke the news to the father of child 11, at first he did not believe me. "Wakefield told us my son was the 13th child they saw," he said, gazing for the first time at the now infamous research paper which linked a purported new syndrome with the measles, mumps, and rubella (MMR) vaccine.¹ "There's only 12 in this."

That paper was published in the *Lancet* on 28 February 1998. It was retracted on 2 February 2010.² Authored by Andrew Wakefield, John Walker-Smith and 11 others from the Royal Free Hospital and School of Medicine, London, it reported on 12 developmentally challenged children, and triggered a decade long public health scare.

"Onset of behavioural symptoms was associated by the parents with measles, mumps, and rubella vaccination in eight of the 12 children," began the paper's "findings." Adopting these claims as fact, its results section added: "In these eight children the average interval from exposure to first behavioural symptoms was 6.3 days (range 1-14)."

Mr 11, an American engineer, looked again at the paper: a five page case series of 11 boys and one girl, aged between 3 and 9 years. Nine children, it said, had diagnoses of "regressive" autism, while all but one were reported with "non-specific colitis." The "new syndrome" brought these findings together,

brain and bowel diseases. Child 11 was the penultimate case.

Running his finger across the paper's tables, over coffee in London, Mr 11 seemed reassured by his anonymised son's age and other details. But then he pointed at table 2—headed "neuropsychiatric diagnosis"—and for a second time objected.

"That's not true." Child 11 was among the eight whose parents apparently blamed MMR. The interval between his vaccination and the first "behavioural symptom" was reported as 1 week. This symptom was said to have appeared at age 15 months. But his father, whom I had tracked down, said this was wrong.

"From the information you provided me on our son, who I was shocked to hear had been included in their published study," he wrote to me, after we met again in California, "the data clearly appeared to be distorted."

He backed his concerns with medical records, including a Royal Free discharge summary. Although the family lived 5000 miles from the hospital, in February 1997 the boy (then aged 5) had been flown to London and admitted for Wakefield's project, the undisclosed goal of which was to help sue the vaccine's manufacturers.

Wakefield's "syndrome"

Unknown to Mr 11, Wakefield was working on a lawsuit,³ for which he sought a bowel-brain "syndrome" as its centrepiece. Claiming an undis-

closed £150 (€180; \$230) an hour through a Norfolk solicitor named Richard Barr, he had been confidentially put on the payroll for two years before the paper was published, eventually grossing him £435 643, plus expenses.⁴

"The regulator's main focus was whether the research was ethical. Mine was whether it was true"

Curiously, however, Wakefield had already identified such a syndrome before the project that would reputedly discover it.

"Children with enteritis/disintegrative disorder [an expression he used for bowel inflammation and regressive autism] form part of a new syndrome," he and Barr explained in a confidential grant application to the UK government's Legal Aid Board,⁵ before any of the children were investigated. "Nonetheless the evidence is undeniably in favour of a specific vaccine induced pathology."

The two men also aimed to show a sudden onset "temporal association"—strong evidence in product liability. "Dr Wakefield feels that if we can show a clear time link between the vaccination and onset of symptoms," Barr told the legal board, "we should be able to dispose of the suggestion that it's simply a chance encounter."

But child 11's case must have proved a disappointment. Records show his behavioural symptoms started too soon. "His developmental milestones were normal until 13 months of age," notes the discharge summary. "In the period 13-18 months he developed slow speech patterns and repetitive hand movements. Over this period his parents remarked on his slow gradual deterioration."

That put the first symptom two months earlier than reported in the *Lancet*, and a



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Improving Childhood Vaccination

Strengthen *and* Enforce School Vaccine Requirements



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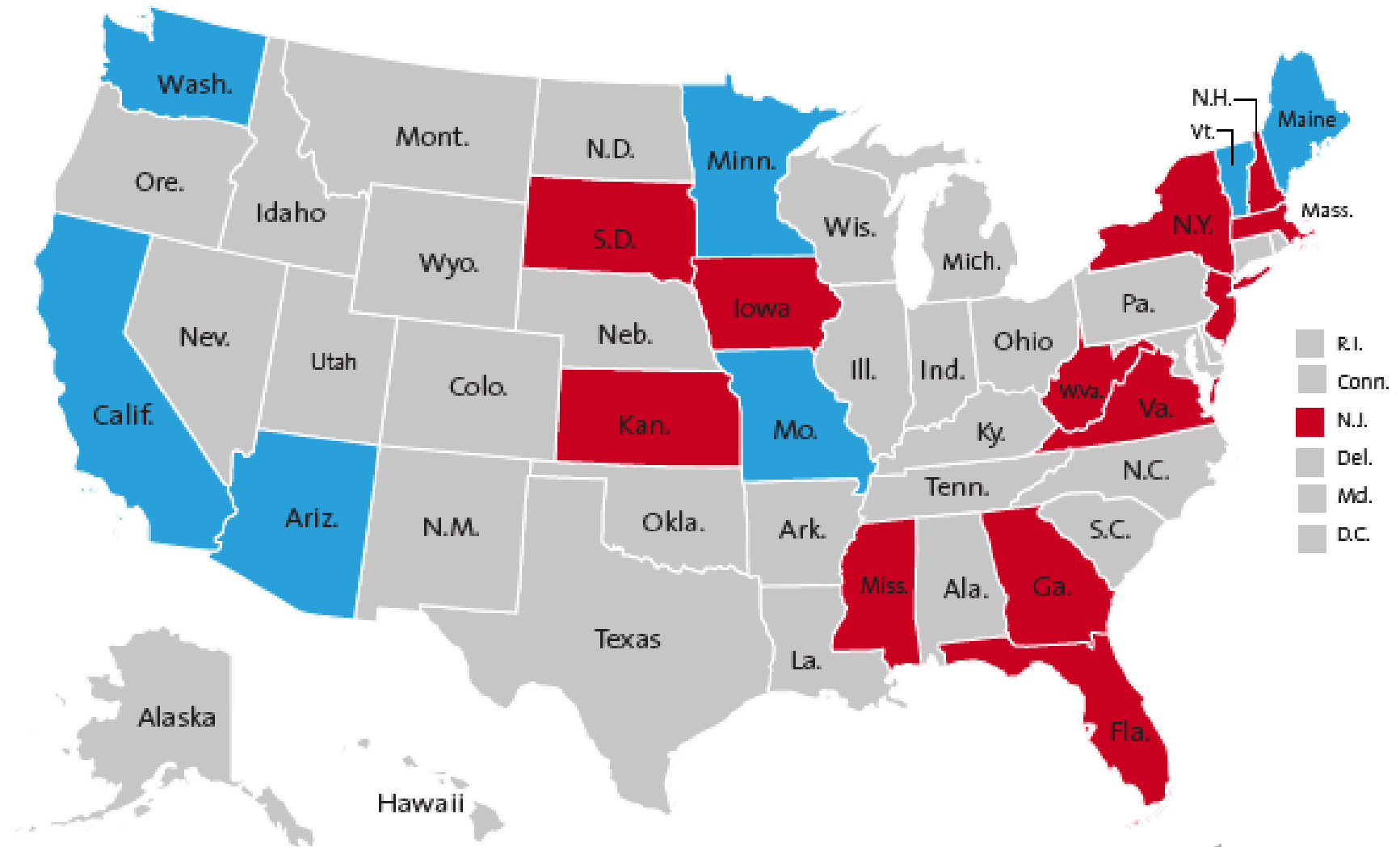
School Vaccine Requirements

- Wide variability between and within US states with regard to:
 - Which vaccinations required
 - Who qualifies for exemption
 - What is required to obtain exemption
 - Enforcement
- Easy exemption associated with high rates of exemption
- High rates of exemption associated with disease outbreaks



States That Had Bills to Make Exemptions Easier or Harder, 2009-2012

■ Easier ■ Harder ■ No bills introduced between 2009-12



Note: Oregon's laws made exemptions harder to get in 2014.
Source: Saad Omer, Emory University

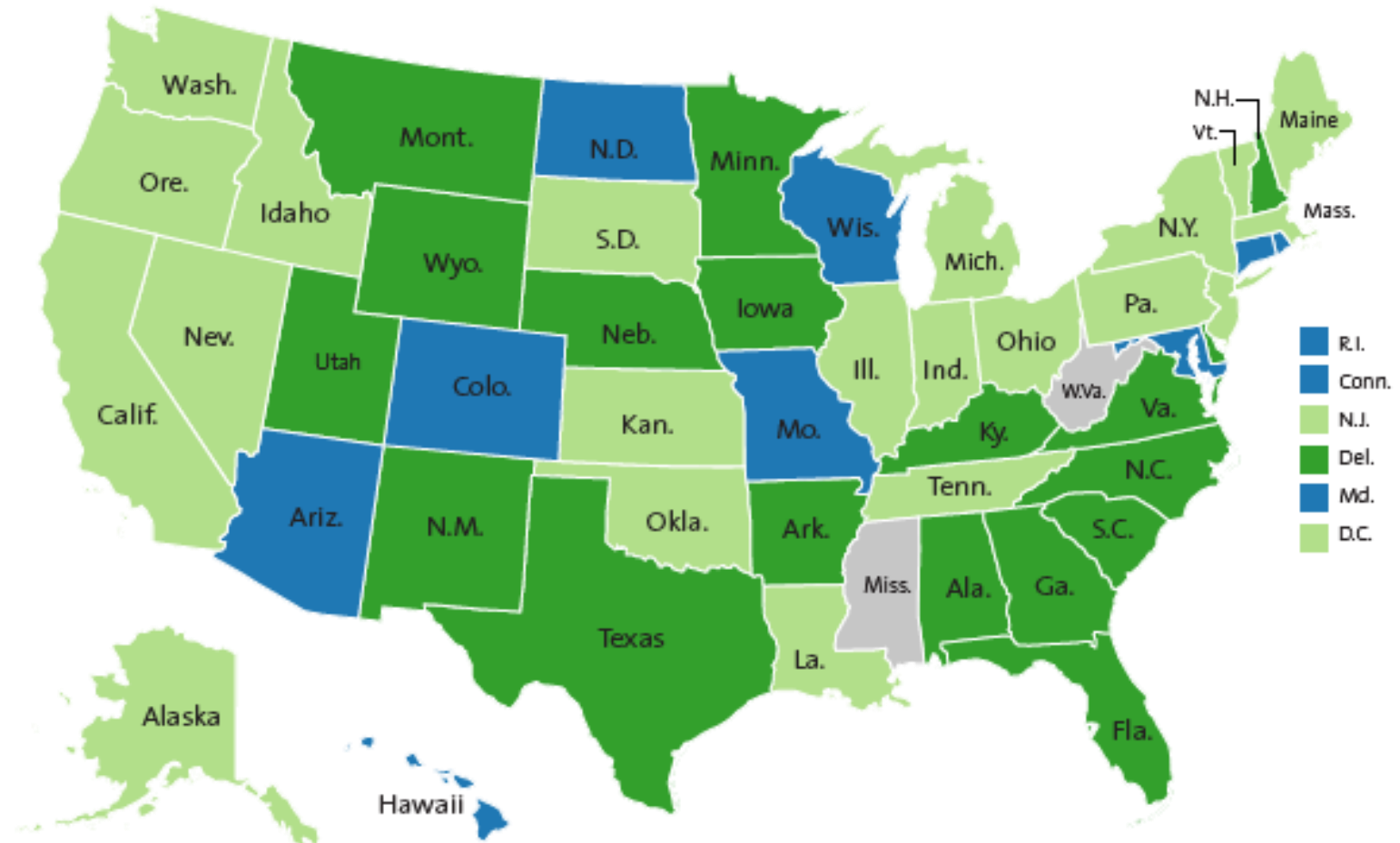
State Coercion and Vaccination

- Safety of children attending school and community interest must be balanced with individual freedom and avoidance of coercion
- Current requirements are not strictly coercive
- Personal belief exemptions remove any coercion
- Personal belief exemptions should require just as much effort and expense as vaccination does



How Hard Is It to Get a Vaccine Exemption in Your State?

- Easy: Parent's signature required.
- Medium: Health care professional's signature required.
- Difficult: Notarized form or both a form signed by a health care professional and a letter of explanation required.
- No data available



Note: States where new requirements were added after the study's release have been adjusted accordingly.
Source: *New England Journal of Medicine*, 2012

State Exemption Requirements Vary

- Sign an exemption form
- In person educational visit with Health Care Provider
- In person educational visit with health department official
- On-line training (print completion certificate)



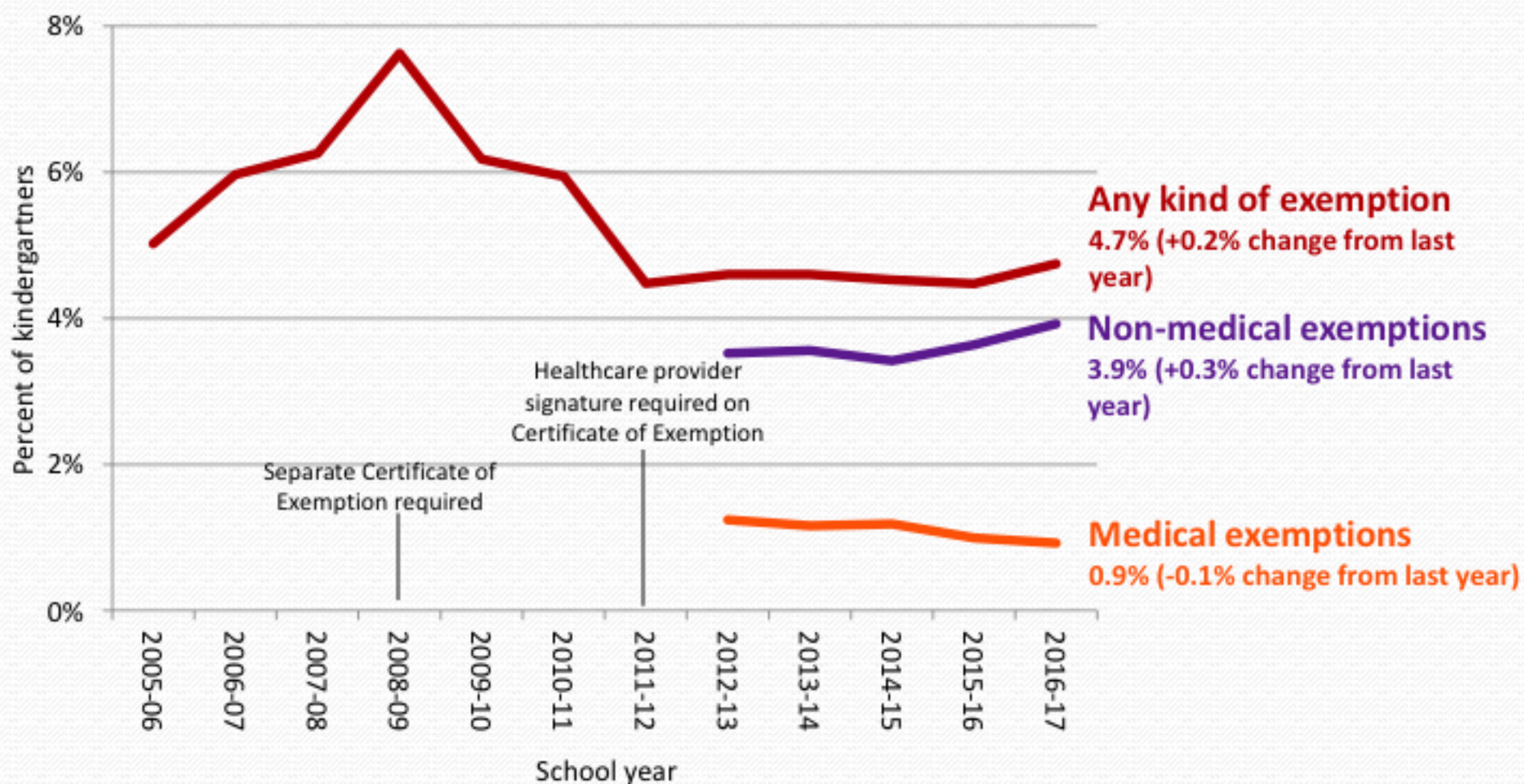
WA State Senate Bill 5005

-
- Past law: signature from medical professional only required when medical exemptions filed
 - New law (signed May 10, 2011 by Gov. Gregoire):
 - *“Modifications are made to the certification, that a parent or guardian must present, to exempt a child from school immunization requirements [for religious or philosophical reasons]...must include a statement, signed by a health care practitioner, that the parent or guardian has been informed of the benefits and risks of the immunization.”*



School immunization exemptions among kindergartners, 2005 - 2017

Exemption rates increased slightly last year after remaining stable over the last five school years. Washington state has one of the highest exemption rates in the country. While most exemptions are for personal/philosophical and religious reasons, Washington's medical exemption rate during 2015-16 was 5 times higher than the national median of 0.2%.



Michigan: The “Inconvenience” Strategy

- Changed rules Jan 1, 2015 to make it more inconvenient to obtain a waiver
- Parents of children entering kindergarten and middle school must be briefed *in person* by a county health education before a waiver will be granted
- Waivers issued dropped from 5.2% to 3.3% of those entering kindergarten
- Percent of children not getting four doses of DTaP dropped from 22% to 15%

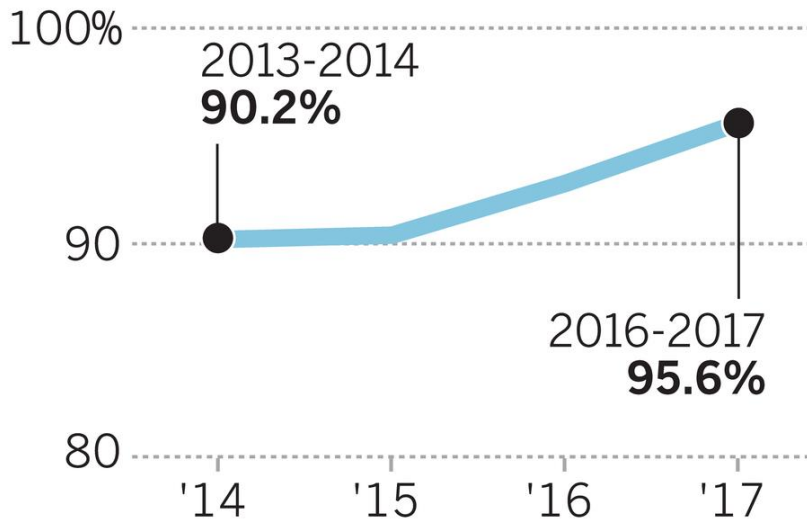


California: Elimination of all NMEs

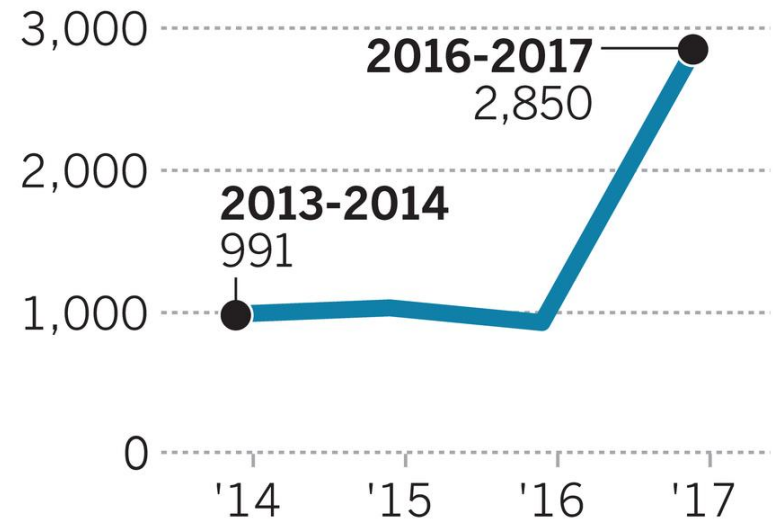
More kindergartners getting their shots

More kindergartners received all of their required vaccinations last year after a new law in California went into effect. But the number who avoided vaccinations by citing medical reasons also went up.

Statewide kindergarten vaccination rate



Number of kindergartners with medical exemptions



Source: California Department of Public Health

@latimesgraphics



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Replacement Effect and Exemption Type

- Elimination of Broad Personal Belief Exemption leads to increase in Religious Exemptions
- Elimination of Religious Exemptions leads to increase in Medical Exemptions
- In US, there is some question as to whether a meaningful distinction can be made between Religious and PB exemptions



Other Strategies

-
- Europe: Some countries use fines for non-compliant. Associated with increased vaccination rates
 - Australia uses financial incentives (tax credit)
 - Could argue that these strategies are more ethical than denial of school entry





Improving Childhood Vaccination

Communication Strategies need
to be optimized



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Communication

A trusted health care provider remains the best avenue for changing minds about vaccination. Asking families to find another provider because they will not vaccinate according to the provider's recommendation does not improve communication and, when families leave, eliminates this as an option



Aristotle's Tools of Rhetoric (Persuasion)

-
- Character (Ethos): The speaker must be trustworthy
 - Logic (Logos): The message must be factually correct and logical
 - Emotion (Pathos): The message must resonate emotionally, eliciting an emotional response to inspire action
 - Telos: Clear goal or end in mind



Fear: Basis of Decision for many Parents

EARLY REPORT

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 assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated, by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in the colon in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0.003$), low haemoglobin in four children, and a low serum IgA in four children.

Interpretation We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351**: 637-41
See Commentary page

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield FRCS, A Anthony MB, J Linnell PhD, A P Dhillon MRCPsych, S E Davies MRCPsych) and the **University Departments of Paediatric Gastroenterology** (S H Murch MB, D M Casson MRCP, M Malik MRCP, M A Thomson FRCP, J A Walker-Smith FRCP), **Child and Adolescent Psychiatry** (M Berelowitz FRCPsych), **Neurology** (P Harvey FRCP), and **Radiology** (A Valentine FRCP), **Royal Free Hospital and School of Medicine, London NW3 2QG, UK**

Correspondence to: Dr A J Wakefield

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 developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward for 1 week, accompanied by their parents.

Clinical investigations

We took histories, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria.¹ Developmental histories included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic-resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.² Chromatograms were scanned digitally on computer, to analyse the methylmalonic-acid zones from cases and controls. Urinary methylmalonic-acid concentrations in patients and controls were compared by a two-sample *t* test. Urinary creatinine was estimated by routine spectrophotometric assay.

Children were screened for antiendomyseal antibodies and boys were screened for fragile-X if this had not been done



2010: Lancet Medical Journal Retracts Wakefield Autism Study

Andrew Wakefield, Scientific Censorship, and Fourteen Monkeys

A statement from Jenny McCarthy and Jim Carrey

Los Angeles, February 5, 2010



Dr. Andrew Wakefield is being discredited to prevent an historic study from being published that for the first time looks at vaccinated versus unvaccinated primates and compares health outcomes, with potentially devastating consequences for vaccine makers and public health officials.

It is our most sincere belief that Dr. Wakefield and parents of children with autism around the world are being subjected to a remarkable media campaign engineered by vaccine manufacturers reporting on the

retraction of a paper published in *The Lancet* in 1998 by Dr. Wakefield and his colleagues.

The retraction from *The Lancet* was a response to a ruling from England's General Medical Council, a kangaroo court where public health officials in the pocket of vaccine makers served as judge and jury. Dr. Wakefield strenuously denies all the findings of the GMC and plans a vigorous appeal.

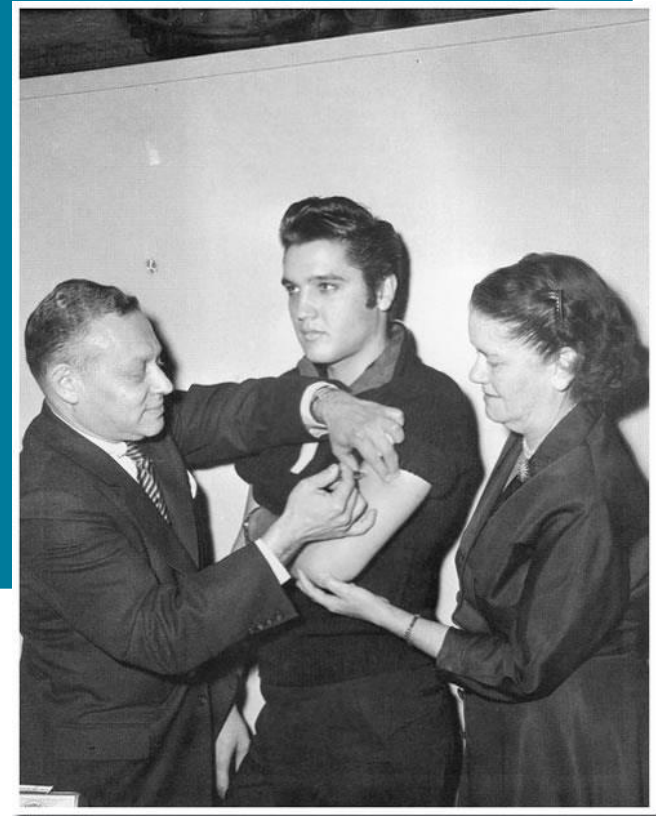
Strategies with Parents

- Seek first to understand: Diagnose the Resistance
- Respond to concerns
- Show respect, find common ground
- Be willing to compromise while educating: The goal is not to win, but to win them over
- Tell personal stories: Appeal to Emotion, Data rarely persuades



Improving Childhood Vaccination

We need to set an example



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