Immunisation Advisory Centre
ĀRAINGA MATE
UNIVERSITY OF AUCKLAND

Immunisation issues

Nikki Turner

May 2010

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- The NZ schedule
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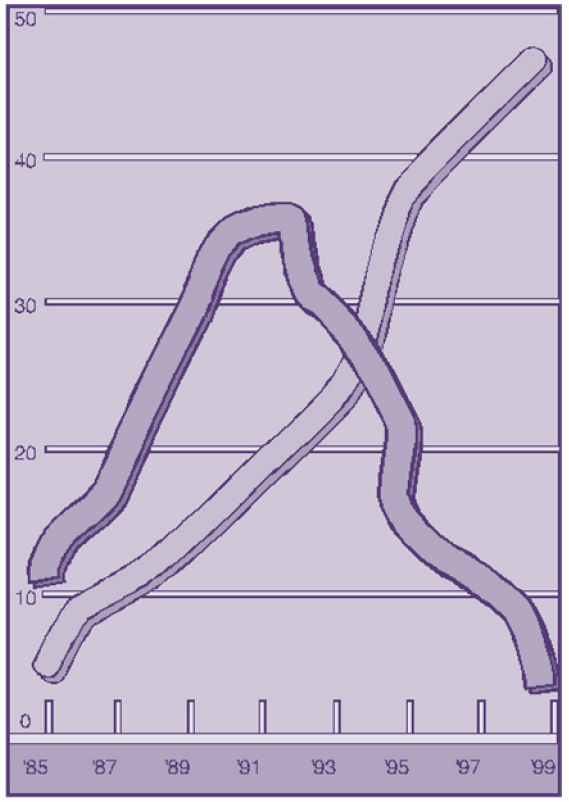
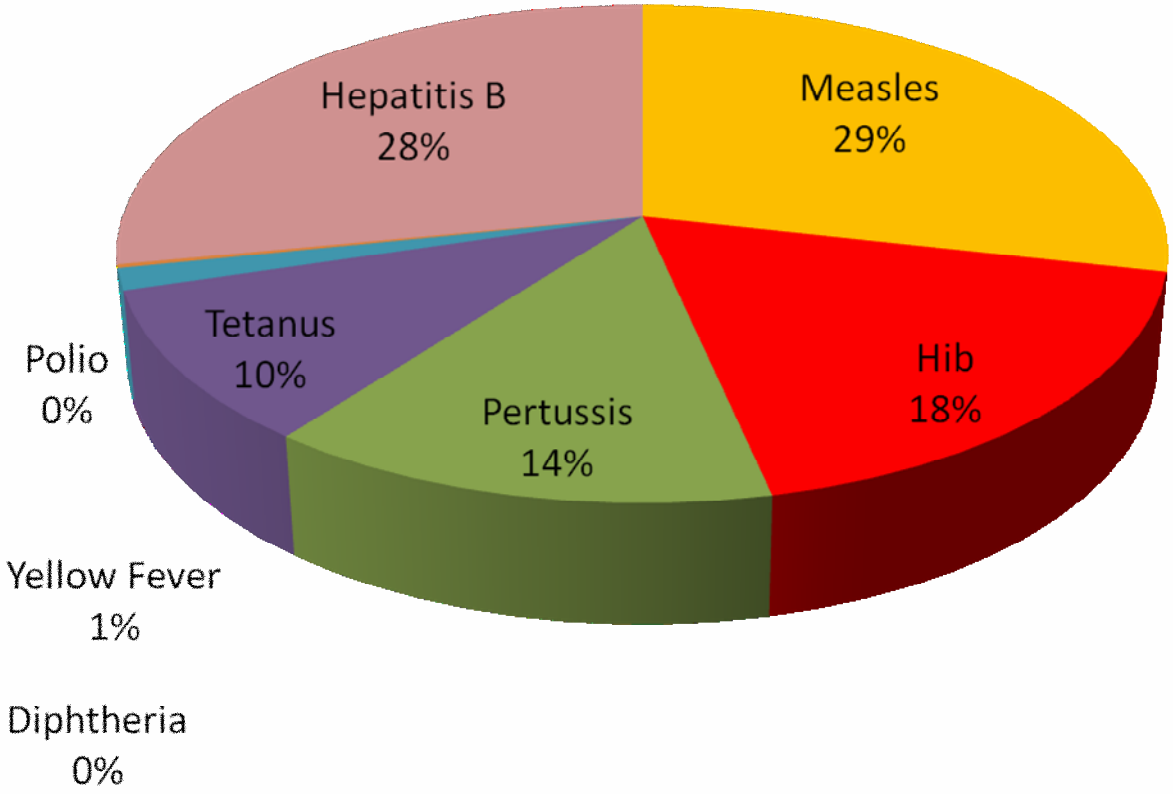


DISEASE CONTROL AND VACCINE EFFECTIVENESS

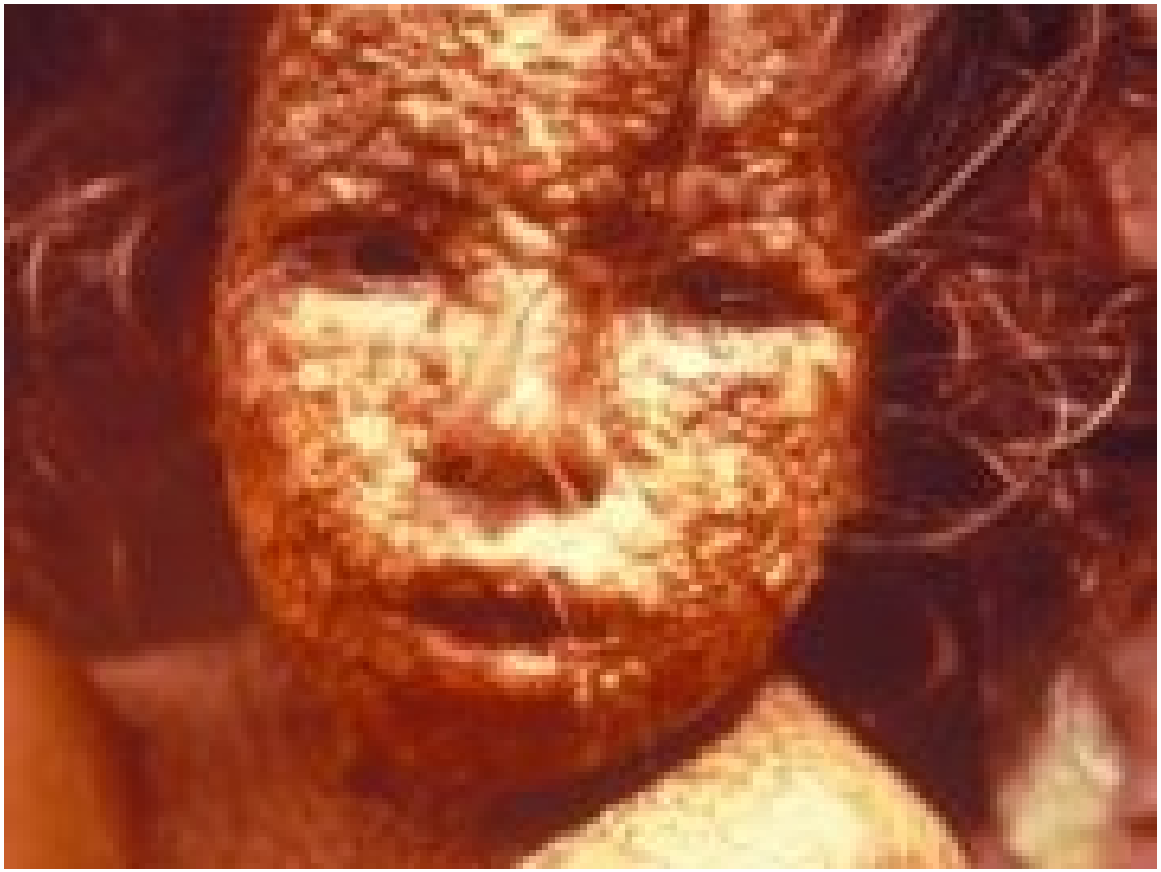
“Only clean water and antibiotics have had an impact on childhood death and disease that is equal to that of vaccines”

World Health Organization

Global burden of VPD



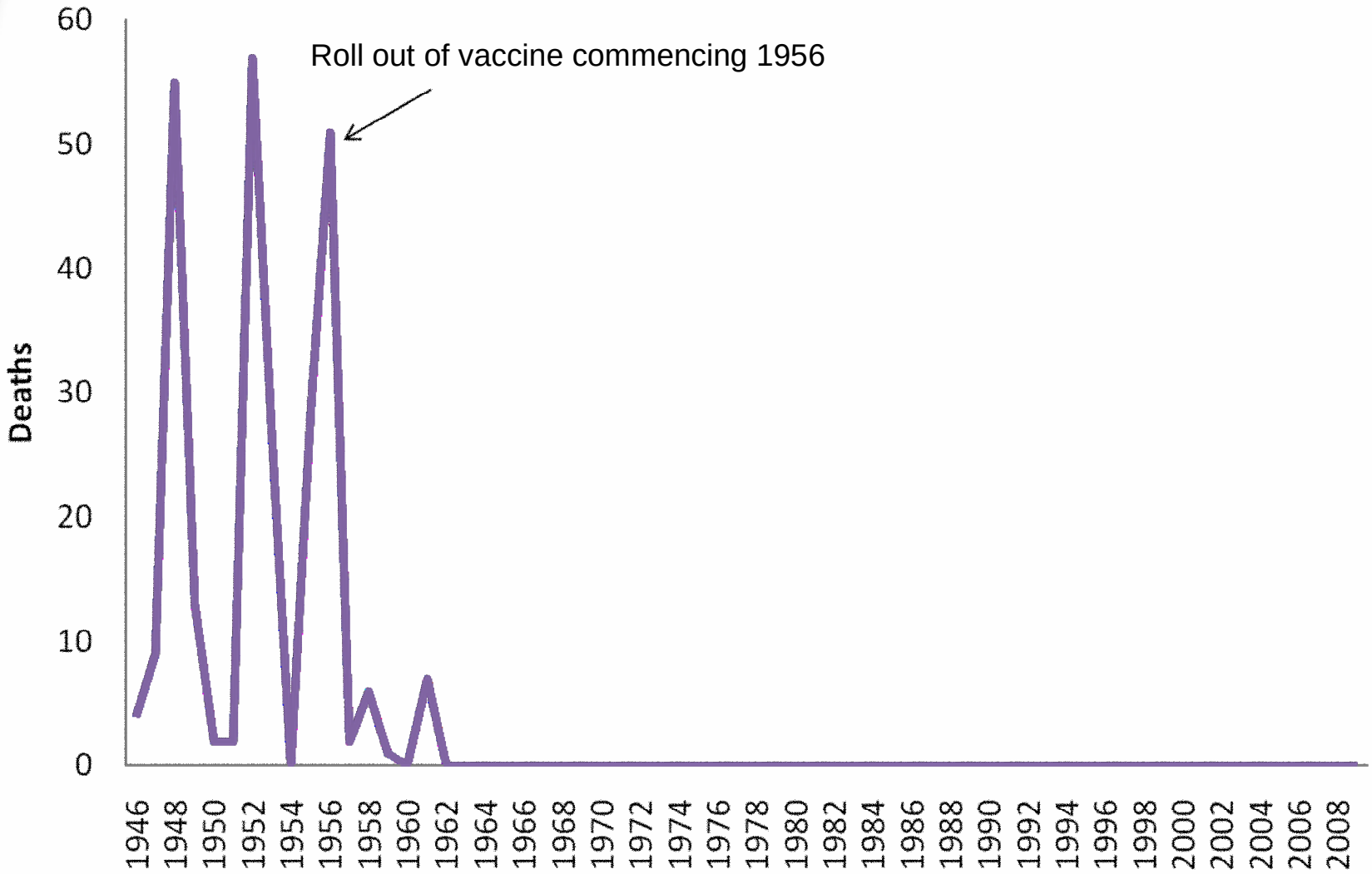
In 2002, WHO estimated that 1.4 million of deaths among children under 5 years were due to diseases that could have been prevented by routine vaccination. This represents 14% of global total mortality in children under 5 years of age .



Smallpox

Bangladeshi girl infected with smallpox (1973).

POLIO

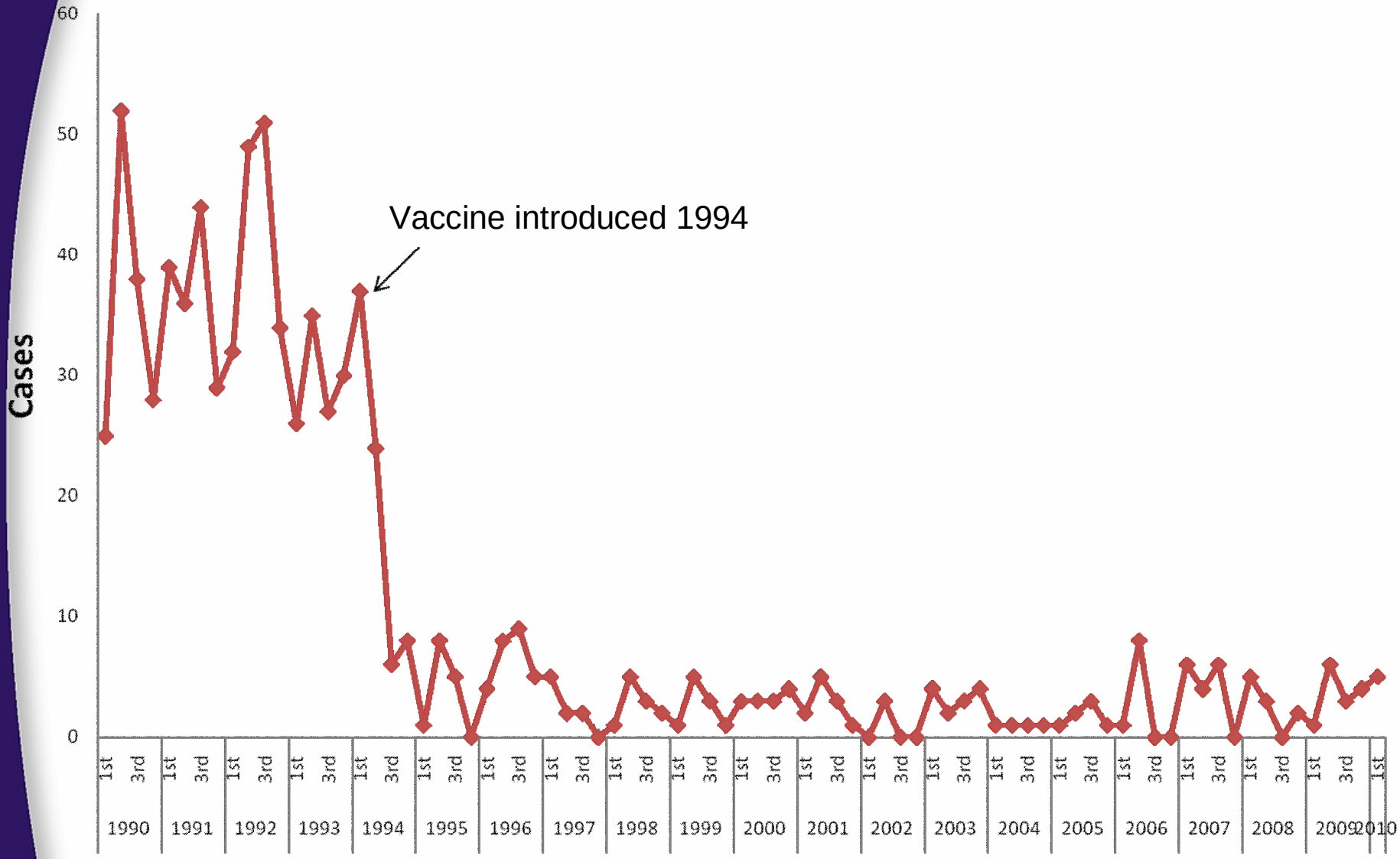


No cases of indigenously acquired poliomyelitis in New Zealand since the OPV mass immunisation campaigns in 1961 and 1962

Wilson Home for crippled children in Takapuna, Auckland, 1943.

Alexander Turnbull Library,
Photographer: John Pascoe Reference: 1/4-000643-F

Hib laboratory confirmations 1990 - 1995 and notified cases 1996 - 2010



Cluster Outbreaks examples:

- **Amish populations in USA 1985 – 1994**
  - 13 outbreaks of measles, 1200 cases, 9 deaths
- **1999 Netherlands unimmunised community**
  - 10 month long outbreak, 2961 cases
- **Colorado vaccine decliners 1987-1988**
  - 22.2 times more likely to acquire measles
  - 5.9 times more likely to acquire pertussis
- **Rubella outbreaks in decliners Netherlands, spreads to Canada**
  - Outbreak 2004/5, 309 lab confirmed cases, 23 in pregnant women: (at least 1 infant death, 9 severe handicap)
  - Travel: 214 cases in Canada, 5 in pregnant women

May T et al, Vaccine 21(2003) 1048-1051
Feikin D et al JAMA 284(2000)3145-3150
Eurosurveillance 2005;10(5):050519

VACCINES ON THE NZ SCHEDULE

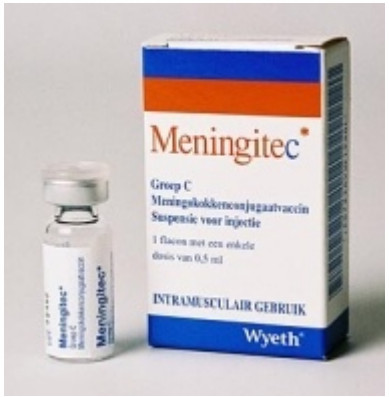
2008 Childhood Schedule (from Sept)

	DTaP-IPV-Hib/HepB (IM)	PCV7 (IM)	Hib (IM)	MMR (S/C)	DTaP-IPV (IM)	dTap (IM)	HPV (IM)
6 weeks	Infanrix®-hexa	Prevenar®					
3 months	Infanrix®-hexa	Prevenar®					
5 months	Infanrix®-hexa	Prevenar®					
15 months		Prevenar®	Hiberix™	MMR-II®			
4 years				MMR-II®	Infanrix™-IPV		
11 years						Boostrix®	
12 years (School year 8 Starts in 2009)							Gardasil®
							Gardasil® 2 months after 1st dose
							Gardasil® 4 months after 2nd dose

VACCINES ON THE HORIZON

Private market vaccines to consider

- **Varicella**
  - Zoster (soon)
- **Rotavirus**
- **Conjugate meningococcal vaccines**



The schedule : What is next.....

- **Conjugate pneumococcal vaccines**
  - 10 and 13 serotypes
- **Next vaccines recommended for the schedule, but not yet.....**
  - Rotavirus
  - Varicella

COMMON PN ISSUES

Catch up schedules

- pp50-52 of 2008 National Immunisation Schedule Health Provider Booklet
- Guidelines for immunisation for immigrant and refugee children from other countries : p66 of the Immunisation Handbook 2006.
- Immigrant kids:**latest** immunisation schedule for that country refer WHO website: www.who.int/vaccines/globalsummary/Immunization/CountryProfileSelect.cfm

NB many 3rd world countries do not as yet include Hib or PCV7 vaccines and may give measles only vaccine

Also a "google" search of a country (name+ immunisation schedule) can be a useful option.

NOTES:

- If the schedule is interrupted, it is not necessary to repeat prior doses
- Hib is not routinely required after the fifth birthday
- MMR, Hib and Pertussis are given as a priority for children 15mths of age and older
- No more than 6 doses of diphtheria-tetanus containing vaccine can be given in the first 4 years of life
- MMR vaccine should be offered to any individual susceptible to any of those three diseases
- If 2 live virus vaccines are not given concurrently, doses should be separated by a minimum of 4 weeks
- Vaccines, including live virus vaccines, may be given concurrently, unless the manufacturer makes a specific recommendation against it
- There are no 'single' measles, mumps, rubella, tetanus or pertussis vaccines available in New Zealand.
- For eligibility for Schedule vaccines – particularly for those over 16 yrs of age – see p 1 Health Provider Booklet 2008

"*Have a go" at planning a catch up immunisation schedule for your client/patient, and if you would like help or confirmation that it is correct do call us. The more you do the easier it gets!!!*

Recurrent problems

- **Leaving a component out of a vaccine eg Hib inInfanrix-Hexa**
- **Infanrix-IPV and Infanrix-Hexa are not given after a child's 7th birthday**
- **The need for Tetanus vaccine and TIG in a previously unimmunised child with a tetanus at risk wound. Refer IMAC tetanus at risk wound chart. Remeber then need a course of 3 tetanus**
- **Parents travelling and want to give immunisations early e.g. asking for 6 week immunisations at 4 weeks of age.**
- **Can we use expired vaccines?**
- **Funded vaccines from ProPharma cannot be sold as travel vaccines or given to ineligible people e.g. HBvaxPRO, ADT Booster, Boostrix, Ipol, Menomune, Pneumovax23, Gardasil , Prevenar**

.

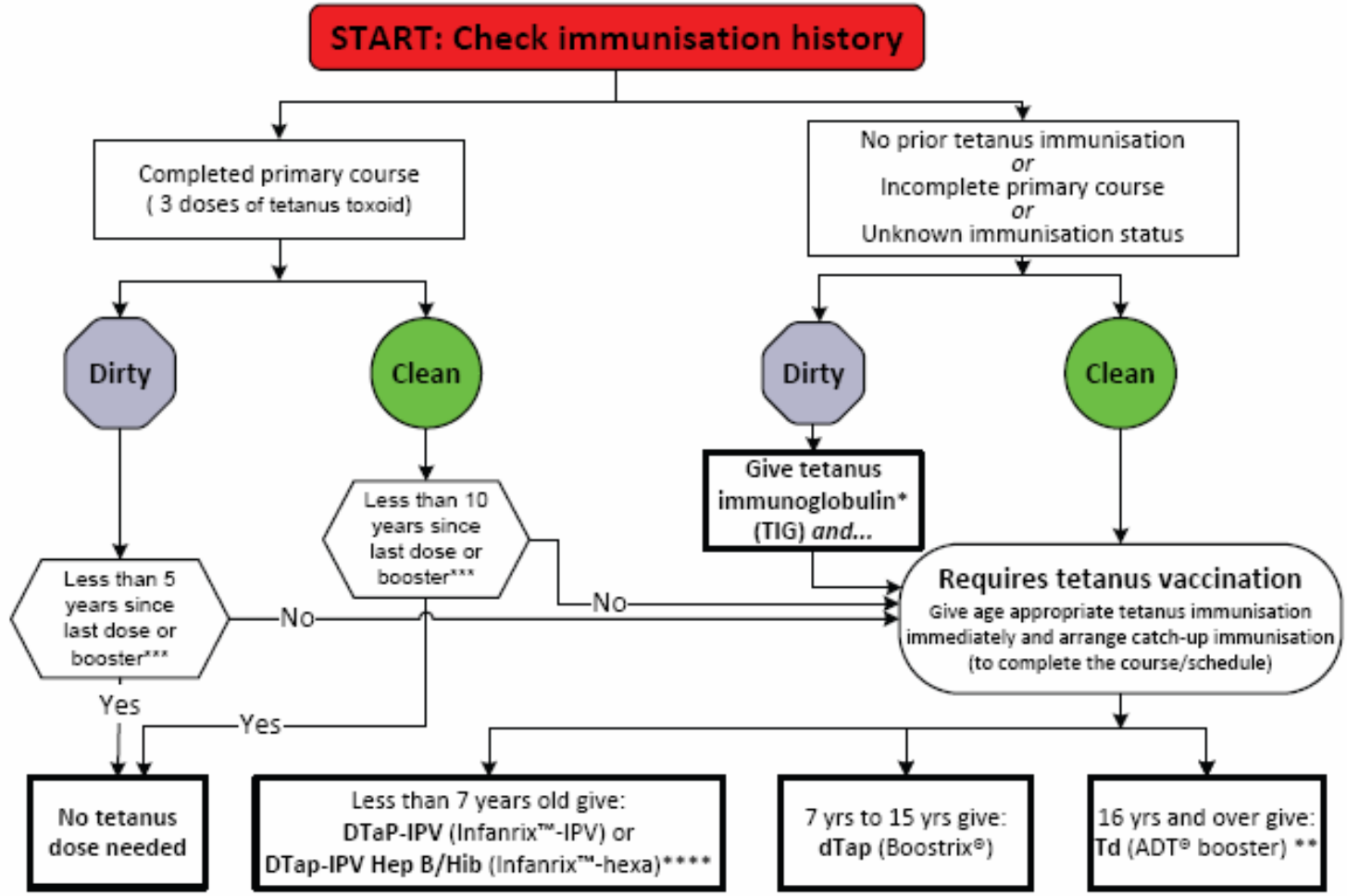
Is breast feeding a contraindication for vaccinating?

Can a child with egg allergy have MMR?

Guidelines for the Management of Tetanus Prone Wounds

Dirty wound
Wounds not classified as clean, which may be contaminated, infected, penetrating, more than six hours old and with tissue damage

Clean wound
Wounds less than six hours old, non-penetrating with negligible tissue damage



IMPROVING COVERAGE

International coverage

In order to prevent the transmission of whooping cough and measles 95% of the population needs to be immune.

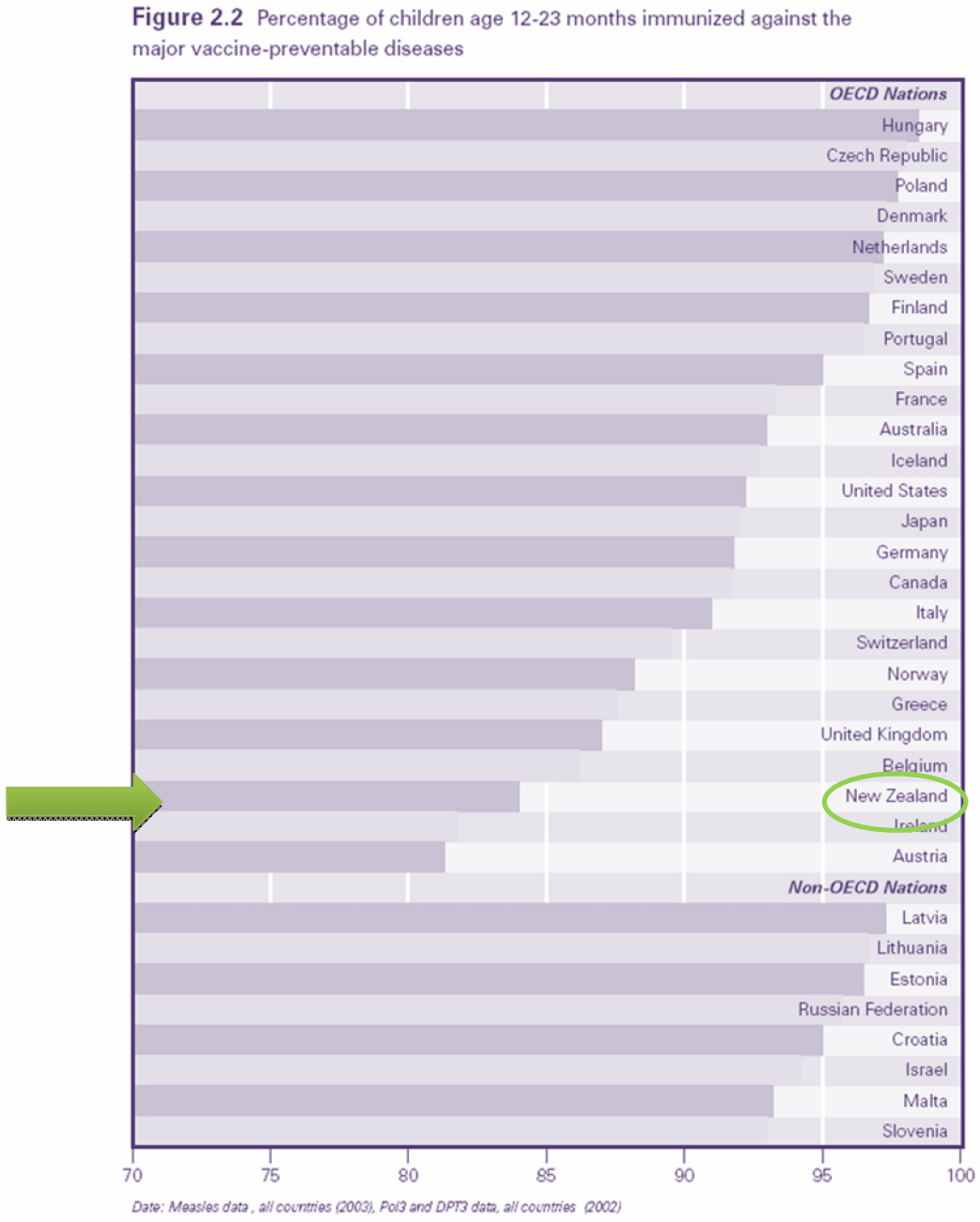
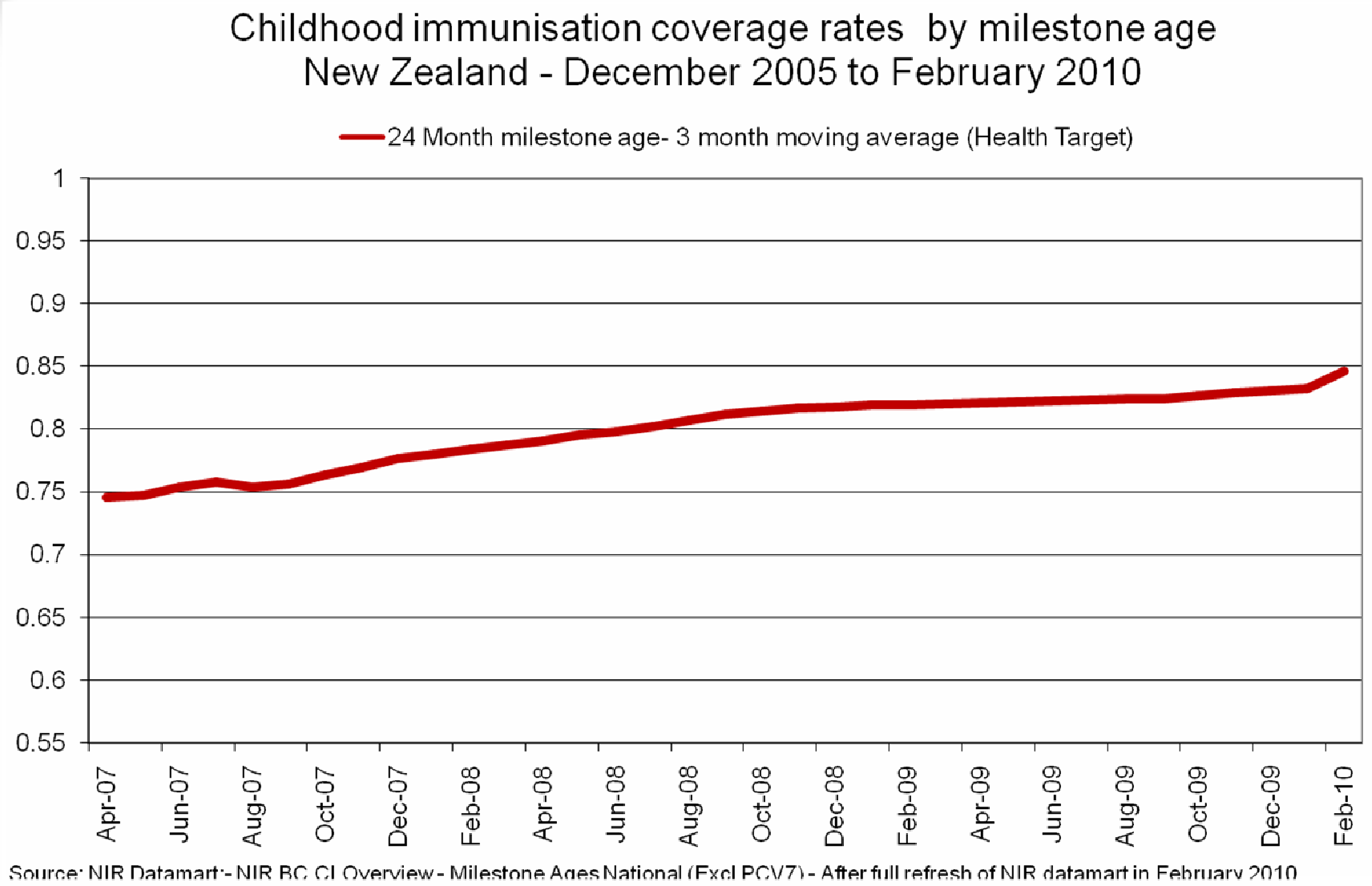
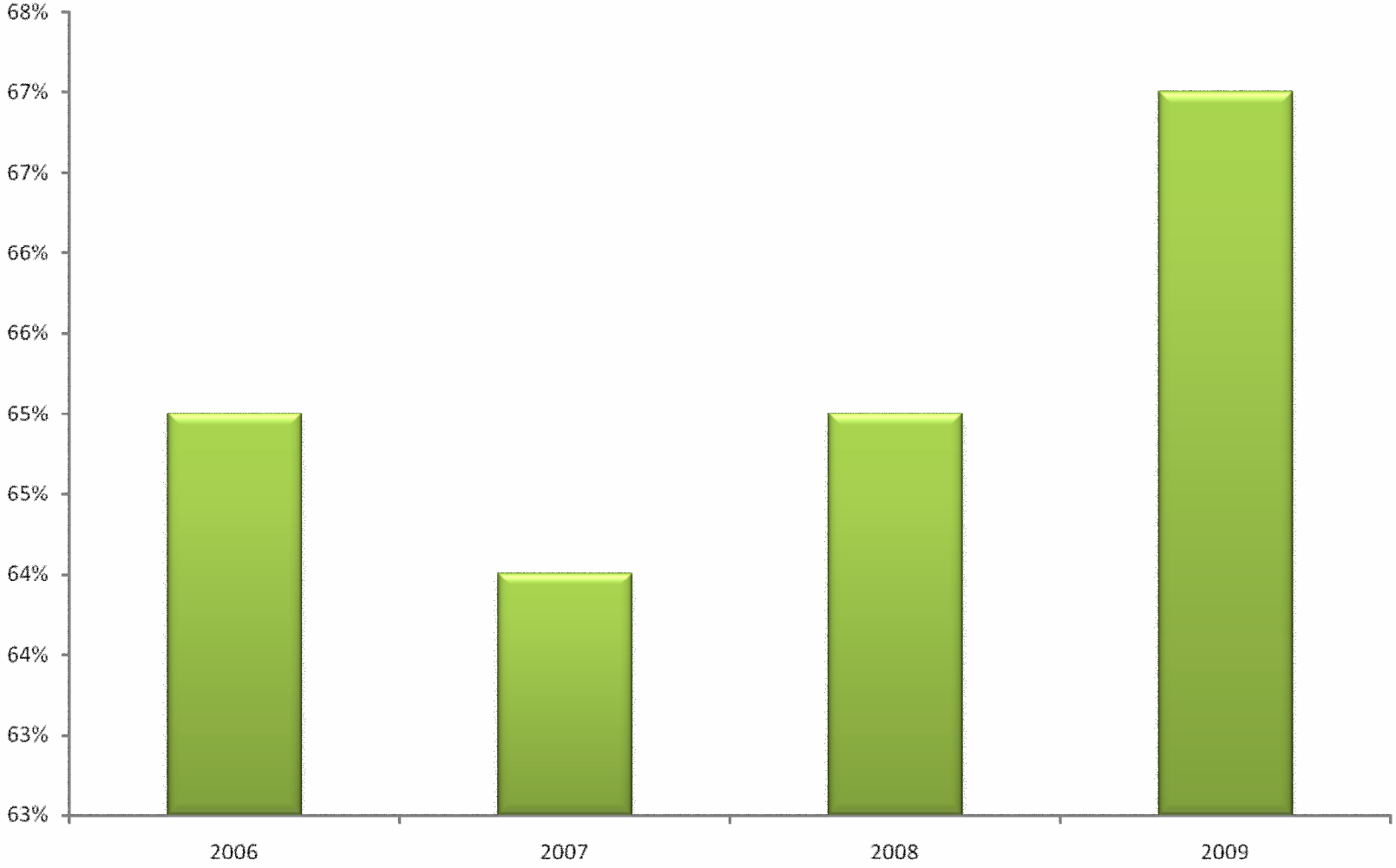


Figure 2.2 Percentage of children age 12-23 months immunized against the major vaccine-preventable diseases

From: UNICEF: Innocenti Report Card 7, UN Childrens Fund 2007


Childhood immunisation coverage rates by milestone age
New Zealand - December 2005 to February 2010
24 Month milestone age- 3 month moving average (Health Target)
1
0.95
0.9
0.85
0.8
0.75
0.7
0.65
0.6
0.55
Apr-07
Jun-07
Aug-07
Oct-07
Dec-07
Feb-08
Apr-08
Jun-08
Aug-08
Oct-08
Dec-08
Feb-09
Apr-09
Jun-09
Aug-09
Oct-09
Dec-09
Feb-10
Source: NIR Datamart:- NIR BC CI Overview - Milestone Ages National (Excl PCV7) - After full refresh of NIR datamart in February 2010

Fully immunised at 6 months of age



Data source: National Immunisation Register 2010

Key areas that can make a difference

HOW TO IMPROVE

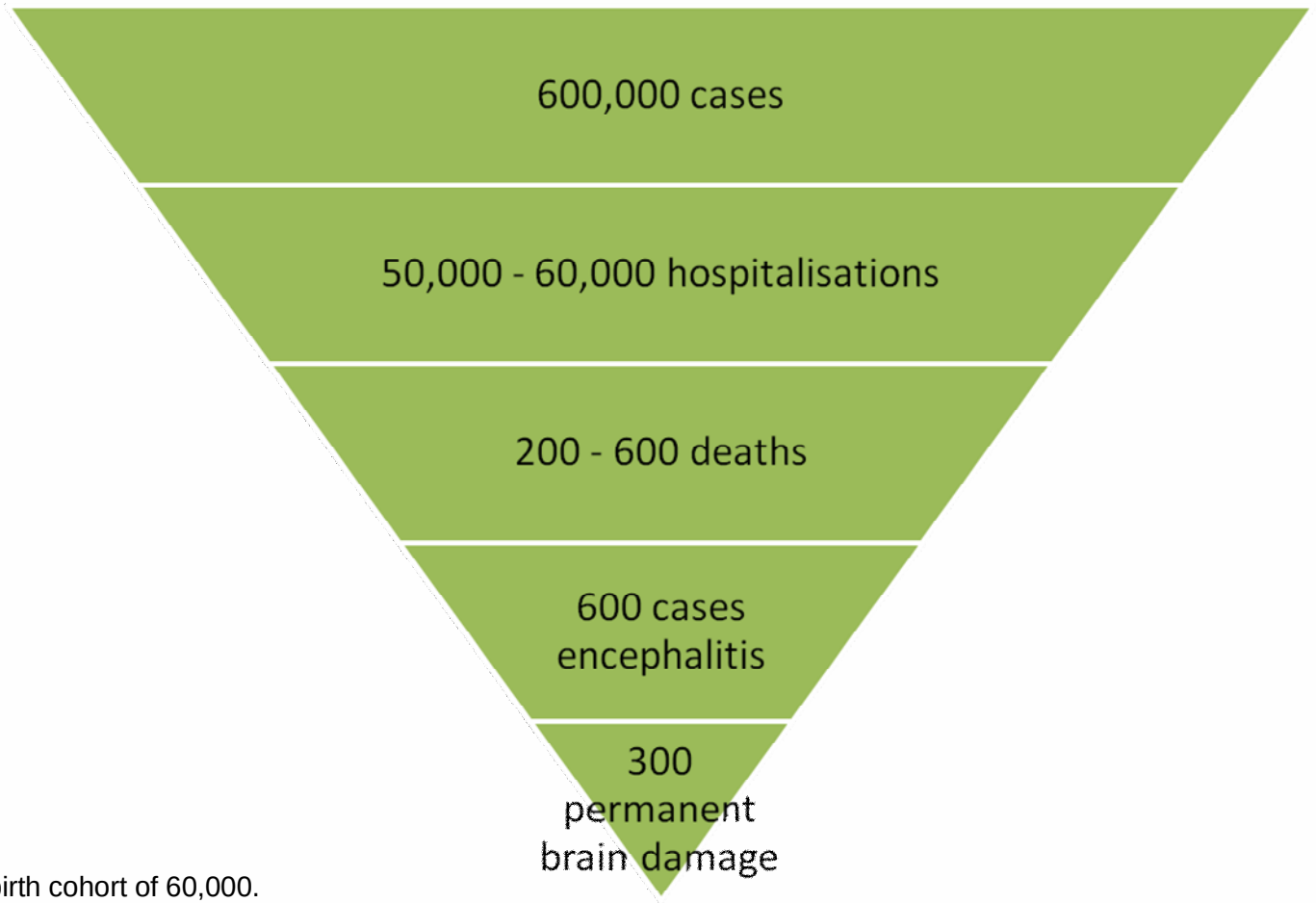
Provider support and improving systems

- Quality systems:
  - enrolment/registration
  - early engagement ?antenatal
- Effective precall/recall
  - chasing DNAs, use of OIS
- Opportunistic efforts/flags/awareness
- Practice champions
- Immunisation/child health a higher priority

Missed Opportunities to Immunise

Out of sight out of mind: Absence of disease is a very hard product to sell

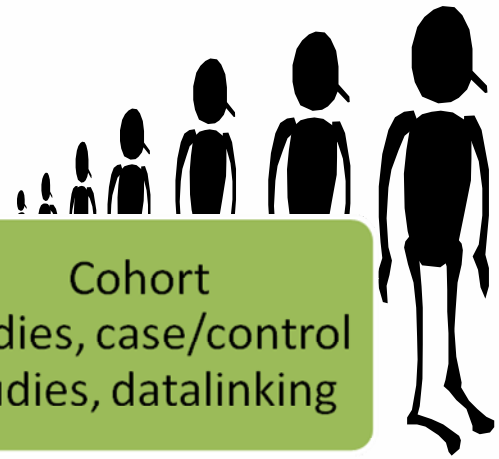
Estimated incidence of severe measles reactions expected over a 10 year period in NZ in the absence of a measles vaccine.



*Based on a birth cohort of 60,000.

VACCINE SAFETY SURVEILLANCE

Vaccine Safety



Clinical Trials	Post marketing surveillance	Cohort studies, case/control studies, datalinking
Compares events between vaccine and no vaccine	Collect reports of adverse events following immunisation	Looks at incidence of adverse events in vaccinated compared with unvaccinated
Tells us if the vaccine contributes to events. **Causality.**	**Cannot tell us if the vaccine caused the event**	Tells us if the vaccine increases the risk of a particular event - **Causality**
E.g. local pain, redness etc, fever, serious events up to 1/10,000	Early warning system for rare or unexpected events	Method used to evaluate possible concerns

Passive safety surveillance systems

Advantages	Disadvantages
• Highly sensitive • Detects rare serious events • An early warning system e.g. Rotashield ®and interssusception	• Not very specific • Common less severe reports underreported • Cannot provide causality e.g. febrile convulsions and flu vaccination in children • Does not have a denominator

Misuse/misunderstanding of passive data

"***Girls given the Gardasil HPV vaccine are at least 16 times more likely to have a serious adverse reaction to it than to develop terminal cervical cancer, which critics say raise doubts about the increasingly controversial vaccine.***

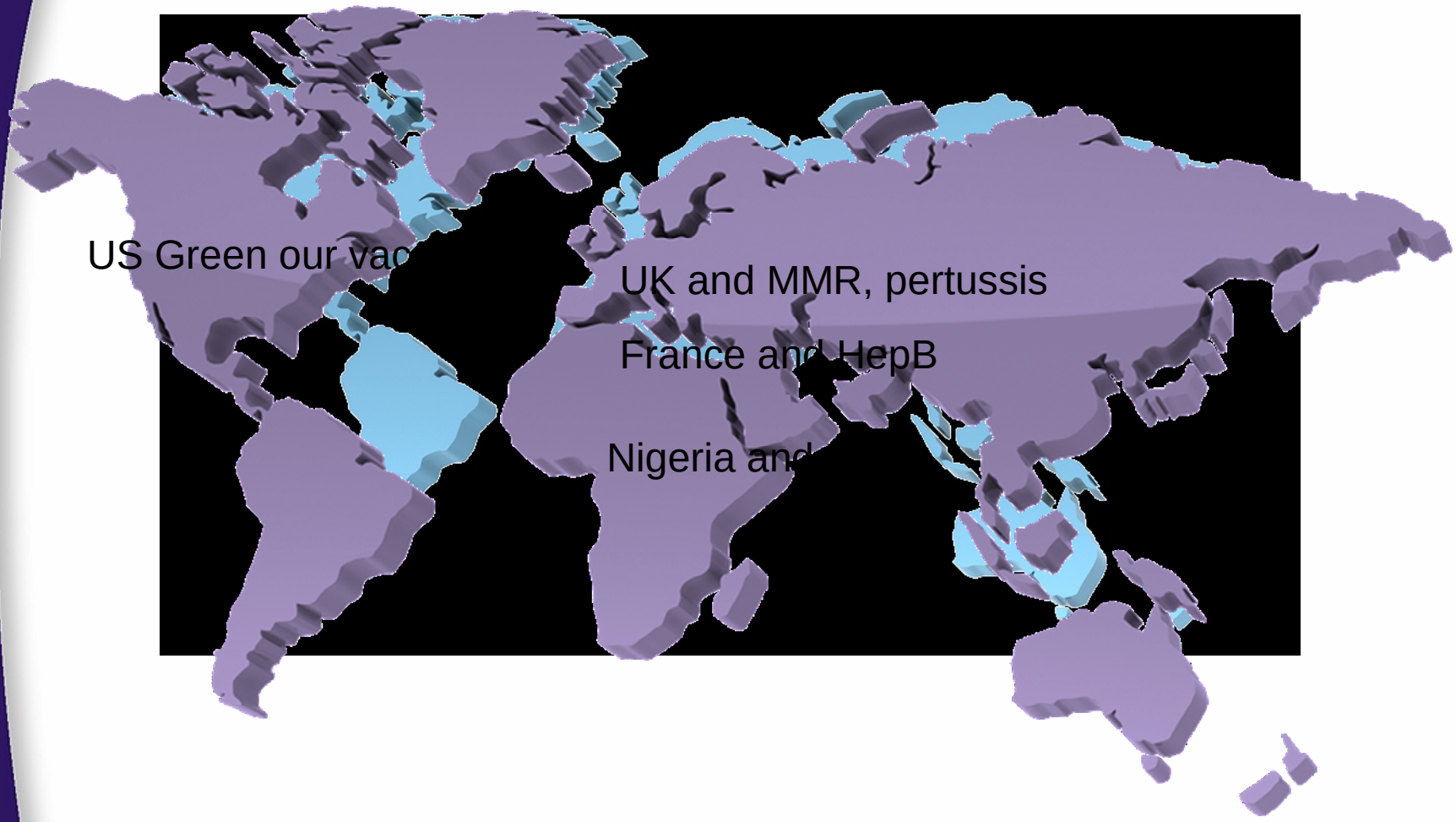
Information released under the Official Information Act shows the death rate for cervical cancer between 2002 and 2005 was 1.95 deaths per 100,000 women. This compares with 31 serious adverse reactions for the 90,000 girls who have been vaccinated with Gardasil so far.
The reactions include the death of an 18-year-old woman in September 2009, and reports of epilepsy, Bells Palsy and collapses"

Timaru Herald, 9 March 2010

COMMON MYTHS

The Cow-Pock — or — the Wonderful Effects of the New Inoculation! — Vide. the Publications of y^e Anti-Vaccine Society

International examples of myths leading to reduction in coverage



A global scare resting on the claims of parents of 8 children

THE MMR/AUTISM STORY

Dr Andrew Wakefield

Gastroenterologist. London.

The Wakefield "Study"

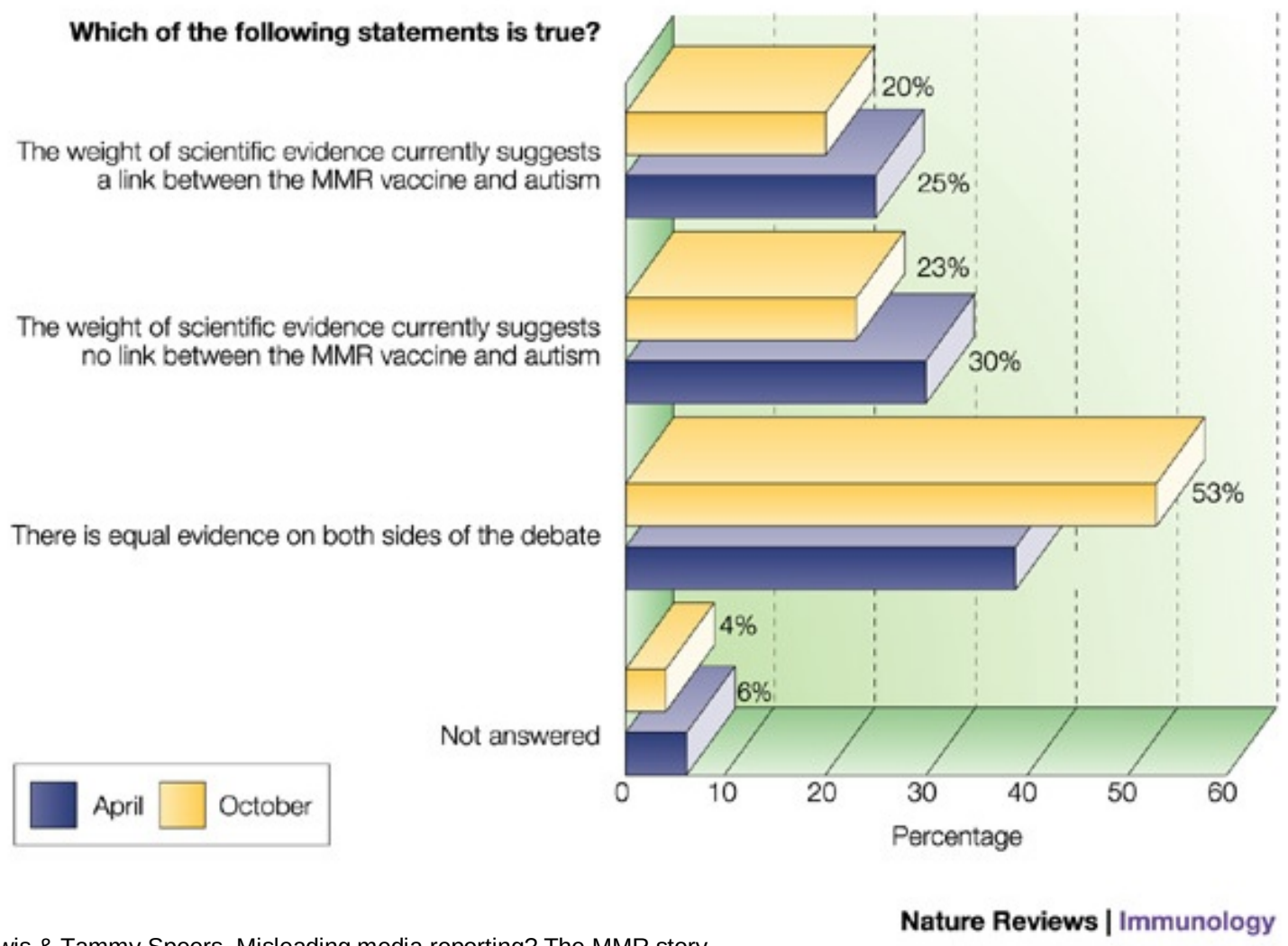
- ***Theory*: The MMR vaccine induces a series of events that includes bowel problems and subsequent development of autism.**
- ***Study design*: 12 children (8 with autism) in the United Kingdom who recently received the MMR vaccine.**
  - 5/8 of those children clients of personal injury lawyer
  - That lawyer paid Dr Wakefield, not disclosed.

Unintended consequences

- **The day after the publication, Wakefield seized the headlines with his contention that the MMR vaccine caused autism.**
- **This statement was picked up by all major newspapers in the United Kingdom.**

1998

Public opinion on the amount of research for and against the link between the MMR vaccine and autism



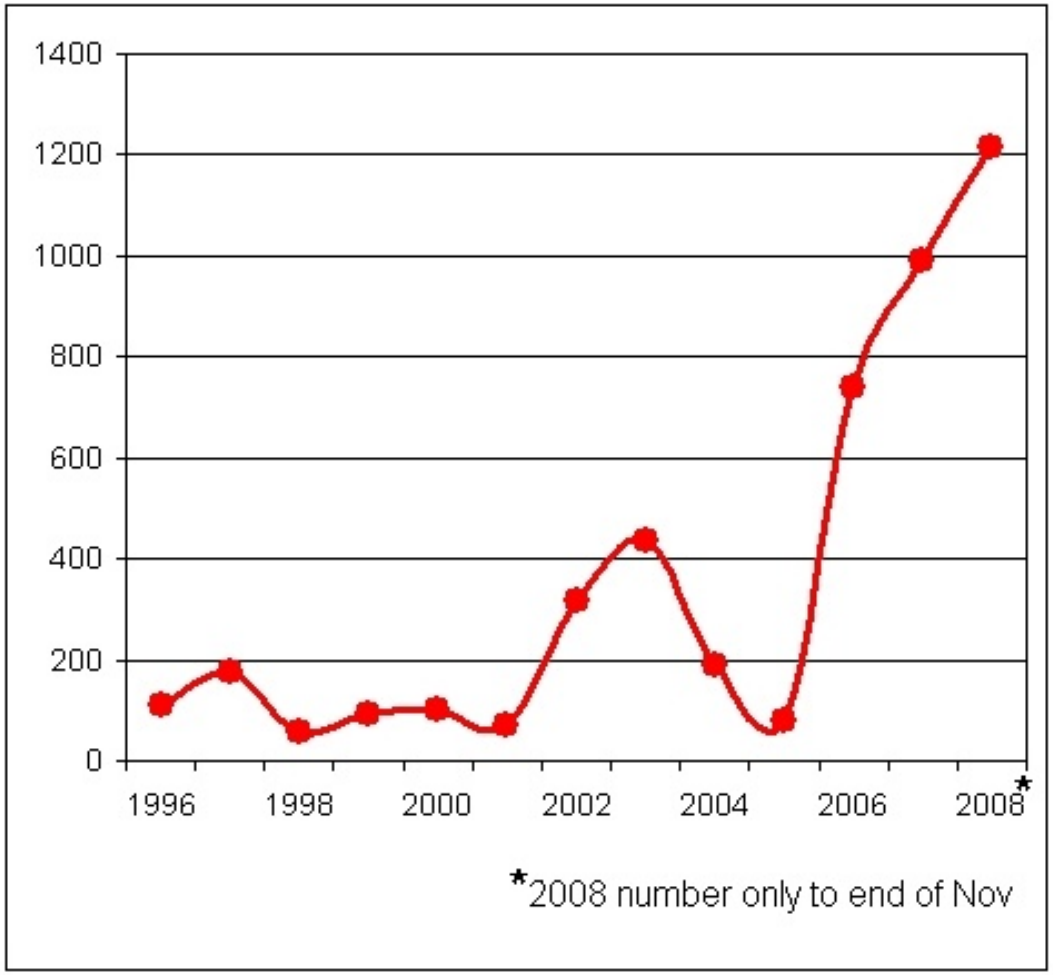
Justin Lewis & Tammy Speers. Misleading media reporting? The MMR story. *Nature Reviews Immunology* **3**, 913-918 (November 2003)

The legacy of Wakefields' "study"

Recent outbreaks of measles in the United Kingdom. Three children in Ireland died of measles.

In the United States some parents still refuse the MMR vaccine for their children or ask that the vaccine be separated into its component parts.

Measles in the UK

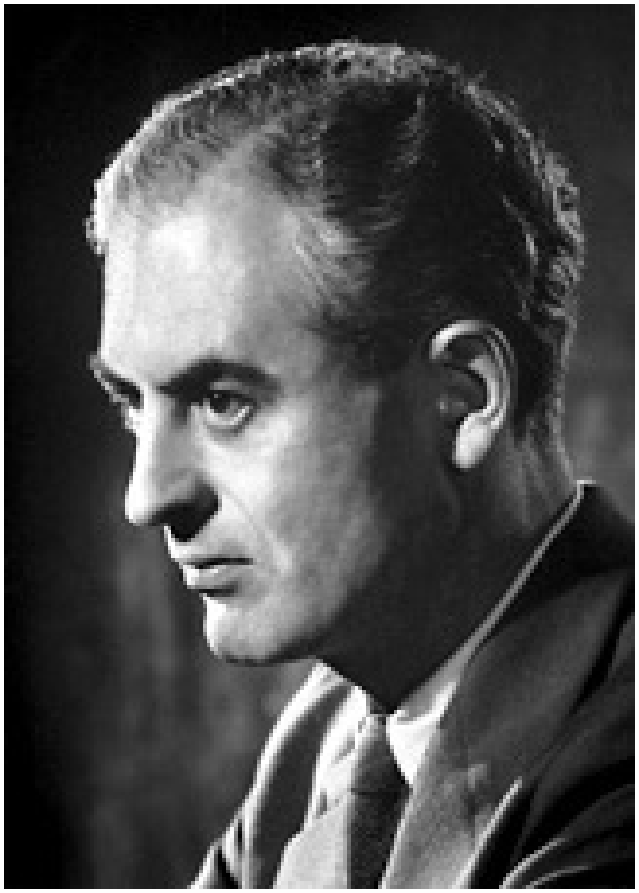


Health Protection Agency

Sir Peter Medawar - Nobel Prize in Physiology or Medicine 1969

"I cannot give any scientist of any age better advice than that the intensity of the conviction that a hypothesis is true has no bearing on whether it is true or not".

1973



VACCINES CONTAIN TOXIC INGREDIENTS

Nasty toxic poisons in vaccines…

Aluminium (adjuvant)

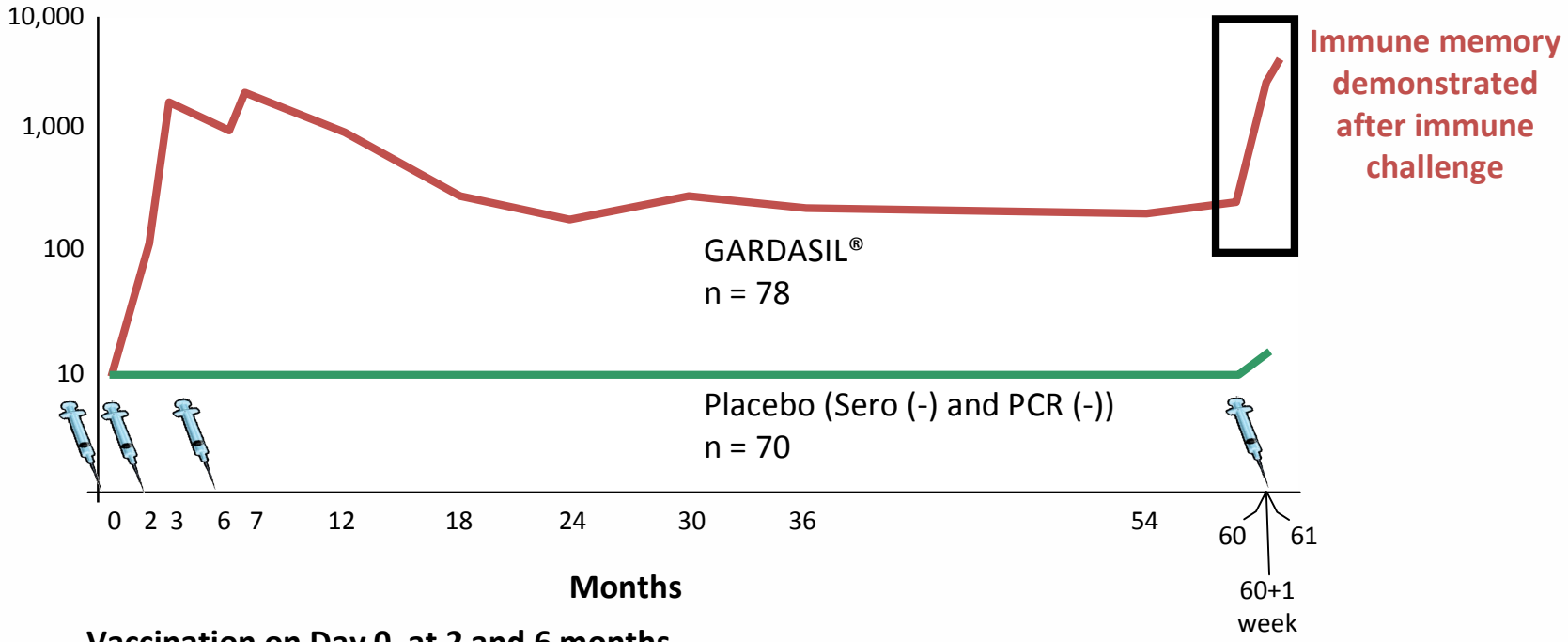
- 8th most abundant element on earth, most common metallic element.
- Found in the blood of all animals, including humans, constantly exposed
- Average daily intake 10-15mg
- Hep B vaccine has 0.235mg of aluminium.
- Average water has about 0.2mg of aluminium per litre
- The amount of aluminium in one dose of HepB = to aluminium in a litre of water - or 1 day worth of baby formula (infant formula has increased aluminium).

- Excreted in urine via kidneys

IMMUNITY TO HPV VACCINE ONLY 5 YEARS

Demonstration of immune memory with an antigen challenge at month 60

HPV 16 responses in 16 to 23 year-old females through 5 years of follow-up and evidence of anamnestic response to immune challenge



Vaccination on Day 0, at 2 and 6 months
Immune challenge at 60 months

COINCIDENCE VS CAUSALITY

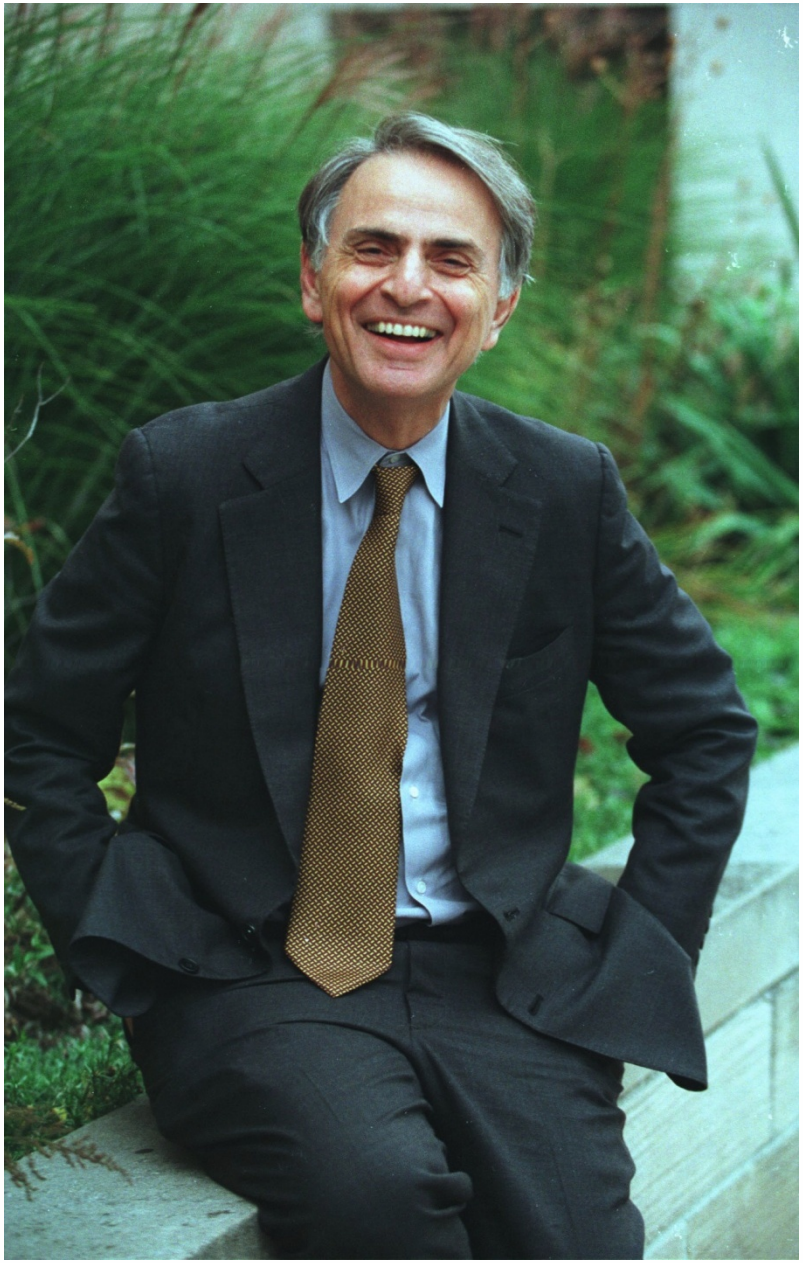
Coincidence vs. Causality

"Regardless of what the research tells us, I know what I saw."

Dr. Kathy Pratt, April 25th, 2001, during a hearing by the Office of Government Reform to investigate MMR and autism

Carl Sagan (1934-1996)

"Extraordinary claims should be backed up by extraordinary evidence"



Credit 1994 by Michael Okoniewski

GARDASIL killed my daughter

I don't know about you ..... but I am sick and tired of hearing and reading usual propaganda from the Ministry of Health. Just because the reactions or side-effects don't match those expected that fall into the so-called category for that particular pharmaceutical product.

http://www.offtheradar.co.nz/vaccines/108-gardasil-killed-my-daughter-rhonda-renata.html (accessed May 2010)

Overloading the infant immune system

TOO MANY VACCINES

US 2008

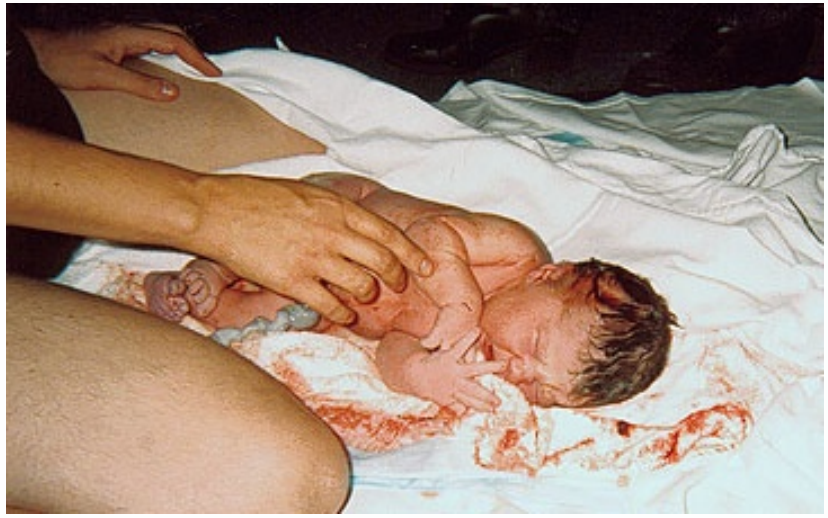

"with the escalation of shots, is the escalation of autism. Literally"


TOO MANY
TOO DUMB
www.safevaccines.org

Overloading the infant immune system

- Infants are too young
- Can’t handle multiple vaccines
- Too many antigens in each vaccine

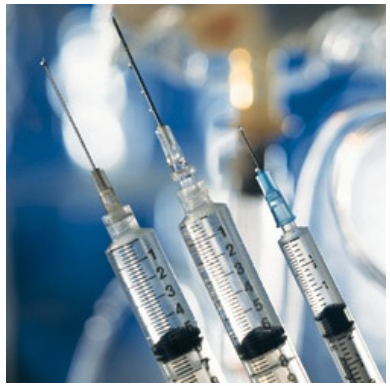
Do multiple vaccines overload the infant immune system?



- More T and B cells per cc of blood than adults
- 10^{16} possibilities!
- Huge Capacity

- **Genital tract flora – 18 species**
- **Faecal flora – 400 species**
- **Breast milk – 8 species**
- **= > 10^6 different foreign proteins**

Multiple vaccines



Year	Antigens	
– 1900	~200	Smallpox vaccine
– 1960	~3217	Included smallpox vaccine and whole cell Pertussis
– 1980	~3041	Included whole cell pertussis
– 2000	~50	Change to acellular pertussis

Infants receiving NZ scheduled vaccines now receive around 50 different antigens at one time, previously it was well over 3000.

VACCINES DON’T WORK

Vaccinated children can still get disease

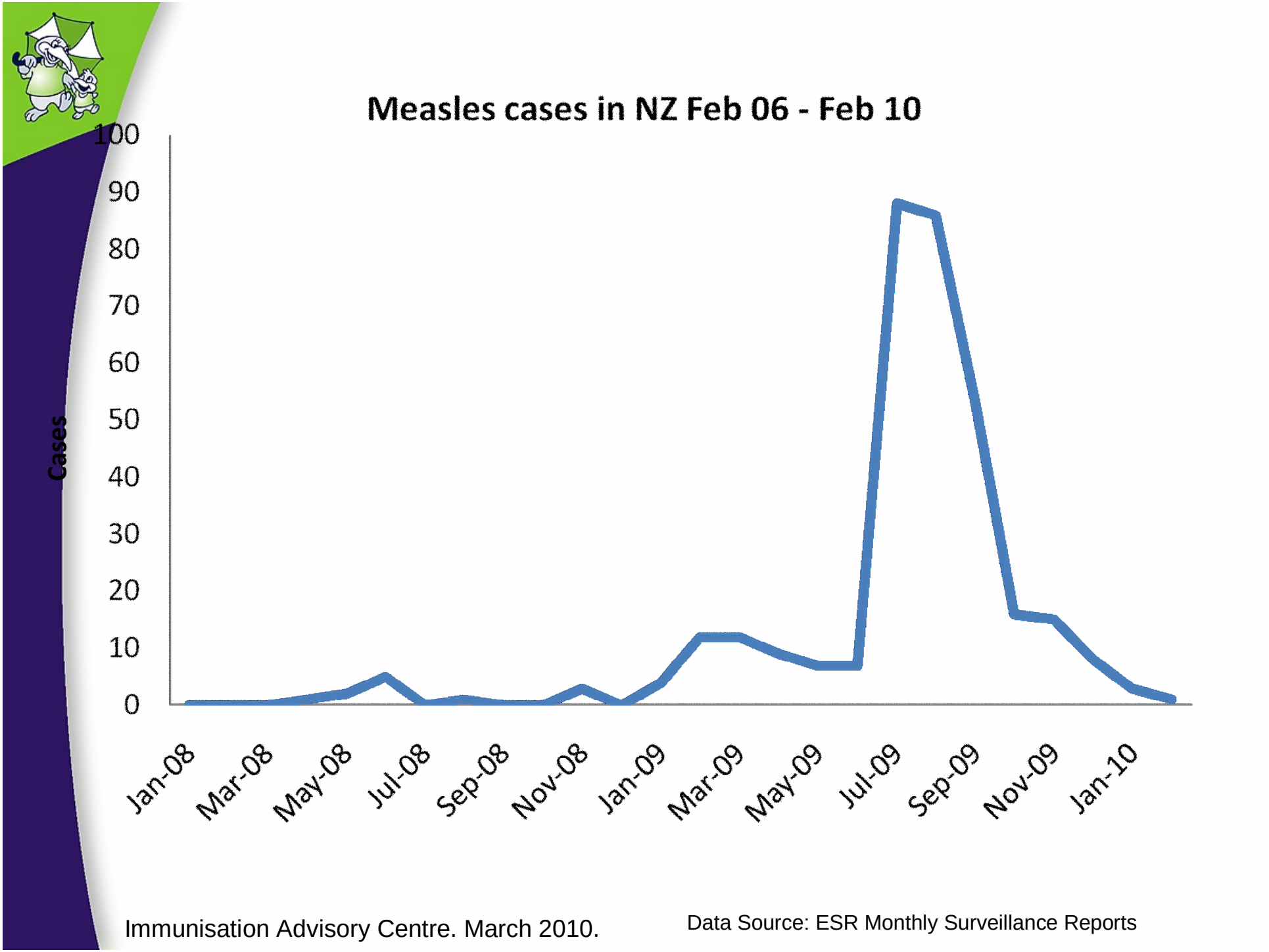
- **No vaccine is 100% effective.**
- **As the proportion of children who are immunised increases, so the proportion of disease cases that are immunised will increase.**
- **Obviously absolute numbers are much lower**

100 school kids exposed to measles which is 100% infective with a 95% effective vaccine

% Immunised	Number of measles cases	% Cases Immunised
100%	5	100%
90%	10 + 5	33%
80%	20 + 4	17%
50%	50 + 3	6%
0%	100	0%

"Thanks to the internet it is now possible to be extremely well informed and completely wrong at the same time!"

RECENT ISSUES



Data Source: ESR Monthly Surveillance Reports

Monthly whooping cough notifications by age group January 2004 – February 2010

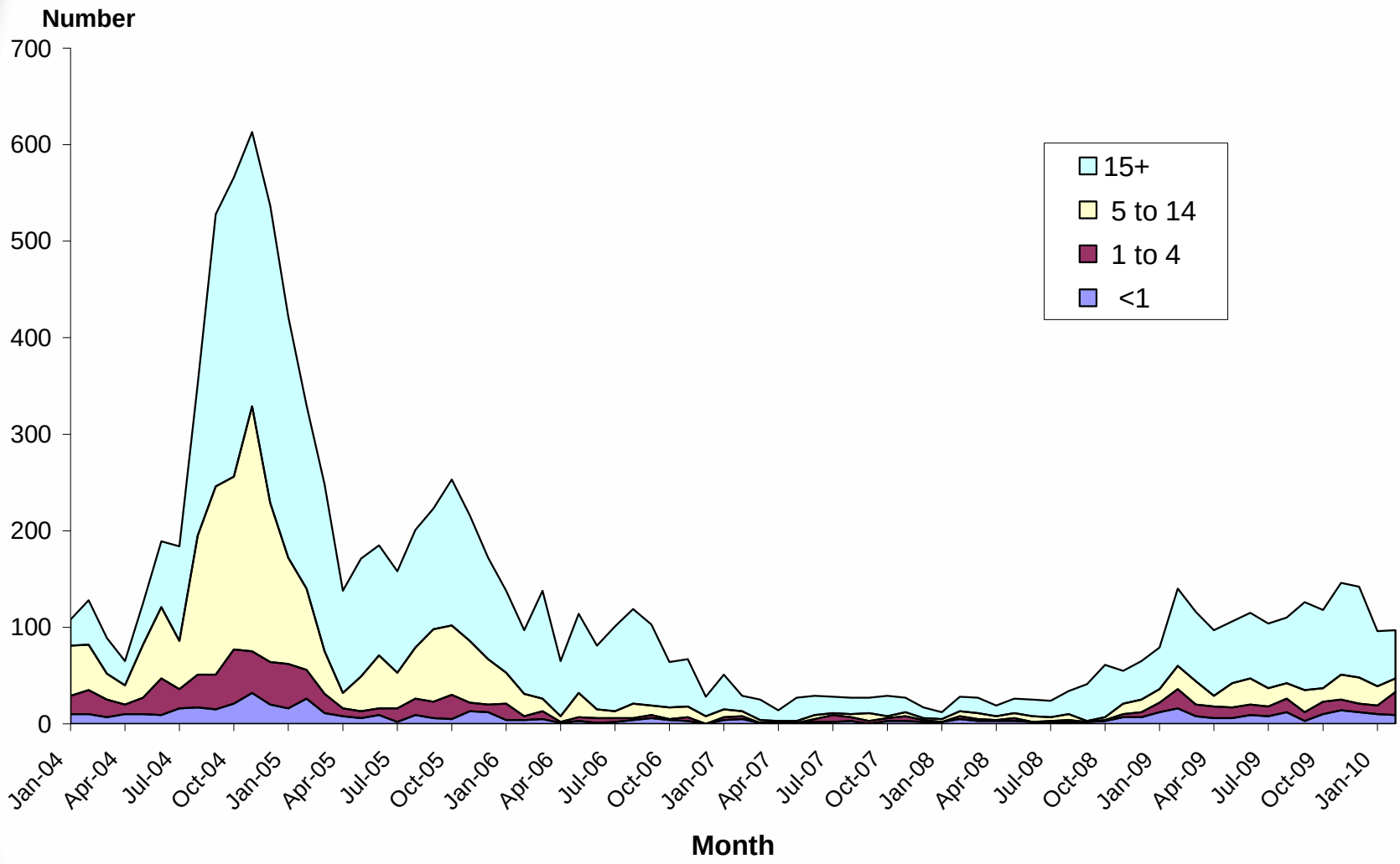
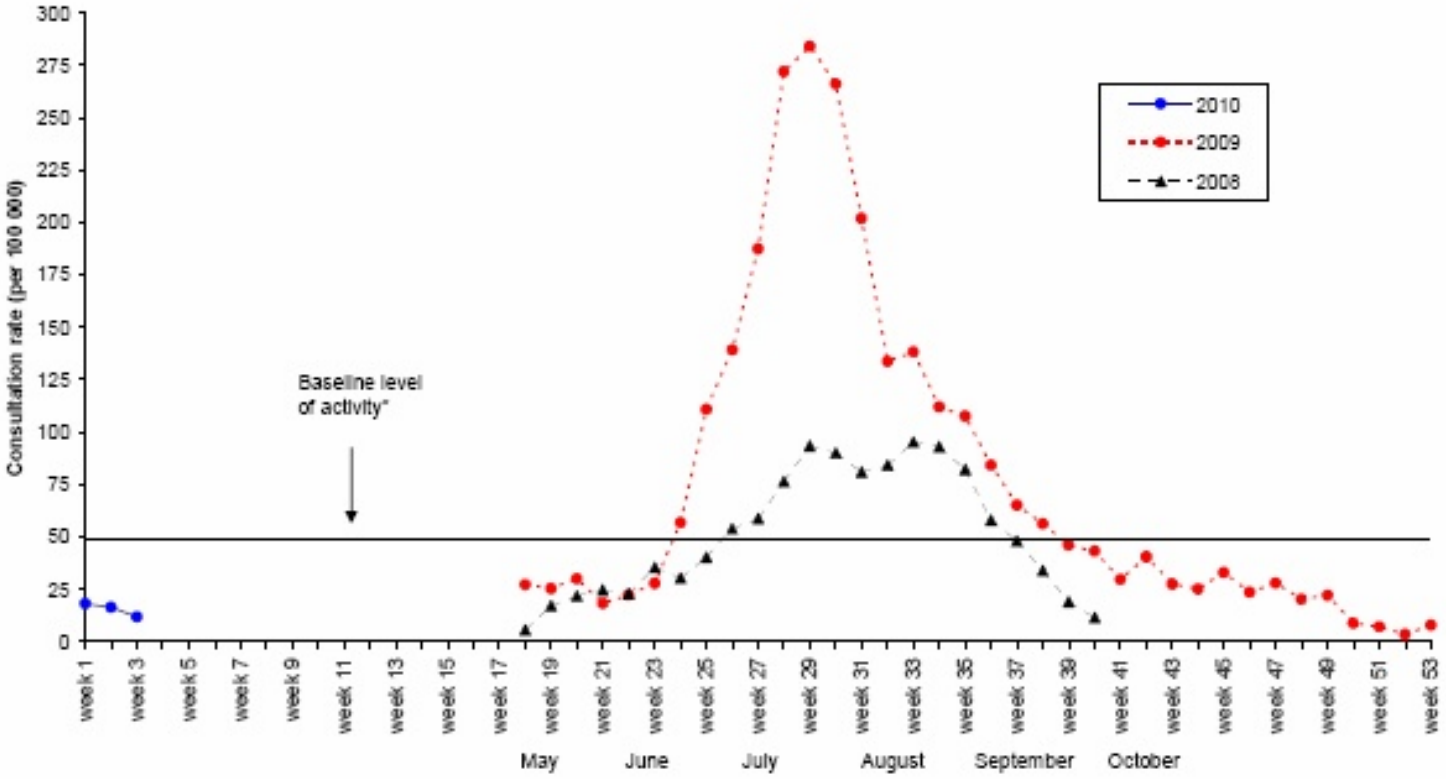


Figure 2: Weekly consultation rates for influenza-like illness in New Zealand, 2008, 2009 and 2010



66

The use of antipyretics

- **No place for routine use**
  - No evidence that antipyretics reduce febrile convulsions
  - Some evidence that antipyretics may blunt immune response

Ref: Prymula R et al Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-label, randomised controlled trials.Lancet. 2009 Oct 17;374(9698):1339-50.

- **It is not necessary to treat fever unless....**
  - For distress or pain
- **But always check for cause of fever...do not just assume it is vaccine related**

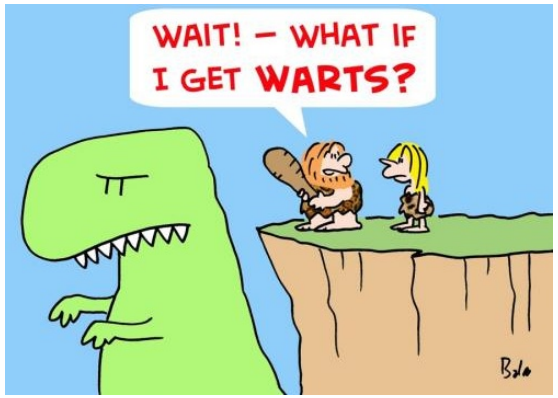
COOL NEW RESEARCH

Could flu vaccines with pandemic H1N1 increase the risk of Guillain-Barré syndrome (GBS)?

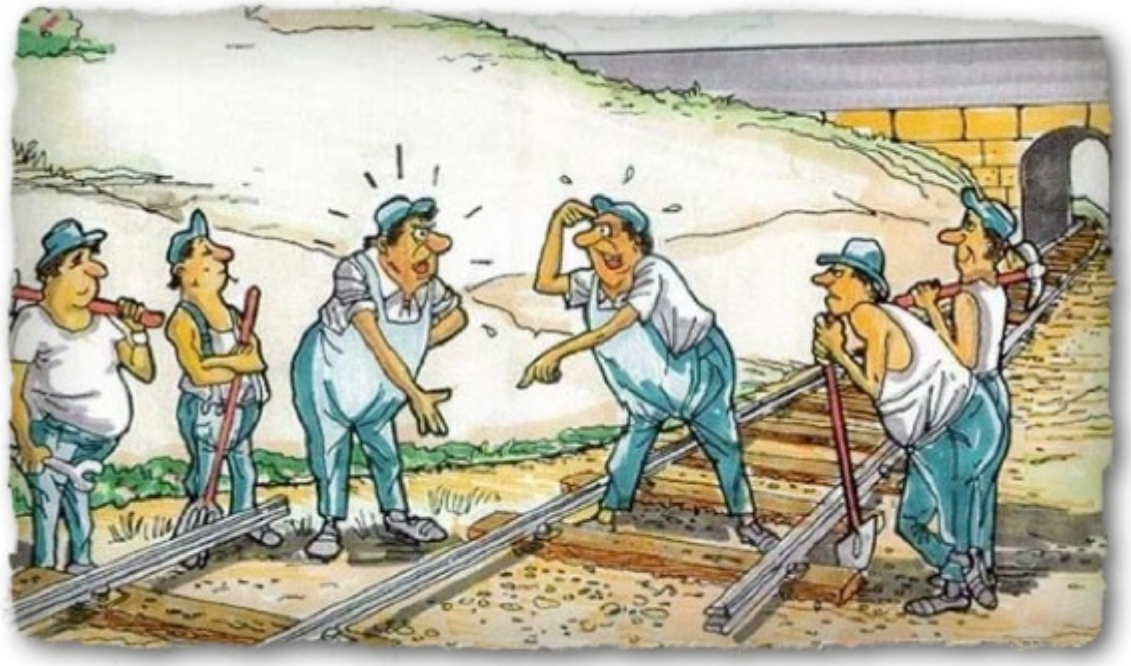
- **Unlikely, but rare so hard to estimate:**
- **Annual incidence 10 – 20 cases per million adults**
- **1970s a specific swine flu immunisation campaign in US observed increased rate to approx 1/100,000**
- **Epidemiological studies cannot show definitely increased link with seasonal flu vaccines**
- **Large UK study relative incidence of GBS:**
  - Within 90 days of vaccine no increase
  - within 90 days of flu-like illness 7 times higher rate

Stowe J et al Am J Epidemiol. 2009;169(3):382-8

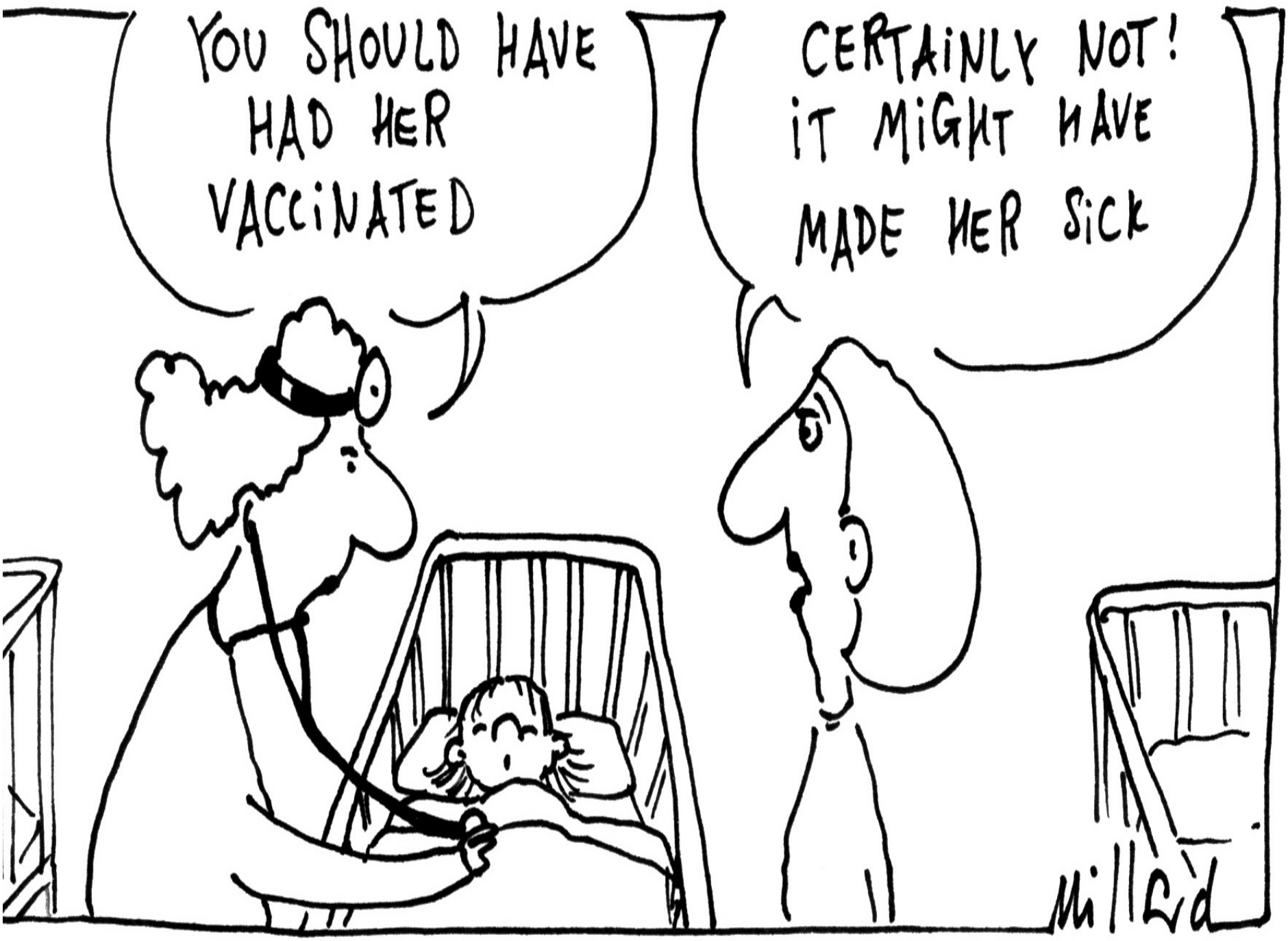
Reduction in Genital Warts



- **Melbourne – >50% reduction in genital warts in women <28 years since 2007 (Fairly C 2009)**
  - New Clients to the Melbourne Sexual Health Clinic 2004-2008
  - Genital warts diagnosed in 3826 (10.6%)
  - Decrease of 25% each quarter in women under 28 years during 2008
  - From 2004 – 2007 this had been increasing by 2% per quarter
  - Also 5% reduction in heterosexual men but not homosexual men or women older than 28 years.



COMMUNICATION CHALLENGES


YOU SHOULD HAVE HAD HER VACCINATED
CERTAINLY NOT! IT MIGHT HAVE MADE HER SICK
Millard

Communicating …….

"I do not believe in vaccines"

1st: open approach…… e.g.

- ***Have you got any specific concerns around vaccines you wish to discuss?***
- ***Would you like to talk further or receive further information***

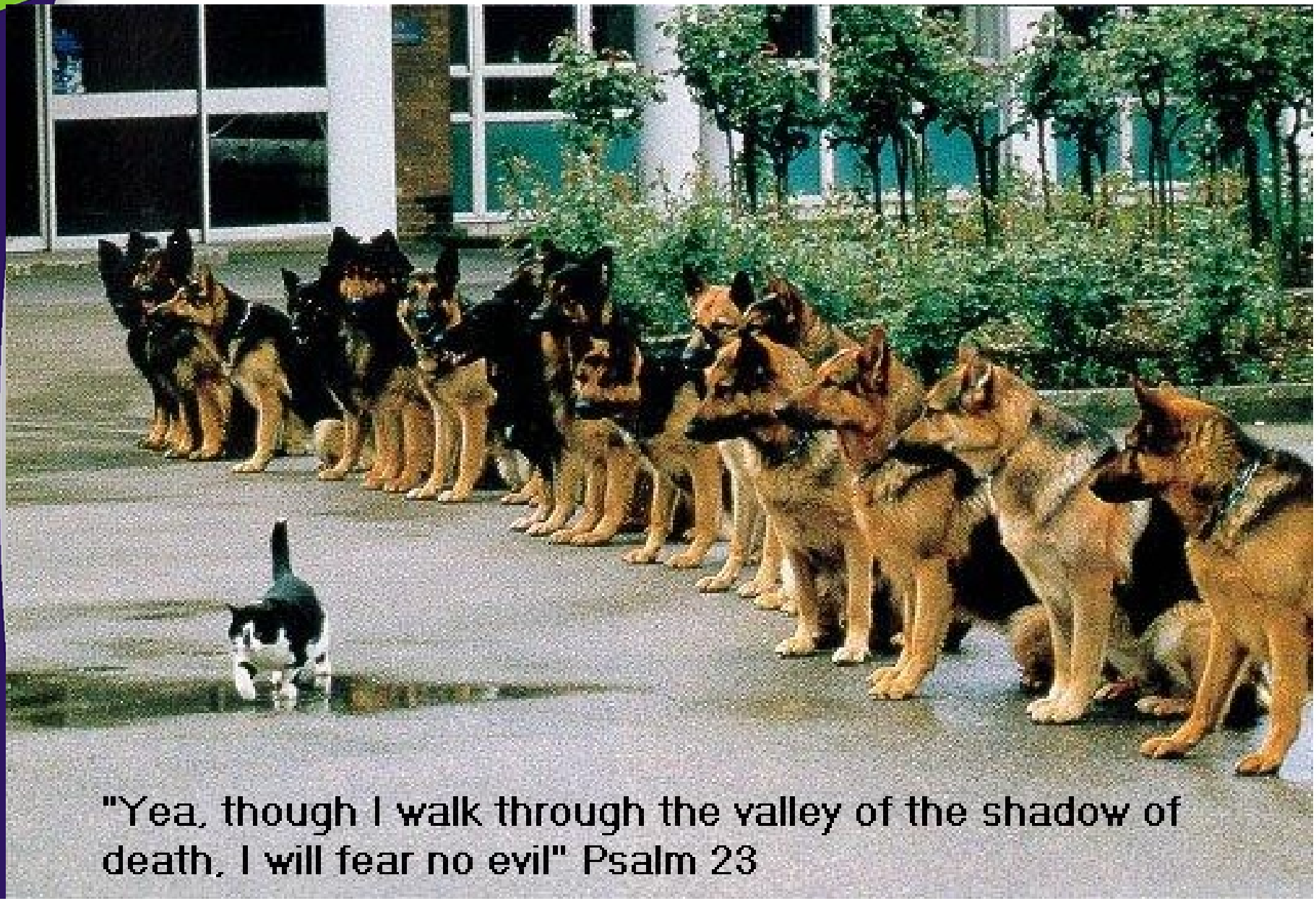
2nd if appropriate raise a bit of dissonance

- ***Do you have any concerns about any of these diseases***
- ***Are you aware XXX will need to show an immunisation certificate when they start preschool/school***
- **3rd if hitting a brick wall stop digging (precontemplator)**

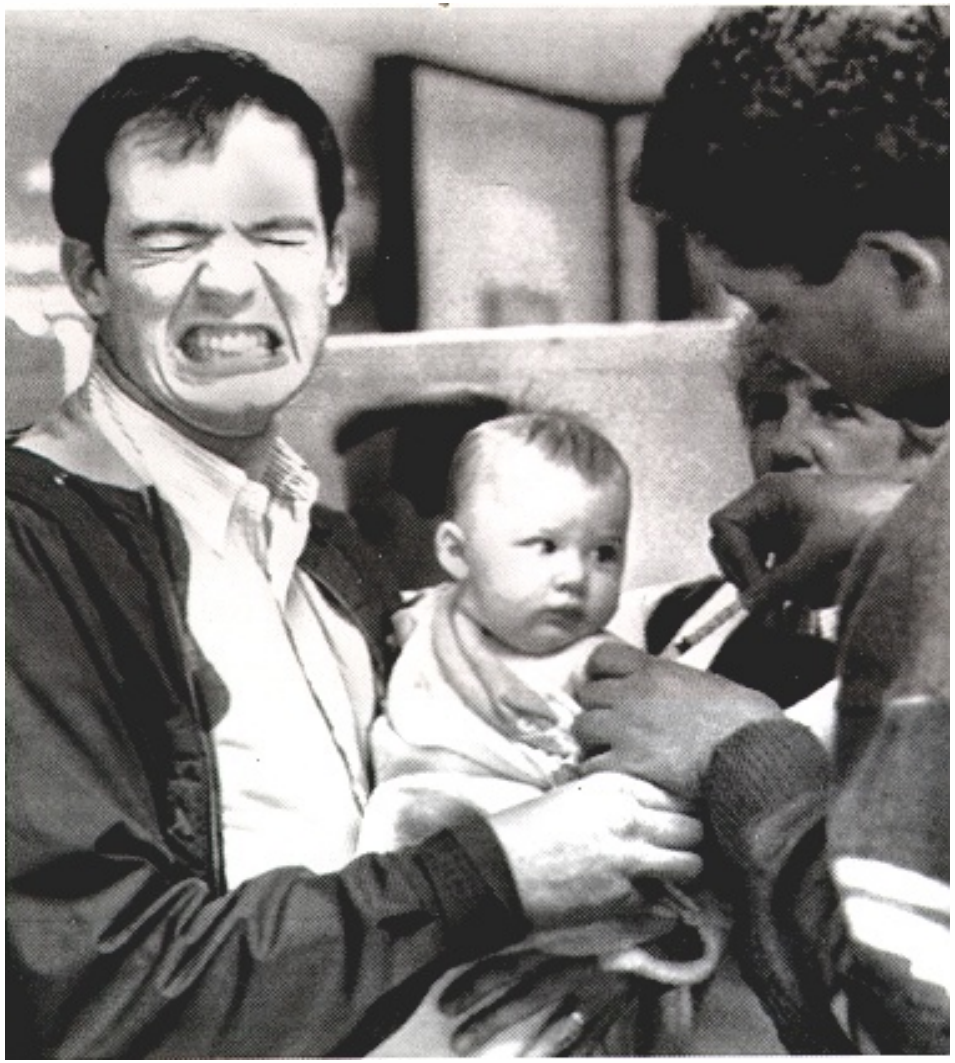
Key points

- **Good engaged relationship: <u>TRUST</u>**
- **Clear and confident in our professional advice**
- **Extra resources when needed**
  - 0800 IMMUNE
  - www.immune.org.nz

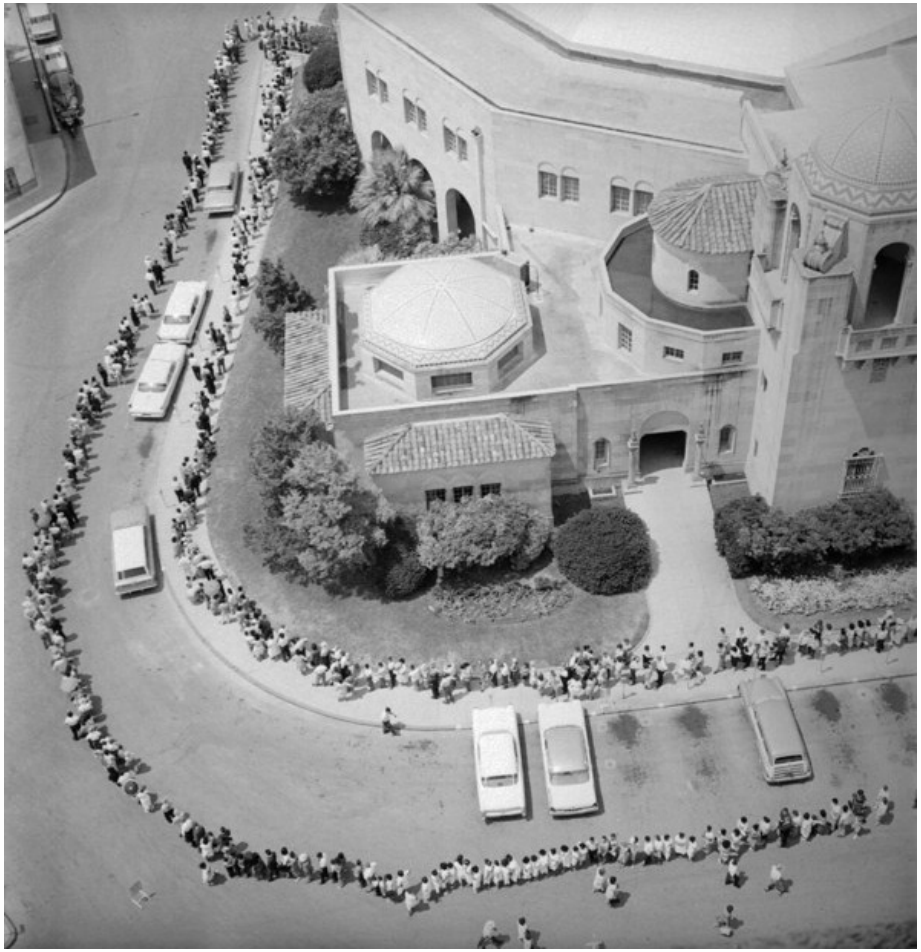
Attitude!


"Yea, though I walk through the valley of the shadow of death, I will fear no evil" Psalm 23

Or is it all a deep-rooted fear of needles!



Waiting for polio immunisation USA 1962

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PNEUMOCOCCAL CATCH UP SCHEDULE FOR CHILDREN BORN AFTER 1 JANUARY 2008

PNEUMOCOCCAL CATCH UP GUIDELINES:

1. No more than 1 dose needs to be given after 24 months of age
2. No more than 2 doses need to be given after 12 months of age
3. No more than 3 doses need to be given after 7 months of age
4. Doses in 1st year must be separated by at least 4 weeks
5. Last dose must always be at least 8 weeks after previous dose
6. For ***High Risk*** Pneumococcal catch ups refer to page 53 2008 National Immunisation Schedule Health Provider Booklet

Age Now	Previous Doses of PCV7	Catch up 1st dose	Catch up 2nd dose	Catch up 3rd dose
3-6 months	None	3 doses 4 weeks apart + 1 dose at 15 months		
7-11 months	None	Give now	4 weeks later	At 15 months of age[1]
	One (received before 7 months)	Give now	4 weeks later	At 15 months of age[1]
	One (received 7 months or later)	Give now	At 15 months of age[1]	-
	Two	Give now	At 15 months of age[1]	-
	Three	At 15 months of age	-	-
12-14 months	None	Give now	At 15 months of age[1]	-
	One	Give now	At 15 months of age[1]	-
	Two (first dose received before 7 months)	Give now	At 15 months of age[1]	-
	Two (first dose received 7 months or later)	At 15 months of age [1]	-	-
	Three	At 15 months of age [1]	-	-
15-23 months	None	Give now	8 weeks later	-
	One (received before 1st birthday)	Give now[1]	8 weeks later	-
	One (received after 1st birthday)	Give now[1]	-	
	Two (first dose received before 7 months)	Give now	8 weeks later	-
	Two (first dose received between 7-11 months)	Give now[1]	-	-
	Three	Give now[2]	-	-
24-59 months	None	Give now	-	-
	One (received before 2nd birthday)	Give now[1]	-	-
	One (received after 2nd birthday)	-	-	-
	Two (any doses received before 1st birthday)	Give now[1]	-	-
	Three	Give now[2]	-	-

[1] Final dose must be 8 weeks after previous dose

[2] Do not give if all 3 doses received after 7 months of age

Immunisation Advisory Centre
ARAINGA MATE
UNIVERSITY OF AUCKLAND

September 2009

RISK VERSUS BENEFIT
- EXAMPLES

Polio Vaccination – Risk vs Benefit

- **Risks from Polio**
  - 1/20 hospitalised
  - 1/100 paralysis (1/75 adults)
  - 2-10/100 fatalities from paralytic polio
  - Post Polio Syndrome

- **Severe Risks from IPV Vaccine**
  - None yet reported after 90 million doses

Efficacy of vaccine >90% after 2 doses

Tetanus vaccination - Risk vs. Benefits

- **Tetanus Disease**
  - Toxins cause painful muscle spasms and jawlock
  - Intensive hospital care needed
  - 1/10 patients die
  - Greater risk in very young and very old

- **Severe Risks from DTaP vaccines**
  - 0.5-1.0/100,000 may develop nerve inflammation in the arm
  - Anaphylaxis extremely rarely 1.6 per million. None in NZ to date

Efficacy of vaccine > 99%

Diphtheria vaccination - Risk vs. Benefits

- **Diphtheria Disease**
  - Toxin can lead to nerve paralysis and heart failure
  - 2-10/100 infected people die

- **Severe Risks from DTaP vaccines**
  - 0.5-1.0/100,000 may develop nerve inflammation in the arm
  - Anaphylaxis extremely rarely

Efficacy of vaccine – about 87-98%

Whooping Cough vaccination – Risks vs. Benefits

- **Risks from Whooping Cough**
  - Cough can last up to 3 months
  - Can lead to pneumonia
  - Brain damage
  - Convulsions
  - Death

- **Severe Risks from aPertussis vaccine**
  - Persistent screaming 44/100,000
  - 7/100,000 seizures
  - Anaphylaxis extremely rarely

Efficacy of vaccine : 84-92%,
- 5-10 years protection

Measles Mumps and Rubella vaccination – Risks vs. Benefits

- **Risks from Measles Disease**
  - 1/10 cases get pneumonia, ear infection or diarrhoea
  - 1/1000 cases get encephalitis, often with brain damage
  - 1/1000 death
  - 1-4/100,000 get subacute sclerosing panenchephalitis several years later – destroys brain - death

- **Severe Risks from MMR vaccine**
  - 1/3000 febrile seizures
  - 1/30,000 Low platelets causing bruising lasting a few weeks
  - 1/million encephalitis
  - <1/100,000 aseptic meningitis

Efficacy of vaccine: 90-95%

Hepatitis B Vaccination – Risks vs. Benefits

- **Risks from hepatitis B**
  - Severe illness rare in children but 1/6 chance of becoming carriers. Babies risk is higher
  - 1/20 carriers develop liver cirrhosis, half die
  - 1/10 male and 1/20 female carriers develop liver cancer - death

- **Severe risks from Hepatitis B vaccine**
  - Anaphylaxis – extremely rare

Efficacy of vaccine: 85-95%
- 95% in younger people

Hib Vaccination – Risks vs. Benefits

- **Severe risks with Hib disease**
  - 1/20 with meningitis dies
  - 1/3 brain damage
  - 1/100 with epiglottitis dies

- **Severe risks of vaccine**
  - None reported
  - Anaphylaxis possible but extremely rare