

Ethics Perspective of Immunisation Programs

with special reference to
Herd Effect

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Defining Herd immunity and Herd effect. Between “participants” and “nonparticipants”

- **Herd immunity** = proportion immune in a herd. Also Called population immunity or community immunity [Actually immunity prevalence, natural / vaccine-induced]
- **Herd effect** = perturbation of epidemiology among the nonparticipants [only for anthoponoses. in case of vaccinations, affected by VE and VC; affected by “force of transmission” of agent]
- Vaccination, DOTS*, bednets etc have **herd effect**
[sanitation, vector control → no participants, no herd effect]

*threshold defined, ethics ignored

Why does State conduct vaccination program?

- [In healthcare vaccinations: medical ethics apply]
- In public health: Program to establish & sustain high herd immunity + herd effect → for **disease control**
- **Epidemiology** (of target diseases) and **Economics** (cost vs benefit etc) applied
- How about **Ethics**? (since benefits & risks involved)
[ethics related to vaccine adverse events not included]

Recent look at ethics and vaccination programmes

- Nuffield Council on Bioethics report: “Public Health: Ethical Issues” (November 2007)
- Disease control (Collective interest): equity of benefits
- Benefits & risks in relation to not only ‘oneself’ but also in relation to ‘others’: so, ethics is involved
- <http://www.nuffieldbioethics.org/go/ourwork/publichealth/introduction>

Nuffield Council Report: on Immunisation Programme

- Choice in self-interest: voluntary (influenced by IEC)
- Coercive: Quasi-mandatory / incentivised – school entry requirement; payment to vaccine-givers; using “Harm principle” = State can act to protect others
- Selective risk; non-selective program (rubella; HPV)
- Vaccinated take risks if any; Vaccine damage payment scheme of UK (and in many other countries)
- Unvaccinated enjoy benefit of herd effect -- equity
No vaccination → unintentional / free-riders

The gap: ethics of herd effect

- Most believe herd effect is always beneficial
- Herd effect can be harmful: ethics must apply
- Herd effect of OPV → **good, bad and ugly**
- Herd effect of rubella, Hep A, varicella vaccinations
- Surrogate approach: mother & infant
- Herd effect of flu vaccination: intention vs effect
- Risk from DTP without polio protection & ethics

Outbreak of Congenital Rubella Syndrome:

Introduction of Immunization in Greece

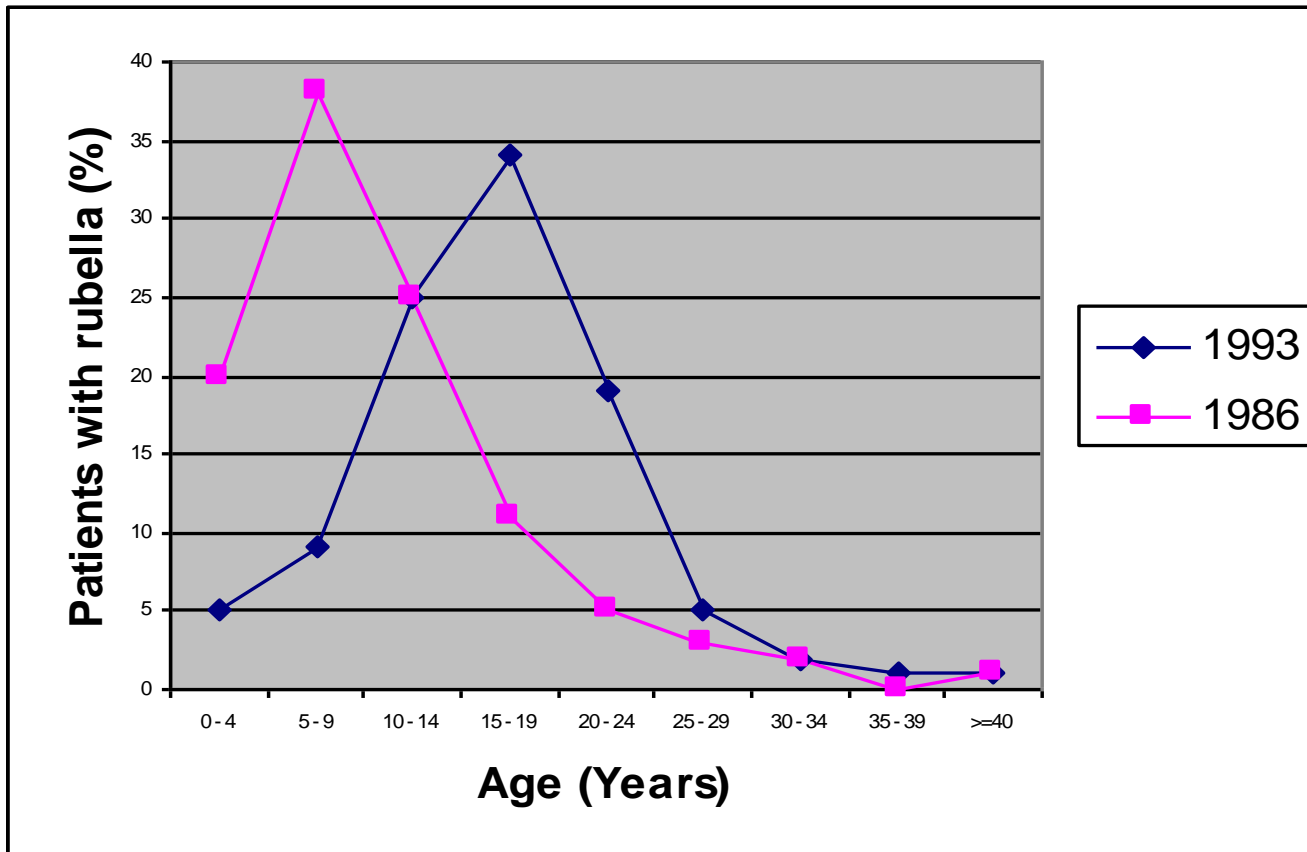
- Introduction of MMR in 1975
- Immunization coverage ~50-60% among boys and girls aged 1 yr

Panagiotopoulos T, et al. BMJ 1999; 319: 1462-67

Outbreak of Congenital Rubella Syndrome:

- Proportion of susceptible women kept on increasing
- Incidence of CRS highest in 1993
- Implication:
 - Shifting epidemiology and susceptible population
 - More harm than good
 - Importance of high coverage at the time introduction

Panagiotopoulos T, et al. BMJ 1999; 319: 1462-67



Age distribution of patients with rubella attending outpatient departments of general hospital in greater Athens, 1986 and 1993. source: Panagiotopoulos et al 1996

Inadequate Vaccination for Rubella & Epidemiological shift

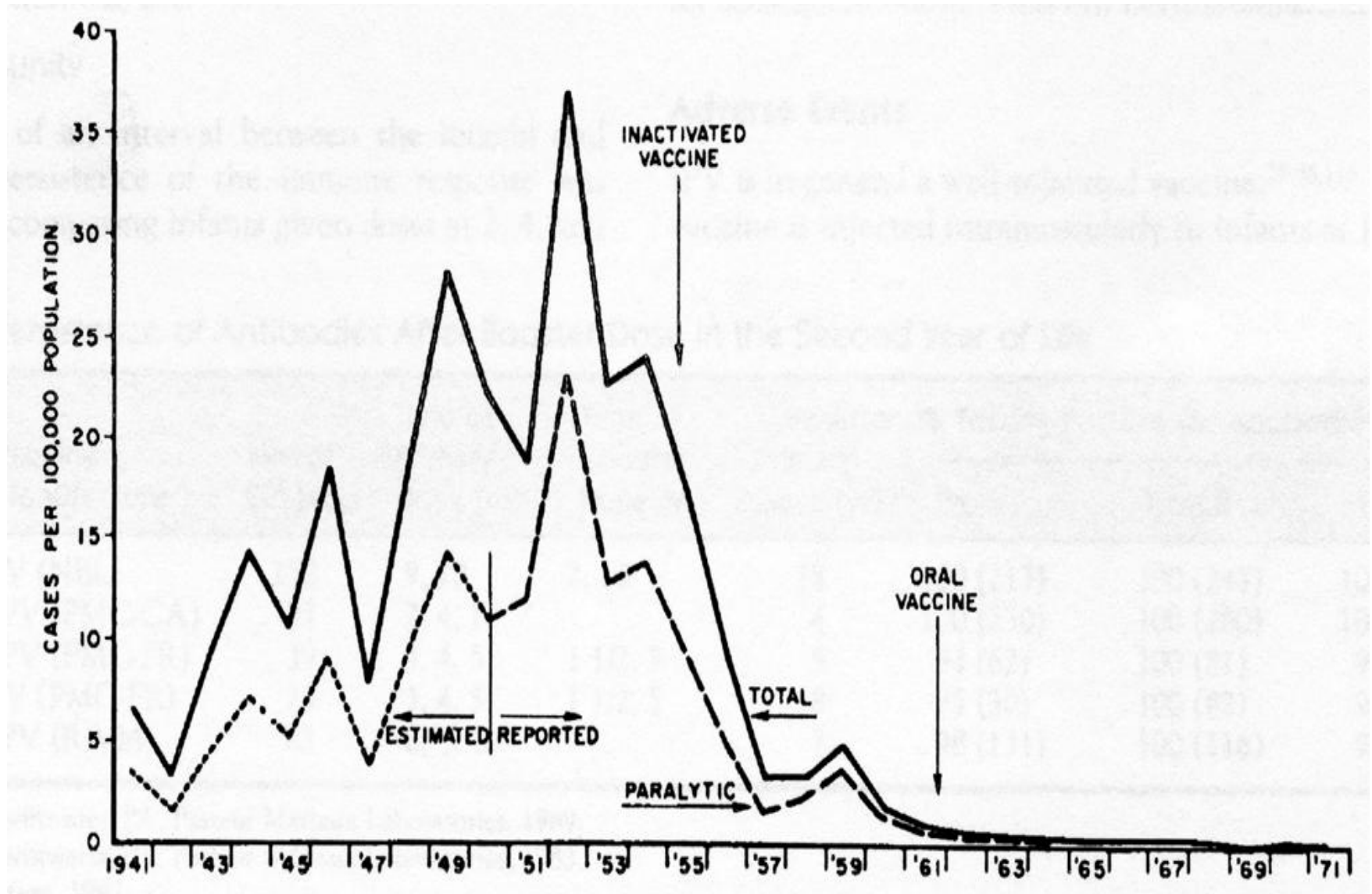
- Introduction of Rubella vaccination in Rio Brabco, Brazil in 2000
 - Target population 1-11 yr olds
- Incidence of confirmed rubella among 12-19 yrs old (3.3/1000 pop) increased 3.7 fold relative to children aged 1–4 yrs within one year

Ref: Lanzieri TM et al. *Pediatr Infect Dis J.* 2003; 22(4): 323-29

What is herd effect of OPV?

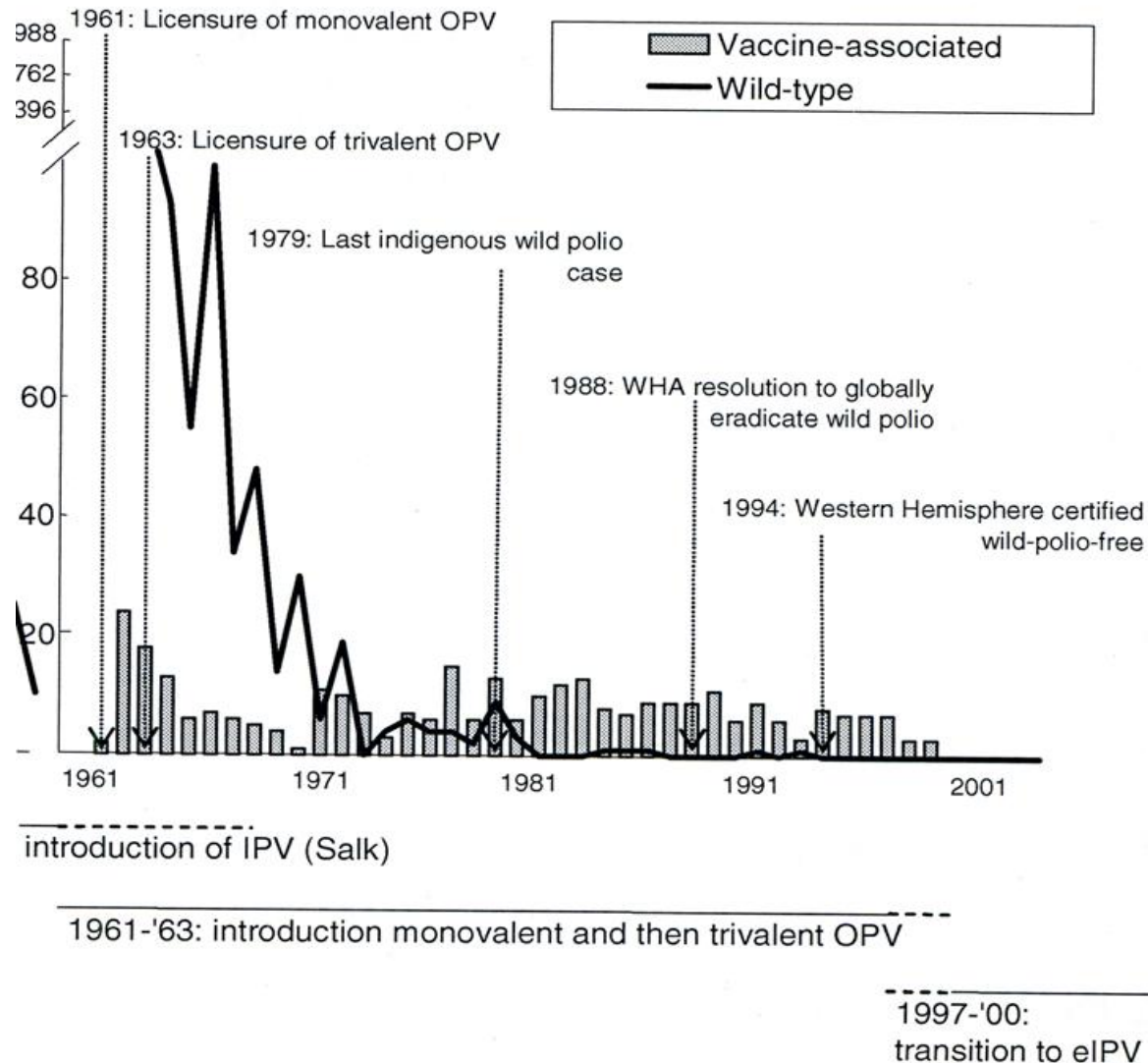
- Incidence-reduction in unvaccinated (not simple)
- Contact-infection → immunity, also risk of VAPP
- ~10 VAPP/yr in USA, >1 mn \$ compensation
- 1 VAPP/500,000 counted “acceptable” risk (by who?)
- ~1 in UK, ~50 in S. America, >100 in India not compensated
- Contact infection → circulation, VDPV, cVDPV
- Risk-benefit of OPV vs WPV excellent
- Risk-benefit of IPV vs OPV not asked (now too late)

Polio and polio vaccination, USA

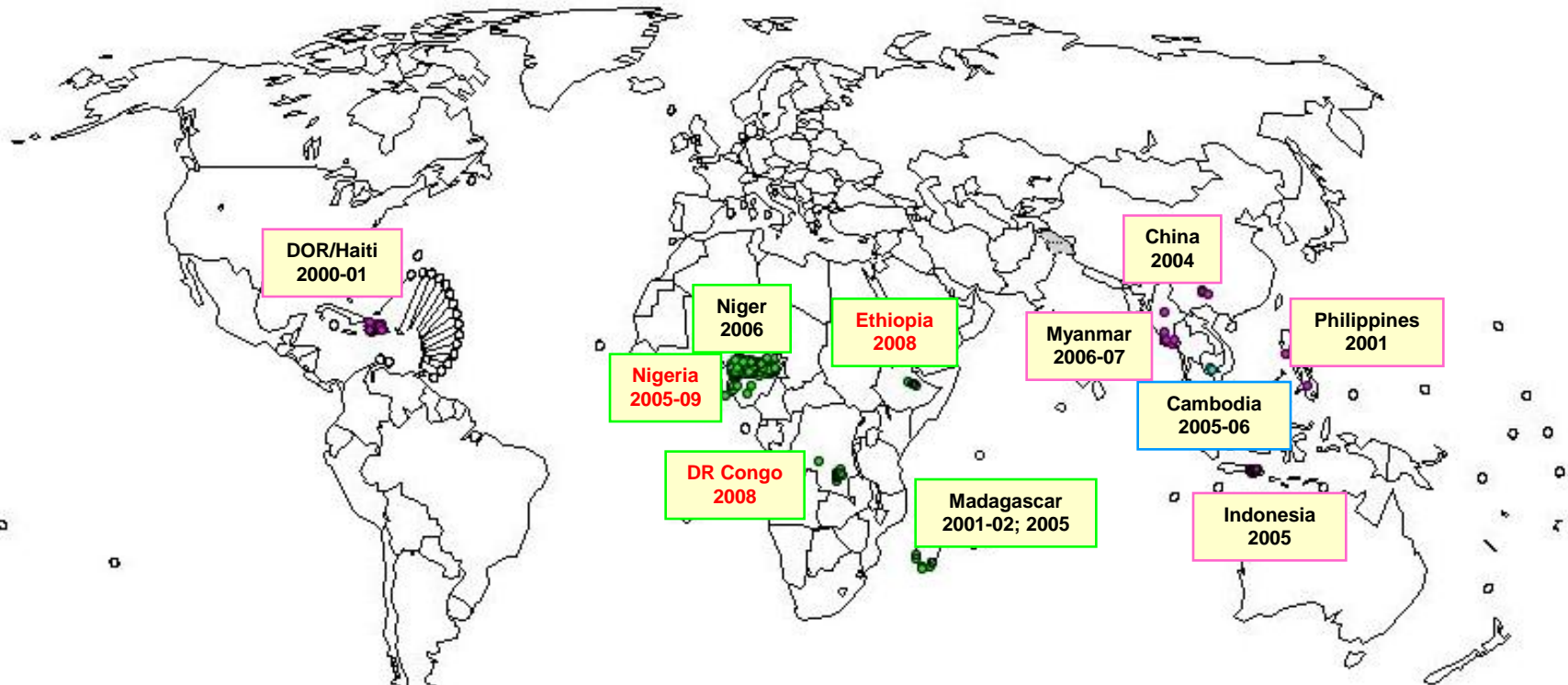


USA identified vaccine-induced polio in 1962 (24 cases) [Cutter incident (1955) had led to careful surveillance]

[from Kimberly Thompson]



Circulating Vaccine-derived Polioviruses*, 2000-09



Country	Type	cVDPV										First case	Last case
		2000	2001	2002	2003	2004	2005	2006	2007	2008	2009		
Nigeria	VDPV 2						1	21	68	62	71	2-Jul-05	26-Apr-09
Ethiopia	VDPV 2									3	1	4-Oct-08	16-Feb-09
DR Congo	VDPV 2									14		22-Mar-08	15-Dec-08
Myanmar	VDPV 1							1	4			9-Apr-06	6-Dec-07
Niger***	VDPV 2							2				28-May-06	3-Oct-06
Cambodia	VDPV 3						1	1				26-Nov-05	15-Jan-06
Indonesia	VDPV 1										46	9-Jun-05	26-Oct-05
Madagascar**	VDPV 2		1	4							3		13-Jul-05
China	VDPV 1					2						13-Jun-04	11-Nov-04
Philippines	VDPV 1		3									15-Mar-01	26-Jul-01
DOR/Haiti	VDPV 1	12	9									12-Jul-00	12-Jul-01

5 outbreaks with cVDPV1
6 outbreaks with cVDPV2
1 outbreak with cVDPV3

- cVDPV type 1 (77 cases)
- cVDPV type 2 (251 cases)
- cVDPV type 3 (2 cases)

** Madagascar: two different outbreaks (2001/02 and 2005)
*** Niger cVDPVs are linked to the Nigeria outbreak

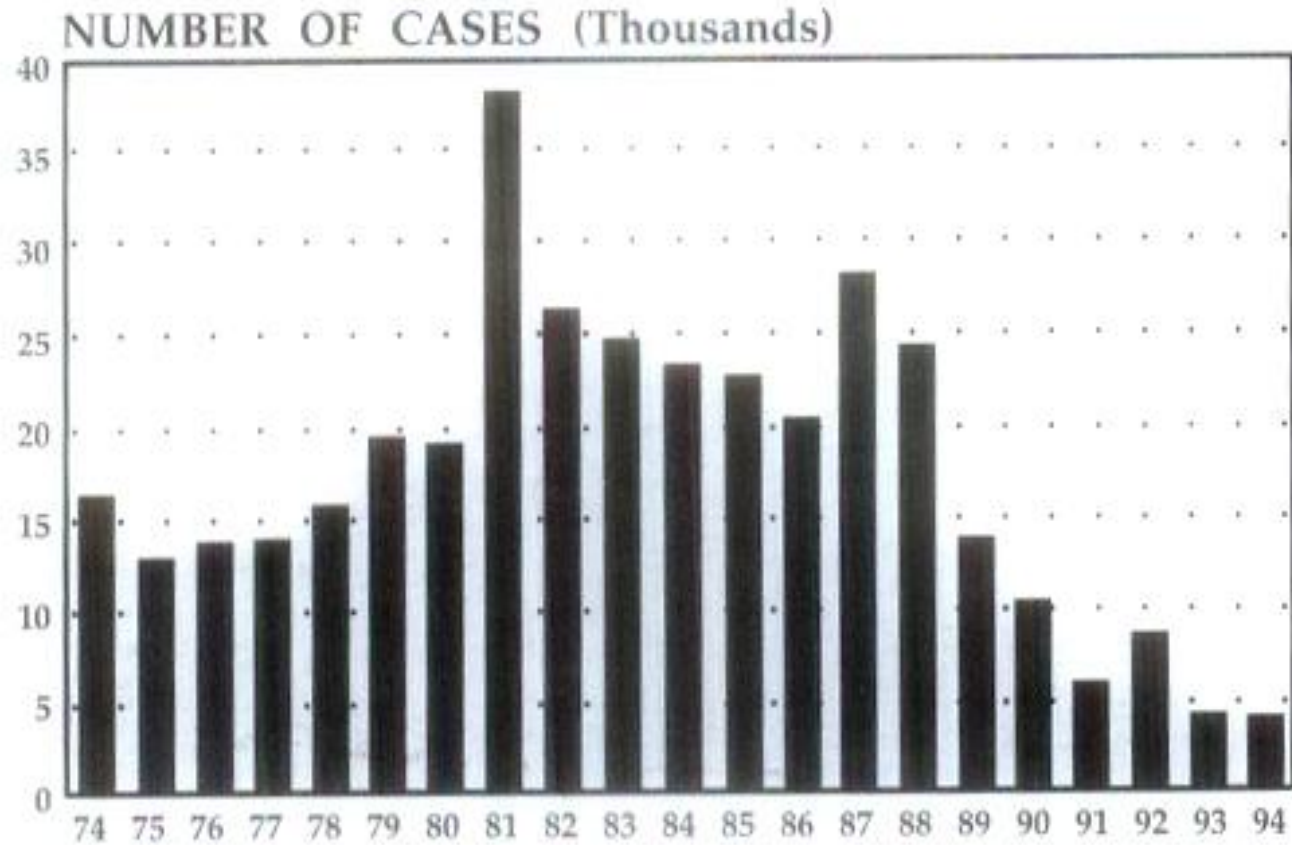
* circulating Vaccine-derived poliovirus (cVDPV) is associated with 2 or more cases of AFP

Complexity of ethics of OPV

- Can you be sure that the one with VAPP was destined to have WPV polio ?
- High risk of VAPP in immunodeficient
- Risk of chronic infection also
- How much harm is acceptable?
- Business consequences: Volume of IPV demand & production decreased and price increased (out of hand)
- Competition (developing country manufacture) disallowed

Polio, sentinel surveillance data, India

EPI 1977-78 (BCG, DTP); OPV 1979-80; MV 1985-90



An epidemic of provocation polio?

	<u>DTP doses</u>	<u>OPV doses</u>
1978-79	27 million	0
1979-80	24 million	500,000
1980-81	24 million	1.3 million
1981-82	29 million	2.3 million

Good intentions do not always result in good outcomes.

John TJ. Did India have the world's largest outbreak of poliomyelitis associated with injections of adjuvanted DPT? Indian Pediatr 1998; 35: 73

Lesson 1

- While healthcare interventions are guided by well-recognised ethical principles, public health interventions are not always well-grounded in ethics
- Therefore there is need to explore and expound ethical issues related to public health interventions (eg. immunisation)

Lesson 2

- In democratic USA, ‘social contract’ and ‘utilitarian’ principles were applied to restrict freedom of choice (collectivism in free market society?)
- The missing element was Ethics
- France allowed choice, truly libertarian
- Ultimately both ended up using only IPV, but for LI countries, “put on tree, ladder removed”
- **Ethical principles have to balance liberties of citizens and authority of State**

Lesson 3

- Ethical choice may be more expensive
- Cost does not necessarily overrule ethics
- If people take the risks, they should know
- ‘Risk-communication’ is often biased or inadequate in many situations providing opportunity for anti-vaccine activists

Lesson 4

- Adverse reactions to therapeutics and vaccines are monitored in healthcare, but adverse impact of public health interventions are not well-studied, especially in those not directly targeted
- **The impact of every public health intervention must be monitored by design and this element is to be included in immunisation programs**

Thank You