

# Ethics and Immunisation

Dr Brenda Corcoran  
HSE National Immunisation Office

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Faculty of Public Health Medicine  
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[www.immunisation.ie](http://www.immunisation.ie)

# Overview

- Background
- Vaccine trials
- Equity of access
- Immunisation policy
- Autonomy and mandatory immunisation
- Communication
- Vaccine Damage Scheme



# History of vaccine development

Smallpox	1798
Rabies	1885
Typhoid	1896
Cholera	1896
Plague	1897
Diphtheria	1923
Pertussis	1923
BCG	1927
Tetanus	1927
Yellow fever	1935
Influenza	1936
IPV	1955
Oral polio	1962
Measles	1964
Mumps	1967
Rubella	1970
Hepatitis B	1981
Men C	1999
PCV	1999
HPV	2006
H1N1	2009



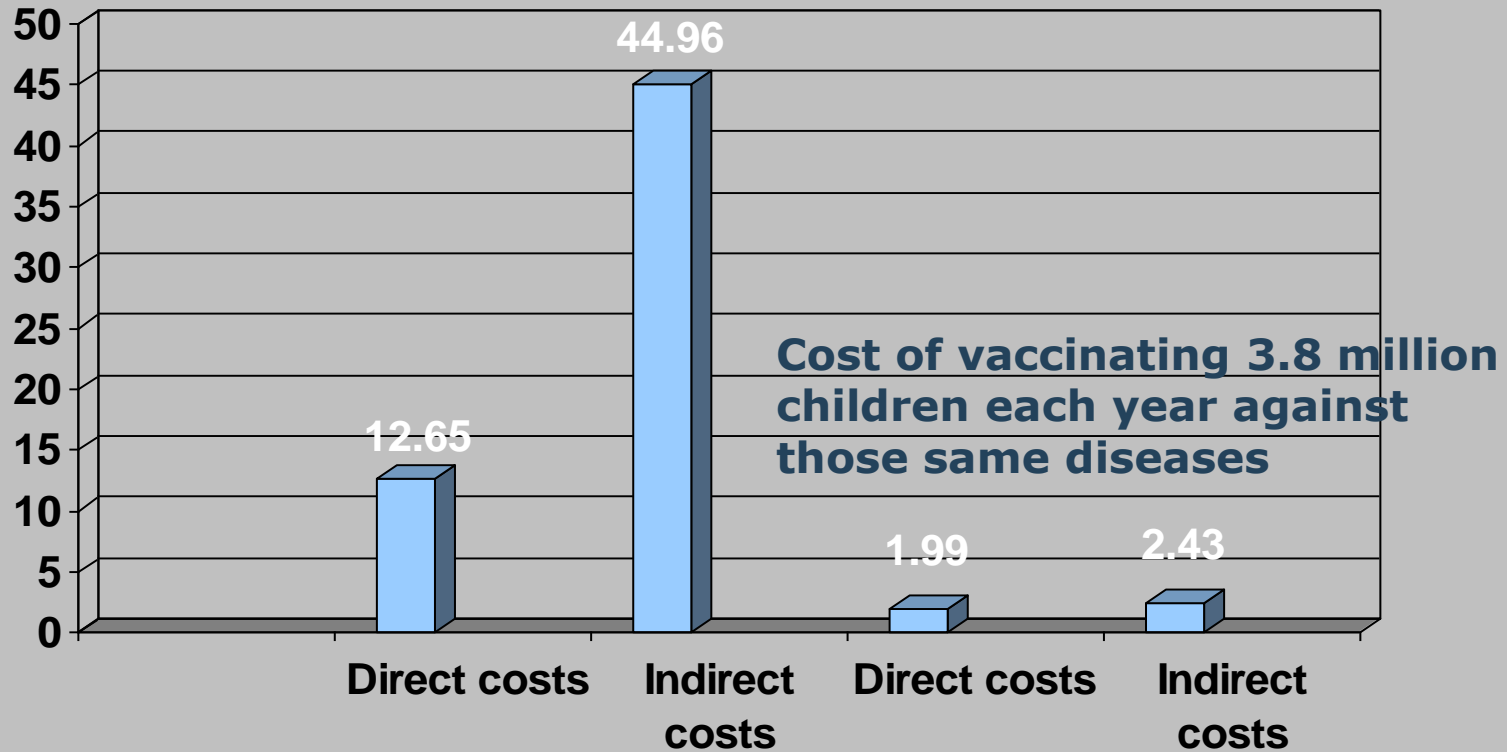
## Average USA Annual Morbidity Due to Vaccine Preventable Diseases in the 20th Century compared with Morbidity in 2004 (for pre-1990 vaccines)

Disease	Morbidity		Percentage decrease in number of deaths
	Average number of cases per year in 20 <sup>th</sup> century	Number of cases in 2004	
Smallpox	48,164	0	100
Diphtheria	175,885	0	100
Polio	16,316	0	100
Measles	503,282	37	99.99
Rubella	47,745	12	99.97
Mumps	152,209	236	99.84
Tetanus	1314	26	98.02
Pertussis	147,271	18,957	87.13



# Economic benefits of immunisation

**Cost of treating more than 10 million cases of various diseases annually**



Infectious Diseases in Children, August 2003, p.19,

[www.immunisation.ie](http://www.immunisation.ie)



# Immunisation programmes in Ireland

- Universal
  - primary childhood
  - schools
  - seasonal influenza
- Targeted
  - at risk groups



# National Immunisation Advisory Committee

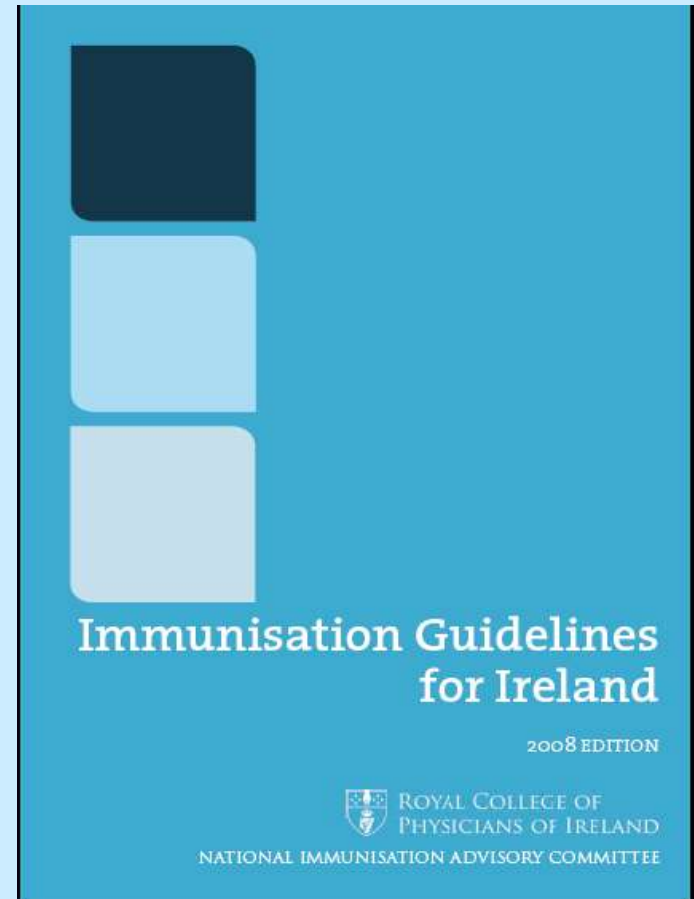
An independent advisory committee of the Royal College of Physicians of Ireland

Comprised of experts in the fields of paediatrics, infectious diseases, general practice, public health, occupational health and nursing

Produces the National Immunisation Guidelines for Ireland

Advises the Department of Health and Children on immunisation policy.

Declaration of interests



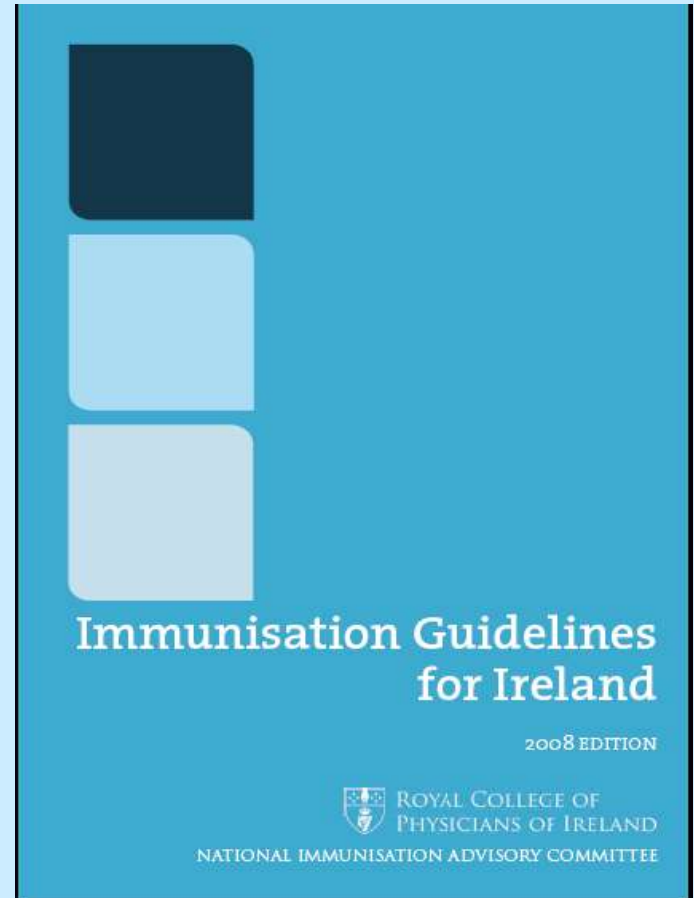
# National Immunisation Advisory Committee

Review process for introduction of new vaccine

Severity of disease and potential harm to individual

Vaccine efficacy in preventing disease/ herd immunity

Adverse events following vaccination



# Vaccine Funding

NIAC Pharmacoeconomics assessments

- Hepatitis B
- Pneumococcal
- HPV
- Rotavirus



Tensions between cost effectiveness and beneficence

# Why does immunisation raise so many ethical issues?

All the fundamental ethical principles

*Beneficence:*

Are vaccines good for patients?

*Distributive justice:*

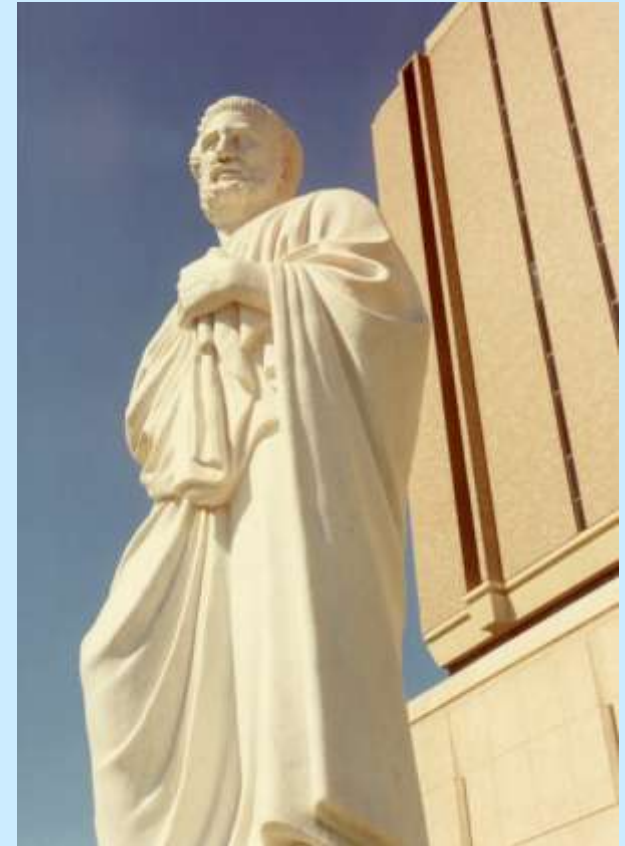
Are they affordable and available to everyone?

*Autonomy:*

Compulsory vs voluntary vaccination.

*Non-Maleficence:*

Are vaccines safe?



“Primum non nocere”



# Vaccine Development

Very few companies in vaccine development and manufacture

Profit driven

Producing a safe and effective vaccine

- 12-15 years of research
- costs estimated between \$500 million - \$1 billion.

Need to take into account different strains

Should be simultaneous in developed and developing countries

Examples:            Men B vaccine in New Zealand - strain specific  
                          Rotavirus

- » Deaths/year
- » US 20, Worldwide 600,000
- » 1998 vaccine developed
- » 1999 Withdrawn in US and clinical trials stopped in developing countries

Public private partnerships



[www.immunisation.ie](http://www.immunisation.ie)



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

# Vaccine trials

Helsinki declaration

Council of international organizations of medical sciences (CIOMS) international ethical guidelines

Differing stakeholder views

- Trial participants
- Research sponsors
- Researchers
- Local health service budget holders



[www.immunisation.ie](http://www.immunisation.ie)

# Issues in vaccine trials

## *1. HIV Anti retroviral treatment and a clinical care package*

To whom?            Participants  
                         Those who are excluded as they test HIV +  
                         Family members/sexual contacts  
                         Other members of the community

For how long?

## *2. Treatment of HIV in non HIV vaccine trials - malaria/TB/ cholera*

Type of care offered may depend

- on phase of trial
- nature, duration and severity of disease

More difficult in

- chronic (Hepatitis C, HIV, HPV) vs acute conditions (malaria)
- resource poor countries

**Essential to have good research governance**



[www.immunisation.ie](http://www.immunisation.ie)

# Equity of access

24 million children under the age of 1 year did not receive DTP3 in 2008



Photo: Courtesy of CDC

GAVI has supported

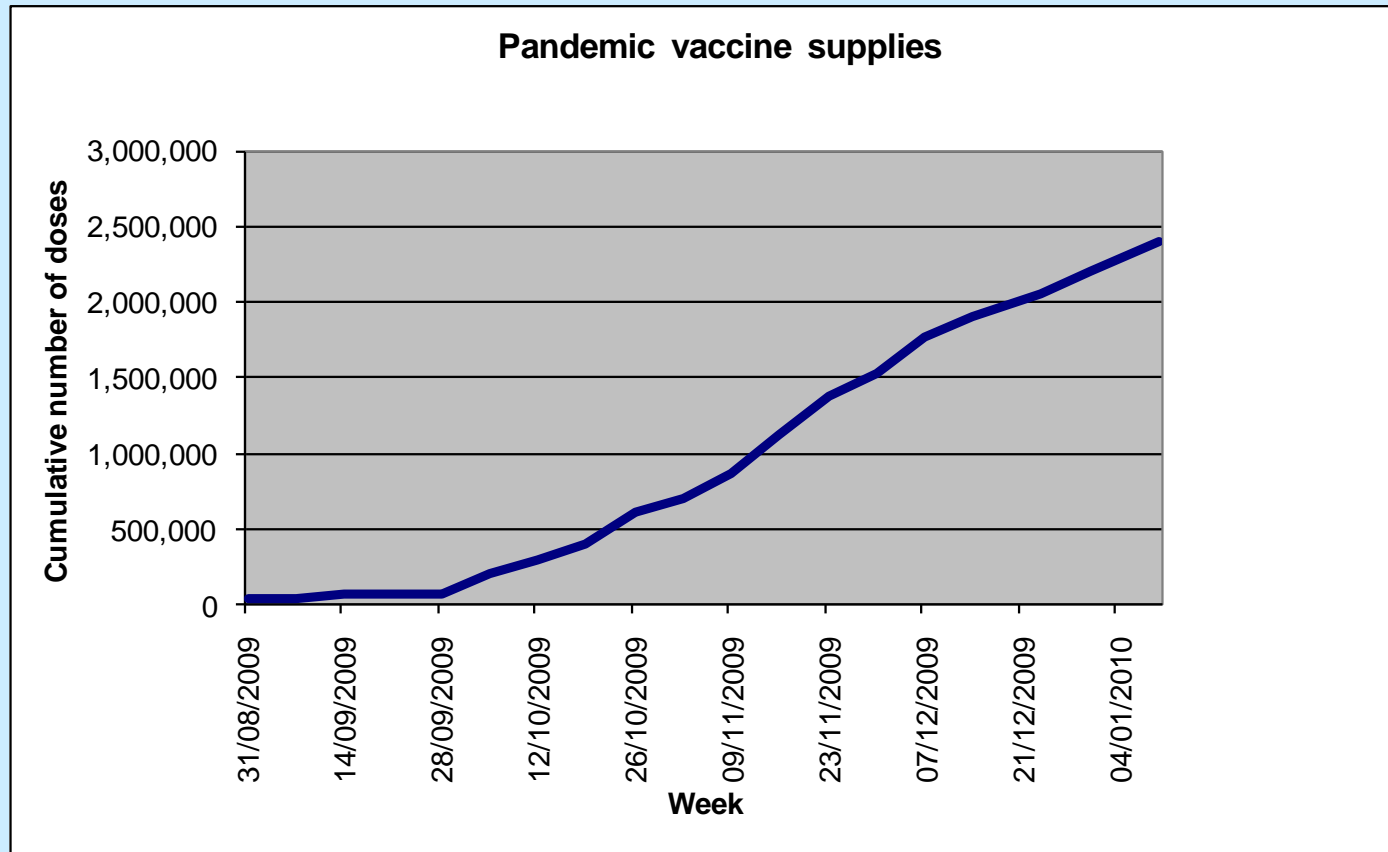
- 67 countries to introduce hepatitis B vaccines
- 61 countries have introduced Hib vaccines
- more than 257 million children immunised
- over 300 million children by 2010.



# Equity of access

Vaccine shortages

Limited supply of H1N1 (2009) pandemic vaccine

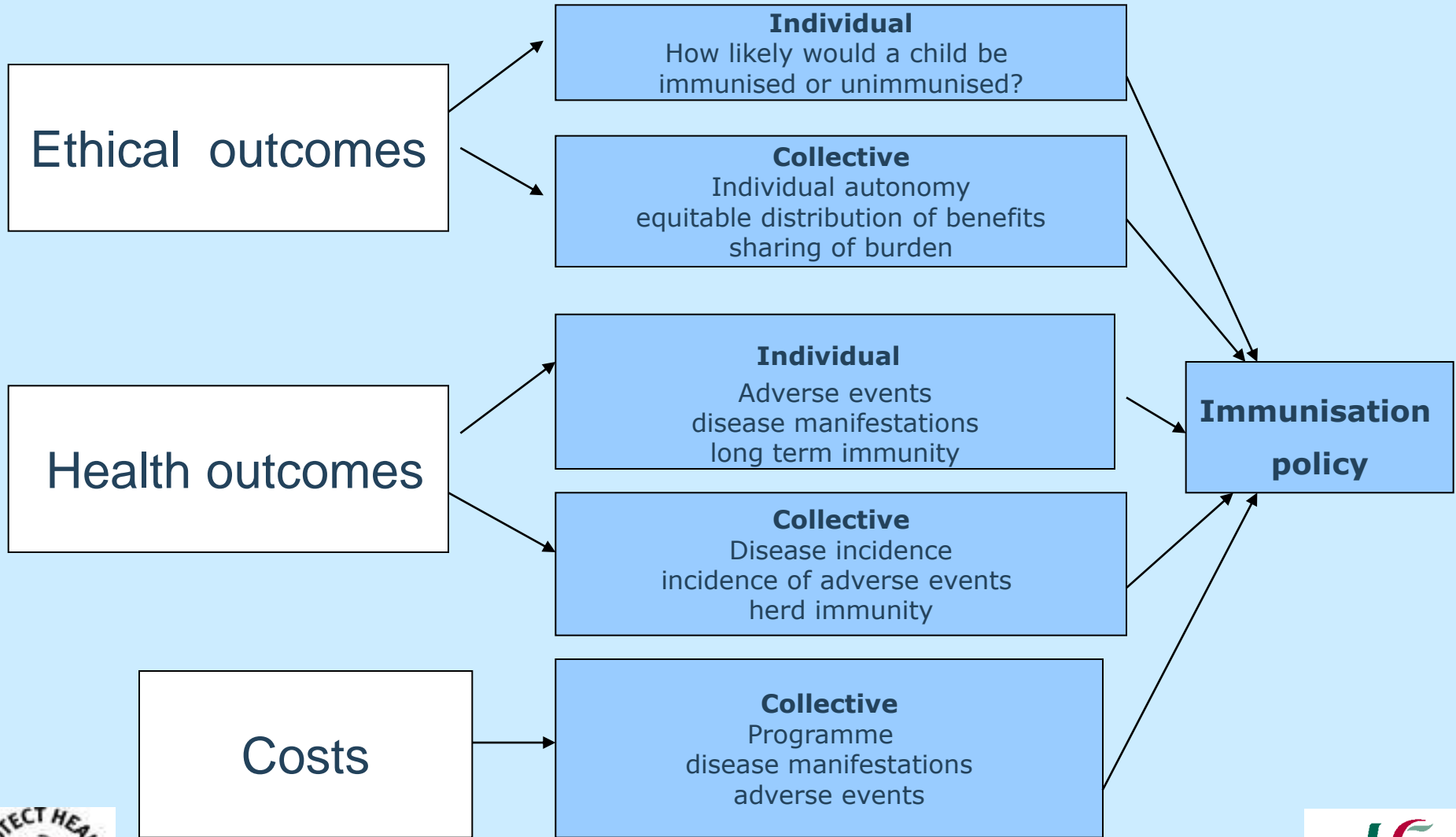


# Objectives of immunisation policy

- Minimise consequences of disease
- Minimise consequences of vaccine
- Optimise personal liberty to choose or refuse immunisation
- Maximise just benefits and burdens across society
- Promote duty of families to protect their child
- Promote long term duty of society to protect all children now and in the future
- Use limited health resources prudently



# Considerations



# Policy options

## Optional policy requiring payment

- Children left unimmunised due to financial reasons
- Programme failed ethically
- Benefits not distributed equitably
- Raised risk of disease to society

## Mandatory policy

- Lower individual risk of disease
- Share burdens of herd immunity
- Violate family's autonomy
- Place children at risk of an adverse event



# Mandatory vaccination

Vaccines are not immediately life saving (rabies vaccine)

Violates parents rights

Compulsion for vaccines which do not induce herd immunity

USA, Australia, Belgium, France, Italy, Croatia, Poland, Taiwan

Linked to

- child care benefits
- school entry



## Parents are sentenced to prison for not vaccinating children (February 2008)

“Two sets of parents in Belgium who refused to have their children vaccinated against polio, which is compulsory under Belgian law, were convicted earlier this month. Each parent was fined €5500 (£4100; \$8000) and sentenced to five months in prison”



	EXEMPTIONS ALLOWED (2005-2006)			
	Medical		Religious	Philosophical
	Temporary	Permanent		
Alabama		X	X	
Alaska	X	X	X	
Arizona	X	X	**	*
Arkansas	X		X	X
California	X	X	X	X
Colorado	X	X	X	X
Connecticut		X	X	
Delaware	X	X	X	
District of Columbia	X	X	X	
Florida	X	X	X	
Georgia	X		X	
Hawaii	X	X	X	
Idaho	X	X	X	X
Illinois		X	X	
Indiana <sup>^</sup>	X	X	X	
Iowa	X	X	X	
Kansas	X		X	
Kentucky	X	X	X	
Louisiana	X	X	X	X
Maine	X		X	X
Maryland	X	X	X	
Massachusetts	X	X	X	
Michigan	X	X	X	X
Minnesota	X	X	X	X
Mississippi	X	X		
Missouri	X		*	**
Montana	X	X	X	
Nebraska	X	X	X	
Nevada	X	X	X	
New Hampshire	X		X	
New Jersey	X	X	X	
New Mexico	X	X	X	X
New York	X	X	X	
North Carolina	X	X	X	
North Dakota		X	X	X
Ohio	X	X	X	X
Oklahoma	X	X	X	X
Oregon	X	X	X	
Pennsylvania	X	X	X	
Rhode Island	X	X	X	
South Carolina	X	X	X	
South Dakota		X	X	
Tennessee	X	X	X	
Texas	X	X	X	X
Utah	X	X	X	X
Vermont	X	X	X	X
Virginia	X	X	X	
Washington	X	X	X	X
West Virginia	X	X		
Wisconsin	X	X	X	X
Wyoming	X	X	X	

X Exemption allowed

\* Allowed in schools only

\*\* Allowed in childcare and head start facilities only

<sup>^</sup> Medical exemptions are referred to as "Acute" and "Chronic"



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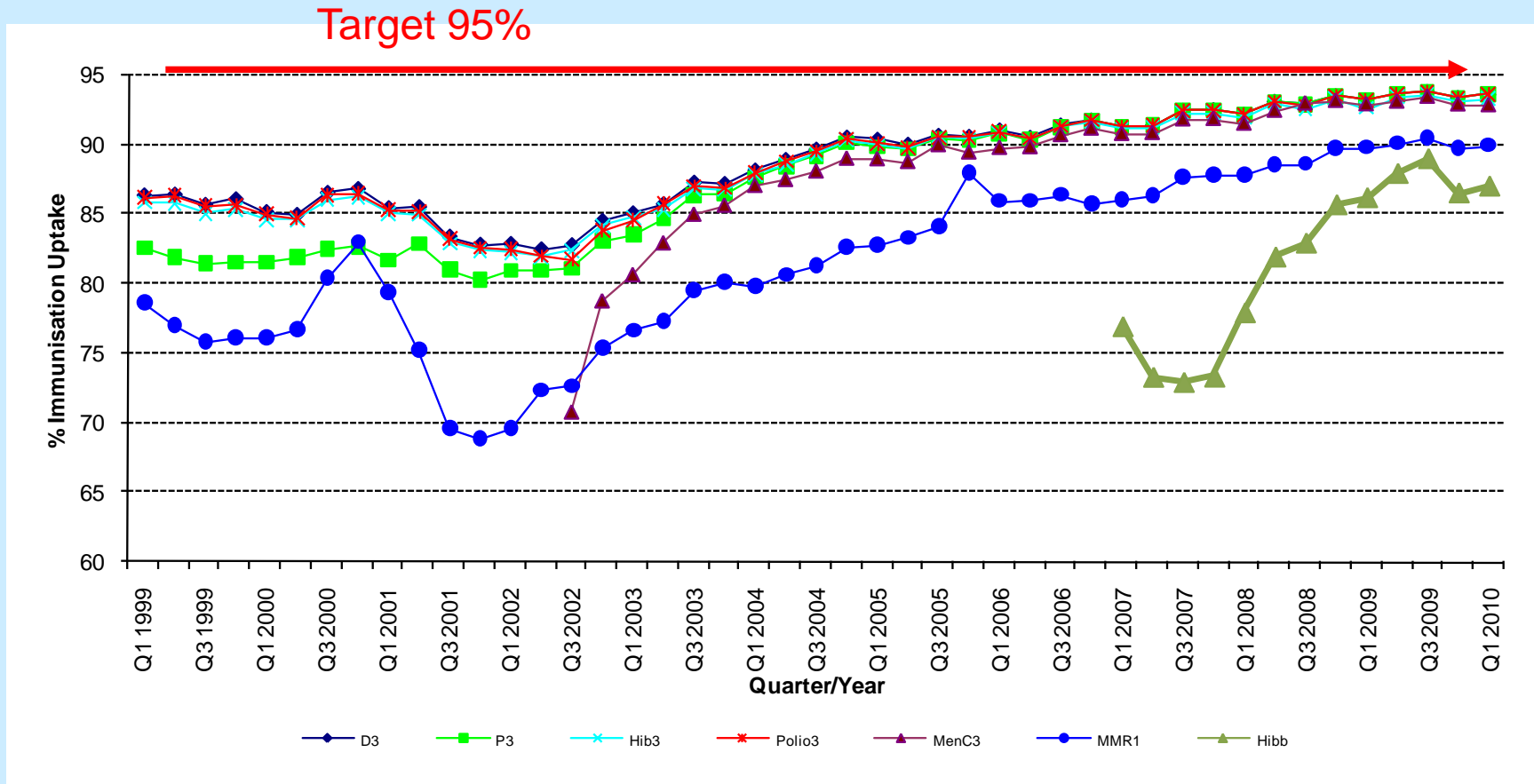
# Mandatory vaccination

## Expert group in Scotland 2002

- Not consistent with key elements of UK immunisation policy – vaccines on voluntary basis
- Not self evident it would lead to higher levels of immunisation



# Primary childhood vaccine uptake rates at 24 months Q1 1999 – Q1 2010



Source:HPSC

[www.immunisation.ie](http://www.immunisation.ie)



# Mandatory vaccination and health care workers

2010 US study HCWs

70% thought influenza vaccine should be mandatory for HCWs

More likely to believe vaccine is safe

55% of those who opposed had been vaccinated

Fears and misconceptions

H1N1 vaccination

Endorsement by professional bodies

Medical Council

An Bord Altranais



# Communication

- Vaccines victim of their own success
- Public confidence
- Access to unbiased information
- Awareness of consequences of failure to vaccinate
- Media
- Vaccines contraindicated in certain individuals (e.g. MMR in immunosuppressed)



***"Earned trust has replaced blind trust".***



# Communication

- Accept and involve the public
- Plan and evaluate efforts
- Listen and be responsive to public concerns
- Be honest, frank and open
- Work with credible sources
- Meet the needs of the media
- Communicate clearly and appropriately with the target group



# Thiomersal

- 1999 FDA raised concerns and asked manufacturers to remove thiomersal from vaccines
- “.... current levels of thiomersal will not hurt children, but reducing those levels will make vaccines even safer”

American Academy of Pediatrics



# Communication



FACTS AND EVIDENCE ARE SEEN AS JUST A MATTER OF OPINION, RATHER THAN A PROVEN TRUTH.



AND BLIND UNREASONING BELIEF IS CONSIDERED AS VALID AS CRITICAL THINKING.



HOWEVER, IN THE INTERESTS OF PROVING WAKEFIELD'S THEORY...



THE CHILDREN WERE GIVEN A BATTERY OF TESTS.



THIS IS ANDREW WAKEFIELD.



A BRITISH FORMER SURGEON, BEST KNOWN FOR HIS WORK REGARDING THE MEASLES, MUMPS AND RUBELLA VACCINE.



COLONOSCOPES, LUMBAR PUNCTURES AND BARIUM MEALS. DISTRESSING PROCEDURES FOR ANY CHILD.



NONE OF WHICH WAS APPROVED BY THE HOSPITAL'S ETHICS COMMITTEE.



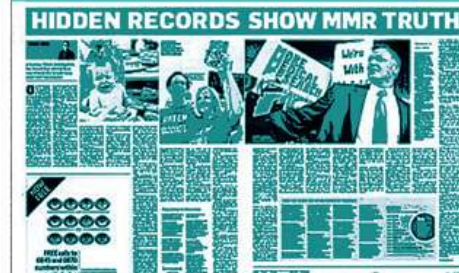
AND THE CLAIMED CONNECTION WITH AUTISM AND INFLAMMATORY BOWEL DISEASE.



WAKEFIELD WAS THE LEAD AUTHOR IN A 1998 PAPER, PUBLISHED IN THE LANCET.



ALL THIS EVIDENCE CRUSHED WAKEFIELD'S DEFENCE.



HE WAS FOUND BY THE GMC TO HAVE ACTED DISHONESTLY AND IRRESPONSIBLY.





# Protect Health - Immunise

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WWW  immunisation

## Who we are

- [Childhood Immunisation](#)
- [HPV Programme](#)
- [Adult Immunisation](#)
- [Healthcare Professionals](#)
- [Vaccine Ordering and Storage](#)
- [Leaflet Translations](#)
- [Ordering Materials](#)
- [FAQs](#)
- [Publications](#)
- [Glossary](#)
- [National Conferences](#)
- [Useful Websites](#)



## Welcome to the Health Service Executive Immunisation Website

This site provides information on immunisation for the General Public and Healthcare Professionals



Childhood Immunisation



Adult Immunisation



Healthcare Professionals

[Click on the link to view Vaccination records](#)



[Primary Immunisation Schedule](#)



## Hot Topic

- [HPV Vaccination Programme](#)
- [Measles Outbreak](#)
- [Pandemic Flu Campaign 2009](#)



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# Vaccine Damage Scheme



Acceptance of a small risk of complications in a few individuals in order to benefit public health by reducing the incidence of an infection or disease in the community

Most countries in Western Europe, Canada, Australia

UK 1978

USA 1988

Ireland

Working group report sent to Minister of Health 2009



*Vaccines are credited with having saved more lives than any medical treatment ever developed. Their continued success depends on thoughtful consideration of the many ethical questions related to their development, regulation, and use.*



VACCINE ETHICS.ORG



[www.immunisation.ie](http://www.immunisation.ie)



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