



# **VACCINATION: ETHICS AND LAW**

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# Why does vaccination raise so many ethical issues

Vaccination touches on all the fundamental ethical principles;

Autonomy: Compulsory vaccination vs voluntary vaccination.

Beneficence: good for patients

Non-Maleficence: (do no harm): are vaccines safe?

Distributive justice: Are they affordable and available to everyone

# The vaccine controversy

- The past achievements of scientific medicine, including vaccination policies, largely developed within the scope of the traditional, individual-based ethics of Hippocrates
- Even Louis Pasteur , who was not a physician, upheld the tradition and ethics of Hippocrates: first do no harm..... Pastuer consulted with several physicians to ascertain there was no other treatment available before rendering experimental treatment against rabies to his young patient, Joseph Meister

Physicians who follow the Oath and ethics of Hippocrates must always be careful to satisfy two conditions:

- That they place their patient's interest above the cost considerations important to third party payers, and even above the physician's own personal or monetary interest; and
- That they uphold the interest of the *individual* patient above that of the collective, be that the health care networks or some "greater good" of society or the state.

Many physicians believe mandatory vaccination programs allow these two conditions to be violated and thus deliberately subordinate the doctor-patient relationship to the interest of the state.

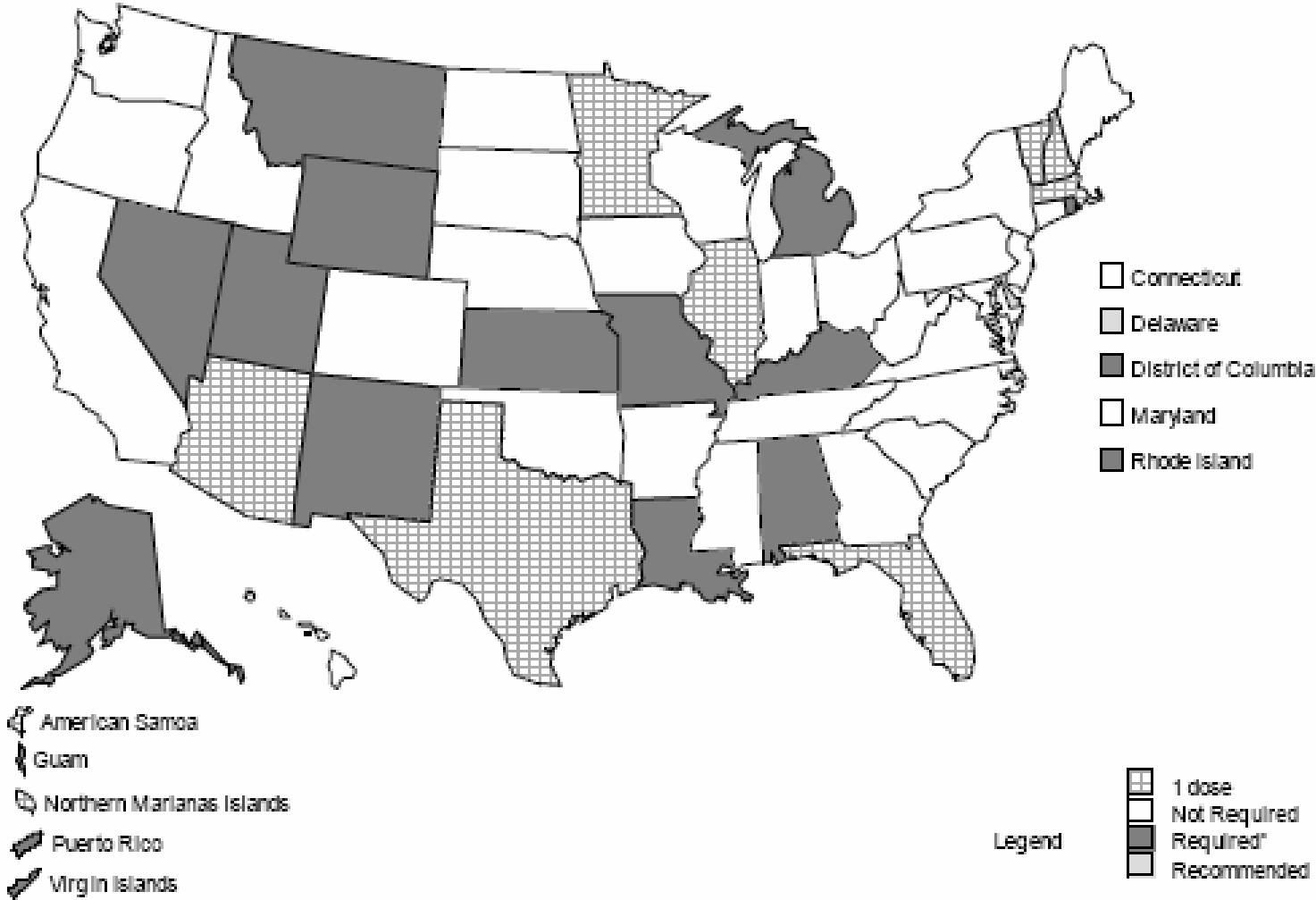
# Medical ethics and public health

- Most public health policy regarding vaccination tend to follow a collectivist, utilitarian ethic which contrasts dramatically with the individual-based ethics that has guided medicine for centuries. The new ethic has caused the development of new “population based” medicine, seen most clearly in the movement towards managed health care and national health.
- The new ethic confronts the physician with a great dilemma that go to the heart of the profession. Am I recommending vaccination to my patients because it is in their best interests , or simply because I must comply with the state’s mandate for universal vaccination.

- IN the last 50 years, mandatory vaccination in the United States has virtually wiped out the incidence of crippling and potentially lethal diseases like measles, rubella, polio and whooping cough, also known as pertussis.
- In the 1930's, there were up to 250,000 cases a year of whooping cough and as many as 7,000 deaths. Currently less than 4,000 cases a year are reported, and they are rarely fatal.
- The national vaccination standard calls for all children to receive diphtheria-pertussis-tetanus, or DPT, shots at 2 months, 4 months, 6 months and 15 months, and then again just before starting school, generally around the age of 5 years.
- Other mandatory vaccinations in New York include three doses of polio vaccine and two measles, mumps and rubella, or MMR, shots. State colleges require proof of MMR immunization before entry.

# 2005 – 2006 TD Vaccination Requirements by State

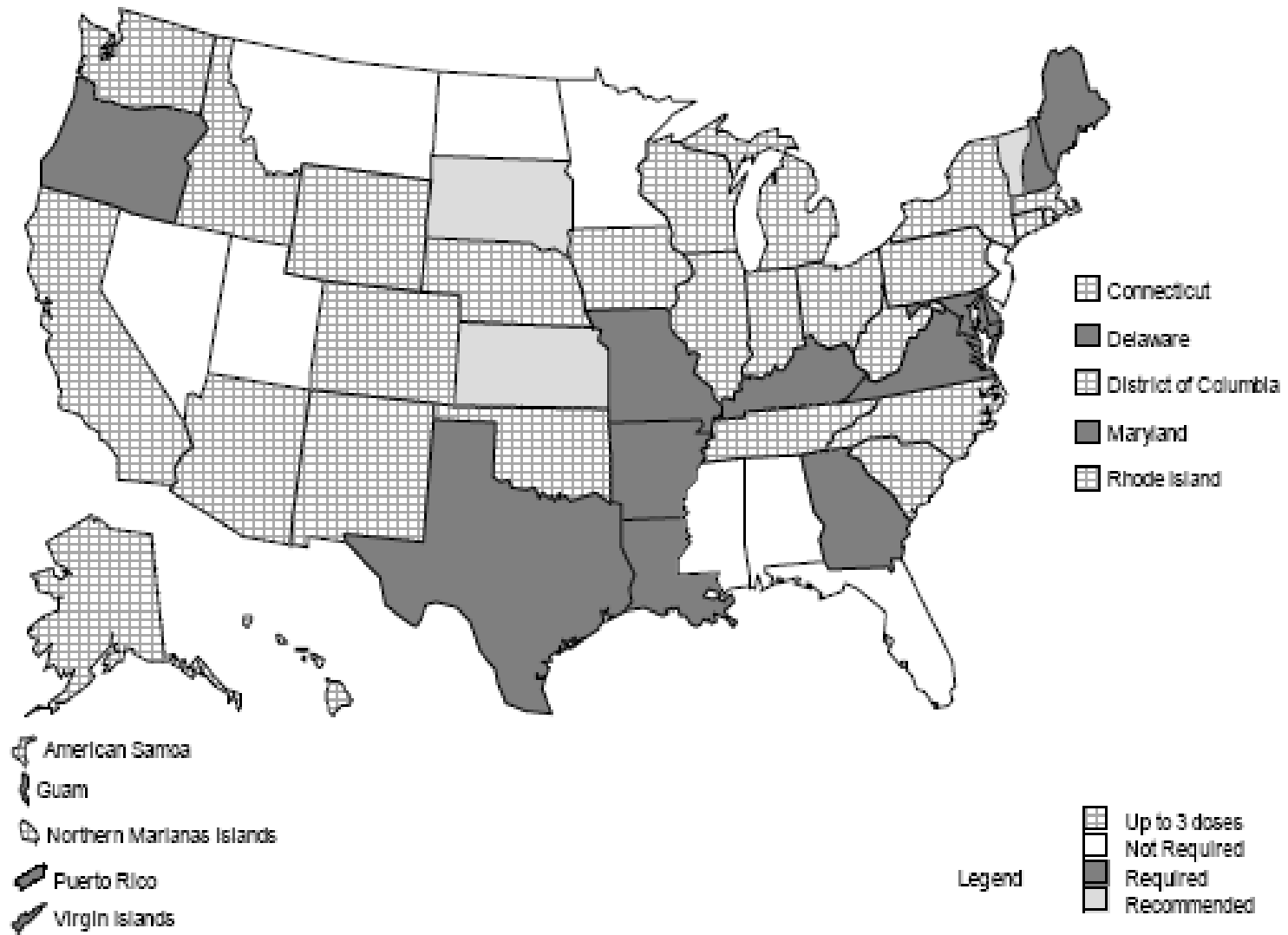
For Middle School



\*LA - Required for New Entrants Only.

# 2005 – 2006 Hep B Vaccination Requirements by State

## For Childcare



## **Enforcement of vaccination**

Those who are not vaccinated face societal punishment, for example:

- Children may not attend school ;
- Their parents may be accused of child abuse ;
- Families may have their welfare benefits slashed ;
- Adults may not attend college ;
- Adults may be forbidden from working in selected professions .

## Exemptions

In many states there are certain categories of persons that are exempt from compulsory vaccination

e.g.

- In Ohio in the United States of America they have a rather liberal religious exemption for those parents who do not want their children to receive hepatitis B vaccine.
- These exemptions are not available, however, for college students or adults who work in professions which require the shots.

	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^	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

^ Medical exemptions are referred to as "Acute" and "Chronic"



## Compulsory vaccination in South Africa

- The only requirement that is currently mandatory in South Africa is proof of immunisation against yellow fever for any person that enters the country from a country that is deemed by the WHO as a country where yellow fever transmission is present.
- Compulsory vaccination can also be enforced where there is a threat to public health.

## The National Health Act (61 of 2003)

Section 8 stipulates that no treatment can be provided without the *informed consent*

of the patient unless:

- The patient is unable to give consent but has mandated another person in writing to give consent on their behalf.
- The patient is unable to give consent and the consent is given by the spouse or partner or, in the absence of these, a parent, grand parent, adult child or brother or sister
- A law or a court has authorised a person to give consent.
- The treatment is authorised in terms of any law or court order
- Failure to treat the patient, or group of people will result in a serious threat to public health.
- Delay in treatment may lead to irreversible damage or death of the patient

# The Communicable Disease Regulations

- Health Act, 63 of 1977, Section 33 still currently in use.
- New Communicable disease regulations are awaited.
- Communicable disease regulations 30 October 1987:
  - Regulation 2: Provides for involuntary quarantine.
  - Regulation 13: Compulsory vaccination

## Regulation 13

If the Director General is satisfied that there is sufficient scientific grounds to suspect that the health of the population of the Republic or any part of the population may be affected by a medical condition against which people can be immunised, he may by means of a notice in the Gazette---

- (a) demarcate an area for compulsory immunisation of all inhabitants.
- (b) Designate the government body, persons that must carry out the immunisation and the period it must be done.
- (c) The designated persons can authorise medical practitioners, nurses and immunisation officers to carry out the immunisation
- (d) No person may disregard or fail to comply with an order.

**Any person who cannot or will not be vaccinated may be placed in quarantine.**

# A human rights approach

Everyone has the right to bodily and psychological integrity including security and control over their body. (“Autonomy clause”)

## South African constitution: Section 12(2)

- This implies that informed consent is required for any medical procedure including vaccination.
- The rights in the Bill of Rights may be limited only in terms of a law of general application to the extent that the limitation is reasonable and justifiable in an open democratic society based on human dignity, equality and freedom, taking into account all relevant factors including:
  - The nature of the right
  - Importance of the purpose of the limitation
  - Nature and extent of the limitation
  - The relationship between the limitation and its purpose
  - Availability of less restrictive means to achieve the purpose

## **What happens if the protection of public health necessitates the restriction of this right?**

- There are a number of human rights that cannot be restricted such as equality, freedom from torture and slavery.
- Limitation and derogation clauses in the international human rights instruments recognise the need to limit human rights at certain times.
- Public health is sometimes used by states as a ground for limiting the exercise of human rights.
- A key factor in ensuring that the necessary protection exists when rights are restricted is that each one of the Siracusa Principles are met.

## The Siracusa principles

- The restriction is provided for and carried out in accordance with the law;
- The restriction is in the interest of a legitimate objective of general interest;
- The restriction is strictly necessary in a democratic society to achieve the objective;
- There are no less intrusive and restrictive means available to reach the same objective;and
- The restriction is not drafted or imposed arbitrarily, i.e. in an unreasonable or discriminatory manner

# Risk-Benefit analysis (RBA)

## Magnitude of Harm

### Probability of Harm

	Major	Minor
High	1	2
Low	3	4

## An example of risk benefit analysis

Whole cell pertussis vaccine = encephalopathy 0-10.5 cases / million vaccinations.

Take a day care facility with 150 children, none of who have immunisation against pertussis:

- If exposed,  $\pm$  135 would get clinical pertussis (90% penetrance)
- 43 would require hospitalisation, 2 would suffer seizures and one child would acquire encephalitis every 3<sup>rd</sup> year.
- If all vaccinated with four doses of DTP:
  - One child would suffer seizures every 78 years
  - One child would suffer an encephalopathy every 667 years.

**Who can give informed consent  
to vaccination in South Africa ?**

## The elements of informed consent

One gives informed consent to an intervention if:

- One is competent to act. (Medico-legal consent)
- One receives a through disclosure. (adequate information)
- One comprehends what has been disclosed
- One acts voluntarily
- One actually consents to the intervention

# Consent must be legal (Medico-legal consent)

ADULTS 18 years or older	MINORS Under the age of 18 years
<ul style="list-style-type: none"><li>★ SOUND AND SOBER SENSES</li> <li>★ MARRIAGE bestows majority irrespective of age</li> <li>★ EMERGENCY: National Health Act</li></ul>	<ul style="list-style-type: none"><li>★ CHILD CARE ACT (74 of 1983)</li> <li>★ MEDICAL TREATMENT: 14 years</li> <li>★ EMERGENCY: Medical superintendent</li> <li>★ UNJUST REFUSAL: Minister or High Court can be approached</li></ul>

## The Children's Act, 38 of 205

- Age of majority now 18 years ( fully autonomous)
- HIV testing: 12 years or older.
- Under 12 – sufficient maturity to understand the benefits, risks and social implications. (Patient confidentiality applies.)
- No person may refuse to sell condoms to a child over the age of 12 years
- Other contraception: 12 years of age.( Patient confidentiality applies)
- Section 129: ( Not yet promulgated)
  - Consent for medical treatment -- 12 years of age and has sufficient maturity and mental capacity.
  - Consent for operation – 12 years of age and has sufficient maturity and mental capacity and is assisted by parents.

THANK YOU

