

# CRITERIA FOR INCLUSION OF VACCINATIONS IN PUBLIC PROGRAMMES

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# GROWTH OF NIP IN THE NETHERLANDS

Diphtheria	1957
Pertussis	1957
Tetanus	1957
Polio	1957
Rubella	1974
Measles	1976
Tuberculosis – children at risk	±1980
Mumps	1987
Hepatitis B – mother HBsAg+	1989
<i>Haemophilus influenzae</i> type b	1993
Hepatitis B – behavioural risk	1996
Influenza – medical risk and $\geq 60$ years	1997
Meningococcal C infections	2002
Hepatitis B – children at risk	2003
Pneumococcal disease	2006
Cervical cancer	2009



# POTENTIAL FUTURE ADDITIONS TO NIP

- ◉ Hepatitis B, universal (2011)
  - ◉ Intestinal rota virus infection
  - ◉ Pertussis: older children and adults
  - ◉ Shingles
  - ◉ Chickenpox
  - ◉ Influenza (children)
  - ◉ Hepatitis A
- 
- ◉ And (?): meningitis B, Helicobacter pylori, Cytomegalovirus, Chlamydia trachomatis, Neisseria gonorrhoeae, herpes genitalis, ..., HIV?



# FOKKE & SUKKE

THINK IT'S BECAUSE OF THE NANOCHIP

NOW THAT WE HAVE BEEN  
VACCINATED, WE GET...

ALL SORTS OF  
TAILORED MAIL  
OFFERS!!!



# POINTS FOR DISCUSSION

- ◉ Universal criteria for inclusion of vaccinations in public programmes, like Wilson and Jungner's criteria for screening?
- ◉ Separate assessments of:
  - Public health value
  - Public support
  - Political decision
- ◉ Feasibility of developing an international set of criteria?!
  - Local disease burden
  - Available means
  - Public support
  - Local politics



## Criteria for inclusion of vaccinations in public programmes:

- May help to make decision making transparent
- May help to set priorities
- May contribute to retention of public confidence

## Multidisciplinary assessment

### Independent from:

- Politics, decision
- Programme execution



The National Immunisation Programme should include a moderate range of vaccinations that are judged to be important, effective and safe

Health Council, 2001



# PRIMARY OBJECTIVE OF THE NIP

- ◉ To protect the people and society of the Netherlands against serious infectious disease by means of vaccination
- ◉ Subtargets:
  1. To eradicate or eliminate a certain disease
  2. To reach and maintain herd immunity
  3. To protect as many individuals as possible

For each vaccination define goal and target group!





Two ethical principles:

1. Best possible protection should be afforded to the population as a whole
2. Benefit should be fairly distributed across population groups, with protection provided on the basis of need

Seven criteria, in hierarchic order

# CRITERION 1: DISEASE BURDEN

Is it a public health problem ?



**Chickenpox**



**Shingles**

Serious for individuals

Affects a large number of people

## CRITERION 2: EFFECTIVENESS

Is vaccination  
a solution ?



**Influenza in infants**

Prevents disease

Reduces symptoms

### Symptoms of Meningitis

#### Central

- Headache
- Altered mental status

#### Ears

- Phonophobia

#### Eyes

- Photophobia

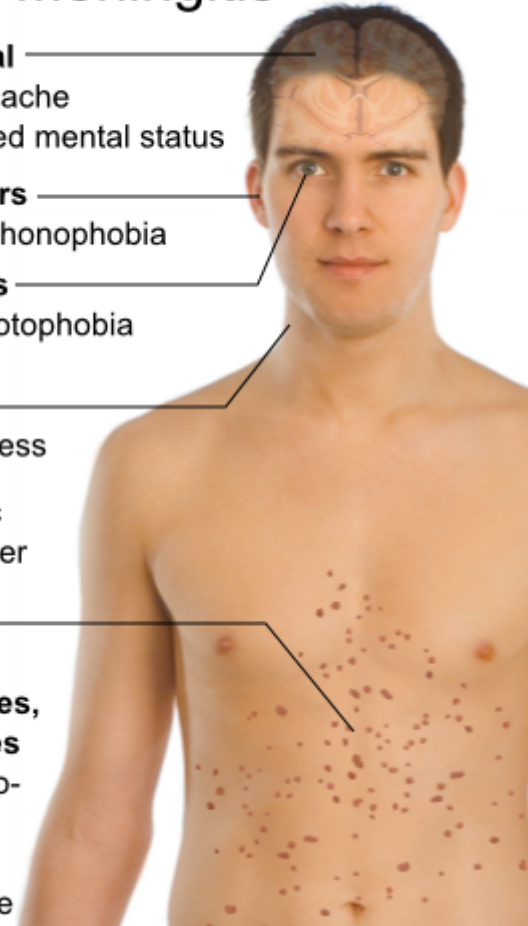
#### Neck

- Stiffness

#### Systemic

- High fever

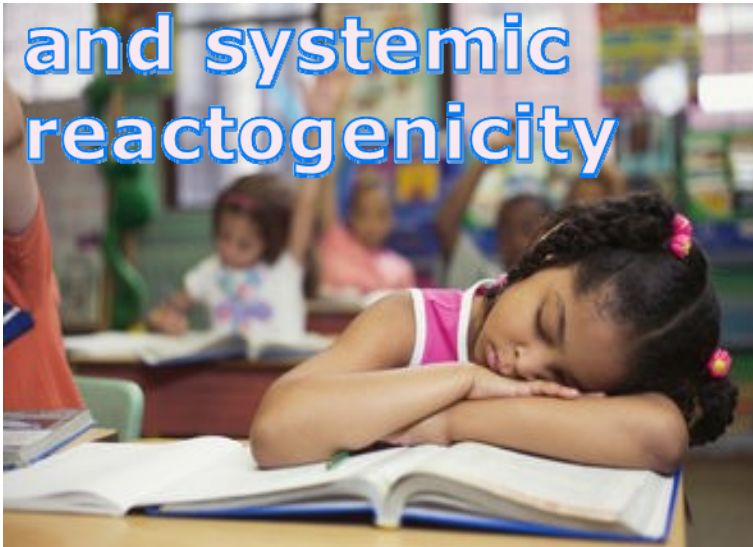
Trunk,  
mucus  
membranes,  
extremities  
(if meningo-  
coccal  
infection)  
- Petechiae



**Meningitis B/C**

## CRITERION 3: SAFETY

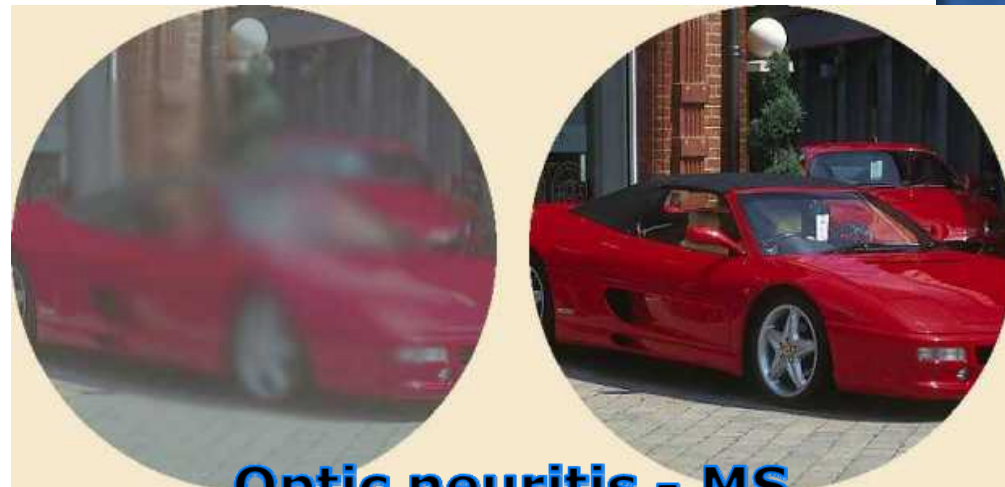
**'Normal' local  
and systemic  
reactogenicity**



**Adverse effects of  
various severity**



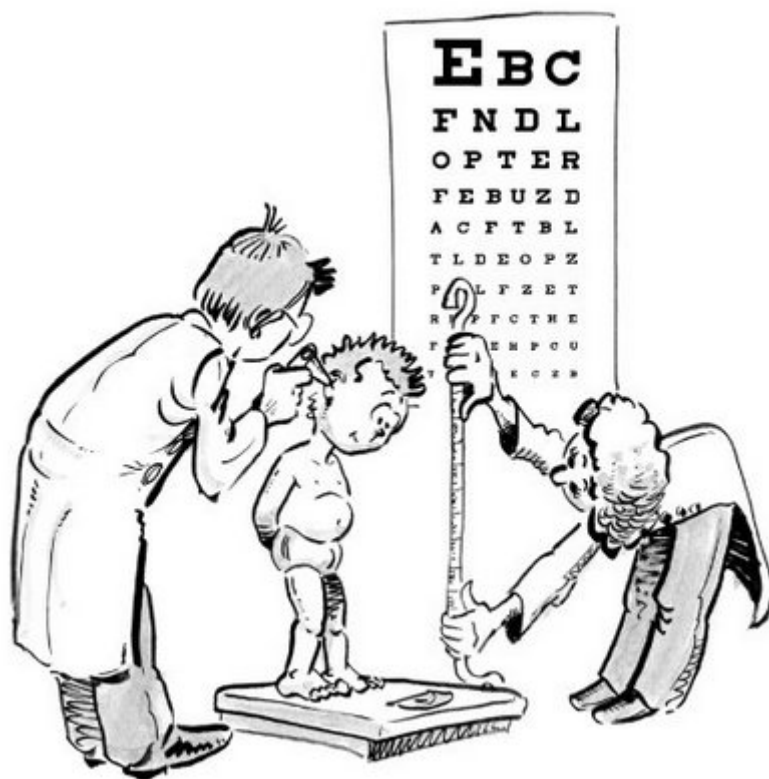
**Diminish  
public health  
benefit  
substantially?**



**Optic neuritis - MS**



## CRITERION 4: ACCEPTABILITY OF THE INDIVIDUAL VACCINATION



Affect a large number of children

Avoid undue inconveniences and discomfort



© Alamy

# CRITERION 5: ACCEPTABILITY OF NIP INCLUDING THIS VACCINATION

## Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B <sup>1</sup>	HepB	HepB	HepB			HepB						
Rotavirus <sup>2</sup>			RV	RV	RV <sup>2</sup>							
Diphtheria, Tetanus, Pertussis <sup>3</sup>			DTaP	DTaP	DTaP	see footnote <sup>3</sup>	DTaP					DTaP
<i>Haemophilus influenzae</i> type b <sup>4</sup>			Hib	Hib	Hib <sup>4</sup>	Hib						
Pneumococcal <sup>5</sup>			PCV	PCV	PCV	PCV					PPSV	
Inactivated Poliovirus <sup>6</sup>			IPV	IPV		IPV						IPV
Influenza <sup>7</sup>						Influenza (Yearly)						
Measles, Mumps, Rubella <sup>8</sup>						MMR		see footnote <sup>8</sup>				MMR
Varicella <sup>9</sup>						Varicella		see footnote <sup>9</sup>				Varicella
Hepatitis A <sup>10</sup>						HepA (2 doses)					HepA Series	
Meningococcal <sup>11</sup>											MCV	

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory

Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

Moderate range  
of important  
vaccinations

No more than two  
injections per session

## CRITERION 6: EFFICIENCY



Costs per  
QALY

Compare options,  
alternatives



## CRITERION 7: URGENCY / PRIORITY

Relative to other  
vaccinations

At reasonable  
individual and  
societal costs

**Rota**



**Hepatitis B**





## THE NIP PUT TO THE TEST (2007)

- ◉ All 15 current vaccinations meet the 7 criteria
- ◉ Of 23 candidate vaccinations no one received an unqualified positive recommendation at the time, but 4 should be assessed more carefully:
  - Cervical cancer (implemented 2009)
  - Universal vaccination against hepatitis B (2011)
  - Intestinal rota virus infection
  - Chickenpox/shingles

# CONCLUSIONS

- ◉ Not an easy exercise in filling out: to most of the criteria only qualified answers are possible
- ◉ Criteria supply a systematic framework to discuss all relevant aspects
- ◉ Evidence-base is input, but does not provide the weights or the answers



# POINTS FOR DISCUSSION

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# THANK YOU FOR YOUR ATTENTION !

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# EXAMPLE OF UNIVERSAL VACCINATION AGAINST HEPATITIS B

Since 1992 WHO recommends universal  
vaccination of infants worldwide

In the Netherlands and other Northwestern  
European countries :

- ◉ Incidence is low
- ◉ Sexual transmission is the major route of  
transmission

> Universal vaccination disputable



## Geographic Distribution of Chronic HBV Infection



level of endemicity	% of general population with chronic HBV infection	% of world population
high endemicity	greater than 8%	about 45%
intermediate endemicity	2% to 7%	about 43%
low endemicity	less than 2%	about 12%

# HEPATITIS B VACCINATION IN THE NETHERLANDS

- Children born to mothers carrying the virus
- Patient groups
- Health care workers and other professional groups
- Children with at least one parent from a middle or high endemic country
- Behavioural risk groups: homo/bisexual men, injecting drug users, promiscuous heterosexuals: outreaching, (rather) good coverage

Should the Netherlands introduce universal vaccination?



# ASSESSMENT OF UNIVERSAL VACCINATION AGAINST HEPATITIS B, THE NETHERLANDS

Is hepatitis B still a public health problem (criterion 1)?

- ◉ Hepatitis B serious, but uncommon in Northwestern Europe, mostly limited to specific risk groups
- ◉ But: transmission patterns in migrant population may mirror those in countries of high endemicity:
  - > horizontal transmission and heterosexual transmission
- ◉ No known risk factor in quarter of acute cases
- ◉ Risk groups add up to a considerable proportion of population

Yes





# ASSESSMENT OF UNIVERSAL VACCINATION AGAINST HEPATITIS B, THE NETHERLANDS

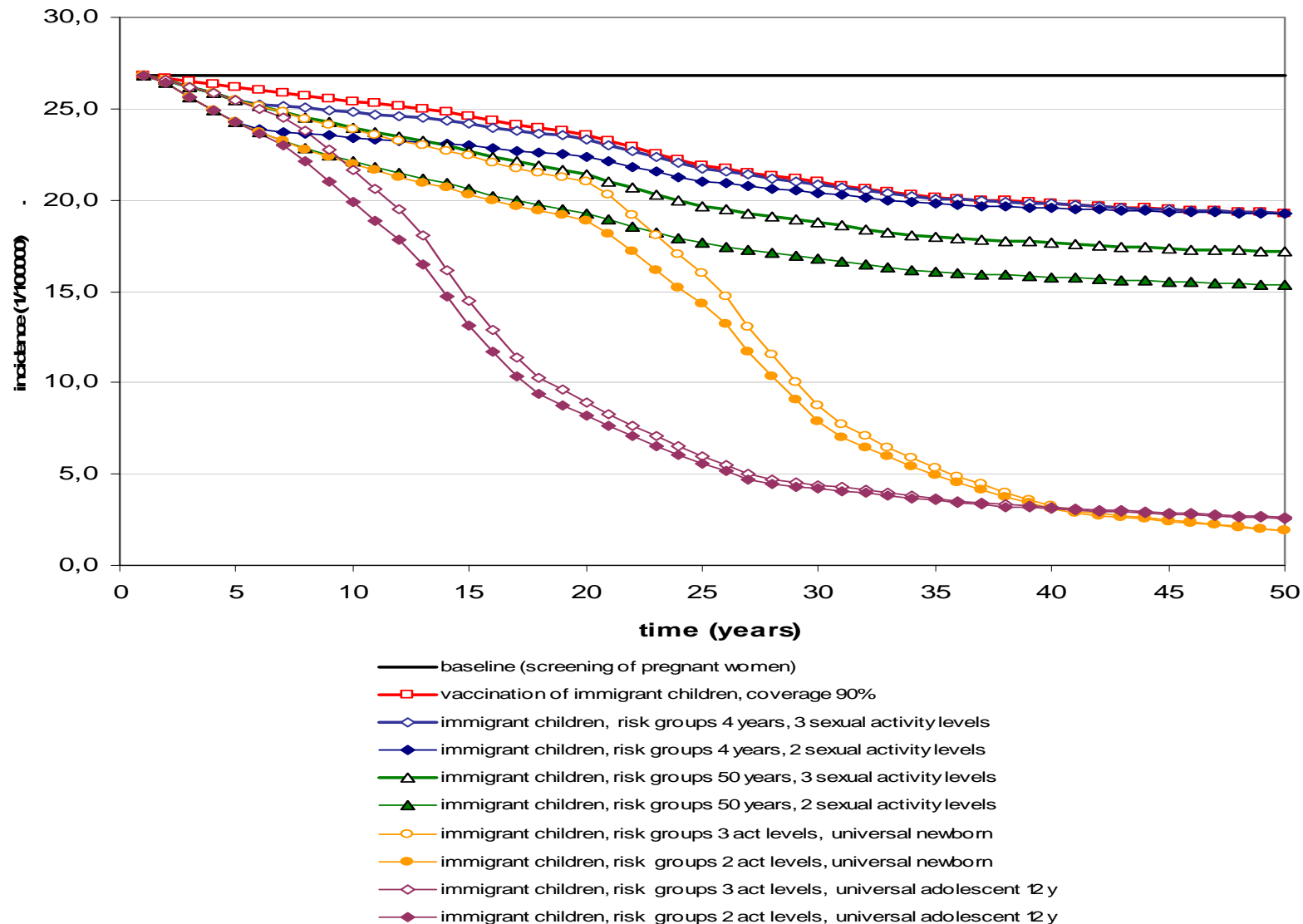
Is vaccination effective and safe (criteria 2 + 3)?

- ⊙ Vaccines: efficacious and safe
- ⊙ But: insufficient coverage of vaccination among homosexual men, despite intensive outreaching programmes, up to 50 % not protected
- ⊙ Difficult to compare targeted approaches and universal vaccination

? / Yes



# Effect of vaccination strategies on incidence of HBV infections, the Netherlands (Kretzschmar, 2009)



# ASSESSMENT OF UNIVERSAL VACCINATION AGAINST HEPATITIS B, THE NETHERLANDS

Is universal vaccination acceptable, both individually (criterion 4) and within the programme as a whole (criterion 5)?

- Vaccination not beneficial for most people, so only acceptable from public perspective, because targeted approach does not reach risk groups sufficiently
- Offers best protection for population as a whole and for risk groups
- Poses limited or no additional vaccination burden
- Can be incorporated in NIP easily

Yes / Yes



# ASSESSMENT OF UNIVERSAL VACCINATION AGAINST HEPATITIS B, THE NETHERLANDS

Is universal vaccination efficient (criterion 6)?

- ◉ Likely to prevent 5000 (universal vaccination) + 650 (catch up) extra mortalities over 50-year period
- ◉ CER of universal vaccination  
2,300-4,800 euro/QALY gained for infants  
2,000-4,200 euro/QALY gained for 12-year olds  
depending on prevalence scenario  
  
5,000-10,000 euro/QALY gained for 11-year catch up of 12-year olds

Yes



# ASSESSMENT OF UNIVERSAL VACCINATION AGAINST HEPATITIS B, THE NETHERLANDS

Is universal vaccination a priority? (criterion 7)

- ◉ Universal vaccination offers additional health benefit for population as a whole and specific risk groups
- ◉ Public health gain comparable to that of vaccination against cervical cancer
- ◉ Compared to other candidate vaccinations, universal vaccination against hepatitis B deserves to be given priority

Yes



## HEALTH COUNCIL ADVICE, MARCH 2009

1. Universal vaccination of infants
2. 11 year catch up of 12-year olds

Alternative: universal vaccination of 12-year olds

3. Pilot projects and studies into public support to guide full scale implementation

Ministerial decision: implement universal infant vaccination by October 2011

