

Risk scales: benefits of vaccines far outweigh the risks



How to use this document

The illustrations in this document can be used to support the message that the benefit of vaccines far outweighs the risks.

The risk of adverse events following vaccination needs to be compared with the risk associated with the disease. The risk of side-effects of the treatment used to alleviate the symptoms of the disease can also be taken into account.

This document illustrates both of these types of risk comparisons for three types of vaccines that are used to prevent highly infectious diseases: measles vaccine, pneumococcal conjugate vaccine and Hib vaccine.

Use it as a fact sheet or as inspiration to prepare messages or prepare for a meeting with key stakeholders.



How was this document developed?

This document is part of a WHO series of supporting documents concerning events that could erode confidence in vaccination. Such events can be related to vaccine safety, adverse events following immunization, changes in the vaccination programme, negative public debate, outbreaks or pandemics.

All documents were developed based on scientific evidence, laboratory research and fieldwork within psychology, social and behavioural science and communication and lessons learnt in countries. For an introduction to the theoretical background and evidence, refer to the WHO publication *Vaccination and trust*, available here: www.euro.who.int/vaccinetrust.

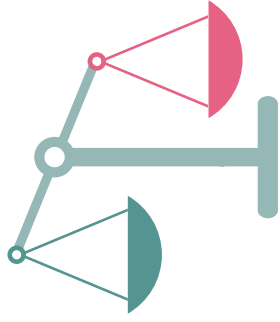
The supporting documents are intended for use by national

- ministries of health
- centers for disease control
- immunization programmes
- regulatory authority institutions.



**World Health
Organization**

REGIONAL OFFICE FOR
Europe



Measles

Possible unwanted side effects of measles vaccine

VERY COMMON

- Mild, local reactions, such as redness and pain at the injection site, occur in more than 10% of vaccinations.

COMMON

- Fever occurs in 5-10% of vaccinations.
- Rash occurs in 5% of vaccinations.

RARE

- Fever with convulsions occur in less than 0.1% of vaccinations.

VERY RARE

- Inflammation of brain and spinal cord (encephalomyelitis) occurs in 1 out of 1 million vaccinations.
- Low blood platelet count (thrombocytopenia) occurs in 1 out of 30 000-40 000 vaccinations.
- Serious allergic reaction (anaphylaxis) occurs in 3.5 out of 10 million vaccinations.

VACCINE

Possible complications of the disease and possible side effects of its treatment

Possible complications of measles

OTITIS (EAR INFECTION)

- 7-9% of infected people.

DIARRHEA

- 6% of infected people.

CHRONIC AND PROGRESSIVE BRAIN INFLAMMATION (SSPE)

- 1 out of every 100 000 infected people.

PNEUMONIA

- 1-6% of infected people.

INFECTION THAT CAUSES BRAIN SWELLING (ENCEPHALOMYELITIS)

- 1 out of every 2000 infected people.

DEATH

- 0.1-1 out of every 1000 infected people.

DISEASE

Most common unwanted side-effects of paracetamol

(often used to treat fever in measles patients)

COMMON

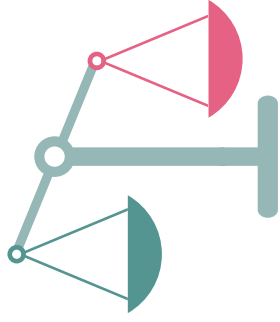
(One or more of the following occurs in 1-9% of people who use the drug):

- Irritation and inflammation inside the nose (rhinitis).
- Severe shortness of breath (dyspnea).
- Coughing, heaviness and tightness in the chest or wheezing (paroxysmal bronchial spasm).
- Bleeding from the gastrointestinal digestive tract (gastrointestinal haemorrhage).
- Indigestion or upset stomach (dyspepsia).
- Abdominal pain.
- Ulcer.
- Other.

IN ADDITION

- Liver and kidney damage may occur in case of an overdose.
- Serious complications may occur in combination with other drugs.

TREATMENT



Hib¹

Possible unwanted side effects of mono-Hib of conjugated vaccine

Possible complications of the disease and possible side effects of its treatment

Possible complications of *Haemophilus influenzae* type B (Hib) infection

DISEASE

INFLAMMATION OF JOINTS (SEPTIC ARTHRITIS)

Can lead to:

- Meningitis occurs in 10–30% of cases.
- Bacterial skin infection (cellulitis) in 10–30% of cases.
- Bone infection (osteomyelitis) in 5–10% of cases.
- Pneumonia in 5% of cases.

MENINGITIS OCCURS IN 50–65% OF ALL INVASIVE HIB CASES

Can lead to:

- Death in 2–5% of cases.
- Long-term effects such as hearing loss or other chronic neurologic conditions, in 15–30% of those who survive.

PNEUMONIA

Can lead to:

- Death.
- Collection of puss inside the body (empyema and abscess).
- Inflammation near to the heart (pericarditis).
- Collapse or closure of the lung (atelectasis).
- Blockage of respiration (endobronchial obstruction).

INFLAMMATION AT THE BACK OF THE TONGUE (EPIGLOTTITIS)

Occurs in 14.7 out of every 100 000 infected children (0–4 yrs).

Can lead to:

- Death.
- Respiratory failure.
- Pneumonia.
- Meningitis.
- Sepsis.

BACTERIAL SKIN INFECTION (CELLULITIS)

- Progresses rapidly.
- Involves face, head or neck.
- Requires antibiotic treatment.

VACCINE

VERY COMMON

- Mild soreness at the injection site occurs in more than 10% of vaccinations.

COMMON

- Fever occurs in 2% of vaccinations.

Possible unwanted side-effects of anti-inflammatory therapy with dexamethasone (commonly used to treat Hib and prevent hearing loss)

TREATMENT

COMMON (occurs in more than 1%):

- Aggression.
- Anxiety
- Irregular heartbeat.
- Swelling of fingers, hands, feet and legs.
- Troubled breathing when resting.
- Headache.
- Dizziness.
- Blurred vision.
- Other.

RARE (occurs in less than 1%):

- Cardiac arrest.
- Enlarged liver (reversible hepatomegaly).
- Blood clot inside deep veins (thromboembolism).
- Severe depression.
- Other.

Possible unwanted side-effects of antibacterial treatment with cefotaxime (commonly used to treat Hib-related infections)

TREATMENT

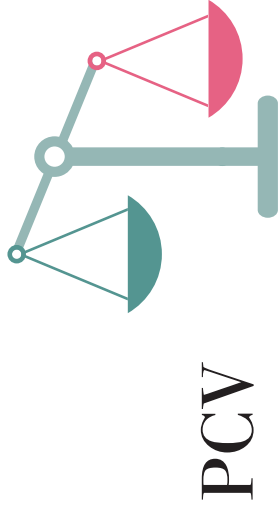
COMMON (occurs in more than 1%):

- Colitis, diarrhea, nausea, vomiting.
- Pseudomembranous colitis (inflammation of the colon).
- Rash, pruritus, urticaria, anaphylaxis (severe allergic reaction)
- Injection site inflammation.
- Fever.
- Dizziness.

RARE (occurs in less than 1%):

- Low count of leukocytes, thrombocytes, neutropenia, neutropenia, thrombocytopenia, neutropenia).
- Irregular heartbeat (Arrhythmic).
- Headache.
- Encephalopathy (brain dysfunction).
- Vaginitis, molimiasis.
- Interstitial nephritis.
- Toxic epidermal necrolysis.
- Other.

¹ Hib: *Haemophilus influenzae* type b – a bacteria which can cause serious diseases like meningitis. Sources: WHO Global Manual on Adverse Events Following Immunization. CDC. The Pink Book: Course Textbook – 12th Edition Second Printing (May 2012). Drugs.com – <http://www.drugs.com/sfx/dexamethasone-side-effects.html>.



PCV

Possible unwanted side effects of pneumococcal conjugate vaccine (PCV)

VACCINE

VERY COMMON

- Mild soreness at the place of injection for less than 3 days occurs in more than 10% of vaccinations.

UNCOMMON

- Slightly raised temperature occurs in less than 1% of vaccinations.

VERY RARE

- Serious allergic reaction occurs for 1 in 1 million vaccinations (not fatal).

Possible complications of the disease and possible side effects of its treatment

Possible complications of a pneumococcal infection (*Streptococcus pneumoniae*)

DISEASE

EAR INFECTIONS

- Repeated ear infections requiring ear tubes.

MENINGITIS

Can lead to:

- Death (1 in 10).
- Inflammation of the protective coverings of the brain and spinal cord.
- Hearing loss.
- Developmental delay.

PNEUMONIA

Can lead to:

- Death.
- Collection of puss inside body/thoracic cavity (empyema and abscess).
- Inflammation near to the heart (pericarditis).
- Collapse or closure of the lung (atelectasis).
- Blockage of respiration (endobronchial obstruction).

SEPSIS

Can lead to:

- Death (4 in 100).
- A severe blood infection that can lead to organ failure and death.

SINUS INFECTION

Most common unwanted side effects of paracetamol* (commonly used to treat a mild case of pneumonia)

TREATMENT

COMMON (occurs in 1–9%):

- Irritation and inflammation inside the nose (rhinitis).
- Severe shortness of breath (dyspnea).
- Coughing, heaviness and tightness in the chest or wheezing (paroxysmic bronchial spasm).
- Bleeding from the gastrointestinal tract (gastrointestinal haemorrhage).
- Indigestion or upset stomach (dyspepsia).
- Abdominal pain.
- Ulcer.
- Other.

IN ADDITION

- Liver and kidney damage may occur in the case of an overdose.
- Serious complications may occur in combination with other drugs.

Possible unwanted side-effects of basic antibiotics* (commonly used to treat a mild case of pneumonia)

TREATMENT

COMMON (occurs in 1–9%):

- Upset stomach, diarrhea, nausea, vomiting, abdominal pain.
- Impaired hearing.
- Eye problems, including drooping eyelids, blurred vision.
- Difficulty in speaking or swallowing, muscle weakness.
- Signs of liver problems.

RARE (occurs in 0.01–0.1%):

- Fast/irregular heartbeat.
- Severe dizziness.
- Fainting.

IN ADDITION

- Serious complications may occur in combination with other drugs.

Sources: Global Manual on Surveillance of Adverse Events Following Immunization, 2014; The National Health Services of the UK website: <http://www.nhs.uk/conditions/vaccinations/pages/pneumococcal-vaccine-side-effects.aspx>; FDA labelling 2014. *If we would compare with the treatment of a more serious case of pneumonia or other diseases caused by *Streptococcus pneumoniae*, such as meningitis and sepsis, the possible side-effects of the treatment would be even more serious.