

# Risk assessment

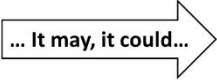
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## *Additional notes on the published presentation.*

Speculating about prevention we suppose that a risk factor contributes to the development of disease. We can derive our knowledge from epidemiological studies: the cohort studies allow us to express results in the form of the relative risk. However, the concept of risk can also be seen in a more general level.

<p style="text-align: center;"><b>Hazard vs Risk</b></p> <ul style="list-style-type: none"> <li>• <b>Hazard</b> <ul style="list-style-type: none"> <li>• Characterizes properties of agents           <ul style="list-style-type: none"> <li>• Pathogenicity, toxicity...</li> </ul> </li> </ul> </li> <li>• <b>Risk</b> <ul style="list-style-type: none"> <li>• chance of harmful effects to health</li> <li>• It is a mathematical function of hazard.           <ul style="list-style-type: none"> <li>• <math>P = 0 \dots 1</math></li> <li>• <math>P = 0 \% \dots 100 \%</math></li> </ul> </li> </ul> </li> </ul> <p style="text-align: center;">  </p>	<p style="text-align: center;"><b>Types of hazard</b> <small>(will be discussed in more detail in specific seminars)</small></p> <ul style="list-style-type: none"> <li>• <b>Biological agents</b> <ul style="list-style-type: none"> <li>• Pathogenic microorganisms <small>(see epidemiological seminars)</small></li> <li>• Non-pathogenic microorganisms related to health</li> <li>• Toxins as by-products of decomposing and primarily non-pathogenic microflora (fungi and aflatoxins)</li> </ul> </li> <li>• <b>Chemicals</b> <ul style="list-style-type: none"> <li>• Irritating, toxic, mutagenic, teratogenic and carcinogenic effects</li> </ul> </li> <li>• <b>Physical factors</b> <ul style="list-style-type: none"> <li>• Noise, vibration</li> <li>• Nonionizing and ionizing radiation: Special features of therapeutic use: benefit / risk ratio</li> <li>• Microclimate, unilateral strain of muscle groups</li> </ul> </li> </ul>
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The risk is in general the probability. It expresses the chance of a biological, chemical or physical agent to cause an adverse change in health.

Health risk has both an objective and a subjective aspect: despite all objective results and observations, each risk can affect specific people in an emotional way. The emotional component of health risk is often greatly underestimated and, which, as a result, leads to a disruption of communication and mutual trust. In his practice, the doctor encounters this

**Risk Assessment**

**Attention focuses on human!**

Hazard identification: can the agent (*specific active factor*) harm health?

1. Dose – response relationship: what is the numerical relationship between the exposure and the effect on health?
2. Exposure assessment: how important is the contact of the individual / population with the agent?
3. Risk characterization: can the assumption of an adverse effect on health be confirmed?

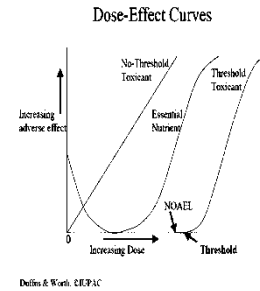
phenomenon in the interpretation of the side effects of drugs, antivaccination campaigns, etc..

The labelling procedure known as a health risk assessment is a sequence of steps to be followed: the first step is determination of health or social importance of risk factor. It should be

replaced later by an effort to express the "strength of harmfulness" of the factor, more precisely the dose-response relationship. In many cases, a detectable harmful effect can only happen when the effective (threshold) dose is exceeded. We also know the stochastic effects of an agent, but even here, when the dose is decreasing, the probability of the disease is reduced up to a certain basal value given genetically.

### Types of dose-response relationship

- Agents with threshold effect
  - Existence of a safe dose defined as No Observed Adverse Effect Level
- Agents with no threshold effect
  - Non-existence of a safe dose, but we can estimate the probability of an adverse health effect
    - „(Cancer) Slope factor" defined as the size of the inclination angle of no-threshold line (see the figure); often associated with cancer



### Exposure assessment

- Potential dose
  - It corresponds to the concentration of the agent in the environment (i. e. in air, water, food, soil), converted to a unit of mass, volume or area of the matrix.
- Applied dose
  - It depends on the speed of diffusion and capacity of receptor.
  - Ingestion, inhalation, contact with skin or mucous membranes
    - Comment: besides the concentration, the duration of exposure can also determine the size of the effect.
- Effective dose
  - Defined by the concentration of agents in the target organ

Exposure assessment is the most difficult part of the process: We have to determine an effective dose, which is expected as harmful. The size of effective doses in the target organs is estimated by indirect and by direct methods.

## Exposure assessment – methods

- Indirect methods
  1. Environmental monitoring: The amount of agent in the matrix multiplied by the average matrix intake by the exposed person:
    - Average lung volume (22 m<sup>3</sup>/person/day)
    - Average water consumption per person (1,9 liter/day)
    - Amount of food consumed per person (e.g. Food pyramid)
    - The average length of stay in the swimming pool
    - Inaccuracy! Interindividual differences are significant!
  2. Exposure scenario or questionnaire survey: A rough estimation of the exposure can be specified, most often in a well defined population group (typically school pupils, members of the army ...)

Indirect methods are easier but less accurate: if we know the amount of hazardous substance in food or water and if we can estimate the amount of food or water that is consumed, using simply multiplying the both values, we get a probabilistic estimate of exposure.

To distinguish the subtle differences in exposures, direct methods of estimating exposure based on individual measurements, polling and tests have been developed. However, individual measurement is always time-consuming and financially demanding.

Only when we gather information on harmfulness and quantitative exposure we can conclude an overall impact on health (characterize the risk). The whole procedure can also be expressed graphically as the risk matrix: the health impact in relation to the likelihood that we will encounter a risk factor to a sufficient extent.

### Exposure assessment – methods II.

- Direct methods are preferred but are generally less accessible.
- Personal monitoring:
  - 24 hrs recall, double portion method...
  - Personal dosimetry - healthcare workers
- Biological monitoring
  - Biomarkers of exposure (DNA adduct in tests of genotoxicity)
  - Biomarkers of effect (measurable pathophysiological changes in organs)
  - Biomarkers of sensitivity (measurable susceptibility to health impairment)



## Risk characterization

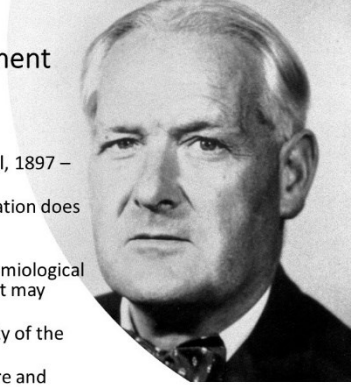
1. Harmful to health has not been confirmed
2. Exposure to harmful factor reduces the level of well-being (health in a broader sense)
  - Example: The source of environmental noise has forced the use of space (more demanding activities are moved to a quieter part of the building).
3. Exposure to a harmful factor poses a threat to health in the longer term, with the factor being considered at most as one of several disease factors (long-term and multifactorial health effects)
4. Exposure to harmful agents poses an immediate threat to human health or lives
  - (See the Czech "methanol affair" in 2012.)

Honesty of any scientific work, incl. health risk assessment cannot be done without a discussion of uncertainties. When using indirect methods of exposure assessment, we work with an "average individual". Nevertheless, individual measurements can be affected by random fluctuations, the body's response to the attack is also strictly individual. Epidemiological methodology brings further inspiration to work, from a scientific point of view, with uncertainties in health risk assessment.

A pioneer in this area was British epidemiologist *Austin Bradford Hill*, who has expressed several postulates, suitable for discussing our conclusions about the size of the risk.

### Epidemiology in health risk assessment

- Problems: transferability of results
- Internal validity of epidemiological studies
- Hill's criteria of causality (Sir Austin Bradford Hill, 1897 – 1991)
  - ✓ Strength of association: Even a weak association does not rule out causality if it is weakened by unrecognized confounders
  - ✓ Consistency: Inconsistency with other epidemiological studies does not exclude causality, the effect may only occur under special circumstances
  - ✓ The causality does not assume the specificity of the effect
  - ✓ The temporality (time sequence) of exposure and effect is a prerequisite!



Some of Hill's causality criteria have been partially exceeded, others revised. Perhaps the most important thing is the postulate of the effect temporality: only such a consequence, which had been proven to occur after known exposure only, it could be responsible for an adverse change in health!

In recent years, some elements of the qualitative research have penetrated the field of the health risk assessment. Quantitative research and qualitative research should form indivisible unity. The complex of health and risk factors that threaten health cannot be summarised in the result formally expressed as " $p < 0.05$ ". Questioning public attitudes and including public attitudes in objective decision-making of authorities should gradually become a matter of course in the protection of public health.

### Public Health and qualitative research

- Qualitative research always just as a complement to epidemiological methods of work
- It enables us to understand the social, cultural, economic and behavioral aspects of public health
- Epidemiological methods: "How many? How much?"
  - ✓ Calculation of frequency, confidence intervals, the probability of the estimation error (magic "*p-value*")
- Qualitative research: how and why?
  - ✓ From the Latin word "Qualis" (= How? What?)
  - ✓ Verbal analysis of relationships and contexts