

Glossary of Risk Terms

absolute risk (AR) — The percentage of people in a group who experience a discrete event (number of people with event / total number of people at risk for the event).

absolute risk reduction (ARR) — The absolute arithmetic difference in rates of bad outcomes between experimental and control participants in a trial.

association — The relationship between a given agent or product may or may not mean that the exposure to the agent or product caused the outcome.

attributable risk — A measurement of the degree of risk associated with exposure (frequency in exposed persons minus the frequency in unexposed persons / frequency in exposed persons).

bias — Any factor that might change the results of a study from what they would have been if that factor were *not* present.

causality — The relating of causes to the effects they produce. Causes are termed *necessary* when they must always precede an effect and *sufficient* when they initiate or produce an effect. Any of several factors may be *associated* with potential causation or outcome, including predisposing factors, enabling factors, precipitating factors, reinforcing factors, and risk factors.

case-control study — A retrospective study that involves patients who have the condition of interest (cases) and subjects without that condition (controls) to identify exposures or other factors that might cause or contribute to the condition.

clinical trials — Prospective studies with human subjects to test the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices, or techniques. Participating subjects must meet predetermined eligibility criteria and are observed for predefined evidence of favorable or unfavorable effects. This definition applies to clinical trials conducted in the United States and in other countries.

clinical trials, phase I — Studies performed to evaluate the safety of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques in healthy subjects and to determine the safe dosage range (if appropriate). These tests also are used to determine pharmacologic and pharmacokinetic properties (toxicity, metabolism, absorption, elimination, and preferred route of administration). They involve a small number of people and usually last about one year. This definition applies to Phase I studies conducted in the United States and in other countries.

clinical trials, phase II — Studies that are usually controlled to assess the effectiveness and dosage (if appropriate) of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques. These studies are performed on several hundred volunteers, including a limited number of patients with the target disease or disorder. They last about two years. This definition applies to Phase II studies conducted in the United States and in other countries.

clinical trials, phase III — Comparative studies to verify the effectiveness of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques determined in phase II studies. During these trials, patients are monitored closely by physicians to identify any adverse reactions from long-term use. These studies are performed on groups of patients large enough to identify statistically significant clinical responses. They usually last about three years. This definition applies to phase III studies conducted in the United States and in other countries.

clinical trials, phase IV — Also called *post-marketing surveillance trials*; planned studies of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques that have been approved for general sale. These studies are often conducted to obtain additional data about the safety and efficacy of a product. This definition applies to phase IV studies conducted in the United States and in other countries.

cohort study — A longitudinal investigation of two groups (cohorts): one that has the condition or received the treatment or exposure of interest, and one that does or did not. Cohorts are defined by one or more common characteristics. Cohort studies attempt to identify whether the condition of interest, such as a disease, is related to the common element that defines the cohort — such as ethnicity or smoking status — or to other factors.

confidence interval (CI) — A statistical range with a specified probability (usually 95 percent) that a given value will be included in the range. CIs quantify the uncertainty of measurements.

meta-analysis — A systematic review that uses quantitative methods to synthesize and summarize the results.

number needed to harm (NNH) — The number of patients who, if they received an experimental treatment, would result in one additional patient being harmed, compared with patients who received a control treatment.

number needed to treat (NNT) — The number of patients who need to be treated to achieve one additional favorable outcome, calculated as $1/ARR$.

odds ratio (OR) — A measure of effect size that has different meanings in different settings. In *case-control* studies, OR is the usual measure of association. It indicates the odds of exposure in the case group divided by the odds of exposure in the control group. If cases and the controls have equal odds of having the exposure, the odds ratio is 1.0, indicating no effect. If the cases have higher odds of exposure than the controls, the ratio is greater than 1.0, implying an increased risk associated with exposure. Similarly, odds ratios less than 1.0 indicate a protective effect. In *cross-sectional, cohort, and randomized* controlled studies, the disease-odds ratio is the ratio of the odds in favor of disease in the exposed versus that in the unexposed. In this context, the odds ratio has some appealing statistical features when studies are aggregated in meta-analysis, but the odds ratio does not indicate the relative risk when the portion with the outcome is greater than 5–10 percent (i.e., the term has little clinical relevance or meaning with higher incidence rates).

randomization — A method for assigning patients to treatment groups with no consideration of individual patients or their characteristics — analogous to a coin toss in which the people whose toss lands on “heads” become the group that receives the experimental treatment and the people whose toss turns up “tails” constitute the group that receives a conventional (standard) control treatment or a placebo. In this example, the “tails” people are the control group.

randomized controlled trial (RCT) — A study in which participants are randomly allocated to the experimental group or the control group and followed over time to identify the effects, variables, or outcomes of interest.

relative risk (RR) — The frequency of outcome in the exposed group divided by the frequency of the outcome (e.g., a disease) in the unexposed group. If the frequency of the outcome is the same in both groups, the ratio is 1.0, indicating no association between exposure and outcome. By contrast, if the outcome is more frequent in those exposed, the ratio will be greater than 1.0, implying an increased risk associated with the exposure. Conversely, if the frequency of disease is less than 1.0, a protective effort is implied.

risk — The possibility of suffering harm or loss. *Risk* encompasses a variety of measures of the probability of a generally unfavorable outcome.

risk assessment — The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences.

risk factor — Any aspect of a person's life, behavior, or genetic inheritance that increases the likelihood of a disease, condition, or injury.

woman-year — A person-time unit, or the total of the units of time—whether weeks, months, or years—that people were exposed to a condition or were actively involved in a study. One person-year can represent either a single person who was exposed for 1 year or an accumulation, such as two people who were each exposed for half a year.

Adapted from

- The American Heritage Dictionary of the English Language. 3rd ed. Boston: Houghton Mifflin Company; 1996.
- Association of Reproductive Health Professionals and Planned Parenthood ® Federation of America. Explaining Contraceptive Risk to Patients [PowerPoint presentation]. Available from: www.arhp.org/CORE. Accessed December 24, 2008.
- Centre for Evidence-Based Medicine. Glossary of EBM Terms. Available from: <http://www.cebm.utoronto.ca/glossary/>. Accessed December 24, 2008.
- Evidence Based Emergency Medicine at the New York Academy of Medicine. Glossary of Terms. Available from: <http://ebem.org/definitions.html>. Accessed December 24, 2008.
- Last JM. A Dictionary of Epidemiology, 2nd ed. New York: Oxford University Press; 1988.
- Schulz KF and Grimes DA. The Lancet: Handbook of Essential Concepts in Clinical Research. London: Elsevier; 2006.
- The University of Chicago Library. Health Statistics: Glossary of Statistical Terms. Available from: <http://www.lib.uchicago.edu/e/su/med/healthstat/statglossary.html>. Accessed December 24, 2008.