# Glossary of Methodologic Terms

**Before-After Trial:** Investigation of therapeutic alternatives in which individuals of 1 period and under a single treatment are compared with individuals at a subsequent time, treated in a different fashion. If the disorder is not fatal and the "before" treatment is not curative, the same individuals may be studied in the before and after periods, strengthening the design through increased group comparability for the 2 periods. *See also* Crossover Trial.

**Blind or Blinded:** Masked. Unaware. The terms may be modified according to the purpose of the blinding. For example, clinicians or patients can be blind to the treatments that patients are receiving and observers can be blind to each other's assessments, making their observations uninfluenced by one another (*see also* Double-Blind).
To avoid confusion, masked is preferred in studies in which vision loss of patients is an outcome of interest.

**Case-Control Study (Case-Referent** or **Case-Comparison Study):** Study generally used to test possible causes of a disease or disorder, in which individuals who have a designated disorder are compared with individuals who do not with respect to previous current exposure to a putative causal factor. For example, persons with hepatic cancer (cases) are compared with persons without hepatic cancer (controls) and history of hepatitis B is determined for the 2 groups. A Case-Control Study is often referred to as a Retrospective Study (even if patients are recruited prospectively) because the logic of the design leads from effect to cause.

**Case Series:** A series of patients with a defined disorder. The term usually describes a study reporting on a consecutive collection of patients treated in a similar manner, without a concurrent control group. For example, a surgeon may describe the characteristics of and outcomes for 100 consecutive patients with cerebral ischemia who received a revascularization procedure. *See also* Consecutive Sample.

**Cohort:** A group of persons with a common characteristic or set of characteristics. Typically, the group is followed for a specified period to determine the incidence of a disorder or complications of an established disorder (ie, prognosis), as in Cohort Study (prospective study). *See also* Inception Cohort.

**Cohort Analytic Study:** Prospective investigation of the factors that may cause a disorder by comparing a cohort of individuals who do not have evidence of an outcome of interest but who are exposed to the putative cause with a concurrent cohort who are also free of the outcome but not exposed to the putative cause. Both cohorts are then followed to compare the incidence of the outcome of interest.

**Confounder, Confounding Variable:** A factor that distorts the true relationship of the study variables of central interest by virtue of being related to the outcome of interest but extraneous to the study question and unequally distributed among the groups being compared. For example, age might confound a study of the effect of a toxin on longevity if subjects exposed to the toxin were older than those not exposed.

**Consecutive Sample:** Sample in which the units are chosen on a strict first come first chosen basis. All subjects who are eligible should be included as they are seen.

**Convenience Sample:** Subjects or groups selected at the investigator's convenience or primarily because they were available at a convenient time or place.

**Cost-Benefit Analysis:** A form of economic assessment, usually from society's perspective, in which the costs of medical care are compared with the economic benefits of the care, with both costs and benefits expressed in units of currency. The benefits typically include reduction in future health care costs and increased earnings due to the improved health of those receiving the care.

**Cost-Effectiveness Analysis:** An economic evaluation in which alternative programs, services, or interventions are compared in terms of the cost per unit of clinical effect (eg, cost per life saved, cost per millimeter mercury of blood pressure lowered, or cost per quality-adjusted life-year gained). The last form of measuring outcomes (and equivalents such as "healthy days of life gained") gives rise to what is also referred to as "cost-utility analysis."

**Cost-Utility Analysis:** *See* Cost-Effectiveness Analysis.

**Criterion Standard:** Preferred term to *gold standard*. A method having established or widely accepted accuracy for determining a diagnosis, providing a standard to which a new screening or diagnostic test can be compared. The method need not be a single or simple procedure but could include follow-up of patients to observe the evolution of their conditions or the consensus of an expert panel of clinicians, as is frequently used in the study of psychiatric conditions. Criterion standard can also be used in studies of the quality of care to indicate a level of performance, agreed to by experts or peers, to which the performance of individual practitioners or institutions can be compared.

**Crossover Trial:** A method of comparing 2 or more treatments or interventions in which subjects or patients, on completion of the course of a treatment, are switched to another. Typically, allocation to the first treatment is by random process. Participants' performance in a period is used to judge their performance in others, usually reducing variability. *See also* Before-After Trial.

**Data Set:** Raw data gathered by investigators.

**Double-Blind or Double Mask:** (1) Neither the subjects or the researchers are aware of the groups or interventions to which subjects have been assigned. (2) Any condition in which 2 different groups of persons are denied access to information so to keep that information from influencing some measurement, observation, or process.

**Economic Evaluation:** Comparative analysis of alternative courses of action in terms of both their costs and consequences.

**End Point:** *See* Outcomes.

**Gold Standard:** *See* Criterion Standard.

**Inception Cohort:** A designated group of persons assembled at a common time early in the development of a specific clinical disorder (eg, at first exposure to the putative cause or at initial diagnosis), who are followed thereafter. *See* also Cohort.

**Likelihood Ratio:** For a screening or diagnosis test (including clinical signs or symptoms), expressing the relative odds that a given test result would be expected in a patient with (as opposed to without) a disorder of interest. *See* Blind.

**Matching:** The deliberate process of making a study group and a comparison group comparable with respect to factors that are extraneous to the purpose of the investigation but which might interfere with the interpretation of the study's findings. For example, in case-control studies, individual cases might be matched or paired with a specific control on the basis of comparable age, sex, clinical features, or a combination.

**Nonrandomized Controlled Trial:** Experiment in which assignment of patients to the intervention groups is at the convenience of the investigator or according to a preset plan that does not conform to the definition of random. *See also* Randomized Trial.

**Outcomes:** All possible changes in health status that may occur in following subjects or that may stem from exposure to a causal factor or from preventive or therapeutic interventions. The narrower term End Point refers to *health* events that lead to completion or termination of follow-up of a subject in a trial or cohort study (eg, death or major morbidity, particularly related to the study question).

**Primary Care:** Medical care provided by the clinician of first contact for the patient. Typically, the primary care physician is a general practitioner, family practitioner, primary care internist, or primary care pediatrician. Primary care may also be administered by health professionals other than physicians, notably, specially trained nurses (nurse practitioners) and paramedics. Usually, a general practitioner, family practitioner, nurse practitioner, or paramedic provides only primary care services but a person with specialty qualifications may provide primary care, alone or in combination with referral services (see also Referred Care). Thus, it is the nature of

the contact (first compared with referred) that determines the care designation rather than the qualifications of the practitioner.

**Primary Care Center/Setting:** Medical care facility that offers first contact health care only. Patients requiring specialized medical care are referred elsewhere. Some primary care centers provide a mix of primary and referred care. Thus it is the nature of the service provided (first contact) rather than the setting per se that distinguishes primary from more advanced levels of care. *See also* Primary Care, Referred Care, Tertiary Care Center.

**Prospective Study:** *See* Cohort, Cohort Analytic Study.

**Random:** Governed by a formal chance process in which the occurrence of previous events is of no value in predicting future events. The probability of assignment of, for example, a given subject to a specified treatment group is fixed and constant (typically .50) but the subject's actual assignment cannot be known until it occurs.

**Random Sample:** A sample derived by selecting sampling units (eg, individual patients) such that each unit has an independent and fixed (generally equal) chance of selection. Whether a given unit is selected is determined by chance (eg, by a table randomly ordered numbers).

**Randomization, Random Allocation:** Allocation of subjects to groups by chance, usually done with the aid of a table of random numbers. Not to be confused with systematic allocation (eg, on even and odd days of the month) or allocation at the convenience or discretion of the investigator.

**Randomized Trial (Randomized Controlled Trial, Randomized Clinical Trial):** Experiment in which subjects are randomly allocated to receive or not receive an experimental preventive, therapeutic, or diagnostic procedure and then followed to determine the effect.

**Referred Care:** Medical care provided to a patient when referred by a health professional to a specialist. There are 2 levels of referred care: secondary and tertiary. Secondary care is usually provided by a specialist (general surgeon, general internist, obstetrician). Tertiary care is provided on referral of a patient to a subspecialist (orthopedic surgeon, neurologist, neonatologist). *See* also Tertiary Care Center.

**Retrospective Study:** *See* Case-Control Study.

**Secondary Care:** *See* Referred Care.

**Sensitivity:** The sensitivity of a diagnostic or screening test is the proportion of people with a designated disorder who are so identified by the test. The text may consist of or include clinical observations.

**Sequential Sample:** *See* Consecutive Sample.

**Single Case Study (Single Subject Experimental Design):** The intensive study of subjects through experimental designs such as the ABA, multiple baseline, and alternating treatment designs. The usual experimental controls to ensure internal and external validity, particularly as they relate to the design used, should be described.

**Specificity:** The specificity of a diagnostic or screening test is the proportion of people free of a designated disorder who are so identified by the text. The test may consist of or include clinical observations.

**Survey:** Observational or descriptive, nonexperimental study in which participants are systematically examined for the absence or presence (or degree of presence) of characteristics of interest.

**Tertiary Care:** *See* Referred Care.

**Tertiary Care Center:** A medical facility that receives referrals from primary and secondary care levels and usually offers test, treatments, and procedures that are not available elsewhere. Most tertiary care centers offer a mixture of primary, secondary, and tertiary care services, hence it is the specific level of service rendered, rather than the facility, that determines the designation of care in a given study. *See also* Referred Care.