PEN Glossary - Research Definitions

Accuracy
“The degree to which a measurement or an estimate based on measurements represents the true value of the attribute that is being measured.” (1)

Algorithm
“An explicit description of an ordered sequence of steps to be taken in patient care under specified circumstances.” (2)

Analytical Research
“Research designed to examine associations, commonly putative or hypothesized causal relationships. An analytic study is usually concerned with identifying or measuring the effects of risk factors or is concerned with the health effects of specific exposures. This is in contrast to a descriptive study which does not test hypotheses. The common types of analytic studies are cross-sectional, cohort, and case control.” (1)

Baseline Risk
“The risk of an adverse outcome in the control group.” (2)

Before-After Design (One-Group Pretest-Posttest Design)
“A study in which the investigators compare the status of a group of study participants before and after the introduction of an intervention.” (2)

Bias
“A systematic error in the design, conduct or interpretation of a study that may cause a systematic deviation from the underlying truth.” (2)

Channeling Effect or Channeling Bias
“Tendency of clinicians to prescribe treatment based on a patient’s prognosis. As a result of the behavior, in observational studies, treated patients are more likely to be high risk patients than untreated patients, leading to biased estimate of treatment effect.” (2)

Data Completeness Bias
“Using a computer decision support system (CDSS) to log episodes in the intervention group and using a manual system in the non-CDSS control group can create variation in the completeness of data.” (2)

Detection Bias
“Tendency to look more carefully for an outcome in one of the comparison groups (also known as surveillance bias).” (2)

Incorporation Bias
“Occurs when investigators study a diagnostic test that incorporates features of the target outcome. The result is a bias toward making the test appear more powerful in differentiating target positive from target negative than it actually is.” (2)

Interviewer Bias
“Greater probing by an interviewer in one of the groups being compared, contingent on particular features of the participants.” (2)

Publication Bias
“Occurs when the publication of research depends on the direction of the study results and whether they are statistically significant.” (2)
Recall Bias
“Occurs when patients who experience an adverse outcome have a different likelihood of recalling an exposure than patients who do not experience the adverse outcome independent of the true extent of exposure.” (2)

Social Desirability Bias
“Study participants misrepresent their responses in the direction of answers consistent with prevailing social norms or socially desirable behavior rather than their true feelings.” (3)

Verification Bias
“Results of a diagnostic test influence whether patients are assigned to intervention group (sometimes called work-up bias).” (2)

Blind (or Blinded or Masked)
“Patients, clinicians, data collectors, outcome adjudicators, or data analysts unaware of which patients have been assigned to the experimental or control group. In the case of diagnostic tests, those interpreting the test results are unaware of the result of the reference standard or vice versa.” (2)

Case Reports
“This is a description of individual people, does not provide any comparison group and is therefore unable to satisfy the requirement that treatment and control groups share a similar prognosis.” (4)

Case Series
“A study reporting on a consecutive collection of patients treated in a similar manner, without a control group. For example, a clinician might describe the characteristics of an outcome for 25 consecutive patients with diabetes who received education for prevention of foot ulcers.” (2)

Case-control Studies
“These studies usually look at rare outcomes or those outcomes that take a long time to develop. People already with the targeted outcome are identified, then the investigator chooses the controls – people who as a group, are reasonably similar to the cases with respect to the important determinants of outcome such as age, sex and concurrent medical conditions but who have not suffered the target outcomes”. (4)

Clinical Practice Guidelines (or Practice Guidelines)
“A strategy for changing clinician behavior. Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They present indications for performing a test, procedure, or intervention, or the proper management for specific clinical problems. Guidelines may be developed by government agencies, institutions, organizations such as professional societies or governing boards, or by convening expert panels.” (2)

Clinical Trial (Intervention Study)
“An experiment to compare the effects of two or more healthcare interventions. Clinical trial is an umbrella term for a variety of designs of healthcare trials, including uncontrolled trials, controlled trials, and randomized controlled trials.” (5)

Cohort
“A group of persons with a common characteristic or set of characteristics. Typically, the group is followed for a specified period of time to determine the incidence of a disorder or complications of an established disorder (prognosis).” (2)

Cohort Studies (Longitudinal or Prospective Study)
“The investigator identifies exposed and non-exposed groups of people, each a cohort, and then follows them forward in time, monitoring the occurrence of the predicted outcome.” (4)
Co-interventions
"Intervention other than intervention under study that may be differentially applied to intervention and control groups and, thus, potentially bias the results of a study." (2)

Co-morbidity
"Disease(s) that coexist(s) in study participants in addition to the index condition that is the subject of the study." (2)

Confidence Interval
"Represents a range of values within which one can be confident that a population parameter is estimated; the range within which the truth plausibility lies; indicates the reliability of an estimate. The smaller the sample size, the wider the confidence interval. As the sample size gets very large, we become increasingly certain that the truth is not far from the point estimate (although the true value lies somewhere in the neighborhood, it is unlikely to be precisely correct) calculated in the experiment and the confidence interval is smaller." (4)

Confounder (or Confounding Variable)
"1. a factor that distorts the true relationship of the study variable of interest by virtue of also being related to the outcome of interest. Confounders are often unequally distributed among the groups being compared. Randomized studies are less likely to have their results distorted by confounders than are observational studies. 2. A factor that is associated with the outcome of interest and is differentially distributed in patients exposed and unexposed to the outcome of interest." (2)

Consecutive Sample
"A sample in which all potentially eligible patients seen over a period of time are enrolled. Used for Sequential Sample Case Series." (4)

Construct Validity
"A construct is a theoretically derived notion of the domain(s) we wish to measure. An understanding of the construct will lead to expectations about how an instrument should behave if it is valid. Construct validity therefore involves comparisons between measures, and examination of the logical relationships, which should exist between a measure and characteristics of patients and patient groups." (2)

Continuous Variables:
“A variable that can theoretically take any value and in practice can take a large number of values with small differences between them (e.g. height). Continuous variables are also sometimes called interval data." (2)

Control Group
“A group that does not receive the experimental intervention. In many studies, the control group receives either usual care or a placebo.” (2)

Controlled Trial (or Randomized Trial or Randomized Controlled Trial)
“Experiment in which individuals are randomly allocated to receive or not receive an experimental preventive, therapeutic, or diagnostic procedure and then followed to determine the effect of the intervention.” (2)

Convenience Sample
“Individuals or groups selected at the convenience of the investigator or primarily because they were available at a convenient time or place.” (4)

Cost-Benefit Analysis
“An economic analysis in which both the costs and the consequences (including increases in the length and quality of life) are expressed in monetary terms.” (2)
Cost-Effectiveness Analysis
"An economic analysis in which the consequences are expressed in natural units. Examples include cost per life saved or cost per unit of blood pressure lowered." (2)

Crossover Study
“A method of comparing two or more treatments or interventions in which the subjects or patient, upon completion of the course of one treatment, are switched to another. In the case of two treatments, A and B, half the subjects are randomly allocated to receive these in the order A,B and half to receive them in the order B,A. A criticism of this design is that effects of the first treatment may carry over into the period when the second is given.” (1)

Cross-sectional Study
“The observation of a defined population at a single point in time or during a specific time interval. Exposure and outcome are determined simultaneously.” (2)

Decision Analysis
“A systematic approach to decision making under conditions of uncertainty. It involves identifying all available alternatives and estimating the probabilities of potential outcomes associated with each alternative, valuing each outcome, and, on the basis of the probabilities and values, arriving at a quantitative estimate of the relative merit of the alternatives.” (2)

Descriptive Study
“A study that describes characteristics of a sample of individuals. Unlike an experimental study, the investigators do not actively intervene to test a hypothesis, but merely describe the health status or characteristics of a sample from a defined population.” (5)

Double-Blind or Double Mask
“1. Neither the subject nor the study staff (those responsible for patient treatment and data collection) are aware of the group or intervention to which the subject has been assigned.
2. Any condition in which two different groups of persons are purposely denied access to information in order to keep that information from influencing some measurement, observation, or process.” (6)

Ecologic Study
“The unit of study is often by country, not of individuals. QOD: weak since there is no control for other important variables. This design is only useful for hypothesis generation.” (1)

Effect Size
“This is the difference in outcomes between the intervention and the control groups divided by the standard deviation. The effect size summarizes the results of each study in terms of the number of standard deviations of difference between the intervention and control groups. Investigators can then calculate the weighted average of effect sizes from studies that measured a given outcome in different ways.” (4)

End Point
Also called outcomes.

Epidemiological Study
“A research study that investigates the factors determining and influencing the frequency and distribution of disease, injury and other health-related events and their causes in a defined human population.” (4)

Evidence-Based Medicine
“1. The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. Evidence-based clinical practice requires integration of individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research, and consideration of available resources. 2. Evidence-based medicine (EBM) can be considered a subcategory of evidence-based health care, which also includes other branches of health
care practice such as evidence-based nursing or evidence-based physiotherapy. EBM subcategories include evidence-based surgery and evidence-based cardiology." (2)

**Evidence-Based Practice (EBP)**

“The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. Evidence-based clinical practice requires integration of individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research, and consideration of available resources.” (2).

**Generalizability (or External Validity)**

“The degree to which the results of a study can be generalized to settings or samples other than the ones studied.” (2)

**Gold Standard**

“A method having established or widely accepted accuracy for determining a diagnosis that provides 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.” (2)

**Incidence**

“Number of new cases of disease occurring during a specified period of time; expressed as a percentage of the number of people at risk during that time.” (2)

**Intention to Treat Analysis (or Intention to Treat Principle)**

“Analyzing participant outcomes according to the group to which they were randomized, even if participants in that group did not receive the planned intervention. This principle preserves the power of randomization, thus ensuring that important known and unknown factors that influence outcomes are likely to be equally distributed across comparison groups. We do not use the term intention-to-treat analysis because of ambiguity created by patients lost to follow-up, which can cause exactly the same sort of bias as failure to adhere to the intention-to-treat principle”. (2)

**Interval Data/Scales**

This possesses all the properties of an ordinal scale, plus the additional property that equal differences between category levels, on any part of the scale, reflect equal differences in the characteristic measured. “An important point to make about interval scales is that the zero point is simply another point on the scale; it does not represent the starting point of the scale, nor the total absence of the characteristic being measured.

Properties of an interval scale:
1. data categories are mutually exclusive,
2. data categories have a logical order,
3. data categories are scaled according to the amount of the characteristic they possess,
4. equal differences in the characteristics are represented by equal differences in the numbers assigned to the categories, and
5. the zero point is completely arbitrary.” (7)

**Longitudinal studies (Cohort or Prospective Study)**

“The investigator identifies exposed and non-exposed groups of people, each a cohort, and then follows them forward in time, monitoring the occurrence of the predicted outcome.” (4)

**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 that 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, gender, clinical features, or a combination).” (6)
Meta-Analysis
“A statistical technique for quantitatively combining the results of multiple studies that measure the same outcome, into a single pooled or summary estimate.” (6)

N of 1 Randomized Controlled Trials
“A single participant undertakes pairs of treatment periods in which they receive target treatment during one period of each pair and a placebo or alternative treatment during the other period. Patients and clinicians are blind to allocation, the order of the target and control is randomized.” (4)

Nominal or Categorical Data/Scales
“This allows subjects to be classified with respect to some characteristic—pairs of categorical variables can be cross-classified to form a contingency table.
Properties of a nominal scale:
1. Data categories are mutually exclusive (an individual can belong to only one category).
2. Data categories have no logical order – numbers may be assigned to categories but merely as convenient labels.
A nominal scale classifies without the categories being ordered.” (7)

Number Needed to Treat (NNT)
“The number of patients who need to be treated over a specific period of time to achieve one additional good outcome. When discussing NNT, it is important to specify the intervention, its duration, and the good outcome. It is the inverse of the absolute risk reduction (1/ARR).” (2)

Observational Studies (or Observational Study Design)
“An observational study can be used to describe many designs that are not randomized trials (e.g., cohort studies or case-control studies that have a goal of establishing causation, studies of prognosis, studies of diagnostic tests, and qualitative studies). The term is most often used in the context of cohort studies and case-control studies in which patient or caregiver preference, or happenstance, determines whether a person is exposed to an intervention or putative harmful agent or behavior (in contrast to the exposure’s being under the control of the investigator, as in a randomized trial).” (2)

Odds Ratio
“In medicine the odds ratio represents the proportion of patients with the target event divided by the proportion without the target event.” (4)

Ordinal Data/Scales
“This is a logical ordering of the categories. With such measurements, the numbers assigned to the categories indicate the amount of a characteristic possessed.
Properties of an ordinal scale:
1. data categories are mutually exclusive,
2. data categories have some logical order, and
3. data categories are scaled according to the amount of a particular characteristic they possess.” (7)

Outcomes
“A component of a participant’s clinical and functional status after an intervention has been applied, that is used to assess the effectiveness of an intervention.” (5)

Precision
“1. [In statistics:] A measure of the likelihood of random errors in the results of a study, meta-analysis or measurement. The greater the precision, the less random error. Confidence intervals around the estimate of effect from each study are one way of expressing precision, with a narrower confidence interval meaning more precision.
2. [In trial searching:] The proportion of relevant articles identified by a search strategy expressed as a percentage of all articles (relevant and irrelevant) identified by that strategy. Highly sensitive strategies tend to have low levels of precision. It is calculated as follows: Precision = Number of relevant articles/Number of articles identified. Also called Positive Predictive Value.” (5)
**Pre-Processed (or Pre-Filtered)**
“A process whereby someone has reviewed the literature, and chosen only the methodologically strongest studies.” (2)

**Prevalence**
“Proportion of persons affected with a particular disease at a specified time. Prevalence rates obtained from high-quality studies can inform pretest probabilities.” (2)

**Prognostic Study**
“A study that enrolls patients at a point in time and follows them forward to determine the frequency and timing of subsequent events.” (2)

**Prospective Study (Cohort or Longitudinal Study)**
“The investigator identifies exposed and non-exposed groups of people, each a cohort, and then follows them forward in time, monitoring the occurrence of the predicted outcome.” (4)

**Qualitative Research**
“Qualitative research focuses on social and interpreted, rather than quantifiable, phenomena and aims to discover, interpret, and describe rather than to test and evaluate. Qualitative research makes inductive, descriptive inferences to theory concerning social experiences or settings, whereas quantitative research makes causal or correlational inferences to populations. Qualitative research is not a single method but a family of analytic approaches that rely on the description and interpretation of qualitative data. Specific methods include, for example, grounded theory, ethnography, phenomenology, case study, critical theory, and historiography.” (2)

**Quantitative Research**
“The investigation of phenomena that lend themselves to test well-specified hypotheses through precise measurement and quantification of predetermined variables that yield numbers suitable for statistical analysis.” (2)

**Quasi-experimental Trial**
“An intervention trial that lacks full control over allocation and/or timing of intervention, therefore study is susceptible to bias. QOD: weak.” (1)

**Random Sample**
“A sample derived by selecting sampling units (for example, individual patients) such that each unit has an independent and fixed chance of selection. Whether a given unit is selected is determined by chance (for example, by a table of randomly ordered numbers).” (6)

**Randomized Controlled Trial (or Randomized Trial or Controlled Trial)**
“Experiment in which individuals are randomly allocated to receive or not receive an experimental preventive, therapeutic, or diagnostic procedure and then followed to determine the effect of the intervention.” (2)

**Ratio Data/Scales**
“The highest level in the hierarchy of measurement scales is the ratio scale. It possesses a true zero point that presents the absence of the characteristic being measured.
Properties of ratio scale:
  1. data categories are mutually exclusive,
  2. data categories have a logical order,
  3. data categories are scaled according to the amount of the characteristic they possess,
  4. equal differences in the characteristic are presented by equal differences in the numbers assigned to the categories, and
  5. the zero point represents an absence of the characteristic being measured.” (7)
Relative Risk (or Risk Ratio)
"Ratio of the risk of an event among an exposed population to the risk among the unexposed." (2)

Relative Risk Reduction (RRR)
"The proportional reduction in rates of harmful outcomes between experimental and control participants. It is calculated by dividing the rate of harmful outcome in the control group (CER) minus the rate of harmful outcome in the experimental group (EER) by the rate of harmful outcome in the control group [(CER–EER)/CER]. Used with a beneficial exposure or intervention." (2)

Reliability
"The degree to which results obtained by a measurement procedure can be replicated. Lack of reliability can arise from divergences between observers or measurement instruments, measurement error, and instability or fluctuation in the attribute being measured." (5)

Reliability Measures of Categorical Data
1. "inter-observer bias: reflected in differences in the marginal distributions of the response variable for each of the observers
2. observer disagreement: indicated by how observers classify individual subjects into the same category on the measurement scale.

One needs to incorporate chance agreement into the assessment of inter-observer reliability. An index that has been suggested is the ratio of the difference in the observed and chance agreement to the maximum possible excess of observed over chance agreement. 1- Pc defines the kappa statistic.

K=1 if there is complete agreement between the two raters
K>0 if the observed agreement is greater than chance
K=0 if observed agreement is equal to chance
K<0 if the unlikely event of the observed agreement is less than chance.

K                     Strength of agreement
      0.01            Poor
0.00 - 0.20         Slight
0.21 – 0.40         Fair
0.41 – 0.60         Moderate
0.61 – 0.80         Substantial
0.81 – 1.00         Almost perfect” (7)

Research
"A class of activities designed to develop or contribute to generalizable knowledge; generalizable knowledge consists of theories, principles, or relationships, or accumulation of information on which these are based, that can be corroborated by acceptable scientific methods of observation, inference, and/or experiment (adapted from CIOMS, 1993).” (1)

Review Paper/Narrative Review/Textbooks
“A summary of the literature on a topic. Collection of studies and their interpretation is determined by the author(s) and may be biased. QOD: weak, but can be useful for general understanding.” (1)

Run-in Period
“A period before a trial is commenced when no treatment is given. The data from this stage of a trial are only occasionally of value but can serve a valuable role in screening out ineligible or non-compliant participants, in ensuring that participants are in a stable condition, and in providing baseline observations. A run-in period is sometimes called a washout period if treatments that participants were using before entering the trial are discontinued.” (5)
Sensitivity/Specificity
“How well the cut off criteria categorize the population is quantified by two measures: sensitivity and specificity.

- **The sensitivity of a test or criterion** is the proportion of afflicted individuals who test positive, i.e., the proportion of those individuals with folate deficiency whose serum folate is less than 6 nmol/L. The sensitivity of a diagnostic or screening test is the proportion of people who truly have a designated disorder who are so identified by the test. The test may consist of or include clinical observations.

- **The specificity of a test or criterion** is the proportion of non-afflicted individuals who are identified as non-afflicted, i.e., who test negative. The specificity of a diagnostic or screening test is the proportion of people who are truly free of a designated disorder who are so identified by the test. The test may consist of or include clinical observations.” (6)

Survey
“Observational study that focuses on obtaining information about activities, beliefs, preferences, knowledge, or attitudes from respondents through interviewer-administered or self-administered methods.” (2)

Systematic Review
“1. The consolidation of research evidence that incorporates a critical assessment and evaluation of the research (not simply a summary) and addresses a focused clinical question using methods designed to reduce the likelihood of bias. 2. The identification, selection, appraisal, and summary of primary studies addressing a focused clinical question using methods to reduce the likelihood of bias.” (2)

Validity
“In relation to studies of diagnosis or therapy, a study is valid insofar as the results represent an unbiased estimate of the underlying truth. In relation to health-related quality of life measures, validity represents the extent to which an instrument is measuring what it is intended to measure.” (4)

Washout Phase
“That stage in a study, especially a therapeutic trial, when treatment is withdrawn so that its effects disappear and the subject’s characteristics return to their baseline state.” (1)

References