Study Designs and Evaluation Models for Emergency Department Public Health Research

Glossary

Assessment Effect / Reactivity: The altering of behavior as a result of its measurement which may bias study results.[1]

Audit Studies: A review or examination that establishes the extent to which a condition, process, or performance conforms to a predetermined standard or criteria. Assessment or review of any aspect of health care to determine its quality; audits may be carried out on the provision of care, compliance, community response, completeness of records, etc.[2]

Capture-Recapture: A method of estimating the size of a target population or a subset of that population. The method originated in population biology where it relied on tagging and releasing captured animals, then recapturing them. The method was adopted in veterinary epidemiology, then in vital statistics (census-taking) and epidemiology. If two independent sources or population estimates are available with a) cases found by both, b) cases found only by the first source, or c) cases found only by the second source, the maximum likelihood population estimate is the product of the total in each source divided by the total found in both sources, i.e. (a + b) x (a + c) / a. If the two sources are positively (or negatively) dependent, the result will be biased towards an underestimate (or overestimate). If three or more sources are available, log-linear methods can sometimes be used to model the degrees of dependence among the sources. Although the capture-recapture methods have some limitations, they are useful to estimate numbers of cases and numbers at risk in elusive populations, such as homeless people and sex workers.[2]

Confounding: A situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.[3]

Confounding Bias: Distortion of the estimated effect of an exposure on an outcome, caused by the presence of an extraneous factor associated both with the exposure and the outcome.[3]

Cost-Benefit Analysis: An analysis in which the economic and social costs of medical care and the benefits of reduced loss of net earnings due to preventing premature death or disability are considered. The general rule for the allocation of funds in a cost-benefit analysis is that the ratio of the marginal benefit (the benefit of preventing an additional case) to marginal cost (the cost of preventing an additional case) should be equal to or greater than 1.[2]

Cost-Effectiveness Analysis: This form of analysis seeks to determine the costs and effectiveness of an activity or to compare similar alternative activities to determine the relative degree to which they will obtain the desired objectives or outcomes. The preferred action or alternative is one that requires the least cost to produce a given level of effectiveness, or provides the greatest effectiveness for a given level of cost. In the health care field, outcomes are measured in terms of health status.[2]

Equivalent Time-Sample Design: A type of quasi-experimental study design. This design attempts to achieve an equivalent sample of persons to provide a baseline against which to compare the effects of the experimental variable. This is accomplished by repeated introduction of the intervention across equivalent time periods. These time periods may be sequential, as in an alternating "off-on-off-on" design, or random.

Experimental Design: A study in which an intervention is introduced by the investigator and subjects are randomized to one of the study arms.[2]

External Validity: A study is externally valid if it can produce unbiased inferences regarding a target population (beyond the subjects in that study). This aspect of validity is only meaningful with regard to a specified external target population. For example, the results of a study conducted using only black females may or may not be generalizable to all females. The evaluation of generalizability/external validity usually involves much more subject matter judgment than internal validity.[2]

Internal Validity: The index and comparison groups are selected and compared in such a manner that the observed differences between them on the dependent variables under study may, apart from sampling error, be attributed only to the hypothesized effect under investigation.[2]

Interrupted Time-Series Design: A type of quasi-experimental study design. This design includes an intervention introduced as a discrete event at a point in time. Data are collected prior to and after the intervention in a chronological fashion. The purpose of an interrupted time-series is to assess the effect of the intervention by attempting to infer if and in what way it has changed the data in the time series.[4]

Intervention Study: An investigation involving intentional change in some aspect of the status of the subjects (e.g., introduction of a preventive or therapeutic regimen), or designed to test a hypothesized relationship; usually an experiment such as a randomized controlled trial.[2]

Measurement Bias: 1) Systematic error (bias) in a measurement, and/or 2) systematic error arising from inaccurate measurement (or classification) of subjects on study variable(s).[5]

Non-Equivalent Control Group Design: A quasi-experimental study design. This is a common design that includes two groups, an experimental group and control group that do not have sampling equivalence prior to the introduction of the intervention.

One Group Pretest-Posttest Design: A pre-experimental study design. This design includes the introduction of an intervention using one group of subjects. No separate control group is included in this type of study.

Selection Bias: Error due to systematic differences in characteristics between those who take part in a study and those who do not. Examples include subjects in a survey limited to participants in a discrete place at a discrete time excluding all others. Selection bias invalidates conclusions and generalizations that might otherwise be drawn from such studies. It is a common and commonly overlooked problem.[2]

Observational Study: Epidemiologic study that does not involve an intervention. Such a study is one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics. Analytical epidemiologic methods,[6] such as case-control and cohort study designs, are properly called observational epidemiology because the investigator is observing without intervention other than to record, classify, count, and statistically analyze results.[2]

Pre-Experimental Design: A general study design category in which an intervention is introduced by the investigator, but where subjects are not randomly assigned to unique study arms; in fact, this design category typically does not include a unique control arm. Several types exist, including one-group pretest-posttest and static-group comparison designs. This general design lacks baseline or reference data and is vulnerable to confounding due to uncontrolled extraneous variables. Causality cannot be determined by this study design (therefore it cannot be classified as a quasi-experimental design), however its main use is to form hypotheses about causality that can be determined by other, more controlled studies.[7]

Quasi-Experimental Design: A general study design category in which an intervention is introduced by the investigator but where subjects are not randomly assigned to unique study arms. Several types exist, including non-equivalent control group, interrupted time-series, and equivalent time-samples designs.

Static Group Comparison: A method of study in which a comparison is made between two groups, one of which receives the experimental treatment and the other which does not receive the experimental treatment, but may receive either a standard treatment or no treatment at all.[3]

Power: The ability of a study to demonstrate an association if one exists. The power of a study is determined by several factors, including the frequency of the condition under study, the magnitude of the effect, the study design, and the sample size. Mathematically, power is defined as the probability that the null hypothesis will be rejected if it is false, and is equal to 1-β where β is the probability of type II error.[5]

Surveillance Studies: Ongoing, systematic collection, analysis, and interpretation of data (e.g., regarding agent/hazard, risk factor, exposure, health event) essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control.

Type 1 Error: The error of rejecting a true null hypothesis (i.e., declaring that a difference exists when it does not). Also called an α error.

Type 2 Error: The error of failing to reject a false null hypothesis (i.e., declaring that a difference does not exist when in fact it does). Also called a β error.

References

1. Allen JP, Columbus M. Assessing Alcohol Problems: A Guide for Clinicians and Researchers. NIAAA Treatment Handbook Series 4. 1995, p. 151.
2. Last JM. A Dictionary of Epidemiology, Fourth Edition. New York, NY: Oxford University Press, 2001.
3. Cottrell RR, McKenzie JF. Health Promotion Education and Research Methods: Using the Five Chapter Thesis/Dissertation Model. Sudbury, MA: Jones and Bartlett Publishers, 2005, p 177.
4. Pedhazur EJ, Schmelkin LP. Measurement, Design, and Analysis: An Integrated Approach. Hillsdale, NJ: Lawrence Erlbaum and Associates, 1991, p 301.
5. Porta M. A Dictionary of Epidemiology, Fifth Edition. New York, NY: Oxford University Press, 2008, pp 150-1 and p.190.
6. Kelsey JL, Thompson WD, Evans AL. Methods in Observational Epidemiology. New York, NY: Oxford University Press, 1986.
7. Gould JE. Concise Handbook of Experimental Methods for the Behavioral and Biological Science. Boca Ratan, FL: CRC Press LLC, 2001, pp 247-8.