Case-Control Studies Retrospective Cohort Studies Nested Case-Control Studies Secular Trend Analyses Drug Utilization Studies Economic Analyses Cost-Benefit Analysis Cost-Effectiveness Analysis Cost-Identification Analysis

Study Designs Used in Applications of Automated Databases for Epidemiologic Research

Case Control Studies

Comparing risk factors in a population with the disease *(cases)* to the risk factors in a sample without the disease *(controls)*, and calculating an *odds* ratio (an approximation of the relative risk)

- Advantages:
 - Best study for relatively rare diseases because it guarantees a sufficient number of cases with the disease
 - o Permits evaluation of multiple possible risk factors for a disease
 - o Relatively small sample size
 - Relatively inexpensive
 - Short duration

• Disadvantages:

- Can only measure one disease variable
- o Does not provide information about prevalence or incidence
- Increased bias due to the retrospective design and the need to obtain information on exposures by recreating events that happened in the past
- Selecting proper controls is challenging and can lead to selection bias

* Retrospective Cohort Studies

Retrospectively (using existing records of events that have already occurred, both past exposures and disease outcomes) following subsets of a defined population over time, looking for differences in their outcomes, and calculating the *relative risk* (the ratio of disease incidence in subjects exposed to certain risk factors against those not exposed).

- Advantages:
 - Can study multiple possible diseases from a single exposure
 - Provides information about prevalence or incidence
 - o Decreased bias

• Disadvantages:

- Requires large sample size
- o Relatively expensive

Nested Case-Control Studies

Case-control study done in the population of an ongoing cohort study, thus "nested" inside the cohort study. In large cohorts, it is often more efficient to construct a case-control study within the cohort, once a significant number of cases have emerged, to study a specific exposure not measured at baseline.

• Advantages:

o Less expensive than analysis of the full cohort

• Disadvantages:

• Non-diseased persons from whom the controls are selected may not be fully representative of the original cohort due to loss to follow-up or death

Secular Trend Analyses

Descriptive time series analyses of diseases or medical treatments or medical services to identify changes in prevalence over time. Known also as ecological studies, examining trends in an exposure that is a presumed cause and trends in a disease that is a presumed effect, and testing whether the trends coincide.

• Advantages:

- Can examine trends over time
- Can examine trends across geographic boundaries
- Can compare variations in prevalence rates by gender and age groups
- Autocorrelation analysis may be used to determine whether cyclic components are present in the time series or whether apparent fluctuations are random

Drug Utilization Studies

Descriptive studies to evaluate patterns of medication use in a population, over time or before and after a change in policy or publication of some study results that may affect drug use.

- Advantages:
 - Can study trends over time in utilization rates
 - Can study multiple therapies
 - Can compare variations in utilization rates by geography, gender, and age groups.
- Disadvantages:
 - Sample size may be insufficient for studying recent newly introduced drugs

Economic Analyses

Attributing unit costs to various clinical interventions in order to assess the cost-effectiveness of treatment alternatives.

• Advantages:

- The cost comparisons can employ alternative measures of outcomes (e.g., days of partial remission, days of full remission, quality-adjusted life years).
- The cost comparisons can employ alternative measures of cost (direct treatment costs, indirect treatment costs (e.g., opportunity costs of patient time), and other economic aspects (e.g., the amortized cost of training therapists).

Cost-Benefit Analysis

Comparing the cost of a medical intervention to its benefit. Both costs and benefits are measured in the same (usually monetary) units (e.g., dollars). These measurements are used to determine either the ratio of dollars spent to dollars saved or the net saving (if benefits are greater than costs) or net cost. An investment should be undertaken when its benefits exceed its costs.

Cost-Effectiveness Analysis

Whereas cost is still calculated only in terms of dollars spent, effectiveness is determined independently and may be measured only in clinical terms (e.g., number of lives saved, complications prevented, or diseases cured). Alternatively, health outcomes can be reported in terms of a change in an intermediate clinical outcome (e.g., cost per percent change in blood cholesterol level). These results are reported as a ratio of costs to clinical benefits, with costs measured in monetary terms but with benefits measured in the units of the relevant outcome measure (e.g., dollars per year of life saved).

Cost-Identification Analysis

Enumerating the costs involved in medical care and ignoring the outcomes that result from that care, to determine alternative ways of providing a service. The analysis might be expressed in terms of the cost per unit of service provided. Cost-identification studies, which include comparisons among different treatments based upon their costs alone, are appropriate only if treatment outcomes or benefits are equivalent for the therapies being evaluated.

Links to online tutorials

http://www.auster.com/gcrc/casecontrol.html

(links to the General Clinical Research Center of Tufts University School of Medicine and the New England Medical Center)

<u>http://www.cdc.gov/eis/casestudies/casestudyex.htm</u> (links to the CDC)

http://www.ttuhsc.edu/SOM/FamMed/lectures/epi3/tsldOIO.htm

http://www.ttuhsc.edu/SOM/FamMed/lectures/epi3/index.htm

http://www.cebm.net/study_designs.asp (links to the Center for Evidence-Based Medicine)

http://www.gfmer.ch/Books/Reproductive health/Cohort and case control studies.html (links to the World Health Organization)

http://www.tufts.edu/~gdallal/STUDY.HTM