Biostatistics and Research Design in Dentistry


Table 2-1 shows a good classification of the types of study designs. Also see Figure 2-5 to get clear on time and its relationship to the direction of inquiry.

The difference between an observational study and an experiment: a planned intervention.

**Observational studies**

What are the characteristics of each kind of study? What are the advantages?

Disadvantages? What are the main forms of bias inherent in this design?

**Comparison of Study Designs**

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**Case-series**

**Characteristics:** The description of interesting observations. No controls.

Purpose: to describe.

**Advantages:** Simple; easy. Generates testable hypotheses.

**Disadvantages:** Not conclusive.

**Bias:** Findings due to chance?

**Cross-Sectional** (surveys and polls)

- Defined population
- Gather data on exposure and disease
- Exposed; have disease
- Exposed; do not have disease
- Not exposed; have disease
- Not exposed; do not have disease

**Characteristics:** data collected on subjects at one point in time. Often looks at prevalence. See Figure 2–2.

**Purpose:** What is happening right now?

**Advantages:** Short duration.

**Disadvantages:** Short duration. Only looks at “now,” not across time.

**Bias:** The inclusion/exclusion of subjects is critical. Representativeness: The sample is representative of what?

**Longitudinal studies:** Case-Control and Cohort studies.

- Begin at a point in time; a process occurs and then time passes; end-of-study assessment
- Cohort studies look forward (prospective) from a risk factor to an outcome
- Case-control studies look backward (retrospective) from an outcome to risk factors

**Case-Control**

- Exposed
- Unexposed

Cases

- Exposed
- Unexposed

Controls

Past → Present
**Characteristics:** Begins with an outcome of interest, then look back to detect risk factors. See Figure 2–1.

**Purpose:** to explain outcomes by evaluating previous events. What happened?

**Advantage:** Good for rare diseases or for those that develop over a long time period. Quick and easy.

**Disadvantage:** The largest number of possible biases and errors, and they depend on high-quality historical records.

**Bias:** The major problem is the selection of the control group; It is never true that—except for the risk factor—the controls are identical to the cases.

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**Experimental studies**

**Clinical trials** involve humans

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**Characteristics:** A controlled study has a control condition.

**Purpose:** All other things being equal, let’s control the exposure of risk factors and see what the differences in outcomes are.

**Types of controls**

- Independent, concurrent controls
- Self-controls, such as cross-over studies. See Figure 2–7
- External controls, *historical controls* are outside of the control of this study. Historical controls are almost always worse off than a concurrent-control group. See Figure 2–8
- Uncontrolled studies are not clinical trials

**Advantage:** A randomized, double-blind, control study is the gold standard; results
are the strongest evidence for causation. The only way to establish *efficacy*.

**Disadvantage:** Difficult; expensive; time consuming. A nonrandomized or nonblinded study is subject to most of the biases of the cohort study.

**Bias:** When using a subject as his/her own control, the Hawthorne effect will be evident. (Subjects improve simply by being in a study.)
Cross-sectional versus Cohort

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