Jane's Corner

This month's topic: **Point Estimates and Confidence Intervals**

Statistical inference can estimate the value of parameters (which describe a population, and are usually represented by Greek letters). For example, for all adult males in the world, one parameter is the mean height. The mean parameter of a population is commonly represented by $\mu$. It is rarely feasible to determine the true value of a parameter because that would entail making measurements on the entire population (i.e., measuring the height of all adult males in the world). So, methods of estimating the values of parameters, such as point estimates (a single number used to estimate the parameter) have been developed. The parameter can be estimated using a formula shown to have good mathematical properties. For the mean height example, sample heights of adult males would be measured and the average of the heights calculated. The average (or sample mean,) is a point estimate of $\mu$. However, we don't know how accurate an estimate this is. Another sample would most likely give us a different estimate. Without some indication of how much the estimated value of the parameter varies from sample to sample, the point estimate is of little value.

In 1937, Dr. Jerzy Neyman discovered confidence intervals as a method of estimating parameters that combines the good mathematical properties of the point estimate with an indication of the variability of the estimate. The typical form of a confidence interval is: estimate $\pm$ margin of error. The estimate is often the point estimate for the parameter and the margin of error (the width of the confidence interval is twice the margin of error) is a measure of how accurate the estimate is. The margin of error is based on two factors, the variability of the estimate (a function in part of the sample size) and the confidence level (typically 95% is chosen). Using a confidence interval, we could state that we are 95% confident that the true mean height of all adult males in the world is between two numbers that we calculate from our sample data using the formula for a confidence interval for the mean of a population. Please contact Jane Johnson (jjohnson@kcom.edu) with suggestions for topics.
Interested in submitting a feature article to Patient Care? They don't publish original research; nor do they publish review articles in the traditional sense. Instead, they aim to provide practical advice on dealing with the clinical problems commonly encountered in day-to-day patient care.

They prefer a somewhat informal, less academic tone than the one found in most medical textbooks and scholarly journals. Keep these guidelines in mind as you're preparing your manuscript but remember also that highly skilled professional editors are on staff and prepared to give you as much help as you need.

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**RESEARCH CORNERSTONES**

**THE YIN AND YANG OF RESEARCH**

**Research Design**

One good way to strengthen your analysis is through a thought-out research design. There are three primary types of research designs:

1. Randomized or true experimental designs, which are the strongest design for establishing a cause and effect relationship, as random assignment is used— and the group involved are considered equivalent. This helps to reduce all of the multiple group threats to internal validity discussed earlier.

2. Quasi-Experimental designs are those which employ multiple measures or a control group without randomly assigning participants to group. The ability of these designs to establish a cause effect relationship is dependent upon the degree to which the two groups in the study are equivalent.

3. Non-experimental designs do not employ multiple measure, do not use a control group and do not use any random assignment in its design. These are usually descriptive studies conducted using a simple survey instrument only once. While they are useful in their own right — they are weak in establishing cause/effect relationships.

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**NIH HIGHLIGHTS ON RESEARCH**

**USE OF HUMAN SUBJECTS**

**Defining Subject:** Human subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. The regulations governing the inclusion of human subjects in research extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

**Intervention:** Intervention includes both physical procedures by which data are gathered (i.e., venipuncture) and manipulations of the subject or subject's environment performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

**Private Information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes (i.e., medical record) and an individual can reasonably expect will not be made public. Private Information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(http://www.niaid.nih.gov/ncn/grants/write/write%5Fal.htm)
RESEARCH REFLECTIONS

Question 2: Continued from February Issue of Research Times

What general type of study was conducted?

Was the study design inappropriate to answer the question?

Types of Study Designs:

- **Case-control (retrospective) studies**: Cases and controls are defined by their disease status, not by being assigned to a treatment or control group, as in an experimental study. Examine several possible determinants of disease and thus are useful for generating hypotheses.

- **Cross-sectional studies (surveys)**: Used to measure the nature and distribution of selected characteristics of a group at a single point in time. Such surveys are descriptive, although they can be used in comparative studies, such as when the same group is surveyed before and after an event or periodically over time. Useful for assessing prevalence rates and for identifying factors associated with a disease.

- **Cohort (prospective) studies**: Identify group of people with similar characteristics (a cohort) and follow them forward in time until the event of interest occurs. Compare the exposures to presumed risk factors of those with and without disease to determine possible causes of the disease. Cannot determine causation. Useful for identifying the natural course of a disease.

- **Randomized controlled trials**: Prospective, experimental study that uses special techniques, such as random assignment, blinding, and placebo-controls to reduce bias. Considered to be the most reliable study design for establishing cause and effect. Not possible or ethical in all situations.

**TECHNIQUE**: see the CONSORT Statement for advice on assessing randomized trials: [http://www.consort-statement.org/revisedstatement.htm](http://www.consort-statement.org/revisedstatement.htm)

**The Hierarchy Methods Used to Gather Evidence in Studies, Ranked in Ascending Order of Sophistication**

1. Anecdotal case reports of single patients
2. Case series without controls
3. Case series with historical controls
4. Analyses of clinical databases or registries
5. Case-control (retrospective) studies
6. Cohort (prospective) studies
7. Single randomized controlled trials
8. Confirmed randomized controlled trials
9. Meta-analyses
10. Cumulative meta-analyses


HISTORY LESSONS

Treatment of Scurvy Through Control Groups: Researcher James Lind (1716-1794)

Born in Edinburgh, in 1731, he registered as an apprentice at the College of Surgeons in Edinburgh and after eight years began serving as a naval surgeon in the Mediterranean. In 1747, while serving in the Channel on H.M.S. Salisbury, he carried out his experiments on scurvy, the symptoms of which included loose teeth, bleeding gums, and hemorrhages.

“Scurvy began to rage after being a month or six weeks at sea... the water on board... was uncommonly sweet and good [and] provisions such as could afford no suspicion... yet, at the expiration of ten weeks, we brought into Plymouth 80 men, out of a complement of 350, more or less afflicted with the diseases.” A Treatise on Scurvy, 1754.

On H.M.S. Salisbury, Lind selected twelve men from the ship, who all suffered from similar symptoms of scurvy, and divided them into six pairs. Two men received a quart of cider a day, and two others were given an unspecified elixir three times a day. One pair was treated with seawater, and another was fed with a combination of garlic, mustard, and horseradish. Two men were given spoonfuls of vinegar, and the last two were given two oranges and one lemon every day.

Four out of the six groups reported no change, the men given cider reported only a slight improvement, but the two seamen fed citrus fruits experienced a remarkable recovery. The benefits of lime juice had been known for centuries, but Lind had definitively established the superiority of citrus fruits above all other ‘remedies’.
SPECIAL FOCUS

Vert Mooney, M.D.
A.T. Still Research Institute
External Board of Scientific Counselors (EBSC)

Dr. Mooney is internationally renowned as a leader in spine surgery and orthopedic rehabilitation medicine. After graduating from Princeton University, he attended Columbia University College of Physicians and Surgeons. He trained in his orthopedic residency under Dr. Albert Ferguson, Jr. at the University of Pittsburgh and in a fellowship at Rancho Los Amigos where he developed his diverse interests.

Dr. Mooney practiced orthopedic surgery in Downey, California, for ten years prior to being recruited as Professor and Chairman at the University of Texas Southwestern Medical School. He was the catalyst to the rapid growth and development of the orthopedic surgery division in the 1980s. Dr. Mooney is now Director of the American College of Spine Surgery.

NIH DICTIONARY

Not recommended for further consideration: Judgment made by a scientific review group or study section that an application has risks or inadequate protections against risks that make it unacceptable and unable to be funded by an IC (major NIH organization).

(https://www.niaid.nih.gov/ncn/tools/gloss.htm)

TIDBITS

The February 2003 North American Primary Care Research Group (NAPCRG) Newsletter is now available and can be accessed from the NAPCRG website at http://www.napcrg.org/napnews0203.pdf.

The deadline for submitting a proposal for the 2003 NAPCRG Annual Meeting is April 23, 2003. The Call for Papers is posted at www.napcrg.org. Read the related article on pp. 6 and 7 of the online Newsletter http://www.napcrg.org/napnews0203.pdf.

The Research Institute will sponsor “The HIPAA Privacy Rule: Enhancing or Harming the Public’s Health?” on March 28, 2003, 1:00-2:00 p.m in Gutensohn 357. To register for this event, go to: http://www.publichealthgrandrounds.unc.edu/privacy/partreq.htm.


The first Clinical Research Workshop for residents and interns met on Tuesday March 2, 2003. Dr. Brian Degenhardt of KCOM and Dr. James Campbell of University of Missouri, Columbia, gave presentations about: defining the Research Question; giving the Origins of the Research Question; defining the Characteristics of a Good Research Question; and Primary and Secondary Questions. Residents then diagrammed their research questions with Dr. Campbell.

Production of this publication is funded by the Academic Administrative Units in Primary Care Grant D12HP00156 between the A.T. Still University/Kirksville College of Osteopathic Medicine and the U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, Division of Medicine.

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