

SECTION 1.2 – Observational Studies versus Designed Experiments

Explanatory (or Predictor variable) – A variable used to predict or explain the values of the response variable.

Response variable – The variable to be measured or observed.

Observational study – A study that measures the value of the response variable without attempting to influence the value of either the response or explanatory variables. That is, in an observational study, the researcher simply observes the behavior of the individuals without trying to influence the outcome of the study.

Designed experiment – When a researcher assigns the individuals in a study to a certain group, intentionally changing the value of an explanatory variable, and then records the value of the response variable for each group.

Census – A list of all individuals in a population along with certain characteristics of each individual.

☺ **Exercises:**

For Exercises 1 through 4, determine whether the study depicts an observational study or an experiment. Explain your reasoning.

- 1) **Do Left-Handers Die Earlier?** According to a study published in the *Journal of the American Public Health Association*, left-handed people do not die at an earlier age than right-handed people, contrary to the conclusion of a highly publicized report done 2 years earlier. The investigation involved a 6-year study of 3800 people in East Boston older than age 65. Researchers at Harvard University and the National Institute of Aging found that the “lefties” and “righties” died at exactly the same rate. “There was no difference, period,” said Dr. Jack Guralnik, an epidemiologist at the institute and one of the coauthors of the report.
 - 2) **Aspirin and Cardiovascular Disease.** Aspirin is the cornerstone of preventive cardiovascular disease (CVD) treatment and bedtime intake of aspirin (chronotherapy) has been shown to reduce morning activity of platelets. It has been shown that platelet reactivity follows a clear circadian rhythm, with a peak of platelet reactivity during the morning (6-12 AM). Importantly, studies have shown in meta-analyses that high platelet activity is predictive of adverse cardiovascular outcomes in patients with stable CVD. Given this knowledge, it is highly likely that the morning peak of platelet reactivity contributes to the morning peak of cardiovascular events and that reduction of morning platelet activity prevents cardiovascular events during morning hours. This may be achieved by intake of aspirin at bedtime instead of on awakening. This study will be a comparative effectiveness research to determine the difference in major adverse cardiovascular events between the group with aspirin after awakening and placebo before bedtime and the group with placebo after awakening and aspirin before bedtime.
 - 3) **Oh Rats!** Rats with cancer are divided into two groups. One group receives 5 milligrams (mg) of a medication that is thought to fight cancer, and the other receives 10 mg. After 2 years, the spread of the cancer is measured.
 - 4) **COVID-19.** Data from up to 5,000 adult patients in the US will be captured from eligible patients enrolled following admission to the hospital. Participants will have de-identified medical records collected from hospital admission to discharge, including but not limited to critical care monitoring, details on mechanical ventilation, laboratory data, imaging reports, medications, and all procedures. Diagnosis and patient management will follow each hospital's standard of care and no specific treatments, procedures or laboratory tests will be dictated by enrollment in TARGET-COVID-19. (Sponsored by and information by Target PharmaSolutions, Inc.)
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