

Types of Studies and the Questions Types they Answer:

Case Series and Case Reports: A report on a patient or a series of patients with an outcome of interest. No control group is involved.

Case-Control Studies: A study which involves identifying patients who have the outcome of interest (cases) and control patients without the same outcome, and looking back to see if they had the exposure of interest. A case control study starts with patients who have the outcome and looks backwards to possible exposures. **(Etiology/Harm)**

Cohort Studies: Involves identification of two groups (cohorts) of patients, one that received the exposure of interest, and one that did not, and following these cohorts forward for the outcome of interest. **(Prognosis)**

Randomized, controlled clinical trials: Participants are randomly allocated into an experimental group or a control group and followed over time for the variables/outcomes of interest. **(Prevention or Therapy)**

Studies that show the efficacy of a diagnostic test are called **Prospective, Blind Comparison to a Gold Standard** study. This is a controlled trial that looks at patients with varying degrees of an illness and administers both diagnostic tests -- the test under investigation and the "gold standard" test -- to all of the patients in the study group. **(Diagnosis or Clinical Exam)**

Systematic Reviews: A summary of the medical literature that uses explicit methods to perform a comprehensive literature search and critical appraisal of individual studies, and the uses appropriate statistical techniques to combine these valid studies. **(Therapy or Prevention)**

Meta-Analysis: A systematic review that uses quantitative methods to synthesize and summarize the results. **(Therapy or Prevention)**

Clinical Trial [Publication Type]: a research activity involving the administration of a test regimen to humans to evaluate its efficacy and safety. The term is subject to wide variation in usage, from the first use in humans without any control treatment to a rigorously designed and executed experiment involving test and control treatments and randomization. Several phases of clinical trials:

- **Phase I:** First introduction of a candidate vaccine or a drug into a human population to determine its safety and mode of action
- **Phase II:** Initial trial to examine efficacy usually in 200 to 500 volunteers. Usually, but not always, subjects are randomly allocated to study and control groups
- **Phase III:** Complete assessment of safety and efficacy. It involves larger numbers, perhaps thousands of volunteers, usually with random allocation to study and control groups, and may be a multicenter trial
- **Phase IV:** Includes research to explore a specific pharmacologic effect, to establish the incidence of adverse reaction, or to determine the effects of long-term use. Ethical review is required.

Bibliography

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