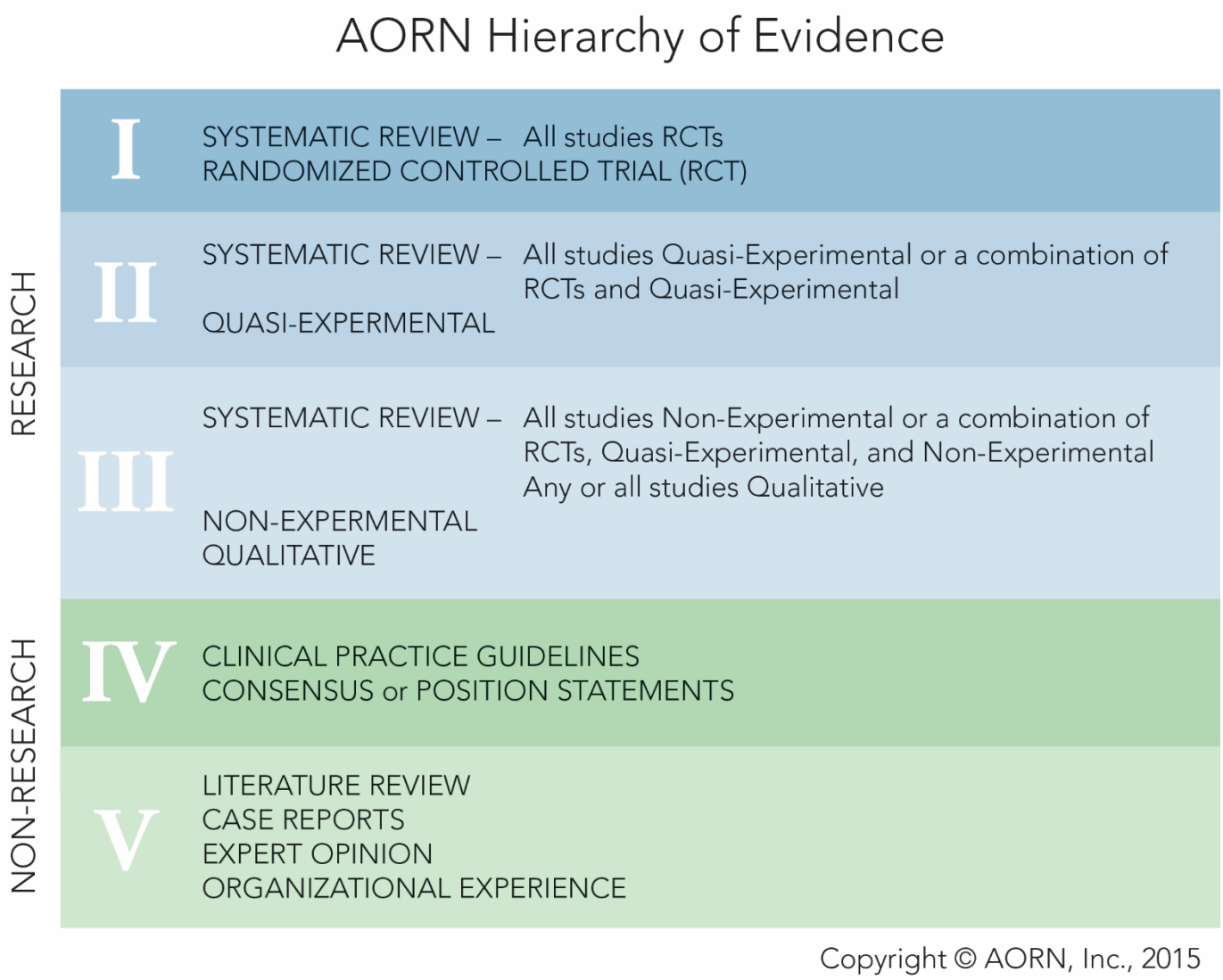


A hierarchy of evidence ranks various types of evidence according to the strength of evidence they provide.

RESEARCH ELEMENTS

Intervention/Manipulation: The researcher does something to at least some of the participants (ie, there is some type of treatment being tested).

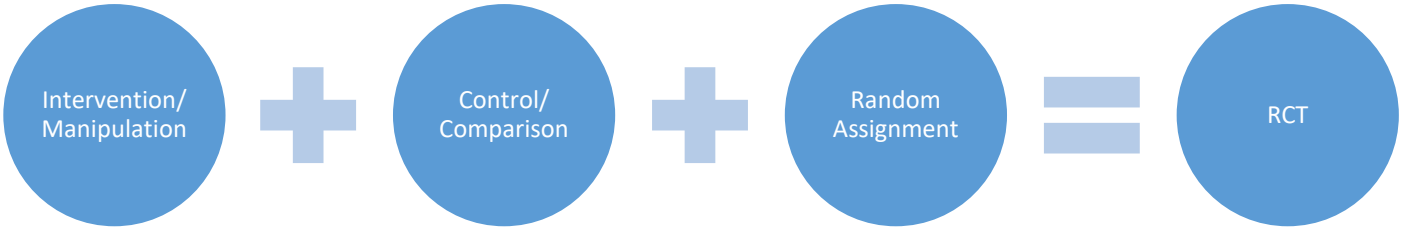
Control/Comparison Group: The researcher provides standard care or a comparison intervention that is different from the experimental intervention. A comparison group is often used in lieu of a control group.

Random Assignment: The researcher assigns participants to a control or treatment group on a random basis (ie, in a manner determined by chance).

RESEARCH EVIDENCE

Randomized Controlled Trial (RCTs): True experiments or RCTs possess three characteristics:

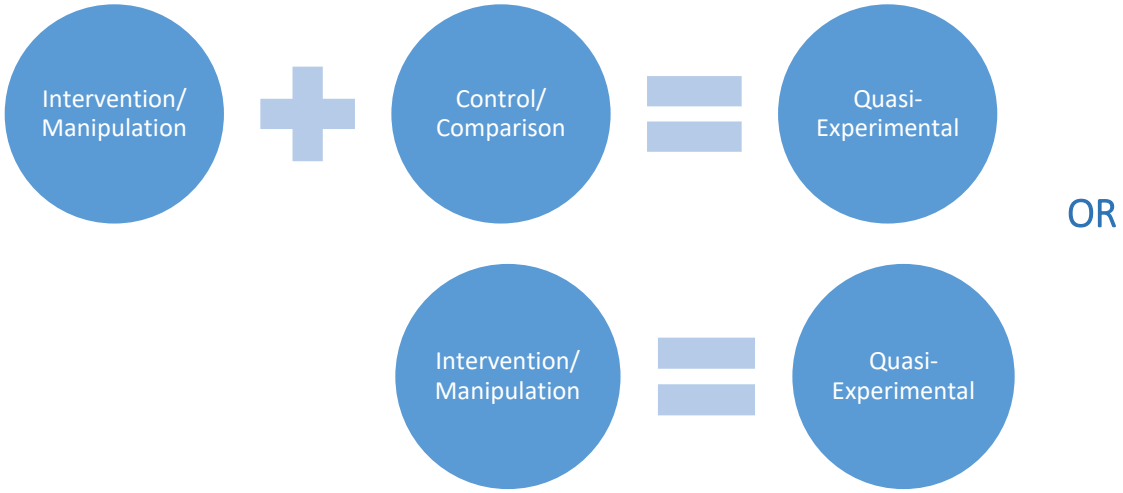
1. An experimental group that receives the treatment or intervention
2. A control or comparison group that receives standard care or a comparison intervention that is different from the experimental intervention
3. Random assignment, or randomization, which is the use of a strategy to randomly assign subjects to the experimental or control groups (ie, in a manner determined by chance)



Examples:

Type of Design	Schematic Diagram	Use
Basic posttest-only	R X O R O or R X_A O R X_B O	Outcome is only relevant after the intervention (eg, length of hospital stay)
Basic pretest-posttest	R O_1 X O_2 R O_1 O_2	a. Focus of intervention is on change (eg, behavior, attitude) b. Researcher wants to assess both group differences and change within groups
Multiple interventions	R O_1 X_A O_2 R O_1 X_B O_2 R O_1 O_2	Test competing interventions or isolate effects of a complex intervention
Wait-list (delay of treatment)	R O_1 X O_2 O_3 R O_1 O_2 X O_3	Patient preference for innovative treatment
Crossover (subjects serve as their own controls)	R O_1 X_A O_2 X_B O_3 R O_1 X_B O_2 X_A O_3	Difficult recruitment and need to control confounding variables. Only appropriate if no expectation of carryover effects from one period to the next (rapid onset, short half-life)
Factorial	R O_1 X_{A1B1} O_2 R O_1 X_{A1B2} O_2 R O_1 X_{A2B1} O_2 R O_1 X_{A2B2} O_2	Testing multiple interventions simultaneously
Key R = Randomization X = Intervention (X_A=Intervention, X_B=Alternative Intervention) O = Outcome Measurement		

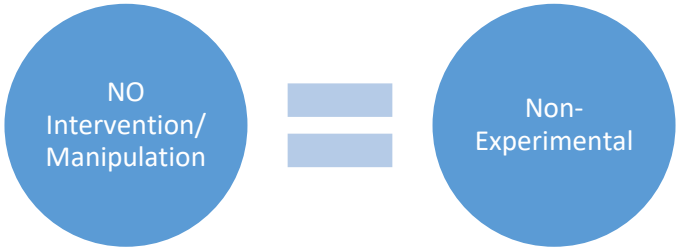
Quasi-experimental: Researchers test an intervention in the absence of randomization; the study design may also lack a control or comparison group.



Examples:

Type of Design	Schematic Diagram	Use
Posttest-only	X O O	Reasonable when some knowledge is available about comparability of groups with regard to outcomes
Pretest-posttest	O_1 X O_2 O_1 O_2	Entire unit gets intervention and a similar unit is not getting the intervention
Pretest-posttest, one group	O_1 X O_2	Reasonable only when intervention impact is expected to be dramatic and other causes have little credibility
Time series	$O_1 O_2 O_3 O_4$ X $O_5 O_6 O_7 O_8$ $O_1 O_2 O_3 O_4$ $O_5 O_6 O_7 O_8$	Entire group gets intervention and a similar group is not getting the intervention, and there is abundant data
Time series, one group	$O_1 O_2 O_3 O_4$ X $O_5 O_6 O_7 O_8$	Good when there is abundant data on key outcome, addresses maturation threat and random fluctuation
Time series, withdrawn and reinstituted intervention	$O_1 O_2$ X $O_3 O_4$ -X $O_5 O_6$ X $O_7 O_8$	Can be used if intervention effects are short-term
Key X = Intervention O = Outcome Measurement		

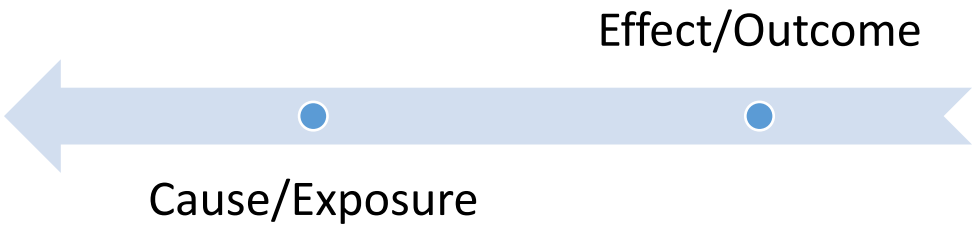
Non-experimental: Researchers do not implement an intervention; there is no manipulation of the independent variable.



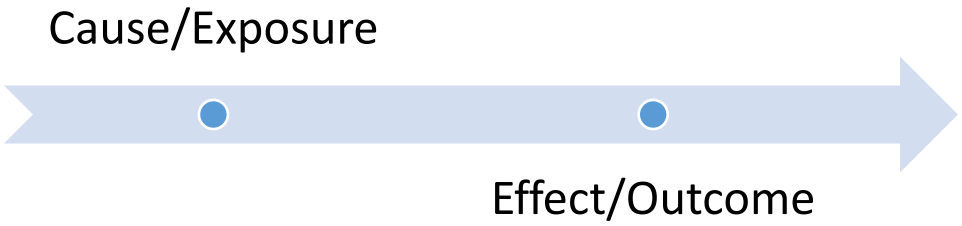
Examples:

- **Correlational or Comparative**: Researchers study the effect of a potential cause that they cannot manipulate to examine relationship or association between variables.

    - **Case-Control**: Researchers start by identifying subjects with the outcome/effect and then examine whether it is related to the cause/exposure in the past; retrospective. (eg, lung cancer [outcome] → smoking [exposure])



    - **Cohort** (with no intervention): Researchers start by identifying subjects with the cause/exposure and then examine whether it is related to the effect/outcome in the future; can be either prospective or retrospective. (eg, smoking [exposure] → lung cancer [outcome]) If a cohort study has an intervention, see RCT or quasi-experimental.



    - **Natural Experiments**: Researchers observe phenomena that effect people at random without intervening by comparing an exposed group to a non-exposed group (may use before-after design). (eg, earthquake, fire, terrorist attack)
    - **Path Analytic**: Researchers test theories of causation based on non-experimental data. (eg, model, diagram)
- **Descriptive or Observational**: Researchers observe, describe, and document aspects of a situation as it naturally occurs.
    - **Descriptive Correlational**: Describe relationships among variables rather than infer causality.
    - **Prevalence Studies**: Estimate the prevalence (number of existing and new cases) of some condition (outcome or exposure) at a particular point in time.

- **Incidence Studies**: Estimate the frequency of developing new cases in a population at risk for the condition (outcome or exposure) at a particular point in time.

NON-RESEARCH EVIDENCE

Clinical practice guideline: Systematically developed recommendations from recognized experts based on evidence or consensus opinion that guides members of a professional organization in decision-making related to practice or a particular issue of concern.

Position statement: Systematically developed recommendations from recognized experts based on evidence or consensus opinion that guides members of a professional organization in decision-making related to a particular issue of concern.

Literature review: A summary of published literature on a topic of interest without a systematic appraisal of the strength and quality of the evidence.

Case report: An in-depth analysis of an individual, group, social unit, issue, or event.

Expert opinion: Advice from an individual(s) with knowledge and expertise on a particular topic or issue.

Organizational experience: Initiative with a goal to improve the processes or outcome of care being delivered within a particular institution.

- Quality Improvement
- Financial

DEFINITIONS

Appraisal: The process of critical review and evaluation that should assist the clinician in deciding whether a study is flawed to the point that it should be discounted as a source of evidence (ie, the results cannot be used in practice).

Bias: An influence that distorts the results of a study and undermines validity.

Blinding: The process of preventing those involved in a study from having information that could lead to bias.

Case-control design: A nonexperimental research design involving the comparison of a "case" (ie, a patient with the condition under study) with a control (ie, a similar patient without the condition).

Cohort design: A nonexperimental research design in which a defined group is followed over a period of time.

Comparison group: The researcher provided standard care or an intervention that was different from the experimental intervention.

Confidence Interval: The range within which one can be confident (eg, 95%) that the value is likely to contain the population parameter of interest.

Confounding variable: A variable that is extraneous to the research question and that confuses the relationship between the independent and dependent variables.

Control group: The researcher provided standard care or a comparison intervention that was different from the experimental intervention.

Correlation: An association between variables with variation in one variable systematically related to variation in another.

Descriptive study: Nonexperimental studies conducted for the purpose of describing the characteristics of certain phenomena or variables.

Effect size: A statistical expression of the magnitude of the relationship between two variables.

Generalizability: The inference that the findings can be applied from the sample to the general population.

Intervention: The researcher did something to at least some of the participants (ie, there was some type of treatment being tested).

Manipulation: The researcher did something to at least some of the participants (ie, there was some type of treatment being tested).

***p* value:** A statistical test of the assumption that there is no difference between an experimental intervention and a control. The *p* value indicates the probability of an event. Traditionally, a *p* value of 0.05 is considered a statistically significant event.

Power Analysis: A procedure used to estimate the sample size required to minimize the potential that the study findings were based on chance and a Type II error has occurred.

Prospective design: A study that goes forward in time to observe presumed effects.

Qualitative: An investigation of phenomena, through the collection of rich narrative materials. Researchers explore people's perceptions of their world, their beliefs, attitudes and experiences, and conceptualize these in ways that are both meaningful and useful. (eg, interviews, surveys, focus groups)

Quality: The extent to which a study design, conduct, and analysis have minimized, selection, measurement, and confounding biases (ie, internal validity).

Quantitative: The investigation of phenomena that lend themselves to precise measurement.

Randomization: The researcher assigned participants to a control or treatment group on a random basis (ie, in a manner determined by chance).

Retrospective design: A study that goes backward in time to search for a presumed cause.

Sample: A subset of the population comprising those selected to participate in a study.

Statistical Significance: The results were not found by chance.

Systematic Review: A rigorous synthesis of research findings on a particular research question, using a comprehensive search strategy and rigorous appraisal.

- **Meta-Analysis:** A method of combining results from studies in a systematic review and analyzing them to generate a new statistic or effect size (measure of strength of relationship between two variables).
- **Meta-Synthesis:** A method of analyzing and synthesizing concepts from qualitative studies in a systematic review.

Time series design: A quasi-experimental design involving the collection of data over an extended time period with multiple data collection points both before and after an intervention.

Type II Error: An error that occurs when the researcher concludes that no relationship exists, when in fact it does (ie, false negative).

Validity: The degree to which inferences made in a study are accurate and well-founded, and the degree to which an instrument measures what it is intended to measure.

Variable: The measurable characteristics or properties of people or things that can take on different values.

- **Independent Variable:** The intervention that is being applied (eg, wearing surgical masks).
- **Dependent Variable:** The phenomenon being studied (eg, sterility of the field).

References

Melnyk BM, Fineout-Overholt E. *Evidence-Based Practice in Nursing & Healthcare*. 3rd ed. Philadelphia, PA: Wolters Kluwer Health; 2015.

Polit DF, Beck CT. *Nursing Research: Generalizing and Assessing Evidence for Nursing Practice*. 9th ed. Philadelphia, PA: Wolters Kluwer Health; 2012.