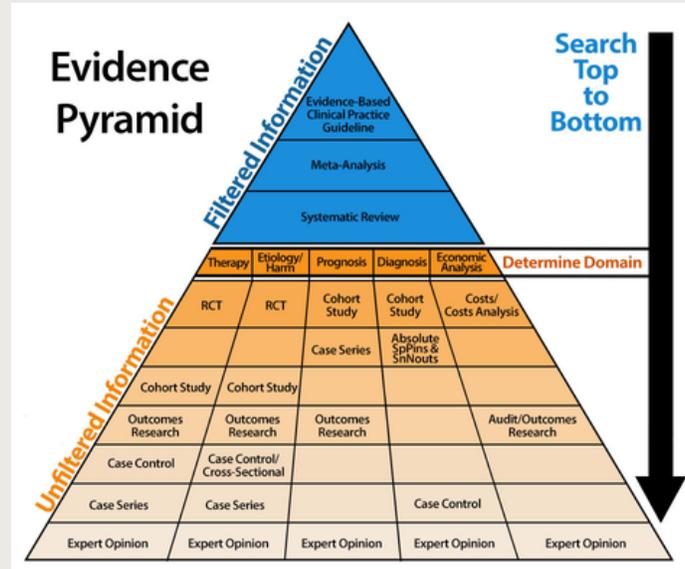


STUDY DESIGNS

EVIDENCE PYRAMID

An evidence pyramid visually depicts the evidential strength of different research designs. The image below is one of several available renderings of an evidence pyramid. Studies with the highest internal validity, characterized by a high degree of quantitative analysis, review, analysis, and stringent scientific methodology, are at the top of the pyramid. Observational research and expert opinion reside at the bottom of the pyramid.

See page 2 for the breakdown of these study types.



Levels of Evidence	Description
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trial) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results.
Level II	Evidence obtained from at least one well-designed RCT (e.g. large multi-site RCT).
Level III	Evidence obtained from well-designed controlled trials without randomization (i.e. quasi-experimental).
Level IV	Evidence from well-designed case-control or cohort studies.
Level V	Evidence from systematic reviews of descriptive and qualitative studies (meta-synthesis).
Level VI	Evidence from a single descriptive or qualitative study.
Level VII	Evidence from the opinion of authorities and/or reports of expert committees.



CONTACT

For more information on the types of study designs available, please contact AAPD Research Project Manager Rachel Wedeward, MLIS, AHIP at rwedeward@aapd.org.

TYPES OF STUDY DESIGNS

- **Clinical Practice Guidelines:** Systematically developed statements to assist clinicians and patients in making decisions about care; ideally, the guidelines consist of a systematic review of the literature, in conjunction with consensus of a group of expert decision makers, including administrators, policy makers, clinicians, and consumers who consider the evidence and make recommendations. *(Level I)*
- **Meta-analysis:** A process of using quantitative methods to summarize the results from the multiple studies, obtained and critically reviewed using a rigorous process (to minimize bias) for identifying, appraising, and synthesizing studies to answer a specific question and draw conclusions about the data gathered. The purpose of this process is to gain a summary statistic (i.e., a measure of a single effect) that represents the effect of the intervention across multiple studies. *(Level I)*
- **Systematic Review:** A summary of evidence, typically conducted by an expert or expert panel on a particular topic, that uses a rigorous process (to minimize bias) for identifying, appraising, and synthesizing studies to answer a specific clinical question and draw conclusions about the data gathered. *(Level I)*
- **Randomized Controlled Trials (RCTs):** A true experiment (i.e. one that delivers an intervention or treatment in which subjects are randomly assigned to control and experimental groups); the strongest design to support cause-and-effect relationships. *(Level II)*
- **Quasi-experiments:** A type of experimental design that tests the effects of an intervention or treatment but lacks one or more characteristics of a true experiment (e.g., random assignment; a control or comparison group). *(Level III)*
- **Cohort Studies:** A longitudinal study that begins with the gathering of two groups of patients (the cohorts), one that received the exposure (e.g., to a disease) and one that does not, and then following these groups over time (prospective) to measure the development of different outcomes (diseases). *(Level IV)*
- **Case-control Studies:** A type of research that retrospectively compares characteristics of an individual who has a certain condition (e.g. hypertension) with one who does not (i.e., a matched control or similar person without hypertension); often conducted for the purpose of identifying variables that might predict the condition (e.g., stressful lifestyle, sodium intake). *(Level IV)*
- **Cross-sectional Studies:** A study designed to observe an outcome or variable at a single point in time, usually for the purpose of inferring trends over time. *(These do not have a designated level as these are "a moment in time" and used in many different study designs).*
- **Meta-synthesis:** A rigorous process of analyzing findings across qualitative studies. The results address a specific research question and are obtained through the synthesis of qualitative studies. The process allows researchers to find greater meaning through interpreting the qualitative data. *(Level V)*
- **Descriptive Studies:** Those studies that are conducted for the purpose of describing the characteristics of certain phenomena or selected variables. *(Level VI)*
- **Qualitative Studies:** Research that involves the collection of data in non-numeric form, such as personal interviews, usually with the intention of describing a phenomenon. *(Level VI)*
- **Case Reports/Series:** Reports that describe the history of a single patient, or a small group of patients, usually in the form of a story. *(Level VII)*
- **Case Study:** An intensive investigation of a case involving a person or small group of persons, an issue, or an event. *(Level VII)*
- **Experiential and non-research evidence:** Literature review, quality improvement, program or financial evaluation, or case report. *(Level VII)*
- **Background Information/Expert Opinion/Evidence Summaries:** Fully referenced expert topic reviews written by recognized authorities who review the topic, synthesize the evidence, summarize key findings, and provide specific recommendations. *(Level VIII)*



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CLINICAL QUESTION AND STUDY DESIGN EXAMPLES

Clinical Question	Corresponding Study Design(s)
All Clinical Questions	Systematic review, meta-analysis
Therapy	Randomized controlled trial (RCT), meta-analysis Also: cohort study, case-control study, case series
Etiology	Randomized controlled trial (RCT), meta-analysis, cohort study. Also: case-control study, case series
Diagnosis	Randomized controlled trial (RCT) Also: cohort study
Prevention	Randomized controlled trial (RCT), meta-analysis Also: prospective study, cohort study, case-control study, case series
Prognosis	Cohort study Also: case-control study, case series
Meaning	Qualitative study
Quality Improvement	Randomized controlled trial (RCT) Also: qualitative study
Cost	Economic evaluation



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