

5 Levels of Evidence

- Scientific evidence is collected in many ways, and the methods of conducting studies depend on resources available.
- Level 1 evidence is the most robust, however these studies require the most resources and it is not always possible to collect evidence at this level.
- Level 2 evidence and Level 3 evidence may be more feasible to conduct in real-world conditions.
- The levels of evidence complement each other and each level has benefits and challenges.
- OPEN's recommendations will reference the levels of evidence that were used to draw conclusions about opioid prescribing, so that providers can make educated determinations about prescribing and care.





Type of Evidence	Definition
 Experimental Designs Randomized Controlled Trials Mixed-Method Designs with Level I Quantitative Studies Systematic Review of Randomized Controlled Trials 	Level I studies are scientific studies in which subjects are randomly assigned a condition of the independent variable; the treatment groups are compared against a control group; all subjects are recruited from the same eligible population. These studies are often used to evaluate medication efficacy and treatment efficacy. These studies can only include prospective data.
 Quasi-Experimental Designs Mixed-Method Designs with Level II Quantitative Studies Systematic Review of Quasi-Experimental Studies and Randomized Controlled Trials Systematic Review of Quasi-Experimental Studies Only 	Level II studies are scientific studies in which subjects from the eligible population are assigned a non-random condition based on factors such as demographic data, previous treatments, or participant choice. These studies are often used to evaluate cause-and-effect relationships and interventions that cannot be randomized. These studies can include retroactive or prospective data.



Level III: Nonexperimental Studies

- Nonexperimental Designs
- Exploratory, Convergent, or Multiphasic Mixed Methods Studies
- Explanatory Mixed-Method Designs with Level III Quantitative Studies
- Systematic Review of Nonexperimental Studies
- Systematic Review of Randomized Controlled Trials,
 Nonexperimental Studies and Quasi-Experimental
 Studies

Level III studies are scientific studies in which a variable is observed and measured without being manipulated. These studies can be used to evaluate phenomena as they exist without intervention and aim to explain how a variable naturally exists. These studies can include retroactive or prospective data. These studies cannot be used to explore cause-and-effect relationships.

Level IV: Research-Based Expert Consensus

- Opinion of Respected Authorities
- Clinical Practice Guidelines
- Opinion of Nationally-Recognized Expert Committees
- Consensus Panel Statements Based on Scientific Evidence

Level IV recommendations are based on the conclusions of multiple experts, such as those belonging to a committee, based on previous scientific research. This evidence can also include clinical practice guidelines that are followed by the majority of experts in the field.



Level V: Experience-Based Expert Opinion Experiential Research Nonresearch Evidence Integrative Reviews Literature Reviews Quality Improvement Evaluations Program Evaluations Financial Evaluations Case Reports Opinion of Nationally Recognized Expert Based on Experiential Evidence	Level V recommendations are based on the opinions of individual experts based on their own professional experiences. This evidence can also include literature reviews of relevant studies, case reports, and institutional reviews of data.

Sources

- Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. Plast Reconstr Surg. 2011 Jul;128(1):305-310. doi: 10.1097/PRS.0b013e318219c171. PMID: 21701348; PMCID: PMC3124652.
- Johns Hopkins Nursing Evidence-Based Practice guide https://libguides.ohsu.edu/ld.php?content_id=16277844
- Stony Brook University Evidence-Based Medicine guide https://guides.library.stonybrook.edu/evidence-based-medicine/levels_of_evidence
- University of California Irvine Evidence-Based Medicine Subject Guide: EBM Pyramid https://guides.lib.uci.edu/ebm/pyramid