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# MEDICINE

The College of Physicians and Surgeons of Columbia University is one of the oldest medical schools in America. It was founded in 1767 as the medical faculty of King's College — renamed Columbia College after the American Revolution — and it was the first institution in the North American colonies to confer the degree of Doctor of Medicine. Since 1891, the College of Physicians and Surgeons has been an integral part of Columbia University. It is affiliated as well with a number of major teaching hospitals, including the Presbyterian Hospital, Harlem Hospital Center, and St. Luke's Hospital. Dr. Harold E. Tinsley, a Canadian-born endocrinologist, became the Dean of the College of Physicians and Surgeons in 1974. During his tenure he has actively supported educational reforms that have resulted in a more modern and relevant curriculum.



Graham MedLegal Research

## Evaluating Medical Literature: A Framework for Expert Witnesses and Legal Nurse Consultants



# Preface

Medical expert witnesses and legal nurse consultants are increasingly expected not only to interpret medical facts, but to **evaluate and explain the quality of the literature** they rely on — often under oath and under pressure. Courts demand more than clinical experience; they want transparency, rigor, and defensible reasoning. That's why I created this framework.

This structured evaluation tool is designed to help experts approach medical literature with clarity and confidence. It's not a rigid checklist or a flowchart. Instead, it provides a set of **10 critical domains** to examine when determining whether a study, article, or source is appropriate to cite in an expert report, deposition, or courtroom testimony. While not exhaustive, the framework is intentionally designed to be **practical, high-impact, and digestible** — allowing expert witnesses and legal nurse consultants to apply it efficiently across a range of cases. Each domain includes questions that challenge you to think like both a clinician and a legal professional. By internalizing these domains, you'll be better prepared to defend your literature choices, spot weak or biased sources, and elevate the standard of your testimony.

Approach this framework not as a gatekeeper, but as a guidepost. You may not need to answer “yes” to every question in every section — but you should be able to explain why a study is or isn't reliable, relevant, or reproducible. This isn't about memorizing study designs or blindly citing systematic reviews. It's about being transparent, methodical, and deliberate in how you anchor your opinions to evidence.

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## About the Author

I'm a medical librarian and the founder of Graham MedLegal Research, where I support attorneys, expert witnesses, and legal teams with evidence-based research in high-stakes cases. With over 20 years of experience in clinical medical libraries — and deep involvement in medical-legal consulting — I've seen firsthand how poorly chosen or misunderstood literature can make or break a case. I built this framework to help experts navigate that challenge with clarity, integrity, and professional rigor.

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# Study Types at a Glance

## **Systematic Review**

A rigorous summary of all high-quality studies on a focused question. Uses predefined methods to search, select, and appraise studies. May include or exclude a meta-analysis.

## **Meta-Analysis**

A type of systematic review that statistically combines results from multiple studies to produce an overall estimate (e.g., risk, odds, effect size). Visualized via a forest plot.

## **Randomized Controlled Trial (RCT)**

Participants are randomly assigned to groups to test an intervention or exposure. Strongest design for determining causality.

## **Cohort Study**

Observational. Follows a group over time to compare outcomes between those exposed and unexposed to a factor (e.g., smokers vs non-smokers). Can be prospective or retrospective.

## **Case-Control Study**

Observational. Compares individuals with a condition (cases) to those without (controls) to identify past exposures or risk factors.

## **Cross-Sectional Study**

Measures characteristics or exposures at a single point in time. Good for estimating prevalence, but cannot determine causality.

## **Case Series**

Descriptive. Reports outcomes in a group of patients with a similar diagnosis or treatment. No comparison group. Useful for identifying early signals or patterns.

## **Case Report**

Detailed narrative of a single patient's condition or outcome. Lowest on the evidence hierarchy. Sometimes valuable for rare or novel situations.

## **Narrative Review**

A summary of the literature based on the author's interpretation. Not systematic, often lacks methods transparency. Can be useful for context but not strong evidence.

## **Expert Opinion / Editorial**

Based on individual experience, not research. Lowest level of evidence. Useful only when higher-level evidence is unavailable.

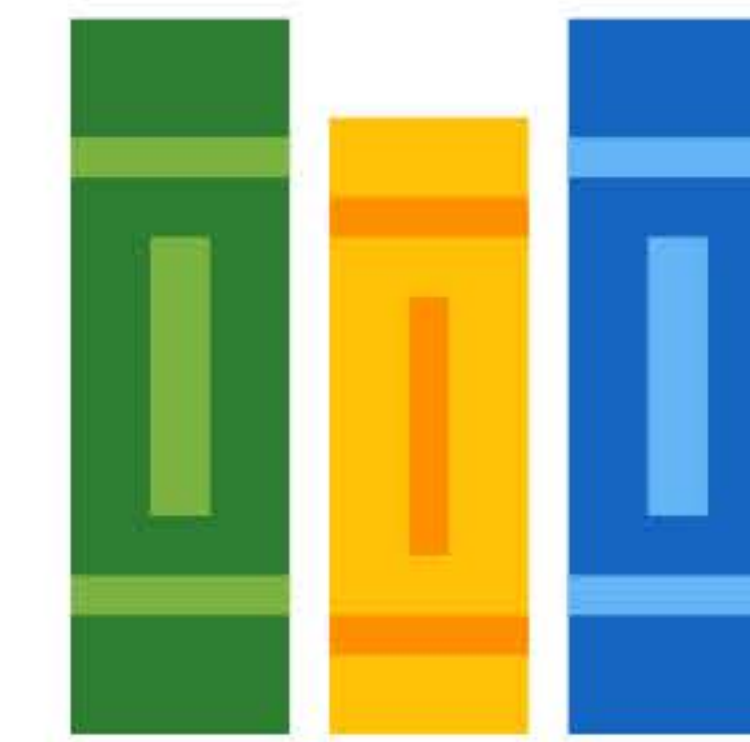
## **Guidelines / Consensus Statements**

Often based on systematic reviews and expert panel interpretation. Can reflect standard of care if published by authoritative bodies (e.g., AHA, CDC, WHO).

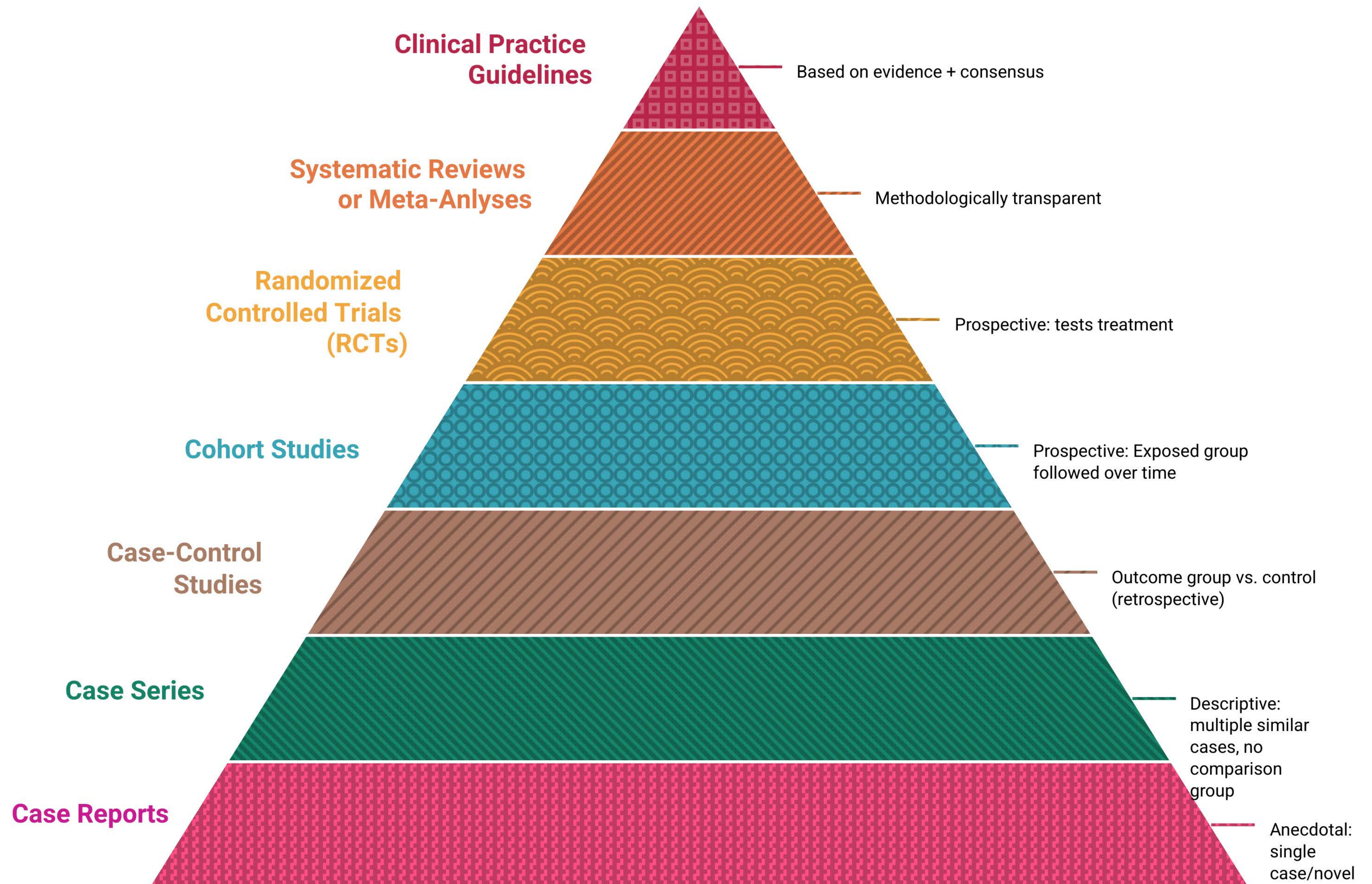


# Evidence Pyramid for Legal Strategy

## Hierarchy of Evidence for Expert Testimony



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Research**



Not all evidence carries equal weight – use this hierarchy to justify your literature choices and explain them clearly in court.



# LITERATURE EVALUATION FRAMEWORK

## 1. What Type of Study Is It?

(Understand where it sits in the evidence hierarchy)

- Systematic Review / Meta-Analysis — Gold standard for causation and consensus
- Randomized Controlled Trial (RCT) — Strongest for interventions
- Cohort Study / Case-Control — Useful for risk, exposure, and outcomes over time
- Cross-Sectional Study — Snapshot in time; useful for prevalence, limited for causality
- Case Series / Case Report — Anecdotal; helpful for rare, novel, or early-signal events
- Narrative Review — Author's selective summary of literature; offers context but lacks methodological transparency
- Expert Opinion / Editorial — Based on personal experience or viewpoint; unsupported by consistent evidence; lowest on the hierarchy



## **2. Where Was It Published?**

- Is it in a peer-reviewed journal?
- Is it indexed in PubMed, Scopus, or Web of Science?
- Was it published by a reputable professional society or government body?
- Is the journal predatory or lacking editorial transparency?
- Use DOAJ.org or Think.Check.Submit to help verify credibility.
- Did the journal endorse recognized reporting guidelines (e.g., PRISMA, CONSORT, STROBE)?

## **3. How Was the Study Designed?**

- Clear research question or hypothesis?
- Was the sample size adequate for detecting meaningful results?
- Were methods and outcomes clearly defined?
- Was there a control or comparison group?
- Were inclusion/exclusion criteria described?
- Are subgroup analyses pre-specified or exploratory?
- Were inclusion and exclusion criteria clearly defined and consistently applied?
- Was a protocol registered in advance (e.g., PROSPERO)?
- Were deviations from the protocol explained?



#### **4. What Are the Risks of Bias or Methodological Flaws?**

- Selection bias — Who was included and why?
- Performance or detection bias — Were participants and assessors blinded?
- Attrition bias — High loss to follow-up or missing data?
- Reporting bias — Only favorable outcomes reported?
- Funding bias — Was the study sponsored by a manufacturer or other stakeholder?
- Are conflicts of interest disclosed?
- Was the study appraised using validated bias or quality tools (e.g., ROB 2, NOS, GRADE, CASP)?
- Were screening and data extraction conducted independently by at least two reviewers?
- Did the study follow relevant reporting guidelines (e.g., PRISMA, CONSORT, STROBE)?
- Was the funder's role disclosed and non-influential on the study design, analysis, or reporting?

#### **5. Are the Results Valid and Interpretable?**

- Is it statistically significant and clinically meaningful?
- Are confidence intervals narrow and relevant?
- Is absolute risk reported (not just relative risk)?
- Do the authors overstate their conclusions?
- Did they acknowledge limitations or sources of uncertainty?
- If a meta-analysis was performed, was it appropriate given heterogeneity across studies?
- Were sources of heterogeneity explored and disclosed?



## **6. How Generalizable Is It?**

- Country of origin: Is the healthcare system comparable to the U.S.?
- Do the patients reflect your case context (age, race, severity, comorbidities)?
- Are the clinical settings, interventions, or timelines realistic for the issue at hand?

## **7. Legal Usefulness and Relevance**

- Is the study recent (preferably within the last 10 years)?

Note: Older studies may still be legally relevant if they reflect the standard of care at the time of the incident or were widely cited.

- Was the study published prior to or during the timeframe of care?

Note: Can it be shown that this knowledge was available to clinicians at the time the alleged harm occurred?

- Does it address or support the standard of care in the relevant setting?
- Can it help establish or refute causation?
- Does it align with or contradict clinical guidelines?
- Is it transparent and reproducible (e.g., could be re-run or replicated)?
- Can you explain how and why you selected it if questioned in court?
- Could the article selection process be explained under questioning?
- Is there documentation of how studies were found, screened, and chosen?



## **8. Contextual Fit and Strategic Value**

- Is the study cited in major guidelines, reviews, or position papers?
- Is it commonly used in medical-legal cases?
- Does it strengthen your report or help rebut weaker evidence?
- Are you prepared to explain its strengths and limitations?

## **9. Conceptual Foundations to Keep in Mind**

- Quality ≠ Bias  
A study can be high-quality and still biased. Use both concepts when evaluating.
- Bias Tools ≠ Judgment Substitute  
Checklists (like ROB2, CASP) help, but cannot replace informed analysis.
- Transparency is Key  
You must be able to justify why you chose a particular source — in court, under oath.
- Were tools for bias risk used alongside discussion of overall research quality?

## **10. Final Checklist Before You Cite or Rely On It**

- ☐ Credible journal and peer-reviewed
- ☐ Methodologically sound with clear, reproducible design
- ☐ Bias minimized or disclosed
- ☐ Statistically and clinically meaningful results
- ☐ Legally defensible under Daubert/Frye
- ☐ Applicable to your patient, population, or legal issue
- ☐ Strategic — supports or disarms key arguments