PERSPECTIVE

Rethinking the "Evidence Pyramid": A shift From Positivism to Pragmatism

Pradeep R Deshmukh[1], Priyanka Yadav[2], Amol R Dongre[3]

[1,2]Department of Community Medicine, All India Institute of Medical Sciences Nagpur

[3]Department of Community Medicine, Sri Manakula Vinayagar Medical College and Hospital, Puducherry

CORRESPONDING AUTHOR

Dr. Priyanka Yadav, Assistant Professor, Department of Community Medicine, AIIMS Nagpur

Email: Priyanka.yadav@aiimsnagpur.edu.in

CITATION

Deshmukh PR, Yadav P, Dongre AR. Rethinking the "Evidence Pyramid": A shift From Positivism to Pragmatism. Indian J Comm Health. 2025;37(3):491-495. https://doi.org/10.47203/IJCH.2025.v37i03.022

ARTICLE CYCLE

Received: 25/04/2025; Accepted: 03/06/2025; Published: 30/06/2025

ABSTRACT

The evidence pyramid ranks study designs by their reliability in establishing causal relationships, with systematic reviews and RCTs at the top due to their ability to minimize bias. However, these studies may have limited external validity, as they often use controlled environments that don't reflect real-world conditions. Observational and quasi-experimental studies offer better external validity but have lower internal validity. The pyramid's structure is based on a positivist paradigm, which emphasizes on the objective truth and empirical methods. However, newer research methodologies recognize the complexity of real-world data and promote social justice and empowerment. The evidence pyramid's overfocus on internal validity may underappreciate external validity, and it often overlooks the importance of qualitative research. With increasing importance of value-based medicine, it is imperative to consider the subjective experiences of patients in informing policies and practices. To address these issues, we have proposed the Evidence Pie model, where all study designs contribute to evidence, with quality of the evidence being determined by rigor rather than design type. This simplistic, single-layered model aims to integrate diverse evidence types for more practical, context-sensitive decision-making.

KEYWORDS

Evidence hierarchy, Evidence-Based Medicine, Qualitative Research, Value-Based Health Care

INTRODUCTION

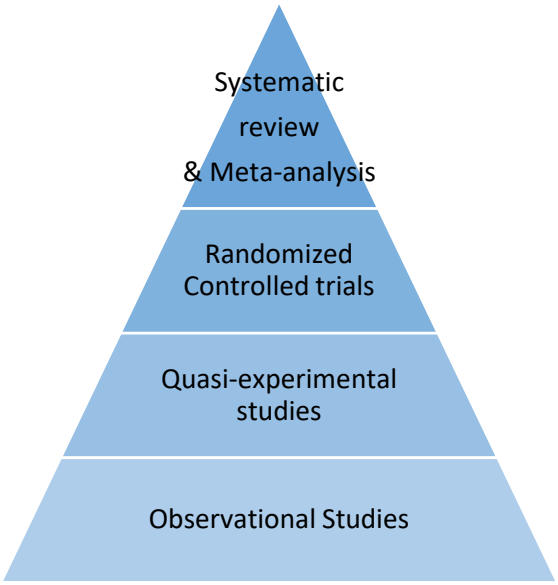
Evidence and The Evidence Pyramid:

Evidence is factual information used to support a claim or belief. It consists of information and research selected from the best available sources to inform decision-making and achieve the most effective outcomes.(1) Evidence alone does not make decisions but helps guide the process. The idea of a neutral, all-purpose evidence base that can answer all our questions is misleading. What counts as evidence, and what qualifies as supportive or conclusive evidence, depends on the questions we try to answer or the problems we aim to solve. No kind of evidence can, on its own, determine what is true or false, or what works, more so, in the field of healthcare. While randomized controlled trials (RCTs) can provide a great deal of reliable knowledge, they sometimes cannot answer all relevant questions.(2) However, advocates of Evidence-Based Medicine (EBM) often view practice as the application of research-based knowledge, overlooking the extent to which it necessarily involves uncertainty, local knowledge, and value judgments.

The evidence pyramid is a conceptual framework that ranks epidemiological study designs based on their methodological rigour and capacity to yield reliable evidence for causal inference in clinical and public health contexts.(3,4) At its apex are systematic reviews and Randomized Controlled Trials (RCTs), which are considered to provide the strongest evidence due to their ability to minimize bias and confounding. In contrast, quasi-experimental designs are supposed to be more vulnerable to biases, leading to weaker causal inferences. Further down the pyramid,

observational studies offer valuable insights but are considered even less dependable for establishing causal relationships. (Fig 1)

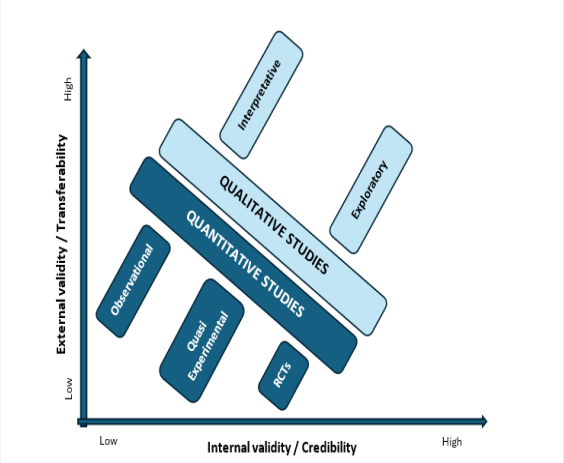
Fig 1: Evidence Pyramid



Internal validity and external validity of epidemiological studies

Despite their methodological strengths in terms of internal validity, studies at the top of the pyramid face limitations regarding external validity or generalizability of findings to broader populations and settings. They employ strict inclusion and exclusion criteria and are conducted in highly controlled environments, which may not reflect the diversity of real-world clinical and public health practice. This can restrict the applicability of their findings to routine settings where patients/populations are more heterogeneous.(5) Conversely, observational and quasi-experimental studies involve more representative samples and naturalistic settings, thereby offering enhanced external validity.(6) Qualitative studies are also placed lower in the traditional pyramid. In 2007, Daly et al. proposed a separate evidence pyramid for Qualitative studies with single Case Studies and descriptive studies (exploratory studies) at the bottom indicating a higher credibility but lower transferability, and generalizable conceptual studies (Interpretative studies) at the top of the pyramid indicating higher transferability.(7) (Fig. 2). In qualitative research, **credibility** and **transferability** are distinct yet interrelated. Credibility builds confidence in the findings, while transferability depends on how well the context is conveyed. Because of this overlap, establishing a hierarchy between them is difficult and cannot be generalized across all qualitative studies.

Figure 2: Internal validity and external validity of epidemiological studies



Ontology, Epistemology and Paradigm of the Evidence Pyramid

The ontology of the evidence pyramid is rooted in realism with the assumption that the truth is objective and can be measured. Its epistemology aligns with empiricism, where knowledge is acquired through observation, experimentation, and systematic analysis. Its positivist paradigm gives us a simplistic and linear view of the world. It assumes that the truth is objective and universal, often overlooks contextual, cultural and individual variations and limits the scope of enquiry. But the world is very complex. To understand the world with its complexities, different paradigms have evolved over the years. The newer paradigms acknowledge that reality is subjective, multiple and influenced by context. The purpose of the positivist approach is to predict and control, while the purpose of the newer paradigms is to promote social justice, empower and transform society and inspire creativity.

Strengths and weaknesses of Evidence Pyramid

A critical aspect of the evidence pyramid is its emphasis on internal validity— the degree to which a study can credibly establish a causal relationship between an intervention and its outcome. RCTs rank highest because it is designed to closely approximate the ideal counterfactual scenario. In a well-conducted RCT, randomization ensures that, on average, all potential confounders are evenly distributed between the treatment and control groups, thereby allowing the observed differences in outcomes to be attributed to the intervention rather than extraneous variables.(8) This method of approximating the counterfactual—considering what would have happened to the same participants in the absence of the intervention—is central to causal inference as outlined by the counterfactual theory of causation.(9)

Quasi-experimental designs, such as controlled before-and-after studies, interrupted time series, and regression discontinuity designs, occupy an important place in this hierarchy. These designs are employed when randomization is impractical or unethical, yet there is still a need to assess causality in a real-world setting. Although quasi-experimental studies do not employ randomization, they use rigorous analytical methods and design features to approximate the counterfactual scenario. For example, interrupted time series analysis can identify changes in trends before and after an intervention, and regression discontinuity designs can exploit naturally occurring thresholds for treatment assignment to infer causality.(10) Despite these strengths, quasi-experimental designs generally offer less internal validity but have better external validity than RCTs. The issues related to the internal validity of the quasi-experimental designs and observational studies (because they are more vulnerable to confounding factors and selection bias) can be addressed through robust design, meticulous implementation and appropriate analysis to an extent.(11) The selection and measurement biases can also be quantified, and effect sizes can be adjusted.(12)

The counterfactual theory of causation further underscores the importance of study design in approximating the ideal "what if" scenario. RCTs are particularly valued because they facilitate a comparison between the actual outcome and the counterfactual scenario—what would have occurred had the intervention not been administered. Quasi-experimental designs, while not as robust as RCTs in creating perfectly comparable groups, strive to emulate this ideal through techniques such as time series analysis and exploiting natural experiments. Observational studies also attempt to emulate the counterfactual through various statistical methods, including matching and propensity score adjustments, yet the absence of randomization means that residual confounding may persist, limiting the strength of causal inferences that can be drawn.(13)

Systematic reviews and meta-analyses, being at the top of the hierarchy of evidence, are commonly used by the policy makers to revise existing or frame new guidelines.(14) However, they have their own challenges. Heterogeneity—whether clinical, methodological, or statistical—is an inherent limitation of meta-analyses. While it can be minimized or explained, it can never be completely eliminated.(15) A study by Dechartres et al. that evaluated 163 metanalyses, shows that the estimation of treatment outcomes varied significantly depending on the analytical strategy being used. This highlights the possibility of uncertainty and error owing to the methodological complexities of systematic reviews.(16) Furthermore Golder et al. compared the metanalyses of data from RCTs and Observational Studies and concluded that there was no difference in the risk estimates.(17)

While the evidence pyramid remains a useful tool for guiding clinical decision-making, it has several limitations. First, its overemphasis on internal validity may lead to an undervaluation of external validity, thereby reducing the practical applicability of research findings. Second, the pyramid presents a simplistic linear hierarchy that does not account for the variability in study quality within each design; for instance, a poorly executed RCT might provide less reliable evidence than a well-conducted observational or quasi-experimental study.(18) Additionally, the pyramid tends to neglect contextual and qualitative data that are increasingly recognized as important for comprehensive evidence-based practice, particularly in the evaluation of complex interventions.(19) Qualitative research studies cannot be evaluated using the same criteria of internal and external validity as quantitative research. Qualitative studies focus on real-life experiences without manipulating the situation, thereby implicating a direct relationship between authenticity and transferability. The more detailed and genuine the study is in describing these experiences, the more its findings can be applied to broader theories about human behaviour and nature.(20) However their importance is undermined in the pyramid. With increasing importance of Value Based Medicine, patients' subjective experiences need to find their place in the hierarchy of evidence.

Evolving approaches and methodologies

To address these limitations, newer methodologies have emerged. Pragmatic clinical trials, for example, are designed to assess the effectiveness of interventions in real-world settings by incorporating broader inclusion criteria and flexible protocols, thereby enhancing external validity while retaining rigorous design features.(21) Adaptive trial designs allow modifications based on interim data analysis, optimizing both internal and external validity without compromising the study's integrity.(22) The integration of real-world evidence (RWE) through electronic health records, registries, and large observational databases further complements traditional RCTs by providing insights into the performance of interventions across diverse clinical environments.(23) Moreover, mixed-methods research and Bayesian approaches offer nuanced frameworks for synthesizing quantitative and qualitative data, thus facilitating a

more comprehensive evaluation of evidence that bridges the gap between controlled experimental settings and everyday practice.(24) Concato et al compared the results of RCTs with observational studies of the same clinical topic and concluded that the observational studies did not significantly overestimate the effect sizes as compared to RCTs.(25)

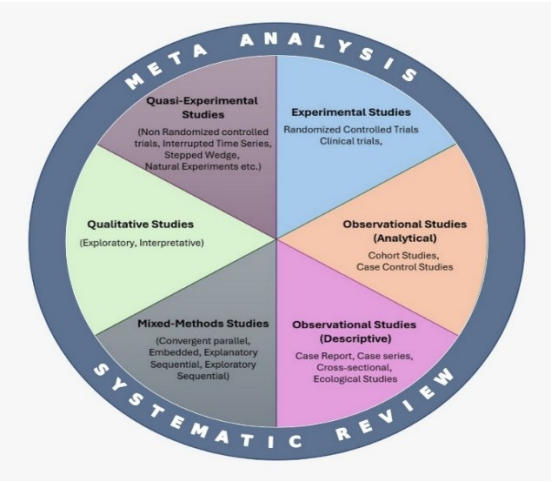
Alternative frameworks

With time and methodological advances in research, a need for redefining the traditional evidence pyramid has been felt and several models have evolved. Borgetto et al(20) modified the pyramid to include qualitative studies and moved from a single hierarchy to multiple hierarchies. The S6 model(26) was created to illustrate the sources of evidence available to evidence-based medicine (EBM) practitioners when addressing foreground questions. It depicts a hierarchy that starts with studies and progresses through synopses, synthesis, synopses of synthesis, summaries, and systems.(26-27) Murad et al(27) suggested two modifications to a traditional evidence pyramid. In the first modification, they made the horizontal lines wavy, indicating that evidence hierarchy is based on the quality of the study and chopping off the systematic review part. In the second modification, which is a modification over the first, systematic review is used as a lens to view the evidence. Gleser et al.(28) proposed a separate hierarchy of evidence-for-practice specific to qualitative methods for assessing the contribution of qualitative empirical studies in health and medicine. However, there is no universal model that fits all the situations. While a researcher may prefer internal validity and thus the traditional evidence pyramid, a policy maker would prefer a model that focuses on external validity, and a healthcare provider would want a balance of both internal and external validity. In 2007, Jonas proposed an Evidence House with "a room for everyone" to allow space for complementary and alternative medicine as well.(29) However, different "rooms" for different types of evidences may create fragmentation in medical knowledge thereby leaving space for a more unified approach. Population health is most likely to improve when the various available research tools are used with consideration of the local context, thoroughly evaluated, and shared with researchers, practitioners, and other relevant stakeholders.(30)

The proposed framework

We propose the Evidence Pie model to be used instead of the pyramid, where evidence is seen as pieces of a pie where multiple study designs contribute to completing the picture of knowledge generation. (Fig 3) The proposed single-layered, simplistic evidence framework will be based on a pragmatic paradigm which will help incorporate evidence from all the study designs including qualitative studies. This will enable consideration of real-world data into the decision making. With this model we aim to emphasise that each study design has its value in providing evidence. Which piece(s) of the pie is(are) to be taken into consideration, will depend on the question that needs to be answered. The quality of the evidence will depend not on the type of study design but on the rigor of the studies. And the outer crust encompassing the pie will be of systematic review and meta-analysis which will help in synthesis of evidence from the studies we choose to answer our question.

Figure 3. The Evidence Pie



CONCLUSION

To conclude, while the traditional evidence pyramid provides a foundational framework that prioritizes study designs with high internal validity and a strong approximation of the counterfactual scenario, it is not without limitations—particularly regarding external validity and the oversimplification of complex research methodologies. Quasi-experimental designs represent an important bridge in circumstances where randomization is not feasible, offering valuable insights despite their inherent limitations in internal validity. Evolving methodologies such as pragmatic trials, adaptive designs, and the incorporation of real-world evidence are critical for overcoming these limitations and ensuring that evidence-based practice remains both methodologically sound and broadly applicable. Each study design has its utility and makes a relevant contribution to evidence generation. They should be assessed only on the rigor and robustness with which they are carried out. Hence, we propose using the single-layered Evidence Pie framework instead of a hierarchical pyramid.

Declaration of Generative AI and AI Assisted Technologies in the Writing Process

The authors haven't used any generative AI/AI assisted technologies in the writing process.

References

1. NSW Department of Communities and Justice. What is evidence? (Internet). Available from: https://dcj.nsw.gov.au/content/dcj/evidenceportal/evidence-portal-home/using-evidence/what-is-evidence
2. Greenhalgh T, Russell J. Evidence-based policymaking: a critique. Perspect Biol Med. 2009;52(2):304-18. doi:10.1353/pbm.0.0085.
3. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-72.
4. Guyatt G, Rennie D, Meade MO, Cook DJ. Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice. 3rd ed. McGraw-Hill Education; 2015.
5. Rothwell PM. External validity of randomised controlled trials: "To whom do the results of this trial apply?". Lancet. 2005;365(9453):82-93
6. Shadish WR, Cook TD, Campbell DT. Experimental and Quasi-Experimental Designs for Generalized Causal Inference. Houghton Mifflin; 2002
7. Jackson S, Fazal N, Giesbrecht N. A hierarchy of evidence: which intervention has the strongest evidence of effectiveness. Canadian Best Practices Portal for Health Promotion and Chronic Disease Prevention. 2010.
8. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0. The Cochrane Collaboration; 2011.
9. Pearl J. Causality: Models, Reasoning, and Inference. 2nd ed. Cambridge University Press; 2009.
10. Shadish WR, Cook TD, Campbell DT. Experimental and Quasi-Experimental Designs for Generalized Causal Inference. Houghton Mifflin; 2002.
11. Craig P, Cooper C, Gunnell D, Haw S, Lawson K, Macinty S, et al. Using natural experiments to evaluate population health interventions: new Medical Research Council guidance. J Epidemiol Community Health. 2012;66(12):1182-1186.
12. Lash TL, Fox MP, Fink AK. Applying Quantitative Bias Analysis to Epidemiologic Data. Springer; 2009.
13. Hernán MA, Robins JM. Causal Inference. Boca Raton: Chapman & Hall/CRC; 2020.
14. Gugnani N. Real world evidence: will the "pyramid" of evidence need some redefining…?.Evid Based Dent 25, 119–120 (2024). https://doi.org/10.1038/s41432-024-01035-1
15. Berlin JA, Golub RM Meta-analysis as evidence: building a better pyramid. JAMA 2014;312:603–5. doi:10.1001/jama.2014.8167
16. Dechartres A, Altman DG, Trinquart L, Boutron I, Ravaud P. Association between analytic strategy and estimates of treatment outcomes in meta-analyses. JAMA. 2014 Aug 13;312(6):623-30. doi: 10.1001/jama.2014.8166. PMID: 25117131.
17. Golder S, Loke YK, Bland M (2011) Meta-analyses of Adverse Effects Data Derived from Randomised Controlled Trials as Compared to Observational Studies: Methodological Overview. PLoS Med 8(5): e1001026. https://doi.org/10.1371/journal.pmed.1001026)
18. Ioannidis JPA. Why most published research findings are false. PLoS Med. 2005;2(8):e124
19. Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? BMJ. 2014;348:g3725.
20. Borgetto B, Born S, Buenemann-Geissler D, Duechting M, Kahrs A M, Kasper N, et al. (2007). Die forschungspyramide: Diskussionsbeitrag zur evidenz-basierten praxis in der ergotherapie (The research pyramid: Contribution to the discussion of evidence-based practice in occupational therapy). Ergoscience, 2, 56–63. doi: 10.1055/s-2007-963004
21. Drazen JM, Harrington DP, McMurray JJ, Ware JH, Woodcock J, Ford I, Norrie J. Pragmatic Trials. N Engl J Med. 2016;375(5):454-463.
22. Berry SM, Carlin BP, Lee JJ, Muller P. Bayesian Adaptive Methods for Clinical Trials. CRC Press; 2010.
23. Sherman RE, Anderson SA, Dal Pan GJ, Gray GW, Gross T, Hunter NL, et al. Real-World Evidence — What Is It and What Can It Tell Us? N Engl J Med. 2016;375(23):2293-2297.
24. Spiegelhalter DJ, Abrams KR, Myles JP. Bayesian Approaches to Clinical Trials and Health-Care Evaluation. Wiley; 2004.
25. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000;342(25):1887-1892.
26. DiCenso, Bayley and Haynes (2009). ACP Journal Club. Editorial: Accessing pre-appraised evidence: Fine-tuning the 5S model into a 6S model. Annals of Internal Medicine, 151(6):JC3-2, JC3-3.
27. Murad MH, Asi N, Alsawas M, Alahdab F. New evidence pyramid. BMJ Evid Based Med. 2016;21:125-127
28. Gleser L, Hubbard R, Heagerty P. Statistical methods for analyzing data from clinical trials and observational studies. J Clin Epidemiol. 2006 Apr;59(4):403-409. doi: 10.1016/j.jclinepi.2005.09.017.
29. Jonas WB. The evidence house: how to build an inclusive base for complementary medicine. West J Med. 2001 Aug;175(2):79-80. doi: 10.1136/ewjm.175.2.79. PMID: 11483539; PMCID: PMC1071485.
30. Jacobs JA, Jones E, Gabella BA, Spring B, Brownson RC. Tools for Implementing an Evidence-Based Approach in Public Health Practice. Prev Chronic Dis 2012;9:110324. DOI: http://dx.doi.org/10.5888/pcd9.110324