

Beyond Levels of Evidence: Critical Appraisal of Clinical Research

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PROBLEM STATEMENT

Healthcare providers use the best evidence available to help guide clinical decision-making. An increase in number of publications, particularly online, is fueled by for-profit and predatory journals with questionable peer-review. Clinicians cannot rely on the *level of evidence* alone to determine the quality or application of research findings. Critical appraisal skills help ensure clinicians can properly assess and interpret new research beyond entry-level training as educated consumers of research.

THEORETICAL FRAMEWORK

- Increase in online publications and predatory journals
- Lack of adequate peer review & oversight
- Decrease in quality & increased bias of published research, including 'peer reviewed' articles



POOR RESEARCH QUALITY
POOR TRANSLATION TO PRACTICE
POOR CLINICAL DECISION MAKING
POOR OUTCOMES

RESEARCH WASTE
FALSE CLAIMS
PATIENT HARM

BACKGROUND

Hierarchy of research design denotes "Levels of Evidence"
(OCEBM V2.1, 2011)

Levels based on research question

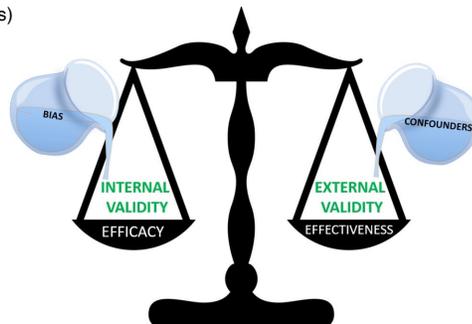
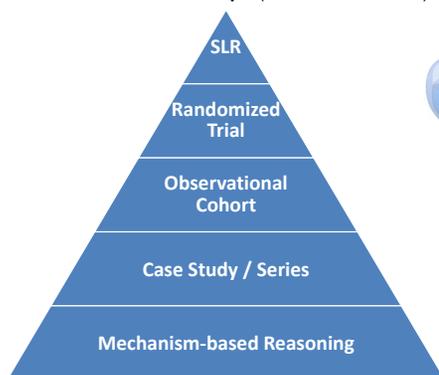
"may be graded down based on the basis of study quality"

Clinical research must balance internal validity and external validity.

Internal Validity: the strength of a study is most limited by **bias**

External Validity: the applicability of a study is most limited by **confounders**

Does this intervention help? (Treatment Benefits)

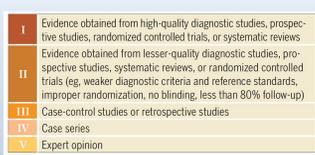


RCTs often sacrifice External Validity for Internal Validity

3 COMPONENTS OF CLINICAL RESEARCH QUALITY

Design / Level of Evidence	Bias & Confounders	Reporting Guidelines
<ul style="list-style-type: none"> • Design based on research question • Level supports strength of evidence 	<ul style="list-style-type: none"> • Factors that influence outcome beyond design • Threats to internal & external validity 	<ul style="list-style-type: none"> • Standards for specific items to be reported based on design • Necessary for replication and quality assessment

4 STEPS TO CRITICAL APPRAISAL OF CLINICAL RESEARCH

1	Identify Research Question / Purpose Determine the Research Design	<ul style="list-style-type: none"> • Define PICO • Define Independent & Dependent Variables • Does the design answer the question? 																					
2	Use Reporting Checklist	www.Equator-Network.org																					
3	Assess for Bias / Confounders	<ul style="list-style-type: none"> • Design bias: answer RQ, "level of evidence" • Procedural bias: test procedure (washout) • Selection bias: sampling, recruiting, random • Measurement bias: valid/reliable outcome • Statistical bias: power, answer RQ, clinical? • Reporting bias: negative results? • Publication bias: peer review • Conflict of Interest: disclosures 																					
	 <p>Cochrane Risk of Bias Tool</p>																						
4	Grade the Evidence	<table border="1"> <thead> <tr> <th>GRADES OF RECOMMENDATION</th> <th>STRENGTH OF EVIDENCE</th> <th>LEVEL OF OBLIGATION</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>Strong evidence A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study</td> <td>Must or should</td> </tr> <tr> <td>B</td> <td>Moderate evidence A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation</td> <td>Should</td> </tr> <tr> <td>C</td> <td>Weak evidence A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation</td> <td>May</td> </tr> <tr> <td>D</td> <td>Conflicting evidence Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies</td> <td></td> </tr> <tr> <td>E</td> <td>Theoretical/foundational evidence A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic sciences/bench research support this conclusion</td> <td>May</td> </tr> <tr> <td>F</td> <td>Expert opinion Best practice based on the clinical experience of the guideline development team</td> <td>May</td> </tr> </tbody> </table>	GRADES OF RECOMMENDATION	STRENGTH OF EVIDENCE	LEVEL OF OBLIGATION	A	Strong evidence A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study	Must or should	B	Moderate evidence A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation	Should	C	Weak evidence A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation	May	D	Conflicting evidence Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies		E	Theoretical/foundational evidence A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic sciences/bench research support this conclusion	May	F	Expert opinion Best practice based on the clinical experience of the guideline development team	May
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	 <p>From the Academy of Orthopedic Physical Therapy Clinical Practice Guidelines</p>																						