

Protocol/Policy/Procedure/Medication:

Submitted by:

Date submitted:

Evidence-based medicine integrates clinical expertise, patient values, and the best research evidence into the decision making process for patient care.

Considered one of the leading experts on evidence-based medicine, Dr. David Sackett defines one of the most widely accepted definitions as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of [EBM] means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”ⁱ

There are many opinions on what exactly constitutes evidence. Jules Rothstein wrote “...evidence is not faith or tradition. Evidence is viable finding from research, not theories underlying practice. Evidence is data that shows whether treatments make a meaningful difference. Evidence is what is published in credible and respected journals.”ⁱⁱ

Be skeptical of the evidence however, even articles that are published in reputable journals. As Rennie tell us however, “No study too fragmented, no hypothesis too trivial, no literature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, and too contradictory, no analysis too self-serving, no argument too circular, no conclusion too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print.”ⁱⁱⁱ

Caution must be used not to exercise flexibility by only considering evidence of the highest value. Often you may find that expert opinion is all that is available or some circumstances that cannot be investigated with study designs that achieve the highest level of evidence standard.

When creating patient care guidelines, it is important consistency is in order to achieve consensus. The following steps should be used when presenting changes to the existing protocols:

- 1. Start with the patient**

A clinical problem / question arising from the care of the patient.

2. What is the question?

Construct a well-built question derived from the case. The mnemonic PICO helps identify components of a well-constructed question.

P (Patient or Problem) – describe the group of patients and their most important characteristics.

I (Intervention, prognostic factor, or exposure) – which one are you considering and what do you want to do for the patient (administer a drug, perform a test, perform a procedure). What factors will influence the decision?

C (Comparison) – main alternatives to compare with proposed intervention. Are you trying to decide between two drugs etc?

O (Outcomes) – What do you hope to accomplish/improve/affect?

3. Literature Search

List your sources searched (i.e.: Medline, Cochrane, Ovid, Science Direct) and keywords used in search (i.e. spinal injury, c-collar, backboards).

4. Evaluate and Assess the Evidence

In order to concisely characterize and communicate information in this document, it is imperative that an explicit approach is utilized so that it is easily understood, and subsequently ensures our members make well-informed decisions when providing patient care. There are numerous methods available to us for evaluating levels of evidence and the strength of the recommendations. Each has their own strengths, and shortcomings.^{iv}

a. Determine the Level of Evidence

Levels of Evidence	
1A	Systematic Review of Randomized Controlled Trials
1B	RCTs with Narrow Confidence Intervals
1C	All or None Case Series
2A	Systematic Review Cohort Studies
2B	Cohort Study / Low Quality RCT
3A	Outcomes Research
3B	Case-controlled Study
4	Case Series, Poor Cohort Case Controlled
5	Expert Opinion

b. Determine the Class of Evidence (adopted from the ACC/AHA Clinical Practice Guidelines)

Class of Recommendation	
Class I	conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective
Class II	conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness / efficacy of a procedure or treatment
Class IIa	weight of evidence/opinion is in favor of usefulness/efficacy
Class IIb	usefulness/efficacy is less well established by evidence/opinion
Class III	conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful

c. Complete the Evidence Evaluation Tool:

<u>Intervention:</u>		<u>Data Base Searched:</u>			<u>Keywords:</u>	
Reference	Journal	Title	Purpose	Results	Class of Recommendation	Level of Evidence
Hoffman JR et al	<i>N Engl J Med</i> 2000; 343:94-99	Validity of a set of clinical criteria to rule out injury to the cervical spine in patients with blunt trauma.	To determine if following a set of criteria can effectively eliminate the need to immobilize blunt trauma patients	In summary, study confirms the validity of a decision instrument based on five clinical criteria for identifying, with a high degree of confidence, patients with blunt trauma who have an extremely low probability of having sustained injury to the cervical spine. The sensitivity of this set of criteria approaches 100 percent for clinically important injuries, and its general application should result in both clinical and economic benefit. As with any other clinical tool, it should be applied with great care and should not replace clinical judgment in the care of individual patients.	2A	Ila

5. Summary of Consultation

6. Protocols Impacted

7. Training Requirements

8. Impact Analysis (Operational and Training Costs).

9. Assessment of merit against the criteria

ⁱ 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

ⁱⁱ Rothstein JM. It is our choice. *Phys Ther.* 1991;77:800-801

ⁱⁱⁱ Rennie D. Guarding the guardians: A conference on editorial peer review. *JAMA.* 1986;256:2391-2392.

^{iv} Atkins D, Eccles M, Flottorp S, et. Al. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches; the GRADE Working Group. *BMC Health Serv Res.* 2004;4(1):38.