Guidelines for Writing and Reviewing a Critical Appraisal
From the Editors of *Clinical Research in Practice: The Journal of Team Hippocrates.*

This journal is dedicated to exploring the science of medical evidence implementation. Our publications include combinations of clinical epidemiology, clinical science, and social science. Our journal is interested in publishing **critical appraisals** that describe the use of clinical research in the decision-making process for the care of one patient. Decision making must include the context of care—social interactions that affect the recommendations. It is an exercise in applied clinical decision-making—the implementation of clinical research. Critical Appraisal manuscripts are case studies about the interface of medical evidence and the patient in a social context. They are NOT case studies of rare diseases.

We reject manuscripts that are technically superlative but read like a mathematical problem that needs to be solved. We call that evidence-based medicine. This journal publishes examples of evidence-based practice. Prospective authors must include a description of conversations between doctors, descriptions of institutional constraints that affect how evidence is used for the patient, or discussions with the patient that reveal the patient’s values. The “voice of the patient” MUST be included in a manuscript.

The author, editor and reviewers all have the same goal—to produce a valid, insightful and well-written critical appraisal manuscript that walks the reader through the entire clinical decision-making process. The end product should enable the reader to:

- understand the salient elements of the clinical case—both medical and social
- be able to reproduce the author’s search for relevant literature
- understand the strengths of the research chosen for appraisal
- understand all of the weaknesses, biases and confounders, and how they affect the validity of the conclusion drawn.
- be able to apply the research results to the given clinical case.
- articulate new knowledge related to Implementation Science

This should all be self-contained; the reader should not be required to personally read the paper reviewed or repeat the search terms to understand the decision-making process. However, the process must be described in enough detail that they could reproduce the process if they desire.

While they have the same goals, the author, reviewers and editors all have different tasks. The author is responsible for the bulk of the work. The author is unlikely to produce a publication-ready manuscript on the first try. The goal of the editor and peer reviewers are to critique and improve the manuscript in order to make it ready for publication.

The editor decides if the manuscript requires an excessive amount of work to make the manuscript ready for publication. If an excessive amount of work is required, the manuscript will be rejected. If the editor sends the manuscript out for peer reviewer, we try to give the author
suggestions on how to fix conditionally accepted manuscripts to improve the quality. These should be as specific as possible. Writing or re-writing sentences or passages is appropriate. Revising entire paragraphs or sections is discouraged. Anything in-between is left to the reviewers and editor. Organization, clarity, copy-editing, grammar, spelling should also be improved, where applicable.

Ultimately, all parties involved in this process (author, peer reviewers, editors) should be conducting literature searches, deciding if the chosen paper is the most appropriate, reading/critiquing the chosen paper and applying the conclusion to the patient. This will improve the learning experience for all involved.
MANUSCRIPT: __________

PAPER: ____________________________________________________________________

When approaching a critical appraisal manuscript there are many factors that need consideration before a manuscript is ready for publication. A stepwise approach, we find, works well.

The following outlines the required sections in each critical appraisal (1-8). The order of the sections is closely related to the process of clinical decision making using clinical research; this is intentional.

Each section includes tips for writing, as well as some points that should almost always appear in a thorough critical appraisal. These “required” points are indicated in bold, and preceded with a checkbox to assist with completeness. However, checking all the boxes does not guarantee suitability for publication. The author, editor and reviewers should use whatever additional methods they feel are appropriate.

1. □ Title
   a. Do not use the title of the research paper.
   b. □ Summarize the full critical appraisal manuscript.
   c. Emphasize the clinical utility of the research paper.

2. □ Clinical Context
   a. The clinical context should be based on an actual patient care situation.
   b. The description of the patient should include enough detail to formulate the clinical question.
   c. Prioritize the patient’s social context in this section. Describe the patient’s and family’s individual concerns and questions related to the care they receive. The “social context” is nothing more than conversations between people that reveal real life concerns. The readers should have a clear idea of who the patient is as a person.
   d. Give the patient a pseudonym and indicate that it is a pseudonym, e.g., “Albert Smith [pseudonym]” and subsequently refer to the patient as “Mr. Smith”, minimizing pronouns to remind readers that the case is about a real person in a social context. You can look online for the favorite names of the patient’s birth year and choose one and give a generic last name.
   e. The description of the patient should also include relevant aspects of the social determinants of health (https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health#.WXXyv0AonPo.twitter):
• Availability of resources to meet daily needs (e.g., safe housing and local food markets)
• Access to educational, economic, and job opportunities
• Access to health care services
• Quality of education and job training
• Availability of community-based resources in support of community living and opportunities for recreational and leisure-time activities
• Transportation options
• Public safety
• Social support
• Social norms and attitudes (e.g., discrimination, racism, and distrust of government)
• Exposure to crime, violence, and social disorder (e.g., presence of trash and lack of cooperation in a community)
• Socioeconomic conditions (e.g., concentrated poverty and the stressful conditions that accompany it)
• Residential segregation
• Language/Literacy
• Access to mass media and emerging technologies (e.g., cell phones, the Internet, and social media)
• Culture

f. Provide enough clinical detail for readers to determine if the clinical research paper chosen can be applied to this particular patient care situation. Be mindful of inclusion and exclusion criteria and generalizability of the research paper reviewed. These aspects of the clinical case help integrate the different sections of the manuscript described below.

g. This section should fully justify the clinical question asked. Remember, there are always many questions while caring for patients, but we are looking to ensure that the clinical question selected responds to the PATIENT’S concerns.

h. Additionally, information important for making statements about implementation science at the end of the manuscript is required. Implementation science is defined as knowledge about the interface of the clinical evidence and the patient in a social context.

3. ☐ Clinical Question
   a. ☐ State the question clearly in one sentence.
b. We give editorial preference to submissions that include the social context of the patient while formulating the clinical question. Health decisions and health care occur within a social context. This journal is seeking to understand how evidence is deployed in social settings related to the individual patient circumstances.

c. Is the question specific enough? The question is derived from the Clinical Context—the question should respond to a specific need of the patient. General questions are not appropriate (“Is X a side effect of Y therapy?”)

d. Is this a question that is relevant, and able to be answered?

e. Is the topic important to the general readership audience? This is not an opportunity to publish interesting cases on rare disease. The goal is describing the application of clinical research to patient care. However, if there is enough clinical research on a rare topic, it may be within the scope of the journal.

4. Research Article Citation

a. AMA format (http://www.amamanualofstyle.com/)

b. Should almost always be a clinical trial, or else the best available evidence. Remember, this is clinical research in practice; try to use patient oriented evidence that matters (POEMs).

5. Description of Related Literature

a. We require that the search strategy to be reproducible, as this is the equivalent of the “methods” section in other medical literature. It is the most difficult section to write and most publication decisions are usually based on how well this is done.

b. Failure to choose the most relevant paper almost always results in rejection.

c. Provide enough detail to convince our readers that your search has found all of the relevant papers.

   i. Our experience demonstrates that you should try multiple different search strategies to ensure that this criterion is met.

   ii. Your search strategy must be detailed:

       1. start with an overview of the results of your search.

       2. describe resources or databases used, keywords and search terms and filters used.

   iii. Several different resources are available to help you explore the literature. They include:
1. Evidence aggregators, such as Dynamed, UpToDate, Essential Evidence Plus, etc.

2. Search Engines / Databases, such as Google Scholar, PubMed, EMBASE, CINAHL, etc.

3. A review of the articles cited in other trials, systematic/clinical reviews and meta-analyses is an appropriate additional step in finding primary research.

iv. Different clinicians favor different search strategies. Whichever search strategies you describe should result in the same most relevant articles as alternative strategies.

v. A brief PICO description of the most relevant articles is a good approach for therapeutic trials.

2. Intervention – description of the intervention/experimental therapy.
3. Control – description of the control/comparator group.
4. Outcome – description of the outcome.

5. An example: “The Genderson study was a prospective cohort study of hospitalized patients with severe pneumonia [patient]. Patients who were given antibiotic therapy [intervention] had improved length-of-stay [outcome] when compared with patients who were given placebo [control].”

vi. □ The author should cite primary research they have reviewed from the literature search. For areas less extensively studied, they would ideally cite EVERY paper found. For areas more extensively studied, this may be too cumbersome. However, they should still reference key studies that were found. This may include high quality studies that were ultimately not chosen.

vii. When searching PubMed, the following search modifiers are helpful:

1. Use the “Advanced” search option on the home page for PubMed to create a Boolean search. Also, use it to only return search results with terms in the title or abstract.
2. The “Clinical Queries” use keywords from the PICO acronym (population, intervention, comparison, outcome).
3. When viewing “Search Results,” sort by best match.
4. In the left-hand margin, there are different filters that may limit the search as appropriate.
5. Use the “similar articles” feature for highly relevant articles, which may find other closely related articles.

6. Look for medical subject headings (MeSH) that can be used to further refine your search.

7. More information can be found here: http://guides.lib.wayne.edu/c.php?g=174848&p=3252652

viii. If you find a systematic review or meta-analysis, it may assist with the literature search. It is not a replacement for a literature search, however. The literature must still be searched for recent studies published since the review, as well as any studies that the review may have missed for various reasons.

ix. We would like to avoid the critical appraisal of meta-analyses or systematic reviews. The critique of such articles often requires more space than we have available.

1. However, if the search includes them, they should be perused. The largest, highest quality individual trial included in the review should be considered for critical appraisal. You must also state whether the article chosen reached similar conclusion as the meta-analysis.

d. After describing the search strategy, the author must describe why the methods of the chosen article are superior to other articles for answering this question.

   i. The author needs to justify their choice of article, especially if the issue is controversial. The author should do this by comparing validity of research papers found in the search. The validity of research papers is based on the research methodology and the risk of bias that comes from the methodology. It does not come from the results. They should appraise the article that is most likely to guide clinical care.

e. At the end of this section, the reader should be convinced that the author found EVERY primary research article that might answer the question. They should also be convinced that the author selected the best article available to answer the question.

6. Critical Appraisal

   a. First and foremost, an appraisal is not an attack on the authors of the appraised article.

   i. Overly critical appraisals will not be accepted for publication. Furthermore, vitriolic language is never appropriate. The author should conduct their appraisal in an objective, professional manner.
ii. We should identify the strengths of the appraised article. Anything worth appraising is peer-reviewed published literature, and as such must have some merit. Being able to recognize why something is good is at least as important, but more difficult, than recognizing why it is not.

b. The critical appraisal should not be primarily guided by the discussion of the authors of the original research. Our authors must utilize their critical thinking skills.

i. Our aim is to encourage authors to ask questions and engage the methods and data directly.

ii. Without engaging your own critical thinking skills, it is easy to miss important biases, confounders and other important issues.

iii. A brief review of the original research’s discussion section may be helpful, but many experienced and skilled clinicians skip this section altogether when reading articles.

c. The level of evidence must be reported, and the tool used to identify the level of evidence referenced appropriately. Preferred taxonomies include:

i. SORT (http://dx.doi.org/10.3122/jabfm.17.1.59)


d. The study design should be identified and commented on. If not a double-blinded placebo controlled RCT, why not? Does the study design favor one group or outcome?

e. Some comment on effect size is mandatory. This may or may not be a numerical value, but if possible, NNT/NNH or likelihood ratio should be calculated and presented.

f. The study protocol should be described in enough detail. Major features of the study design should be described. Any features of the study design which are particularly strong or weak or introduce the risk of bias should be described in more detail.

g. The author should take the standardized critical appraisal questions and convert them into statements with an evaluative component, e.g., “the patients meeting inclusion criteria were dissimilar to my patient population, which will affect how this paper is used clinically.” These questions usually help to identify weakness (sources of bias or confounding). Their effect on the conclusions drawn should also be considered. These questions are listed below.

h. Critical appraisal questions related to an article on therapy:
Selection Bias: How were patients enrolled or selected for the study? By doing it this way, are we getting a representative sample?

Was the assignment of patients to treatments really randomized? Was the randomization successful? Usually addressed in Table 1.

Participation Bias: How were patients recruited? Patients who volunteer for studies are more likely to pay close attention to their health and have less disease burden.

What is the intervention group exposed to that the control group is not?

Were all clinically relevant outcomes reported? What were they?

Were the study patients similar to your own?

Were both clinical significance and statistical adequacy considered?

Is the therapeutic maneuver feasible in your practice?

Attrition Bias: How many patients dropped out of the study?

Were patients analyzed in the groups to which they were randomized? If so, this is an intention-to-treat analysis, which is stronger. If not, it is likely a per-protocol analysis.

Performance Bias / Detection Bias: Were all patients, health workers, and study personnel blinded? Was this blinding sufficient? Was there anything in the study protocol that may have allowed any party to guess what group they were allocated to?

Aside from the experimental intervention, were the groups treated equally?

Indication Bias: For cohort studies, why was the therapy given? Are patients who are started on that therapy typically because they are sicker or their disease is more poorly controlled?

Critical appraisal questions related to a diagnostic article:

Were patients recruited in a consecutive manner?

Was there an independent comparison against a “gold standard”?

Was this comparison blind? Were the investigators responsible for assessing the diagnostic test aware of the result of the gold standard beforehand?

Was the setting for the study as well as the filter through which study patients passed, adequately described? (Inclusion/Exclusion Criteria)
v. □ Did the patient sample include an **appropriate spectrum of patient** to whom the diagnostic will be applied in clinical practice?

vi. □ Have the **reproducibility** of the test result and its **interpretation** been determined?

j. □ Identify other potential sources of confounding or bias.

  i. □ **Funding Bias**: Was the study **sponsored** in any way? What role did the sponsor have in the design, monitoring, and analysis of the study? Did they provide money/medication only? Did they perform safety monitoring, perform statistical analysis or edit or write the manuscript?

  ii. □ **Publication Bias**: Was the trial **registered prospectively**? (ClinicalTrials.gov, or equivalent) If so, are there significant deviation from the study protocol? Are the reported outcomes different than those registered? Are there missing data that was collected, but not reported?

  iii. Any other sources not already mentioned.

7. □ Clinical Application

  a. □ To the extent possible, the patient’s individual preferences and concerns should be described again. This is another opportunity to include the “voice of the patient”. This section should be a demonstration of shared decision making.

  b. □ This section **must address the social determinants of how care and treatment suggestions fit with the individual’s life**. If transportation, financing, insurance, family structure, disabilities, housing, nutrition, activities of daily living, etc. cause barriers to care, demonstrate how they can be overcome or how the treatment decisions are modified as a result.

  c. DO NOT repeat an extensive recap the clinical research paper appraised. This section should inform the reader how the clinical evidence was applied to the care of the patient in the Clinical Scenario.

  d. □ **Internal Validity**: Does the conclusion of the research article **make sense**, based on the **results of the study**?

  e. □ **External Validity**: How was this conclusion **applied to the particular patient** in question?

     i. Are there any patient specific factors that make this research more or less applicable? This can turn a good manuscript into a great manuscript.

  f. □ What are the potential **benefits and harms** of applying the research? Were these communicated to the patient?

8. □ New Knowledge Related to Implementation Science
The Aims and Scope of the journal are to explore implementation science, defined as knowledge about the interface of the clinical evidence and the patient in their social context. We do not publish case reports about rare diseases; we publish cases that add to the scholarship of implementation science.

Statements about implementation science should acknowledge three levels:

1. Lessons learned about implementing evidence for the specific patient described.

2. More general teaching points about the decision making and processes of care related to implementing clinical evidence.

3. Reflections from clinical practice about improving the implementation of research evidence; directions for future study.

9. □ References / Bibliography

   a. We highly recommend the use of a citation manager, such as EndNote®. EndNote® is freely available to the Wayne State University community here.

   b. □ AMA format (http://www.amamanualofstyle.com/)

   c. □ All claims of fact require reference, unless they can be considered common knowledge. When in doubt, cite.

      i. Requests for citation will be considered very seriously. Inadequate citation is a bad habit and leads to propagation of falsehood.

10. Quality of manuscript (this is a not a required section)

   a. Manuscripts should be of high technical quality on first submission. They should not be sloppily written or have extensive typographic or grammatical errors.

   b. Reviewers and editors are expected to identify errors or confusing passages and suggest corrections or improvements. Your job is to assist the authors in improving the quality of their manuscripts. Your greatest success is a published manuscript.

   c. Feel free to comment on writing style, but remember that style is subjective, and oftentimes up to preference. You must try to keep the manuscript clear, but also allow the author to speak in their own voice. It is often a difficult balance.

   d. □ The word limit for critical appraisals is 2000 words. The count does NOT include references, but does including everything else, such as section headings.

   e. The Abstract format used when uploading a manuscript should be: “A critical appraisal and clinical application of [full citation of article reviewed] for a patient with [insert social context of the patient]”.

This document is available on the Clinical Research in Practice Journal of Team Hippocrates website, under “Author Instructions.”

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