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

Our journal is interested in publishing critical appraisals that describe the use of clinical research in the decision making process for a specific aspect of the care of one patient. Decision making must include the context of care—social determinants that affect the recommendations. It is an exercise in applied clinical decision-making. Health-policy and more general decision-making are outside the scope of a critical appraisal manuscript.

The author, editor and reviewers all have the same goal – to produce a valid, insightful and well-written critical appraisal 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
- 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.

This should all be self-contained; the reader should not be required to personally read the paper or enter 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.

Importantly, it is not a requirement that the author arrive at the same conclusion as the editor/reviewer. Reasonable clinicians can arrive at different decisions based on the evidence. However, the decision made must be well-supported by the literature search and the clinical research presented. Additionally, one of the essential components describes how the research relates to the clinical context and is applied to the care of the patient.

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. This is the first decision to be made, with the assistance of the peer reviewers. If an excessive amount of work is required, the manuscript should be rejected. In addition, the editor and peer reviewers should give the author suggestions on how to fix accepted manuscripts to improve the quality. These should be as specific as possible. Writing or re-writing sentences or passages is appropriate. 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 comprehensive 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. □ To the extent possible, the patient’s **individual preferences and concerns** should be described.
   d. □ We give **editorial preference to submissions that include the social context of the patient.** 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.
   e. 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. These aspects of the clinical case help integrate the different sections of the manuscript described below.
3. □ Clinical Question

a. □ State the question **clearly in one sentence**.

b. □ 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?”)

c. □ Is this a question that is **relevant**, and able to be answered?

d. □ 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


b. Should almost always be a clinical trial, or else the best available evidence. Remember, this is clinical research in practice.

5. □ Description of Related Literature

a. This is the most time-consuming step, but the one that provides the greatest educational opportunities.

b. □ **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.**

c. Look on **Up-to-Date®** or equivalent resource to get a feel for the problem at hand. What is the historic standard of treatment? What are the current areas of controversy? Having a basic understanding of the clinical question is necessary to write or understand a critique.

   i. What types of articles are being cited by that resource? If the article being appraised is being cited, then it is **LIKELY** relevant and worth critique (though not necessarily the MOST appropriate); but being absent is not an absolute contraindication for appraisal. In general, though, unless the article is cutting edge, the author should be appraising articles that impact a field, and as such have been cited.

d. □ the author must **search a publication database**. Pubmed is a preferred database, and the one we typically use. However, Google Scholar, EMBASE and CINAHL may also be used if available.
The author must describe a systematic search strategy.

- This must include search terms.
  - A review of the articles cited in other trials, systematic/clinical reviews and meta-analyses is an appropriate additional step in finding primary research.
  - The search can be refined until it results in a reasonable number of articles. We find about 200 papers is doable. One can quickly read the titles to decide which articles might be primary research. A reading of the abstract should confirm.
  - When searching Pubmed, the following search modifiers are helpful:
    1. term[title] – the search returns articles that have “term” in the title.
    2. term[tiab] – the search returns articles that have “term” in the title or abstract
    3. term[MeSH] – the search returns articles that contain “term” the Medical Sub-Headings, which are tags that describe the most relevant concepts of the article.
    4. term* - the search returns articles containing words that are partial matches with term. For instance, term* may return “termite”, “terminal” or “termination” as potential results.
    5. AND/OR – AND will help to specify the clinical context. OR will help to broaden the search for synonymous terms (lactams OR penicillins).
    6. Parentheses can be used to clarify the intent of your Pubmed search.
    7. More information can be found here: [http://guides.lib.wayne.edu/c.php?g=174848&p=3252652](http://guides.lib.wayne.edu/c.php?g=174848&p=3252652)
  - 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.
  - Saying “I looked at UpToDate®/DynaMed® and read their citations” is unacceptable as the only search strategy. It can/should be used as an adjunct.

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.

- 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.
g. □ 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. 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].”

   ii. 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.

   iii. □ 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.

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:

   i. ☐ **Selection Bias:** **How were patients enrolled or selected** for the study? By doing it this way, are we getting a representative sample?

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

   iii. ☐ **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.

   iv. ☐ What is the **intervention** group exposed to that the **control** group is not?

   v. ☐ Were all **clinically relevant outcomes reported**? What were they?
vi. □ Were the study patients similar to your own?

vii. □ Were both clinical significance and statistical adequacy considered?

viii. □ Is the therapeutic maneuver feasible in your practice?

ix. □ Attrition Bias: How many patients dropped-out of the study?

x. □ 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.

xi. □ 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?

xii. □ Aside from the experimental intervention, were the groups treated equally?

xiii. □ 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?

i. Critical appraisal questions related to a diagnostic article:

i. □ Were patients recruited in a consecutive manner?

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

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

iv. □ 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.

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. □ What is the conclusion drawn from the study?

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?

g. □ Did the patient meet the study’s inclusion criteria? If not, is it still reasonable to apply the conclusions?

h. □ Include three learning points. Learning points may come from didactic knowledge about disease, therapy or diagnosis. They may also come from the critical appraisal process.

8. □ 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.
9. 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 1500 words. The count does NOT include references, but does including everything else, such as section headings.