III Selective 2 - Critical Review of the Literature
Guidelines

A critical review of the literature (also called Systematic Literature Review) poses an unresolved scientific question relevant to the practice of clinical medicine, and attempts to answer that question from evidence published in the medical literature. A critical review can take other forms as well, such as the analysis of an issue in health policy or biomedical ethics or an historical investigation. The research may be initiated by you or by the sponsoring faculty member, as long as you make an intellectual contribution to the project.

A. Key Steps

a) Identify a specific unresolved scientific question relevant to the practice of clinical medicine, its scientific base, or the administration, regulation, or financing of medical care.

b) Conduct a comprehensive, systematic search to identify the existing literature.

c) Critically review this literature with particular attention to methodological strengths and weaknesses in the publications.

d) Summarize the status of this question with particular attention to areas of uncertainty; in most cases, produce one or more tables called Evidence Tables, demonstrating the evidence that addresses your research question.

e) Recommend a logical next step for research. A hypothesis to test and suggested experimental approaches would be appropriate.

B. Faculty Advisor. You will work on your research with guidance from a faculty advisor. Any regular or clinical faculty member in any department at any WWAMI university is eligible to be a faculty advisor. The advisor's role is to help you plan your study, to meet with you as necessary during the execution of the project, and to read and provide feedback on your final paper. Your advisor must sign and approve your research proposal, your fourth year status report, and your final paper.

The faculty advisor you choose and the relationship you build will be among the most important considerations in making this experience successful, enjoyable and valuable. Faculty advisors need to be:

- Interested in your topic (though not necessarily expert in it)
- Familiar with systematic literature reviews
- Available to you through phone, email and scheduled meetings

The ideal faculty advisor will also be:

- A role model for qualities you seek to emulate in your professional development
- Enthusiastic about working with you
- Experienced with the clinical problem, scientific question or policy issue you will be studying
- Someone with skills and knowledge that complement those you bring to the project

In your search for your faculty advisor, start first with the III Departmental Coordinator (list on page). A faculty member from each department has been designated III Departmental Coordinator. You may ask the departmental coordinator for suggestions of faculty who may be

interested in serving as faculty advisor for your III project. Other good sources are people you know: professors, guest lecturers, residents, fellows, other students, and preceptors. You might also consult departmental websites and faculty interest databases such as the Community of Science (COS), http://www.cos.com/. When you first contact a potential faculty advisor, be prepared to explain something about the III requirement as not all faculty members are familiar with III.

C. Proposal. A written proposal describing your plan must be submitted to the III Approval Committee for review. Proposals may be turned in at any time prior to the deadline for presentation to the III Approval Committee. The Committee will: approve your proposal, ask for further information, or ask that you meet individually with the Research Advisor or a Committee member. Your will receive notice in writing once your proposal has been reviewed.

A successful literature review begins with a clear, concise problem statement. This problem (purpose) should be reflected in each of the components of the study described below, which will dictate which databases to search, which articles to select and what information to use from the articles you read.

The proposal should be brief; generally, 1-2 typed pages, but should provide enough information to give the committee a good idea of what you plan to do. If additional information can be presented in non-narrative form, such as a graph, bulleted list, or flow diagram, etc., please include that as well.

Below are guidelines for what should be included in your proposal.

Background and Rationale. Provide a brief introduction to the problem you are investigating. This might include:

- What is the medical-health problem?
    - Describe the who, what, when, why, where and how as appropriate.
- Why is the problem important? Use real data to back your claims whenever possible.
    - Are a lot of people affected by the problem?
    - Are the consequences of not addressing the problem severe?
    - Is this problem costly?
    - What is the public health or societal impact of this problem?
- How will your study contribute to this field of knowledge?
    - What have previous reviews and meta-analyses covered?
    - How does your approach differ?

Research Question and Hypothesis to be investigated. The specificity of the research question should be tailored to the quantity of literature available, as described below under "Selection Criteria." A hypothesis is a testable assertion about the relationship between variables in your study. Provide a preliminary estimate of the number of articles available that address your research question.

Methods:

Search Strategy. A good search strategy contains details on the databases to be searched, key terms to be used, publication dates considered and information on other strategies used to locate articles. Other items that may be included in a search strategy are descriptions of any limits used (e.g. only humans, only articles with abstracts) and any special functions used (e.g. Related Articles or Clinical Queries in PubMed).

Selection Criteria. All selection criteria should consider the following elements:

Study Design – What types of study designs will be included? Only clinical trials? Would case series be included? Would animal studies be considered? If your question concerns the quality of life following two surgical treatments for a certain cancer, will you only include studies comparing the procedures head-to-head, or will you also include case series that describe outcomes for each procedure alone?

Study Population – What characteristics do the subjects need to have? Do they need to be a certain age, gender, race or ethnicity? Do animals need to be a certain breed? Should subjects be healthy or have a pre-existing disease? Are non-English speakers included?

Sample Size – How many subjects does a study need to have in order to be included? What range of follow-up times will you include?

Outcome Assessment – Are there requirements for how outcomes can be measured? Do all outcomes need to be assessed with a specific diagnostic test, such as a CT scan? Do all studies need to use a certain quality of life questionnaire? Do outcomes need to be assessed at a particular time? Will you only use studies that use the same definition of a stroke?

Confounding Variables - Will studies be included that don't take into consideration confounding factors such as patient age or disease severity?

Publication Dates – Were there any changes in measurement, reporting or technology that would affect the interpretation of studies published before a certain date? Will you only include studies published after a certain date when there was a significant change in how one of the procedures was performed?

Your answers to such questions will depend, in part, on the amount of literature available. If there is a large amount of literature, i.e. over 100 articles, you should focus your question to a subset of studies homogeneous with respect to population, study design, and other research methods. If the body of literature is small, you will have to use studies that are more heterogeneous.

Variables. Indicate how, for purposes of the review, you will define the exposures and outcomes of interest and how the outcomes are measured. If there are important confounding variables, describe these as well. Your definitions should be reasonably consistent with definitions used in the studies included in your evidence table.

Strategy for Data Synthesis. Describe how you will integrate information across studies to answer the research question. You do *not* need to perform a meta-analysis or mathematically pool data across studies.

D. Timetable. As best you can, lay out a realistic timetable for completing the key steps of the project, paying attention to the deadlines described below.

E. Preliminary Literature Review. Demonstrate that there are enough published studies that address your question to proceed with your review. Attach a list of a minimum of 10 published studies to your proposal. The III Approval Committee will not consider your proposal without this.

F. Deadlines (note: due dates are deadlines).

	Selective 1	Selective 2	Selective 3	Selective 4
Year 1 Proposals Due	MSRTP - Proposal due the last Friday of January 2009 ALL OTHER SELECTIVE 1 options- proposal due last Friday of March 2009**	Proposal due last Friday of March, 2009	R/UOP III-3 application will be available online by the last Friday of the Autumn Quarter Application deadline is the last Friday in January 2009	Application due the last Friday in January
Year 2 Final project due	Final paper due January 2010	Final paper due January 2010	Final R/UOP III-3 project is complete once final poster is presented in Autumn 09*	Final project due January 2010

G. Final paper.

The Title should be brief and narrowly focused. It will become a permanent part of your curriculum vitae, so give it considerable thought. It does not need to be identical to the title on your proposal.

The Abstract is a succinct summary of the paper's methods and results, usually about 250 words.

The Introduction provides a rationale for why the study was done. Think of the introduction as a funnel. It can begin with a broad introduction to the issues, but quickly narrows its focus to the specific research problem being investigated. It should convince the reader that an important research problem has been addressed in the literature and now calls for systematic review. It should include data on the public health impact (e.g. incidence rate, mortality rate, costs) of the problem whenever possible. By the end of the introduction, the reader should understand what your study will be about and why it is an important study to do.

The Methods section ought to contain enough detail to enable another investigator to replicate your study. This section must describe:

- How articles were selected (your search strategy)
- Why articles were included or excluded (your selection criteria including all elements described above)
- How you created your evidence table(s) and may include:
    - Definitions of important variables
    - Descriptions of any calculations you made

The Results section is the meat of the paper. Typically, the first results presented describe the sample of articles on which the remaining results are based. Describe the studies in your evidence table in general. How many articles with a specific study design were found? How many head-to-head comparisons were found? How many with a particular type of study population? How many studies used a certain type of outcome assessment? You may want to create a table summarizing this information.

Example Outline of a Summary Table

Summary of Study Designs Reviewed

Study Design	# of Studies
Clinical Trial	
Cohort Study	
Case Series	

After you have described the studies in general, describe the studies in detail in an evidence table. At a minimum, you should touch upon some of the elements listed in the selection criteria and give the main results of the paper. The text should refer to the tables and graphs but should not reiterate the information contained in them. The text can, however, guide the reader toward the message contained in the table or graph: *"Table 2 shows that the treatment and control groups had similar hospital lengths of stay within studies, although length of stay varied considerably among the studies."*

An example evidence table for a best clinical practices or an etiology study is presented below. In the table, you would list the first author, year, and study design and write a short description of the study population. For example, if we were studying the effect of hormone replacement therapy on stroke, you might have a study that included "post-menopausal women aged 50-85." Under therapy or exposure, you might write "cyclic hormone therapy." For outcomes, you might have results for any stroke, ischemic stroke and hemorrhagic stroke. Depending on the purpose of our review, you could include all three types or just one or two. For outcome, you could report odds ratios, relative risks, incidence or other measures. The purpose of the review would guide you as to which to select. The comment column would be used for information that affects interpretation of the results. For example, were results adjusted for age?

Example Outline of an Evidence Table

First Author	Year	Study Design	Study Population	Therapy or Exposure	Outcome	Results	Comments

The Discussion should be an interpretation of the results. Begin by providing an answer to the research question posed earlier. Discuss the weaknesses of the studies reviewed and how those weaknesses could influence the results of the individual studies and the results of your review. Comment on the generalizability of your review. After taking the weaknesses into consideration, what is the meaning of the study for the field of medicine? What questions has your review resolved? What questions or directions for future research has your review generated?

Final Paper Review Guidelines
The following guidelines are given to reviewers for Selective 2:

Section	Required Criteria	Criteria of Excellence
Question	Important *or* interesting/creative, somewhat focused in terms of population, intervention/exposure and outcome; no fatal flaws in question.	Important *and* interesting/creative, clearly focused in terms of population, intervention/exposure and outcome.
Method	Describes strategy for literature search, study inclusion criteria and methods of data synthesis.	Clearly describes excellent strategy for literature search, study inclusion criteria and methods of data synthesis.
Results	Demonstrates general understanding of relevant concepts. Results described appropriately (i.e., reviewed studies relevant to research question; not missing important studies; not drawing inappropriate conclusions or going beyond the data, enough detail provided to understand conclusions without just listing studies, results are related specifically back to question)	Demonstrates clear understanding of relevant concepts and thorough literature review. Well-articulated and makes interesting or creative points. Results well articulated, appropriate use of tables and figures. Appropriate synthesis of results across studies, with attention to methodological heterogeneity and quality.
Discussion/ Conclusions	Demonstrates adequate understanding of the results in relation to the question. Articulates limitations of the review.	Draws interesting implications, strong understanding of the results in relation to the literature, clearly articulates the limitations of the review and future directions suggested by it.
Presentation	Reasonable organization and readability, formatted in style for refereed journal, few spelling or grammatical errors.	Well-organized, readable, clear, style appropriate for refereed medical journal, almost no spelling or grammatical errors.

H. <u>Key Personnel</u>

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