

**Foundations of Medicine 2 Course
2023**

**Session Name:** Introduction to Critical Appraisal

**Hours:** 10:00AM - 12:00PM (Lecture & Small Group Session Format)

**Date:** February 9, 2023

**Faculty**: Dr. Stacy Rubin & Ms. Michelle Keba Knecht

In this session, first year medical students in their second semester of study are introduced to the concept of critical appraisal. During the first hour, students will receive an introductory lecture on critical appraisal and the CASP checklist tool. During the second hour, students will be provided with discussion questions and an article on labor induction versus expectant management in low-risk nulliparous women. Students will review the article and answer the discussion questions in their small groups with their small group facilitators.

The session introduces critical appraisal topics including blinding, randomization, concealment allocation, intention-to-treat analysis, power, statistical significance, and clinical significance.

Objectives:

1. Recognize basic statistical and epidemiologic principles and methods in a randomized control trial.
2. Critically appraise a randomized control trial that is published in a peer-reviewed journal.

Session plan:

1. All students should meet in the Gelb Classroom at 10:00 AM. Ms. Knecht will provide an introductory lecture on critical appraisal and the CASP checklist tool from 10:00-10:50AM.
2. From 11:00-11:30 AM, students will review the New England Journal of Medicine article “Labor Induction versus Expectant Management in Low-Risk Nulliparous Women” and answer the associated discussion questions in their small groups with their small group facilitators. **Reading this paper prior to the session is encouraged**.
3. From 11:30-11:50 AM Dr. Rubin and Ms. Knecht will hold a large group discussion and review the discussion questions with the class.

Related course assignment:

In March, students will be given a randomized control trial related to a standardized patient in their Clinical Learning Group. Each student will read the article and independently complete a critical appraisal of the study using the CASP checklist tool. Students’ assignments will be graded on the clarity and quality of their rationale for each response with well-supported statements using evidence from the study.

Reference:

1. Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med*. 2018;379:513-523.

**Intro to Critical Appraisal Lecture Outline:** (60 minutes)

* **Agenda & Tie Back to Prior Learning**
	+ Definition of evidence-based medicine and its importance to patient care
	+ Brief overview of the 5A’s of EBM
	+ Assignment objective, instructions, and grading
* **Intro to Critical Appraisal**
	+ Dopesick example – “Research study” quoted by Purdue Pharma sales reps was actually a 5 sentence NEJM letter to the editor
	+ Importance of critical appraisal
* **CASP Checklist**
	+ Overview of CASP Checklists – this assignment will use the checklist for RCTs
	+ Critical appraisal in 3 Steps
	+ Overview of each question in detail – (expanded info provided below for some questions)
* **2. Was the assignment of patients to interventions randomized?**
	+ If time, ask students:
		- What could happen if the researchers or the patients were able to choose which group they were in? (There could be an issue of selection bias.)
	+ **Selection bias**: Systematic differences between baseline characteristics of the groups that are compared (biased allocation to interventions).
* **3. Were all patients who entered the study accounted for at its conclusion?**
	+ If time, ask students:
		- How many of these patients were lost to follow up? (none)
		- What would happen if too many patients were lost to follow up? (attrition bias.)
	+ **Attrition bias:** Systematic differences between groups in withdraws from the study
* **4. Were participants, investigators and people assessing/analyzing outcomes ‘blind’ to the intervention?**
	+ If time, ask students**:**
		- What could happen if the people involved in the study aren’t blinded? (performance bias)
	+ **Performance bias:** Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest.
* **5. Were the study groups similar at the start of the randomized control trial?**
	+ If time, ask students**:**
		- Were these groups similar at the start of the trial? (Yes)
* **Statistical vs. Clinical Significance**
	+ The p-value DOES NOT tell us how large the differences between the two groups are.
	+ These results are statistically significant but we don’t know if they are clinically significant. We don’t know if the difference between groups is large enough for the treatment to be worth it.
	+ Studies can be statistically significant yet not clinically insignificant.
* **8. Was the precision of the estimate of the intervention or treatment effect reported?**
	+ Patients who received gastric-bypass were 7.5 times as likely to have diabetes remission as those who had medical-therapy.
	+ Patients who received bibliopancreatic-diversion were 9.5 times as likely to have diabetes remission as those who had medical-therapy.

**Intro to Critical Appraisal Small Group Activity Outline:** (60 minutes)

* Divide the students into groups of approximately 8-10 students per group
* Start by playing the quick take video (1min 31sec) for the students at: <https://www.nejm.org/doi/full/10.1056/NEJMoa1800566>
* Pass out the Small Group Activity Intro to Critical Appraisal Discussion Questions – Student Copy to each student
* As a group, go over the discussion questions in the Small Group Activity Intro to Critical Appraisal Discussion Questions – Instructor Copy
* Encourage the students to answer on their own first, but guide them to the answer if they are unable to determine the correct response
* Share the Small Group Activity CASP-RCT-Checklist Example for Discussion Article document with the students at the end of the session