

PHA6791 Systematic Reviews and Meta-Analyses for Pharmaceutical Interventions

Class Periods: Sundays, 6:00pm-8:00pm

Location: Canvas course website

Academic Term: TBD

Instructor:

TBD

[Email Address](#)

[Office Phone Number](#)

[Office Hours:](#) TBD

Teaching Assistants:

TBD, Please contact through the Canvas website

Course Description

The purpose of this course is to enable students to be able to participate in and complete systematic reviews for pharmaceutical interventions and to complete meta-analyses. Students will learn how to build a team, formulate research questions and hypotheses, develop search strategies, and abstract, collect and report data. Students who complete this course will understand the importance of systematic reviews in making clinical and policy decisions in health care.

Course Pre-Requisites / Co-Requisites

PHA 6793 Evidentiary Basis of Pharmaceutical Use (or its equivalent) and prior graduate-level statistics coursework or undergraduate level applied statistics. Students without prior statistics courses may be required to take *PHA 6935 Quantitative Methods in Evidence-Based Pharmacy*.

Course Objectives

Upon completion of this course, the student will:

1. Differentiate systematic reviews from other types of assessments (e.g., narrative reviews, scoping reviews)
2. State the role of systematic reviews and meta-analyses in pharmaceutical value assessment and communication.
3. Define appropriate research questions for a systematic review and meta-analysis.
4. Conduct an appropriate search strategy for a systematic review.
5. Apply eligibility (i.e., inclusion and exclusion) criteria, data extraction, and data quality scoring.
6. Explain how to do data synthesis for meta-analysis.
7. Calculate effect sizes and confidence intervals.
8. Identify and quantify heterogeneity.
9. State when to use a fixed versus random-effects model.
10. Develop a plan for data synthesis.
11. Execute a meta-analysis of randomized controlled trials or observational studies.
12. State the importance of and assess for publication bias and other potential sources of bias.
13. State when a meta-analysis should not be done and how to report a systematic review instead of a meta-analysis.
14. Explain the special considerations for applying meta-analyses to economic evidence, patient-reported outcomes, a network of randomized controlled trials (network meta-analysis), or drug safety.

Materials and Supply Fees

The student will use software to do the synthesis for the meta-analysis:

- Covidence (<https://guides.himmelfarb.gwu.edu/Covidence>), an evidence-synthesis cooperative, will be used for the systematic review.
- Excel will be used [Neyeloff JL, Fuchs SC, Moreira LB. Meta-analyses and Forest plots using a Microsoft Excel spreadsheet: step-by-step guide focusing on descriptive data analysis.
- *BMC Research Notes*. 2012;5(52). <https://doi.org/10.1186/1756-0500-5-52>] for the data synthesis. Neither Covidence nor Excel requires extensive technical experience or a license fee.

Required Textbooks and Software

Cochrane Handbook for Systematic Reviews of Intervention, Version 6. [Updated July 2019]. The Cochrane Collaboration, 2019. Available from <http://handbook.cochrane.org>

This course will supplement the required text with timely academic articles and examples of recent meta-analyses, and reporting guidelines (e.g., Preferred Reporting Items for Systematic Reviews and Meta-Analyses, available at <http://www.prisma-statement.org/>).

Recommended Materials

The following texts are not required but may provide the student with supplemental background about systematic reviews and meta-analyses.

- Lipsey MW, Wilson DB. *Practical Meta-Analysis*. Thousand Oaks, CA: Sage. 2000.
- Cooper H. *Research Synthesis and Meta-Analysis: A Step-by-Step Approach*. 5th Ed. Thousand Oaks, CA. Sage. 2017.
- Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. *Introduction to Meta-Analysis*, 1st Ed. West Sussex, UK. Wiley. 2009.

Course Schedule

Week and Date	Learning Activities/Topic
Course Overview	
<date>	Course Introduction
	Why do a Meta-Analysis?
	Final Project Overview
	Working in a Team on a Systematic Review and Meta-Analysis
Module 1: Systematic Review and Meta-Analysis Overview	
Week 1 <date>	Fundamentals of a Systematic Review
	Fundamentals of a Meta-Analysis
	Role in Pharmaceutical Value Assessment and Communication
	Critical Evaluation of Published Meta-Analyses
	Determining the Scope and Research Questions (i.e., PICOT)
Module 2: Methods—Learning How to Do a Meta-Analysis	
Week 2* <date>	Inclusion Criteria and Grouping for Synthesis
	Search Strategy and Study Selection
	Collecting and Quality Scoring Data
	Effect Measures
Week 3 <date>	Bias and Conflicts of Interest
	Risk of Bias in Randomized Trials
	Preparing for Synthesis
Week 4 <date>	Coding Schemes
	Effect Sizes and Confidence Intervals
	Fixed versus Random Effects
	Heterogeneity
Week 5 <date>	Applying Bias Detection Techniques (e.g., Funnel Plots)
	Summary of Findings, Tables and, Grading the Certainty of the Evidence

Week and Date	Learning Activities/Topic
	Reporting Guidelines
Module 3: Considerations for Application	
Week 6 <date>	Meta-Analyses versus Large Trials: Reasons for Agreement and Disagreement
	Limitations of Meta-Analyses for Studying Drug Safety
	Economic Evidence
	Patient-Reported Outcomes
Week 7 <date>	What is a Network Meta-Analysis?
	Advantages of Network Meta-Analyses
	Performing a Network Analysis
	Evaluating Confidence in the Results of a Network Meta-Analysis
	The Limitations of Network Meta-Analyses

Attendance Policy, Class Expectations, and Make-Up Policy

Unexcused absences from the online group discussions carry a 4-point (~1/2 letter grade) reduction in the final grade. Absences due to illness, job conflicts, and other emergencies must be conveyed by email to [<insert course coordinator email>](#) before the group discussion begins. Email via Canvas is preferred, but a telephone text will be accepted if you cannot email. Messages from friends or classmates will not be accepted, except under exceptional circumstances. When a student has an excused absence, they will receive no deduction for participation. Excused absences will require a make-up reflection paper within 2 weeks of the missed class to obtain your participation points. This paper requires you to listen to the recorded class session and write a reflection paper on the content covered during the missed classed.

The course coordinator will address more than two excused absences; an incomplete grade (i.e., I grade) is a strong possibility.

Excused absences must be consistent with university policies in the [Graduate Catalog](#) and require appropriate documentation. Additional information can be found in [Attendance Policies](#).

Active Learning Requirements

Participation in the live online classroom sessions is mandatory. These sessions are an essential part of this course. Students may be permitted to submit a make-up assignment for up to two excused absences.

Make-up Quiz/Exam Policy

The course coordinator will handle make-up quizzes on a case-by-case basis. Usually, these will be considered a zero score and be the dropped quiz grade. If more than two quizzes are missed for a valid reason (i.e., medical excuse), the course coordinator will make accommodations on a case-by-case basis.

Policy on Old Quizzes and Assignments

No old quizzes, exams, or assignment examples will be provided.

Assignment Deadlines

Assignments will be posted with precise due dates. Students are responsible for complying with these deadlines. Late assignments will not be graded (0 points). Delays due to unforeseen and/or distressing events will be treated on a case-by-case basis by the course coordinator.

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations

4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Evaluation of Grades

Online quizzes: This course will be a mixture of mandatory readings and pre-recorded lectures that must be reviewed before each weekly quiz. The weekly quiz will be available for at least three days before each class. Quizzes will include ten multiple-choice or short-answer questions over 15 minutes. There will be seven quizzes, and the lowest quiz grade will be dropped. The purpose of the quizzes will be to assess readiness for the weekly discussions and understanding of the course materials. The quiz average will contribute 24% towards the final grade in this course (i.e., each quiz will contribute 4% towards your final grade).

Class participation: Class participation is mandatory. Discussion board participation, class attendance, and participation in class will be used to award 28% of the final grade. There are eight participation grades (seven weeks plus the introductory session); thus, each week will contribute 4% towards your final grade. Each student is expected to post one substantial comment to the discussion board each week. What constitutes a "substantial comment" is described in the Introductory class session. The discussion board post may offer an opinion regarding one of the topics covered, a thoughtful reaction to another student's post, an extension of the concepts covered in readings or lectures, or an addition to the general theme of the week (e.g., Methods).

Final Project: Students will be assigned a topic for a [limited] systematic review and meta-analysis. The number of teams and size of each group will be determined by the course coordinated based on enrollment. Students will be assigned a subject for in-depth evaluation consistent with pharmaceutical assessment and communication. Proper attribution is mandatory; plagiarism will be assessed using Turnitin. References should be sequentially numbered and listed as a superscript at the end of a sentence and sequentially at the end of the paper. All students must watch and follow the instructions contained in the pre-recorded lecture, *Working in a Team on a Systematic Review and Meta-Analysis*. All papers will be due on *<insert date>*. The final paper will count for 40% of your final grade. Refer to Appendix C for a grading rubric.

Final Project Participation: Students will peer evaluate the members of their team. Students will assess their team members on the following criteria: contributing to the team's work (up to 20 points), interacting with teammates (up to 20 points), keeping the team on track (up to 20 points), expecting quality (up to 20 points), and having the relevant knowledge, skills, and abilities (up to 20 points). The average of the team member scores will be used for this assessment. This peer assessment will contribute 8% to your final grade.

Grading	% of grade
Final Project [topic assigned by the course coordinator] <i>Grades will be based on a rubric following the assignment directions</i>	40%
Final Project Participation [peer evaluation by team members] <i>Grades will be determined by a peer evaluation tool</i>	8%
Class Participation* <i>Bulletin board participation, class attendance, and class participation will be used to award a weekly participation score</i>	28%
Online quizzes (6 of 7; the lowest grade will be dropped) <i>Dropped for technical problems or excused absences</i>	24%

*There will be seven sessions from <insert dates>.

Grading Scale

>92.500%	A
89.500–92.499%	A-
86.500–89.499%	B+
82.500–86.499%	B
79.500–82.499%	B-
76.500–79.499%	C+
72.500–76.499%	C
69.500–72.499%	C-
66.500–69.499%	D+
62.500–66.499%	D
59.500–62.499%	D-
<59.499%	E

Note: this scale already reflects a rounding of grades! A grade of 92.4 is not 0.1 from an A; it is 0.6 points from an A. There will be no additional rounding or awarding of "extra" points because a grade is close to the cut-off. This course's rounding policy already considers these issues.

More information on UF grading policy may be found at:

[UF Graduate Catalog](#)
[Grades and Grading Policies](#)

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the [Disability Resource Center](#). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course Evaluation

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. [Click here for guidance on how to give feedback in a professional and respectful manner](#). Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via ufl.bluera.com/ufl/. [Summaries of course evaluation results are available to students here](#).

University Honesty Policy

UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” [The Honor Code](#) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Software Use

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see the [Notification to Students of FERPA Rights](#).

Campus Resources:

Health and Wellness

U Matter, We Care:

If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.

Counseling and Wellness Center: counseling.ufl.edu/cwc, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

Sexual Assault Recovery Services (SARS)

Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu.

Academic Resources

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.

Career Resource Center, Reitz Union, 392-1601. Career assistance and counseling.

Library Support, Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.

Student Complaints Campus

On-Line Students Complaints

Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty

Canvas will be used for most communications between the faculty and students. Check for new announcements at least once a day for any course updates. An email will also be used occasionally for mass communication to the class, so please check your email at least once a day. All emails sent out to the entire class will also be posted as an announcement on Canvas.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not been addressed/answered already. Please include precise subjects for your post topics.

Emotions can easily be misinterpreted on discussion boards/emails, so make sure your message is clear before sending it. There are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case by case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions, please email *<insert course coordinator email>*. Be sure to include in your subject line the course listing and then a quick subject (i.e., PHA6935 – Your Name -). Titling your email this way allows the course coordinator to quickly identify emails related to the course amongst the plethora of junk and other emails that are received each day. Emails not correctly addressed may get lost in the shuffle and unintentionally deleted or ignored, so follow the guidelines exactly.

Should you experience any technical issues with course media or content, email Distance Education Support Services: DESS@ahc.ufl.edu.

Appendix B. Schedule of Course Activities/Topics

Week and Date	Learning Activities/Topic
Course Overview	
<date>	Course Introduction
	Why do a Meta-Analysis?
	Final Project Overview
	Working in a Team on a Systematic Review and Meta-Analysis
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Week 1 <date>	Fundamentals of a Systematic Review
	Fundamentals of a Meta-Analysis
	Role in Pharmaceutical Value Assessment and Communication
	Critical Evaluation of Published Meta-Analyses
	Determining the Scope and Research Questions (i.e., PICOT)
Module 2: Methods—Learning How to Do a Meta-Analysis	
Week 2* <date>	Inclusion Criteria and Grouping for Synthesis
	Search Strategy and Study Selection
	Collecting and Quality Scoring Data
	Effect Measures
Week 3 <date>	Bias and Conflicts of Interest
	Risk of Bias in Randomized Trials
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Week 4 <date>	Coding Schemes
	Effect Sizes and Confidence Intervals
	Fixed versus Random Effects
	Heterogeneity
Week 5 <date>	Applying Bias Detection Techniques (e.g., Funnel Plots)
	Summary of Findings, Tables and, Grading the Certainty of the Evidence
	Reporting Guidelines
Module 3: Considerations for Application	
Week 6 <date>	Meta-Analyses versus Large Trials: Reasons for Agreement and Disagreement
	Limitations of Meta-Analyses for Studying Drug Safety
	Economic Evidence
	Patient-Reported Outcomes
Week 7 <date>	What is a Network Meta-Analysis?
	Advantages of Network Meta-Analyses
	Performing a Network Analysis
	Evaluating Confidence in the Results of a Network Meta-Analysis
	The Limitations of Network Meta-Analyses

*Specific notations about a week's class (i.e., voluntary participation on a holiday weekend).

Appendix C. Final Project Grading Rubric

	Excellent	Acceptable	Poor
Introduction/Problem Statement (10 points)			
Title	2 The Title is appropriate, identifying the project as a systematic review, meta-analysis, or both.	1 The Title is acceptable and identifies the project as a systematic review, meta-analysis, or both.	0 The Title is unacceptable—not identifying the project as a systematic review and/or meta-analysis.
Rationale	3 The Introduction describes the rationale for the review in the context of what is already known	2 The Introduction provides acceptable justification for the review	1/0 The explanation for the project is incomplete, flawed, or not discussed in the Introduction.
Objectives	5 Specific questions being addressed are stated regarding participants, intervention, comparisons, outcomes, and study design (i.e., PCOS).	3 Questions that are being addressed are stated but are incomplete regarding the PCOS	1/0 Questions being addressed are reported with a limited context, or the questions are not stated.
Establishment of Eligibility Criteria (5 points)			
Eligibility Criteria	5 Study (e.g., PCOS,* length of follow-up) and report (e.g., years considered, language(s), publication status) characteristics are specified and used as eligibility criteria. The rationale for these criteria is stated.	3 Study and report characteristics are incomplete and/or are not linked to eligibility criteria or presented without rationale.	0 Study and report characteristics are not stated or linked to the eligibility criteria.
The Search of the Literature (15 points)			
Information Sources	5 All information sources (e.g., databases with dates of coverage and methods to identify additional sources) used for the search are described, including the date last searched.	3 The information sources searched are not entirely described, or the date of the last search is not explicitly stated.	0 The information sources searched are not described, and the date of the search is not stated.
Search	5 Full electronic search strategies are presented for at least one database, including limits used so the search could accurately be repeated.	3 Search strategies are incompletely described.	0 The search strategy is not described.
Study Selection	5 The process for selecting studies (i.e., screening, eligibility) is clearly stated.	3 The process for selecting studies is not described, but it is not explicit.	0 The process for selecting studies is not described.
Data Extraction (23 points)			
Data Collection Process	5 The methods used to extract data from reports (e.g., independently, in-duplicate) and any processes for obtaining and confirming data are clearly stated.	3 The methods used to extract data is incomplete.	0 There is no discussion of the methods used to extract data.
Data Items	5 All variables for which data are sought (e.g., PICOS,* funding sources) are explicitly	3 Variables sought are listed but incompletely described.	1/0 Variables sought are partially listed or not listed.

	stated, and any assumptions and simplifications are indicated.		
Individual Study Results	5 Data items for each study are presented (e.g., table)	3 Data items from studies are incompletely presented.	1/0 Data items are incorrectly presented or not listed.
Data Quality Scoring	2 A method for data quality is correctly applied to each study.	1 A data quality method is partially applied.	0 A data quality method is either incorrectly applied or not applied.
Risk of Bias Assessment	3 For each study, an assessment of the risk of bias is done appropriately and presented.	2 An assessment of bias is done, but there are errors.	1/0 An assessment of bias is done incorrectly or not done.
Information included	3 A figure is created including identification (# of records identified through database searching and # of additional records identified via other sources), screening (i.e., # of records after duplicates removed, # of records screened and excluded), eligibility (# of full-text articles assessed for eligibility and excluded, including reasons), and included (#number of studies included in the qualitative synthesis and # of articles included in the quantitative synthesis) reports.	2 A figure presents how information was identified, screened, eligibility determined, and the final number of reports included is presented; however, a figure describing the results of this process is incomplete or has inaccuracies.	0 No figure describes how the final studies included where selected.
Synthesis of Evidence (20 points)			
Summary Measures	5 Results of each meta-analysis, including confidence intervals and measures of consistency, are presented.	3 The results of each meta-analysis are incompletely presented.	1/0 The meta-analysis results are incorrect or not presented.
Heterogeneity	3 Appropriate measures of heterogeneity are synthesized and related to the methods used	2 Heterogeneity is partially addressed	0 Heterogeneity is not addressed.
Sensitivity Analyses	2 When necessary, appropriate sensitivity analyses are done and put into context (e.g., limit analysis to only high-quality studies). If not needed, this is explicitly expressed.	1 Sensitivity analyses are partially addressed.	0 The need for sensitivity analyses is not addressed
Result Tables	5 Tables are effectively used to present results, when necessary.	3 Result tables are incomplete or confusing.	0 No result tables are included when applicable.
Result Figures	5 Figures are effectively used to present results.	3 Figures are ineffective, duplicative, or incorrect.	0 When figures are necessary, they are not included.
Discussion (22 points)			
Summary of Evidence	5	3	1/0 A summary is included in the Discussion,

	A single paragraph in the Discussion clearly states the most important findings and the clinical implications of these findings.	A summary of evidence is included in the Discussion, but it is not concise or emphasize the most important findings.	but it is inaccurate, or no summary is included.
Potential Effects of Biases	5 Assessments of bias are clearly stated linking the potential implications are presented (e.g., publication bias [funnel plots], selective reporting within studies)	3 There is a limited or incomplete assessment of the possible effects of bias on the results.	0 Bias is not addressed in the Discussion.
Comparison to Existing Evidence	5 The findings of this analysis are compared with the conclusions of the individual studies and/or any previous systematic reviews and/or meta-analyses.	3 The findings of this analysis are incompletely compared to the results of the individual studies or previous systematic reviews or meta-analyses.	0 There is no comparison to existing evidence.
Limitations	5 The limitations of the review and analysis are identified and discussed in the Discussion.	3 The limitations of the review and meta-analysis are incompletely addressed in the Discussion.	1/0 The limitations of the review and meta-analysis are incorrect or not addressed in the Discussion.
Implications for Future Research	2 The need for future research to address deficiencies in the existing evidence is stated and justified.	1 The need for future research is addressed but is incomplete.	0 The need for future research is not addressed.
Conclusions (5 points)			
	5 The general interpretation of the results is clearly stated and are justified by the design and execution of the systematic review and meta-analysis	3 The interpretation of the results is stated and are mostly justified by the design and execution of the systematic review and meta-analysis	1 The conclusions are not clearly stated and/or cannot be justified based on the design and execution of the systematic review and meta-analysis
Final Grade (100 points)			Total Points: _____

*PICOS: P = Patient, Population, or Problem; I = [Pharmaceutical] Intervention; C = Comparison; O = Outcome; and S = Study Design