

PHCY 074
Drug Literature Analysis and Interpretation
UNC-CH School of Pharmacy



Fall Session, 2005
Classroom: Kerr Hall, Room 2001
Class Hours: 10:00 - 11:50, Tuesdays and Thursdays
4 credit hours

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Table of Contents

TABLE OF CONTENTS	1
GOAL OF THE COURSE	2
OVERVIEW AND OBJECTIVES	2
RATIONALE	2
PREREQUISITES	2
TEXTS AND READINGS.....	2
COURSE WEBSITE	3
EXTRA HELP – RECOMMENDED TEXTS & RESERVE ITEMS IN THE LIBRARY... 	3
COURSE REQUIREMENTS AND EVALUATION	4
ASSIGNMENT DUE DATES AND POINTS AVAILABLE.....	5
GRADING	6
FINAL GRADE.....	6
OTHER POLICIES AND MISSED WORK.....	7
ACADEMIC INTEGRITY	8
STUDENT-INITIATED CHANGES IN CLASS POLICIES OR SCHEDULE.....	9
MODULE COORDINATORS AND INSTRUCTORS.....	10
COURSE SCHEDULE	11
TERMS & LEARNING OBJECTIVES	17

Goal of the Course

The goal of the course is for students to acquire the skills used by pharmacists to seek, appraise, and apply new knowledge relevant to improving pharmacy practice and patient care.

Overview and Objectives

This course is designed to provide a learning experience through which students will develop critical appraisal skills for solving clinical problems. The course contains three didactic modules. The objectives of the modules are to enable the student to: (1) identify appropriate resources for drug information and use the resources for clinical decision-making; (2) understand and apply the methods of epidemiology and statistics to reach valid conclusions about clinical problems; and (3) critically evaluate published research studies to make judgments about the validity, value, and applicability of the findings to patient care.

Lectures and reading assignments provide core course content. Group assignments provide students an opportunity to apply concepts learned through readings and lectures to answer a clinical research question by identifying, analyzing, and interpreting relevant literature.

Rationale

The purpose of the course is to support the role of the pharmacist as a clinician, educator, and life-long learner.

Prerequisites

Prior to enrolling in the course, students must have successfully completed (1) one 3-credit course in statistics (preferably biostatistics) and (2) at least one year of pharmacy school or have a Bachelor of Science degree in Pharmacy. Students are expected to be able to interpret basic descriptive and inferential statistics that are commonly used in health studies.

Texts and Readings

There are two required books and two recommended books. Additional required and recommended readings will be available on the course website.

Required

- Norman GR, Streiner, DL. *Biostatistics: The bare essentials, 2nd. Edition*. Hamilton, Ontario: Decker, 2000. ISBN: 1-55009-123-9
- Bowers D, House A, Owens D. *Understanding Clinical Papers*. New York: Wiley, 2001. ISBN: 0-471-48976-X

Recommended

- Fletcher RH, Fletcher SW. *Clinical Epidemiology: The essentials, 4th Edition*. Baltimore: Lippincott, Williams, and Wilkins, 2005. ISBN: 0-7817-5215-9
- Guyatt G, Rennie D. *Users' Guides to the Medical Literature: Essentials of evidence-based clinical practice*. Chicago: AMA Press, 2002. ISBN: 1-57947-191-9

Course Website

This course will participate in the UNC School of Pharmacy initiative to use websites designed by Blackboard. To succeed in this class, you need to check your e-mail account and the Blackboard site regularly. Announcements, class notes, and important documents are posted on the website. Any changes to the course schedule will also be posted.

Extra Help – Recommended Texts & Reserve Items in the Library

Module 1: For more help with study design and statistics:

Slaughter RL, Edwards DJ. *Evaluating Drug Literature: A Statistical Approach*. McGraw Hill, 2001. ISBN: 0071347291.

Dawson B, Trapp RG. *Basic and Clinical Biostatistics, 3rd Edition*. New York: McGraw Hill, 2001. ISBN: 0-07-137052-8

Module 2 - For more help with drug information and writing:

Malone PM, Mosdell KW, Kier KL, and Stanovich JE. *Drug Information: A Guide for Pharmacists*. Second Edition. New York: McGraw-Hill, 2001. ISBN: 0838515770

Module 3 – For more examples on how to critically appraise a published article:

Dawes M., et al. *Evidence-based Practice: A Primer for Health Care Professionals*. Edinburgh: Churchill Livingstone, 1999. ISBN: 0443061262

Greenhalgh T, Donald A. *Evidence Based Health Care Workbook: Understanding Research*. London: BMJ, 2000. ISBN: 0727914472

Course Requirements and Evaluation

Evaluations for this course are based on class preparation, class participation, examination scores, and the successful completion of assignments. The UNC Honor Code governs your behavior throughout the course.

Reading Assignments. You are expected to complete the assigned readings *before* each class meeting.

Exams. There will be two 2-hour exams during the semester. These exams will be scheduled during exam week with the time, date, and location determined by the Office of Professional Education. There will also be a take-home exam testing student comprehension and ability to apply material covered in the Drug Information Module. This exam will be due on November 8, 2005. Finally, there will be a comprehensive final exam scheduled by the Office of Professional Education. See class schedule for exam dates.

On-line Drug Information Tutorials. Material for two classes will be delivered primarily via two on-line tutorials. These tutorials cover: secondary literature and tertiary literature. Both tutorials will be available at the beginning of the semester. Students may complete the tutorials at their own pace, as long as they are completed by the dates that appear in the class schedule. At the completion of each tutorial, students must take an on-line quiz to evaluate mastery of the material presented. Four help sessions are scheduled to provide a format for students to ask questions about the material presented in the tutorials and, thereby, enhance their mastery of the material. Students should come to these sessions prepared to ask questions.

Drug Literature Analysis and Interpretation Group Project. This project provides students an opportunity to apply concepts learned through readings and lectures to answer a clinical research question by identifying, analyzing, and interpreting relevant literature. The project will require students to complete six assignments. First, students will form research teams, each with 4-5 members. Second, each group must specify a research question concerning a pharmaceutical product or service. Third, each group will prepare a written synthesis of relevant background information using references from the tertiary literature. Fourth, each group will develop and implement a search strategy using PubMed to identify relevant studies in the primary literature. Fifth, each group will prepare a written analysis and interpretation of at least three of the studies identified via the PubMed search. Finally, each group will prepare a written synthesis of conclusions drawn from the studies analyzed. Information concerning due dates and the maximum number of points that will be awarded for each assignment are shown on the next page. A separate handout provides more explicit project instructions.

Assignment Due Dates and Points Available

On-Line Drug Information Tutorial Quizzes

Class	Due Date	Points
Secondary Literature	9/8	15
Tertiary Literature	10/27	15
Total		30

Drug Literature Analysis and Interpretation Group Project

Assignment	Due Date	Points
Formation of research team	8/30	5
Specification of research question	9/6	10
Tertiary literature synthesis	9/13	20
Primary literature search	10/4	20
Primary literature analysis and interpretation	11/10	50
Final paper	12/6	55
Total		160

All students in a particular group will receive the same grade for each assignment. It is expected that all group members will actively participate in all group activities. To encourage participation, in conjunction with the final assignment, students will be asked to evaluate the contributions of other group members. Each student may receive up to 10 additional points based on these peer evaluations. The number of points awarded may vary across students. Thus, if all group members actively participate, all will receive the full 10 points. However, if some group members fail to participate fully, they may receive less than 10 points, whereas the remaining group members will receive the full 10 points.

Grading

The table below summarizes the number of points allocated to each component of the course.

Evaluation	Points
Drug Literature Analysis and Interpretation Group Project (10 Points of total will be based on peer evaluations of student participation)	170
On-Line Drug Information Tutorial Quizzes (2 total, 15 points each)	30
Exam #1	200*
Exam #2	200*
Take Home Exam (Drug Information Module)	100
Cumulative Final Exam	300
TOTAL	1000

* If a student earns less than 140 points (70%) on either Exam #1 or Exam #2, but does better on the final, a score of 140 will be substituted for their lowest exam score. Only one low exam score will be replaced. A hypothetical scenario is shown below.

Exam	Points Earned on Exams	Points After Substitution
#1	100	140
#2	120	120
Final	300	300
Total	520	560

Final Grade

Final grades will be assigned based on the number of points earned according to the following point distribution. No students will be allowed to retake any tests or make up any assignments in order to improve their final grade in the course.

Points	Final Grade
900 – 1000	A
800 – 899	B
700 – 799	C
Below 700	F

Other Policies and Missed Work

Attendance. Class attendance, while not mandatory, is required if you want to receive a top grade in the course. Some of the material we cover in class is not in the assigned readings. Other material is covered sufficiently in the readings. Therefore, class time will be used to expand and discuss materials in the readings, not simply restate it.

Classroom Decorum: Throughout the semester, we almost always hear complaints about students coming into class late, loudly rifling through backpacks as they attempt to locate the items they need, and sometimes whispering to fellow students to find out what they missed. These distractions pose a serious barrier to learning for all students and will not be tolerated in Pharmacy 74. With this in mind, students are expected to arrive prior to the start of class and to have all needed materials out and ready to go when class begins. Students are also expected to refrain from any activities that distract from learning. This includes, but is not limited to, the use of cell phones. Please turn cell phones off prior to coming to class.

Missed On-Line Drug Information Tutorial Quizzes. There will be no make-up of missed On-Line quizzes. If you do not complete a quiz before the assigned date, you will receive a zero. No quiz scores may be dropped.

Missed/Late Drug Literature Analysis and Interpretation Group Project Assignments. Assignments are due in class at 10:00 am on the designated dates. Late assignments are only accepted with the permission of the course coordinator and will always include a point penalty. With permission, you will be penalized 10% of the total points available for the assignment for each day the assignment is late. Without permission, you will receive a zero for a late assignment. All group members are responsible for ensuring that assignments are turned in on time. Therefore, all group members will receive the same penalty for any assignments that are turned in late.

Missed Exams. Missed exams can only be made up in cases of very extreme circumstances (e.g., prolonged illness or death in the family) and with permission of the course coordinator. If you know you will miss an exam, please contact the course coordinator as soon as possible. In most cases, appropriate documentation of the circumstances will be required. Students missing the final exam for any reason will be assigned a temporary grade of "AB" per university policy. An "AB" will revert to an "F" if the grade is not cleared within a reasonable time (i.e., approximately one month) from the original examination.

Academic Integrity

From the UNC Instrument of Student Governance as revised and adopted July 2003
(<http://instrument.unc.edu/instrument.text.html>):

It shall be the responsibility of every student at The University of North Carolina at Chapel Hill to obey and to support the enforcement of the Honor Code, which prohibits lying, cheating, or stealing when these actions involve academic processes or University, student, or academic personnel acting in an official capacity.

The University and the School of Pharmacy take very seriously all violations of academic integrity. It is the responsibility of all students and faculty to promote an environment of intellectual honesty and to commit to maintaining the level of academic integrity essential to an effective learning experience. **Student Responsibilities** under the University's Honor Code system are defined in Appendix A of the *Instrument of Student Governance*. You should review these to make sure you understand the expectations for academic integrity for this course. **Faculty Responsibilities** are defined in Appendix B of the *Instrument of Student Governance*. You may also wish to review these.

The Pharmacy Faculty are committed to conducting the course in accordance with the Instrument for Student Governance. Please note also that we will use every means allowed under Appendix B of the code to prevent cheating on exams, including assigned seating, use of multiple exam versions, removal of study aids from the exam room, and moving students during an exam when it appears they may be cheating and/or that another student is attempting to copy their paper.

Evidence of cheating on exams or quizzes, plagiarism, copying of homework assignments or any other form of academic dishonesty will result in a required conference with the course director and immediate referral to the Office of the Associate Dean for Professional Education and/or the Student Attorney General for review and adjudication. If you have any questions or concerns regarding these matters, please ask us for clarification.

Additional statements supporting the University's Honor code:

- **Pledge:** To indicate your acceptance of the statement, "*On my honor, I have neither given nor received unauthorized aid on this assignment,*" you should write "*pledge*" and sign your name at the end of all papers, and exams.
- **Exams / assessment:** All exams and assessments are to be completed without the assistance of books, notes, or other people unless otherwise specified.
- **Personal safeguards:** In order to prevent others from copying your work, we encourage you to protect written copies of your work at all times. Do NOT leave copies of your working files on any of the public drives of the SoP computer network.
- **Plagiarism:** We encourage you to use a variety of information resources to support your assignments, but you must give credit for any and all ideas that are not originally your own, whether or not those ideas have been formally published. In addition to citing published works, you must also reference any ideas derived from the Internet, lectures or seminars, or personal correspondence.
- **Reference citations:** Use the standard biomedical manuscript citation format published by the International Committee of medical Journal Editors in *Requirements for Manuscripts Submitted to Biomedical Journals* (*Ann Intern Med* 1997; 125: 36-47 OR *N Engl J Med* 1997; 336(4): 309-315.) Full text manuscripts are available on Medline at <http://www.uncle.unc.edu/> or from Annals of Internal Medicine website.

TO REPORT OR CONSULT ABOUT POSSIBLE VIOLATIONS OF THE CODE, CONTACT

Pharmacy Student Attorney General
UNC-CH School of Pharmacy
CB# 7360, Beard Hall
Chapel Hill NC 27599-7360
919/843-4699

e-mail: PharmacyAttorneyGeneral@unc.edu

web address: www.pharmacy.unc.edu/pharmacy/studentcentral/current/judicial.html

Please refer to the Student Guide to the Pharmacy Student Judicial System for additional information.

Student-initiated Changes in Class Policies or Schedule

Throughout the semester, student(s) occasionally request a change in the class schedule or one of the policies. These requests may pose a dilemma for the instructors because any change potentially affects other students' final grade, work schedule, family life, and planned activities. Students affected by a change are sometimes reluctant to express their opinion and concerns, particularly in a public forum. As a result, some students are adversely affected or unduly burdened by changes. At times, requests are also controversial. Under these circumstances, important class time is expended to debate the merits and demerits of the request. Since class time is limited, spending time to discuss controversial requests often distracts from learning.

Nevertheless, some requests are reasonable and important. The PHCY 74 instructors are interested in accommodating your requests and doing whatever we can to you assist you with learning the course material. Therefore, we have established the following procedure to quickly and *fairly* address important student requests.

PROCEDURES FOR MAKING A CHANGE IN CLASS POLICY OR SCHEDULE

1. Requests for changes should be made in the form of a question with multiple response options.
2. Send a brief rationale for the request and the multiple-choice question to the T.A.'s by email.
3. If more than one person is sponsoring the request, list the names of the other supporters.
4. The T.A. will review the request and if it is reasonable, it will be forwarded to the course coordinator.
5. The course coordinator will also review the request. If the request is reasonable, the coordinator will announce that a change has been requested at the next class meeting.
6. Following the announcement, the request will be put forth to the class in the form of an online vote.
7. The rationale and multiple choice question will be published on the course website and students will have approximately 2 or 3 days to vote before the polls close. Any vote not cast before polls close will be considered as not supporting the request.
8. At least two-thirds of the class must agree to support the request in order for it to be implemented. Depending upon final course enrollment, two-thirds means approximately 75 votes must be cast in favor of the change in order for it to be implemented.
9. At the discretion of the course coordinator, the threshold for passing a change may be increased up to 100% of the class. For example, changing the time of a scheduled exam will require 100 percent agreement by the class.
10. Debate and discussion about the request should be done outside of class so that it does not distract from learning.
11. Votes are 'confidential' but not completely anonymous. The T.A.'s and instructors have access to the voting records but other students in the class will not.

Module Coordinators and Instructors

Module I – Statistics and Clinical Epidemiology

<i>Coordinator:</i>	Susan J. Blalock, Ph.D. Associate Professor, Pharmaceutical Policy & Evaluative Sciences Room 205-Q, Beard Hall s_blalock@unc.edu 962-0080 Office Hours: Monday, 10:00-12:00, and by appointment
<i>Instructors:</i>	Dale B. Christensen, Ph.D. Professor, Pharmaceutical Policy and Evaluative Sciences Room 201, Beard Hall (PPES Office Annex) Dale_Christensen@unc.edu 966-1271 Office Hours: By appointment

Module II – Drug Information

<i>Coordinator:</i>	Maryann Oertel, PharmD, BCPS Director, Drug Information Services UNC Hospitals moertel@unch.unc.edu 966-5133 Office Hours: By appointment (email is quickest way to set up appt.)
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Module III – Evidence-based Health Care and Critical Appraisal

<i>Coordinator:</i>	Michael D. Murray, PharmD Professor Pharmaceutical Policy and Evaluative Sciences Room 205-R, Beard Hall mick@unc.edu 966-9445 Office Hours: Tuesday and Thursday, 12:00 to 1:00 pm
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COURSE SCHEDULE

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	ASSIGNMENTS/QUIZZES
MODULE I: STATISTICS AND CLINICAL EPIDEMIOLOGY					
MODULE II: DRUG INFORMATION					
1	Tues, 8/23 10:00-10:50	Class Overview	Blalock	<p>Ioannidis JPA: Contradicted and initially stronger effects in highly cited clinical research. JAMA 2005;294:218-228.</p> <p>Recommended (We will be looking at the following four papers throughout the statistics portion of the class. It is not necessary to read them thoroughly at this point in time. But, you may find it helpful to make a copy of each paper and bring them to each "statistics" class.)</p> <p>Solomon DH et al: Relationship between selective cyclooxygenase-2 inhibitors and acute myocardial infarction in older adults. Circulation 2004;109:2068-2073.</p> <p>Solomon DH et al: Relationship between COX-2 specific inhibitors and hypertension. Hypertension 2004;44:140-145.</p> <p>Solomon SD et al: Cardiovascular risk associated with celecoxib in a clinical trial for colorectal adenoma prevention. N Engl J Med 2005;352:1071-80.</p> <p>Bresalier RS et al: Cardiovascular events associated with rofecoxib in a colorectal adenoma chemoprevention trial. N Engl J Med 2005;353:1092-102.</p>	
2	11:00-11:50	Overview of Study Design	Blalock	Bowers: Ch 1-6	
3	Thur, 8/25 10:00-10:50	Descriptive Statistics	Blalock	Norman Ch 1-3	
4	11:00-11:50	Descriptive Statistics (cont)	Blalock	<p>Bowers Ch 11: Identifying the characteristics of data</p> <p>Bowers Ch 12: Summarizing the characteristics of data</p> <p>Bowers Ch 29: Results in pictures</p>	
5	Tue, 8/30 10:00-10:50	Statistical Inference: Basic concepts	Blalock	Norman Ch 4-6	Project Assignment Due: Formation of Research Team
6	11:00-11:50	Statistical Inference: Basic concepts (cont)	Blalock	Bowers Ch 18: Confidence intervals for means, proportions, and medians.	
7	Thur, 9/1 10:00-10:50	FDA Drug Approval Process	Oertel	Malone pp 525-534.	
8	11:00-11:50	Tertiary Literature, Part 1	Oertel	<p>Shiisky RL. Drug Information Journal 2000;34:301-304.</p> <p>Complete the Tertiary Online Module, Section: General References prior to class.</p>	
9	Tues, 9/6 10:00-10:50	T-Tests	Blalock	Norman Ch 7: Comparing two groups, pp 62-64	Project Assignment Due: Specification of Research Question
10	11:00-11:50	Student Self-Assessment	Blalock	<p>Norman Ch 10: Two repeated observations</p> <p>Bowers Ch 20: Hypothesis tests and p-values (pp 117-120)</p>	

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	ASSIGNMENTS/QUIZZES
11	Thur, 9/8 10:00-10:50	Tertiary Literature, Part 2	Oertel	Complete the Tertiary Online Module, Section: Adverse Effects and Drug Interactions prior to class	
12	11:00-11:50	Secondary Literature Help	Oertel	Complete the Secondary Lit Tutorial prior to class. Come to class prepared to ask questions about the tutorial. This help session will be structured around student questions.	Complete the Secondary Literature Tutorial Quiz prior to class
13	Tues, 9/13 10:00-10:50	Analysis of Variance	Blalock	Norman Ch 8-9	Project Assignment Due: Tertiary Literature Synthesis
14	11:00-11:50	Analysis of Variance (cont)	Blalock		
15	Thur, 9/15 10:00-10:50	Analysis of Variance (cont)	Blalock	Norman Ch 11-12	
16	11:00-11:50	Student Self-Assessment	Blalock		
9/19-9/23		Exam Week	NO CLASS		
Fri, 9/23 3:00-5:00		EXAM			
17	Tues, 9/27 10:00-10:50	Correlation and Regression	Blalock	Norman Ch 13-14 Bowers Ch 21: Measuring association Bowers Ch 23: Linear regression	
18	11:00-11:50	Correlation and Regression (cont)	Blalock		
19	Thur, 9/29 10:00-10:50	Micromedex & UptoDate	Oertel		Homework Assignment / Exam Practice: Using Drug Information Resources (not graded)
20	11:00-11:50	Systematic Approach	Oertel		
21	Tues, 10/4 10:00-10:50	Introduction to Clinical Epidemiology and Abnormality (validity, reliability, regression to the mean)	Christensen	Bowers Ch 13: Measuring the characteristics of subjects	Project Assignment Due: Primary Literature Search
22	11:00-11:50	Diagnosis	Christensen	Fletcher Ch 3: Diagnosis	
23	Thur, 10/6 10:00-10:50	Frequency and Risk (sensitivity and specificity, incidence and prevalence)	Christensen	Bowers Ch 14 Measuring the characteristics of measures Fletcher Ch 4: Frequency	
24	11:00-11:50	Student Self-Assessment	Christensen		
25	Tues, 10/11 9:00-9:30	Logistic Regression and Advanced Topics	Blalock	Norman 15-16 Bowers Ch 24: Logistic regression	
26	11:00-11:50	Student Self-Assessment	Blalock		

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	ASSIGNMENTS/QUIZZES
27	Thurs, 10/13 10:00-10:50	Tertiary Literature, Part 3	Oertel	Complete the Tertiary Online Module, Section: Pediatric & Specialty References prior to class.	
28	11:00-11:50	Cochrane Databases	Collins		
29	Tues, 10/18 10:00-10:50	Nonparametric methods: Analysis of nominal data	Blalock	Norman Ch 20: pp 203-210	
30	11:00-11:50	Nonparametric methods: Analysis of ordinal data	Blalock	Norman Ch 22	
Thurs, 10/20		FALL BREAK	NO CLASS		
31	Tues, 10/25 10:00-10:50	Survival analysis	Blalock	Norman Ch 24: Life-table (survival) analysis Bowers Ch 16, 17, 19, 25, 27	
32	11:00-11:50	Student Self-Assessment	Blalock		
33	Thur, 10/27 10:00-10:50	Tertiary Literature, Part 4	Oertel	Complete the Tertiary Online Module, Section: Herbal/Natural, Injectable & Identification References prior to class	Complete the Tertiary Literature Tutorial Quiz prior to class
34	11:00-11:50	Student Self-Assessment	Oertel		
10/31-11/4		Exam Week	NO CLASS		
Mon, 10/31 1:00-3:00		EXAM			

MODULE III: Evidence-based Health Care and Critical Appraisal

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	ASSIGNMENTS/QUIZZES
35	Tues, 11/8 10:00-10:50	Introduction	Murray	Murray MD. Pharmacoepidemiology. In Remington: The science and practice of pharmacy. 21 st Ed., Chapter 108. pp. 1958 – 1967, Baltimore: Lippincott, Williams, and Wilkins, 2005.	Take Home Drug Information Exam Due
36	11:00-11:50	Evidence Based Medicine	Murray	JAMA Users' Guide to the Medical Literature, Ch1A, pp 5-20. Fletcher RH, Fletcher SW. Evidence-based approach to the medical literature. <i>Journal of General Internal Medicine</i> 1997; 12 Suppl 2:S5-14. Etminan M, Wright JM, Carleton BC. Evidence-based pharmacotherapy: review of basic concepts and applications in clinical practice. <i>Annals of Pharmacotherapy</i> 1998; 32:1193-200.	
37	Thur, 11/10 10:00-10:50	Critical Appraisal	Murray	Straus SE, Sackett DL. Getting research findings into practice: using research findings in clinical practice. <i>BMJ</i> 1998;317: 339-342.	Project Assignment Due: Primary Literature Analysis and Interpretation
38	11:00-11:50	Causal Relationships	Murray	Fletcher Ch 11, Cause. pp. 187 – 203.	
39	Tues, 11/15 10:00-10:50	Appraisal of Randomized Controlled Trials	Murray	Greenberg, Raymond et al., Chapter 7: Clinical Trials, In: Medical Epidemiology, 3rd Ed. McGraw Hill: New York, 2001:91-112.	
40	11:00-11:50	Appraisal of Randomized Controlled Trials (Continued)	Murray	Study Example for Class: Murray MD, Deer MM, Ferguson JA, Dexter PR, Bennett SJ, Perkins SM, Smith FE, Lane KA, Adams LD, Tierney WM, Brater DC. Open label randomized trial of torsemide compared with furosemide in patients with heart failure. <i>Am J Med.</i> 2001;111: 513-520.	

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	GRADED ASSIGNMENTS
41	Thur, 11/17 10:00-10:50	Appraisal of Case Control Studies	Murray	Greenberg, Raymond et al., Chapter 9: Case Control Studies, In: Medical Epidemiology, 3rd Ed. McGraw Hill: New York, 2001:127-139. JAMA Users' Guide to the Medical Literature, Chapter 1B2, pp 133-135.	
42	11:00-11:50	Appraisal of Case Control Studies (continued)	Murray	Study Example for Class: Fored MC, Ejerblad E, Lindblad P, et al. Acetaminophen, aspirin, and chronic renal failure. NEJM 2001; 345: 1801-1808.	
43	Tues, 11/22 10:00-10:50	Appraisal of Cross-Sectional Studies	Murray	Study Example for Class: Hope CJ, Wu J, Tu W, Young J, Murray MD. Association of medication adherence, knowledge, and skills with emergency department visits by adults 50 years or older with congestive heart failure. American Journal of Health- System Pharmacy 2004; 61:2043-9.	
44	11:00-11:50	Appraisal of Cohort/Longitudinal Studies	Murray	Greenberg, Raymond et al., Chapter 8: Cohort Studies, In: Medical Epidemiology, 3rd Ed. McGraw Hill: New York, 2001:113-126. Study Example for Class: Murray MD, Lane KA, Gao S, Evans RM, Unverzagt FW, Hall KS, Hendrie HC. Preservation of cognitive function with antihypertensive medications: A longitudinal analysis of a community-based sample of African-Americans. Archives of Internal Medicine 2002;162: 2090-2096. Study Example for Class: Murray MD, Brater DC, Tierney WM, Hui SL, McDonald CJ. Ibuprofen-associated renal impairment in a large general internal medicine practice. Am J Med Sci. 1990; 299: 222-229.	
Thur, 11/24		THANKSGIVING	NO CLASS		
45	Tues, 11/29 10:00-10:50	Biases in Study Population Selection and Measures of Treatment Effect Size	Murray	Anonymous. Glossary. ACP Journal Club, 138;2003:A-19. Katz, DL. Table 5.1: Clinically relevant measures of risk. Clinical Epidemiology & Evidence-based medicine, 2001:98.	
46	11:00-11:50	Biases in Study Population Selection and Measures of Treatment Effect Size (cont)	Murray	Sackett DL. Bias in analytical research. J Chronic Disease 1979; 32:51-63.	

#	DATE	TOPIC	INSTRUCTOR	CLASS PREP & READING	GRADED ASSIGNMENTS
47	Thur, 12/1 10:00-10:50	Appraisal of Clinical Practice Guidelines	Murray	Feder G. Clinical guidelines: Using clinical guidelines. <i>BMJ</i> , 318;1999:728-730. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive services task force: A review of the process. <i>Am J Preventive Med</i> 2001; 20 (3S): 21-35.	
48	11:00-11:50	Practical Application of Clinical Practice Guidelines	Murray	Fletcher Ch 13, Knowledge Management. pp. 221 – 231. Study Example for Class: Tierney WM, Overhage JM, Murray MD, Harris LE, Zhou XH, Eckert GJ, Smith FE, Nienaber N, McDonald CJ, Wolinsky FD. Can computer-generated evidence-based care suggestions enhance evidence-based management of asthma and chronic obstructive pulmonary disease? A randomized, controlled trial. <i>Health Services Research</i> 2005, 40(2):477-497.	
49	Tues, Dec 6 10:00-10:50	Student Self-Assessment	Murray		Project Assignment Due: Final Paper
50	11:00-11:50	Student Self-Assessment	Murray		
51	Thurs, Dec 8 10:00-10:50	EXAM REVIEW	Blalock		
52	11:00-11:50	EXAM REVIEW	Blalock		
	Thurs, Dec 15 1:00-3:00	FINAL EXAM			

Bowers refers to D Bowers, *Understanding Clinical Papers*, 2001, ISBN: 047148976X. **Norman** refers to GR Norman, *Biostatistics: the bare essentials*, 2000. ISBN: 1-55009-123-9. **Fletcher** refers to RH Fletcher, *Clinical Epidemiology: The essentials, 4th Edition*. Baltimore: Lippincott, Williams, and Wilkins, 2005. ISBN: 0-7817-5215-9

Terms & Learning Objectives

MODULE I: STATISTICS AND CLINICAL EPIDEMIOLOGY

DATE	TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
Tues, 8/23	Overview of Study Design	<ol style="list-style-type: none"> 1) Describe the basic structure of a scientific report 2) Discuss criteria that can be used to evaluate scientific journals 3) Describe the basic study designs 4) Distinguish between a review article and a meta-analysis 	<p>Given a scientific study, be able to recognize the study design used.</p>	<p>Abstract, experimental study, observational study, cohort study, case-control study, refereed, non-refereed, review article, meta-analysis</p>
Thurs, 8/25	Descriptive Statistics	<ol style="list-style-type: none"> 5) Identify, describe, and differentiate between the two broad areas of statistics 6) Explain what a variable is and differentiate between independent and dependent variables 7) Describe three measures of central tendency and three measures of dispersion, explain the situations in which different measures are used, and interpret data presented using these measures 8) Interpret data presented in the form of histograms and box plots 	<p>Given a set of data, compute a mean, mode, median and standard deviation.</p> <p>Use the z-transformation to convert a raw value into a z-score and interpret the results</p> <p>Given a clinical variable, determine if it was assessed at the nominal, ordinal, interval or ratio level of measurement.</p> <p>Given a histogram or the mean and standard deviation of a variable, assess whether the variable is normally distributed.</p>	<p>Mean, median, mode, range, interquartile range, standard deviation, frequency distribution, percentiles, normal distribution, skewed distribution, z-transformation, histogram, boxplot</p>
Tue, 8/30	Statistical Inference: Basic concepts	<ol style="list-style-type: none"> 9) Distinguish between sample statistics and population parameters 10) Explain the difference between the standard deviation of a variable and the standard error of the mean 11) Describe the null hypothesis and the relationships between the null hypothesis, Type I (alpha) error, Type II (beta) error, and power 12) Identify acceptable levels for Type I error, Type II error, and power 13) Explain how sample size influences Type I and Type II error 14) Interpret statistical nomenclature such as “ $p < 0.05$” 15) Distinguish between statistical and clinical significance 16) Describe the relationship between hypothesis testing and estimation of confidence intervals 	<p>Given the mean and standard deviation of a variable from a sample of a specific size, calculate the standard error of the mean</p> <p>Given the mean of a variable and the standard error of the mean, calculate and interpret a 95% confidence interval</p> <p>Given the results of a study, determine: whether an observed difference is statistically significant, the likelihood that any observed differences were due to chance, and the likelihood that any statistically nonsignificant differences were due to a lack of power</p>	<p>Sample statistic, population parameter, confidence interval, precision of estimate, standard error, p-value, Type I (alpha) error, Type II (beta) error, null hypothesis, 1- versus 2-tailed hypothesis test, Central Limit Theorem, random sampling, random allocation, z-test, clinical significance, statistical significance</p>
Tues, 9/6	T-Tests	<ol style="list-style-type: none"> 17) Describe the situations in which a t-test, or a nonparametric alternative to a t-test, would be used 18) Identify and distinguish between three types of t-tests 19) State the assumptions upon which t-tests are based 20) Explain why multiple comparisons create a problem in the interpretation of t-tests 	<p>Given a research question and summary statistics (e.g., mean, standard error), determine whether the question can be answered via a t-test, select the appropriate t-test given the design of the study, perform the t-test, and interpret the results</p>	<p>1-group t-test, independent groups t-test, paired t-test, nonparametric statistics, equality of variances, pooled standard error, multiple comparisons</p>

MODULE I: STATISTICS AND CLINICAL EPIDEMIOLOGY (CONTINUED)

DATE	TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
Tues 9/13 & Thurs, 9/15	Analysis of Variance	21) Describe the situations in which 1-way ANOVA, factorial ANOVA, and ANOVA with repeated measures, or a nonparametric alternative to these procedures, would be used 22) State the assumptions upon which ANOVA is based 23) Describe the post-hoc comparison process and explain how post-hoc comparisons attempt to minimize problems caused by multiple comparisons	Given the results of an ANOVA in the form of a table or text, identify and interpret observed relationships Given the results of an ANOVA in the form of a graph, interpret both main effects and interactions	One-way analysis of variance, factorial analysis of variance, analysis of variance with repeated measures, between group variance, within group variance, total variance, F test, post-hoc comparisons
Tues, 9/27	Correlation and Regression	24) Describe the situations in which correlations or linear regression analyses would be used 25) Differentiate between the type of information conveyed by regression coefficients versus correlation coefficients 26) Describe the information captured by the R^2 for a regression model	Given the results of a regression analysis, interpret observed relationships, distinguishing between significant versus nonsignificant relationships and positive versus negative relationships Given a scatter plot of two variables, describe the nature of the observed relationship	Regression, correlation, standardized regression coefficient, statistical control, regression model, sums of squares, residuals, confounding, effect modifier
Tues, 10/4	Introduction to Clinical Epidemiology and Abnormality (validity, reliability, regression to the mean)	27) Define epidemiology and clinical epidemiology 28) Distinguish between a population and sample. 29) Identify, recognize and distinguish between sampling, measurement, and confounding bias. 30) Differentiate between validity and reliability 31) Identify at least 2 measures of validity and 2 measures of reliability 32) Differentiate between internal and external validity 33) Identify 4 threats to internal validity associated with a particular study design.	Given a clinical epidemiological study, be able to identify potential sources of bias inherent in the design of the study For a given measure of a health condition, be able to describe ways that it could be tested for validity and reliability. Be able to critique the design of a study in terms of whether it contained threats to internal and external validity Identify 2 ways to address selection bias in the design of a study, and 2 ways of controlling for bias in the analysis phase of a study.	Epidemiology, Clinical epidemiology, Pharmacoepidemiology, Chance Bias (sampling, measurement, confounding) Validity (Internal, External), Reliability, Threats to internal validity (selection, maturation, history, regression, testing)
Tues, 10/4	Diagnosis	34) Define and distinguish between sensitivity, specificity, positive and negative predictive values 35) Understand how different cutoff values affect the above measures. 36) Know when higher or lower values of sensitivity and specificity are clinically important. 37) Understand how the prevalence of a disease affects the above measures 38) Define likelihood ratios and accuracy of a test 39) Know the difference between and when to apply serial vs. sequential testing	Evaluate a screening test based on sensitivity, specificity, and predictive value measures	sensitivity, specificity, and + or – predictive value, accuracy, likelihood ratio, ROC curves

MODULE I: STATISTICS AND CLINICAL EPIDEMIOLOGY (CONTINUED)

DATE	TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
Thurs, 10/6	Frequency and Risk	40) Differentiate between incidence vs. prevalence measures 41) Know the difference between period and point prevalence 42) Know the relative strengths and weaknesses in an incidence and prevalence study 43) Know how to compute and differentiate among the following measures: risk ratio, relative risk, attributable risk, odds ratio	Be able to interpret and distinguish between incidence and prevalence values Given relative risk, attributable risk and odds ratio values in a study, be able to provide a clinical interpretation Recognize a study as being an incidence or prevalence study	Incidence, prevalence, period prevalence, point prevalence, duration, survival cohort, risk ratio, relative risk, attributable risk, odds ratio
Tues, 10/11	Logistic Regression and Advanced Topics	44) Describe the situations in which it would be appropriate to use logistic regression 45) Explain the type of information conveyed by odds ratios 46) Determine if an odds ratio is statistically significant	Given the results of a study involving logistic regression, interpret observed relationships in terms of statistical significance and magnitude of risk	Odds ratios
Tues, 10/18	Nonparametric methods: Analysis of nominal data	47) Describe the situations in which it is appropriate to use the following: χ^2 test, Fisher's exact test, binomial test, McNemar test 48) Identify the assumptions underlying a χ^2 test 49) Describe the logic underlying the analysis of frequency data 50) Explain the distinction between parametric and nonparametric statistics	Given the results of a study involving the analysis of nominal data, determine whether the appropriate statistical tests were used and interpret observed relationships	Chi-square test, binomial test, Fisher's exact test, McNemar's test, observed frequencies, expected frequencies, nonparametric
Tues, 10/18	Nonparametric methods: Analysis of ordinal data	51) Describe the situations in which it is appropriate to use the following: Wilcoxon Rank Sum test, Kruskal-Wallis One-way ANOVA, Wilcoxon signed ranks test 52) Describe the logic underlying the use of nonparametric statistics to analyze ordinal data	Given the results of a study involving the analysis of ordinal data, determine whether the appropriate statistical tests were used and interpret observed relationships	Mann-Whitney U test, Kruskal-Wallis One-way ANOVA, sign test, Wilcoxon rank sum test
Tues, 10/25	Survival Analysis	53) Describe the situations in which it would be appropriate to use survival analysis 54) Explain the types of information conveyed by hazard ratios 55) Determine if a hazard ratio is statistically significant	Given the results of a study involving survival analysis, interpret observed relationships in terms of statistical significance and magnitude of risk Interpret a Kaplan-Meier curve	

Model II: Drug Information

TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
FDA Drug Approval Process	<ol style="list-style-type: none"> 1) Describe the path a drug takes from initial discovery to use in patients, and through the FDA from pre-filing to postmarketing 2) Define phase I, phase II, phase III, phase IV trials 3) Recognize the link between research / drug development and primary literature 4) Recognize the limitations of knowledge about a new drug when first approved by the FDA. 	<p>Given a journal article, be able to distinguish between phase I, II, III, and IV trials.</p> <p>Recognize the stages of development of a new drug.</p>	Phase I trial, phase II trial, phase III, phase IV, IND, NDA
Secondary Literature	<ol style="list-style-type: none"> 5) State the definition of secondary literature resources and their purpose. 6) Distinguish between Medline and IPA. 7) Define controlled vocabulary and identify which secondary resources discussed in class require controlled vocabulary. 8) Utilize the steps involved in searching for medical literature using secondary resources. 	Be able to search a topic in Medline and IPA and retrieve relevant information.	Secondary literature, controlled vocabulary, noncontrolled vocabulary, lag time, boolean operators, citation, key word, MeSH heading
Tertiary Literature	<ol style="list-style-type: none"> 9) Distinguish between primary, secondary, and tertiary literature and given an example of each. 10) Recognize the process for utilizing primary literature as a basis for tertiary references. 11) Critically evaluate the merits and limitations of a tertiary reference. 12) State the advantages and disadvantages of the tertiary references discussed in the reading assignment, lecture, and assignment #3. 13) Recognize which tertiary references are available via UNCLE. 14) Distinguish which tertiary references would be used to best answer the following: dosing, indications, adverse drug reactions, drug-drug interactions, herbal, over-the-counter, drug identification, pediatric, IV admixture, vaccine, pregnancy and lactation, and renal failure questions. 	<p>Given resources such as textbooks, Medline, International Pharmaceutical Abstracts, Micromedex, Internet Web sites, review articles, meta-analysis, or clinical trials, be able to determine whether these are primary, secondary, or tertiary resources.</p> <p>Given drug information questions, use the most appropriate tertiary references to answer the questions in the most efficient manner.</p>	Tertiary literature
Micromedex & UptoDate	<ol style="list-style-type: none"> 15) Describe advantages and disadvantages of Micromedex. 16) Distinguish between databases within Micromedex including advantages and disadvantages of each. 	Given drug information questions, use the various databases within Micromedex to answer the questions.	
Systematic Approach	<ol style="list-style-type: none"> 17) Recognize different types of information needs. 18) Summarize various ways to ask questions, depending on the informational need. 19) Formulate a process for clinical decision-making. 20) Utilize resources discussed to date to make a clinical decision. 21) Recognize the process for communicating a clinical decision. 	<p>Given a group of drug information questions, identify the type of information being asked; be able to ask appropriate background questions to get at the true informational need.</p> <p>Given a clinical scenario, formulate a therapeutic decision based on the evidence available.</p> <p>Given a clinical question, communication a response effectively.</p>	
Cochrane Database	<ol style="list-style-type: none"> 22) Distinguish between Cochrane database and other databases such as Medline. 23) Recognize the difference between Cochrane database and AMA Journal Club. 	Given a clinical question, identify when it is appropriate to search the Cochrane database.	

MODULE III: EVIDENCE-BASED MEDICINE & CRITICAL APPRAISAL

DATE	TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
Tues, 11/8	Introduction	<ol style="list-style-type: none"> 1) State the rationale for evidence based medicine; 2) State the rationale for critical appraisal of clinical research; 3) Describe the relation between evidence based medicine and critical appraisal, and 4) Explain how evidence based medicine and critical appraisal apply to the practice of pharmacy and to your personal continuing career development. 	Communicate to policy makers the need to address variations in health care utilization and costs.	appraisal, evidence, clinical entropy, clinical inertia, variation
Tues, 11/8	Evidence based medicine (EBM)	<ol style="list-style-type: none"> 5) Provide two reasons why EBM is important to improving health care, 6) Describe key principles needed to effectively practice EBM; 7) Identify the skills needed to practice EBM, and 8) Compare and contrast the major study designs used in research. 	<p>Given two study designs, determine which provides the greatest strength of evidence.</p> <p>List the steps involved in the EBM process.</p>	EBM, clinical decision, sample/sampling, eligible population, spurious results
Thurs, 11/10	Critical Appraisal of Clinical Research	<ol style="list-style-type: none"> 9) Explain the methods used to critically appraise a published research article, and 10) Identify threats to the statistical, internal, and external validity of a research study. 	For a study, examine threats to internal validity and determine how applicable the results are to your practice environment.	bias, contamination, reliability, external validity, internal validity, generalizability
Thurs, 11/10	Causal Relationships	<ol style="list-style-type: none"> 11) Using Hill's postulates, assess whether study results provide evidence for a causal relationship between exposure and outcome; 12) Describe the difference between proof of causation and establishing an association, and 13) Explain why in clinical medicine proof of causation or proof of treatment effect are often elusive entities. 	<p>Given a study, determine whether it is confirmatory or explores an association.</p> <p>Given a study, provide alternative reasons for a particular medication's beneficial or adverse effects.</p>	association, causation, biologic plausibility, case report, case series, confirmatory study, consistency, counterfactual, descriptive study, dose-response relationship, experimental design, intervention, natural history, non-experimental design, plausibility, quasi-experimental, temporal relationship.

DATE	TOPIC	LEARNING OBJECTIVES	APPLICATION SKILLS	TERMS
Tues, 11/15	Appraisal of the Randomized Controlled Trial (RCT)	14) Describe the randomized controlled clinical trial (RCT) and list its major strengths compared to other designs; 15) List two limitations of the RCT; 16) Explain the rationale for the following features of clinical trials: sampling, control group, blinding, stratification, and randomization; 17) Explain the effects on RCTs of the following issues: Hawthorne effect, natural history, and placebo effect; 18) Differentiate efficacy, efficiency, and effectiveness; 19) Identify and describe common sources of variability in a research study; 20) Calculate the magnitude of a treatment effect using absolute risk reduction, relative risk and relative risk reduction, and 21) Explain and interpret the precision of a treatment effect.	Given a published RCT, interpret and apply the results appropriately to patient care including the evaluation of the potential harm and costs of a treatment.	absolute risk, blinding, controlled clinical trial, efficacy, efficiency, effectiveness, endpoint, exclusion criteria, external validity inclusion criteria, internal validity, generalizability, Hawthorne effect, loss to follow-up, masking, negative or null study, number needed to treat (NNT), open-label, population, power, random variability, randomization, relative risk, reliability, representativeness, sample, stratification, treatment effect, variability
Thurs, 11/17	Appraisal of Case Control Studies	22) Critically evaluate a published case-control study; 23) Identify common sources of bias and recommend ways to minimize its impact; 24) Estimate the strength of an association between exposure and outcome with the odds ratio; 25) Explain and interpret the meaning of the odds ratio, and 26) Compare and contrast case-control studies with controlled clinical trials.	Given a published case control study, interpret and apply the results to patient care.	bias, case, control, dose-response gradient, prognostic factor, odds ratio, risk factor
Thurs, 11/22	Appraisal of Cross-Sectional Studies	27) Describe the differences between a cross-sectional study and a cohort or longitudinal study, and 28) Critically evaluate a published cross-sectional study.	Given a published cross-sectional study, be able to interpret and apply the results appropriately to patient care including the evaluation of the potential harm and costs of a treatment.	cross-section, prevalence
Thurs, 11/22	Appraisal of Cohort/ Longitudinal Studies	29) Identify sources of confounding in cohort and longitudinal studies and recommend ways to control it; 30) Distinguish confounding and bias; 31) Estimate the strength of an association between exposure and outcome with the relative risk; 32) Explain and interpret the meaning of the risk and relative risk, and 33) Compare and contrast cohort studies with RCTs and case-control studies.	Given a published cohort study, be able to interpret and apply the results appropriately to patient care including the evaluation of the potential harm and costs of a treatment.	absolute risk, attributable proportion, cohort, follow-up, incidence, relative risk, risk difference
Tues, 11/29	Biases in Clinical Research	34) Diagram and explain the levels of subject selection into a research study; 35) Explain ways internal and external validity are influenced by selection and retention of subjects into a study; 36) Identify potential sources of selection bias and assess the degree to which it affects the results of an observational study, and 37) Identify sources of bias in a given published research article.	Interpret common measures of treatment effect sizes from published articles.	bias, blinding, confounding, contamination, masking, misclassification, information bias, measurement bias, restriction, selection bias, sensitivity analysis, stratification, validity
Thurs, 12/1	Appraisal of Clinical Practice Guidelines	38) Critically evaluate a clinical practice guideline; 39) Explain the purpose, strengths and limitations of practice guidelines; 40) Identify whether an explicit and sensible process was used to develop a given practice guideline, and 41) Determine whether a given guideline's recommendation is warranted.	Interpret and apply a practice guideline to the pharmacy practice setting.	expert panel, guideline, peer review, performance measure, prediction rule, recommendation, suggestion