

**University of California, San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences
SPPS 212B – THERAPEUTICS
Winter Quarter, 2014**

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Course Description

SPPS 212 is a 3 quarter cumulative sequence of courses on the therapeutic management of disease. In this series of courses, students will use their previous knowledge of anatomy, physiology, pathophysiology, pharmaceuticals, pharmacokinetics, pharmacology and literature evaluation to formulate appropriate therapeutic decisions. Each week students will apply the knowledge acquired from lectures and readings to patient cases that will be discussed with peers in weekly conference sections. By the end of the series, students will have reviewed the pathophysiology of major disease states, the pharmacology of the drugs used to treat these disease states, and critically analyzed the decision processes to create and implement therapeutic plans. The therapeutics series of courses is the culmination of knowledge gained in previous years to prepare students for the practice of pharmaceutical care on clinical rotations. Pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

Students are expected to continue learning to organize patient data in order to design a logical pharmaceutical care plan. Refer to the course schedule for a detailed review of the disease states that will be covered during this quarter.

Course Objectives

- I. Identification and assessment of patient complaints as they relate to drug therapy and drug-related problems.

- A. Upon clinical presentation of a patient with multiple medical problems (including signs, symptoms, laboratory and radiographic test results, and medication use history), the student is able to:
 - 1. Discuss the pathophysiology, etiology and risk factors of the disease processes occurring in the patient.
 - 2. Prioritize the active medical problems, disease states, symptoms, and/or abnormal laboratory values that may:
 - a. require drug therapy
 - b. be aggravated or induced by drug therapy
 - c. alter the drug selection or dosage regimen (e.g., because of altered renal or liver function, or allergies)
 - B. Upon review of current and past medication history, the student is able to identify the drug-induced problems and be able to discuss:
 - 1. The risk(s) and benefit(s) of maintaining drug therapy
 - 2. The clinical importance of the drug-induced reactions
 - 3. The mechanism(s) and management of the drug-induced problems
- II. Drug selection
- For problems that require drug therapy, the student is able to:
- A. Assess and describe the possible risks and the anticipated benefits of any required drug therapy.
 - B. Establish the therapeutic goals and a time frame for anticipated response.
 - C. Design the most efficacious, least toxic and most cost-effective drug regimen for the patient.
 - D. Prioritize therapeutic alternatives, both drug and non-drug treatments, and recognize their comparative efficacy, ease of administration, toxicity, and cost.
 - E. Discuss the differences in efficacy, toxicity, routes of administration, elimination, distribution, and cost among the classes of drugs available for the treatment of the given disease state.
 - F. Select the appropriate drug therapy based upon the severity of the disease state and appropriateness of each drug class (i.e., advantages and disadvantages).
 - G. Predict the influence of selected drug(s) on patients' comorbid conditions and design an appropriate regimen (drug, dosage form, dosage regimen, drugs to be avoided, goals, monitoring parameters) based upon these influences.
 - H. Identify potentially clinically relevant drug-drug, drug-food, drug-disease or drug-laboratory test interactions based upon the recommended regimen and design an appropriate course of action that should be taken (discontinuation of therapy, alteration in timing of administration, etc).
- III. Dosage regimens
- A. For each of the drugs selected, the student is able to:
 - 1. Describe the pharmacodynamics of the drug
 - 2. Design a safe and efficacious dosage regimen including the dose, dosage interval, route, rate and time of administration, taking into account the patient's age, weight, organ function, or other medical problems that may alter drug pharmacokinetics or selection of

administration route (e.g., NPO status, thrombocytopenia, bowel resection).

- IV. Monitoring therapy
 - A. For each established therapeutic goal, disease state, or drug therapy, the student is able to:
 - 1. List all parameters that must be monitored for achievement of outcome, toxicity or adverse effects.
 - 2. Predict the time at which maximum efficacy or toxicity may be expected from a given dosage and route of administration.
 - 3. Assess the patient for therapeutic or toxic outcomes and determine the degree of success or failure of the current regimen.
 - 4. Determine the length of therapy and frequency of evaluation, if therapy achieves the desired outcome(s).
 - 5. Identify factors that may have contributed to therapeutic failure if therapy does not achieve the outcome(s).
 - 6. Select an alternative therapy that should be used in case of therapeutic failure.
- V. Monitoring for adverse effects
 - A. For each drug, the student is able to list and describe the most frequent adverse reactions. The student is able to explain the clinical importance of these adverse reactions.
 - B. For each adverse reaction, the student is able to:
 - 1. Recommend monitoring parameters.
 - 2. Determine whether the reaction is being experienced by a specific patient.
 - 3. List appropriate questions to be asked of the patient to determine if adverse effects are occurring.
 - 4. Determine (using appropriate reference sources) whether the presence of this effect warrants discontinuance of the drug.
 - a. If the medication is continued, the student is able to recommend concurrent treatment of the reaction, if necessary.
 - b. If the medication is discontinued, the student is able to suggest a therapeutic alternative.
- VI. Patient education
 - A. The student is able to demonstrate the ability to communicate effectively with the patient by using lay language and techniques appropriate to ensuring patient adherence to the therapeutic plan.
 - B. For each drug or device, the student is able to counsel the patient to achieve safe and effective use.
 - C. For each drug, the student is able to counsel the patient on the most common side effects of the specified drug.
- VII. Special populations
 - A. For each disease state where it is relevant, the student is able to discuss the factors to consider in the overall therapeutic plan in the following special populations:
 - 1. Neonates
 - 2. Children
 - 3. Elderly
 - 4. Pregnant women

5. Nursing mothers

Recommended References

1. Koda-Kimble MA, Young LY, Kradjan WA, Guglielmo BJ, Alldredge BK, Corelli RL, eds. *Applied Therapeutics: The Clinical Use of Drugs*, 10th ed., Lippincott Williams & Wilkins, 2012.
2. DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, eds. *Pharmacotherapy: A Pathophysiologic Approach*, 8th edition. McGraw-Hill, New York, 2011.
3. Therapeutics 212A, 212B, & 212C Conference Case & Keys workbook (available at the UCSD Bookstore only).
4. Kasper DL, Braunwald E, Fauci AS, Hauser SL, Longo DL, Jameson JL, Isselbacher KJ, eds. *Harrison's Principles of Internal Medicine*, 18th edition. McGraw-Hill, New York, 2012. Available on-line (free-of-charge) through the UCSD Biomedical Library at <http://www.accessmedicine.com/resourceTOC.aspx?resourceID=4>
5. Pharmacology textbook. Example: Goodman & Gilman's *The Pharmacological Basis of Therapeutics*, 12th edition. McGraw-Hill, New York, 2010. Available on-line (free-of-charge) through the UCSD Biomedical Library Online Clinical Library at <http://www.accessmedicine.com/resourceTOC.aspx?resourceID=28>
6. Helms R, Quan DJ, Herfindal ET, Gourley DR, et al, eds. *Textbook of Therapeutics: Drug and Disease Management*, 8th ed., Lippincott Williams & Wilkins, 2006.
7. The Medical Letter on Drugs and Therapeutics and The Medical Letter Treatment Guidelines. available on-line (free-of-charge) through the UCSD Biomedical Library at <http://medicalletter.org/index.html>
8. Medical dictionary. Examples: Stedman's Medical Dictionary, Dorland's Medical Dictionary.

Additional Recommended Reading

Additional recommended readings suggested by each lecturer will be posted in pdf format to the Electronic Reserves section of the Biomedical Library at <http://reserves.ucsd.edu/> or on the course website.

Grading

<u>Assessment Tool</u>	<u>Percentage of Final Grade</u>
MIDTERM	35%
WRITTEN FINAL	35%
ORAL FINAL	
Objective Assessment	15%
Behavioral Evaluation	5%
CONFERENCE PARTICIPATION*	10%
TOTAL	100%

*See specific guidelines in syllabus

Students will be graded Honors (H), Pass (P), or No Pass (NP) in accordance with the SSPPS Grading Policy.

H:	≥ 90%
P:	≥ 70%
NP:	< 70%

Written Examinations

There will be 2 written examinations (1 midterm and 1 cumulative final). The examinations are intended to reflect content materials presented during lecture, in assigned reading, in lecture notes, and during case discussions. Examinations will be entirely case-based and designed to demonstrate knowledge and practice skills in assessing application of knowledge in patient case scenarios. For each written exam, questions may be created based on the required textbook readings. Answers that are illegible will be graded as incorrect. Students arriving after the start of the exam risk not being allowed to take the exam, at the discretion of the course chairs.

Oral Final Examination

There will be 1 oral final examination that will be cumulative. Each student will be assigned an examination time and will be given a patient case with 3 medical problems. The student will have 30 minutes to SOAP the case and then 25 minutes to present the case in proper SOAP format to 2 examiners. The medical problems will be stated on the exam. Identification and prioritization of the medical problem will not influence your Oral Final Examination grade. Student SOAPing of each medical problem can be performed in any order. The oral final exam final grade includes an objective assessment (15% of final course grade) and a behavioral evaluation (5% of final course grade). The student will be evaluated using two metrics: 1) Objective assessment involving the student's ability to orally present patient-specific information (e.g., subjective and objective information, etiology, assessment of the medical problem, therapeutic recommendations, monitoring parameters, patient education, etc.) and 2) Behavioral evaluation that measures student organization skills, oral presentation skills, integration of co-morbid disease states, etc. (see Oral Examination Behavioral Evaluation Form).

On the day of the exam, do not bring any notes, books, syllabi, calculators, etc to the examination. You may bring a pencil and/or a pen. You must submit the case and all of your SOAP sheets at the end of the oral exam to the examiner. DO NOT discuss the case with your classmates until everyone has finished the exam (5 pm). The exam will

be graded on a curve so it will not be to your advantage to tell your classmates anything about the case.

Examination Review and Regrade

Once the midterm examination has been graded, a post-exam review session will be conducted between the course co-chair and students. During the review session, exams will be handed out to review the exam and answers. During this time, no writing instruments will be allowed.

If you desire an examination regrade, writing instruments will then be provided and a written request for regrades may be made at this time. Reference the question by number and provide an explanation. Additionally, other requests may be made by email. For all examination re-grade requests, students must submit in writing within one week after the examination review. No requests for re-grades will be accepted for any reason after this date. Once an examination has been submitted for re-grading, the course co-chairs reserve the right to re-grade the entire examination, not just the section for which the examination has been submitted for re-grade. This may result in a revised examination score.

Rescheduling of Examinations

SPPS212 A, B, and C adhere to the SSPPS policy of rescheduling of examinations. The policy is available at: <http://pharmacy.ucsd.edu/current/policies.shtml>

Repeat or Missed Examinations

Faculty reserve the right to provide or not provide repeat examinations depending on the student's individual situation. Faculty reserve the right to change the format, content, and scheduling of the examination, depending on the circumstances. The co-chairs for the course will confer with the Associate Dean for Student Affairs to determine the appropriate course of action for missed examinations, if necessary.

Progression Policy

If a student does not pass one quarter of Therapeutics, a repeat examination may or may not be provided (see above). If a student does not pass two quarters of Therapeutics, the student will not be eligible for a make-up examination, and will be required to retake the entire Therapeutics series.

Honor Code

Students are expected to act in accordance with the SSPPS Honor Code which was read and signed by each student during the first-year orientation. Participation in group preparation and study is expected and encouraged. Cheating or plagiarism will not be tolerated and will result in severe disciplinary action. To address any questions regarding the definitions of cheating or plagiarism, please see either course co-chair.

Student Communications-TED

TED will be used to facilitate communication between the faculty and students and also among the students. Students may post questions regarding the course and the material on TED. This can be done anonymously if the student desires. Faculty will then post answers to questions for all students to see and discuss. In addition, class announcements, changes to the schedule, changes to the lectures or the syllabus may be posted during the quarter. Failure to check TED or UCSD e-mail is not a valid excuse for missing an assignment, event, meeting, or other course activity.

Course and Instructor Evaluations

Course and faculty evaluations provide important feedback to instructors to improve course content and teaching methodology. Teaching evaluations are also an important factor in faculty advancement, merit and promotion. The School and the University require this information. As such, completion of course and instructor evaluations is a requirement for successful completion of this course. This is also part of developing professional conduct and behavior. To facilitate ease of completion of evaluations an electronic format has been implemented. (Please see the SSPPS website for the link). Students who have academically passed this course but who have not completed 1) the evaluation of the course, 2) the evaluation of the course chair(s) and 3) evaluations of at least 90% of guest lecturers will receive a grade of "I" (Incomplete) for the course. If an "I" grade has been assigned due to incomplete evaluations, changing the "I" grade, will require completion of the evaluations prior to the start of the next academic quarter. A grade of "I" must be changed to an "H" (Honors) or "P" (Pass) by the end of the next academic quarter in which the student is enrolled or the grade is automatically changed by the Registrar's Office to an "F" (Fail). A petition is required to change the "I" grade.

Conferences and OSCE

Seven conferences and 1 OSCE per quarter will be held to discuss patient cases on the disease topic(s) previously discussed in lecture. Students should come prepared to discuss the disease topic(s) of the week and be prepared to integrate previously mastered disease states into assessment and management of current active problems. Students are responsible for all lectures, lecture materials, handouts and reading assignments. In order to stimulate active discussion of the specific patient cases, no lecture notes or books will be allowed during the conference session.

Attendance at conference is MANDATORY unless approved by the Conference Chair, Dr. Jahansouz. For each conference, attendance will be taken and students will be evaluated on a Pass or No Pass basis. To receive a Pass for each conference, active participation is MANDATORY. Students will be evaluated on the quality and quantity of participation in conference.

Examples of active participation:

- a) Student provides patient-specific information that is supported by the lecture or the reading;
- b) Student poses a pertinent or relevant question that demonstrates that substantial thought has been given to the material;
- c) Student communicates to classmates or faculty when information presented that is controversial or incorrect.

Examples of ineffective participation (resulting in an NP for that conference):

- a) Student sits in conference without speaking for the entire conference;
- b) Student offers one sign and symptom (already given in the case), then sits silently the entire conference;
- c) Student is belligerent towards peers or faculty or dominates the entire conference.
- d) Student is late to conference

An absence from conference is subject to "No Pass" for that conference, unless the following actions by the student occur. A student should inform the conference

preceptors and the Conference Chair, Dr. Jahansouz *prior to* the conference whenever possible. An excused absence may be considered due to a medical illness, bereavement/family death, or attendance at a professional meeting. Registration meeting documentation is needed for confirmation of meeting attendance. Students are responsible for all materials covered during the conference section. Points will be deducted for an unexcused absence. All issues of determining an excused or unexcused absence will be left to the discretion of the course co-chairs and conference chair.

A variety of conference formats will be utilized throughout the year in order to learn the application of lecture material to patient cases.

(1) SOAPing

A patient case will be posted on TED prior to conference. 2 students will be assigned to “lead” the SOAPing of the patient cases with the class during conference. The pharmacy resident will serve as a facilitator for discussion.

(2) MOCK Orals

The patient case will be conducted utilizing a “mock” oral exam and will be provided at the start of conference to all students. The patient case will not be posted on TED. Thirty minutes will be allowed for all students to SOAP the patient case. Afterwards, 3 students will be selected to conduct an oral SOAP presentation of each problem from the patient case. Each student will be provided 20 minutes to present their problem to the resident facilitator who will be the “examiner”. This will be followed by a 10 minute discussion and feedback session with the resident facilitator. You will be evaluated on your active participation and preparedness for the examination. Case keys will not be handed out to students after case presentation.

(3) OSCE (Objective, Structured Clinical Exercise)

These involve simulation of a clinical scenario at a frequency of no more than 1 per quarter. Students will be placed in groups and will be engaged in a clinical exercise involving a standardized patient. The students will be expected to interview the patient, gather all of the appropriate information, assess the standardized patient’s therapy, formulate a care plan and communicate this plan to the standardized patient. The student pharmacist will be expected to counsel the patient on their drug therapy including indication of the drug, the time course for symptom resolution, monitoring efficacy, dose, route, frequency, administration instructions, anticipated adverse events, advice on contacting prescriber for adverse events, as well as demonstration of drug administration using any demo products available. This is a formative exercise that will be evaluated based on active participation. Facilitators will debrief students on how the interaction went with respect to standardized patient experience, communication skills and the appropriateness of the care plan. After the OSCE, students will be expected to write a SOAP note detailing out their assessment and plan. These notes will be submitted to the pharmacy resident conference facilitators to review and provide feedback.

(4) SOAP Note (Optional. To be determined during quarter.)

After reviewing a patient case, students will write a chart note similar to what is done in clinical practice for an electronic medical record. Students will use the SOAP format to organize the patient note.

Therapeutics “Best Practices”

One of the challenging aspects for the course is the ability to provide patient specific rationale for drug selection. For example for some written responses to exams and/or completion of SOAP note for a specific disease state, there is often confusion as to the types of patient specific information to provide.

The following examples and suggestions are intended to provide clarification and guidance. Please note that these are general guidelines and that there may be situations requiring slight deviation. In such cases, the decision to determine if the response is patient specific or appropriate, will be determined by course co-chairs.

1. Stating a drug property may or may be not patient specific enough. A property of a drug can entail several aspects (e.g., MOA, formulation, dosage strength, side effects, monitoring parameters, etc.). Additional detail is needed in order to provide a patient specific response

- Example 1: “This is a beta blocker that can be used to decrease high blood pressure for this patient” is not patient specific enough vs. “Patient is not at goal BP of <140/90 for primary prevention and starting a beta blocker will help to decrease BP”

- Example 2: “This is a once daily formulation” is not patient specific enough vs. “This is a once daily formulation and will improve compliance in this patient with a history of poor compliance to medications.”

2. “First line” therapy may or may not be patient specific. This depends on the disease state and how this phrase is specifically stated.

- Example: “An ACE inhibitor is first line for treatment of HTN” is not patient specific enough vs. “An ACE inhibitor is first line for treatment in this patient with HTN and diabetes”

-Example: “AC chemotherapy is first line for treatment for breast cancer” in not patient specific enough vs. “AC chemotherapy is first line chemotherapy for Stage III breast cancer”

3. A side effect or laboratory value of a drug may or may not be patient specific. If a side effect of a drug may worsen a current patient symptom or be compounded by another current therapy or disease state, then these would be appropriate rationale to rule out possible therapy. In contrast, stating a side effect of a drug without any patient context is not appropriate

- Example 1: “Atorvastatin will increase ALT and AST liver enzymes” is not patient specific enough vs. “Patient currently has high ALT and AST and atorvastatin may worsen liver function”

- Example 2: “Methadone may cause QT prolongation” is not patient specific enough vs. “Patient is currently on amiodarone and adding methadone will increase patient’s QT prolongation risk”

4. Drug class vs. specific drug in a drug class. This depends on the disease state. It would be unrealistic for students to provide a rationale for every single drug in a class. For HTN, there are an abundance of beta blockers that are available and we would not expect a student to SOAP out each individual beta blocker. However, there are times where it is critical to know specific drugs in a drug class as rationale for use. For

example, for CHF and MI disease states, there are specific beta blockers that are appropriate for use based on the strength of the published literature that students are expected to know.

Therapeutics “Pearls”

In this series of courses, patient case scenarios will be presented to illustrate potential real-life cases seen in clinical practice. The following guidelines are provided to begin developing the “art” of pharmacy practice.

- 1. Know generic names of drugs**
 - It is important as clinicians to speak in terms of the generic name of a drug. As clinicians we give unbiased information about pharmacological agents. It also helps the student as a future clinician to learn the generic names because it helps in remembering the class and therapeutic use of the drug.

- 2. It is important to know dosages, routes of administration, and dosage schedules**
 - Make sure to give a specific dose. Know the dosage range; and take into consideration where in the range the specific patient should be started (given the patient’s age, sex, ethnicity, renal and hepatic function, concomitant disease states, etc.). Then, pick the best starting dosage. The same is true for route and schedule. Make sure to pay attention to all units (e.g., mg, mcg, ng).

- 3. Be firm in your decisions – be responsible**
 - Many healthcare professionals will depend upon the pharmacist to make a therapeutic decision. It is important to be knowledgeable and provide them with the best possible decision based upon the scientific evidence and patient-specific factors. Students should come to a conclusion and be prepared to defend the rationale for the conclusion.

- 4. Use appropriate language – be professional**
 - Know the audience. Whether speaking or writing, it is important to always be appropriate and professional. When explaining the mechanism of action of a drug to a physician, it is important to not only give correct information, but also to cover the breadth and depth of the information. When speaking with a patient, try to assess his or her educational level and understanding of the information....use lay language.

- 5. Always remember to be patient-specific**
 - It is one thing to memorize facts given in lectures or in readings. Anyone (i.e., physician, nurse, etc) can look up drug information. However, the service that clinical pharmacists provide involves synthesizing and analyzing the patient-specific factors with the scientific facts that we know and making a rational recommendation for that particular patient.