Note that all underlined and blue text is a hyperlink.

This syllabus is likely to be updated or corrected during the semester. If it is, you will be notified via email from Canvas. Check the Change Log on the course home page for the details of updates.

**Pre-Lab:** Monday — 1:00 PM – 2:00 PM (Central Time).

**Lab:** See specific section by city below. Activities vary weekly.

**Course Director:** Stephen R Saklad, Pharm.D., BCPP
Office: UT Health Science Center San Antonio
Pharmacotherapy Education and Research Center (PERC)
McDermott Clinical Sciences Building
7703 Floyd Curl Drive, MSC 6220
San Antonio, TX 78229-3900
Office Telephone: 210-567-8355
Mobile/Text: 210-326-9086 (Emergencies 24/7)
FAX: 210-567-8328
Email: Saklad@uthscsa.edu (preferred)

**Austin Coordinator:** James Wilson, Ph.D.
Office: PHR 3.210A
University of Texas at Austin
College of Pharmacy
Austin, TX 78712
Telephone: 512-471-6978
FAX: 512-471-8762
Email: WilsonJ@austin.utexas.edu

**El Paso Coordinator:** Celeste Vinluan, Pharm.D.
Office: UTEP/UT Austin Cooperative Pharmacy Program
1101 Campbell St, Rm 703
El Paso, TX 79902
Telephone: (915)747-8302
Email: CMVinluan@utep.edu

**RGV Coordinator:** Bianca Cruz, Pharm.D.
Office: Assistant Professor
UT Rio Grande Valley/UT Austin
Cooperative Pharmacy Program
1201 W. University Dr.,
E-RAHC 1.100
Edinburg, TX 78539-2999
Telephone: (956) 665-3761
Email: Bianca.Cruz@utrgv.edu

Revised 01–25–2016
PHR 194P – Advanced Pharmacotherapy Skills Lab
Spring 2016

Course Director Accessibility: Dr. Saklad is available most of the time by email, while tutoring lab, presenting in the pre-lab, via telephone, FAX, and additional face-to-face, or webcam meetings may be scheduled as needed. Please contact your lab facilitator about your section’s schedule or approval of a presentation before contacting Dr Saklad. Please contact Dr. Saklad if you have a question about the overall lab course or another topic of concern to you.

Comments, constructive criticism, and suggestions by students, lab facilitators, or local course coordinators to improve the educational content and delivery of this course material are always welcomed by Dr. Saklad. The structure and content of this course has changed every year based upon student and faculty input. Frequently, very helpful student input has been received during their P4 year while on clinical rotations.

To permit rapid identification of email about this course, please include in all Subject lines of your emails “PHR 194P” and sent to the course director at: Saklad@uthscsa.edu.

If the Subject line of your email does not include “PHR 194P” email filters may not bring your message to Dr. Saklad’s attention.

Messages without “PHR 194P” in the Subject line or sent through Canvas are not considered “official” communications about this course to the course director.
PHR 194P – Advanced Pharmacotherapy Skills Lab
Spring 2016

Lab Sections:

### Austin

<table>
<thead>
<tr>
<th>Unique #</th>
<th>Day</th>
<th>Time (CT)</th>
<th>Location</th>
<th>Lab Facilitator(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>59315</td>
<td>T</td>
<td>3:30 - 6:30</td>
<td>PHR 2.214</td>
<td>Amy Frederick, Sandy Diec, Ryan Kuel</td>
</tr>
<tr>
<td>59320</td>
<td>W</td>
<td>3:30 - 6:30</td>
<td>MEZ 1.104</td>
<td>Philip Dollin, Matt Jirasek, Saeed Alzghari, Ryan Kuel</td>
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<tr>
<td>59325</td>
<td>W</td>
<td>3:30 - 6:30</td>
<td>PHR 2.208</td>
<td>Kim Vo, Sarah Klembith</td>
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<tr>
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<td>PHR 2.214</td>
<td>Brendon Hogan, Jennifer Jiang</td>
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<tr>
<td>59335</td>
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<td>Bella Mogaka, Nancy Johnson, Ryan Kuel, Saeed Alzghari</td>
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<tr>
<td>59340</td>
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<tr>
<td>59345</td>
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<td>4:00 - 7:00</td>
<td>PHR 2.208</td>
<td>Germaine Williams, Jim Wilson</td>
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### San Antonio

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<tr>
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<td>McD 2.104</td>
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<tr>
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<td>McD 2.104</td>
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<tr>
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<td>McD 2.108</td>
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### El Paso

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<tr>
<td>59350</td>
<td>T</td>
<td>2:30 - 5:30</td>
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<td>Celeste Vinluan</td>
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### Rio Grande Valley

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<th>Day</th>
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</thead>
<tbody>
<tr>
<td>59370</td>
<td>T</td>
<td>TBD</td>
<td>TBD</td>
<td>Bianca Cruz, Daniela Bazan</td>
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</table>

**Course Competencies:** Advanced pharmacotherapy lab provides a safe, structured, and supportive setting for the P3 student to develop excellent presentation skills necessary for professional practice.
The presentations include development of a brief data-driven drug therapy algorithm, two journal clubs, a brief drug monograph, and two very brief case presentations that are intended as practice for presenting your patients as you will commonly find yourself doing during work rounds on acute inpatient clinical rotations.


Additional materials (readings, videos, etc.) may be provided to cover recent advances in pharmacotherapy and pathophysiology. You will be notified by an announcement through Canvas.

**Prerequisite:** Admission to the Doctor of Pharmacy program, completion of the Pharmacotherapeutics sequence, or consent of the instructor and dean.

**Web Resources:** The official Canvas web site for this course can be accessed directly at [https://utexas.instructure.com/courses/1164165](https://utexas.instructure.com/courses/1164165). The access point is UTEID-protected. You must visit this site for additional resources associated with this course (syllabi, rubrics your grades, submitting handouts, discussions, contacting faculty and lab facilitators by email, prerecorded modular lectures, etc.). For reasons that remain unexplained, Safari did not work last year. It does appear to work currently, but YMMV. If you are using Safari and get an Authentication Error, try using Chrome [www.google.com/chrome](http://www.google.com/chrome) or FireFox [www.mozilla.org/en-US/firefox/new/]. Other browsers (Edge) may work as well. So, if you have a problem accessing Canvas using one browser, stay calm and just try a different browser before you do anything else (panic, scream, or even ask for help [https://www.utexas.edu/its/canvas-project/forms](https://www.utexas.edu/its/canvas-project/forms)).

The email sent from the Canvas website is the official method for course-related announcements and for exchanging class information and questions. Be sure to check the email account that you have registered with the university for important announcements. If you are not receiving any emails from Canvas, check with your classmates. If they are receiving emails and you are not, you have a problem with your email address registered in Canvas. You can check all of your addresses that are associated with you at the Registrar’s Office [utdirect.utexas.edu/apps/utd/all_my_addresses](http://utdirect.utexas.edu/apps/utd/all_my_addresses). You can check your email and contact methods used by Canvas at this page [utexas.instructure.com/profile/settings](http://utexas.instructure.com/profile/settings).

Beware of “link decay” [www.biomedcentral.com/content/pdf/1471-2105-14-S14-S5.pdf](http://www.biomedcentral.com/content/pdf/1471-2105-14-S14-S5.pdf) where the target of the URL has changed and you are confronted with the always disappointing “404 Page Not Found” error, or even worse, the URL points to outdated or incorrect information. If you read the article that I just linked, you will perhaps be able to estimate, as I did, that the half-life of “medicine” URLs is ~3.3 years. If you find any broken URLs in any of this course’s materials, please notify Dr Saklad to repair the link.

**Library resources** are available to all students in this course. ClinIC [www.lib.utexas.edu/lsl/clinic](http://www.lib.utexas.edu/lsl/clinic) provides you with access to most of the resources you will need. However, your need for secondary and tertiary references will be minimal for this lab. You will primarily need to obtain direct access to the full text articles of primary literature [http://www.lib.utexas.edu/indexes/titles.php?subject=Pharmacy](http://www.lib.utexas.edu/indexes/titles.php?subject=Pharmacy). Remember that primary literature contains the data, not a review or compilation of previously collected or reported data.
If you are at one of the non-Austin clinical rotation sites, do not forget that you may have free access to “Get A Scan” services <https://lib-pclcz020.austin.utexas.edu/Illiad/IXA/illiad.dll?Action=10&Form=30&genre=Article>, if you are more than 50 miles from Austin. To see if you qualify, you need to go to the LIS page <http://www.lib.utexas.edu/services/ils/> and select Remote Delivery. In addition to the library resources of UT Austin, those students located on another campus have access to that campus’ library.

**Recordings of Lectures:** Taped and video-streamed recordings of pre-labs are intended to facilitate learning for those students who find this type of supplementation useful; they are not a substitute for attending pre-lab. Although recordings of these pre-labs will be available to you for the semester, this is for supplementation only; you are expected to attend all scheduled pre-labs that are identified as mandatory. If an individual faculty member chooses to not make lectures available by videotape and/or videostreaming, it is that faculty member’s responsibility to so inform you. The lack of availability of any videostream materials due to technical malfunction is not the responsibility of the presenter. Reasonable precautions have been taken to prevent or correct technical problems.

Viewing video-streamed recordings of lectures is primarily intended for on-campus computer facilities (e.g., LRC Library, 3.116 computer lab, or other computer facilities available on your specific campus). However, it should be possible to view the streaming video off-campus using broadband connections. Your faculty are not in a position to troubleshoot your video-streaming problems, so please do not ask them to do so; rather, you should access the LRC website at www.utexas.edu/pharmacy/help/ to address those problems. Any other questions should be go to the Director of the LRC, Oliver Gomez.

**Redistribution of Class Recordings:** If video recordings of a class are made available by the College of Pharmacy for any course, they are intended solely for the purpose of review by student currently enrolled in the that class. Faculty and students utilizing class video recordings should be careful to not compromise the privacy of either themselves other users <registrar.utexas.edu/students/records/ferpa>, or the rights of the presenter. Students are free to make their own recordings of lectures unless specifically prohibited from doing so by the presenter. Any additional distribution of College- or student-generated recordings (regardless of format) is prohibited without the written and signed permission of the presenter and any students identifiable on the recording.

**Examinations:** There will be no formal written examinations. You will receive rubric-derived scores based upon your presentations and your active participation in discussions in the lab sections. All grades are earned individually based upon the lab-section adjusted scores. There are no group grades.

**Lab Presentation Score Reconsideration Requests:** If there is a disagreement over a presentation or participation rubric-derived score, the student should send their exposition with appropriate documentation to their laboratory facilitator within one week of the scoring of the Rubric. Appropriate supporting documentation may include statements from required or optional textbooks, class handouts / packets, or current scientific literature (attach readable image or full text PDF or accessible link). Personal lecture notes are not authoritative documentation. The explanation must be clear, rational, and concise. If there is still a disagreement, the laboratory facilitator should forward the materials to Dr. Saklad for discussion. After the laboratory facilitator’s review with Dr. Saklad, the decision of the laboratory facilitator is final.
Academic Dishonesty: The “Statement on Scholastic Dishonesty of the College of Pharmacy” (November 8, 2010) reads in part:

Pharmacy practitioners enjoy a special trust and authority based on the profession’s commitment to a code of ethical behavior in its management of patient-centered pharmaceutical care. The inculcation of a sense of responsible professional behavior is a critical component of professional education, and high standards of ethical conduct are expected of pharmacy students and faculty. Violators of University rules on scholastic dishonesty are subject to appropriate disciplinary penalties. Since dishonesty harms the individual, fellow students, and the integrity of the University and the College of Pharmacy, policies on scholastic dishonesty must be strictly enforced.

<www.utexas.edu/pharmacy/students/handbook98/3code.html#policy>
<www.utexas.edu/pharmacy/nso/honor.pdf>

Students shall work independently on all presentations. Practicing your presentations with your classmates as a live audience is allowed, but there shall not be any prearrangement of specific questions and answers that will be used in the final lab presentation. This would be collusion: see Institutional Rules on Student Services and Activities; Sections 11-402(c)(4) & 11-402(e).
<deanofstudents.utexas.edu/sjs/downloads/InstitutionalRules1112.pdf>

Any student that is dishonest or witnesses dishonesty and does not report it appropriately (confidentially to Dr. Saklad) in a timely manner will be minimally given a score of “zero” on the presentation and class discussion for the day. Substantially greater penalties can be levied when appropriate. Unintentional violations that are reported as soon as possible may be corrected without penalty, if no harms have occurred. Any student suspected of dishonesty will be reported to the Dean of the College of Pharmacy and to the Dean of Students, as per University regulations. Students are expected to have read and understood the current issue of the General Information Catalog published by the Registrar’s Office for information about procedures and about what constitutes scholastic dishonesty <deanofstudents.utexas.edu/sjs/scholdis.php>.

Students with Disabilities: The University of Texas at Austin provides upon request appropriate academic accommodations for qualified students with disabilities. All University rules concerning accommodations must be followed, including the student arranging for special accommodations prior to each class where needed. In the absence of such prearrangement, the student will be assumed that the student is not requesting special accommodations for that class, and will be expected to participate with the rest of the class at the regularly scheduled time. For more information, contact the Office of the Dean of Students at 512-471-6259, 512-471-4641 TTY.
<deanofstudents.utexas.edu/>

Lab Sections: A faculty member or pharmacist post-doctoral trainee (post-Pharm.D. graduate student, PGY1 / PGY2 pharmacy resident, or fellow), will be assigned as your facilitator for each lab section to support and guide the students in the planning and development of their presentations, and provide the timely grading of in-class written and verbal presentations as well as active participation when not presenting. While the lab facilitator is responsible for your evaluations and coordination of the lab section, students are ultimately responsible for their own education. If you are unable to attend your scheduled lab session for a legitimate reason, you might be able to attend a different session with the permission of both sessions’ lab facilitators and your local coordinator. Any changes that are agreed to by the student and lab facilitators should be copied by
email or Canvas to Dr. Saklad in advance. The purpose of providing this electronic, date and
time stamped, documentation to Dr. Saklad is to avoid any disagreements or misunderstandings.

**Student Number Assignment:** On the first day of lab (Week 3), each student will be assigned a
sequential integer by their facilitator from one through 14, based on the alphabetical order of the
student’s name (Last, First, MI). This will determine the order of presentations given during the
class as shown on the class presentation schedule. The sequence was determined to avoid, when
possible, having two presentations by the same student on the same day. The schedule allows for
up to 14 presentation slots, so there will be at least three “empty slots” that can be used to im-
prove the flow of the presentations, as needed, in the opinion of the lab facilitator following a
written student request. If a student has a known conflict with a presentation date, they may re-
quest by email or Canvas to their lab facilitator that they be reassigned an alternate student num-
ber that avoids the conflict. This must be done before any presentation would be due in either
student number. Student numbers may not be changed after any presentation is given or sched-
uled to be given.

In addition to the above permanent change in a student’s number, students may switch individual
presentation dates with another student with the consent, at least one week in advance, of their
facilitator. This should be done by email or Canvas and Cc’d to your local coordinator and Dr.
Saklad. Each student must present their Level II Case Presentation before their Level III Case
Presentation. This flexibility is intended to allow students attending special events to not miss a
presentation date. It is not to be used to postpone a presentation because of lack of preparation.
Unexcused absence from a scheduled presentation will receive a zero score for the presentation.
Review of the course grading policy will show that a zero on a presentation will result in a de-
creased final letter grade.

In the event that two or more students make unresolvable conflicting requests, the earliest server
time stamp on the message header will prevail.

In some past lab sections, the lab facilitator and students have compressed the presentation
schedule and reduced the number of lab sessions. This must be an unforced and unanimous deci-
sion of everyone affected using a secret ballot of some kind (for example, small pieces of folded
paper with Yes / No on them, folded and placed in a jar). Dr. Saklad and your local coordinator
need to be informed in advance and receive approval before the schedule can be compressed.
Please note that decreasing the number of lab meetings will have an impact on grading as the rel-
ative weight of each participation grade will be proportionally increased.

**Dress Code:** This laboratory is intended to be a dress rehearsal for part of your role as a pharma-
cy student in the capacity of a state-registered intern pharmacist on clinical rotations next se-
mester. Therefore, appropriate dress for this laboratory is obligatory.
<www.tsbp.state.tx.us/infocist/internship.htm>

As a pharmacist, you are expected by your patients, subordinates, employers, and colleagues, to
dress in a professional manner. Professional dress needs to be appropriate to the clinical envi-
ronment. Patient’s expectations for professional dress differ depending upon the setting where
they receive their care. At this time, for a pharmacist in most clinical settings, professional dress
includes a clean, pressed, white lab coat with your name clearly identified. Specifically, you
should look the way that you are expected to look in that environment. Your clothing should not
be the first thing that should call attention to you.
A growing body of evidence shows that wearing clothing that is not changed between patients may be a source of cross-patient contamination and is becoming prohibited in some settings (see Weber RL, Kahn PD, Fader RC, and Weber RA. Prospective study on the effect of shirt sleeves and ties on the transmission of bacteria to patients. J Hosp Infect. 2012;80(3):252-4). I expect that only scrubs or gowns will be allowed eventually…and the scrubs or gown will be changed between every patient.

Not every pharmacist should be expected to wear the exact same professional attire. At the Texas Center for Infectious Disease (TCID), the pharmacist wears a respirator and scrubs while on the units where patients with infectious cases of tuberculosis are located. If the pharmacist is preparing chemotherapy, then an appropriate environment and protective clothing are obviously essential. In most mental health, some pediatric, and some family practice settings, a lab coat and tie are intentionally not worn, as these are believed to represent a barrier to communication with the patient and family.

In all clinical settings, the pharmacist should always be clean, well kempt, and present a professional image.

All pharmacist interns shall wear an identification tag or badge which bears the person’s name and identifies him or her as a pharmacist intern (TAC 22.15 §283.4e(3)). Name tags may be ordered through pharmacy student organizations. Most organized health care settings will provide their staff with photo identification including their name and title.

For purposes of this laboratory course, the appropriate professional dress for men is slacks, shirt, and perhaps a tie (lab facilitator’s discretion). Women may wear slacks, or skirts and blouses, or dresses. Lab coats may be required or not, depending upon the preference of the lab facilitator. All clothing, including lab coats if worn, must always be correctly sized, neat, clean, and unwrinkled.

Based upon previous incidents reported to me in this lab by lab facilitators, I am explicitly informing you that no swimsuits, shorts, jeans, backless or muscle shirts, tennis shoes, or thongs may be worn. Not all possibilities can be included in any set of rules, but inappropriate dress, in the opinion of the lab facilitator, may result in dismissal from the lab and zero scores for that day. If there is any doubt as to the correct dress in any setting, always ask well in advance. Please do not give any of your lab facilitators a reason to make the list that begins this paragraph any longer.
Emergency Evacuation: The following has been requested to be added to all UT Austin syllabi by Dr. Robert Harkins, Associate Vice President for Campus Safety and Security. Supplementary information can be found at [http://www.utexas.edu/emergency](http://www.utexas.edu/emergency). While this information does not completely apply to students located in San Antonio [<http://research.uthscsa.edu/safety/emergencyresponse.pdf>], El Paso [<http://admin.utep.edu/LinkClick.aspx?link=UTEP+EMP+Public+Web+Site+-+10-08.pdf&tabid=50482&mid=137358>], or Edinburg [<http://www.utrgv.edu/police/>], similar advice is to be implemented on those campuses. Occupants of buildings on The University of Texas at Austin campus are required to evacuate buildings when a fire alarm is activated. Alarm activation or announcement requires exiting and assembling outside.

- Familiarize yourself with all exit doors of each classroom and building you may occupy. Remember that the nearest exit door may not be the one you used when entering the building.
- Students requiring assistance in evacuation shall inform their instructor in writing during the first week of class.
- In the event of an evacuation, follow the instruction of faculty or class instructors.
- Do not re-enter a building unless given instructions by the following: Austin Fire Department, The University of Texas at Austin Police Department, or Fire Prevention Services office.
- On other campuses, the corresponding emergency services, or the designated incident commander, will provide permission to re-enter an evacuated building.

It is now common for government units (country, state, county, city, etc.), university campuses, health-care facilities, and agencies responsible for public safety and welfare to have emergency alert notification systems, usually sending email or text messages. Please sign up for those where you are located. To find these, just do a search for emergency alert or emergency notification system and where you live and have rotations. If you have signed up previously, please take the time to verify that your registration is current.
# PHR 194P – Advanced Pharmacotherapy Skills Lab
## Spring 2016

### Scheduled Presentations by Week

<table>
<thead>
<tr>
<th>Week #</th>
<th>Monday's Date</th>
<th>Student # Presenting</th>
<th>Algorithm</th>
<th>Monograph</th>
<th>Journal Club</th>
<th>Case Presentation</th>
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<tr>
<td>1</td>
<td>01-19-2016</td>
<td>None [MLK Day]</td>
<td>#1</td>
<td>#2</td>
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<td>Orientation to Course (Mandatory Pre-lab only)</td>
<td>#1</td>
<td>#2</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>02-01-2016</td>
<td>First Lab Sessions: Assign Student #'s; Discussion of Presentations</td>
<td>#1</td>
<td>#2</td>
<td></td>
<td></td>
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<tr>
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<td>5 / 10</td>
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<td>14</td>
<td>04-18-2016</td>
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</tbody>
</table>
Course Grading and Student Evaluation

Class Attendance:

Attendance in every laboratory session is mandatory.

Attendance will be taken in each lab, and your active participation graded every week. You cannot pass this course without attending laboratory sections.

There will be one mandatory pre-lab session given during pre-lab on 01-25-2016 providing an orientation to the course and reviewing each type of presentation. There will be optional pre-lab sessions most weeks that are opportunities to discuss issues and ask questions about your presentations from Dr. Saklad. Depending upon circumstances, some or all of the optional pre-lab sessions will be made mandatory. You will be notified in advance by Canvas.
PHR 194P – Advanced Pharmacotherapy Skills Lab  
Spring 2016

Absences are in addition to any individual office hour appointments that you may schedule with Dr. Saklad.

- Absence is only excused due to illness, *bona fide* family emergency or life-cycle events, or participation in a university-sanctioned activity such as attending a professional meeting.
- Documentation will be required for the absence to be excused.
- Contact your lab facilitator, your local coordinator, or Dr. Saklad (see beginning of this syllabus for contact info) by Canvas or email in advance for a university-sanctioned activity, or as soon as possible if you are absent from class for another reason.
- It is the policy of this course to be as flexible as possible in accommodating legitimate problems in attending lab sections, consistent with fairness to all students.
- Depending upon your individual circumstances, the excused absence may be made up by attending another section’s lab, reduction in the possible points in the class, or additional assignments. Which option is most appropriate will be decided by Dr. Saklad, after consultation with lab facilitators and/or local coordinators. Unexcused absences will result in zero scores that can’t be made up.
- Multiple excused absences will be addressed by a discussion among all local coordinators to determine appropriate ways to permit course credit to still be awarded, if possible.
- Again: You must attend all lab sessions, even if you are not presenting that day: your active participation is essential. Unexcused absence from lab sessions may result in a lower grade in the course. Lab facilitators are requested to notify the local coordinator and Dr. Saklad by Canvas or email if anyone is absent as soon as possible, but no longer than 24 hours after the end of the missed session, other than a previously arranged excused absence.

**Topic Selections:**

Exposure to as broad a range of clinical states as possible is important, overlap of subject areas between presentations of the same student should not occur. Therefore, you should not select Journal Club articles on the same topic, your Monograph should be for another indication, and the Algorithm on yet another. Similarly, you should have your Case Presentations on unique disease states. This is too early in your career to focus to narrowly.

All topic selections for your presentation must be made no later than one week in advance of your presentation. At the latest, the day of the lab session the week before you present, before Midnight. At the discretion of your lab facilitator, earlier deadlines may be required. The earliest request for a selection made by two students in the same section will be permitted to have their choice. However, with the lab facilitator’s permission, you may be able to change your selection as long as it is still at least one week prior to your presentation.
Point Assignment:

You will be evaluated on your presentation skills, written work, and active participation in lab discussions. All of the rubric-derived scores will be individually earned; there are no group scores. The distribution of points awarded is based upon your performance in the lab sections as shown:

<table>
<thead>
<tr>
<th>Lab Evaluation Components</th>
<th>Points</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monograph</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Algorithm</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Journal Club #1</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Journal Club #2</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Case Presentation Level II</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Case Presentation Level III</td>
<td>150</td>
<td>14.085%</td>
</tr>
<tr>
<td>Active Participation in Lab (15 points/week)</td>
<td>165</td>
<td>15.493%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,065</strong></td>
<td><strong>100.000%</strong></td>
</tr>
</tbody>
</table>

All presentations should be graded by the laboratory facilitator strictly and consistently according to the requirements of the appropriate rubric. During the lab, the lab facilitator will use a paper version of the rubric to take brief, but detailed notes.

The online version of the rubric in Canvas will be completed by assigning scores for each component of the rubric including comments explaining any points that were not earned in that component due to missing, incomplete, or incorrect information presented during the in-lab presentation either verbally or in the handout that was distributed. The official rubric in Canvas should be entered within one week of the presentation. The lab facilitator will only score the handout version used during the in-lab Presentation.

Following their presentation, the student should edit their handout to incorporate the constructive criticism received following their in-lab presentation and then upload it into the appropriate assignment in Canvas. Taking the time to make usually minor changes prior to uploading the handout will improve retention by the student of where they need to make improvements in future presentations. Students would be wise to additionally use this revised version in their ePortfolio and other purposes. There are no graded or uploaded versions of any presenter’s notes used during Case Presentations.

Any questions or challenges must be submitted by Canvas or email to the lab facilitator within one week from when the graded rubric is scored in Canvas. See the previous section on Lab Presentation Reconsideration Requests.
Historically, the letter grades assigned in this course are typically quite high. See the corrected percentage of points earned and grade distribution for last year below. The green represents “A” and the yellow-green “A-”.

The high scores reflect that almost everyone did a very good job.

Grades in this course will be assigned to students based upon the corrected total points earned in class (see Point Assignment) using the table shown at the right.

Before the overall course grade is assigned, there needs to be an adjustment for having multiple sections where scores are assigned by several different laboratory facilitators in different regions. In part, some of the differences are compensated for by strictly using the the rubric-based scoring assignment.
However, as in previous years, there were statistically significant differences between sections (see examples from last year before and after this correction, above); ANOVA $F = 10.49$, $df = 11,105$, $P < 0.0001$). The box plots (red) and mean (green) of each section are shown. Therefore, the grades in each section will be proportionately adjusted (up or down) to the same course mean percentage of total points earned. Notice that the mean lines are equal after the correction. This method compensates for any systematic differences in laboratory facilitator’s grading between sections, based on two assumptions:

1. the sections are composed of academically similar students due to random assignment, and
2. each lab section’s facilitator(s) use the rubrics consistently throughout the semester.

Calculations will be made with five significant figures (two guard digits). Since there is a statistical adjustment being made to equalize the mean between sections, no other adjustments will be made. There is no rounding prior to assigning the letter grade.

It will be difficult for you to easily determine your final grade in Canvas due to the different presentations in the lab being done at different times by different students, and the end of semester adjustments for systematic grading differences between sections.

If you have any concerns, please discuss them with the Course Director as soon as possible.
Background:

You will review a therapeutic area and develop an algorithm to be used to guide decision making. An algorithm is the procedure or formula for solving a problem. There are many examples of outstanding clinical algorithms available ([National Guideline Clearinghouse](https://www.guideline.gov), etc.). Reviewing these will give you an idea of what guidelines or algorithms exist, but they are not good templates for this laboratory. Most of these are very extensive and detailed. They may have been developed by a large group of experienced clinicians, researchers, and support staff over several years. Many have been repeatedly validated, revised, and improved. *This is not what you are supposed to be developing for this laboratory.*

You may start at any point in a disease process and end three decision steps later. *Do not attempt to produce the master algorithm to treat all persons in all situations.* That is way beyond the scope and intent of this lab, but perhaps something that may be approached during your professional career. It is the core of the artificial intelligence system that needs to be added to an Electronic Health Record (EHR) system to make the information truly useful for patient care.

Some algorithm resources are more narrow in their use of algorithm; this represents a valid alternative method of presenting an algorithm. Some great resource here are [Guidelines.gov](https://www.guidelines.gov) or the [Medical Algorithm Project](https://www.medicalalgorithmproject.com). As an alternative to the diagrammatic flowsheet method of presenting an algorithm, a spreadsheet, web page, or an app may be developed. If one of these alternatives is desired, please discuss this with your facilitator and notify [Dr. Saklad](mailto:dr.saklad@pharmacy.wright.edu), in advance.
The most difficult point that students have had in the past was understanding that each of the decision points in an algorithm needs to *measurable*. That is they need to be compared to the patient’s condition in some way that will result in a *specific decision* being made by the clinician.

It is very important to understand that *multiple attribute decision making* (the formal name of complex algorithm research) currently has relatively limited research in the clinical arena. If you think about it, you will see that this concept is closely related to the Bayesian approach that you have been given for other presentations. As a clinical example see Kent DM and Hayward RA. Limitations of Applying Summary Results of Clinical Trials to Individual Patients: The Need for Risk Stratification. *JAMA.* 2007;298(10):1209–1212. For those with limited fear of mathematics, you might consider reading Xu Z and Chen J. An Interactive Method for Fuzzy Multiple Attribute Group Decision Making. *Information Sciences.* 2007;177(1):248–263. If that doesn’t work try [doi:10.1016/j.ins.2006.03.001](http://dx.doi.org/10.1016/j.ins.2006.03.001). Please let me know what you think 😊.

As an example of a useful *single* decision point consider the example using a patient’s weight to the shown below.

![Weight Decision Diagram](image)

One enters the diagram from the top and is given a clear-cut question that should be read as: “Is the weight greater than 80 kg?” If the answer is “Yes” then you continue on with the next decision on the right. If not then you continue to the left.

Other decision points could be similar such as:

- **BMI >30 kg/m²?**
- **CrCl ≤20 mL/min?**
- **Diagnosed with Pneumonia?**
- **Age ≥18 & <65 y/o?**

The important issue is that a *clinically useful decision point* is not vague and indeterminate. “Does patient have a high fever?” is an example of a poor decision point. The problem here is that a “high fever” is not defined and should be reworded to, “T >40°C?” as supported by empirical data. If you have data about the patient’s condition, you can unambiguously answer this clinical question.

In some situations you might have to select one of several outcomes (as opposed to just a binary “Yes” or “No”) depending upon the results of a test. For example, selecting an antibiotic based upon the target organism’s sensitivity profile. Another case would be the calculation of a patient-
specific drug dose based upon body weight, renal clearance, or other parameter. As you begin to include more decision attributes, the difficulty of arriving at the optimal course of action becomes more difficult as shown in the multiple attribute decision making literature.

The support for a decision point should be made using primary literature citations. Remember that primary literature contains the data collected from patients and doesn’t summarize it from other sources.

Consider the previously controversial use of analgesics in children for acute abdominal pain of unknown etiology.

The support for his could then be that, “… administration of morphine in young patients age 5 to 16 years old that have acute abdominal pain does not prevent making a confident diagnosis of appendicitis and provides the patient with some decrease in pain.¹


Some students are always asking how to correctly draw a flow chart. Other students do not realize that each specific shape has meaning. Flowcharting is done in many fields and has been adapted to clinical use using a very small subset of the range of symbols (ISO 5807). A reasonable summary for clinical uses can be found by searching on the web. You can draw the flowchart in many programs (Word, Google Docs, Omnigraffle, PowerPoint, etc.) or I have found one free online flowcharting program and one that you can download that will run in a Java-enabled web-browser and have 10 min learning curve. They do much more than just flowcharts. Let me know if you find any others that you like better.
Algorithm Presentation

Written Algorithm

- Five page limit + reference list (3–10 primary references; non-primary literature can be added without limit if desired for clinical context and background).
- First page is diagrammatic flowchart of the algorithm (may vary with explicit permission in advance). The remainder of the algorithm should be a discussion of the rationale for each of the decision points with fully referenced primary literature support.
- Provide enough copies for everyone in your section prior to your presentation. If possible, try to send a PDF to avoid wasting resources. Print only when an alternative will not be useful.
- The copy for your lab facilitator should have a full-text copy of all references attached to permit easy verification of algorithm for grading.
- Submit a copy of your final, edited algorithm to Dr. Saklad following your presentation using Canvas.
  - If you will permit your name to appear on the algorithm when used as an example, please state that you give your permission in your email. If you don’t state your preference either way, this is the default.
  - If you do not wish to have your algorithm used as an example for future classes, please let me know in your Email.

Presentation of Algorithm

- Each student will verbally present their algorithm to their lab section
- Following each presentation there will be an opportunity for other students to discuss the algorithm and critique it with the intent of making it more usable
- Incorporate the useful comments and suggestions into the version submitted to Canvas

Algorithm Topics

These are potential topics that you can select for your project. Please select a topic from this list of projects that were done by previous years’ classes (you are encouraged to identify your own topic, but it must be a substantive clinical issue) and have it approved by your lab facilitator. The approval must be submitted and confirmed by email. Research your proposed topic before making a decision. Algorithm topics will be assigned based upon order of the emails received by the facilitator if two or more students request the same or similar topics. Duplicate or similar topics will not be allowed in any lab section. Each project must be an individual effort, this is not a group project.

Pain & Inflammation

- Chronic pain in cancer patient
- Rheumatoid arthritis treatment
- Treatment of chronic cancer pain upon failure of NSAID management started on morphine therapy
Algorithm Presentation

- Treatment of migraine headache
- Use of ketorolac for a post-op orthopedic patient
- Treatment of irritable bowel syndrome
- Treatment of constipation due to narcotic analgesics

**Metabolic Disorders**
- Drug treatment of obesity
- Initial treatment of hyperlipidemia
- Selection of a thyroid dose in hypothyroidism
- Selection of insulin product
- Stimulation of appetite in elderly
- Treatment of diabetic ketoacidosis
- Treatment of new onset diabetes in obese adolescent
- Treatment of new onset diabetes in obese adult
- Treatment of Prader-Willi Syndrome

**Women’s & Men’s Health**
- Treatment of erectile dysfunction
- Use of hormone replacement therapy
- Aromatase therapy in breast cancer
- Use of Plan B
- Treatment of benign prostatic hypertrophy

**Cardiovascular**
- Loop diuretics in congestive heart failure
- Treatment of CHF
- Prevention of second myocardial infarction
- Pulmonary hypertension
- Selection of initial treatment of hypertension
- Treatment of atrial fibrillation
- Treatment of COPD
Algorithm Presentation

Psychiatry & Neurology

• Treatment selection for smoking cessation
• Selection of mood stabilizer in bipolar disorder (depressed)
• Treatment of psychotic depression with mifepristone
• Treatment of alcohol dependence
• Treatment of initial drug treatment in schizophrenia
• Treatment of cognitive decline in Alzheimer’s Disease (early stage)
• Treatment of depression in adult
• Treatment of multiple sclerosis
• Treatment of tardive dyskinesia
• Treatment of weight gain due to atypical antipsychotic

Pediatrics

• Treatment of asthma in a child
• Treatment of a child that is small for gestational age
• Treatment of otitis media in a child

Infectious Disease

• Treatment of chronic sinusitis
• Treatment of community acquired pneumonia
• Treatment of Hansen’s Disease
• Treatment of multiple drug resistant TB
• Treatment of otitis media in a adult
Algorithm Presentation Evaluation Rubric (150 Points Total)

**Rating Criteria for Each Component:**
- **Excellent:** All Relevant Information Presented Succinctly and Correctly.
- **Very Good:** Didn’t Include or Incorrectly Presented One Required Component.
- **Needs Improvement:** Didn’t Include or Incorrectly Present Multiple Required Components

<table>
<thead>
<tr>
<th>Required Components</th>
<th>Points</th>
</tr>
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<tbody>
<tr>
<td><strong>1. Presentation of pertinent data:</strong> ☐ Applicable pharmacotherapy, disease state, and basic sciences concepts are covered ☐ Always or nearly always are correctly interpreted. ☐ Contains two or three decision points only ☐ Matches audience’s needs. [Point Ranges 50–41; 40–21; 20–0]</td>
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<tr>
<td><strong>2. Critical thinking skills:</strong> ☐ Provides sound assessments and makes original recommendations based on inquiry, extensive analysis, and scientific reasoning. ☐ Does not merely duplicate an existing algorithm ☐ Ample citations of current literature are provided to support each decision point [Point Ranges 50–41; 40–21; 20–0]</td>
<td></td>
</tr>
<tr>
<td><strong>3. Audiovisual materials:</strong> ☐ Slides, handouts, or other materials are provided and support presentation appropriately. ☐ All required information is in handout or slides. ☐ Graphical flowchart is used to illustrate algorithm on one page ☐ Tables, graphs, or diagrams are used whenever possible in place of text. ☐ No errors in spelling, grammar, punctuation, sentence structure, etc. [Point Ranges 10–8; 7–5; 4–0]</td>
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<tr>
<td><strong>4. Communication skills:</strong> ☐ The presentation is logically organized and the information is clearly explained. ☐ Delivery includes direct eye contact, clarity and proper rate of speech, absence of nervousness and distracting habits, and appropriate terminology and pronunciation. [Point Ranges 10–8; 7–5; 4–0]</td>
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<tr>
<td><strong>5. Demonstration of mastering subject and responses to questions:</strong> ☐ Able to answer questions in logical fashion and has the ability to think on his or her feet. ☐ Answers are accurate and correspond with the expected degree of competence. ☐ Acknowledges when the answer is not known by them at this time. [Point Ranges 10–8; 7–5; 4–0]</td>
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</tr>
<tr>
<td><strong>6. Connection to Audience:</strong> Student is interactive and maintains eye-contact with entire audience during the presentation. [Point Range 10–0]</td>
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<tr>
<td><strong>7. Professional dress &amp; behavior</strong> [Point Range 10–0]</td>
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Comments on back: Why Were Points Lost? What Was Done Particularly Well? What Could Be Improved?
Background:

Presenting clinical cases, typically at the patient’s bedside, has a long history as a part of clinical teaching. Being able to summarize the patient’s clinical findings (history, presenting problems, exam, lab, medications, etc.) and present these succinctly is critical to effective communication. This presentation component is included this laboratory to provide essential practice in this skill. For a humorous take on the bedside clinical presentation, you might want to see Bennett HJ. How to Survive a Case Presentation. Chest. 1985;88(2):292.

Just to be clear: this presentation has nothing in common with the SOAP note cases that you did in previous Pharmacotherapy Labs. There is no SOAP note involved in this presentation. This is a verbal presentation of a clinical case that is intended to be a dress rehearsal of your being on an acute care medicine team doing work rounds in front of your attending at 07:15. See the video examples provided on Canvas.

Case Selection:

Each student will individually select two cases from the current edition of Pharmacotherapy Case Book. Your first case should be Level II, and your second Level III. The presentation schedule is in the syllabus.

Abridged Instructions for Oral Case Presentations of New Inpatients on Work Rounds

• Overview
  ‣ Make a convincing case for the important problems, the differential, and the plan.
  ‣ Make it structured, organized and targeted, as it should take only 3–5 minutes.

• Opening Statement
  ‣ Brief statement of chief complaint and why patient was admitted.
  ‣ Include pointed and relevant historical information.
  ‣ Include name of the patient’s PCP and site of care.

• Source
  ‣ Briefly note if / why the patient cannot give reliable history.
  ‣ Note any information sources besides the patient.
  ‣ No comment assumes that all info came from a reliable patient.

• Present Illness
  ‣ The differential diagnosis you considered should guide what you include.
  ‣ Consider starting with: “…usual state of health until…”
  ‣ Be chronologically organized and clear without analyzing.
  ‣ Remember OPQRST: Onset, Palliate/Provoke, Quality, Region/Radiation, Symptoms (associated), Temporal aspects.
  ‣ Include elements of past history (with supporting studies and therapeutic interventions), meds, family history, social history (including psychosocial factors) that specifically contribute to the Present Illness.
  ‣ Pertinent positives and negatives to make the listener understand your Ddx.
Each student must submit the case number and title that they select to their lab facilitator via email for approval to prevent duplications of cases within a lab section. The lab facilitator will approve cases selected by the student on a “first-come, first-served” basis. Cases preferentially should not be ones that you have reviewed in previous Pharmacotherapy Labs.

Cases should not be selected where it would not be appropriate to have a pharmacotherapy plan that covers only the next day.

**Organization**

You should abstract the case as presented in the *Pharmacotherapy Case Book* onto a clinical monitoring form for your own use during your presentation. An example of the form that is currently used on some Acute Care Medicine Rotations in San Antonio is attached. Your presentation should be given from the form you have prepared. You will find that this is still a common way for you to track and monitor your patients.

The monitoring form that is attached (full size form is available on Canvas) is most certainly not the only such form or way to moni-

- Pertinent = relevant to the differential diagnosis and management considered.
- Only include E/R course if it significantly affects/alters triage or immediate treatment decisions prior to coming to your unit. Report facts and events, NOT E/R diagnoses.
- For ICU or other transfers, summarize course using problem list.
- **Other History**
  - Important PMH (with supporting history / data).
  - Exclude minor diagnoses without impact on current care.
  - Important meds with doses and duration. Omit unimportant medications when sure.
  - Allergies and sensitivities.
  - Focused FH / SH / ROS. Do not repeat previously stated information.
- **Physical Exam**
  - Always include general appearance and specific vitals.
  - Include pertinent elements of exam and any abnormal findings.
  - Remainder may be noted as “noncontributory.”
- **Labs/Data**
  - Include pertinent or otherwise significant labs/studies.
  - Start with basic blood tests first. CBC → Chem → Coags → Urine → ECG → Rad → Other
  - OK to mention other tests as being “normal.”
- **Synthesis**
  - Consider beginning with: “And in summary…” but...
  - Assess and synthesize, don’t summarize and regurgitate.
  - Demonstrate your thinking about the patient specific differential diagnosis.
  - If multiple issues present, weave together or discuss lesser issues in problem list below.
- **Enumerated Problem List**
  - Start with most important problem first.
  - Use most specific label for the problem you can.
  - Avoid labeling a problem solely by its system.
  - Include your understanding of the cause of the problem.
  - Include a specific plan for addressing it.

**Note.** PCP = primary care physician; Ddx = differential diagnosis; E/R = emergency department; PMH = past medical history; FH/SH/ROS = family history/social history/review of systems; CBC = complete blood count; Chem = chemistry panel; Coags = coagulation panel; ECG = electrocardiogram; Rad = radiology.

Case Presentation

tor your patients, but it does cover most of the information that is relevant for a pharmacist case presentations. You are encouraged to modify and adapt monitoring forms for the particular service that you are working on. For example, on a psychiatry rotation, adding a section on mental status examination would be essential. To make it fit, some other sections would need to be trimmed.

Beyond paper forms are systems that can be used on smartphones, tablets, or laptops. They may or may not be connected to the facility EHR or the internet. There is a real trade off between each of these in availability, ease of use, and depth of information. The “best” way to monitor and track your patients is evolving continuously. Your goal should be to remain flexible and keep up with what works best for you.

Presentation

A typical case presentation format for physicians is shown in the sidebar on the first page of this handout. You shouldn’t necessarily cover all of these areas, as a pharmacist’s focus should be on the drug therapy issues and the problems in that case. A common format to start a case presentation might begin, “Mr. Smith is a 24 y/o that was in good health until….”

Your presentation will only be verbal. There is no SOAP note. The worksheet is only for your own use. You should not need to turn it in, but your lab facilitator may ask to review it with you. It should not be provided to other members of your lab section or the lab facilitator during your presentation. You may use an alternate worksheet of your own devising to abstract the case so that you can present it verbally. You may not use the Pharmacotherapy Case Book (or a direct copy of any kind). Failure to have a patient worksheet that you prepared for your case presentation prohibits your verbal presentation and you will receive zero (0) points for that presentation. Zero point presentations have been failed and can not be made up. This will almost certainly result in a full grade decrease in your class grade (see main syllabus).

Following your presentation of the case information abstracted from the Pharmacotherapy Case Book, you will need to present your explicit pharmaceutical care-focused problem list, and finally your, “plan for the day.” This will require you to review the literature on how to treat the problems that are present in your patient in sufficient detail to know what to do in the next 24 hours. Do not include a discussion of the pathophysiology of the disease states (this should be known by your team), information that is irrelevant to your patient’s pharmacotherapy-related problems, or your treatment plan for more the next 24 hours. In some cases, knowing when to do nothing but wait for labs or steady state to be reached is the correct plan. However, you should always plan on monitoring for potential adverse effects.

Your entire presentation will be allowed to take no more than 5 minutes. Your lab facilitator shall time your presentation and terminate it at 5 minutes, even if incomplete. This simulates the real situation where students that, “drone on and don’t get to the point” are cut off. Their patients might be transferred to another student that is more competent. Following your presentation, there will be 5–10 minute discussion with the others in your section about the case and your presentation. Be prepared for any questions, including subjects that you have been explicitly told to exclude from your presentation: pathophysiology of the disease state, why you made the pharmacotherapy decisions you presented in your plan for the day or your plan for a longer period of time.
# PHR 194P – Advanced Pharmacotherapy Lab
## Spring 2016
### Case Presentation Evaluation Rubric (150 Points Total)

<table>
<thead>
<tr>
<th>Required Components</th>
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<tbody>
<tr>
<td><strong>1. Patient Identifying Information, Chief Complaint &amp; HPI:</strong></td>
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<tr>
<td>□ Identifying Information (Age, Ethnicity, Gender)</td>
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<tr>
<td>□ Reason for admission (Chief Complaint, Brief Relevant Medical, Psychiatric, Social, etc. Histories. No unnecessary information included)</td>
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<tr>
<td>□ Brief History of Present Illness (chronological without analysis, use “OPQRST” when appropriate to describe signs and symptoms) [Point Ranges 30–25; 24–13; 12–0]</td>
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<td><strong>2. Exams, Laboratory &amp; Assessments:</strong></td>
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<td>□ Physical Exam (Always include general appearance and vital signs (P, BP, R, T, Pain), Include pertinent elements of exam and any abnormal findings, Remainder may be noted as “noncontributory”</td>
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<td>□ Generally start with basic blood tests first (CBC, Chemistries, Coagulation, Urine, ECG, Imaging, Others), okay to mention specific tests as being “normal” or “unremarkable,” unless need to be monitored □ Consultations or other relevant reports [Point Ranges 30–25; 24–13; 12–0]</td>
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<td><strong>3. Problem List &amp; Pharmaceutical Care Plan:</strong></td>
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<td>□ Brief Problem List (In descending order of severity, use most specific terminology possible, include your understanding of the cause of the problem, do not explain the pathophysiology, Explicitly and clearly state your pharmaceutical care plan (medications, additional assessments, monitoring, and counseling) for the next 24 hours only (do not include anything past 24 hours) □ Pharmaceutical Care Plan includes generic name only…unless Brand is significant, dose, route, frequency □ Information that is not known, but needed, should be explicitly identified [Point Ranges 30–25; 24–13; 12–0]</td>
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<td><strong>4. Relevant and Brief:</strong></td>
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<tr>
<td>□ No background on pathophysiology, disease or medications (you are providing information to expert clinicians that know all of this background) □ Completed within 5 minutes [Point Ranges 20–16; 15–10; 9–0]</td>
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*Comments here and on back: Why Were Points Lost? What Was Done Particularly Well? What Could Be Improved?*
Background:

Each student will individually select one of the 41 new molecular entity or biologic approved during the 2015 and prepare a monograph. Each student must submit the drug that they select to their lab facilitator via email for approval to prevent duplications of drugs within a lab section. The lab facilitator will approve any new molecular entity (NME) or biologic selected by the student on a “first-come, first-served” basis. The monograph should be approximately two pages in length, including reference list, and summarize the important information that every pharmacist or prescriber should know about that medication. This would be representative of what may be provided as a executive summary to a P&T (Pharmacy and Therapeutics) committee or a brief review for your medical team. The student will present this information verbally to the members of the lab section. The lab facilitator will score the verbal presentation and handling of questions. References cited should be copied and attached to the facilitator’s copy of the monograph. After the presentation, helpful suggestions should be incorporated into your handout before submitting it within one week to Canvas.

Each written monograph should roughly correspond to a brief version of the American Hospital Formulary Service format. Not all sections or subsections should be included in a specific monograph.

In particular, some of the information is potentially unavailable for a newly marketed agent. The information should be obtained from primary literature (whenever available), manufacturer-provided “formulary packets,” FDA’s CDER website, and the approved product label (aka the package insert). Try a URL of the form “http://www.BrandNameOfDrug.com/” to find the product label there. Be sure to replace BrandNameOfDrug with the actual product. In case you are wondering why I explicitly included this, I received an email a couple of years ago from a student saying the link didn’t work. I recommended more sleep. So now the link is clearly broken if/when you try it. Additional subsections that are not listed may be used when appropriate. When information that you feel is important to know to successfully use this drug is unavailable, this should be indicated as Not Available.

Sometimes the only publicly available information will be available in a poster presentation at a scholarly meeting or the published abstract of that presentation, prior to the publication in a journal. Sometimes these will be summarized in a newsletter or clipping service shortly after the meeting. Occasionally, the best data may be found in a press release from the drug manufacturer.
Monograph Presentation

or in a required SEC filing. You may be able to locate some of these abstracts or summaries by doing a Google search. The corresponding author on that presentation has an email address and you may be able to obtain a copy of their presentation by requesting it from them. It is occasionally possible to request this material from the manufacturer of the new product. Note that if you suggest or imply that the information is for treatment of a patient and not for development of a monograph, you will likely receive a nice but content-free thank you letter with a copy of the product label. If you do send an email to the corresponding author, don’t refer to yourself as a pharmacy student; you can correctly say that you are with The University of Texas at Austin College of Pharmacy and you are reviewing the drug to develop a monograph.

A brief presentation such as this does not lend itself well to the use of PowerPoint slides or overheads. Therefore, the student is encouraged to include any complicated materials (such as charts, graphs, or diagrams) on the handout. Whenever possible, the material should be presented in bullet point formats or tables, as opposed to paragraphs of text, to improve the “information density” of the handout. Don’t read your handout. Rather, the student should explain the material using the handout to support their presentation.
### Drug Monograph Presentation Evaluation Rubric (150 Points Total)

**Rating Criteria for Each Component:**

- **Excellent:** All Relevant Information Presented Succinctly and Correctly.
- **Very Good:** Didn’t Include or Incorrectly Presented One Required Component.
- **Needs Improvement:** Didn’t Include or Incorrectly Present Multiple Required Components

<table>
<thead>
<tr>
<th>Required Components</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Description of Drug &amp; indications:</strong> ☐ Brief description of drug and FDA-approved or AHFS-accepted indications. ☐ Describe incidence for all indications. ☐ What are existing alternatives?</td>
<td>[Point Ranges 10–8; 7–5; 4–0]</td>
</tr>
<tr>
<td>2. <strong>Pharmacology &amp; Pharmacokinetics:</strong> ☐ MOA, ADME for each indication should be described. ☐ Describe place in therapy.</td>
<td>[Point Ranges 15–11; 10–7; 6–0]</td>
</tr>
<tr>
<td>3. <strong>Dosing &amp; Special Populations:</strong> ☐ Dosing and adjustments needed for safe and effective use in children, adults, elderly, pregnancy, lactation, renal disease, hepatic disease, etc. ☐ Note where information is lacking.</td>
<td>[Point Ranges 10–8; 7–5; 4–0]</td>
</tr>
<tr>
<td>4. <strong>Clinical Efficacy:</strong> ☐ Presentation of sufficient data to determine and report effect size of each specific benefit claimed. Depending on available data, this might include Cohen's d, Hedges g, NNTB, Hazard Ratio, etc. ☐ Measures of statistical significance (p-value and/or confidence intervals) should be presented. ☐ Any data not available should be explicitly identified as unavailable and what sources were searched to try to find the missing data. <strong>Students are not responsible for data that are not available, but they are responsible for trying to find it.</strong></td>
<td>[Point Ranges 15–11; 10–7; 6–0]</td>
</tr>
<tr>
<td>5. <strong>Warnings &amp; Precautions:</strong> ☐ Describe all Warnings and Precautions in the product label and/or Medication Guide that should be reviewed with the patient. ☐ Is there a REMS? If so, what does it require?</td>
<td>[Point Ranges 10–8; 7–5; 4–0]</td>
</tr>
<tr>
<td>6. <strong>Adverse Effects:</strong> ☐ Presentation of sufficient data to determine effect size (NNTH, or similar) of adverse effects. ☐ Measures of statistical significance should be presented (p-values or confidence intervals) if available. ☐ Drug AEs (All CDRAEs or five most common AEs if less than 5 CDRAEs) should be shown as NNTH in a column graph sorted from low to high. CDRAEs are the Common Drug-Related Adverse Effects where the reported incidence is ≥5% in any dose group AND ≥2 times the placebo rate. ☐ Dose-related AEs should be identified.</td>
<td>[Point Ranges 15–11; 10–7; 6–0]</td>
</tr>
<tr>
<td>7. <strong>Drug Interactions:</strong> ☐ Quantify (change in C&lt;sub&gt;max&lt;/sub&gt;, AUC, etc.) all reported interactions by specific drug or by mechanism and differentiate between effects on the drug and from the drug. Include Drug-Drug, Drug-Food, Drug-Disease, Drug-Laboratory, or other interactions. ☐ Identify appropriate amelioration strategies.</td>
<td>[Point Ranges 15–11; 10–7; 6–0]</td>
</tr>
</tbody>
</table>

Revised 01–17–2016
# Drug Monograph Presentation Evaluation Rubric

<table>
<thead>
<tr>
<th>Required Components</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8. Auxiliary Labeling:</strong> List auxiliary labeling (“Take with Food”, “May Impair Driving”, etc.) that should be on the prescription bottle. [Point Ranges 10–8; 7–5; 4–0]</td>
<td></td>
</tr>
<tr>
<td><strong>9. Audiovisual Materials:</strong> □ Slides, handouts, or other materials are provided and support presentation appropriately. □ All required information is in handout or slides. □ Tables, graphs, or diagrams are used creatively in place of text. □ No errors in spelling, grammar, punctuation, sentence structure, etc. [Point Ranges 10–8; 7–5; 4–0]</td>
<td></td>
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<tr>
<td><strong>10. Communication skills:</strong> □ The presentation is logically organized and the information is clearly explained. □ Delivery includes direct eye contact, clarity and proper rate of speech, absence of nervousness and distracting habits, and appropriate terminology and pronunciation. [Point Ranges 10–8; 7–5; 4–0]</td>
<td></td>
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<tr>
<td><strong>11. Demonstration of mastering subject and responses to questions:</strong> □ Able to answer questions in logical fashion and has the ability to think on his or her feet. □ Answers are accurate and correspond with the expected degree of competence. □ Acknowledges when the answer is not known by them at this time. [Point Ranges 10–8; 7–5; 4–0]</td>
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<tr>
<td><strong>12. Connection to Audience:</strong> Student is interactive and maintains eye-contact with entire audience during the presentation. [Point Range 10–0]</td>
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<tr>
<td><strong>13. Professional dress &amp; behavior</strong> [Point Range 10–0]</td>
<td></td>
</tr>
</tbody>
</table>

*Comments here and on back:* Why Were Points Lost? What Was Done Particularly Well? What Could Be Improved?
Background:

Publishing an article, even in a peer reviewed journal, does not necessarily mean that its conclusion is correct or true. Your job in reviewing, summarizing, comparing, and presenting a Journal Club is to distill the important points that will help to guide treatment of patients and present this to your treatment team colleagues (in this exercise, your lab partners).

Evaluation of a randomized controlled trial (RCT) report is made much easier with good tools. There are a large number of papers describing the various evaluation tools that are available [Google Scholar]. For example, the Center for Evidence Based Medicine [CEMB] at Oxford University has useful tools and calculators that you can download and extensive help on how to use them effectively. Oxford University also hosts Bandolier, which is an outstanding (but no longer updated) resource for evidence-based care, particularly background material, in an easily readable format.

Whenever possible, present the information from the article you are reviewing in an appropriate manner, even if the author’s didn’t. See Editors. Measurement Scales and Their Summary Statistics. BMJ 2004;164(2) for some guidelines. You should always report the effect size (number needed to treat to benefit or harm when there are dichotomous outcomes [another calculator], Cohen’s d, Glass’s Δ, or Hedges’ g for parametric outcomes. When possible, you should also include the confidence intervals for the effect size(s) you are reporting. Please do not be dissuaded from the the statistical concepts by the math here. It is only clinically important that you understand the concepts, not the derivation of the equations. There are many calculators available online or downloadable for your computer, smartphone, or tablet that are free and let you easily jump from the raw percentages to understanding.

Transparency

These EMB tools emphasize the need for thoughtful and critical thinking about what the article includes…and what it omits.

Revised 02-03–2016
Authors, like everyone else, always have a viewpoint (or a bias) that they are trying to convince you is correct. Most articles should now contain a small section describing the author’s disclosure of interests. You should immediately be very suspicious of anyone that declares that they have no interests to disclose. At the very least, they are significantly influenced by their employer or the funding source for their research. An author’s interests may or may not intentionally or unintentionally influence their results, but I’d like to know about it to let me decide if I think it might be important. It is up to each reader to decide if the author’s conclusions are an over- or under-interpretation (or even a misinterpretation) of the results. You should always report the funding source for the research reported in that article. See this news article reporting on a controversy that has just erupted due to a failure to disclose interests in a January 14, 2016 article in Cell. The authors reported no conflicts, but their institutions have patents filed on the reported discovery.

Remarkably, in some cases, the abstract will not accurately summarize the article’s results. Be particularly wary of articles that don’t report on their primary outcome, but instead focus on secondary or exploratory outcomes. Only the primary outcome, the one that the study was designed to test, can be truly answered by that study. The other outcomes might be interesting, but are not necessarily as likely to be true. All clinical trials that should be published require that they be registered in a database prior to enrolling the first subject. By far, the most common registry is ClinicalTrials.gov. You should look up the study and see what the original protocol looked like during the interval when patients were being enrolled and if it differs from the published version. This frequently requires that you look at the archived version of the registry entry. One article that a P4 student presented on their rotation reported that it was assigned the registry number “NCT00667745”. Usually, just entering that number in Google will bring up the ClinicalTrials.gov record.

While there is a trend toward improvement, there are still discrepancies between the registry protocol and subsequent the publication. All discrepancies should be reported by you. A report of a discrepancy might be worded as, “While the published study reported the primary outcome was change in blood pressure, the original protocol’s primary outcome reported in ClinicalTrials.gov was reduction in all-cause mortality. All-cause mortality was not reported in this publication.” This is an accurate description of your review. It is also certainly a rebuke of the report if it wasn’t addressed by the authors.

The alarmingly high rate of discrepancies between protocol-defined outcomes and reported outcomes is the focus of a new CEBM website: http://COMPare-trials.org/. This site only focused on the “big five” medical journals (Ann Int Medicine, JAMA, BMJ, Lancet, and NEJM). Since they did so poorly (<14% of studies correctly reported), I’ll be very interested in finding out how the rest of the journals you report on are doing. This is also covered in the Journal Club video. You should report how many outcomes are defined in the registry entry for the dates when they were enrolling subjects (usually ClinicalTrials.gov), how many of these are in the article you are reviewing, and how many other outcomes are reported, but undisclosed as not part of the protocol. See the COMPare-trials.org site for how these are correctly defined if you are confused.

Use of EBM in your routine clinical care will demonstrably improve the outcomes in your patients. These techniques should be used for your other presentations for this lab as well.
Journal Club Presentation

Objectives:

• To provide experience in critically evaluating and concisely summarizing articles using EBM tools
• To encourage students to develop critical reading habits
• To share knowledge on current therapeutic issues

Article Selection:

• Randomized clinical trials (RTCs) of medications on humans published in English in 2015 are required for this course’s Journal Club presentations. For example, this search in PubMed returned 3730 total citations, 3662 have abstracts, 3607 as full text, and 1100 free full text from the publisher. By the end of the year, these numbers will have doubled as entries are added.

• While about 30% of these are available as full text to anyone, you have much greater access using your university library access instead of just PubMed Central. Also, do not forget that you have free access to Get A Scan if you are more than 50 miles from Austin. If you are close to the library, you can even go retro and scan the printed article yourself if there is no PDF available. Don’t have a scanner? What about that camera on your phone? Try it directly or you can get a scanner app (some are free) that will automatically de-skew, correct the contrast, and convert it into a PDF for you. I particularly like Evernote for this lately. You can email the link, or citation if not available full text online, to your section for them to read in advance.

• Notify your lab facilitator via email of your article selection as early as possible so that the facilitator can make sure that only one person is presenting that article to your lab section. In the event that two students wish to do the same article, the first one that asks (by email date and time) will be approved and the second will have to find another article. Your lab facilitator may require earlier article selection.

• While you should not print or copy the whole article for each student in your lab section, everyone needs to read the article before your presentation to permit an informed discussion. Avoid printing on dead trees when possible.

Handout:

• A handout summarizing the pertinent points of the article should be provided in advance to each member of your section for their use during your presentation. The Journal Club template is provided with extensive annotations to guide you and was specifically designed for RCTs, based upon the 25 items in current publication requirements. Your handout should be significantly shorter than the template with the annotations. Much of the purpose of the template is to let you notice what is missing from the article.

✓ Older pharmacists and some faculty were trained with journal club templates and formats that were handed down from before the establishment of publication requirements (original CONSORT publication in 2001) and were therefore incomplete. One of the most difficult tasks you have for the rest of your career is to recognize when something significant has changed and adapt. Learning to keep your balance
under stressful situations is essential. When a updated CONSORT statement is published, a new template will be needed.

✓ During rotations, you will undoubtedly hear that a, “Journal Club handout should not be over,” one page or two, etc. Despite this usually being given as an authoritative sounding commandment, the length of a Journal Club handout was not carved into stone on Mount Sinai. On the other hand, you need to comply with the requirements you are provided during rotations by your current supervisor.

✓ The length in pages of your handout (a PDF and not dead trees hopefully) is no longer relevant. What is critical today is the length of time needed to convey your message. If the handout is complete in one page, that is good. If it were to take five pages to allow you to finish explaining your understanding of the article faster, that too is good.

- Most graphs, charts, or tables in the study should not be copied into the handout. The listener’s are expected have a copy (a PDF is recommended) of the original article that they can refer to easily. If you want to refer to the Inclusion / Exclusion Criteria, don’t copy them, just put in a reference to the information in the article. For example, “See page 613, Table 1.”

- Sometimes, it may be useful to create a new table for the handout showing only a portion or reanalysis (adding your calculation of effect size, adding a comparison to previous literature, etc.) of a table in the paper, including the data that you want to emphasize or contrast. Similarly, graphing data presented in the article in text, or a table, may make it easier to explain an important point.

- Each point presented verbally does not have to be on the handout. Avoid writing full sentences: it is preferable to use graphs, tables, or at least an outline format of bullet points and then discuss them in more detail during the presentation. Don’t Read Your Handout (“boring”). The handout is there to support your presentation…it is not the written form of your presentation. Similarly, you don’t have to discuss in detail everything on your handout, but you should at least introduce it and explain why it is there. For example, you might include a table of previous literature and mention one or two details, but are not planning on discussing all of it.

- The presenter must review prior studies on the same topic to explain how this study fits into the context of the prior literature. Does this article confirm, extend, refute, or confuse your understanding of this topic? This is a critical component of a useful presentation, as it puts the new literature into context with the prior literature. Include the citations (AMA format) of the other literature that you reviewed.

- Be sure that your presentation answers two key questions:
  ✓ What did we know before this article?
  ✓ What did this article contribute that we didn’t know before?

- Submit a copy of your final, edited Journal Club presentation handout to Canvas within one week following each presentation. Please specify one of the three following options:
Journal Club Presentation

- You do not want your name to appear on the Journal Club when used as an example. **This is the default option and if you do not explicitly select one of the other options, this will be your choice.** Your handout will have your name redacted before it is distributed.
- You do permit your name to appear on the Journal Club when used as an example.
- If you do not wish to have your Journal Club, without your name, used as an example for future classes

**Presentation:**

- Each student will give a short (approximately 15 minutes) oral synopsis of the journal article. You should refer to the distributed article or your handout when making detailed points.
- The presenter should be familiar with the study; it is unacceptable to read from a prepared text of the presentation, although referring to notes periodically is acceptable. **Don’t read to your audience.**

**Questions:**

1. After the verbal presentation, other students in your lab section should ask the presenter questions in order to clarify certain points of the trial report or to bring up points for discussion.
2. The presenter should be prepared to answer questions pertaining to the disease states mentioned in the study, other drug therapy of the disease, statistical design, etc. The critique / question / answer period should last approximately 5 minutes.
3. Incorporate useful suggestions into your handout prior to submitting it to Canvas.

**Evaluation:**

A special purpose rubric will be used to assess your Journal Club presentations for this laboratory. Like the template, it is specifically constructed to comply with the the current CONSORT Statement requirements.

FYI: An evaluation form that was approved by the Joint Committee Internship Programs is used on your P4 clinical rotations. This form is attached for your review, but will not be used for this laboratory.
The student addresses the following in their critique:

### Introduction: Background and Objectives

- Objective of the study clearly stated
- Article peer-reviewed prior to publication
- Any information present which suggests bias identified
- Funding disclosed
- Potential conflicts of interest identified
- Introduction provides adequate and current background information
- Recent clinical trials of the same topic identified

#### Score

<table>
<thead>
<tr>
<th>5 = Excellent</th>
<th>4.5 = Very Good</th>
<th>4 = Good</th>
<th>3.5 = Minimal Competency</th>
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<th>2 = Significant Deficits Exist</th>
<th>1 = Unacceptable</th>
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<td>1  2  3  3.5  4  4.5  5</td>
<td>Comments</td>
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</table>

### Study Design and Methods

- Explained and critiqued hypothesis and objectives
- Student clearly and precisely explains study design
- Discussed the target population
- Explained and critiqued methods
- How well were the inclusion and exclusion criteria addressed
- Addressed validity of methodology
- Student interprets statistical tests and analysis

#### Score

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### Results and Data Analysis

- Reviewed patient enrollment
- Discussed efficacy and safety outcomes
- Appropriately described contents in tables, descriptive and inferential statistical methods used and the statistical significance of the study
- Formulated an appropriate conclusion independent of the author’s and was supported by study results

#### Score

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### Conclusions

- Critiqued the author’s discussion
- Discussed the clinical significance of the study
- Identified and analyzed the strengths and weaknesses of the study
- Formulated an appropriate conclusion independent of the author’s and supported by study results
- Student addressed any additional questions that the study raised

#### Score

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### Delivery of Presentation/Handouts

- Presented in a logical, organized sequence
- Was able to work from notes/did not read the presentation verbatim
- Highlighted pertinent information
- Demonstrated an ability to answer questions accurately
- Displayed competent presentation and communication skills
- Used professional terminology, proper rate of speech, direct eye contact
- Facilitated an interactive discussion
- Handout was complete and concise

#### Score

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**Overall Score:** _____

Approved by the Joint Committee on Internship Programs
The Journal Article Citation Goes Here (AMA Style)

The handout is not your presentation. It is only there to supplement the article and support your verbal presentation. Therefore, use bullet points, tables, graphs, diagrams, figures, pictures, etc. Never use sentences if it can be avoided. An audience will always read the handout when it is possible, instead of listening to the presentation.

In general, do not duplicate information that is in the article. You should just reference it in your handout (i.e. “see page xxx”). If something is missing, that fact should be in your handout (i.e. “Not Reported”). You are not responsible for the content or quality of the article (that was the authors’ and editors’ job), just fairly reporting about the article and putting it into context for your audience. Put your version of the information in the handout when you have a different interpretation of the data or have a better way to make a point: e.g. you make a table that shows only four of six columns and only the three of eight rows that are statistically significant. Similarly, if you have value-added information that is not obvious in the article, e.g. creating a graph from a table, including data from a previous study, creating a table showing NNTH instead of AE rates for active and control groups, etc.

In 2015, a Journal Club presentation is limited by time, not the length of the handout! Putting an arbitrary limit on the length of the handout is following a ritual that has been handed down without a second thought. Most people will read this handout on a tablet or computer and never print it. Use as much handout space (one page or five pages) as you need to make your presentation understandable in the limited time you have available.

In the table below, the headings on the right should generally remain, but the material on the right is just to guide your development of your handout. This handout is typically much longer than your handout.

<table>
<thead>
<tr>
<th>Introduction</th>
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<tr>
<td><strong>Context</strong></td>
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**Background**  
If this article one part of a series of publications on the same study, then what was the citation of the main study publication? Note that the prior publications might contain some of the information missing from this article that you should report.

**Registration**  
clinicaltrials.gov (or if other registrar, specify) registration number.  
1. Does this publication match the protocol design in the registration?  
2. Be sure to look at the history of the registration and see what the protocol looked like when they started to enroll (match up the dates). How does that version differ from what was in the article?  
3. If not, where are the discrepancies, and are they discussed in the article? For example, the might mention that they changed the inclusion criteria due to low enrollment after six months.

**Funding**  
Sources of funding and other support (such as supplying drugs, providing facilities or personnel) and role of funders. Did the authors disclose any possible sources of bias?

**Methods**

<table>
<thead>
<tr>
<th>Trial Design</th>
<th>Was this a parallel (most common), crossover, factorial, non-inferiority, or other [example] design?</th>
</tr>
</thead>
</table>

| Randomization Method, & Blinding | 1. How did the investigators assign subjects to groups?  
2. What was the allocation of subjects to groups?  
3. Were they assigned in blocks or stratified?  
4. How did they blind the randomization?  
5. How did they blind the assessments? |
|-------------------------------|-----------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Participants &amp; Setting</th>
<th>Eligibility (Inclusion &amp; Exclusion) criteria for subjects. Settings, dates and locations where the data were collected. Usually, this can be referenced from the handout to the page in the article.</th>
</tr>
</thead>
</table>

| Interventions & Comparators | Describe each intervention and control group (drug, dose, titration, sequence, etc.).  
1. Why were these groups selected (if known)?  
2. Were all of the comparators (active or placebo) indistinguishable?  
3. Were the doses fixed or flexible? If flexible, based upon what criteria? |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Outcomes** | 1. Rationale, study objectives (primary and secondary), and hypotheses.  
2. How were pre-specified primary, secondary, and post-hoc outcome(s) measured?  
3. When they were assessed. Flowchart or grid of assessments by time or visit is helpful if confusing or complicated. |
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<tr>
<td><strong>Sample Size</strong></td>
<td>Each group and total.</td>
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| **Statistical Methods** | 1. Discuss any significant manipulations of raw data (baseline subtracted from later measurements, log-transformed, etc.).  
2. What was there a specific definition of categorical responses that were used, such as cured, remission, response, improved, or failure, etc.). For example, a response might be a 50% reduction from baseline, or a cure might be survival for five years after diagnosis.  
3. What P-value (probability of finding a false positive) was used for statistical significance? Typically, but not necessarily P <0.05.  
4. If any result was not significant, then what was the statistical power (probability of finding a false negative)? Typically, but not necessarily ≥80%.  
5. How were groups compared for primary and secondary outcomes (efficacy and adverse effects)?  
   a. Were the statistical tests appropriate to the type of data and the same as previous similar studies?  
   b. Were they the common tests (have you heard of them before?), if not why were they selected? It is fast and easy to do every test in your stat package and to see if any of them show that the results are significant. This is not acceptable for Primary or Secondary (pre-defined) Outcomes.  
   c. Were raw group means compared or was the baseline subtracted from the later assessment for each patient and then compared?  
6. If more than one primary outcome was claimed, did they correct for multiplicity (use MANOVA, Bonferroni, etc.)?  
7. Were covariates used? Were these preplanned? If pre-defined, this is fine for Primary or Secondary Outcomes, but if not pre-defined, the results reported are really exploratory. For an example of how this could be pre-defined: the study could state that any baseline assessments that were statistically different between the groups would be used as a covariate in subsequent analyses. |
<table>
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<tr>
<th>Results</th>
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| **Participant Flow:** | A diagram is strongly recommended. Most studies will include this.  
1. Were you able to follow every person from all the way from screening to when they left the study and why?  
2. Did they have preplanned interim analyses?  
3. Was the study terminated early? Why? |
| **Baseline Data** | Frequently this is Table 1, showing baseline demographic and clinical characteristics for each group.  
1. Were there any statistical differences between groups? This might be in the text and not the table.  
2. Were any differences compensated for in the main analysis (covaried, etc.)? |
| **Cohorts Analysed** | 1. For each treatment group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups (switching a subject’s treatment assignment is very hard to interpret).  
2. Cohorts generally are one (or more) of the following types for each treatment group.  
   a. Intent to Treat (ITT is generally everyone that received an intervention and has at least one post-intervention observation)  
   b. Modified Intent to Treat (some of the ITT cohort was excluded for some reason. Not a rare occurrence in real studies. What was the reason (this is a potential source of bias)  
   c. Observed Cases (OC is everyone in the study at that time-point)  
   d. Completers (watch out for excessive loss of subjects, particularly in long studies)  
   e. Safety (anyone exposed to an intervention whether or not they has a post-intervention assessment; ≥ITT cohort) |
**Outcomes**

1. For each primary and secondary outcome, results for each group, what kind of comparison [see this], and the estimated effect size (NNTB, Cohen’s d, Hedge’s g, Hazard Ratio, as appropriate) and its precision (such as 95% confidence interval). If you have trouble with the math needed to do these calculations (mostly just simple arithmetic), there are calculators available on the web that will also do the confidence intervals for you [see one of these].

2. Always include the statistical results in a table or text. (For example: Group A (N=12) = 5.92±1.73, Group B (N=12) = 6.08±1.62; z=-2.836, df=2.24, p=0.005.) Frequently, this will be Table 2 in the article. You can refer to that here and not include it, but usually it is better to put in a table here with just a subset of the results. For example, just the significant effects or the Primary Outcome. Alternately, or in addition, present results as a column graph with error bars (it takes some work, but you can do error bars in Excel). Include any post-hoc results (these are all comparisons not explicitly included in the protocol designed before the study began) and any other analyses reported.

3. Remember that only the Primary Outcome is truly tested by a study. Secondary Outcomes are preplanned but the study wasn’t powered to detect them, and everything else is post-hoc (and therefore much less believable because it is much more likely to be a false positive finding).

4. If results are not significant, then post-hoc power should be reported: what was the chance of seeing a statistical difference if there was a real difference (false negative rate)? If a statistical difference was observed, then the power was obviously sufficient. See section on Statistical Methods.

**Adverse Effects**

1. All important harms or unintended (adverse) effects in each group. If possible, present as NNTH, perhaps in a column graph comparing each group.

2. Identify “common drug-related AEs”: those that are ≥5% in any group and twice placebo.

3. Some statisticians will assert that statistical tests should not be performed on adverse effect data as this is not preplanned. Others (including the FDA) will do analysis of this data. In my opinion, numbers are there to be crunched; just be careful with your interpretation of what the statistics might mean.
<table>
<thead>
<tr>
<th><strong>Discussion</strong></th>
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<tbody>
<tr>
<td><strong>Author's Explicit Limitations</strong></td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td><strong>Author's Generalizability</strong></td>
<td>External validity, and applicability of the trial findings</td>
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</table>
| **Reviewer's Interpretation**   | 1. Your opinion of this report’s limitations, generalizability, potential for bias, and conclusion.  
2. Did they report on a study that matched the protocol they originally intended to perform?  
3. Do the outcomes in the clinical trial registry match the reports outcomes, or do they report only significant and favorable post hoc outcomes?  
4. Do you agree with the report’s conclusions? Consider design, prior literature, results, balancing benefits and adverse events.  
5. What do the results tell us now that we didn’t know before this study was performed and how should this information be used in clinical practice? |
| **Citations of Previous Literature Reviewed** | Include some of the previous findings presented in Background / Context section or elsewhere for comparison with current study. |
Journal Club Presentation Evaluation Rubric (150 Points Total)

**Rating Criteria for Each Component:**

**Excellent:** All Relevant Information Presented Succinctly and Correctly.  **Very Good:** Didn’t Include or Incorrectly Presented One Required Component.  **Needs Improvement:** Didn’t Include or Incorrectly Present Multiple Required Components.

<table>
<thead>
<tr>
<th>Required Components</th>
<th>Points</th>
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<tbody>
<tr>
<td>1. Background and Objectives: □ Context □ Background □ Registration □ Funding [Point Ranges 25–20; 20–11; 10–0]</td>
<td></td>
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<tr>
<td>2. Study Design and Methods: □ Trial Design □ Participants &amp; Interventions &amp; Comparators □ Outcomes to be Measured □ Sample Size □ Randomization Method □ Blinding □ Statistical Methods [Point Ranges 25–20; 20–11; 10–0]</td>
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<tr>
<td>3. Results and Data Analysis: □ Participant Flow □ Baseline Data □ Cohorts Analyzed □ Outcomes Reported including Effect Sizes □ Adverse Effects including Effect Sizes [Point Ranges 25–20; 20–11; 10–0]</td>
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<tr>
<td>4. Discussion: □ Author’s Explicit Limitations □ Author’s Generalizability □ Reviewer’s Interpretation □ Citations of Previous Literature Reviewed [Point Ranges 25–20; 20–11; 10–0]</td>
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<tr>
<td>5. Audiovisual materials: □ Slides, handouts, or other materials are provided and support presentation appropriately. □ All required information is in handout or slides. □ When possible, presenter’s materials cite, not duplicate article □ Tables, graphs, or diagrams are used whenever possible in place of text. □ No errors in spelling, grammar, punctuation, sentence structure, etc. [Point Ranges 10–8; 7–5; 4–0]</td>
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<td>6. Communication skills: □ The presentation is logically organized and the information is clearly explained. □ Delivery includes direct eye contact, clarity and proper rate of speech, absence of nervousness and distracting habits, and appropriate terminology and pronunciation. [Point Ranges 10–8; 7–5; 4–0]</td>
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<td>7. Demonstration of mastering subject and responses to questions: □ Able to answer questions in logical fashion and has the ability to think on his or her feet. □ Answers are accurate and correspond with the expected degree of competence. □ Acknowledges when the answer is not known by them at this time. [Point Ranges 10–8; 7–5; 4–0]</td>
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<tr>
<td>8. Connection to Audience: Student is interactive and maintains eye-contact with entire audience during the presentation. [Point Range 10–0]</td>
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<tr>
<td>9. Professional dress &amp; behavior [Point Range 10–0]</td>
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Comments on back: Why Were Points Lost? What Was Done Particularly Well? What Could Be Improved?

Revised 01–17–2016
# Lab Participation Evaluation Score Sheet

(15 points)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Facilitator / Day</th>
<th>Week #</th>
<th>Ratings</th>
<th>Date</th>
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<tbody>
<tr>
<td>Participated in Discussion</td>
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<td>Excellent: ≥ Twice (4–5 points)</td>
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<td>Very Good: Once Only (2–3 points)</td>
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<td>Needs Improvement: Did Not Participate (0–1 point)</td>
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<tr>
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<td>Professional Dress &amp; Behavior</td>
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<td>Role Model (4–5 points)</td>
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<td>Unremarkable (2–3 points)</td>
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<td></td>
<td>Poor Role Model (0–1 point)</td>
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*Revised 12–20–2015*
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**Additional Comments on Student's Behavior (“Why didn’t they get all of the points?”)**

<table>
<thead>
<tr>
<th>Student</th>
<th>Comment</th>
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