# Clerkship Snapshot

<table>
<thead>
<tr>
<th>Week</th>
<th>Monday</th>
<th>Wednesday - Friday</th>
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<tbody>
<tr>
<td>Week 1</td>
<td>- Orientation</td>
<td>- Clinic</td>
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<td></td>
<td>- HDA Check In</td>
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<td>Week 2</td>
<td>- HDA Check In</td>
<td>- Clinic</td>
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<td>- OSCE</td>
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<td>Week 3</td>
<td>- HDA Check In</td>
<td>- Clinic</td>
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<td>- Midrotation Feedback</td>
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<td>Week 4</td>
<td>- HDA Check In</td>
<td>- Clinic</td>
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<td>- Reflection</td>
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<td>Week 5</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; to last day of clerkship: Reading Day (no clinic)</td>
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<td>Last day of the clerkship: Final Exam. (PxDx and fmCases due)</td>
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+ 1 Saturday clinic during the rotation
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I. Introduction

The University of Chicago, Department of Family Medicine welcomes you to the Family Medicine Clerkship. Our goal is to provide you with an exciting and growth-producing educational experience.

This Handbook is designed to help you make the most of this educational venture into the specialty of family medicine. The Handbook will explain what you can expect to learn, what is expected of you, and how you will be graded.

We invite your comments and suggestions now and throughout your clerkship. Our most important goal is to make the Family Medicine Clerkship a stellar educational experience for you and your classmates.

For further information or questions about the Family Medicine Clerkship, or the specialty of family medicine contact:

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II. The Specialty of Family Medicine

WHAT IS FAMILY MEDICINE?
DEFINING THE SPECIALTY

The American Academy of Family Practice defines the specialty of family medicine as centered on lasting, caring relationships with patients and their families. Family physicians integrate the biological, clinical and behavioral sciences to provide continuing and comprehensive health care. The scope of family medicine encompasses all ages, sexes, each organ system and every disease entity. Family physicians provide comprehensive care that includes prevention, acute intervention, chronic disease management, end-of-life care, and coordination of care. Family Medicine physicians also provide personal medical care to people of all socioeconomic strata and in all regions of the United States.

Family Physicians are experts in the complexity of care of patients who have acute and chronic problems and managing them over time with the inclusion of preventive care. Family Physicians believe in the importance of creating and managing partnerships with their patients. The family medicine model of health care is a Patient Centered medical home that provides patients with a personal medical home through which they receive a full range of services within the context of a continuing relationship with their family physician. Creating this family medicine model of care relies on the idea of using a team approach to care, timely access to care and using information systems to advance care. Family Medicine physicians rely increasingly on information systems and electronic medical records to provide assessments, checklists, protocols, and access to patient education and clinical support.

The Future of Family Medicine project has six aims that are crucial for health care. These aims are that health care be: “Safe-avoiding injuries to patients from the care that is intended to help them; Effective-providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit; Patient-centered- Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions; Timely-Reduction of waits and sometimes harmful delays for both those who receive and those who give care; Efficient-Avoiding waste, including waste of equipment, supplies, ideas and energy; Equitable-Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.”

Research shows that countries that emphasize primary care have better health outcomes at lower costs. Recent research has shown that increasing the number of family physicians is associated with significant reductions in hospital readmissions and substantial cost savings. Multiple researchers from various disciplines have found that when people have access to primary care, treatment occurs before more severe problems can develop, patients have fewer emergency room visits, improved detection of and reduction in mortality from several cancers, use fewer tests and spend less money. Access to primary care, especially for the poor, is associated with improved outcomes, better blood pressure control, more complete immunizations, improved dental health, reduced mortality and improved quality of life.

Of the primary care specialties (family medicine, general internal medicine and pediatrics), family physicians provide the most care - managing nearly one-fourth of all primary care visits and can provide more than 90 percent of the health care that patients need throughout their lives. Family physicians also deliver hospital care, perform surgical procedures, work in emergency rooms, provide obstetrical care and take care of newborns. Some family medicine physicians will also go on to do fellowships in Sports Medicine, Geriatrics, Palliative Care, Integrative Medicine, Addiction Medicine, Adolescent Medicine, Obstetrics, International Medicine, Rural Medicine, Preventive Medicine, Faculty Development and Research. Many family medicine physicians
are involved in research that emphasizes practice-based primary care research that improves health care and benefits the health of patients, their families and communities.

**COMMON MEDICAL PROBLEMS ENCOUNTERED BY FAMILY PHYSICIANS**

1. Clinical Preventive Services and Special Assessments
   - Well Child Exams & Normal Pediatric Development
   - Immunizations
   - Psychosocial Risk Factor Assessment in Adolescents
   - Contraception
   - Routine Prenatal Care
   - Pap Smear/Well-Women Exams
   - Preventive Health Examinations
   - Smoking Cessation

2. Evaluation of Common Presenting Signs and Symptoms
   - Abdominal Pain
   - Abnormal Uterine Bleeding
   - Headache
   - Back Pain
   - Dysuria
   - Dizziness
   - Fatigue
   - Rash

3. Chronic Diseases
   - Chronic Allergic Rhinitis
   - Asthma
   - Hypertension
   - Diabetes
   - Coronary Artery Disease
   - Osteoarthritis
   - Chronic Pain Syndromes
   - Depression and Anxiety

4. Acute Illnesses
   - Upper Respiratory Infections & Sinusitis
   - Otitis Media
   - Pharyngitis
   - Gastroenteritis
   - Common Sports Injuries: Ankle Sprains, Knee Pain, etc.

Regardless of your chosen specialty, these topics will be important to you, because they are important to your patients. They are common health concerns no matter what specialty you practice. In addition, if you are in a non-primary care specialty, it is important that you understand when to send patients to see their primary physician for management of a new or ongoing problem; or to follow up on a problem that you have already addressed. You will also learn how to provide useful consultation or management of specific problems as requested by primary care physicians. Also Step 3 of the NBME is based on the broad level of knowledge acquired at the end of a first year in a Family Medicine Residency.
III. The Objectives of Family Medicine

1. Learn how to diagnose and treat common clinical problems confronted by family physicians.
2. Obtain a focused or comprehensive history and physical examination appropriate to the constraints of the encounter and the patient’s presenting complaint.
3. Demonstrate an understanding of basic sciences and their application to the practice of medicine and to medical research.
4. Generate differential diagnoses for patient’s problems, with special consideration of the common disorders that present in a primary care setting.
5. Develop a reasonable evaluation and treatment plan for the patient, taking into account patient preferences, psychological state, cultural background, financial resources and other life circumstances.
6. Describe and research resources important in ensuring patient and community health.
7. Support the importance of being mentors to members of your community.
9. Demonstrate an understanding of mental health issues in primary care.
10. Communicate effectively with patients and their families.
11. Conduct professional relationships with patients, staff and colleagues.
12. Exhibit the highest moral and ethical standards in the care of patients and in their interactions with others.
13. Solve clinical problems by generating clinical questions and answering them with the best evidence through effective searches of electronic databases.
14. Practice efficiently searching electronic databases to find the best available answers to clinical questions.
15. Practice assessing the internal and external validity of resources for answering clinical questions.
16. Demonstrate the ability to apply best evidence (regardless of the level or strength of evidence) to individual patients, taking into account potential biological variability, personal financial issues, patient preferences, cultural issues and access to care considerations. Learn the role and essential characteristics of family physicians.
17. Understand roles of members of health care team and appropriate use of resources.
18. Support the importance of quality and safety as determinants of health care delivery.
19. Understand health care systems and their effect on health care delivery.
IV. Clinical Sites

You will be assigned to either one or two sites for the clinical portion of the rotation. The clinical sites for fourth year students are primarily affiliated with the NorthShore University HealthSystem.

If you are assigned to one site you will probably split your time between two preceptors. Some students will be assigned to two separate practices, and spend two days a week working at each site.

During orientation you will be given information on your site(s), including names of the preceptor(s), addresses and phone numbers, and directions to the office(s) from the University of Chicago. We suggest calling your preceptor(s’)’s offices prior to your first session to confirm the start time for that day.

You will be engaged in clinical activities Tuesday through Friday throughout the rotation as well as one Saturday during the rotation. You may also have an evening clinic, depending on your clinic site. On Mondays, you will be free from clinical duties but will have meetings with Family Medicine EBM Faculty to be arranged by the clerkship coordinator. This day is free to work on an independent project, and you may attend any MS3 didactics. You have no clinical responsibilities on the reading day or the day of the exam.

Make sure to seek out and be open to many types of experiences outside of the ambulatory one you will spend most of your time in. If your preceptor invites you to a practice management meeting, shares their research or volunteer efforts, inpatient rounds or delivering a baby…do not hesitate and participate! You will have a much better idea of what is means to be full scope family medicine physician.
V. Requirements

ATTENDANCE
Students are expected to attend all lectures and meetings as scheduled by the clerkship director. Any scheduled absences must be approved by the clerkship director. Any unforeseen absence must be reported both to the education coordinator and to your preceptor. Absences require remediation at the discretion of the clerkship director. Absences may result in receiving an incomplete grade. Participation and punctuality in lectures and meetings will contribute to your professionalism grade. An important aspect of the Family Medicine Clerkship is timeliness to your clinics as well as completing and submitting all required assignments.

PROFESSIONAL CONDUCT
All University of Chicago standards apply.

COMPLETION OF STUDENT ENCOUNTER LOG
You are also required to complete the Student Encounter Log, which is done through E*Value (PxDx). The Encounter Log helps you track the common diagnoses that we expect you to see on the rotation. You can fulfill a requirement EITHER by seeing a patient with the condition OR by doing an fmCASE on the topic. A completed PxDx log is due on the last day of the rotation. Incomplete or late PxDx logs will affect your clerkship grade.

MIDROTATION FEEDBACK
You will meet with one of the Clerkship Directors on the 3rd Monday of the rotation. Prior to this meeting, you should solicit midrotation feedback from each of your preceptors (ie, during the second week of the rotation). The clerkship directors will review this form with you, as well as the rotation in general.

MS3 LECTURE SCHEDULE
You are welcome to attend and participate in any of the MS3 lectures; however, a complete lecture series may not occur over the month due to the different MS3 calendar. A copy of the current month’s MS3 lecture schedule is included in your packet. If you are interested in attending any of the other topics in other months, please contact us for more information. Handouts from each lecture are on chalk. Topics covered during the MS3 lecture schedule include:

- Adolescent Health
- Behavioral Change: Nutrition and Exercise
- Dermatology
- Diabetes
- Domestic Violence
- Family Planning
- Health Care Maintenance
- Health Care Reform
- Hypertension
- Integrative Medicine
- Prenatal Care
- Sports Medicine

There is no required text for this clerkship. We have collected articles that you can use to prepare for the didactics and clinic. While we do not expect you to read through all of these articles and electronic resources,
you should become familiar with these topics through your clinic experience and didactics. To access some of the more recent articles, you will need to use your Intranet or the Crerar site. Readings are available at:

http://familymedicine.uchicago.edu/Education/FamilyMedicineClerkships/ReadingsResources

Clerkship information, course documents, and handbooks are also available on Chalk and the Family Medicine website at:

http://chalk.uchicago.edu
http://familymedicine.uchicago.edu

COMPLETION OF HELP DESK ANSWER
You are required to complete all HDA assignments, including progress meetings and a final presentation on the last day of the rotation. This project counts for 30% of your total grade.

fmCASES
These online learning modules are very similar to the CLIPP you have or will do on Pediatrics. These replace a textbook and the didactic portion of the M3 curriculum. The cases will provide you with background knowledge on common outpatient conditions and can be used to learn about topics that you may not have a chance to see during the rotation. The first 33 cases listed were created specifically for family medicine.

During this assignment, you are required to complete 18 of the family medicine cases (the first 33). Pediatric (CLIPP) and Internal Medicine (SIMPLE) cases will not count toward the total. 14 of these cases are required:

Required Cases:
Cases 1, 2, 3, 4, 6, 8, 9, 10, 11, 13, 14, 16, 18, and case 25.

Additional Required Cases:
You may choose any of the other four cases created for family medicine (case 1-33) for the remaining four cases. Completing a case in a subject area fulfills the requirement for your student encounter log, so please complete cases in any subject areas required in the encounter log that you have not seen in clinic.

The main page for fmCASES is http://www.med-u.org/
To sign up, go to http://www.med-u.org/support/logging_in

Start with Step 2: register for access using your uchicago email address. You will be able to complete the sign-up with an outside address, but will be removed from the system in a few days. Once you complete Step 2, you should be able to immediately proceed to Step 3 to start the cases. If you have already signed up for CLIPP, you do not need to re-register.

OSCE
There will be an OSCE on the second or third Monday of the rotation. The purpose is to enhance your clinical skills in an ambulatory setting. You can review your materials, including standardized patient feedback, through CPC B-line and can discuss it with the clerkship director during your midrotation meeting. While the primary purpose of the OSCE is to enhance your clinical skills, particularly your ability to complete a focused history and physical, you must achieve minimum scores on both the history/physical standardized patient (SP) checklist and the patient perception questionnaire (PPQ) to complete the rotation. If you do not pass either part, you are required to meet with the clerkship director and retake and successfully pass the OSCE another time it is being offered in the next three months.
The University of Chicago Pritzker School of Medicine

Guiding Principles of Professionalism

Professional Responsibilities

As a medical student and a future physician, I have chosen to pursue a profession which requires personal integrity, compassion, and a constant awareness of the commitment I have made to myself, my parents, and to the other members of the teams with whom I work. Exhibiting personal behaviors consistent with a respect for my chosen profession and having pride in my work are central tenets of professionalism which I will strive to incorporate into my daily life. To demonstrate my commitment to these responsibilities while enrolled at the Pritzker School of Medicine, I will:

1) Seek and accept feedback and constructive instruction from teachers, peers, residents and faculty in order to continually improve my educational experience, knowledge and clinical skills.

2) Commit to the highest standards of competence both for myself and for those with whom I work.

3) Recognize the importance of life-long learning and commit to maintaining competence throughout my medical career.

4) Be mindful of my demeanor, language, and appearance in the classroom, in the presence of patients, and in all health care settings.

5) Be accountable to all members of the Pritzker community, including students, residents, faculty and support staff.

6) Admit to and assume responsibility for mistakes in a mature and honest manner and develop productive strategies for correcting them.

7) Refrain from using illicit substances. Refrain from using alcohol, non-prescription or prescription drugs in a manner that may compromise my judgment or my ability to contribute to safe and effective patient care.

8) Be considerate and respectful of others’ (teachers, peers, residents and faculty) time, rights, values, religious, ethnic and socioeconomic backgrounds, lifestyles, opinions and choices, even when they differ from my own.

9) Meet the expectations for participation and timeliness that are communicated to me by those who teach me.

10) Take an active role in caring for the diverse patient population served by The University of Chicago Medical Center.

11) Recognize my limitations and seek help when my expertise, knowledge, or level of experience is inadequate to handle a situation in the classroom, hospital or research setting.
The University of Chicago Pritzker School of Medicine

Guiding Principles of Professionalism

Professional Relationships

Establishing productive and respectful relationships with patients, faculty, residents, staff and colleagues is an essential component of providing the best possible health care. To strive for professionalism and kindness in all of my daily encounters, I will:

1) Maintain appropriate relationships with patients, teachers, peers, residents and faculty.

2) Treat all members of the UCMC and Pritzker community, patients, and their families with respect, compassion and dignity.

3) Be mindful to avoid intentionally embarrassing or deriding others.

4) Provide feedback to others (both colleagues and superiors) in a constructive manner, with the goal of helping them to improve.

5) Treat those who participate in my education (e.g. standardized patients) with dignity and respect.

6) Actively work to create an atmosphere in classrooms, clinical settings and in laboratories that is conducive to optimal, interactive learning.

7) Help and support my peers during difficult times in their academic, professional and personal lives.

8) Attend to my own physical and emotional well-being.
Guiding Principles of Professionalism

Professional Ethic

Certain personal values and behaviors will be expected of me as a care-giver and as an ambassador of the Pritzker School of Medicine. Through my behaviors, I will demonstrate a commitment to honoring and upholding the expectations of the medical profession, and, in doing so, I will contribute to maintaining society’s trust in it. In particular, I will:

1) Maintain the highest standard of academic and scholarly honesty throughout my medical education, by behaving in a trustworthy manner.

2) Recognize and function in a manner consistent with my role as a student on a team.

3) Maintain a commitment to patient confidentiality, recognizing that patients will trust me with sensitive information.

4) Place my patients’ interests and well-being at the center of my educational and professional behavior and goals.

5) Treat cadaveric and other scientific specimens with respect.

6) Adhere to the standards of the profession as put forth by the American Board of Internal Medicine Physician Charter (Appendix A) whose fundamental principles are social justice, patient autonomy, and the primacy of patient welfare.

7) Learn about and avoid conflicts of interest as I carry out my responsibilities.

8) Contribute to medical knowledge through active scholarship and discovery.
VI. Evaluation

GRADING
Your grade for the clerkship will be determined by:

- Clinical Performance ..................35%
- Professionalism ...........................20%
- Help Desk Answer .....................20%
- Final Examination .......................20%
- Reflection ......................................5%

You must also pass the OSCE to complete the rotation. Your Clinical Preceptors will each complete the Final Student Evaluation form, which is the basis of your grade in the clinical area. The grading scale for the Family Medicine Clerkship is honors, high pass, pass, and fail.

FINAL EXAMINATION
The final exam is given on the last day of the clerkship and is drawn from the required fmCASES. The Education Coordinator notifies you of the room and time and administers the exam. You must score 60% to pass the exam. If you fail the exam, you must retake it. If you fail a second time, you must repeat the entire clerkship.

EVALUATION FORMS
Included on following pages are clinical rating forms that must be completed by your preceptor(s) during your month in Family Medicine. You are responsible for giving the forms to your preceptor to have them completed.

At the end of Week Two: Mid-Rotation Student Evaluation form. At the end of the first two weeks, you should ask your preceptor(s) to complete the Mid-Rotation Student Evaluation form and then meet with you to discuss your progress to date. If you have two preceptors, either preceptor can complete this form, but having both of them complete a midterm evaluation is ideal.

End of rotation: Final Student Evaluation form. Your preceptors will complete the Final Student Evaluation on E*value, which will be available for you to view once you have completed your course evaluation.
**Student Encounter Log**  
**Family Medicine Clerkship**  
**Pritzker School of Medicine**  

Name: ___________________________ Date: ___________________________

This form should be completed on E*value. These are the common conditions and preventive health issues you should be seeing while doing the Family Medicine clerkship. Please complete this form as you see patients during the clerkship. **You must see at least one condition in each subject area** (but don’t need to see them all). If you are unable to see any of these while in clinic, you can complete them by doing the fmCASE on that topic.

At your midterm feedback session, please review this form with your preceptor(s), and make efforts to see patients with the conditions you have not yet encountered during the second half of the rotation.

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<th>SUBJECT AREA</th>
<th>CONDITION</th>
<th>CHECK IF SEEN</th>
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<td><strong>Abdominal Pain</strong></td>
<td>Appendicitis</td>
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<td>Cholecystitis</td>
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<td>Diverticulitis</td>
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<td>Dyspepsia</td>
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<td>Ectopic Pregnancy</td>
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<td>Gastroenteritis</td>
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<td>GERD</td>
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<td>Irritable Bowel Syndrome</td>
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<td>Peptic Ulcer disease</td>
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<td>Urinary Tract infection</td>
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<td><strong>Adult Male Check-Up</strong></td>
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<td><strong>Asthma</strong></td>
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<td><strong>Common Skin Lesions/Rashes</strong></td>
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<td>Actinic Keratosis</td>
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<td>Atopic Dermatitis</td>
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<td>Basal cell carcinoma</td>
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<td>Melanoma</td>
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<td>Scabies</td>
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<td>Seborrhie dermatitis</td>
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<td>Squamous cell carcinoma</td>
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<td>Warts</td>
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<td><strong>Contraception</strong></td>
<td>DepoProvera</td>
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<td>Implanon</td>
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<td>Intrauterine Device</td>
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<td>Oral Contraceptive pills</td>
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<td>Pregnancy Options</td>
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<td></td>
<td>Counseling</td>
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<td><strong>Diabetes Mellitus (Type 2)</strong></td>
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<td><strong>Headache</strong></td>
<td>Brain tumor</td>
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<td></td>
<td>Meningitis</td>
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<td>Migraine</td>
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<td>Sinus</td>
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<td>Subarachnoid hemorrhage</td>
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<td>Tension</td>
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<td><strong>Hyperlipidemia</strong></td>
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<td><strong>Hypertension</strong></td>
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<td><strong>Joint Pain and Injury</strong></td>
<td>Ankle sprain</td>
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<td></td>
<td>Knee pain</td>
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<td>Shoulder injury</td>
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<td><strong>Low Back Pain</strong></td>
<td>Compression fracture</td>
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<td>Herniated disc</td>
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<td>Lumbosacral strain</td>
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<td>Malignant neoplasm</td>
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<td>Spondylolisthesis</td>
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<td><strong>Mental Health</strong></td>
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<td>Depression</td>
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<td><strong>Observed History</strong></td>
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<td><strong>Observed Physical Exam</strong></td>
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<td><strong>Pregnancy</strong></td>
<td>Pregnancy options counseling</td>
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<td>Prenatal care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spontaneous/threatened abortion</td>
<td></td>
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<tr>
<td><strong>Substance use/ dependence/abuse</strong></td>
<td>Alcohol</td>
<td></td>
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<tr>
<td></td>
<td>Illicit drugs</td>
<td></td>
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<tr>
<td></td>
<td>Prescription pain medication</td>
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<tr>
<td></td>
<td>Tobacco</td>
<td></td>
</tr>
<tr>
<td><strong>Upper Respiratory Infections</strong></td>
<td>Acute Rhinosinusitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Common cold</td>
<td></td>
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<tr>
<td></td>
<td>Otitis Media</td>
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<tr>
<td></td>
<td>Pharyngitis</td>
<td></td>
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<tr>
<td><strong>Vaginal discharge</strong></td>
<td>Atropic vaginosis</td>
<td></td>
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<tr>
<td></td>
<td>Bacterial Vaginosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chlamydia</td>
<td></td>
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<td></td>
<td>Gonorrhea</td>
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<tr>
<td></td>
<td>Normal physiological changes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trichomoniasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yeast</td>
<td></td>
</tr>
<tr>
<td><strong>Well Child Exam</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Well Woman Exam</strong></td>
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</tr>
</tbody>
</table>
Midrotation Feedback Report

Student Name: ___________________ Clerkship Name: ________________
Clerkship Period: ________________

This form should be used to facilitate feedback to students:

<table>
<thead>
<tr>
<th></th>
<th>Something to focus on</th>
<th>Doing Well</th>
<th>A particular strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>History &amp; Physical Exams</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Decision-Making</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compassion/Humanism</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professionalism</td>
<td></td>
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</tbody>
</table>

What was done particularly well?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

What would you suggest the student do differently?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

Feedback to Student: ___________________ Date Done: ___________________

Student Signature: _____________________________________
Evaluator Signature: _____________________________________
Family Medicine Student Evaluation

This is a summative evaluation of your Pritzker School of Medicine, University of Chicago Family Medicine student.

<table>
<thead>
<tr>
<th>1.) Medical Knowledge – Students are expected to demonstrate knowledge of evolving clinical and biophysical science.</th>
<th>□ Not observed</th>
<th>□ Sometimes demonstrates understanding of basic fund of knowledge of diseases and pathophysiology. Rarely applies knowledge to specific patient conditions.</th>
<th>□ Usually demonstrates understanding of basic fund of knowledge of diseases and pathophysiology. Often applies knowledge to specific patient conditions.</th>
<th>□ Consistently demonstrates understanding of basic fund of knowledge of diseases and complex cases as well. Consistently applies knowledge to specific patient conditions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exhibits knowledge and applies it to clinical cases.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Comments:

<table>
<thead>
<tr>
<th>2.) History – Students are expected to conduct a focused history of the reason for visit (chief complaint or routine follow up).</th>
<th>□ Not observed</th>
<th>□ Sometimes obtains basic history, often misses important information.</th>
<th>□ Usually obtains basic history. Organized, usually complete, including pertinent ROS. Identifies most patient concerns.</th>
<th>□ Consistently obtains basic history, appropriate and relevant to the chief complaint.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elicits focused and effective history.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Comments:

<table>
<thead>
<tr>
<th>3.) Physical Exam – Students are expected to perform an appropriately focused physical examination, with attention to presenting signs and symptoms.</th>
<th>□ Not observed</th>
<th>□ Sometimes obtains basic focused physical. Frequently demonstrates incorrect physical exam technique. Often misses significant abnormal findings.</th>
<th>□ Usually obtains focused physical, demonstrates correct technique with organization. Complete and usually recognizes abnormal findings.</th>
<th>□ Consistently obtains a thorough and accurate physical exam. Focused on the problem and recognizes abnormal physical exam findings.</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tbody>
</table>

Additional Comments:
4.) Diagnosis – **Students are expected to use appropriate clinical decision making skills to develop an accurate diagnosis and differential of the presenting problems that are commonly encountered in Family Medicine.**

| □ Not observed | □ Sometimes generates a complete differential diagnosis. Includes basic information but rarely analyzes new data. | □ Usually generates a complete differential diagnosis and accurate diagnosis. | □ Consistently generates a complete differential diagnosis and is able to demonstrate clinical reasoning. |

Additional Comments:

5.) Treatment – **Students are expected to outline appropriate treatment plans for a wide range of complaints and illnesses, including primary and secondary prevention measures.**

| □ Not observed | □ Sometimes contributes to treatment plan or management of patients. Plan often neglects important components including education and follow-up. | □ Usually gives treatment plans that are appropriate, complete, timely and contribute to the management of patients. | □ Consistently generates treatment plans that are excellent including follow-up, education and prevention. |

Additional Comments:

6.) Knowledge of psychosocial & family issues – **Students are expected to integrate psychosocial factors (including primary and secondary prevention measures.**

| □ Not observed | □ Sometimes addresses psychosocial and family issues in assessing and treating patients. Underestimates the impact of these issues on patient care. | □ Usually considers psychosocial and family issues in assessing and treating patients. | □ Consistently considers psychosocial and family issues and their impact on patient care, treatment and disease management. |

Additional Comments:

7.) Incorporates health promotion and disease prevention – **Students are expected to incorporate prevention and health maintenance in all patient encounters.**

| □ Not observed | □ Sometimes includes preventive services, does not appreciate the effect of patient’s behaviors on risk of disease and treatment. | □ Usually will identify and include age specific preventive services. | □ Consistently includes prevention, identifies patient’s high risk behaviors and offers counseling. |

Additional Comments:
8.) Intellectual Curiosity – *Students are expected to investigate patient care practices by assessment and evaluation of the medical literature and to demonstrate skills in evidence based medicine.*

<table>
<thead>
<tr>
<th>Grade Level</th>
<th>Performance Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Not observed</td>
<td>□ Sometimes reads; reads only when asked or provided literature. Uses inappropriate sources. Inconsistently applies evidence to patient care.</td>
</tr>
<tr>
<td>□ Usually reads both primary and review literature. Often applies evidence to patient’s problems. Reads up on patient’s problems daily.</td>
<td></td>
</tr>
<tr>
<td>□ Consistently reads primary and review literature. Actively, searches appropriate databases and consistently applies it to patient’s problem. Reads and researches on topics other than the patient’s clinical problems.</td>
<td></td>
</tr>
</tbody>
</table>

*Additional Comments:*

9.) Oral and Written Presentation Skills

<table>
<thead>
<tr>
<th>Grade Level</th>
<th>Performance Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Not observed</td>
<td>□ Sometimes includes basic information. Poorly organized. Student often includes extraneous information. Has difficulty highlighting the pertinent positive and negatives.</td>
</tr>
<tr>
<td>□ Usually oral presentations and written record are organized and thorough. Information is accurate, focused and complete with little extraneous material and focusing on the chief complaint.</td>
<td></td>
</tr>
<tr>
<td>□ Consistently oral presentations and written record are organized and through. Information is accurate, focused and complete. Attending can rely on these presentations and/or written record to contain all relevant material necessary to determine plan of care.</td>
<td></td>
</tr>
</tbody>
</table>

*Additional Comments:*

10.) Demonstrates Reliability and Professional Responsibility

<table>
<thead>
<tr>
<th>Grade Level</th>
<th>Performance Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Not observed</td>
<td>□ Sometimes is able to get tasks completed on time. Has been late to clinic. Sometimes follows through with assigned tasks.</td>
</tr>
<tr>
<td>□ Usually follows through with assigned tasks. Student is on time and usually prepared. Usually dependable and accepts responsibility.</td>
<td></td>
</tr>
<tr>
<td>□ Consistently on time and prepared. Follows through with assigned tasks and often volunteers additional effort with patient care. Readily assumes responsibility.</td>
<td></td>
</tr>
</tbody>
</table>

*Additional Comments:*
### 11.) Educational Attitude – Student’s responsiveness to feedback, adaptability, self-improvement and self-directed learning.

<table>
<thead>
<tr>
<th>Not observed</th>
<th>Sometimes responds appropriately to feedback but will take feedback too personally. Sometimes is engaged in active learning.</th>
<th>Usually open to feedback and constructive criticism. Willing and able to change. Usually is actively engaged in learning.</th>
<th>Consistently does what is required and often seeks additional learning opportunities beyond required levels. Consistently seeks feedback and responds appropriately. Consistently and actively engaged in learning.</th>
</tr>
</thead>
</table>

Additional Comments:

### 12.) Relationships with Patients and Families

<table>
<thead>
<tr>
<th>Not observed</th>
<th>Sometimes shows respect, empathy and compassion. Sometimes solicits the patient’s perspective. Uncomfortable in patient interactions.</th>
<th>Usually demonstrates empathy, respect and compassion. Usually solicits patient’s perspective. Interacts well with patients and families.</th>
<th>Consistently collaborates and/or establishes appropriate relationships with team. Consistently compassionate when interacting with team. Consistently respectful towards team.</th>
</tr>
</thead>
</table>

Additional Comments:

### 13.) Functions Effectively Within Healthcare Team

<table>
<thead>
<tr>
<th>Not observed</th>
<th>Sometimes collaborates and/or establishes appropriate relationships with team. Occasional misunderstanding of student in role of team. Does not consistently communicate effectively with team.</th>
<th>Usually collaborates and/or establishes appropriate relationships with team. Often recognizes and respects roles of all team members.</th>
<th>Consistently collaborates and/or establishes appropriate relationships with team. Consistently compassionate when interacting with team. Consistently respectful towards team.</th>
</tr>
</thead>
</table>

Additional Comments:

Please provide your overall evaluation of this student’s performance.

- Top 20% of students I have worked with. Exceeds all expectations.
- Met most or exceeded all expectations.
- Good solid performance. Needs improvement in a few areas.
- Below acceptable level. Have concerns about Student’s performance.
VII. Help Desk Answers

HelpDesk Answers (HDAs) are brief, structured evidence-based answers to clinical questions written by physicians for physicians. HDAs are 500 to 600 words, drawing from the best available recent evidence including: meta-analyses, evidence-based guidelines, or original research. HDAs are peer reviewed and published in Evidence-Based Practice, a monthly journal produced by the Family Physicians Inquiries Network (FPIN) and distributed to more than 4,000 physicians and libraries, world-wide.

HDA’s:
- Address physician questions on patient care issues
- Use the best available evidence
- Present information in a brief, clinically useful format

Your main assignment outside of clinic will consist of writing an answer to a clinical question related to primary care and of interest to you. You have each Monday free to work on this (or attend any lectures of your choosing). We will meet with you to discuss your progress on this project each week and to discuss your clinical experience. If you have any concerns about the assignment, please let us know as soon as possible so that we can work together to figure out an appropriate solution. If your project is not complete by the last day of the month, you will receive an incomplete in the rotation (notwithstanding any special circumstances, which must be discussed with us in advance.) Failure to complete individual components of the project on time will affect your grade.

More information and examples can be found in the appendices and at http://www.fpin.org → HelpDesk Answers → HDA resources

GOALS FOR THE PROJECT

- Develop search strategy skills
- Learn how to grade the evidence using Levels of Evidence (LOE) and Strength of Recommendations Taxonomy (SORT)
- Interpret and synthesize the evidence and convert research data into user-friendly statistics
- Present your interpretations of research data in clear and concise language

GENERAL TIMELINE FOR THE PROJECT

1st WEEK – Devise your question according to PICO guidelines (see Appendix A). Complete your literature search, (Appendix B) and identify five to six research studies you feel are appropriate. With the Clerkship Directors, select three of these to use for your manuscript and assign Levels of Evidence (LOE) to your selected references (Appendix E). Articles should be original studies, randomized control trials, meta-analyses, or systematic reviews. Review articles and guidelines may not be used though you can utilize these for general background and to find the articles you wish to use.

1st / 2nd WEEK – Read and complete critical appraisal sheets for three articles (Appendix D). These must be turned in with the manuscript.
2\textsuperscript{nd} \textbf{WEEK} – Draft the Answer to your HDA question. (Appendix B). We suggest developing an outline for your manuscript or shaping one paragraph around each study, beginning with the strongest and moving to the least strong.

3\textsuperscript{rd} / 4\textsuperscript{th} \textbf{WEEKS} – Complete the manuscript and submit to course directors by last day of rotation.

4\textsuperscript{th}/LAST \textbf{WEEK} – Present your project in 20’ PowerPoint presentation, using the grading sheet as a guide for what to include in the presentation. Turn in your final draft by the last day of the rotation.
HDA Grading Sheet

Name:           Date of clerkship:

HDA Question:

Case presentation and Clinical Question Points ____/10
- Relevance to family medicine
- Clarity of question/ PICO model

Search Strategy Points ____/20
- Preferential search of high-quality evidence-based sources.
  (DynaMed, Cochrane, Essential Evidence Plus, USPSTF, Trip Database, Healthlinks)
- Appropriate search terms utilized.

Critical Appraisal Points ____/30
- Correct critical appraisal form for treatment, diagnosis, meta-analysis, etc selected.
- Key features and findings of each of three articles, including following elements
  - Detailed description of populations studied, external validity addressed.
  - Clear description of study designs, intervention/comparator if relevant, any internal validity issues.
  - Presentation and explanation of key results including adverse effects (NNT, confidence intervals).
  - Discussion of clinical and statistical significance of results.
  - Patient-oriented and disease-oriented outcomes distinguished.
  - Potential sources of bias, other limitations, strengths assessed.
  - Accurate Levels of Evidence.
- Appropriate synthesis of Evidence-Based Answer with accurate SORT grade.

Organization, clarity, timeliness Points ____/10

Participation in classmates’ presentations Points ____/10

Reviewer: Total points ____/80
VIII. Reflection assignment

Write about an interaction you witnessed between a primary care physician and a consultant that dealt with clinical care. How did the communication occur? What facilitated patient care in this scenario? What impeded it? What might have been done differently? What systematic issues contributed to the situation, either by enabling or by preventing effective patient care? What system solutions have been utilized to manage such issues? Discuss the literature demonstrating effectiveness of such a solution.

Example

A 2 week old infant presented to clinic after being admitted at age 1 week for seizures eventually found to be caused by hypocalcemia related to hypoparathyroidism. I was notified by telephone when the patient was admitted and updated via telephone on discharge that outpatient lab monitoring would be needed. The patient was undergoing endocrinology evaluation to determine the cause of the hypoparathyroidism, and his family preferred to have all required outpatient labs done at our clinic. They presented for follow up to clinic without documentation from the hospital stay. Thus, our knowledge of the inpatient workup, working diagnosis, and prescribed treatments were essential to minimize his risk of recurrent seizures.

Provision of inpatient care by a patient’s primary care physician is becoming less common. Patients at community clinics may experience further fragmentation in care by seeking care at multiple hospitals. Elderly patients may be at higher risk due to frequent hospitalizations and cognitive impairment. Alongside these communication challenges, hospital administrators are placing more emphasis on duration of stays, which often results in completion of diagnostic workups in the outpatient setting.

To optimize patient care with these competing tensions, clear communication between an inpatient team and primary care provider is essential. One such method is routine notification of primary care physicians by the admitting and discharging inpatient teams. While a telephone call is likely most effective, this could also take a paper (or electronic, when possible) form. A retrospective analysis from a primary care office in 2009 showed that 93% of patient admissions (of 120) were documented by receipt of a hospital summary and 6% by phone call\(^1\). While all admissions were eventually communicated, 21% occurred after hospital discharge and 7% after the first follow up visit.

Vulnerable populations are more likely to suffer adverse effects from inadequate interphysician communication, and a good first step to bridging this transition in care is timely notification of primary care providers by the discharging team via a hospital summary such as occurred with my patient. Such a communication should be sought with every inpatient admission with context-specific tools in mind.

COMMON TYPES OF CLINICAL QUESTIONS

**Diagnosis:** How to select and interpret diagnostic tests.

**Therapy:** How to select treatments that do more good than harm and that are worth the efforts and costs involved.

**Prognosis:** How to estimate the clinical course of the condition and anticipate likely related complications.

**Etiology:** How to identify causes for disease (including iatrogenic forms.)

**Screening:** How to screen for a disease effectively in at risk asymptomatic patients.

DISTILLING THERAPY QUESTIONS TO PICO

<table>
<thead>
<tr>
<th>Key Elements</th>
<th>Search Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient / Problem</td>
<td>Patient cohort, age, sex, Problem, disease, or co-existing conditions</td>
</tr>
<tr>
<td>Intervention</td>
<td>Proposed drug, therapy, test, intervention etc. Possible prognostic factor or exposure</td>
</tr>
<tr>
<td>Comparison</td>
<td>Alternative course of action/inaction?</td>
</tr>
<tr>
<td>Outcome</td>
<td>Goal, ie relieve or eliminate the symptoms? Reduce the number of adverse events? Improve function or test scores?</td>
</tr>
</tbody>
</table>

EXAMPLE

<table>
<thead>
<tr>
<th>Key Elements</th>
<th>Search Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient /Problem</td>
<td>Atrial Fibrillation, elderly</td>
</tr>
<tr>
<td>Intervention</td>
<td>Heparin, warfarin</td>
</tr>
<tr>
<td>Comparison</td>
<td>None, placebo</td>
</tr>
<tr>
<td>Outcome</td>
<td>Reduced need for hospitalization Reduced mortality</td>
</tr>
</tbody>
</table>

DISSECTING DIAGNOSTIC QUESTIONS

- What is the condition (disease) of interest?
- What is the test of interest?
- What is the comparison test (gold standard) of interest?
- What do you want to know about the test, e.g. the test related "outcome"?

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Examples of PICO questions:

1. **EBM Question:** Do adults with acute bronchitis who are treated with antibiotics note earlier improvement in clinical symptoms, compared to those who are given inhaled albuterol?
   - **P:** Adults with acute bronchitis
   - **I:** Antibiotics
   - **C:** Inhaled albuterol
   - **O:** Earlier improvement in clinical symptoms

2. **Clinical Description:** 34 year-old Caucasian female is seen for routine annual well-woman exam. Patient has been taking a monophasic OCP continuously to suppress her menstrual cycle for the last 5 months and has no problems related to her current OCP use. She asks whether she could continue this indefinitely.

   Desired information: Is it safe to take continuous OCPs for menstrual suppression?)

   **EBM Question:** In premenopausal women using combined OCPs does continuous cycling increase the risk of long-term complications compared to traditional OCP cycling?
   - **P:** Premenopausal women using combined OCPs
   - **I:** Continuous cycling
   - **C:** Traditional OCP cycling or placebo
   - **O:** Long term safety (endometrial or ovarian ca, breast cancer, cardiovascular, bone, fertility, etc.)

3. **Desired information:** Should I use a statin in a diabetic with LDL < 100?

   **EBM Question:** Do statins improve mortality/morbidity in DM pts without known CAD and w/ LDLs<100 compared to no treatment?
   - **P:** Diabetics (w/o known CAD) w/ LDL <100
   - **I:** Statin
   - **C:** Placebo or no tx
   - **O:** Stroke, MI, CV mortality, or overall mortality (etc)

4. **EBM Question:** In adults with mild depression, is St John’s wort or an SSRI more effective at relieving symptoms?
   - **P:** Adults with minor depression
   - **I:** St. John’s wort
   - **C:** An SSRI
   - **O:** Relief of depression symptoms

5. **EBM Question** (Diagnostic Question): In smokers with cough, does chest x-ray or chest CT have a better positive or negative predictive value for lung cancer?
   - **P:** Adult smokers with cough
   - **I:** Chest x-ray
   - **C:** Chest CT
   - **O:** Positive and negative predictive value for lung cancer
Appendix B: Author Instructions

All HDAs have the following style elements:

Title: Shortened version of the HDA topic question.
Word Count: Total including article and references (count does not include the CME question)

Question

Evidence-Based Answer (35–75 words)
The bottom-line conclusion based upon the best-available evidence. The strength of recommendation (from A to C) should be stated. The grade will be based on the level of evidence of the study or studies most central to the bottom-line conclusion. Each SORT grade must be followed by a brief explanation of why that grade is appropriate.

Evidence Summary (250–350 words)
Concise discussion of each piece of evidence used to answer the question. While the details of a full appraisal are not required (or desired), important validity considerations should be discussed, and the results should be presented with conversions to user-friendly statistics. P values alone are not informative unless the reference number is also provided. Other important information may be considered if truly relevant (large on-going trials, etc.) but a lengthy background section is not appropriate. Present evidence from the best to the least best.

References (100–200 words)
List limited to the most important references, not exceeding five. Key, original research articles from which the evidence is summarized, including meta-analyses should be cited. If more original research articles are summarized than can be cited, a review article citing those research articles may be cited; otherwise, review articles are not be cited. Include levels of evidence with each reference.
Appendix C – Electronic Knowledge Resources

The easiest way to access many of these resources (DynaMed, Trip Database, UpToDate, PubMed) is through the UCMC Intranet for Physicians page or Crerar.

http://www.lib.uchicago.edu/e/crerar/index.html
https://webapps.uchospitals.edu/

The following electronic resources are useful for your HDA and for answering clinical questions that will arise in the course of clinical care.

Databases:

DynaMed
Most easily accessed through Crerar under ‘Science Databases Quicklinks’
Direct link: http://www.ebscohost.com/dynamed
Updated daily, drawing from multiple sources of original literature. Short summaries of new studies are added to each topic, along with direct links and a level of evidence. Comprehensive list of existing studies on a topic, and clearly referenced.

Essential Evidence Plus
http://www.essentialevidence.com
Username: chicago2011
Password: EEP2011
Covers wide variety of clinical topics, including some background information. Summarizes and rates original research. Recommendations are graded based on merits of underlying research. Cross-references Cochrane and various guideline organizations, and also has original topic summaries with explicit evidence ratings.

Cochrane Database of Systematic Reviews
http://summaries.cochrane.org/
The Cochrane Collaboration is a volunteer international group that conducts rigorous systematic reviews. Cochrane conducts exhaustive literature searches then utilizes specific selection criteria and thorough critical appraisal of included studies. Updated quarterly and often considered the highest level of evidence available, especially for questions about therapy. Only covers selected topics and is therefore not comprehensive. Subscriber access to full-text of Cochrane reviews is provided through Crerar.

Healthlinks
http://hsl.uw.edu/ Toolkits Care Provider
University of Washington Health Sciences library site. The ‘Find the Evidence’ heading contains a useful pre-programmed evidence-based filter through PubMed (‘HSL Select Evidence Sources’) as well as a collection of high-quality EBM sites.

U.S. Preventive Services Task Force (USPSTF)
http://www.ahrq.gov/clinic/uspstf.htm
The USPSTF systematically reviews published literature with a focus on screening and prevention. This site provides synopses of recommendations about screening based on these reviews and much more detailed descriptions of the support and rationale for these recommendations. Very rigorous and considered high quality.
Trip Database
http://www.tripdatabase.com/
The Trip Database is a search engine incorporating many high-quality evidence sites (such as Cochrane, Clinical Evidence) as well as occasional nonmedical sources. A wide variety of topics are covered. Search results may be broad and can be filtered by study type (e.g. evidence-based synopses, systematic reviews, e-textbooks) though not by clinical topic.

ACP Journal Club
http://acpjc.acponline.org/index.html
Identifies and analyzes original studies, then includes those that are methodologically sound. Provides abstracts and structured commentary on general internal medicine topic. Driven by new research, and therefore not comprehensive.

UpToDate
http://www.uptodate.com
UpToDate is a well-referenced e-textbook that is peer-reviewed. It is not explicitly evidence based and does not utilize specific methodologic quality criteria. It generally has good coverage of internal medicine topics, and often provides useful clinical overviews.

Other search engines you may try:

1. MEDLINE/PubMed (best for finding specific articles on a topic); Comprehensive, but difficult to search. Used mostly for foreground questions rather than background. Using ‘Clinical Queries’ or ‘Systematic Reviews’ may help narrow findings to clinically relevant ones.

2. Google/Google Scholar: difficult to filter, may or may not find high-quality information

3. National Guideline Clearinghouse
Freely available resource linking to various organizations’ guidelines. http://www.ngc.gov
**Example: Treatment Question**

<table>
<thead>
<tr>
<th>Evidence Table</th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>What:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tabular description of the studies.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compare studies by characteristics.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Why:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevent errors of interpretation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase clarity of analysis.</td>
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<tr>
<td>Plan a statistical analysis.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Citation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Design</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
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</tr>
<tr>
<td>(N in the Group)</td>
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<tr>
<td>Comparison</td>
<td></td>
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<tr>
<td>(N in the Group)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-Up Period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes Measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effect Estimate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(CI or p)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Quality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviewer Comments</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# HDA Evidence Table - Therapy Studies

## Question:

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Citation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>(N in the Group)</td>
<td></td>
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<tr>
<td><strong>Comparison</strong></td>
<td></td>
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<tr>
<td>(N in the Group)</td>
<td></td>
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<tr>
<td><strong>Follow-Up Period</strong></td>
<td></td>
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</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
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<tr>
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<td></td>
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</tr>
<tr>
<td><strong>Study Quality</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reviewer Comments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**CRITICAL REVIEW FORM FOR THERAPY STUDY**

<table>
<thead>
<tr>
<th>Users’ Guide:</th>
<th>Article:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Are the Results Valid?</strong></td>
<td></td>
</tr>
<tr>
<td>Did experimental and control groups begin the study with a similar prognosis?</td>
<td></td>
</tr>
<tr>
<td>Were patients randomized?</td>
<td></td>
</tr>
<tr>
<td>Was randomization concealed?</td>
<td></td>
</tr>
<tr>
<td>Were patients analyzed in the groups to which they were randomized?</td>
<td></td>
</tr>
<tr>
<td>Were patients in the treatment and control groups similar with respect to known prognostic factors?</td>
<td></td>
</tr>
<tr>
<td><strong>Did experimental and control groups retain a similar prognosis after the study started?</strong></td>
<td></td>
</tr>
<tr>
<td>Were 5 important groups (patients, caregivers, collectors of outcome data, adjudicators of outcome, data analysts) aware of group allocation?</td>
<td></td>
</tr>
<tr>
<td>Aside from the experimental intervention, were groups treated equally?</td>
<td></td>
</tr>
<tr>
<td><strong>What are the Results?</strong></td>
<td></td>
</tr>
<tr>
<td>How large was the treatment effect?</td>
<td></td>
</tr>
<tr>
<td>How precise was the treatment effect?</td>
<td></td>
</tr>
<tr>
<td><strong>How can I apply the results to my patient care?</strong></td>
<td></td>
</tr>
<tr>
<td>Were the study patients similar to my patient?</td>
<td></td>
</tr>
<tr>
<td>Were all patient-important outcomes considered?</td>
<td></td>
</tr>
<tr>
<td>Are the likely benefits worth the potential harms and costs?</td>
<td></td>
</tr>
</tbody>
</table>

From McMaster EBCP Workshop/Duke University Medical Center
CRITICAL REVIEW FORM FOR DIAGNOSIS STUDY

Citation:

<table>
<thead>
<tr>
<th>Users’ Guide:</th>
<th>Article:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the Results Valid?</td>
<td></td>
</tr>
<tr>
<td>Did the clinicians face diagnostic uncertainty?</td>
<td></td>
</tr>
<tr>
<td>Was there blind comparison with an independent gold standard?</td>
<td></td>
</tr>
<tr>
<td>Did the results of the test being evaluated influence the decision to perform the gold standard?</td>
<td></td>
</tr>
<tr>
<td>What are the Results?</td>
<td></td>
</tr>
<tr>
<td>What likelihood ratios are associated with the range of possible test results?</td>
<td></td>
</tr>
<tr>
<td>How can I apply the results to my patient care?</td>
<td></td>
</tr>
<tr>
<td>Will the reproducibility of the test result and its interpretation is satisfactory in my setting?</td>
<td></td>
</tr>
<tr>
<td>Are the results applicable to my patient?</td>
<td></td>
</tr>
<tr>
<td>Will the results change my management?</td>
<td></td>
</tr>
<tr>
<td>Will patients be better off as a result of the test?</td>
<td></td>
</tr>
<tr>
<td>Are the benefits worth the potential harms and costs?</td>
<td></td>
</tr>
</tbody>
</table>
The HelpDesk Search Strategy

HelpDesk Answers are intended to provide the same quality response to a clinical question as would be achieved by a search-savvy physician spending an hour or so on the Internet. Authors of HelpDesk Answers are directed to search Healththinks (http://healththinks.washington.edu/search_evidence) and the TRIP database (www.tripdatabase.com). These portals provide access to more than a dozen sources of the highest quality evidence-based clinical information, including BMJ Clinical Evidence, the Guide to Clinical Preventive Services, AHRQ Evidence Reports, and others. Searches of the Cochrane Database, Medline, and other databases, are conducted as needed.

Does early insertion of tympanostomy tubes improve developmental outcomes of children with chronic middle ear effusion?

Evidence-Based Answer

Early placement of tympanostomy tubes for chronic middle ear effusion does not improve developmental outcomes compared with delayed placement in children followed up to 11 years of age. (SOR A, based on a systematic review and RCTs.)

A meta-analysis evaluated the effect of tympanostomy tubes on multiple outcomes in children with otitis media with effusion (OME), including the outcome of language and cognitive development. The investigators searched multiple databases for RCTs comparing early insertion of tympanostomy tubes versus delayed insertion or no insertion and found 4 RCTs (841 preschool-aged children) measuring the outcomes of language and cognitive development. Children were included if OME was present for at least 3 to 4 months. Those randomized to “early” insertion received tubes as soon as possible, whereas children randomized to “delayed treatment” were given tubes if OME persisted for another 6 to 12 months. In all the studies the developmental assessors were blinded to treatment. In pooled results, 24% of the children in the delayed group had surgery and 15% of the children in the early group did not have surgery.

Meta-analysis was performed on the standardized mean differences (SMD) for 3 developmental areas using validated assessment tools. No significant differences were found between the early and delayed groups for language comprehension (SMD 0.09; 95% CI, −0.21 to 0.17), expressive language (SMD 0.02; 95% CI, −0.45 to 0.49), or general development (SMD −0.03; 95% CI, −0.31 to 0.26). Clinical heterogeneity was noted among the studies for populations studied (1 study included children with development problems), the time to follow-up assessment (6–22 months), and the developmental tests used.

The children in 1 of the RCTs were subsequently reassessed at 6 years of age and 9 to 11 years of age. Before 3 years of age, these children had bilateral OME for more than 90 days or unilateral OME for more than 135 days and were randomized to prompt insertion of tympanostomy tubes or delayed insertion 9 months later if still needed. The original assessments of these children at 3 and 4 years of age were included in the above meta-analysis.

Of the 429 children originally enrolled, 395 were reassessed at age 6, and 391 were reassessed at ages 9 to 11. Investigators assessing the patients’ development were blinded to treatment assignment and patients were analyzed in the groups to which they were randomized. In the 213 children randomized to delayed treatment, 79 had tubes inserted by age 6 and 88 by ages 9 to 11. The cognitive, language, speech, and psychosocial development of the children were assessed using 9 tests at 6 years of age, and their literacy, auditory processing, attention, behavior, social skills, and academic achievement were assessed using 12 tests at 9 to 11 years of age.

The studies showed no significant difference in mean developmental test scores between early and delayed insertion of tympanostomy tubes, even though the studies had sufficient power to detect a difference of 0.33 standard deviations on any of the outcome measures.

Stephanie Hemmer, DO
Thomas Satre, MD
U of MN/ST Cloud Hospital FM
ST Cloud, MN

Is cinnamon effective for reducing blood glucose in patients with type 2 diabetes?

Evidence-Based Answer

Use of *Cinnamon cassia*, in addition to usual care, may modestly lower blood glucose in patients with type 2 diabetes (No SOR, due to apparent conflict between RCTs and meta-analysis results.)

Several studies have evaluated the effectiveness of cinnamon in reducing blood glucose in patients with type 2 diabetes mellitus. In a prospective RCT, 60 patients were divided into 6 groups: groups 1–3 received cinnamon at 1, 3, and 6 g/day for 40 days, respectively; groups 4–6 received the corresponding placebo. Baseline fasting blood glucose (FBG) levels ranged from 205 to 300 mg/dL. Patients receiving insulin were excluded from the study.

FBG reductions were noted in all 3 active groups, ranging from 18% to 29% (P<0.05), compared to no significant differences in the placebo groups.

Another RCT included 79 patients with a mean baseline HbA1c of 6.8% and FBG level of 161 mg/dL. Patients continued 1 or more oral antidiabetic medications or diet and received either 1 g aqueous cinnamon extract or placebo 3 times daily with meals for 4 months. Patients using insulin were excluded.

A significant reduction was noted in FBG (10.35% ± 13.2%) compared with the placebo group (3.37% ± 14.2%; P<0.038). Two other smaller RCTs failed to find any effect (TABLE).

In the most recent RCT, 109 patients with an HbA1c >7% were randomized to usual care or usual care plus 1 g cinnamon daily. After 90 days, HbA1c levels decreased in the cinnamon-treated group by an absolute 0.83%, compared with 0.37% in the control group (P<0.04).

In stark contrast, a meta-analysis published as a brief report in 2008 identified 5 clinical trials (n=282) and reported data on FBG and HbA1c levels. One of the trials included adolescents with type 1 diabetes, whereas the rest included patients with type 2 diabetes.

Subgroup analysis for type 2 trials alone (including the 2 later trials above and 2 negative trials not discussed) revealed that cinnamon was associated with a mean FBG reduction of 17.15 mg/dL (95% CI, −47.58 to 13.27) and a HbA1c increase of 0.01% (95% CI, −0.20 to 0.22). The authors concluded that the use of cinnamon did not significantly alter FBG or HbA1c levels.


TABLE

<table>
<thead>
<tr>
<th>Study design, length</th>
<th>Reference</th>
<th>n</th>
<th>Dose (g)</th>
<th>Results</th>
<th>Statistically significant</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT, 3 months</td>
<td>Crawford, 2009</td>
<td>109</td>
<td>1</td>
<td>Lowered HbA1c</td>
<td>Yes</td>
<td>External Validity</td>
</tr>
<tr>
<td>Meta-analysis, 3 months</td>
<td>Baker et al, 2008</td>
<td>282</td>
<td>1–6</td>
<td>No change in FBG or HbA1c</td>
<td>No</td>
<td>May be underpowered. No statistical heterogeneity</td>
</tr>
<tr>
<td>RCT, 3 months</td>
<td>Bealins et al, 2007</td>
<td>58</td>
<td>1</td>
<td>No change in FBG or HbA1c</td>
<td>No</td>
<td>Many exclusions. Baseline HbA1c near goal</td>
</tr>
<tr>
<td>RCT, 4 months</td>
<td>Meng et al, 2006</td>
<td>79</td>
<td>3</td>
<td>Reduced FBG by 10.4%. No effect on HbA1c</td>
<td>Yes</td>
<td>Strong evidence. Moderate effect on FBG</td>
</tr>
<tr>
<td>RCT, 6 weeks</td>
<td>Yansouni-Cox et al, 2006</td>
<td>25</td>
<td>1.5</td>
<td>No change in FBG, insulin, HbA1c, or oral glucose tolerance</td>
<td>No</td>
<td>Good evidence. Men included, Short study duration</td>
</tr>
<tr>
<td>RCT, 40 days</td>
<td>Khan et al, 2003</td>
<td>60</td>
<td>1, 3, or 6</td>
<td>Reduced FBG by 18%–29%; did not measure HbA1c</td>
<td>Yes</td>
<td>Strong effect on FBG</td>
</tr>
</tbody>
</table>

*RCTs conducted in US patients with type 2 diabetes. FBG=fasting blood glucose; HbA1c=glycosylated hemoglobin; RCT= randomized controlled trial.*
**DETERMINING LOEs AND SORs**

Using the Center for Evidence-Based Medicine (CEBM) table below, locate the article’s type of study in the column headings. Within that column, identify the specifics of the study to determine the **Level of Evidence (LOE).** Each article referenced will have its own LOE.

**Oxford Centre for Evidence-based Medicine - Levels of Evidence (March 2009)**
http://www.cebm.net/index.aspx?o=1025  (See notes and glossary on the following pages.)

<table>
<thead>
<tr>
<th>Level</th>
<th>Therapy / Prevention, etiology / Harm</th>
<th>Prognosis</th>
<th>Diagnosis</th>
<th>Differential diagnosis / symptom prevalence study</th>
<th>Economic and decision analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>SR (with homogeneity*) of RCTs</td>
<td>SR (with homogeneity*) of inception cohort studies; CDR validated in different populations</td>
<td>SR (with homogeneity*) of Level 1 diagnostic studies; CDR with 1b studies from different clinical centres</td>
<td>SR (with homogeneity*) of prospective cohort studies</td>
<td>SR (with homogeneity*) of Level 1 economic studies</td>
</tr>
<tr>
<td>1b</td>
<td>Individual RCT (with narrow Confidence Interval )</td>
<td>Individual inception cohort study with &gt; 80% follow-up; CDR validated in a single population</td>
<td>Validating** cohort study with good reference standards; or CDR tested within one clinical centre</td>
<td>Prospective cohort study with good follow-up****</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>1c</td>
<td>All or none§</td>
<td>All or none case-series</td>
<td>Absolute SpPins and SnNouts</td>
<td>All or none case-series</td>
<td>Absolute better-value or worse-value analyses</td>
</tr>
<tr>
<td>2a</td>
<td>SR (with homogeneity*) of cohort studies</td>
<td>SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs</td>
<td>SR (with homogeneity*) of Level &gt;2 diagnostic studies</td>
<td>SR (with homogeneity*) of 2b and better studies</td>
<td>SR (with homogeneity*) of Level &gt;2 economic studies</td>
</tr>
<tr>
<td>2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
<td>Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR or validated on split-samples only</td>
<td>Exploratory** cohort study with good reference standards; CDR after derivation, or validated only on split-sample or databases</td>
<td>Retrospective cohort study, or poor follow-up</td>
<td>Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>2c</td>
<td>&quot;Outcomes&quot; Research; Ecological studies</td>
<td>&quot;Outcomes&quot; Research</td>
<td>Ecological studies</td>
<td>Audit or outcomes research</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>SR (with homogeneity*) of case-control studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td></td>
</tr>
<tr>
<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Non-consistently studied; or without consistently applied reference standards</td>
<td>Non-consistently cohort study, or very limited population</td>
<td>Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Case-series (and poor quality cohort and case-control studies§)</td>
<td>Case-series (and poor quality prognostic cohort studies*** )</td>
<td>Case-control study, poor or non-independent reference standard</td>
<td>Case-series or superseded reference standards</td>
<td>Analysis with no sensitivity analysis</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on economic theory or &quot;first principles&quot;</td>
<td></td>
</tr>
</tbody>
</table>

This table was produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick, in March 2009.
Notes to CEBM table of Medicine Levels of Evidence *(previous page)*:

| *  | By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "*" at the end of their designated level. |
| †  | Clinical Decision Rule. (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category.) |
| ‡  | See note above for advice on how to understand, rate and use trials or other studies with wide confidence intervals. |
| §  | Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it. |
| §§ | By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders. |
| §§§ | Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples. |
| ‡‡ | An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis. |
| ‡‡‡ | Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits. |
| ‡‡‡‡ | Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study. |
| ‡‡‡‡‡ | Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive. |
| ‡‡‡‡‡ | Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'. |
| ‡‡‡‡‡‡ | By poor quality prognostic cohort study we mean one in which sampling was biased in favor of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors. |
| ‡‡‡‡‡‡‡ | Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (for example 1-6 months acute, 1 - 5 years chronic) |
The **Strength of Recommendation** is determined based upon the LOEs of the articles used to determine the Evidence-Based Answer. This is also described as **Grading the Evidence**.

http://www.jfponline.com/Pages.asp?AID=1635 accessed on 5-31-10

**SORT GRADES**

<table>
<thead>
<tr>
<th>Strength of recommendation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recommendation based on consistent and good-quality patient-oriented evidence.*</td>
</tr>
<tr>
<td>B</td>
<td>Recommendation based on inconsistent or limited-quality patient-oriented evidence.*</td>
</tr>
<tr>
<td>C</td>
<td>Recommendation based on consensus, usual practice, opinion, disease-oriented evidence,* or case series for studies of diagnosis, treatment, prevention, or screening</td>
</tr>
</tbody>
</table>

**Definition of ‘Consistency across studies’**

<table>
<thead>
<tr>
<th>Consistent</th>
<th>Most studies found similar or at least coherent conclusions (coherence means that differences are explainable); or if high-quality and up-to-date systematic reviews or meta-analyses exist, they support the recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconsistent</td>
<td>Considerable variation among study findings and lack of coherence; or if high-quality and up-to-date systematic reviews or meta-analyses exist, they do not find consistent evidence in favor of the recommendation</td>
</tr>
</tbody>
</table>

*Patient-oriented evidence measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, and quality of life. Disease-oriented evidence measures intermediate, physiologic, or surrogate endpoints that may or may not reflect improvements in patient outcomes (i.e., blood pressure, blood chemistry, physiologic function, and pathologic findings).


The flow chart on the following pages is extracted from an example on the JFP online web page.
DETERMINING THE STRENGTH OF A RECOMMENDATION BASED ON A BODY OF EVIDENCE

1. Is this a key recommendation for clinicians regarding diagnosis or treatment that merits a label?
   - **NO**: Strength of Recommendation not needed
   - **YES**
     2. Is the recommendation based on patient-oriented evidence (i.e., an improvement in morbidity, cost, mortality, symptoms, or quality of life)?
        - **NO**: Strength of Recommendation = C
        - **YES**
          3. Is the recommendation based on opinion, bench research, a consensus guideline, usual practice, clinical experience, or a case series study?
             - **NO**
               4. Is the recommendation based on 1 of the following?
                  - Cochrane Review with a clear recommendation
                  - USPSTF Grade A recommendation
                  - "Clinical Evidence" rating of "beneficial"
                  - Consistent findings from at least 2 good-quality randomized controlled trials or a systematic review/meta-analysis of same
                  - Validated clinical decision rule in a relevant population
                  - Consistent findings from at least 2 good-quality diagnostic cohort studies or systematic review/meta-analysis of same
                    - **YES**: Strength of Recommendation = A
                    - **NO**: Strength of Recommendation = B
             - **YES**
               5. Strength of Recommendation = A
      - **YES**
        3. Strength of Recommendation = C
CHART B
DETERMINING THE LEVEL OF EVIDENCE FOR AN INDIVIDUAL STUDY

Is the study a key citation for an important point of evidence under discussion?

NO  Level of Evidence not needed

YES

Is the key outcome the study based on patient-oriented evidence (i.e., an improvement in morbidity, mortality, symptoms, or quality of life)?

NO  Level of Evidence = 3

YES

Is the study based on opinion, bench research, a consensus guideline, usual practice, clinical experience, or a case series?

NO

Is the study 1 of the following?
1) SR/meta-analysis of high quality studies with consistent findings?
2) High-quality randomized control trial?
   • Allocation concealed
   • Blinding if possible
   • Intention-to-treat analysis
   • Adequate size
   • Adequate follow-up (>80%)
3) High-quality cohort study for prognosis (prospective with >80% follow-up)?
4) Validated clinical decision rule in a relevant population?
5) High-quality diagnostic cohort study?
   • Adequate size
   • Adequate spectrum of patients
   • Blinding
   • Consistent reference

NO  Level of Evidence = 2

YES  Level of Evidence = 1

Note: The JFP SORT Taxonomy is easily applied by authors and physicians, and explicitly addresses the issue of patient-oriented versus disease-oriented evidence. These SORs also create some limitations. On the JFP website, you can read about the walkover between the two methods of grading the evidence.
http://www.jfponline.com/Pages.asp?AID=1635
Appendix G. EBM Glossary

CLINICALLY MEANINGFUL OUTCOMES

Clinical VERSUS Statistical Significance
In a large study, a small difference may be statistically significant. For example, does a 1- or 2-point difference on a 100-point dementia scale matter to your patients? It is important to ask whether statistically significant differences also are clinically significant. Conversely, if a study finds no difference, it is important to ask whether it was large enough to detect a clinically important difference and if a difference actually existed. A study with too few patients is said to lack the power to detect a difference.

Patient-Oriented Evidence
Patient-oriented evidence (POE) refers to outcomes of studies that measure things a patient would care about, such as improvement in symptoms, morbidity, quality of life, cost, length of stay, or mortality. Essentially, POE indicates whether use of the treatment or test in question helped a patient live a longer or better life.

Disease-Oriented Evidence
Disease-oriented evidence (DOE) refers to the outcomes of studies that measure physiologic or surrogate markers of health. This would include things such as blood pressure, serum creatinine, glycohemoglobin, sensitivity and specificity, or peak flow. Improvements in these outcomes do not always lead to improvements in patient-oriented outcomes such as symptoms, morbidity, quality of life, or mortality.

Relative and Absolute Risk Reduction
Studies often use relative risk reduction to describe results. For example, if mortality is 20 percent in the control group and 10 percent in the treatment group, there is a 50 percent relative risk reduction \([\frac{20 - 10}{20}] \times 100\) percent. However, if mortality is 2 percent in the control group and 1 percent in the treatment group, this also indicates a 50 percent relative risk reduction, although it is a different clinical scenario. Absolute risk reduction subtracts the event rates in the control and treatment groups. In the first example, the absolute risk reduction is 10 percent, and in the second example it is 1 percent. Reporting absolute risk reduction is a less dramatic but more clinically meaningful way to convey results.

Number Needed to Treat/Number Needed to Harm
The absolute risk reduction (ARR) can be used to calculate the number needed to treat, which is … number of patients who need to receive an intervention instead of the alternative for one additional patient to experience an adverse event. The NNH is calculated as: \(\frac{1}{ARI}\), where ARI is absolute risk increase (see NNT). For example, if a drug causes serious bleeding in 2 percent of patients in the treatment group over one year compared with 1 percent in the control group, the number needed to treat to harm is 100 percent \(\div (2\text{ percent} - 1\text{ percent}) = 100\text{ per one year}\). The absolute increase (ARI) is 1 percent.

ADEQUATE COMPARATORS
Bias—Intentional and Unintentional
Unintentional bias is the result of using a weaker study design (e.g., a case series or observational study), not designing a study well (e.g., using too low a dose of the comparator drug), or not executing the study well (e.g.,
making it possible for participants or researchers to determine to which group they are assigned). Intentional bias also exists. Examples of study techniques that are designed to make a favorable result for the study drug more likely include a run-in phase using the active drug to identify compliant patients who tolerate the drug; per protocol rather than intention-to-treat analysis; and intentionally choosing too low a dose of the comparator drug or choosing an ineffective comparator drug.

**Blinding and Allocation Concealment**
Allocation concealment recently has been recognized as an important element of randomized controlled trial design. Allocation is concealed when neither the participants nor the researchers know or can predict to which group in a study (control or treatment) the patient is assigned. Allocation concealment takes place before the study begins, as patients are being assigned. Blinding—concealing the study group assignment from those participating in the study—occurs after the study begins. Blinding should involve the patient, the physicians caring for the patient, and the researcher. It is particularly important that the persons assessing outcomes also are blinded to the patient’s study group assignment.

**VALIDITY**

**External and Internal Validity**
External validity is the extent to which results of a study can be generalized to other persons in other settings, with various conditions, especially "real world" circumstances. Internal validity is the extent to which a study measures what it is supposed to measure, and to which the results of a study can be attributed to the intervention of interest, rather than a flaw in the research design. In other words, the degree to which one can draw valid conclusions about the causal effects of one variable or another.

**Observational vERSUS Experimental Studies**
In an observational study of a drug or other treatment, the patient chooses whether or not to take the drug or to have the surgery being studied. This may introduce unintentional bias. For example, patients who choose to take hormone therapy probably are different from those who do not. Experimental studies, most commonly randomized controlled trials (RCTs), avoid this bias by randomly assigning patients to groups. The only difference between groups in a well-designed RCT is the treatment intervention, so it is more likely that differences between groups are caused by the treatment. When good observational studies disagree with good RCTs, the RCT should be trusted.

**Intention-to-Treat Analysis**
Were the participants analyzed in the groups to which they were assigned originally? This addresses what happens to participants in a study. Some participants might drop out because of adverse effects, have a change of therapy or receive additional therapy, move out of town, leave the study for a variety of reasons, or die. To minimize the possibility of bias in favor of either treatment, researchers should analyze participants based on their original treatment assignment regardless of what happens afterward. The intention-to-treat approach is conservative; if there is still a difference, the result is stronger and more likely to be because of the treatment. Per protocol analysis, which only analyzes the results for participants who complete the study, is more likely to be biased in favor of the active treatment.

**STUDY TYPES**

**Systematic Reviews and Meta-Analyses**
Frequently, there are many studies of varying quality and size that address a clinical question. Systematic reviews can help evaluate the studies by posing a focused clinical question, identifying every relevant study in the literature, evaluating the quality of these studies by using predetermined criteria, and answering the question
based on the best available evidence. Meta-analyses combine data from different studies; this should be done only if the studies were of good quality and were reasonably homogeneous (i.e., most had generally similar characteristics).

Multiple-Treatments Meta-Analysis
A multiple-treatments meta-analysis allows you to compare treatments directly (for example, head-to-head trials) and indirectly (for example, against a first-line treatment). This increases the number of comparisons available and may allow the development of decision tools for effective treatment prioritization.

DIAGNOSTIC TESTING

Sensitivity and specificity
Sensitivity is the percentage of patients with a disease who have a positive test for the disease in question. Specificity is the percentage of patients without the disease who have a negative test. Because it is unknown if the patient has the disease when the tests are ordered, sensitivity and specificity are of limited value. They are most valuable when very high (greater than 95 percent). A highly Sensitive test that is Negative tends to rule Out the disease (SnNOut), and a highly Specific test that is Positive tends to rule In the disease (SpPIn).

Pretest and Post-test Probability
Whenever an illness is suspected, physicians should begin with an estimate of how likely it is that the patient has the disease. This estimate is the pretest probability. After the patient has been interviewed and examined, the results of the clinical examination are used to revise this probability upward or downward to determine the post-test probability. Although usually implicit, this process can be made more explicit using results from epidemiologic studies, knowledge of the accuracy of tests, and Bayes’ theorem. The post-test probability from the clinical examination then becomes the starting point when ordering diagnostic tests or imaging studies and becomes a new pretest probability. After the results are reviewed, the probability of disease is revised again to determine the final post-test probability of disease.

Positive and Negative Predictive Value
Predictive values help interpret the results of tests in the clinical setting. The positive predictive value (PV+) is the percentage of patients with a positive or abnormal test who have the disease in question. The negative predictive value (PV−) is the percentage of patients with a negative or normal test who do not have the disease in question. Although the sensitivity and specificity of a test do not change as the overall likelihood of disease changes in a population, the predictive value does change. For example, the PV+ increases as the overall probability of disease increases, so a test that has a PV+ of 30 percent when disease is rare may have a PV+ of 90 percent when it is common. Similarly, the PV changes with a physician’s clinical suspicion that a disease is or is not present in a given patient.

MISCELLANEOUS

Confidence Intervals and P Values
The P value tells us how likely it is that the difference between groups occurred by chance rather than because of an effect of treatment. For example, if the absolute risk reduction was 4 percent with \( P = .04 \), if the study were done 100 times, the risk reduction would be expected to be caused four times by chance alone. The confidence interval gives a range and is more clinically useful. A 95 percent confidence interval indicates that if the study were repeated 100 times, the study results would fall within this interval 95 times. For example, if a study found that a test was 80 percent specific with a 95 percent confidence interval of 74 to 85 percent, the specificity would fall between 74 and 85 percent 95 times if the study were repeated 100 times.
Sample Size
The number of patients in a study, called the sample size, determines how precisely a research question can be answered. There are two potential problems related to sample size. A large study can give a precise estimate of effect and find small differences between groups that are statistically significant, but that may not be clinically meaningful. On the other hand, a small study might not find a difference between groups (even though such a difference may actually exist and may be clinically meaningful) because it lacks statistical power. The “power” of a study takes various factors into consideration, such as sample size, to estimate the likelihood that the study will detect true differences between two groups.

Odds Ratios and Relative Risk
Observational studies usually report their results as odds ratios or relative risks. Both are measures of the size of an association between an exposure (e.g., smoking, use of a medication) and a disease or death. A relative risk of 1.0 indicates that the exposure does not change the risk of disease. A relative risk of 1.75 indicates that patients with the exposure are 1.75 times more likely to develop the disease or have a 75 percent higher risk of disease. Odds ratios are a way to estimate relative risks in case-control studies, when the relative risks cannot be calculated specifically. Although it is accurate when the disease is rare, the approximation is not as good when the disease is common.

Likelihood Ratios
Likelihood ratios (LRs) correspond to the clinical impression of how well a test rules in or rules out a given disease. A test with a single cutoff for abnormal will have two LRs, one for a positive test (LR+) and one for a negative test (LR–). Tests with multiple cutoffs (i.e., very low, low, normal, high, very high) can have a different LR for each range of results. A test with an LR of 1.0 indicates that it does not change the probability of disease. The higher above 1 the LR is, the better it rules in disease (an LR greater than 10 is considered good). Conversely, the lower the LR is below 1, the better the test result rules out disease (an LR less than 0.1 is considered good).

Permuted block randomization
Simple randomization does not guarantee balance in numbers during a trial. If patient characteristics change with time, early imbalances cannot be corrected. Permuted block randomization ensures balance over time. The basic idea is to randomize each block such that m patients are allocated to A and m to B.