<table>
<thead>
<tr>
<th>Week 1</th>
<th>Monday</th>
<th>Wednesday/Thursday</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Orientation</td>
<td>Clinic</td>
<td>Clinic</td>
</tr>
<tr>
<td></td>
<td>Clinic</td>
<td>Community Site</td>
<td>Community Site</td>
</tr>
<tr>
<td>Week 2</td>
<td>OSCE</td>
<td>Clinic</td>
<td>Clinic</td>
</tr>
<tr>
<td></td>
<td>Advance Care Directives</td>
<td>Community Site</td>
<td>Community Site</td>
</tr>
<tr>
<td></td>
<td>Point of Care Question 1 due</td>
<td>Advance Care Directives</td>
<td>Advance Care Directives</td>
</tr>
<tr>
<td>Week 3</td>
<td>Midrotation Feedback</td>
<td>Clinic</td>
<td>Clinic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Community Site</td>
<td>Community Site</td>
</tr>
<tr>
<td>Week 4</td>
<td>Point of Care Questions 2/3 due</td>
<td>Clinic</td>
<td>Final Exam</td>
</tr>
<tr>
<td></td>
<td>Community Medicine Reflection</td>
<td>Community Site</td>
<td>Advance Care Directives essay due</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thurs: Reading Day</td>
<td>PxDx due</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>fmCases due</td>
</tr>
</tbody>
</table>

+ 1 Saturday clinic during the rotation
Table of Contents

I. INTRODUCTION ____________________________________________ 4

II. THE SPECIALTY OF FAMILY MEDICINE _____________________ 5

III. OBJECTIVES OF FAMILY MEDICINE ________________________ 8

IV. CLINICAL SITES __________________________________________ 9

V. COMMUNITY SERVICE SITES _______________________________ 10

VI. DIDACTICS _______________________________________________ 11

VII. EVIDENCE-BASED MEDICINE CURRICULUM_______________ 12
  Description, Assignments and Resources
  Evaluation Forms for the Clinical Questions Curriculum

VIII. ADVANCED CARE PLANNING ASSIGNMENT ________________ 21

IX. REQUIREMENTS __________________________________________ 23
  Attendance
  Professional Conduct
  Clinical Questions Curriculum Assignments
  Midrotation Feedback
  OSCE
  Observed History and Physical
  fmCASES

X. EVALUATION ______________________________________________ 25
  Grading
  Final Examination / Course Encounter Log
  Student Encounter Log
  Mid-Rotation Student Evaluation Form
  Final Student Evaluation Form
  Principles of Professionalism

APPENDICES ________________________________________________ 38
  A. Constructing a Clinical Question
  B. “SORT” Article
  C. EBM Glossary
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:

Mari Egan, MD, MHPE
Co-Clerkship Director
Director of Medical Student Education
Department of Family Medicine
The University of Chicago
773-834-2850
megan@bsd.uchicago.edu

Sonia Oyola, MD
Co-Clerkship Director
Department of Family Medicine
The University of Chicago
773-702-5509
soyola@bsd.uchicago.edu

Shewanna Wackman
Education Coordinator
Department of Family Medicine
The University of Chicago
773-834-6852
swackman@bsd.uchicago.edu

Alicia Frasz
Education Coordinator, NorthShore
Department of Family Medicine
The University of Chicago
847-657-1801
afrasz@northshore.org

Janice Benson, MD
Vice Chair for Education
Department of Family Medicine
The University of Chicago
847-657-1801
jbenson@northshore.org

Bernard Ewigman, MD, MSPH
Chair
Department of Family Medicine
The University of Chicago
773-834-9852
bewigman@uchicago.edu
II. The Specialty of Family Medicine

WHAT IS FAMILY MEDICINE?
DEFINING THE SPECIALITY

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**—Reducing 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. Objectives of the Family Medicine Clerkship

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.
7. Communicate effectively with patients and their families.
8. Learn the role and essential characteristics of family physicians and the role of health care providers in their team.
9. Describe and research resources important in ensuring patient and community health.
10. Support the importance of being mentors to members of your community.
11. Demonstrate an understanding of mental health issues in primary care.
12. Conduct professional relationships with patients, staff and colleagues.
13. Exhibit the highest moral and ethical standards in the care of patients and in their interactions with others.
14. Solve clinical problems by generating clinical questions and answering them with the best evidence through effective searches of electronic databases.
15. Practice efficiently searching electronic databases to find the best available answers to clinical questions.
16. Practice assessing the internal and external validity of resources for answering clinical questions.
17. 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. 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 include community health centers, private practices, and the NorthShore Family Practice Residency Program.

If you are assigned to one site you will probably split your time with two preceptors. Most students will be assigned to two separate practices, and spend two days a week working at each site as well as one Saturday during the rotation. When rotating at a residency program, you will work with both faculty and residents.

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 three days per week throughout the rotation. You may also have an evening or Saturday clinic, depending on your clinic site. On Mondays, you will return to the University for Clerkship Didactics and small group discussions. The day before your exam is a designated as a reading day. You have no clinical responsibilities this day. You also have no clinical responsibilities 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. Community Service Sites

As a family physician, one of the many important roles we have is as a collaborator with our local, national and global community. It is this collaboration that teaches us how our positive influence need not be contained within the walls of the clinical office but actually extends well beyond and in powerful, meaningful ways. When our work extends outside of these walls, we often reconnect to our purpose and our calling. In addition, by working in the community we have a better understanding of the social and cultural influences on our patients’ health. With this intention the clerkship will be connecting you, one day per week, to one of many community agencies near your clinical site. These agencies were chosen because they represent innovation, creativity and altruism in the truest sense.

You will be devoting one ½ day per week to this endeavor. Each agency has specific needs, programs and projects that you will assist in developing, creating or supporting. The intention is to either create a sustainable project that each student thereafter and the agency can build upon throughout the 3rd year of medicine or enrich an existing agency program.

Community Agencies:

Better Boys Foundation
Health Leads
Howard Brown Health Center
Inspiration Café
Instituto Health Sciences Career Academy
Project Brotherhood
Project Vida
Salvation Army
YWCA

In addition: throughout the year, various Pritzker Medical Student Interest Groups will ask for volunteers as well and you may be able to work with these groups as well.

Community Medicine Reflection

One of the required assignments for this clerkship is to reflect and write about your community medicine selective.

In the reflective portion of the curriculum, you will be asked to reflect on and write about a moment during your community service assignment that you found especially inspiring, thought-provoking or challenging. What was your community site and your project? What were the circumstances of the encounter? Why did the encounter make a lasting impression on you? What will you take way from this community service experience for your future practice? Can you think of anything you (or your community partner) could do to further enrich the services being rendered and the health of the community?

In a session on the final Monday of the rotation, you will be asked to share your writing (it can be your entire piece, a portion or a summary) with others.
VI. Clerkship Didactics

Mondays in the Family Medicine clerkship are for lectures, cases discussions, point of care and clinical question presentations. We will be at the University of Chicago on Mondays and the schedule can go from 7am-6pm. Please plan on being present during these times every Monday. A schedule will be provided to you at the clerkship orientation but changes to the schedule can occur. Please do not schedule any other activities for Mondays. The lectures and case discussions will cover important Family Medicine topics such as:

- Diabetes
- Domestic Violence
- Family Planning
- Health Care Maintenance
- Health Care Reform
- Hypertension
- Integrative Medicine
- Motivational Interviewing
- 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. Please note that some of these articles are required to be read before the corresponding didactic. Other articles are only suggested and are you to use to pursue further knowledge. 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. 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
VII. Evidence-Based Medicine Curriculum

SUMMARY OF LEARNING ACTIVITIES AND ASSIGNMENTS

Point of Care Questions. Complete and turn in a total of 3 Point of Care Question forms on questions that arise in the course of solving problems for patients that you see with your preceptor. You should discuss the questions and answers with your preceptor. The goals of this activity are to familiarize you with different electronic resources that summarize original research and apply information from these sources to patient care. You will email your first POC questions to Shewanna Wackman and then be prepared to present your other two answers at the Point of Care Questions Case Conferences on the fourth Monday of the rotation.

DUE DATES FOR POINT OF CARE ASSIGNMENTS

Second Monday, Point of Care Question Due
- Email one completed point of care clinical question form from your first week of clinic to Shewanna Wackman at swackman@bsd.uchicago.edu.
- You will receive written feedback on this question during the second/third week of the rotation.

Fourth Monday, Point of Care Questions Case Conference
- Bring two completed Point of Care questions to the session on the fourth Monday of the rotation. Each student will briefly (10 minutes) present one answer.

EDUCATIONAL GOALS FOR THE CLINICAL QUESTIONS CURRICULUM

There are three educational goals for the EBM Curriculum.

1. Develop your skills in solving clinical problems by formulating effective questions.

2. Develop your skills in using electronic knowledge resources (EKRs)

3. Learn an effective strategy for mastering content in the domain of expertise of family medicine
DETAILED DESCRIPTION OF THE EVIDENCE-BASED MEDICINE CURRICULUM

Background

The dominant manner in which adults learn is asking questions, and there are few professions that encounter problems that need urgent resolution more than in medicine. This is a primary method by which you will learn for the rest of your career, so it is important to master the technique of doing it well. In addition, learning by solving problems (answering clinical questions) enhances memory retention and the development of clinical judgment.

All physicians have questions about patient care every day. Research has shown that family physicians have an average of three questions for every five patients they see. Answering these questions, and thereby solving their patient’s problems, adds to the knowledge base they need for the commonly seen problems. The assignments for the EBM Curriculum are designed to increase your skills at asking and answering clinical questions as an effective means of learning.

There are six steps involved in effective learning through clinical questions:

1. Ask important questions – Identify questions about real patient problems that need to be solved.
2. Ask clear questions – Formulate your questions clearly so that they are specific, “searchable” and answerable.
3. Use the best resources – Search the appropriate databases; don’t use out of date sources or sources that do not incorporate the most valid and relevant research unless that is the only source available.
4. Read critically – Select, read and critique the highest quality sources; don’t waste your time with inadequate resources (drug reps, un-referenced reviews, textbooks or databases that are poor quality) if high quality information is available.
5. Develop and formulate your answer. Be sure that you actually answer your question and include a brief summary of the evidence that justifies your response.
6. Apply and adapt your answer to your patient and other clients you may encounter with this problem. Recognize that findings from clinical populations may not apply to each individual patient. Use clinical judgment and integrate research findings - don’t apply them without thinking about how each patient differs physiologically, have variations of disease manifestations, co-morbid conditions (unlike many patients enrolled in research studies) or have cultural, psychological or economic considerations that you must take into account. Population based evidence from clinical research provides information to consider, not cookbook answers to follow rigidly.

Your family physician preceptor will identify questions about the patients you see together that you can answer for this assignment. You may identify your own, or you may choose to address a question posed by a patient.
Electronic Knowledge Resources

The easiest way to access many of these resources (e.g., DynaMed, UpToDate, PubMed) is through Crerar (with your cnet ID) or UCMC Intranet for Physicians page.

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

The following electronic resources are useful for answering clinical questions that will arise in the course of clinical care. They each have different strengths and limitations. You should try each of these resources at least once during the rotation. During the point of care and clinical questions discussions, we will discuss which resources you found most useful.

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)
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

**Centre for Health Evidence Users’ Guide**
http://www.cche.net/usersguides/main.asp
This is an online resource which provides a lot of definitions, explanations, statistical formulas (for number needed to treat, etc) that you may want to use in summarizing and interpreting the data from the original research study, systematic review or meta-analysis that you decide to critique for your POC.
**Other Resources**
You may find Fletcher’s Clinical Epidemiology and Medical Statistics at a Glance, the required textbooks for your first year Epidemiology and Clinical Investigation course useful to refresh your memory on specific topic.

**Assignment: Complete four Point of Care Questions Forms (each POC is worth 20 points, first two receive all points if complete, third/fourth graded on quality)**

Answer three questions from practice using the most valid resources—complete a Point of Care Questions form for each of your questions. The purpose of this assignment is to give you practice and feedback on answering questions about the problems of the patients you see with your preceptor.

**Step #1** Identify a question from your patient care, your preceptor, or directly from a patient. Ideally you will look up questions every day in the course of patient care, but you are required to turn in three forms. Question should be labeled by type:
- PROGNOSIS
- DIAGNOSIS
- SCREENING (must do at least one screening question)
- TREATMENT

**Step #2** Modify your question if needed to make it answerable and specific. See Appendix A (Constructing a Clinical Question) for more information about how to make the question manageable for this assignment.

**Step #3** Search the databases, search engines and other sources you have learned about; record which EKRs you have used and try to use all the listed EKRs at least once during the rotation.

**Step #4** Complete a Point of Care Questions Form for each question.

**Step #5** Discuss findings with preceptor after filling out the form.

**Step #6** Turn in one Point of Care Questions on the second Monday of the rotation and two on the fourth Monday of the rotation. Each student will present one of their questions (about 5 minutes) at the session on the fourth Monday.

Be prepared to present the case, your question, your search strategy, the sources you used, which sources you found most helpful, the research studies addressing your question, and how it impacted (or could have impacted) care of the patient. We have included a sample point of care assignment completed by a past student to give you an idea of how to do this assignment.
Evaluation of Your Performance in the EBM Curriculum

The EBM assignments are graded and are worth 10% of your final grade. This assignment includes a grading component for response to classmates’ presentations. Please bring the EBM glossary in the appendix to each EBM session and be prepared to comment on its elements. The template for the point of care assignment follows. You will be graded with the point of care grading sheet for the second and third point of care questions. The first point of care question will receive full credit if complete. They are included to guide the completion of the assignment and presentation.

POINT OF CARE QUESTION FORM

Name of student: 
Name of preceptor:   Date:   Question#
Type of question (circle):  Screening Diagnosis Prognosis Treatment

Step 1. Clinical scenario and question (5 points, for PICO-formatted question, relation to clinical scenario)

Step 2. Search strategy: specify search term/ sites and resulting references used; clearly associate references with search strategy that yielded them (5 points for trying preferred sites, appropriate search terms, and article selection)

Preferred high-quality sites: DynaMed, Cochrane, Essential Evidence Plus, USPSTF, Trip Database, Healthlinks

Others: ACP Journal Club, UpToDate, Google/Google scholar, PubMed (searching under “systematic review” on Healthlinks page, or “Clinical Queries” from main PubMed page may be higher yield)

Step 3. Evidence synopsis from search results—from the study summaries you find in the sites listed in #2, describe the key study features (such as inclusion criteria, intervention, important results) of main articles that would inform patient management. You can copy and paste study summaries from the above references, but please use quotation marks, clearly label source, and then briefly summarize main finding(s) in your own words. It is not necessary to consult the original article. (5 points for correct use of statistics, clear and concise summary of study findings)

Step 4. Application of evidence to your patient (5 points, for your independent interpretation of the studies, the relevance of articles to your question, assessment of applicability of findings to your scenario, accounting for individual patient or community needs in your conclusion, as necessary)
POINT OF CARE QUESTION FORM

Name of student: 
Name of preceptor: 
Date: May 2011 
Question#1

Type of question (circle): Screening Diagnosis Prognosis Treatment

Step 1. Clinical scenario and question (5 points for quality/specificity of question and relation to clinical scenario)

A 35 year old man with hypertension has elevated cholesterol (total cholesterol 290, TG 224, LDL 199, HDL 46) and declines a statin. He is very interested in using “natural” treatments to bring down his cholesterol and mentions that he has been reading about red yeast rice on the internet. Does red yeast rice improve CV outcomes when used to treat hyperlipidemia?

Step 2. Search strategy: specify search term/sites and resulting references used; clearly associate references with search strategy that yielded them. Briefly indicate why you chose to focus on the studies you discuss in Step 3 (5 points for using preferred sites first, appropriate search terms, and appropriate articles)

Preferred high-quality sites: DynaMed, Cochrane, Essential Evidence Plus, USPSTF, Trip database, Healthlinks

Others: ACP Journal Club, UpToDate, Google/Google scholar, PubMed (searching under “systematic review” on Healthlinks page, or “Clinical Queries” from main PubMed page may be higher yield)

Searched DynaMed, USPSTF, Trip for “red yeast rice” and found these references in Trip or DynaMed. No USPSTF recommendations on this subject. Selected RCTs. All looked at patient-oriented outcomes for tolerability of drugs, but only one included patient-oriented outcomes for efficacy (eg, CV events), and the rest focused on lab changes.


Step 3. Evidence synopsis from search results— from the study summaries you find in the sites listed in #2, describe the key study features (such as inclusion criteria, intervention, important results) of main articles that would inform patient management. You can copy and paste study summaries from the above references, but please use quotation marks, clearly label
Red yeast rice is dietary supplement widely for hyperlipidemia. It contains 14 active compounds called monacolins, one of which is chemically identical to lovastatin. For the treatment of dyslipidemia, for both “numbers” improvement (disease-oriented) and actual patient outcomes, there are RCTs looking at both red yeast rice compared to placebo, and red yeast rice compared to the current pharmaceutical standard of care, statins.

A 2010 RCT (identified/summarized through DynaMed- #2) compared the tolerability of red yeast rice and pravastatin in patients unable to tolerate other statins because of myalgias. A total of 43 adults with dyslipidemia and a history of statin discontinuation due to myalgias were randomized to red yeast rice 2,400 mg bid or pravastatin 20 mg bid for 12 weeks. All patients were concomitantly enrolled in a 12-week therapeutic lifestyle change program. There was no significant difference in daily pain severity score, muscle strength, or withdrawal due to myalgia [5% (1/21) in the red yeast rice group and 9% (2/22) in the pravastatin group (P = 0.99)]. The low-density lipoprotein cholesterol level decreased 30% in the red yeast rice group and 27% in the pravastatin group (P not significant acc to DynaMed, values not given for LDL).

Another 2008 RCT (identified/summarized through DynaMed) included patient-oriented outcomes, CV events (3). ~5,000 Chinese patients with a prior MI and baseline tchol 170-250 were randomly assigned either to placebo or to Xuezhikang (XZK), an extract from red yeast Chinese rice, 600 mg bid for an average of 4.5 years. The primary end point was a major coronary event that included nonfatal myocardial infarction and death from coronary heart disease. Frequency of the primary end point was 10.4% in the placebo group and 5.7% in the XZK-treated group, with absolute risk reduction of 4.7% and NNT ~20. All-cause mortality was 5.2% in the XZK group and 7.7% in the placebo group (P=0.0003, NNT 40). CV mortality was 3.8% in the XZK group compared to 5.5% in the placebo group (P=0.005, NNT 59).

Step 4. Application of evidence to your patient (5 points, for your independent interpretation of the studies, the relevance of articles to your question, assessment of applicability of findings to your scenario, accounting for individual patient or community needs in your conclusion).

We counseled the patient that red yeast rice can decrease cholesterol levels and has been shown to improve cardiovascular outcomes, but it is unclear how applicable the results of the Chinese RCT would be to patients in the U.S. We further advised him that small studies have suggested they are well-tolerated.
Criteria for grading questions:

- Formulation of question from clinical scenario (5 points)
- Search strategy including use of preferred sources (5 points)
- Evidence synopsis (5 points)
- Application/relevance of evidence to care of the patient (5 points)

Question 1:
Comments: Points ____/20

Question 2:
Comments: Points ____/20

Question 3:
Comments: Points ____/20

Presentation of POC: Points ____/30
Comments:

Participation in classmates’ presentations: Points ____/10

Total points ____/100
VIII. Advanced Care Planning Assignment

Advance Care Planning Interviews with Older Adult Trained Patients
Instructions for third year medical students

Within your Family Medicine Clerkship, you will be taking part in a pilot curriculum on holding a discussion about advance care planning with an older adult “trained patient.” The curriculum will be centered around an interview with an older adult, designated a “trained patient,” who is part of a pool of volunteers from Montgomery Place Retirement Community trained to participate in these interviews and provide you with feedback on your interviewing skills. These volunteers have completed advance directives with their doctors or the chaplain at Montgomery Place and are enthusiastic about the opportunity to aid in your medical education. Many of these volunteers have also participated in the GATE MS-1 Curriculum on Geriatric Functional History-Taking.

We hope that this experience will help you to become more comfortable with holding a discussion regarding a patient’s end-of-life care preferences. These conversations can be difficult; remember that you are not expected to be proficient by the end of this experience. Nor should you feel the need to give advice about end-of-life care planning during the interviews. Your goal is to acquire experience and become more comfortable discussing end-of-life decisions with an elder, learn about the beliefs, values and preferences for end-of-life care from an older adult, and become more knowledgeable about end-of-life and palliative care options.

Learning Objectives:
By the end of the trained patient experience, you should be able to:
1. Define and differentiate among types of code status, health care proxies, and advance directives in Illinois
2. Utilize effective communication techniques in completing an advance directive discussion with a patient
3. Identify own biases and attitudes toward advance care planning

The tasks you will be asked to perform are as follows.

Before the interview:
1. Complete the University of North Carolina online module on advance care planning. The module should take about 30-45 minutes to complete.
   http://clipper.med.unc.edu/acp/welcome.htm
   a. PLEASE COMPLETE “Attitudes and Beliefs” and “Knowledge Assessment” and CLICK SUBMIT. Correct answers and explanations are provided.

2. Read supplementary materials available on Chalk on advance directives.
   ISMS “A Personal Decision” (mandatory)
   Emanuel “Advance care planning as a process: structuring the discussions in practice” (optional)
3. Watch a 10-minute video demonstration of an interview about advance care planning available on TIME/SPACE and on CHALK.

4. You will receive an email with the date, time, and the name of the trained patient whom you will be interviewing. Montgomery Place Retirement Community is located at 5550 S. South Shore Drive in Hyde Park. It is 1 block due north of the Museum of Science and Industry.

**During the interview:**

1. In groups of two, facilitate a discussion on advance care planning with a “trained patient” in his/her home at Montgomery Place. **Expect the interviews to last roughly one to 1.5 hours; however, you may find that you finish in less time.**

Interview logistics:

- The “trained patient” will provide you with an Advance Care Planning worksheet that will contain questions to help you to guide the discussion. This worksheet will also be available on CHALK; however, you do not need to bring your own copy to the interview.
- You will conclude the interview by asking the trained patient if he/she has completed a Durable Power of Attorney for Health Care. The trained patient will have this form with them, so you can “provide” it; however, you will not be reviewing or filling out the form during the interview.

Home visit recommendations for a smooth and successful interview:

- Be courteous and respectful.
- Be on time.
- Address the “patient” as Mr, Ms, or Mrs. (or Dr.), and ask how he/she prefers to be addressed.
- Dress professionally.
- Introduce yourself with your first and last name.
- Bring hand sanitizer/hand wipes if you intend to shake hands.
- Be sure to tell the “trained patient” the objective of the interview.

2. Following the interview, the “trained patient” will provide verbal feedback and will complete a written evaluation form. You can view this form on CHALK prior to the visit.

**After the interview:**

1. Complete a post-experience survey on e-value.

**Important:** You may take notes on the interview question worksheet provided if you feel you need to; however, please remember to maintain the volunteer’s privacy. These volunteers are graciously agreeing to share their personal experiences and wishes with you, and we want to maintain their confidentiality. Do not include any identifying information in your reflections.

Some of the volunteers may not feel comfortable with you taking notes on your conversation. Ask them at the start of the interview if you may take notes.
IX. Requirements

ATTENDANCE
Students are expected to attend all didactics and other events and activities scheduled by the Clerkship Director with active engagement in all of these activities. Any scheduled absences must be approved by the Clerkship Director. Any unforeseen absence (eg. illness) should be reported to the Clerkship Director and Coordinator as soon as possible. Either type of absence may need to be remediated. You are expected to notify your preceptor of any sessions you will miss. Excessive absences will result in an incomplete. **If you are late or do not participate in required didactics or other activities, your grade will be affected negatively.**

EDUCATIONAL ATTITUDE AND PROFESSIONALISM
Students are expected to be actively engaged in the clerkship curriculum. Participation and intellectual curiosity are important elements in this clerkship. In addition, all University of Chicago professional standards apply. Since there can be varying definitions of unprofessional behavior, these are some examples: texting during didactics, interrupting your classmates or lecturer during discussions, repeated tardiness, inappropriate dress, incomplete assignments, reporting inaccurate work time (either in clinic or with assignment completion), inappropriate communication with patients and preceptors.

POINT OF CARE ASSIGNMENTS
The Point of Care Clinical Questions component is required for completion of your Family Medicine Clerkship.

COMPLETION OF STUDENT ENCOUNTER LOG (PXDX)
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 fmCASEon the topic. A completed PxDx log is due on the last Thursday of the rotation. Tardiness in completing your PxDx or the log being incomplete will impact 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 OSCE and rotation in general.

OSCE
There will be a formative OSCE the second Monday afternoon of the rotation. The purpose of this is to enhance your clinical skills in an ambulatory setting. This is also an opportunity for you to have and observed history and physical. You can review your material through CPC B-line and will discuss it with the Clerkship Directors during your mid-rotation meeting.
OBSERVED HISTORY and PHYSICAL
During the clerkship rotation we ask your preceptors to observe you performing a history and physical. Your preceptor will then fill out an Observed H and P form which is formative and is not included into your final grade.

fmCASES
These online learning modules are very similar to the CLIPP you have or will do on Pediatrics. 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 34 cases listed were created specifically for family medicine.

During this assignment, you are required to complete 10 of the family medicine cases. The modules are case-based learning and reviewing these cases will help you prepare for the NBME shelf exam. Five of the fmCases are required and are listed below:

Required Cases:
Case 1: 45-year-old female annual exam
Case 2: 55-year-old man annual exam
Case 13: 40-year-old male with a persistent cough
Case 14: 35-year-old female with missed period
Case 16: 68-year-old male with skin lesion

Additional Required Cases:
You may choose any of the other cases created for family medicine (case 1-34) for the remaining five 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. All cases need to be completed and checked off by the last day of the clerkship. Failure to complete all 10 cases will affect your clerkship grade.

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.
IX. Evaluation

GRADING
Your grade for the Clerkship consists of:

Clinical Performance__________________________  45%
Point of Care________________________________   10%
Advance Care_____________________________________ 5%
Professionalism_______________________________10%
Educational Attitude (didactics, OSCE)_________________10%
Community Selective participation and reflection________10%
Shelf Examination____________________________10%

SHELF EXAMINATION
The shelf exam, which is given on the last day of the clerkship, will test material that comes from the NBME. The Medical Education Coordinator administers the exam on the last day of the rotation. The room and time for the examination is emailed to you prior to the start of the rotation.

You must score 50% percentile to pass the exam. If you score below this percentile you will need to retake the exam. You will be contacted by the Medical Education Coordinator to reschedule the exam. If you fail the exam a second time, the entire clerkship must be repeated.

Your preceptors will each complete the Final Student Evaluation form, which is the basis of your grade for clinical performance.

The grading scale for the Family Medicine Clerkship is honors, high pass, pass, and fail.

EVALUATION FORMS
Included on the following pages are clinical rating forms that your preceptor will complete.

At the end of Week Two: Mid-Rotation Student Evaluation form. At the end of the first two weeks, you should ask your preceptors 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.

COURSE EVALUATION FORMS
All of these must be complete before your final grade will be released to you; please complete these evaluations in a timely manner so your grade will not be delayed.
At the end of the course, please go to the E*Value site (www.e-value.net) to complete the evaluation forms for the Family Medicine Clerkship. You will need to complete:

1. Lecturers/lectures
2. Clerkship evaluation
3. Mistreatment evaluation
4. Preceptor evaluation
5. the encounter log (PxDx)
6. Advance care directives
7. OSCE
8. Point of Care
9. Community Medicine Selective
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 every one of the 20 diagnosis in the bolded subject area columns.** The second column is examples of some of the diagnosis that might count. 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.

<table>
<thead>
<tr>
<th>SUBJECT AREA</th>
<th>CONDITION</th>
<th>CHECK IF SEEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Pain</td>
<td>Appendicitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cholecystitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diverticulitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dyspepsia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ectopic Pregnancy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gastroenteritis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GERD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irritable Bowel Syndrome</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peptic Ulcer disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urinary Tract infection</td>
<td></td>
</tr>
<tr>
<td>Adult Male Check-Up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Skin Lesions/Rashes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Actinic Keratosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atopic Dermatitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Basal cell carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Melanoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Scabies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seborrheic dermatitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Squamous cell carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Warts</td>
<td></td>
</tr>
<tr>
<td>Contraception</td>
<td>DepoProvera</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implanon</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intrauterine Device</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral Contraceptive pills</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pregnancy Options Counseling</td>
<td></td>
</tr>
<tr>
<td>Diabetes Mellitus (Type 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>Brain tumor</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meningitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Migraine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sinus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subarachnoid hemorrhage</td>
<td></td>
</tr>
<tr>
<td><strong>Hyperlipidemia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Joint Pain and Injury</strong></td>
<td>Ankle sprain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Knee pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shoulder injury</td>
<td></td>
</tr>
<tr>
<td><strong>Low Back Pain</strong></td>
<td>Compression fracture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Herniated disc</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lumbosacral strain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Malignant neoplasm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spondylolisthesis</td>
<td></td>
</tr>
<tr>
<td><strong>Mental Health</strong></td>
<td>Anxiety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td></td>
</tr>
<tr>
<td><strong>Observed History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Observed Physical Exam</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pregnancy</strong></td>
<td>Pregnancy options counseling</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prenatal care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spontaneous/threatened abortion</td>
<td></td>
</tr>
<tr>
<td><strong>Substance use/ dependence/abuse</strong></td>
<td>Alcohol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Illicit drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prescription pain medication</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td></td>
<td>Otitis Media</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharyngitis</td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal discharge</strong></td>
<td>Atropic vaginosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bacterial Vaginosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chlamydia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gonorrhea</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td><strong>Well Woman Exam</strong></td>
<td></td>
<td></td>
</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>
<td></td>
<td></td>
</tr>
</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. When completing this form, please use as comparison, the other Pritzker Family Medicine students you have worked with at the same point in the medical school year.

## 1.) Medical Knowledge – *Students are expected to demonstrate knowledge of evolving clinical and biophysical science.*

<table>
<thead>
<tr>
<th>Exhibits knowledge and applies it to clinical cases.</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>
</table>

*Additional Comments:*

## 2.) History – *Students are expected to conduct a focused history of the reason for visit (chief complaint or routine follow up).*

<table>
<thead>
<tr>
<th>Elicits focused and effective history.</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>
</table>

*Additional Comments:*

## 3.) Physical Exam – *Students are expected to perform an appropriately focused physical examination, with attention to presenting signs and symptoms.*

<table>
<thead>
<tr>
<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>
</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.

<table>
<thead>
<tr>
<th>Observation Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not observed</td>
<td>□ Not observed</td>
</tr>
<tr>
<td>Sometimes</td>
<td>□ Sometimes generates a complete differential diagnosis. Includes basic information but rarely analyzes new data.</td>
</tr>
<tr>
<td>Usually</td>
<td>□ Usually generates a complete differential diagnosis and accurate diagnosis.</td>
</tr>
<tr>
<td>Consistently</td>
<td>□ Consistently generates a complete differential diagnosis and is able to demonstrate clinical reasoning.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Observation Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not observed</td>
<td>□ Not observed</td>
</tr>
<tr>
<td>Sometimes</td>
<td>□ Sometimes contributes to treatment plan or management of patients. Plan often neglects important components including education and follow-up.</td>
</tr>
<tr>
<td>Usually</td>
<td>□ Usually gives treatment plans that are appropriate, complete, timely and contribute to the management of patients.</td>
</tr>
<tr>
<td>Consistently</td>
<td>□ Consistently generates treatment plans that are excellent including follow-up, education and prevention.</td>
</tr>
</tbody>
</table>

**Additional Comments:**

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

<table>
<thead>
<tr>
<th>Observation Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not observed</td>
<td>□ Not observed</td>
</tr>
<tr>
<td>Sometimes</td>
<td>□ Sometimes addresses psychosocial and family issues in assessing and treating patients. Underestimates the impact of these issues on patient care.</td>
</tr>
<tr>
<td>Usually</td>
<td>□ Usually considers psychosocial and family issues in assessing and treating patients.</td>
</tr>
<tr>
<td>Consistently</td>
<td>□ Consistently considers psychosocial and family issues and their impact on patient care, treatment and disease management.</td>
</tr>
</tbody>
</table>

**Additional Comments:**

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

<table>
<thead>
<tr>
<th>Observation Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not observed</td>
<td>□ Not observed</td>
</tr>
<tr>
<td>Sometimes</td>
<td>□ Sometimes includes preventive services, does not appreciate the effect of patient’s behaviors on risk of disease and treatment.</td>
</tr>
<tr>
<td>Usually</td>
<td>□ Usually will identify and include age specific preventive services.</td>
</tr>
<tr>
<td>Consistently</td>
<td>□ Consistently includes prevention, identifies patient’s high risk behaviors and offers counseling.</td>
</tr>
</tbody>
</table>

**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></th>
<th>□ Not observed</th>
<th>□ Sometimes reads; reads only when asked or provided literature. Uses inappropriate sources. Inconsistently applies evidence to patient care.</th>
<th>□ Usually reads both primary and review literature. Often applies evidence to patient’s problems. Reads up on patient’s problems daily.</th>
<th>□ 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.</th>
</tr>
</thead>
</table>

*Additional Comments:*

9.) Oral and Written Presentation Skills

<table>
<thead>
<tr>
<th></th>
<th>□ Not observed</th>
<th>□ Sometimes includes basic information. Poorly organized. Student often includes extraneous information. Has difficulty highlighting the pertinent positive and negatives.</th>
<th>□ 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.</th>
<th>□ 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.</th>
</tr>
</thead>
</table>

*Additional Comments:*

10.) Demonstrates Reliability and Professional Responsibility

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

- 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.
Evaluation of Observed History and Physical Examination

Student:_______________________________________________________________________
Preceptor:_____________________________________________________________________

Instructions
Based upon your observation of the interview and physical exam performed by this student, please value the interview and physical examination skills using the following criteria. Please provide written comments to explain your scores.

<table>
<thead>
<tr>
<th>History-Taking Skills</th>
<th>Unacceptable</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Establishing and maintaining rapport.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>2. Taking focused history of present illness.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>3. Obtaining relevant past medical history.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>4. Obtaining appropriate social and family history.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>5. Making use of good verbal and non-verbal communications.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>6. Controlling the flow of the interview.</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Comments to explain scores:

<table>
<thead>
<tr>
<th>Physical Examination Skills</th>
<th>Unacceptable</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Performing maneuvers appropriate to patient problem.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>8. Sequencing maneuvers logically.</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>10. Eliciting abnormal findings.</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Comments to explain scores:
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.
The University of Chicago Pritzker School of Medicine
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.
APPENDICES

Appendix A. Constructing a Clinical Question

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.)

**Prevention**

**Cost:** Economic and decision analyses. What is the most cost effective alternative?

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</td>
</tr>
<tr>
<td></td>
<td>Problem, disease, or co-existing conditions</td>
</tr>
<tr>
<td>Intervention</td>
<td>Proposed drug, therapy, test, intervention etc.</td>
</tr>
<tr>
<td></td>
<td>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?</td>
</tr>
<tr>
<td></td>
<td>Reduce the number of adverse events?</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>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"?
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 symptom

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. 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, ESRD, 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 mild 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. SORT Article

Strength of Recommendation Taxonomy (SORT): A Patient-Centered Approach to Grading Evidence in the Medical Literature

MARK H. EBELL, M.D., M.S., Michigan State University College of Human Medicine, East Lansing, Michigan
JAY SIWEK, M.D., Georgetown University Medical Center, Washington, D.C.
BARRY D. WEISS, M.D., University of Arizona College of Medicine, Tucson, Arizona
STEVEN H. WOOLEE M.D., M.P.H., Virginia Commonwealth University School of Medicine, Richmond, Virginia
JEFFREY SUSMAN, M.D., University of Cincinnati College of Medicine, Cincinnati, Ohio
BERNARD EWIGMAN, M.D., M.P.H., University of Chicago, Pritzker School of Medicine, Chicago, Illinois
MARIJOS BOWMAN, M.D., M.P.A., University of Pennsylvania Health System, Philadelphia, Pennsylvania

A large number of taxonomies are used to rate the quality of an individual study and the strength of a recommendation based on a body of evidence. We have developed a new grading scale that will be used by several family medicine and primary care journals (required or optional), with the goal of allowing readers to learn one taxonomy that will apply to many sources of evidence. Our scale is called the Strength of Recommendation Taxonomy. It addresses the quality, quantity, and consistency of evidence and allows authors to rate individual studies or bodies of evidence. The taxonomy is built around the information mastery framework, which emphasizes the use of patient-oriented outcomes that measure changes in morbidity or mortality. An A-level recommendation is based on consistent and good-quality patient-oriented evidence; a B-level recommendation is based on inconsistent or limited-quality patient-oriented evidence; and a C-level recommendation is based on consensus, usual practice, opinion, disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening. Levels of evidence from 1 to 3 for individual studies also are defined. We hope that consistent use of this taxonomy will improve the ability of authors and readers to communicate about the translation of research into practice. (Am Fam Physician 2004;69:548-56. Copyright© 2004 American Academy of Family Physicians.)

R eview articles (or overviews) are highly valued by physicians as a way to keep up-to-date with the medical literature. Sometimes, though, these articles are based more on the authors' personal experience, anecdotes, or incomplete surveys of the literature than on a comprehensive collection of the best available evidence. As a result, there is an ongoing effort in the medical publishing field to improve the quality of review articles through the use of more explicit grading of the strength of evidence on which recommendations are based.1-4

Several journals, including American Family Physician and The Journal of Family Practice, have adopted evidence-grading scales that are used in some of the articles published in those journals. Other organizations and publications also have developed evidence-grading scales. The diversity of these scales can be confusing for readers. More than 100 grading scales are in use by various medical publications.5 A level B recommendation in one journal may not mean the same thing as a level B recommendation in another. Even within journals, different evidence-grading scales sometimes are used in separate articles within the same issue. Journal readers do not have the time, energy, or interest to interpret multiple grading scales, and more complex scales are difficult to integrate into daily practice.

Therefore, the editors of the U.S. family medicine and primary care journals (i.e., American Family Physician, Family Medicine, The Journal of Family Practice, Journal of the American Board of Family Practice, and BMJ-USA) and

See editorial on page 483.

Downloaded from the American Family Physician Web site at www.aafp.org/afp. Copyright© 2004 American Academy of Family Physicians. For the private, noncommercial use of one individual user of the Web site. All other rights reserved.
the Family Practice Inquiries Network (FPIN) came together to develop a unified taxonomy for the strength of recommendations based on a body of evidence. The new taxonomy should: (1) be uniform in most family medicine journals and electronic databases; (2) allow authors to evaluate the strength of recommendation of a body of evidence; (3) allow authors to rate the level of evidence for an individual study; (4) be comprehensive and allow authors to evaluate studies of screening, diagnosis, therapy, prevention, and prognosis; (5) be easy to use and not too time-consuming for authors, reviewers, and editors who may be content experts but not experts in critical appraisal or clinical epidemiology; and (6) be straightforward enough that primary care physicians can readily integrate the recommendations into daily practice.

Definitions
A number of relevant terms must be defined for clarification.

Disease-Oriented Outcomes. These outcomes include intermediate, histopathologic, physiologic, or surrogate results (e.g., blood sugar, blood pressure, flow rate, coronary plaque thickness) that may or may not reflect improvement in patient outcomes.

Patient-Oriented Outcomes. These are outcomes that matter to patients and help them live longer or better lives, including reduced morbidity, reduced mortality, symptom improvement, improved quality of life, or lower cost.

Level of Evidence. The validity of an individual study is based on an assessment of its study design. According to some methodologies,6 levels of evidence can refer not only to individual studies but also to the quality of evidence from multiple studies about a specific question or the quality of evidence supporting a clinical intervention. For purposes of maintaining simplicity and consistency in this proposal, we use the term "level of evidence" to refer to individual studies.

Strength of Recommendation. The strength (or grade) of a recommendation for clinical practice is based on a body of evidence (typically more than one study). This approach takes into account the level of evidence of individual studies; the type of outcomes measured by these studies (patient-oriented or disease-oriented); the number, consistency, and coherence of the evidence as a whole; and the relationship between benefits, harms, and costs.

Practice Guideline (Evidence-Based). These guidelines are recommendations for practice that involve a comprehensive search of the literature, an evaluation of the quality of individual studies, and recommendations that are graded to reflect the quality of the supporting evidence. All search, critical appraisal, and grading methods should be described explicitly and be replicable by similarly skilled authors.

Practice Guideline (Consensus). Consensus guidelines are recommendations for practice based on expert opinions that typically do not include a systematic search, an assessment of the quality of individual studies, or a system to label the strength of recommendations explicitly.

Research Evidence. This evidence is presented in publications of original research, involving collection of original data or the systematic review of other original research publications. It does not include editorials, opinion pieces, or review articles (other than systematic reviews or meta-analyses).

Review Article. A nonsystematic overview of a topic is a review article. In most cases, it is not based on an exhaustive, structured review of the literature and does not evaluate the quality of included studies systematically.

Systematic Reviews and Meta-Analyses. A systematic review is a critical assessment of existing evidence that addresses a focused clinical question, includes a comprehensive literature search, appraises the quality of studies, and reports results in a systematic manner. If the studies report comparable quantitative data and have a low degree of variation in their findings, a meta-analysis can be performed to derive a summary estimate of effect.
Existing Strength-of-Evidence Scales

In March 2002, the Agency for Healthcare Research and Quality (AHRQ) published a report that summarized the state-of-the-art in methods of rating the strength of evidence. The report identified a large number of systems for rating the quality of individual studies: 20 for systematic reviews, 49 for randomized controlled trials, 19 for observational studies, and 18 for diagnostic test studies. It also identified 40 scales that graded the strength of a body of evidence consisting of one or more studies.

The authors of the AHRQ report proposed that any system for grading the strength of evidence should consider three key elements: quality, quantity, and consistency. Quality is the extent to which the identified studies minimize the opportunity for bias and thus are synonymous with the concept of validity. Quantity is the number of studies and subjects included in those studies. Consistency is the extent to which findings are similar between different studies on the same topic. Only seven of the 40 systems identified and addressed all three of these key elements.

Strength of Recommendation Taxonomy (SORT)

The authors of this article represent the major family medicine journals in the United States and a large family medicine academic consortium. Our process began with a series of e-mail exchanges, was developed during a meeting of the editors, and continued through another series of e-mail exchanges.

We decided that our taxonomy for rating the strength of a recommendation should address the three key elements identified in the AHRQ report: quality, quantity, and consistency of evidence. We also were committed to creating a grading scale that could be applied by authors with varying degrees of expertise in evidence-based medicine and clinical epidemiology, and interpreted by physicians with little or no formal training in these areas. We believed that the taxonomy should address the issue of patient-oriented evidence versus disease-oriented evidence explicitly and be consistent with the information mastery framework proposed by Stavros and Shanglmes.

After considering these criteria and reviewing the existing taxonomies for grading the strength of a recommendation, we decided that a new taxonomy was needed to reflect the needs of our specialty. Existing grading scales were based on a particular kind of study (e.g., prevention or treatment), were too complex, or did not take into account the type of outcome.

Our proposed taxonomy is called the Strength of Recommendation Taxonomy (SORT). It is shown in Figure 1. The taxonomy includes ratings of A, B, or C for the strength of recommendation for a body of evidence. The table in the center of Figure 1 explains whether a body of evidence represents good-quality or limited-quality evidence, and whether evidence is consistent or inconsistent.

The Authors

MARK H. EBELL, M.D., M.S., is associate professor at Michigan State University College of Human Medicine, East Lansing, Mich., and deputy editor of evidence-based medicine for American Family Physician.

JAY SWEK, M.D., is professor and chair of the Department of Family Medicine at Georgetown University Medical Center, Washington, D.C. He is also the editor of American Family Physician.

BARRY D. WISS, M.D., is professor at University of Arizona College of Medicine, Tucson, and editor of Family Medicine.

STEVEN H. WOOG, M.D., M.P.H., is professor in the family practice, preventive medicine, and community health departments at Virginia Commonwealth University School of Medicine, Richmond, Va. He is past North American editor for BMJ.

JEFFREY SUSMAN, M.D., is professor at the University of Cincinnati College of Medicine, Cincinnati, Ohio, editor of The Journal of Family Practice, and editor for the American Academy of Family Physicians' Home Study Self-Assessment monographs.

BERNARD EWIGMAN, M.D., M.P.H., is professor at the University of Chicago, Pritzker School of Medicine, Chicago, and editor for the Family Practice Inquiries Network.

MARJORIE BOWMAN, M.D., M.P.A., is professor at the University of Pennsylvania Health System, Philadelphia, Pa., and editor of the Journal of the American Board of Family Practice.

Address correspondence to Mark Ebell, M.D., M.S., 330 Snapfinger Dr., Athens, GA 30605 (e-mail: ebell@msu.edu). Reprints are not available from the authors.
Strength of Recommendation Taxonomy (SORT)

In general, only key recommendations for readers require a grade of the "Strength of Recommendation." Recommendations should be based on the highest quality evidence available. For example, vitamin E was found in some cohort studies (level 2 study quality) to have a benefit for cardiovascular protection, but good-quality randomized trials (level 1) have not confirmed this effect. Therefore, it is preferable to base clinical recommendations in a manuscript on the level 1 studies.

<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>

Use the following table to determine whether a study measuring patient-oriented outcomes is of good or limited quality, and whether the results are consistent or inconsistent between studies.

<table>
<thead>
<tr>
<th>Study quality</th>
<th>Diagnosis</th>
<th>Treatment/prevention/screening</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1—good-quality patient-oriented evidence</td>
<td>Validated clinical decision rule; SR/meta-analysis of high-quality studies; High-quality diagnostic cohort study</td>
<td>SR/meta-analysis of RCTs with consistent findings; High-quality individual RCT; All-or-none study; Case-series study</td>
<td>SR/meta-analysis of good-quality cohort studies; Prospective cohort study with good follow-up</td>
</tr>
<tr>
<td>Level 2—limited-quality patient-oriented evidence</td>
<td>Unvalidated clinical decision rule; SR/meta-analysis of lower-quality studies or studies with inconsistent findings; Lower-quality diagnostic cohort study or diagnostic case-control study</td>
<td>SR/meta-analysis of lower-quality clinical trials or studies with inconsistent findings; Lower-quality clinical trial; Cohort study; Case-control study</td>
<td>SR/meta-analysis of lower-quality cohort studies or with inconsistent results; Retrospective cohort study or prospective cohort study with poor follow-up; Case-control study; Case-series study</td>
</tr>
<tr>
<td>Level 3—other evidence</td>
<td>Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention, or screening</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Consistency across studies

| Consistent | 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 |
| Inconsistent | 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 |

*—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 (e.g., blood pressure, blood chemistry, physiologic function, pathologic findings).

†—High-quality diagnostic cohort study; cohort design, adequate size, adequate spectrum of patients, blinding, and a consistent, well-defined reference standard.

‡—High-quality RCT allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80 percent).

§—In an all-or-none study, the treatment causes a dramatic change in outcomes, such as antibiotics for meningitis or surgery for appendicitis, which produces study in a controlled trial.

FIGURE 1. The Strength of Recommendation Taxonomy. (SR = systematic review; RCT = randomized controlled trial)
The quality of individual studies is rated 1, 2, or 3; numbers are used to distinguish ratings of individual studies from the letters A, B, and C. Used to evaluate the strength of a recommendation based on a body of evidence. Figure 2 provides information about how to determine the strength of recommendation for management recommendations, and Figure 3 explains how to determine the level of evidence for an individual study. These two algorithms should be helpful to authors preparing papers for submission to family medicine journals. The algorithms are to be considered general guidelines, and special circumstances may dictate assignment of a different strength of recommendation (e.g., a single, large, well-designed study in a diverse population may warrant an A level recommendation).

Recommendations based only on improvements in surrogate or disease-oriented outcomes are always categorized as level C, because improvements in disease-oriented outcomes are not always associated with improvements in patient-oriented outcomes, as exemplified by several well-known findings from the medical literature. For example, doxazosin lowers blood pressure in black patients—a seemingly beneficial outcome—but it also increases mortality rates. Similarly, enoxaparin and flufenamic acid may reduce the incidence of arrhythmias after acute myocardial infarction, but they also increase mortality rates. Finasteride improves urinary flow rates, but it does not significantly improve urinary tract symptoms in patients with benign prostatic hypertrophy, while arthroscopic surgery for osteoarthritis of the knee improves the appearance of cartilage but does not reduce pain or improve joint function. Additional examples of clinical situations where disease-oriented evidence conflicts with patient-oriented evidence are shown in Table 1.
FIGURE 3. Algorithm for determining the level of evidence for an individual study.

apply the taxonomy are given in Table 2. We believe there are several advantages to our proposed taxonomy. It is straightforward and comprehensive, is easily applied by authors and physicians, and explicitly addresses the issue of patient-oriented versus disease-oriented evidence. The latter attribute distinguishes SORT from most other evidence-grading scales. These strengths also create some limitations. Some clinicians may be concerned that the taxonomy is not as detailed in its assessment of study designs as others, such as that of the Centre for Evidence-Based Medicine (CEBM). However, the primary difference between the two taxonomies is that the CEBM version distinguishes between good and poor observational studies while the SORT version does not. We concluded that the advantages of a system that provides the physician with a clear recommendation that is strong (A), moderate (B), or weak (C) in its support of a particular intervention outweighs the theoretic benefit of distinguishing between lower quality and higher quality observational studies, particularly because there is no objective evidence that the latter distinction carries important differences in clinical recommendations.

Any publication applying SORT (or any other evidence-based taxonomy) should describe carefully the search process that preceded the assignment of a SORT rating. For example, authors could perform a comprehensive search of MEDLINE and the gray literature, a comprehensive search of MEDLINE alone, or a more focused search of MEDLINE plus secondary evidence-based sources of information.
### Table 1
Examples of Inconsistency Between Disease-Oriented and Patient-Oriented Outcomes

<table>
<thead>
<tr>
<th>Disease or condition</th>
<th>Disease-oriented outcome</th>
<th>Patient-oriented outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxazosin for blood pressure</td>
<td>Reduces blood pressure in blacks</td>
<td>Increases mortality</td>
</tr>
<tr>
<td>Lidocaine for arrhythmias following acute myocardial infarction</td>
<td>Suppresses arrhythmias</td>
<td>Increases mortality</td>
</tr>
<tr>
<td>Finasteride for benign prostatic hypertrophy</td>
<td>Improves urinary flow rate</td>
<td>No clinically important change in symptom scores</td>
</tr>
<tr>
<td>Arthroscopic surgery for osteoarthritis of the knee</td>
<td>Improves appearance of cartilage after dislocation</td>
<td>No change in function or symptoms at one year</td>
</tr>
<tr>
<td>Sleeping infants on their stomach or side</td>
<td>Knowledge of anatomy and physiology suggests that this will decrease the risk of aspiration</td>
<td>Increases risk of sudden infant death syndrome</td>
</tr>
<tr>
<td>Vitamin E for heart disease</td>
<td>Reduces levels of free radicals</td>
<td>No change in mortality</td>
</tr>
<tr>
<td>Histamine antagonists and proton-pump inhibitors for nonulcer dyspepsia</td>
<td>Significantly reduce gastric pH levels</td>
<td>Little or no improvement in symptoms in patients with nonulcer peptic disease, nonulcer dyspepsia</td>
</tr>
<tr>
<td>Hormone therapy</td>
<td>Reduces low-density lipoprotein cholesterol levels, increases high-density lipoprotein cholesterol</td>
<td>No decrease in cardiovascular or all-cause mortality and an increase in cardiovascular events in women older than 60 years (Women's Health Initiative) with combined hormone therapy</td>
</tr>
<tr>
<td>Insulin therapy in type 2 diabetes mellitus</td>
<td>Keeps blood glucose levels below 120 mg per dl (6.7 mmol per l)</td>
<td>Does not reduce overall mortality</td>
</tr>
<tr>
<td>Sodium fluoride for fracture prevention</td>
<td>Increases bone density</td>
<td>Does not reduce fracture rate</td>
</tr>
<tr>
<td>Lidocaine prophylaxis following acute myocardial infarction</td>
<td>Suppresses arrhythmias</td>
<td>Increases mortality</td>
</tr>
<tr>
<td>Clofibrate for hyperlipidemia</td>
<td>Reduces lipid levels</td>
<td>Does not reduce mortality</td>
</tr>
<tr>
<td>Beta blockers for heart failure</td>
<td>Reduce cardiac output</td>
<td>Reduce mortality in moderate to severe disease</td>
</tr>
</tbody>
</table>

Information from references 12 through 24

### Table 2
Examples of How to Apply the Strength of Recommendation Taxonomy in Practice

Example 1: While a number of observational studies (level of evidence—2) suggested a cardiovascular benefit from vitamin E, a large, well-designed, randomized trial with a diverse patient population (level of evidence—1) showed the opposite. The strength of recommendation against routine, long-term use of vitamin E to prevent heart disease, based on the best available evidence, should be A.

Example 2: A Cochrane review finds seven clinical trials that are consistent in their support of a mechanical intervention for low back pain, but the trials were poorly designed (i.e., unblinded, nonrandomized, or with allocation to groups unblinded). In this case, the strength of recommendation in favor of these mechanical interventions is B (consistent but lower quality clinical trials).

Example 3: A meta-analysis finds nine high-quality clinical trials of the use of a new drug in the treatment of pulmonary fibrosis. Two of the studies find harm, two find no benefit, and five show some benefit. The strength of recommendation in favor of this drug would be B (inconsistent results of good-quality, randomized controlled trials).

Example 4: A new drug increases the forced expiratory volume in one second (FEV1) and peak flow rate in patients with an acute asthma exacerbation. Data on symptom improvement is lacking. The strength of recommendation in favor of using this drug is C (disease-oriented evidence only).
TABLE 3
Suggested Walkovers Between Taxonomies for Assessing the Strength of a Recommendation Based on a Body of Evidence

<table>
<thead>
<tr>
<th>SORT</th>
<th>CEBM</th>
<th>BMJ's Clinical Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Recommendation based on consistent and good-quality patient-oriented evidence</td>
<td>A. Consistent level 1 studies</td>
<td>Beneficial</td>
</tr>
<tr>
<td>B. Recommendation based on inconsistent or limited-quality patient-oriented evidence</td>
<td>B. Consistent level 2 or 3 studies or extrapolations from level 1 studies</td>
<td>Likely to be beneficial Likely to be ineffective or harmful (recommendation against)</td>
</tr>
<tr>
<td>C. Recommendation based on consensus, usual practice, disease-oriented evidence, case series for studies of treatment or screening, and/or opinion</td>
<td>C. Level 4 studies or extrapolations from level 2 or 3 studies</td>
<td>Unlikely to be beneficial (recommendation against)</td>
</tr>
<tr>
<td>D. Needs evidence or troublingly inconsistent or inconclusive studies of any level</td>
<td>D. Level 5 evidence or troublingly inconsistent or inconclusive studies of any level</td>
<td>Unknown effectiveness</td>
</tr>
</tbody>
</table>


Walkovers: Creating Linkages with SORT

Some organizations, such as the CEBM,25 the Cochrane Collaboration,7 and the U.S. Preventive Services Task Force,9 have developed their own grading scales for the strength of recommendation based on a body of evidence and are unlikely to abandon them. Other organizations, such as the PPIN,26 publish their work in a variety of settings and must be able to move between taxonomies. We have developed a set of optional walkovers that suggest how authors, editors, and readers might move from one taxonomy to another. Walkovers for the CEBM and BMJ Clinical Evidence taxonomies are shown in Table 3.

Many authors and experts in evidence-based medicine use the "Level of Evidence" taxonomy from the CEBM to rate the quality of individual studies.25 A walkover from the five-level CEBM scale to the simpler three-level SORT scale for individual studies is shown in Table 4.

Final Comment

The SORT is a comprehensive taxonomy for evaluating the strength of a recommendation based on a body of evidence and the quality of an individual study. If applied consistently by authors and editors in the family medicine literature, it has the potential to make it easier for physicians to apply the results of research in their practice through the information mastery approach and to incorporate evidence-based medicine into their patient care.

Like any such grading scale, it is a work in progress. As we learn more about biases in study design, and as the authors and readers who use the taxonomy become more sophisticated about the principles of information mastery, evidence-based medicine, and critical appraisal, it is likely to evolve. We remain open to suggestions from the primary care community for refining and improving SORT.

The authors thank Lee Green, M.D., M.P.H., John Epling, M.D., Kurt Stange, M.D., Ph.D., and Margaret Courney, M.D., for helpful comments on the manuscript.

TABLE 4
Suggested Walkover Between the SORT and the CEBM Taxonomies for Assessing the Level of Evidence of an Individual Study

<table>
<thead>
<tr>
<th>SORT Level</th>
<th>CEBM</th>
<th>Other categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Levels 1a to 1c</td>
<td>Levels 1a to 1c</td>
</tr>
<tr>
<td>2</td>
<td>Levels 2 or 3</td>
<td>Levels 2 to 4</td>
</tr>
<tr>
<td>3</td>
<td>Levels 4 or 5 and any study that measures intermediate or surrogate outcomes</td>
<td>Levels 5 and any study that measures intermediate or surrogate outcomes</td>
</tr>
</tbody>
</table>

CEBM = Centre for Evidence-Based Medicine. SORT = Strength of Recommendation Taxonomy.
The authors indicate that they do not have any conflicts of interest. Sources of funding: none reported.

Simultaneously published in print and online by American Family Physician, Journal of the American Board of Family Practice, and online by Family Practice Inquiries Network. Copyright © 2000 American Family Physician, a publication of the American Academy of Family Physicians. All rights reserved.

REFERENCES

Appendix C. 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 \( \frac{20 - 10}{20} \times 100 \text{ percent} \). 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 be treated to prevent one additional bad outcome. For example, if the annual mortality is 20 percent in the control group and 10 percent in the treatment group, then the ARR is 10 percent \( (20 - 10) \), and the number needed to treat is 100 percent \( \div \) ARR \( (100 \div 10) = 10 \text{ per year} \). That is, for every 10 patients who are treated for one year, one additional death is prevented. The same calculation can be made for harmful events. The 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: 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 ÷ (2 percent – 1 percent) = 100 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.