

**UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
DEPARTMENT OF FAMILY MEDICINE**

FUNDAMENTALS OF FAMILY MEDICINE CLERKSHIP

**STUDENT MANUAL
2019 - 2020**

**University of Michigan
Department of Family Medicine
300 North Ingalls Building, NI4C06
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<http://medicine.umich.edu/dept/family-medicine/education/predoctoral-education>

September 2019

Clerkship Description

The Fundamentals of Family Medicine Clerkship is a required four-week clinical rotation for second-year medical students at the University of Michigan. The purpose of this clerkship is to expose each student to ambulatory family medicine in a community-based clinical setting. In addition, students will attend didactic teaching sessions which will present core concepts of family medicine and allow them to develop a knowledge base which will be reinforced through their clinical experiences in family medicine offices.

Family medicine encompasses the spectrum of medical care during a patient's life cycle. The student will be exposed to a wide range of clinical experiences, including but not limited to routine health maintenance exams for children and adults, evidence-based preventive medicine, acute care visits, prenatal care, office-based procedures, and chronic medical conditions within the paradigm of population management. Most importantly, the student will be exposed to the concept of primary care and the unique relationship that exists between the patients and their family physician in the patient-centered medical home model

Clerkship Faculty and Staff

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General Information

The family medicine clerkship provides an opportunity for students to learn about the comprehensive diagnosis and management of patients with common undifferentiated problems. In addition they will experience the key features of family medicine such as diagnosis and management in the ambulatory setting, continuity of care, caring for the whole patient, appreciation of the effect of family and social factors, preventive medicine and the team approach including involvement with community agencies. The clerkship experience should also provide opportunities for the students to improve their basic skills in doctor-patient communication, history-taking and physical examination, differential diagnosis formation, stepwise decision-making to yield a cogent therapeutic plan, and office-based procedures.

Family Medicine Clerkship Goals

At the end of the family medicine clerkship, each student should be able to:

- Discuss the principles of family medicine.
- Gather information, formulate differential diagnoses, and propose plans for the initial evaluation and management of patients with common presentations.
- Manage follow-up visits with patients having one or more common chronic disease.
- Develop evidence-based health promotion/disease prevention plans for patients of any age or gender.
- Demonstrate competency in advanced elicitation of history, communication, physical examination, and critical thinking skills.
- Discuss the critical role of family physicians within any health care system.

Site Assignment

All students will be assigned to a family medicine site for their patient care activities. Students will be notified of their site assignment prior to starting the clerkship and will be provided with the following information: primary preceptor's name, phone number, address, and map. Some students will be assigned to sites outside the Ann Arbor/Washtenaw County area. Students may request "outstate" sites such as Holland, Kalamazoo, Marshall, and Petoskey but will not be placed at these sites unless specifically requested. Living accommodations for "outstate" areas are the responsibility of the student.

Orientation Session

All students report to the Family Medicine conference room, N15E18 North Ingalls Building on the first day of the clerkship period. During the orientation session the clerkship schedule, goals and requirements are presented. Didactic sessions are also conducted during this session.

Textbook

Each student receives the following textbook to use during the clerkship. Core clerkship topics and teaching sessions are addressed by chapters in this text and by chapters from a web-based resource described later. Students must turn in the textbook at the completion of the clerkship.

- 1) **Case Files Family Medicine.** 4th Edition. Toy, Briscoe, Britton, Heidelbaugh, 2016
- 2) **See Handouts and Readings**

Aquifer Family Medicine Cases

The Aquifer Family Medicine Cases are part of a comprehensive Internet-based learning program designed for use by second-year medical students during their family medicine clerkship. 40 cases are available through the Aquifer system.

Handouts and Readings

In addition to the textbook, each student receives a set of handouts and readings. These include chapters from other textbooks, articles, and faculty developed materials.

The U.S. Preventive Services Task Force **Guide to Preventive Services** is available as a web-based resource. The URL is provided in the Handouts and Readings Section.

Clerkship Schedule/Didactic Sessions

Students will learn the fundamentals of family medicine through a combination of clinical and classroom experiences. In general, students will spend 60% of the clerkship in patient care, 20% in clerkship sessions, 10% on clerkship assignments, and 10% in department conferences and the Friday seminars. Clerkship sessions include a series of presentations on core topics in family medicine as well as case discussions based on patients seen by the students during the clerkship. All clerkship sessions are held in the Family Medicine conference room, NI5E18 North Ingalls Building.

Clinical Experience

The majority of the clerkship will be spent in patient care at the family medicine office to which you have been assigned. Students will see patients who have appointments at the site. The number of patients that the student will see is determined by his/her level of experience as well as by the office schedule and other constraints of the individual preceptors.

The expectation is that by the end of the clerkship you should be seeing four to five patients per half-day. This means that you do the initial history and physical as appropriate before the preceptor comes to see the patient and review your findings. In progressing to the point where you are seeing four to five (and perhaps even more) patients in a half-day you will need to spend some time observing the preceptor and other office staff working with patients so you can learn how to fit into the busy office schedule. By the end of the first week you should be

seeing three patients per half-day on your own as you develop the knowledge and skills required to see five or more patients per half-day by the end of the clerkship.

Students review and discuss each patient with the supervising attending physician or resident. They are required to document each visit with a progress note in the medical chart and/or electronic medical record. Chart documentation will vary between the different sites, however, there is one basic rule to follow:

1. Each office has a set of documentation standards which should be followed. Sometimes special forms are used, such as for health maintenance exams, well child visits and prenatal visits. If this does not apply to your patient encounter, you should use the standard S.O.A.P. format to document your visit (see medical records documentation).

Other activities and opportunities are available to students on an elective basis. Students are strongly encouraged to accompany faculty or resident preceptors on hospital rounds, nursing home rounds, home visits, deliveries, and other "after hours" activities. There may also be opportunities for students to observe and assist during minor surgeries and procedures.

Documentation of Patient Encounters/Required Clinical Experiences

Each student will be required to document a minimum of 60 patient encounters during the clerkship. Students should document 15-20 encounters per week using the documentation system provided by the medical school. Students must also document six required clinical experiences as described during the orientation session.

Attendance

Participation in all clerkship activities is essential to meeting the requirements for this clerkship. You should recognize that unlike other clerkships, you cannot simply make up lost time by taking extra call or working over the weekend. You may have to work evening or Saturday clinics to make up missed patient care time. The schedule is arranged to maximize your clinical and educational experience. If you do have to miss any time, for whatever reason, you should contact the Education Office in Ann Arbor (734-998-7138) and your preceptor's office to let them know where you are. If you miss required activities, you will have to make these up. In short, there is a little flexibility in the attendance policy. Do not abuse the policy and it will remain flexible.

Core Topics

Listed below are the core topics which will be covered during the clerkship. Some of these will be addressed during the didactic teaching sessions but others will be sufficiently common as to be inevitably encountered by the students during your clinical activities. There handouts related to some of these topics. There are suggested readings for many of these topics.

Abdominal and pelvic pain
Approach to children

Approach to the elderly
Asthma
Chest pain
Common skin problems
Communication skills
Community agencies and resources
Contraception
COPD (chronic obstructive pulmonary disease)
Depression and anxiety
Diabetes
Doctor-patient relationship
Family life cycle and genogram
Headache
Health maintenance exam
Hypertension
Information Mastery
Lifestyle issues/modification
Low back pain
Men's Health
Musculoskeletal problems
Prenatal care
Prevention and screening
Substance abuse
Upper respiratory infections
Vertigo/dizziness

Document your clinical experience using the school's documentation system. We suggest that you regularly review the patients that you document in the school's documentation system with the preceptor to try to ensure that you are exposed to a broad range of conditions.

Grading Policy and Evaluation

Clerkship grading is based on an assessment of the student's performance during the rotation. The following are used to determine the final grade:

1. Clinical performance 70%
2. Online written examination 30%
3. Miscellaneous requirements
 - a. Participation in educational sessions
 - b. Mid-Clerkship Feedback Form/Direct Observation Checklist
 - c. Documentation of patient encounters/required clinical experiences
 - d. Case discussions
 - e. Community agency report

Clinical Performance: This component of the grade will be determined by the student's preceptor(s) at the clinical site to which the student has been assigned. When the student has worked with more than one preceptor, this portion of the grade will be based on the evaluations of all of his/her preceptors who had significant contact with the student.

Online Written Examination: All students will take the National Board of Medical Examiners (NBME) Family Medicine Subject Examination. This is a standardized, nationally-administered examination. It covers topics relevant to family medicine, including knowledge, principles and concepts that are learned in other clerkships. It will be administered on the final morning of the clerkship. Exam scores are generally available within three to five days.

Failure on the online examination will result in a grade of "I/A" and remediation of the "I/A" by re-taking the examination regardless of the summary clinical grade.

Final Grade: Results of student performance on all of these evaluations are combined to determine a final grade. A final grade is sent to the medical school's Registrar's Office electronically. Other grading and feedback materials are kept on file electronically for students to review if they have questions about their grades.

To receive "Honors" you must have "Honors" on your clinical performance and "Honors" on the exam. To receive "High Pass" as a final grade, you must have at least a "High Pass" on your clinical performance and at least a "High Pass" on your exam. Failing or near failing performance on the shelf exam can result in the lowering of your final grade. Superior performance in one component does not compensate for average or below average performance in the other component.

Failure in the clinical component will result in a final grade of "Fail" regardless of exam performance.

****Concerns regarding documented unprofessional behavior will result in the lowering of your final grade.**

It is expected that 25-30% of students will receive Honors. Grades will be assigned within each period (12 periods) with a retrospective assessment at the end of the academic year. In the past, there has been a range of High Pass (30-40%) and Pass (30-40%) grades assigned.

Grievance Policy: If you have concerns about your final grade, please contact Dr. Sheets. If you have a grievance you will be directed to follow the grievance procedures outlined in the current version of the medical school's "Policies and Procedures for Medical Student Evaluation, Advancement, and Promotion."

Miscellaneous Requirements: Students are also required to complete other clerkship assignments.

1. Student attendance and participation in educational sessions is required.
2. Review the mid-clerkship feedback form with the preceptor and return the form to the clerkship coordinator, Andrea Murawa, by the end of the second week of the clerkship. Return the Direct Observation Checklist by the end of the clerkship.
3. Documentation of at least 60 patient encounters in the school's documentation system is required, as is documentation of the six required clinical experiences.
4. Present at least one patient during case discussion sessions.
5. Present and submit a community agency report.

Optional: Each student will receive a blank Student Profile during clerkship orientation. Complete this profile and give it to your preceptor when you meet him/her. This will help provide background information the preceptor can use to get to know you better and to coordinate your clinical experience.

Summary

The family medicine clerkship is designed to give you an introduction to the types of patients and problems commonly encountered in family medicine and other primary care settings. The clerkship activities include clinical, classroom, and self-directed learning activities to help you accomplish the goals of the clerkship and acquire knowledge and skills which you will be able to apply as part of your general education as a medical student.

Please do not hesitate to ask questions. You will be working in busy office practices with highly experienced physicians, nurses, other health care providers, and staff who are used to working with learners. If you have questions about the schedule, assignments, or other educational aspects of the clerkships contact Dr. Sheets, Dr. Heidelbaugh or Andrea Murawa for clarification.

Family Medicine Clerkship Session Objectives, 2019-2020

Session Title	Clerkship Orientation/Introduction to Family Medicine
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Joel J. Heidelbaugh, MD
Contact Hours	1
Instructional Method Type:	Lecture

This presentation is given at the very beginning of our 4-week clerkship rotation. It outlines the goals and objectives of the clerkship for the students with respect to their role in the outpatient setting. A brief history of the specialty is given, dating from the original paradigm of the “general practitioner” to the current day family physician and its many diverse roles. Specific attention is given to the role of the family physician in the healthcare system, ranging from predominantly outpatient care to inpatient and obstetrical/surgical/ER/ICU care, and focus on opportunities for developing a specialized niche through fellowship training (e.g. sports medicine, women’s health, academics, palliative and hospice care, etc.). Current data is highlighted that outlines the most common diagnoses encountered in family medicine, foreshadowing what students are expected to see during this rotation. Trends in supply and demand of primary care versus specialty care physicians are also discussed.

Session Learning Objectives:

By the end of this session, students are expected to:

1. Define the evolution of the specialty of family medicine up to present day status, with acknowledgement that family medicine and primary care are in great demand but continue to be in decline with respect to student interest and recruitment
2. Understand the role of the family physician in the healthcare system at large, with specific focus on acute and chronic care relative to population management, cost-effective and evidence-based provisions of care, and the diverse roles and specialized niches that family physicians possess
3. Conceptualize what a common day in the practice of a family physician is comprised of, understanding the wide variety and depth of our specialty
4. Recognize the importance of the value of preventive medicine in achieving and maintaining good health and well-being, not only to prevent chronic diseases, but also to minimize preventable healthcare expenditures

Session Title	Common Skin Problems
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Joel J. Heidelbaugh, MD
Contact Hours	1.5
Instructional Method Type:	Lecture

This lecture is comprised of a vast compendium of slides highlighting many common skin disorders encountered in family medicine. Epidemiology of dermatologic conditions, both in general and with relation to specific disorders, is discussed. Students are taught how to identify and characterize various skin conditions using descriptive terms (e.g. macular, papular, vesicular, etc.) and how to formulate a differential diagnosis based upon such characteristics. Common skin conditions discussed are divided into categories of common rashes, infections and infestations, subcutaneous/cutaneous lesions, and atypical versus neoplastic lesions. Treatment options for each condition are discussed, with specific focus on when a rash or lesion should be biopsied, and when a patient should be referred to

Family Medicine Clerkship Session Objectives, 2019-2020

dermatology for further evaluation. Epidemiology, identification, and preliminary triage of potentially cancerous skin lesions are highlighted.

Session Learning Objectives:

By the end of this session, students are expected to:

1. Utilize dermatologic terms in developing a differential diagnosis for commonly encountered skin conditions in family medicine
2. Understand common treatment options of various dermatologic conditions
3. Determine indications for lesion biopsy and/or referral to dermatology for further evaluation

Session Title	Approach to the Musculoskeletal Exam
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Robert Kiningham, MD
Contact Hours	1.5
Instructional Method Type:	Lecture, Demonstration

Session Learning Objectives:

By the end of the session, students are expected to:

1. Identify the important information to obtain when interviewing a patient with a musculoskeletal problem.
2. Realize the importance of determining the patient's baseline functioning and goals in formulating a treatment plan for musculoskeletal problems.
3. Appreciate the factors that perpetuate chronic musculoskeletal problems, and the importance of addressing these factors in the treatment plan.
4. Understand the basic principles and techniques of the musculoskeletal exam.
5. Apply a structured approach to the examination of joint complexes.

Session Title	Examination of the knee
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Amy Miller, MD
Contact Hours	1.5
Instructional Method Type:	Lecture, Demonstration

Session Learning Objectives:

By the end of the session students are expected to:

1. Identify relevant knee anatomy and typical presentations or mechanisms of common knee injuries/conditions.
2. Take a complete focused history in a patient with a knee complaint.
3. Conduct a thorough exam on a patient with a knee complaint.
4. Determine appropriate use of radiological studies to assist in the evaluation of a patient with knee complaints.

Session Title	Population Health and Prevention
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Caroline Richardson, MD
Contact Hours	1.5
Instructional Method Type:	Lecture

Family Medicine Clerkship Session Objectives, 2019-2020

Session Learning Objectives:

At the conclusion of this session the student will be able to:

- 1) Describe strengths and weaknesses of current prevention efforts observed in clinic.
- 2) Identify prevention services and classify as primary, secondary or tertiary.
- 3) Describe provider and practice issues related to adopting preventive services
- 4) Describe and compare the relationship of screening to diagnostic work-up and treatment
- 5) Identify key patient issues related to accepting preventive services and how patient autonomy interacts with preventive services effectiveness.
- 6) Analyze practice organization issues that contribute to the delivery of preventive services
- 7) Describe the potential for decreased prevention strategy effectiveness when strategies are not delivered to the appropriate at risk target populations.
- 8) Distinguish between cost saving and cost-effective interventions from an economic perspective
- 9) Be aware of the data on effectiveness and cost-savings, the target population and the intervention goals for the diabetes prevention program lifestyle intervention.

Session Title	Acute, Chronic, General Case Discussions
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Joel J. Heidelbaugh, MD, Eric P. Skye, MD, Jean Wong, MD,
Contact Hours	2.0
Instructional Method Type:	Case-based Instruction/Learning

Each student is randomly assigned to one of three groups (acute, chronic or general cases) and expected to present the details of a case that they encountered during the clerkship to the small group and facilitate a discussion.

Acute case discussions are presented initially as a chief complaint (e.g. a 58-year-old male presents with chest pain), then the group asks the student presenter details about the patient's history. The primary focus in this exercise is to develop skills in forming a differential diagnosis that allows students to direct their line of questioning. Pertinent physical examination information is given, then students are asked to finalize their differential diagnosis. Based upon a preliminary differential diagnosis list, students are then asked to plan a reasonable therapeutic workup. The student who is presenting the case offers direction to the other students with regard to what is reasonable versus potentially unnecessary, then offers a resolution to the case on the workup that was actually performed, as well as any known test results and follow-up.

Chronic case discussions are presented initially also with a chief complaint (e.g. 64-year-old male with long-standing Type 2 diabetes mellitus and hypertension), yet the focus is predominantly aimed at a group discussion on how to manage chronic diseases. Evidence-based guideline review (institutional, specialty organization, etc.) and primary literature review is incorporated. Specific detail toward guideline goals (e.g. HBA1C < 7.0%) for each chronic disease presented is discussed, as well as discussion of pay-for-performance initiatives and motivational interviewing relative to each case.

General case discussions allow students to choose either an acute case or chronic case, and presentations follow the guidelines above.

Family Medicine Clerkship Session Objectives, 2019-2020

Session Learning Objectives:

By the end of these three sessions, students are expected to:

1. Develop skills to present a detailed acute or chronic medical case in a logical and organized fashion
2. Develop skills in formulating a differential diagnosis and cogent therapeutic care plan
3. Improve understanding of how to implement evidence-based guidelines in acute and chronic disease management
4. Discuss challenging barriers encountered during patient encounters that impact health outcomes (e.g. psychosocial issues, insurance issues, compliance issues, etc.)
5. Improve ability to lead a small group discussion

Session Title	Acute Low Back Pain
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Pamela Rockwell, D.O.
Contact Hours	1.0
Instructional Method Type:	Lecture, Demonstration

Session Learning Objectives:

By the end of this session, students are expected to:

1. Define common etiologies of acute low back pain.
2. Perform a complete history in working up a patient with low back pain.
3. Recognize the “red flags” which may present in the evaluation of a patient with low back pain and what their importance is.
4. Perform a thorough physical exam on the patient with acute low back pain.
5. Recite the evidence-based recommendations regarding how to treat acute low back pain.

Session Title	Contraception
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Pamela Rockwell, DO
Contact Hours	1.0
Instructional Method Type:	Lecture

Session Learning Objectives:

By the end of this session, students are expected to:

1. Describe all the common forms of contraception available to women, including seeing and handling these contraceptives.
2. Explain the use of hormonal contraceptives and how they work
3. Describe how to better select various forms of contraception in accordance with what may work best with individual patients
4. Understand the common side effects seen in patients on contraceptives and understand some of the common clinical scenarios encountered in the family medicine office when problems occur in women using contraceptives.
5. Identify the medical conditions which may warrant the use of hormonal contraceptives
6. Understand HPV (human papilloma virus) and how it affects women and men

Family Medicine Clerkship Session Objectives, 2019-2020

Session Title	Community Agency Visit Debriefing
Course title:	M3 Family Medicine Clerkship
Responsible Faculty Member (s):	Amy Hansen, LMSW, Katherine Lehmann, MSW, Matthew Zimmer, MSW
Contact Hours	1.5
Instructional Method Type:	Case-based Instruction/Learning

Session Learning Objectives:

By the end of this session, students are expected to:

1. Have an understanding why community based programs are so important in the total health care of their patients
2. Have information on a variety of programs that are available in the community, throughout the state and throughout the country
3. Understand when it would be helpful to refer a patient to a community program and why
4. Understand how to make a referral to a community program
5. Develop an appreciation for difficulties many people face that interfere with getting health care or being able to follow through on a treatment program
6. Recognize the burden that substance abuse, extremely dysfunctional families, mental health issues, the working poor and those in extreme poverty put on our health system and why it is so costly to everyone

Family Medicine Clerkship Goals

At the end of the family medicine clerkship, each student should be able to:

- Discuss the principles of family medicine.
- Gather information, formulate differential diagnoses, and propose plans for the initial evaluation and management of patients with common presentations.
- Manage follow-up visits with patients having one or more common chronic disease.
- Develop evidence-based health promotion/disease prevention plans for patients of any age or gender.
- Demonstrate competency in advanced elicitation of history, communication, physical examination, and critical thinking skills.
- Demonstrate competency in advanced elicitation of history, communication, physical examination, and critical thinking skills.
- Discuss the critical role of family physicians within any health care system.

Family Medicine Clerkship Learning Objectives

1. Biopsychosocial Model

Patient-centered communication skills

- Demonstrate an empathic response to patients using active listening skills.
- Demonstrate the ability to set a collaborative agenda with the patient during any patient encounter.
- Demonstrate the ability to elicit, prioritize, and attend to the patient's specific concerns.
- Review patient's history, physical examination, and test results using terminology that the patient can understand.
- Clarify information obtained by a patient from popular media, friends and family, or the Internet.
- Validate a patient's feelings by naming emotions and expressing empathy
- Effectively incorporate psychological issues into patient discussions and care planning.
- Use empathy and active listening skills to improve patient adherence to medications and lifestyle changes.
- Explain treatment plans for prevention and management of acute and chronic conditions to the patients.
- Reflect on personal frustrations and the patient's situation to better understand why patients do not adhere to offered recommendations or plans.

Psychosocial awareness:

- Explain why physicians have difficulty in situations such as patients' requests for disability documentation, non-adherence, and chronic narcotic use.
- Describe the influence of psychosocial factors on a patient's ability to provide a history and carry out a treatment plan.

Patient education:

- Describe mechanisms to improve adherence to and understanding of screening recommendations.
- Provide patient education tools that account for literacy and cultural factors (e.g., a handout on how to read nutrition labels.)
- Describe the patient education protocols for core chronic illnesses at their assigned clerkship sites.
- Identify resources in a local practice community that support positive health outcomes for diverse patients and families.
- Promote the use of support groups and other community resources to assist patients with mental health needs.
- Identify and distribute current resources for patients with substance abuse problems at their clinic sites (e.g., lists of treatment referral centers, self-help groups, substance abuse counselors, etc.)

2. Comprehensive Care

Information gathering and assessment:

- Apply critical appraisal skills to assess the validity of resources.
- Formulate clinical questions important to patient management.
- Conduct an appropriate and comprehensive literature search to effectively answer clinical questions.
- Apply evidence-based medicine (EBM) to determine a cost-effective use of diagnostic imaging in the evaluation of core, acute presentations.
- Demonstrate ability to discriminate between high and low-quality evidence when searching the medical literature.
- Utilize high-quality Internet sites as resources for use in caring for patients with core conditions.
- Curate a set of high quality mobile apps for quick reference when delivering patient care.

Lifelong learning:

- Demonstrate an appropriate level of meta-cognitive skills to assess and remediate one's own learning needs.
- Describe an individualized, evidence-based process on how to keep current with preventive services recommendations.
- Create an evolving set of learning goals and measures of success for those goals that address areas for improvement.

3. Contextual Care

Person in context of family:

- Conduct an encounter that includes patient and families in the development of screening and treatment plans.
- Demonstrate caring and respect when interacting with patients and their families even when confronted with atypical or emotionally charged behaviors.
- Demonstrate interpersonal and communication skills that result in effective information exchange between patients of all ages and their families.

Person in context of community:

- Incorporate knowledge of local community factors that affect the health of patients into daily patient care.
- Demonstrate awareness of local, regional, and national health disparities and their impact on patient care.
- Practice interpersonal and communication skills that result in effective information exchange between patients of all ages and professionals from the other disciplines and other specialties.

Person in context of their culture:

- Communicate effectively with patients and families from diverse cultural backgrounds.
- Identify areas where a patient's cultural context can impact health through comprehension, cultural perspective, access and utilization of health care.
- Describe one's own cultural influences and biases as they impact one's ability to effectively deliver patient care.

4. Continuity of Care

Barriers to access:

- Define social determinants of health and their role in continuity of care.

- Describe the social determinants that can affect a patient's ability to access and utilize the health care system at multiple levels:
 - Individual patient barriers
 - Community barriers
 - Health care system barriers

5. Coordination/Complexity of Care

Team Approach:

- Describe the benefits of interdisciplinary health care teams in patient care (e.g., pharmacy, nursing, social work, and allied health).
- Demonstrate skills in effective teamwork (e.g., sharing information, solving clinical problems as a team, etc.).

Quality and Safety:

- Define clinical processes established to improve performance of a clinical site.

Complexity of Care:

- Identify diagnostic uncertainty and the role of multi-systemic influence on a patient's condition.
- Adapt to changing patient presentation and needs
- Utilize effective patient care management strategies in patient's presenting with complex conditions.
- Describe the use of health information technology to enhance care coordination.
- Summarize the importance of linking resources with patient and population needs.

Source: Society of Teachers of Family Medicine: National Clerkship Curriculum. Second Edition, 2018.

**UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
DEPARTMENT OF FAMILY MEDICINE
Family Medicine Clerkship**

Summary of Student Responsibilities and Tasks

1. Review student manual and materials.
2. Attend and participate in all clerkship educational sessions.
3. Identify patients to present during the case discussions.
4. Attend at least 24 scheduled patient care sessions.
5. Write progress notes on patients you see in the office.
6. Accompany your preceptor to an “after hours” activity (i.e. home visit, delivery, hospital rounds).
7. Take the NBME examination.
8. Return your textbook at the end of the clerkship.
9. Document a minimum of 60 patient encounters using the school’s documentation system.
10. Document six required clinical experiences in the school’s documentation system.
11. Return your mid-clerkship feedback form and direct observation checklist after they are completed by your preceptor.
12. Present and submit your Community Agency Report/Form.
13. Complete clerkship classroom teaching evaluation forms and evaluate the clerkship and your preceptor using the online system.
14. Contact the Education Office, 734-998-7138, if you have questions or concerns.

**UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
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Family Medicine Clerkship**

Summary of Preceptor Responsibilities and Tasks

1. Review preceptor manual materials.
2. Review student information packet.
3. Discuss expectations with student at beginning of clerkship.
4. Orient student to your site.
5. Observe the student frequently.
6. Give the student feedback frequently.
7. Review and critique medical records (progress notes, data recording, etc.)
8. Conduct a mid-clerkship debriefing to discuss progress, concerns, and other issues.
9. Encourage the student to accompany you or your colleagues in an “after hours” activity (i.e. home visit, nursing home rounds, delivery, hospital rounds)
10. Complete and return the mid-clerkship feedback form and direct observation checklist.
11. Help the student identify patients for their assigned case discussions. (See preceptor manual)
12. Conduct final debriefing to discuss progress, concerns, and evaluation.
13. Evaluate the student using the on-line grading system or complete and return the student grade sheets you receive in your student information packet and/or by fax or email.
14. Contact the Education Office, 734-998-7138, if you have questions or concerns.

Additional Readings

URL List

Community Agency Resources

**How to Decide Whether a Clinical Practice
Guideline is Trustworthy**

**The Patient-Centered Medical Home:
A Brief Educational Agenda for
Teachers of Family Medicine**

University of Michigan Clinic Trunk Policies and Procedures

<https://medstudents.medicine.umich.edu/umms-bulletin>

Prevention

General/home page: <http://www.ahrq.gov/professionals/clinicians-providers/>

Clinical Task Force book: <https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/index.html>

Sections for students to read:

Background:

<http://www.ahrq.gov/professionals/clinicians-providers/index.html>

Aspirin/NSAIDs for Prevention of Colorectal Cancer

<https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/aspirin-nsaids-for-prevention-of-colorectal-cancer-preventive-medication>

Screening for Lead Levels in Childhood & Pregnancy

<http://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-rules-and-reminders/lead-age-2-years-due-screening>

Dementia (Alzheimer's Disease): Screening

<http://archive.ahrq.gov/news/press/pr2003/dementpr.htm>

Breast Cancer:

<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening1>

Prostate Cancer:

<http://www.ahrq.gov/clinic/uspstf/uspsprca.htm>

Healthy People 2010

<http://www.healthypeople.gov/>

Dermatology

<http://www.visualdxhealth.com/diseaseList.htm>

UMHS Guidelines for Clinical Care

Acute low back pain:

<http://www.med.umich.edu/1info/FHP/practiceguides/back.html>

Pediatric Growth Charts:

<http://www.cdc.gov/growthcharts>

**DEPARTMENT
OF
FAMILY MEDICINE**

COMMUNITY AGENCY RESOURCES

Resources for Uninsured/Underinsured Patients

Standardized Patient Program, University of Michigan Medical School

This information is always subject to **CHANGE**. Check the resources before providing this information to patients.

UMHS Department of Social Work

<http://www.med.umich.edu/socialwork/>

D2202 MPB
1500 E. Medical Center Dr.
Ann Arbor, MI 48109-0718
734-764-3140 (phone)
734- 936-9110 (fax)

The Department of Social Work is here to assist our patients with support services and resources while they are receiving medical and mental care at the University of Michigan Health System. Resources available include help with psychosocial issues or concerns, bereavement, domestic violence/sexual assault, counseling referrals, adjustment to illness, caregiver needs, long-term discharge planning, housing concerns, Advance Directive issues, and resources related to your diagnosis. Some limited resources are also available to assist you with emergency tangible needs such as clothing, transportation, food, prescriptions, and discounted parking.

Resource Finding at UMHS:

When in doubt about who to call for a social work referral (although check with your service first—there is a social worker assigned to most services at UMHS), call the GAP (Guest Assistance Program) Office at 764-6893 (M-F 9AM-5PM). They will triage and delegate to the appropriate social worker.

Outside Resources for Patients:

Insurance Resources:

Medicaid vs. Medicare

Medicaid is the **state** program that assists low-income individuals and families. Medicare is the **federal** program that provides health insurance coverage for the elderly (65+) and the disabled.

Medicaid:

Income limits depend on the county of residence, family size, etc... BUT the income limits are usually **very** low. Patients must contact their local Department of Human Services (DHS—formerly Family Independence Agency (FIA)) office to begin the application process for Medicaid coverage.
State of Michigan, Department of Human Services
Washtenaw County Office

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Standardized Patient Educator
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22 Center St.
Ypsilanti, MI 48198-9965
(734) 481-2000

Maternity Outpatient Medical Services (MOMS)

This program is for low-income pregnant women who do not qualify for Healthy Kids/Medicaid (including teenagers who choose not to apply for Healthy Kids/Medicaid for confidentiality reasons). This program covers outpatient pregnancy-related services (both pre- and post-natal). MOMS enrollees should also apply for Emergency Only Medicaid (covers inpatient labor and delivery) **and** Washtenaw Health Plan- "Plan B." These patients should apply for these programs at their local DHS office or online: <https://www.mibridges.michigan.gov/access/>

Emergency Only Medicaid:

This program is for low-income children, elderly (age 65 and older), and pregnant women who do not qualify for Healthy Kids/Medicaid, MICHild, or full Medicaid. This program covers inpatient labor and delivery services for pregnant women; covers "emergency" services for children and elderly. Patients should apply for this program at their local DHS office.

Healthy Kids/Medicaid:

An income-based program through Michigan Medicaid for children under 19 years of age and low-income pregnant women of any age. Contact information: 1-888-988-6300 or contact the local DHS office for details.

Washtenaw Health Plan (WHP)-"Plan B:"

For low-income Washtenaw County resident without health insurance. Provides coverage for primary care for WHP Primary Providers, diagnostic tests such as x-rays, lab tests and others, some pre-approved specialty care services; inpatient hospitalizations (in Washtenaw County only); Emergency room services for "true emergencies," limited number of prescription drugs (mostly generics); limited outpatient mental health visits. WHP Plan B generally does not cover pregnancy-related services! **NOTE: WASHTENAW HEALTH PLAN B IS NO LONGER ACCEPTING NEW MEMBERS**

Maternal Infant Health Program (MIHP—formerly MSS-ISS):

This is a program offered FREE to women with Medicaid (including Healthy Kids, MOMS, etc...) to provide multidisciplinary support/preventive services to aid in healthy pregnancies and delivery of healthy infants. Services include nutrition counseling and social work services (resource finding, counseling). Patients also work with doctors and nurses as part of this Program. Patients have access to childbirth and parenting classes as well as can receive transportation to and from appointments to encourage adherence with prenatal care. Patients may sign themselves up for this Program or may be referred by a Primary Medical Provider by calling (734) 544-2984 or (734) 544-6800.

Title XV/Breast and Cervical Cancer Control Program (BCCCP):

A federally funded program that provides free breast and cervical cancer screening to women in Washtenaw and Livingston Counties who are between the ages of 40 and 64 and who meet

financial and insurance criteria. Care is provided by physicians and nurse practitioners through UMHS and St. Joseph Mercy Health System. Contact information: 1-877-221-6505. Patients will go through an initial telephone screening interview and once determined eligible, will receive a phone number to make an appointment.

Women, Infants and Children (WIC):

Women, Infants and Children (WIC) is a federally funded health and nutrition program that provides pregnant women, new mothers, and young children with nourishing supplemental foods, nutrition education and counseling, breastfeeding promotion as well as health and social service referrals. The participants of WIC are either pregnant, breastfeeding, or postpartum women, and infants and children under age five who meet income guidelines and have a medical or nutritional risk. Contact information: (734) 544-6800. Additional information can be found at:

http://www.ewashtenaw.org/government/departments/public_health/family_health/fam_health_mhp_wic_nursing/WIC/ph_hltwic.html

For additional state sponsored programs for other populations (special needs children, disabled adults, elderly, etc...), please see the State of Michigan's website: www.michigan.gov.

Prescription Drug Assistance:

MANY patients, even with insurance, do not have prescription drug coverage. Because this has become such a large problem in this country, many of the drug companies have implemented programs to assist patients in need—either discount cards to use at a pharmacy of the patient's choice or sending the patient the medications directly from company free of charge. The website www.needymeds.com has put together a comprehensive listing of drug companies that offer programs and user-friendly instructions on how to get their applications (or download them directly from their website) and the various criteria that the drug companies use to determine who they are able to assist. The service social workers [see above (Resource Finding at UMHS) for contact information] are familiar with this resource and can assist with the application process. Please keep in mind that the application process is lengthy (often taking 6-8 weeks after the initial application is submitted) and patients may be unable to obtain the medications they need without further assistance with samples, etc...

UMHS Pharmacy Assistance:

UMHS Outpatient Pharmacy offers a program where patients may be billed later for medications ("OK to Bill") and then allowed to set up a payment plan to pay off the bill. This is to be done on an emergency only basis through the GAP Office/Social Work (see above resources) and the Pharmacy.

Local free/low-cost clinics:

Planned Parenthood:

A clinic that provides comprehensive women's health services.

Note that because Planned Parenthood does provide abortions to women (although with extensive counseling and education about **ALL options), some patients may not be open to this as a resource**

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Standardized Patient Educator
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Additionally, Planned Parenthood is the Title X Family Planning provider in Southeast Michigan. These services include physical exams (pelvic exams and cervical cancer screening, pregnancy diagnosis and counseling, contraceptive counseling and supplies).

Locations:

Ann Arbor Health Center: 3100 Professional Dr.

Ann Arbor West Health Center: 2370 W. Stadium Blvd.

Phone Number: 800-230-7526

Website: www.plannedparenthood.org/midsouthmi/

The Corner Health Center:

A clinic that offers comprehensive, multidisciplinary services to adolescents (ages 12-21) of Washtenaw, Wayne and Livingston counties. WIC (Women, Infants and Children) services are available at The Corner Health Center. They accept insurances, but also use a sliding scale for patients who are uninsured/unable to pay or who have concerns regarding confidentiality issues.

Location: 47 N. Huron St. in Ypsilanti

Phone Number: 734-484-3600

Website: <http://www.cornerhealth.org>

Hours: Monday through Friday, variable hours. Existing patients can walk-in on Mondays and Fridays from 9:30-11:30 am for STI testing, birth control visits, pregnancy tests, and Emergency Contraception; Closed Saturdays and Sundays.

Hope Medical Clinic:

A non-profit, interdenominational Christian medical and social service organization that provides general medical services and specialized clinics to those without insurance or medical benefits. Hope Clinic also has a network of >80 specialists who will see patients free of charge in their offices. They ask for a \$5 contribution per visit, but it's not required of those who cannot pay. Hope Clinic also offers some social service programs to help address both emergency and basic needs.

Location: 518 Harriet St. in Ypsilanti

Phone Number: 734-481-0111

Website: <http://thehopeclinic.org>

Hours: Variable, including some walk-in appointments. Call for specific details.

Hope Dental Clinic

Hope Dental Clinic provides general preventive and restorative care to those without dental insurance or the ability to pay for dental care.

Location: 518 Harriet St. in Ypsilanti

Phone Number: 734-480-9575

Hours: Monday-Friday 9am-12pm and 1-5pm.

Shelter Association Health Clinic (at the Delonis Center):

A clinic operated through the Shelter Association of Washtenaw County that provides free care to people without insurance/means to pay. The clinic is staffed by volunteer physicians and nurses

from UMHS. They have nurse practitioner clinics as well as a medical student run clinic on Monday nights. Location: 312 W. Huron St in Ann Arbor
Phone Number: 734-662-2829 ext 238
Website: www.annarborshelter.org

Packard Health:

Packard Health is a Federally Qualified Health Center Look-Alike (FQHC-LAL) clinic that works with patients with or without insurance. They accept all major insurances and have a sliding scale fee schedule for patients who are uninsured. Packard Health provides comprehensive care—pediatrics, adult general medicine, women’s health, geriatrics. Packard Health is the largest Primary Care Provider for the Washtenaw Health Plan (see resources above).

Packard Health Main: 3174 Packard in Ann Arbor

Phone Number: 734-971-1073

Packard Health West: 501 N Maple Rd in Ann Arbor

Phone Number: 734-926-4900

Website: www.packardhealth.org

Note: Please note that this is not a comprehensive listing of all resources for patients in the area. Also—clinic and local resource information tends to change on a regular basis so it is always a good idea to verify information you are handing out to your patients.

Additional resources may be found through service social workers.

**University of Michigan
Department of Family Medicine
Community Resources**

Remember to call behavioral science support staff
at 734-475-4487 for more information.

“211” Help/Information lines

Washtenaw County – (734) 222-4357 (Washtenaw “211”)
also website: www.washtenaw211.org
Jackson County – (866) 561-2500
Ingham County – (866) 561-2500
Wayne County – (313) 226-9200
Lenewee County – (866) 561-2500

Websites:

www.mhweb.org (*substance abuse and mental
health resources for Michigan, also self-help groups*)
<http://mentalhelp.net/selfhelp/> (*National
and International self-help info*)
<http://michigan.gov/dhs-> (*child abuse website*)
<http://needymeds.com> (*meds for limited income*)
www.aardvarc.org (*domestic violence programs in MI*)

Child Care/Special Needs/Parenting:

Children with Special Needs:

Child Care Network – (734) 975-1840 (for all children)
Early On (birth – 3 yrs) – (734) 994-8100
Learning Disabilities Assoc. of MI – (517) 319-0270
Children’s Special Health Care Services (CSHCS) – (800) 359-3722
(also local Public Health Dept and School Districts)

Parenting:

Child and Parent Center – (517) 788-4445
Parent HELpline – (855) 427-2736
Parents as Teachers – *Website:*
Chelsea.k12.mi.us/chelseapreschool/parents-and-teachers-home

Department of Human Services (DHR):

Washtenaw – (734) 481-2000
Jackson – (517) 780-7400
Livingston – (517) 548-0200
Ingham – (517) 887-9400

Food/Clothing/Dental/Shelter:

Faith in Action – (Chelsea) (734) 475-3305
Hope Dental Clinic – (734) 480-9575
Hope Medical Clinic – (734) 481-0111
Salvation Army -
Ann Arbor (734) 668-8353
Jackson (517) 782-7185
Howell (517) 546-4750
Shelter Association – (734) 662-2829
SOS Community Crisis Center – (734) 485-8730
Stockbridge Outreach – (517) 851-7275
U of M Dental School – (734) 763-6933
WIC (Women, Infant & Children) – (734) 544-6800
Manchester Community Resource Center – (734) 428-7722

Grief and Loss:

Arbor Hospice – (734) 662-5999
Hospice of Michigan – (888) 247-5701
Miscarriage/Newborn death – (734) 973-1014
Website: therapeuticresources.com

Legal Aid:

Ann Arbor – (734) 665-6181
Jackson – (517) 787-6111
Migrant Legal Assistance – (616) 454-5055
Website: MichiganLegalAid.org

Mental Health Resources:

Alliance for the Mentally Ill of
Washtenaw Co – (734) 544-3050
ACCESS – 800-440-7548
*Catholic Social Services – (734) 971-9781
Community Support and Treatment
(Washtenaw) – (734) 544-3050 (Access)
Community Mental Health/Lifeways
(Jackson) – (866) 630-3690 or (517) 780-3332
Community Mental Health
(Livingston) – (517) 546-4126 or (800) 615-1245
Community Mental Health
(Ingham) – (517) 346-8200 (Access)
U of M Psychological Clinic – (734) 764-3471
*(*Sliding scale or reduced fees available)*
Suicide Prevention:
Allegiance Hospital – 517-788-4811
U of M Psych ER – (734) 936-5900

Public Health:

Washtenaw Co Health Department – (734) 544-6700
Ingham Co Health Department – (517) 887-4311
Jackson Co Health Department – (517) 788-4420
Livingston Co Health Department – (517) 546-9850
(for Maternal/Infant Support Services also)

Senior Services:

Alzheimer's Disease Association – (734) 475-7043
Area Agency on Aging (Washtenaw) – (800) 852-7795
Chelsea Senior Center – (734) 475-9242
Generations Together – (734) 426-4091
Jackson Crouch Center – (517)788-4364
Silver Club – (Ann Arbor) (734) 998-9352
Turner Senior Resource Center – (734) 998-9353
Nursing Home Website (Consumer Guide): www.hcam.org/

Substance Dependence:

Access – (Washtenaw County) (734) 544-3050 or (800) 440-7548
Alano Club – (734) 668-8138
Al-Anon – (734) 995-4949

March 2014 dp

Substance Dependence (continued):

AA (local meetings) - (734) 482-5700
AA (Jackson Co) – (517) 789-8883
Dawn Farm – (734) 485-8725
Narcotics Anonymous (local) - (734) 913-9839
Narcotics Anonymous (24 hour) – (877) 589-4611
U of M Alcohol Management – (734) 998-2017
UMATS (734) 764-0231 or (800) 525-5188

Violence:

Child Abuse:

Child Protective Services

Washtenaw– (855) 444-3911
Jackson - (855) 444-3911
Livingston – (855) 444-3911
Ingham – (855) 444-3911
Wayne - (313) 396-0300
National Child Abuse Hotline – (800) 422-4453
National Parent HELP Line – (855) 427-2736
U of M Child Protection Team – (734) 763-0215

Elder Abuse/Neglect:

Adult Protective Services
Washtenaw – (855) 444-3911
Jackson – (855) 444-3911
Livingston – (855) 444-3911
Ingham – (855) 444-3911
Elder Abuse Hotline – 1-800-677-1116

Partner Violence:

Alternatives to Domestic Aggression – (734) 971-9781
Aware (Jackson Co) – (517) 783-2861
Eve's House (Ingham Co) - (517) 372-5976
LACASA (Livingston Co) – (517) 548-1350
National Domestic Violence Hotline – (800) 799-3224
SAFE House – (Ann Arbor) (734) 995-5444
SAFE House Website – <http://www.safehousecenter.org/>

Sexual Assault/Incest:

LACASA (Livingston Co) – (866) 522-2725
SAFE House – (Ann Arbor) (734) 995-5444

How to Decide Whether a Clinical Practice Guideline Is Trustworthy

David F. Ransohoff, MD

Michael Pignone, MD, MPH

Harold C. Sox, MD

THE PROLIFERATION OF PRACTICE GUIDELINES AND RECENT controversies about cancer screening guidelines highlight the need to decide which guidelines are trustworthy. Cancer screening guidelines exemplify the challenge of public trust in guidelines. A firestorm of controversy (created in part by news media, professional organizations, disease advocacy groups, and politicians) surrounds discussions of screening for prostate cancer (should screening be routinely recommended, discussed, or discouraged?), breast cancer (should screening start at age 40 or 50 years?), and colon cancer (is colonoscopy preferred or are any of several test strategies acceptable?). Trust is important because guidelines set the de facto standard for medical practice and therefore influence clinical decisions about individual patients, practice measures, insurance coverage, and reimbursement.

The question of trust is important enough that Congress in 2008 charged the Institute of Medicine (IOM) of the National Academies with developing standards for objective, scientifically valid, and consistent approaches to developing practice guidelines.¹ Measurement of adherence to such standards could provide an indication of trustworthiness, which could help users decide which of several conflicting guidelines to adopt. In a recent evaluation of 114 randomly chosen guidelines, researchers found poor adherence to the IOM standards, raising questions about the best approach to use guidelines as a benchmark of excellent care.²

Concerns About the Process of Developing Practice Guidelines

The public should trust practice guidelines only if the recommendations accurately reflect the underlying evidence about benefits and harms to individual patients. Therefore, the first requirement for earning trust is a rigorous process for assembling, evaluating, and summarizing the evidence. This requirement is satisfied by performing a systematic review and assessing the quality and strength of the body of evidence. This process requires clinical epidemiological skills and a substantial investment of resources.

The second requirement is a process for deciding, based on evidence, which of the possible clinical strategies offers the most

favorable balance of harms and benefits and should therefore become recommended practice.³ Because benefits and harms are often measured in different units, quantitative estimation of net benefit is necessarily subjective and therefore potentially influenced by financial or intellectual conflicts of interest. Because objective methods to estimate net effect at a population or individual patient level are still in an early stage of development,³ a guideline development panel that is free from conflicts of interest provides the best safeguard against bias.

Guideline panels have taken different approaches to ensure methodological rigor and manage conflict of interest, thereby placing the public and practicing clinicians in a vulnerable position; by 2008, more than 350 groups had created several thousand practice guidelines.⁴ This chaotic practice guidelines scene led to the Congressionally mandated IOM study.¹

The IOM Committee's Work

The IOM committee built on the work of others. Since 2003, the Appraisal of Guidelines, Research and Evaluation (AGREE) system had been the most widely accepted set of standards for rating the quality of the process of guideline development.^{1,5} The IOM committee took a more comprehensive view of guideline development, summarizing its recommendations as 8 standards (BOX). The IOM included items that AGREE omitted: updating guidelines, external review and public comment, the funding of guideline development, and the interplay of the guideline group with the team developing the systematic review of pertinent evidence. Most importantly, the IOM recommendations on managing conflict of interest were more extensive and much stronger than the AGREE standards. Of equal importance, while AGREE specified a systematic search of the literature, the IOM committee set a higher standard by specifying a systematic review, which is a more rigorous and better standardized approach to characterizing a body of evidence.⁶ Taken as a whole, the IOM recommendations are an important step forward. The American Cancer Society has adopted similar standards to direct its guidelines process,⁷ a hopeful sign that guidelines developers may move toward a set of common practices that strengthen trustworthiness.

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Box. A Summary of the Institute of Medicine (IOM) Standards for Trustworthiness

1. **Transparent process:** The processes by which a clinical practice guideline is developed and funded should be described transparently.
2. **Conflicts of interest:** Potential guideline development group members should declare conflicts. None, or at most a small minority, should have conflicts, including services from which a clinician derives a substantial proportion of income. The chair and co-chair should not have conflicts. Eliminate financial ties that create conflicts.
3. **Guideline development group composition:** The group should be composed of methods experts, clinicians, representatives of stakeholders, and affected populations.
4. **Systematic reviews:** Essential to the process, systematic reviews must meet the IOM's methodological standards.
5. **Evidence quality and recommendation strength:** Explain the reasoning behind each recommendation, summarize evidence for benefits and harms, characterize the quality and quantity of relevant evidence and the role of subjective judgments. Rate the level of evidence and the strength of the recommendation. Describe differences of opinion about recommendations.
6. **Articulating recommendations:** Describe the action recommended by the guideline and when it should be used; wording should facilitate measurement of adherence.
7. **External review:** Essential to the process, external review should include a full spectrum of stakeholders, reviewers not identified by name, explain all changes done in response to reviewers, and post for public comment.
8. **Updating:** Document the dates of the guideline, systematic review, and planned update; monitor the literature and update the guideline when new evidence suggests the need for change.

Source: Abstracted by the authors from the IOM committee report.¹

While the IOM committee provided a comprehensive set of standards, it imposed an impractical definition of trustworthiness. According to its report, “to be trustworthy, a clinical practice guideline should comply with proposed standards 1-8.” This definition of trustworthiness sets a very high, inflexible standard: a guideline is trustworthy only if it meets all 8 standards. A close analysis of this definition reveals important difficulties. First, as summarized in the Box, most of the standards have several elements; must each element of a standard be present to declare that a guideline adheres to that standard, or would only 1 element be sufficient? Second, the decision to define trustworthiness as meeting all 8 standards—with anything less presumably constituting “untrustworthy”—does not meet the need for nuanced guidance in interpreting different degrees of adherence to a standard. Suppose that none of the guidelines scored an 8 of 8. How should a guideline user decide which guideline is the most trustworthy?

As noted earlier, a recent study showed poor adherence to the IOM's trustworthiness standards.² By the IOM committee's strict definition, none of the 114 guidelines were trustworthy. On this evidence, guideline users must choose between several imperfect guidelines. They will need a method to measure partial adherence to the IOM standards and their related subelements.

Future Work

The task of developing measures of trustworthiness is formidable but doable. First, identify a transparent, trustworthy process for developing a set of measures. Second, find reliable measures to express the degree of adherence to each standard, determine how to combine each individual element into a composite measure of adherence to an individual standard, and derive a total trustworthiness score, reflecting adherence to all standards and subelements. Third, recognize that the process of developing measures of trustworthiness is likely to be a work in progress, with stakeholders' comments and revision playing an important role. Fourth, identify an institutional home that can sustain the process of developing measures of trustworthiness. Fifth, develop a marketplace for trustworthy guidelines, one in which trustworthiness ratings of guidelines for a problem (eg, screening for cancer) are displayed alongside the recommendations.⁴ As with readers of publications that evaluate consumer goods, many guidelines users will gravitate toward the most highly rated guidelines.

Guidelines, especially those that try to set limits, will always raise controversy. Clinicians, patients, and policy makers should insist upon a constructive dialog about the evidence and its translation into recommendations. An explicit, transparent process for evaluating adherence to the IOM committee's standards should elevate this conversation to a higher plane.

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Additional Contributions: The authors are members of the Institute of Medicine committee.

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The Patient-Centered Medical Home:

A Brief Educational Agenda for Teachers of Family Medicine

Jerry Kruse, MD, MSPH

(Fam Med 2013;45(2):132-6.)

In 2007 and 2008, STFM President John Rogers, MD, MPH, MEd, wrote a series of articles that outlined an educational agenda for the patient-centered medical home (PCMH).¹⁻⁶ Over the past 5 years, data compiled by the Patient Centered Primary Care Collaborative (PCPCC) have corroborated the historical evidence and added new evidence that the PCMH is a clinical model that improves health care outcomes and lowers health care costs.^{7,8} All family medicine educators should have a clear understanding of the effective elements of the PCMH, and this knowledge should be transmitted to all of our learners, to our colleagues in other disciplines, to the leaders of our local institutions, and to legislators, regulators, members of the media, insurers, and business leaders. The educational agenda for the PCMH is broad, and I will address the current status of the agenda in this article.

A Brief History of the Effectiveness of the PCMH

The term “medical home” was coined by pediatricians in the late 1960s. The model used by this discipline coordinated health care services for children with chronic illnesses. In 2002, consultants for the Future of Family Medicine project encouraged family physicians to use clear language to identify their profession and practice. The consultants recommended that we call ourselves family physicians (not family practitioners), that we call our discipline family medicine (not family practice), that we call our practice the Personal Medical Home, and that we call our facility for ambulatory

care the Family Medicine Center. In 2004 and 2005, a series of articles by Barbara Starfield, MD, MPH, articulated the elements of primary care practice that improve outcomes and lowers costs.^{9,10} These essential elements are listed on the top portion of Figure 1 and subsequently became the foundational elements of the PCMH.

On September 28, 2006, Thomas Weida, MD, representing the American Academy of Family Physicians (AAFP), testified about the effectiveness of the Medical Home to the House Energy and Commerce Subcommittee on Health. This committee embraced the medical home concept as the basis for ongoing health care reform legislation. In March 2007, the AAFP, the American Academy of Pediatrics, the American College of Physicians, and the American Osteopathic Association produced *The Joint Principles of the Patient-Centered Medical Home*, a summary of which is found on the bottom portion of Figure 1. It was then that the term “patient-centered medical home” became the legislative definition for the type of primary care practice that improved outcomes and lowered system-wide costs. The Joint Principles incorporated the seven effective elements articulated by Starfield and visionary elements that emphasize the effective use of health information technology, evidence-based medicine, and care coordination. A critical appraisal of each of the bulleted points of the Joint Principles was published by Rosenthal.¹¹ The two documents produced by the Patient Centered Primary Care Collaborative have corroborated the effectiveness of the visionary elements advanced by the authors of the Joint Principles.^{7,8}

Definition and Implementation of the PCMH

The top portion of Figure 1 shows the simplicity of the seven foundational elements of the PCMH. Implementation of these relatively simple concepts has proven to be a complex process. Family medicine educators must treat foundational principles of the PCMH much like the major elements of a strategic plan. The foundational principles of the PCMH should be known cold by all family medicine educators and should be used to guide us as we develop the educational environment and learning objectives for the PCMH in our local environments. When developing educational programs, we must not become enveloped by details that do not directly relate to foundational principles of the PCMH. Though certification agencies often include details outside the realm of the foundational principles, we must remain true to the foundational principles when assembling the PCMH and developing educational programs therein.

Educational Agenda for the Patient Centered Medical Home

1. Medical Student Education

Family medicine educators must assure that the principles of the PCMH are taught to medical students at all level of training, Year 1 through Year 4. We must develop new educational models to deliver the PCMH curriculum. In 2007, in response to the evidence from Starfield and the Joint Principles, the Department of Family and Community Medicine (FCM) at Southern Illinois University (SIU) School of Medicine changed the focus of the 6-week, Year 3 clerkship. The major educational emphasis of the clerkship changed from one that emphasized presenting complaints and care of acute and chronic illnesses to one that emphasized systems of care delivery and the PCMH model. Figure 1 is used as the major reference guide for students on this clerkship. Since the institution of this new model of clerkship training, the FCM clerkship has become the highest rated clerkship in the SIU system. Student scores on the Family Medicine National Board of Medical Examiners shelf test have not declined over this period of time.¹² For such a model to be successful, family medicine clerkship directors must identify clinical practices and preceptors who successfully model the foundational elements of the PCMH.

2. Residency Education

Family medicine resident physicians should practice in environments that use the foundational elements of the PCMH. Most of these experiences should be in practices that are dedicated to residency training, and others should be undertaken in an apprenticeship model in PCMH practices with physicians that provide one-on-one training for the family medicine resident physician. Needless to say, all family medicine resident physicians should master the material cited in this article.

3. Longitudinal PCMH Training Experiences

An excellent way to introduce the principles of effective primary care practice to medical students is through longitudinal experiences in exemplary PCMH practices as early as possible in medical school training. The development of a hierarchal curriculum in effective practice by usual sources of comprehensive longitudinal care will provide the student an appreciation for the effectiveness of such model.

4. Block Training in the PCMH

Longitudinal experiences in the PCMH are not enough for medical students. Block PCMH experiences provide educational experience considerably different than that provided in longitudinal training. It is my opinion that every medical student should have one or more block experiences in an exemplary PCMH for a sustained period of time, at least 4 weeks. The student must live and breathe the practice day to day to truly understand the meaning of first contact access, comprehensive care, patient-focused care over time, and coordinated care. Family medicine resident physicians should also have block experiences in which they live and breathe such exemplary practices.

5. Inter-Professional Education

If family physicians are to become adept at team-based and coordinated care, early inter-professional educational experiences are a necessity. The earlier such educational experiences occur in the student's training, the more likely the student is to incorporate coordinated team-based care in later practice. Students from a variety of disciplines – medical assistants, nursing students, nurse practitioner students, physician assistant students, pharmacy students, counselors, social workers, physicians—should have early training

Figure 1: The Patient-Centered Medical Home: Outline for the Southern Illinois University Family Medicine Clerkship

Characteristics of Practices of Personal Physicians Associated With Improved Health Outcomes and Equity and With Lower Costs ^{9,10}	
The Four Essential Functions of Primary Care	
1.	First Contact Access. The degree to which patients seek advice and care first at the practice of the personal physician, except for medical catastrophes
2.	Patient-focused Care Over Time. The degree to which the practice emphasizes patient-focused care, rather than disease-focused care, and longitudinal care, rather than episodic care
3.	Comprehensive Care. The degree to which the personal physician provides a broad range of health services
4.	Coordinated (Integrated) Care. The degree of integration of care among health professionals and staff, both within the patient-centered medical home and with outside organizations and consultants and the degree to which talents of all members of the team are used optimally
The Three Corollary Functions of Primary Care	
5.	Family Orientation. The degree to which medical services are provided to family members by the same personal physician
6.	Community Orientation. The degree to which the practice assesses the needs of the community, designs interventions, and measures outcomes
7.	Cultural Competence. The degree to which the biopsychosocial model is employed and health beliefs are addressed
Joint Principles of the PCMH AOA, AAFP, AAP, and ACP Legislative Definition of the PCMH and Vision for the Practice of the Future http://www.medicalhomeinfo.org/Joint%20Statement.pdf	
<ul style="list-style-type: none"> • Personal Physician • Physician Directed Medical Practice • Whole Person Orientation • Coordinated and Integrated Care 	<ul style="list-style-type: none"> • Quality and Safety Measures Evident <ul style="list-style-type: none"> • EBM and Clinical Decision Support • Voluntary CQI Processes • Patient's Expectation Met • HIT Used Appropriately • Voluntary Recognition Process • Enhanced Access • Appropriate Payment
<p>The four essential functions of primary care and the three corollary functions of primary care (together the seven foundational elements of primary care) have long been known to improve health care outcomes and lower cost. Recently, high-functioning data management systems and systems of care coordination, such as the elements listed under "Quality and Safety Measures Evident," have also been shown to improve outcomes and lower costs. Reports of the Patient Centered Primary Care Collaborative have provided this new data.^{7,8}</p>	

experiences together in a PCMH setting. A progressive, inter-professional curriculum through training will give our medical students and resident physicians the best opportunity to "practice at the top of their training" and to allow those in other disciplines to do likewise.

6. Simulated Practice

Simulation in health care education is gaining in popularity and efficacy. Too often, simulation of team-based care in office and community settings is neglected. Family medicine educators should develop curricula that provide

simulated practice experience in community and primary care office-based settings.

7. Care Coordination

The PCMH must model appropriate care coordination. At the least, family medicine resident physicians should understand and should be able to supervise the following categories of care coordination: (1) Care coordination/case management oversight (project manager). This coordinator will have mastered the skills of the other three types of care coordinators below and will have skills in administration and team building, (2) Case management for the vulnerable, high-risk, high-cost patient (case manager). Patients in need of this level of care will be identified on a population basis and will require the services of an RN or social worker, (3) Care coordination for transitions of care (transition coordinator). Most transitions of care will occur between the hospital, the home, and the primary care office but also will include transitions to nursing homes and other living facilities. It is best that this care coordinator's office be located physically in the PCMH, (4) Longitudinal care coordinator for registry function (registry coordinator). This position will manage data, registries, visit summaries, pre-visit preparation, referral tracking, and meaningful use.

8. Mental Health Services

Co-location of mental health services under the roof of the PCMH has become increasingly popular in the United States and Canada. Comprehensive mental health services, which include counseling by social workers and licensed clinical professional counselors and periodic on-site consultations by psychiatrists, has proven beneficial as a component of the comprehensive care needed in the PCMH.

9. Information Technology and Health Information Exchange

All of our learners must be adept at using electronic medical records (EMRs) and interpreting data provided by EMRs. EMRs must give an advantage in the utilization of evidence-based medicine by providing point-of-service clinical decision support. The EMR must also provide rapid feedback of packaged information to the providers in a continuous quality improvement process. Family medicine educators should insist that utilization of this type of information technology leads to the granting of continuing medical education credit, enabling

CME credit for utilization of point of service decision support and reinforcing CME credit for CQI processes.

10. Advocacy

Family medicine educators should advocate for activities that will promote the development of a pervasive network of PCMHs. We must collectively develop advocacy skills for payment reform and blended systems of payment, for new legislation related to the PCMH, and for systems of health information exchange.

11. Leadership Training

To date, required curricular elements for leadership training for medical students and family medicine resident physicians have been meager. Required leadership training experiences are needed for family physicians to direct inter-professional care and to lead health system reform, both vital to the development of effective and pervasive PCMHs.

12. Faculty Development

We must provide resources to train faculty members in leading change and in PCMH educational initiative. We await implementation of the Primary Care Faculty Development Initiative (PCFDI), an initiative developed jointly by HRSA, the American Board of Internal Medicine, the American Board of Pediatrics, and the American Board of Family Medicine as a pilot program designed to provide four interdisciplinary faculty teams in internal medicine, pediatrics, and family medicine an opportunity to engage in a collaborative learning experience that focuses on new models of health care delivery.

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REQUIREMENTS

**CASE DISCUSSIONS
REQUIRED READINGS**

CASE DISCUSSIONS

Each student will present a brief patient case (~15 minutes) within one of the following categories. The purpose of the case presentations is for the group to discuss the relevant points of each case in detail, facilitated by a faculty preceptor. These sessions are designed to be interactive, as the majority of the information regarding each case should be obtained by the case presenter's peers. While handouts are not needed for these discussions (and patient confidentiality should be protected), case presenters should know all pertinent details of each case to be presented. Presenters should be well acquainted with the case history, physical findings, genogram, lab and radiographic results, and treatments and outcomes (if known). If you have access to copies of EKG tracings, radiographs, photos, or other relevant materials you could bring one copy to pass around the table.

Note: Special attention will be given to the role of the family physician within the healthcare system at large, the appropriateness of specialty referral, evidence-based guidelines, and cost-effective provisions of care. The concepts of the patient-centered medical home, population management, role of accountable care organizations, and quality metrics should be discussed in each case, where applicable. Be prepared to teach your classmates. Review of pertinent diagnostic and treatment guidelines by each presenter is strongly encouraged.

ACUTE CASES

Group A

Presenters will identify one case of a patient who presents with an acute problem or complaint (not for a routine follow-up visit pertaining to a chronic problem – see below) that requires a detailed evaluation and a diagnostic workup. Prior to the presentation, you will need to make some short notes on the case. Your presentation should include the presenting history, pertinent examination findings, any laboratory or radiographic investigations, and the initial management plan for the patient. The focus of the discussion will be to solicit group questioning on the differential diagnosis and therapeutic planning strategies for each case and on how these may differ in patients seen in primary care compared with other settings.

*****Do not share your case in advance with other students.**

CHRONIC CASES

Group B

Presenters will identify one case of a patient who is being followed for a chronic disease (e.g. hypertension, diabetes, asthma, chronic pain, coronary artery disease, chronic obstructive pulmonary disease, GERD, etc. – there are many possibilities here...). Prior to the presentation, you will need to make some short notes on the case. Your presentation should include a summary of the history and focus predominantly on the management of the case, including note of any agencies involved in the care or support of the patient as well as arrangements for follow-up of the patient. The focus of the discussion will be on the management of the complexities of the chronic disease and its impact on the life of the patient and his/her family, within the construct of the principles of population management.

*****Discuss your topic(s) with the other students within this group to prevent overlap (READ: not everyone should present a case on diabetes management).**

GENERAL CASES

Group C

Presenters will identify one case that can fit into either the acute or chronic case discussion category as above. Any patient is appropriate to present during this session.

REQUIRED CLERKSHIP READINGS

Students are **required** to read the following six chapters from the **Guide to Clinical Preventive Services** before the session on prevention and screening. Students are encouraged to read other chapters in this web-based resource that are relevant to patients that you see during the clerkship.

Current Methods of the U.S. Preventive Services Task Force: A Review of the Process

1. Aspirin/NSAIDS for prevention of Colorectal Cancer
2. Screening for Lead Levels in Childhood and Pregnancy
3. Dementia (Alzheimer's Disease) Screening
4. Screening for Breast Cancer
5. Screening for Prostate Cancer
6. Family Violence: Screening

ORIENTATION

September 2019

ORIENTATION TO FAMILY MEDICINE

Practical Pointers to Help Make Outpatient Visit Run Smoothly

1. Review Chart/Electronic Medical Record

Patient Name

- Reason for this visit
- Problem list
- Medication list – Joint commission standard to update this at every site

a) New Problem: think about what other information you might need (ie: cough?smoker?)

b) Follow-up: Read previous notes/lab results/consultant letters etc.

c) Health Maintenance: Take into account patient problems, age appropriate screening/advice re: behavioral change

2. Knock and open door slowly in case pt. getting undressed or child behind the door

3. Introduce yourself:

- Name
- Student doctor working with (provider's name) who will join you later

HISTORY

- Open ended: "Tell me about your concerns today" or closed: "I see you are here for ...can you tell me about that:"
- "Is there something else you would like to discuss?"
- Keep problem focused but be alert to related or other concerns. Only ROS that are related to problem are necessary.
- Also keep chronic problems/med etc. in mind which might have an impact.

PHYSICAL EXAM

- If necessary for patient to undress, step out of room.
- Keep focused on acute/chronic problem
- HME's – even this is focused on problems and prevention and screening
- Explain what you're doing and keep movements smooth but firm
- **Always have preceptor present for breast/genitourinary/rectal exams**
- Ask preceptor to recheck/refine your exam whenever you want feedback.

ORAL PRESENTATION:

- How formal/broad will depend on preceptor, but follow usual order unless asked to do otherwise.
- If waiting for preceptor READ, go back and ask more questions, formulate assessment, start typing/writing your note

ASSESSMENT AND PLAN

- Mostly formulated by preceptor early on but late students do more of this. **Big** differences in style
- What is the working diagnosis, how certain?
- Further testing
- Treatment – recommendations and option
- Discussion of what to expect/side effects, etc.
- Follow-up – interval, warning signs
- Instructions – Written if more complex

WHAT IS FAMILY MEDICINE?

I. DEFINITIONS

General Practitioner

A physician trained before 1969 to give primary care to individuals regardless of age, gender or type of health problem. Training included four years of medical school and a one-year rotating hospital based internship.

Family Physician

A physician trained (after 1969) in the discipline of family medicine to provide care to patients and their *families* with a focus on their *community*. The care provided is *continuing, comprehensive, coordinative, preventive*, and delivered in a personalized manner to patients regardless of age, gender, presence of disease or organ system affected.

Family Medicine

An academic discipline which includes a body of knowledge, skills and attitudes that constitute the medical discipline and are necessary for a family physician to provide clinical care and conduct the research and educational activities which affect the delivery of primary care.

Primary Care

...emphasizes *first-contact* and assumes...[*continuing*] responsibility for the patient in both health maintenance and therapy of illness. It is *personal* care involving a unique interaction and communication between the patient and the physician. It is *comprehensive* in scope and includes the overall *coordination* of the care of the patient's health problems, be they biological, behavioral or social...[including] appropriate use of consultants and community resources (AAFP Reporter)

Level of medical services which is community based as opposed to that of a consultant or specialist (secondary care) or use of hospital services (tertiary care). It includes the tasks of:

- 1) medical diagnosis and treatment
- 2) psychological assessment and management
- 3) personal support
- 4) communication of information about illness, prevention and health maintenance
- 5) maintenance of patients with chronic illness
- 6) prevention of disability and disease through detection, education, persuasion and preventive treatment.

Ambulatory Care

Personal health services rendered to individuals in an outpatient setting, at any time when they are not currently admitted to a hospital or health care institution.

Medical Record Documentation

After a patient encounter in the clinic, you will be expected to document the visit in the patient's medical record. The organization of the medical record will vary depending on your site. It is a good idea to familiarize yourself with the layout of the medical record during your first visit to your preceptor's clinic. Follow that site's guidelines for documentation. In general, most visits will be documented with a "S.O.A.P" note (see below). However, many clinics use special forms/on-line templates for certain types of visits, including but not limited to the following: health maintenance exams, prenatal visits, well child visits. Be aware of your clinic's guidelines and you will save yourself extra work. This information should be reviewed with you at the beginning of your first week - by all means ASK if you have any questions.

S.O.A.P. notes

If you have completed other clinical rotations, you are probably already familiar with this form of documentation. In general, visits should be documented in the progress notes using this format, unless you are instructed otherwise. If you are hand writing notes, always use a black pen.

S: (Subjective)

This section describes the patient's complaint, or the reason for the visit. Use the patient's own words when appropriate. Use dates or "3 day history" rather than "last Friday." Any pertinent past medical history, medication use, etc. should be included here.

(Social History may be documented here)

O: (Objective)

This section describes physical examination findings. Document only relevant positive or negative findings. You should always include the patient's vital signs (temperature, blood pressure, etc.) at the beginning of this section, if relevant, then list examination findings in the standard format you have been taught.

A: (Assessment)

You should include the patient's diagnosis (obtained from the visit) in this section. If a patient has multiple diagnoses that were addressed at the visit, they should all be included in the assessment. This section should be written after you have discussed the case with your preceptor.

P: (Plan)

Outline the treatment plan for the patient. Be sure to include medications prescribed, tests ordered, and plans for future visits. This section should be written after you have discussed the case with your preceptor.

Note: It is often beneficial to combine the assessment and plan when multiple diagnoses/systems are addressed.

Choose an interesting diagnosis, symptom, or treatment that you see in patient care and read more about it that night—this is one of the most effective methods to absorb and retain new information.

Prescription Writing

At your patient care site, you may be expected to write out prescriptions which will then be reviewed and co-signed by your preceptor. If you are not familiar with how to write a prescription, you may find it helpful to review this section prior to starting your clinical experience.

Prescription Requirements

- 1. Patient Information** - usually just the patient's full name.
- 2. Medication name, dosage and type**
 - a. Medication name - may use the generic or trade name
 - b. Dosage - most medications come in difference strengths, so you need to include the strength prescribed.
 - c. Type - which form of the medication are you prescribing (capsule, suspension, rectal suppository, etc.)
- 3. Directions for taking medication**
 - a. Amount (number of pills, quantity of suspension, etc.)
 - b. Route of administration (orally, rectally, intramuscular, etc.)
 - c. Frequency (how many times per day the medication should be taken)
- 4. Quantity Dispensed** - this should be written in numerical form and then the quantity should also be written out.
- 5. Number of Refills** - this should never be left blank.
- 6. Date that the prescription was issued will automatically print.**
- 7. Prescriber Information**
 - a. Physician signature
 - b. Physician number (will automatically print on script)

Sample Prescription

Name: John Doe

Hydrochlorothiazide 25 mg

Sig: i tab po Q Day

Disp: 90 (thirty)

Refill: 3 times

Commonly used abbreviations

a.c. before food or meals

bid twice daily

c with

cap capsule

gm gram

gtt. drop

h hour

hs at bedtime

p after

p.c. after food or meals

p.o. by mouth

p.r. per rectum

prn as needed

qh every hour

qhs every bedtime

qid four times/day

q 4h every 4 hours

s without

stat now

tab tablet

tid three times/day

HANDOUTS AND READINGS

Musculoskeletal

1. General/Shoulder
2. Knee Evaluation

Acute Low Back Pain

Contraceptives

Population Health and Prevention

**DEPARTMENT
OF
FAMILY MEDICINE**

**MUSCULOSKELETAL
HANDOUTS**

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Principles of the Musculoskeletal Exam

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Department of Family Medicine
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I. History

- A. Presentation or chief complaint
 1. Pain
 2. Instability
 3. Stiffness
 4. Weakness
 5. Catching or locking
 6. Swelling
 7. Paresthesias
- B. History of current illness
 1. Onset
 2. Clinical course and influence of treatment
 3. Progression of the process
 - a. Progressive
 - b. Improving
 - c. Up and down
 4. Current status of the problem
 - a. Character and intensity
 - b. How does it interfere with activities of daily living, work, and recreation?
 5. Problems or symptoms from other muscles or joints
 6. Systemic signs or symptoms (e.g., fever, night sweats, fatigue, etc)
- C. Past medical history
 1. Previous injuries or problems involving the same muscle group or joint
 2. Previous history of injury
 3. Previous surgeries
 4. Medical problems
 - a. Rheumatologic diseases
 - b. Endocrine disorders (e.g., diabetes mellitus, thyroid disease, osteoporosis)
 - c. Medications
 - d. Drug allergies
- D. Review of systems
 1. Problems or symptoms from other muscles or joints
 2. Systemic signs or symptoms (e.g., fever, night sweats, fatigue)
 3. Other signs or symptoms (e.g., swelling, shortness of breath, chest pain)
- E. Family history
- F. Social history

1. Job activity
2. Recreational activity and/or sports
3. Drug, ergogenic aide, and supplement use

G. Summary

1. Get enough information about the injury so that you can confidently classify it into one of four categories:
 - a. Acute injury
 - b. Chronic injury
 - c. Acute on chronic injury
 - d. Chronic on acute injury
2. Try to generate a hypothesis regarding “why now?”

II. Physical exam

A. Overall format (Hawkins)

1. Initial impression
2. Inspection
3. Palpation
4. Range of motion
5. Neurological examination
6. Stability assessment
7. Special tests
8. Measurements
9. Vascularity
10. Gait analysis
11. General assessment

B. General approach (Cyriak)

1. Observation
2. Active range of motion
3. Passive range of motion
4. Resisted muscle testing
5. Special tests

C. **Observation**

1. General distress and disability
2. Functional assessment
3. Gross swelling and/or deformity
4. **Attitude:** Position in which the patient holds the involved part relative to the body, and the posture of the segment in that position.
5. **Alignment**
 - a. Varus deformity: Distal segment is deviated toward the midline
 - b. Valgus deformity: Distal segment is deviated away from the midline
6. Muscle bulk and contour
 - a. Acute hypertrophy indicates muscle spasm
 - b. Atrophy indicates neurologic deficiency or musculotendinous rupture

D. Active range of motion

1. Observation of movement in the basic planes of movement
 - a. Frontal plane: flexion and extension
 - b. Coronal plane: abduction (away from the body) and adduction (toward the body)
 - c. Transverse plane: internal and external rotation
2. Note range of motion (compare sides) and amount of pain (and when the pain occurred)

E. Passive range of motion

1. Patient relaxes the muscles completely while examiner moves the affected joint through the planes of motion
2. Note range of motion and pain

F. Resisted muscle testing

1. Resist patient's movement in the planes of movement – do not allow movement
2. Position yourself at a mechanical advantage over the limb you are testing.
3. Note pain and strength
 - 0 = no contraction felt
 - 1 = muscle can be felt to tighten but cannot produce movement
 - 2 = produces movement with gravity eliminated but cannot function against gravity
 - 3 = can raise against gravity
 - 4 = can raise against outside moderate resistance as well as against gravity
 - 5 = normal full strength

G. Palpation

1. Assess for swelling
2. Be systematic in palpating. Use bones and joint lines as frames of reference
3. Identifying joint line pain is important

H. Special tests

1. Includes tests for ligament integrity and joint stability
2. Used primarily to confirm a diagnosis

COMMON MUSCULOSKELETAL PROBLEMS

Case Presentation

A 19-year-old female freshman runner presents with a 5 week history of bilateral anterior knee pain. She does not recall an acute injury. The pain is exacerbated by running hills, and over the past few weeks her knees ache during long car trips and with prolonged sitting in class. There is a small amount of knee swelling after work-outs. She denies any knee locking, but has experienced a few episodes of a “giving way” sensation while running, although she has not fallen down.

Knee Injuries

I. Patello-femoral stress syndrome

A. The most common source of knee pain. May affect up to 1 out of 4 individuals

- female athletes particularly susceptible

B. Proper biomechanics of patella during knee extension requires balance of lateral and medial forces

1. Lateral patellar movement controlled by:
 - a. Anterior projection of lateral femoral condyle
 - b. Static pull of medial retinaculum
 - c. Dynamic medial pull of vastus medialis oblique (VMO)
2. Forces pulling patella laterally
 - a. Lateral retinaculum
 - b. Ilio-tibial band

C. Anatomic predispositions

1. Increased “Q-angle”
2. High riding patella (“patella alta”) or low riding patella (“patella baja”)
3. Small lateral femoral condyle
4. Shallow patellofemoral groove

D. Biomechanical predispositions

1. Weak medial quadriceps mechanism
2. Foot strike pronation
 - causes a compensatory internal rotation of the tibia and increases the rotatory stress absorbed by the peripatellar structures
3. Hamstring muscle tightness
 - causes increased flexion of the knee, thereby increasing patellofemoral compression during the stance phase of gait
4. Gastrocnemius muscle tightness
 - gastroc and/or hamstring tightness causes compensatory foot pronation
5. Ilio-tibial band tightness
6. Medial structure laxity
7. Hip adductor muscle weakness
 - VMO muscle fibers originate from the tendon of the adductor magnus. A strong adductor magnus gives the VMO an anchor from which to contract

E. Evaluation of patellar pain

1. History

- a. Anterior knee pain around the patella.
- b. Exacerbated by walking steps (especially going down), raising from squatting position, prolonged sitting with knee flexed.
- c. "Pseudolocking" and "giving way" sensation

2. Physical exam

- a. Peripatellar tenderness, especially medially.
- b. Patellar apprehension test: Push patella laterally.
- c. "Distal push" or "inhibition test"
- d. Palpation of patellar tendon
 - 1) Tenderness at origin - c/w patellar tendinitis
 - 2) Tenderness at insertion onto tibial tuberosity - c/w Osgood-Schlatter's disease in the patient who is still growing.
- e. Evaluation of ligaments and menisci

3. Radiographs

- a. Standing AP
patellar position & height
symmetry of femoral condyles
- b. Lateral (30° of flexion)
patellar height: ratio of patella length to tendon should be 1:1.
Variation > 20% is abnormal
- c. Axial view
height of femoral condyles
depth of sulcus between condyles
"sulcus angle"
orientation of patella between condyles
arthritic changes

F. Patellofemoral syndromes

1. Patellar dislocation
2. Patellar subluxation
3. Patellar stress syndromes
4. Symptomatic patella plica

G. Treatment

1. Physical therapy

- a. Vastus medialis strengthening
straight leg raises
quad sets
closed chain exercises
- b. Hip adductor strengthening
straight leg raises with femur externally rotated
"pillow squeezes"
resistance exercises

- c. Stretching exercises to increase flexibility of hamstrings, gastrocnemius, ilio-tibial band
 - 2. Cryotherapy
 - 3. Non-steroidal anti-inflammatory medications (NSAIDs)
 - 4. Patella stabilizing braces and taping
 - 5. Surgery
- consider if no improvement after 6 months of physical therapy

II. Meniscal injuries

A. Symptoms

- Swelling proportional to activities
- Pain on rotary or flexion motion, particularly near extremes of flexion
- Pain on joint line
- Feeling of weakness and insecurity
- Giving way
- Locking
- Generalized aching in knee joint itself
- Popping, catching, or grinding

B. Signs

- Effusion
- Joint line tenderness (71%)
- Locking

C. Provocative maneuvers

- 1. Full extension and flexion- jointline pain indicative of meniscal tear
- 2. McMurray test
 - a. Forced internal and external rotary motion of tibia with full flexion and valgus-varus stress
 - b. Pain with internal rotation = lateral tear
Pain with external rotation = medial tear
 - c. Report as: "negative"
"positive for joint line pain"
"positive for pain and a clunk"
- 3. Steinman's test
 - a. Knee at 90° of flexion, external and internal rotation
-external rotation with medial joint line pain
-internal rotation with lateral joint line pain
 - b. Joint line pain moves posteriorly with flexion and anteriorly with extension
- 4. Appley's compression and distraction tests
- 5. Anderson test
 - Knee at 45° of flexion, apply valgus stress as knee is flexed and varus stress as knee is extended

D. Diagnostic imaging

1. X-rays to rule out other disorders (especially osteochondral defects)
2. MRI
 - a. A good exam is more sensitive for meniscal tears than an MRI exam
 - b. Useful when there is an intermediate probability of meniscal tear

E. Treatment is symptom driven

1. Physical therapy
2. Arthroscopy

III. Patella tendon overuse injuries

- A. Patella tendinitis ("Jumper's knee")
- B. Osgood-Schlatter disease (tibial tuberosity)
- C. Sinding-Larsen-Johansson disease (distal pole of patella)

IV. Lateral knee pain

Iliotibial band syndrome
Lateral meniscus tear
Lateral meniscal cyst
Lateral joint arthrosis
Lateral patellar facet syndrome
Lateral collateral ligament sprain
Biceps femoris tendinitis
Popliteal tendinitis

V. Medial knee pain

Medial meniscal tear
Medial collateral ligament sprain
Semimembranosus tendonitis
Pes anserine bursitis (sartorius, gracilis, semitendinosus insertion)

VI. Instability testing for ligamentous tears

A. Anterior cruciate tears

1. One plane anterior instability
 - a. Lachman's test (20-30° knee flexion)
 - b. Anterior drawer test (90° knee flexion)
2. Rotary instability tests
 - a. Anteromedial rotary instability
 - 1) Anterior drawer in 25-30° of external rotation
 - 2) Positive test implies disruption of posteromedial joint structures (MCL and posterior oblique fibers) as well as MCL
 - b. Anterolateral rotary instability
 - 1) MacIntosh lateral pivot shift
Lift internally rotated foot off table with knee extended. Flex the knee while applying valgus stress. Reduction in full extension with subluxation

at 5-10° and sudden relocation at 30-40° is positive test.

2) Losee's anterolateral subluxation test

Knee and hip flexed to 45° with tibia externally rotated. Slowly extend knee while applying valgus stress. Tibia goes from reduced position in flexion to sudden subluxation as it approaches extension to reduction in full extension.

3) Hughston's jerk test

Start with leg at 45° flexion of hip and 90° flexion of knee. Hold tibia in internal rotation. Slowly extend the knee while applying valgus stress.

Subluxation of the lateral tibial condyle on the femur occurs at about 20° of flexion, with sudden relocation with further extension.

B. Posterior cruciate insufficiency

1. One-plane instability
 - a. Posterior sag during extension
 - b. Posterior drawer test at 90° of flexion
2. Posterolateral instability
 - a. External rotation recurvatum test
 - b. Reverse pivot shift

Start at 90° of flexion, external rotation, apply valgus stress while extending knee

Reduction of posterolateral subluxation occurs at about 30°.

- c. Abduction (valgus) stress in full extension.

C. Lateral collateral ligament

1. Adduction (varus) stress with knee in full extension tests the LCL as well as the PCL and posterolateral capsule.
2. Adduction (varus) stress with knee flexed 20-30° and tibia externally rotated relaxes the cruciate ligaments and isolates the LCL. The IT band lies over the center of the lateral joint line in this position.

D. Medial collateral ligament

1. Abduction (valgus) stress with knee in full extension tests the MCL as well as the posterior oblique ligament and the cruciate ligaments. 3+ opening indicates a PCL and MCL tear.
2. Abduction (valgus) stress with knee flexed 20-30° and tibia externally rotated isolates the MCL.

Case Presentation

JS is a 46-year-old male who swims one mile a day 4 to 5 times a week. He complains of pain in the anterior aspect of his right shoulder over the past 4 weeks. He does not recall an acute injury. He first noticed the pain after his swim work-outs, but over the past few weeks it has been limiting his ability to finish his swims. The pain has also become more frequent in his daily activities, occurring with overhead activity or lifting of objects with a straight arm. During the past week, achiness in his shoulder has made it difficult to sleep at night.

Shoulder Rotator Cuff Injuries

I. Functional anatomy of shoulder girdle

A. 4 articulations

1. Sternoclavicular joint
 - accommodates 30° of clavicular elevation
2. Acromioclavicular joint
 - accommodates 30° of clavicular elevation
3. Glenohumeral joint
 - a. Designed for mobility: radius of humeral head is 3 times the radius of glenoid fossa
 - b. Motions
 - Abduction/Adduction
 - Flexion/Extension
 - Internal/external rotation
 - Translation
 - c. Capsule extends from the glenoid fossa to anatomic neck of the humerus with an inferior redundancy
 - d. Glenoid labrum
 - 1) Fibrocartilaginous rim that deepens the glenoid fossa
 - 2) Attachment for capsule and long head of biceps
4. Scapulothoracic articulation
 - a. Scapular rotation about 60°
 - b. Scapular translation about 15 cm

B. Passive stabilizing mechanisms

1. Bony
 - Glenoid is tilted posteriorly and humeral head is retroverted
2. Labrum
 - Inferior glenohumeral ligament attaches to anteroinferior aspect of labrum
3. Ligaments
 - a. Coracoacromial arch
 - b. Glenohumeral ligaments
 - Inferior glenohumeral ligament is primary restraint to anterior and inferior translation when arm abducted $>45^{\circ}$
 - c. "Dynamic ligament": Passive elements of subscapularis muscle restrain anterior translation up to 90° abduction

C. Dynamic stabilizing mechanisms

1. Maintain glenohumeral instant center of rotation
2. Force couples with rotator cuff muscles and scapular stabilizers
3. Muscles
 - a. Rotator cuff
 - Supraspinatus
 - Infraspinatus
 - Teres minor
 - Subscapularis
 - b. Major movers of humerus
 - Latissimus dorsi
 - Pectoralis major
 - Deltoid
 - Biceps brachi and triceps (long heads)
 - c. Scapular stabilizers
 - Trapezius
 - Levator scapulae
 - Rhomboids
 - Serratus anterior

D. Nerves

- Suprascapular (C4,5,6): Supraspinatus, Infraspinatus
- Subscapular (C6,7): Teres major, Subscapularis
- Axillary (C4,5,6): Deltoid, Teres minor
- Musculocutaneous (C5,6,7): Coracobrachialis, Biceps brachii
- Long thoracic (C5,6,7): Serratus anterior
- Dorsal scapular (C4,5): Rhomboids, Levator scapulae

II. Pathomechanics of “impingement”

- A. Scapulothoracic dysfunction
- B. Rotator cuff dysfunction
- C. Capsular dysfunction

III. Evaluation

A. History

1. Pain localized anteriorly and anterolaterally on the shoulder.
2. Exacerbated by overhead activities.
3. Often painful at night while in bed.

B. Physical exam

1. Assess active range of motion
 - a. Observe scapular movement during shoulder abduction
 - b. Apply's scratch tests
2. Assess passive range of motion
 - a. Impingement signs:
 - 1) Pain at 90-110⁰ of passive abduction
 - 2) Anterior impingement with forward flexion

- 3) Pain with forward flexion and internal rotation while examiner applies downward pressure on the acromion.
 - a) Cross flexion test for AC joint pain or posterior instability
- 3. Resisted muscle testing
 - a. Rotator cuff strength testing
 - 1) Resisted internal and external rotation
 - 2) Supraspinatus testing (“Dump the cans” in 30° of forward flexion)
 - b. Abduction and adduction
 - c. Speed’s test for biceps tendinitis:
 - Resisted shoulder flexion with the forearm supinated and the elbow extended.
- 4. Tests of glenohumeral stability and ligamentous laxity
 - a. Apprehension test (Jobe’s relocation test)
 - Firmly externally rotate the 90° abducted arm with the elbow flexed to 90°.
 - Place your hand behind the shoulder and apply force anteriorly. Then place your hand anteriorly over the proximal humerus and apply force posteriorly.
 - Apprehension and pain with external rotation that is relieved by anterior support is a “positive” relocation test
 - b. Anterior and posterior glide test.
 - c. Long arm glenoid traction to look for a visible sulcus sign (depression anteriorly and laterally in the subacromial region)

C. Diagnostic imaging

1. Radiographs

- a. AP views in internal and external rotation
 - True AP is a 40° posterior oblique view to visualize glenoid
- b. Axillary or scapular Y view (60° anterior oblique)
 - Important to obtain a lateral view of some sort to assess glenohumeral alignment
- c. Special views
 - 1) West Point axillary to demonstrate anteroinferior glenoid rim (“Bony Bankart lesion”)
 - 2) Stryker notch view to better visualize the humeral head (Hill-Sachs lesion = compression fracture of posterior aspect of the humeral head)

2. Imaging the rotator cuff

- a. Ultrasound
- b. Shoulder arthrogram
- c. MRI
 - High rate of “false positives”

IV. Differential diagnosis

Instability vs. rotator cuff tendinitis
Rotator cuff tear
Glenoid labrum tear
Adhesive capsulitis
Distal clavicle osteolysis
AC joint osteoarthritis
Calcific tendinitis
Biceps tendinitis
Cervical spondylosis
Suprascapular nerve compression
Infection

V. Treatment

A. Acute inflammation and pain

1. Ice
2. Non-steroidal anti-inflammatory medications
3. Subacromial bursa injection of lidocaine (or bupivacaine) and corticosteroid

B. Recovery phase

1. Range of motion exercises
2. Rotator cuff strengthening
Avoid resisted external rotation in patients with glenohumeral instability
3. Strengthening of scapular stabilizers
4. Coordinated shoulder movements

C. Surgery

1. Indicated for rotator cuff tears in patients who desire full use of shoulder and are committed to extensive rehabilitation after surgery
2. Stabilization procedures have best results in patients with history of acute, traumatic dislocations
3. Most cases of “impingement” best treated with activity modification and muscle strengthening. Resection of acromion does not treat underlying problem in most cases.
4. Glenoid labral tear should be suspected in throwing athletes with persistent “dead arm”. Diagnosis often only made during arthroscopy

Case Presentation CC is a 38-year-old female recreational tennis player with a 3 week history of pain on the lateral aspect of her right elbow. The pain occurs while playing tennis, particularly with backhand strokes. She had been playing 3 to 4 times a week in a tennis league, but has had to reduce her playing time because of the pain. She recently developed elbow pain while carrying her briefcase at work and with other lifting activities.

Lateral epicondylitis

I. Functional anatomy

- A. Lateral epicondyle of the distal humerus is the origin of the extensor carpi radialis longus and brevis
- B. Extensor carpi radialis brevis is under maximum tension when contracting while the forearm is pronated with the wrist flexed and ulnar deviated
- C. Posterior interosseous nerve is the main motor branch of the radial nerve that passes between the 2 heads of the supinator under the “arcade of Frohse”
- D. Wrist extensor strength should be 45-50% of flexor strength
- normally, wrist flexor strength > radial deviators > ulnar deviators > extensors. Supinator strength is normally > pronator strength.

II. Pathology and etiology of lateral epicondylitis

- A. More recent studies have found that microtearing of the common extensor tendon with granulation and degenerative changes rather than a true tendinitis
- B. Etiologic factors
 1. Prolonged repetitive use of wrist extensors
 2. Sustained contraction of wrist extensors
 3. Grip, eccentric loading, and impact
 4. Other areas that have been implicated include:
 - periostitis
 - radiohumeral bursitis
 - lateral ligament sprain
 - inflammation of annular ligament
 - posterior interosseous nerve entrapment
 - cervical radiculopathy

III. Evaluation

A. History

1. Area of pain, exacerbating activities, timing of pain in relation to activities
2. Previous history of elbow or wrist pain
3. Recent change in frequency or intensity of activity requiring wrist stabilization, especially gripping and/or forceful pronation and supination
4. If involved in athletics, recent change in equipment (eg, tennis or racquetball racquet)

B. Physical exam

1. Local tenderness on lateral aspect of elbow at common extensor origin
2. Resisted wrist extension and radial deviation (with elbow extended) causes pain at extensor origin
3. Resisted middle finger extension causes pain
4. Passive wrist flexion and pronation causes pain at common extensor origin
5. Elbow should have full range of motion without pain

C. Radiographs

1. Ordinarily not needed
2. Consider in the skeletally immature patient
3. Consider if decreased range of motion of elbow, or pain with elbow movement

IV. Differential diagnosis

- A. Lateral epicondylitis
- B. C6 radiculopathy
- C. Posterior interosseous nerve entrapment
- D. In skeletally immature patient lateral epicondylar epiphyseal injure fragmentation of the capitellum (Panner's disease)
- E. Elbow joint arthrosis

V. Treatment

- A. Ice, nonsteroidal anti-inflammatory drugs, relative rest
- B. Local injection of lidocaine (or bupivocaine) and a corticosteroid
- C. Analysis of exacerbating activity
 1. In tennis, common contributing factors are
 - poor stroke technique, using arm instead of body
 - raquet grip that is too small or large
 - too high string tension
 - racquet that is too heavy or stiff
 2. In all cases, there is inadequate wrist extensor power, flexibility, and/or endurance for the demands of the activity
 3. Orthoses
 - a. Forearm band (epicondylar splint)
 - b. Wrist resting splint (volar splint in 20° of extension)

D. Physical therapy

1. Local modalities to common extensor origin
2. Stretching of forearm muscles
3. Isometric, then isotonic and eccentric, strengthening of wrist extensors
4. Gradual return to activity
5. Surgery
 - a) Release of fascia and common extensor origin is most common
 - b) A procedure of last resort

Case Presentation SR is a 26-year-old male who injured his left ankle while playing volleyball 3 days ago. He remembers jumping and “turning his ankle over” when he landed. He had difficulty bearing weight after the injury, but continued to play the remainder of the game. A few hours later he had a great deal of swelling over the lateral aspect of his ankle. He went to the local ER where he was told he did not have a fracture and was placed in a posterior splint with instructions to use crutches for walking.

I. Ankle injuries

A. Functional anatomy

1. “Ankle joint” is actually 2 joints
 - a. Talocrural joint
 - 1) Formed by the distal tibia, fibula, and the talus
 - 2) Hinged joint that allows dorsiflexion and plantar flexion
 - b. Subtalar (talocalcaneal) joint
 - 1) Formed by talus, calcaneus, navicular, and cuboid
 - 2) Gliding and rotation produces inversion and eversion
 - 3) Posterior, anterior, and middle facets
 - a) Sinus tarsi is an opening just anterolateral to the posterior facet. The insertion for the: extensor digitorum brevis lateral talocalcaneal ligament extensor retinaculum
 - b) Tarsal canal is a small area between the posterior and middle facets which houses the interosseus ligament and the artery of the tarsal canal
2. Ankle mortise
 - a. Formed by the tibial and fibular components of the ankle which roof the talus
 - b. Plafond = tibial portion of the mortise
3. Talus
 - a. Head articulates with navicular bone
 - b. Neck
 - c. Body
 - 1) Lateral process articulates with posterior calcaneal facet distal fibula
 - 2) Posterior process: Formed by medial and lateral tubercles
 - a) Flexor hallucis longus tendon runs in a groove between containing the tubercles
 - b) Os trigonum
 - 1) Located just posterior to lateral tubercle
 - 2) Unfused accessory bone in 6.5% of adults
 - 3) Elongated lateral tubercle (Steeda’s process) in 50% of adults
 - 4) Posterior impingement symptoms can be caused by a symptomatic os trigonum or a fracture of the lateral tubercle (Shepherd’s fracture)
4. Supporting structures of ankle mortise
 - a. Subtalar inversion limited by
interosseous ligament
peroneal tendons
lateral ankle ligaments
 - b. Subtalar eversion limited by
deltoid ligament

- posterior tibial tendon
- anterior tibial tendon
- 5. Lateral ligament complex
 - a. **Anterior talofibular ligament** passes anteriorly from anterior aspect of the lateral malleolus to the lateral talar articular facet
 - 1) Restrains anterior talar motion
 - 2) Highest strain in plantar flexion
 - b. **Calcaneofibular ligament** lies nearly vertical from the inferior tip of the lateral malleolus across the subtalar joint to the lateral calcaneus
 - 1) Prevents excessive inversion
 - 2) Highest strain in dorsiflexion
 - c. **Posterior talofibular ligament** courses transversely from the posterior aspect of the lateral malleolus to the posterior process of talus (lateral tubercle)
 - 1) Prevents posterior talar motion
 - 2) Highest strain in full dorsiflexion, lax in normal standing position
- 6. Medial collateral ankle ligament = **Deltoid ligament**
 - a. Superficial portion goes from the medial malleolus to the navicular tuberosity, sustentacular tali, and talus
 - b. Deep portion attaches to medial talus
 - c. Provides medial stability and prevents excessive abduction and eversion of the ankle
- 7. Distal **tibiofibular articulation**
 - a. 4 syndesmosis ligaments
 - Anterior inferior tibiofibular ligament
 - Posterior inferior tibiofibular ligament
 - Transverse tibiofibular ligament
 - Interosseus ligament (distal portion of interosseus membrane)
 - b. Classic injury described as eversion and external rotation, but more commonly disrupted during ankle inversion injuries
- 8. Tendons: 13 tendons cross the ankle joint
 - a. Laterally: **Peroneal tendons**
 - 1) Function
 - a) Major dynamic stabilizers of ankle
 - b) Ankle eversion
 - 2) Peroneus brevis
 - a) Inserts on the base of 5th metatarsal
 - b) Everts subtalar joint
 - 3) Peroneus longus
 - a) Runs across the foot to insert on the base of the 1st metatarsal
 - b) Primary plantar flexor of first metatarsal-medial forefoot column
 - b. Posteriorly
 - Achilles tendon
 - c. Medially: **Tarsal tunnel**
 - 1) Contains (anterior to posterior from medial malleolus)
 - Tibialis posterior

Flexor digitorum longus

Posterior tibial artery, vein, and nerve

Flexor hallucis longus

2) Flexor retinaculum: Roof of tarsal tunnel

a) Distally encompasses the abductor hallucis

b) Confluent with plantar fascia distally

c) Anteriorly

1) **Tibialis anterior**

*Major dorsiflexor of ankle and foot, and decelerator of foot during heel strike

2) Others

Extensor hallucis longus

Extensor digitorum longus

Peroneus tertius

B. Biomechanics of injury

1. Ankle joint is most stable in dorsiflexion - talus is locked between the tibia and fibula
2. Least stable in plantar flexion - the talus is more narrow posteriorly, and therefore there is less bony stability within the mortise when in plantar flexion
3. Inversion sprains constitute over 70% of all ankle injuries because of the relative weakness of the ligaments and the inherent instability when the ankle is inverted and plantar flexed
4. Accessory movements
 - a. Plantarflexion
 - 1) Fibula moves medially, posteriorly, and inferiorly
 - 2) Anterior slide of the talus on the tibia
 - 3) Results in approximation of the inferior tibiofibular joint and the malleoli move closer together
 - b. Dorsiflexion
 - 1) Fibula moves laterally, anteriorly, and superiorly
 - 2) Posterior slide of the talus on the tibia
 - 3) Results in spreading of the inferior tibiofibular joint and the malleoli separate

C. Evaluation

1. History

- a. Mechanism of injury
- b. Level of activity after the injury - could the patient bear weight?
- c. Treatment after the injury
- d. Previous ankle injuries

2. Physical exam

- a. Inspection
 - 1) Swelling, bruising, deformities
 - 2) General assessment of foot biomechanics pes cavus vs. pes planus

- b. Range of motion
 - 1) Dorsiflexion 10-20° past right angle with leg
 - 2) Plantar flexion 30-40° past neutral
 - 3) Inversion and eversion normal is two thirds more inversion than eversion
- c. Palpation
 - 1) Have the patient point to the area of most pain
 - 2) Palpate other areas to assess for occult or coexisting injuries
 - lateral ligament complex
 - lateral and medial malleolus
 - base of 5th metatarsal
 - distal tibial-fibula articulation
 - talus, cuboid, navicular bones
 - deltoid ligament
 - peroneal tendons
 - Achilles tendon (Thompson test)
 - proximal fibula
- d. Specific diagnostic tests
 - 1) Anterior drawer test
 - a) Assesses the integrity of the anterior talofibular ligament when done in slight plantar flexion
 - b) Positive test
 - Talus slides >3 mm more than uninjured ankle or absence of distinct endpoint
 - c) Grading
 - Grade I: stable
 - Grade II: minimal anterior motion, firm endpoint
 - Grade III: anterior motion with soft endpoint
 - 2) Talar tilt test (inversion stress)
 - a) Assesses anterior talofibular ligament when ankle is plantar flexed
 - b) Assesses calcaneofibular ligament when ankle is in neutral or dorsiflexed
 - c) Positive test
 - Ankle opens > 25°
 - or > 10° difference between ankles
 - 3) Coronal drawer test ("Clunk" test)
 - a) Grasp distal tibia and fibula just above the ankle with one hand while grasping the heel with the other hand. Move the heel medially and laterally with side-to-side repetitive motions to determine if there is any increased "play" in the coronal plane of the ankle (motion of talus and calcaneus). Compare to uninjured side.
 - b) Assesses for syndesmosis injury
 - 4) Peroneal tendon subluxation or dislocation
 - a) Palpate the peroneal tendons while the patient everts the ankle from an inverted position in dorsiflexion
 - b) Feel for subluxation or dislocation of the peroneal tendons as they pass around the lateral malleolus

- c) Peroneus longus testing
Patient everts the foot and resists dorsiflexion of 1st metatarsal
- 5) Posterior tibiales testing
Resisted inversion of foot with foot starting in eversion
 - a) Neurologic assessment
Decreased sensation in the first web space indicates injury to the cutaneous branch of the deep peroneal nerve

3. Radiographs

- a. Standard views
Anteroposterior
Lateral

Mortise (foot internally rotated 15-20°)
- b. Areas to assess on radiographs
 - 1) Widening of the mortise (best seen on mortise view)
 - a) The space between the talar margin and medial malleolus and between the plafond and lateral malleolus should be equal
 - b) The distal tibiofibular joint space should not exceed 5 mm
 - 2) Malleoli fractures
 - 3) Calcaneal anterior process fractures
 - 4) Lateral and posterior process fractures of the talus
 - 5) Talar dome osteochondral fractures
 - a. If syndesmosis disruption is suspected, or there is a deltoid ligament injury, always visualize the entire tibia and fibula to r/o
 - b. Maisonneuve -type high fibular fracture
 - c. Ottawa ankle rules
In acute ankle injuries (presenting within 10 days of injury), an ankle radiographic series is only required if there is pain in the malleolar zone (distal 6 cm of tibia and fibula, and talus) and any of the following:
 - ◇ Bone tenderness at posterior edge or tip of lateral malleolus
 - ◇ Bone tenderness at posterior edge or tip of medial malleolus
 - ◇ Inability to bear weight (4 steps) both immediately and in the office

D. Differential diagnosis: Ankle inversion injury

- 1. Lateral ankle sprain (85%)
- 2. Fractures
 - a) Avulsion of distal fibula most common
 - b) Avulsion of base of 5th metatarsal at insertion of peroneus brevis
 - c) Osteochondral fracture of talar dome
 - d) Talar neck, anterior process of calcaneus, cuboid
- 3. Syndesmosis ruptures
- 4. Peroneal tendon subluxation or dislocation
- 5. Achilles tendon injury

E. Syndesmosis ankle sprains

1. Mechanism of injury

- a. External rotation with eversion (“pushed back on a planted foot”) is classic mechanism
 - b. However, either internal or external rotation can cause the ankle mortise to widen
- 2. Physical exam**
- a. Swelling can be minimal
 - b. Difficulty bearing weight and rising up on toes
 - c. Tenderness over anterior inferior tibiofibular ligament that may extend proximally up the interosseus membrane
 - d. Dorsiflexion limited because of pain
 - e. Squeeze test squeeze the fibula and tibia together at midshaft will cause pain in syndesmosis area
 - f. External rotation stress test (Kleiger test) externally rotate ankle while stabilizing tibia and fibula with ankle in neutral position and knee flexed 90°
 - g. Always look for associated medial or lateral ligament injuries
- 3. Grading the sprain**
- Grade 1: Interstitial tears to ligaments without elongation or loss of stability
 Grade 2: Partial tearing of ligaments with incomplete loss of stability
 Grade 3: Complete rupture of ligaments with resulting instability
- 4. Diagnostic imaging**
- a. Most useful to distinguish grade 2 injuries, in which there is no widening of mortise or separation of tibia from fibula, from grade 3
 - b. Standard AP, lateral, and mortise views. Look for:
 - 1) Avulsion fracture of tibial tubercle
 - 2) Incongruence of tibial plafond and talar dome on lateral
 - 3) Heterotopic ossification can be seen as early as 4 weeks post-injury
 - 4) Synostosis
 - c. External rotation stress radiographs
 - 1) Widening of anterior tibial tubercle - fibula interval > 5 mm on mortise view
 - 2) Widening of posterior tibial tubercle - fibula interval > 5 mm on AP view is most diagnostic
 - d. Arthrogram will reveal leakage of contrast into distal tibiofibular syndesmosis in a grade 3 tear
- 5. Treatment**
- a. Grade 1: Aggressive functional rehab
 - b. Grade 2: Aggressive functional rehab
May require crutches with partial weight bearing initially
 - c. Grade 3: Stabilize syndesmosis by cast immobilization or syndesmosis screws
- 6. Prognosis and complications**
- a. Recovery prolonged - at least twice that of uncomplicated lateral ligament sprains
 - b. Heterotopic ossification in the interosseus membrane in the absence of frank synostosis does not effect long term outcome

F. Treatment of lateral ankle inversion injuries

- 1. RICE (Rest, Ice, Compression, Elevation)
- 2. NSAIDs
- 3. Crutches

- a. Use if patient cannot walk normally without pain
- b. Instruct on proper use - always walk with heel-to-toe motion and use crutches to reduce weight bearing
- c. Use of a functional brace will allow most patients to be off crutches within a few days
4. Functional bracing
 - pneumatic compression braces
 - lace-up braces
 - semi-rigid support wraps
5. Early mobilization
 - a. Non-weight bearing range of motion exercises (eg., “drawing the alphabet”) should start as soon as possible
 - b. Functional bracing should allow early weight bearing
6. Physical therapy
 - a. Range of motion exercises
 - b. Muscle strengthening
 - c. Proprioception exercises
7. Surgery
 - a. Rarely indicated acutely in the stable ankle
 - b. May be appropriate for chronic functional instability
8. Orthopedic referral
 - a. Unstable ankles with significant widening and abnormal laxity of ankle mortise
 - b. Significantly displaced fractures
 - c. Talar dome fractures (including OCD)
 - d. Non-healing stress fractures
 - e. Achilles tendon rupture
 - f. Chronic ankle instability unresponsive to physical therapy
 - g. Any condition with which you are uncomfortable or unfamiliar

**DEPARTMENT
OF
FAMILY MEDICINE**

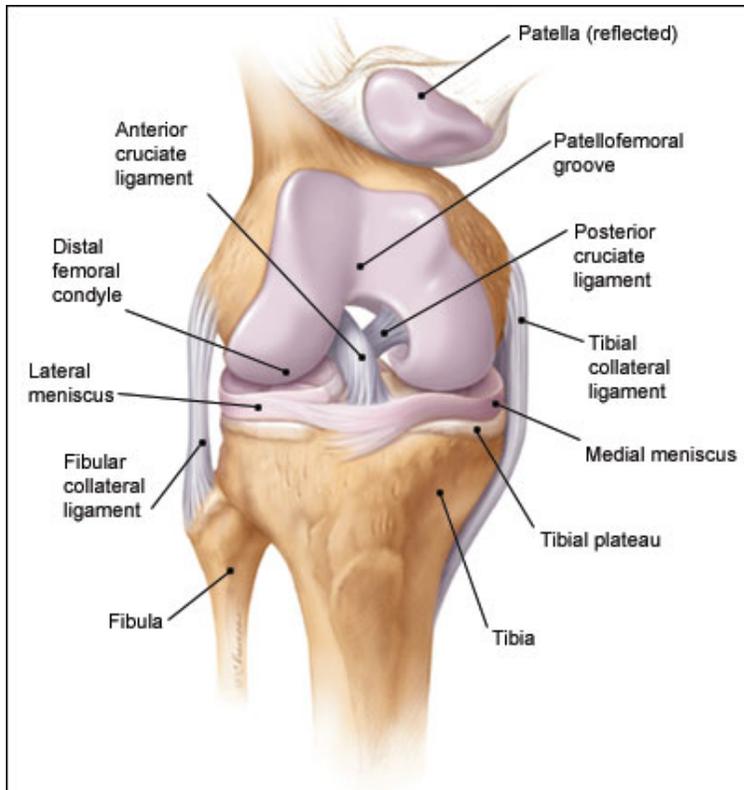
**KNEE EVALUATION
HANDOUTS**

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Knee Evaluation

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Knee Anatomy



I. Bony Anatomy

A. Joints

1. Tibiofemoral Joint – modified hinge joint
2. Patellofemoral Joint – modified plane joint
3. Proximal Tibiofibular Joint – plane synovial joint

B. Femoral Condylus

1. Primary motion is flexion and extension on its transverse axis
2. Secondary motion is axial rotation when the knee is flexed
3. Rolling and gliding form the basic motion

C. Tibial Plateau

1. Reciprocally curved surfaces separated by a blunt eminence with medial lateral spines extending anterior to posterior
2. The eminence is one of the factors preventing rotation in extension
3. The lateral tibial plateau is convex in the anteroposterior plane which allows the lateral femoral condyle to move further backwards and causes automatic internal tibial rotation with flexion

D. Patella

1. Sesamoid bone with two concave surfaces separated by a vertical ridge containing the thickest layer of cartilage in the body
2. Embedded in the extensor mechanism/patellar tendon increasing efficiency of extension by 1 ½ times holding the extensor mechanism away from the tibiofemoral joint
3. Functions as a guide for the quadriceps or patellar tendon, decreases friction of the quadriceps mechanism, controls capsular tension in the knee, acts as a bony shield for the cartilage of the femoral condyles and improves the aesthetic appearance of the knee

II. Ligaments

A. Anterior Cruciate Ligaments (ACL)

1. Three bands – anteromedial, posterolateral, and intermediate – run inferiorly, anteriorly, and medially from high on the back of the lateral eminence intercondylar notch to just lateral to the medial tibial eminence
2. Its main functions are to prevent anterior movement of the tibia on the femur, to check lateral rotation of the tibia in flexion, and to a lesser extent, to check extension and hyperextension at the knee.
3. Tighter in full extension and looser in midflexion
4. Mechanisms of injury
 - a. Loads applied when the ligaments are under maximum tension result in greatest strain
 - b. Most injuries occur during jumping and cutting of cleats or skis
 - c. Noncontact, deceleration – valgus- external rotation is a common mechanism of injury
 - d. Forced hyperextension and deceleration with internal rotation another possible mechanism
 - e. Tibial spine avulsions are associated with ACL tears in children < 13 years old

B. Posterior Cruciate Ligament

1. A fan-shaped ligament that runs inferiorly, posteriorly, and laterally from the front of the medial intercondylar notch to just lateral to the posterior tibial plateau

2. The primary restraint to posterior tibial subluxation and a secondary restraint to medial instability
3. Mechanisms of injury
 - a. Direct blow to the front of the tibia with the knee flexed (i.e., car dashboard) is the most frequent cause of PCL injuries
 - b. Hyperflexion is a common mechanism during athletics

C. Medial Collateral Ligament

1. Attaches on the posterosuperior aspect of the medial femoral condyle and runs anteroinferiorly to the upper end of the tibia
2. Maximal tension at full extension, minimal between 25 and 80 degrees
3. Abduction stress increases tension at increasing degrees of flexion
4. Mechanisms of injury
 - a. Noncontact valgus stress with or without external rotation
 - b. Contact valgus stress with or without external rotation

D. Lateral Collateral Ligament

1. Attaches posterosuperiorly on the lateral femoral condyle and runs obliquely to attach anterior to the fibula styloid
2. Primary restraint to varus stress in extension
3. Adduction stress increases tension to peak at 70 degrees flexion
4. Structurally weakest of the four main ligaments but works in conjunction with the posterolateral corner to prevent varus and external rotation
5. Mechanisms of injury
 - a. Contact varus stress
 - b. Most LCL injuries are in combination with ACL or PCL injuries

E. Posterior Oblique Ligament

1. Attaches the posterior medial meniscus to the tibia and femur
2. Resists external rotation and restrains posterior drawer in internal rotation
3. Mechanism of injury – Contact to lateral lower thigh or upper tibia injures the posteromedial corner

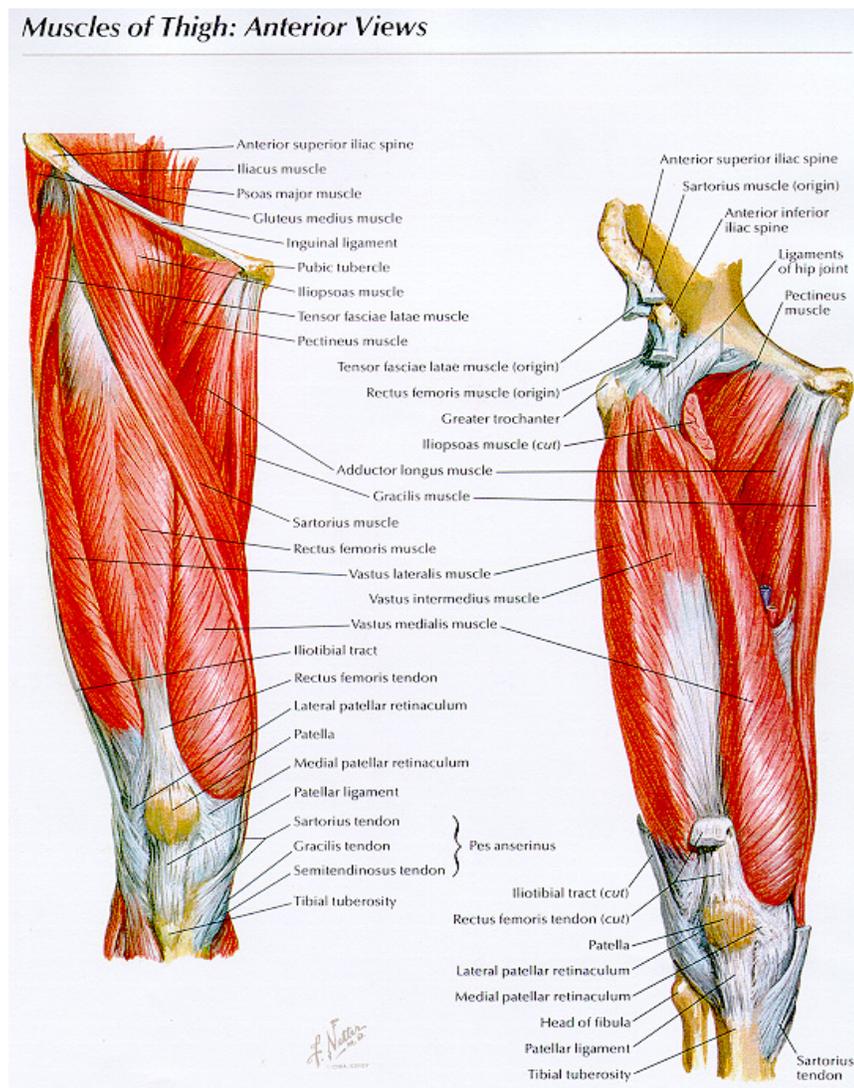
F. Arcuate Popliteal Ligament

1. Reinforcing ligament of the lateral side with injury resulting in posterolateral rotary instability
2. Attaches to the posterior horn of the lateral meniscus
3. Most important secondary restraint to posterior tibial subluxation
4. Mechanisms of injury
 - a. Blow to the anteromedial tibia, which causes knee hyperextension is a mechanism for posterolateral corner tear
 - b. Noncontact, hyperextension external rotation with varus force is a mechanism for posterolateral injury

III. Menisci

- A. Medial is "C" shaped and thicker posteriorly than anteriorly while Lateral is "O" shaped and equal thickness throughout
- B. Allows for load bearing joint stability and shock absorption
- C. Avascular in their cartilaginous inner two thirds and partly vascular and fibrous in their outer one third
- D. Held in place by the coronary ligaments attaching to the tibia
- E. Mechanism of injury
 1. Combined valgus and external rotation, where the posterior horn of the medial meniscus is trapped by the posterior condyles
 2. Forced extension of the knee where one of the menisci fails to move forward with the femur

IV. Muscles



- A. Quadriceps
- B. Hamstrings
- C. Iliotibial Tract (IT Band)
- D. Pes Anserine
- E. Mechanisms of injury – Usually from quick or explosive movement (strain/pull)

V. Anterior Soft Tissues

- A. There are three synovial folds: suprapatellar, medial patellar, and lateral patellar
- B. The medial fold is most likely of all to become symptomatic (plica syndrome)
- C. The anterior fatpad is rich in small vessels and nerve endings
- D. There are several bursae of note including the prepatellar and pes anserinus bursae, which lubricate areas of repetitive friction

Patient History

I. Age

- A. Growth disorders such as Osgood Schlatter at younger age
- B. Older patients may have degenerative issues

II. Occupation

- A. Key to injury may be in details of the patient's occupation
- B. Recreational activities or hobbies may be related to onset of symptoms

III. Inciting Trauma

- A. May be obvious macrotrauma or overuse/microtrauma
- B. Knee position and direction of forces contribute to the mechanism of injury which may give clues to type of injury sustained

IV. Timing of onset

- A. Sudden vs. Gradual
- B. Temporally related to specific incident or new activity

V. Nature of the symptoms

- A. Pain
- B. Swelling
- C. Numbness
- D. Weakness
- E. Loss of function or motion

VI. Location symptoms

- A. Location can help narrow the differential
- B. More generalized symptoms may be part of a larger process

VII. Quality and quantity of symptoms

- A. Amount of pain can help determine the potential severity of problem
- B. Quality can sometimes help determine type of structure involved

VIII. Duration and frequency of symptoms

- A. Constant vs. limited
- B. Random and often vs. occasional and specific timing

IX. Exacerbating and relieving factors

- A. Motions or activities
- B. Therapeutic modalities
- C. Medications

X. Prior history of similar presentation or injury in same location

XI. Clicking or pop

- A. Clicking often described in patellofemoral issues
- B. Pop can be indicative of an ACL injury

XII. Locking/catching or giving way

- A. Locking or catching can be related to meniscal pathology
- B. Giving way may suggest some sort of ligamentous instability

XIII. Swelling

- A. Localized vs. more generalized (possible effusion)
- B. Timing of swelling important in cases such as ACL tear

Observation

I. Anterior View Standing

- A. Genu valgum – knock-knee
- B. Genu varum – bowleg
- C. Extension
- D. Swelling/Ecchymosis
- E. Patella position – “grasshopper eyes” or “Squinting patellae”

II. Lateral View Standing

- A. Genu recurvatum – hyperextended
- B. Patella alta or baja

III. Posterior view Standing

- A. Similar positioning to anterior view
- B. Posterior swelling

IV. Anterior and Lateral Views Sitting

- A. Patella position
- B. Obvious swellings
- C. Osgood-Schlatter's changes
- D. Tibial torsion

V. Gait

- A. General changes in gait
- B. Motion of patella

Examination

I. Palpation

A. Anterior with knee extended

- 1. Swelling or Effusion
- 2. Patella, patellar tendon, plica
- 3. Quadriceps musculature
- 4. MCL/LCL
- 5. Pes Anserinus
- 5. IT Band

B. Anterior with knee flexed

- 1. Medial and Lateral joint line
- 2. Tibial Plateau
- 3. Femoral Condyles

C. Posterior with slight flexion

- 1. Hamstring musculature
- 2. Gastrocnemius
- 3. Arcuate-popliteus complex
- 4. Baker's Cyst

II. Range of Motion

A. Active

- 1. Flexion – 135 degrees
- 2. Extension – 0 degrees
- 3. Medial rotation of tibia on femur – 20-30 degrees
- 4. Lateral rotation of the tibia on the femur – 30-40 degrees

B. Passive

- 1. Flexion, extension, medial and lateral rotation
- 2. Medial and lateral motion of patella

III. Strength Testing (5 point scale)

A. Flexion

1. Hamstring musculature L5 – S2
2. Grackles, Sartorial L2-3
3. Popliteus L4-S1
4. Gastrocnemius S1-2
5. Tensor Fascia Latae L4-5
6. Plantaris S1-2

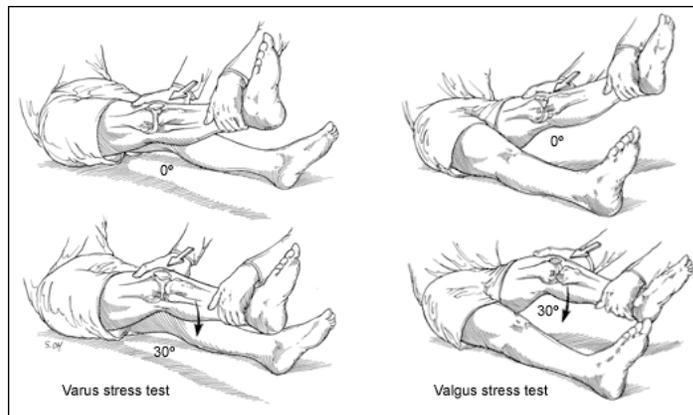
B. Extension

1. Quadriceps L2-4
2. Tensor Fasciae Latae L4-5

IV. Special testing

A. Collateral Ligaments

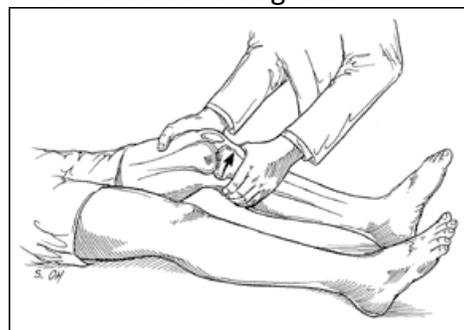
1. MCL – Valgus stress at 0 and 30 degrees (also see Anterior Drawer with ACL)
2. LCL – Varus stress at 0 and 30 degrees



B. Cruciate Ligaments

1. ACL

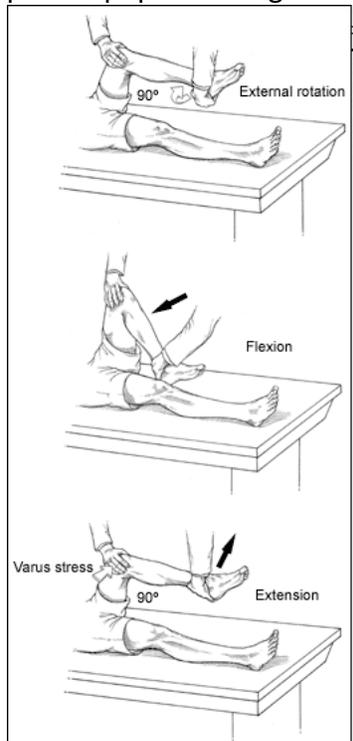
- a. Lachman – Lack of firm endpoint with anterior translation of tibia holding distal femur in one hand and proximal tibia in the other with knee flexed at 20 degrees



- b. Anterior Drawer Test – Excessive translation of both tibial condyles when applying anterior pull to proximal tibia while patient supine and relaxed with hip at 45 degrees, knee at 90 degrees, and foot in neutral position (Can externally rotate foot looking for just anterior rotation of medial condyle to suggest MCL injury)
 - c. Pivot Shift – Patient supine and relaxed. Knee extended with foot and tibia internally rotated. Valgus applied at the knee and knee progressively flexed. Anterior subluxation of lateral tibial condyle seen and felt at 30 degrees which suddenly reduces with further flexion.
2. PCL
- a. Posterior Sag – Patient in anterior drawer position with tibia dropping or sagging back indicative of PCL tear
 - b. Posterior Drawer – Same as anterior drawer with exception of looking for posterior translation with posterior force
 - c. Godfrey (gravity) Test – Patient supine while examiner holds both legs while flexing the patient’s hips and knees to 90 degrees. Posterior sag/instability for PCL tear

C. Meniscus

- 1. McMurray’s test – Patient supine and relaxed. Flex knee maximally with external tibial rotation (medial) or internal tibial rotation (lateral). While maintaining rotation, bring knee into full extension. Positive test is painful pop occurring over medial joint line or lateral joint line.



- 2. Apley’s compression test – Patient is in prone position. Knee flexed to 90 degrees with external tibial rotation (medial) or internal tibial rotation

(lateral). Apply axial compression to tibia while flexing and extending knee. Positive test is painful pop over medial joint line or lateral joint line

3. Bounce home test – Patient lies in supine position and the heel of the patient's foot is cupped in the examiner's hand. The patient's knee is completely flexed, and the knee is passively allowed to extend. If extension is not complete or if with sharp pain along joint line, may be meniscus tear.

D. Patellofemoral

1. Clarke's Sign (Patellar Grind Test) – Pain with contraction of quadriceps as the examiner presses down slightly proximal to the upper pole of the patella with the patient supine, relaxed and with extended knee
2. Active patellar grind test – Crepitus felt by the examiner as the patient extends the knee while seated with the knee in 90 degrees flexion
3. Apprehension/Hypermobility test – Pain, apprehension, or excessive motion with lateral displacement of the patella by the examiner as the patient is supine and relaxed with the knee slightly flexed

E. Others

1. Q angle - Angle defined as the angle between the quadriceps muscles and the patellar tendon representing the angle of the quadriceps muscle force. Obtained by drawing a line from ASIS to midpoint of patella and intersecting with a line from tibial tubercle through midpoint of patella. Normal angle for males is 13 degrees and for females is 18 degrees.
2. Leg length – Measurement from ASIS to medial or lateral malleolus

V. Diagnostic Imagine

A. X-rays

1. Ottawa rules – X-rays only necessary in acute knee injuries if the patient is great than or equal to 55 years of age or had isolated tenderness of the patella, tenderness at the head of the fibula, inability to flex the knee to 90 degrees, or an inability to walk four steps.
2. AP – weight bearing vs. non-weight bearing
3. Lateral
4. Skyline – used to evaluate the patellofemoral joint
5. Intercondylar Notch – Notch often smaller in women and may contribute to ACL injury.

B. CT – Allows more detailed bony evaluation

C. MRI – Can give better bony evaluation and very good evaluation of soft tissue structures.

D. Ultrasound – Good, detailed evaluation of soft tissue structures

**DEPARTMENT
OF
FAMILY MEDICINE**

**LOW BACK PAIN
EXERCISES**

From:
UMHS Guidelines for Clinical Care



Acute Low Back Pain

What is low back pain?

Almost everyone has back pain at one time or another. The pain may be in the center of the back or to one side, or even move down the leg. Symptoms may also include pain in the back and the buttocks or legs, stiffness, limited motion and spasm.

What are the risk factors?

Risk factors for back pain include:

- Obesity
- Lack of exercise
- Heavy physical work
- Accidents
- Vibration (i.e., driving a truck),
- Smoking

Family history may add to the chance of having low back pain.

Being overweight may increase the risk for low back pain because of the added stress on the back.

How does it occur?

Spinal Disks (also called: **Intervertebral disks**) are stacked between the spine bones. When you walk or run, the disks act as shock absorbers and prevent the spine bones from bumping against one another.

We don't know a lot about what causes low back pain. Some likely causes include: pulled muscles, strained ligaments, tight joints or small tears in the spinal disks. The problem is that these tears and pulls don't show up well on x-rays.

Should I have an x-ray?

Most people with low-back pain do not need an x-ray. X-rays do not provide any useful information that has an effect on treatment. Your doctor may order x-rays or other studies if your specific symptoms indicate a need for these tests or if your back pain does not go away in 4-6 weeks.

What is the treatment?

The good news is that 90% of people with acute low back pain recover within 4 - 6 weeks.

Most treatment plans for low back pain include the following:

- **Staying active.** Lying in bed or cutting back on activity is not helpful. People get better faster if they stay active at home and work. Common exercise such as walking, swimming or riding a stationary bike can be helpful in many cases. Your doctor may limit your activity if your job or the sports you play are very physical.
- **Stretching.** Most patients with acute low back pain benefit from doing stretches 2-3 times daily. Hold the stretch for 20-30 seconds, take a break and do it again. If a stretch seems to make things worse, or if it causes pain to go down your leg, seek further advice from a healthcare provider or your doctor.
- **Ice packs.** (plastic bag with ice cubes and water, wrapped in a towel). Apply the ice pack for 20-30 minutes at a time. The pack will feel cold at first, but it may help to decrease pain, spasm and inflammation in the back. There's nothing wrong with trying heat if it works, but ice may be better.
- **Exercise.** Common aerobic and conditioning exercises, such as brisk walking, swimming or riding a stationary bicycle can be very helpful.
- **Medications.** If your doctor recommends medications, it is very important that you take them on a regular basis and not only when you hurt.

When should I call my doctor?

Call your doctor right away if you have:

- Trouble controlling your bladder or bowels
- Numbness or weakness in the feet legs, groin or rectal area
- Pain that gets worse or extends into your leg and below the knees
- Pain that limits your normal activities for more than 4 weeks
- Shooting pain down the leg

How do I rest my back?

Hold each of these positions for 5 minutes or longer. Start each exercise lying on your back.

- Put pillows under your knees and bend your knees.
- Lie on a floor in front of a chair. Put a pillow under your neck, bend your knees to a 90-degree angle, and place your lower legs and feet on the chair.
- Bend your knees. Bring one knee up to your chest. Grab your thigh with your hand and hold it there. Repeat with the other knee. Bring both knees to your chest and hold. Grabbing your thigh rather than your lower leg prevents over-flexing your knee.

When can I return to my activity or sport?

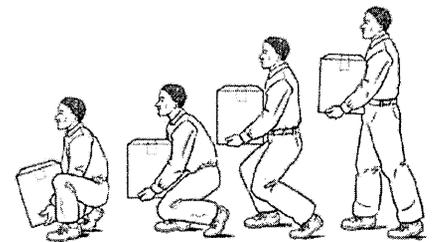
Returning to activity or sport too soon may worsen your injury and could lead to lasting damage. When you can return to activities will depend on how soon your back gets better. The rate of recovery is not the same for all people. Some people recover in days, but for others it may take several weeks or months until their back is strong enough. As a general rule, the longer you have symptoms before you start treatment, the longer it will take to get better.

It is very important that you follow your doctor's advice about returning to activities. Your back must be fully recovered before returning to sports or strenuous activities. This means that you have the same range-of-motion you had before the injury and that you are able to run, jump and twist without pain. Your doctor will allow you to return to activities as soon as it is safe to do that.

What can I do to help prevent low back pain?

The following tips may help to reduce the strain on your back:

- When you move a heavy object do not push it with your arms. Turn around and push it backwards. This shifts the strain from your back to your legs.
- When you lift a heavy object follow these instructions:
 - keep the object close to your body with your arms bent
 - bend your knees and hips
 - keep your back straight
 - do not lift heavy objects higher than your waistThe stronger your legs are, the easier it will be to lift.
- Sit in straight back chairs. Hold your spine against the back of the chair when you sit.
- Do not sit in one place or in one position for a long time. Get up and stretch, walk about and change positions.
- When you sit in one spot for a long time, use a footrest for one foot. This will help to keep your back straight.
- When you drive sit close to the pedals and use your seat belt and a hard backrest or pillow.
- When you sleep or rest lie on your side and bend your knees. You can



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CDC

also try putting a pillow between your knees.

- When you sleep on your back put a pillow under your knees.
- If you smoke, ask your doctor for help on how to quit. Smoking limits blood flow to the discs and muscles in your back and slows their healing.
- A regular exercise program will help your back and keep you healthy overall. Talk with your doctor before starting any exercise program. Also, see a professional trainer or a physical therapist for exercise advice that fits your specific needs.
 - For aerobic exercise such as walking, bicycling or swimming, start with low intensity exercise about 5 - 10 minutes of exercise a day, three days a week, and slowly work up to 30 minutes of exercise a day for five days a week. If you can't start with 5 - 10 minutes of exercise, do 2-3 minutes, or whatever you can.
 - Strength training is also good for your body and back. You can start with leg strengthening exercises that will help your back when it comes to lifting heavy objects. Use strength training machines if you can. Start with lighter weights, completing 10 to 15 repetitions before increasing the weight at your next workout. Keep in mind that stronger muscles will allow you to do more work and help reduce the risk of back injury.

Disclaimer: This document is for informational purposes only and is not intended to take the place of the care and attention of your personal physician or other professional medical services. Talk with your doctor if you have Questions about individual health concerns or specific treatment options.

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Patient Education Handout associated with UMHS Clinical Care Guideline
Last Revised: 03/10/2011

**DEPARTMENT
OF
FAMILY MEDICINE**

CONTRACEPTION

HANDOUTS



BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

Most Effective

Least Effective

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects*	
Sterilization Surgery for Women	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection or other complications after surgery	
Sterilization Implant for Women	Less than 1	Onetime procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding	
Sterilization Surgery for Men	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection	
IUD Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods	
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain	
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes Weight gain Acne	Mood swings or depressed mood Headache
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ Bleeding between periods Headaches Nervousness Abdominal discomfort	Weight gain Dizziness
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache	
Oral Contraceptives "The Pill" (Extended/Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache	
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache	
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea Breast tenderness Skin irritation	Stomach pain Headache
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache Nausea	Mood changes Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection	
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation	
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test	
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions	
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching	
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection	
OTHER CONTRACEPTION				
Emergency Contraceptives (EC):				
May be used if you did not use birth control or if your regular birth control fails (such as a condom breaks). It should not be used as a regular form of birth control. Emergency contraception prevents about 55 - 85% of predicted pregnancies.				
Levonorgestrel 1.5 mg (1 pill) Levonorgestrel .75 mg (2 pills)	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills as soon as possible within 3 days after having unprotected sex.	Menstrual changes Headache Dizziness Breast pain Lower stomach (abdominal) pain	Nausea Vomiting Tiredness
Ulipristal Acetate	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking this EC.	Swallow the pills within 5 days after having unprotected sex.	Headache Abdominal pain Tiredness	Nausea Menstrual pain Dizziness

*For more information on the chance of getting pregnant while using a method or on the risks of a specific product, please check the product label or Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5):397-404.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age	Menarche to <20 yrs: ²												
	Menarche to <20 yrs: ²												
	Menarche to <20 yrs: ¹												
Anatomical abnormalities	a) Distorted uterine cavity	4	4										
	b) Other abnormalities	2	2										
Anemias	a) Thalassemia	2	1	1	1	1	1	1	1	1	1	1	1
	b) Sickle cell disease [†]	2	1	1	1	1	1	1	1	1	1	2	2
	c) Iron-deficiency anemia	2	1	1	1	1	1	1	1	1	1	1	1
Benign ovarian tumors	(including cysts)	1	1	1	1	1	1	1	1	1	1	1	1
Breast disease	a) Undiagnosed mass	1	2	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	b) Benign breast disease	1	1	1	1	1	1	1	1	1	1	1	1
	c) Family history of cancer	1	1	1	1	1	1	1	1	1	1	1	1
	d) Breast cancer [†]												
	i) Current	1	4	4	4	4	4	4	4	4	4	4	4
ii) Past and no evidence of current disease for 5 years	1	3	3	3	3	3	3	3	3	3	3	3	
Breastfeeding	a) <21 days postpartum					2*	2*	2*	2*	2*	2*	4*	4*
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE					2*	2*	2*	2*	2*	2*	3*	3*
	ii) Without other risk factors for VTE					2*	2*	2*	2*	2*	2*	3*	3*
	c) 30-42 days postpartum												
	i) With other risk factors for VTE					1*	1*	1*	1*	1*	1*	3*	3*
	ii) Without other risk factors for VTE					1*	1*	1*	1*	1*	1*	2*	2*
d) >42 days postpartum					1*	1*	1*	1*	1*	1*	2*	2*	
Cervical cancer	Awaiting treatment	4	2	4	2	2	2	1	1	1	2	2	2
Cervical ectropion		1	1	1	1	1	1	1	1	1	1	1	1
Cervical intraepithelial neoplasia		1	2	2	2	2	2	1	1	1	2	2	2
Cirrhosis	a) Mild (compensated)	1	1	1	1	1	1	1	1	1	1	1	1
	b) Severe [†] (decompensated)	1	3	3	3	3	3	3	3	3	4	4	4
Cystic fibrosis [‡]		1*	1*	1*	1*	2*	2*	1*	1*	1*	1*	1*	1*
Deep venous thrombosis (DVT)/Pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy												
	i) Higher risk for recurrent DVT/PE	1	2	2	2	2	2	2	2	2	4	4	4
	ii) Lower risk for recurrent DVT/PE	1	2	2	2	2	2	2	2	2	3	3	3
	b) Acute DVT/PE	2	2	2	2	2	2	2	2	2	4	4	4
	c) DVT/PE and established anticoagulant therapy for at least 3 months												
	i) Higher risk for recurrent DVT/PE	2	2	2	2	2	2	2	2	2	4*	4*	4*
	ii) Lower risk for recurrent DVT/PE	2	2	2	2	2	2	2	2	2	3*	3*	3*
	d) Family history (first-degree relatives)	1	1	1	1	1	1	1	1	1	2	2	2
	e) Major surgery												
	i) With prolonged immobilization	1	2	2	2	2	2	2	2	2	4	4	4
ii) Without prolonged immobilization	1	1	1	1	1	1	1	1	1	2	2	2	
f) Minor surgery without immobilization	1	1	1	1	1	1	1	1	1	1	1	1	
Depressive disorders		1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*

Key:	
1 No restriction (method can be used)	3 Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	4 Unacceptable health risk (method not to be used)

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC		
		I	C	I	C	I	C	I	C	I	C	I	C	
Diabetes	a) History of gestational disease	1	1	1	1	1	1	1	1	1	1	1	1	
	b) Nonvascular disease													
	i) Non-insulin dependent	1	2	2	2	2	2	2	2	2	2	2	2	
	ii) Insulin dependent	1	2	2	2	2	2	2	2	2	2	2	2	
	c) Nephropathy/retinopathy/neuropathy [†]	1	2	2	2	3	3	2	2	3/4*	3/4*	3/4*	3/4*	
d) Other vascular disease or diabetes of >20 years' duration [†]	1	2	2	2	3	3	2	2	3/4*	3/4*	3/4*	3/4*		
Dysmenorrhea	Severe	2	1	1	1	1	1	1	1	1	1	1	1	
Endometrial cancer [†]		4	2	4	2	1	1	1	1	1	1	1	1	
Endometrial hyperplasia		1	1	1	1	1	1	1	1	1	1	1	1	
Endometriosis		2	1	1	1	1	1	1	1	1	1	1	1	
Epilepsy [†]	(see also Drug Interactions)	1	1	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
Gallbladder disease	a) Symptomatic													
	i) Treated by cholecystectomy	1	2	2	2	2	2	2	2	2	2	2	2	
	ii) Medically treated	1	2	2	2	2	2	2	2	2	3	3	3	
	iii) Current	1	2	2	2	2	2	2	2	2	2	2	2	
	b) Asymptomatic	1	2	2	2	2	2	2	2	2	2	2	2	
Gestational trophoblastic disease [†]	a) Suspected GTD (immediate postevacuation)													
	i) Uterine size first trimester	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	ii) Uterine size second trimester	2*	2*	2*	2*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Confirmed GTD													
	i) Undetectable/non-pregnant β-hCG levels	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	ii) Decreasing β-hCG levels	2*	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	iii) Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2*	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	iv) Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*	1*	1*	1*	1*	1*	1*	1*	
	Headaches	a) Nonmigraine (mild or severe)	1	1	1	1	1	1	1	1	1	1	1	1*
	b) Migraine													
i) Without aura (includes menstrual migraine)	1	1	1	1	1	1	1	1	1	1	2*	2*		
ii) With aura	1	1	1	1	1	1	1	1	1	1	4*	4*		
History of bariatric surgery [†]	a) Restrictive procedures	1	1	1	1	1	1	1	1	1	1	1	1	
	b) Malabsorptive procedures	1	1	1	1	1	1	3	3	3	3	3	3	
History of cholestasis	a) Pregnancy related	1	1	1	1	1	1	1	1	1	1	1	1	
	b) Past COC related	1	2	2	2	2	2	2	2	2	3	3	3	
History of high blood pressure during pregnancy		1	1	1	1	1	1	1	1	1	1	1	2	
History of Pelvic surgery		1	1	1	1	1	1	1	1	1	1	1	1	
HIV	a) High risk for HIV	2	2	2	2	1	1	2*	2*	1	1	1	1	
	b) HIV infection					1*	1*	1*	1*	1*	1*	1*	1*	
	i) Clinically well receiving ARV therapy	1	1	1	1	If on treatment, see Drug Interactions								
ii) Not clinically well or not receiving ARV therapy [†]	2	1	2	1	If on treatment, see Drug Interactions									

Abbreviations: C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and, ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring + Condition that exposes a woman to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (properly taken measurements)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100 [†]	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	1		1		1		2		2		2/3*	
Ischemic heart disease [‡]	Current and history of	1		2	3	2	3	3		2	3	4	
Known thrombogenic mutations [‡]		1*		2*		2*		2*		2*		4*	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	1		2		2		2		2		2	
	ii) Hepatocellular adenoma [‡]	1		3		3		3		3		4	
	b) Malignant [‡] (hepatoma)	1		3		3		3		3		4	
Malaria		1		1		1		1		1		1	
Multiple risk factors for atherosclerotic cardiovascular disease	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1		2		2*		3*		2*		3/4*	
Multiple sclerosis	a) With prolonged immobility	1		1		1		2		1		3	
	b) Without prolonged immobility	1		1		1		2		1		1	
Obesity	a) Body mass index (BMI) ≥30 kg/m ²	1		1		1		1		1		2	
	b) Menarche to <18 years and BMI ≥ 30 kg/m ²	1		1		1		2		1		2	
Ovarian cancer [‡]		1		1		1		1		1		1	
Parity	a) Nulliparous	2		2		1		1		1		1	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a) Past												
	i) With subsequent pregnancy	1	1	1	1	1	1	1	1	1	1	1	1
	ii) Without subsequent pregnancy	2	2	2	2	1	1	1	1	1	1	1	1
	b) Current	4	2*	4	2*	1	1	1	1	1	1	1	1
Peripartum cardiomyopathy [‡]	a) Normal or mildly impaired cardiac function												
	i) <6 months	2		2		1		1		1		4	
	ii) ≥6 months	2		2		1		1		1		3	
	b) Moderately or severely impaired cardiac function	2		2		2		2		2		4	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	2*		2*		1*		1*		1*		1*	
	c) Immediate postseptic abortion	4		4		1*		1*		1*		1*	
Postpartum (nonbreastfeeding women)	a) <21 days					1		1		1		4	
	b) 21 days to 42 days												
	i) With other risk factors for VTE					1		1		1		3*	
	ii) Without other risk factors for VTE					1		1		1		2	
	c) >42 days					1		1		1		1	
Postpartum (in breastfeeding or non-breastfeeding women, including cesarean delivery)	a) <10 minutes after delivery of the placenta												
	i) Breastfeeding	1*		2*									
	ii) Nonbreastfeeding	1*		1*									
	b) 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c) ≥4 weeks	1*		1*									
	d) Postpartum sepsis	4		4									

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Pregnancy		4*		4*		NA*		NA*		NA*		NA*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
	b) Not on immunosuppressive therapy	1		1		1		2		1		2	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver [‡]	1		1		1		1		1		1	
Sexually transmitted diseases (STDs)	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	1		1		1		1	
	c) Other factors relating to STDs	2*	2	2*	2	1		1		1		1	
Smoking	a) Age <35	1		1		1		1		1		2	
	b) Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c) Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation [‡]	a) Complicated	3	2	3	2	2		2		2		4	
	b) Uncomplicated	2		2		2		2		2		2*	
Stroke [‡]	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
Superficial venous disorders	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial venous thrombosis (acute or history)	1		1		1		1		1		3*	
Systemic lupus erythematosus [‡]	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*	
	b) Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c) Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d) None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis [‡] (see also Drug Interactions)	a) Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b) Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a) Uncomplicated	1		1		1		1		1		2	
	b) Complicated [‡]	1		1		1		1		1		4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		1		2		2		2		1	
	b) Heavy or prolonged bleeding	2*		1*	2*	2*		2*		2*		1*	
Viral hepatitis	a) Acute or flare	1		1		1		1		1		3/4*	2
	b) Carrier/Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretroviral therapy All other ARV's are 1 or 2 for all methods.	Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*		2*		2*		3*	
	Anticonvulsant therapy												
	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b) Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Updated in 2017. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV.

SECTION IV. Reproductive Health

97 Contraception

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KEY POINTS

- More than half of all pregnancies in the United States are unintentional, as are 92% of pregnancies in adolescents aged 15 to 19 years. Unintentional pregnancies occur because contraceptives are not used, because they are used sporadically or incorrectly, or due to failure of the contraceptive method despite proper use.
- Knowledge of contraceptive failure rates, risks, benefits, and acceptability allows the provider to “match” the contraceptive method to the needs and desires of the patient.
- Hormonal methods of birth control are the most commonly used reversible method; however, at 1 year, only about two-thirds of women continue their use.
- Long-acting reversible contraceptive (LARC) methods such as IUDs and implants can be used by women of all ages and are two of the most efficacious contraceptive methods available. An increase in use of LARC can be helpful in reducing unintended pregnancy.
- Condoms are the only method that offer some protection against sexually transmitted infections.
- Emergency contraception (postcoital contraception) is available as levonorgestrel 1.5 mg single dose; available as a nonprescription product and ulipristal a 30 mg single dose prescription medication. Levonorgestrel provides about a 75% reduction in risk of pregnancy while ulipristal reduces pregnancy risk by 85%. Ulipristal is more effective especially at >72 hours after unprotected intercourse.

I. Introduction. Contraception is an important topic to discuss with all sexually active men and women of childbearing age.

A. More than half of all pregnancies in the United States are unintentional, as are 92% of pregnancies in adolescents aged 15 to 19 years. Unintentional pregnancies occur because contraceptives are not used, because they are used sporadically or incorrectly, or due to failure of the contraceptive method despite proper use.

B. Numerous contraceptive options are available, so the choice of a particular option should take place after a review of the risk and benefits of all appropriate choices, and education on the option chosen so correct use is assured.

C. The only 100% effective method of birth control is abstinence. Correct use of any contraceptive device does not guarantee protection. Many women who experience unintended pregnancy use their selected methods consistently and properly; pregnancy rates also depend on the efficacy of the method in a typical user (see Table 97-1).

D. Long-acting reversible contraceptive (LARC) methods, primarily intrauterine devices (IUDs), are contributing to an increase in contraceptive effectiveness in the United States. The proportion of US women using the IUD and implant increased from 2.4% in 2002 to 8.5% in 2009, more than offsetting decreases in sterilization. These LARC methods require little intervention on the part of the user and do not interfere with sex.

II. Choosing a Birth Control Method. Consideration of the following factors will help patients make the best possible choices: accessibility, efficacy, safety, and acceptability. It is important to take the time also to educate patients about the risks and benefits of their birth control options. Studies have found that many women who begin using a contraceptive method stop using it within the first year of use. Less than half of women using spermicides alone, withdrawal, sponge, or condoms are still using them at 1 year; just over half continue use of Depo-Provera or diaphragms, and about two-thirds continue use of combined hormonal contraceptives. Rates of continued use are higher with IUDs and implants (78%–84%). Providing more complete information about the method may prevent discontinuation and can help women be knowledgeable about other options.

Desirable properties of contraceptives are a high rate of effectiveness, prolonged duration of action, reversibility for those desiring future fertility or permanence for those who

TABLE 97-1. CONTRACEPTIVE OPTIONS AVAILABLE IN THE UNITED STATES IN 2012

Method	Unintended Pregnancies with 1 yr of Use (%)		Noncontraceptive Benefits	Use with Breastfeeding
	Typical Use	Theoretical		
None	85	85	—	—
Spermicide	29	18	None	Yes
Withdrawal	27	4	None	Yes
Periodic abstinence (fertility awareness)	25	3-5	None	Yes
Diaphragm with spermicide	16	6	None	Yes
Female condom	21	5	Prevents STDs	Yes
Male condom	15	2	Prevents STDs	Yes
Oral contraceptive pills (OCPs)—combined and progestin-only	8	0.3	Regulation of menstrual cycle and dysmen- orrhea, possible decrease in ovarian and endometrial cancer risk, acne	No
Contraceptive patch	8	0.3	Same as OCPs	No
Vaginal ring	8	0.3	Same as OCPs	No
Depo-Provera	3	0.3	Same as OCPs	Yes
Copper-containing IUD	0.8	0.6	None	Yes
Levonorgestrel IUD	0.2	0.2	Regulation of men- strual cycles and dysmenorrhea	Yes
Female sterilization	0.5	0.5	None	Yes
Male sterilization	0.15	0.10	None	Yes
Etonogestrel implant	0.05	0.05	Same as OCPs	Safety conditional

Source: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D, Policar M, eds. *Contraceptive Technology*. 20th rev ed. New York, NY: Ardent Media; 2011:827-1010; Herndon EJ, Ziemann M. New contraceptive options. *Am Fam Physician*. 2004;69:853-860; Herndon EJ, Ziemann M. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva, Switzerland: Reproductive Health and Research, World Health Organization, 2000. <http://whqlibdoc.who.int/publications/2004/9241562668.pdf>. Accessed July 4, 2006; Speroff L, Fritz MA. *Clinical Gynecologic Endocrinology and Infertility*. 7th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2005.

wish to have no future fertility, privacy of use, protection against sexually transmitted infections (STIs), safety, and acceptable or minimal side effects. To support informed contraceptive decision-making, healthcare professionals should realize that a woman's view of a method's ease of use is more important than perceived efficacy, tolerability, health benefits, or risks.

A. Efficacy

- Theoretical efficacy rates** are defined as the rate of unintended pregnancies per 100 women estimated to occur during the first year of use of a given contraceptive method assuming correct and consistent use.
- Actual efficacy rates** reflect the actual rate of unintended pregnancies per 100 women during the first year of use of a given contraceptive method if they do not stop using the method for any other reason. The efficacy of a given contraceptive method is influenced by many factors including fertility, the frequency of intercourse, the ability of the patient to use the method properly, and the theoretical efficacy rate of the method.
- Safety concerns** include risks of morbidity and mortality as well as noncontraceptive safety benefits (see Table 97-2), such as protection from STIs or resolution of menstrual problems.
- Acceptability** of a method depends on a number of subjective factors:
 - Cost.** What is the out of pocket cost to the individual using the method? Cost will vary based on health insurance coverage, retail pricing of nonprescription

TABLE 97-2. NONCONTRACEPTIVE HEALTH BENEFITS OF CONTRACEPTIVE METHODS

Agent	Benefits
Combined hormonal contraceptives	Decreased dysmenorrhea Decreased menstrual blood loss and anemia Possible reduction of premenstrual syndrome (PMS) Decreased risk of ectopic pregnancy Decreased risk of endometrial and ovarian cancer Decreased risk of pelvic inflammatory disease Reduction of acne
Progesterone-only contraceptives	Decreased dysmenorrhea Amenorrhea May reduce dysfunctional uterine bleeding in women who are overweight Decreases risk of endometrial and ovarian cancer Decreases risk of pelvic inflammatory disease Can decrease the number/severity of crises in patients with sickle-cell anemia Can decrease frequency of seizures, does not interact with antiepileptic medications Reduces risk of uterine leiomyomata formation
Levonorgestrel IUD	Decreases menstrual blood loss Decreased dysmenorrhea
Male/female condom	Decreased risk of STI transmission including HIV

methods, and should consider time off work for surgical or irreversible methods.

- b. Individual preferences.** Does the patient have any ethical or religious concerns regarding the method? Do they have a preference based on frequency (or lack) of menstrual cycles or based on noncontraceptive benefits of a particular method?
- c. Duration.** How long after initiation of the method is it considered effective? For what duration can the method be used and be considered effective?
- d. Reversibility.** For reversible methods: after discontinuation how long until the patient is able to conceive? For permanent methods, is irreversibility desired?
- e. Privacy.** Does the method afford the patient enough privacy? This includes having to purchase a nonprescription contraceptive at a retail store, having to store the contraceptive in a private location, taking time to see a healthcare provider for an injection, the visibility of a subdermal implant, or even a scar from a surgical procedure.
- f. Availability.** Does the method require office visits, a prescription, or any other special situation to obtain?
- g. Convenience.** Is it easy to use the method when needed? Does it require an intentional action to apply or is it available when needed without additional effort?

B. Patient education. Providing clear instruction on proper use, expected side effects and how to minimize them, and potential risks of any contraceptive method is important. Pointing the patient to on-line educational resources such as www.womenshealth.gov can facilitate better understanding of options, side effects, and proper use.

III. Hormonal Contraception. This method works by suppressing ovulation and follicle maturation, thickening cervical mucus so that sperm are less effective, and making the endometrium less receptive to embryo implantation.

A. Oral contraception—combination of estrogen-progestin pills. This birth control method is used by an estimated 28% of reproductive-aged women and is the most popular form of reversible contraception in the United States. Oral contraceptives (OCs) contain different doses and two types of estrogen (ethinyl estradiol and mestranol, a pro-drug converted to ethinyl estradiol) and different doses and types of progestin. Biphasic

TABLE 97-3. CHOOSING AMONG ORAL CONTRACEPTIVES (OCs)

Patient Characteristics	Preferred Type of Oral Contraceptive	Generic Examples (Brand Name) Estrogen Content and Comments
Acne	Less androgenic activity pills: those containing third-generation progestins: norgestimate, desogestrel or drospirenone, or low-dose norethindrone	Norgestimate (Ortho Tri-Cyclen ^a , Ortho-Cyclen, Sprintec); desogestrel (Desogen/Ortho-Cept, Apri, Mircette, Kariva, Ortho Tri-Cyclen Lo, Cyclessa); low-dose norethindrone (Ovcon 35, Brevicon, Modicon), norethindrone acetate (Estrostep ^a), drospirenone (Yaz, Beyaz, Yasmin, Safyral)
Nausea or breast tenderness when taking OCPs	Progestin-only or lower (20 mcg) estrogenic activity pills	Progestin-only: see above 20 mcg pills (Alesse, Loestrin 1/20, Aviane, Yaz)
No prior use of OCPs	Lower-dose pills minimize side effects	20 mcg pills, see above 30 mcg pills (Desogen, Ortho-Cept, Apri, Yasmin, Levlen, Levora, Loestrin 1.5/30, Lo/Ovral, Cryselle) 35 mcg pills (Ortho Novum 1/35, Ovcon 35, Demulen 1/35, Zovia 1/35E, Brevicon, Modicon, Neocon 0.5/35, Ortho-Cyclen, Sprintec, Norinyl 1+35, Necon 1/35, Tri-Norinyl, Ortho Novum 7/7/7)
Nursing women	Progestin-only pills will not interrupt milk supply	Norethindrone (Ovrette, Micronor)
Scanty or absent withdrawal bleeding	Build up endometrium	Increase estrogen dose or lower progestin dose/potency
Spotting/break-through bleeding (BTB)	Stabilize endometrium	Explore reasons for spotting: missing pills, erratic timing, drug interactions Reassure women that BTB is common during the first several month of OC use. Changing estrogen dose or type of progestin does not alter bleeding rates. Do not use progestin-only pills for women concerned about BTB (SOR B)
Use of rifampin, phenytoin, barbiturates or other liver enzyme-inducing medications	Use an alternative contraceptive (preferred; increased side effects of 50 mcg dose, uncertain contraceptive efficacy of higher estrogen dose) or increase estrogen to 50 mcg/tablet.	50 mcg pills (Ovral, Ovcon 50, Demulen, Ortho-Novum 1/50, Norinyl 1/50)

^aFDA-approved for the treatment of acne.

and triphasic OCs contain different amounts of hormone throughout the menstrual cycle in an attempt to more closely mimic natural hormone production. However, there is insufficient evidence to support any clear benefit of multiphasic over monophasic formulations. Choosing among the many OCs can be done on the basis of characteristics of both the patient and the OC. See Table 97-3 for common characteristics and recommendations for use.

1. Failure rate for typical use is 9 pregnancies expected per 100 women per year; **correct use** <1 pregnancy per 100 women per year.

2. Risks include dizziness, nausea, breast tenderness, elevated blood pressure, thromboembolic disease, and change in menstruation and mood. It should be noted that the risk of deep vein thrombosis (DVT) or pulmonary embolus (PE) with any of these methods is significantly lower than that for pregnancy.

a. Contraindications. For a complete list of conditions where the health risks likely outweigh the benefits of use or for which there are unacceptable health risks, the reader is referred to the Centers for Disease Control and Prevention at http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/PDF/effectiveness_of_contraceptive_methods.pdf. OCs should not be used in the following cases:

(1) Women older than 35 years who smoke more than 15 cigarettes per day.

- (2) Women with cardiovascular problems, such as a history of thromboembolic disease or thrombogenic conditions, uncontrolled hypertension (>stage 2), cerebrovascular disease, and ischemic heart disease.
- (3) Any woman who has migraine headaches with aura or any woman over age 35 years with migraine, due to an increased risk for stroke.
- (4) Women <1 month postpartum because OCs can diminish breast milk production in the first month postpartum and increase risk for thromboembolic disease in the first 21 days postpartum. Progestin-only pills are acceptable. The American Academy of Pediatrics advises against the use of OCs as long as the woman is exclusively breastfeeding; women can begin OCs as soon as supplemental nutrition is part of the infant's diet.
- (5) Known or suspected pregnancy is a contraindication; although these medications have no proven teratogenic potential, there is clearly no benefit for pregnant women.
- (6) Women with other conditions including breast cancer, liver tumor, and cirrhosis of the liver.

3. Benefits

- a. **Reduction in risk of endometrial and ovarian cancers.** (SOR B)
- b. **More regular and less painful menstrual periods** with less bleeding and iron-deficiency anemia. Premenstrual syndrome may be less common and less severe in women using OCs, as are benign breast disease and benign ovarian cysts, endometriosis, acne, hirsutism, and anovulatory bleeding. (SOR B)

4. Acceptability

- a. **Convenience.** Must be taken daily.
- b. **Availability.** Current FDA regulations require a prescription.

5. **Extended use of combined OC pills.** Three agents are FDA approved for extended use. *Seasonale* and *Seasonique* contain 84 days of active tablets and seven placebo tablets, and *Lybrel* contains a full year of active tablets with no placebos. These agents are equally effective as more traditional monthly cycling, but have a greater risk for breakthrough bleeding during the first few months of use. Other monophasic combined OCs can be dosed for extended use, but are not FDA approved for this purpose. If doing so, typically, active tablets of three pill packs are used consecutively (63 tablets) followed by a 7-day placebo or no pill period.

- B. **Oral contraception—progestin-only pills.** These medications contain only progestin and are most often used when combination pills are contraindicated. They work by reducing and thickening cervical mucus, decreasing tubal motility and suppressing ovulation to prevent fertilization and by making the endometrium less receptive to embryo implantation. The only progestin-only pill available in the United States is norethindrone 0.35 mg, which is taken daily throughout the entire month with no week off for a menstrual period.

1. **Failure rate for typical use** is 9 pregnancies expected per 100 women per year; **correct use** <1 pregnancy per 100 women per year.

2. **Risks** include irregular bleeding, acne, and breast tenderness.

- a. **Contraindications.** This method should not be used in women with breast cancer. Known or suspected pregnancy, current DVT or PE, active hepatitis, severe cirrhosis, or benign/malignant liver tumors are also contraindications.

3. **Benefits include** the ability to use the methods during lactation, reduced risk of endometrial and ovarian cancers, and the fact that the progestin-only pill does not carry the cardiovascular and thromboembolic risks of combination OCs.

4. Acceptability

- a. **Convenience:** Must be taken daily. Due to relatively short duration of action and short half-life of medication, it must be taken at the same time every day for maximum efficacy. Because of compliance issues and increased rates of breakthrough bleeding compared with combined OCs, the progestin-only contraception pill is generally recommended only in breastfeeding women or for women who have a contraindication to estrogen use.

- b. **Availability.** Daily contraceptive agent requires a prescription. Progestin-based emergency contraceptive agents (see section III.G) are available as nonprescription products in the United States.

- C. **Injectable hormones.** Depo-medroxyprogesterone acetate (Depo-Provera; DMPA) is a widely used contraceptive that is given as either a deep intramuscular injection of

150 mg or a subcutaneous injection of 104 mg every 12 weeks. The slower rate of absorption of the subcutaneous formulation allows for a lower dose of DMPA.

- 1. Failure rate for typical use** is 6 pregnancies expected per 100 women per year; **correct use** <1 pregnancy/100 women/year.
 - 2. Risks include** irregular bleeding, weight gain, breast tenderness, headaches, and potentially delayed return of fertility (may be delayed as long as 10–18 months).
 - a. Contraindications.** This method should not be used in women with breast cancer or known or suspected pregnancy and used with caution in women at an increased risk for osteoporosis. There is considerable controversy over DMPA's effect on bone. Bone loss does occur and is greater with increasing duration of use. Most studies have shown that bone loss is reversible once a woman stops DMPA; however, especially in teenagers who have not reached their maximum bone density, clinical implications are unclear. Most experts agree that it is safe to use DMPA for over 2 years if it is the best contraceptive option available. All women on DMPA should be counseled about the potential risk of bone loss and should make sure to get adequate calcium and vitamin D intake. Prescribing oral estrogen supplementation may mitigate bone loss. There is insufficient evidence to support screening bone mineral density in long-term users.
 - 3. Benefits include amenorrhea** in addition to reduction in menorrhagia, dysmenorrhea, and iron-deficiency anemia. **Lactation is not adversely affected;** trace amounts are detectable in breast milk without apparent adverse effects to infants.
 - 4. Acceptability**
 - a. Convenience.** One injection every 3 months.
 - b. Availability.** Must have a prescription and access to a facility with the ability to administer the injection appropriately.
- D. Transdermal hormonal patch. Norelgestromin and ethinyl estradiol (Ortho Evra)** is a combination contraceptive that is provided in a transdermal system. Patches containing 6.00 mg norelgestromin and 0.75 mg ethinyl estradiol are placed on the skin of the buttocks, abdomen, upper torso, or upper outer arms weekly. Each patch releases 150 µg of norelgestromin and 20 µg of ethinyl estradiol daily. The patch functions similarly to combination OCs, but provides higher cumulative doses of estrogen, whereas pills have higher peak doses.
- 1. Failure rate for typical use** is 9 pregnancies expected per 100 women per year; **correct use** <1 pregnancy per 100 women per year.
 - 2. Risks** are similar to combination OCs; however, the patch may be associated with an increased risk of blood clotting compared with OCs, based on early European studies. (SOR ⓑ) Some women experience skin irritation and/or difficulty with getting the patches to stick to the skin for an entire week.
 - a. Contraindications.** Same as those for combination OCs.
 - 3. Benefits** are the same as for OCs. The patch is more convenient in a transdermal route for some women.
 - 4. Acceptability** is enhanced over that of OCs because of the weekly transdermal route of administration.
 - a. Convenience.** The patch is applied once a week for 3 weeks. Patch is not worn during the fourth week, and women have a menstrual cycle during that week.
 - b. Availability:** Must have a prescription.
- E. Vaginal ring. A flexible silicone ring impregnated with etonogestrel and ethinyl estradiol (Nuvaring)** is another alternative route of administration for combination hormonal contraceptives. It delivers 0.120 mg of etonogestrel and 0.015 mg ethinyl estradiol daily. The ring is placed in the posterior fornix of the vagina; the exact position of the ring is not important for contraceptive function. Because of the "local" administration of hormones, lower doses can be used.
- 1. Failure rate for typical use** is 9 pregnancies expected per 100 women per year; **correct use** <1 pregnancy per 100 women per year.
 - 2. Risks** include vaginal discharge and irritation; otherwise similar to combination OCs.
 - a. Contraindications** are the same as those for combination OCs.
 - 3. Benefits** are similar to those of OCs. May be associated with less prolonged bleeding or spotting.
 - 4. Acceptability.** It does not require daily administration and is a good choice for women who desire a lower dose of hormones.

a. Convenience. Inserted by the woman, the ring remains in place for 3 weeks and is then removed for 1 week. If out of place for more than 3 hours, an alternative method is required for 7 days after reinsertion.

b. Availability. Must have a prescription.

F. Subdermal Implant of etonogestrel is a long-term hormonal contraceptive available under the brand name "Nexplanon," which replaced the previous implant "Implanon." The implant is a 40 mm × 2 mm semirigid, radio-opaque plastic rod containing 68 mg of etonogestrel released over 3 years (initially 60–70 mcg per day, falling to 25–30 mcg per day at the end of the third year). As a progestin-only method, mechanisms of action are similar to those of the progestin-only contraceptive pill.

1. Failure rate is <1 for both "typical" and "correct" use. There may be decreased contraceptive efficacy in obese women.

2. Risks include unscheduled bleeding, especially in the first 3 months of use which decreases during the first year. Other side effects are headache, weight gain, acne, and breast tenderness.

a. Contraindications. Should not be used in women with breast cancer, a history of breast cancer, or known or suspected pregnancy.

3. Benefits. No action required for contraceptive efficacy once placed.

4. Acceptability. Because unscheduled bleeding is commonly experienced; however, the discontinuation rate does not appear to be higher for this method.

a. Convenience. Must be placed by a physician via minor surgery. May remain in place for up to 3 years, and requires removal by a physician.

b. Availability. Must have a prescription.

G. Postcoital contraceptives (emergency contraceptives). The hormones that make up the medication appear to inhibit ovulation if it has not occurred. Two formulations are available in the United States, "Plan B One-Step, Next Choice One-Step" and My Way (levonorgestrel 1.5 mg single dose), and "Ella" (ulipristal 30 mg single dose). In addition, OCs containing levonorgestrel or norgestrel can be used as an emergency contraceptive (Yuzpe regimen). When OCs are used as an emergency contraceptive, it is necessary to give two doses 12 hour apart. Each dose must contain the number of OC tablets needed to provide at least 100 mcg of ethinyl estradiol and at least 0.5 mg of levonorgestrel or 1 mg of norgestrel. The Yuzpe regimen is less effective than levonorgestrel or ulipristal and is associated with more side effects as it contains estrogen. However, it may be available as an option when the other agents are not.

1. Failure rate. Best taken as soon after unprotected sex as possible for highest effectiveness. About 75% reduction in risk of pregnancy for a single act of unprotected sex for levonorgestrel products and 85% for ulipristal. Ulipristal is more effective especially at >72 hours after unprotected intercourse.

2. Risks include nausea, vomiting, abdominal pain, fatigue, and headache. Ulipristal should not be administered more than once in a menstrual cycle due to lack of safety data. In addition, because it binds to progesterone receptors, ulipristal may affect the efficacy of OCs. Barrier contraceptives should be used in addition to the OC for the remainder of a cycle in which ulipristal has been taken.

a. Pregnancy. No specific contraindications to its use. The levonorgestrel emergency contraceptives do not have an adverse fetal effect if inadvertent exposure occurs during early pregnancy. A pregnancy test should be obtained prior to use of ulipristal as it is not known if it will harm a fetus. **None of the emergency contraceptives disrupt an established pregnancy.**

3. Benefits. Only contraceptive available for emergency postcoital use.

4. Acceptability

a. Convenience. Levonorgestrel should be taken within 72 hours of unprotected intercourse, but may be effective up to 120 hours after unprotected intercourse. Ulipristal should be taken within 120 hours of unprotected intercourse. The earlier these methods are used, the more effective. (SOR ⓑ)

b. Availability. Levonorgestrel 1.5 mg (Plan B One-Step) has recently been approved by the FDA for over-the-counter sale to anyone regardless of age. Next Choice One-Step and My Way are only available to women over age 17 years without a prescription. Ulipristal is only available by prescription.

5. Special note. Clinicians should provide information on Emergency contraceptions (ECs) when prescribing a non-long-acting contraceptive. It is also important to discuss this method of contraception with female victims of sexual assault.

6. Administration. Levonorgestrel 1.5 mg and ulipristal are both administered as a single oral dose taken as soon after unprotected intercourse as possible. Women should be counseled to expect their menses within 3 weeks of taking emergency contraception; if not, they should obtain a pregnancy test.

IV. Barrier Methods. These methods prevent conception by providing a mechanical barrier to sperm. Avoid using oil-based lubricants and medications (e.g., vaginal antifungals) because they can cause latex condoms to deteriorate. (SOR \oplus) Polyurethane and plastic condoms are not adversely affected by non-water-based lubricants or vaginal antifungals.

A. Male condoms are made of latex, the cecum of lambs (skins), or polyurethane (for latex-sensitive individuals). Most condoms have a shelf-life of 5 years if stored properly in a cool place.

1. Failure rate is 18 pregnancies expected per 100 women per year. Condoms with lubrication and a receptacle end (to hold the ejaculate) are less likely to tear or split.

2. Risks. Irritation, allergic reactions, and unintended device failure. Condoms with spermicidal lubrication are higher in cost, have a shorter shelf-life, and are associated with a greater risk of urinary tract infections among female partners.

a. Contraindications. Latex condoms should not be used if one or both partners are allergic to latex.

3. Benefits include some (but not 100%) protection from STIs for latex and polyurethane condoms; skin condoms are too porous to provide this benefit.

4. Acceptability. Limited if a couple finds using condoms distracting or embarrassing.

a. Convenience. Applied before intercourse, one time use.

b. Availability. No prescription needed.

B. Female condom. This is made of polyurethane and provides coverage of the external genitalia and lines the vagina entirely. It can be inserted 6 hours before intercourse.

1. Failure rate is 21 pregnancies expected per 100 women per year.

2. Risks. Irritation and allergic reaction.

3. Benefits. Some protection from STI.

4. Acceptability.

a. Convenience. Inserted before intercourse, one time use.

b. Availability. No prescription needed, but it is more expensive than male condoms.

C. Diaphragms are dome-shaped, rubber cups with arching or coiled rims. This device is used in conjunction with spermicide applied to the inner cup and around the rim. Additional spermicide can be inserted before repeated intercourse.

1. Failure rate is 12 pregnancies expected per 100 women per year.

2. Risks. Irritation and urinary tract infection.

a. Contraindications. A history of toxic shock syndrome.

3. Benefits. Possible protection against some STIs, reduced cervical cancer, and privacy of use.

4. Acceptability

a. Convenience. Inserted up to 6 hours prior to intercourse and left in place at least 6 hours following intercourse. The diaphragm can be left in place for 24 hours with additional spermicide inserted vaginally for repeated intercourse. May be difficult for some women to insert easily.

b. Availability. Must have a prescription and fitting managed by an experienced provider.

D. Cervical cap: Soft rubber cup with a round rim, which fits snugly around the cervix; used with spermicide.

1. Failure rate (number of pregnancies expected per 100 women per year): prentif Cap 17, FemCap 23.

2. Risks include irritation, abnormal Pap test, and toxic shock.

3. Benefit. Privacy.

4. Acceptability.

a. Convenience. May be difficult to insert, can remain in place for 48 hours without reapplying spermicide for repeated intercourse.

b. Availability. Must have a prescription and fitting managed by an experienced provider.

E. Sponge. One-size polyurethane foam single-use device containing spermicide. Mechanism of action includes physical blockage and absorption of sperm and spermicidal effect (see later).

1. **Failure rate for typical use** (number of pregnancies expected per 100 women per year): nulliparous women 12, parous women 24.
 2. **Risks** include increased risk of vaginal infection, urinary tract infection, and toxic shock. The sponge should not be used by menstruating women (increased risk of toxic shock syndrome).
 3. **Benefit.** Protection against some STIs lasts 24 hours including for multiple acts of intercourse and privacy of use.
 4. **Acceptability**
 - a. **Convenience.** Additional spermicide does not need to be added for additional act(s) of intercourse. The sponge should be removed within 24 hours and may be difficult to remove.
 - b. **Availability.** No prescription needed.
- V. Spermicide.** These methods inactivate sperm by destroying the sperm cell membrane and interfering with motility. Spermicides are available in the form of gels, creams, foams, tablet, suppositories, and film.
- A. Failure rate for typical use** is 28 pregnancies expected per 100 women per year.
 1. **Risks** include irritation, allergic reaction, and urinary tract infection. High rate of unintended pregnancy occurs when used as a solitary agent.
 2. **Benefits.** Privacy of use. Best when used in combination with a barrier method such as condom, diaphragm, and cervical cap.
 3. **Acceptability**
 - a. **Convenience.** Inserted between 5 and 90 minutes before intercourse and usually left in place at least 6 to 8 hours later.
 - b. **Availability.** No prescription needed.

VI. Intrauterine Devices. IUD use in the United States is on the rise as it is recognized as a highly effective, long-acting, and safe form of reversible contraception. The mechanism of action of IUDs is not entirely clear, but the foreign body effect of the IUD is thought to immobilize sperm and therefore prevent fertilization of ova. Levonorgestrel IUDs also create a thick cervical mucus and, in some women, inhibit ovulation. The common misperception that IUDs function by preventing fertilized ovum from implantation has not been proven. (SOR B)

There are three types of IUDs approved for use in the United States. All are T-shaped; the ParaGard T380A has copper wound around the base, and LNG20 Mirena and LNG14 Skyla are impregnated with levonorgestrel. All three have fine, nylon tails that hang through the cervix, which allows women to check for the presence of the IUD.

- A. Failure rate** is <1 pregnancy expected per 100 women per year.
- B. Risks.** Cramping, bleeding, and rarely (<1 in 1000) perforation of the uterus during placement. IUDs do not increase the risk of pelvic inflammatory disease.
- C. Contraindications.** Known anatomic uterine anomaly such as bicornuate uterus or large distorting fibroids or pregnancy. Abnormal bleeding should be investigated before placing an IUD.
 1. Preexisting severe dysmenorrhea may become worse with the copper IUD and will likely improve with levonorgestrel IUDs. Use of a levonorgestrel IUD is not recommended in women who have had breast cancer.
- D. Benefits.** The levonorgestrel IUDs decrease the volume of menstrual blood and dysmenorrhea in symptomatic women. All IUDs are long acting and not coital dependent.
- E. Acceptability**
 1. **Convenience.** Once in place, provides reliable long-term contraception (10 years for the copper T, 5 years for Mirena, and 3 years for Skyla). IUD string check by a provider is recommended 4 to 8 weeks after placement, and then annually.
 2. **Availability.** Must have a provider with procedural experience in placing IUDs.
- F. Special notes.** Always read the manufacturer's instructions for the specific kind of IUD to be used. Both the insertion and the removal of an IUD are office procedures. A consent form should be signed and lot number of the device recorded. Pregnancy testing should be performed and documented as negative immediately prior to placement. In addition, age- and risk-appropriate testing for chlamydia and gonorrhea should be completed either before or at the time of IUD placement.
 1. The IUD can be placed in both nulliparous and parous women dependent on depth of the uterine cavity.
 2. One dose of a nonsteroidal anti-inflammatory drug is helpful to reduce discomfort from cramping if taken 1 hour prior to insertion or removal.

3. Insertion is easiest during menses because the cervix is slightly dilated, although the incidence of expulsion is slightly higher if the IUD is inserted at this time. Any time during the cycle is acceptable for insertion. The IUD may be removed at any time during the cycle.
4. Insertion can also be performed in the immediate postpartum period (10 minutes after the placenta is delivered) although expulsion rate with this timing is quite high (58%).
5. Leave a tail of at least 3 cm to allow the patient to check for expulsion of her IUD and to allow for later trimming if needed and easy removal. Let her feel the remnant of string so that she knows what to feel for monthly after her menses.
6. IUD removal is not required in the setting of STI. Treatment of the STI should be performed, and removal of the IUD only considered in the setting of more severe pelvic inflammatory disease. (SOR B)
7. There is an immediate return to fertility upon IUD removal. Hence, appropriate counseling regarding contraceptive options is recommended upon removal.
8. Placement of a copper IUD is an alternative, recognized method of emergency contraception. (SOR A) The copper IUD is extremely effective, more effective than the oral emergency contraceptives. Women using the copper IUD had pregnancy rates of 0.09% compared to women using an oral emergency contraceptive who had pregnancy rates of 1% to 2%. The IUD must be inserted within 5 days after unprotected intercourse.

VII. Natural Family Planning

A. Periodic abstinence depends on avoidance of intercourse during fertile days. Fertile days can be determined by many different methods. The Billings method of family planning relies on changes in cervical mucus. Other methods use the length of past menstrual cycles or a combination of basal body temperature and cervical mucus changes (symptothermal method). These methods rely heavily on motivated patients, but can enhance awareness of a woman's body and cycles. Other methods which have been described are the Creighton model NaProEducation system and the Standard Days Method. Abstinence is usually required for 6 to 9 days during the cycle. Some couples use barrier methods during the fertile time.

1. **Failure rate** is 24 pregnancies expected per 100 women per year.

2. Risks

- a. There are no contraindications to the use of natural family planning. The calendar method alone should not be used in women with irregular menstrual cycles (as in lactating or nearing menopause).
- b. Due to relatively higher rates of unintended pregnancy compared to other methods, the most significant risk of this method is unintended pregnancy.

3. **Benefits.** Self-knowledge of a woman's cycles, which can be helpful if desiring pregnancy as well. This information also enhances both partners' awareness and involvement in family planning.

4. Acceptability.

- a. **Convenience.** Requires frequent monitoring of body functions.
- b. **Availability.** Requires special instructions.

5. **Special notes.** Patient instructions are complex initially and take some time to master. A course with a trained instructor may be necessary. More information is available through American Pregnancy Association (<http://americanpregnancy.org/preventingpregnancy/fertilityawarenessNFP.html>), Couple to Couple League (<http://www.ccli.org/nfp/>), or Georgetown University Institute for Reproductive Health (<http://irh.org/>).

B. Lactation amenorrhea method (LAM) is based on the normal time of infertility after pregnancy. If a woman breastfeeds exclusively, the average length of infertility is 14 months. If a woman has given birth in the past 6 months, is exclusively breastfeeding (no solids, water, juice, or pacifier), and has not yet menstruated, she has approximately 98% effectiveness for breastfeeding alone. Increasing the time between feedings is the strongest factor leading to the return of fertility. Efficacy is limited to only those women who nurse exclusively on demand.

C. Coitus interruptus, or the withdrawal method, depends on withdrawal of the penis from the vagina before ejaculation occurs. Some ejaculate, however, is released before climax, and the failure rate is similar to the rate of pregnancy when using periodic abstinence or spermicide alone (Table 97-1).

VIII. Sterilization is a permanent form of birth control resulting from ligation/obstruction of the vas deferens in men (vasectomy) or ligation/obstruction of the fallopian tubes in women. It is the most prevalent form of birth control used in the United States.

- A. Vasectomy.** Sealing, tying, or cutting the vas deferens inhibiting sperm travel.
- 1. Failure rate** is <1 pregnancy expected per 100 women per year.
 - 2. Risks.** Swelling, bruising, pain, and hematoma epididymitis. There is no increased risk for testicular or prostate cancer in men receiving a vasectomy. (SOR A)
 - 3. Benefits.** The safest and most effective method for couples in a stable, monogamous relationship with no desire for future fertility. Irreversibility. Since this method involves the male partner, it facilitates avoidance of hormonal agents for women with potential contraindications for their use or who experience adverse effects.
 - 4. Acceptability**
 - a. Convenience.** Outpatient surgical procedure.
 - b. Availability.** Widely available by trained physicians.
- B. Sterilization implants.** Small metallic implant (essure) placed into the fallopian tubes through a hysteroscopic procedure. The device causes scarring blocking fallopian tubes.
- 1. Failure rate** is <1 pregnancy expected per 100 women per year.
 - 2. Risks.** Pain and ectopic pregnancy.
 - 3. Benefit.** Permanence.
 - 4. Acceptability**
 - a. Convenience.** Outpatient surgical procedure.
 - b. Availability.** Trained physician with appropriate facilities and equipment. May require a follow-up hysterosalpingogram to document successful blockage.
- C. Transabdominal surgical sterilization.** Fallopian tubes are blocked, so the egg and sperm cannot meet. This can be done in the immediate postpartum period prior to hospital discharge after a delivery, or at any time after 6 weeks postpartum.
- 1. Failure rate** is <1 pregnancy expected per 100 women per year.
 - 2. Risks.** Pain bleeding, infection, surgical complications, and ectopic pregnancy.
 - 3. Benefit.** Permanence.
 - 4. Acceptability**
 - a. Convenience.** Operative procedure, often but not always performed laparoscopically.
 - b. Availability.** Surgical centers or hospitals with trained, credentialed surgeons with experience performing tubal ligations.
- D. Special notes**
- 1.** Informed consent is critical for a surgical procedure and must describe the methods as irreversible, yet acknowledge a small risk of failure and pregnancy (possibly ectopic for the tubal ligation).
 - 2.** Because of the permanence of these methods, it is important for patients to think carefully about whether any change such as death or separation from a partner or from a child would make them regret the choice. A good question to ask is "If anything were to happen to your current spouse and children, would you want to have another child?"

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ABSTRACT The YMCA of the USA received a Health Care Innovation Award from the Centers for Medicare and Medicaid Services to provide a diabetes prevention program to Medicare beneficiaries with prediabetes in seventeen regional networks of participating YMCAs nationwide. The goal of the program is to help participants lose weight and increase physical activity. We tested whether the program reduced medical spending and utilization in the Medicare population. Using claims data to compute total medical costs for fee-for-service Medicare participants and a matched comparison group of nonparticipants, we found that the overall weighted average savings per member per quarter during the first three years of the intervention period was \$278. Total decreases in inpatient admissions and emergency department (ED) visits were significant, with nine fewer inpatient stays and nine fewer ED visits per 1,000 participants per quarter. These results justify continued support of the model.

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More than one-third of US adults are at risk of developing diabetes.¹ Approximately 20 percent of people with prediabetes will go on to develop diabetes in the next five years.^{2,3} The Diabetes Prevention Program Research Group showed that losing a modest amount of weight through healthy eating and moderate physical activity reduces the incidence of diabetes by 58 percent over three years.^{4,5} However, it is unclear whether weight-loss interventions can yield reductions in medical spending and the use of health care services.

The YMCA of the USA—a nondenominational, nonprofit community-based organization—received a Health Care Innovation Award of \$11,885,134 from the Centers for Medicare and Medicaid Services (CMS) to test a lifestyle intervention prevention model for Medicare beneficiaries with prediabetes in seventeen regional YMCA networks nationwide⁶ (for a list of partic-

ipating YMCAs and enrollment numbers by location, see online Appendix Exhibit A-1).⁷ The YMCAs use an evidence-based curriculum based on the Y's adaptation of the National Diabetes Prevention Program of the Centers for Disease Control and Prevention (CDC).⁸ The goal of the Y model is to get participants to lose 5 percent or more of their body weight and gradually increase their physical activity to 150 minutes per week.

The curriculum comprises sixteen core sessions that cover the following topics: healthy eating strategies, understanding fat and calories, and learning about foods that are high in nutritional value; strategies for increasing physical exercise, including incorporating exercise as part of one's lifestyle and setting and achieving exercise goals; and strategies for changing one's environment to help facilitate weight loss, using positive thinking, managing stress, and improving motivation. During the core sessions, lifestyle coaches facilitate group discussions of behavior changes, challenges, and solutions.

The coaches collect information on participants' weight, food, and activity trackers as a way to monitor each participant's progress.

The core sessions are followed by eight monthly maintenance sessions that are focused on maintaining lifestyle changes and receiving continued support. The maintenance sessions are less structured than the core sessions and allow participants to continue meeting and discussing strategies to maintain or continue their weight loss. A participant can attend a maximum of twenty-four one-hour sessions over twelve months.

The objective of our analysis was to establish whether the Y Diabetes Prevention Program reduces health care spending and hospital admissions and prevents unnecessary emergency department (ED) visits among fee-for-service Medicare beneficiaries.

Study Data And Methods

STUDY SAMPLE The Y enrolled participants from January 2013 through June 2015. We analyzed fee-for-service Medicare claims data for the period January 2010 through December 2015 for 3,319 participating beneficiaries enrolled in Parts A and B during the intervention period. Details on the sample exclusions in the claims data are available in Appendix Exhibit A-2.⁷

Medicare beneficiaries were eligible for the Y model if their results on a blood test—such as a hemoglobin A1c (HbA1c), fasting plasma glucose, or oral glucose tolerance test—indicated that they had prediabetes. Approximately 60 percent of the program's participants were covered by fee-for-service Medicare, and the remainder were covered by Medicare Advantage. To obtain fee-for-service Medicare claims, we linked valid Medicare beneficiary identification numbers or Social Security numbers, depending on their availability, to information in the Chronic Conditions Data Warehouse. We did not analyze spending or utilization for participants enrolled in Medicare Advantage plans because these plans do not generate cost data that are included in the warehouse.

DEFINING THE COMPARISON GROUP To estimate what would have happened to the beneficiaries had they not participated in the intervention, we constructed a comparison group as a proxy for the beneficiaries in the absence of the intervention. Comparison beneficiaries had to have been enrolled in fee-for-service Medicare for at least one month after the intervention began enrolling beneficiaries. We restricted the comparison sample to people who lived in the same counties as the participants and who met the requirement criteria for enrollment in the Y model (being at

least age sixty-five and having been diagnosed with prediabetes). To identify patients with prediabetes, we used the following *International Classification of Diseases*, Ninth Revision (ICD-9), codes: 790.29 (abnormal glucose), 277.7 (metabolic syndrome), 790.21 (impaired fasting glucose levels, but not yet diagnosed with diabetes), and 790.22 (failed glucose tolerance test, but still not diagnosed with diabetes).

The challenges with constructing a comparison group were that the model test used rolling enrollment over a twenty-nine-month period, and there was no enrollment date for nonparticipants. To overcome the challenge of selecting a baseline period for potential comparators, we applied a process called rolling enrollment matching to introduce multiple versions of a comparator—one for each intervention quarter—into the data before estimating a propensity score.⁹ In doing so, we exploited the rolling enrollment approach to evaluate the model's impacts over time after each participant's enrollment date, instead of assuming a fixed enrollment date for all participants.

Using a caliper-matching approach with replacement, for each beneficiary in the model, we assigned up to three comparison beneficiaries whose propensity scores fell within the prespecified 20 percent of the standard deviation.^{10,11} Intervention and comparison beneficiaries were matched using a logit model predicting the likelihood that a beneficiary was enrolled in the model test as a function of age, sex, race/ethnicity, disability, end-stage renal disease, dually enrollment in Medicare and Medicaid, number of chronic conditions, number of ED visits and inpatient stays in the calendar quarter before the intervention, total Medicare payments in the calendar quarter and calendar year before the intervention, and living in the ZIP code of a participating YMCA.^{12,13}

We used two diagnostic tests to assess the similarity of the intervention and matched comparison groups: a balancing table, which assessed differences between the groups one variable at a time; and the kernel density plot of the propensity score, which was a summary measure of all covariates included in the propensity score model. An absolute standardized difference of 0.10 or lower was considered an acceptable level of balance between the groups, and overlap in the density implied that the propensity score estimates were similarly distributed in the groups.¹⁴ Appendix section A.2 provides technical details on the rolling enrollment matching and propensity score methodology.⁷

ESTIMATING PROGRAM EFFECTS ON CORE OUTCOMES The average treatment effect for the treated per quarter—that is, the average differ-

ence between the observed outcomes for the beneficiary population (intervention group) and the counterfactual (comparison group) in the postintervention quarters—was measured using a difference-in-differences quarterly fixed-effects model. Total spending was estimated using ordinary least squares regression. Inpatient hospital admissions and ED visits were estimated using a negative binomial count model. Further details on the specification are provided in Appendix section A.3.⁷

LIMITATIONS Because of the policy importance of the diabetes prevention model, it is important to note three limitations of this analysis. First, Medicare beneficiaries were not randomly assigned to intervention and comparison groups. We used propensity score matching to select members of the comparison group who had prediabetes. Although that process selected healthier people with lower spending, fewer hospitalizations, and fewer ED visits, compared to the average Medicare beneficiary, it could not control for any unobservable differences between the intervention and comparison groups in motivation or other factors.

Second, although all participants should have had prediabetes at the time of enrollment in the model, some of them might have received a formal diabetes diagnosis before enrolling. Using the same criteria discussed above—based on geographical location, prediabetes status, and fee-for-service Medicare coverage—we defined a new comparison group based on propensity score matches to people who had not received a diabetes diagnosis before enrollment. For this subset of healthier people, the Y program showed slightly larger savings, compared to those for the full sample. Results for this subset are presented below.

Third, we did not have claims data on the large share (approximately 40 percent) of participants enrolled in Medicare managed care programs, and we were unable to match some patient identifiers for fee-for-service Medicare participants to the claims data. Managed care beneficiaries and unmatched individuals represented approximately 44 percent of the overall population reached by the intervention. Fee-for-service Medicare participants included in the analysis sample were statistically comparable to those not included because of their different insurance or our inability to match them to information in the Chronic Conditions Data Warehouse (Appendix Exhibit A-3).⁷

Study Results

DESCRIPTIVE RESULTS Baseline characteristics of the 3,319 subjects who participated in the Y

model are presented in Appendix Exhibit A-4.⁷ The average age at enrollment was seventy-one, 69 percent were female, and 34 percent were missing information on race/ethnicity. Among those with available information, approximately 85 percent were non-Hispanic white; 12 percent were non-Hispanic black; 2 percent were Hispanic; and the remaining 1 percent were Asian, American Indian or Alaska Native, or Native Hawaiian or other Pacific Islander. On average, participants lost 9.5 pounds over the course of the program (measured at participants' last session, up to a year after enrollment), and average body mass index (BMI) dropped from 33.6 to 32.0 kg/m². Weight loss was strongly correlated with the number of sessions attended (correlation coefficient: 0.47; $p \leq 0.001$). Similar results have been obtained in other studies of diabetes prevention programs.^{15,16}

Exhibit 1 presents the mean values and standardized differences of the variables of interest that were included in the propensity score model before and after matching. Appendix Exhibit A-5⁷ shows the distribution of the propensity scores for the intervention and comparison groups before and after matching. Appendix Exhibit A-5b⁷ indicates that the propensity scores for the matched comparison beneficiaries were similar to those for the intervention beneficiaries. Seventeen beneficiaries in the model were dropped from the subsequent analyses because an appropriately matched comparison beneficiary was not available. Propensity score matching reduced the absolute standardized differences and achieved adequate balance for all variables (the standardized difference was less than 0.1 throughout).

The difference in Medicare spending between the intervention and matched comparison groups represents crude savings per patient. Intervention participants had lower spending than members of the comparison group throughout the first six intervention quarters (Exhibit 2). The differences in the first three intervention quarters (with other factors not controlled for) were significant ($p < 0.05$). Thereafter, because intervention quarters were based on each participant's length of exposure, variability increased as the number of participants declined—which reflected the lower recruitment in the first quarters of the model relative to subsequent quarters.

The comparison group had slightly higher inpatient admission rates than the intervention group in several baseline quarters, and this difference widened during all but three of the intervention quarters (Exhibit 3). Similar to the case with spending, the first three intervention quarters showed significant differences in admission rates between the intervention and comparison

EXHIBIT 1

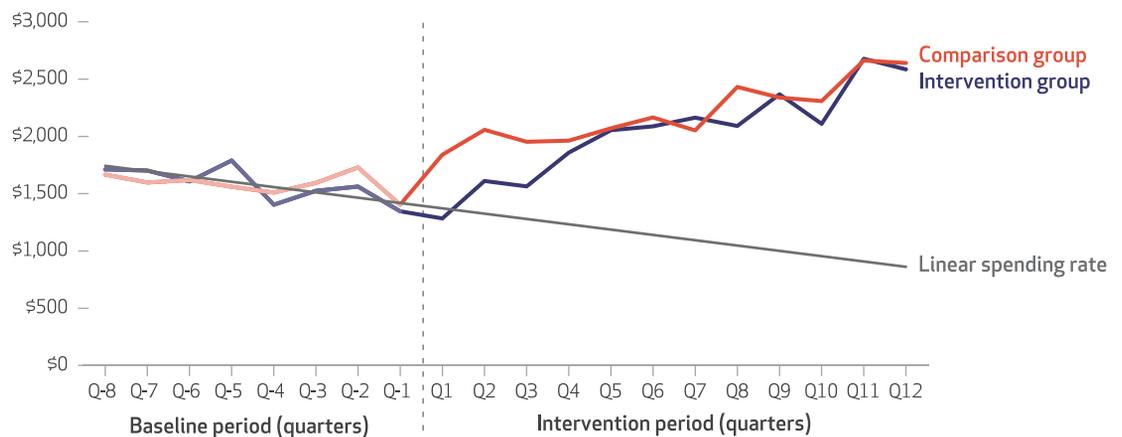
Balance of variables in propensity score model between the YMCA of the USA diabetes prevention intervention and comparison groups

Variable	Before matching					After matching				
	Intervention group		Comparison group		Standardized difference	Intervention group		Comparison group		Standardized difference
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Payment in quarter before enrollment	\$1,345	\$3,466	\$1,888	\$5,930	0.11	\$1,346	\$3,473	\$1,404	\$4,143	0.02
Total payments in 2-5 quarters before enrollment	\$5,832	\$11,503	\$6,707	\$13,935	0.07	\$5,829	\$11,510	\$6,048	\$11,798	0.02
Age (years)	70.18	5.78	74.47	7.38	0.65	70.29	5.54	70.25	5.14	0.01
Male	31.15%	46.31%	41.99%	49.35%	0.32	31.24%	46.35%	31.86%	46.59%	0.02
White	81.98%	38.43%	87.30%	33.30%	0.21	82.10%	38.33%	81.17%	39.10%	0.03
With ESRD	0.21%	4.58%	0.19%	4.35%	0.01	0.21%	4.59%	0.26%	5.10%	0.01
Living in participating YMCA's ZIP code	44.30%	49.67%	15.19%	35.89%	0.95	44.14%	49.66%	43.94%	49.63%	0.01
Dual-eligible months in previous year	0.49	2.31	0.84	3.00	0.13	0.49	2.3	0.47	2.25	0.01
No. of chronic conditions	5.73	3.14	6.25	3.28	0.16	5.74	3.14	5.71	3.18	0.01
ED visits in quarter before enrollment	0.07	0.32	0.07	0.32	0.03	0.06	0.32	0.07	0.30	0.01
Inpatient stays in quarter before enrollment	0.02	0.17	0.05	0.26	0.13	0.02	0.17	0.02	0.17	0.00
Beneficiaries	3,336	— ^a	4,387,776	— ^a	— ^a	— ^a	— ^a	— ^a	— ^a	— ^a
Unique beneficiaries ^b	— ^a	— ^a	457,774	— ^a	— ^a	3,319	— ^a	9,861	— ^a	— ^a
Weighted beneficiaries	— ^a	— ^a	— ^a	— ^a	— ^a	3,319	— ^a	3,319	— ^a	— ^a

SOURCE Authors' analysis of fee-for-service Medicare claims data from the Chronic Conditions Data Warehouse. **NOTES** The intervention and comparison groups are defined in the text. "Dual eligible" refers to being eligible for both Medicare and Medicaid. SD is standard deviation. ESRD is end-stage renal disease. ED is emergency department. ^aNot applicable. ^bBefore matching, differences in the number of beneficiaries and the number of unique beneficiaries in the comparison group are due to multiple observations of each comparison beneficiary (clones). After matching, the differences are due to weighting.

EXHIBIT 2

Quarterly spending per participant, for Medicare beneficiaries in the YMCA of the USA diabetes prevention intervention and comparison groups

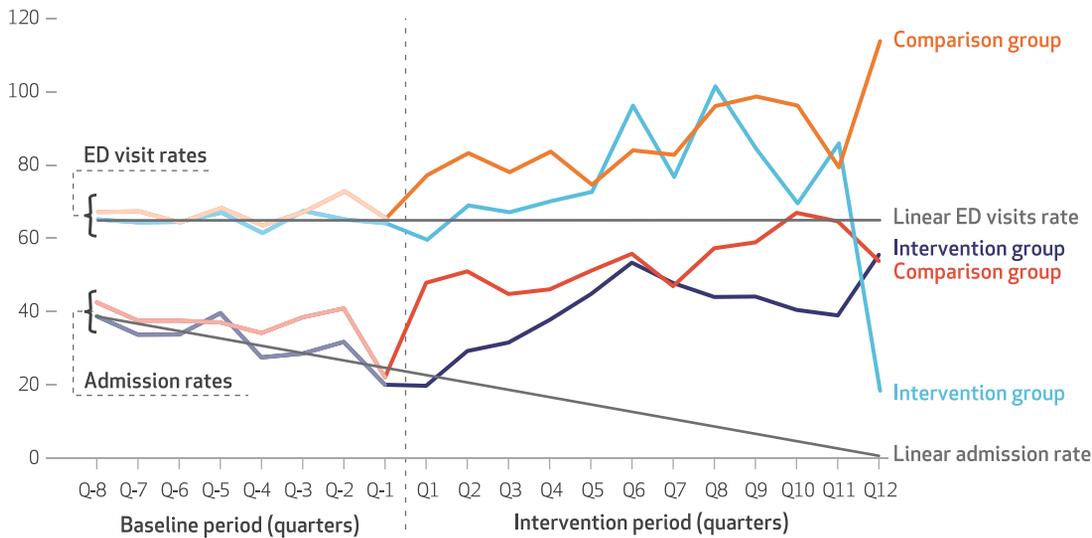


SOURCE Authors' analysis of fee-for-service Medicare claims data from the Chronic Conditions Data Warehouse. **NOTES** The intervention and comparison groups are defined in the text. The intervention period began in January 2013. The linear spending rate continues the trend in the baseline spending, if the intervention had not occurred.

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EXHIBIT 3

All-cause inpatient admissions and emergency department (ED) visits per 1,000 Medicare beneficiaries in the YMCA of the USA diabetes prevention intervention and comparison groups



SOURCE Authors' analysis of fee-for-service Medicare claims data from the Chronic Conditions Data Warehouse. **NOTES** The intervention and comparison groups are defined in the text. The intervention period began in January 2013. The linear admissions rate continues the trend in the baseline admissions, and the linear ED visits rate continues the trend in the baseline ED visits, if the intervention had not occurred.

groups ($p < 0.05$). Because index admission rates were low in this population, the unplanned readmissions rate was highly variable for both groups (data not shown). Throughout the baseline period, the ED visit rate was similar in the intervention and comparison groups (Exhibit 3). In the first four intervention quarters, the ED visit rate was significantly higher in the comparison group than in the intervention group.

REGRESSION RESULTS We found significant differences in per participant spending between the intervention and comparison groups in the first three intervention quarters (Exhibit 4). These savings became insignificant in subsequent quarters. To interpret results from inpatient hospital admissions and ED visits in a standardized form, we multiplied the coefficients and standard errors in Exhibit 4 by 1,000, so that the adjusted estimates show visit rates per 1,000 participants. Exhibit 5 also presents, in graphic form, the savings in total Medicare spending per patient for the three years (twelve quarters) following enrollment.

The weighted average quarterly saving differential per member per quarter over the three-year intervention period was \$278 (Exhibit 4) (90% confidence interval: \$159, \$396). This effect was significant, with the model generating savings of \$5,048,449 for the 3,319 participants included in the regression analysis (Exhibit 4). Savings were highest in the first year (\$364; 90%

CI: \$241, \$488). The impact of the model decreased thereafter.

Decreases in inpatient admissions and ED visits for the intervention group compared to the comparison group were significant for the entire intervention period, with nine fewer inpatient stays (90% CI: -12, -6) and nine fewer ED visits (90% CI: -14, -5) per 1,000 participants per quarter. The model's impact on inpatient stays and ED visits was also highest in the first year (with twelve and eleven fewer inpatient and ED visits, respectively, in the intervention sample per 1,000 participants per quarter).

SUBANALYSIS FOR PEOPLE NEVER RECEIVING A DIABETES DIAGNOSIS Using claims data to define diabetes status, we found that approximately 30 percent of model participants had diabetes-related claims. We hypothesized that cost savings might differ among the subgroup of "healthier" people who had never received a diabetes diagnosis. Using the same criteria discussed above—based on geographical location, prediabetes status, and fee-for-service Medicare coverage—we defined a new comparison group based on propensity score matches to people who had not received a diabetes diagnosis before enrollment in the Y program. This subanalysis focused on 2,322 beneficiaries in the intervention group who had never had diabetes (based on claims history in the Chronic Conditions Data Warehouse).

EXHIBIT 4

Difference-in-differences estimates of outcomes between the YMCA of the USA diabetes prevention intervention and comparison groups

Intervention quarter	Per participant		Per 1,000 participants			
	Medicare spending (\$)		Inpatient admissions		ED visits	
	Coefficient	SE	Coefficient	SE	Coefficient	SE
1	-521	82***	-22	4***	-14	6**
2	-406	139***	-14	4***	-11	6*
3	-370	104***	-7	4*	-8	6
4	-98	136	-2	5	-11	7
5	-37	199	-1	7	-3	9
6	-122	178	0	8	8	11
7	68	205	5	8	-10	11
8	-394	285	-8	10	2	16
9	-91	356	-14	13	-25	18
10	-241	311	-16	15	-32	20
11	9	688	-20	24	5	32
12	-43	938	4	45	-98	38**
Average impact per quarter	Medicare spending (\$)		Acute care inpatient stays		ED visits not leading to a hospitalization	
Total	-278***		-9***		-9***	
Year 1	-364***		-12***		-11***	
Year 2	-92		-1		-1	
Year 3	-126		-15		-27	
Aggregated results	Total spending (\$ millions)		Acute care inpatient stays		ED visits not leading to a hospitalization	
Total	-5.048***		-167***		-168***	
Year 1	-4.466***		-149***		-137***	
Year 2	-0.453		-3		-3	
Year 3	-0.129		-15*		-28**	

SOURCE Authors' analysis of fee-for-service Medicare claims data from the Chronic Conditions Data Warehouse. **NOTES** The intervention and comparison groups are defined in the text. Spending per participant, acute care inpatient stays, and ED visits not leading to a hospitalization are the weighted average quarterly fixed effects. Results for all of the covariates included in the regressions are presented in Appendix Exhibit A-6 (see Note 7 in text). ED is emergency department. SE is standard error. **p* < 0.10 ***p* < 0.05 ****p* < 0.01

We found greater savings for this subset of healthier people than for the full intervention group. For the healthier people, the model generated \$303 in savings (90% CI: \$176, \$430) per member per quarter for the entire intervention period. However, total decreases in inpatient admissions and ED visits were relatively unchanged, at 8 (90% CI: 12, 4) and 9 (90% CI: 14, 4), respectively, per 1,000 participants per quarter (Appendix Exhibit A-6).⁷

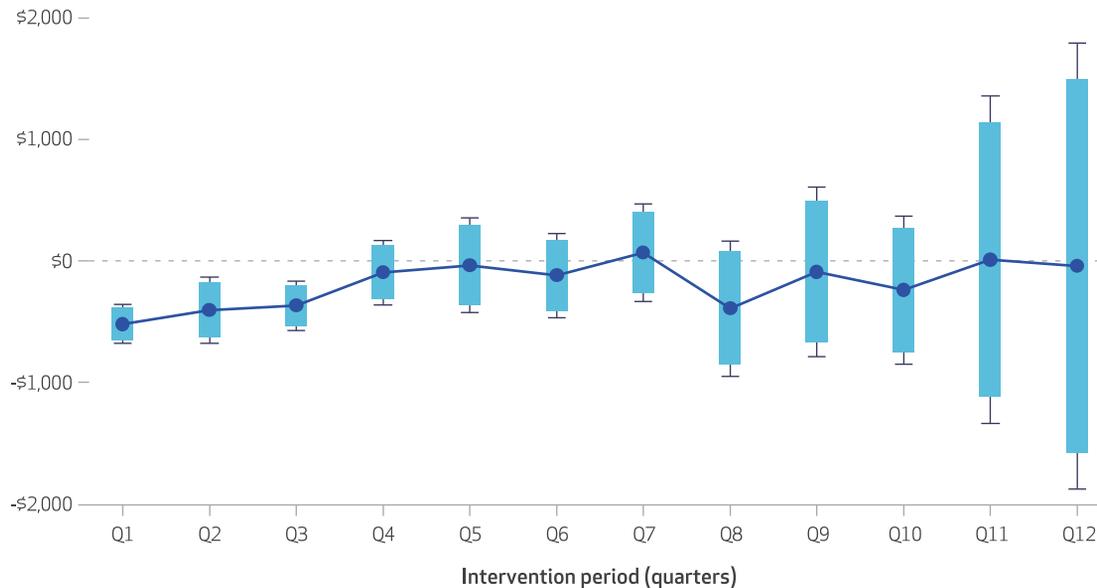
Discussion

The results show that the YMCA of the USA diabetes prevention model was associated with significant reductions in Medicare spending, inpatient admissions, and ED visits in the intervention group, relative to the comparison group. The evidence that the model led to lower spending for the intervention group was strongest in the first three quarters after enrollment. This may be because maximum weight loss in the

program occurs during the first three to six months, and initial weight loss predicts longer-term weight maintenance.¹⁷⁻²⁰ Cost savings may also occur initially as a result of a reduction in outpatient spending, an increase in participants' physical activity, or both.

Results on spending estimates from the first two years of this evaluation²¹ were cited in CMS's policy determination that Diabetes Prevention Program services were eligible for coverage as additional preventive services under Medicare.²² The evaluation of the Y model is ongoing. While we now have three years of post-intervention data, we do not yet have three years of exposure data for participants who recently enrolled in the model test. The last participant has claims data for two post-enrollment quarters, but our aim is to collect at least one year of post-enrollment data for all participants.

To address the growing incidence of diabetes in the United States, the model must be expandable, to achieve population-level impacts. The

EXHIBIT 5**Changes in quarterly Medicare spending per beneficiary in the YMCA of the USA diabetes prevention intervention group, compared to changes in the comparison group, after the intervention**

SOURCE Authors' analysis of fee-for-service Medicare claims data from the Chronic Conditions Data Warehouse. **NOTES** The exhibit shows the results of ordinary least squares regression. The intervention and comparison groups are defined in the text. The error bars show 90% confidence intervals. The whiskers on the error bars show 95% confidence intervals.

benefits and costs of large-scale diabetes prevention efforts need to be rigorously assessed so that resources can be allocated optimally among competing aims.

This study evaluated the effect of the Y's adaptation of the CDC's Diabetes Prevention Program on spending and medical utilization. Several previous studies¹⁵ have shown a causal link between weight loss and diabetes prevention. We did not collect information on HbA1c or diabetes onset as an endpoint and therefore were not able to report information on diabetes risk reduction. Nonetheless, this study shows that the Y's large-scale model test of the original CDC program in a real-life setting reduced spending and medical utilization.

One of the Social Security Act's criteria for expansion of a Center for Medicare and Medicaid Innovation model is for a model to improve quality without increasing spending or not reduce quality while reducing spending.²³ The cost of participating in a CDC-recognized lifestyle change program varies, depending on the location, organization offering it, and type of program (in person or online). Participation costs were waived for participants of this study. CMS

has proposed the following reimbursement structure based on historical evidence from other translational versions of the CDC's Diabetes Prevention Program nationwide:²⁴ \$360 per person for the first six months, \$450 for the first year, and \$180 in subsequent years for maintenance sessions. Based on the proposed reimbursement rates and our estimates of reduced spending, the return on investment of this program would be \$2.2 per \$1 for the first year and \$3 per \$1 for the three years for which we have data, assuming a 3 percent discount rate.²⁵

This simple calculation does not include Part D claims, and hence it does not include potential savings from drug expenditures. Nor does it include the cost of screening and recruiting participants. More research is needed to understand the extent to which these two offset each other. Based on the literature regarding the clinical trial of the CDC's Diabetes Prevention Program and follow-up studies showing that the lifestyle intervention has a long-term effect on diabetes incidence, beneficiaries may experience greater longevity and quality of life as a result of the Y model—further increasing the return on investment in it. ■

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article are solely those of the authors and do not necessarily reflect the opinions of RTI or CMS.

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THE HEALTH CARE COSTS OF SMOKING

JAN J. BARENDREGT, M.A., LUC BONNEUX, M.D., AND PAUL J. VAN DER MAAS, PH.D.

ABSTRACT

Background Although smoking cessation is desirable from a public health perspective, its consequences with respect to health care costs are still debated. Smokers have more disease than nonsmokers, but nonsmokers live longer and can incur more health costs at advanced ages. We analyzed health care costs for smokers and nonsmokers and estimated the economic consequences of smoking cessation.

Methods We used three life tables to examine the effect of smoking on health care costs — one for a mixed population of smokers and nonsmokers, one for a population of smokers, and one for a population of nonsmokers. We also used a dynamic method to estimate the effects of smoking cessation on health care costs over time.

Results Health care costs for smokers at a given age are as much as 40 percent higher than those for nonsmokers, but in a population in which no one smoked the costs would be 7 percent higher among men and 4 percent higher among women than the costs in the current mixed population of smokers and nonsmokers. If all smokers quit, health care costs would be lower at first, but after 15 years they would become higher than at present. In the long term, complete smoking cessation would produce a net increase in health care costs, but it could still be seen as economically favorable under reasonable assumptions of discount rate and evaluation period.

Conclusions If people stopped smoking, there would be a savings in health care costs, but only in the short term. Eventually, smoking cessation would lead to increased health care costs. (N Engl J Med 1997;337:1052-7.)

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SMOKING is a major health hazard, and since nonsmokers are healthier than smokers, it seems only natural that not smoking would save money spent on health care. Yet in economic studies of health care it has been difficult to determine who uses more dollars — smokers, who tend to suffer more from a large variety of diseases, or nonsmokers, who can accumulate more health care costs because they live longer. The Surgeon General reported in 1992 that “the estimated average lifetime medical costs for a smoker exceed those for a nonsmoker by more than \$6,000.”¹ On the other hand, Lippiatt estimated that a 1 percent decline in cigarette sales increases costs for medical care by \$405 million among persons 25 to 79 years

old.² Manning et al. argued that although smokers incur higher medical costs, these are balanced by tobacco taxes and by smokers’ shorter life spans (and hence their lower use of pensions and nursing homes).³ Leu and Schaub showed that even when only health care expenditures are considered, the longer life expectancy of nonsmokers more than offsets their lower annual expenditures.⁴

We have analyzed comprehensively the health care costs of smoking. In doing so we have distinguished between the assessment of differences between smokers and nonsmokers and the assessment of what would happen after interventions that changed smoking behavior. Would a nonsmoking population have lower health care costs than one in which some people smoke? Are antismoking interventions economically attractive? We sought to answer these questions and to determine the consequences for health policy.

METHODS

Analysis of Smokers and Nonsmokers

We examined the effect of smoking in the general population (a mixture of smokers and nonsmokers). We studied the incidence, prevalence, and mortality associated with five major categories of disease — heart disease, stroke, lung cancer, a heterogeneous group of other cancers, and chronic obstructive pulmonary disease (COPD). We used data on these diseases, in addition to mortality from all other causes, in an extension of the standard life table, the multistate life table, that includes multiple health states, such as “alive, healthy” and “alive, with heart disease.”^{5,6}

Differences in the frequency of the smoking-related diseases between smokers and nonsmokers are commonly expressed as rate ratios. Using these rate ratios, the prevalence of smoking in the population, and the age- and sex-specific incidence of the smoking-related diseases in the mixed population of smokers and nonsmokers, we can estimate the incidence of the diseases separately among smokers and nonsmokers.⁶

Assuming that the relative survival of persons with these diseases is the same among both smokers and nonsmokers, two additional life tables can be calculated — one for smokers and one for nonsmokers. The three life tables differ with regard to the incidence of the smoking-related diseases and therefore in their associated prevalence, disease-specific mortality, and overall mortality. Because of the difference in mortality, more people remain alive in the life table for nonsmokers than in the table for smokers, particularly in the older age groups, and there are corresponding differences in life expectancies.

In constructing the life tables, we used epidemiologic data on the incidence and prevalence of the diseases,⁷⁻¹⁰ data on mortality from Statistics Netherlands,¹¹ data on smoking (Table 1),¹² and rate ratios from an overview of the literature.¹³ We tested the sen-

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sitivity of the analysis by recalculating the life tables with excess risks (the rate ratio - 1) that were 50 percent higher and 50 percent lower (Table 2).

The medical costs we used were based on a study that allocated the total costs for health care in the Netherlands in 1988 (39.8 billion guilders, or \$19.9 billion, at the present exchange rate) to categories of age, sex, and disease.¹⁴ We used the Dutch population in 1988 and the prevalence rates of the smoking-related diseases from the life table for mixed smokers and nonsmokers to estimate the costs per case of disease according to age and sex. The remaining costs were assigned to "per capita costs for all other diseases" (in categories according to age and sex) by dividing the costs by the number of people in the category in question. Using the per capita costs for each disease and the "all other disease" costs, we calculated the health care costs for the populations included in the three life tables.

Assessment of the Effect of Complete Smoking Cessation

The estimated health care cost derived from the life table of nonsmokers can be seen as an estimate of the cost of health care if no one ever smoked. It does not provide an estimate of the health care cost if all smokers stopped smoking. In the latter case, the size of the elderly population would initially be the same as in the mixed population of smokers and nonsmokers. For it to become similar in size to the elderly population among nonsmokers, in which more elderly people are alive, would take several years, even if mortality declined rapidly.

To describe the epidemiologic changes and the changes in the population over time, a dynamic model is needed. For this purpose, we needed a series of linked life tables, one for each point in time, with the population at a given age (a) and time (t) depending on the population at age $a-1$ and time $t-1$, and on the incidence of disease and the associated mortality between $t-1$ and t . We used the Prevent Plus computer program, which is designed to evaluate interventions concerning risk factors dynamically.^{6,15}

This dynamic analysis produces a projection of future health care costs. To assess the economic attractiveness of an intervention that would make smokers quit, these costs are compared with those expected when no intervention is made. One difficulty in such an evaluation is the fact that most people prefer to receive benefits as soon as possible and to postpone payments. Economists call this phenomenon "time preference,"^{16,17} and it is taken into account by discounting the future benefits and costs — that is, those further away in time are given lower weights in the overall evaluation.

The degree of time preference is expressed in the discount rate. Typical values range from 0 to 10 percent, with 0 percent meaning that there is no discounting and no time preference and 10 percent meaning that there is a strong time preference. Since there is no generally agreed-upon discount rate, we used various rates (0, 3, 5 and 10 percent) in evaluating the intervention.

A second difficulty in evaluating future costs and benefits is deciding how far into the future the analysis should go. There is no generally agreed-upon duration of follow-up in this type of analysis. For each projection of discounted costs and benefits, we therefore report the duration of follow-up at which the benefits and costs expected in the future exactly balance each other (the break-even year) — the point at which carrying out the intervention is neither more nor less economically attractive than not doing so.

RESULTS

Figure 1 shows the annual per capita health care costs for male smokers and nonsmokers 40 to 89 years old, in 5-year age groups (the costs for women in the same age groups are very similar). Per capita costs rise sharply with age, increasing almost 10 times from persons 40 to 44 years of age to those 85 to 89 years of age. In each age group, smokers

TABLE 1. PREVALENCE OF SMOKING.*

AGE (YR)	SMOKERS	
	MALE	FEMALE
	percent	
0-14	0	0
15-19	20	20
20-34	39	37
35-49	42	36
50-64	39	27
≥65	34	13

*Data are averages for 1988-1992 in the Netherlands.¹²

TABLE 2. RATE RATIOS AND SENSITIVITY RANGES ASSOCIATED WITH FIVE CATEGORIES OF DISEASE.

CATEGORY	RATE RATIO (SENSITIVITY RANGE)*
Heart	3 (2-4)
Lung cancer	10 (5.5-14.5)
Stroke	2 (1.5-2.5)
Other cancers†	2 (1.5-2.5)
COPD‡	25 (13-37)

*Rate ratios refer to the rate of the disease in smokers as compared with nonsmokers. The lower and upper bounds of the sensitivity range were calculated as $1+0.5(RR-1)$ and $1+1.5(RR-1)$, respectively, where RR denotes the rate ratio.

†This category includes neoplasms except for stomach, colorectal, lung, breast, prostate, and skin cancers, and benign tumors.

‡COPD denotes chronic obstructive pulmonary disease.

incur higher costs than nonsmokers. The difference varies with the age group, but among 65-to-74-year-olds the costs for smokers are as much as 40 percent higher among men and as much as 25 percent higher among women.

However, the annual cost per capita ignores the differences in longevity between smokers and nonsmokers. These differences are substantial: for smokers, the life expectancies at birth are 69.7 years in men and 75.6 years in women; for nonsmokers, the life expectancies are 77.0 and 81.6 years (these life-table estimates agree very well with the empirical findings of Doll et al.¹⁸). This means that many more nonsmokers than smokers live to old age. At age 70, 78 percent of male nonsmokers are still alive, as compared with only 57 percent of smokers (among women, the figures are 86 percent and 75 percent); at age 80, men's

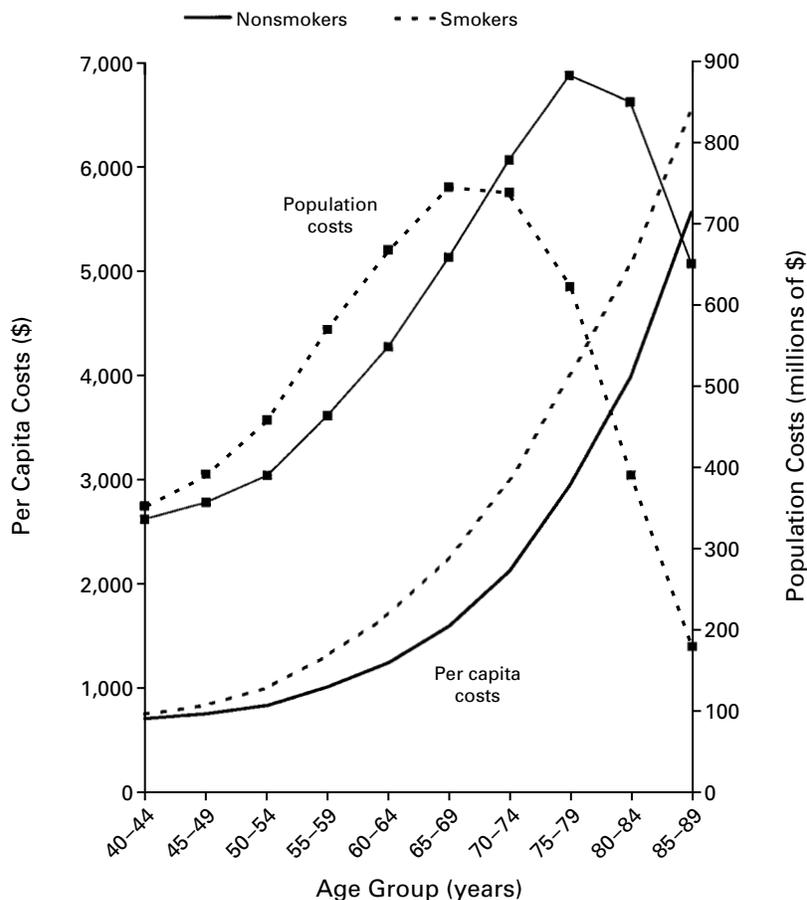


Figure 1. Estimated Annual per Capita Health Care Costs for Dutch Men in 1988 and for the Male Population in a Life Table, According to Age and Smoking Status. Per capita health care costs for women in the same age groups are very similar to those for men.

survival is 50 percent and 21 percent, respectively (among women, 67 percent and 43 percent).

These differences in the numbers of elderly people have a profound effect on the health care costs for the population, as Figure 1 shows. In the younger age groups, in which mortality even among smokers is quite low, a population of smokers has higher health care costs than a population of nonsmokers, but in the groups of men 70 to 74 and over (and those of women 75 to 79 and over), the lower per capita cost of the nonsmokers is outweighed by the greater number of people remaining alive.

As Figure 1 shows, the nonsmoking population as a whole is more expensive than the smoking population. The area between the curves in which the smokers have higher health care costs than the nonsmokers is smaller than the area between the curves in which the nonsmokers have higher health care costs. This is shown in greater detail in Table 3, where the total health care costs for

the mixed, the smoking, and the nonsmoking populations are presented according to disease category.

All the smoking-related diseases (with the notable exception of stroke among men) are associated with higher costs in a population of smokers and lower costs in a population of nonsmokers. This relation is particularly strong for the diseases with the highest excess risk: lung cancer and COPD. However, in the mixed population of smokers and nonsmokers, smoking-related diseases account for only 19 percent of total costs among men and 12 percent of total costs among women, and the costs of all the other diseases have precisely the opposite relation. In a population of smokers, the costs associated with all the other diseases are less than those in the mixed population: 14 percent less for men and 18 percent less for women. Among nonsmokers, the costs of all the other diseases are 15 percent higher for men and 7 percent higher for women.

The risk of the diseases not related to smoking is

considered equal for smokers and nonsmokers, but the nonsmoking population lives longer and therefore incurs more costs due to those diseases, particularly in old age, when the costs are highest. On balance, the total costs for male and female nonsmokers are 7 percent and 4 percent higher, respectively, than for a mixed population, whereas for smokers the total costs are 7 percent and 11 percent lower.

Table 3 also shows that changing the assumptions about the excess risk associated with smoking-related diseases by as much as 50 percent in either direction does not change the conclusion, except in the case of stroke. The age-related increase in incidence is steepest for stroke, and there is also an age-related increase for stroke in the cost per case; therefore the health care costs associated with stroke are the most sensitive to changes in life expectancy.

Because of the costs of other diseases, the population of nonsmokers has higher health care costs, partly because these costs increase with age. To test the sensitivity of the analysis to this age-related increase, we recalculated the three life tables, keeping

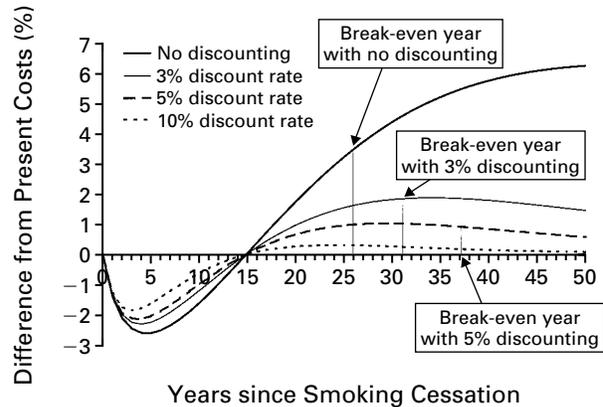


Figure 2. Percent Changes in Total Health Care Costs for the Male Population after Smoking Cessation, as Determined in a Dynamic Analysis, According to the Number of Years since Cessation, with No Discounting and with Three Discount Rates. The labels show the “break-even” years, when the cost and benefit of the intervention balance each other. Shorter follow-up times make smoking cessation attractive economically, and longer follow-up makes it unattractive. With 10 percent discounting, the break-even year is later than 50 years.

TABLE 3. HEALTH CARE COSTS FOR THE THREE POPULATIONS STUDIED WITH LIFE TABLES, ACCORDING TO SEX AND DISEASE CATEGORY, WITH THE RATIOS OF THE COSTS FOR SMOKERS AND NONSMOKERS TO THOSE FOR THE MIXED POPULATION CONTAINING BOTH.

SEX AND DISEASE CATEGORY*	POPULATION			SMOKERS: MIXED POPULATION	NONSMOKERS: MIXED POPULATION
	MIXED	SMOKERS	NONSMOKERS		
	millions of \$			cost ratio (sensitivity range)†	
Men					
Heart	525	676	371	1.29 (1.18–1.35)	0.71 (0.84–0.61)
Stroke	416	390	428	0.94 (0.91–0.97)	1.03 (1.06–0.98)
Lung cancer	114	211	33	1.85 (1.76–1.87)	0.29 (0.44–0.22)
Other cancers	226	254	203	1.12 (1.05–1.18)	0.90 (0.97–0.83)
COPD	165	275	23	1.67 (1.72–1.63)	0.14 (0.23–0.11)
All other	6,360	5,463	7,284	0.86 (0.89–0.84)	1.15 (1.09–1.18)
Total	7,806	7,270	8,342	0.93 (0.95–0.92)	1.07 (1.04–1.09)
Women					
Heart	386	538	330	1.39 (1.24–1.48)	0.86 (0.93–0.79)
Stroke	510	571	502	1.12 (1.04–1.19)	0.98 (1.01–0.96)
Lung cancer	23	70	9	3.10 (2.61–3.32)	0.39 (0.55–0.31)
Other cancers	297	387	264	1.30 (1.16–1.42)	0.89 (0.95–0.84)
COPD	102	254	20	2.48 (2.45–2.45)	0.20 (0.31–0.15)
All other	9,358	7,653	10,013	0.82 (0.87–0.79)	1.07 (1.04–1.09)
Total	10,676	9,473	11,138	0.89 (0.92–0.87)	1.04 (1.03–1.05)

*COPD denotes chronic obstructive pulmonary disease.

†The sensitivity range was calculated with the lower and upper bounds of the rate ratios in Table 2. A lower rate ratio reduces the difference between smokers and nonsmokers in the incidence, prevalence, and mortality from smoking-related disease. Therefore, nonsmokers avert fewer cases of smoking-related disease (leading to lower savings) but simultaneously gain less in life expectancy (leading to lower added costs from “other” diseases). For most smoking-related diseases and “other” diseases, lower rate ratios make the difference in costs smaller.

the health care costs associated with “all other disease” at the 65-to-69-year-old level for people over the age of 65. The costs for the mixed population and for the nonsmoking population became virtually the same, and those for the smoking population were still the smallest, albeit by a small margin.

Figure 2 shows what the economic consequences would be if all smokers stopped smoking. After this abrupt change, the total health care costs for men (the “no discounting” curve) would initially be lower than they would have been (by up to 2.5 percent), because the incidence of smoking-related diseases among the former smokers would decline to the level among nonsmokers. Prevalence rates start to decline, costs decline, and the intervention shows a benefit. With time, however, the benefit reverses itself to become a cost. The reason is that along with incidence and prevalence, smoking-related mortality declines and the population starts to age. Growing numbers of people in the older age groups mean higher costs for health care. By year 5, the benefit derived from the presence of the new nonsmokers starts to shrink, and by year 15 these former smokers are producing excess costs. Eventually a new steady state is reached in which costs are about 7 percent higher — the difference between the mixed and the nonsmoking populations.

Figure 2 shows the consequences of discounting the projected costs and benefits by various percentages. It is apparent that discounting, even at a rate as low as 3 percent, has a huge impact, and this impact becomes greater as the costs become more distant in time.

Having all smokers quit becomes economically attractive when the future benefits are larger than the future costs or, in terms of Figure 2, when the area below the x axis is bigger than the area above it. From the figure it is clear that this depends heavily on the duration of follow-up considered and on the discount rate. With a shorter evaluation period and higher discount rates, stopping smoking looks economically more attractive. With a longer evaluation period and lower discount rates, quitting smoking loses its economic advantages. The break-even year, when the initial benefit is exactly balanced by the eventual cost, occurs after 26 years of follow-up when there is no discounting, after 31 years with 3 percent discounting, and after 37 years with 5 percent discounting. At 10 percent discounting, the break-even year occurs after more than 50 years and may not occur at all.

DISCUSSION

This study shows that although per capita health care costs for smokers are higher than those of nonsmokers, a nonsmoking population would have higher health care costs than the current mixed population of smokers and nonsmokers. Yet given a short

enough period of follow-up and a high enough discount rate, it would be economically attractive to eliminate smoking.

Some earlier studies have had differing results, partly because many have focused on costs attributable to smoking. From rate ratios and the prevalence of smoking in a population, the proportion of the total number of cases of a disease that can be attributed to smoking — the population attributable risk — can be calculated.¹⁹ Given the costs according to disease, one can calculate the costs attributable to smoking.²⁰ For instance, in the life-table population of mixed smokers and nonsmokers about 8 percent of total health care costs among men and almost 3 percent of total costs among women can be attributed to smoking. Attributable costs, however, can be interpreted as potential savings only when the diseases do not affect mortality. In the case of most smoking-related diseases, reductions in smoking reduce mortality, creating new possibilities for morbidity from other diseases in the years of life gained.

Other studies of this subject estimate lifetime health care costs, taking the differences in life expectancy into account, and find that smokers have higher medical costs.^{3,21,22} In our study, lifetime costs for smokers can be calculated as \$72,700 among men and \$94,700 among women, and lifetime costs among nonsmokers can be calculated as \$83,400 and \$111,000, respectively. This amounts to lifetime costs for nonsmokers that are higher by 15 percent among men and 18 percent among women.

The studies cited above apply discounting to the lifetime cost estimate. Because costs incurred at older ages are discounted more, this approach reduces lifetime costs for nonsmokers more than those for smokers. For example, when one applies discounting to our life tables for smokers and nonsmokers, smokers have higher health care costs when the discount rate is at least 4.5 percent in men or at least 5.5 percent in women. We disagree with this approach, however. Discounting should be used for purposes of evaluation and should not be applied in a descriptive context, such as the estimation of lifetime costs.

Our analysis is not very sensitive to substantially different values in the rate ratio. Neither is it very sensitive to the age-related increase in the cost of “all other diseases”; that is, an increase that is less steep in the United States than in the Netherlands will not lead to different conclusions. Including additional smoking-related diseases could change the results only if those diseases generate morbidity and costs without raising the excess risk of mortality. There may be some of these conditions, such as cataracts, but they are unlikely to change outcome. For example, in our data all eye diseases, most of which are not related to smoking, account for about 1 percent of total health care costs.

This study relied on rate ratios from epidemiologic studies to express the differences between smokers and nonsmokers. To the extent that the rate ratios do not describe these differences sufficiently, the results will be affected. For example, the much lower cost for lung cancer among female smokers than among male smokers (Table 3) is hard to explain physiologically. But as long as the smokers have higher rates of lung cancer than the nonsmokers, such shortcomings of the data will not affect the overall conclusions.

The results of this study illustrate the ambiguities in any economic method of evaluation. Even a well-designed study of this type is marred by inevitable arbitrariness concerning what costs to include, which discount rate to apply, and what duration of follow-up to use. There are differences of opinion — on the discounting of lifetime costs, for example, and the evaluation of long-term effects.^{23,24} Recent efforts at standardization will remedy some of the arbitrariness,²⁵⁻²⁷ but fundamental problems with the method still remain.

Finally, with respect to public health policy, how important are the costs of smoking? Society clearly has an interest in this matter, now that several states are trying to recoup Medicaid expenditures from tobacco firms and the tobacco companies have agreed to a settlement. Yet we believe that in formulating public health policy, whether or not smokers impose a net financial burden ought to be of very limited importance. Public health policy is concerned with health. Smoking is a major health hazard, so the objective of a policy on smoking should be simple and clear: smoking should be discouraged.

Since we as a society are clearly willing to spend money on added years of life and on healthier years, the method of choice in evaluating medical interventions is cost-effectiveness analysis, which yields costs per year of life gained. Decision makers then implement the interventions that yield the highest return in health for the budget.²⁸ We have no doubt that an effective antismoking policy fits the bill.

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REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP*

ABSTRACT

Background Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors — elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle — are potentially reversible. We hypothesized that modifying these factors with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes.

Methods We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups.

Results The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin.

Conclusions Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin. (N Engl J Med 2002; 346:393-403.)

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TYPE 2 diabetes mellitus, formerly called non-insulin-dependent diabetes mellitus, is a serious, costly disease affecting approximately 8 percent of adults in the United States.¹ Treatment prevents some of its devastating complications^{2,3} but does not usually restore normoglycemia or eliminate all the adverse consequences. The diagnosis is often delayed until complications are present.⁴ Since current methods of treating diabetes remain inadequate, prevention is preferable. The hypothesis that type 2 diabetes is preventable^{5,6} is supported by observational studies and two clinical trials of diet, exercise, or both in persons at high risk for the disease^{7,8} but not by studies of drugs used to treat diabetes.⁵

The validity of generalizing the results of previous prevention studies is uncertain.⁹ Interventions that work in some societies may not work in others, because social, economic, and cultural forces influence diet and exercise. This is a special concern in the United States, where there is great regional and ethnic diversity in lifestyle patterns and where diabetes is especially frequent in certain racial and ethnic groups, including American Indians, Hispanics, African Americans, Asians, and Pacific Islanders.¹⁰

The Diabetes Prevention Program Research Group conducted a large, randomized clinical trial involving adults in the United States who were at high risk for the development of type 2 diabetes. The study was designed to answer the following primary questions: Does a lifestyle intervention or treatment with

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metformin, a biguanide antihyperglycemic agent, prevent or delay the onset of diabetes? Do these two interventions differ in effectiveness? Does their effectiveness differ according to age, sex, or race or ethnic group?

METHODS

We conducted a clinical trial involving persons at 27 centers who were at high risk for diabetes. The methods have been described in detail elsewhere,⁶ and the protocol is available at <http://www.bsc.gwu.edu/dpp>. The institutional review board at each center approved the protocol, and all participants gave written informed consent.

Participants

Eligibility criteria included an age of at least 25 years, a body-mass index (the weight in kilograms divided by the square of the height in meters) of 24 or higher (22 or higher in Asians), and a plasma glucose concentration of 95 to 125 mg per deciliter (5.3 to 6.9 mmol per liter) in the fasting state (≤ 125 mg per deciliter in the American Indian clinics) and 140 to 199 mg per deciliter (7.8 to 11.0 mmol per liter) two hours after a 75-g oral glucose load. These concentrations are elevated but are not diagnostic of diabetes according to the 1997 criteria of the American Diabetes Association.¹¹ Before June 1997, the criterion for plasma glucose in the fasting state was 100 to 139 mg per deciliter (5.6 to 7.7 mmol per liter), or ≤ 139 mg per deciliter in the American Indian clinics. Eligible persons were excluded if they were taking medicines known to alter glucose tolerance or if they had illnesses that could seriously reduce their life expectancy or their ability to participate in the trial. Recruitment was designed to enroll approximately half the participants from racial or ethnic minority groups. A four-step screening and recruitment process was developed to identify eligible participants.^{6,12,13}

Interventions

Eligible participants were randomly assigned to one of three interventions: standard lifestyle recommendations plus metformin (Glucophage) at a dose of 850 mg twice daily, standard lifestyle recommendations plus placebo twice daily, or an intensive program of lifestyle modification. The study initially included a fourth intervention, troglitazone, which was discontinued in 1998 because of the drug's potential liver toxicity.⁶ The results in the troglitazone group are not reported here.

Treatment with metformin was initiated at a dose of 850 mg taken orally once a day, with placebo tablets also given once a day initially. At one month, the dose of metformin was increased to 850 mg twice daily, unless gastrointestinal symptoms warranted a longer titration period. The initiation of treatment with half a tablet was optional. Adherence to the treatment regimen was assessed quarterly on the basis of pill counts and structured interviews. The standard lifestyle recommendations for the medication groups were provided in the form of written information and in an annual 20-to-30-minute individual session that emphasized the importance of a healthy lifestyle. Participants were encouraged to follow the Food Guide Pyramid¹⁴ and the equivalent of a National Cholesterol Education Program Step 1 diet,¹⁵ to reduce their weight, and to increase their physical activity.

The goals for the participants assigned to the intensive lifestyle intervention were to achieve and maintain a weight reduction of at least 7 percent of initial body weight through a healthy low-calorie, low-fat diet and to engage in physical activity of moderate intensity, such as brisk walking, for at least 150 minutes per week. A 16-lesson curriculum covering diet, exercise, and behavior modification was designed to help the participants achieve these goals. The curriculum, taught by case managers on a one-to-one basis

during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes.

Outcome Measures

The primary outcome was diabetes, diagnosed on the basis of an annual oral glucose-tolerance test or a semiannual fasting plasma glucose test, according to the 1997 criteria of the American Diabetes Association: a value for plasma glucose of 126 mg per deciliter (7.0 mmol per liter) or higher in the fasting state or 200 mg per deciliter (11.1 mmol per liter) or higher two hours after a 75-g oral glucose load.¹¹ In addition to the semiannual measurements, fasting plasma glucose was measured if symptoms suggestive of diabetes developed. The diagnosis required confirmation by a second test, usually within six weeks, according to the same criteria. If diabetes was diagnosed, the participants and their physicians were informed and glucose-tolerance tests were discontinued, but fasting plasma glucose was measured every six months, with glycosylated hemoglobin measured annually. As long as the fasting plasma glucose concentration was less than 140 mg per deciliter, participants were asked to monitor their blood glucose and to continue their assigned study treatment. If the fasting plasma glucose concentration reached or exceeded 140 mg per deciliter, the study medication was discontinued and the participant was referred to his or her physician for treatment. Measurements of glucose and glycosylated hemoglobin (HbA_{1c}) were performed centrally. All tests were performed without interrupting the assigned treatment, except that placebo or metformin was not taken on the morning of the test. The investigators and the participants were unaware of the results of these measurements and were informed only if the results exceeded the specified threshold for a change in the treatment.

Self-reported levels of leisure physical activity were assessed annually with the Modifiable Activity Questionnaire.¹⁶ The physical-activity level was calculated as the product of the duration and frequency of each activity (in hours per week), weighted by an estimate of the metabolic equivalent of that activity (MET) and summed for all activities performed, with the result expressed as the average MET-hours per week for the previous year. Usual daily caloric intake during the previous year, including calories from fat, carbohydrate, protein, and other nutrients, was assessed at base line and at one year with the use of a modified version of the Block food-frequency questionnaire.¹⁷

Statistical Analysis and Early Closure

Random treatment assignments were stratified according to the clinical center. Assignments to metformin and placebo were double-blinded. The study design and analysis followed the intention-to-treat principle. Nominal (unadjusted) P values and confidence intervals are reported.

The blinded treatment phase was terminated one year early, in May 2001, on the advice of the data monitoring board, on the basis of data obtained through March 31, 2001, the closing date for this report. By then, we had obtained evidence of efficacy on the basis of 65 percent of the planned person-years of observation. To maintain a type I error level of 0.05 for significance in pairwise comparisons of the risk of diabetes between groups, with adjustment for repeated interim analyses, the group-sequential log-rank test¹⁸ required a P value of less than 0.0159. For pairwise comparisons of other outcomes, a Bonferroni-adjusted criterion of $P < 0.0167$ was used. The study design provided 90 percent power to detect a 33 percent reduction from an incidence of 6.5 cases of diabetes per 100 person-years, with a 10 percent rate of loss to follow-up per year.

The time to the outcome was assessed with the use of life-table methods.¹⁹ Modified product-limit curves for the cumulative incidence of diabetes were compared with the use of the log-rank test. The estimated cumulative incidence at three years and the

Greenwood estimate of the standard error were used to calculate the number of persons who would need to be treated in order to prevent one case of confirmed diabetes during a period of three years and the associated 95 percent confidence interval. Risk reduction, heterogeneity among strata, and interactions between treatment assignments and covariates were assessed by proportional-hazards regression. Fixed-effects models with the assumption of normally distributed errors²⁰ were used to assess differences over time in body weight and plasma glucose and glycosylated hemoglobin values among the three groups.

RESULTS

Study Cohort and Follow-up

From 1996 to 1999, we randomly assigned 3234 study participants to one of the three interventions (1082 to placebo, 1073 to metformin, and 1079 to the intensive lifestyle intervention). Base-line characteristics, including all measured risk factors for diabetes, were similar among the three study groups (Table 1).¹² The participants were followed for an av-

erage of 2.8 years (range, 1.8 to 4.6). At the close of the study, 99.6 percent of the participants were alive, of whom 92.5 percent had attended a scheduled visit within the previous five months.

Adherence to Interventions

Fifty percent of the participants in the lifestyle-intervention group had achieved the goal of weight loss of 7 percent or more by the end of the curriculum (at 24 weeks), and 38 percent had a weight loss of at least 7 percent at the time of the most recent visit; the proportion of participants who met the goal of at least 150 minutes of physical activity per week (assessed on the basis of logs kept by the participants) was 74 percent at 24 weeks and 58 percent at the most recent visit. Dietary change was assessed only at one year. Daily energy intake decreased by a mean (\pm SE) of 249 ± 27 kcal in the placebo group, 296 ± 23 kcal in the metformin group, and 450 ± 26

TABLE 1. BASE-LINE CHARACTERISTICS OF THE STUDY PARTICIPANTS.*

CHARACTERISTIC	OVERALL (N=3234)	PLACEBO (N=1082)	METFORMIN (N=1073)	LIFESTYLE (N=1079)
Sex — no. (%)				
Male	1043 (32.3)	335 (31.0)	363 (33.8)	345 (32.0)
Female	2191 (67.7)	747 (69.0)	710 (66.2)	734 (68.0)
Race or ethnic group — no. (%)				
White	1768 (54.7)	586 (54.2)	602 (56.1)	580 (53.8)
African American	645 (19.9)	220 (20.3)	221 (20.6)	204 (18.9)
Hispanic	508 (15.7)	168 (15.5)	162 (15.1)	178 (16.5)
American Indian	171 (5.3)	59 (5.5)	52 (4.8)	60 (5.6)
Asian†	142 (4.4)	49 (4.5)	36 (3.4)	57 (5.3)
Family history of diabetes — no. (%)	2243 (69.4)	758 (70.1)	733 (68.3)	752 (69.8)‡
History of gestational diabetes — no. of women (%)	353 (16.1)	122 (16.3)	111 (15.7)‡	120 (16.3)
Age — yr	50.6 \pm 10.7	50.3 \pm 10.4	50.9 \pm 10.3	50.6 \pm 11.3
Weight — kg	94.2 \pm 20.3	94.3 \pm 20.2	94.3 \pm 19.9	94.1 \pm 20.8
Body-mass index	34.0 \pm 6.7	34.2 \pm 6.7	33.9 \pm 6.6	33.9 \pm 6.8
Waist circumference — cm	105.1 \pm 14.5	105.2 \pm 14.3	104.9 \pm 14.4	105.1 \pm 14.8
Waist-to-hip ratio	0.92 \pm 0.09	0.93 \pm 0.09	0.93 \pm 0.09	0.92 \pm 0.08
Plasma glucose — mg/dl§				
In the fasting state	106.5 \pm 8.3	106.7 \pm 8.4	106.5 \pm 8.5	106.3 \pm 8.1
Two hours after an oral glucose load	164.6 \pm 17.0	164.5 \pm 17.1	165.1 \pm 17.2	164.4 \pm 16.8
Glycosylated hemoglobin — %	5.91 \pm 0.50	5.91 \pm 0.50	5.91 \pm 0.50	5.91 \pm 0.51
Leisure physical activity — MET-hr/wk¶	16.3 \pm 25.8	17.0 \pm 29.0	16.4 \pm 25.9	15.5 \pm 22.1

*Plus-minus values are means \pm SD.

†Twenty Pacific Islanders were included in this category.

‡Information was not available for one participant.

§To convert the values for glucose to millimoles per liter, multiply by 0.05551.

¶Data are based on responses to the Modifiable Activity Questionnaire.¹⁶ MET denotes metabolic equivalent. MET-hours represent the average amount of time engaged in specified physical activities multiplied by the MET value of each activity.

kcal in the lifestyle-intervention group ($P<0.001$). Average fat intake, which was 34.1 percent of total calories at base line, decreased by 0.8 ± 0.2 percent in the placebo and metformin groups and by 6.6 ± 0.2 percent in the lifestyle-intervention group ($P<0.001$). The proportion of participants who took at least 80 percent of the prescribed dose of the study medication was slightly higher in the placebo group than in the metformin group (77 percent vs. 72 percent, $P<0.001$). Ninety-seven percent of the partic-

ipants taking placebo and 84 percent of those taking metformin were given the full dose of one tablet (850 mg in the case of metformin) twice a day; the remainder were given one tablet a day to limit side effects.

Changes in weight and leisure physical activity in all three groups and adherence to the medication regimen in the metformin and placebo groups are shown in Figure 1. Participants assigned to the lifestyle intervention had much greater weight loss and a great-

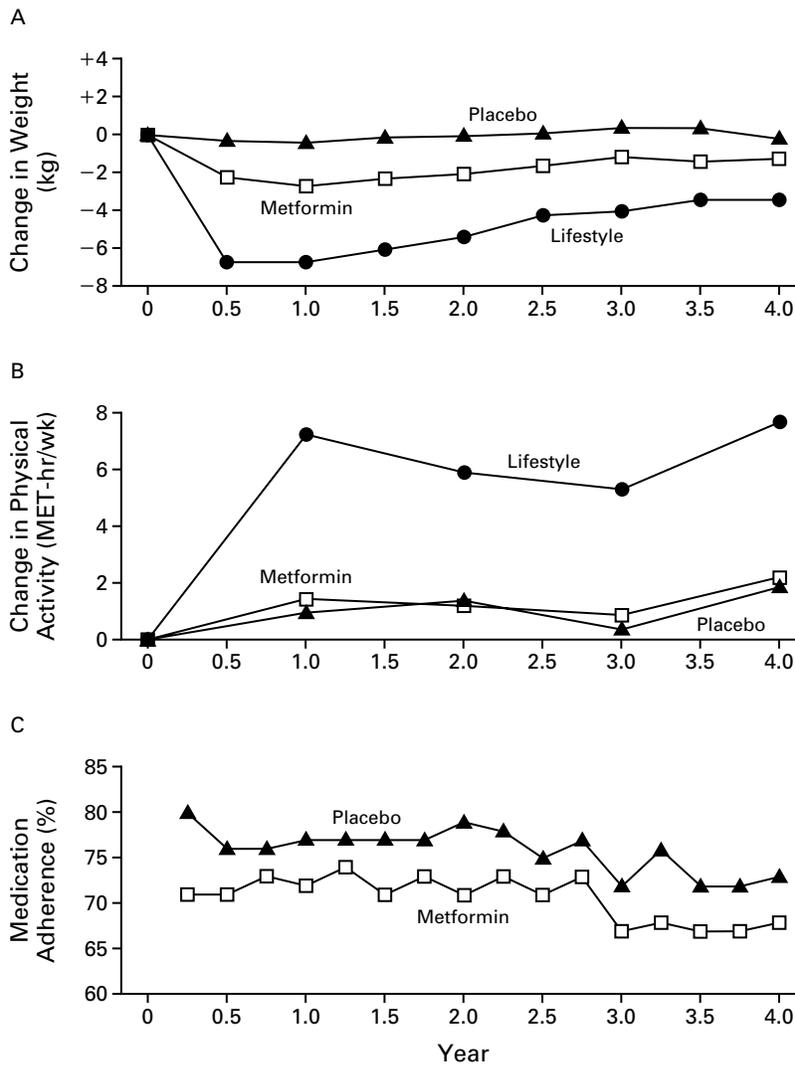


Figure 1. Changes in Body Weight (Panel A) and Leisure Physical Activity (Panel B) and Adherence to Medication Regimen (Panel C) According to Study Group.

Each data point represents the mean value for all participants examined at that time. The number of participants decreased over time because of the variable length of time that persons were in the study. For example, data on weight were available for 3085 persons at 0.5 year, 3064 at 1 year, 2887 at 2 years, and 1510 at 3 years. Changes in weight and leisure physical activity over time differed significantly among the treatment groups ($P<0.001$ for each comparison).

er increase in leisure physical activity than did participants assigned to receive metformin or placebo. The average weight loss was 0.1, 2.1, and 5.6 kg in the placebo, metformin, and lifestyle-intervention groups, respectively ($P < 0.001$).

Incidence of Diabetes

The cumulative incidence of diabetes was lower in the metformin and lifestyle-intervention groups than in the placebo group throughout the follow-up period (Fig. 2). The crude incidence was 11.0, 7.8, and 4.8 cases per 100 person-years for the placebo, metformin, and lifestyle-intervention groups, respectively (Table 2). The incidence of diabetes was 58 percent lower (95 percent confidence interval, 48 to 66 percent) in the lifestyle-intervention group and 31 percent lower (95 percent confidence interval, 17 to 43 percent) in the metformin group than in the placebo group. The incidence of diabetes was 39 percent lower (95 percent confidence interval, 24 to 51 percent) in the lifestyle-intervention group than in the metformin group. The results of all three pairwise group comparisons were statistically significant by the group-sequential log-rank test. None of these results were materially affected by adjustment for base-line characteristics. The estimated cumulative incidence of diabetes at three years was 28.9 percent, 21.7 percent, and 14.4 percent in the placebo, metformin, and lifestyle-intervention groups, respectively. On the basis of these rates, the estimated number of persons who would need to be treated for three years to prevent one case of diabetes during this period is 6.9 (95 percent confidence interval, 5.4 to 9.5) for the lifestyle intervention and 13.9 (95 percent confidence interval, 8.7 to 33.9) for metformin.

Treatment Effects among Subgroups

Incidence rates and risk reductions within subgroups of participants and the results of tests of the homogeneity of risk reduction among subgroups are shown in Table 2; 95 percent confidence intervals for the subgroup data indicate the precision of the risk-reduction estimate for each stratum. The study had inadequate power to assess the significance of effects within the subgroups, nor were such tests planned. Significant heterogeneity indicates that treatment effects differed according to the values of the covariates. Treatment effects did not differ significantly according either to sex or to race or ethnic group (Table 2). The lifestyle intervention was highly effective in all subgroups. Its effect was significantly greater among persons with lower base-line glucose concentrations two hours after a glucose load than among those with higher base-line glucose values. The effect of metformin was less with a lower body-mass index or a lower fasting glucose concentration than with higher

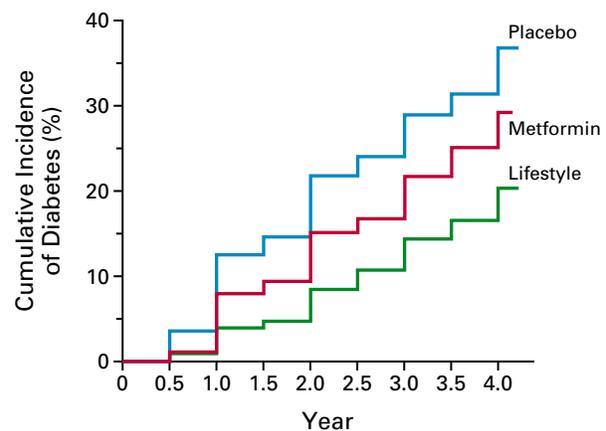


Figure 2. Cumulative Incidence of Diabetes According to Study Group.

The diagnosis of diabetes was based on the criteria of the American Diabetes Association.¹¹ The incidence of diabetes differed significantly among the three groups ($P < 0.001$ for each comparison).

values for those variables. Neither interaction was explained by the other variable or by age. The advantage of the lifestyle intervention over metformin was greater in older persons and those with a lower body-mass index than in younger persons and those with a higher body-mass index.

Glycemic Changes

In the first year, there was a similar reduction in the mean fasting plasma glucose values in the metformin and lifestyle-intervention groups, whereas the values rose in the placebo group (Fig. 3). The values rose in parallel in all three groups in subsequent years. There was a similar temporal pattern in the values for glycosylated hemoglobin, except that the values in the metformin group were in between those in the lifestyle-intervention and placebo groups. Figure 4 shows the percentage of participants who had normal glucose concentrations (fasting values, post-load values, and both) at each annual examination. Metformin and the lifestyle intervention were similarly effective in restoring normal fasting glucose values, but the lifestyle intervention was more effective in restoring normal post-load glucose values.

Adverse Events

The rate of gastrointestinal symptoms was highest in the metformin group, and the rate of musculoskeletal symptoms was highest in the lifestyle-intervention group (Table 3). Hospitalization and mortality rates were unrelated to treatment. No deaths were attributed to the study intervention.

TABLE 2. INCIDENCE OF DIABETES.

VARIABLE	NO. OF PARTICIPANTS (%)	INCIDENCE			REDUCTION IN INCIDENCE (95% CI)*		
		PLACEBO	METFORMIN	LIFESTYLE	LIFESTYLE VS. PLACEBO	METFORMIN VS. PLACEBO	LIFESTYLE VS. METFORMIN
		cases/100 person-yr			percent		
Overall	3234 (100)	11.0	7.8	4.8	58 (48 to 66)	31 (17 to 43)	39 (24 to 51)
Age							
25–44 yr	1000 (30.9)	11.6	6.7	6.2	48 (27 to 63)	44 (21 to 60)	8 (–36 to 37)†
45–59 yr	1586 (49.0)	10.8	7.6	4.7	59 (44 to 70)	31 (10 to 46)	41 (18 to 57)†
≥60 yr	648 (20.0)	10.8	9.6	3.1	71 (51 to 83)	11 (–33 to 41)	69 (47 to 82)†
Sex							
Male	1043 (32.3)	12.5	8.1	4.6	65 (49 to 76)	37 (14 to 54)	46 (20 to 63)
Female	2191 (67.7)	10.3	7.6	5.0	54 (40 to 64)	28 (10 to 43)	36 (16 to 51)
Race or ethnic group							
White	1768 (54.7)	10.3	7.8	5.2	51 (35 to 63)	24 (3 to 41)	36 (14 to 52)
African American	645 (19.9)	12.4	7.1	5.1	61 (37 to 76)	44 (16 to 63)	29 (–18 to 58)
Hispanic	508 (15.7)	11.7	8.4	4.2	66 (41 to 80)	31 (–9 to 56)	51 (13 to 72)
American Indian	171 (5.3)	12.9	9.7	4.7	65 (7 to 87)	25 (–72 to 68)	52 (–35 to 83)
Asian‡	142 (4.4)	12.1	7.5	3.8	71 (24 to 89)	38 (–55 to 75)	52 (–46 to 84)
Body-mass index§							
22 to <30	1045 (32.3)	9.0	8.8	3.3	65 (46 to 77)	3 (–36 to 30)†	63 (44 to 76)†
30 to <35	995 (30.8)	8.9	7.6	3.7	61 (40 to 75)	16 (–19 to 41)†	53 (28 to 70)†
≥35	1194 (36.9)	14.3	7.0	7.3	51 (34 to 63)	53 (36 to 65)†	–4 (–47 to 26)†
Plasma glucose¶							
In the fasting state							
95–109 mg/dl	2174 (67.2)	6.4	5.5	2.9	55 (38 to 68)	15 (–12 to 36)†	48 (27 to 63)
110–125 mg/dl**	1060 (32.8)	22.3	12.3	8.8	63 (51 to 72)	48 (33 to 60)†	30 (6 to 48)
Two hours after an oral load							
140–153 mg/dl	1049 (32.4)	7.1	4.3	1.8	76 (58 to 86)†	41 (11 to 61)	59 (27 to 77)
154–172 mg/dl	1103 (34.1)	10.3	6.6	4.4	60 (41 to 72)†	38 (13 to 56)	34 (2 to 56)
173–199 mg/dl	1082 (33.5)	16.1	12.3	8.5	50 (33 to 63)†	26 (3 to 43)	33 (9 to 51)

*CI denotes confidence interval.

†P<0.05 for the test of heterogeneity across strata. Age, body-mass index, and plasma glucose were analyzed as continuous variables.

‡This category includes 20 Pacific Islanders.

§The eligibility criterion was a body-mass index of at least 22 for Asians and at least 24 for all other persons.

¶To convert the values for glucose to millimoles per liter, multiply by 0.05551.

||This category includes American Indian participants who had a fasting glucose concentration that was less than 95 mg per deciliter, according to the eligibility criteria.⁶

**This category includes 54 participants with a fasting glucose concentration of 126 to 139 mg per deciliter who were enrolled before June 1997,⁶ when the eligibility criteria were changed to conform to the diagnostic criteria of the American Diabetes Association, published that year.¹¹

DISCUSSION

Our results support the hypothesis that type 2 diabetes can be prevented or delayed in persons at high risk for the disease. The incidence of diabetes was reduced by 58 percent with the lifestyle intervention and by 31 percent with metformin, as compared with placebo. These effects were similar in men and women and in all racial and ethnic groups. The intensive lifestyle intervention was at least as effective in older participants as it was in younger participants. The results of our study extend previous data showing that lifestyle interventions can reduce the incidence of diabetes^{7,8} and demonstrate the applicability of this finding to the ethnically and cul-

turally diverse population of the United States. The risk reduction associated with the lifestyle intervention in our study was the same as that in a study conducted in Finland,⁸ and was higher than the reductions associated with diet (31 percent), exercise (46 percent), and diet plus exercise (42 percent) in a study in China.⁷

Our lifestyle intervention was systematic and intensive, with the study participants receiving detailed, individualized counseling. The study, however, was not designed to test the relative contributions of dietary changes, increased physical activity, and weight loss to the reduction in the risk of diabetes, and the effects of these components remain to be determined.

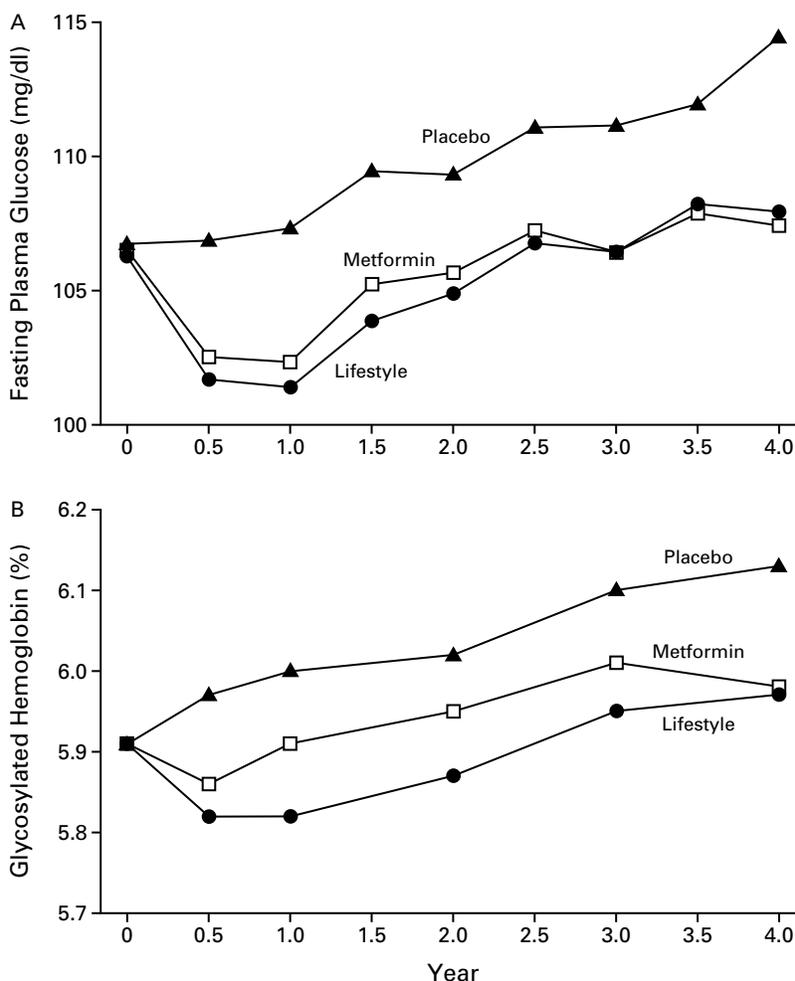


Figure 3. Fasting Plasma Glucose Concentrations (Panel A) and Glycosylated Hemoglobin Values (Panel B) According to Study Group.

The analysis included all participants, whether or not diabetes had been diagnosed. Changes in fasting glucose values over time in the three groups differed significantly ($P < 0.001$). Glycosylated hemoglobin values in the three groups differed significantly from 0.5 to 3 years ($P < 0.001$). To convert the values for glucose to millimoles per liter, multiply by 0.05551.

The incidence of diabetes in our placebo group (11.0 cases per 100 person-years) was higher than we had anticipated⁶ and was higher than the incidence in observational studies,²¹ perhaps owing to the greater frequency of glucose testing or to the selection of persons at higher risk in our study. The incidence of diabetes in the placebo group was similar among racial and ethnic groups despite differences in these subgroups in observational, population-based studies.¹⁰ Racial and ethnic-group differences in the incidence of diabetes were presumably reduced in

our study by the selection of persons who were overweight and had elevated fasting and post-load glucose concentrations — three of the strongest risk factors for diabetes.

Previous studies have not demonstrated that drugs used to treat diabetes are effective for its prevention, perhaps because of small samples and the lack of data on adherence to the prescribed regimens.⁵ In contrast, metformin was effective in our study, although less so than the lifestyle intervention. Metformin was less effective in persons with a lower base-line body-

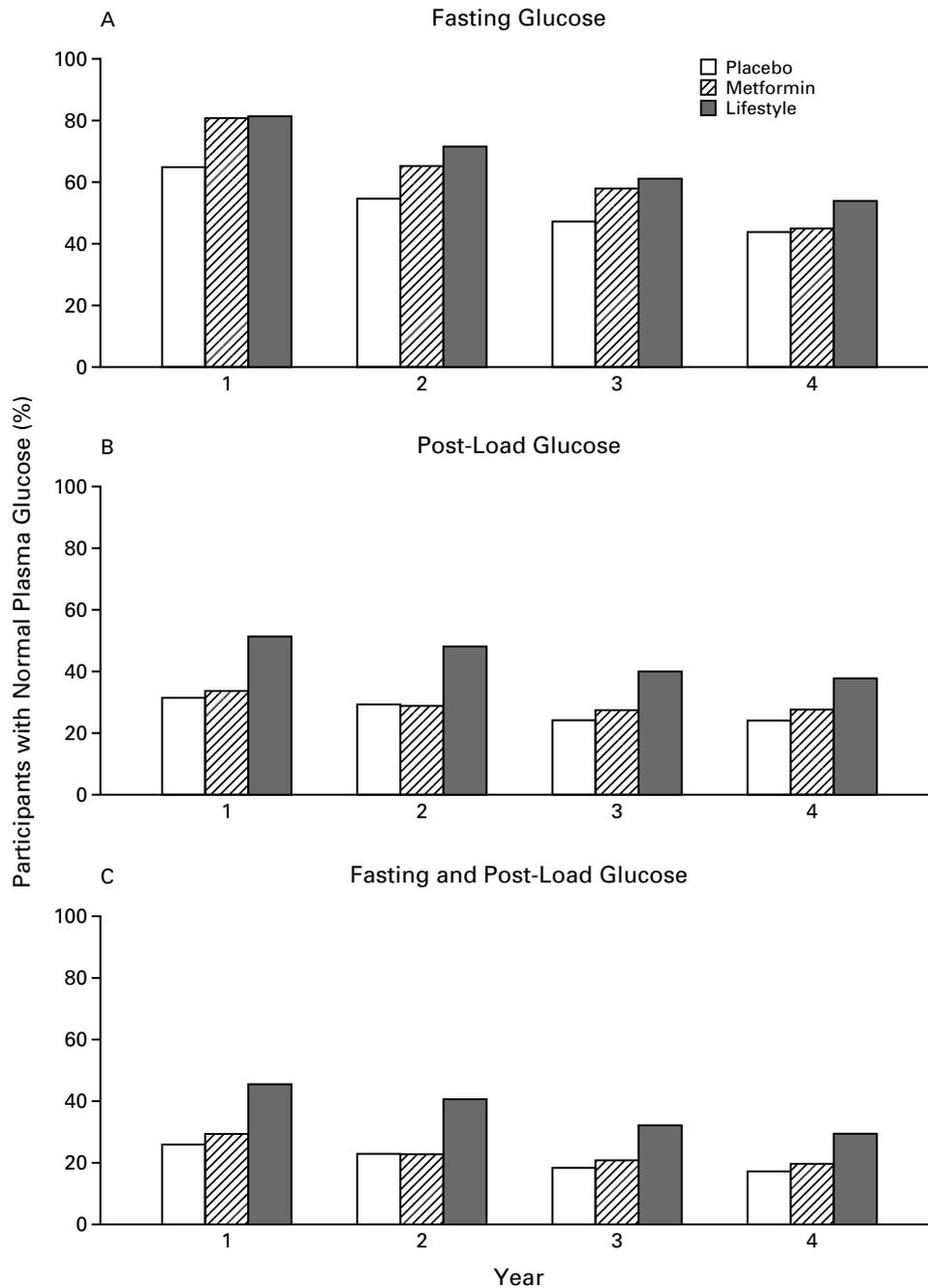


Figure 4. Participants with Normal Plasma Glucose Values, According to Study Group.

Panel A shows the proportions of participants with normal glucose values in the fasting state (<110 mg per deciliter [6.1 mmol per liter]), Panel B the proportions with normal values two hours after an oral glucose load (<140 mg per deciliter [7.8 mmol per liter]), and Panel C the proportions with normal values for both measurements. Persons in whom a diagnosis of diabetes had been made were considered to have abnormal values, regardless of the actual values at the time. By design, no participants had normal post-load glucose values at base line, but base-line fasting glucose values were normal in 67 percent of persons in the placebo group, 67 percent of those in the metformin group, and 68 percent of those in the lifestyle-intervention group. Metformin and lifestyle intervention were similarly effective in restoring normal fasting glucose concentrations, but lifestyle intervention was more effective in restoring normal post-load glucose concentrations.

TABLE 3. ADVERSE EVENTS.

EVENT	PLACEBO	METFORMIN	LIFESTYLE
Gastrointestinal symptoms (no. of events/100 person-yr)*	30.7	77.8†	12.9†
Musculoskeletal symptoms (no. of events/100 person-yr)‡	21.1	20.0	24.1†
Hospitalization			
One or more admissions (% of participants)	16.1	15.9	15.6
Rate (no. of admissions/100 person-yr)	7.9	8.4	8.0
Median stay (days)	3	3	3
Deaths (no./100 person-yr)	0.16	0.20	0.10

*Gastrointestinal symptoms included diarrhea, flatulence, nausea, and vomiting.

†P<0.0167 for the comparison with placebo.

‡Most participants with musculoskeletal symptoms had myalgia, arthritis, or arthralgia.

mass index or a lower fasting plasma glucose concentration than in those with higher values for these variables. The reduction in the average fasting plasma glucose concentration was similar in the lifestyle-intervention and metformin groups, but the lifestyle intervention had a greater effect than metformin on glycosylated hemoglobin, and a larger proportion of participants in the lifestyle-intervention group had normal post-load glucose values at follow-up. These findings are consistent with the observation that metformin suppresses endogenous glucose production, the main determinant of fasting plasma glucose concentrations.²²

Rates of adverse events, hospitalization, and mortality were similar in the three groups, except that the rate of gastrointestinal symptoms was highest in the metformin group and the rate of musculoskeletal symptoms was highest in the lifestyle-intervention group. Thus, the interventions were safe in addition to being effective.

An estimated 10 million persons in the United States resemble the participants in the Diabetes Prevention Program in terms of age, body-mass index, and glucose concentrations, according to data from the third National Health and Nutrition Examination Survey.²³ If the study's interventions were implemented among these people, there would be a substantial reduction in the incidence of diabetes. Ultimately, the benefits would depend on whether glucose concentrations could be maintained at levels below those that are diagnostic of diabetes and whether the maintenance of these lower levels improved the long-term outcome. These questions should be addressed by continued follow-up of the study participants and by

analysis of the main secondary outcomes — reductions in risk factors for cardiovascular disease, in the proportion of participants with atherosclerosis, and in the proportion with cardiovascular disease, which is the leading cause of death among patients with type 2 diabetes.^{24,25}

Optimal approaches to identifying candidates for preventive measures remain to be determined. Although elevation of either the fasting or the post-load glucose concentration strongly predicts diabetes,^{26,27} both were required for eligibility in this study. Whether the results would be similar in persons with an isolated elevation of the fasting or post-load glucose concentration or other risk factors for diabetes is likely but unknown.

In summary, our study showed that treatment with metformin and modification of lifestyle were two highly effective means of delaying or preventing type 2 diabetes. The lifestyle intervention was particularly effective, with one case of diabetes prevented per seven persons treated for three years. Thus, it should also be possible to delay or prevent the development of complications, substantially reducing the individual and public health burden of diabetes.

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Dr. Hamman owns stock in Bristol-Myers Squibb, which sells metformin in the United States.

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APPENDIX

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Greater Use Of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost

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ABSTRACT There is broad debate over whether preventive health services save money or represent a good investment. This paper analyzes the estimated cost of adopting a package of twenty proven preventive services—including tobacco cessation screening, alcohol abuse screening, and daily aspirin use—against the estimated savings that could be generated. We find that greater use of proven clinical preventive services in the United States could avert the loss of more than two million life-years annually. What's more, increasing the use of these services from current levels to 90 percent in 2006 would result in total savings of \$3.7 billion, or 0.2 percent of U.S. personal health care spending. These findings suggest that policy makers should pursue options that move the nation toward greater use of proven preventive services.

When is preventive medicine a good investment? Some experts have suggested that clinical preventive services—such as immunizations, screenings, and counseling—are worthwhile when they save more money than they cost. Others have suggested that the appropriate standard should instead be that prevention offer good “value” for the net dollars spent.^{1–3} *Good value* can be defined as providing substantial health benefit per dollar spent net of any savings, without necessarily saving money.

The long-standing focus on prevention and its cost savings, rather than its value, has been challenged by recent analyses that question the potential for preventive services to deliver broad savings. For example, in a review of the cost-effectiveness literature on selected clinical preventive services, Louise Russell found that the evidence does not support the idea that prevention typically reduces medical costs, although it sometimes does.⁴ Similarly, Joshua Cohen and colleagues warned against sweeping statements about savings through prevention and pointed to evidence indicating that the vast majority of

clinical preventive services do not save money.⁵ David Brown reported in the *Washington Post* that overall costs to the health care system typically go up when disease-preventing strategies are put into practice.⁶

Although these reviews reach the same general conclusion that some clinical preventive services save money but overall they may not, none focused on the specific services that evidence-based panels recommend. The pertinent question for policy makers who want to account for both the disease and money savings is whether those evidence-based clinical preventive services offer good value for the dollar.

Others have assessed the cost-effectiveness of various interventions. But to our knowledge, until now, no one has estimated the impact on overall population health, medical costs, and medical savings when a package of evidence-based preventive services is delivered to a targeted population. This paper attempts to do that.

Cost-effectiveness models were developed to support the work of the National Commission on Prevention Priorities.⁷ Using these models, we estimated the life-years saved, and total medical costs and savings, that could have been

achieved in 2006 from increased use of twenty clinical preventive services with good evidence of effectiveness. We then compared the net costs to U.S. personal health care spending to provide a context for the level of investment required to achieve those health benefits.

Study Data And Methods

DATA SOURCES The evidence-based preventive services we examined were limited to those clinical services recommended for the general population by the U.S. Preventive Services Task Force or the Advisory Committee on Immunization Practices. The services were previously evaluated for the National Commission on Prevention Priorities.⁷ They include the childhood immunization series, three adult immunizations, three counseling services, and thirteen screening services. The task force recommends only primary and secondary preventive services offered by primary care clinicians to asymptomatic people in clinical settings. The included services are described in more detail in Table 1 of the online Supplemental Appendix.⁸

The models developed for the National Commission on Prevention Priorities were carefully designed so that the results for each service could be compared to those for all other services. The data to estimate the models were obtained from structured literature reviews.⁹

ANALYSES We first calculated the total life-years that could have been saved per 10,000 people in the U.S. population in 2006 if each service had been delivered to the recommended population at recommended intervals in prior years. Likewise, we calculated the medical costs and savings per person-year of intervention.

We then multiplied the costs per person-year of intervention by the size of the target population in 2006 to compute the medical costs of using the services for the U.S. population. We multiplied the life-years and medical savings by the same population size to approximate the health benefits and medical savings that could have been realized in 2006, had the population in 2006 used the services in prior years. Total medical costs, along with net medical costs (costs minus savings), were then compared to 2006 U.S. personal health care spending.¹⁰

In this analysis, medical costs include the initial cost of the preventive service, such as screening or counseling, plus follow-up. Follow-up costs could include diagnostic testing; pharmacotherapy; and intensive interventions, such as for weight management. Savings include the expense of all care prevented by avoiding injury and disease or by treating at an earlier stage.

We excluded the value of a patient's time spent

to receive preventive services and any productivity gains from reduced illness. We did not discount future costs and savings to their present value. This budgetary approach permits direct comparisons of the results to U.S. personal health care spending, but it differs from cost-effectiveness analyses. The net costs of each service thus cannot be compared to net costs produced by cost-effectiveness analysis models.

When we used this budgetary approach, the estimates of costs and savings reflect what the net impact on U.S. personal health care spending would have been in 2006 if this package of evidence-based clinical preventive services had been used by 90 percent of the population for which each service was recommended. We calculated both the total costs and savings of providing the total package of services to 90 percent of the recommended U.S. population, and the additional—or marginal—costs and savings of increasing the use of the package from existing rates up to 90 percent.¹¹ The estimate of additional net costs shows the difference that could have been made in 2006 U.S. personal health care spending had these services been more widely used. The estimate of total net costs shows the impact of services that were delivered plus the additional impact of undelivered services.

Likewise, we computed the total and additional effects of achieving a 90 percent utilization rate on years of life saved for the U.S. population. We measured the additional gains in life-years to approximate the number of people who could have been alive in 2006 if they had received preventive care. We also measured the total gains in life-years to approximate the number of people who were alive in 2006 because they had received preventive care plus those who could have been alive if they had done so.

We chose an upper bound of 90 percent utilization to reflect the fact that for virtually all services, there are contraindications for some portion of the target population. The risk-benefit ratio for preventive services is an individual decision based on medical history, among other factors. Not everyone will obtain preventive services even if the services are promoted and widely available. We assumed that the services would be offered to 90 percent of the target population with no refusals.

Additional methods details, with illustrations of how calculation issues were handled and a summary of limitations of the methods, are provided in the online Supplemental Appendix.⁸

Study Results

Life-years saved, medical costs, medical savings, and net costs for twenty clinical preventive ser-

vices are shown in Exhibit 1. Services that have the potential to save the most life-years are the childhood immunization series, smoking cessation advice and assistance, discussion of daily aspirin use to prevent cardiovascular disease, and breast and colorectal cancer screening.

Clinical preventive services that produce net medical savings from the budgetary perspective include the childhood immunization series, pneumococcal immunization for adults, discussion of daily aspirin use, smoking cessation advice and assistance, vision screening in older adults, alcohol screening and brief advice, and obesity screening.

INCREASING USE FROM ZERO We estimated the total cost of 90 percent utilization of the package of services by the U.S. population in 2006 to be \$72.1 billion, or 4.1 percent of U.S. personal health care spending in 2006 (Exhibit 2). The total savings resulting from 90 percent utilization is \$61.9 billion. The result then is a net cost of \$10.2 billion, or 0.6 percent of U.S. personal health care spending in 2006.

INCREASING USE FROM CURRENT RATES In contrast, our calculated additional cost of increasing use of these services from current levels to 90 per-

cent is less than the additional savings, resulting in a small negative net cost—or savings. The additional cost of increasing use to 90 percent is \$18.3 billion, or 1.0 percent of U.S. personal health care spending in 2006. The savings resulting from increasing use rates is \$21.9 billion, and the net cost is -\$3.7 billion, or -0.2 percent of U.S. personal health care spending in 2006.

INFLUENTIAL SERVICES These cost savings from incremental improvements in use are the result of gaps in the current use of services that have the potential to save money. Three services contributed more than \$1 billion each to the net additional medical savings: tobacco cessation screening and assistance; discussing daily aspirin use; and alcohol screening with brief counseling. These three services plus colorectal cancer screening each would have contributed more 100,000 years of life in 2006 had screening been increased to 90 percent.

Large changes in any single service do not alter the results. For example, doubling the cost of the service that adds the most to the 2006 additional cost of preventive care—colorectal cancer screening—would increase our estimates of total and net costs by only 0.25 percent of U.S. personal

EXHIBIT 1

Life-Years Saved, Costs, And Savings From Twenty Evidence-Based Clinical Preventive Services (2006 Dollars)

Clinical preventive service	Life-years saved per 10,000 people per year of intervention	Medical cost of service per person per year	Medical savings of service per person per year	Annual net medical costs per person per year
Childhood immunizations	1,233.1	\$306	\$573	-\$267
Influenza immunization	23.8	28	20	8
Pneumococcal immunization	6.4	46	113	-67
Tetanus-diphtheria booster	0.1	4	0.2	4
Discuss daily aspirin use	63.0	21	87	-66
Discuss folic acid use	2.0	9	2	7
Smoking cessation advice and assistance	97.5	10	50	-40
Alcohol screening and brief counseling	7.0	9	20	-11
Breast cancer screening	45.0	64	3	61
Cervical cancer screening	2.1	49	8	41
Chlamydia screening	0.0	18	12	6
Cholesterol screening	27.8	128	24	104
Colorectal cancer screening	40.8	46	31	15
Depression screening	0.0	42	0	42
Hearing screening	0.0	23	0	23
Hypertension screening	10.7	79	50	29
Obesity screening	1.0	10	15	-5
Osteoporosis screening	1.5	90	19	71
Vision screening (adults)	2.1	5	22	-17
Vision screening (children)	0.0	14	0	14

SOURCE Authors' analyses; sources for data used in each model are available from the authors.

EXHIBIT 2

Total And Additional Life-Years Saved, Costs, And Savings From Twenty Evidence-Based Clinical Preventive Services (Millions Of 2006 Dollars)

	Total life-years saved ^a	Percent of personal health care spending ^b	Additional life-years saved ^c	Percent of personal health care spending ^b
Life-years saved	7,233,195	–	2,335,140	–
Cost	\$72,114	4.1	\$18,281	1.0
Savings	\$61,927	3.5	\$21,954	1.2
Net cost	\$10,188	0.6	–\$3,673	–0.2

SOURCE Authors' analyses; sources for data used in each model are available from the authors. **NOTE** Costs minus savings might not add up to net costs because of rounding. ^aCost of 90 percent utilization of twenty clinical preventive services (see Exhibit 1). ^bPercentage of personal health care spending in 2006. ^cCost of eliminating the difference between existing use rates and 90 percent use rates.

health care spending. Similarly, doubling the savings of the service that would produce the most additional savings—smoking cessation advice and assistance—would increase our estimates of savings and decrease our estimate of net costs by only 0.4 percent of U.S. personal health care spending.

Discussion

These findings with respect to increasing use from current rates to 90 percent suggest that investing in an evidence-based package of preventive services for the general population could produce more than two million additional years of life each year they are delivered. What's more, the increased costs of doing so would be recouped. Put differently, more than two million people would have been alive during 2006—or 780 people in a city of 100,000—if preventive care had been widely delivered in prior years, all without an increase in net cost.

LIMITATIONS These findings are not without limitations.⁸ Our goal was to estimate the populationwide value and net medical costs of a package of evidence-based services. Because no single service drives these results, even a large error in measuring costs or use for a service would not affect the conclusions of this paper.

Despite several compilations of published cost-effectiveness ratios, there are no prior studies of the population impact of a wide range of primary and secondary preventive services to which we can directly compare our results. Richard Kahn and colleagues recently estimated the lifetime financial impact of a different set of services.¹² Despite a different scope of services and different methods, their findings would also translate into important health benefits costing only a very small portion of U.S. personal health care spending on an annualized basis.

Reviews and registries of published cost-effectiveness ratios have shown wide variation for

clinical preventive services.^{2,4-5,12-15} Similarly, our prior work found wide variation in cost-effectiveness ratios with six cost-saving services among them.⁷ Our prior work differs from the analysis presented here because it employed a societal perspective to capture costs beyond the medical sector and because it discounted spending and benefits realized in future years to reflect their current value. The budgetary analysis used for this study might be expected to produce different results because only medical costs are included and future spending and benefits are not discounted. However, only one additional service was found to be cost saving in this budgetary analysis: screening for obesity. This service became cost saving because the value of patient time to engage in intensive interventions following a positive screen were excluded from the current analysis.

The budgetary analysis leaves out some important nonmedical savings, such as productivity gains and reduced costs of motor vehicle accidents and crime. Net savings would have been higher had these savings been included. They may be particularly important to some decision makers and could be included in cost and cost-effectiveness analysis from various perspectives.

SPENDING EFFECTS This analysis shows what could have occurred in a single year compared to current and past use. The cumulative effect of prior years' use provides a picture of the long-run potential value of an evidence-based package of preventive services. Going forward, the costs of increasing use will occur in more immediate years than the savings. Thus, in the short run, the impact on U.S. personal health care spending would be different.

Without factoring in any savings, the marginal delivery costs of achieving 90 percent use is 1 percent of U.S. personal health care spending (Exhibit 2). Therefore, with any realistic timetable for improving use rates, the short-run impact of increasing delivery rates would be a blip

in annual medical spending increases that have averaged 7 percent per year or more since the 1960s.

Whether scaled to annual spending for the nation, annual spending per person, or health plan spending per member per month, increased use would be a virtually undetectable portion of annual health care spending increases and in the long run would be cost-neutral, once savings are factored in, while providing health benefits.

NEED TO SPECIFY PREVENTIVE SERVICES As pointed out by others, preventive services are often lumped into one large, undifferentiated group.³ There are certainly questionable preventive services for which there is not yet good evidence of effectiveness or cost-effectiveness. Payers and consumers should focus on reputable guidelines that are based on rigorous assessments of each service's effectiveness, such as those of the U.S. Preventive Services Task Force. Efforts to improve health could be further refined by first focusing on the most valuable evidence-based services.⁷ Some services with high cost savings are poorly used at present. Of those, two have very large health impact—smoking cessation advice and assistance, and discussion of daily aspirin use. Meanwhile, two services have lesser, but still important, health impacts: alcohol screening with brief counseling, and

pneumococcal immunization.

INCREASING USE FROM CURRENT RATES The opportunities for cost savings were greater with increasing use from current rates than they were with getting from zero use to current rates. This is because current use is relatively low for services that can produce high cost savings. This dynamic explains our seemingly contradictory estimates indicating that increasing all services from current use to 90 percent would result in cost savings while increasing use from zero to 90 percent would result in a small increase in U.S. personal health care spending.

CONCLUSION These findings are good news for purchasers and insurers. This evidence-based package of preventive services is essentially cost-neutral, while conferring large health benefits. That is also good news for patients. Payers and policy makers should support increased use of evidence-based preventive services for the right reasons and with reasonable expectations of their impact on health spending. Preventive services, as well as diagnostic and treatment services, should be judged by their effectiveness in improving health and the resources they consume to do so. Effective clinical preventive services can achieve the dual goals of improving the health of all Americans and making prudent use of scarce resources. ■

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