



INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Health Care Guideline

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- researchers;
- federal, state and local government health care policy makers and specialists; and
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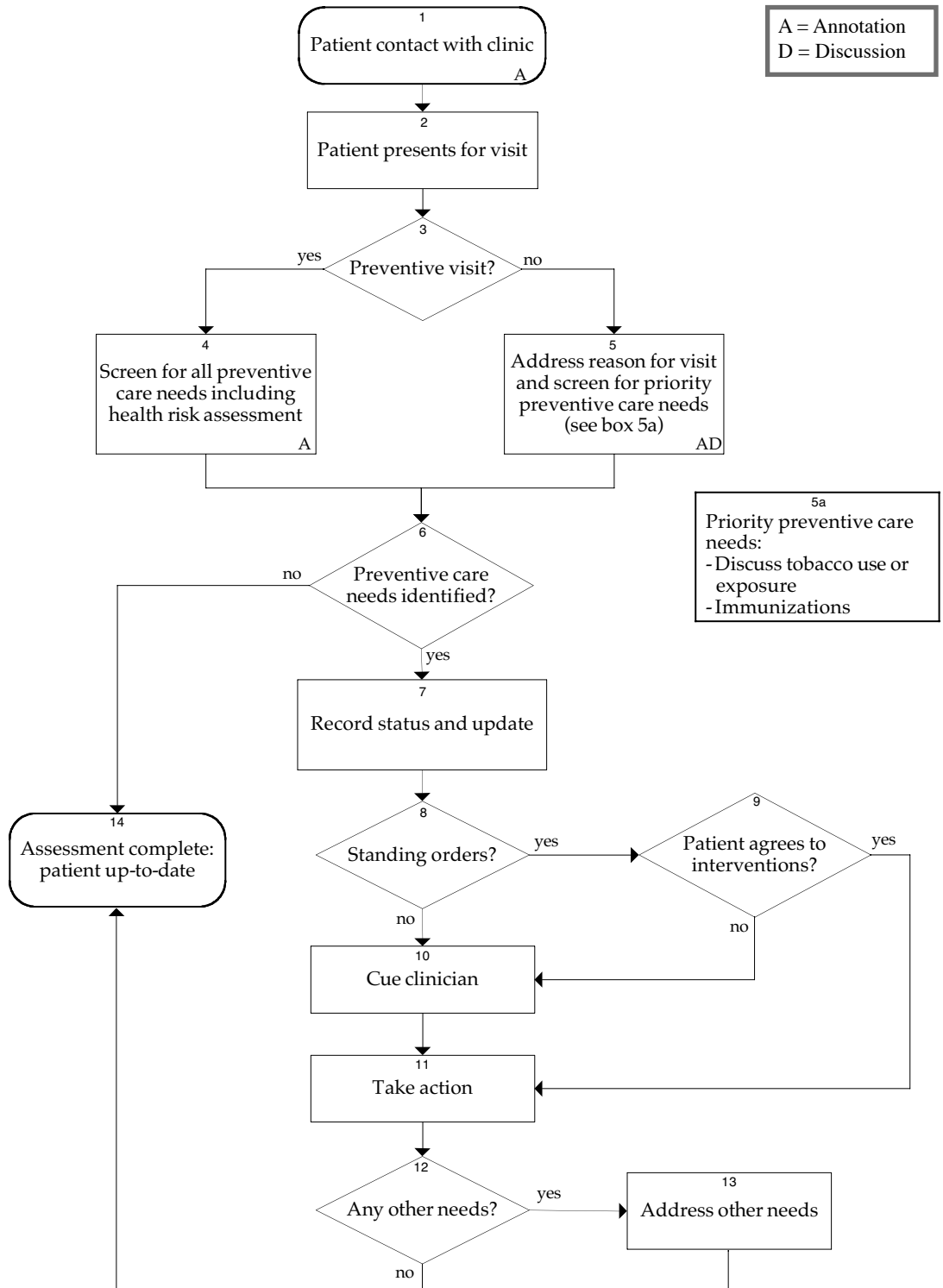
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These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.



A = Annotation
D = Discussion

5a
Priority preventive care needs:
- Discuss tobacco use or exposure
- Immunizations

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Preamble

The central purpose of this guideline is to clearly identify those preventive services which are essential to provide to all low-risk/asymptomatic members/patients on the basis of either **good** or **fair** evidence for inclusion in a periodic health evaluation (per USPSTF rules). A secondary purpose is to identify those services which should **not** be included in light of similarly strong evidence.

We recognize that many aspects of traditional periodic examinations, especially much of the traditional history and physical examination, will not be mentioned because they do not fall into either of the above categories. In some cases, this is because there is no evidence; in others, the evidence is conflicting or primarily anecdotal. We also recognize that changing these elements will be difficult for some providers and some patients. Therefore, we leave unaddressed components to the desires of individual medical groups while encouraging them to focus primarily on seeing that everyone gets the described essential components and eliminating services clearly of no overall value.

This guideline encompasses both preventive services and disease screening. The Preventive Guidelines Subcommittee used a multidisciplinary process and evidence-based methods to develop this guideline. This approach emphasizes the critical evaluation of scientific evidence, rather than expert opinion or consensus, to define necessary and appropriate care. Judging health benefit on the basis of scientific evidence provides a rational, defensible basis for directing resources toward effective preventive care and away from ineffective services or interventions for which risks may exceed benefits. When the scientific data are lacking or the evidence is equivocal, then a preference-based approach is recommended, allowing patients and providers to collectively make complex value judgments about specific preventive interventions.

The proper selection of screening tests requires careful consideration of the age, sex, and other individual risk factors of the patient. Recommended screening tests must meet the following criteria:

- a. Early diagnosis must be scientifically proven to lead to improved clinical outcome.
- b. Additional resources must be available to confirm the diagnosis and provide care for those who screen positive.
- c. Patients who are screened must be willing to comply with subsequent treatment recommendations.
- d. The burden of disability from the target disease must warrant action.
- e. The effectiveness of the individual components of the screening test must have been documented prior to their combination.
- f. The cost, accuracy, and acceptability of the screening test must be adequate for the population to be screened.

Preventive Services for Ages 19-39

Superscript numbers refer to specific annotations or discussion

Visit Schedule¹⁵

The schedule of visits will largely be determined by completion of necessary preventive services and screening maneuvers. For the purposes of this guideline, a reasonable schedule to follow is: one preventive visit every 5 years for males; every 3-5 years for females.

Screening Maneuvers

- Risk Assessment every 5 years¹⁶
- Height and weight every 3-5 years¹⁷
- Blood pressure every 2 years¹⁸
- Clinical breast exam (every 3 years beginning at age 20)¹⁹
- Total cholesterol and HDL-cholesterol (for men, every 5 years beginning at age 35)²⁰
- Papanicolaou smear (maximum interval once every 3 years after 3 consecutive normal results)²¹

Additional Screening Maneuvers for High-Risk Groups

- Sexually transmitted disease testing²²
- Tuberculin skin testing²⁵

Counseling and Education²⁴

| There is <i>good</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination | There is <i>fair</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination. | There may be <i>insufficient direct</i> evidence that counseling on these topics leads to a specific change of behavior; however there is evidence linking these topics to health conditions and/or diseases. |
|--|---|--|
| <ul style="list-style-type: none"> • Limit dietary fat • Folic acid supplements • Tobacco cessation • Problem drinking • Advance directives | <ul style="list-style-type: none"> • Caloric balance/nutrient balance • Physical activity • Drinking and driving motor vehicles • Safety belts • Unintended pregnancy prevention • Protection from UV light • Dental and periodontal disease | <ul style="list-style-type: none"> • 5 a day (fruits and vegetables) • Calcium intake • Start of tobacco use • Alcohol and other drugs • Motor vehicle operation • Motor vehicles/bicycles • Helmets for motorcyclists • Safety helmets • Fire safety • Firearm storage • Promotion of nonviolent behavior and screen for family violence • STD prevention • Depression/anxiety awareness • Coping skills/stress reduction • Preventive care visits • Preconception counseling |

Immunizations and Chemoprophylaxis²⁶

| Vaccine | 19-39 Years | 40-64 Years | 65 Years & Older |
|------------------------------|---|-----------------------------|--|
| Td | Booster every 10 years | | |
| MMR | Persons born after 1956 should have 2 doses measles; additional doses should be given as MMR. | | |
| Pneumococcal (PPV 23) | Immunize high-risk groups once. Re-immunize those at risk of losing immunity after 5 years. | | Immunize at 65 if not done previously. Re-immunize if 1 st received >5 years ago and before age 65. |
| Varicella | Persons ≤ 50 with no history of varicella, do titre. If negative, immunize. If >50, assume they are immune. | | |
| Hep B | Universal immunization | Immunize those at high risk | |
| Influenza | Annually between October and March for individuals age 50 and older, those at high risk, and others | | |
| Hep A | Immunize those in risk groups. | | |
| Meningococcal | Immunize those in risk groups. | | |

Preventive Services for Ages 19-39

Practices Reviewed, But Not Recommended³¹

- Diabetes Screening
- Depression Screening

Practices to Consider Discontinuing³²

- Routine blood chemistries
- Routine hemoglobin testing
- Resting EKG
- CA 125 and pelvic ultrasound screening for ovarian cancer
- Routine urinalysis
- Objective vision and hearing screening

Preventive Services for Ages 40-64

Superscript numbers refer to specific annotations or discussion

Visit Schedule¹⁵

The schedule of visits will largely be determined by completion of necessary preventive services and screening maneuvers. For the purposes of this guideline, a reasonable schedule to follow is: one preventive visit every 5 years for males; every 3-5 years for females.

Screening Maneuvers

- Risk assessment every 5 years¹⁶
- Height and weight every 3-5 years¹⁷
- Blood pressure every 2 years¹⁸
- Clinical breast exam (annually)¹⁹
- Total cholesterol and HDL-cholesterol (every 5 years for men older than 34 and women older than 44)²⁰
- Papanicolaou smear (maximum interval once every 3 years after 3 consecutive normal results)²¹
- Mammograms (optional ages 40-49; recommended annually to biennially for ages 50-75)²³
- Colon cancer screening (ages 50-80)²⁷
- PSA/DRE³⁰

Additional Screening Maneuvers for High-Risk Groups

- Sexually transmitted disease testing²²
- Tuberculin skin testing²⁵

Counseling and Education²⁴

| There is <i>good</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination | There is <i>fair</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination. | There may be <i>insufficient direct</i> evidence that counseling on these topics leads to a specific change of behavior; however there is evidence linking these topics to health conditions and/or diseases. |
|--|---|--|
| <ul style="list-style-type: none"> • Limit dietary fat • Tobacco cessation • Problem drinking • Advance directives | <ul style="list-style-type: none"> • Caloric balance/nutrient balance • Physical activity • Drinking and driving motor vehicles • Safety belts • Unintended pregnancy prevention • Protection from UV light • Dental and periodontal disease | <ul style="list-style-type: none"> • 5 a day (fruits and vegetables) • Calcium intake • Alcohol and other drugs • Motor vehicle operation • Motor vehicles/bicycles • Helmets for motorcyclists • Safety helmets • Fire safety • Firearm storage • Promotion of nonviolent behavior and screen for family violence • STD prevention • Depression/anxiety awareness • Coping skills/stress reduction • Preventive care visits • Preconception counseling |

Preventive Services for Ages 40-64

Immunizations and Chemoprophylaxis²⁶

| Vaccine | 19-39 Years | 40-64 Years | 65 Years & Older |
|------------------------------|---|-----------------------------|--|
| Td | Booster every 10 years | | |
| MMR | Persons born after 1956 should have 2 doses measles; additional doses should be given as MMR. | | |
| Pneumococcal (PPV 23) | Immunize high-risk groups once. Re-immunize those at risk of losing immunity after 5 years. | | Immunize at 65 if not done previously. Re-immunize if 1 st received >5 years ago and before age 65. |
| Varicella | Persons ≤ 50 with no history of varicella, do titre. If negative, immunize. If >50, assume they are immune. | | |
| Hep B | Universal immunization | Immunize those at high risk | |
| Influenza | Annually between October and March for individuals age 50 and older, those at high risk, and others | | |
| Hep A | Immunize those in risk groups. | | |
| Meningococcal | Immunize those in risk groups. | | |

- Aspirin prophylaxis should be discussed with adults between age 50 and 75 who are at increased risk of CHD²⁶
- Hormone replacement therapy should be addressed²⁶

Practices Reviewed, but Not Recommended³¹

- Diabetes screening
- Osteoporosis screening
- Routine thyroid screening in women older than 45 years of age
- Depression screening

Practices to Consider Discontinuing³²

- Routine blood chemistries
- Routine tuberculin skin testing
- Routine hemoglobin testing
- Resting EKG
- CA 125 and pelvic ultrasound screening for ovarian cancer
- Routine urinalysis
- Objective vision and hearing screening

Preventive Services for Ages Over 65

Superscript numbers refer to specific annotations or discussion

Visit Schedule¹⁵

The schedule of visits will largely be determined by completion of necessary preventive services and screening maneuvers. For the purposes of this guideline, a reasonable schedule to follow is: one preventive visit every 1-2 years.

Screening Maneuvers

- Risk assessment every 1-2 years¹⁶
- Review medications
- Height and weight every 1-2 years¹⁷
- Blood pressure every 1-2 years¹⁸
- Clinical breast exam (annually)¹⁹
- Total cholesterol and HDL-cholesterol every 5 years²⁰
- Papanicolaou smear (may be performed at the mutual consent of the patient and provider after age 65; recommended for women 65 years of age and older who have a new sexual partner)²¹
- Mammograms (annually to biennially for ages 50-75; may be performed at the mutual consent of the patient and provider after age 75)²³
- Colon cancer screening (ages 50-80) may be performed after age 80 at the mutual consent of the patient and provider²⁷
- Objective visual acuity testing (after age 74)²⁸
Subjective hearing testing (after age 74)²⁸
- Osteoporosis screening (review risk factors and order BMD if indicated)²⁹
- PSA/DRE³⁰

Additional Screening Maneuvers for High-Risk Groups

- Sexually transmitted disease testing²²
- Tuberculin skin testing²⁵

Counseling and Education²⁴

| There is <i>good</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination | There is <i>fair</i> evidence to support counseling on these topics. Counseling should be included in a periodic health examination. | There may be <i>insufficient direct</i> evidence that counseling on these topics leads to a specific change of behavior; however there <i>is</i> evidence linking these topics to health conditions and/or diseases. |
|--|---|--|
| <ul style="list-style-type: none"> • Limit dietary fat • Tobacco cessation • Problem drinking • Advance directives | <ul style="list-style-type: none"> • Caloric balance/nutrient balance • Physical activity • Drinking and driving motor vehicles • Safety belts • Unintended pregnancy prevention • Protection from UV light • Dental and periodontal disease | <ul style="list-style-type: none"> • 5 a day (fruits and vegetables) • Calcium intake • Alcohol and other drugs • Motor vehicle operation • Motor vehicles/bicycles • Helmets for motorcyclists • Safety helmets • Fire safety • Firearm storage • Promotion of nonviolent behavior and screen for family violence • STD prevention • Depression/anxiety awareness • Coping skills/stress reduction • Preventive care visits • Preconception counseling |

Preventive Services for Ages 65 and Over

Immunizations and Chemoprophylaxis²⁶

| Vaccine | 19-39 Years | 40-64 Years | 65 Years & Older |
|------------------------------|---|-----------------------------|--|
| Td | Booster every 10 years | | |
| MMR | Persons born after 1956 should have 2 doses measles; additional doses should be given as MMR. | | |
| Pneumococcal (PPV 23) | Immunize high-risk groups once. Re-immunize those at risk of losing immunity after 5 years. | | Immunize at 65 if not done previously. Re-immunize if 1 st received >5 years ago and before age 65. |
| Varicella | Persons ≤ 50 with no history of varicella, do titre. If negative, immunize. If >50, assume they are immune. | | |
| Hep B | Universal immunization | Immunize those at high risk | |
| Influenza | Annually between October and March for individuals age 50 and older, those at high risk, and others | | |
| Hep A | Immunize those in risk groups. | | |
| Meningococcal | Immunize those in risk groups. | | |

- Aspirin prophylaxis should be discussed with adults between age 50 and 75 who are at increased risk of CHD²⁶
- Hormone replacement therapy should be addressed²⁶

Practices Reviewed, but Not Recommended³¹

- Diabetes screening
- Depression screening
- Routine thyroid screening in women older than 45 years of age
- Screening for dementia

Practices to Consider Discontinuing³²

- Routine blood chemistries
- CA 125 and pelvic ultrasound screening for ovarian cancer
- Routine tuberculin skin testing
- Routine urinalysis
- Routine hemoglobin testing
- Objective vision and hearing screening
- Resting EKG

Foreword

Scope and Target Population

To provide a comprehensive approach to the provision of preventive services, counseling, education, and disease screening for low-risk, asymptomatic adults. This guideline generally does not address the needs of pregnant women, individuals with chronic disorders, or high-risk populations.

Related ICSI Scientific Documents

Other ICSI guidelines whose scope and/or recommendations are closely related to the content of this guideline are:

1. Preventive Counseling and Education
2. Lipid Screening in Adults
3. Tobacco Use Prevention and Cessation for Adults and Mature Adolescents
4. Cervical Cancer Screening
5. Immunizations
6. Colorectal Cancer Screening
7. Menopause and Hormone Therapy (HT): Collaborative Decision-Making and Management
8. Diagnosis of Breast Disease
9. Diagnosis and Treatment of Osteoporosis
10. Hypertension Diagnosis and Treatment

Technology Assessment Reports related to the content of this guideline are:

1. Computed Tomography Colonography for Detection of Colorectal Polyps and Neoplasms (#58, 2001)
2. Computed Tomography Screening for Lung Cancer (#52, 2001)
3. Densitometry as a Diagnostic Tool for the Identification and Treatment of Osteoporosis in Women (#31, 2000)
4. HPV DNA Testing for Cervical Cancer (#56, 2001)
5. Prostate Specific Antigen as a Screening Test for Prostate Cancer (#8, 1999)
6. Screening Tests (Report #9, 1993)

Clinical Highlights and Recommendations

1. Incorporate assessments of preventive service needs and counseling and education as appropriate into acute visits when possible. (*Annotations #1,4*)
2. Assess patients for risk factors at periodic intervals and provide counseling and education for identified risk factors. (*Annotation #16*)

3. All clinic visits, whether acute or chronic in nature, are opportunities for preventive counseling. (*Annotations #1,4*)
4. At each preventive visit:
 - Update previously obtained medical and family history
 - Identify risk factors and provide counseling or special testing as needed (*Annotation #16*)
 - Subjective vision and hearing testing (*Annotation #28*)
 - Sexually transmitted disease testing for patients identified as at-risk (*Annotation #22*)

Priority Aims and Suggested Measures

1. Increase the percentage of patients who are up-to-date on preventive services.
Possible measure of accomplishing this aim:
 - a. Percentage of patients who are up-to-date on preventive services.
2. Increase the percentage of services up-to-date.
Possible measure of accomplishing this aim:
 - a. Percentage of preventive services that are up-to-date.
3. Increase regular use of health risk assessments.
Possible measures of accomplishing this aim:
 - a. Percentage of patients who have a current risk assessment tool in their medical record.
 - b. Percentage of patients seen in the clinic who have a completed risk assessment tool in their medical record.

The measure of services up-to-date (aim #2) assists member groups in developing processes to make progress toward aim #1. Therefore, when measuring aim #2 member groups should also be reporting aim #1.

Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Key conclusions are assigned a conclusion grade: I, II, III, or Grade Not Assignable.

A full explanation of these designators is found in the Discussion and References section of the guideline.

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at <http://www.icsi.org>.

Algorithm Annotations

Introduction

In a meta-analysis of the 108 controlled clinical trials of interventions to improve immunization and cancer screens that passed a quality screen for good studies from 552 that were identified between 1966 and 1999, the following conclusions were reached:

- By far, the most effective strategy for improvement was implementation of specific organizational changes that make identification of need and delivery of services routine.
- Involving patients in self-management through patient financial incentives and reminders is also likely to positively affect performance, although at a much lower level for most services.
- Patient education was somewhat effective.
- However, provider feedback was consistently ineffective and provider reminders or education showed no consistent pattern.

1. Patient Contact with Clinic

Nearly every patient contact for any reason should be used to identify and address preventive service needs. Possible examples might include the following:

- A 55 year old female patient calls requesting an appointment for preventive visit, which would trigger the scheduler to ask patient about need for mammogram. The scheduler could simultaneously schedule both appointments.
- A 65 year old patient calls for any reason (e.g., wishing to schedule any appointment type, or to speak with clinician or nurse) during the 4th quarter of the year. The scheduler/receptionist could ask patient about flu shot status and facilitate the process for completion of this service, if needed.
- A new patient calls to schedule a preventive service visit. Scheduler can remind patient to bring or arrange to have mailed his/her medical records, as well as to present early for the appointment to complete a health risk assessment form.

4. Screen for all Preventive Care Needs Including Health Risk Assessment

Preventive counseling and education should be emphasized to change health habits before disease develops. Health risk assessment and health education are of greater value to patients than most routine screening tests.

5. Address Reason for Visit and Screen for Priority Preventive Care Needs

Priority preventive care needs that can and should be addressed at every visit include:

- Discussing tobacco use with every user and recent (< 12 months) quitter
- Immunizations

Algorithm Annotations

- Blood pressure screening
- Identifying needed cancer screens (breast, cervix, and colon) and scheduling an appropriate visit

Supporting evidence is of class: M

15. Visit Schedules

The schedule of visits will largely be determined by completion of necessary preventive services and screening maneuvers listed for each age group. There is insufficient evidence to recommend one visit schedule over another in terms of lowering mortality and morbidity, recognizing disability, promoting optimal growth and development, or helping patients achieve longer more productive lives. For the purposes of this guideline, a reasonable schedule to allow for the completion of needed preventive services and screening maneuvers is as follows:

- Ages 19-39, one preventive visit every 5 years for males and every 3-5 years for females
- Ages 40-64, one preventive visit every 5 years for males and every 3-5 years for females
- Ages 65 and older, one preventive visit every 1-2 years

Many services can be provided during routine visits. Similarly, an assessment of preventive needs can be incorporated into any visit. The visit schedules recommended in the guidelines serve to augment a clinic's ability to assure provision of preventive services, and may in some clinics be unnecessary over time as effective clinic systems allow the services to be incorporated into other clinic visits.

Supporting evidence is of class: R

16. Risk Assessment

A systematic method for risk factor assessment should be employed periodically (every 3-5 years) to identify needs for counseling or special testing. In addition, at least those risk factors with evidence of counseling efficacy should be informally assessed and addressed at every opportunity and especially at every preventive visit. These higher priority items have been identified with an asterisk on the age tables.

17. Height and Weight

Height and weight measurement is recommended at intervals outlined in the schedule of visits for all adults. The Body Mass Index (BMI) table should be used rather than Metropolitan Life or NHANES tables. (See Annotation Appendix A, "Body Mass Index Table" for BMI table.)

Supporting evidence is of class: R

18. Blood Pressure Screening

See the ICSI Hypertension Diagnosis and Treatment guideline.

19. Clinical Breast Exam

Routine physical examination of the breast by a health care professional should start at age 20 and occur with routine gynecologic screening at least every three years.

Algorithm Annotations

Starting at age 40, when breast cancer becomes a more common occurrence, yearly breast examinations are recommended. This yearly practice should continue after menopause. However, it will need to be incorporated into other visits for patients having periodic health evaluations less frequently than yearly.

See the ICSI Diagnosis of Breast Disease guideline.

20. Total Cholesterol and HDL-Cholesterol

Routine lipid screening is recommended for men over age 34 and women over age 44. It is recommended that patients and providers discuss the issues surrounding lipid screening with men between the ages of 20-34 years and women between the ages of 20-44, and men and women after age 75.

There are no clinical trials that address the treatment of dyslipidemia among men aged 20-34 years, among women aged 20-44 years, or among men and women older than 75 years. Individuals in these groups should be screened on the basis of their non-lipid risk factors and treatment availability after discussion of patient preference and risks and benefits of treatment.

Patients with histories of coronary heart disease (CHD), cerebrovascular disease (CVD), peripheral vascular disease (PVD), or diabetes mellitus (DM) or who are being case managed for dyslipidemia are outside the scope of this guideline. Their disease management will involve a more aggressive approach to lipid monitoring. Patients whose health status or life expectancy would not be affected by knowledge of their lipid status (e.g., those with comorbid conditions such as terminal cancer) should not be screened. In certain circumstances, cholesterol levels may not be representative of a patient's usual levels. These situations include acute illness, hospitalization, weight loss, pregnancy, lactation, or myocardial infarction within the previous three months. Screening should be delayed under these circumstances.

Lipid screening is recommended at five year intervals for those who meet the screening criteria noted above and whose prior screen revealed a total cholesterol < 200 mg/dl and an HDL > 35 mg/dl. A fasting test is not required. The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) recommends providing education to the patient on modifying CHD risk factors. Cholesterol screening includes both laboratory testing and a nutrition/exercise assessment. A brief discussion should occur in which the provider encourages the patient's positive behaviors and suggests necessary improvements. A second opportunity to convey concern exists when lab results are communicated to the patient. A brief written comment on current nutrition and exercise behaviors should accompany the results. The comment should be accompanied by an educational brochure or include a referral to a cholesterol class if possible.

Please refer to the ICSI Lipid Screening in Adults guideline for more information.

21. Papanicolaou Smear

Initially, all women should have annual Pap smear screening beginning at age 21 or with the onset of sexual activity. After three consecutive normal Pap smears, women may have their screening performed less frequently at the discretion of the clinician and patient. Screening for cervical cancer should be performed at least every three years. Women who have had a total hysterectomy for benign disease, who also have no history of CIN 2/3 may cease routine screening. In the asymptomatic patient, there is no known benefit to performing a pelvic exam as a screening procedure for gynecological disease.

Patients with a history of dysplasia should have annual Pap smears until they no longer have a history of dysplasia within the last five years. At this point they need not be repeated more frequently than the standard recommendation.

Although the standard is three annual normal Pap smears, a wider time frame is acceptable as long as there are no intervening abnormal Pap smear results. This interval time frame should be three normal Pap smears in a period not to exceed five years.

Algorithm Annotations

After age 65, there is no clear evidence on the need for Pap smears in women who have had previous adequate screening. Pap smears may be performed at the mutual consent of the patient and provider. Women age 65 and older who have a new sexual partner should resume routine screening.

Pap smears should not be performed too soon after delivery. The recommended interval should be no sooner than 8 weeks postpartum.

See the ICSI Cervical Cancer Screening guideline.

22. Sexually Transmitted Disease Testing

Routine screening for gonorrhea and chlamydia by endocervical sampling is recommended for asymptomatic women at high risk for infection. Risk assessment is determined by a history of:

- commercial sex work;
- repeated episodes of STD's; or
- women under age 25. USPSTF suggests that for chlamydia the testing be done for all women under age 25, whereas for gonorrhea the testing should be done for those who have had more than one sexual partner in the past year.

Optimal frequency is unclear. Screening in high-risk men lacks sufficient evidence, and routine screening of low-risk adults is not recommended.

Routine screening for HIV should be offered to all persons at high risk after assessing the following risk factors:

- those seeking treatment for any standard STD;
- men who have had sex with men after 1975;
- any history of injection drug use;
- commercial sex work;
- past or present sex partner with HIV, bisexuality, or injection drug use; or
- history of blood transfusion between 1978 and 1985.

There is insufficient evidence to recommend for or against routine HIV screening in low-risk persons.

Routine screening for syphilis is recommended for all persons at high risk after assessing the following risk factors:

- commercial sex work;
- presence of other STD's; or
- sexual contact with active syphilis.

Routine screening for genital herpes simplex in asymptomatic persons is not recommended.

Supporting evidence is of classes: C, D, R

23. Mammograms

Given the conflicting evidence regarding the benefit of screening mammography for women 40-49 years of age, the use of screening mammography is considered to be optional in this age group. This issue is

Algorithm Annotations

left to the discretion of the primary care provider and the patient. Mammography for this age group would be appropriate for women with high-risk criteria, as well as for low-risk women who choose to undergo screening mammography.

Breast cancer high-risk criteria include:

1. Previous breast biopsy demonstrating atypical hyperplasia;
2. Family history of breast cancer in the patient's mother, sister or daughter;
3. Past personal history of breast cancer.

Since there is no evidence that annual versus biennial mammography is more effective in reducing breast cancer mortality a screening mammogram every 1-2 years is felt to be appropriate for women between the ages of 50 and 75 years. Mammograms may be performed at the mutual consent of the patient and provider in women over the age of 75.

Supporting evidence is of classes: M, R

24. Counseling and Education

The Preventive Counseling work group recommends that implementation of the Preventive Counseling and Education guideline be tied to a system to perform risk assessment of patients. This enables the provision of a tailored approach to counseling that is specific to an individual patient's risks.

Counseling and educational messages are to be provided by the primary care physician, nurse, or other health professional or educator.

Frequency of counseling is included in the ICSI Preventive Counseling and Education guideline under each topic-specific annotation. In general, some counseling should be carried out at each preventive care visit as well as at other times at clinical discretion. Once compliance with a health behavior has been attained, intermittent reinforcement messages may be substituted. Employers are encouraged to provide educational opportunities for employees using as many different methods as possible at regular intervals.

Counseling and education should be carried out at every opportunity. As repetition of counseling messages is desirable, there should be shared responsibility between employers and medical groups for communicating these messages.

A wide variety of counseling and education messages are recommended. Delivering them all in one visit or setting may be overwhelming to both the patient and the provider. Therefore, the recommendation is to spread out the messages across several visits when possible. Several provider attributes favorably impact patients' responses to messages.

See the ICSI Preventive Counseling and Education guideline.

25. Tuberculin Skin Testing

Routine tuberculin skin testing of all patients is not recommended. High-risk groups identified below should be tested using 5 tuberculin units (TU) of Purified Protein Derivative (PPD) injected intradermally by standard "Mantoux" techniques.

Suggested Tuberculin Skin Testing (TST) Schedule Based on Risk Factors

1. Immediate TST for persons:
 - with symptoms or radiographs suggestive of TB
 - who are contacts of persons with confirmed or suspected TB

Algorithm Annotations

- immigrating from endemic areas, especially Asia, the Middle East, Africa, and Latin America
 - who will undergo long-term immunosuppressive therapy
2. Annual TST for persons:
 - who are HIV-positive or living with an HIV-positive person
 - who are incarcerated
 - who are health care workers
 3. TST every 2-3 years for persons:
 - with ongoing exposure to persons who are: HIV-positive, homeless, nursing home residents, institutional residents, illicit drug users, migrant farm workers
 4. Possible TST at 4-6 years and 11-16 years old for children:
 - who are second-generation of immigrant families from high TB prevalence countries, or who travel to such countries
 - without risk factors, who live in high prevalence areas as identified by local health authorities
 5. Chronic disease:
 - Risk awareness and exposure screening for patients with underlying disease (diabetes, chronic renal disease, malnutrition) is necessary, but no screening is recommended routinely.

26. Immunizations and Chemoprophylaxis

| Vaccine | 19-39 Years | 40-64 Years | 65 Years & Older |
|-------------------------|--|--|------------------|
| 1. Td | Booster every 10 years | | |
| 3. MMR | Persons born after 1956 should have 2 doses measles; additional doses should be given as MMR. | | |
| 4. Pneumococcal (PPV23) | Immunize high-risk groups once. Re-immunize those at risk of losing immunity once after 5 years. | Immunize at 65 if not done previously. Re-immunize once if 1 st received > 5 years ago and before age 65. | |
| 5. Varicella | Persons ≤ 50 with no history of varicella, do titre. If negative, immunize. If > 50; assume they are immune. | | |
| 7. Hep B | Universal immunization | Immunize those at high risk | |
| 9. Influenza | Annually between Oct-Mar for individuals age 50 and older, those at high risk, and others | | |
| 10. Hep A | Immunize those in risk groups. | | |
| 11. Meningococcal | Immunize those in risk groups. | | |

Hormone Therapy

See the ICSI Menopause and Hormone Therapy (HT): Collaborative Decision-Making and Management guideline.

Algorithm Annotations

Aspirin Prophylaxis for the Primary Prevention of Myocardial Infarction

Aspirin prophylaxis should be discussed with adults between ages 50 and 75 who are at increased risk for coronary heart disease (CHD) because of tobacco use, dyslipidemia, hypertension, or family history of premature CHD.

Discussion should address potential benefits and harms of aspirin therapy. Aspirin therapy decreases the incidence of CHD, but also increases the incidence of gastrointestinal bleeding and hemorrhagic strokes. The balance of benefits and harms is most favorable among adults who are at high-risk of CHD. Aspirin 75 81 mg is as effective as higher doses in decreasing risk for CHD.

Supporting evidence is of class: M

27. Colon Cancer Screening

Patients age 50 to < 80 should receive colon cancer screening. Patients with the high-risk criteria noted below require colonoscopic surveillance at 3 to 5 year intervals, and are outside the scope of this guideline.

- Prior polyp (adenoma with villous component, or any adenomatous polyp > 10 mm.)
- Prior colorectal cancer.
- Family history of colorectal cancer involving:
 - one first-order relative with a diagnosis before age 65; or
 - two first-order relatives with a diagnosis at any age
 - a single first-order relative diagnosed after age 65 may put patients at a very slightly increased risk
- Family history of adenomatous polyps in first-order relatives diagnosed before age 60.

First-order relatives include only siblings, parents and children.

Certain patients are considered to be at high-risk for development of colorectal cancer. Relevant conditions include familial polyposis coli and variants, long-standing chronic ulcerative colitis, and non-polyposis hereditary colorectal cancer. Surveillance of patients with these disorders falls outside the scope of this screening guideline.

The following screening intervals apply to patients age 50 to < 80 years of age without clinical factors that place them at risk for colorectal cancer:

Possible screening test pathways include:

- 60 cm flex sig every 5 years
- FOBT annually
- Combination of both 60 cm flex sig every 5 years and FOBT annually. When this path is chosen, FOBT should be completed before doing the prep for the flex sig exam.
- Total colon evaluation. Within this choice, options include colonoscopy, flexible sigmoidoscopy combined with fluoroscopic barium enema, and CT colonography. If the sigmoid is not well visualized on double contrast barium enema, a flexible sigmoidoscopy should be obtained. The interval between exams within this choice is 5 years as well (5-10 years for colonoscopy).

Clinical groups may decide internally as to which pathway will be offered routinely at their site. Alternatively, individual clinicians may advise each patient as to which pathway might be most suitable, and with the patient's preference in mind, choose one of the above pathways.

See the ICSI Colorectal Cancer Screening guideline.

28. Visual Acuity and Hearing

Objective vision testing (Snellen chart) is recommended only for asymptomatic adults over the age of 74. Before that age, one can rely on a question about vision problems and the likelihood of patients complaining about vision problems.

There is insufficient evidence to recommend any hearing screening until age 74 when subjective questioning is recommended. Even in this age group, objective screening by audiometry is not recommended unless such questions indicate a potential problem.

Supporting evidence is of class: R

29. Osteoporosis Screening

There is evidence to support screening for osteoporosis in women age 65 and older, based on the presence of two known risk factors: advanced age and postmenopausal status. Presence of additional risk factors (please refer to the ICSI Diagnosis and Treatment of Osteoporosis guideline) may strengthen the recommendation for screening.

30. Prostate Specific Antigen and Digital Rectal Exam of the Prostate

While there is good evidence that PSA screening can detect early stage prostate cancer, the evidence is mixed or inconclusive as to whether early detection improves health outcomes. It should be noted, as well, that screening is associated with important potential harms to include frequent false positive rates leading to undue anxiety and unnecessary biopsies, and potential complications of treatment of some cancers that may not have affected the patient's health. The work group concurs with the USPSTF, and recommends that clinicians discuss the potential harms and benefits of PSA/DRE screening with the patient, after which the patient and provider can come to a mutually acceptable agreement on whether or not to screen.

Supporting evidence is of classes: C, D, M, R

31. Practices Reviewed, but Not Recommended

Traditional arguments for screening tests have emphasized the potential value for some individuals. However, it is increasingly apparent that many tests with low predictive value or with uncertain beneficial action for true positives may in fact cause considerable physical and psychological harm as well as excess costs. Tests that fall in the D or E recommendation strength of the U.S. Preventive Services Task Force are candidates for inclusion in this list as well as tests which have been routine and which have no real value.

Routine Thyroid Screening in Women Older Than 45 Years of Age

At this time, there is insufficient evidence to recommend universal screening for thyroid disease in asymptomatic individuals. Thyroid disease prevalence is higher in women and persons with Down Syndrome, and increases with age. Clinicians should remain alert to subtle symptoms and signs of thyroid dysfunction in this population.

Supporting evidence is of class: R

Diabetes Screening

There is still no direct evidence that screening the general population for diabetes improves long-term outcomes. For this reason, we do not recommend general screening for asymptomatic patients. Screening high-risk patients may be useful if both the screener and subject are willing to follow-up with either lifelong metformin or an intensive lifestyle modification program. There is limited evidence that screening high-risk groups improves outcomes. The randomized studies, to date, have involved very intensive lifestyle interventions that are unlikely to be provided or adhered to in real-life practice. *[Conclusion Grade III: See Conclusion Grading Worksheet – Appendix A – Annotation #31 (Diabetes Screening – High-risk)]*

Supporting evidence is of classes: A, D

There is substantial evidence that aggressive glycemic control compared to very loose glycemic control in newly diagnosed diabetics can reduce diabetic complications, and that excellent blood pressure control also has a powerful effect on complication rate. ICSI guidelines that address the treatment of dyslipidemia, hypertension, and coronary artery disease recommend that patients with these conditions be screened for diabetes. Screening patients with other risks for developing diabetes is left to provider/patient preference.

Although early intervention appears to reduce the burden of diabetes and its complications, there is no direct evidence that screening the general population improves outcomes. *[Conclusion Grade Not Assignable, See Conclusion Grading Worksheet – Appendix B – Annotation #31 (Diabetes Screening - General Population)]*

Supporting evidence is of classes: A, R

Depression Screening

While accurate screening tests and treatments for depression are available, little evidence exists about the potential benefits and harms of screening and treating depression outside of medication side effects. Feedback to providers of screening results does appear to increase recognition of depression in adults, but its effect on treatment and clinical outcomes is mixed.

Screening for Dementia

There is no direct evidence that routine screening for dementia in the older adult population is beneficial in primary care settings.

Alzheimer's and vascular disease are the two most common causes of dementia. Loss of cognitive function from dementia does pose a large burden of suffering on patients and their families who care for them, and estimated annual costs are \$100 billion dollars annually in the US. There are screening tools available for dementia, such as the MMSE (Mini Mental Status Exam.) While these tests have good sensitivity, they only have fair specificity. Accuracy is limited by age, ethnicity and education level.

Early detection and treatment does not appear to have a significant impact on the course of the disease – which is slowly progressive. Drug therapy is available, but results are mixed, and show at best, small

benefits. Although the burden of illness is great, noting the lack of screening tests with good predictive value, no treatment available with significant beneficial results, and insufficient clinical evidence, the work group does not recommend routine screening in older adults for dementia at this time.

32. Practices to Consider Discontinuing

Traditional arguments for screening tests have emphasized the potential value for some individuals. However, it is increasingly apparent that many tests with low predictive value or with uncertain beneficial action for true positives may in fact cause considerable physical and psychological harm as well as excess costs. Tests that fall in the D or E recommendation strength of the U.S. Preventive Services Task Force are candidates for inclusion in this list as well as tests which have been routine and which have no real value.

Routine Screening Hemoglobin

The guideline recommends considering discontinuing the performance of hemoglobin screening for all adults without clinical indications.

Supporting evidence is of class: R

Routine Blood Chemistries

This recommendation refers to multiple chemistry tests, often grouped in a 6-18 test group or panel, collected without indication in hopes of identifying diseases unsuspected on clinical grounds.

Supporting evidence is of classes: D, R

Routine Urinalysis

The guideline recommends considering discontinuing the use of routine urinalysis.

Supporting evidence is of class: R

Objective Vision and Hearing Testing

The guideline recommends considering discontinuing the use of objective hearing and vision testing for all asymptomatic adults ages 18-74. Subjective testing through history and observation is appropriate for adults in this age group. When diminished hearing is noted, the patient's interest in obtaining hearing aids should be established before audiometric testing. When audiometric testing is indicated, office-based testing is encouraged.

Supporting evidence is of class: R

Resting EKG

The guideline recommends considering discontinuing the performance of a resting electrocardiogram for all patients, including those at risk for cardiovascular disease.

Supporting evidence is of classes: C, R

CA 125 and Pelvic Ultrasound Screening for Ovarian Cancer

The guideline recommends considering discontinuing the screening of asymptomatic women for ovarian cancer. It is common practice to perform a pelvic examination when performing gynecologic examinations for other reasons.

Supporting evidence is of classes: M, R

Annotation Appendix A – Body Mass Index Table

BODY MASS INDEX

Body mass index (BMI) is a height-weight calculation that helps to determine if a patient is at an increased risk for weight-related illnesses such as diabetes, heart disease, hypertension and certain cancers. BMI = weight (kg) / height squared (m²).

Underweight is defined as a BMI less than 18.5 kg/m²

Normal weight is defined as a BMI of 18.5 to 24.9 kg/m²

Overweight is defined as a BMI of 25 to 29.9 kg/m²

Obesity is defined as a BMI greater than or equal to 30 kg/m²

Extreme obesity is defined as BMI greater than or equal to 40 kg/m²

How to use this chart:

1. Look across the top row to find the patient's height.
2. Look down the left column to find the patient's approximate weight.
3. Find where the two numbers meet on the graph. That is the patient's BMI.

| | 5'0" | 5'1" | 5'2" | 5'3" | 5'4" | 5'5" | 5'6" | 5'7" | 5'8" | 5'9" | 5'10" | 5'11" | 6'0" | 6'1" | 6'2" | 6'3" | 6'4" |
|-----|------|------|------|------|------|------|------|------|------|------|-------|-------|------|------|------|------|------|
| 100 | 20 | 19 | 18 | 18 | 17 | 17 | 16 | 16 | 15 | 15 | 14 | 14 | 14 | 13 | 13 | 12 | 12 |
| 105 | 21 | 20 | 19 | 19 | 18 | 17 | 17 | 16 | 16 | 16 | 15 | 15 | 14 | 14 | 13 | 13 | 13 |
| 110 | 21 | 21 | 20 | 19 | 19 | 18 | 18 | 17 | 17 | 16 | 16 | 15 | 15 | 15 | 14 | 14 | 13 |
| 115 | 22 | 22 | 21 | 20 | 20 | 19 | 19 | 18 | 17 | 17 | 17 | 16 | 16 | 15 | 15 | 14 | 14 |
| 120 | 23 | 23 | 22 | 21 | 21 | 20 | 19 | 19 | 18 | 18 | 17 | 17 | 16 | 16 | 15 | 15 | 15 |
| 125 | 24 | 24 | 23 | 22 | 21 | 21 | 20 | 20 | 19 | 18 | 18 | 17 | 17 | 16 | 16 | 16 | 15 |
| 130 | 25 | 25 | 24 | 23 | 22 | 22 | 21 | 20 | 20 | 19 | 19 | 18 | 18 | 17 | 17 | 16 | 16 |
| 135 | 26 | 26 | 25 | 24 | 23 | 22 | 22 | 21 | 21 | 20 | 19 | 19 | 18 | 18 | 17 | 17 | 16 |
| 140 | 27 | 26 | 26 | 25 | 24 | 23 | 23 | 22 | 21 | 21 | 20 | 20 | 19 | 18 | 18 | 17 | 17 |
| 145 | 28 | 27 | 27 | 26 | 25 | 24 | 23 | 23 | 22 | 21 | 21 | 20 | 20 | 19 | 19 | 18 | 18 |
| 150 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 23 | 23 | 22 | 22 | 21 | 20 | 20 | 19 | 19 | 18 |
| 155 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 | 21 | 20 | 20 | 19 | 19 |
| 160 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 | 21 | 21 | 20 | 19 |
| 165 | 32 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 | 21 | 21 | 20 |
| 170 | 33 | 32 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 | 21 | 21 |
| 175 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 | 21 |
| 180 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 22 | 22 |
| 185 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 27 | 27 | 26 | 25 | 24 | 24 | 23 | 23 |
| 190 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 27 | 26 | 26 | 25 | 24 | 24 | 23 |
| 195 | 38 | 37 | 36 | 35 | 33 | 32 | 31 | 31 | 30 | 29 | 28 | 27 | 26 | 26 | 25 | 24 | 24 |
| 200 | 39 | 38 | 37 | 35 | 34 | 33 | 32 | 31 | 30 | 30 | 29 | 28 | 27 | 26 | 26 | 25 | 24 |
| 205 | 40 | 39 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 29 | 28 | 27 | 26 | 26 | 25 |
| 210 | 41 | 40 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 28 | 27 | 26 | 26 |
| 215 | 42 | 41 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 28 | 28 | 27 | 26 |
| 220 | 43 | 42 | 40 | 39 | 38 | 37 | 36 | 34 | 33 | 32 | 32 | 31 | 30 | 29 | 28 | 27 | 27 |
| 225 | 44 | 43 | 41 | 40 | 39 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 31 | 30 | 29 | 28 | 27 |
| 230 | 45 | 43 | 42 | 41 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 30 | 29 | 28 |
| 235 | 46 | 44 | 43 | 42 | 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 | 29 | 29 |
| 240 | 47 | 45 | 44 | 43 | 41 | 40 | 39 | 38 | 36 | 35 | 34 | 33 | 33 | 32 | 31 | 30 | 29 |
| 245 | 48 | 46 | 45 | 43 | 42 | 41 | 40 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 31 | 30 |
| 250 | 49 | 47 | 46 | 44 | 43 | 42 | 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 | 30 |
| 255 | 50 | 48 | 47 | 45 | 44 | 42 | 41 | 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 |
| 260 | 51 | 49 | 48 | 46 | 45 | 43 | 42 | 41 | 40 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 32 |
| 265 | 52 | 50 | 48 | 47 | 45 | 44 | 43 | 42 | 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 |
| 270 | 53 | 51 | 49 | 48 | 46 | 45 | 44 | 42 | 41 | 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 |
| 275 | 54 | 52 | 50 | 49 | 47 | 46 | 44 | 43 | 42 | 41 | 39 | 38 | 37 | 36 | 35 | 34 | 33 |
| 280 | 55 | 53 | 51 | 50 | 48 | 47 | 45 | 44 | 43 | 41 | 40 | 39 | 38 | 37 | 36 | 35 | 34 |
| 285 | 56 | 54 | 52 | 50 | 49 | 47 | 46 | 45 | 43 | 42 | 41 | 40 | 39 | 38 | 37 | 36 | 35 |
| 290 | 57 | 55 | 53 | 51 | 50 | 48 | 47 | 45 | 44 | 43 | 42 | 40 | 39 | 38 | 37 | 36 | 35 |
| 295 | 58 | 56 | 54 | 52 | 51 | 49 | 48 | 46 | 45 | 44 | 42 | 41 | 40 | 39 | 38 | 37 | 36 |
| 300 | 59 | 57 | 55 | 53 | 51 | 50 | 48 | 47 | 46 | 44 | 43 | 42 | 41 | 40 | 39 | 37 | 37 |



INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

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Evidence Grading System

I. CLASSES OF RESEARCH REPORTS

A. Primary Reports of New Data Collection:

- Class A: Randomized, controlled trial
- Class B: Cohort study
- Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study
- Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

- Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis
- Class R: Consensus statement
Consensus report
Narrative review
- Class X: Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or \emptyset to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Evidence Grading System

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **-**, **∅**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

- indicates that these issues have not been adequately addressed;

∅ indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Discussion and References

Introduction

Stone EG, Morton SC, Hulscher ME, et al. "Interventions that increase use of adult immunization and cancer screening services: a meta-analysis." *Ann Intern Med* 136:641-51, 2002. (Class M)

Appropriate Preventive Services Practitioners

Research indicates that nurse practitioners, physician assistants, certified nurse-midwives and other clinical professionals with advanced training are cost-effective providers of primary care services. The continued and expanded use of these providers is encouraged.

Brown SA, Grimes DE. Nurse Practitioners and Certified Nurse-Midwives: a Meta-Analysis of Studies on Nurses in Primary Care Roles. Washington, DC: Amer Nurses Publ, 1993. (Class M)

DeAngelis CD. "Nurse practitioner redux." *JAMA* 271:868-71, 1994. (Class X)

Jones PE, Cawley J. "Physician assistants and health system reform: clinical capabilities, practice activities, and potential roles." *JAMA* 271:1266-72, 1994. (Class R)

Physical Examination

Most of the elements of the traditional physical examination are notably absent from these recommendations. The physical examination was originally developed and taught as a way to thoroughly evaluate the patient with a significant health problem or complaint, particularly one in a hospital setting. It was not designed as a screening test for an asymptomatic person, and it fails nearly all of the criteria for a screening test for an asymptomatic person identified by most authorities and the ICSI Technology Assessment Committee.

The ICSI Preventive Services guideline work group also recognizes that changing the content of the physical examination will be difficult for some providers and some patients. Therefore, we leave inclusion of specific examinations to the desires of individual medical groups, while encouraging them to focus primarily on the provision of essential services and the elimination of services which are clearly of no overall value.

Eddy DM. "How to think about screening." In Common Screening Tests. Eddy DM, ed. Philadelphia: American College of Physicians, 1991. (Class R)

Frank SH, Stange KC, Moore P, et al. "The focused physical examination: should checkups be tailor made?" *Post-grad Med* 92:171-86, 1992. (Class R)

Institute for Clinical Systems Improvement. "Screening tests." Technology Assessment Report #9, 1993. (Class R)

Oboler SK, LaForce FM. "The periodic physical examination in asymptomatic adults." *Ann Intern Med* 110:214-26, 1989. (Class R)

5. Address Reason for Visit and Screen for Priority Preventive Care Needs

Priority preventive care needs that can and should be addressed at every visit include:

- Discussing tobacco use with every user and recent (< 12 months) quitter
- Immunizations

Discussion and References

- Blood pressure screening
- Identifying needed cancer screens (breast, cervix, and colon) and scheduling an appropriate visit.

Coffield AB, Maciosek MV, McGinnis M, et al. "Priorities among recommended clinical preventive services." *Am J Prev Med* 21:1-9, 2001. (Class M)

15. Visit Schedules

There have been no studies comparing the efficacy of various scheduled frequencies of preventive services visits. Furthermore, little information is available about what patients prefer for preventive visits, although their behavior suggests that a fairly large minority either doesn't believe in the value of existing approaches or cannot afford them. Thus, all existing schedules are attempts to combine various medical opinions with the frequency required for *certain* preventive services, especially immunizations and cancer screening tests.

The work group acknowledges that decreasing the frequency from the current tradition of an annual visit to every 3-5 years may cause transitional confusion and unhappiness for some patients and providers. This will require education, support, and some flexibility in application. It will also require the establishment of alternative methods of providing those preventive services required at a more frequent interval (e.g., clinical breast examinations, mammograms, and blood pressure). Thus, a practical system for routinely assessing patients' prevention needs and arranging for them during other office visits will be needed.

U.S. Preventive Services Task Force. "The periodic health examination: age specific charts." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, 1996: lxxiv. (Class R)

17. Height and Weight

Height and weight measurements are designed primarily to identify significant obesity (BMI \geq 30), and secondarily to follow weight trends over time. The interpretation of obesity is best done using the table included in Annotation Appendix A, "Body Mass Index Table" section, which was derived from the Dietary Guidelines for Americans.

Oboler SK, LaForce FM. "The periodic physical examination in asymptomatic adults." *Ann Intern Med* 110:214-26, 1989. (Class R)

22. Sexually Transmitted Disease Testing

Allard R, Robert J, Turgeon P, et al. "Predictors of asymptomatic gonorrhea among patients seen by private practitioners." *Can Med Assoc J* 133:1135-46, 1985. (Class C)

Handsfield HH, Lipman TO, Harnish JP, et al. "Asymptomatic gonorrhea in men: diagnosis, natural course, prevalence and significance." *N Engl J Med* 290:117-23, 1974. (Class D)

Kamwendo F, Johansson E, Moi H, et al. "Gonorrhea, genital chlamydia infection, and nonspecific urethritis in male partners of women hospitalized and treated for acute pelvic inflammatory disease." *Sex Transm Dis* 20:143-46, 1993. (Class D)

Potterat JJ, Duker RL, Rothenberg RB. "Disease transmission by heterosexual men with gonorrhea: an empirical estimate." *Sex Transm Dis* 14:107-10, 1987. (Class C)

U.S. Preventive Services Task Force. "Clinical intervention." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, 1996: 325-34. (Class R)

23. Mammograms

The most important tool in the early detection of breast cancer is screening mammography. The USPSTF updated its recommendation in 2002, finding "fair evidence that mammography screening every 12-33 months significantly reduces mortality from breast cancer." They concluded that the evidence is strongest for women aged 50-69 and that the clinical trials reveal no clear difference due to interval within the 12-33 month time range. Nevertheless, their recommendation is for "mammography, with or without clinical breast exam (CBE) every 1-2 years for women aged 40 and older."

This extension to the 40-49 year old group has been controversial. Of the seven randomized controlled trials of mammography effectiveness since 1963 (only one of which was planned to evaluate this age group), two showed no benefit for this age group and five did. Meta-analyses of these studies have also had mixed results. The most negative review, by Olsen and Gotzsche for the Cochrane Library in 2001 and 2002, stirred a great deal of controversy by concluding that the currently available reliable evidence does not show a survival benefit of mass screening for breast cancer. Nevertheless, this analysis has not caused either the USPSTF nor any of the other organizations with recommendations for mammographic screening (CTFPHC, AAFP, ACPM, AMA, ACOG, ACR, and ACS) to change their recommendations (which vary in recommendations for starting age).

Humphrey LL, Helfand M, Chan BKS, et al. "Breast cancer screening: a summary of the evidence for the U.S. preventive services task force." *Ann Intern Med* 137:347-60, 2002. (Class M)

Olsen O, Gotzsche PC. "Cochrane review on screening for breast cancer with mammography." *Lancet* 358:1340-41, 2001. (Class not assignable)

U.S. Preventive Services Task Force. "Screening for breast cancer: recommendations and rationale." *Ann Intern Med* 137:344-46, 2002. (Class R)

26. Immunizations and Chemoprophylaxis

See the ICSI Immunizations guideline.

Aspirin for the primary prevention of myocardial infarction

USPSTF (2002) guideline recommends a discussion of aspirin therapy for primary prevention of myocardial infarction with patients at risk of coronary heart disease (CHD).

Five trials have examined the effects of aspirin therapy for the primary prevention of myocardial infarction. Most participants in these trials have been men between 50 and 75 years of age. Meta-analyses of pooled data from these studies showed that aspirin therapy reduced the risk of CHD by 28%. These primary prevention trials, and a larger number of trials of secondary prevention, also demonstrate that aspirin therapy increases rates of gastrointestinal bleeding and hemorrhagic stroke.

Estimates of the magnitude of benefits and harms of aspirin therapy vary with an individual's risk for CHD. The balance of benefits and harms of aspirin therapy is most favorable when 5-year cardiovascular risk is greater than or equal to 3%. Estimates of benefits and harms of aspirin therapy to 1,000 of these individuals is as follows: CHD events avoided, 2-12; major gastrointestinal bleeding events caused, 2-4; hemorrhagic strokes caused, 0-2.

Using a risk calculator provides a more accurate estimate of cardiovascular risk.

The optimum dosage of aspirin therapy is not known. Doses of 81 mg per day appear as effective as higher doses.

Hayden M, Pignone M, Phillips C, Mulrow C. "Aspirin for the primary prevention of cardiovascular events: a summary of the evidence for the U.S. preventive services task force." *Ann Intern Med* 136:161-72, 2002. (Class M)

28. Visual Acuity and Hearing Testing

Objective vision and hearing testing (e.g., Snellen chart, audiometry, or other quantifiable testing) is not recommended in normal adults until at least after age 74 because:

- Uncorrected defects before this age are unusual; and
- Either spontaneous or questioned (i.e., subjective) identification of a vision problem will identify those defects that do exist.

After age 74 neither of these statements is likely to be true.

U.S. Preventive Services Task Force. "The periodic health examination: age specific charts." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, Ivii-ixxiv, 1996. (Class R)

30. Prostate Specific Antigen and Digital Rectal Exam of the Prostate

While there is good evidence that PSA screening can detect early stage prostate cancer, the evidence is mixed or inconclusive as to whether early detection improves health outcomes. It should be noted, as well, that screening is associated with important potential harms to include frequent false positive rates leading to undue anxiety and unnecessary biopsies, and potential complications of treatment of some cancers that may not have affected the patient's health. The work group concurs with the USPSTF, and recommends that clinicians discuss the potential harms and benefits of PSA/DRE screening with the patient, after which the patient and provider can come to a mutually acceptable agreement on whether or not to screen.

Chan ECY, Vernon SW, O'Donnell FT, et al. "Informed consent for cancer screening with prostate-specific antigen: how well are men getting the message?" *Am J Public Health* 93:779-85, 2003. (Class C)

Harris R, Lohr KN. "Screening for prostate cancer: an update of the evidence for the U.S. preventive services task force." *Ann Intern Med* 137:917-29, 2002. (Class M)

Institute for Clinical Systems Improvement. "Prostate specific antigen as a screening test for prostate cancer." *Technology Assessment Report #8*, 1993. (Class R)

Sirovich BE, Schwartz LM, Woloshin S. "Screening men for prostate and colorectal cancer in the United States: does practice reflect the evidence?" *JAMA* 289:1414-20, 2003. (Class D)

31. Practices Reviewed, but Not Recommended

Traditional arguments for screening tests have emphasized the potential value for some individuals. However, it is increasingly apparent that many tests with low predictive value or with uncertain beneficial action for true positives may in fact cause considerable physical and psychological harm as well as excess costs. Tests that fall in the D or E recommendation strength of the U.S. Preventive Services Task Force are candidates for inclusion in this list as well as tests which have been routine and which have no real value.

Routine Thyroid Screening in Women Older Than 45 Years of Age

At this time, there is insufficient evidence to recommend universal screening for thyroid disease in asymptomatic individuals. Thyroid disease prevalence is higher in women and persons with Down Syndrome, and increases with age. Clinicians should remain alert to subtle symptoms and signs of thyroid dysfunction in this population.

Discussion and References

U.S. Preventive Services Task Force. "Screening for thyroid disease." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, 1996: 209-18. (Class R)

Diabetes Screening

Diabetes is a common disease, with 12-14 million Americans having diabetes. The burden of suffering related to diabetes is great. There is a reliable, cost-effective test to identify diabetes (especially since 1997, when the American Diabetes Association defined new criteria for diagnosis with fasting blood sugar [FBS] greater than 126), and good treatment is available.

The single criterion lacking for recommending screening for diabetes is evidence that screening the general population improves outcomes. In RCTs published in 2001 and 2002, it was demonstrated that screening high-risk patients may be useful if both the screeners and the subjects are willing to follow-up with either lifelong metformin treatment or an extremely intensive lifestyle modification program. However, if that is not the case, then it still appears to be inadvisable to screen even high-risk patients, since there may be harmful side effects on mental health or quality of life, and those risks have not been measured in the above trials. Furthermore, the O'Connor study suggests that there may be relatively few cases of undiagnosed diabetes or impaired glucose tolerance found in our high-risk populations. There is limited evidence that screening high-risk groups improves outcomes. The randomized studies, to date, have involved very intensive lifestyle interventions that are unlikely to be provided or adhered to in real-life practice. [*Conclusion Grade III, See Conclusion Grading Worksheet – Appendix A – Annotation #31 (Diabetes Screening – High-risk)*]

Diabetes Prevention Program Research Group. "Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin." *N Engl J Med* 346:393-403, 2002. (Class A)

O'Connor PJ, Rush WA, Cherney LM, Pronk NP. "Screening for diabetes mellitus in high-risk patients: cost, yield and acceptability." *Eff Clin Pract* 4:271-77, 2001. (Class D)

Tuomilehto J, Lindstrom J, Eriksson JG, et al. "Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance." *N Engl J Med* 344:1343-50, 2001. (Class A)

There was a significant group of studies published by the United Kingdom Prospective Study Group (UKPDS) in 1998. Findings from this study produced data showing that aggressive glyceemic control of new diabetics decreased microvascular complications significantly, and found a 16% risk reduction for MI. (Interestingly, the glyceemic control difference between the two groups was huge. "Usual care goal: fasting plasma glucose less than 15 mmol/L = FBS 272. Intensive control goal: fasting plasma glucose 6 mmol/L = FBS less than 108. Good control of blood pressure was shown to be as significant to decreasing risk of complications as glyceemic control.")

Although early intervention appears to reduce the burden of diabetes and its complications, there is no direct evidence that screening the general population improves outcomes. [*Conclusion Grade Not Assignable, See Conclusion Grading Worksheet – Appendix B – Annotation #31 (Diabetes Screening – General Population)*]

Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. "Report of the expert committee on the diagnosis and classification of diabetes mellitus." *Diabetes Care* 20:1183-97, 1997. (Class R)

Laakso M. "Glyceemic control and the risk for coronary heart disease in patients with non-insulin-dependent diabetes mellitus: the Finnish studies." *Am Coll of Phys* 124:127-30, 1996. (Class R)

Ohkubo Y, Kishikawa H, Araki E, et al. "Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study." *Diabetes* 44:28:103-17, 1995. (Class A)

Discussion and References

UK Prospective Diabetes Study (UKPDS) Group. "Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34)." *Lancet* 352:854-65, 1998. (Class A)

UK Prospective Diabetes Study (UKPDS) Group. "Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33)." *Lancet* 352:837-53, 1998. (Class A)

UK Prospective Diabetes Study (UKPDS) Group. "Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38." *BMJ* 317:703-13, 1998. (Class A)

UK Prospective Diabetes Study (UKPDS) Group. "Efficacy of atenolol and captopril in reducing risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 39." *BMJ* 317:713-20, 1998. (Class A)

Screening for Dementia

There is no direct evidence that routine screening for dementia in the older adult population is beneficial in primary care settings.

Alzheimer's and vascular disease are the two most common causes of dementia. Loss of cognitive function from dementia does pose a large burden of suffering on patients and their families who care for them, and estimated annual costs are \$100 billion dollars in the U.S. There are screening tools available for dementia, such as the MMSE (Mini Mental Status Exam.) While these tests have good sensitivity, they only have fair specificity. Accuracy is limited by age, ethnicity and education level.

Early detection and treatment does not appear to have a significant impact on the course of the disease – which is slowly progressive. Drug therapy is available, but results are mixed, and show at best, small benefits. Although the burden of illness is great, the lack of screening tests with good predictive value, no treatment available with significant beneficial results, and insufficient clinical evidence, the work group does not recommend routine screening in older adults for dementia at this time.

Boustani M, Peterson B, Hanson L, et al. "Screening for dementia in primary care: a summary of the evidence for the U.S. Preventive Services Task Force." *Ann Intern Med* 138:927-937, 2003. (Class M)

U.S. Preventive Services Task Force. "Screening for dementia: recommendation and rationale." *Ann Intern Med* 138:925-26, 2003. (Class R)

32. Practices to Consider Discontinuing

Traditional arguments for screening tests have emphasized the potential value for some individuals. However, it is increasingly apparent that many tests with low predictive value or with uncertain beneficial action for true positives may in fact cause considerable physical and psychological harm as well as excess costs. Tests that fall in the D or E recommendation strength of the U.S. Preventive Services Task Force are candidates for inclusion in this list as well as tests which have been routine and which have no real value.

Routine Screening Hemoglobin

The burden of suffering and the benefits of detection of anemia in the presymptomatic phase in a low-risk population without clinical indications are so low that they do not warrant the cost of routine testing. (This argument does not apply to infants and pregnant women.)

U.S. Preventive Services Task Force. "The periodic health examination: age specific charts." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, Ivii-ixxiv, 1996. (Class R)

Routine Blood Chemistries

Most evaluations of benefit have concluded that in a well population, multiple chemical screens find few unsuspected conditions and create considerable worry as well as subsequent diagnosis testing with its own costs and hazards. These screens may be useful for patients suspected of having a serious illness, but even for those patients the selection of specific tests is usually more efficacious.

Berwick DM. "Screening in health fairs: a critical review of benefits, risks, and costs." *JAMA* 254:1492-98, 1985. (Class R)

Romm FJ. "Routine chemistry testing." *Fam Med* 18:230-32, 1986. (Class D)

Routine Urinalysis

In general, the predictive value and potential benefits of routine urinalysis are uncertain, and the risk of harm and costs from further evaluation of abnormalities are such that this test should not be done without some clinical indication. One such indication is for those at high-risk for bladder cancer. However, in women, this benefit might be negated by the frequency of false positive findings.

U.S. Preventive Services Task Force. "The periodic health examination: age specific charts." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, Ivii-ixxiv, 1996. (Class R)

Objective Hearing and Vision Testing

There is no evidence that examining asymptomatic, mentally competent adults for visual or hearing defects in formal, quantifiable ways is of benefit to them. Questioning such individuals is an option for those with clinical reason for concern. However, beyond some age (arbitrarily identified as 75 years) the more frequent occurrence of problems and the potential for patient denial or unawareness is such that objective vision testing may be advisable.

U.S. Preventive Services Task Force. "The periodic health examination: age specific charts." *In United States Preventive Services Task Force Report*, 2nd ed. Baltimore: Williams & Wilkins, Ivii-ixxiv, 1996. (Class R)

Resting EKG

The performance of resting EKGs is recommended against by the USPSTF, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination on the grounds that in low-risk populations it has a high false positive rate, producing expensive and physical/psychological damage without evidence of benefit. Although screening in high-risk populations has better specificity and sensitivity, benefits are uncertain and its use is optional. Even use of the results as a baseline is of little value.

Hayward RSA, Steinberg EP, Ford DE, et al. "Preventive care guidelines: 1991." *Ann Intern Med* 114:770-83, 1991. (Class R)

Discussion and References

Rubenstein LZ, Greenfield S. "The baseline ECG in the evaluation of acute cardiac complaints." *JAMA* 244:2536-39, 1980. (Class C)

CA 125 and Pelvic Ultrasound Screening for Ovarian Cancer

Multiple analyses of the evidence, including a recent NIH consensus panel, have concluded that there is no evidence that even combining these tests will effectively reduce mortality and morbidity. The recommendation to consider discontinuing screening is based on this information plus the physical, psychological, and financial harm caused by frequent false positives resulting in unnecessary surgery. Although pelvic examinations are also of uncertain value for this condition, they have other benefits and are not included in this recommendation.

Grimes DA. "Primary prevention of ovarian cancer." *JAMA* 270:2855-56, 1993. (Class R)

Marwick C. "Consensus panel says benefits of screening women for ovarian cancer currently unproven." *JAMA* 271:1305-06, 1994. (Class not assignable)

Schapira MM, Matcher DB, Young MJ. "The effectiveness of ovarian cancer screening: a decision analysis model." *Ann Intern Med* 118:838-43, 1993. (Class M)

Conclusion Grading Worksheet – Appendix A – Annotation #31 (Diabetes Screening – High-Risk)

Work Group's Conclusion: There is limited evidence that screening high-risk groups improves outcomes. The randomized studies, to date, have involved very intensive lifestyle interventions that are unlikely to be provided or adhered to in real-life practice.

Conclusion Grade: III

| Author/Year | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|------------------------|-----------------|-------|---------|---|---|--|
| O'Connor et al. (2001) | Cross-sectional | D | 0 | -Patients from 3 clinics; high-risk based on diagnoses of dyslipidemia and hypertension -Excluded: history of diabetes, screened for diabetes in past year -Eligible volunteers had random plasma glucose test; if results normal, received advice on activity & weight management; if not normal, invited back for oral glucose tolerance test (GTT) | -1,548 high-risk patients identified, 469 eligible for screening -206 (44%) had random plasma glucose test: 1 new diabetes diagnosis, 103 with abnormal results (invited for GTT), 102 with normal results -73 (71% of 103) had GTT: 4 new diabetes diagnoses, 11 with impaired glucose tolerance, 58 normal -3 of 5 newly diagnosed patients had HBA _{1c} tested before starting treatment (6.7%, 6.9%, & 7.2%) -Overall cost was \$4,064 per new case of diabetes detected (not including costs of additional care for newly diagnosed patients) | -The acceptability and yield of systematic screening of high-risk patients were low and the costs were relatively high. Screening during routine office visits using a one-step, non-fasting screening test (e.g., HBA _{1c}) was recommended. NOTES: first screening patients were invited by letter with follow-up postcard at 1 wk and 2nd letter at 3 wks; test results by mail with invitation back for GTT if abnormal; 5 newly diagnosed by WHO criteria, 3 of the 5 met NDDG criteria. |

**Conclusion Grading Worksheet – Appendix A –
Annotation #31 (Diabetes Screening – High-Risk)**

| Author/Year | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|--|---|---|
| Tuomilehto et al., for the Finnish Diabetes Prevention Study Group (2001) | RCT | A | + | <p>-Subjects identified from high-risk groups: 1st-degree relatives of type 2 patients; overweight, age 40-65 yrs, impaired GT</p> <p>-Excluded: diagnosis of diabetes, survival ≥ 6 yrs unlikely, other characteristics likely to interfere with study</p> <p>-Randomized to a) intervention - detailed advice about wt loss, dietary changes, and exercise including sessions with nutritionist and supervised exercise sessions or b) control - general information about diet and exercise at annual visits</p> <p>-Annual medical history and physical exam with GTT and plasma glucose</p> <p>-Primary outcome: new diabetes diagnoses</p> | <p>-265 in intervention group, 257 in control group, mean follow-up of 3.2 years (90% enrolled ≥ 2 yrs)</p> <p>-Groups similar at baseline</p> <p>-At 1 & 2 yrs intervention group had significantly greater decreases in weight, fasting plasma glucose, plasma glucose after glucose challenge, serum insulin concentration after glucose challenge, triglyceride concentration, and blood pressure (all $p < 0.05$)</p> <p>-Intervention group more likely to report changes in diet and exercise habits ($p < 0.05$)</p> <p>-Diabetes diagnosed in 27 intervention and 59 control subjects (32 and 78 cases per 1000, respectively)</p> <p>-Cumulative incidence of diabetes lower in intervention group - significant at 2 yrs (6% vs 14%); for all person-years accumulated cumulative incidence was 58% lower in intervention group than control (hazard ratio 0.4; 95%CI 0.3-0.7, $p < 0.001$); cumulative incidence lower for both men and women</p> <p>-Strong inverse correlation for success in achieving diet/exercise goals and incidence of diabetes; intervention subjects who achieved $> 5\%$ wt loss by 1 yr had odds ratio for diabetes of 0.3 (95%CI 0.1-0.7) vs. those who did not</p> <p>-40 subjects (8%) withdrew from study (23 intervention, 17 control); mostly for personal reasons.</p> | <p>-Type 2 diabetes can be prevented by changes in the lifestyles of both women and men at high risk for the disease. In this study, the overall incidence of diabetes was reduced by 58%.</p> <p>NOTES: study was terminated early due to reduced incidence of diabetes in intervention group; study design was partly blinded; analysis was by intention-to-treat</p> <p><i>Work Group's Comments: Insufficient information about subject recruitment to know how highly selected and atypical the subjects may have been</i></p> |

**Conclusion Grading Worksheet – Appendix A –
Annotation #31 (Diabetes Screening – High-Risk)**

| Author/Year | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|---|--|--|
| Diabetes Prevention Program Research Group (2002) | RCT | A | ++-0 | <p>-High-risk patients from 27 sites</p> <p>-Included: age ≥ 25 yrs; BMI ≥ 24; plasma glucose 95-125 mg/dL fasting and 140-199 mg/dL after glucose challenge</p> <p>-Excluded: taking medicines that affect glucose tolerance; illness that reduced life expectancy or affected ability to participate</p> <p>-Randomized to a) standard lifestyle recommendations (written information and annual individual session) plus metformin (850 mg twice daily), b) standard lifestyle recommendations plus placebo twice daily, or c) intensive program of lifestyle modification (individualized 16 lesson curriculum on diet, exercise, and behavior modification plus individual sessions)</p> <p>-Primary outcome: new diabetes diagnoses</p> | <p>-Completed 65% of planned person-years of observation before early termination; average follow-up of 2.8 yrs (range 1.8-4.6)</p> <p>-3,234 randomized (1082 placebo, 1073 metformin, 1079 intensive lifestyle intervention); groups similar at baseline</p> <p>-50% of intensive intervention group achieved wt loss of $\geq 7\%$ at end of curriculum (24 wks); 38% had $\geq 7\%$ loss at last visit; daily energy intake and average fat intake decreased significantly more and physical activity increased significantly more in lifestyle intervention group (all $p < 0.001$)</p> <p>-Crude incidence of diabetes: 11.0, 7.8, and 4.8 cases per 100 person-years in placebo, metformin, and lifestyle groups; 58% reduction in incidence for lifestyle vs. placebo, 31% for metformin vs. placebo, and 39% for lifestyle vs. metformin (all $p < 0.05$); estimated cumulative incidence at 3 yrs was 29% (placebo), 22% (metformin), and 14% (lifestyle)</p> <p>-Treatment effects did not differ significantly according to gender or race or ethnic group; some differences related to baseline glucose levels, BMI, & age</p> <p>-More gastrointestinal symptoms in metformin group & more musculoskeletal symptoms in lifestyle group (both $p < 0.05$); hospitalization and mortality rates (no deaths attributable to treatment) same across groups</p> | <p>-Type 2 diabetes can be prevented or delayed in persons at high risk for the disease; the lifestyle intervention was particularly effective. The effects of intervention are similar for men and women and for all racial and ethnic groups.</p> <p>NOTES: study was terminated early due to efficacy of intervention; subject recruitment designed to enroll approximately half the participants from racial or ethnic minority groups; some eligibility criteria varied by population; fourth intervention (troglitazone) was discontinued due to potential liver toxicity; analysis was by intention-to-treat; continued follow-up planned</p> <p><i>Work Group's Comments: Insufficient information about subject recruitment to know how highly selected and atypical the subjects may have been</i></p> |

Conclusion Grading Worksheet – Appendix B – Annotation #31 (Diabetes Screening – General Population)

Work Group's Conclusion: Although early intervention appears to reduce the burden of diabetes and its complications, there is no direct evidence that screening the general population improves outcomes.

Conclusion Grade: Grade not assignable

| Author/Yr | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|--|--|---|
| Ohkubo, Kishikawa, Araki, et al. (1995) | RCT | A | + | <p>-110 type 2 diabetes patients; treated with 1-2 daily injections of intermediate-acting insulin; type 2 diabetes diagnosed by no history of ketoacidosis, negative islet cell antibody, & urinary C-peptide excretion >20g/day</p> <p>-Included: no retinopathy or simple retinopathy, urinary albumin excretion <300 mg/24h and serum creatinine level <1.5 mg/dl, absence of diabetic somatic or autonomic neuropathy severe enough to require treatment, <70 yrs of age, otherwise healthy</p> <p>-2 cohorts - 55 patients each: primary-prevention (PP) (no retinopathy and albumin excretion <30 mg/24h) or secondary-intervention (SI) (simple retinopathy and albumin excretion <300 mg/24h)</p> <p>-Within cohorts patients randomly assigned to a) conventional insulin injection therapy (1-2 daily injections) (CIT) or b) multiple insulin injection therapy (≥3 injections daily) (MIT); insulin dosage adjusted based on blood glucose levels</p> <p>-Follow-up at 3 mos and 6 mos and then every 6 mos to 72 mos (6 yrs)</p> | <p>-After 6 yrs, 102 patients remained (3 deaths, 3 relocated, 2 changed treatments)</p> <p>-Glycemic control (including FBG, HbA1c, MBG, M-value, & MAGE): near normoglycemia obtained in the MIT group during 3rd month after initiation of tx and maintained over 6 yrs; mean values significantly lower (p<0.001) in MIT group than CIT group; both groups had non-significant decrease in insulin dosage</p> <p>-Retinopathy: percentage of PP patients who developed retinopathy after 6 yrs lower in MIT group (p=0.039); percentage of SI patients with progression of retinopathy lower in MIT group (p=0.049); overall percentage of patients with worsening of retinopathy lower in MIT group (p=0.007)</p> <p>-Neuropathy: percentage of PP patients with development of neuropathy lower in MIT group (p=0.032); percentage of SI patients with progression of neuropathy lower in MIT group (p=0.044); overall percentage of patients with worsening of neuropathy lower in MIT group (p=0.005)</p> <p>-Neuropathy: median nerve conduction velocities (motor and sensory) increased in MIT group, median sensory conduction velocity decreased in the CIT group [differences between groups significant at 6 yrs (p<0.05)]; vibration thresholds showed slight increase in MIT group and significant increase (p<0.05) in CIT group [differences between groups significant at 6 yrs (p<0.05)]; no differences between groups in postural hypotension or coefficient of variation of the R-R interval at rest or during deep breathing</p> <p>-Patients without worsening of microangiopathy over 6 yrs had lower (p<0.001) mean glycemic control than patients with worsening</p> <p>-6 patients in MIT group and 4 in CIT group had 1 or more episodes of mild hypoglycemic reaction</p> | <p>-Intensive glycemic control with multiple insulin injection therapy effectively delayed the onset and the progression of diabetic retinopathy, nephropathy and neuropathy in type 2 diabetes patients</p> <p>-The glycemic threshold to prevent the onset and progression of diabetic microangiopathy is indicated by HbA1c<6.5%, FBG<110 mg/dl, and 2-h post-prandial blood glucose concentration<180mg/dl</p> <p><i>Work Group's Comments:</i></p> <p>-Analysis was not by intention to treat (the 8 who left the study were not included)</p> <p>-Sample size was small (102 total in analysis)</p> <p>-Study does not provide direct evidence about the effect of early screening and diagnosis on improving outcomes</p> |

**Conclusion Grading Worksheet – Appendix B –
Annotation #31 (Diabetes Screening – General Population)**

| Author/Yr | Design Type | Class | Quality +,-,0 | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|--|-------------------------|-------|------------------|---|--|---|
| Laakso (1996) | Review of 2 case series | R | N/A | <p>-Study 1: 133 patients (ages 45-64 yrs) newly diagnosed with type 2; diagnosis of myocardial infarction (MI) by major Q-QS abnormalities or documented MI</p> <p>-Evaluated blood glucose level and glycated HbA1c</p> <p>-Follow-up at 10 yrs</p> <p>-Study 2: 1299 patients (ages 65-74 yrs) (71% of those eligible); 299 had type 2 diabetes</p> <p>-Used WHO criteria for definite and possible MI and for type 2 diabetes</p> <p>-Evaluated plasma glucose, glycated HbA1c</p> <p>-Follow-up at 3.5 yrs</p> | <p>-In 10 yr follow-up, 28 died of cardiovascular (CV) causes; CV mortality significantly associated with age, elevated total and low-density lipoprotein triglyceride levels, and hyperglycemia; high fasting blood glucose level significantly predicted CV mortality (independently of other factors)</p> <p>-10 yr CV mortality higher in patients treated with dietary modification (for middle and high fasting blood glucose tertiles but not for low tertile); CV mortality highest in highest tertile compared to lowest tertile regardless of treatment</p> <p>-In 3.5 yr follow-up, 15 died of coronary heart disease (CHD) and 33 experienced a severe CHD event; glycated HbA1c most important single risk factor associated with CHD death or event (also after adjustment for sex, history of previous MI, current smoking, waist-to-hip ratio, systolic BP, high-density lipoprotein levels, and duration of diabetes); for highest glycated HbA1c tertile CHD risk was about 3 times that of lowest tertile</p> | <p>Degree of hyperglycemia in frank diabetes linearly increases the risk for CHD and CV events.</p> <p>NOTES: evaluation of glycemic control was based on a single measurement of the fasting blood glucose or GHBA1c level; it is impossible to separate the direct effects of hyperglycemia on the risk for CHD from its indirect effects on CF risk factors; elevated glucose levels may be a surrogate measure for other metabolic derangements in diabetes that are directly responsible for increased risk of macrovascular disease</p> <p><i>Work Group's Comments:</i></p> <p><i>-There is no reference to the expected number of deaths in this population</i></p> <p><i>-Support for glycemic control in type 2 diabetes</i></p> <p><i>-Indirect support for early detection and thus screening</i></p> |
| Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (1997) | Consensus Report | R | N/A | <p>-Review of literature since 1979</p> <p>-Sponsored by the American Diabetes Association</p> | <p>-Patients with undiagnosed type 2 diabetes are at risk for CHD, stroke, and peripheral vascular disease and have greater likelihood of having dyslipidemia, hypertension, and obesity</p> <p>-Early detection and treatment may reduce the burden of type 2 diabetes and its complications</p> <p>-Testing should be considered in asymptomatic, high risk populations according to the following criteria:</p> <ol style="list-style-type: none"> 1. All individuals age 45 and above (with repeat testing at 3 yr intervals if results are normal) 2. At a younger age (or with more frequent testing) in individuals who are obese, have first degree relative with diabetes, members of high-risk ethnic populations, have delivered a baby weighing >9lb or diagnosed with GDM, hypertensive (140/90 or greater), HDL cholesterol of 35 mg/dl or lower and/or triglyceride level of 250 mg/dl or greater, on previous testing had IGT or IFG | <p>The FPG is strongly recommended in clinical settings because it is easier and faster to perform, more convenient and acceptable to patients, more reproducible, and less expensive</p> |

**Conclusion Grading Worksheet – Appendix B –
Annotation #31 (Diabetes Screening – General Population)**

| Author/Yr | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|--|--|--|
| UK Prospective Diabetes Study Group (1998) [UKPDS 33] | RCT | A | ++-0 | <p>-3867 newly diagnosed patients with type 2 diabetes (23 centers); ages 25-65 yrs</p> <p>-Included: FPG>6mmol/L on 2 mornings</p> <p>-Excluded: ketonuria>3mmol/L; serum creatinine >175µmol/L; MI in previous yr; current angina or heart failure; >1 major vascular event; retinopathy requiring laser treatment; malignant hypertension; uncorrected endocrine disorder; occupation that precluded insulin therapy; severe concurrent illness; inadequate understanding; unwillingness to enter study</p> <p>-3 month dietary run-in (low saturated fat, moderately high fiber, 50% of calories in carbohydrates)</p> <p>-Stratified on ideal body weight; non-overweight patients randomized to intensive tx with insulin (30%), sulphonylurea (40%), or conventional tx with diet (30%); overweight patients randomly assigned tx with added possibility of metformin (see UKPDS 34)</p> <p>-Conventional tx (CT) goal: FPG<15 mmol/L (FBS 272) without symptoms of hyperglycemia; additional medications used if goal not achieved</p> <p>-Intensive tx (IT) goal: FPG<6mmol/L (FBS 108)</p> <p>-Clinic visits every 3 mos (4 mos after 1990) or as needed</p> <p>-Full clinical examination at entry and every 3 yrs</p> <p>-Median follow-up: 10 yrs</p> | <p>-Progressive hyperglycemia observed in all groups so protocol modified to allow early addition of metformin when on maximum doses of sulphonylurea, changed to insulin if hyperglycemia recurred</p> <p>-21 clinical endpoints and 7 aggregate endpoints for differences between CT & IT (3867 patients); 4 additional clinical endpoints for differences between IT regimens (3041 patients)</p> <p>-Subclinical endpoints were assessed every 3 yrs</p> <p>-At end of trial vital status of 76 (2%) who had emigrated was unknown; 91 (2.4%) could not be contacted in last yr of study</p> <p>-FPG and HbA1c increased steadily over 10 yrs in the CT group; IT group had initial decrease to 1 yr and then increased similar to CT group; median HbA1c over 10 yrs lower in IT group (7.0% vs. 7.9%; p<0.0001); median HbA1c values over 10 yrs with different regimens also lower than CT group (p<0.0001)</p> <p>-Significant increase in weight in IT group (p<0.0001); those treated with sulphonylureas gained more weight than CT; those treated with insulin gained more than those treated with sulphonylureas</p> <p>-Median fasting plasma insulin increased in the IT group and was greater than in CT group (p<0.0001)</p> <p>-Systolic and diastolic blood pressure higher in those assigned chlorpropamide than any other therapy</p> <p>-Significant (p<0.05) reduction in risk of any diabetes-related endpoint (RR=0.88) and microvascular endpoints (RR=0.75); significant (p<0.01) reduction in risk for retinal photocoagulation (RR=0.71); no significant difference between the three intensive treatments on microvascular endpoints or the risk reduction for retinal photocoagulation</p> <p>-No differences between CT and IT in deterioration of visual acuity, % with absent ankle reflexes, heart rate responses to deep breathing and standing, impotence, or proportion with other cardiovascular conditions</p> <p>-Significantly higher proportion of patients with hypoglycemic episode in the IT group (especially those whose actual treatment was insulin)</p> | <p>-An intensive blood-glucose control policy with an 11% reduction in median HbA1c over first 10 yrs decreased the frequency of some clinical complications of type 2 diabetes. The IT group had a 25% reduction in risk of microvascular endpoints mostly due to fewer patients requiring photocoagulation. There was a 16% (p=0.052) risk reduction for MI in the IT group. Diabetes-related mortality and all-cause mortality did not differ between IT and CT. The progression of subclinical surrogate variables of microvascular disease was also decreased. The median complication-free survival was 1.3 yrs longer in IT group.</p> <p>-The data do not support the suggestion of adverse CV effects from sulphonylureas and there was no evidence of an increase in MI in the insulin treated group.</p> <p>-The disadvantages of IT were greater weight gain and increased risk of hypoglycemic events.</p> <p>-NOTE: sulphonylurea group received chlorpropamide, glibenclamide, or glipizide; plan to carry out post-study monitoring for an additional 5 yrs since the 10 yr follow-up is short compared to median life expectancy of 20 yrs in those diagnosed at median age of 53</p> |

**Conclusion Grading Worksheet – Appendix B –
Annotation #31 (Diabetes Screening – General Population)**

| Author/Yr | Design Type | Class | Quality +,-,0 | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|------------------|--|---|---|
| UK Prospective Diabetes Study Group (1998) [UKPDS 34] | RCT | A | + | -Subset of 1704 overweight patients from UKPDS 33; randomly assigned to conventional tx (CT) or intensive tx (IT) with chlorpropamide, glibenclamide, insulin, or metformin; this paper focuses on CT vs IT with metformin (with secondary analysis of metformin vs. other intensive tx) -CT and IT described in UKPDS 33 -Also evaluated sulphonylurea with metformin vs. continued sulphonylurea alone | -Median follow-up for comparison of IT with metformin and CT in overweight patients: 10.7 yr; 13 (1.8%) emigrated and 43 (2.5%) couldn't be contacted -FPG and HbA1c decreased in first yr in metformin group but then increased and from 10 yrs approached that of CT group; change in body weight similar in both groups -Rate of hypoglycemic episode higher in patients taking metformin as allocated than in those on diet alone; lower than in those taking sulphonylureas as allocated -IT with metformin group: 32% lower risk of developing any diabetes-related endpoint than those in CT group (p=0.0023); also 42% lower risk of diabetes-related death (p=0.017) and 36% lower risk (p=0.011) of all-cause mortality; greater risk reduction than in groups assigned IT with sulphonylurea or insulin; metformin group had 39% lower risk (p=0.01) of MI and 30% lower risk for all macrovascular diseases (p=0.02) -IT with metformin group had lower rate of progression to retinopathy than CT group (p=0.044 at 9 yrs) -If metformin added to maximum sulphonylurea tx (vs sulphonylurea alone) - 96% increased risk of diabetes-related death (p=0.04) and 60% increased risk of death from any cause (p=0.04) | -Metformin in diet-treated overweight patients reduced risk for any diabetes-related endpoint, diabetes-related death, and all-cause mortality. HbA1c levels were improved as with sulphonylurea and insulin therapy but metformin did not induce weight gain and was associated with fewer episodes of hypoglycemia. -Metformin should be chosen as the first-line pharmacological therapy in overweight patients with type 2 diabetes. -Metformin added to sulphonylurea therapy in overweight and non-overweight patients increased the risk for diabetes-related deaths and all-cause mortality. This finding requires further study. |

**Conclusion Grading Worksheet – Appendix B –
Annotation #31 (Diabetes Screening – General Population)**

| Author/Yr | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|---|--|--|
| UK Prospective Diabetes Study Group (1998) [UKPDS 38] | RCT | A | +, -, 0 | <p>-Hypertension study embedded in UKPDS; 1,148 hypertensive type 2 diabetes patients (defined as $\geq 160/90$ mmHg in patients not receiving antihypertensive tx or $\geq 150/85$ mmHg in those receiving antihypertensive tx)</p> <p>-Excluded: clinical requirement for strict blood pressure control or β blockade, severe vascular disease, severe concurrent illness or contraindications to β blockers, pregnancy, or unwilling to enter</p> <p>-Randomized to tight control of BP (n=758) (goal of $<150/85$ mmHg with use of angiotensin converting enzyme inhibitor or β blocker) or less tight control (n=390) (goal of $<180/105$ mmHg without inhibitors or blockers)</p> <p>-Clinic visits and evaluations as described in UKPDS 33</p> | <p>-Median follow-up: 8.4 yrs (14 emigrated, 33 could not be contacted)</p> <p>-Mean blood pressure over 9 yrs of follow-up in 297 from tight control group was 144/82 mmHg and 154/87 mmHg in 156 from less tight control group (p<0.0001); over time an increasing number of antihypertensive agents were required to maintain blood pressure below target levels</p> <p>-HbA1c comparable in both groups over the follow-up period</p> <p>-Compared to less tight control group, the tight control group had:</p> <p>a. a 24% reduction in risk of developing any diabetes-related end point (p=0.0046)</p> <p>b. a 32% reduction in risk of diabetes-related mortality (p=0.019) and a non-significant 18% reduction in risk of all-cause mortality</p> <p>c. a non-significant 21% reduction in risk for MI and a 44% reduction in risk of stroke (p=0.013) (overall a 34% reduction in risk of macrovascular disease; p=0.019)</p> <p>d. a 37% reduction in risk of microvascular disease (p=0.0092)</p> <p>e. a 56% reduction in risk of heart failure (p=0.0043) and a 35% reduction in risk of retinal photocoagulation (p=0.023)</p> <p>-Compared to less tight control group: 34% reduction in risk of retinopathy (p=0.004) and 47% reduction in risk of decrease in vision (p=0.004)</p> <p>-No significant difference in cumulative incidence of hypoglycemia between groups; weight gain similar</p> | <p>-Treatment with an angiotensin converting enzyme inhibitor or β blocker aiming for a blood pressure of $<150/85$ mmHg substantially reduces the risk of death and complications due to diabetes. Management of blood pressure should have a high priority in the treatment of type 2 diabetes.</p> |

**Conclusion Grading Worksheet – Appendix B –
Annotation #31 (Diabetes Screening – General Population)**

| Author/Yr | Design Type | Class | Quality | Population Studied/Sample Size | Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat) | Authors' Conclusions/ <i>Work Group's Comments (italicized)</i> |
|---|-------------|-------|---------|--|--|---|
| UK Prospective Diabetes Study Group (1998) (UKPDS 39) | RCT | A | +, -, 0 | -Subset of UKPDS 38 (758 patients randomized to tight control of BP) -400 patients randomly assigned to captopril (an angiotensin converting enzyme inhibitor) and 358 to atenolol (a β blocker); captopril dose started at 25 mg 2X per day increasing to 50 mg 2X per day; atenolol started at daily dose of 50 mg and increased to 100 mg if required; if BP criteria not met other agents added | -2 groups had same mean BP (159/93 mmHg) at randomization; reduction in BP over 9 yrs similar (to 144/83 mmHg in captopril group and to 143/81 mmHg in atenolol group) -Compliance with allocated tx similar over the first 4 yrs of follow-up but more patients in atenolol group discontinued tx (p<0.0001) (most because of impaired peripheral circulation or bronchospasm); captopril withdrawn for 5 patients because of elevated creatinine concentration; patients assigned captopril took tx for 80% of total person yrs of follow-up (74% for atenolol group) -No difference in incidence of end points related to diabetes (including micro- and macrovascular complications); incidence of diabetic deaths and all-cause mortality also similar -No difference in incidence of any microvascular or macrovascular disease endpoint (including retinal photocoagulation, progression to renal failure, amputation, heart failure, or angina) -No difference in progression to retinopathy, deterioration of visual acuity, progression of albuminuria, plasma creatinine concentration, silent infarction or other electrocardiogram abnormalities -Patients allocated to atenolol had higher HbA1c over first 4 yrs of follow-up but no differences over second 4 yrs (after 4 yrs 66% of those allocated to atenolol were receiving additional glucose lowering tx compared to 53% in those allocated to captopril, p=0.0015; difference was also present at 8 yrs - 81% vs. 71%, p=0.029) -No difference in rates of hypoglycemia -Greater weight gain in atenolol group (p=0.02) -No consistent trends in triglyceride concentrations -Development of cold feet, intermittent claudication, or bronchospasm in patients allocated to atenolol accounted for lower compliance; similar proportion of patients developed peripheral vascular disease, had absent foot pulses, or had amputations | -Atenolol and captopril are equally effective and safe in lowering blood pressure and reducing risk of fatal and nonfatal macrovascular and microvascular complications in patients with type 2 diabetes. |

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
 - Measurement Specifications
- Recommended Website Resources
- Key Implementation Recommendations

Priority Aims and Suggested Measures

1. Increase the percentage of patients who are up-to-date on preventive services.

Possible measure of accomplishing this aim:

- a. Percentage of patients who are up-to-date on preventive services.

2. Increase the percentage of services up-to-date.

Possible measure of accomplishing this aim:

- a. Percentage of preventive services that are up-to-date.

3. Increase regular use of health risk assessments.

Possible measures of accomplishing this aim:

- a. Percentage of patients who have a current risk assessment tool in their medical record.
- b. Percentage of patients seen in the clinic who have a completed risk assessment tool in their medical record.

The measure of services up-to-date (aim #2) assists member groups in developing processes to make progress toward aim #1. Therefore, when measuring aim #2 member groups should also be reporting aim #1.

Measurement Specifications

Possible Success Measure #1a

Percentage of patients who are up-to-date for the ten key preventive services.

Population Definition

Medical groups may choose to specify age parameters to simplify measurement.

Data of Interest

of patients up-to-date for ten key preventive services

Total # of patients who present in the clinic for a non-emergent primary care visit

Numerator/Denominator Definitions

Numerator: A patient must be up-to-date on all applicable preventive services to meet the criteria. For a service to be counted as provided, it should be documented with a date of service. If the medical record documents that the service was offered to the patient and the patient declined the test or procedure, that it should be counted as a "yes" to the criteria.

Denominator: Patients who present in the clinic for a non-emergent primary care visit. Some medical groups may choose to calculate a measurement on the entire clinic population.

Method/Source of Data Collection

Patients who have had an office visit of any kind within the preceding month can be randomly sampled to produce a sample of at least 20 records for review. Selected records are audited using the checklist tool to determine a patient's status on each of the preventive services listed.

Time Frame Pertaining to Data Collection

Data can be collected monthly.

Notes

This measure has been collected concurrently with measure 2a by some medical groups. While it is a better measure of the overall preventive services delivery system, it will however change more slowly over time and can be frustrating as an improvement measure. Up-to-date rates by service will show improvement earlier and faster than the up-to-date rates by patient.

Probing Measures

Measure #2a is composed of essential component preventive services. For probing measure purposes, that measure may be further analyzed to identify the completion rate for each specific service component. This analysis would identify services for which the medical group is performing well and those services which present an opportunity for improvement. Performance results for component services may also be broken down by site or department or by age group or gender to produce information to guide improvement activities.

Another useful probing measure would be the frequency with which measures recommended to consider discontinuing are still being done.

Other Options for Measurement

Use the same approach with specified age groups such as 19-64 or 65+ looking at services specific to them.

Data Collection Worksheet

Auditor: _____

Date: _____

| Audit Item | Pt. #1 | Pt. #2 | Pt. #3 | Pt. #4 | Pt. #5 | Total #+ /#+ and 0 |
|---|--------|--------|--------|--------|--------|-----------------------|
| Age | | | | | | / |
| Gender | | | | | | / |
| BP in the last 2 years | | | | | | / |
| if BP abnormal, advice | | | | | | / |
| Tobacco use noted at last visit, or identified as non-user overall | | | | | | / |
| If tobacco user, quitting discussed at last visit | | | | | | / |
| Tetanus booster < 10 yr | | | | | | / |
| Influenza 50+ yrly | | | | | | / |
| Pneumovax 65+ once | | | | | | / |
| Cholesterol Total < 5 yrs. (males older than 34) | | | | | | / |
| HDL < 5 yrs. (females older than 44) | | | | | | / |
| Colon cancer screen < 5 yrs if 50-80 yrs | | | | | | / |
| WOMEN ONLY | | | | | | |
| Clinical breast exam 20-39 < 3 yrs; yearly 40+ | | | | | | / |
| Mammography every 1-2 years if 50-75 | | | | | | / |
| Cervical Pap smear q 3 yrs 18-65 | | | | | | / |
| Percent up-to-date N= total # of + designations D= total # of 0 and + marks | | | | | | / |

Enter + if there is documentation the service has been done.

Enter 0 if **not** done. (If there is no information about a service, assume it has not been done.)

Enter N/A if not applicable because of sex or age OR there is documentation that the patient refused this screening.

Data Collection Worksheet Definitions

1. > = greater or more than < = fewer or less than
2. **Risk Assessment** = completion of a form that assesses risks listed in the Preventive Counseling and Education guideline and the latest date of receipt of other services.
3. **Preventive Counseling** = completion of a form documenting discussion or giving written information or referral to health educator for ANY ONE OR MORE of the risk areas assessed as present.
4. **Tobacco discussion** = any evidence that a current tobacco user was given advice to quit or was assessed for readiness to quit.
5. **Cholesterol** = determine if only a total cholesterol was done or if the test included HDL-cholesterol determination; males 35-75, females 45-75.
6. **Possible screening pathways** = flexible sigmoidoscopy every 5 years or FOBT annually or combination of flex sig every 5 years and FOBT annually, or total colon evaluation.
7. Female patient records need to show evidence of at least 1 cervical Pap smear test within a 3-year period for patients 18-65.
8. Female patient records 20-39 years need to show evidence of clinical breast exam once every 3 years; patients age 40+ should show evidence of this exam annually.
9. Annual to biennial mammography done for female patients 50-75.

Recommended Website Resources

The websites were viewed by the ICSI *Preventive Services for Adults* guideline work group as credible resources. ICSI does not have the authority to monitor the content of these sites. Any health-related information offered from these sites should not be interpreted as giving a diagnosis or treatment.

| Website Sponsor | Target Audience | Description | Website Address |
|--|-----------------------------------|---|---|
| Agency for Health Research and Quality | Consumers Health Professionals | The Guide to Clinical Preventive Services provides the latest available recommendations on preventive interventions: screening tests, counseling, and immunizations, for more than 80 conditions. The 3rd Edition, 2000-2002, updates recommendations from the 2nd Edition and evaluates new topics. Reviews and recommendations will be released as they are completed. These recommendations are made by the U.S. Preventive Services Task Force. | http://www.ahrq.gov/clinic/prevnew.htm |
| Centers for Disease Control | Consumers Health Professionals | Comprehensive site provides information on immunizations and CDC prevention guidelines. | http://www.cdc.gov |
| U.S. Department of Health and Human Services | Consumers Health Professionals | Comprehensive site provides information on Healthy People 2010. Leading health indicators, guidelines, data and health information is given. | http://www.healthypeople.gov |

Criteria for Selecting Websites

The preceding websites were selected by the *Preventive Services for Adults* guideline work group as additional resources for practitioners and the public. The following criteria were considered in selecting these sites.

- The site contains information specific to the particular disease or condition addressed in the guideline.
- The site contains information that does not conflict with the guideline's recommendations.
- The information is accurate and/or factual. The author of the material or the sponsor of the site can be contacted by means other than e-mail. For example, a nurse line or other support is provided.
- The material includes the source/author, date and whether the information has been edited in any way. The site clearly states revision dates or the date the information was placed on the internet.
- The site sponsor is an objective group without an obvious or possible bias. For example, the site does not promote a product, service or other provider.
- The coverage of the topic is appropriate for the guideline's target audience. It is clearly written, well-organized and easy to read. The site is easy to navigate.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

Clinics are encouraged to initiate a system by which:

1. Patients complete a risk assessment questionnaire prior to preventive visits.
2. The results of the questionnaire are used to identify needs for counseling and other preventive services.
3. The provision of needed preventive services are documented and monitored.
4. Patients behind in their preventive visit schedule are identified at routine office visits.