Complete Summary

GUIDELINE TITLE

Recommendations from the American Cancer Society Workshop on Early Prostate Cancer Detection, May 4-6, 2000 and ACS guideline on testing for early prostate cancer detection: update 2001. In: American Cancer Society guidelines for the early detection of cancer.

BIBLIOGRAPHIC SOURCE(S)

Recommendations from the American Cancer Society Workshop on Early Prostate Cancer Detection, May 4-6, 2000 and ACS guideline on testing for early prostate cancer detection: update 2001. CA Cancer J Clin 2001 Jan-Feb;51(1):39-44. [181 references]

Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2003. CA Cancer J Clin 2003 Jan-Feb;53(1):27-43. [57 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previous version: von Eschenbach A, Ho R, Murphy GP, et al. American Cancer Society guideline for the early detection of prostate cancer: update 1997. CA Cancer J Clin 1997 Sep-Oct;47(5):261-4.

Each year the American Cancer Society publishes a summary of existing recommendations for early cancer detection, including updates, and/or emerging issues that are relevant to screening for cancer.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Prostate cancer

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Oncology
Preventive Medicine
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the 1997 American Cancer Society guideline pertaining to prostate cancer screening
- To offer recommendations to health care professionals and the public for informed decision-making related to early detection of prostate cancer

TARGET POPULATION

- Men aged 50 years and older who have a life expectancy of at least 10 years and younger men who are at high risk for prostate cancer
- Men aged 45 years and older of Sub-Saharan African descent or with a first-degree relative diagnosed at a young age
- Men 40 and older with multiple first-degree relatives diagnosed with prostate cancer at an early age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Prostate-specific antigen (PSA) blood test
2. Digital rectal examination (DRE)
3. Prostate-specific antigen density and percentage of free prostate-specific antigen
4. Information provided to patients about prostate cancer and the potential benefits and risks associated with prostate cancer screening
5. Supportive strategies for men and their health care providers for informed decision-making

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality related to prostate cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Workshop participants revisited the historical evidence, but focused especially on research findings since 1997 and studies now underway. During the current guideline review, published articles related to prostate cancer detection, risk, and risk factors were identified using MEDLINE (National Library of Medicine) for the years 1995 through 2000, bibliographies of identified articles, and from the personal files of the advisory group and expert panel members.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Following the May 2000 workshop, a writing committee assembled by the workshop chairs discussed recent evidence and recommendations from the three workgroups for guideline modification, which were then decided by consensus. Each member reviewed the draft of this manuscript.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not stated

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

In May 2000, the American Cancer Society (ACS) convened a workshop to review data accumulated since 1997, and update guidelines for prostate cancer testing. Following the workshop, a writing committee assembled by the workshop chairs discussed recent evidence and recommendations from the three workgroups for guideline modification, which were then decided by consensus. Each member reviewed a draft of the guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC):

The prostate-specific antigen (PSA) test and the digital rectal examination (DRE) should be offered annually beginning at age 50 to men who have a life expectancy of at least 10 years. Men at high risk should begin testing at age 45. Information should be provided to patients about benefits and limitations of testing. Specifically, prior to testing, men should have an opportunity to learn about the benefits and limitations of testing for early prostate cancer detection and treatment.

Men who ask the clinician to make the testing decision on their behalf should be tested. A clinical policy of not offering testing, or discouraging testing in men who request early prostate cancer detection tests, is inappropriate.

High-risk groups include men of African descent (specifically, sub-Saharan African descent) and men with a first-degree relative diagnosed at a young age. Risk increases with the number of first-degree relatives affected by prostate cancer. The workgroup recommended that these men begin testing for early prostate cancer detection at age 45. Among men of African descent, age-specific risk increases steadily beginning at age 45. Men at appreciably higher risk of prostate cancer due to multiple first-degree relatives who were diagnosed with prostate cancer at an early age could begin testing at age 40. However, if prostate-specific antigen is less than 1.0 ng/ml, no additional testing is needed until age 45. If prostate-specific antigen is greater than 1.0 ng/ml but less than 2.5 ng/ml, annual testing is recommended. If prostate-specific antigen is 2.5 ng/ml or greater, further evaluation with biopsy should be considered. Men at high risk also should be informed about the benefits, limitations, and uncertainties associated with testing for early prostate cancer detection.

Prostate Cancer Early Detection Tests

Measurement of serum prostate-specific antigen level is the most accurate method for the detection of prostate cancer and is superior to digital rectal examination. Nevertheless, digital rectal examination should be included in testing whenever appropriate. The positive predictive value of an abnormal digital rectal examination in patients with low prostate-specific antigen levels (i.e., 1.0 ng/ml) is very low and does not warrant further evaluation. In men for whom digital rectal examination is an obstacle to testing, prostate-specific antigen alone is an acceptable alternative.

Since prostate-specific antigen is prostate-tissue specific and not prostate-cancer specific, there is no absolute value that is applicable to all men. The range of "normal" prostate-specific antigen levels has conventionally been considered to be between zero and 4.0 ng/ml. A lower cut-off value of 2.5 ng/ml has been shown to improve the early detection of organ-confined prostate cancers; however, this also increases the number of men undergoing biopsy in whom no cancer is detected.

Age-specific reference ranges and prostate-specific antigen density (amount/volume) have been employed to improve specificity. Because prostate-specific antigen is prostate-tissue specific and not prostate-cancer specific, elevations of prostate-specific antigen into the "abnormal" range may occur due to benign prostatic hyperplasia or prostatitis. Benign prostate tissue produces a higher percentage of free prostate-specific antigen than does cancerous tissue.

This biologic observation can be used to improve the predictive value of the test in men with elevated total prostate-specific antigen levels. For men with prostate-specific antigen results between 4.0 and 10.0 ng/ml, restricting transrectal ultrasound-guided biopsy to men with less than 20% free-prostate-specific antigen improves testing accuracy. Applying this strategy to men with prostate-specific antigen levels between 2.5 and 10.0 ng/ml may lead to detection of early

disease in a larger number of men and may result in a lower biopsy rate compared with older strategies.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Mortality decrease: Among men prostate cancer is the most common cancer diagnosed, and the second leading cause of death from cancer. Prostate cancer five-year survival is nearly 100% when the disease is diagnosed at a local or regional stage, but poor when diagnosed with distant metastases (32.6%). International data were presented that are consistent with an association between prostate cancer testing and reduced prostate cancer mortality.

Subgroups Most Likely to Benefit:

Men of African descent (specifically, sub-Saharan African descent) and men with a first-degree relative diagnosed at a young age.

POTENTIAL HARMS

Since prostate-specific antigen is prostate-tissue specific and not prostate-cancer specific, there is no absolute value that is applicable to all men. The range of "normal" prostate-specific antigen levels has conventionally been considered to be between zero and 4.0 ng/ml. A lower cut-off value of 2.5 ng/ml has been shown to improve the early detection of organ-confined prostate cancers; however, this also increases the number of men undergoing biopsy in whom no cancer is detected.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- No direct evidence exists to date to show that prostate-specific antigen (PSA) screening decreases prostate cancer mortality rates.
- International data were presented that are consistent with an association between prostate cancer testing and reduced prostate cancer mortality. Although randomized trial data confirming a reduction in mortality as a result

of testing are not yet available, the consensus of the workshop participants was that evidence indicating a benefit from testing is significantly stronger today than it was in 1997.
- Since prostate-specific antigen is prostate tissue-specific and not prostate cancer-specific, there is no absolute value that is applicable to all men.
- Screening individuals outside of the clinical arena, for example, in community settings or health fairs, is only warranted if patients have the opportunity to participate in an educational process and to discuss their decision with a clinician. The advisory group believes that individuals are more likely to discuss these issues freely with their own clinicians and recommends that testing for early prostate cancer detection should occur within the context of the patient's usual clinical care.
- The new guideline represents a stronger recommendation than was issued in the 1997 update. Because the potential benefits of early detection must be balanced against the potential risks, the new guideline is consistent with the 1997 guideline insofar as it is not a recommendation for mass screening for prostate cancer in average-risk men. Rather, it is an endorsement that men should have an opportunity to be tested and should actively participate in the testing decision. However, by including "should" in the recommendation, the American Cancer Society is more clearly stating that asymptomatic men age 50 and older ought to have an annual opportunity to make an informed decision about testing for early prostate cancer detection. For this reason, the Advisory Group felt that it is improper to discourage testing or not to offer testing.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Recommendations from the American Cancer Society Workshop on Early Prostate Cancer Detection, May 4-6, 2000 and ACS guideline on testing for early prostate cancer detection: update 2001. CA Cancer J Clin 2001 Jan-Feb;51(1):39-44. [181 references]

Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2003. CA Cancer J Clin 2003 Jan-Feb;53(1):27-43. [57 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001

GUIDELINE DEVELOPER(S)

American Cancer Society - Disease Specific Society

SOURCE(S) OF FUNDING

American Cancer Society

GUIDELINE COMMITTEE

American Cancer Society Prostate Cancer Guidelines Review Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Participants in American Cancer Society Prostate Cancer Guidelines Review: Andrew von Eschenbach, MD (chair), University of Texas M.D., Anderson Cancer Center; Richard C. Wender, MD (co-chair), Thomas Jefferson University; Gerald L. Woolam, MD (co-chair), Immediate Past President, American Cancer Society; Richard Atkins, MD, National Prostate Cancer Coalition; Richard Babaian, MD, University of Texas M.D. Anderson Cancer Center; Georg Bartsch, MD, University of Innsbruck; Peter Boyle, PhD, European Institute of Oncology, Milan; Michael Brawer, MD, Northwest Prostate Institute; Otis Brawley, MD, National Cancer Institute; Bernard Candas, PhD, CHUL Research Center, Quebec City; William Catalona, MD, Washington University; Gerald Chodak, MD, Louis Weiss Memorial Hospital; Ralph Coates, PhD, Centers for Disease Control and Prevention; Vilma Cokkinides, PhD, American Cancer Society; E. David Crawford, MD, University of Colorado; Harmon Eyre, MD, American Cancer Society; Lewis Foxhall, MD, University of Texas M.D. Anderson Cancer Center; Ben Hankey, ScD, National Cancer Institute; Thomas Houston, MD, American Medical Association; Richard

Howe, PhD, Houston, Texas; Peter Humphrey, MD, MPH, Washington University School of Medicine; Steven Jacobsen, MD, Mayo Clinic; Neal Kohatsu, MD, MPH, American College of Preventive Medicine; Fernand Labrie, MD, CHUL, Research Center, Quebec City; *Kenneth Martin-Shultz, MD, PhD EAGLE Associates, Brooklyn Heights, Ohio; LaMar McGinnis, MD, FACS American Cancer Society; Curtis Mettlin, PhD, Roswell Park Cancer Institute; Edmond Paquette, MD, Walter Reed Army Medical Center; Hank Porterfield, US TOO International, Inc.; *Isaac Powell, MD, Wayne State University; Mack Roach, III, MD, University of California, San Francisco; Carmen Rodriguez, MD, American Cancer Society; Fritz Schroeder, MD, Erasmus University, Rotterdam; Robert A. Smith, PhD, American Cancer Society; Vincenza Snow, MD, American College of Physicians-American Society of Internal Medicine; Hugh Stallworth, MD, MPH American Cancer Society; Robert Stephenson, MD, University of Utah; Ian Thompson, MD, University of Texas Health Sciences Center at San Antonio; *Andrew Wolf, MD, University of Virginia School of Medicine; Steven Woolf, MD, MPH, Virginia Commonwealth University

* Member, American Cancer Society Advisory Group on Prostate Cancer

Additional Members, American Cancer Society Advisory Group on Prostate Cancer: Freeman Bradley, San Mateo, California; Jenny Cook, Past Officer Director, American Cancer Society; Thomas Fogel, MD, Cabrillo Radiation Oncology Center, Ventura, California; M. Regina Martinez, RN, BSN, Albuquerque, New Mexico; Abraham Mittleman, MD, New York Medical College; Bill Winans, Bridgeport, New York

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previous version: von Eschenbach A, Ho R, Murphy GP, et al. American Cancer Society guideline for the early detection of prostate cancer: update 1997. CA Cancer J Clin 1997 Sep-Oct;47(5):261-4.

Each year the American Cancer Society publishes a summary of existing recommendations for early cancer detection, including updates, and/or emerging issues that are relevant to screening for cancer.

GUIDELINE AVAILABILITY

Print copies: Available from the American Cancer Society, 1599 Clifton Rd NE, Atlanta, GA 30329; Web site: www.cancer.org.

AVAILABILITY OF COMPANION DOCUMENTS

These guidelines are published as a component of the following:

- Smith RA, von Eschenbach AC, Wender R, Levin B, Byers T, Rothenberger D, Brooks D, Creasman W, Cohen C, Runowicz C, Saslow D, Cokkinides V, Eyre

H. American Cancer Society guidelines for the early detection of cancer: update of early detection guidelines for prostate, colorectal and endometrial cancers. Also: update 2001-testing for early lung cancer detection. CA Cancer J Clin 2001 Jan-Feb;51(1):38-75.

Print copies: Available from the American Cancer Society, 1599 Clifton Rd NE, Atlanta, GA 30329; Web site: www.cancer.org.

PATIENT RESOURCES

The following is available:

- Guidelines for the Early Detection of Cancer. Available from the American Cancer Society (ACS) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on April 29. 2001. The information was verified by the guideline developer as of September 10, 2001.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 10/6/2008