General

Guideline Title

Recommendations on screening for prostate cancer with the prostate-specific antigen test.

Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


A complete list of planned reviews, updates and revisions is available under the What’s New section at the Canadian Task Force on Preventive Health Care Web site.

This guideline meets NGC’s 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The grades of recommendations (strong, weak) and grades of evidence (high, moderate, low, very low) are defined at the end of the "Major Recommendations" field.

The recommendations apply to all men without a previous diagnosis of prostate cancer.

For men aged less than 55 years, the Task Force recommends not screening for prostate cancer with the prostate-specific antigen (PSA) test. (Strong recommendation; low-quality evidence)
For men aged 55–69 years, the Task Force recommends not screening for prostate cancer with the PSA test. (Weak recommendation; moderate-quality evidence)
For men 70 years of age and older, the Task Force recommends not screening for prostate cancer with the PSA test. (Strong recommendation; low-quality evidence)

Definitions:
Quality of Evidence

<table>
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Grading of Recommendations

Strong recommendations are those for which the Task Force is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). A strong recommendation implies that most people will be best served by the recommended course of action.

Weak recommendations are those for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or the undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists. A weak recommendation implies that most men would want the recommended course of action but that many would not. For clinicians, this means they must recognize that different choices will be appropriate for each person, and they must help each patient arrive at a management decision consistent with his values and preferences. Policy-making will require substantial debate and involvement of various stakeholders. Weak recommendations result when the balance between desirable and undesirable effects is small, the quality of evidence is lower, or there is more variability in the values and preferences of patients.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Prostate cancer

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Oncology
Intended Users
Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

Guideline Objective(s)
To provide recommendations on screening for prostate cancer using the prostate-specific antigen (PSA) test with or without digital rectal examination in men in the general population

Target Population
Men in the general population, including men with lower urinary tract symptoms (e.g., nocturia, urgency, frequency and poor stream) and those with benign prostatic hyperplasia

Interventions and Practices Considered
Screening for prostate cancer using the prostate-specific antigen (PSA) test (not recommended)

Major Outcomes Considered
- Sensitivity and specificity of the tests
- Mortality
  - Prostate cancer mortality
  - All-cause mortality
- Survival ratio

Methodology

Methods Used to Collect/Select the Evidence
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence
Note from the National Guideline Clearinghouse (NGC): A systematic review was prepared by the Evidence
Review and Synthesis Centre (ERSC) at McMaster University for the Canadian Task Force on Preventive Health Care (CTFPHC) (see the "Availability of Companion Documents" field).

The ERSC at McMaster University (Hamilton, Ont.) conducted a systematic review of the available evidence with the aid of a urologist, who served as an independent technical advisor, and scientific staff at the Public Health Agency of Canada. The systematic review was done according to the final, peer-reviewed protocol (see the "Availability of Companion Documents" field) of the analytical framework and followed the methods described in the procedure manual (see the "Availability of Companion Documents" field). Because a previous search by the U. S. Preventive Services Task Force (USPSTF) was used to identify data, the timeline to review the benefits of screening was extended from the time of the previous search by the USPSTF until August 15, 2014, to include eligible trials that reported extended follow-up. Databases searched included PubMed, Ovid MEDLINE, MEDLINE, the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.

Search Strategy

The search updated those conducted for the USPSTF reviews for screening and treatment of prostate cancer. The ERSC searched MEDLINE, MEDLINE In-process and Other Non-Indexed Citations, The Cochrane Control Trial Registry, EMBASE and PubMed for studies published between July 2011 and November 2012 (treatment) and July 2011 to November 2013 (screening). The search was limited to languages of English and French but was not limited by study design. They also searched reference lists of on-topic systematic reviews. The search identified 6704 unique citations of which 40 new papers met the inclusion criteria for this review and as such were added to the studies included in the USPSTF reviews.

A separate search was conducted for contextual questions. The ERSC searched MEDLINE, EMBASE and PsycINFO for studies published between January 2007 and November 2012. The search strategy is reported in Appendix 1 (see the systematic review document [see the "Availability of Companion Documents" field]). To ensure that all the harms of screening of interest to the Prostate Working Group were available, the ERSC undertook a separate search. The databases searched included MEDLINE, The Cochrane Library and EMBASE for January 2000 to November 2013 (see Appendix 1 in the systematic review).

Inclusion/Exclusion Criteria

Screening

For inclusion in this review the population of interest was men asymptomatic for prostate cancer (although men with chronic, mild lower urinary tract symptoms were included). The intervention of interest was one or more prostate-specific antigen (PSA) measurements, with or without additional methods such as digital rectal examination. The comparison was to no screening/usual care in the asymptomatic general primary care population. Men who had previous PSA screens were not excluded. The outcomes for effectiveness were all-cause or prostate cancer-specific mortality, or harms associated with screening. Harms of screening included false positives, overdiagnosis/overtreatment, and post biopsy harms such as infection, bleeding, composite medical harms, and hospitalization. Study design for assessing effectiveness of screening was limited to randomized control trials (RCTs). There were no limitations on study design for the harms outcomes.

Treatment

The population of interest was men treated for screen-detected prostate cancer. Because most studies do not describe whether the prostate cancer was screen detected, studies of localized (T1 or T2) prostate cancer were also included (as most screen-detected cancer is localized). The treatments of interest were radical prostatectomy, radiation therapy, hormonal therapy, cryotherapy, and high-intensity focused ultrasonography (HIFU). Control treatments defined in the included studies were: observation (no immediate treatment), deferred treatment (no initial treatment for 6 months following diagnosis), and conservative management (non-curative treatment which could include hormone therapy or palliative therapy). Because of the lack of detail in the studies, it is unclear if these control treatments were active surveillance (continued PSA monitoring) or watchful waiting (monitoring for symptom progression). The
outcomes of interest were all-cause mortality, prostate cancer-specific mortality, and harms associated with prostatectomy, radiation therapy, hormonal therapy, cryotherapy, and HIFU. The harms of interest included mortality, reduced quality of life or function, increased urinary incontinence, bowel dysfunction, erectile dysfunction, surgical complications, and 30 day post-surgical complications. Acceptable study designs included RCTs and cohort studies. If no RCTs, cohort studies, or large (n>1,000) uncontrolled studies were available, smaller uncontrolled studies were used. For harms, uncontrolled observational studies were included if they reported on perioperative harms.

Number of Source Documents

• Key Question 1: 6 randomized controlled trials (RCTs) (15 papers)
• Key Question 2: 38 observational (39 papers)
• Key Question 3: 3 RCTs (11 papers); 11 observational (13 papers)
• Key Question 4: 0 papers
• Key Question 5: 3 RCTs (4 papers); 15 observational (16 papers); 9 non-controlled (10 papers)

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic review was prepared by the Evidence Review and Synthesis Centre (ERSC) at McMaster University for the Canadian Task Force on Preventive Health Care (CTFPHC) (see the "Availability of Companion Documents" field).

Selection

The titles and abstracts of papers considered for the key questions were reviewed independently by two members of the synthesis team; any article marked for possible inclusion by either team member went on to full-text rating. Full-text inclusion, quality assessment and data extraction were also completed by two team members. All disagreements were resolved through discussions. The inclusion results were reviewed by a third investigator. Data were extracted by one investigator using a standard format with this extraction being checked by a second investigator. The exceptions to this process were studies related to the contextual questions and grey literature, for which title and abstract screening and data extraction
were done by one investigator. There was no assessment of the quality of the evidence used to answer the contextual questions. The flow diagram of included studies in reported in Appendix 2 of the systematic review.

Quality Assessment

The strength of the evidence supporting the key questions was assessed through the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system which grades the quality of evidence as high, moderate, low or very low. Each of the four levels reflects the likelihood that further research will impact the estimate of effect (e.g., high quality: further research is unlikely to change confidence in the estimate of effect). A GRADE quality rating is based on an assessment of five conditions: (1) limitations in study designs (risk of bias), (2) inconsistency (heterogeneity) in the direction and/or size of the estimates of effect, (3) indirectness of the body of evidence to the populations, interventions, comparators and/or outcomes of interest, (4) imprecision of results (few events/observations, wide confidence intervals), and (5) indications of reporting or publication bias. Each of these components is rated as high, low or unclear risk of bias. In order to achieve a high or low risk of bias for a particular component the ERSC looked for explicit statements from the authors as to what they did or did not do methodologically. In the absence of information they assessed that component as "unclear". To determine the overall risk of bias they placed a higher value on random sequence generation, allocation concealment and blinding. As well, components assessed as unclear were considered equivalent with high risk of bias. The Cochrane Risk of Bias tool was used to assess risk of bias in the randomized control trials (RCTs), and the Newcastle Ottawa Scale was used for the cohort studies. Therefore RCTs which in GRADE begin with a high quality rating may be downgraded if there were serious or very serious concerns across the studies related to one or more of the five conditions. Quality ratings can also be upgraded based on an assessment of three conditions: (1) large effect size, (2) dose response effect, and (3) plausible confounding. All groups of observational studies begin with a low quality rating which were further downgraded based on assessments of the same five criteria. All other types of evidence were assigned a very low quality rating.

Data Analysis

For the benefits of prostate-specific antigen (PSA)-based screening, the results were synthesized descriptively using median with ranges, since the studies were methodologically and clinically too different from each other to allow for a quantitative synthesis of data. The results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) trial for the outcome of prostate cancer-specific mortality were separated based on screening interval, as all centers except Sweden used a 4 year screening interval while the Swedish center (Göteborg) used a 2 year screening interval. For the harms of PSA-based screening, the results were reported descriptively using proportions (%) with 95% confidence intervals, since the data were primarily obtained from uncontrolled or modelling studies.

For benefits and harms of treatments of localized prostate cancer, the preferred measure was the number of events from each intervention group (radical prostatectomy, radiotherapy, hormonal therapy) compared to control group in the meta-analysis. The DerSimonian and Laird random effects models with inverse variance method were utilized to generate the summary measures of effect in the form of risk ratio for each outcome. The risk ratio was used as a summary statistic because only a few studies reported the time-to-event data or hazard ratios, and adjustment of various factors along with length of follow-up varied across studies reporting hazard ratios. In this situation, it was necessary to utilize the number of events data to maximize the number of included studies in quantitative synthesis and to provide statistical stability. For studies where events data were not reported for each intervention arm, the ERSC contacted the authors. Two of the studies reported survival, and therefore the number of deaths was estimated from the survival proportion/percentage provided using Kaplan-Meier curves.

To compare the direction and magnitude of effect obtained from risk ratios (RR) using events data for mortality outcomes, the ERSC also pooled adjusted hazard ratios (HR's) reported in papers using DerSimonian and Laird random effects models with inverse variance method, and no significant differences were found between results obtained from risk ratios and hazard ratios. The Cochrane's Q
(α=0.10) and $I^2$ statistic were employed to quantify the statistical heterogeneity between studies, where p<0.10 indicated a high level of statistical heterogeneity between studies. Sensitivity analyses were performed on the type of intervention, study design, and study risk of bias to evaluate statistical stability and effect on statistical heterogeneity.

In order to investigate the clinical relevance of the results, the number needed to screen/treat (NNS/NNT) and the absolute risk reductions were generated. NNS/NNT were calculated by taking the inverse of the risk difference between the control and intervention groups. The direction of effect was presented with the corresponding 95% confidence interval. NNS/NNT were only presented when the estimate of effect (RR) showed a statistically significant effect.

Methods Used to Formulate the Recommendations

Other

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): A systematic review was prepared by the Evidence Review and Synthesis Centre (ERSC) at McMaster University for the Canadian Task Force on Preventive Health Care (CTFPHC) (see the "Availability of Companion Documents" field).

The CTFPHC is an independent panel of volunteer clinicians and methodologists that makes recommendations about clinical manoeuvres aimed at primary and secondary prevention (www.canadiantaskforce.ca). Work on each set of recommendations is led by a workgroup of two to six members of the Task Force. Each workgroup establishes the research questions and analytical framework for the guideline. More information about the Task Force's methods can be found in the CTFPHC methods manual (see the "Availability of Companion Documents" field).

The development of these recommendations was led by a workgroup of six members of the Task Force and scientific staff at the Public Health Agency of Canada. Guideline development was based on an analytical framework (see below) that established the overall purpose and background of the guideline, framed the literature review and outlined the key and contextual research questions. The key and contextual questions in the analytical framework examined the benefits and harms of prostate-specific antigen (PSA) screening with or without digital rectal examination and the benefits and harms of treatment of prostate cancer on decreasing prostate cancer mortality and all-cause mortality.

Analytical Framework and Key Questions

Key Questions

What is the direct evidence that screening for prostate cancer with PSA, as a single-threshold test or as a function of multiple tests over time, decreases prostate cancer specific and all-cause mortality?

1b. Is there evidence to support differential screening based on individual risk factors for prostate cancer such as age, African descent, family history of prostate cancer or previously assessed increased PSA values – either absolute values or increased PSA measures over time?

What are the harms of PSA-based screening for prostate cancer?

What are the benefits of treatment of early-stage or screen-detected prostate cancer?

Is there evidence that tailoring the method of following up abnormal screening results to patient characteristics (example: active surveillance vs. treatment A vs. B) lead to clinically important differences in the harms and benefits of screening with PSA?

What are the harms of treatment of early-stage or screen-detected prostate cancer?

Contextual Questions

Contextual questions will be addressed in two stages, depending on whether evidence of PSA test
screening performance of screening is identified.

**Stage One**

Question that is necessary to assist in making a decision about the direction of the recommendation:

What are the patient values and preferences for PSA screening for prostate cancer?

**Stage Two**

If evidence of effectiveness is sufficient for the Task Force to recommend screening, the following additional questions will be added:

- What process and outcome performance measures or indicators have been identified in the literature to measure and monitor the impact of PSA screening for prostate cancer?
- What is the optimal screening interval for PSA screening for prostate cancer and should this interval vary based on risk level (e.g., age, prior PSA levels, or other measures such as Gleason score)?
- What are the most effective (accurate and reliable) risk assessment tools to identify: a) risk of prostate cancer and b) risk of poor outcomes after PSA testing and biopsy?
- What is the cost-effectiveness of PSA screening asymptomatic adults for prostate cancer? Costs to the system and to patients will be included if found.

**Grading of Recommendations**

Recommendations are graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE offers two strengths of recommendation: strong and weak. The strength of recommendations is based on the quality of supporting evidence, the degree of uncertainty about the balance between desirable and undesirable effects, the degree of uncertainty or variability in values and preferences, and the degree of uncertainty about whether the intervention represents a wise use of resources.

**Rating Scheme for the Strength of the Recommendations**

**Grading of Recommendations**

**Strong recommendations** are those for which the Task Force is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). A strong recommendation implies that most people will be best served by the recommended course of action.

**Weak recommendations** are those for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but uncertainty exists. Weak recommendations result when the balance between desirable and undesirable effects is small, the quality of evidence is lower, and there is more variability in the values and preferences of individuals. A weak recommendation implies that the Task Force believes most people would want the recommended course of action but that many would not. Clinicians must recognize that different choices will be appropriate for different individuals, and they must support each person in reaching a management decision consistent with his/her values and preferences. Policy-making will require substantial debate and involvement of various stakeholders.

**Cost Analysis**

A formal cost analysis was not performed and published analyses were not reviewed.
Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The protocol, systematic review and guideline underwent external peer review by academic and clinical experts.

Table 3 in the original guideline document provides a comparison between the current and previous Task Force guidelines, as well as recommendations from other groups.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Reduced number of false positives, overdiagnosis, and unnecessary treatment

Potential Harms

- False-positive results and diagnosis of indolent tumors with no clinical significance
- Harms of prostate biopsy resulting from a positive prostate-specific antigen (PSA) test result
- Overdiagnosis when cancer is detected correctly but would not cause symptoms or death

See the "Harms of Screening" section in the original guideline document for further information concerning the harms of PSA screening.

Qualifying Statements

Qualifying Statements

- Any use of prostate-specific antigen (PSA) testing to screen for prostate cancer requires a thoughtful discussion between the clinician and the patient about the balance between unclear benefits and substantial harms.
- The views of the funding bodies have not influenced the content of the guideline; competing interests have been recorded and addressed. The views expressed in this article are those of the authors and do not represent those of the Public Health Agency of Canada.
Limitations

The screening randomized controlled trials (RCTs) varied in their screening interval, age range, follow-up period, and PSA threshold for biopsy. Quality of the studies also varied, with three having a low risk of bias and three with a high risk of bias. Of the low risk of bias studies, one study did not have an unscreened population for comparator, but rather compared population based screening to opportunistic screening. This trial reported no effect of screening and therefore the effect of screening may be underestimated.

Implementation of the Guideline

Description of Implementation Strategy

Considerations for Implementation

Patient Values and Preferences

Because of recent efforts to encourage screening for prostate cancer, some men may be interested in prostate-specific antigen (PSA) screening despite the current recommendations. Evidence suggests that a patient’s perceived vulnerability to the disease, as a result of family history or otherwise, and physician recommendation are both associated with patient request for screening with the PSA test. Although high-quality evidence on the best way to facilitate informed decision-making about prostate cancer screening is lacking, such discussions should aim to elicit the knowledge, preferences and values of patients who ask about PSA screening. Many men view screening positively but are unaware of the potential harms. In addition to a focus on the patient’s values and preferences, informed decision-making requires practitioners to distinguish between the benefits and harms of screening, subsequent investigations and treatment, including an overview of diagnostic and therapeutic options in the event that the PSA test result is abnormal.

The Task Force recognizes that some men may place greater value on the potential benefits of screening than on the harms and risks associated with diagnosis and treatment and may choose to be screened with the PSA test. To facilitate informed decision-making about screening for prostate cancer, the Task Force has developed decision aids and tools that are available at www.canadiantaskforce.ca.

The implication of the strong recommendations against screening men less than 55 years of age and those 70 years of age and older is that clinicians should not routinely discuss screening with men in these age groups unless the topic is raised by the patient. The implication of the weak recommendation against screening men aged 55–69 years is that clinicians who believe a patient places a high value on the small potential benefit of screening and is less concerned about the harms may wish to discuss the benefits and harms of screening with the patient so that he can make an informed decision about whether to be screened. Any use of PSA testing to screen for prostate cancer requires a thoughtful discussion between the clinician and the patient about the balance between unclear benefits and substantial harms.

Costs

The Task Force did not consider the costs of screening or treatment of prostate cancer when formulating these recommendations.

Suggested Performance Indicators

Suggested performance measures include rates of PSA testing and subsequent follow-up, and the degree to which men who request screening were accurately informed of the risks and benefits of screening (ideally using an evidence-based decision aid). Incidence and mortality data related to prostate cancer should continue to be monitored at the provincial, territorial and national levels.
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)


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

Date Released
1994 Jun (revised 2014 Nov 4)

Guideline Developer(s)
Canadian Task Force on Preventive Health Care - National Government Agency [Non-U.S.]
Source(s) of Funding

Funding for the Canadian Task Force on Preventive Health Care is provided by the Public Health Agency of Canada and the Canadian Institutes of Health Research.

Guideline Committee

Canadian Task Force on Preventive Health Care (CTFPHC) Guideline Writing Group

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

None of the authors (members of the guideline writing group) have declared competing interests.

Guideline Endorser(s)

College of Family Physicians of Canada - Professional Association

Guideline Status

This is the current release of the guideline.


A complete list of planned reviews, updates and revisions is available under the What's New section at the Canadian Task Force on Preventive Health Care Web site.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability


Availability of Companion Documents

The following are available:

Screening for prostate cancer with prostate specific antigen and treatment of early-stage or screen-detected prostate cancer: a systematic review of the clinical benefits and harms. Hamilton (ON): Evidence Review and Synthesis Centre, McMaster University; 2014 May. 134 p. Available from the


There is a CTFPHC mobile app for primary care practitioners available for download from the CTFPHC Web site.

Patient Resources

The following are available:


Prostate cancer—the prostate specific antigen (PSA) test video. 2014. Available from the CTFPHC 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 Institute on December 7, 1999. The information was verified by the guideline developer on February 24, 2000. This summary was updated by ECRI Institute on February 18, 2015. The updated information was verified by the guideline developer on March 4, 2015.

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