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NIH State-of-the-Science Conference Statement on
Role of Active Surveillance in the Management
of Men With Localized Prostate Cancer

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All of the panelists who participated in this conference and contributed to the writing of this statement were identified as having no financial or scientific conflict of interest, and all signed forms attesting to this fact. Unlike the expert speakers who present scientific data at the conference, the individuals invited to participate on NIH Consensus and State-of-the-Science Panels are reviewed prior to selection to ensure that they are not proponents of an advocacy position with regard to the topic and are not identified with research that could be used to answer the conference questions.

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Archived Conference Webcast

Abstract

Objective
To provide healthcare providers, patients, and the general public with a responsible assessment of currently available data on the use of active surveillance and other observational management strategies for low-grade, localized prostate cancer.

Participants
A non-U.S. Department of Health and Human Services, nonadvocate 14-member panel representing the fields of cancer prevention and control, urology, pathology, epidemiology, genetics, transplantation, bioethics, economics, health services research, shared decisionmaking, health communication, and community engagement. In addition, 22 experts from pertinent fields presented data to the panel and conference audience.

Evidence
Presentations by experts and a systematic review of the literature prepared by the Tufts Evidence-based Practice Center, through the Agency for Healthcare Research and Quality (AHRQ). Scientific evidence was given precedence over anecdotal experience.

Conference Process
The panel drafted its statement based on scientific evidence presented in open forum and on published scientific literature. The draft statement was presented on the final day of the conference and circulated to the audience for comment. The panel released a revised statement later that day at http://consensus.nih.gov. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.
Conclusions

Prostate cancer screening with prostate-specific antigen (PSA) testing has identified many men with low-risk disease. Because of the very favorable prognosis of low-risk prostate cancer, strong consideration should be given to modifying the anxiety-provoking term “cancer” for this condition. Treatment of low-risk prostate cancer patients with radical prostatectomy or radiation therapy leads to side effects such as impotence and incontinence in a substantial number. Active surveillance has emerged as a viable option that should be offered to patients with low-risk prostate cancer. More than 100,000 men a year diagnosed with prostate cancer in the United States are candidates for this approach. However, there are many unanswered questions about active surveillance strategies and prostate cancer that require further research and clarification. These include:

- Improvements in the accuracy and consistency of pathologic diagnosis of prostate cancer
- Consensus on which men are the most appropriate candidates for active surveillance
- The optimal protocol for active surveillance and the potential for individualizing the approach based on clinical and patient factors
- Optimal ways to communicate the option of active surveillance to patients
- Methods to assist patient decisionmaking
- Reasons for acceptance or rejection of active surveillance as a treatment strategy
- Short- and long-term outcomes of active surveillance.
Well-designed studies to address these questions and others raised in this statement represent an important health research priority. Qualitative, observational, and interventional research designs are needed. Due to the paucity of evidence about this important public health problem, all patients being considered for active surveillance should be offered participation in multicenter research studies that incorporate community settings and partners.
Introduction

Prostate cancer is the most common nonskin cancer in men. In 2011, more than 240,000 men are projected to be diagnosed with prostate cancer and 33,000 are projected to die from this condition. More than 2.5 million men in the United States are long-term survivors of prostate cancer. Men with a strong family history of prostate cancer and African American men are at increased risk for developing prostate cancer. Most prostate cancer is localized at diagnosis and detected as a result of screening with PSA testing. Most of these screen-detected prostate cancers are low risk and are unlikely to be the cause of death. The natural history of prostate cancer has changed dramatically in the past three decades because of PSA screening.

Although most prostate cancers are slow growing and unlikely to spread, most men receive immediate treatment with surgery or radiation. These therapeutic strategies are associated with short- and long-term complications, including impotence and urinary incontinence. Only a small number of men choose observational strategies, which may delay the initiation of curative therapy or avoid it completely. Given the high prevalence of low-risk prostate cancer, there is an urgent need to clarify the role of active surveillance and other observational strategies as alternatives to immediate treatment.

To provide healthcare providers, public health practitioners, policymakers, and the general public with a comprehensive assessment of the current role of active surveillance in the management of men with localized prostate cancer, the National Cancer Institute, the Centers for Disease Control and Prevention, and the Office of Medical Applications of Research in the NIH
Office of Disease Prevention convened a State-of-the-Science Conference on December 5–7, 2011, to assess the available scientific evidence. The panel was asked to address the following key questions:

1. How have the patient population and the natural history of prostate cancer diagnosed in the United States changed in the last 30 years?

2. How are active surveillance and other observational strategies defined?

3. What factors affect the offer of, acceptance of, and adherence to active surveillance?

4. What are the patient-experienced comparative short- and long-term health outcomes of active surveillance versus immediate treatment with curative intent for localized prostate cancer?

5. What are the research needs regarding active surveillance (or watchful waiting) in localized prostate cancer?

During the first 2 days of the conference, experts presented information on each of the key questions. After weighing the scientific evidence—including the data presented by the speakers, input from the attendees, and a formal evidence report commissioned through the Agency for Healthcare Research and Quality—an independent panel prepared and presented a draft of this State-of-the-Science Statement addressing the conference questions.
1. How Have the Patient Population and the Natural History of Prostate Cancer Diagnosed in the United States Changed in the Last 30 Years?

Prior to the adoption of PSA screening, the majority of prostate cancer was detected because of symptoms of advanced cancer or a nodule found on digital rectal examination. These symptomatic tumors were usually high grade, advanced, and often lethal. Other tumors were found incidentally at the time of surgery for benign enlargement of the prostate. These were often low grade and localized.

After the introduction of PSA screening in 1987, there was a spike in the rate of prostate cancer cases detected, followed by a persistent elevation above the pre-PSA testing era (see Figure 1) but no increase in prostate cancer deaths. Other 20-year follow-up studies indicate that only 5 percent of these men die from prostate cancer.

All of these trends led to the need for modifications in the approach to diagnosis and treatment of prostate cancer. Today, most prostate cancer is diagnosed by multiple core needle biopsies, which are graded using a prognostic system called Gleason scoring. In this system, the patterns of arrangement of tumor cells are given a pattern designation from 1 to 5, based on their relationship to normal prostate glands. Pattern 1 is the lowest grade, and pattern 5 is the highest grade. Each tumor is assigned two patterns, one of which is the most frequently seen and the other being the highest grade in the nondominant area. The pattern numbers are then added to provide a pathologic diagnosis called the Gleason score. For example, if the most common tumor pattern is grade 3, and the next most common tumor pattern is grade 4, the Gleason score would be 3+4=7. The Gleason scores are relied upon as the most powerful
indication of the patient’s expected outcome and are commonly used to define treatment strategies. Tumors called Gleason 3+3=6 are the lowest scores usually given in needle biopsy core specimens. Although Gleason scoring is the most important diagnostic tool used, the method suffers from interobserver variation and from difficulties with sampling, as biopsies constitute less than 0.5 percent of prostate tissue even when multiple cores are obtained.

**Figure 1. Prostate Cancer Incidence (1975–2008)**

Incidence source: Surveillance, Epidemiology and End Results (SEER) 9 areas (San Francisco, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, and Atlanta).
Since the initiation of PSA screening, more low-risk prostate cancer has been detected and, by 2002, more than 63 percent of all prostate cancers detected in one large series were Gleason 3+3=6. It is likely that the percentage of cases labeled as Gleason score 6 has increased since that time. Gleason score changes parallel the increased number of prostate cancer patients diagnosed with PSA less than 10 ng/mL.

Decisions about prostate cancer treatment depend on accurate pathologic diagnosis. There is a need to ensure that the level of agreement of Gleason scoring among doctors who examine prostate tissue has consistent scoring results. Additional research is needed to evaluate prostate cancer biomarkers that are different from PSA and are predictive of cancer behavior.

2. How Are Active Surveillance and Other Observational Strategies Defined?

There are two observational strategies: active surveillance and watchful waiting. These terms have evolved over time and have not been consistently applied. Active surveillance is a disease management strategy that delays curative treatment until it is warranted based on defined indicators of disease progression. In contrast, watchful waiting is a disease management strategy that forgoes curative treatment and initiates intervention only when symptoms arise.

The three components of a given observational management strategy are eligibility criteria, follow-up protocols to monitor disease progression, and indicators for treatment. The evidence report identified 16 studies that meet the definition of active surveillance and another 13 that followed patients who did not receive treatment and were followed for symptom progression (watchful waiting).
The most widely accepted criterion for active surveillance eligibility is the presence of low-risk clinically localized prostate cancer. Tumor characteristics commonly used to identify such low-risk cancers include tumor stage (T1c, PSA detected or T2a, small palpable nodule); PSA value (less than 10 ng/mL); Gleason score (less than or equal to 6); and extent of disease on biopsy. Patient characteristics have been used inconsistently to determine eligibility and include age and overall health status, which are reflections of life expectancy.

Watchful waiting, which predated active surveillance as an observational strategy, arose out of the recognition that death from other causes exceeded death from prostate cancer in men with shorter life expectancies. Thus, watchful waiting studies used less rigid eligibility criteria, accommodating men who were older, who had more chronic illnesses, or who preferred less invasive treatment. These criteria, while similar to those used in active surveillance, allow for inclusion of men with higher PSA values and higher clinical stage in the absence of metastatic disease.

The purpose of the active surveillance follow-up protocol is to detect disease progression. In previous studies, follow-up parameters included PSA, digital rectal examination, and rebiopsy. PSA and digital rectal exam were variably assessed every 3 to 12 months, but no consensus exists as to the optimal schedule. Repeat biopsy is included in all U.S. studies of active surveillance to detect disease progression and misclassification of the original biopsy. The frequency varies from one to four biopsy procedures during the initial 4-year period, with surveillance continuing indefinitely.
The intent of follow-up strategies differs between active surveillance and watchful waiting. In watchful waiting, intervention is reserved for relief of symptomatic disease progression. Therefore, follow-up of prostate cancer in patients on watchful waiting is minimal.

Indicators of disease progression that may lead to the recommendation for curative treatment under active surveillance include increased Gleason score on rebiopsy (e.g., a Gleason score greater than or equal to 7); shorter PSA doubling time (e.g., doubling time of less than 3 years may indicate the need for rebiopsy); or increased extent of disease (more of the biopsy tissues involved with cancer) on biopsy. Men on active surveillance may opt to undergo curative treatment at any time; no studies formally define or measure patient factors or preferences leading to abandoning active surveillance for curative treatment.

In contrast, the development of symptoms (e.g., urinary obstruction, pain, or bony fractures) is the primary indication for treatment under watchful waiting. However, some patients do opt for treatment based on individual preferences, even though these choices are not well studied.

More research is needed about the two broad categories of observational follow-up, active surveillance and watchful waiting, particularly since there are variable protocols for each. As the methods are further developed and refined, new terminology may be needed to distinguish consensus-based methods from historical practices and to offer patients the appropriate strategy for their prostate cancer.

Tumor characteristics derived from the prostate biopsy have been the mainstay to determine eligibility for active surveillance of men with low- and very low-risk tumors.
The minimum number of biopsy cores required for representative sampling of the prostate and the value of normalizing PSA values to prostate volume need clarification. Alternatives to Gleason scoring are needed to best identify candidates for active surveillance, to avoid sampling error, and to reduce misclassification of tumors.

Patient characteristics should be measured with standardized self-report instruments and integrated into eligibility decisionmaking. Such characteristics include attitudes and preferences with regard to general and disease-specific quality of life, life expectancy, and anxiety about cancer diagnosis.

Follow-up under active surveillance is variable and not currently evidence based. The types of monitoring and their optimal frequency need to be defined. It is important to consider whether follow-up should vary based on tumor and patient characteristics. Alternatives to repeat biopsy should be investigated to reduce morbidity and to encourage compliance with active surveillance. However, such new technologies must balance cost and burden to the patient. Follow-up also should monitor ongoing patient concerns with risks of complications, anxiety, and worry about progression.

Predicting whether a particular individual’s cancer will progress is difficult. The only clear current indicator of disease progression is an increase in Gleason score. The value of PSA doubling time is uncertain. New indicators of disease progression are needed, potentially including imaging techniques to identify clinically important tumors, molecular classification of cancers, and genetic classification of a patient’s risk for progression.
3. What Factors Affect the Offer of, Acceptance of, and Adherence to Active Surveillance?

Active surveillance is underutilized as a treatment strategy for men with low-risk prostate cancer, for reasons that are not fully understood. Studies addressing the offer of, acceptance of, and adherence to active surveillance have important limitations. Many studies are small, are unlikely to be representative, and evaluate a limited number of societal and individual factors. These limitations make it difficult to draw clear inferences, but the available data suggest the following:

Offer of Active Surveillance

Observational strategies are not consistently discussed as a treatment option for localized prostate cancer. When active surveillance is included as a treatment option, it may be presented in a negative way—for example, characterizing an observational approach as “doing nothing.” Unfavorable presentations of active surveillance may reflect physician opinion, but also may be an unintended consequence of a specialist’s perspective and training. Clinical factors also influence the offer of observational treatment. Physicians are more likely to recommend an observational strategy for men with low-risk disease (e.g., low Gleason score, PSA, stage) and limited life expectancy.

Acceptance of Active Surveillance

Approximately 10 percent of men who are eligible for observational strategies choose this approach. Perhaps the most critical reason for acceptance is physician recommendation. Other reasons include patients’ perception that their cancer is not serious and their concern about treatment side effects. Support from
family and friends as well as personal experience with cancer also are important. Patients’ decisions also are influenced by information from promotional materials, the Internet, other media, and family and friends.

**Adherence to Active Surveillance**

Approximately a quarter of patients embarking on observational treatment will undergo curative therapy within 2 to 3 years of diagnosis, and as many as half by 5 years. The reasons for leaving active surveillance are often unclear. Different active surveillance protocols specify various indicators for moving to curative treatment, including reclassification based on repeat biopsy. In addition, patients often choose to move to active treatment for reasons other than disease progression. Because patients need to reaffirm their commitment to active surveillance on a recurring basis, ongoing physician and family support are important. The same factors that contributed to the acceptance of active surveillance also likely influence adherence.

Future studies of active surveillance would benefit from a robust conceptual framework that better explains the many influences on decisionmaking. Research should explore physician, patient, health system, communications, and other societal factors that influence decisionmaking, and the ways in which these factors interact.

Examples include:

- Methods to improve physician counseling about active surveillance
- Methods to improve patient satisfaction and reduce regret in decisionmaking
- Methods to support shared decisionmaking, including participation of nonphysician healthcare providers and the use of decision support tools
• Reasons that patients leave active surveillance
• The effect of emotions (e.g., anxiety) and perceptions about being given a cancer diagnosis
• Coping factors and the role of the patient’s partner, family, and friends
• The impact and timing of communicating an observational strategy as an active care plan
• The role of the media, the Internet, and other communication sources in shaping views about active surveillance
• The impact of race, ethnicity, social class, and access to care in shaping views and decisions about active surveillance.

Ideally, future research also should include comparisons of different strategies for offering and supporting continued participation in active surveillance.

4. What Are the Patient-Experienced Comparative Short- and Long-Term Health Outcomes of Active Surveillance Versus Immediate Treatment With Curative Intent for Localized Prostate Cancer?

There are no completed randomized clinical trials to determine whether patients who undergo active surveillance have better or worse outcomes than those who receive immediate curative treatment. However, there are noncomparative cohort studies that are examining active surveillance in men with low-risk disease. Early results demonstrate disease-free and survival rates that compare favorably to curative
therapy. There is no standardized reporting of complications associated with the active surveillance strategy in any of the studies reviewed.

The Scandinavian Prostate Cancer Group 4 Trial reported significantly higher prostate cancer-specific and overall mortality rates in patients who were randomized to watchful waiting compared with radical prostatectomy. These patients were enrolled in the pre-PSA era and had more clinically advanced disease than is seen today. These results may not apply to current populations who are identified with low-risk disease by PSA screening. There is weak evidence from comparative cohort studies that watchful waiting results in an increase in death rates relative to both radiation therapy and radical prostatectomy.

The Prostate Cancer Intervention Versus Observation Trial, a randomized controlled trial that included a large proportion of patients identified by PSA screening, compared watchful waiting with radical prostatectomy. With a median follow-up of 10 years, there were no statistically significant differences in prostate cancer mortality or all-cause mortality. However, this trial has yet to be published. Another large randomized trial is under way in the United Kingdom, but results will not be available for 5–10 years. Supporting data from additional cohort studies give us confidence that the risk of death from prostate cancer is minimal in a low-risk population followed for 10–20 years.

There are side effects associated with any treatment strategy for prostate cancer. Radical prostatectomy causes sexual dysfunction and urinary incontinence in a substantial proportion of patients. In addition, there is 30-day mortality of one-half percent. Radiation therapy often causes bowel, sexual, and urinary dysfunction. Active surveillance complications include biopsy-related infections, pain, and anxiety. Rates of these or other
complications have not been reported systematically. These patients also experience the treatment side effects of curative therapy when they undergo therapy. However, only those patients who require curative therapy will experience the side effects, enabling a substantial number of patients receiving active surveillance to avoid or delay these side effects.

There is limited evidence to determine the short-term impact of active surveillance, compared with immediate treatment strategies, on general health-related quality of life measures such as physical functioning, mental health, social interactions, and role performance. There is some evidence that, for all strategies, general physical and mental health recover similarly in the long term. In contrast, for disease-specific quality of life, both radical prostatectomy and radiation therapy patients experience worse urinary and sexual functioning compared with observation patients. These differences persist over time.

In spite of insufficient evidence to determine the outcomes associated with active surveillance compared with other immediate treatment options for prostate cancer, we do not believe that randomized clinical trials are necessary to define this for all populations. As there are no clinically important differences in mortality between observational strategies and immediate curative treatment for men with low-risk prostate cancer, future efforts should focus on the impact of various active surveillance strategies on treatment morbidity and health-related quality of life. We have a particular concern with the complications that result from image-guided transrectal biopsies of the prostate. Standardized protocols need to be developed to minimize the frequency and intervals of biopsies and to reduce associated pain and infection rates. Furthermore, in all future studies, patients’ self-reported health-related quality of life indicators both for generic and disease-specific measures are warranted.
Costs of different treatment strategies should be measured prospectively, including the costs that accrue to patients.

Additional data are still needed to determine how all outcomes—including mortality, morbidity, health-related quality of life, and costs—differ between observational and curative treatment strategies for men with intermediate- to high-risk prostate cancer. Given the variation in how observational strategies have been implemented, we also need to know how active surveillance impacts outcomes relative to other observational strategies.

5. What Are the Research Needs Regarding Active Surveillance (or Watchful Waiting) in Localized Prostate Cancer?

In summary, we have identified the following major areas as critical in the advancement of our understanding of active surveillance in the management of men with localized prostate cancer:

1. Develop or improve pathologic, molecular, genetic, and imaging predictive markers, and evaluate their validity and reliability.

2. Examine the differential impact of socioeconomic status, race/ethnicity, and other social determinants on the offer of, acceptance of, and adherence to active surveillance and their effect on morbidity and mortality, and address any disparities emerging from these differences.

3. Determine optimal protocols for active surveillance that balance the need to detect disease progression with the need to minimize the frequency and intensity of monitoring.
4. Compare the effectiveness of different active surveillance protocols in studies of short- and long-term outcomes on patients and their families. Ideally, trials should be done in cooperative or multicenter group settings, should include a variety of populations eligible for active surveillance, and should be large enough to conduct thorough predetermined subgroup analyses.

5. Develop methods to enhance the decisionmaking process related to acceptance of and adherence to active surveillance. These studies should include patients, family, physicians, health systems, communications, and other societal factors that influence patient choices and the ways in which they interact.

6. Investigate the comparative effectiveness of active surveillance versus curative therapy for low-risk patients with long life expectancy and for intermediate- and high-risk patients with limited life expectancy.

7. Create registry-based cohort studies that collect longitudinal data on active surveillance participants, including clinical and patient-reported outcomes. Establish incentives to encourage participation.

8. Study lifestyle and therapeutic interventions for patients undergoing active surveillance.

**Conclusions**

Prostate cancer screening with PSA testing has identified many men with low-risk disease. Because of the very favorable prognosis of low-risk prostate cancer, strong consideration should be given to modifying the anxiety-provoking term “cancer” for this condition. Treatment of low-risk prostate cancer
patients with radical prostatectomy or radiation therapy leads to side effects such as impotence and incontinence in a substantial number. **Active surveillance has emerged as a viable option that should be offered to patients with low-risk prostate cancer.** More than 100,000 men a year diagnosed with prostate cancer in the United States are candidates for this approach. However, there are many unanswered questions about active surveillance strategies and prostate cancer that require further research and clarification. These include:

- Improvements in the accuracy and consistency of pathologic diagnosis of prostate cancer
- Consensus on which men are the most appropriate candidates for active surveillance
- The optimal protocol for active surveillance and the potential for individualizing the approach based on clinical and patient factors
- Optimal ways to communicate the option of active surveillance to patients
- Methods to assist patient decisionmaking
- Reasons for acceptance or rejection of active surveillance as a treatment strategy
- Short- and long-term outcomes of active surveillance.

Well-designed studies to address these questions and others raised in this statement represent an important health research priority. Qualitative, observational, and interventional research designs are needed. Due to the paucity of evidence about this important public health problem, all patients being considered for active surveillance should be offered participation in multicenter research studies that incorporate community settings and partners.
State-of-the-Science Panel

Patricia A. Ganz, M.D.
Panel and Conference Chairperson
Professor, Health Services and Medicine
School of Public Health and David Geffen School of Medicine
University of California, Los Angeles
Division of Cancer Prevention and Control Research
Jonsson Comprehensive Cancer Center
Los Angeles, California

Phaedra S. Corso, Ph.D., M.P.A.
Professor and Head
Department of Health Policy and Management
College of Public Health
University of Georgia
Athens, Georgia

John M. Barry, M.D.
Emeritus Professor of Surgery
Divisions of Urology and Abdominal Organ Transplantation
Oregon Health & Science University
Portland, Oregon

Everett Dodson
Community Health Educator
Lombardi Comprehensive Cancer Center
Georgetown University Medical Center
Washington, District of Columbia

Wylie Burke, M.D., Ph.D.
Professor and Chair
Department of Bioethics and Humanities
University of Washington
Seattle, Washington

M. Elizabeth Hammond, M.D.
Pathologist
Intermountain Healthcare
Professor of Pathology
University of Utah School of Medicine
Salt Lake City, Utah

Nananda F. Col, M.D., M.P.P., M.P.H., FACP
Professor of Medicine
Center for Excellence in the Neurosciences, Departments of Medicine and Geriatrics
University of New England
President
Shared Decision Making Resources
Georgetown, Maine

Barry A. Kogan, M.D., FAAP, FACS
Professor of Urology and Pediatrics
Chief
Division of Urology
Albany Medical College
Albany, New York

Charles F. Lynch, M.D., Ph.D., M.S.
Professor and Associate Head of Research
Department of Epidemiology
College of Public Health
The University of Iowa
Iowa City, Iowa
Lee Newcomer, M.D., M.H.A.
Senior Vice President
of Oncology
United Healthcare
Minneapolis, Minnesota

Eric J. Seifter, M.D., FACP
Associate Professor of
Medicine and Oncology
The Johns Hopkins University
School of Medicine
The Sidney Kimmel
Comprehensive Cancer Center
Johns Hopkins at
Greenspring Station
Lutherville, Maryland

Janet A. Tooze, Ph.D., M.P.H.
Associate Professor
Department of
Biostatistical Sciences
Division of Public
Health Sciences
Wake Forest
School of Medicine
Winston Salem, North Carolina

Kasisomayajula “Vish”
Viswanath, Ph.D.
Associate Professor
Department of Society, Human
Development, and Health
Harvard School of Public Health
Associate Professor
Department of Medical
Oncology
Dana Farber Cancer Institute
Boston, Massachusetts

Hunter Wessells, M.D., FACS
Professor and Chair
Department of Urology
Nelson Chair in Urology
University of Washington
School of Medicine
Seattle, Washington
Speakers

Peter Albertsen, M.D.  
Medical Director  
UConn Medical Group  
Associate Dean  
Clinical Research Planning and Administration  
Chief  
Division of Urology  
University of Connecticut Health Center  
Farmington, Connecticut

H. Ballentine Carter, M.D.  
Professor  
Urology and Oncology  
Johns Hopkins Medicine  
Director  
Division of Adult Urology  
Brady Urological Institute  
The Johns Hopkins Hospital  
Baltimore, Maryland

Gerald L. Andriole, M.D.  
Robert K. Royce  
Distinguished Professor  
Chief of Urologic Surgery  
Washington University School of Medicine  
Barnes-Jewish Hospital  
Siteman Cancer Center  
St. Louis, Missouri

Mei Chung, Ph.D., M.P.H.  
Assistant Director  
Tufts Evidence-based Practice Center  
Tufts Medical Center  
Boston, Massachusetts

Otis W. Brawley, M.D.  
Chief Medical Officer  
American Cancer Society  
Professor of Oncology and Epidemiology  
Emory University  
Atlanta, Georgia

Issa Dahabreh, M.D., M.S.  
Research Associate  
Tufts Evidence-based Practice Center  
Tufts Medical Center  
Boston, Massachusetts

Peter R. Carroll, M.D., M.P.H.  
Ken and Donna Derr – Chevron Distinguished Professor  
Department of Urology  
University of California, San Francisco (UCSF)  
Associate Dean  
UCSF School of Medicine  
Director of Clinical Services and Strategic Planning  
UCSF Helen Diller Family Comprehensive Cancer Center  
San Francisco, California

Jenny Donovan, Ph.D.  
Head of School  
Professor of Social Medicine  
School of Social and Community Medicine  
University of Bristol  
Bristol  
UNITED KINGDOM

Ann S. Hamilton, Ph.D.  
Associate Professor of Research  
Department of Preventive Medicine  
Division of Epidemiology  
Keck School of Medicine  
University of Southern California  
Los Angeles, California
Richard M. Hoffman, M.D., M.P.H.  
Professor of Medicine  
University of New Mexico  
School of Medicine  
Staff Physician  
New Mexico Veterans Affairs Health Care System  
Albuquerque, New Mexico

Lars Holmberg, M.D., Ph.D.  
Professor of Cancer Epidemiology  
Division of Cancer Studies  
King’s College London  
School of Medicine  
Guy’s Hospital  
London, England  
UNITED KINGDOM

Stanley Ip, M.D.  
Associate Director  
Tufts Evidence-based Practice Center  
Tufts Medical Center  
Boston, Massachusetts

Laurence Klotz, M.D.  
Chief  
Division of Urology  
Sunnybrook Health Sciences Centre  
Professor of Surgery  
University of Toronto  
Toronto, Ontario  
CANADA

David A. Lipton, J.D.  
Director  
Securities Law Program  
Catholic University of America School of Law  
Washington, District of Columbia

Mark S. Litwin, M.D., M.P.H.  
Professor of Urology and Health Services Chair  
Department of Urology  
David Geffen School of Medicine at the University of California, Los Angeles (UCLA)  
UCLA School of Public Health  
Los Angeles, California

M. Scott Lucia, M.D.  
Professor and Vice Chair of Anatomic Pathology Director  
Prostate Diagnostic Laboratory Director  
Prostate Cancer Research Laboratories  
University of Colorado Denver School of Medicine  
Aurora, Colorado

David F. Penson, M.D., M.P.H.  
Professor of Urologic Surgery Director  
Center for Surgical Quality and Outcomes Research  
Institute for Medicine and Public Health  
Vanderbilt University  
Nashville, Tennessee

Daniella J. Perlroth, M.D.  
Instructor  
Center for Health Policy  
Center for Primary Care and Outcomes Research  
Stanford University  
Stanford, California
Mack Roach III, M.D., FACR  
Professor  
Departments of Radiation Oncology and Urology  
Chairman  
Department of Radiation Oncology  
University of California, San Francisco  
Helen Diller Family Comprehensive Cancer Center  
San Francisco, California  

Paul F. Schellhammer, M.D., FACS  
Professor  
Eastern Virginia Medical School  
Medical Director  
Virginia Prostate Center  
Norfolk, Virginia  

Ian M. Thompson, Jr., M.D.  
Professor  
Department of Urology  
Executive Director  
Cancer Therapy and Research Center  
University of Texas Health Science Center at San Antonio  
San Antonio, Texas  

Timothy J. Wilt, M.D., M.P.H.  
Professor of Medicine and Core Investigator  
Minneapolis Veterans Affairs Center for Chronic Disease Outcomes Research and the University of Minnesota School of Medicine  
Minneapolis, Minnesota
Planning Committee

Bhupinder Mann, MBBS
*Head*
Genitourinary and Brain Cancer Therapeutics
Cancer Therapy Evaluation Program
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Peter Albertsen, M.D.
*Medical Director*
UConn Medical Group
Associate Dean
Clinical Research Planning and Administration
Associate Dean
Clinical Affairs
Division of Urology
University of Connecticut Health Center
Farmington, Connecticut

Otis W. Brawley, M.D.
*Chief Medical Officer*
American Cancer Society
Atlanta, Georgia

Patricia A. Ganz, M.D.
*Panel and Conference Chairperson*
Professor, Health Services and Medicine
School of Public Health and David Geffen School of Medicine
University of California, Los Angeles
Division of Cancer Prevention and Control Research
Jonsson Comprehensive Cancer Center
Los Angeles, California

Ingrid Hall, Ph.D., M.P.H.
*Lead Epidemiologist/Team Lead*
Health Services Research Team Epidemiology and Applied Research Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention
Atlanta, Georgia

Barnett S. Kramer, M.D., M.P.H.
*Associate Director for Disease Prevention*
Office of the Director
National Institutes of Health
Bethesda, Maryland

William Lawrence, M.D., M.S.
*Medical Officer*
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, Maryland

Kelli K. Marciel, M.A.
*Communications Director*
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Jeffrey Metter, M.D.
*Medical Officer*
Longitudinal Studies Section
National Institute on Aging
National Institutes of Health
Baltimore, Maryland

Planning Committee members provided their input at a meeting held August 11–13, 2010. The information provided here was accurate at the time of that meeting.
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