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**Panel endorses active monitoring and delay of treatment for low-risk prostate cancer, Urges further research to clarify management strategies**

An independent panel convened this week by the National Institutes of Health has concluded that many men with localized, low-risk prostate cancer should be closely monitored, permitting treatment to be delayed until warranted by disease progression. However, monitoring strategies—such as active surveillance—have not been uniformly studied and available data do not yet point to clear follow-up protocols. The panel recommended standardizing definitions and conducting additional studies to clarify which monitoring strategies are most likely to optimize patient outcomes.

“It’s clear that many men would benefit from delaying treatment, but there is no consensus on what constitutes observational strategies and what criteria should be used to determine when treatment might ultimately be needed among closely-monitored men,” said Dr. Patricia A. Ganz, conference panel chairperson and director of the Division of Cancer Prevention and Control Research at the Jonsson Comprehensive Cancer Center at the University of California in Los Angeles.

Prostate cancer is the most common non-skin cancer in men in the United States. It is estimated that in 2011, approximately 240,000 men will be newly diagnosed with prostate cancer and 33,000 will die of the disease. More than half of these cancers are localized (confined to the prostate), not aggressive at diagnosis, and unlikely to become life-threatening. However, approximately 90 percent of patients receive immediate treatment, such as surgery or radiation therapy. For many of these patients, treatment has substantial short- and long-term side effects, such as diminished sexual function and loss of urinary control, without clear benefits, such as improved survival. Identifying appropriate management strategies for different subgroups of patients is critical to improving survival and reducing the burden of adverse effects.

Currently, clinicians often describe two alternatives to immediate treatment of low-risk prostate cancer: observation with and without the intent to cure. Observation without intent to cure, sometimes referred to as watchful waiting, is a passive approach, with treatment provided to alleviate symptoms if they develop. Observation with intent to cure, often referred to as active surveillance, involves proactive patient follow-up in which blood samples, digital rectal exams,

and repeat prostate biopsies are conducted on a regular schedule, and curative treatment is initiated if the cancer progresses.

The panel identified emerging consensus in the medical community on a definition for low-risk prostate cancer: a prostate-specific antigen (PSA) level less than 10 ng/mL and a Gleason score of 6 or less. Using this definition, the panel estimated that more than 100,000 men diagnosed with prostate cancer each year would be candidates for active monitoring rather than immediate treatment. Importantly, however, the panel found that protocols to manage active monitoring still vary widely, hampering the evaluation and comparison of research findings.

“Prostate cancer affects some 30-40 percent of men over the age of 50. Some of these men will benefit from immediate treatment, others will benefit from observation. We need to standardize definitions, group patients by their risks, and conduct additional research to determine the best protocols for managing low-risk disease,” stated Dr. Ganz.

The panel further recommended that disease terminology should be refined as a result of changes in the patient population with prostate cancer due to prostate-specific antigen (PSA) testing. Because of the very favorable prognosis of PSA-detected, low-risk prostate cancer, the panel recommended that strong consideration be given to removing the anxiety-provoking term “cancer” for this condition.

The panel also found that clinicians’ framing of disease management options is an important factor in patient decision-making. Other influential factors include views of family members, cancer experiences of family and friends, lifestyle priorities, and personal philosophy. Findings from studies in communication sciences and behavioral economics could be applied in clinical settings to promote informed, shared decision-making. While research continues to fill knowledge gaps and develop consensus, the decisions faced by men and their providers following a diagnosis of localized, low-risk prostate cancer should be highly individualized, and include the consideration of biological, psychological, social, and cultural factors.

With regard to future research, the panel recommended against future federal funding for single-institutional site studies, and emphasized instead the importance of supporting multisite clinical research studies. The panel also supports the establishment of registry-based cohort studies that collect longitudinal data on active monitoring participants, including clinical and patient-reported outcomes.

An updated version of the panel's draft statement, which incorporates public comments received in an open conference session this morning, will be posted later today at <http://consensus.nih.gov>.

The panel will hold a press telebriefing to discuss their findings today at 2 p.m. eastern time. To participate, call 888-428-7458 (inside the United States) or 201-604-5177 (International) and reference the NIH State-of-the-Science Conference. Audio playback will be available shortly after conclusion of the telebriefing and can be accessed by calling 888-632-8973 (US) or 201-499-0429 (International) and entering replay code 11996437.

The state-of-the-science conference was sponsored by the NIH Office of Medical Applications of Research, the National Cancer Institute, and the Centers for Disease Control and Prevention, along with other NIH and U.S. Department of Health and Human Services components. This conference was conducted under the NIH Consensus Development Program, which convenes

conferences to assess the available scientific evidence and develop objective statements on controversial medical issues.

The 14-member state-of-the-science panel included experts in the fields of cancer prevention and control, urology, pathology, epidemiology, genetics, transplantation, bioethics, economics, health services research, shared decision-making, health communication, and community engagement. A complete listing of the panel members and their institutional affiliations is included in the draft conference statement. Additional materials, including panel biographies, photos, and other related resources, are available at <http://consensus.nih.gov/2011/prostatemedia.htm>. Interviews with panel members can be arranged by contacting Elizabeth Neilson at 301-496-4999 or NeilsonE@od.nih.gov.

The conference was webcast live and will be archived shortly. Links to the archived webcast will be available at <http://consensus.nih.gov/2011/prostate.htm>.

Individuals interested in obtaining information about prostate cancer may wish to contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or via email at [cancergovstaff@mail.nih.gov](mailto:cancergovstaff@mail.nih.gov) and the Centers for Disease Control and Prevention's National Contact Center at 1-800-CDC-INFO (1-800-232-4636) or via email at [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov).

In addition to the material presented at the conference by speakers and the comments of conference participants presented during discussion periods, the panel considered pertinent research from the published literature and the results of a systematic review of the literature. The systematic review was prepared through the Agency for Healthcare Research and Quality Evidence-based Practice Centers (EPC) program by The Tufts Medical Center Evidence-based Practice Center. The EPCs develop evidence reports and technology assessments based on rigorous, comprehensive syntheses and analyses of the scientific literature, emphasizing explicit and detailed documentation of methods, rationale, and assumptions. A link to the evidence report on the role of active surveillance in the management of men with localized prostate cancer is available at <http://consensus.nih.gov/2011/prostate.htm>.

The panel's statement is an independent report and is not a policy statement of the NIH or the Federal Government. The NIH Consensus Development Program was established in 1977 as a mechanism to judge controversial topics in medicine and public health in an unbiased, impartial manner. NIH has conducted 123 consensus development conferences and 35 state-of-the-science (formerly "technology assessment") conferences, addressing a wide range of issues. A backgrounder on the NIH Consensus Development Program process is available at <http://consensus.nih.gov/backgrounder.htm>.

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