

National Institutes of Health State-of-the-Science Conference: Role of Active Surveillance in the Management of Men With Localized Prostate Cancer

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The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research. The following statement is an abridged version of the panel's report, which is available in full at <http://consensus.nih.gov/2011/prostatefinalstatement.htm>

In 2011, more than 240 000 men are projected to receive a diagnosis of prostate cancer and 33 000 are projected to die of 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 prostate cancer. Most cases of prostate cancer are localized at diagnosis and detected as a result of screening with prostate-specific antigen (PSA) testing. Most of these screen-detected cases of cancer are low risk and are unlikely to cause death. The natural history of prostate cancer has changed dramatically in the past 3 decades because of PSA screening.

Although most cases of prostate cancer 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 few men choose observational strategies, thereby delaying the initiation of curative therapy or avoiding it completely. Given the high prevalence of low-risk prostate cancer, the roles of active surveillance and other observational strategies as alternatives to immediate treatment need to be clarified.

The National Cancer Institute, the Centers for Disease Control and Prevention, and the NIH Office of Medical Applications of Research convened a State-of-the-Science Conference on 5 to 7 December 2011 to assess the available scientific evidence about active surveillance for men with localized prostate cancer. The conference, which addressed 5 key questions, was informed by a formal evidence report commissioned through the Agency for Healthcare Research and Quality, data presented by speakers, and input from attendees.

QUESTION 1

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

Before the adoption of PSA screening, most cases of prostate cancer were detected because of symptoms of advanced cancer or a nodule found on digital rectal examination. These

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* Panel statement from an NIH State-of-the-Science Conference held on 5–7 December 2011 at the National Institutes of Health, Bethesda, Maryland. The Appendix (available at www.annals.org) lists the members of the NIH State-of-the-Science Conference Panel and other participants.

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symptomatic tumors were usually high-grade and advanced and were often fatal. 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 over the pre-PSA testing era but no increase in prostate cancer deaths. Other 20-year follow-up studies indicate that only 5% of these men die of prostate cancer.

All of these trends led to the need to modify the approach to diagnosis and treatment of prostate cancer. Today, most cases of prostate cancer are diagnosed by examining multiple core-needle biopsy specimens, which are graded by using a prognostic system called Gleason scoring. In this system, the arrangement of tumor cells is given a pattern designation ranging from 1 (lowest) to 5 (highest) on the basis of their relationship to normal prostate gland cells. Each tumor is assigned 2 pattern grades: the most frequently seen grade and the highest grade in the non-dominant area. The pattern numbers are then added to provide a pathologic diagnosis called the Gleason score. For example, if the most common tumor pattern was grade 3 and the next most common was grade 4, the Gleason score would be $3 + 4 = 7$. Gleason scores are considered the most powerful indication of the patient's expected outcome and are commonly used to define treatment strategies. A Gleason score of $3 + 3 = 6$ is the lowest score usually given in core-needle biopsy specimens. Although Gleason scoring is the most important diagnostic tool, the method is subject to interobserver variation and difficulties with sampling because biopsy samples constitute less than 0.5% of prostate tissue even when multiple cores are obtained.

Since the initiation of PSA screening, more cases of low-risk prostate cancer have been detected, and by 2002, more than 63% of all cases of prostate cancer detected in 1 large series were Gleason $3 + 3 = 6$. The percentage of cases labeled as having a Gleason score of 6 has probably increased since that time. Gleason score changes parallel the increased number of patients with prostate cancer who have PSA values less than $10 \mu\text{g/L}$.

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

QUESTION 2

How are active surveillance and other observational strategies defined?

Two observational strategies exist: 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 on the basis of defined indicators of disease progression. In contrast, watchful waiting is a strategy that forgoes curative treatment and initiates intervention only when symptoms occur.

The 3 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. Characteristics commonly used to identify such low-risk tumors include tumor stage (T1c, PSA detected; T2a, small palpable nodule), PSA value ($<10 \mu\text{g/L}$), Gleason score (≤ 6), and extent of disease on biopsy. Patient characteristics have been used inconsistently to determine eligibility and include age and overall health status, which reflect life expectancy.

Watchful waiting, which predated active surveillance as an observational strategy, was based on 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, had more chronic illnesses, or preferred less invasive treatment. These criteria, although similar to those used in active surveillance, allow for inclusion of men with higher PSA values and higher clinical stage tumors 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 assessments included PSA level, digital rectal examination, and repeated biopsy. Measurement of PSA level and digital rectal examination were performed every 3 to every 12 months, but no consensus exists as to the optimal schedule. Repeated biopsy is included in all U.S. studies of active surveillance to detect disease progression and misclassification of the original biopsy specimen. The frequency varies from 1 to 4 biopsy procedures during the initial 4-year period, with surveillance continuing indefinitely.

The intention 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 managed with 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 repeated biopsy (for example, a Gleason score ≥ 7), shorter time for doubling of PSA level (for example, a doubling time <3 years may indicate the need for repeated biopsy), or increased extent of disease (more of the biopsied tissues involved with cancer) on biopsy. Men receiving 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 (such as urinary obstruction, pain, or bony fractures) is the primary indication for treatment under watchful waiting. Some patients do opt for treatment on the basis of individual preferences; however, these choices are not well-studied.

More research is needed about the 2 broad categories of observational follow-up, active surveillance and watchful waiting, particularly because each has variable protocols. 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 tumors at low and very low risk. 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-reporting instruments and be integrated into decisions about eligibility. 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 varies and is 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 on the basis of tumor and patient characteristics. Alternatives to repeated biopsy should be investigated to reduce morbidity and encourage adherence to active surveillance. However, such new technologies must balance cost and burden to the patient. Follow-up also should monitor ongoing patient concerns with risk for complications, anxiety, and worry about progression.

Predicting whether a particular person's cancer will progress is difficult. The only clear current indicator of disease progression is an increase in Gleason score. The value of PSA level doubling time is uncertain. New indicators of disease progression are needed, such as imaging techniques to identify clinically important tumors, molecular classification of types of cancer, and genetic classification of a patient's risk for progression.

QUESTION 3

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

Active surveillance is underused as a treatment strategy in 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, by 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 (such as those with a low Gleason score, low PSA level, or early cancer stage) and limited life expectancy.

Acceptance of Active Surveillance

Approximately 10% 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, is also important. Patients' decisions also are influenced by information from promotional materials, the Internet, other media, and family and friends.

Adherence to Active Surveillance

Approximately one quarter of patients starting observational treatment will undergo curative therapy within 2 to 3 years of diagnosis, and as many as one 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 repeated 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 probably influence adherence.

Future studies of active surveillance would benefit from a robust conceptual framework that better explains the many influences on decision making. Research should explore physician, patient, health system, communication, and other societal factors that influence decision making and the ways in which these factors interact. The full report provides a detailed list of examples for future research. Future research also should compare different strategies for offering and supporting continued participation in active surveillance.

QUESTION 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?

No completed randomized clinical trials have assessed whether patients who undergo active surveillance have better or worse outcomes than those who receive immediate curative treatment. However, noncomparative cohort studies are examining active surveillance in men with low-risk disease. Early results demonstrate disease-free and survival rates that compare favorably with those reported for curative therapy. None of the studies reviewed used standardized reporting of complications associated with the active surveillance strategy.

The Scandinavian Prostate Cancer Group 4 Trial reported higher prostate cancer-specific and overall mortality rates in patients who were randomly assigned to watchful waiting than in those assigned to radical prostatectomy. These patients were enrolled in the pre-PSA screening era and had more clinically advanced disease than is seen today. These results may not apply to current populations who are identified as having low-risk disease by PSA screening. Weak evidence from comparative cohort studies suggests that watchful waiting increases mortality rates relative to both radiation therapy and radical prostatectomy.

The Prostate Cancer Intervention Versus Observation Trial, a randomized, controlled trial that includes a large proportion of patients identified by PSA screening, compared watchful waiting with radical prostatectomy. With a median follow-up of 10 years, prostate cancer and all-cause mortality did not significantly differ between groups. 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 to 10 years. Supporting data from additional cohort studies give us confidence that the risk for death from prostate cancer is minimal in a low-risk population followed for 10 to 20 years.

Side effects are associated with any treatment strategy for prostate cancer. Radical prostatectomy causes sexual dysfunction and urinary incontinence in a substantial proportion of patients and has a 30-day mortality rate of 0.5%. 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 side effects of curative therapy when they undergo this therapy. However, only patients who require curative therapy will experience the side effects, enabling a substantial number of patients undergoing active surveillance to avoid or delay these side effects.

Compared with immediate treatment strategies, evidence to determine the short-term effect of active surveillance on such general health-related quality-of-life measures as physical functioning, mental health, social interactions, and role performance is limited. Some evidence indicates that general physical and mental health

recover similarly in the long term with all strategies. In contrast, for disease-specific quality of life, patients who undergo radical prostatectomy or radiation therapy experience worse urinary and sexual functioning than patients following an observation strategy. These differences persist over time.

Despite the 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 outcomes for all populations. Because no clinically important differences in mortality have been found between observational strategies and immediate curative treatment for men with low-risk prostate cancer, future efforts should focus on the effect 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 are warranted for both generic and disease-specific measures. The costs of different strategies, including the costs that accrue to patients, should be measured prospectively.

Additional data are 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. Because of the variation in how observational strategies have been implemented, we also need to know how active surveillance affects outcomes compared with other observational strategies.

QUESTION 5

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

We identified several major areas as critical for advancing our understanding of active surveillance in the management of men with localized prostate cancer. These areas, which are detailed in the full report, address such issues as evaluation of various markers of disease; evaluation of factors that affect the offer of, acceptance of, and adherence to active surveillance; development and evaluation of optimal protocols for active surveillance; study of methods to enhance shared decision making about active surveillance; comparisons of active surveillance with curative therapy; registry-based cohort studies; and 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,

modifying the anxiety-provoking term “cancer” for this condition should be strongly considered. Treatment of low-risk prostate cancer with radical prostatectomy or radiation therapy leads to side effects, such as impotence and incontinence, in a substantial number of patients. Active surveillance has emerged as a viable option that should be offered to patients with low-risk prostate cancer. More than 100 000 men per year who receive a diagnosis of prostate cancer in the United States are candidates for this approach. However, many unanswered questions about active surveillance strategies and prostate cancer 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 on the basis of clinical and patient factors, optimal ways to communicate the option of active surveillance to patients, methods to assist patient decision making, reasons for accepting or rejecting active surveillance as a treatment strategy, and 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. Because of the paucity of evidence about this important public health problem, all patients being considered for active surveil-

lance should be offered participation in multicenter research studies that incorporate community settings and partners.

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APPENDIX

State-of-the-Science Panel

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