

original report, we presented them for discussion with a newly convened TEP for this update and made changes as necessary. This update will summarize the more recent evidence comparing the relative effectiveness and safety of treatment options for clinically localized prostate cancer. The key questions we will address are as follows:

Key Question 1

What are the comparative risks and benefits of the following therapies for clinically localized prostate cancer?

- a. Radical prostatectomy, including open (retropubic and perineal) and laparoscopic (with or without robotic assistance) approaches.
- b. External Beam Radiotherapy, including standard therapy and therapies designed to decrease exposure to normal tissues such as 3D conformal radiation therapy, intensity-modulated radiation therapy, proton beam therapy, and stereotactic body radiation therapy.
- c. Interstitial brachytherapy.
- d. Cryosurgery.
- e. Watchful waiting.
- f. Active surveillance.
- g. Hormonal therapy as primary therapy, adjuvant, or neoadjuvant to other therapies.
- h. High-intensity focused ultrasound.

Key Question 2

How do specific patient characteristics (e.g., age, race/ethnicity, presence or absence of comorbid illness, preferences such as trade-off of treatment-related adverse effects vs. potential for disease progression) affect the outcomes of these therapies overall and differentially?

Key Question 3

How do provider/hospital characteristics affect outcomes of these therapies overall and differentially (e.g., geographic region, case volume, learning curve)?

Key Question 4

How do tumor characteristics (e.g., Gleason score, tumor volume, screen-detected vs. clinically detected tumors, and PSA levels) affect the outcomes of these therapies overall and differentially?

Population, Interventions, Comparators, Outcomes, Timing, Settings Criteria Population

• Key Questions 1, 2, 3, and 4: Men considered to have clinically localized prostate cancer (T1 to T2, N0 to X, M0 to X) regardless of age, histologic grade, or PSA level. Articles will be excluded if men with disease stage higher than T2

were enrolled and outcomes were not stratified by stage.

Interventions

• For Key Questions 1, 2, 3, and 4, we will include treatment options for men with clinically localized prostate cancer: radical prostatectomy (including retropubic, perineal, laparoscopic, robotic-assisted), watchful waiting, active surveillance, External Beam Radiotherapy (including conventional radiation, Intensity Modulated Radiotherapy, 3D conformal radiation, proton beam, and stereotactic body radiation therapy), brachytherapy, androgen deprivation therapy, high-intensity focused ultrasound, and cryotherapy.

Comparators

• Any of the interventions of interest above or watchful waiting.

Outcomes

• The primary outcome is overall mortality or survival. Additional outcomes include prostate-cancer-specific mortality or survival, biochemical (PSA) progression, metastatic and/or clinical progression-free survival, health status, and quality of life. We will focus primarily on common and severe adverse events of treatment including bowel, bladder, and sexual dysfunction, as well as harms from biopsy such as bleeding and nosocomial infections.

• For Key Question 3, we plan to examine outcomes after radical prostatectomy, the most common treatment for localized prostate cancer, in association with provider location, case volume, and affiliation with academic centers.

Timing

• Duration of follow-up will be appropriate for the outcome under consideration.

Settings

• No restrictions by setting.

Dated: April 15, 2013.

Carolyn M. Clancy,

AHRQ, Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation, Funding Opportunity Announcement (FOA) TS13-001, Initial Review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

Time and Date: 12:00 p.m.–3:30 p.m., June 13, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation, FOA TS13-001."

Contact Person for More Information: Jane Suen, Dr.P.H, M.S., M.P.H., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F63, Atlanta, Georgia 30341, Telephone: (770) 488-4281.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act