

Policy statement and recommended actions for early detection of prostate cancer in the Eastern Mediterranean Region

Policy goal

Implement an early detection programme to detect prostate cancer and precancerous lesions, at an early stage when they are small and localized; thus reducing prostate cancer mortality rates.

Background

Although the age-standardized incidence of prostate cancer in countries of the Eastern Mediterranean Region is lower than that in the high-income industrialized countries, the incidence is steadily increasing in those countries of the Region where data are available.¹ The increasing incidence presents a challenge to the existing cancer health care services in all countries. However, in a considerable proportion of men with prostate cancer, the disease does not become clinically significant during the patient's lifetime. Therefore, although early diagnosis of symptomatic men is essential, asymptomatic persons will receive little or no benefit from the detection of localized, low-risk, non-lethal cancers which, if treated, might result in substantial harm such as impaired urinary function and erectile dysfunction.

Common symptoms of prostatic enlargement in men above 50 years are those of bladder outflow obstruction, which includes hesitancy, incomplete voiding, nocturia, urinary incontinence, double stream and reduced flow. These are also symptoms of prostate cancer. Patients with prostate cancer may present with symptoms of metastasis, the most common being acute bone pain with or without fracture.

The tests used for early detection of prostate cancer are prostate-specific antigen (PSA) testing, prostate cancer antigen 3 (PCA-3) testing and digital rectal examination. Estimation of PSA levels in the blood and digital rectal examination are the most widely used prostate cancer screening early detection tests. PSA levels above 3 ng/mL, 4 ng/mL or 5 ng/mL in men aged 50–59 years, 60–69 years and 70 years or above, respectively, are considered abnormal. Elevated levels of PSA or an abnormal digital rectal examination should prompt further investigation with transrectal ultrasound-guided biopsy to confirm diagnosis.

A careful digital rectal examination can reveal the size of the prostate, indurations and hardness, nodularity, extension of tumour through the capsule and involvement of the seminal vesicles. If the test is available, PSA should be estimated in such symptomatic patients. The higher the level of PSA the greater the likelihood of cancer. The risk of prostate cancer on biopsy in symptomatic men with a PSA level above 10 ng/mL can exceed 60%, especially if associated with enlarged prostate on digital examination. The PSA level also correlates with the stage and aggressiveness of cancer. Men with localized disease can have very different prognoses and treatment options, ranging from observation alone through to radical surgery.

¹ Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers Cet al. GLOBOCAN 2012 v1.0, Cancer incidence and mortality worldwide: IARC CancerBase no. 11 [internet]. Lyon, France: International Agency for Research on Cancer. Available from <http://globocan.iarc.fr>, accessed 26 July 2016.

Key definitions

Early diagnosis aims to detect cancer in its early stages in people with symptoms, when treatment is simple and affordable, resulting in higher cure rates. Early diagnosis is based on improved public and professional awareness of signs and symptoms of cancer. It entails recognizing possible warning signs and taking prompt action, and requires education of the public to improve cancer awareness, training of health care professionals to improve their professional awareness and skills in recognizing early signs and symptoms of common cancers, availability, affordability and good access to diagnostic and staging investigations, treatment services and follow-up care in public health services.

Screening is the process of identifying apparently healthy, asymptomatic people who are at high risk of having clinically undetectable early disease. It involves routine application of a screening test at specified intervals and referring those with “abnormal” (positive) screening tests for further diagnostic investigation and treatment. A screening test may be offered to a large number of asymptomatic people in the population, when it is called population-based screening, or it may be offered by a provider to asymptomatic individuals during routine health care interactions, when it is called opportunistic or spontaneous screening.

Population-based screening programmes are characterized by centralized screening invitations to a well-defined target population; systematic call and recall for screening; timely delivery of test results, diagnostic investigations, treatment and follow-up care; centralized quality assurance; and a programme database with linkages to other information systems (such as cancer and death registration systems) for monitoring and evaluation of the programme.

Opportunistic screening programmes provide unsystematic screening to subjects on request or coincidentally during routine health care interactions. There is no predetermined eligible population or protocol, and no systematic invitation at predefined intervals.

Recommended actions

1. **Conduct a situation analysis for planning.** Each country in the Region should review the burden, the current status of prostate cancer early detection and treatment in the context of the situation analysis performed for its national cancer control plan (if available) and the availability and quality of resources including infrastructure, trained human resources and health care financing for early detection, treatment and follow-up care. The situation analysis should include the following steps.

- Assess the current situation. Consider demographic data, available cancer data, data on other diseases potentially competing for resources, data on health care facilities and personnel.
- Assess the need to build capacity. Countries should consider whether primary care practitioners and specialists receive appropriate in-service training and reorientation, so they can promptly recognize those with a high clinical suspicion of prostate cancer based on symptoms and signs, and refer them for timely early diagnosis and management. They should also assess whether early diagnosis of prostate cancer is included in the medical school curricula in each country.
- Determine whether investment is required in health services infrastructure including diagnostic PSA, transrectal ultrasound, and histopathology as well as treatment services. Consider whether appropriate health care financing mechanisms are in place to ensure availability and access to timely diagnostic investigations and management.
- Determine availability and access to affordable diagnostic and treatment facilities. All countries should review their prostate cancer treatment policies and facilities to ensure they

are accessible, affordable, efficient and effective according to quality assured evidence-based guidelines. Countries should assess the availability of national guidelines for the diagnosis and management of prostate cancer. Financial, logistic and sociocultural barriers to patient access should be assessed.

- Include a clinical pathway starting from symptoms and signs, imaging and laboratory diagnosis.

2. **Improve diagnosis, treatment and follow-up care services.** Investment should be made in health services infrastructure and treatment services, and appropriate health care financing mechanisms evolved, to ensure availability and adequate access to diagnostic investigations and management in a timely and effective manner. Financial, logistic and sociocultural barriers to service access should be removed. National guidelines should be developed for the diagnosis and management of prostate cancer, if such guidelines do not already exist.

With regard to prostate cancer screening, meta-analyses of randomized trials do not demonstrate a reduction in prostate cancer mortality. Furthermore, due to significant over diagnosis, as well as the harm (impotence and incontinence) associated with prostate cancer screening, PSA screening is not currently recommended for any country in the world.

3. **Implement an early diagnosis programme.** A national committee should be established, with defined strong leadership, to implement and oversee the country's prostate cancer early detection programme. As far as possible, all relevant stakeholders should be included. The relevant government departments should ensure that financing is available to support the work of the committee. A prostate cancer control plan should be developed as part of the country's national cancer control plan (or reviewed and revised as necessary if one is already available). All steps in the plan should be carefully followed. It is strongly advised that pilot or demonstration projects should first be implemented in defined areas to establish that education, diagnosis and treatment can be delivered in an effective and timely manner. This is because several elements required for effective prostate cancer control may not yet be available in the country. Prostate cancer diagnosis and care will be facilitated if specialized urology units are established in second tier health care institutions, bringing together diagnostic and treatment expertise, as well as the availability of PSA testing for diagnosis (which should be done prior to a digital rectal examination), cystoscopy and trans-rectal biopsy.

4. **Conduct regular monitoring and evaluation.** Monitoring and evaluation are essential to ensure quality assurance and programme improvement. A prerequisite for an effective prostate cancer control strategy is the availability and accessibility of good quality medical records. These are the basis of efficient cancer registration. If a cancer register is not yet available, a special register of the diagnosis and stage (as well as survival) of all prostate cancer patients should be established. This can later be extended to all cancers when the resources are available. General indicators that will have to be monitored include:

- stage at diagnosis of prostate cancer cases
- incidence of and mortality from prostate cancer by 5-year age groups (40–44, 45–49, 50–54, 55–59, etc.)
- number of health care workforce (nurses, surgeons, urologists, pathologists), and the number of those trained in prostate cancer care
- availability of radiotherapy and essential medicines for the treatment of prostate cancer.