

**Executive Summary**

[Adapted from the report by DR JUNAINAH SABIRIN]

**Authors:**

Dr Junainah Sabirin  
Mr Syful Azlie bin Md Fuzi  
Madam Maharita bt Abd Rahman

**Expert Committee:**

Dr Kulendran Sivapragasam  
Dr Nor Saleha Ibrahim Tamin  
Dr Sharifah Mastura Syed Abu Bakar  
Dr Rosna bt Yunus  
Dr Arumuga Kumar  
Dr Muhammad Azrif Ahmad Anuar  
Dr Zainal Fitri Zakaria  
Dr Saunthari Somasundram  
Datin Dr Rugayah Bakri

**External Reviewer:**

Dato' Dr Mr Rohan Malek bin Dato'  
Dr Johan Thambu  
Professor Dr Azad Hassan bin Abdul Razak  
Professor Dr Mohd Nor Gohar Rahman

**Information specialist:**

Madam Zalina Ahmad  
Madam Sin Lian Tye

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Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia  
Level 4, Block E1, Precinct 1  
Government Office Complex  
62590 Putrajaya.

Tel: 603 8883 1246

Fax: 603 8883 1230

Available at the following website:  
<http://www.moh.gov.my>

**Background**

The incidence of prostate cancer is rising worldwide caused mainly by demographic factors and the increase in the number of suspected cases identifies following the introduction of PSA testing. Prostate cancer is least common in South East Asia, more common in Europe and most common in the United States. The risk factors for prostate cancers are age, family history and race. The natural history of prostate cancer is variable, ranging from indolent to strikingly aggressive with long preclinical phase. While the intention of screening for prostate cancer is to decrease mortality and increase patient's quality of life, the true benefit of screening remains uncertain. This has been highlighted by the conflicting recommendations made by various medical entities.

**Technical Features**

Prostate cancer is classified as an adenocarcinoma, or glandular cancer, that begins when normal semen-secreting prostate gland cells mutate into cancer cells. The PSA test and the digital rectal examination (DRE) are used as primary screening tools in the early detection of prostate cancer. Transrectal ultrasound (TRUS)-guided needle biopsies are performed to confirm diagnosis following PSA and/or DRE testing. The reference standard for these tests is histological confirmation of cancer.

**Policy Question**

Should screening for prostate cancer among asymptomatic men be carried out as part of the Malaysia National Cancer Control Programme?

**Objective**

To assess the effectiveness, safety and economic implications of screening asymptomatic men for prostate cancer compared to no screening or usual care.

**Methods**

Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-HTA databases, EBM Reviews-NHS Economic Evaluation Database, EBM Reviews-Cochrane Methodology Register, INAHTA database, HTA database and FDA database were searched. No limits were applied to the search. Additional articles were identified from bibliographies of retrieved articles and hand-searching of journals. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) and evidence was graded based on guidelines from U.S./Canadian Preventive Services Task Force.

**Result and conclusion**

The available evidence on prostate cancer mortality rates from two large randomised controlled trials was conflicting with the European Randomised Study of Screening for prostate cancer (ERSPC) reporting a 20% reduction in prostate cancer mortality but the Prostate, Lung, Colorectal and Ovarian cancer (PLCO) cancer screening study did not. In the ERSPC for every prostate cancer death prevented 1,410 men have to undergo screening, while 48 need to be treated in excess of control population to save one prostate cancer death.

There was good level of evidence to suggest that screening for prostate cancer led to positive stage and grade shift, however, it also led to overdetection and overtreatment. A considerable percentage of screened-detected prostate cancers is indolent and is difficult to differentiate from aggressive cancers. There was no retrievable evidence to determine the long term impact of prostate cancer

screening on quality of life and or its economic value.

There was good level evidence to suggest that complications associated with PSA test and DRE were mild and infrequent, and major complications associated with TRUS guided needle biopsies were rare. However, false-positive PSA screening test results were associated with adverse psychological effects and prostate cancer treatments were associated with more serious complications which include infection, impotence, incontinence and bowel dysfunction.

There was good level of evidence to suggest that the sensitivity and specificity of PSA test are not ideal leading to high false-positive and false-negative rate and there was no PSA threshold that effectively discriminates between the presence and absence of prostate cancer. Higher PSA level, positive family history of prostate cancer and abnormal DRE result were predictors for prostate cancer.

For mass screening programme to be medically and ethically acceptable, the WHO criteria for mass screening programmes have to be met. Given the uncertainty about the benefits and risks of mass screening for prostate cancer, men should be provided with current information about the benefits and risks of prostate cancer screening (the screening tests, the diagnostic and treatment path) so that each man can make his own decision whether or not to undergo individual screening.

#### **Recommendation**

Based on the above review, there was evidence to suggest that prostate cancer screening may reduce the likelihood of men dying from prostate cancer. However, current published data are insufficient to recommend the adoption of population screening for prostate cancer as a public health policy because of the significant overdiagnosis and overtreatment that would result from the screening. Since men with family history of prostate cancer have a significantly higher risk of developing prostate cancer, we therefore recommend selective screening of asymptomatic men with a family history of prostate cancer from the age of 40 years and above.

PSA test may be used for prostate cancer screening. However, there was no PSA threshold that effectively discriminates between the presence and absence of prostate cancer. DRE may be used as an adjunct to PSA test.

Men who expressed an interest in prostate cancer screening need to be properly informed on the potential benefits and harms associated with prostate cancer screening. A standard guideline for prostate cancer screening need to be established.

Organizational issues such as training, manpower, good referral system, treatment and funding need to be addressed at all levels.