

**Title** HPV URINE TEST FOR CERVICAL CANCER SCREENING

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**Reference** Health Technology Assessment Report  
<http://www.moh.gov.my/index.php/pages/view/113>

#### **Aim**

Should HPV urine test be used as a screening method in the cervical cancer screening programme in Malaysia?

#### **Conclusions and results**

##### **Clinical performance (diagnostic accuracy)**

Limited fair level of retrievable evidence to suggest that:

a. In a combination population of symptomatic (78%) and asymptomatic (22%) women, sensitivity and specificity of urine test varies with the types of HPV. Pooled sensitivity and specificity was 87% and 94%, respectively, for urine detection of any HPV. Urine detection of high risk HPV had a pooled sensitivity of 77% and specificity of 88%, while urine detection of HPV 16 and 18 had a pooled sensitivity of 73% and specificity of 98%.

b. In symptomatic population, overall sensitivity and specificity has been quite variable, ranging from 44.8% to 90.5% and 34.8% to 85.0%, respectively. Positive predictive value (PPV) ranged from 37.2% to 86.4% whereas NPV ranged from 75.6% to 89.8%.

##### **HPV detection and genotyping**

Substantial fair level of retrievable evidence to suggest that:

a. Detection of HPV DNA in urine among screened asymptomatic women varies depending on the chosen population. HPV DNA detection ranged from 4.2% to 28.6% in sexually active women, and ranged from 9.2% to 19.2%, particularly in young sexually unexposed girls and healthy tribal girls

b. Detection of HPV DNA in urine was increased among screened symptomatic women ranging from 34.5% to 78.1%

c. HPV type 16 was identified most frequently in both urine and cervical samples

##### **HPV concordance in paired urine and cervical samples**

Substantial fair level of retrievable evidence to suggest that:

a. Overall concordance for HPV positivity and negativity between cervical and urine samples in symptomatic women varied from 69.3% to 90.0% (agreement,  $\kappa$  from 0.41 to 0.80)

b. Type specific concordance rates in the paired samples have been very good for invasive cervical cancer (79.0%)

#### **Safety**

There was no retrievable evidence on adverse events or complications associated with HPV urine test used for cervical cancer screening.

#### **Cost / cost-effectiveness / economic evaluation**

There was no retrievable evidence on the cost-effectiveness of HPV urine test for cervical cancer screening. However, the average cost per HPV-DNA test for cervical specimen using PCR-based method ranged from RM 91.50 to RM 183.00. Hence, it is assumed that the cost for HPV-DNA detection in urine will most probably the same. The average cost per Pap smear test performed in Malaysia is RM 20.12

#### **Recommendations (if any)**

HPV urine test may have the potential as one of the screening method to be used in the cervical cancer screening. However, in view of the wide range of sensitivity and specificity in detecting HPV DNA in urine (symptomatic and combination of symptomatic and asymptomatic population) and no diagnostic accuracy study was retrieved among asymptomatic population, hence, currently HPV urine test is not recommended to be used as one of the screening method in the cervical cancer screening programme in Malaysia until there is more evidence on its diagnostic accuracy.

#### **Methods**

Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-Health Technology Assessment, EBM Reviews-Cochrane Methodology Register, EBM Reviews-NHS Economic Evaluation Database, Database of Abstracts of Reviews of Effects (DARE), Horizon Scanning database, INAHTA database, HTA database and FDA database were searched. Additional articles were identified from bibliographies of retrieved articles and hand-searching of journals. General search engine was used to get additional web-based information. No limits were applied to the search. Studies were selected based on inclusion and exclusion criteria. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) tool. All full text articles were graded based on guidelines from the U.S./Canadian Preventive Services Task Force.

#### **Further research/reviews required**

More evidence on the diagnostic accuracy is needed before recommending HPV urine test for population screening.

#### **Written by**

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