[redacted] CERVICAL SCREENING TEST KIT
Executive Summary

Adapted from the report by ASMIRAH MD REDZUAN & DR. SYAHARATUL PATIMAH]

MaHTAS
Malaysian Health Technology Assessment Section

Review Group Membership

MaHTAS Reviewer:
Asmirah Md Redzuan
Dr. Syaharatul Patimah Kamarudin
Datin Dr. Rugayah Bakri
Dr. Izzuna Mudla Mohamed Ghazali

External Reviewer:
Dr. Yong Chee Meng
Datin Dr. Fauziah Kassim

For further information please contact:

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

2014

Introduction

Cancer of the cervix is the third most common cancer among women and fifth most common cancer in the entire general population in Malaysia. There are a total of 847 cases diagnosed in 2007 registered at National Cancer Registry. Cervical cancer incidence rate increased with age after 30 years old and has its peaks at ages 65 – 69 years.

In Malaysia, the cervical cancer screening programme was established in 1969 to ensure early detection of cervical cancer among the target group of women aged 20 – 65 years. In 1995, the Ministry of Health launched the “Healthy Life Style Campaign against Cancer”, an open invitation to women aged 20 – 65 years to have Papanicolaou (Pap) smear taken every three years for free. However, only 47.3% of Malaysian women have been screened via Pap smears.

Currently, the cervical cancer screening in Malaysia uses the conventional Pap smears. However, there is a new technology named [redacted] Cervical Screening Test Kit.

[redacted] Cervical Screening Test Kit.is used for the detection elevated levels of E6 oncoprotein expressed by human papillomavirus (HPV) types 16 and 18. The manufacturer claims that it can demonstrate outstanding clinical performance with high specificity and high positive predictive value. Thus it can be used to triage patients with high-risk HPV and other abnormal screening results to avoid unnecessary treatment procedures.

This test is used to analyze cells extracted from cervical cytology swab specimens. It is based on the capture and detection of HPV E6 oncoproteins using high-affinity monoclonal antibodies (mAb) in a lateral-flow assay format. This technology relies on the capillary migration of the analyte through a nitrocellulose membrane, where specific capture antibodies are immobilized. The analyte is detected by an alkaline phosphatase (AP) conjugated mAb. The mAb-AP-analyte complex on the test is visualized by the addition of an enzyme substrate, producing a coloured line. A positive result is a visible test line.

The [redacted] Cervical Screening Test Kit is claimed to have high specificity, high positive predictive value, and stable at room temperature and does not require any complex equipment which allows cervical cancer detection to be carried at point-of-care. However, it is not known whether the claim is supported by scientific evidence. Thus, this technology review was conducted following a request from Senior Principal Assistant Director, Disease Control Division.

Objective/Aim

The objective of this technology review is to assess the safety, efficacy/effectiveness and cost-effectiveness of [redacted] Cervical Screening Test Kit at point-of-care.

Results and Conclusions

There was limited good level of evidence retrieved on the efficacy/effectiveness of [redacted] Cervical Screening Test Kit. However, there was no retrievable evidence on safety and cost-effectiveness of this test. The test is certified with CE-IVD and the market price for this test is MYR 126 per kit for private sector.

Based on the above review, the evidence seems to indicate potential benefit of [redacted] Cervical Screening Test Kit in detecting HPV 16 and 18 in CIN2+, CIN3+ and cervical cancer. It may be feasible to be used as point-of-care. However, other factors such as cost of equipments and consumables also training need to be considered.

Methods

Literature was searched through electronic databases which included MEDLINE(R), Cochrane Database of Systematic Reviews, Health Technology Assessment, Embase, NHS Economic Evaluation Database, Database of Abstracts of Review of Effects, PubMed, other websites; INAHTA, U.S. FDA, NIHR Centre for Reviews and Dissemination – CRD Database, EuroScan International Network, Australia and New Zealand Horizon Scanning Network, Health Policy Advisory Committee on Technology (HealthPACT) and general databases such as Google.