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The feasibility and acceptability of self-sampling and HPV testing using Cepheid Xpert® HPV in a busy primary care facility

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Abstract

Malaysia's approach to reducing the burden of HPV-related disease has centred on adolescent vaccination and cervical screening with Pap smears. While the vaccination programme has been broadly successful, Pap smear screening has been less successful. In an effort to improve screening uptake, the ROSE 1.0 pilot aimed to create more efficient screening, with improved quality and lower total cost.

Background

Malaysia's approach to reducing the burden of HPV-related disease has centred on adolescent vaccination and cervical screening with Pap smears. The national vaccination programme has been broadly successful, achieving 84.07% coverage for the third dose among girls aged 13 in 2016 [1]. While not as high as infant/childhood immunisation rates, which exceed 98% for BCG, DPT-HIB, polio and hepatitis B and 93% for MMR, this achievement was acknowledged by the Asia-Oceania Research Organisation in Genital Infection and Neoplasia, which presented a *Recognition of Effort* award at its 2016 Congress.

In contrast, Pap smear screening has been less successful. A programme has been in place since 1969 but in 2015 the uptake among eligible women varied between states from only 17% to 35%. Opportunistic screening is offered by a variety of agencies (Ministry of Health, National Population and Family Development Board, university hospitals, private hospitals and clinics, Ministry of Defense and NGOs) but there is no formal registry nor a centralised system of cytology laboratories. Quality assurance measures across the public and private sector are not standardised. Barriers to uptake of Pap screening have included both patient and healthcare system factors.

Patient factors:

- Fear, embarrassment and shame;
- Lack of perceived benefits;
- Inconvenience (no time);
- Negative experience;
- Poor awareness.

Healthcare factors:

- Primary care facilities – lack of space and privacy;
- Inadequate human resources;
- Limited screening infrastructure – cytopathologists, registry for call and recall;
- Poor sensitivity of Pap smear.

ROSE 1.0 (Removing Obstacles to Cervical Screening) Pilot Project

Together with our partners, VCS Foundation, we sought to improve screening uptake by applying design thinking to cervical cancer screening. This involved human-centred research, collective and diverse teamwork, and rapid prototyping to develop an innovative approach to the complex and persistent problem of HPV-related cervical cancer. The goals of the ROSE 1.0 pilot aimed to create more efficient screening, with improved quality and lower total cost.

In coming up with the ROSE solution, we visited Ministry of Health community clinics and conversed with healthcare professionals there to better understand the challenges they faced. Through these discussions, we came up with a ROSE solution that was specifically designed for Malaysian women.

The outcome of this design process was a new cervical screening approach, based on self-sampling using Copan FLOQswabs™ (Copan, Brescia, Italy) in community clinics (Klinik Kesihatan) and the Cepheid Xpert® HPV assay system, with testing performed on site. Advantages of this switch from Pap smear to HPV DNA testing include improved sensitivity (90% compared with 50%) and an automated, objective process enabling greater cost effectiveness. Onsite testing reduces risk of attrition due to failures in processing requests, samples, results and verifications between clinic and laboratory, but a further important element of the ROSE 1.0 pilot was development of an e-health workflow system based on a population registry powered by canSCREEN™ (VCS Foundation, Melbourne, Victoria, Australia; www.vcsdigital.com.au/canscreen) and mobile technology. This digital component allows participants to pre-register via mobile phone and obtain an SMS verification code to facilitate rapid registration on clinic arrival and subsequent receipt of test results. This is important as ensuring follow-up care and appropriate treatment has a greater impact on mortality reduction than increasing screening coverage.

Preliminary results of the ROSE 1.0 Pilot

In the initial phase of ROSE 1.0, 1997 women were recruited through three community clinics during April–July 2018. Their median age was 43 years, the HPV positivity rate was 5.5%, while 0.65% (13 out of 1997 women screened) of samples were inadequate for testing. Among those who tested positive, 91% engaged in further follow up.

In terms of user experience, the mobile workflow enabled brief attendances typically lasting 11 minutes, comprising 0.5 minutes for eligibility checking, 1.75 minutes for education, 2.5 minutes for registration, and 6.25 minutes for sample collection. With no need for a bed for speculum examination, a simple screened area allowed for privacy during self-sampling (Figure 1). Test results were provided within 3 working days to the participants' mobile phones.

Feedback from pilot participants was excellent, with 99% of women saying they would be willing to do ROSE again, 95% that they would recommend it to family/friends and 94% saying they preferred it to Pap smear screening. Reasons why women liked ROSE included that it was simple (96%), quick (87%),

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Figure 1. A ROSE screening area in one of the Ministry of Health community clinics.

self-performed (89%), enabled fast results (82%), enabled receipt of results by phone (76%), and offered follow up/treatment (62%) (individuals could select more than one reason). Moreover, some participants actively promoted ROSE through positive reviews on social media, amplifying the success of the project:

> *Assalamualaikum wbit dan Salam Sejahtera.*
>
> *A zillion thanks to the team of:*
>
> *Pilot Project Rose at Klinik Kesihatan Sect 19, Shah Alam*
>
> *Team Project Rose at PPUM especially Prof Woo and all the members (doctors, nurses etc).*
>
> *All of you are very kind and superb in rendered the services to us. Keep up the excellence works and may all of you granted good health and happiness in life.*
>
> *Regards*
>
> (Example of a message posted on the Facebook page for ROSE 1.0.)

In recognition of these achievements, the ROSE 1.0 pilot was a finalist for the Union for International Cancer Control's (UICC) 2018 Collaboration Award. The UICC awards aim to identify and celebrate best practices across UICC members and inspire the cancer control community. The Collaboration Award recognises collaborative initiatives, whether national, regional or international, that exhibit innovative models of engagement and outcomes.

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Cepheid does not endorse the testing of alternate specimen types (specimen types that are not cleared/approved/registered by any regulatory body, per the package insert). If you choose to use the assay with alternate testing types, it is your laboratory's responsibility to validate the assay for each alternate specimen type in accordance with federal, state, and local laws.

Reference

1. Ministry of Health Malaysia. Health Facts 2016.MOH/S/RAN/17.16(AR). August 2016. Available at: www.moh.gov.my/images/gallery/publications/KKM%20HEALTH%20FACTS%202016.pdf (accessed February 2019).