Health service delivery models for scaling use of point-of-care HPV 'test and treat' strategies in high-burden, low-income settings

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Abstract

Visual inspection of the cervix with acetic acid (VIA) has shown disappointing performance when used alone as part of screen and treat strategies for cervical cancer prevention in Papua New Guinea. Point-of-care testing with the Xpert® HPV assay (Cepheid, Sunnyvale, CA, USA) offers a new approach, enabling 'test and treat' services using self-collected specimens with same-day curative cervical ablation (cryotherapy or thermocoagulation).

Background and significance

Visual inspection of the cervix with acetic acid (VIA) has shown disappointing performance when used alone as part of screen and treat strategies for cervical cancer prevention in Papua New Guinea (PNG). Point-of-care (POC) testing with the Xpert® HPV assay (Cepheid, Sunnyvale, CA, USA) offers a new approach, enabling 'test and treat' services using self-collected specimens with same-day curative cervical ablation (cryotherapy or thermocoagulation).

In the first evaluation of a potentially scalable model for cervical screening in lower and middle-income country (LMIC) settings, we found that POC Xpert® HPV testing using self-collected vaginal specimens had excellent performance for the detection of underlying high-grade disease among 1005 women attending routine cervical screening services in PNG [1–5]. A second field trial is now under way at four clinical sites in PNG to confirm these initial findings, and to establish the cost-effectiveness and health system implementation requirements of this POC test and treat strategy.

Model of care

The POC test and treat model comprises self-collection of samples for rapid turnaround Xpert® HPV screening, followed by assessment and treatment as shown in Figures 1 and 2. Significantly, VIA is used not for diagnostic purposes or clinical triage but to determine eligibility for same-day clinic-based cryotherapy or thermocoagulation among women who test positive for HPV. Those not considered eligible for same-day treatment are referred for appropriate specialist review and treatment, for example due to a lesion suspicious of cancer being seen on examination.

Preliminary results

Analysis of data from 770 women enrolled out of a planned total of 3400 participants indicates that around 12.5% of women tested at POC were hrHPV positive, among whom, 94% were treated on the same day by thermocoagulation and 6% were referred for specialist review. All women referred to date for specialist review have completed follow-up and received appropriate diagnosis and treatment.

The POC test and treat approach appears highly acceptable to women and to clinic staff, offering significant time savings both for the women and for skilled healthcare providers. Compared with either screening by VIA examination alone, or a combined screening protocol comprising Xpert® HPV testing followed by VIA, the POC test and treat approach enables significant improvements in clinic flow and efficiency, is feasible to implement in routine clinical settings, and as we have previously demonstrated [1,2,5], has superior performance for the detection of underlying high-grade disease.

From innovation to impact: what next?

Considerable progress has been made in developing this new cervical screening and treatment strategy, but further work is needed to achieve a real impact on the burden of HPV-related disease in PNG and other LMIC settings. Facilitating factors are that the model is well defined and has been successfully field tested, and builds on established clinical expertise in VIA and cryotherapy in many LMICs. Moreover there are now established technical and logistic networks for use of the Xpert® system following its introduction for tuberculosis (TB) testing, with good national and international support. There is scope for integration of HPV testing into established HIV treatment and care services alongside Xpert® testing for HIV viral load, TB, chlamydia/gonorrhoea and hepatitis C infection. A number of key knowledge gaps and challenges remain however, including:

- Optimal service delivery strategies for those at greatest need, for example women living with HIV infection and women in rural and remote communities in LMIC settings;
- The role of visualisation for clinical triage in certain situations, for example the use of portable digital colposcopy to guide management among hrHPV-positive women living with HIV;
- Establishing appropriate financing and cost-sharing models to enable widespread scale-up.

Addressing these gaps in understanding will be essential to translating the potential impact of HPV POC test and treat strategies into public health reality in LMICs.

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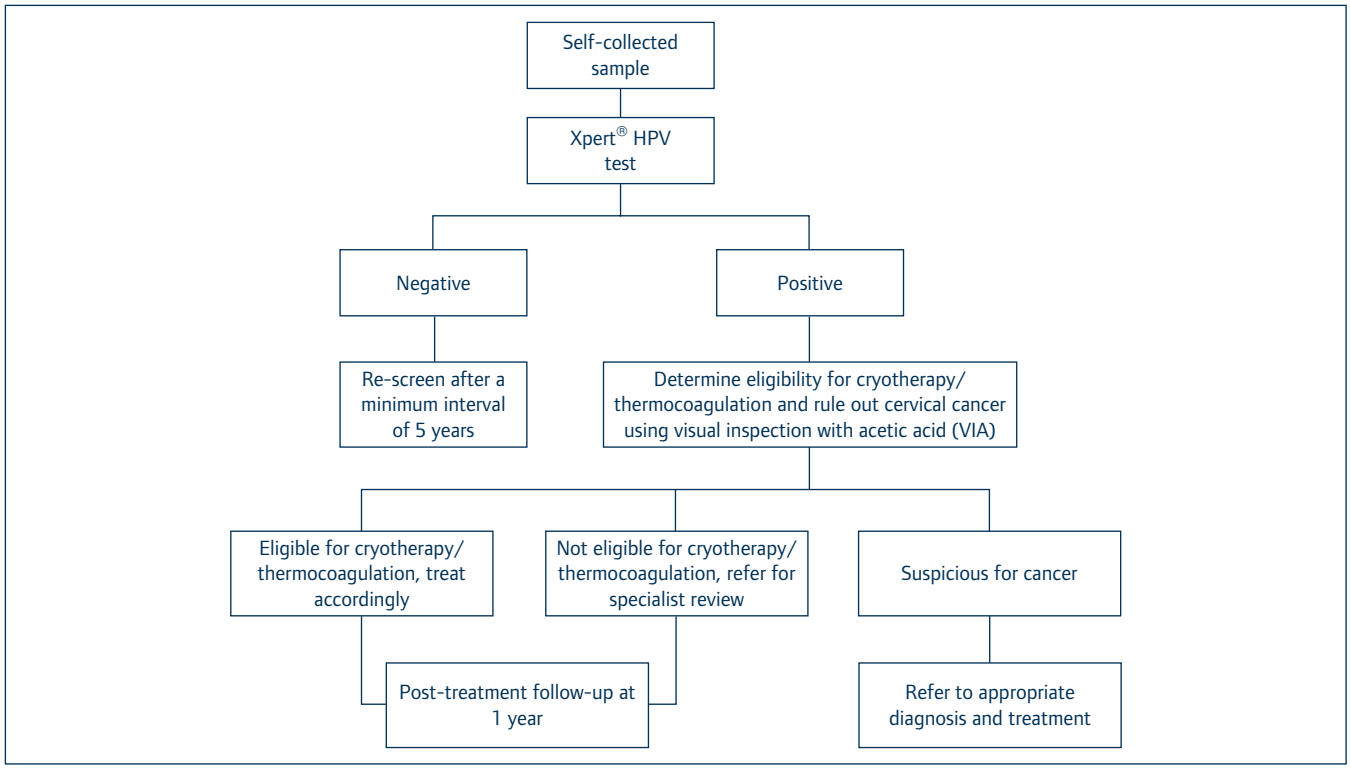

Figure 1. Model of care for 'test and treat' services using self-collected specimens with same-day curative cervical ablation

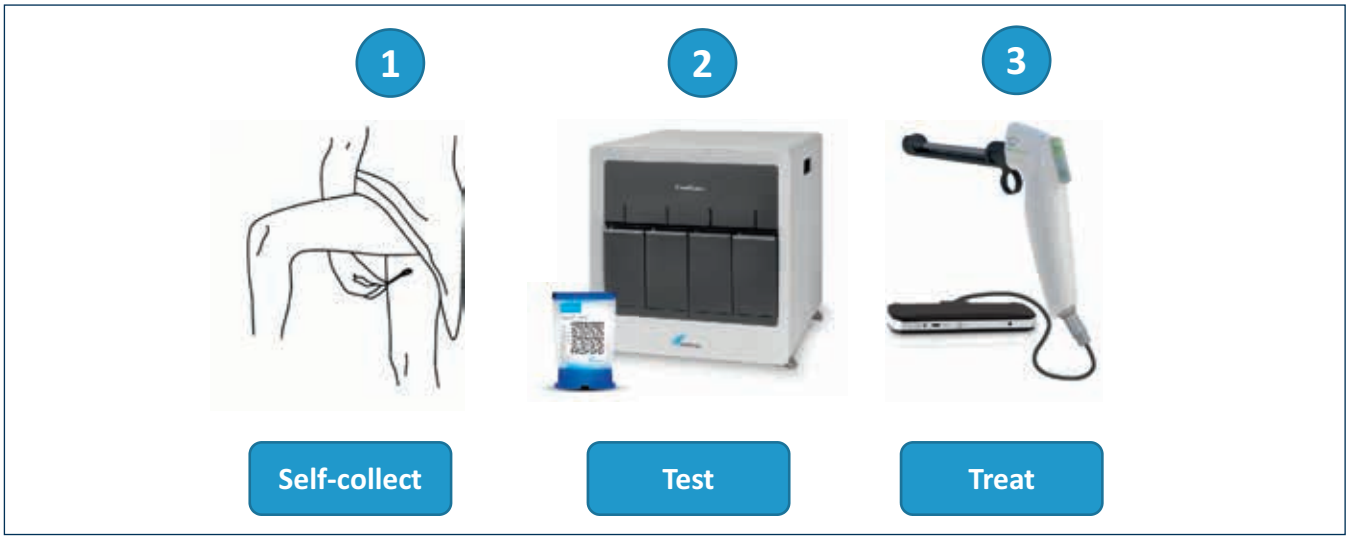

Figure 2. Visual summary of the POC test and treat model

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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.

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