

HPV testing in self-collected samples



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Women have problems accessing screening services due to a complexity of factors that include socio-economic conditions, subjective factors and cultural values and norms, and health services organization and management. Self-collection of a vaginal sample for HPV testing gives them the possibility of collecting the sample by themselves, in a private room, with no other person looking at their body. This unique characteristic of HPV-testing makes it a revolutionary tool for screening programs. After decades of work to understand and try to overcome barriers faced by women to access screening, the medical community has a tool that allows overcoming some of the most important problems, for example the shame of the gynecological visit or the scarcity of sample takers in remote areas. Studies carried out in different settings have shown that it is highly accepted by women.^{1,2} A study carried out in Argentina where women had the option to choose showed that women preferred self-collection to clinician-collected HPV testing, even when they lived in rural areas and when self-collection was offered by male community health workers (CHWs).³ HPV-self collection is a highly effective method to detect precancerous disease and cancer, especially when compared to cytology.⁴ It is less sensitive than clinician collected HPV-testing, and that is why self-collection has been mainly recommended for screening under-users. However, women get screened at great cost in terms of loss of workdays, childcare limitations, and psychological stress. Therefore, self-collection could be offered to all women and allow

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them to choose based on their preference. This would allow including women preferences as a decisive factor in the equation to recommend and choose between two screening methods that are both highly effective. As the difference in sensitivity might be reduced with PCR-based methods, more evidence is needed about how these tests perform for self-collection in programmatic conditions. Several studies have used different methods to offer women HPV self-collection. In European studies, women received self-collection through the mail system, and this has resulted in a moderate increase in screening uptake.⁵ In several studies carried out in middle/low income settings, self-collection was offered at home by a health provider, such as CHWs



Laboratory technicians in a screening site in Argentina

in Argentina⁵ or a nurse in Chile.¹ This strategy is more suitable to those settings considering that using the mail would not be feasible, and in many countries CHWs are already part of the first level of care and they have good relationships with the community. The possibility of offering self-collection in health centers could be also considered, but in this case the impact on barrier reduction will be limited. In Argentina, self-collection has also been

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promoted in community fairs, with rooms specially arranged to provide adequate privacy.

HPV+ women need to be triaged to identify those who need diagnostic follow-up and eventually treatment, adding a visit to the screening process. In several countries, this limitation of HPV-testing has been overcome by taking samples for HPV

testing and triage cytology in the same visit, but this is not possible with HPV-self collection, and this is probably its major shortcoming. Women with HPV+ results would need 2-3 visits to the health facility, increasing the risk of not completing the triage/diagnosis/treatment process. See-and-treat approaches can be a solution, but they are not feasible in all settings. Therefore, the ideal self-collection test would allow for screening and triage in the same sample and provide results immediately. This would not only reduce the number of visits, but also give health providers the possibility of providing on-the-spot appointments for next steps, and specific counseling targeted at increasing adherence to follow-up among women at high risk of cervical cancer. In the meantime, it is very important to devise strategies and mechanisms to facilitate women access to health services for triage. If self-collection is offered at home it is very important to strengthen the coordination within the health system; then HPV+ women are visualized as patients even if their “point of entry” has not been the health center. The use of health technologies to send reminders to women and health providers should be further explored and investigated.

Self-collection is a tool for overcoming barriers to health services, but it is not a magic bullet that makes barriers disappear. This reminds us that screening technologies are only effective if applied in

organized programs. This means, among other aspects, having a coordinated referral network, quality health services that are responsive to women needs, well-established responsibilities for each level of the health system, and information systems that allow tracking of the entire continuum of care.

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TABLE 1

Self-collection of vaginal specimens for HPV testing in cervical cancer prevention (MARCH study): a community-based randomised controlled trial in Mexico

	SELF SAMPLING AND HPV SCREENING	INVITATION FOR A PAP SMEAR
Number	12.330	12.731
Positive Test	9.8%	0.38%*
CIN 2+ x10 ⁴	117.4 (RS: 3.4)	34.4 (Ref.)
Invasive cancer x10 ⁴	30.4 (RS: 4.2)	7.2 (Ref.)
PPV CIN 2+	12.2%	90.5%

HPV= human papillomavirus. CIN=cervical intra-epithelial neoplasia. | PPV=positive predictive value. (RS, Ref) = relative sensitivity compared to the reference | *: threshold of abnormality defined as ASCUS+

In this randomized trial in Mexico, some 25,000 women were offered either self sampling advise and devices or conventional gynecological examination for a PAP smear test. Participation rates were 98% in the self sampling arm vs. 87% in the Pap test arm. Self samples were then tested for HPV DNA using Hybrid Capture 2 (HC2) in a centralized laboratory. The number of screen-positive women was 9.8% in the HPV arm vs. 0.38% in the Pap smear arm (cutoff ASCUS+). However the number of CIN 2+ cases or invasive cancer cases was 3 to 4-fold higher in the self sampling and HPV testing arm (RS: 3.4 and 4.2) compared to the Pap smear arm. Although the PPT of a positive cytology was much higher than the one for HPV The authors concluded that the high sensitivity of the self sampling and HPV test was a strong asset in populations with limited opportunities for screening in their lifetime.