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Performance of Pap among HPV positive women according to laboratory characteristics in Latino America: an analysis within the ESTAMPA study

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Introduction
Cervical cancer is the fourth most frequently occurring cancer in women around the world, most of cases occurring in low- and middle-income countries. High risk human papilloma virus (HR-HPV) DNA test is highly sensitive to detect cervical intraepithelial neoplasia grade 2 or worse (CIN2+). However, the specificity is limited as HPV infections are very common and the majority clear spontaneously. A good performance of cervical cancer screening program based on HPV requires a secondary triage technique which, within the group of HPV-positive women, will identify those women with risk of developing pre-invasive or invasive cervical lesions. Pap test represents the immediate test of triage because of the available installed capacity in many countries, particularly in Latin America. The aim of this work is to evaluate the performance of Pap read without knowledge of HPV status to detect CIN3+ among HPV positives women according to laboratory characteristics across Latin America countries participating in the ESTAMPA study (Multicentric study of cervical cancer screening triage with HPV testing, NCT01881659).

Methods
In nine Latin American countries, 45,000 women are being screened with Pap and HPV; those with ASCUS+ or being HPV+ have colposcopy, biopsy and treatment as needed. Women without disease are those with negative screening, negative colposcopy, or negative/CIN1 histology. Pap laboratories were classified by :1) type of laboratory (public vs private), and, 2) cytology interpretation protocol (pathologists read 100% of smears vs they only read ASCUS+ based on cyto-technicians interpretation), and in one public laboratory only Paps of HPV+ were processed and read. The sensitivity and specificity of Pap for CIN3+ detection among HPV+ were estimated overall and by laboratory characteristics.
Results
Among 4,661 HPV positive women included in the analysis, 223 (4.8%) CIN2, 422 (9.1%) CIN3 and 44 (0.9%) cancers were detected. Overall, the sensitivity and specificity for CIN3+ detection were 53.9% (95%CI 49.3-58.3) and 86.0% (95%CI 84.9-87.0), respectively. No differences in sensitivity between public and private laboratories were observed (49.5% [95%CI 42.6-56.4] vs. 48.1% [95%CI 40.4%-55.9]); and or when Paps were interpreted first by cytotechnicians and only smears ASCUS+ by pathologist and when pathologists interpreted 100% smears (42.9% [95%CI 35.3-50.8] vs. 53.5% [95%CI 46.6-60.2]). However, the laboratory where only Paps of HPV+ were processed and read had sensitivity and specificity of 70.0% (95%CI 60.9-77.8) and 85.9% (95%CI 83.7-87.8), respectively.
Conclusions
Pap sensitivity for CIN3+ detection among HPV+ was limited. However, the highest sensitivity was observed where only HPV+ smears were read. This suggests that Pap performance may be improved when HPV status is known, supporting its use as triage until better/accessible biomarkers are available. In this context, in the ESTAMPA study Paps are being re-read knowing HPV positivity in 12 laboratories to confirm this hypothesis.

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