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Field evaluation of the Xpert® HPV Test for the detection of human papillomavirus infection in women using self-collected vaginal compared to clinician-collected cervical specimens

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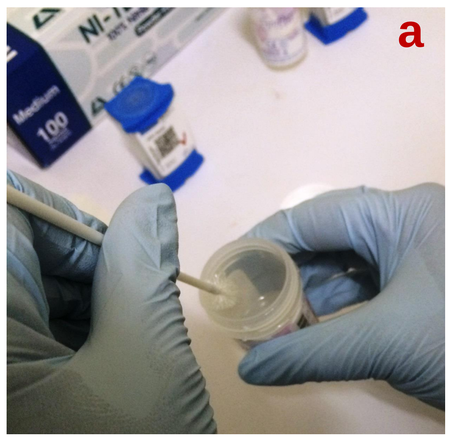
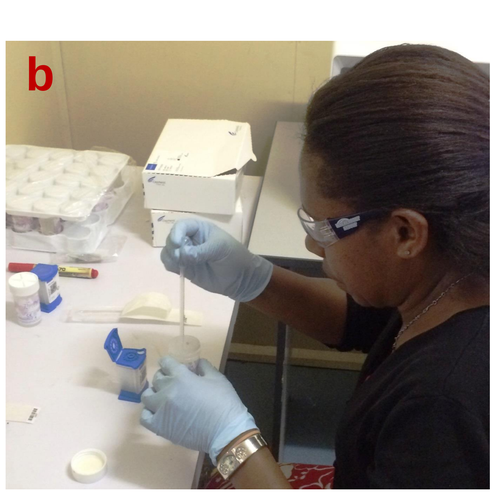
Introduction

- Papua New Guinea has among the highest estimated burdens of cervical cancer globally but Pap test screening has been unable to achieve adequate coverage and visual inspection methods found to be inaccurate.
- The Xpert® HPV Test (Cepheid, Sunnyvale, CA, USA) is a CE-IVD Mark real-time nucleic acid amplification assay that uses the established GeneXpert® platform and simultaneously detects 14 oncogenic HPV types.
- The test takes 60 minutes, is easy to use, and has the potential to be provided at point-of-care but has not previously been validated for self-collected vaginal specimens.





a: cytobrush specimen is prepared in PreservCyt (ThinPrep)

b: 1mL is removed from the PreservCyt vial and transferred to the Xpert HPV Test cartridge

c: Xpert HPV Test cartridge is placed in the GeneXpert machine for testing

Methods

Study population

- Women aged 30-54 years attending two well woman clinics in PNG are being invited to participate (N=1000)

Study procedures

- After informed consent, a self-collected vaginal ('V') specimen and a clinician-collected cervical ('C') specimen are taken using a cytobrush and tested by Xpert HPV in the clinic.
- Women are given their cervical HPV test result the same day.
- Those with a positive HPV test and a positive examination on visual inspection of the cervix after acetic acid (VIA) are offered same-day ablative cervical cryotherapy.

Results

HPV-16		GX 'C' POS	GX 'C' NEG	
GX 'V'	POS	20	1	21
	NEG	0	570	570
		20	571	591
	PPA	100.0%		
	NPA	99.8%		
	OPA	**99.8%**		

HPV 18_45		GX 'C' POS	GX 'C' NEG	
GX 'V'	POS	9	4	13
	NEG	2	576	578
		11	580	591
	PPA	81.8%		
	NPA	99.3%		
	OPA	**99.0%**		

Other hrHPV		GX 'C' POS	GX 'C' NEG	
GX 'V'	POS	55	30	85
	NEG	4	502	506
		59	532	591
	PPA	93.2%		
	NPA	94.4%		
	OPA	**94.2%**		

All hrHPV types		GX 'C' POS	GX 'C' NEG		
GX 'V'	POS	73	30	103	
	NEG	6	482	488	
		79	512	591	
	PPA	92.4%	(90.2, 94.6)		
	NPA	94.1%	(92.2, 96.0)		
	OPA	**93.9%**	(91.9, 95.9)		

- The Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA) and Overall Percentage Agreement (OPA) between self-collected and clinician-collected specimens was 94-99% (N=591)
- Around 23% of women had a positive VIA exam but only 6% had both a positive Xpert HPV Test (all hrHPV types) and a positive VIA exam.

Conclusion

- Self-collected vaginal specimens compared favourably to clinician-collected cervical specimens for the detection of high risk HPV infection using the Xpert HPV Test.
- An algorithm that combines point-of-care HPV-DNA testing followed by VIA examination would reduce over treatment and allow clinicians to focus on those most at risk of cervical pre-cancer.

Acknowledgements

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