



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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Background

- Papua New Guinea (PNG) has among the highest estimated burdens of cervical cancer globally, with an age-standardized incidence of 23.7/100,000 compared to 5.0/100,000 in Australia and New Zealand.
- Preliminary findings from our on-going research in PNG have highlighted the difficulties of implementing a cervical screening 'test and treat' strategy based on visual inspection of the cervix with acetic acid (VIA) alone in this setting.
- Newly available technologies for point-of-care (POC) HPV-DNA testing could:
 - a) improve the efficiency and impact of clinic-based VIA and cryotherapy services (by acting as a triage mechanism);
 - b) enable community-based HPV-DNA screening by mobile outreach teams and the referral of those most at-risk into clinic-based services.



POC HPV-DNA testing for cervical screening

- The Cepheid Xpert® HPV Test is a rapid, highly-accurate, easy to use and fully automated, non-batch test that uses the Cepheid GeneXpert platform.
- Xpert HPV has >90% overall agreement with Roche cobas 4800 HPV Test, and >85% agreement with Qiagen Hybrid Capture 2 HPV DNA Test.
- Xpert HPV has high sensitivity and specificity for the detection of CIN2/CIN2+ and CIN3/CIN3+ compared to both Roche cobas 4800 and Qiagen hc2 assays.

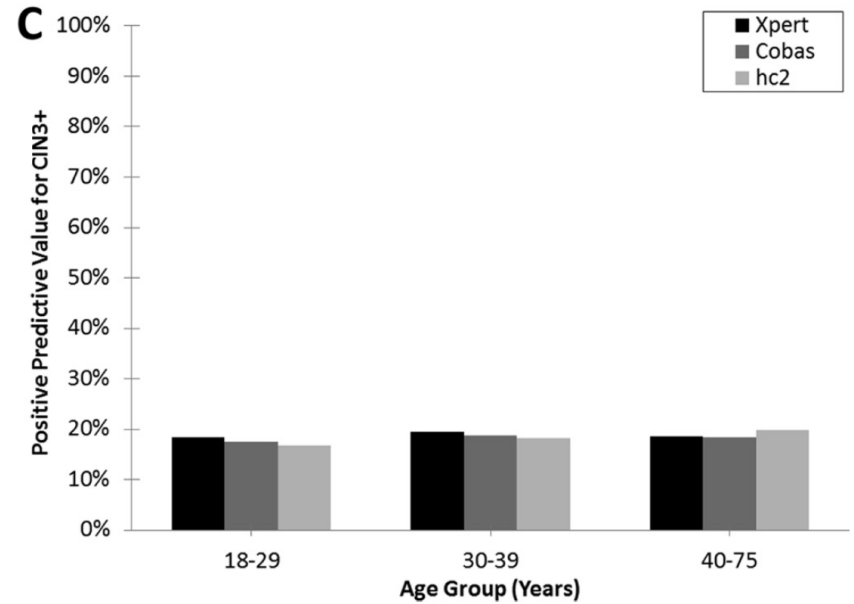
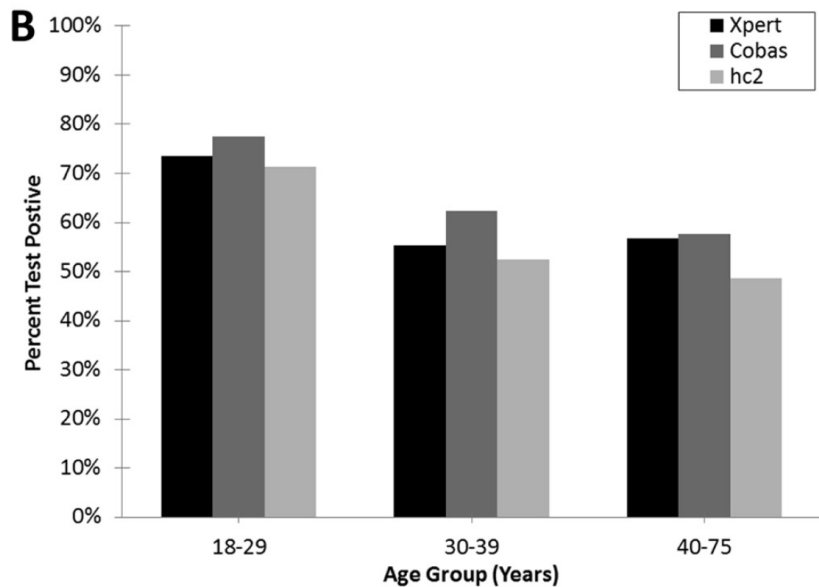
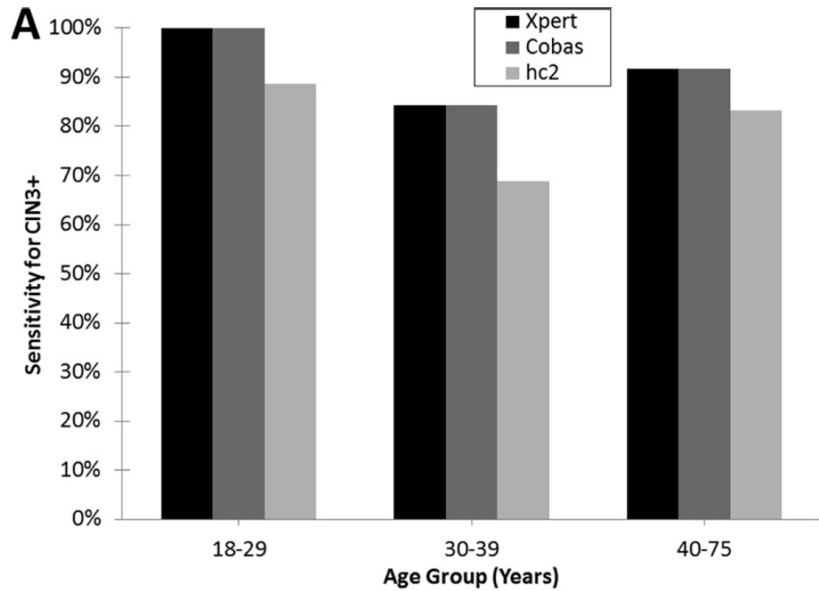
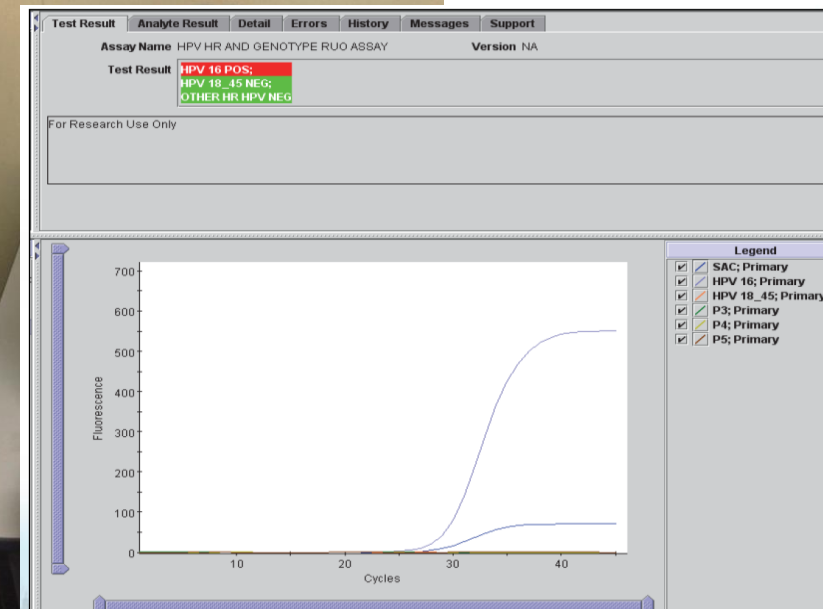


FIG 1 Sensitivity of Xpert (Cepheid), cobas (Roche), and hc2 (Qiagen) for cervical intraepithelial neoplasia grade 3 (CIN2) or more-severe CIN (CIN3+) (A), percent positive specimens (B), and positive predictive value for CIN3+ by age group (C).

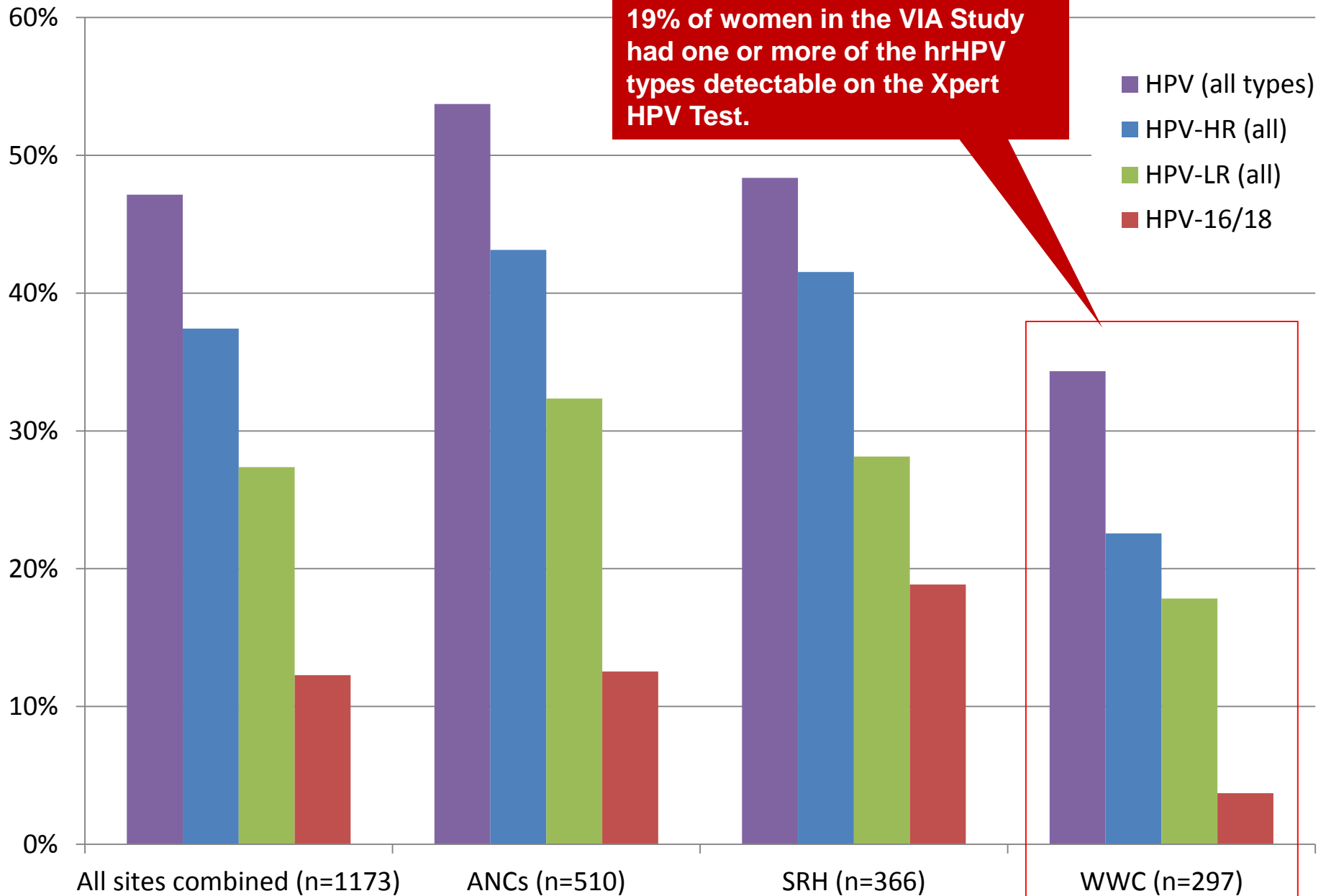
Xpert HPV Test



- Simultaneous detection of HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.
- Also contains a human reference gene and an internal Probe Check Control (PCC).
- Results available in 60 mins



Prevalences of HPV infection among 1173 women attending antenatal, sexual & reproductive health and well woman clinics in Papua New Guinea





Xpert HPV Study PNG

Rationale

- Xpert HPV has not been evaluated using self-collected vaginal specimens.
- If found to have comparable performance to cervical specimens this finding would have important implications for cervical cancer screening programs in high-burden, resource-limited settings.

Aims

- To evaluate the Xpert HPV Test for the detection of hrHPV infection using self-collected vaginal specimens compared to clinician-collected cervical specimens.
- To evaluate the feasibility of POC Xpert HPV testing in routine clinical settings in PNG.



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Study population

- Women aged 30-54 years attending Well Woman Clinics in Goroka and Mt Hagen (N=400)

Study procedures

- Following informed consent procedures, women complete a short interview and clinical examination, and provide self-collected and clinician-collected genital specimens for clinic-based Xpert HPV testing.
- Cervical specimens are collected as part of routine clinical examination, immediately prior to VIA.
- Cervical and vaginal specimens are each collected using a cytobrush and tested side by side by Xpert HPV.
- Women are given their cervical Xpert HPV test result at point-of-care.
- Those with a positive HPV test and a positive VIA examination are offered same-day cervical cryotherapy.

Preliminary findings (Aim 1; N=313)

HPV-16		GX 'C'		
		POS	NEG	
GX 'V'	POS	13	0	13
	NEG	0	300	300
		13	300	313
PPA		100.0%		
NPA		100.0%		
OPA		100.0%		

HPV 18_45		GX 'C'		
		POS	NEG	
GX 'V'	POS	4	0	4
	NEG	1	308	309
		5	308	313
PPA		80.0%		
NPA		100.0%		
OPA		99.7%		

Other hrHPV		GX 'C'		
		POS	NEG	
GX 'V'	POS	34	16	50
	NEG	3	260	263
		37	276	313
PPA		91.9%		
NPA		94.2%		
OPA		93.9%		

All hrHPV types		GX 'C'		
		POS	NEG	
GX 'V'	POS	45	14	59
	NEG	4	250	254
		49	264	313
PPA		91.8% (95% CI: 88.7, 94.9)		
NPA		94.7% (95% CI: 92.2, 97.2)		
OPA		94.2% (95% CI: 91.6, 96.9)		



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Preliminary findings (Aim 2)

- One early-career researcher from our in-country laboratory team (Goroka) and one research nurse/midwife (Mt Hagen) conducted onsite Xpert testing.
- Study-specific QC and QA procedures were completed at each site prior to commencing enrolment, and support supervision provided by PNGIMR, Goroka and Mt Hagen General Hospital Pathology Department throughout the study.
- Around 8-12 women were tested per day at each clinic and received their 'C' specimen Xpert HPV test result at POC (total of 16-24 tests conducted per day per site). Study completed 3 months early in Mt Hagen and will complete 1 month early in Goroka.
- High acceptability of POC Xpert testing among clinic staff and clients.



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Conclusions

- Preliminary results suggest that (a) self-collected vaginal specimens compare favourably to clinician-collected cervical specimens for the detection of HPV infection in women using the Xpert HPV Test; (b) this approach is feasible and acceptable in routine clinical settings.
- Stored specimens will be tested at study completion on Roche cobas 4800 and OPA of cervical and vaginal Xpert tests compared.
- Funding is being sought in 2015 to undertake a field trial to investigate the impact, cost effectiveness and acceptability of point-of-care (POC) Xpert HPV testing for cervical cancer screening in high-burden, resource-limited settings.

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