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**Our Issues, Our Drugs,
Our Patients**

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Self-collected vs. Provider-collected Samples For Cervical Screening Using Xpert HPV

Abstract # 208

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2016

Disclosure

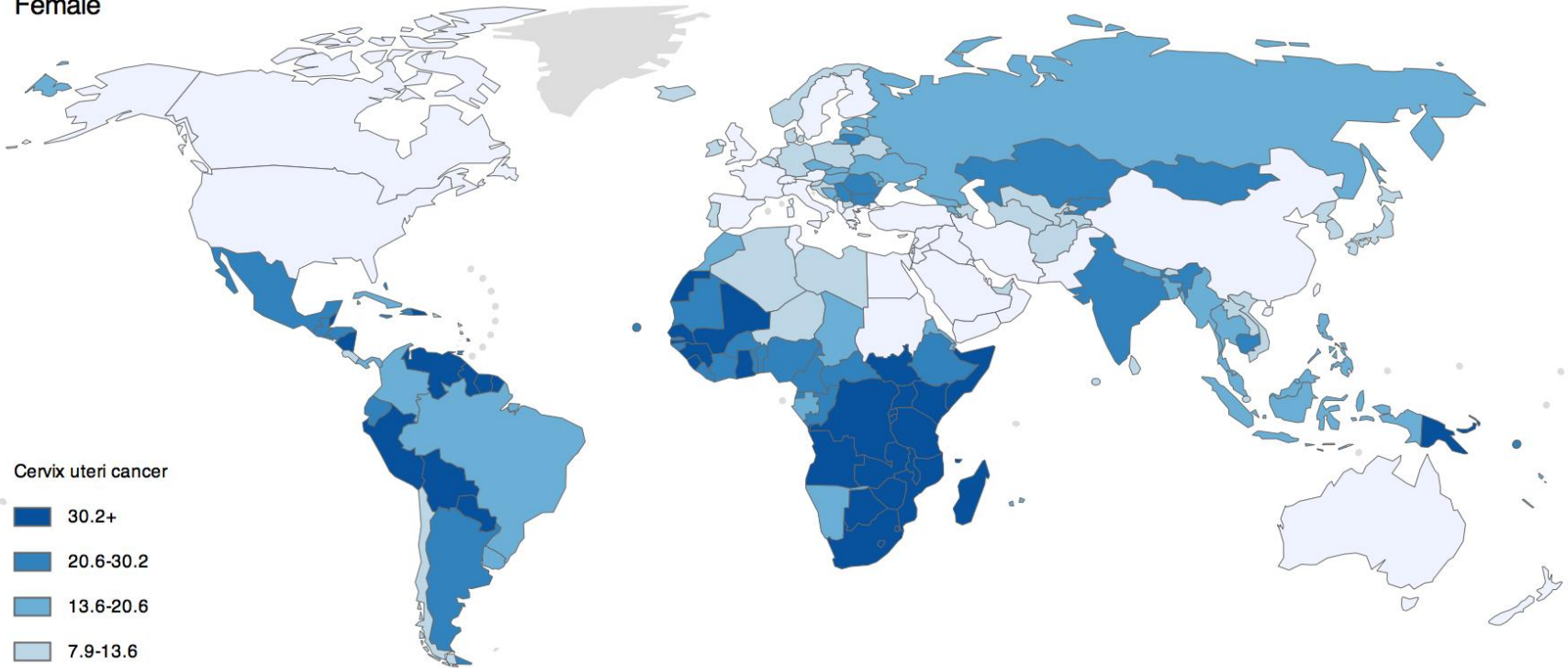
- These data were presented, in part, at the the 30th International Papillomavirus Conference, Lisbon, Portugal, 2015



2016

Estimated cervical cancer incidence worldwide (2012)

Incidence ASR
Female



International Agency for Research on Cancer



GLOBOCAN, 2012



2016

Xpert HPV (GeneXpert, Cepheid)

- Xpert HPV is a point-of-care rtPCR test for 14 hrHPV types:
HPV **16, 18**, 31, 33, 35, 39, **45**,
51, 52, 56, 58, 59, 66, 68
- 1-hour run time
- All reagents contained in single cartridge
- No cold chain required
- Multichannel instruments available



Rationale

- The availability of Xpert HPV should expand access to cervical cancer screening through HPV “test-and-treat” strategies
- It is critical to understand how this test performs in HIV-infected women
- HPV self-testing may also improve screening coverage and should be investigated, including within HPV test-and-treat paradigms

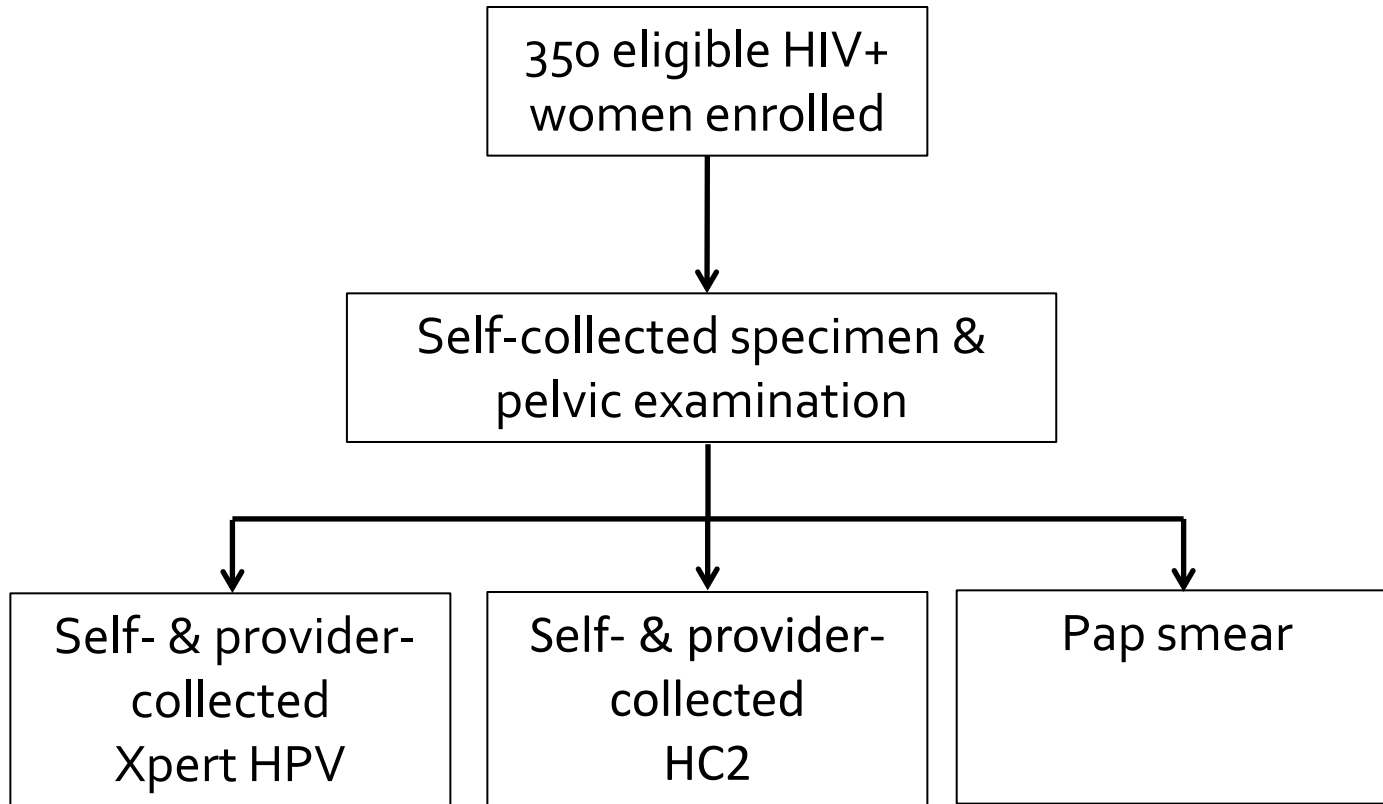
Objectives

- To determine agreement between self- and provider-collected samples using Xpert HPV
- To evaluate the sensitivity, specificity, and agreement beyond chance of Xpert HPV as compared to Digene HC2 in HIV-infected women

Methods

- Design: Cross-sectional performance validation study
- Population: HIV-infected women
25-65 years
Not pregnant
No cervical HSIL
No treatment for HSIL
- Setting: Urban hospital and mobile clinic
- Sample size: 350

Schema



Statistical Analysis

- For this interim report (N=150) on accuracy of self-collected vaginal swabs for Xpert HPV we calculated:
 - Agreement beyond chance (Cohen's Kappa statistic)
 - Percent agreement among positives between self-collected and provider-collected swabs

Demographic Characteristics

Age	39 years [35-44]
Education	
< High school	39%
Completed high school	48%
Completed tertiary education	13%
Employed	75%
Receiving ART	98%
CD4+ cell count, median [IQR]	437 cells/uL [285-613]
HIV-1 viral load < 200 copies/mL	72%
Prior pap smear	77%

Agreement Between Self- & Provider-Collected Xpert HPV

	Self-collected	Provider-collected	Kappa (95% CI)	Agreement
Any hrHPV	45%	37%	0.65 (0.52-0.77)	83%
HPV16	8%	6%	0.74 (0.53-0.96)	97%
HPV18/45	12%	8%	0.69 (0.48-0.89)	95%
HPV31/33/35/52/58	26%	20%	0.66 (0.51-0.80)	88%
HPV 51/59	8%	6%	0.61 (0.34-0.87)	96%
HPV39/68/56/66	18%	15%	0.80 (0.67-0.93)	95%

Conclusions

- We observed robust agreement between self- and provider-collected Xpert HPV samples
- There was also greater cellularity and increased hrHPV detection in self-collected samples
- Our preliminary results suggest a potential role for self-collected samples in future HPV test-and-treat programs