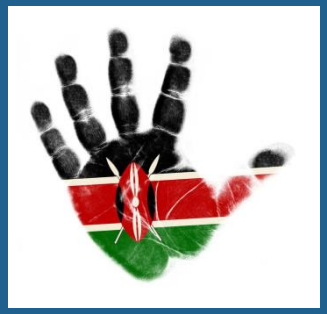


WACHA!!!

Self Sampling: the Kenya experience

Hillary Mabeya, Davy Vanden Broeck, Ina Benoy,
John-Paul Bogers

ICRH

Introduction

- Self Sampling for CxCa prevention:
  - Based on the presence of HPV testing
  - Depending on quality of the sample
  - Tool to reach more (and other) women
  - Less need for medical staff
  - Conclusion: Self sampling has all potential to become an interesting option in Kenya.

Study setup

- 287 women (age 18 – 65 year)
- Recruited from the AMPATH clinic (Eldoret)
- Majority HIV positive
- Informed consent

- First Self-collected sample
- Followed by phycisian taken sample

- All preserved in Thinprep medium (Hologic)

CareHPV and brush

Some history

- Samples would be analyzed using the Qiagen CareHPV system.
- Self sampling device was the CareBrush (Qiagen)
- Preservative was the enclosed sollution

But: issues with the delivery of reagents and the collection medium

-> Switch to Hologic Thinprep and Riatol qPCR

Research Questions

- Performance of self sampling versus clinician (DNA yield)
- Prevalence of HPV in specified population
- Genotype-specific epidemiology

- Feasability to detect Trichomonas Vaginalis using self-sampling
- Prevalence of Trichomonas in the population

Performance – DNA yield

Age (years)	Clinician-taken sample (ng/µl)	careBrush self-sampling (ng/µl)
<20	31,7	49,2
20-24	26,7	46,9
25-29	16,8	45,0
30-34	20,8	71,8
35-39	20,9	47,4
40-44	44,3	32,5
45-49	57,3	64,5
50-54	42,8	44,7
55-59	30,8	51,0

careBRUSH collects more DNA than clinician-taken sample, independent of the age of the woman

HPV prevalence

- Prevalence:
  - Self-collected: 49.48% positive
  - Clinician-taken: 41.81% positive
- Concordance:
  - Majority of the cases concordant results

	Self sampling negative	Self sampling positive
PAP negative	128	35
PAP positive	14	108

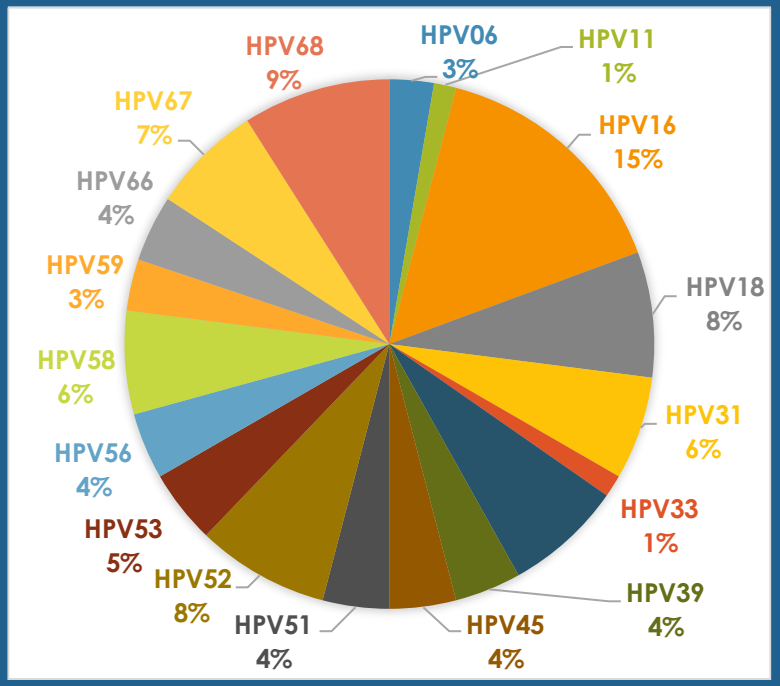
- Comparable number of insufficient samples (1%)

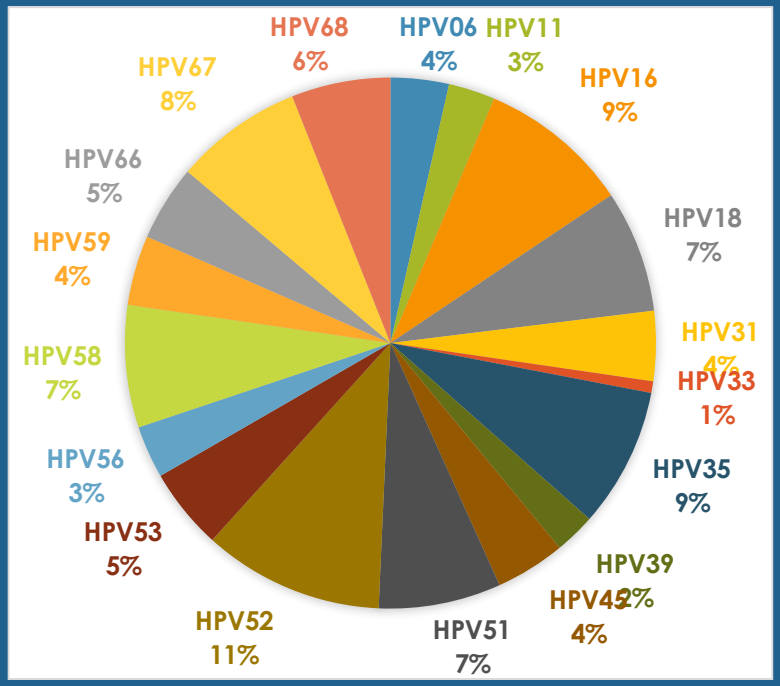
Genotype-specific findings

– Differences between self-collected and clinician-taken samples: Top 5

Clinician-taken	Self-collected
HPV 16	HPV 52
HPV 68	HPV 16
HPV 52	HPV 35
HPV 18	HPV 67
HPV 67	HPV 18

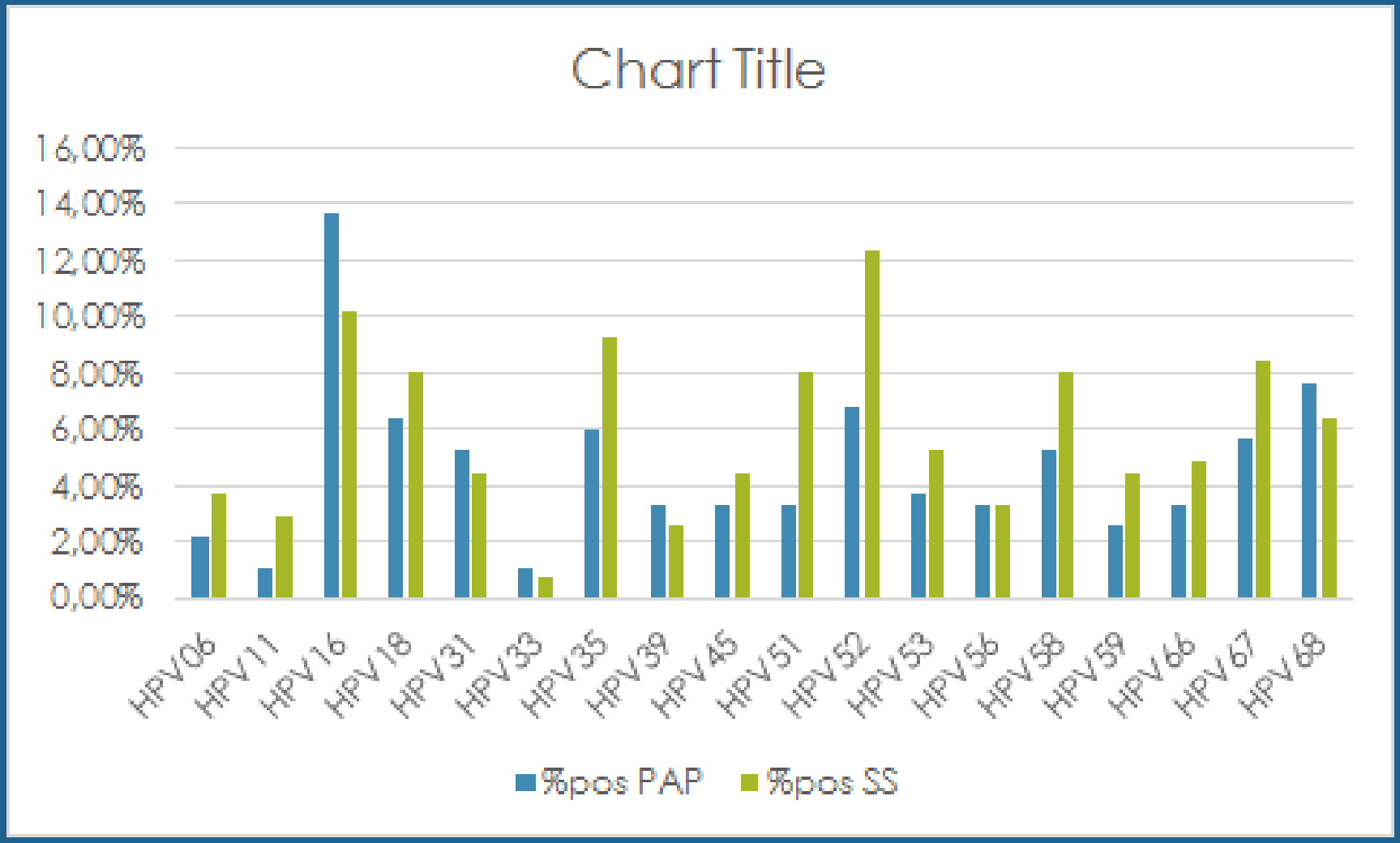
Genotype-specific findings





Clinician-taken

Self-collected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HPV45
HPV51
HPV52
HPV53
HPV56
HPV58
HPV59
HPV66
HPV67
HPV68
%pos PAP
%pos SS

ICRH

Trichomonas Vaginalis

- Valid results were obtained in 99% of all samples
- HIGH PREVALENCE WAS FOUND!!!!
  - Self-sampling: 12.11%
  - Clinician-taken: 8.71%

Conclusions

- Self-Sampling is an effective tool to collect samples
- Performance is non-inferior versus clinician-taken samples
- Self-collected samples allow also to test for other STIs, i.e. Trichomonas vaginalis (others???)

- BUT:
  - Differences in HPV types found
  - Differences in prevalence
    - Uncompletely known clinical relevance

Conclusions

- Lessons learned:
  - Issues to find careHPV reagents
    - Logistics remain considerable!!!
  - Complaints of women regarding the self-collection device
    - High yields in DNA and good performance, but women disliked to insert the device
    - Better to perform a study towards the user-perspective of the best device to be used prior to roll out.

Ongoing activities

- Aim is:
  - To further evaluate the performance of self-sampling in detection of other STIs (one-sample-for-all???)
  - To compare performance of HPV tests designed for developing countries (+/- VALHUDES – PERHLA study)
  - To improve laboratory quality system and introduce barcodes for tracebility and chain of custody
  - To perform outreach in MSM population for epidemiology

Thank you!

Asante Sana!