



SELF-COLLECTION BY VEIL COLLECTOR DEVICES FOR HPV MOLECULAR SCREENING IN AFRICA

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INTRODUCTION

- Cervical and anal cancers are caused by high risk-human papillomavirus (HR-HPV) infection.
- Self-collection of genital and anal specimens and HPV DNA molecular testing by multiplex PCR platforms are methods that increase screening rates.

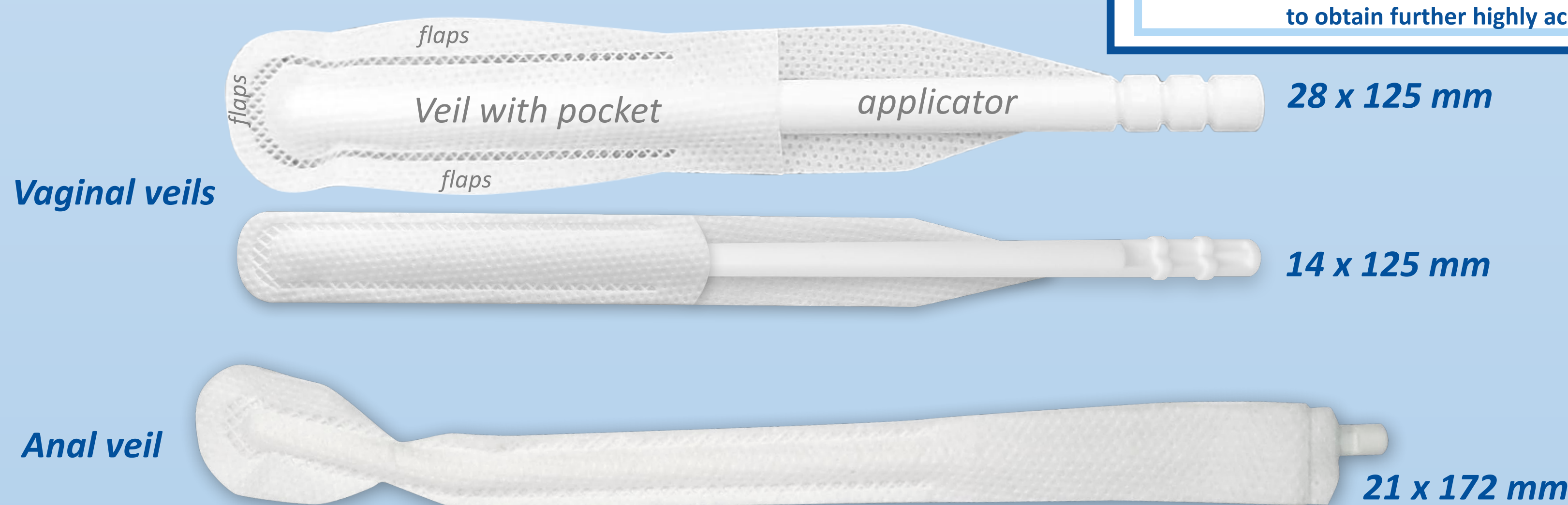
AIM

- To assess the usability and accuracy of self-sampling by veil in various populations living in sub-Saharan Africa.
 - Adult **general female population**.
 - **Female sex workers (FSW)**.
 - **Men who have sex with men (MSM)**.
- To establish **molecular epidemiology** of HR-HPV.
- To predict possible **efficiency of prophylactic Gardasil-9[®] vaccine** from HPV genotypes.

METHOD

- Genital and anal veil-based self-collection devices (**Veil Collector V-Veil UP2[™]**, V-Veil-Up Production SRL, Romania ; hvp-veil.com) were used.
- Samples were conserved in the universal medium Cyt-All (Alphaphath, Mauguio, France).
- HPV DNA detection was carried out using Anyplex[™] II HPV28 test (Seegene, Seoul, South Korea) or Papilloplex High Risk HPV (GeneFirst, Abingdon, United Kingdom).

SELF-COLLECTION DEVICES



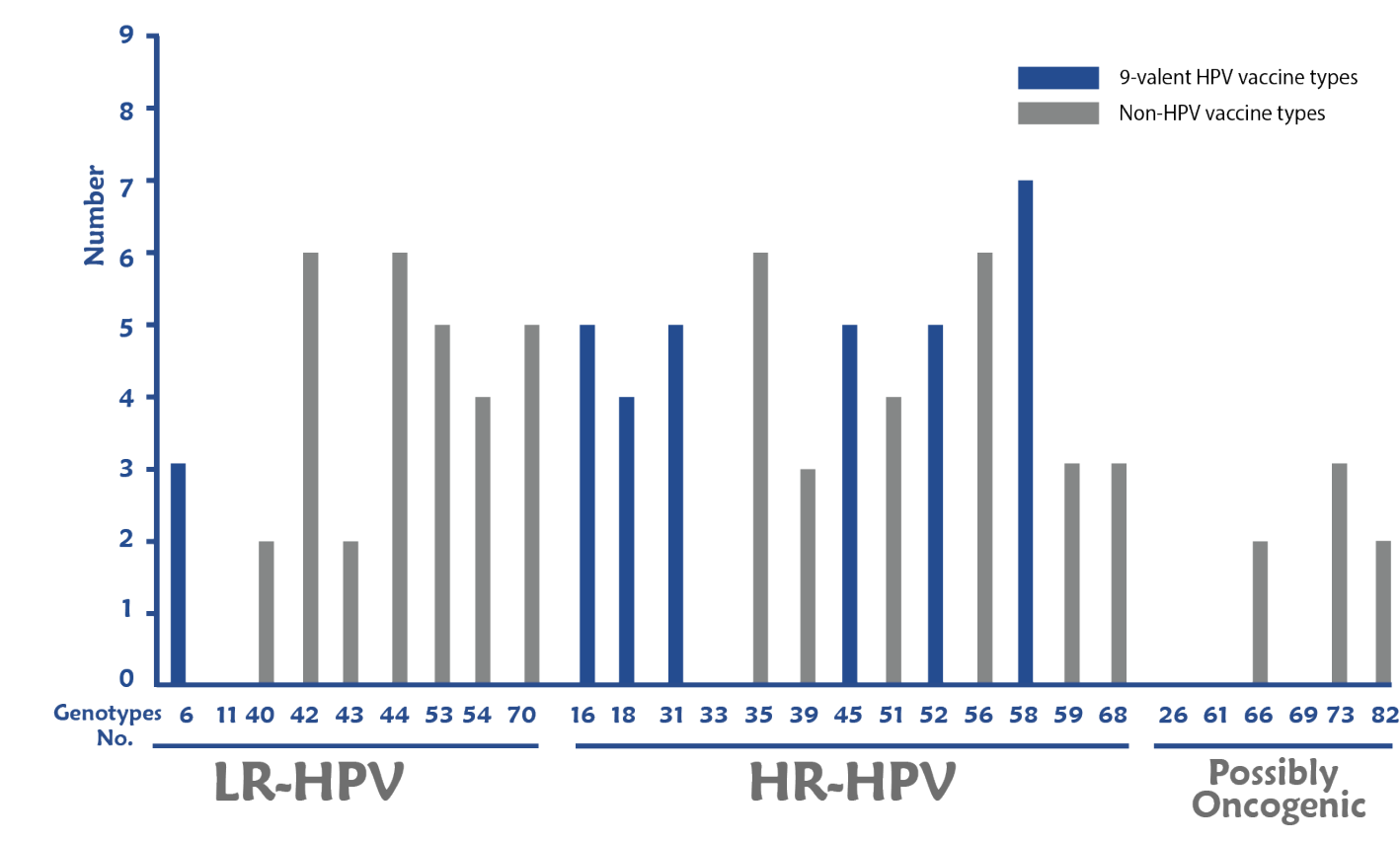
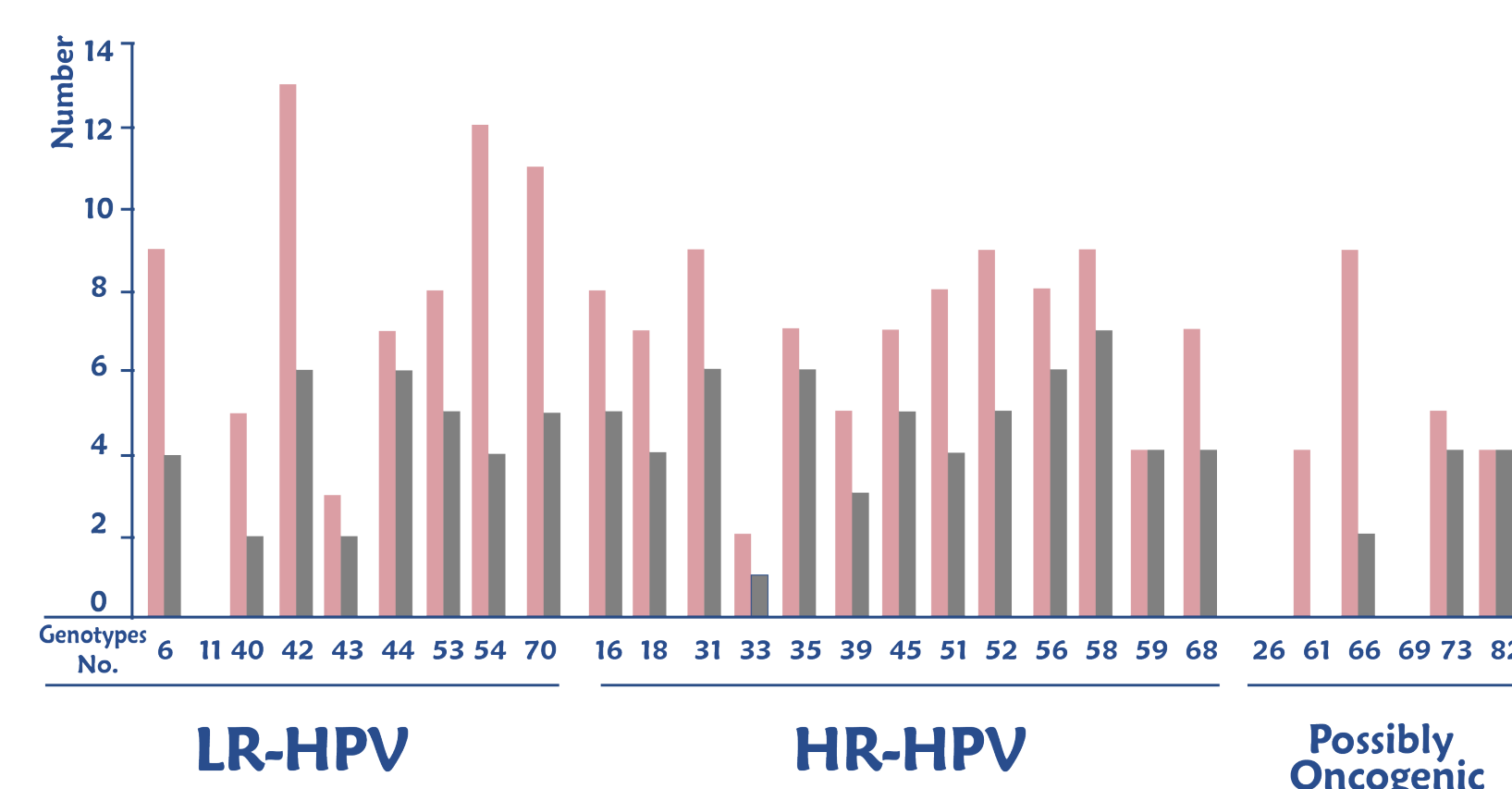
STUDIES RESULTS

V-VEIL UP2[™] STUDY IN GENERAL 253 FEMALE POPULATION: A prospective randomized non-inferiority trial

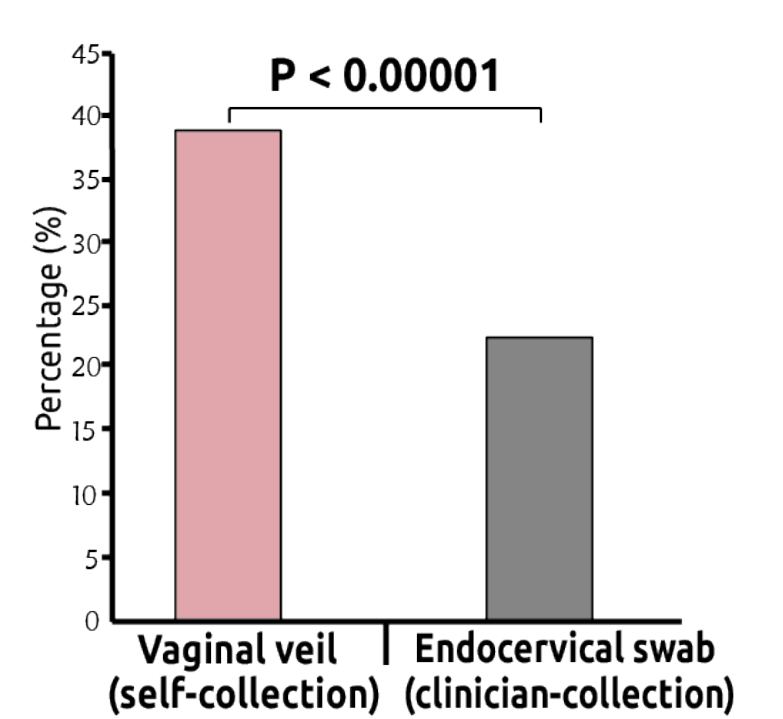
- Sample size: 253 women (mean age, 35.0 years).
- **High acceptability (≥96%), feasibility and satisfaction** for veil-based genital self-collection.
- **High accuracy: Self-collection by veil: non-inferior to clinician-collection for HR-HPV DNA molecular testing (P<0.001).**
- **High sensitivity (95.0%; 95%CI: 88.3-100.0%) and specificity (88.2%; 95%CI: 83.9-92.6%).**
- **Self-sampling with veil : ≈ 2-fold detection rates of cervical HPV DNA and HR-HPV DNA.**

The graphic below compares the molecular detection of HPV genotypes performed from:

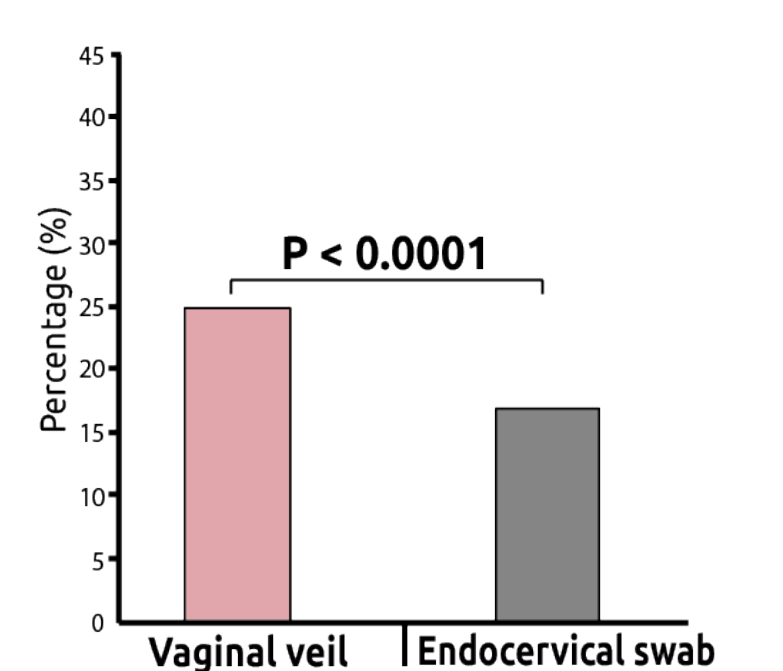
- Genital secretions self-collected by women themselves, using the Vaginal Veil Collector V-Veil Up2
- Genital secretions collected by a gynaecologist or a nurse, using a flocked swab



A. HPV detection



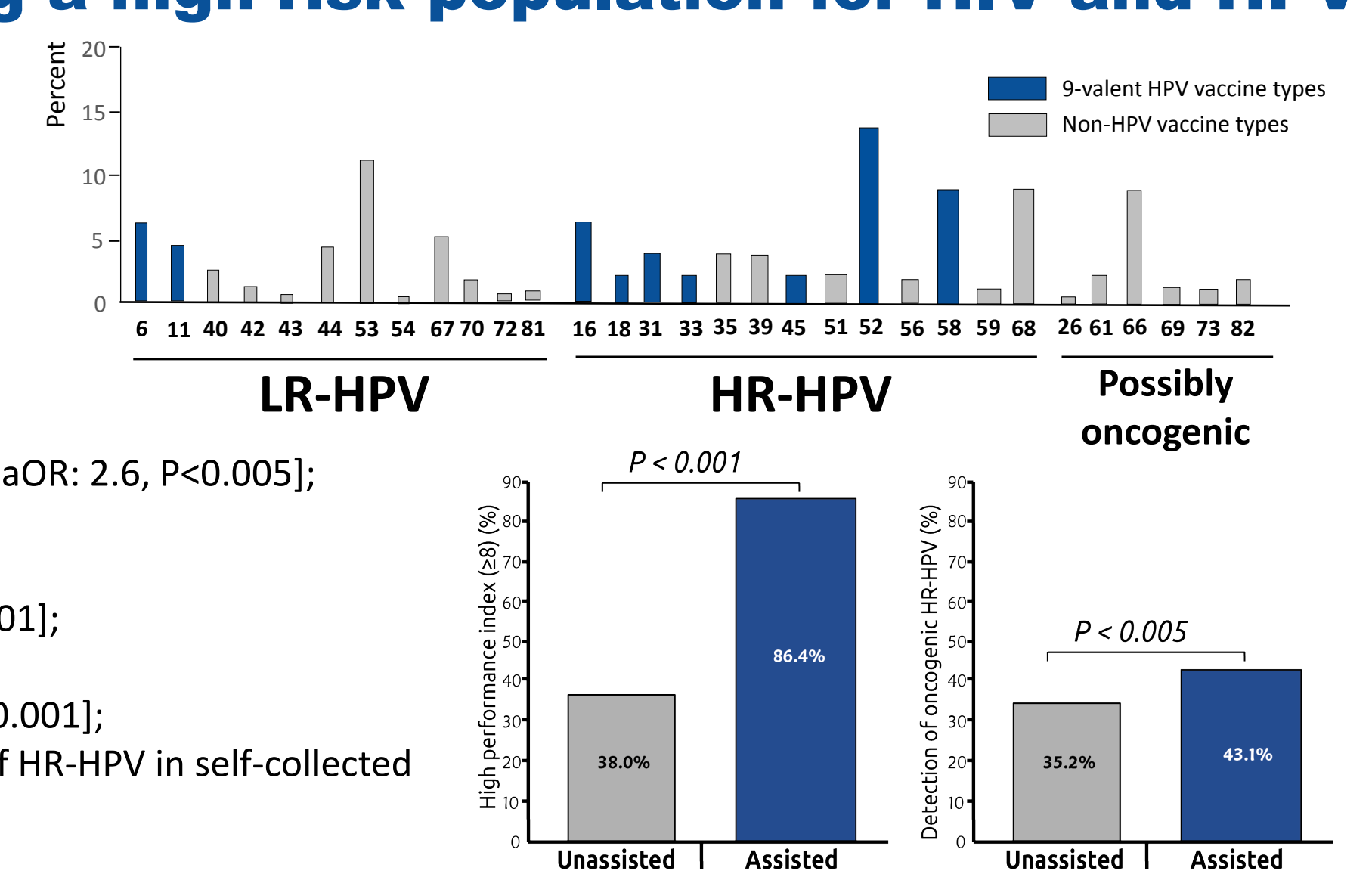
B. HR-HPV detection



V-VEIL UP2[™] STUDY IN 415 FEMALE SEX WORKERS:

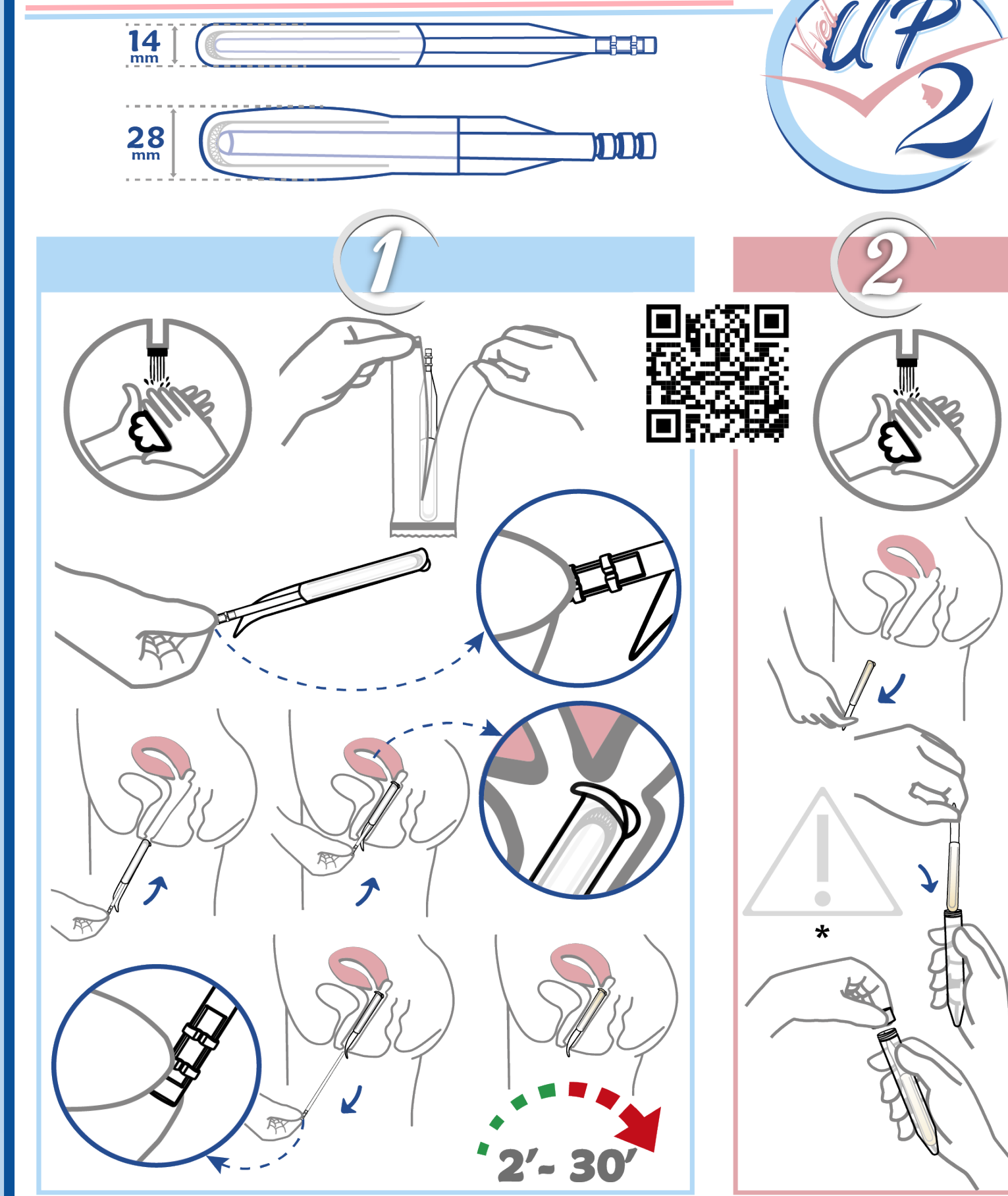
A randomized, non-blinded, non-inferiority trial among a high-risk population for HIV and HPV

- Sample size: 415 FSW (mean age, 28.1 years).
- Intervention: Unassisted veil-based self-sampling *versus* directly assisted veil-based self-sampling.
- Main outcome: Veil-based self-sampling achievement using quantitative performance index (PI; 0 to 10; High≥8; low ≤ 4; moderate: 5-7).
 - **Prevalences of HPV and HR-HPV infections at baseline:**
 - ✓ 54% and 29%, respectively, mainly HPV-52 (14%), HPV-66 (10%), HPV-58 (9%);
 - ✓ Only two-third of HR-HPV would be covered by Gardasil-9[®] vaccine.
 - **Intervention trial :**
 - ✓ **High acceptability (≥99%) and satisfaction** for veil-based genital self-collection at baseline;
 - ✓ Performance index (baseline): The variable « education level » associated with low performance [aOR: 2.6, P<0.005];
 - ✓ Performance index (after intervention):
 - **Higher in directly assisted than in unassisted groups** [High PI in 86.4% of intervention group *versus* 38.0% of unassisted group; aOR: 3.6, P<0.001];
 - The variable « education level » no more associated with low PI [aOR: 1.2, NS];
 - The variable « knowledge on genital self-sampling » associated with high PI [aOR: 2.9, P<0.001];
 - Directly assisted veil-based allowed to increase the performance of molecular detection of HR-HPV in self-collected genital secretions by 1.3-fold.



- **Conclusions:**
 - ✓ Insufficient education is a **key factor** of low performance of veil-based self-sampling by poorly instructed and vulnerable FSW living in Africa;
 - ✓ Simple intervention of direct assistance by trained personals (physician, nurse or community staff) allows the majority of FSW to carry out correctly genital self-sampling, and to obtain further highly accurate molecular analysis.

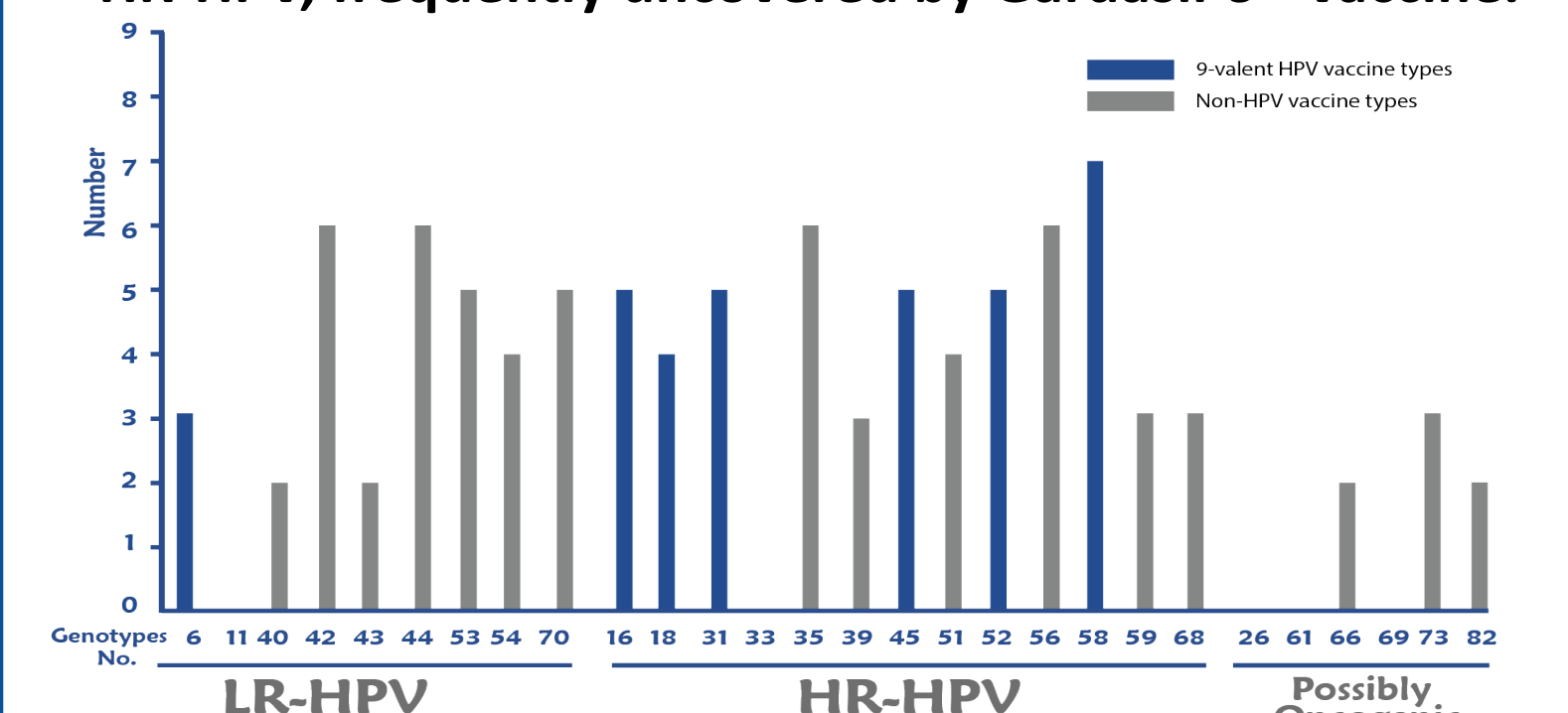
Instructions for use



STUDY RESULTS

V-VEIL UP2[™] PILOTE FEASIBILITY STUDY IN 57 MSM

- Sample size: 57 MSM (mean age, 25.3 years) ; HIV-1: 68.9%.
- **High acceptability (≥93%)** for anal self-collection.
- **High HPV anal carriage** : HPV and HR-HPV detected in 74.1% and 59.6% of study MSM, mainly HPV-35, HPV-58, HPV-59 and HPV-31.
- Multiple HR-HPV : frequent in HIV-positive MSM (66%).
- Only 65% of anal HR-HPV would be covered by Gardasil-9[®] vaccine.
- **MSM in Central Africa are at-risk of HIV and anal HR-HPV infections, with unusual and unique distribution of anal HR-HPV, frequently uncovered by Gardasil-9[®] vaccine.**



CONCLUSIONS

- These observations in the field highlight the high burden of cervical and anal HR-HPV infection in various high-risk populations living in Africa.
- **The Veil Collector V-Veil UP2[™] collection devices are a simple, highly acceptable and powerful tool for self-collection of genital and anal secretions for further molecular testing and screening of HR-HPV that could be easily implemented in national programs for cervical and anal cancer prevention (prophylactic vaccine and molecular diagnosis) and care in Africa.**

REFERENCES

Bélec L et al. Acceptability and Accuracy of Cervical Cancer Screening Using a Self-Collected Veil for HPV DNA Testing by Multiplex Real-Time PCR among Adult Women in sub-Saharan Africa. *J Clin Res Med* 2019 1(1): 1–15.
Mbomba Bouassa RS et al. High prevalence of cervical high-risk human papillomavirus infection mostly covered by Gardasil-9 prophylactic vaccine in adult women living in N'Djamena, Chad. *PLoS One*. 2019 Jun 3;14(6): e0217486.

Conflict of interest: None

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