

Development of a cervical cancer screening approach based on first-void urine: verification of standardized and volumetric collection.

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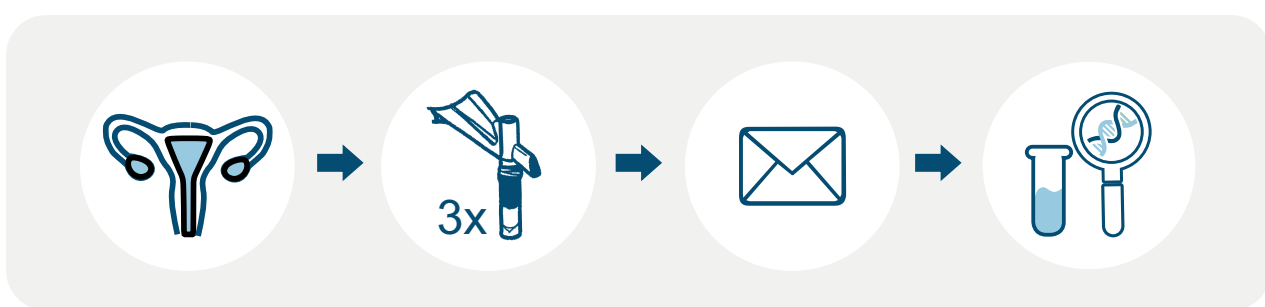
Novosanis, Belgium

INTRODUCTION

The CASUS project aims to develop the first integrated, fully molecular and non-invasive cervical cancer screening approach where one first-void urine (FVU) sample is used for hrHPV detection and methylation-based triage testing.

Current screening non-attendance rates are high due to reluctance of women to accept gynecological examinations. Self-samples offer a solution to increase screening coverage, with urine as the most accepted and preferred sample type.^{1,2,3} To increase the performance of urine samples for HPV detection, Colli-Pee[®] was developed by Novosanis. Colli-Pee[®] provides a standardized and volumetric FVU sample which contains the highest washout of cellular debris including HPV DNA.

METHODS



A total of 25 women with an hrHPV infection collected FVU samples as part of the CASUS project. Each woman collected 3 samples, 1 with each Colli-Pee[®] variant for the collection of 20, 10 and 4 mL, to find the optimal sample volume for cervical cancer screening. Participants sent the samples to the laboratory of the University of Antwerp by postal mail. The volume of the samples was measured with a pipette. Tubes designed to fit the high-throughput machines were used for the 10 mL collection device.

In addition, Novosanis evaluated the volumetric collection by lab and real-life testing. Lab testing was performed at predefined high, medium and low average flowrates of resp. 25, 17 and 4 mL/s (n=24 for all flowrates). Participants of the real-life tests received 1 Colli-Pee[®] device with a scale on the collector tube to read and report the volumes. Self-reported flowrate during urine collection was also registered. Participants were asked to collect 5 urine samples. A total of 22 participants used Colli-Pee[®] 10 mL (11 males, 11 females), and 24 participants used Colli-Pee[®] 4 mL (12 males, 12 females). Generic tubes were used for the Colli-Pee[®] 10 mL. All results are reported as the mean and SD.

RESULTS

Higher variability in collected volume with urine cups compared to Colli-Pee[®] 20 mL and 10 mL has been observed (Fig. 1). This study aimed to evaluate the accuracy of the volumetric collection of FVU with Colli-Pee[®] Small Volumes i.e. Colli-Pee[®] 10 mL and 4 mL.

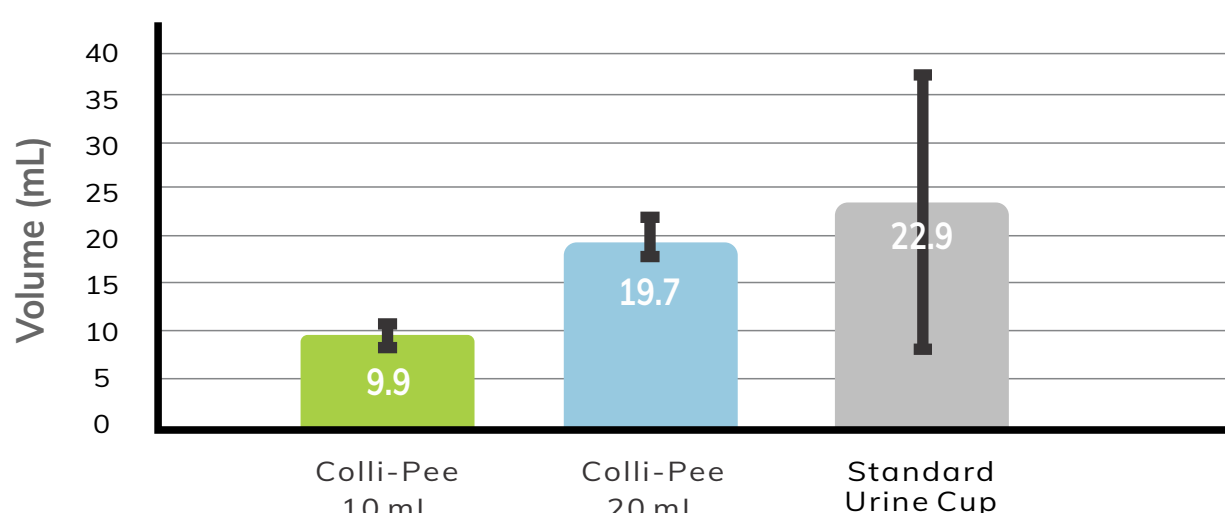


Fig. 1 Volumetric collection of 1006 samples, where 87 users used the Colli-Pee[®] (CP) 10 mL device, 476 used the CP 20 mL, and 443 users used the urine cup. Bars represent the mean, and error bars the standard deviation (SD). Adapted from Meers et al. 2019⁴.

RESULTS continued

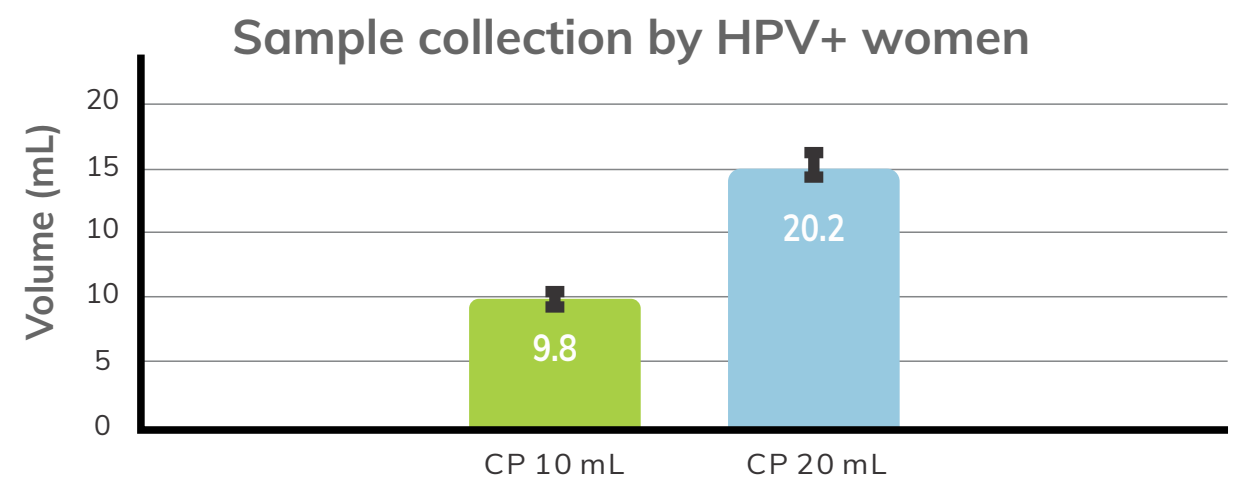


Fig. 2 Volumetric collection in a home-based sampling setting, and postal mail delivery. The volume of the 4 mL samples was not assessed since they were frozen immediately. For each collection device, one sample was left out of the analysis due to user error.

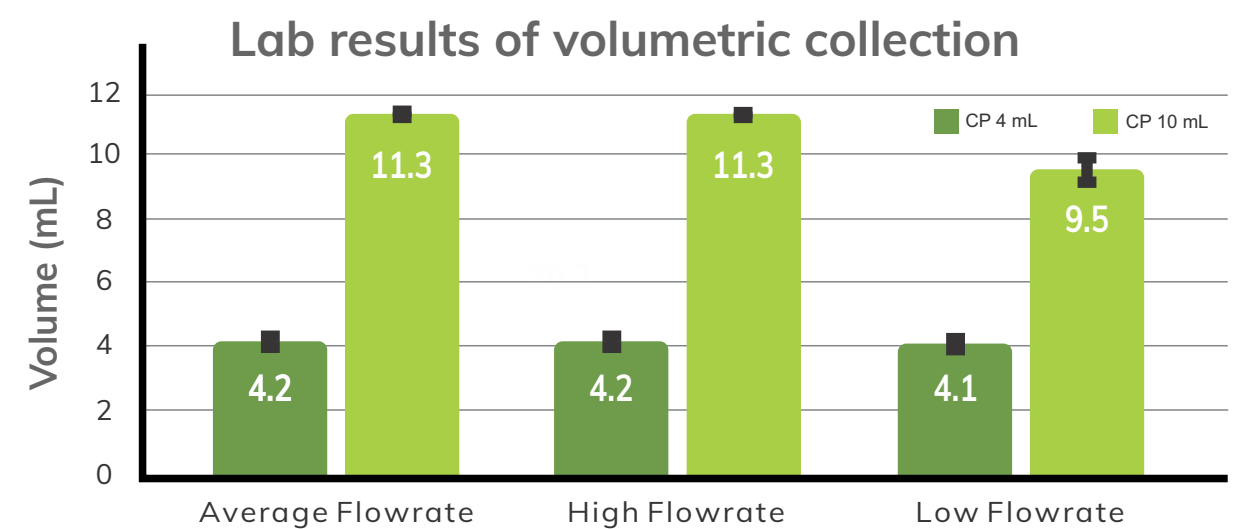


Fig. 3. Volumetric collection in the lab setting where the floater functionality was observed. The floater moved up with the initial water flow, enabling collection of FVU without interruption of urination.

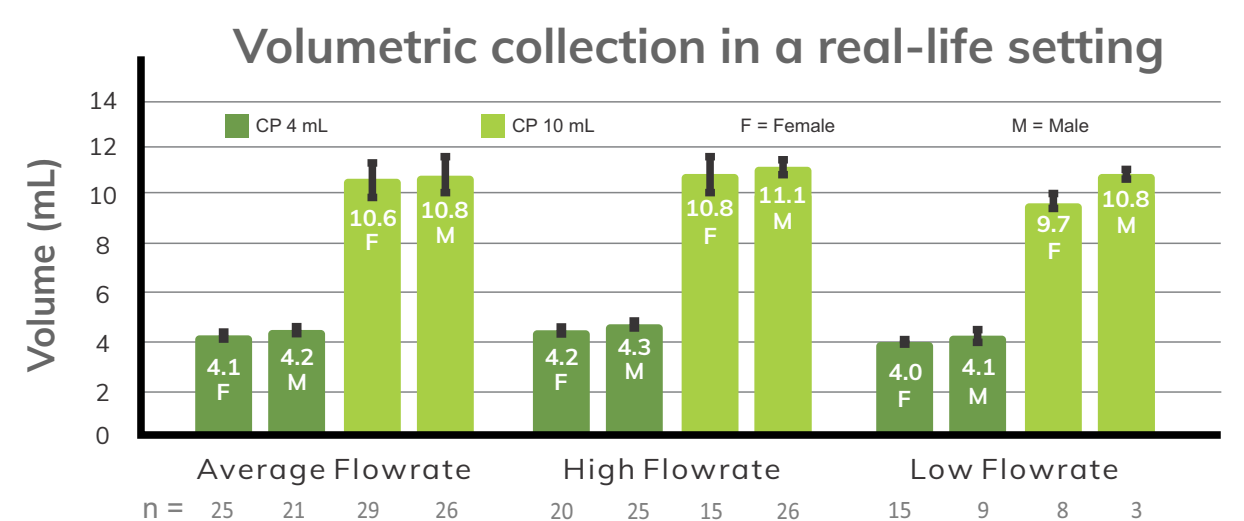


Fig 4. Slightly higher volumes collected by males and in case of high flowrates. One use error was observed in reading the volume (floater still attached to the tube, CP 4 mL), and 2 women collected less than 5 samples (2 and 3 out of 5, CP 10 mL).

CONCLUSION

Accurate volumetric collection of Colli-Pee[®] Small Volumes was observed in real life and lab settings, for both genders and at multiple flowrates.

In addition, Colli-Pee[®] Small Volumes enables integration with commercially available high-throughput machines, which reduces manual handling and errors.

This enables increased reproducibility of sample quality and performance and improves confidence in the first fully molecular integrated cervical cancer screening approach based on FVU.

References

- Rohnen et al. (2020)
- Van Keer et al. (2018)
- Sellors et al. (2000)
- Meers et al. (2019)