

Assessment of acceptability of first-void urine sampling for HPV DNA detection in young women



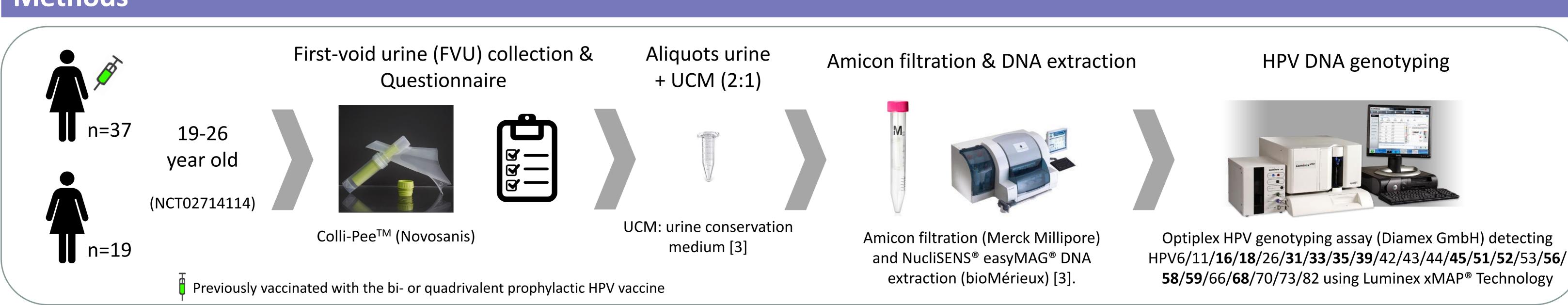
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Background/objectives

Feasibility of first-void urine (FVU) sampling to monitor the impact of HPV vaccination has recently been reported [1]. The fact that a FVU device is non-invasive, guarantees first-void sampling (i.e. first 15-20ml of urine void), and can be collected at home and mailed to the lab [2] represents major assets. As limited data are available on sampling preference in vaccinees, we assessed the acceptance of using FVU self-sampling as a monitoring tool in vaccinated and unvaccinated women.

Methods



Results

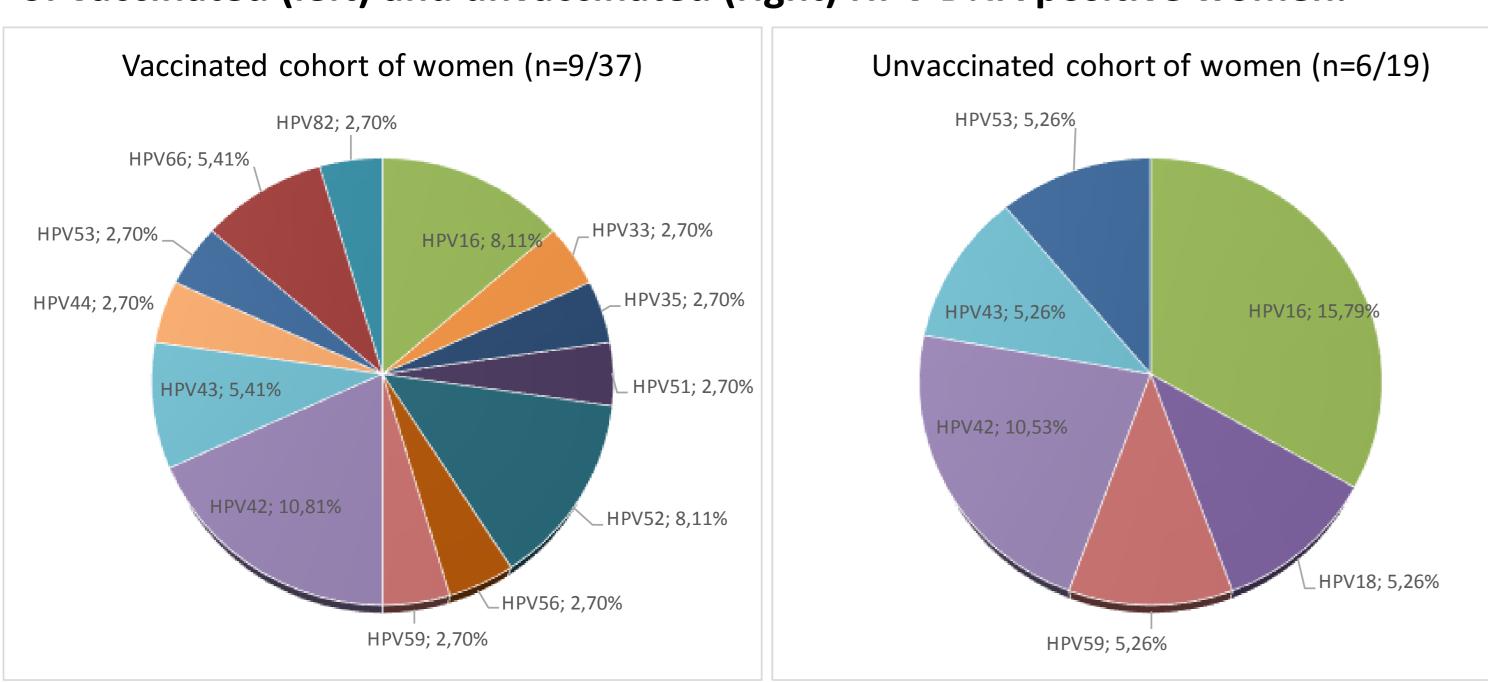
- Study population (n=56): 19 to 26 year old women
- Mean age: 22.11 ± 1.97 (vaccinated ♠); 22.68 ± 2.08 year (unvaccinated ♠)
- Mean age of first vaccine dose: 15.15 ± 1.66 year
- Overall prevalence HPV16/18 in FVU samples: 13% (7/56)
- Lower overall HPV DNA, and HPV16/18 prevalence in vaccinated versus unvaccinated women (Table 1)

Table 1. Frequencies and percentages of HPV DNA in first-void urine samples.

	Total	Vaccinated	Unvaccinated
	N (%)	N (%)	N (%)
Total	56	37	19
HPV DNA positive	15 (26.79)	9 (24.32)	6 (31.58)
Single infection	9 (16.07)	6 (16.22)	3 (15.79)
Multiple infection	6 (10.71)	3 (8.11)	3 (15.79)
HPV16/18 (bivalent HPV vaccine	7 (12.50)	3 (8.11)	4 (21.05)
types)			
HPV6/11/16/18 (quadrivalent HPV vaccine types)	7 (12.50)	3 (8.11)	4 (21.05)
HPV6/11/16/18/31/33/45/52/58	9 (16.07)	5 (13.51)	4 (21.05)
(9valent HPV vaccine types)			
High-risk HPV positive ¹	10 (17.86)	6 (16.22)	4 (21.05)

No statistically significant associations were found (Chi square test; p-value < 0.05) ¹Classification of high- and low-risk HPV types included in the Optiplex HPV genotyping kit (Diamex), according to the HPV classification from the International Agency for Research on Cancer (IARC) 2012.

Figure 1. Percentages of the prevalence of individual HPV types in first-void urine of vaccinated (left) and unvaccinated (right) HPV DNA positive women.

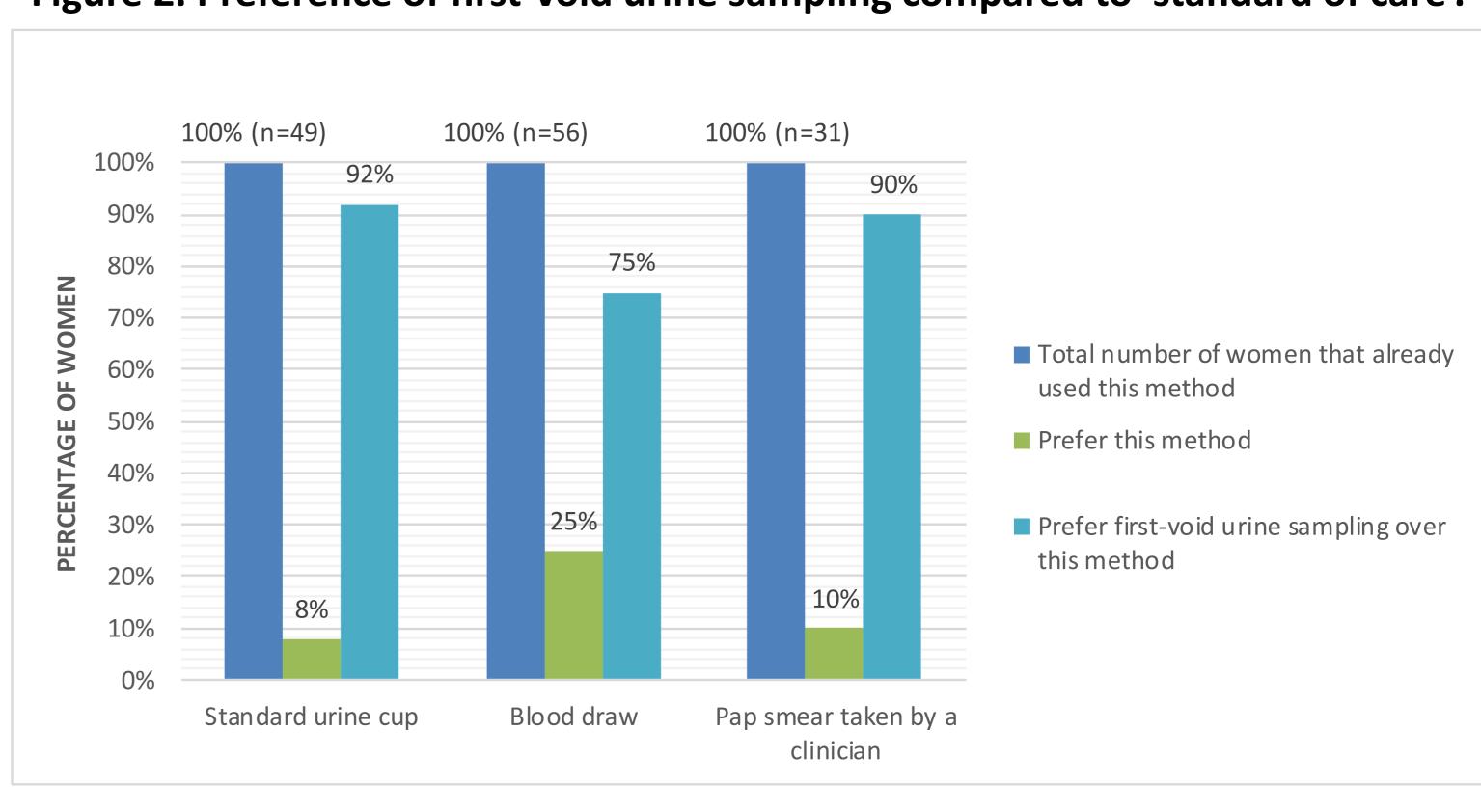


- Mean age of first sexual contact: 17.54 ± 1.85 (vaccinated \P); 16.40 ± 1.55 year (unvaccinated \P) (p<0.05; unpaired student T-test, equal variances assumed)
- All sexually inactive women (2/37 vaccinated, 4/19 unvaccinated) are FVU HPV DNA negative

Questionnaires

 Most women agreed that FVU sampling with the Colli-Pee[™] device is a good method for urine collection at home (95%; 53/56) or at the clinic (65%; 38/56)

Figure 2. Preference of first-void urine sampling compared to 'standard of care'.





75-92% of women saw FVU sampling with the Colli-Pee[™] device as an improvement over the other methods

Conclusion

- This study illustrates that **FVU sampling is highly accepted** in this population of 19 to 26 year old women in Belgium.
- Consistent with previous studies, our study also demonstrates the feasibility of FVU
 to detect HPV DNA in young women, vaccinated against HPV after pre-adolescence.

References

- 1. Franceschi S, Umulisa MC, Tshomo U, Gheit T, Baussano I, Tenet V, et al. Urine testing to monitor the impact of HPV vaccination in Bhutan and Rwanda. Int J Cancer 2016.
- 2. Vorsters A, Van Keer S, Biesmans S, Vankerckhoven V, de Koeijer M, Beyers K, et al. HPV DNA detection in urine: Effect of a first-void urine collection device and time of collection. In: 30th International Papillomavirus Conference. Lisbon, Portugal; 2015.
- 3. Vorsters A, Van den Bergh J, Micalessi I, Biesmans S, Bogers J, Hens A, et al. Optimization of HPV DNA detection in urine by improving collection, storage, and extraction. Eur J Clin Microbiol Infect Dis 2014,33:2005-2014.

Acknowledgements & Conflicts of interest

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Alex Vorsters and Pierre Van Damme are co-founders of Novosanis (Belgium).