HOME-BASED SELF-SAMPLING OF FIRST-VOID URINE FOR hrHPV TESTING IN CERVICAL CANCER SCREENING: USABILITY FEEDBACK FROM A BELGIAN COLPOSCOPY REFERRAL POPULATION

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OBJECTIVE

Cervical cancer is the seventh most common cancer in Europe with 99% of cases caused by oncogenic infections with high-risk human papillomavirus (hrHPV) strains. Women with socio-economical disadvantages and lower education are often under-screened and hard-to-reach leading to an increased risk of developing Cervical cancer. Successful Cervical cancer screening programs strongly depend on the participation of the target population. Various barriers are known to contribute to lower participation such as physical discomfort, poor access to health services, time constraints and lack of knowledge. Here we report interim usability feedback results from the CASUS study (NCT04530201, Belgium) using first-void urine (FVU) as a liquid biopsy.

MATERIALS & METHODS

BELGIUM

CASUS trial (NCT04530201)

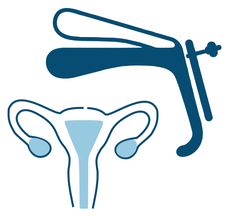
Colposcopy centers:
- Vrouwenkliniek - Universitair Ziekenhuis Gent (UZ Gent)
- Femicare VZW & Departement Verloskunde & Gynaecologie - Regionaal Heilig Hart Ziekenhuis Tienen
- Gynécologie-obstétrique - CHU de Liège

n= 280 women
Age= 25 - 64 years

Home-based collection and return of samples to the lab by postal mail

Novosanis Colli-Pee™ FV-5010 containing UCM™
± 10 mL, 2.33:1 urine:chemistry

Colposcopy visit



Physician-taken PAP smear

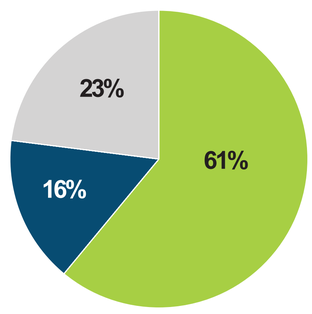
Usability questionnaire

Of the 280 women providing informed consent for the study, **204 women** completed the **usability questionnaire** from which **197 valid SUS-scores** were obtained.

SUS-score = Average calculated System Usability Scale (SUS) for usability performance. A SUS-score > 80.3 (Grade A) is considered excellent.

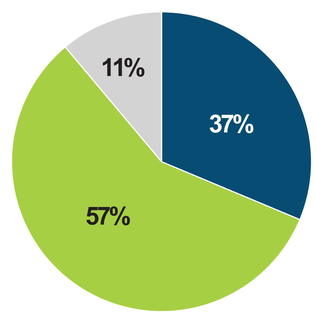
RESULTS

A *"Which urinary collection method do you prefer?"*



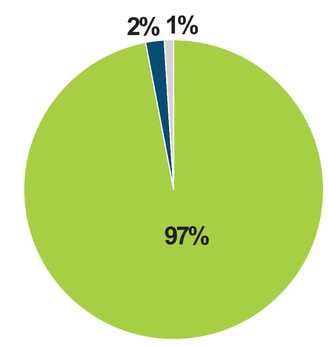
61% women indicated to prefer the use of Colli-Pee™ FV-5010 containing UCM™ over a urine cup

B *"Which sample type would you prefer for future Cervical Cancer screening?"*



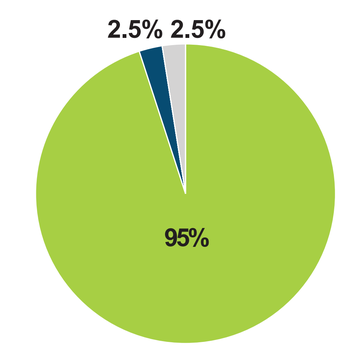
57% of women indicated to prefer First-void urine self-sampling over a physician taken PAP smear (37%) for their next Cervical Cancer screening.

C *"Would you prefer to use the Colli-Pee™ FV-5010 containing UCM™ device again in the future for Cervical Cancer screening?"*



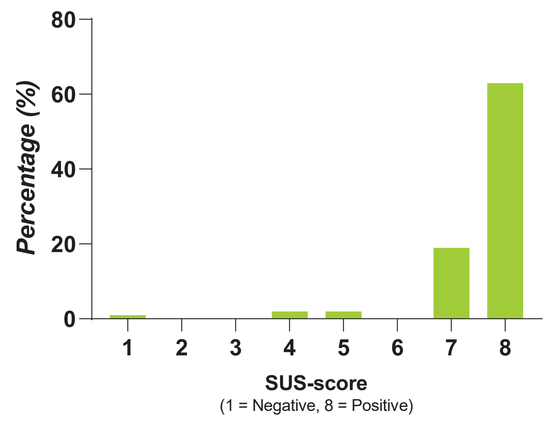
97% of participants indicated that they would use Colli-Pee™ FV-5010 containing UCM™ device again.

D *"Would you recommend to use the Colli-Pee™ FV-5010 containing UCM™ device for Cervical Cancer screening?"*



95% of participants experienced the Colli-Pee™ FV-5010 containing UCM™ device as easy to use.

E *"I had the impression the sample collection went well?"*



F

SUS – score = 85.49 ± 15.60

63% of participants indicated they had the impression that sample collection with the Colli-Pee™ FV-5010 containing UCM™ device went well. In addition an average SUSscore of 85.49 ± 15.60 was calculated.

CONCLUSION

The results of this study show that most women would prefer a urine self-sample at home over a physician-taken PAP smear for their next Cervical Cancer screening. Moreover, Colli-Pee™ FV-5010 containing UCM™ was considered an easy-to-use and well-accepted self-sampling device for Cervical cancer screening in a Belgian colposcopy referral population.

EUROGIN, March 2022
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