Feedback from a colposcopy referral population on the use of Colli-Pee® for HPV-based cervical cancer screening (CASUS)

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Figure 1: Colli-Pee® Small Volumes containing UCM

BACKGROUND & OBJECTIVES

The CASUS project (NCT04530201) aims to develop the first fully molecular cervical cancer screen and triage approach, based on first-void urine as an easily accessible and non-invasive source of biomarkers. Colli-Pee® Small Volumes (Novosanis, Belgium) is used for the collection of urine, which is a user-friendly device that allows for standardized and volumetric collection of the initial urine stream (i.e., first-void). In addition, Colli-Pee® allows for immediate mixing with a preservative for HPV DNA. As part of this project, a clinical validation study is in progress, where the goal is to recruit 300 women who are referred to colposcopy. This population also provides user feedback on Colli-Pee® Small Volumes and participation in cervical cancer screening programs. The aim of this study is to provide insights on usability of Colli-Pee® Small Volumes.

METHODS

Women collected two first-void urine samples on the day before colposcopy and completed an online usability questionnaire. A paper questionnaire was completed during the colposcopy visit if the woman indicated that she did not complete the online questionnaire.

Figure 2: visual representation of CASUS methods

The Systems Usability Scale (SUS) is a questionnaire that provides a standardized score to evaluate systems. The SUS consists of 10 questions which are adapted to provide a usability score for Colli-Pee®. All questions are rated on a 5-point scale where 5 means "strongly agree', and 1 represents "strongly disagree'. The score is calculated by subtracting 1 from odd numbered questions, and the value of even numbered questions is subtracted from 5.

The sum is multiplied by 2.5 to obtain the SUS score which is considered good when it is greater than 68. Women also indicated whether urine was spilled during collection, the time needed to collect the urine sample from reading of the manual, whether they had read the manual and which sample type was preferred for cervical cancer screening. A random entry was selected if a participant completed the questionnaire multiple times online (see Figure 2).

RESULTS

Up to April 2021, 243 women provided informed consent to participate in the clinical study of which 161 completed the questionnaire. A total of 159 valid SUS scores were calculated. Two scores could not be calculated since the SUS tool was not completed. An average SUS score of 73.25±15.70 was observed (see Table 1).

Enrolment (Provided ICF)	243
Completed Questionnaire	161
Valid SUS tools	159
Average SUS score	73.25 ± 15.70

Table 1: Summary participation questionnaire

Effect of different usability aspects of Colli-Pee® Small Volumes on the SUS score

The SUS score changed when the self-reported time needed for collection increased i.e., the SUS decreased with an average of 12.46 points if the time from reading the manual to closing the tube was longer than five minutes compared to shorter than two minutes. Women who reported to prefer urine self-sampling over clinician-taken cervical samples for screening showed a trend towards higher SUS score by an average of 4.09 points (see Table 2).

Variable	Answers	Results (n)	Effect on SUS (Δ Points)
Time needed to collect the urine sample from reading of the manual	< 2 minutes 2-5 minutes 5 minutes	54 73 34	Reference -4.02 -12.46*
Urine spilling during collection	YES NO	61 99	Reference 8.97
Reading of the manual	YES NO	129 31	Reference 4.51
Preference for sample type	Cervical sample Urine sample	49 (main reason: trust in results) 111	Reference +4.09 (p=0.07)

Table 2: Effect of different characteristics of the usability of Colli-Pee® on the SUS score

98% of women answered 'Yes' to the question if they would use Colli-Pee® Small Volumes again

97% of women answered that Colli-Pee® Small Volumes was easy to use

CONCLUSION

Colli-Pee® Small Volumes shows good usability results which are impacted by sample preference and the time needed for sampling. This research allows to further improve usability of Colli-Pee® Small Volumes for the collection of first-void urine. We suggest to increase the use of standardized scores to study sample preference and usability.

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