

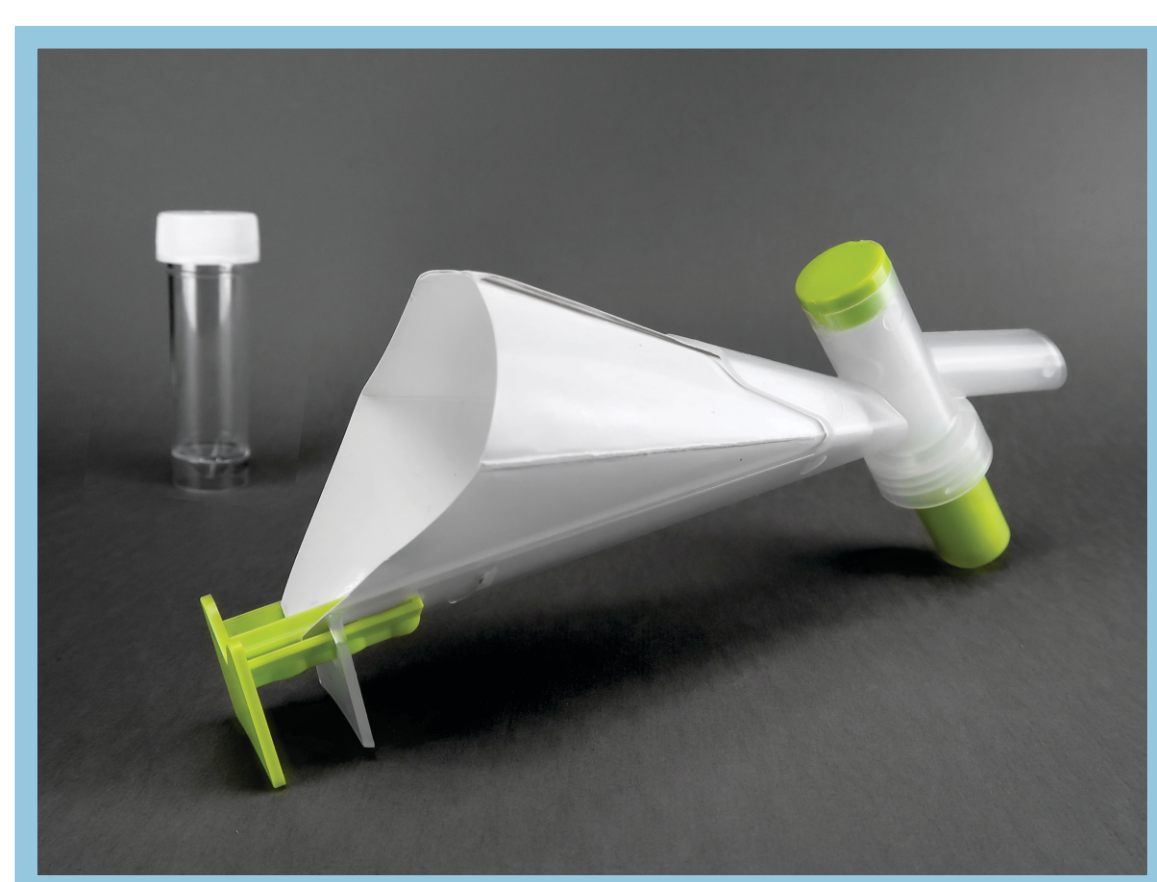
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OBJECTIVES

The first-void/first-catch urine (first 20 ml of the urine flow) is being used for the detection of sexually transmitted infections (STIs), including (1) *Chlamydia trachomatis*, (2) *Neisseria gonorrhoeae*, (3) *Mycoplasma genitalium* and (4) *Trichomonas vaginalis*. Novosanis' Colli-Pee[®] is an innovative device for standardized, volumetric and hygienic self-collection of first-void urine.

The aim of this study was to evaluate the usability of different generations of the Colli-Pee[®] device (CP-2000, FV-5000 20ml and FV-5000 10ml) for urine collection and in addition compare the Colli-Pee[®] as self-sampling device to the standard urine cup.



CP-2000



FV-5000 (20ml)



FV-5000 (10ml)



Regular urine cup

MATERIALS AND METHODS

Usability data collected from four studies was compiled. A total of 290 participants were included in the studies, of which 200 men and 90 women. All participants had to be within the age range of 18-65 years old. For each study, a questionnaire on usability was completed by the participants using one of the Colli-Pee[®] devices (10ml or 20ml variant). Two studies also included a comparator questionnaire for urine sampling with the standard urine cup.

An important instruction was to not urinate 1 to 2 hours prior to collection. The participants were requested to complete the survey after each collection.

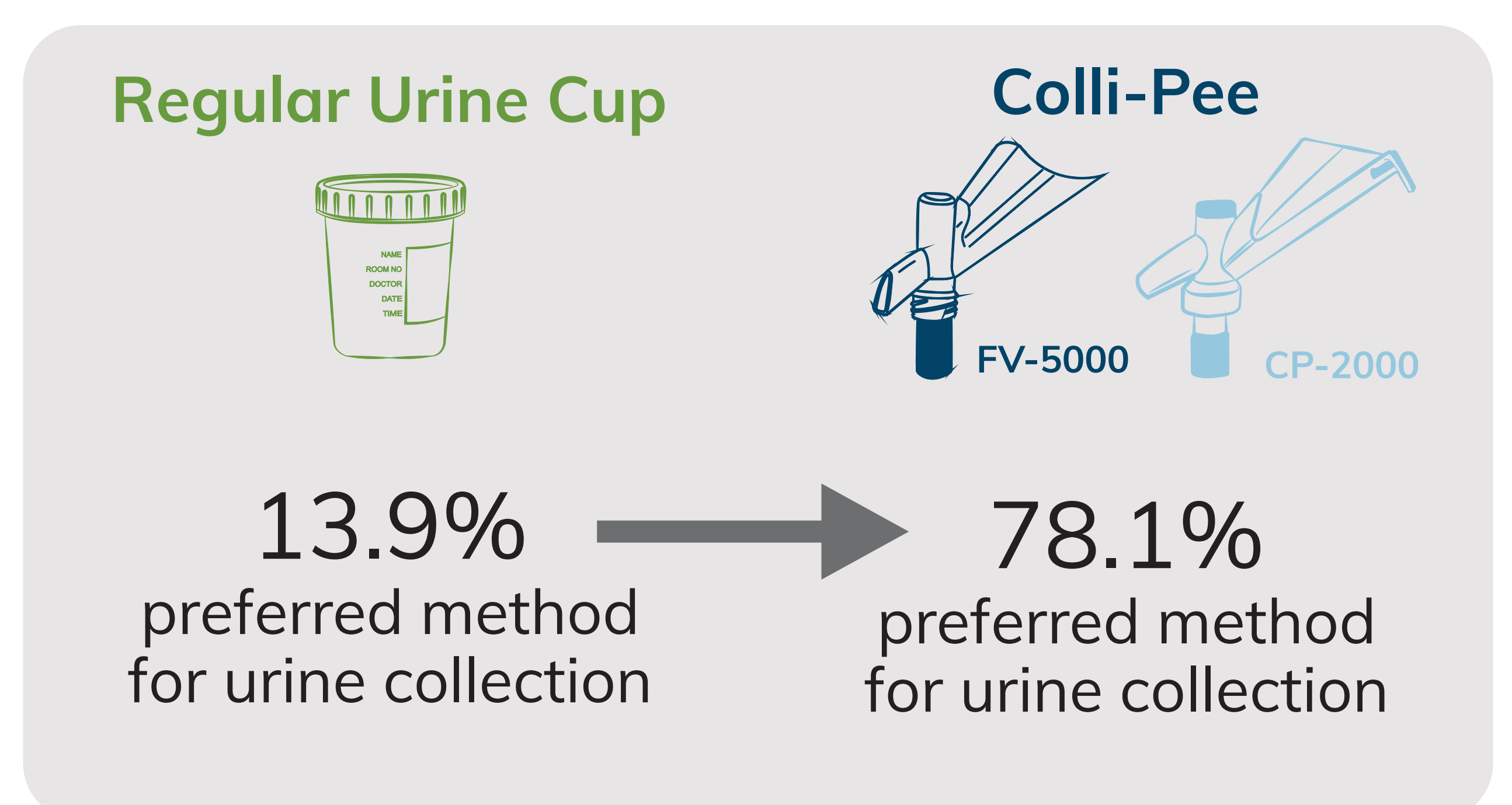
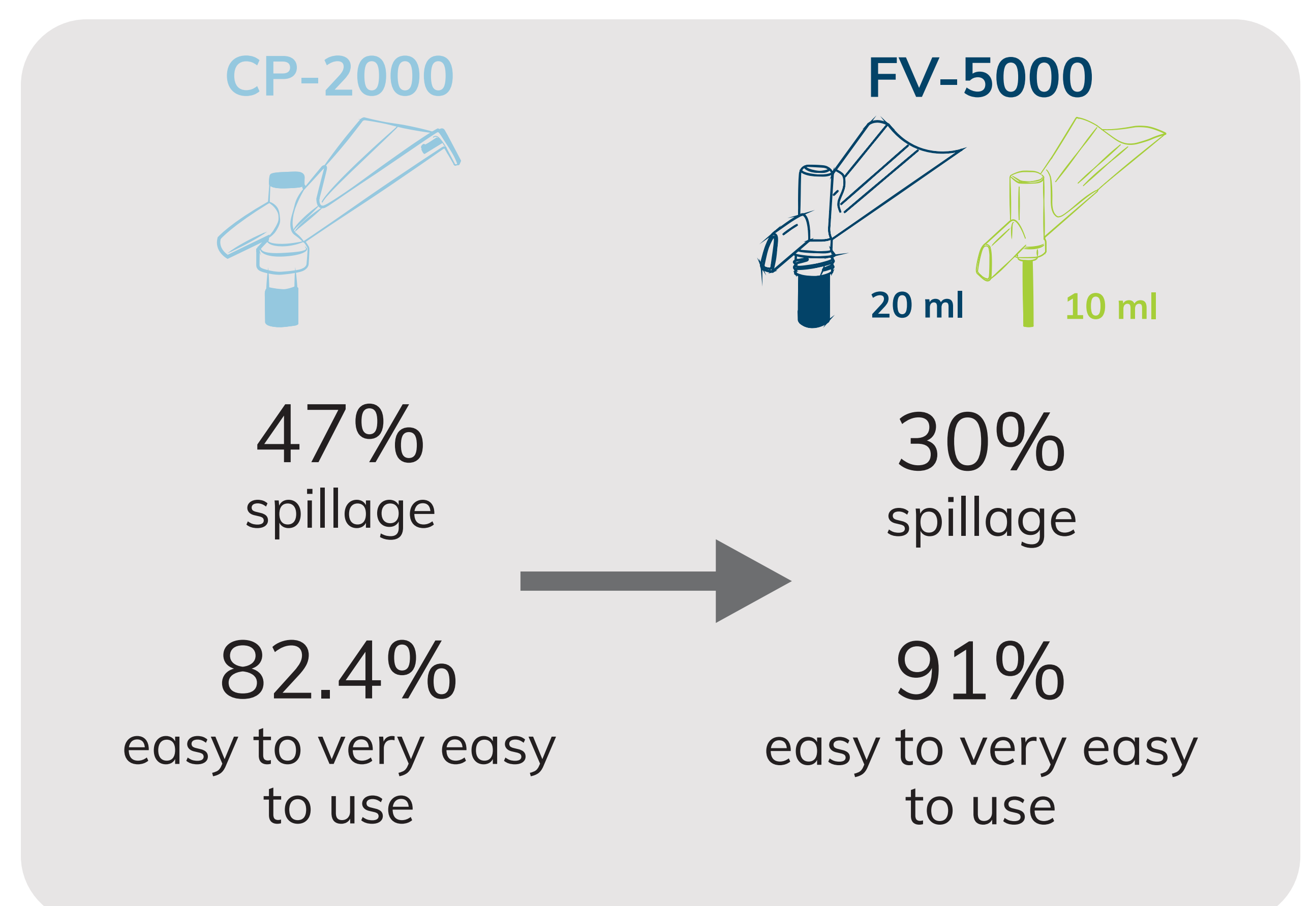
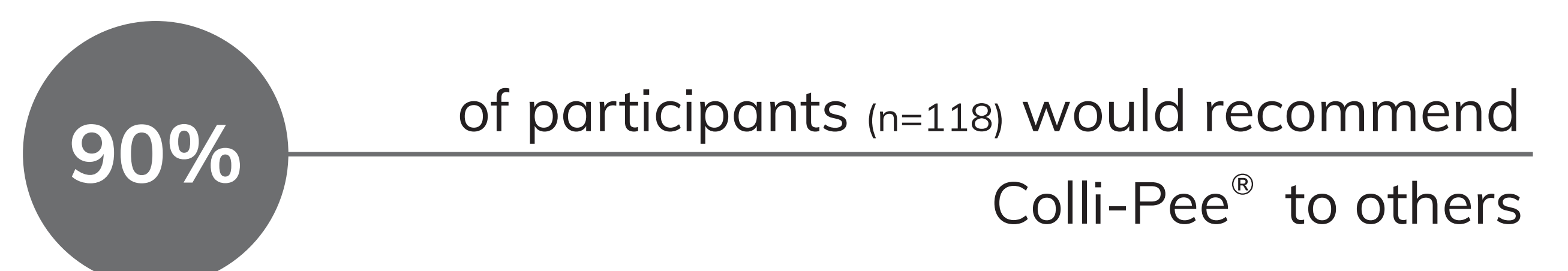
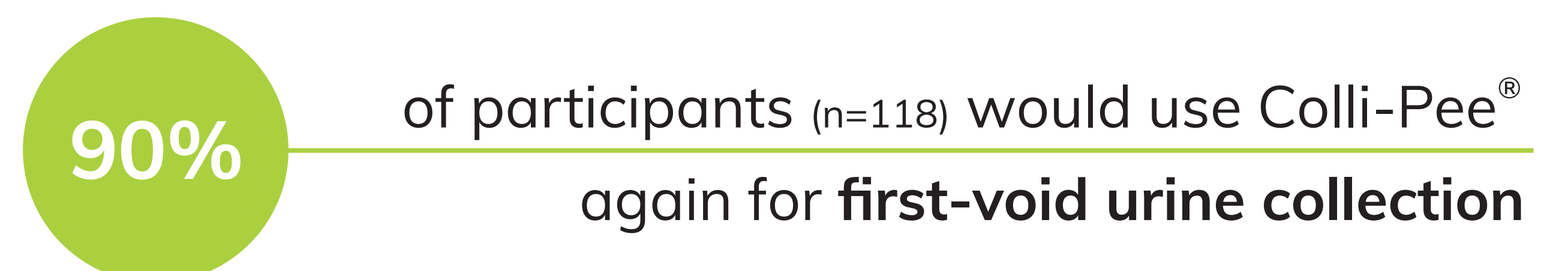
RESULTS

Of all participants, 12% used CP-2000, 59% FV-5000 20ml and 29% FV-5000 10ml.

The majority (90%) found Colli-Pee[®] easy to very easy to use, of which FV-5000 (20ml) was rated better for ease of use compared to CP-2000 ($p=0.001$, Mann-Whitney U). FV-5000 version had less urine spillage during and/or after collection: 30% compared to 47% for CP-2000.

Three of the four studies ($n=118$) showed that almost 90% of the users would recommend Colli-Pee[®] to others and 90% would use Colli-Pee[®] again for collection of urine.

Two out of four studies, that made the comparison with a regular urine cup, showed that Colli-Pee[®] is preferred for urine collection (78.1%).



CONCLUSION

The Colli-Pee[®] device is a feasible and convenient way to collect first-void urine at home, e.g. for STI testing. Design updates were shown effective since the FV-5000 series showed improvement in easiness of use compared to the previous CP-2000 design and a reduction in urine spillage. Usability was rated higher for the Colli-Pee[®] compared to the regular urine cup, for which collecting the specified volume is liked least.