Scientific Booklet

Self-Collection

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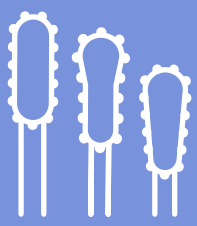

Copan

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Acknowledgments:

We would like to express our gratitude to the authors whose works have been arranged in this booklet: their insights and expertise greatly assisted this prime selection.

We are dedicated to developing and providing high-quality and cutting-edge biological sample collection products for human genomics, infectious diseases, environmental and forensic applications, along with automated workflow solutions. Copan's innovative approach enables an ever-expanding community of laboratories, scientists, and institutions to benefit from an accessible sample collection that guarantees reliable quality performance.

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In this booklet, you'll find a selection of the most interesting and recent independent studies where our products designed specifically for self-collection are used. By reading them, you'll discover how self- collection offers many advantages, such as lowering cultural barriers that limit testing and increasing participation in clinical studies and screening programs while simultaneously saving time and resources in hospitals and POC.

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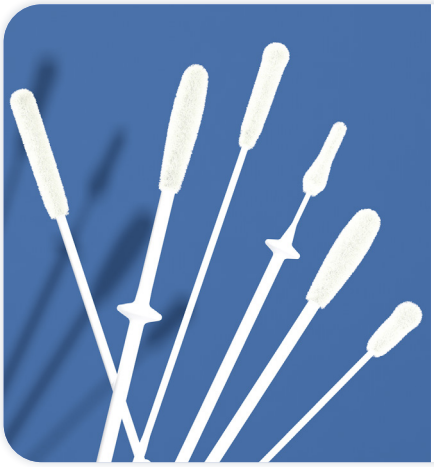

FLOQSwabs®

FLOQSwabs® are made of a solid molded plastic applicator shaft with a tip, which they can both vary in size and shape. Thanks to their patented flocked tip, FLOQSwabs® ensure a flawless specimen collection, which expands downstream diagnostic testing capabilities.

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Self-Collection

Self-Collection

PLoS One. 2019 Oct 10;14(10):e0223612

Self-Collection

An Observational Study Comparing HPV Prevalence and Type Distribution Between HPV-Vaccinated and -Unvaccinated Girls After Introduction of School-Based HPV Vaccination in Norway

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Keywords

FLOQSwabs®	Oral Sampling	HPV	HPV Vaccination

Abstract

Background: Many countries have initiated school-based human papillomavirus (HPV) vaccination programs. The real-life effectiveness of HPV vaccines has become increasingly evident, especially among girls vaccinated before HPV exposure in countries with high vaccine uptake. In 2009, Norway initiated a school-based HPV vaccination program for 12-year-old girls using the quadrivalent HPV vaccine (Gardasil®), which targets HPV6, 11, 16, and 18. Here, we aim to assess type-specific vaginal and oral HPV prevalence in vaccinated compared with unvaccinated girls in the first birth cohort eligible for school-based vaccination (born in 1997).
Methods: This observational, cross-sectional study measured the HPV prevalence ratio (PR) between vaccinated and unvaccinated girls in Norway. Facebook advertisement was used to recruit participants and disseminate information about the study. Participants self-sampled vaginal and oral specimens using an Evalyn® Brush and a FLOQSwab®, respectively. Sexual behaviour was ascertained through a short questionnaire.
Results: Among the 312 participants, 239 (76.6%) had received at least one dose of HPV vaccine prior to sexual debut. 39.1% of vaginal samples were positive for any HPV type, with similar prevalence among vaccinated and unvaccinated girls (38.5% vs 41.1%, PR: 0.93, 95% confidence interval [CI]: 0.62–1.41). For vaccine-targeted types there was some evidence of lower prevalence in the vaccinated (0.4%) compared to the unvaccinated (6.8%) group (PR: 0.06, 95%CI: 0.01–0.52). This difference remained after adjusting for sexual behaviour (PR: 0.04, 95%CI: 0.00–0.42). Only four oral samples were positive for any HPV type, and all of these participants had received at least one dose of HPV vaccine at least 1 year before oral sexual debut.
Conclusion: There is evidence of a lower prevalence of vaccine-targeted HPV types in the vagina of vaccinated girls from the first birth cohort eligible for school-based HPV vaccination in Norway; this was not the case when considering all HPV types or types not included in the quadrivalent HPV vaccine.

BMJ Open. 2020 Jan 29;10(1):e031602

Self-Collection

STOP HPV Study Protocol: a Nationwide Case–Control Study of the Association Between Oropharyngeal Cancer and Human Papillomavirus (HPV) Infection in Brazil

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Keywords

FLOQSwabs®	HPV	Genital Sampling

Abstract

Introduction: Human papillomavirus (HPV) is the most common sexually transmitted infection and is associated with several types of cancer. The number of cases of HPV-associated head and neck squamous cell carcinomas (HNSCCs), especially oropharyngeal carcinomas, has increased significantly in recent years despite decreased tobacco smoking rates. Currently, no data concerning the risk factors and prevalence of HPV in HNSCC patients in all regions of Brazil are available, making it difficult to promote advances in this field of public health. Therefore, our goal is to determine the impact of infection by HPV, including HPVs with different genotypes, on head and neck cancer and the risk factors associated with the development of head and neck cancer in all regions of Brazil.

Methods and analysis: This is a case–control study that will include 622 patients and 622 controls from all regions of Brazil. A questionnaire will be applied to gather information on sociodemographic, behavioural and health factors. Oral, cervical or penile/scrotal, and anal specimens and serum samples will be collected from all participants with Copan FLOQSwabs®. Formalin-fixed paraffin-embedded tissue from tumour biopsies will be analysed only in the case group. Molecular and serological analyses will be performed to evaluate the presence and role of HPV in the development of head and neck cancer.

Results: The results will provide a better understanding of the association between HPV infection and head and neck cancer, allowing the identification of at-risk individuals and generating hypotheses for the use of preventive or screening measures in specific population groups.

J Clin Virol. 2020 Jun;127:104375

Self-Collection

Analytical Performance of HPV Assays on Vaginal Self-Collected vs Practitioner-Collected Cervical Samples: the SCoPE Study

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Keywords

FLOQSwabs®	Vaginal Sampling	HPV	Diagnostics Platforms

Abstract

Background: In the last decade, human papillomavirus (HPV) testing has been evaluated extensively for cervical screening, with studies finding increased sensitivity compared to cytology. Another advantage of HPV based-screening is the ability to test vaginal samples that can be collected by women themselves. Self-collection has the potential to extend cervical screening coverage by increasing participation rates, particularly among women who are under-screened or have never screened. This could have a significant impact on cervical cancer prevention, as the majority of invasive cervical cancer cases occur among under-screened women. Both the Netherlands and Australia have transitioned their national programs from cytology to HPV as the primary screening test and both countries include a pathway for self-collection.

Objectives: We evaluated the relative sensitivity for HPV detection of self-collection compared with practitioner-collected cervical specimens in the context of the Australian National Cervical Screening Program (NCSP). Study Design:303 women aged ≥18 years attending a single tertiary referral centre took their own sample using a Copan FLOQSwabs®, and then had a practitioner-collected sample taken at colposcopy. All samples were tested at a single laboratory on the six PCR-based HPV assays which can be utilised in the NCSP; Roche cobas 4800 and cobas, Abbott Real Time, BD Onclarity, Cepheid Xpert, and Seegene Anyplex.

Results:HPV16/18 results had high observed agreement between self- and practitioner-collected samples on all assays (range: 0.94-0.99), with good agreement for non-HPV16/18 oncogenic HPV types (range: 0.64-0.73).

Conclusions: Self-collection for HPV-based cervical screening shows good concordance and relative sensitivity when compared to practitioner collected samples across assays in the NCSP.

Clin Infect Dis. 2021 Mar 1;72(5):e103-e111

Self-Collection

Population Impact of Girls-Only Human Papillomavirus 16/18 Vaccination in The Netherlands: Cross-Protective and Second-Order Herd Effects

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Keywords

FLOQSwabs®	HPV	Vaccination	Genital Sampling

Abstract

Background: Human papillomavirus (HPV) vaccination programs achieve substantial population-level impact, with effects extending beyond protection of vaccinated individuals. We assessed trends in HPV prevalence up to 8 years postvaccination among men and women in the Netherlands, where bivalent HPV vaccination, targeting HPV types 16/18, has been offered to (pre)adolescent girls since 2009 with moderate vaccination coverage.
Methods. We used data from the PASSYON study, a survey initiated in 2009 (pre-vaccination) and repeated biennially among 16- to 24 year-old visitors of sexual health centers obtained starting from genital self-collection swab (Copan FLOQSwabs®). We studied genital HPV positivity from 2009 to 2017 among women, heterosexual men, and unvaccinated women using Poisson generalized estimating equation models, adjusted for individual- and population-level confounders. Trends were studied for 25 HPV types detected by the SPF10-LiPA25 platform.
Results. A total of 6354 women (64.7% self-reported unvaccinated) and 2414 heterosexual men were included. Percentual declines in vaccine types HPV-16/18 were observed for all women (12.6% per year [95% confidence interval {CI}, 10.6–14.5]), heterosexual men (13.0% per year [95% CI, 8.3–17.5]), and unvaccinated women (5.4% per year [95% CI, 2.9–7.8]). We observed significant declines in HPV-31 (all women and heterosexual men), HPV-45 (all women), and in all high-risk HPV types pooled (all women and heterosexual men). Significant increases were observed for HPV-56 (all women) and HPV-52 (unvaccinated women).
Conclusions. Our results provide evidence for first-order herd effects among heterosexual men against HPV-16/18 and cross protective types. Additionally, we show second-order herd effects against vaccine types among unvaccinated women. These results are promising regarding population-level and clinical impact of girls-only bivalent HPV vaccination in a country with moderate vaccine uptake.

BMC Infect Dis. 2020 Nov 11;20(1):834

Self-Collection

Treating Male Partners of Women with Bacterial Vaginosis (Stepup): a Protocol for a Randomised Controlled Trial to Assess the Clinical Effectiveness of Male Partner Treatment for Reducing the Risk of Bv Recurrence

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Keywords

FLOQSwabs®	Bacterial Vaginosis	Male Partners	Antibiotic Treatment

Abstract

Background: Bacterial vaginosis (BV) is estimated to affect 1 in 3 women globally and is associated with obstetric and gynaecological sequelae. Current recommended therapies have good short-term efficacy but 1 in 2 women experience BV recurrence within 6 months of treatment. Evidence of male carriage of BV-organisms suggests that male partners may be reinfecting women with BV-associated bacteria (henceforth referred to as BV-organisms) and impacting on the efficacy of treatment approaches solely directed to women. This trial aims to determine the effect of concurrent male partner treatment for preventing BV recurrence compared to current standard of care.

Methods: StepUp is an open-label, multicentre, parallel group randomised controlled trial based on genital self-collection (Copan FLOQSwabs®) for women diagnosed with BV and their male partner. Women with clinical-BV defined using current gold standard diagnosis methods (≥3 Amsel criteria and Nugent score (NS) = 4–10) and with a regular male partner will be assessed for eligibility, and couples will then be consented. All women will be prescribed oral metronidazole 400 mg twice daily (BID) for 7 days, or if contraindicated, a 7-day regimen of topical vaginal 2% clindamycin. Couples will be randomised 1:1 to either current standard of care (female treatment only), or female treatment and concurrent male partner treatment (7 days of combined antibiotics - oral metronidazole tablets 400 mg BID and 2% clindamycin cream applied topically to the glans penis and upper shaft [under the foreskin if uncircumcised] BID). Couples will be followed for up to 12 weeks to assess BV status in women, and assess the adherence, tolerability and acceptability of male partner treatment. The primary outcome is BV recurrence defined as ≥3 Amsel criteria and NS = 4–10 within 12 weeks of enrolment. The estimated sample size is 342 couples, to detect a 40% reduction in BV recurrence rates from 40% in the control group to 24% in the intervention group within 12 weeks.

Discussion: Current treatments directed solely to women result in unacceptably high rates of BV recurrence. If proven to be effective the findings from this trial will directly inform the development of new treatment strategies to impact on BV recurrence.

Curr Oncol. 2019 Jun;26(3):167-172

Self-Collection

Assessing the Impact of Mailing Self-Sampling Kits for Human Papillomavirus Testing to Unscreened Non-Responder Women in Manitoba

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Keywords

FLOQSwabs®	HPV	Cancer Screening	Mailing Self Sampling Kits

Abstract

Background: CervixCheck, Manitoba's cervical cancer screening program, conducted a pilot study to assess whether screening participation could be improved in unscreened women by offering a mailed self-sampling kit for human papillomavirus (HPV) testing instead of a Pap test.
Methods: In a prospective cohort study design, a sample of unscreened women (n = 1052) who had been sent an invitation letter from CervixCheck in the past but who did not respond were randomized to either an intervention group or a control group. The intervention group received a mailed HPV self-sampling kit with Copan FLOQSwabs®; the control group received no additional communication. Returned HPV self-sampling swabs were analyzed by a provincial laboratory. After 6 months, screening participation in the two study groups was compared using a logistic regression model adjusted for age and area of residence (urban or rural). Secondary outcomes included HPV positivity, specimen inadequacy, compliance with follow-up, and time to colposcopy.
Results: Screening participation was significantly higher in the intervention group than in the control group (n = 51, 9.6%, vs. n = 13, 2.5%; odds ratio: 4.7; 95% confidence interval: 2.56 to 8.77). Geographic area of residence (urban or rural) and age were not statistically significant.
Conclusions: The study demonstrated that HPV self-sampling kits can enhance screening participation in unscreened non-responder women in the setting of an organized screening program. Next steps should include additional research to determine the best implementation strategy for HPV self-sampling in Manitoba.

Curr Oncol. 2018 Feb;25(1):e27-e32

Self-Collection for Under-Screened Women in a National Cervical Screening Program: Pilot Study

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Keywords

FLOQSwabs®	National Program	HPV	Cervical Cancer Screening

Abstract

Background: Commencing 1 December 2017, Australia introduced human papillomavirus (HPV)-based cervical screening. As part of this Australian renewed National Cervical Screening Program (NCSP) women who are either never- or under-screened and who refuse a practitioner collected sample will be able to collect their own sample for cervical screening. The aim of this study is to examine the quantitative results of a pilot study into the acceptability of the self-collection alternative pathway.
Methods: Eligible participants were offered the opportunity to collect their own sample. Those who agreed were given a flocked swab and an instruction sheet and took their own sample in an area of the health care clinic that afforded them adequate privacy. These samples were then given to clinic staff who returned them to Victorian Cytology Service (VCS) Pathology for HPV nucleic acid testing.
Results: Of 98 eligible women, seventy-nine undertook self-collection for HPV-based cervical screening. Seventyseven produced valid results, 14 were positive for oncogenic HPV, with 10 undertaking follow-up. Three women were found to have cervical squamous abnormalities with two of those being high-grade intraepithelial squamous lesions.
Conclusion: The pilot study for self-collection for cervical screening produced quantitative data that were similar to that already reported in the literature but had a much higher rate of acceptance compared with self-collection programs based in the home.

Int J Womens Health. 2018 May 15;10:229-236

Self-Collection

A Comparison of Cotton and Flocked Swabs for Vaginal Self-Sample Collection

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Keywords

FLOQSwabs®	HPV	Sample Release	Cellular Retrieval

Abstract

Objective: Vaginal self-sampling for human papillomavirus (HPV) testing has recently been proposed to optimize cervical cancer screening coverage. The objective of this study was to compare the performance of self-taken samples using flocked and cotton swabs for HPV detection and cellular retrieval.
Methods: We recruited women aged 21-65 years, referred to colposcopy at the Division of Gynecology of the Geneva University Hospitals between May and September 2016. Each participant collected 2 vaginal samples: 1 with a cotton swab (Copan ClassiqSwabs™) and 1 with a flocked swab (Copan FLOQSwabs®). A 1:1 randomization determined the order in which the 2 samples were taken. The swabs were introduced into a 20 mL PreservCyt® vial. Real-time polymerase chain reaction analysis using the Anyplex™ II HPV HR assay, cytofluorometric analysis and cytological cell counting were performed on each sample.
Results: A total of 119 participants were recruited in the study. Their mean ± standard deviation age was 35.1±8.9 years. The HPV prevalence was 29.7% and 38.1% according to the cotton and flocked swab, respectively (p=0.006). The mean number of cells collected per milliliter according to cytofluorometry was 96,726.6 with the cotton swab and 425,544.3 with the flocked swab (p<0.001). The mean number of cells detected at cytological cell count was 13,130.42 using the cotton swab and 17,503.6 using the flocked swab (p<0.001).
Conclusion: The flocked swab achieved a greater cellular retrieval and showed an improved performance in HPV detection. Further studies are needed to assess the usability and cost-effectiveness of the 2 self-sampling devices.

PLoS One. 2015 Dec 2;10(12):e0143644

Self-Collection

Randomized Comparison of Two Vaginal Self-Sampling Methods for Human Papillomavirus Detection: Dry Swab versus FTA Cartridge

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Keywords

FLOQSwabs®	Storage	HPV	Stability

Abstract

Background: Human papillomavirus (HPV) self-sampling (self-HPV) is valuable in cervical cancer screening. HPV testing is usually performed on physician-collected cervical smears stored in liquid-based medium. Dry filters and swabs are an alternative. We evaluated the adequacy of self-HPV using two dry storage and transport devices, the FTA cartridge and swab.
Methods: A total of 130 women performed two consecutive self-HPV samples. Randomization determined which of the two tests was performed first: self-HPV using Copan FLOQSwabs® (s-DRY) or vaginal specimen collection using a cytobrush applied to an FTA cartridge (s-FTA). After self-HPV, a physician collected a cervical sample using liquid-based medium (Dr-WET). HPV types were identified by real-time PCR. Agreement between collection methods was measured using the kappa statistic.
Results: HPV prevalence for high-risk types was 62.3% (95%CI: 53.7–70.2) detected by s-DRY, 56.2% (95%CI: 47.6–64.4) by Dr-WET, and 54.6% (95%CI: 46.1–62.9) by s-FTA. There was overall agreement of 70.8% between s-FTA and s-DRY samples (kappa = 0.34), and of 82.3% between self-HPV and Dr-WET samples (kappa = 0.56). Detection sensitivities for low-grade squamous intraepithelial lesion or worse (LSIL+) were: 64.0% (95%CI: 44.5–79.8) for s-FTA, 84.6% (95%CI: 66.5–93.9) for s-DRY, and 76.9% (95%CI: 58.0–89.0) for Dr-WET. The preferred self-collection method among patients was s-DRY (40.8% vs. 15.4%). Regarding costs, FTA card was five times more expensive than the swab (~5 US dollars (USD)/per card vs. ~1 USD/per swab).
Conclusion: Self-HPV using dry swabs is sensitive for detecting LSIL+ and less expensive than s-FTA.

BMC Public Health. 2016 Jan 28;16:83

Self-Collection

The Acceptability and Cost of a Home-Based Chlamydia Retesting Strategy: Findings from the REACT Randomised Controlled Trial

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Keywords

UriSwab™	*Chlamydia trachomatis*	Cost and Acceptability	Retesting

Abstract

Background: Chlamydia retesting three months after treatment is recommended to detect reinfections, but retesting rates are typically low. The REACT (retest after Chlamydia trachomatis) randomised trial demonstrated that home-based retesting using postal home-collection kits that included Copan UriSwab™ for urine self-collection and SMS reminders, resulted in substantial improvements in retesting rates in women, heterosexual men and men who have sex with men (MSM), with detection of more repeat positive tests compared with SMS reminder alone. In the context of this trial, the acceptability of the home-based strategy was evaluated and the costs of the two strategies were compared.
Methods: REACT participants (200 women, 200 heterosexual men, 200 MSM) were asked to complete an online survey that included home-testing acceptability and preferred methods of retesting. The demographics, sexual behaviour and acceptability of home collection were compared between those preferring home-testing versus clinic-based retesting or no preference, using a chi-square test. The costs to the health system of the clinic-based and home retesting strategies and the cost per infection for each were also compared.
Results: Overall 445/600 (74 %) participants completed the survey; 236/445 from the home-testing arm, and 141 of these (60 %) retested at home. The majority of home arm retesters were comfortable having the kit posted to their home (86 %); found it easy to follow the instructions and collect the specimens (96 %); were confident they had collected the specimens correctly (90 %); and reported no problems (70 %). Most (65 %) preferred home retesting, 21 % had no preference and 14 % preferred clinic retesting. Comparing those with a preference for home testing to those who didn't, there were significant differences in being comfortable having a kit sent to their home ($p = 0.045$); not having been diagnosed with chlamydia previously ($p = 0.030$); and living with friends ($p = 0.034$). The overall cost for the home retest pathway was $154 (AUD), compared to $169 for the clinic-based retesting pathway and the cost per repeat infection detected was $1409 vs $3133.
Conclusions: Among individuals initially diagnosed with chlamydia in a sexual health clinic setting, home-based retesting was shown to be highly acceptable, preferred by most participants, and cost-efficient. However some clients preferred clinic-based testing, often due to confidentiality concerns in their home environment. Both options should be provided to maximise retesting rates.

Sex Health. 2017 Nov;14(6):502-506

Self-Collection

UriSwab™: an Effective Transport Medium for Nucleic Acid Detection of *Chlamydia Trachomatis, Mycoplasma Genitalium And Neisseria Gonorrhoeae*

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Keywords

FLOQSwabs®	Chlamydia trachomatis	Neisseria gonorrhoeae	Mycoplasma genitalium

Abstract

Background: Patient self-sampling allows for remote collection and return to clinic or laboratory by post. Urine samples, although convenient, are challenging to post. This study evaluated UriSwab™ (Copan, Brescia, Italy) as a collection and transport vessel for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) and Mycoplasma genitalium (MG) detection by polymerase chain reaction, compared with flocked swab and neat urine.
Methods: Five replicates of each specimen type were prepared from previously characterised urine samples (n = 330), stored at room temperature (RT) or 37°C, then extracted on day 1, 3, 7, 10 and 16 (VERSANT kPCR Sample Prep System, Siemens, Munich, Germany). Crossing thresholds (Cq) from CT and NG detection (VERSANT CT/GC DNA 1.0 assay kit, Siemens) and MG detection (real-time polymerase chain reaction assay) were compared using logistic regression, stratified by sample type, temperature and analyte. Mixed-model statistical techniques were used to assess correlation between repeated observations.
Results: UriSwab™ showed an increasing trend in Cq values at RT and 37°C for CT and NG, and RT for MG (all $P < 0.01$). UriSwab™ was not statistically significantly different to neat urine, except CT at RT (0.83, 95% confidence interval: 0.51–1.15). Flocked swab similarly showed increasing Cq values at 37°C for CT, a significant decreasing trend at RT for MG and increasing trend at 37°C for MG. Flocked swab was not statistically significantly different from neat urine at RT and 37°C for CT and MG. Conclusion: UriSwab allows transport of urine for CT, NG and MG detection regardless of storage time or temperature, suggesting that CT and NG are stable for up to 16 days and MG up to 10 days.

Note

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