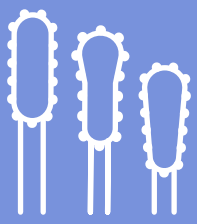
Scientific Booklet

STIs & HPV



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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. Our goal is to continue this innovation by providing products, customized services, and prime solutions to improve patients' health and wellness.
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Sexually Transmitted Infections

Sexually Transmitted Infections

Sexually Transmitted Infections

PLoS One. 2018 Apr 11;13(4):e0195386

Sexually Transmitted Infections

Urogenital *Chlamydia trachomatis* Multilocus Sequence Types and Genovar Distribution in Chlamydia Infected Patients in a Multi-Ethnic Region of Saratov, Russia

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Keywords

FLOQSwabs®	Chlamydia trachomatis	Sequencing Analysis	Russia

Abstract

Background: This is the first report to characterize the prevalence and genovar distribution of genital chlamydial infections among random heterosexual patients in the multi-ethnic Saratov Region, located in Southeast Russia.
Methods: Sixty-one clinical samples (cervical or urethral Copa FLOQSwabs® collected from a random cohort of 856 patients (7.1%) were *C. trachomatis* (CT) positive in commercial nucleic acid amplification tests (NAATs) and duplex TaqMan PCRs.
Results: Sequence analysis of the VDII region of the ompA gene revealed seven genovars of *C. trachomatis* in PCR-positive patients. The overall genovars were distributed as E (41.9%), G (21.6%), F (13.5%), K (9.5%), D (6.8%), J (4.1%), and H (2.7%). CT-positive samples were from males (n = 12, 19.7%), females (n = 42, 68.8%), and anonymous (n = 7, 11.5%) patients, with an age range of 19 to 45 years (average 26.4), including 12 different ethnic groups representative of this region. Most patients were infected with a single genovar (82%), while 18% were co-infected with either two or three genovars. The 1156 bp-fragment of the ompA gene was sequenced in 46 samples to determine single nucleotide polymorphisms (SNP) among isolates. SNP-based subtyping and phylogenetic reconstruction revealed the presence of 13 variants of the ompA gene, such as E (E1, E2, E6), G (G1, G2, G3, G5), F1, K, D (D1, Da2), J1, and H2. Differing genovar distribution was identified among urban (E>G>F) and rural (E>K) populations, and in Slavic (E>G>D) and non-Slavic (E>G>K) ethnic groups. Multilocus sequence typing (MLST) determined five sequences types (STs), such as ST4 (56%, 95% confidence interval, CI, 70.0 to 41.3), ST6 (10%, 95% CI 21.8 to 3.3), ST9 (22%, 95% CI 35.9 to 11.5), ST10 (2%, 95% CI 10.7 to 0.05) and ST38 (10%, 95% CI 21.8 to 3.3). Thus, the most common STs were ST4 and ST9.
Conclusion: *C. trachomatis* is a significant cause of morbidity among random heterosexual patients with genital chlamydial infections in the Saratov Region. Further studies should extend this investigation by describing trends in a larger population, both inside and outside of the Saratov Region to clarify some aspects for the actual application of *C. trachomatis* genotype analysis for disease control.

PLoS One. 2018 May 1;13(5):e0196925

Sexually Transmitted Infections

Streptococcus agalactiae Carriage Among Pregnant Women Living in Rio De Janeiro, Brazil, over a Period of Eight Years

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Keywords

FLOQSwabs®	Group B Streptococcus	Pregnant Women	Anogenital Colonization

Abstract

Group B Streptococcus (GBS) carriage by pregnant women is the primary risk factor for early-onset GBS neonatal sepsis. Intrapartum antibiotic prophylaxis (IAP) can prevent this transmission route, and two main approaches are recommended to base the selection of pregnant women to be submitted to IAP: the risk-based and the culture-based strategies. In Brazil, compliance to such recommendations is poor, and not much is known about GBS carriage. In the present study, 3,647 pregnant women living in Rio de Janeiro State, Brazil, were screened for GBS anogenital colonization with Copan FLOQSwabs®, over a period of 8 years (2008–2015). GBS was detected in 956 (26.2%) of them, and presence of vaginal discharge was the only trait associated with a higher risk for GBS colonization. Serotypes Ia (257; 37.3%) and II (137; 19.9%) were the most frequent among 689 (72.1% of the total) GBS isolates evaluated, followed by NT isolates (84; 12.1%), serotype Ib (77; 11.1%), V (63; 9.1%), III (47; 6.8%) and IV (24; 3.5%). Estimated coverage of major serotype-based GBS vaccines currently under clinical trials would vary from 65.2% to 84.3%. All 689 isolates tested were susceptible to ampicillin and vancomycin. Resistance to chloramphenicol, clindamycin, erythromycin, levofloxacin, and tetracycline was observed in 5% (35), 2% (14), 14% (97), 5% (35) and 86% (592) of the isolates, respectively. No significant fluctuations in colonization rates, serotype distribution and antimicrobial susceptibility profiles were observed throughout the period of time investigated. The culture-based approach for IAP recommendation showed to be the best choice for the population investigated when compared to the risk-based, since the first did not increase the number of pregnant women submitted to antibiotic therapy and covered a larger number of women who were actually colonized by GBS. The fact the not all isolates were available for additional characterization, and serotype IX antiserum was not available for testing represent limitations of this study. Nevertheless, to the best of our knowledge, this is the largest investigation on GBS carriage among pregnant women in Brazil up to date, and results are useful for improving GBS prevention and treatment strategies.

J Clin Microbiol 2019 Dec 3;58(1):e01375-19

Sexually Transmitted Infections

Bacterial Load of *Chlamydia trachomatis* in the Posterior Oropharynx, Tonsillar Fossae, and Saliva among Men Who Have Sex with Men with Untreated Oropharyngeal Chlamydia

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Keywords

Urisponge™	Saliva	*Chlamydia trachomatis*	STD

Abstract

The aim of this study was to determine whether *Chlamydia trachomatis* could be detected in saliva and if infection is specific to an anatomical site in the oropharynx. Men who have sex with men (MSM) who were diagnosed with oropharyngeal chlamydia at the Melbourne Sexual Health Centre in 2017-2018 were invited to participate upon returning for treatment. Copan UriSwabs™ (Know as Urisponge™) at the tonsillar fossae and posterior oropharynx and a saliva sample were collected. Throat samples were tested for *C. trachomatis* by the Aptima Combo 2 assay. The bacterial loads of *C. trachomatis* in all samples were assessed by quantitative PCR (qPCR) detecting the ompA gene. We calculated the positivity and bacterial load of *C. trachomatis* for all samples. Fortytwo MSM were included. The median age was 28 years (interquartile range [IQR], 24 to 33 years). Thirty-two participants (76.2%; 95% confidence interval [CI], 60.5% to 87.9%) had C. trachomatis detected by qPCR at both the tonsillar fossae and the posterior oropharynx, followed by 9.5% (n 4; 95% CI, 2.7% to 22.6%) positive at the posterior oropharynx only and 4.8% (n 2; 95% CI, 0.58% to 16.2%) positive at the tonsillar fossae only. Twenty-nine MSM had *C. trachomatis* detected in saliva (69.0%; 95% CI, 52.9% to 82.3%). The median *C. trachomatis* load in saliva was 446 copies/ml (IQR, 204 to 1,390 copies/ml), that in the tonsillar fossae was 893 copies/ swab (IQR, 390 to 13,224 copies/ml), and that in the posterior oropharynx was 1,204 copies/swab (IQR, 330 to 16,211). There was no significant difference in *C. trachomatis* load between the tonsillar fossae and the posterior oropharynx (P 0.119). Among MSM with oropharyngeal chlamydia, nearly three-quarters had chlamydia DNA detected in saliva, although the viability and implications for transmission are unknown.

Southern African Journal of Infectious Diseases. 2017 October ;32(3):96-99

Sexually Transmitted Infections

Evaluation of the Copan eSwab®, a Liquid-Based Microbiology Transport System, for the Preservation of *Neisseria gonorrhoeae* at Different Temperatures

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Keywords

eSwab® | Neisseria gonorrhoeae | Different Temperatures Preservation

Abstract

Aims and objectives: To evaluate the survival duration of *Neisseria gonorrhoeae* from male urethral discharge specimens collected using the Copan eSwab® liquid-based microbiology transport system, at both ambient and refrigerator temperatures.
Methods: Three urethral swabs (one Dacron, two Copan eSwabs®) were collected from each male patient presenting with purulent urethral discharge to a community-based primary healthcare centre in Johannesburg. The Dacron swab was directly inoculated onto New York city agar medium, and the Copan eSwabs® transported and held at room and refrigerator temperature, for daily sub-culture onto New York city agar over a total period of seven days (168 h). The utility of Copan eSwabs® for the transport and survival of *N. gonorrhoeae* at different temperatures was determined by comparison to culture obtained by 'gold standard' direct plate inoculation.
Results: *N. gonorrhoeae* isolation rates from Copan eSwabs® at fridge temperature and ambient temperature were as follows: 87.9% vs 79.3% at 48 h; 67.2% vs 60.3% at 72 h; 60.3% vs 22.4% at 96 h; and, 53.4% vs 3.4% at 120 h, respectively. The viability of subculture decreased significantly from eSwabs® maintained at room temperature from 96 h onwards of specimen collection.
Conclusion: To ensure the preservation and an acceptable isolation rate of *N. gonorrhoeae* from urethral discharge specimens, Copan eSwabs® should be transported and maintained at refrigerator temperatures, and must reach the processing laboratory by at least 120 h (5 days) after collection.

J Clin Microbiol. 2019 May 24;57(6):e01958-18

Sexually Transmitted Infections

Comparison of Three Nucleic Acid Amplification Tests and Culture for Detection of *Group B Streptococcus* from Enrichment Broth

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Keywords

eSwab®	Group B Streptococcus	Early-Onset Disease	Pregnancy &Prenatal

Abstract

Colonization of the gastrointestinal and genitourinary tracts of pregnant women with *group B Streptococcus* (GBS) can result in vertical transmission to neonates during labor/delivery. GBS infections in neonates can cause severe complications, such as sepsis, meningitis, and pneumonia. Accurate detection is critical because administration of intrapartum antibiotics can significantly reduce transmission. We compared the clinical sensitivities of three nucleic acid amplification tests (NAATs), the Hologic Panther Fusion GBS, Luminex Aries GBS, and Cepheid Xpert GBS LB assays, to that of the standard of care culture method recommended for GBS screening using 500 vaginal-rectal Copan eSwab® specimens after 18 to 24 h of broth enrichment. We identified 108 positive specimens (21.6%) by culture, while at least 1 of the 3 NAATs was positive for GBS in 155 specimens (31.0%). All 108 specimens positive by culture were also detected by the Panther Fusion assay, while 107/108 (99.1%) were detected by the Cepheid Xpert and Luminex Aries assays. Of the 61 specimens positive by at least 1 NAAT but negative by culture, 24 (39.3%) were positive by all 3 NAATs, suggesting that they represent true positives (TPs). NAATs offer less hands-on time, greater throughput, faster time to result, and potentially greater sensitivity than culture methods, and they should be considered the new gold standard for intrapartum GBS screening.

J Clin Microbiol. 2019 Jan 30;57(2):e01324-18

Sexually Transmitted Infections

Multicenter Evaluation of NeuMoDx *Group B Streptococcus* Assay on the NeuMoDx 288 Molecular System

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Keywords

eSwab®	Group B Streptococcus	NeuMoDx 288 System

Abstract

Group B Streptococcus (GBS) is the leading cause of neonatal sepsis and meningitis in developed countries. Recommendations for antepartum GBS detection include enriched culture with several options for identifying GBS, some of which are time-consuming. To reduce the time for identification and determination of the maternal GBS colonization status, rapid nucleic acid amplification technologies have been developed and commercialized. For rapid detection of GBS, a three-site clinical study was conducted to evaluate the NeuMoDx GBS assay, a real-time PCR test performed for vaginal/rectal Copan eSwab® specimens in Lim broth enrichment culture on the NeuMoDx 288 molecular system (NeuMoDx system); these data were used to a support 510(k) submission. A total of 1,250 eligible remnant samples were prospectively enrolled and tested during the study. The results of the PCR assay were compared to the results of the Centers for Disease Control and Prevention (CDC)-recommended enriched-culture method, which served as the gold standard reference method for the study. The NeuMoDx GBS assay results yielded a sensitivity of 96.9% (95% confidence interval [CI] 94.1 to 98.4), specificity of 96.0% (95% CI 94.6 to 97.1), and a total agreement with the reference method of 96.2% (95% CI 93.8 to 98.3). NeuMoDx GBS assay results were also compared to results obtained using the BD MAX GBS assay on the BD MAX system. The two systems demonstrated a total percent agreement of 98.0% (95% CI 95.5 to 100.0). The performance of the NeuMoDx GBS assay implemented on the NeuMoDx system compared favorably to the CDC enriched-culture method and to the BD MAX GBS assay.

EBioMedicine. 2018 Feb;28:120-127

Sexually Transmitted Infections

A 30-Min Nucleic Acid Amplification Point-of-Care Test for Genital *Chlamydia trachomatis* Infection in Women: A Prospective, Multi-center Study of Diagnostic Accuracy

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Keywords

eNAT®	Chlamydia trachomatis	Rapid Test	Point-of-Care

Abstract

Background: Rapid Point-Of-Care Tests for *Chlamydia trachomatis* (CT) may reduce onward transmission and reproductive sexual health (RSH) sequelae by reducing turnaround times between diagnosis and treatment. The io® single module system (Atlas Genetics Ltd.) runs clinical samples through a nucleic acid amplification test (NAAT)-based CT cartridge, delivering results in 30 min. Methods: Prospective diagnostic accuracy study of the io® CT-assay in four UK Genito-Urinary Medicine (GUM)/ RSH clinics on additional-to-routine self-collected vulvovaginal swabs. Samples were tested "fresh" within 10 days of collection, or "frozen" at –80 °C for later testing. Participant characteristics were collected to assess risk factors associated with CT infection. Results: CT prevalence was 7.2% (51/709) overall. Sensitivity, specificity, positive and negative predictive values of the io® CT assay were, respectively, 96.1% (95% Confidence Interval (CI): 86.5–99.5), 97.7% (95%CI: 96.3– 98.7), 76.6% (95%CI: 64.3–86.2) and 99.7% (95%CI: 98.9–100). The only risk factor associated with CT infection was being a sexual contact of an individual with CT. Conclusions: The io® CT-assay is a 30-min, fully automated, high-performing NAAT currently CE-marked for CT diagnosis in women, making it a highly promising diagnostic to enable specific treatment, initiation of partner notification and appropriately intensive health promotion at the point of care.

Pathogens. 2020 Jul 31;9(8):625

Sexually Transmitted Infections

The Prevalence of *Chlamydia trachomatis* and Three Other Non-Viral Sexually Transmitted Infections among Pregnant Women in Pemba Island Tanzania

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Keywords

eNAT®	Chlamydia trachomatis	Pregnancy	Point-of-Ca Sexual Health re

Abstract

Efforts to map the burden of infections globally have shown a high prevalence of genital infections, including *Chlamydia trachomatis,* in sub-Saharan Africa. This retrospective study aimed to investigate the prevalence of selected non-viral genital infections among pregnant women in Pemba Island, Tanzania. Vaginal swabs were collected during pregnancy and stored in Copan eNAT® buffer. Detection of *C. trachomatis, Neisseria gonorrheae, Trichomonas vaginalis, and Mycoplasma genitalium* pathogens was performed by PCR using validated detection kits. Vaginal samples of 439 pregnant women between 16 and 48 years were tested. In fifty-five (12.5%) of them, at least one genital pathogen was detected. The most prevalent pathogen was *T. vaginalis* (7.1%), followed by *C. trachomatis* (4.6%) and *M. genitalium* (2.1%). None of the vaginal samples tested positive for *N. gonorrheae*. Consequently, among positive samples, 7.3% were for *C. trachomatis* and at least one other genital pathogen. This study provides insights on the burden of the four studied genital infections, and on the coinfections among pregnant women in Pemba Island, Tanzania. These results offer a starting point that can be useful to design further research in the field of maternal and child health in Pemba Island.

Microorganisms. 2019 Nov 12;7(11):557

Sexually Transmitted Infections

Sexually Transmitted Infections and Behavioral Determinants of Sexual and Reproductive Health in the Allahabad District (India) Based on Data from the ChlamIndia Study

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Keywords

eNAT®	Chlamydia trachomatis	Neisseria gonorrhoeae	Sexual Health

Abstract

Background: Sexually transmitted infections (STIs), like *Chlamydia trachomatis and Neisseria gonorrhoeae* (CT and NG, respectively) are linked to an important sexual and reproductive health (SRH) burden worldwide. Behavior is an important predictor for SRH, as it dictates the risk for STIs. Assessing the behavior of a population helps to assess its risk profile.
Methods: Study participants were recruited at a gynecology outpatient department (OPD) in the Allahabad district in Uttar Pradesh India, and a questionnaire was used to assess demographics, SRH, and obstetric history. Patients provided three samples (urine, vaginal swab stored in Copan eNAT® medium, and whole blood). These samples were used to identify CT and NG using PCR/NAAT and CT IgG ELISA.
Results: A total of 296 women were included for testing; mean age was 29 years. No positive cases of CT and NG were observed using PCR/NAAT. A 7% (22/296) positivity rate for CT was observed using IgG ELISA. No positive association was found between serology and symptoms (vaginal discharge, abdominal pain, dysuria, and dyspareunia) or adverse pregnancy outcomes (miscarriage and stillbirth). Positive relations with CT could be observed with consumption of alcohol, illiteracy, and tenesmus (p-value 0.02–0.03). Discussion: STI prevalence in this study was low, but a high burden of SRH morbidity was observed, with a high symptomatic load. High rates of miscarriage (31%) and stillbirth (8%) were also observed among study subjects. No associations could be found between these ailments and CT infection. These rates are high even for low- and middle-income country standards.
Conclusion: This study puts forward high rates of SRH morbidity, and instances of adverse reproductive health outcomes are highlighted in this study, although no associations with CT infection could be found. This warrants more investigation into the causes leading to these complaints in the Indian scenario and potential biases to NAAT testing, such as consumption of over-the-counter antimicrobials.

BMJ Open. 2019 Nov 19;9(11):e031358

Sexually Transmitted Infections

Evaluating Sexual Health in Sex Workers and Men Who Have Sex with Men: the SMESH Cross-Sectional Protocol Study

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Keywords

eNAT®	HPV	MSM	Sexual Health

Abstract

Introduction: Human papillomavirus (HPV) infection is transmitted through skin-to-skin contact, and vaginal and anal sex are the most common transmission routes. Sex workers and men who have sex with men (MSM) are more exposed to the virus, and therefore, a higher frequency of this infection would be expected. The prevalence of HPV infection types and the forms and factors of transmission must be investigated to control infection-related outcomes. This protocol study will be the first nationwide study with a uniform methodology to evaluate HPV prevalence of and infection types among sex workers and MSM in Brazil.

Methods and analysis: This multicentre cross-sectional study will be conducted with a respondent-driven sampling method to recruit 1174 sex workers and 1198 MSM from all regions of Brazil. The study will consist of preliminary interviews to verify the eligibility criteria and characterise the network size as well as a second questionnaire to obtain sociodemographic, behavioural and sexual information. Specimens from the oral cavity and anal and cervical or penile/scrotal sites will be collected with Copan FLOQSwabs® and stored in Copan eNAT® medium. All HPV samples will be processed in a certified central laboratory. Other sexually transmitted infections will be evaluated by interview and by rapid testing for HIV and syphilis. Strict quality control will be conducted using different procedures, including the training and certification of the health professionals responsible for acquiring data and monitoring visits.

Pathology. 2021 Feb;53(2):264-266

Sexually Transmitted Infections

A Comparison of ThinPrep Against Four Non-Volatile Transport Media for HPV Testing at or Near the Point of Care

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Keywords

MSwab®	GeneXpert	HPV	Point of Care

Abstract

The Xpert HPV Test is used at point of care for cervical screening in a number of low and middle income countries (LMIC). It is validated for use with ThinPrep-PreservCyt transport medium which has a high methanol content and is therefore classified as a dangerous good for shipping, making cost, transportation and use challenging within LMIC. We compared the performance of ThinPrep against four non-volatile commercially available media for human papillomavirus (HPV) point of care testing. Ten-fold serial dilutions were prepared using three HPV cell lines each positive for 16, 18 or 31 and with each suspended in five different media types. The media types consisted of Phosphate Buffered Saline (ThermoFisher Scientific, USA), Sigma Virocult (Medical Wire and Equipment, UK), MSwab® (Copan, Italy) Xpert Transport Media (Cepheid, USA) and ThinPrep-PreservCyt (Hologic, USA). A total of 105 Xpert HPV tests were conducted in a laboratory setting, with seven 10-fold dilutions of each of the three HPV genotypes tested in all five media types. The lowest HPV 10-fold dilution detected for any media, or cell line was the fifth dilution. MSwab® was the only medium to detect HPV to the fifth dilution across all three cell types. MSwab® transport media may be a suitable alternative to ThinPrep for Xpert HPV point of care testing. A field based, head to head comparison of both media types using the Xpert HPV assay is warranted to confirm these laboratory based findings.

Iran J Microbiol. 2020 Jun;12(3):216-222

Sexually Transmitted Infections

Comparison of Deferred and Bedside Culture of *Neisseria gonorrhoeae*: a Study to Improve the Isolation of Gonococci for Antimicrobial Susceptibility Testing

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Keywords

Transystem®	Neisseria gonorrhoeae	Culture Isolation	Susceptibility Testing

Abstract

Background and Objectives: Antimicrobial resistance of *Neisseria gonorrhoeae* is globally spread and threatening. Culturing of *N. gonorrhoeae* is the only method to collect live isolates for investigation antimicrobial resistance profile. Therefore, quality assessment of *N. gonorrhoeae* culture is essential for successful isolation of gonococci. This study was conducted to evaluate deferred and bedside culture of *N. gonorrhoeae* depending on the year season and temperature condition of transport media temporary storage. Materials and Methods: Urogenital swabs from 46 symptomatic heterosexual patients with gonorrhoea and subculture of *N. gonorrhoeae* in 46 suspensions in concentrations 1.5 × 108 CFU/ml were subjected to the study. Non-nutritive transporting medium Amies Agar Gel Medium with charcoal (Copan, Brescia, Italy) was used for deferred culture and selective Chocolate agar TM+PolyViteX VCAT3 (BioMérieux, Marcy-l'Étoile, France) for both tested methods of culture.
Results: The specificity of both bedside and deferred methods of culture was 100%. The sensitivity of deferred culture was higher than of bedside culture (82.6% vs 47.8%, p<0.0005). Deferred culture showed significantly higher sensitivity comparing to bedside culture in summer (100% vs 50%, p=0.003), and comparably the same as for bedside culture in autumn, winter and spring.
Conclusion: The viability of *N. gonorrhoeae* subcultures was significantly higher in refrigerated samples from transport media than from ambient one after exposition from 48 to 96 hours. Optimal viability of *N. gonorrhoeae* was observed when transport swabs were kept refrigerated up to 48 h (73.9–93.5%) or ambiently – up to 24 h (87%). Updating laboratory guidelines regarding sampling and timely specimen processing might improve gonococcal culture performance.

J Med Microbiol. 2020 Jun;69(6):824-829

Sexually Transmitted Infections

Optimizing a Real-Time PCR assay for Rapid Detection of *Candida auris* in Nasal and Axillary/Groin Samples

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Keywords

eSwab®	*Candida auris*	Rapid Detection	Surveillance Sample

Abstract

Introduction: *Candida auris* is an emerging fungal pathogen. The organism can cause invasive infections associated with high mortality, has been implicated in outbreaks in healthcare settings and is frequently resistant to multiple antifungal agents, making it a significant challenge to infection prevention and patient treatment.
Aim: To implement a real-time PCR assay for detection of ***C. auris*** in patient surveillance samples collected with the Copan Liquid Amies elution swab (eSwab®) collection and transport system.
Methodology: We optimized a real-time PCR testing procedure based on the sample collection device used in our institution.
Results: eSwab® transport medium was strongly inhibitory to the real-time PCR. Removing the medium with centrifugation, followed by suspending the pellet in PBS-BSA buffer (concentration 1%), sufficiently eliminated the inhibition. The manual sample preparation method, freeze–thaw followed by mechanical disruption, allowed the detection of ***C. auris*** at the lowest cell concentration.
Conclusion: The optimized procedure was used to test 1414 patient surveillance samples. The real-time PCR detected all culture-positive samples with 100% sensitivity and 100% specificity.

J Antimicrob Chemother. 2021 Dec 24;77(1):218-222.

Sexually Transmitted Infections

Antimicrobial susceptibility of Neisseria gonorrhoeae isolates and syndromic treatment of men with urethral discharge in Kingston, Jamaica, 2018–19

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Keywords

Copan eSwab®	Urethral sampling	*Neisseria Gonorrhoeae*

Abstract

Objectives: To quantitatively determine the antimicrobial susceptibility of clinical *Neisseria gonorrhoeae* isolates from men with urethral discharge in Jamaica and to describe the syndromic treatment therapies administered. Methods: Urethral eSwabs (Copan Italia) were collected from 175 men presenting with urethral discharge to the Comprehensive Health Centre STI Clinic, Kingston, Jamaica. Clinical information was collected and MICs of eight antimicrobials were determined for *N. gonorrhoeae isolates* (n = 96) using Etest and interpreted using CLSI criteria. Results: The median age of the subjects was 28 years (range: 18–73 years) with a median of 2 sexual partners (range: 1–25) per male in the previous 3 months. All examined *N. gonorrhoeae* isolates were susceptible to ceftriaxone (96/96), azithromycin (91/91), cefixime (91/91) and spectinomycin (91/91). For ciprofloxacin and gentamicin, respectively, 98.9% (91/92) and 91.3% (84/92) of the isolates were susceptible and 1.1% (1/92) and 8.7% (8/92) showed intermediate susceptibility/resistance. For tetracycline and benzylpenicillin, respectively, 38.0% (35/92) and 22.0% (20/91) of the isolates were susceptible, 52.2% (48/92) and 74.7% (68/91) showed intermediate susceptibility/resistance and 9.8% (9/92) and 3.3% (3/91) were resistant. Syndromic treatment was administered as follows: 93.1% received 250 mg of ceftriaxone intramuscularly plus 100 mg of doxycycline orally q12h for 1–2 weeks and 6.9% received 500 mg of ciprofloxacin orally plus 100 mg of doxycycline orally q12h for 1 week. Conclusions: Ceftriaxone (250 mg) remains appropriate for gonorrhoea treatment in the examined population of men in Kingston, Jamaica. Surveillance of *N. gonorrhoeae* AMR should be expanded in Jamaica and other Caribbean countries to guide evidence-based treatment guidelines.

PLoS One. 2021 Oct 25;16(10):e0257939.

Sexually Transmitted Infections

Prevalence, risk factors and adverse pregnancy outcomes of second trimester bacterial vaginosis among pregnant women in Bukavu, Democratic Republic of the Congo

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Keywords

Copan FLOQSwabs®	*Candida*	*Trichomonas vaginalis*	Bacterial vaginosis

Abstract

Background Bacterial vaginosis (BV) is the most common gynaecological condition in women of reproductive age and associated with adverse pregnancy outcomes. In the Democratic Republic of the Congo (DRC), neonatal mortality rate is as high as 2.8 percent with preterm birth (PTB) and low birth weight (LBW) as leading causes. Because no studies have addressed BV in DRC, we aimed to investigate the prevalence of BV, the risk factors and the association between BV and adverse pregnancy outcomes in a population of pregnant women from Bukavu, DRC. Methods A total of 533 pregnant women in the second trimester of pregnancy were recruited in the Provincial Reference Hospital of Bukavu, DRC, between January and October 2017, and followed until delivery. Clinical and sociodemographic data of mother and new-born, and data on (vaginal) hygiene practices, sexual behaviour and reproductive history were collected. BV was diagnosed by Nugent scoring of Gram-stained vaginal smears starting from a vaginal swab (FLOQSwabs, Copan Italia). Two multivariate regression models were built to identify risk factors for BV and to investigate BV as a risk factor for adverse pregnancy outcomes. Results The prevalence of BV was 26.3% and approximately half of the women with BV were asymptomatic. Independent risk factors for BV were the use of alternatives to water for intravaginal washing, concurrent partners, unemployed status, the presence of vaginal Candida and clay consumption. BV was independently associated with both LBW and PTB of an infant with LBW. Conclusion The prevalence of BV in Bukavu is high but in line with the global average. BV was associated with adverse pregnancy outcomes in our study population. Hence, research on modifiable risk factor-based interventions to reduce the prevalence of BV, and on screening/treatment of BV during antenatal care should be explored to reduce neonatal mortality and morbidity.

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Sexually Transmitted Infections

Molecular epidemiology of non-viral sexually transmitted infections in the central Alpine province of Bolzano, northern Italy from April 2016 to March 2017

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Keywords

Copan eNAT®	Ureaplasma	Chlamydia	Trichomonas

Abstract

Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis and Mycoplasma genitalium are established or presumed STI pathogens. The present study aims to describe the one-year molecular epidemiology of these seven pathogens in the Province of Bolzano, Northern Italy. From April 2016 to March 2017, 2,949 patients, mainly females, were enrolled and 3,427 urines, vaginal, endocervical and/or urethral samples, collected in eNAT medium (Copan Italia), were subjected to simultaneous analysis of the seven pathogens by means of Real Time Polymerase Chain Reaction (Anyplex™ II STI-7 Detection Kit Seegene, Seoul, Korea). At least one of the seven microorganisms were detected in 40.7% of patients, with uneven distribution: 43.1% in females (F) and 29.8% (P<0.001) in males (M). The prevalence of microorganisms was as follows: 30.3% U. parvum (F: 35.6%, M: 8.3%), 6.9% *U. urealyticum* (F: 6.8%, M: 7.0%), 49% *M. hominis* (F: 5.4%, M: 2.3%), 4.9% *C. trachomatis* (F: 3.4%, M: 11.4%), 1.1% *M. genitalium* (F: 1.0%, M 1.2%), 1.2% *N. gonorrhoeae* (F: 0.17%, M: 5.6%) and 0.40% *T. vaginalis* (F: 0.38%, M: 0.53%). Mixed infections were detected in 7.4% of patients. Highest prevalence was observed for *U. parvum*, followed by *U. urealyticum* and *M. hominis* and significant presence of multi-pathogen infections was registered.

Int J Environ Res Public Health. 2019 Dec; 16(24): 5000.

Sexually Transmitted Infections

Prevalence of Human Papillomavirus (HPV) and Other Sexually Transmitted Infections (STIs) among Italian Women Referred for a Colposcopy

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Keywords

L-shaped FLOQSwabs®	HPV	STI co-infections

Abstract

Sexually transmitted infections (STIs) represent a major cause of morbidity in women and men worldwide. Human Papillomavirus (HPV) infections are among the most prevalent STIs and persistent infections with high-risk HPV (hrHPV) genotypes can cause cervical dysplasia and invasive cervical cancer. The association of other STIs with HPV cervical infection and/or dysplasia has however not yet been fully elucidated. The aim of this study was to assess the prevalence of HPV and other STIs among women presenting with an abnormal cervical cytology using a FLOQSwabs (Copan Italia) for cervical collection. Cervical infections with 28 HPV genotypes and seven other sexually transmitted pathogens were evaluated in 177 women referred for a colposcopy after an abnormal Pap smear. Positivity for at least one hrHPV genotype was shown in 87% of women; HPV 16 was the most prevalent (25.0%), followed by HPV 31 and HPV 51. The overall positivity for other STIs was 49.2%, with Ureaplasma parvum being the most prevalent microrganism (39.0%). Co-infections between hrHPV and other STIs were demonstrated in 17.5% of women; no significant association was demonstrated between multiple infections and the colposcopy findings. This study provides new epidemiological data on the prevalence of cervical infections associated with HPV and seven other common sexually transmitted pathogens in a population of women presenting with an abnormal cervical cytology.

PLoS One. 2021 Sep 1;16(9):e0256852.

Sexually Transmitted Infections

Human papillomavirus 16 L1 gene methylation as a potential biomarker for predicting anal intraepithelial neoplasia in men who have sex with men (MSM)

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Keywords

Copan FLOQSwabs®	HPV	Men who have sex with men	Rectal sampling

Abstract

The human papillomavirus (HPV) 16 early promoter and L1 gene methylation were quantitatively measured using pyrosequencing assay in anal cells collected from men (Copan FLOQSwabs) who have sex with men (MSM) to determine potential biomarkers for HPV-related anal cancer. The methylation patterns of HPV16 genes, including the early promoter (CpG 31, 37, 43, 52, and 58) and L1 genes (CpG 5600, 5606, 5609, 5615, 7136, and 7145), were analyzed in 178 anal samples. The samples were diagnosed as normal, anal intraepithelial neoplasia (AIN) 1, AIN2, and AIN3. Low methylation levels of the early promoter (< 10%) and L1 genes (< 20%) were found in all detected normal anal cells. In comparison, medium to high methylation (≥ 20–60%) in the early promoter was found in 1.5% (1/67) and 5% (2/40) of AIN1 and AIN2-3 samples, respectively. Interestingly, slightly increased L1 gene methylation levels (≥ 20–60%), especially at the HPV16 5'L1 regions CpGs 5600 and 5609, were demonstrated in AIN2-3 specimen. Moreover, a negative correlation between high HPV16 L1 gene methylation at CpGs 5600, 5609, 5615, and 7145 and a percentual CD4 count was found in AIN3 HIV positive cases. When comparing the methylation status of AIN2-3 to that of normal/AIN1 lesions, the results indicated the potential of using HPV16 L1 gene methylation as a biomarker for HPV-related cancer screening.

BMJ Open. 2019 Feb 19;9(2):e026888.

Sexually Transmitted Infections

Diagnostic accuracy of the Xpert CT/NG and OSOM Trichomonas Rapid assays for point-of-care STI testing among young women in South Africa: a cross-sectional study

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Keywords

Copan ESwab®	*Chlamydia trachomatis*	*Neisseria gonorrhoeae*	*Trichomonas vaginalis*

Abstract

Objectives: Syndromic management of sexually transmitted infections (STIs) omits asymptomatic infections, particularly among women. Accurate point-of-care assays may improve STI care in low- and middle-income countries (LMICs). We aimed to evaluate the diagnostic performance of the *Xpert Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) and OSOM *Trichomonas vaginalis* (TV) Test as part of a STI care model for young women in South Africa.
Design: Diagnostic evaluation conducted as part of a prospective cohort study (CAPRISA 083) between May 2016 and January 2017.
Setting: One large public healthcare facility in central Durban, KwaZulu-Natal, South Africa
Participants: 247 women, aged 18–40 years, attending for sexual and reproductive services to the clinic who undergone a vaginal swab sampling (ESwab, Copan Italia). Pregnant and HIV-positive women were excluded.
Outcomes: Diagnostic performance of the Xpert CT/NG and OSOM TV assays against the laboratory-based Anyplex II STI-7 Detection. All discordant results were further tested on the Fast Track Diagnostics (FTD) STD9 assay. Results: We obtained vaginal swabs from 247 women and found 96.8% (239/247) concordance between Xpert and Anyplex for CT and 100% (247/247) for NG. All eight discrepant CT results were positive on Xpert, but negative on Anyplex. FTD STD9 confirmed three positive and five negative results, giving a confirmed prevalence of CT 15.0% (95% CI 10.5 to 19.4), NG 4.9% (2.2–7.5) and TV 3.2% (1.0–5.4). Sensitivity and specificity of Xpert CT/NG were 100% (100-100) and 97.6% (95.6–99.7) for CT and 100% (100-100) and 100% (100-100) for NG. The sensitivity and specificity of OSOM TV were 75.0% (45.0–100) and 100% (100-100). Conclusion: The Xpert CT/NG showed high accuracy among young South African women and combined with the OSOM TV proved a useful tool in this high HIV/STI burden setting. Further implementation and cost-effectiveness studies are needed to assess the potential role of this assay for diagnostic STI testing in LMICs.

BMJ Open. 2019 Feb 19;9(2):e026888.

Sexually Transmitted Infections

Comparison of BD MAX GBS and GenomEra GBS assays for rapid intrapartum PCR detection of vaginal carriage of group B streptococci

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Keywords

Copan Eswab®	Group B *Streptococcus*	*Streptococcus Agalactie*	Pregnant Women

Abstract

Objective: To compare the diagnostic performance of BD MAX and GenomEra PCR assays for a rapid PCR detection of vaginal carriage of group B streptococci at delivery. Methods: This is a retrospective laboratory analysis of vaginal swab samples taken intrapartum from a randomly selected cohort of pregnant women giving birth at a single childbirth and maternity unit. Results: Ninety-one culture-positive and 279 culture-negative vaginal samples (ESwab, Copan Italia) were included from a cohort of 902 women. One-hundred-and-two specimens were found positive with the BD MAX and 84 with the GenomEra PCR assay. No statistically significant difference was observed compared to culture, sensitivity of BD MAX 84.6% (77/91) [95%CI 75.5–91.3] and of GenomEra 71.4% (65/91) [95%CI 61.0–80.4]. When compared to a combined reference standard, no statistically significant differences were seen between culture, BD MAX and GenomEra PCR assays. The sensitivities were 82.7% (91/110) [95%CI 74.3–89.3], 87.3% (96/110) [95%CI 79.6–92.9], and 79.1% (87/110) [95%CI 70.3–86.3], respectively. Conclusion: Both PCR assays performed comparably to culture of the intrapartum vaginal samples. In particular, the GenomEra assay is potentially an easy and rapid on-site PCR test for intrapartum detection of vaginal carriage of group B streptococci at a maternity ward to identify women who should receive intrapartum antibiotic prophylaxis.

Heliyon. 2019 Apr 24;5(4):e01522.

Sexually Transmitted Infections

Comparison of collection methods for molecular detection of -herpes viruses and Treponema pallidum, including evaluation of critical transportation conditions

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Keywords

Copan Eswab®	Herpes virus	*Treponemal pallidum*	Sample stability

Abstract

The detection of herpes simplex viruses and T*reponemal pallidum* from genital lesions requires efficient sampling of genetic material for a reliable molecular diagnosis. From 460 patients attending the Public Health clinic, two swabs (dry cotton swabs and Copan Eswabs) per patient were collected in alternating order from the same lesion. Additionally, three storage conditions of Eswabs up to 28 days were evaluated to assess the stability of DNA over time. Out of the 830 PCRs performed, 20 (2.4%) PCRs were discordant between the two swabs. No significant differences were observed between the two sample types. HSV1 and HSV2 could be reliably detected from Eswabs up to 28 days when kept at room temperature. A single swab from a genital lesion is sufficient for reliable diagnosis of α-herpes viruses and *Treponemal pallidum*, for which both a dry cotton swab or Eswab could be used.

BMC Pregnancy Childbirth. 2020 Aug 11;20(1):456.

Sexually Transmitted Infections

Mycoplasma and Ureaplasma carriage in pregnant women: the prevalence of transmission from mother to newborn

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Keywords

Copan UTM®	*Mycoplasma*	*Ureaplasma*	Vaginal sampling

Abstract

Background: *Mycoplasma* and *Ureaplasma* have been extensively studied for their possible impact on pregnancy, and their involvement in newborn diseases. This work examined *Mycoplasma* and *Ureaplasma* carriage among gravidas women and newborns in Israel, as well as associations between carriage and demographic characteristics, risk factors, pregnancy outcomes, and newborn morbidity rates. Methods: A total of 214 gravidas women were examined for vaginal pathogen carriage through standard culture and polymerase chain reaction assay, starting from vaginal swab (Copan UTM® kit). Pharyngeal swabs were collected from newborns of carrier mothers. Clinical and demographic data were collected and infected newborn mortality was monitored for 6 months. Results: Nineteen mothers were carriers, with highest prevalence among younger women. Pathogen carriage rates were 2.32% for *Mycoplasma genitalium* (Mg), 4.19% for *Ureaplasma parvum* (Up) and 2.32% for *Ureaplasma urealyticum* (Uu). Arab ethnicity was a statistically significant risk factor ($p=0.002$). A higher prevalence was seen among women residing in cities as compared to villages. Thirteen (68%) newborns born to carrier mothers were carriers as well, with a higher prevalence among newborns of women delivering for the first time, compared to women that had delivered before. Infection rates among newborns were 20% for Mg ($p=0.238$), 100% for Up ($p<0.01$), and 28.5% for Uu ($p=0.058$), with more male than female newborns being infected. No association was found between maternal carriage and newborn morbidity. Conclusions: Maternal *Mycoplasma* or *Ureaplasma* carriage may be associated with ethnicity and settlement type. Further studies will be needed to identify factors underlying these associations and their implications on delivery.

Front Cell Infect Microbiol. 2021 Nov 17;11:770367.

Sexually Transmitted Infections

Copan Walk Away Specimen Processor (WASP) Automated System for Pathogen Detection in Female Reproductive Tract Specimens

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Keywords

Copan WASP®	Copan eSwab®	Female reproductive tract specimens	Automation

Abstract

Objective: Automation is increasingly being applied in clinical laboratories; however, preanalytical processing for microbiology tests and screening is still largely performed using manual methods owing to the complex procedures involved. To promote automation of clinical microbiology laboratories, it is important to assess the performance of automated systems for different specimen types separately. Therefore, the aim of this study was to explore the potential clinical application of the Copan Walk Away Specimen Processor (WASP) automated preanalytical microbiology processing system in the detection of pathogens in female reproductive tract specimens and its feasibility in optimizing diagnostic procedures. Methods: Female reproductive tract specimens collected from pregnant women at their first obstetric check-up were inoculated into culture media using the Copan WASP automated specimen processing system and were also cultured using a conventional manual inoculation method. After 48 h of culture, the growth of colonies was observed, and the types of bacteria, number of colonies, and efficiency in isolating single colonies were compared between the automated and manual groups. The specimens collected from the WASP system using the Copan-ESwab sample collection tubes were further analyzed for the presence of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Ureaplasma urealyticum* (UU) via fluorescence quantitative polymerase chain reaction (qPCR) and an immunochromatographic assay to investigate the feasibility of this method in optimizing detection of these common pathogens of the female reproductive tract. Results: Compared with the manual culture method, the Copan WASP microbiology automation system detected fewer bacterial types (P<0.001) and bacterial colonies (P<0.001) but had a higher detection rate of single colonies (P<0.001). There was no significant difference in the detection rates of common pathogens encountered in clinical obstetrics and gynecology, including *group B Streptococcus* (GBS) (P=0.575) and *Candida* (P=0.917), between the two methods. Specimens collected in the Copan-ESwab tubes could be used for screening of GBS and CT via fluorescence-based qPCR but not with immunochromatography. However, UU and NG were not detected in any sample with either method; thus, further validation is required to determine the feasibility of the Copan system for screening these pathogens. Conclusion: The Copan WASP microbiology automation system could facilitate the optimization of diagnostic procedures for detecting common pathogens of the female reproductive system, thereby reducing associated costs.

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Sexually Transmitted Infections

High Prevalence of Genital Human Papillomavirus Infection in Patients With Primary Immunodeficiencies

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Keywords

Copan FLOQSwabs®	Copan UTM®	HPV	Primary immunodeficiency	Genital warts

Abstract

Background: Genital human papillomavirus (HPV)-infections are common in the general population and are responsible for relevant numbers of epithelial malignancies. Much data on the HPV-prevalence is available for secondary immunodeficiencies, especially for patients with human immunodeficiency virus (HIV)-infection. Little is known about the genital HPV-prevalence in patients with primary immunodeficiencies (PIDs). Methods: We performed a cross-sectional study of patients with PIDs and took genital swabs from male and female patients, which were analyzed with polymerase chain reaction for the presence of HPV-DNA. Clinical and laboratory data was collected to identify risk factors. Results: 28 PID patients were included in this study. 10 of 28 (35.7%) had HPV-DNA in their genital swabs. 6 patients had high-risk HPV-types (21.4%). Most patients had asymptomatic HPV-infections, as genital warts were rare (2 of 28 patients) and HPV-associated malignancy was absent. Differences in the HPV-positivity regarding clinical PID-diagnosis, duration of PID, age, sex, immunosuppression, immunoglobulin replacement, or circumcision in males were not present. HPV-positive PID patients had higher numbers of T cells (CD3+), of cytotoxic T cells (CD3+/CD8+), of transitional B cells (CD19+/CD38++/CD10+/IgD+), and of plasmablasts (CD19+/CD38+/CD27++/IgD-) compared to HPV-negative. Conclusion: PID patients exhibit a high rate of genital HPV-infections with a high rate of high-risk HPV-types. Regular screening for symptomatic genital HPV-infection and HPV-associated malignancy in PID patients seems recommendable.

Note

Note

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