# Abstract 867 - SCREENING FOR EXTRAGENITAL CT/GC AMONG HIV-INFECTED MSM : A COMPARISON OF 4 NAATS

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## BACKGROUND

- CDC recommends annual screening for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) using nucleic acid amplification tests (NAAT) at exposure sites in adults with HIV.[1 2]
- HIV-infected men who have sex with men (MSM) have elevated rates of GC/CT infection but clinic screening rates are suboptimal and often limited to the urethral site.[3]
- NAAT is highly sensitive but testing is not FDA-approved at rectal and pharyngeal sites.
- Several testing platforms for GC/CT NAAT have become available but comparison data is needed.

## OBJECTIVE

To compare testing platforms and to examine the effectiveness of CT/GC testing at different exposure sites among HIV-infected MSM

## HYPOTHESIS

The four NAAT testing platforms will perform well at each site with similar test characteristics.

## METHODS

- HIV-infected adult MSM who presented to the UAB 1917 HIV clinic for routine care and reported receptive anal intercourse in the past 30 days were eligible. Exclusion criteria included receipt of antibiotics in the past 30 days.
- Self-collected rectal swabs, urine, and provider-collected pharyngeal samples were run on at least two of four platforms and positivity rates for CT and GC were determined. Treatment was provided for infections detected.
- Some participants were enrolled more than once. Comparison across platforms was performed using repeated measures analysis to test for within-subject effects.
- Estimates of sensitivity and specificity for rectal and urine samples were obtained separately relative to the composite infection standard (CIS) defined as ≥2 positive NAATs.
- Estimates of sensitivity and specificity for oropharyngeal samples were obtained relative to the patient infection standard (PIS) in which two NAATs had to be positive.
- All statistical analyses were performed using SAS 9.4. The study was approved by the UAB IRB.

## RESULTS

Table 1: Participant Characteristics (n=175)

| | Total n (%) or mean +/- SD |
|---|---|
| Age in years | 37.6 +/- 10.3 |
| Presence of STI Symptoms | 47 (28.5) |
| Site of Sex (not including oral sites)<br>Receptive only<br>Receptive and Insertive | <br>65 (39.4)<br>100 (60.6) |
| Number of Partners over past 30 days | 2.1 +/- 4.9 |
| Condom Use "Always" | 44 (27.2) |
| STI History<br>Any STI<br>GC<br>CT | <br>126 (76.4)<br>79 (48.5)<br>53 (32.5) |

Table 2: Positive Test Results by Site (n (%))

| | CT | GC | Coinfection (CT + GC) | Any STI (CT or GC) |
|---|---|---|---|---|
| Rectal Only | 23 (13.1) | 15 (8.6) | 10 (5.7) | 32 (18.3) |
| Urine Only | 6 (3.4) | 6 (3.4) | 5 (2.9) | 9 (5.1) |
| Pharynx Only | 0 (0) | 4 (2.3) | 0 (0) | 4 (2.3) |
| Rectal and Urine | 2 (1.1) | 1 (0.6) | 1 (0.6) | 3 (1.7) |
| Rectal and Pharynx | 0 (0) | 2 (1.1) | 0 (0) | 2 (1.1) |
| Urine and Pharynx | 0 (0) | 1 (0.6) | 0 (0) | 1 (0.6) |

Table 3: Clinical Performance for CT/GC Detection Among HIV-Infected MSM by Sample Type

| | Sensitivity (%, n, range) | | | | Specificity (%, n, range) | | | |
|---|---|---|---|---|---|---|---|---|
| Sample Type | Panther | Viper | Cobas | GeneXpert | Panther | Viper | Cobas | GeneXpert |
| Rectal CT | 95.7% [22/23] (78.1-99.9%) | 92.0% [23/25 ] (74-99.0%) | 80.8% [21/26] (65.6-95.9%) | 92.3% [24/26] (74.9-99.1%) | 98.5% [199/202] (95.7-99.7%) | 99.0% [202/204] (96.5-99.9%) | 99.5% [199/200] (97.3-100%) | 99.5% [196/197] (97.2-100%) |
| Urine CT | 100.0% [4/4] (39.8-100%) | 100.0% [4/4] (39.8-100%) | 100.0% [4/4] (39.8-100%) | 100.0% [4/4] (39.8-100%) | 100.0% [225/225] (98.4-100%) | 99.6% [223/224] (97.5-100%) | 100.0% [223/223] (98.4-100%) | 100.0% [213/213] (98.3-100%) |
| Pharynx CT | N/A | 100% [1/1] - | N/A | N/A | 99.6% [221/222] (98-100%) | 100.0% [221/221] (98-100%) | N/A | N/A |
| Rectal GC | 100.0% [11/11] (71.5-100%) | 64.3%* [9/14] (35.1-87.2%) | 92.3% [12/13] (64.0-99.8%) | 92.3% [12/13] (64.0-99.8%) | 99.1% [213/215] (96.7-99.9%) | 100.0% [214/214] (98.3%-100%) | 99.1% [211/213] (96.7-99.9%) | 99.5% [209/210] (97.4-100%) |
| Urine GC | 100.0% [1/1] (2.5-100%) | 100.0% [1/1] (2.5-100%) | 100.0% [1/1] (2.5-100%) | 100.0% [1/1] (2.5-100%) | 99.1% [226/228] (96.9-99.9%) | 99.6% [226/227] (97.6-100%) | 100.0% [226/226] (98.4-100%) | 100.0% [215/215] (98.3-100%) |
| Pharynx GC | 69.2% [9/13] (38.6-90.9%) | 81.8% [9/11] (48.2-97.7%) | N/A | N/A | 99.0% [206/208] (96.6-99.9%) | 98.1% [206/210] (95.2-99.5%) | N/A | N/A |

**P-value<0.05*

- Of 175 MSM enrolled between 2014 and 2016, 19.4% had CT or GC detected in at least one of three sites.
- CT was identified in 13.1% of rectal swabs, 3.4% of urine, and 0.0% of pharyngeal swabs.
- GC was identified in 8.6% of rectal swabs, 3.4% of urine, and 2.3% of pharyngeal swabs.
- CT sensitivity estimates ranged from 80.8%-100.0% and specificity was >98.5%.
- GC sensitivity estimates ranged from 64.3%-100.0% using CIS and 69.2-81.8% using PIS; specificity was >98.1%.
- Rectal GC testing was less sensitive with the Viper assay (64.3%) compared to Panther (100%), Cobas (92.3%), and GeneXpert (≥92.3%) assays. (p-value=0.03).
- All platforms had similar test characteristics for urine/pharyngeal samples.

## LIMITATIONS

- There is no current gold standard for determining performance of CT/GC NAATs.

## CONCLUSIONS

- CT or GC was detected in nearly 1 in 5 HIV-infected MSM who reported receptive anal intercourse in the past 30 days.
- Most extra-genital infections were at the rectal site.
- Each of four testing platforms performed similarly well at urine and pharyngeal sites. Rectal testing using the Viper assay was less sensitive compared to other platforms.

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