IUSTI Asia Pacific Sexual Health Congress 2018

EVALUATION OF A SPECIMEN POOLING METHOD FOR MOLECULAR POINT-OF-CARE DETECTION OF CHLAMYDIA AND GONORRHOEA

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BACKGROUND/AIMS & METHODS:

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Guidelines: test multiple sites for $CT/NG \rightarrow \uparrow costs$ and workload

Evaluate pooling at point-of-care (POC) by trained lay providers

Evaluate performance of pooled self-collected urogenital. pharyngeal and anorectal specimens compared to individual specimen results for the molecular detection of CT/NG near to the POC

Established

sensitivity of

Current knowledge



Importance



Study aim

GeneXpert

CT/NG Assav



Prospective consecutive recruitment at 1 clinic and 3 sex-on-premises venues (SOPV)

387 participants provided 3 specimens

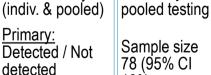
- 76 (19.6%) CT/NG detected at ≥1 site → pooling and retesting
 - 94.7% MSM
 - 29 yrs median age
 - 50% SOPV clients

Design & population



Assessment

values



78 (95% CI 10% error Secondary: margin) Cycle threshold

Primary:

sensitivity, specificity, PPV, NPV by infection type & anatomical site

Secondary:

paired sample t-test & Wilcoxon signed-rank test

Endpoint



Statistical analysis



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RESULTS: www.iustiap18.com

Performance of Xpert CT/NG assay of pooled specimen testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG)

		Xpert in	dividual test		Test performance (95% CI) Discordant results
C.tracl	nomatis	Detected	Not Detected	Total	Sens. 90.0% (77.4-96.3%) 5 CT discordant =
	Detected	45	0		Spec.100.0% (83.9-100%) rectal samples only
pooled	Not detected	5	26	31	PPV 100.0% (90.2-100%) Median cycle threshold
test	Total	50	26	76	NPV 83.9% (65.5- 93.9%) CT1 37.5
N gong	orrhoeae	Detected	Not Detected	Total	4 NG discordant =
	Detected	35			Sens. 89.7% (74.8-96.7%) pharyngeal samples
pooled	Not detected	4	37		Spec.100.0% (88.3-100%) only
test	Total	39	37		PPV 100.0% (87.7-100%) Median cycle thresholds
					NPV 90.2% (75.9-96.8%) NG2 32.9 NG4 34.1













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CONCLUSIONS/IMPLICATIONS:

Main

- Pooled specimen sensitivity: chlamydia 90.0%; gonorrhoea 89.7%
- Pooled false negative results more likely it associated with low DNA loads especially in pharyngeal and rectal specimens

Next Steps

Optimisation of pooling approach - reduce urine volume 7mL to 1mL

Potential Implications Community **Impact**

- Health systems savings: pathology, staffing
- Increased accessibility to and choice of services and test types
 - higher risk populations, limited resource settings
- 1 time to treatment if same day test and treat employed in future

Research into practice

- · Test validation: all anatomical sites, pooling method
- Regulatory / health system issues
 - Screening vs. diagnostic test?
 - Integration into automated notifiable diseases surveillance?
 - Feasibility of registered community POC testing sites?













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