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

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BACKGROUND/AIMS & METHODS:

Current knowledge

Guidelines: test multiple sites for CT/NG → ↑ costs and workload

Importance

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

Study aim

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

Design & population

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

Assessment

GeneXpert CT/NG Assay (indiv. & pooled)

Primary:
Detected / Not detected

Secondary:
Cycle threshold values

Endpoint

Established sensitivity of pooled testing

Sample size 78 (95% CI 10% error margin)

Statistical analysis

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

Secondary:
paired sample t-test & Wilcoxon signed-rank test

RESULTS:

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

		Xpert individual test			Test performance (95% CI)	Discordant results
C.trachomatis		Detected	Not Detected	Total	Sens. **90.0%** (77.4-96.3%)	**5 CT discordant = rectal samples only**
Xpert pooled test	Detected	45	0	**45**	Spec.100.0% (83.9-100%)	
	Not detected	5	26	**31**	PPV 100.0% (90.2-100%)	Median cycle threshold
	Total	**50**	**26**	**76**	NPV 83.9% (65.5- 93.9%)	**CT1 37.5**
N.gonorrhoeae		Detected	Not Detected	Total		**4 NG discordant = pharyngeal samples only**
Xpert pooled test	Detected	35	0	**35**	Sens. **89.7%** (74.8-96.7%)	
	Not detected	4	37	**41**	Spec.100.0% (88.3-100%)	
	Total	**39**	**37**	**76**	PPV 100.0% (87.7-100%)	Median cycle thresholds
					NPV 90.2% (75.9-96.8%)	**NG2 32.9 NG4 34.1**

CONCLUSIONS/IMPLICATIONS:

Main findings

- 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
- ↓ **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?