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A diagnostic evaluation of a molecular assay used for testing and treating anorectal chlamydia and gonorrhoea infections at the point-of-care in Papua New Guinea

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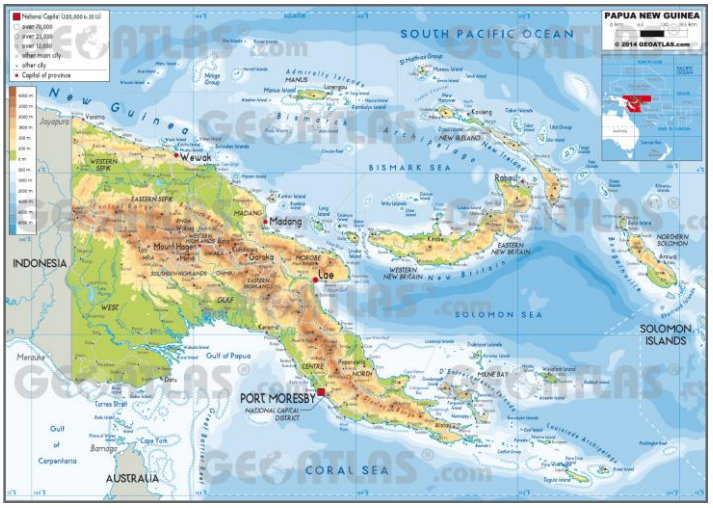
UNSW SYDNEY Australia's Global University

PNGIMR PAPUA NEW GUINEA INSTITUTE OF MEDICAL RESEARCH

SAVE TAMBUIM SIK

Study location: Papua New Guinea (PNG)



Background on PNG

- **Australia's most immediate northern neighbour**
- **Population = 7 million people**
- **800 sub language groups (largest number in the world)**
- **Climatically, culturally and geographically diverse**
- **Has a HIV epidemic (0.9%) in the general population**
- **Little known about risk behaviours or BBV or STI prevalence among men who have sex with men (MSM), transgender women (TGW) or female sex workers (FSW)**

"Kauntim me tu" study (count me too)

- First large scale bio-behavioural study (BBS) conducted in PNG from to June 2015 to Dec 2016
- Total of 2995 participants enrolled across 3 study sites in Port Moresby, Lae and Mt Hagen
- Participants recruited using response driven sampling methods (RDS) and led by study peers
- With consent, an extensive behavioural survey was undertaken by each participant in phases on the same day.

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Biological POC testing

- With consent, each participant also undertook extensive onsite – same day - POC testing for HIV, syphilis, Hep B by rapid detection test (RDT) and Xpert NAAT using self collected urogenital and anorectal CT/NG samples.

- Additional Xpert testing was done for TB (if 2 or more symptoms were present), plus HIV viral load and a CD4 count if HIV + by RDT confirmation.

- Up to 9 POC tests on one day per participant (if HIV and TB+)

Mobile POC field laboratory at each study site

Why evaluate the Xpert CT/NG test?

- **This test has not been approved for use with anorectal samples**
- **We wanted to know how accurate the Xpert CT/NG test was for use at the POC and if feasible in a low resource setting**
- **From the first two study sites (N=2135) we randomly selected 396 self collected CT/NG samples already tested on Xpert**
- **All samples stored for up to 12 months at -80c in PNG**
- **Sent them frozen to Sydney Australia for comparison testing using a well known commercial NAAT (Cobas 4800)**

Laboratory results

- Also pretested 36 QC and clinical anorectal samples in Xpert transport medium to ensure compatibility with Cobas test – all valid results
- All PNG samples were laboratory tested in a blind fashion
- 326 (from 396) samples from PNG provided valid CT/NG results in the laboratory
- 70 samples generated invalid results on Cobas – most likely due to faecal clumping after freezing
- Unable to retest those 70 due to inadequate sample volume – a lesson for the future

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Breakdown of results

Table I – Combined test performance by assay type and pathogen

Men who have sex with men, transgender women and female sex workers		Cobas CT test		Xpert Test Performance %
		Positive	Negative	
Xpert CT (new test)	Positive	144	8	PPA 96.7% (CI: 92.3%, 98.9%)
	Negative	5	169	NPA 95.5% (CI: 91.3%, 98.0%)
				ORA 96.0% (CI: 93.3%, 97.8%)
Men who have sex with men, transgender women and female sex workers		Cobas NG test		
		Positive	Negative	
Xpert NG (new test)	Positive	93	0	PPA 93.0% (CI: 86.1%, 97.1%)
	Negative	7	226	NPA 100.0% (CI: 98.3%, 100.0%)
				ORA 97.8% (CI: 95.6%, 99.1%)

PPA = positive percentage agreement, NPA = negative percentage agreement, ORA= overall rate of agreement

Findings

- **Small number of discordant results (between Xpert and Cobas tests) were due to low organism loads**
- **Combined results for MSM, TGW and FSW show the Xpert assay had an overall rate of agreement of 96.0% for the detection of CT and 97.8% for NG compared to established NAAT methods**
- **This indicates few anorectal CT and NG infections would be missed by this molecular POC testing approach and compares well with other NAAT**

Findings

- **98% of all Xpert anorectal CT/NG tests produced a valid test result at the POC**
- **The Xpert CT/NG POC testing pathway detected 489 individuals with an anorectal CT infection (23%) and 336 with an anorectal NG infection (16.1%) across 2 study sites**
- **As the first study to evaluate the diagnostic performance of Xpert CT/NG at the POC – almost all detected bacterial infections (99%) received same day treatment**

Conclusions

- **Overall performance data indicates the Xpert CT/NG test is reliable and feasible for use at the POC**
- **Upscaling and cost effective testing the next major challenges in this setting**
- **Pooling of anorectal, urogenital and pharyngeal samples into 1 Xpert CT/NG test cartridge also being explored by UQ for screening high risk individuals. Can pooling increase screening rates and reduce costs?**

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Tenkyu tru (Thank you)