GC/CT testing with Cepheid GeneXpert

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Background for GC/CT testing for MTN

- 2004 ProbeTec was chosen for HPTN 035
  - Abbott LCX was being pulled from the market
  - Amplicor/Cobas was not FDA approved for female urine GC testing
  - ProbeTec had as good or better sensitivity compared to other NAAT on the market at that time
  - Becton Dickinson could provide service for instrument in Africa and India
New generation of NAAT in 2008

- Gen-Probe Aptima
- Abbott M2000
- ProbeTec Viper
- All three extract and purify the DNA
  - Less indeterminate results
  - Higher sensitivity
- All three are moderately complex to use
- None are FDA approved for rectal testing
Cepheid GeneXpert

- Instrument extracts, purifies, and amplifies the DNA from sample in a closed system.
- Designed for testing in remote locations if needed and to be easy to use and repair.
- RT-PCR targets chromosomal DNA
  - 2 target for GC and 1 of CT
- Sample adequacy control
- GC/CT testing FDA approved 2012
Instrument range in size from 1 to 16 sample modules
Processing specimens

• Swab or urine in transport tube
  – Stable at 4°C for 60 days
• Add 300 µL of sample to cartridge
• Insert into instrument
• Results in 90 minutes
Comparison of GeneXpert to ProbeTec Viper & Gen-Probe

• Gados, 2012
  – 1722 female, vaginal and urine specimens
  – CT: 98.7% sensitivity, 99.4% specificity
  – GC: 100% sensitivity, 99.9% specificity
Comparison of GeneXpert and M2000 to Roche Amplicor

- Dize & Gaydos, 2013
- 300 eye swabs of children in Tanzania
- Tested for CT only
- Used Gen-Probe Aptima for confirmation
- M2000: 100% sensitivity, 98% specificity
- GeneXpert: 100% sensitivity, 100% specificity
Justification for using GeneXpert

• Comparable sensitivity and specificity to other NAAT
• Less chance for cross-contamination with closed system
• Very easy to use
• Takes up less space than other NAAT instruments
• Widely used in Africa for TB testing
Validation of the GeneXpert by MTN

• November 2013 MTN NL testing duplicate swabs from 500 men and women
  – Vaginal
  – Rectal
  – Pharyngeal
  – Urine

• Test with Gen-Probe and GeneXpert for GC/CT
Questions

• Do you have GeneXpert in your lab?
• What is it used to test and how often is it used?
• How many samples do you test for GC/CT with ProbeTec per week or month?
• Is there another instrument you would consider instead of GeneXpert?