

Transmissibility of GC and Ct Diagnosed using NAAT

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Abstract. Infections with *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (Ct) are known to facilitate HIV transmission. It is estimated, for example, that the presence of untreated chlamydial infection increases the likelihood per contact of HIV transmission by a relative risk of 3 about 6. These STDs have other important health consequences, including pelvic inflammatory disease, perinatal complications, and subsequent risks of infertility and ectopic pregnancy in women.

The development of nucleic acid amplification tests (NAAT) that can be used with urine specimens has permitted a new paradigm for epidemiological research on these STDs. Urine specimens for STD detection can easily be obtained in population surveys and public health programs to enable generalizations about the prevalence of symptomatic and asymptomatic infections in the population at large and among hard to reach at-risk populations. Results of these studies are disturbing. In one major U.S. city, for example, it is estimated that 8.3 percent of adults ages 18-35 has an untreated GC or Ct infection. Most of these infections were diagnosed among adults who report no recent symptoms and who do not present the classic STD behavioral risk profile. These results could indicate a large and hidden epidemic of asymptomatic infections that are unlikely to be detected and treated without vigorous public health interventions. However, it is also possible that NAAT testing is identifying clinically inconsequential infections because of the assay's ability to detect extremely low levels of viable organisms (i.e., below the infectious inoculum) or amplifiable DNA (or RNA) from residual pathogens (i.e., non-viable organisms) of past infections that are well on their way to being cleared.

We propose to explore this issue by testing a sample of 8,000 adults, ages 18-35, attending the Johns Hopkins Adult Emergency Department. Subjects testing positive for GC or Ct will be re-evaluated using traditional diagnostic tests for these infections and be treated. Recent sexual partners of infected subjects and a random subsample of partners from uninfected subjects will also be contacted and tested. The proposed research will allow us to: (1) determine whether the probabilities of infection transmission are equivalent for GC and Ct infections detectable only by NAAT versus infections detectable by traditional testing procedures; (2) determine whether asymptomatic infections have an equivalent probability of transmission as symptomatic infections; (3) determine whether infections that can only be detected by NAAT testing have the same clinical consequences as infections that are detectable by traditional assays; and (4) examine the correlates of infections detected by NAAT versus traditional diagnostic tests.

Thesaurus Terms: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, communicable disease diagnosis, communicable disease transmission, diagnosis, research design, evaluation, diagnosis quality, standards, nucleic acid amplification technique, sexually transmitted disease HIV infection, diagnostic test, urinalysis clinical research, human subject.