Mycoplasma genitalium: An Emerging Issue in the World of Sexually Transmitted Infections

WHAT IS *MYCOPLASMA GENITALIUM*?

Mycoplasma genitalium—frequently referred to as MG or MGen—is a small bacterium of the *Mycoplasma* genus that can cause a sexually transmitted infection, specifically it has been strongly and consistently associated with non-gonococcal urethritis (NGU). More limited data suggest associations with cervicitis, pelvic inflammatory disease (PID),[1] female infertility, pre-term birth, spontaneous abortion[2,3] and HIV transmission.[4,5] Lastly, varying rates of asymptomatic infections of males[6] and females[7,8] have been reported.[9] Sexual transmission is primarily through direct genital-genital mucosal contact but may also occur through genital-anal mucosal contact.[10]

M. genitalium belongs to the bacterial class, Mollicutes, which lack cell walls, making them inherently more resistant to antibiotics that target cell wall synthesis such as beta-lactams or glycopeptides.[11] Additionally, up to 50% (although percentages varies by study) of *M. genitalium* isolates are resistant to azithromycin which makes appropriate treatment challenging.[12]

In the last several years, it has gained notoriety as an emerging sexually transmitted infection by the US Centers for Disease Control and Prevention (CDC) and others.[1,13,14] Despite the increased interest in the infection, there are limited data available regarding the prevalence of *M. genitalium* in the general population. In two studies published to date, it was reported to be 1.1-3.3%.[15–17] A study performed in a US STD clinic population reported prevalence in women of 16.1% and in men 17.2%.[12] Additional studies examining rates in women only at STD clinics ranged from 7-26% depending on sample type and risk.[15,18] Due to these and other gaps in current knowledge of *M. genitalium*, there are no national screening recommendations at this time.

HOW IS *M. GENITALIUM* DETECTED?

M. genitalium is refractory to culture due to slow growth and inefficient culture systems. Therefore, a nucleic acid amplification test (NAAT) is the preferred diagnostic method. At the time of publication, FDA-cleared assays were available in the US to aid in the diagnosis of urogenital infections in male and female patients suspected of *M. genitalium* infection. However, at this time there are no commercially available methods to detect antibiotic resistance in *M. genitalium*. Diagnosis or surveillance efforts in the US may utilize the FDA-cleared test or the use of a laboratory developed tests (LDT).

Prior to FDA-clearance of an in-vitro diagnostic assay, clinical and public health laboratories implemented LDTs by either developing their own assay in-house, using research-use only (RUO) assays, purchasing analyte specific reagents (ASR), or some combination of the above. Assays and products that are currently available for purchase in the US are listed below. There are other commercially available assays that have been utilized in research studies and clinical practice outside the US, but they are not listed since they cannot be purchased for use in the US at the time of publication.

Hologic, Inc: Aptima *Mycoplasma genitalium* Assay (FDA-cleared) and *Mycoplasma genitalium* Primers, Probe and RNA (ASR)

Roche Diagnostics: cobas® TV/MG (FDA-cleared)

SeeGene Technologies: Novaplex STI Essential Assay or Novaplex MG & AziR Assay (RUO)

GeneSig: *Mycoplasma genitalium*, qPCR (RUO)

Key Points

- *Mycoplasma genitalium* (MG or MGen) is an emerging sexually transmitted infection that can manifest as urethritis, endocervicitis, endometritis, and pelvic inflammatory disease
- Up to 50% of *M. genitalium* isolates are resistant to azithromycin
- NAAT is the preferred diagnostic method and there are FDA-cleared assays available
- Health care providers should consult the CDC STD Treatment Guidelines for syndromic management and additional considerations for *M. genitalium*

Published studies have shown that *M. genitalium* is detectable in a number of male and female samples including urine and urogenital specimens (urethral swab, penile meatal swab, vaginal swab, cervical specimens, endocervical specimens, and endometrial biopsies). The recently FDA-cleared in vitro NAATs can be used to test the following specimens: clinician collected and self-collected (in a clinical setting) vaginal swabs, clinician collected endocervical swabs, female and male urine, clinician collected male urethral swabs (Hologic, Inc. only), and self-collected penile meatal swabs (in a clinical setting)(Hologic Inc. only). Despite the lack of published evidence-based consensus for the optimal specimen type for detecting *M. genitalium*, the package insert for FDA-cleared assays note that in females there is higher clinical sensitivity with vaginal swabs than other specimen types. Specimen types that are acceptable for testing will depend on the method and specimen type the laboratory has validated. Contact the laboratory that is performing the testing for information about acceptable specimen types and specimen collection procedures.

Health care providers suspecting *M. genitalium* should refer to the CDC's 2015 STD Treatment Guidelines[1] for general STI screening recommendations and considerations.

HOW IS *M. GENITALIUM* TREATED?

At this time, treatment for *M. genitalium* will likely depend on syndromic management by the healthcare provider according to the CDC's 2015 STD Treatment Guidelines and other published infectious disease guidelines. In Europe and Australia, the treatment recommendations are being reviewed and revisited based on studies of drug resistance and treatment failure.

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