

## CLINICAL COMMENTARY

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# Implementing a Self-Collection Protocol for Sexually Transmitted Infections

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Daniela Delgado, MD, Bernard J. Katz, MD, MBA and Janet Pregler, MD

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### **Background**

Sexually transmitted infections (STIs) are increasingly common in the United States and around the world.<sup>1</sup> In 2018, the Centers for Disease Control and Prevention (CDC) estimated that at any given time about 1 in 5 people in the United States had a STI, with a total of 26 million new STIs in this one year.<sup>2</sup> Rates have increased in all regions of the US and in all racial and ethnic groups.<sup>3</sup> Each year in the US, the direct medical cost of STIs in the US is about \$16 billion. Treating gonorrhea, chlamydia and/or syphilis combined exceeding one billion dollars. Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) are two common STIs, with a prevalence of 2.4 million cases for chlamydia and 209,000 for gonorrhea in any given day in the US.<sup>2</sup> Most infections for CT and NG are asymptomatic. The asymptomatic nature of these infections facilitates spread as the host is unaware of their presence. When transmitted to another individual, these infections can still cause symptoms. Gonorrhea and chlamydia infections can also increase the rate of HIV acquisition, pelvic inflammatory disease, epididymitis, infertility, and other complications.<sup>4</sup> In addition, with the prevalence of these infections increasing, resistant strains especially of gonorrhea, are posing a threat to further antibiotic resistance.<sup>5</sup> Therefore, it is critical to achieve an early diagnosis and treatment strategy.

Nucleic acid amplification tests (NAATs) have a high sensitivity and specificity for detecting gonorrhea and chlamydia through urine or genital tract specimens.<sup>6,7</sup> In addition, more recent data has shown greater detection and prevention of transmission of gonorrhea and chlamydia when extragenital sites, such as pharynx and rectum, are also tested.<sup>8</sup> Infection with CT and NG at the anorectal site was thought to be common only for men who have sex with men. More recent data have shown prevalence of rectal CT for people self-identifying as women who report anal sex or rectal symptoms of 1-18%, similar for men who have sex with men. However, these studies screened only women with risk factors and the prevalence for those who do not report rectal intercourse is not well known.<sup>9</sup> Other

studies have shown broader prevalence ranges for this population, with a reported prevalence of 0.6-35.8% (median of 1.9%) for rectal gonorrhea and 2.0-77.3% (median 8.7%) for rectal chlamydia.<sup>10</sup> Infection with CT and NG are also common for transgender and non-binary people, including extragenital sites.<sup>11</sup> A study analyzing the data from the STD Surveillance Network, for which data collection is done in collaboration with local US clinics and the CDC, found a significant proportion of CT and NG infections being extragenital infections for transgender men and women. For transgender women (n=506), the positive rate of rectal CT (15.4%) and NG (11.8%) was higher than the positive rate for urogenital CT (0.8%) or NG (2.8%). Similarly, for transgender men (n=120), the positive rate for rectal CT (15.6%) and NG (14.7%) was higher than the urogenital rate for either, 4.1% and 7.1% respectively.<sup>12</sup>

Current guidelines for CT and NG screening vary between the CDC and the US Preventive Services Task Force (USPSTF). The CDC recommends screening for chlamydia in sexually active women under age 25, sexually active women 25 years and older at increased risk (new sex partner, more than one sex partner, sex partner with concurrent partners, and new sex partner who has a STI) pregnant women age 25 and older if at increased risk, and annually for men who have sex with men. The CDC reports insufficient evidence for screening heterosexual men. For transgender and gender diverse people, they recommend adapting screening recommendations based on reported sexual behavior and exposure. The updated CDC recommendations also specify that vaginal swabs are the preferred screening specimen for women, and that the use of rectal and oropharyngeal specimens should be used among people at risk for extragenital infections.<sup>13</sup> The USPSTF guidelines recommend screening for gonorrhea and chlamydia in all sexually active women age 24 or younger, and age 25 or older at increased risk. USPSTF reports insufficient evidence to screen in men. Unfortunately, the USPSTF guidelines do not comment on transgender or gender diverse individuals.<sup>14</sup>

Table 1. Gonorrhea and Chlamydia Screening Recommendations<sup>13,14</sup>

	Cis-gender women	Cis-gender men	Transgender/Gender Diverse
CDC	<ul style="list-style-type: none"> <li>• All under age 25 (a)</li> <li>• Age 25+ AND increased risk (a,b)</li> <li>• Consider pharyngeal (GC only) and rectal screening based on sexual behaviors and risk</li> </ul>	<ul style="list-style-type: none"> <li>• Annually if sexually active with men at point of contact (urethra, rectum) regardless of condom use</li> <li>• Every 3-6 months if sexually active with men AND increased risk (c)</li> <li>• Consider pharyngeal (GC only) screening based on point of contact and increased risk (c)</li> </ul>	<ul style="list-style-type: none"> <li>• Adapt based on anatomy (e.g., under age 25 yrs. if cervix present)</li> <li>• Adapt based on exposure (e.g. rectal screening based on sexual behaviors)</li> <li>• Adapt based on HIV positive status, minimum annually, more frequently if high risk (b) (c)</li> </ul>
USPSTF	<ul style="list-style-type: none"> <li>• All under age 25</li> <li>• Age 25+ AND increased risk (d)</li> </ul>	<ul style="list-style-type: none"> <li>• Insufficient evidence for population as whole.</li> <li>• Separate recommendations for high-risk populations not addressed.</li> </ul>	<ul style="list-style-type: none"> <li>• Not addressed</li> </ul>

- (a) If pregnant, rescreen in 3<sup>rd</sup> trimester
- (b) New sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI, HIV positive and sexually active
- (c) On pre-exposure prophylaxis for HIV (PrEP), with HIV infection, or if they or their sex partners have multiple partners
- (d) History of previous or coexisting STI, new or more than 1 sex partner, a sex partner having sex with other partners at the same time, a sex partner with a STI, inconsistent condom use when not in a mutually monogamous relationship, a history of exchanging sex for money or drugs, a history of incarceration

According to the CDC, pharyngeal and rectal chlamydia screening can be considered based on reported sexual behaviors and exposure, with shared decision making.

Limiting STI testing to a clinician collected specimen creates a barrier for this much needed screening. Self- screening for STIs can be an effective and reliable method of collection. Multiple studies have shown that self-collected vaginal swabs for NG and CT are either superior or non-inferior to a clinician collected endocervical swab.<sup>15,16</sup> A self-collected vaginal swab has also been shown to be superior for screening for CT compared to first void urine.<sup>17-19</sup> A 2015 meta-analysis by Lunny et al., included 21 randomized, quasi-randomized controlled trials, and cross-sectional observational studies examining self-collected versus clinician-collected samples for nucleic acid amplification test (NAAT) screening for gonorrhea and chlamydia. From these, six studies specifically compared chlamydia results from self-collection by vaginal swab to a clinician-collected cervical swab, with sensitivity at 0.92 (95% CI 0.87-0.95), and specificity at 0.98 (95% CI 0.97-0.99).<sup>20</sup> Although less data is available, similar high levels of sensitivity and specificity have been shown for self-collected rectal swabs. A cross sectional study (N = 2394) compared self-collected rectal samples using NAATs for both assigned females and males at birth who participated in receptive anal sex. For both NG and CT, the self-collected rectal swabs versus the clinician collected

swabs were greater than 98% concordant.<sup>21</sup> Other studies have shown a self-collected rectal swab is an effective means of screening for NG and CT.<sup>8</sup>


In addition, patients find self-collection easy and minimally invasive. Although some patients, specifically patients assigned female at birth, may at times prefer having a clinician genital exam, self-collection is a way to decrease barriers for some who are asymptomatic and may be more reluctant to a provider exam.<sup>21</sup> CDC guidelines state that self-collected vaginal swabs are equivalent in sensitivity and specificity to those collected by a clinician.<sup>13</sup> Self-swabs are also an important option for patients who do not otherwise require a clinical exam, decline a clinician exam, or do not have access to this exam.

### ***Proposed Intervention***

A primary care physician is often the first and main contact with the health care system. Screening for STIs is an important component of routine primary care. Therefore, optimizing this process is essential for busy primary care providers and their clinics. Self-collected vaginal and rectal swabs for NG and CT are a crucial step to facilitating this screening. By implementing a self-screening protocol for NG and CT across primary care sites, we are assuring the necessary screenings get completed and listening to patients' preferences for collection. Specific-

ly, patients can complete self-collection of vaginal and rectal swabs at clinic sites. Figure 1 illustrates the steps for a patient to complete self-collection. These steps can serve as a guide for

instructions provided by medical assistants, and may also be posted in the areas where patients will complete this collection process.



## SELF-COLLECTION OF GENITAL OR RECTAL SPECIMENS

### PATIENT INSTRUCTIONS

MRN:

Patient Name:

One way of testing for sexually transmitted infections (STIs) is for the patient to do a self-collected swab. This is done in the clinic at the time of a visit and is available if you agree to perform the collection. Alternatively, the provider may collect the specimen during the visit.

If you want to do a self-collection in the clinic (the specimen may not be removed from the clinic), please follow these instructions:

1. Wash your hands.
2. Undress, as appropriate for the area being swabbed, in the examination room or restroom.
3. The staff will provide you with a specimen package including a swab and collection tube. If you are swabbing multiple sites, the staff will indicate which tube is for which area being swabbed. **DO NOT MIX UP THE COLLECTION TUBES** – Be sure that you use the appropriate collection tube for the site being swabbed.
4. Remove the swab from the package and only touch the swab from the stick end; do not touch the spongy "collection end" of the swab.
5. Carefully insert the swab into your vagina or rectum about 2 inches (5 cm) and gently rotate the swab for 20 to 30 seconds. Make sure that the swab touches the walls of the vagina or anus so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.
6. While continuing to hold the swab in the same hand, unscrew the cap from the collection tube and insert the swab, spongy end first, into the tube.
7. Break off the end of the swab that is sticking out of the top of the tube.
8. Carefully screw on the top of the collection tube.
9. Wash your hands.
10. Hand the specimen to the clinic staff.





  


Figure 1.

### Conclusion

Sexually transmitted infections are highly prevalent in the US and are a significant public health burden. Screening for sexually transmitted infections can prevent unnecessary complications from disease. The high prevalence and associated morbidity of NG and CT infections can be significantly reduced by broad screening programs. Developing and implementing a self-screening protocol can reduce barriers to screening and is an important step in patient-centered delivery of primary care.

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