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Overfilled urine specimens for gonorrhea and chlamydia testing: Implications for practice

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ABSTRACT

In clinical practice, patients provide samples that violate specimen collection guidelines. As no research exists to guide clinical practice for such situations involving sexually transmitted infections (STIs), we reviewed our clinical data to determine how to proceed when patients provided urine specimen > 30 mL. We tracked the quantity of urine, test outcomes, and whether or not patients returned to provide subsequent samples when notified to do so. Over 6 months, 33 patients provided overfilled samples; we submitted 70% (n = 23/33). From the submitted specimens, 5 infections were identified from 4 patients: all were positive for chlamydia and 1 for gonorrhea and chlamydia. This yielded the following positivity rates: 17.4% for chlamydia (n = 4/23), and 4.3% for gonorrhea (n = 1/23). For the group, the positivity rate was 17.4% (4 of 23 patients with infections), or 21.7% (5 infections from 23 patients). Lastly, only 60% of the patients instructed to return to clinic for retesting did so. Due to the possibility of false negative results, the ability to detect infections in overfilled samples, and because patients may not return for retesting, we recommend submitting overfilled samples, while also notifying patients to return to retest. This approach could maximize diagnostic rates, at least within STI testing clinics.

1. Introduction

For *Neisseria gonorrhoea* and *Chlamydia trachomatis* testing, for males, current American and Canadian guidelines recommend collecting urine samples because, compared to urethral swabs, they are less invasive, better accepted, and have superior sensitivity (CDC, 2014; PHAC, 2016). These guidelines also note that such testing is acceptable for females, "but might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples" (CDC, 2014, p10; PHAC, 2016). Despite these benefits, the clinical utility of such testing can be limited when patients do not provide samples according to validated specimen collection procedures; e.g., when they provide samples that exceed the maximum allowable quantity (henceforth referred to as "overfilled specimens"). In these cases, nurses must balance competing interests: (1) the clinical and public health need to test for sexually transmitted infections (STIs), (2) the potential that overfilled specimens could be too dilute, and might yield false-negative results, (3) the probability that overfilled specimens would yield positive results, as they do not immediately become invalid with minimal excess urine, and (4) the possibility that, if specimens are discarded, patients' may not return to clinic to submit second samples.

In our local STI clinic, we encounter this situation, but – because, to the best of our knowledge, no published studies address this topic – we make decisions about how to proceed on a case-by-case and theoretical basis. To generate preliminary data about how to handle these specimens more generally, we tracked overfilled specimens for six months, and submitted a subset for testing. In undertaking this study, we had three questions: (1) How frequently do patients provide overfilled urine samples?; (2) What were the test results of overfilled samples we submitted to the laboratory for testing?; and (3) How many of the patients we instructed to return to clinic for retesting did so (and after how many days)? In other words, our intention was to establish if specimens should be submitted or if patients should be contacted and informed to return to clinic to provide new samples, or a combination thereof.

2. Background

2.1. Situating the issue

In the United States and Canada, *Chlamydia trachomatis* ("chlamydia") and *Neisseria gonorrhoea* ("gonorrhea") are the two most commonly diagnosed bacterial STIs (CDC, 2017; PHAC, 2016). In 2015, there were 1,526,658 cases of chlamydia in the United States, for a rate of 478.8/100,000, and 395,216 cases of gonorrhea, for a rate of 123.9/

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100,000 (CDC, 2017). In Canada, in 2012 (last year of published national data), there were 103,716 chlamydia diagnoses, for a rate of 298.7/100,000, and 12,561 gonorrhea diagnoses, for a rate of 36.2/100,000 (PHAC, 2016). Compared to data from a decade earlier, the Canadian rates have increased by 57.6% (chlamydia) and 38.9% (gonorrhea) (PHAC, 2016).

The impetus to screen for these STIs is not to simply identify and eradicate these pathogens, but to prevent their potential sequelae, which can be systemic (e.g., reactive arthritis, disseminated gonococcal infection) (CDC, 2017; PHAC, 2012), gynecologic (e.g., pelvic inflammatory disease, infertility, ectopic pregnancy, chronic pelvic pain) (Deal, Cates, Peeling, & Wald, 2004; Haggerty et al., 2010; Price, Ades, Welton, Soldan, & Horner, 2013), and immunologic (i.e., localized inflammation caused by gonorrhea and chlamydia can increase the risk of HIV acquisition because this inflammatory process is characterized by, in the genital tract, rising numbers of the immune targets cells HIV uses to enter the body) (Galvin & Cohen, 2004). Diagnosing and treating gonorrhea and chlamydia are thus essential components of good clinical and public health nursing practice, making it important for clinicians to know how to proceed with overfilled samples.

2.2. Current guidelines

Recommendations about urine specimen collection for gonorrhea and chlamydia testing are as follows: the *Canadian Guidelines on Sexually Transmitted Infections* (STI) indicate that an "initial 10 to 20mL of urine" should be obtained after a patient has not voided for 2 h (PHAC, 2016); in its latest publication, the United States CDC (2014), meanwhile, advises first-catch specimen collection without noting a volume or time frame from last voiding for collection, although the 2002 guideline indicated 10–30 mL of first-catch urine at least 1 h from last voiding (CDC, 2002); lastly, the product monograph for the test used in Ontario, Canada (the *Gen Probe Aptima Urine Specimen Collection Kit*) indicates that a 20–30 mL first-void urine should be collected after a patient has not voided for 1 h (Gen Probe, 2015). The sensitivities and specificities for this testing (using *Gen Probe Aptima*) are, for females, for chlamydia, 94.3% and 98.0%, respectively, and, for gonorrhea, 92.0% and 99.8%, respectively; for males, these numbers are, for chlamydia, 96.0% and 97.2%, respectively, and, for gonorrhea, 98.9% and 99.2%, respectively (Public Health Ontario, 2011). Overall, it appears that approximately 20 mL, to a maximum of 30 mL, of first catch urine after a patient has not voided for at least 1 h is ideal specimen collection for gonorrhea and chlamydia urine testing.

Guidance about how to proceed if a sample is collected < 2 h since last void is less clear, although the Canadian guidelines (2016) state that, "having voided more recently [than two hours ago] does not preclude testing". This agency cites two studies that tested urine samples less than versus more than 2 h since last void, which found no statistical difference in test performance (Manavi & Young, 2006; Mathew, O'Mahony, & Malllison, 2009). No such guidance exists about how to proceed if a patient submits a midstream specimen: "Performance estimates for urine specimens are based on evaluation of urine obtained from the first part of the urine stream; performance on midstream collections has not been determined" (MayoClinic, 2017). Laboratory instructions about how to handle overfilled specimens are unambiguous: samples must be discarded if they exceed the maximum allowable sample volume.

However, because it is unlikely that specimens which exceed the validated sample volume (by even 1 mL) would immediately yield false-negative results, and in light of the complications associated with gonorrhea and chlamydia infection, automatically discarding such samples should likely be balanced against the potential harms of missing opportunities to identify these infections. In other words, nurses should make informed decisions about whether or not they should discard a sample knowing that (1) the overfilled specimen could still possibly identify gonorrhea and/or chlamydia, (2) a patient may not return to clinic for retesting after the specimen has been discarded, while (3) a patient could decide not to return to clinic for retesting because the nurse processed the overfilled specimen (i.e., the patient feels reassured because his/her overfilled specimen was submitted for testing). As noted previously, however, there are no published studies to help guide how to proceed in this scenario.

2.3. Data collection

From July 10, 2014 through January 20, 2015, we tracked clinic attendance, the total number of urine tests submitted, and urine specimens that exceeded 30 mL. This time frame was selected based on the rationale that it was both adequate for the number of overfilled samples that would occur, and was a sufficiently brief time to enable prompt resolution of the clinical issue. During these six months, we recorded the volume of urine provided, whether or not we submitted the test, the results of the submitted specimens, whether or not patients returned to our clinic to provide new samples, how many days it took patients to return to the clinic after notification (if they returned), and the result of subsequent samples. We established a priori that we would not submit specimens containing > 50 mL of urine, and would instead instruct these patients to return to clinic to provide new samples. We collected these data at the Sexual Health Centre in Ottawa Canada, which is an STI testing clinic that, as detailed elsewhere (O'Byrne et al., 2016), has > 20,000 patient visits per annum. The research ethics board at Ottawa Public Health approved this project (#196-14).

3. Results

Over the six-month data collection period, there were 10,344 patient visits, of which 5841 were for gonorrhea and chlamydia testing, with approximately 50% of these having been collected as urine samples (n = ~2900). For overfilled urine samples, 33 patients provided urine samples > 30 mL, giving us a rate of occurrence of ~1.1% (n = 33/2900). Only one of these patients was female. The average volume of urine provided in these samples was 48 mL, ranging between approximately 35–100 mL. We submitted 70% (n = 23/33) of these samples for testing. Of those submitted, all but three were < 50 mL, ranging from 35 to 70 mL. Eight of the 10 samples we did not submit were > 50 mL; two were 40 mL. We did not submit the sample from the one female patient because she opted to undergo an endocervical gonorrhea and chlamydia test before leaving the clinic. See Table 1.

Of the 23 samples submitted to the laboratory, four yielded five positive results: all were positive for chlamydia; one was positive for gonorrhea as well. As each patient's sample (n = 23) was tested for chlamydia and gonorrhea (n = 46 tests performed), the overall positivity rate was 10.8% (five infections from 46 tests). By infection, this rate was 17.4% for chlamydia (n = 4/23), and 4.3% for gonorrhea (n = 1/23). By the number of patients tested, the positivity rate was 17.4% (four of 23 patients), or 21.7% (5 infections from 23 patients).

A few patients were noteworthy. One patient whose urine test was negative for gonorrhea and chlamydia had positive pharyngeal and rectal gonorrhea cultures; he also complained of distal urethral irritation at the time of testing, and was diagnosed with non-gonococcal urethritis clinically, based on both presentation and the result of an onsite gram stain of his urethral smear, which showed 0–2 white blood cells per high-powered field. No gram-negative diplococcic were identified. His overfilled urine volume was 35 mL. Another patient had negative urine test results after complaining of distal urethral tingling; he also had 0–2 white blood cells per high-powered field on on-site gram stain of his urethral smear, and his overfilled sample was 50 mL. A third patient, who presented as a contact of chlamydia, had a negative urine test result from an overfilled sample of 45 mL. A fourth patient whose urine test was negative for STIs returned to clinic one week later because a sexual partner was diagnosed with chlamydia; his follow-up test results were negative for gonorrhea and chlamydia. His initial