Comparison of self-collected meatal swabs with urine specimens for the diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in men

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**Abstract**

**Purpose.** *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are common bacterial causes of sexually transmitted infections. Self-taken meatal swabs are a possible alternative to urine samples in testing for infection; however, the data surrounding their use are limited.

**Methodology.** We carried out a prospective service review in a large sexual health clinic comparing urine samples and self-taken meatal swabs in men presenting for sexual transmissible infection screening for CT and GC with the BD Viper XTR system.

**Results.** We found an overall prevalence of 10.5% for CT infections and 4.2% for GC infections in our patient population. Meatal swab testing had a sensitivity and specificity of 91 and 99% with an negative predictive value (NPV) of 99% and a positive predictive value (PPV) of 96% for CT testing compared to a sensitivity and specificity of 100 and 99% with an NPV of 100% and a PPV of 98% for urine samples. The sensitivity and specificity of meatal swabs was 100 and 99%, respectively, for GC detection with an NPV of 100% and PPV of 89% compared to urine which had 93% sensitivity and 99% specificity with an NPV and PPV of 93 and 93%, respectively.

**Conclusions.** Meatal samples were not inferior to urine samples for the detection of CT and GC. Male urethral meatal self-sampling offers an alternative sample type when compared to male urine specimens.

**INTRODUCTION**

*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are common causes of bacterial sexually transmitted infections which if left untreated can result in significant sequelae including infertility in men and pelvic inflammatory disease, increased risk of ectopic pregnancy and tubal infertility in women. It is estimated that 45 and 77% of all cases of GC and CT infections, respectively, are never symptomatic [1], and remain a reservoir for ongoing transmission. Early identification and treatment of infection may reduce significant reproductive sequelae and avoid onward transmission. Therefore, it is important to screen the asymptomatic as well as test the symptomatic individuals. Advances in nucleic acid amplification tests (NAATs) and non-invasive sampling have enabled increased screening of those at risk of infection regardless of symptoms.

Numerous evaluations exploring the utility of CT and GC NAATs have been published proving to be sensitive, fast and reliable[2–5]. NAATs are recommended for all CT testing and are considered the gold standard for this. NAATs are used widely for GC detection in high-risk populations; however, GC NAATs are not recommended as a lone diagnostic test in areas or populations where the prevalence of GC is low [6].

In high-risk groups dual testing enables the simultaneous detection of CT and GC infections resulting in rapid identification and treatment of patients. Thus, NAATs form the backbone of GC and CT screening in the UK.

NAATs have allowed less invasive sampling methods to be utilized. Women are now encouraged to undertake vulvo-vaginal self-sampling. This has been demonstrated to be more sensitive for the detection of CT in women than urine sampling [7], whereas men are still requested...
to provide a urine sample for testing. Although easy to collect, urine samples are prone to leakage during transportation and they require transfer from a collection receptacle into the testing tube. This means that urine samples are prone to cause contamination of the clinic and laboratory environment.

Self-taken meatal swabs are a possible alternative sample type. However, the data surrounding their use are limited [8–11]. Our review of male clinic attenders at the sexual health service in Coventry aimed to compare the sensitivity and specificity of self-taken meatal samples with urine samples in men presenting for sexual transmissible infection screening for CT and GC using the BD Viper XTR system.

METHODS
Samples
Samples were collected between January 2014 and October 2014 from 1728 men attending a sexual health clinic in Coventry. Participants being investigated for CT and GC as part of sexual health screening were asked to provide both a urine sample and a self-taken meatal swab. Patients were requested to take the meatal sample using the BD ProbeTec ET CT/GC Amplified DNA Assay Collection kit for male urethral specimens (BD Diagnostics) as shown in Fig. 1. This study was deemed to be a service evaluation by our local research and development team and therefore had ethics exemption.

Nucleic acid detection
Samples were tested on the BD Viper XTR platform (BD diagnostics) following manufacturer’s instructions. Samples that were positive on the BD Viper XTR were retested using the Abbott Real-Time CT/NG assay following the manufacturer’s instructions with the exception of the sample buffer. The BD Viper collection system was validated for use with the Abbott Real-Time CT/NG assay (data not shown).

Statistical methods
Patients were considered positive for CT or GC if they had a positive result in both their urine sample and meatal swab sample. Where the meatal swab result and urine result were discordant in the BD Viper XTR screen; samples were considered true positive if they confirmed using the Abbott Real-Time CT/NG assay or were GC culture positive.

The study was powered for non-inferiority with a 95% confidence interval [12]. Based on a GC prevalence of 3.5%, the prevalence from the year prior to the study, and an assay that is 97% sensitive and 98% specific the sample number needed to test was 1397. The kappa statistic was calculated to describe the agreement between the sample types [13].

RESULTS
A total of 1517 patients provided evaluable paired samples, out of which 211 patient episodes were excluded as they provided only one sample type. Of the patients who provided dual samples, 138 (9.1%) were CT positive in at least one sample type, 42 (2.7%) were GC positive in at least one of the samples and 22 (1.4%) patients were both CT and GC positive in at least one of the samples. This gave an overall prevalence of 10.5% for CT and 4.2% for GC.

Concordance between urine and meatal swabs was 99% (1506/1517) for GC and 98% (1497/1517) for CT with a κ value of 0.87 for GC and 0.92 for CT, which means there is an almost perfect statistical agreement between sample types [13].

Table 1 shows the overall data of the meatal swab and urine testing for GC detection. The overall data comparing the meatal swabs and urine testing for CT detection are shown in Table 2 and the discordant results are detailed in Table 3. The sensitivity and specificity of meatal swabs was 100 and 99.7%, respectively, for GC detection with a negative predictive value (NPV) of 100% and positive predictive value (PPV) of 89.4% compared to urine which had 92.9% sensitivity and 99.8% specificity with an NPV and PPV of 99.8 and 92.8%, respectively. Meatal swab testing had a sensitivity and specificity of 92.0 and 99.6% with an NPV of 99.2% and a PPV of 96.2% for CT testing compared to a sensitivity and specificity of 100 and 99.7% and an NPV of

![Instructions for sample collection](https://www.microbiologyresearch.org/images/Instructions_for_sample_collection.png)

**Table 1.** Results of urine samples and meatal samples for GC testing

<table>
<thead>
<tr>
<th></th>
<th>Swab</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Total</td>
</tr>
<tr>
<td>Urine</td>
<td>39</td>
<td>3</td>
<td>42</td>
</tr>
<tr>
<td>Negative</td>
<td>8</td>
<td>1467</td>
<td>1475</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>1470</td>
<td>1517</td>
</tr>
</tbody>
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![Fig. 1. Instructions given to patients as to how to take the self-collected meatal swab and urine sample.](https://www.microbiologyresearch.org/images/Fig_1_instructions.png)
100 % and a PPV of 97.2 % for urine samples. Therefore, meatal swab samples are not inferior to urine samples for the detection of CT and GC in samples sent from men attending sexual health services for screening.

**DISCUSSION**

Self-collected meatal swabs were not inferior to urine when tested on the BD Viper XTR system. Therefore, self-collected male meatal swabs are a possible alternative sample type to male urine samples for testing CT and GC. This has advantages for the laboratory as self-collected swabs reduce the opportunities for leaking and cross-contamination. In addition, postal screening programmes could benefit from the use of samples that require less packaging and have lower leakage risk. It also provides a sampling method that can be used for men who cannot pass urine at the time of examination and may not return for re-sampling.

However, a reduction in the sensitivity of CT detection was seen in meatal swab testing, although this could be a genuine difference in the detection of CT or it may be that the swabs were poorly taken. Presence or absence of urine is obvious, but the existence of a swab does not guarantee use. Some discrepant results may be due to reluctance of participants to self-swab, and failing to declare this.

Two hundred and eleven patient episodes were excluded due to patients not providing paired samples. Thirty-two patients provided only a swab sample; anecdotally, some of these were because the patients could not pass urine at the time of testing, either because it was too painful due to symptoms or because they were not able to void their bladder on request. One hundred and sixty-three patients provided a urine sample only with many of them refusing to use the swab.

Patient preferences may be influenced by many factors including personal familiarity with a method and clinician confidence, awareness and habit. Although GC culture from urethral swab sampling in patients is still required in order to determine GC sensitivities, urine sampling has become the norm for CT/GC screening. This study demonstrated that self-taken urethral meatal samples are an alternative sample type that can be used to diagnose CT and GC in men presenting for sexual health screening.

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**Conflicts of interest**

The authors declare that there are no conflicts of interest.

**References**