



Public Health
England

Protecting and improving the nation's health

Guidance for the detection of gonorrhoea in England

Updated guidance 2021

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Key points

This guidance aims to inform the commissioning and delivery of gonorrhoea testing in England and provides recommendations for best practice. It updates the previous 2014 guidance.

Recommendations

1. Testing for gonorrhoea is recommended in any setting where it is clinically indicated, such as for symptomatic patients, contacts of those infected or attendees of sexual health clinics.
2. The use of dual nucleic acid amplification tests (NAATs), detecting both chlamydia and gonorrhoea, could lead to inappropriate testing for gonorrhoea.
3. Below a prevalence of 1%, the majority of initial positive test results for gonorrhoea are likely to be false positives. To minimise this risk, the testing algorithm should give a minimum positive predictive value (PPV) of 90%. In most cases this will require the use of a supplementary NAAT with a different nucleic acid target to confirm the result.
4. Oropharyngeal specimens always require confirmation as commensal *Neisseria* sp in the pharynx may cause cross-reaction with NAAT targets.
5. Culture is necessary in patients with signs and symptoms compatible with gonorrhoea or with a confirmed NAAT result so that antibiotic susceptibility testing can be performed.
6. It is important to ensure the patient is fully informed about each infection they are being tested for and what the test involves; this is particularly important for assays which test for more than one infection.
7. Care pathways must be in place to ensure prompt and effective treatment of confirmed gonorrhoea, test of cure, partner notification and a full sexually transmitted infection (STI) screen according to national guidelines; where a service cannot meet these requirements, patients should be referred to a specialist sexual health service for further management.

1. Introduction

1.1 Purpose of this guidance

Laboratories use nucleic acid amplification tests (NAATs) to detect both *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Although 'single' NAATs are available to detect just one of these infections, laboratories more commonly use 'dual' NAATs to simultaneously test for both infections, as this is more efficient for laboratory workflows and is of no additional cost to the laboratory. The use of dual NAATs could however lead to inappropriate testing for gonorrhoea.

While testing for gonorrhoea is recommended within specialist sexual health clinics targeting higher risk populations or where clinically indicated, there is no evidence to support widespread opportunistic screening for gonorrhoea in community-based settings where prevalence is low (1) indeed, there may be harms.

This document aims to inform decisions about how to mitigate any risks and recommends best practice for testing.

1.2 Public health importance and epidemiology of gonorrhoea

Gonorrhoea, caused by the bacterium *Neisseria gonorrhoeae*, is primarily associated with uncomplicated infection of the lower genital tract, which is symptomatic in most men (>90%) and approximately half of women (2, 3). Infection also occurs at extra-genital sites (the rectum or pharynx), which is usually asymptomatic (2, 3). Undetected or inadequately treated gonorrhoea may lead to complicated infection of the upper genital tract; this includes epididymo-orchitis in men and pelvic inflammatory disease which may result in tubal infertility and ectopic pregnancy in women. Gonorrhoea is also known to facilitate the acquisition and transmission of HIV (4). The emergence of antimicrobial resistant (AMR) gonococcal strains is a threat to global public health (5).

Unlike chlamydia, gonorrhoea infection in England is concentrated in core risk groups including men who have sex with men (48% of all diagnoses) and people of black Caribbean ethnicity (6, 7). It is also highly geographically concentrated and infection is strongly associated with deprivation, mainly amongst young heterosexuals in urban areas (8). Transmission is perpetuated by higher rates of partner change and complex sexual networks, which can lead to localised outbreaks (9). A British population-based survey detected gonorrhoea only in those aged 20 to 24 years; in this age group the prevalence was 0.1% in men and 0.2% in women. In contrast, in the same survey the prevalence of chlamydia was 3.4% in men and 2.7% in women aged 20 to 24 years (10).

1.3 Benefits and risks of gonorrhoea testing

The main benefit of gonorrhoea testing arises from the diagnosis and treatment of a sexually transmitted infection that can have serious complications and halting transmission within the population through case and partner management.

The major risk associated with testing for gonorrhoea within the general population concerns the increased likelihood of false positive test results in low prevalence populations, and cross reaction with non-gonococcal *Neisseria* species (11-13). Returning misdiagnoses risks direct harm to affected individuals arising from an incorrect and stigmatising diagnosis and partner notification, and at a population level through the unnecessary use of antibiotics and avoidable financial costs.

1.4 What is the PPV?

The positive predictive value (PPV) is the likelihood that patients with an initial positive test result are subsequently confirmed to have the infection (see **Box 1**). Calculation of PPVs requires data on gonorrhoea prevalence or test positivity in the population being tested, as well as the sensitivity and specificity for each specimen type for the assay being used. If the estimated PPV is less than 90%, a care pathway including supplementary testing is essential.

Box 1: Worked example of calculating PPV

A population with a true prevalence of 1% tested with a hypothetical screening test with sensitivity and specificity of 99% would result in the PPV being 50%, equivalent to 50 unconfirmed gonorrhoea diagnoses (false positives) for every 100 initial positive test results. In fact, in this example, gonorrhoea prevalence would need to be 8% or above before the PPV reached 90% when using a single unconfirmed test.

1.5 Establishing the need for gonorrhoea detection

Gonorrhoea testing is essential for symptomatic patients, contacts of those infected, and those with recognised risk factors. Asymptomatic screening for gonorrhoea is recommended in 'high prevalence populations', such as attendees of sexual health services, but there is limited evidence to provide a robust definition of high prevalence populations for use in practice.

Population screening where prevalence is low is of limited public health benefit, but in practice, may be taking place in lower prevalence settings. For example, if a sample is taken as part of the National Chlamydia Screening Programme from a non-specialist

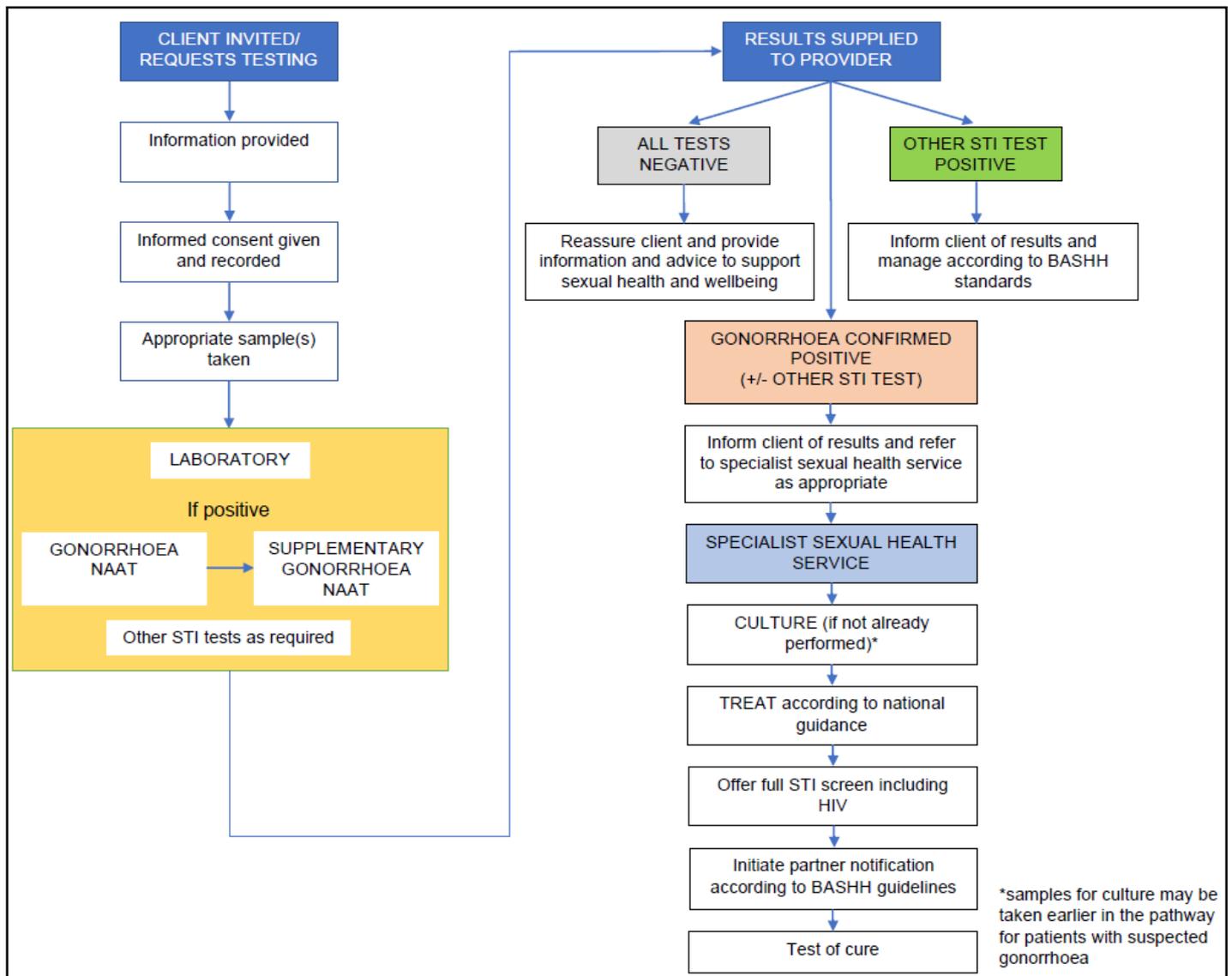
sexual health service and it is processed in a laboratory using dual NAATs, then it will be tested for gonorrhoea as well as chlamydia (12). Additionally, online self-testing services which offer screening for both infections are directly available to the public. Test sensitivity and specificity varies by specimen type and the diagnostic platform used, but below a prevalence of 1%, most initial positive test results (using a single target NAAT) are likely to be false positives, and confirmation of all gonorrhoea reactive tests is essential.

2. Best practice for managing gonorrhoea testing

2.1 Care pathway

Any gonorrhoea-testing service, including online services, should include a specific care pathway that sets out how to gain consent for the test, how and when to notify the patients of the results, what is the appropriate treatment and how partner notification should be performed. An example care pathway is presented in **Box 2**.

Box 2: Flow chart of best practice case management/patient pathway for gonorrhoea testing and case management



2.2 Patient information and consent

It is important to ensure the patient is fully informed about the infection they are being tested for and what the test involves. It is the healthcare practitioner's responsibility to ensure informed consent is gained for any testing that is undertaken. When offering testing using dual NAATs, consent to test for both infections should be explicitly obtained but is particularly important where individuals are being screened opportunistically (14).

It is best practice to provide written information, for example through patient information leaflets (PIL). Since gonorrhoea testing occurs in many different settings (including home self-sampling where the patient has limited or no access to a health professional), the PIL needs to provide comprehensive information on the test, and the consequences of the result, in a manner that is accessible.

To ensure that the PIL is informative, accurate and acceptable, commissioners and providers may wish to work together with public and user groups to ensure that the most effective communication tool is produced. They may also wish to consult examples of PIL produced by other organisations, for example the [BASHH PIL](#).

2.3 Initial detection of gonorrhoea – specimens and type of test

The test used should be validated for the specimen type and sampling site. The United Kingdom Accreditation Service requires that validation data are available and validation files are completed and reviewed.

There are many commercially available NAAT platforms with different nucleic acid targets and employing different amplification technologies. The sensitivity of these tests is high (>90%) for all genital specimens (endocervical swabs, self-taken vaginal swabs, urethral swabs and male urines), although may be lower for female urines on some platforms.

2.4 Extra-genital samples

Detection of gonococcal infection in extra-genital sites, the rectum and the pharynx, using NAATs is more sensitive than culture and NAATs are the test of choice at these sites. Some of the commercial assays have been approved for use at extra-genital sites; however, all tests used should be locally validated.

2.5 Handling of the specimen

NAATs are extremely sensitive and will detect very small amounts of nucleic acid (DNA or RNA). Note that detection of very small amounts of nucleic acid does not indicate that the organism is viable. Care should be taken to regularly clean (or decontaminate) both clinic and laboratory areas where positive specimens have been collected or processed. All healthcare workers handling specimens should be aware that DNA or RNA can be easily transferred to inanimate objects during specimen collection, which might contaminate other patients' specimens and could potentially lead to false positive results. Providers and laboratories must have decontamination protocols in place to prevent cross contamination.

2.6 Confirmation

Supplementary testing is recommended to reduce the risk of false positive test results. This requires additional testing (on the original patient specimen) using an alternative molecular target to the first test; this may be performed either by using a separate assay that detects a different target, or by using a single assay that detects 2 different gonococcal targets. The testing algorithm will depend on the commercial assay being used by the laboratory. Commissioners should ensure that all laboratories undertaking gonorrhoea testing are able to undertake supplementary testing or have an agreement in place with another accredited laboratory to do so.

2.7 When to use supplementary testing

Testing algorithms should give a minimum PPV of 90% within the local setting or population group. Even in settings where prevalence exceeds 1% (as in many sexual health clinics), it may be necessary to use a supplementary test to achieve an acceptable PPV, at least for extra-genital specimens (15, 16). Where the PPV is greater than 90%, a supplementary test is not required for genital and rectal specimens. For oropharyngeal specimens, cross-reactivity may occur with commensal *Neisseria* species present in the pharynx. It is therefore essential that all initial positive test results from oropharyngeal specimens are confirmed by supplementary testing.

2.8 Issuing test results

Diagnostic samples should be processed promptly so that results can be conveyed within an acceptable time frame (17). Laboratories should only issue positive test results that are confirmed by supplementary testing or where the PPV of the initial NAAT has been validated by the laboratory as being $\geq 90\%$.

2.9 Gonorrhoea culture for monitoring AMR

Microbial culture is the process by which viable organisms are isolated from an infected patient and grown in the laboratory for identification and antimicrobial susceptibility testing.

Although culture for *N. gonorrhoeae* is less sensitive than NAATs, it is still required to detect clinical isolates with resistance to first line treatment, to inform individual patient management (especially where treatment failure is suspected) and for national public health surveillance.

Wherever possible, samples for culture must therefore be taken prior to treatment commencing from all patients with suspected gonorrhoea or with a confirmed positive NAAT. Urine and vaginal swabs are not suitable specimens for culturing. The sensitivity of culture depends on several factors including time from sample collection to plating. Services should seek to minimise this time whether by direct plating in the clinic or use of transport media with prompt transfer for plating in the laboratory.

2.10 Management

Robust care pathways need to be in place for those with a confirmed positive test result to ensure prompt treatment and further management in line with BASHH guidelines (18).

Where a service is not able to (i) treat in line with current guidelines, (ii) offer further STI testing, or (iii) offer partner notification, patients should be referred to a specialist sexual health service for further management. The referring service should actively follow up referred patients to ensure successful transfer of care. If there is concern that referral risks the patient not receiving treatment, that is due to non-attendance, then the primary service should make every effort to treat the patient according to national treatment guidelines.

3. Reporting data for public health surveillance

Public health surveillance data are collected and analysed to monitor trends in STI diagnoses to determine specific groups at risk of infection. This information is used to inform the public health response by:

- improving the planning and management of services
- developing, adapting and refining interventions
- monitoring the effectiveness of sexual health policies
- enabling effective commissioning of sexual health services

All sexual health services are required to report data on all STI tests and diagnoses, including those for gonorrhoea, through the GUMCAD STI Surveillance System.

Testing activity and diagnoses of gonorrhoea made through any testing service that does not submit data through GUMCAD, for example community pharmacy, GP etc, will not be captured through national surveillance data collection unless patients are referred to a sexual health service for ongoing management.

See the [commissioners' starter packs and guidance for providers](#) for submitting to GUMCAD.

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