



Public Health
England

Protecting and improving the nation's health

Guidance for the detection of gonorrhoea in England

Including guidance on the use of dual nucleic acid amplification tests (NAATs) for chlamydia and gonorrhoea

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Executive summary

This guidance aims to inform the commissioning and clinical delivery of gonorrhoea testing in England and provides recommendations for best practice. It replaces the previous 2010 guidance. New guidance is needed to take account of the widespread use of testing assays using nucleic acid amplification tests (NAATs) which simultaneously detect both chlamydia and gonorrhoea (dual NAATs).

Recommendations for commissioners and providers

1. The prevalence of gonorrhoea in most areas is low. Opportunistic screening for gonorrhoea is not recommended unless there is a clear local public health need
2. Testing for gonorrhoea is recommended in any setting or situation where it is clinically indicated, such as for symptomatic patients, contacts of those infected or according to sexual history
3. Screening for gonorrhoea is recommended in any population or setting where gonorrhoea prevalence is $\geq 1\%$; below a prevalence of 1%, the majority of initial positive test results are likely to be false positives, suggesting unselected screening would be of limited public health benefit¹
4. A suitable testing algorithm must be in place to avoid high rates of false positive test results; the testing algorithm should give a minimum positive predictive value (PPV) of 90% (in almost all cases this will require the use of a supplementary NAAT with a different nucleic acid target to confirm the result, even in settings where prevalence exceeds 1%)
5. Where there is a lack of evidence about the likely PPV of the testing algorithm (for example where testing is newly introduced to a population), piloting should be undertaken to determine whether there is a need for testing
6. Sexual health 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
7. 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
8. 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 service for further management, usually a genitourinary medicine (GUM) clinic

¹ This prevalence cut-off assumes a test sensitivity and specificity of 99% and is intended only as a guide to help decision-making. Validated data from the local laboratory should be used to inform decision-making wherever possible. See section 2 for further details.

Recommendations for laboratories

9. Laboratories undertaking testing for gonorrhoea should have Clinical Pathology Accreditation/United Kingdom Accreditation Service accreditation and must ensure that they use recommended algorithms for testing (including supplementary testing)
10. NAATs can be used with a range of invasively and non-invasively taken genital samples; urine from women is not considered the optimal sample for NAAT-based detection of gonorrhoea
11. Supplementary testing will be required when an initial positive NAAT result has a PPV of <90%: this should be done using a second NAAT which detects a different nucleic acid target on the same sample
12. NAATs have a superior sensitivity to culture for the detection of gonorrhoea in extra-genital samples; all positive NAATs from extra-genital samples must be confirmed by a supplementary test with a different nucleic acid target and care should be taken to use a NAAT which exhibits little cross-reactivity in order to reduce misdiagnosis
13. Culture should not be considered as a first-line confirmation test for genital or extra-genital sites unless a culture-positive result is already available, ie all culture-negative, positive NAATs should be confirmed using a supplementary NAAT
14. Laboratories should only issue positive test results that are confirmed by supplementary testing or, for genital samples, where the PPV of the initial NAAT has been validated in the local laboratory as being $\geq 90\%$
15. Diagnostic samples should be processed promptly so that results can be conveyed in a timely fashion; laboratories should provide final reports on supplementary testing to the clinician within 10 working days of the specimen being received by the laboratory
16. Culture is necessary in patients with signs and symptoms compatible with gonorrhoea and/or with a confirmed NAAT result so that antibiotic susceptibility testing can be performed

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Section 1: Introduction

1.1 Purpose of this guidance

This guidance aims to inform the commissioning and clinical delivery of gonorrhoea testing in England and replaces the 2010 guidance.²

New guidance is needed to take account of the widespread availability of assays using nucleic acid amplification tests (NAATs) which simultaneously detect both chlamydia and gonorrhoea (dual NAATs). This has led to their use in areas where the prevalence of gonorrhoea is likely to be low. In recent surveys in England, nearly 90% of laboratories used dual NAAT platforms for some samples³, and over 50% of local authorities commissioned use of dual NAATs on samples collected in community-based settings participating in the National Chlamydia Screening Programme (NCSP).⁴ These assays are used in a broad range of settings from level 1 services offering self-sampling kits ordered via text or the Internet through to level 3 specialist genitourinary medicine (GUM) clinics (see Glossary for definitions of service levels).

While testing for gonorrhoea is recommended within specialist sexual health clinics targeting higher risk populations or where clinically indicated,⁵ there is no evidence to support widespread opportunistic screening for gonorrhoea in community-based settings, and the evidence for selected screening in UK community-based settings is sparse.⁶

Commissioners and providers should therefore carefully consider the benefits and risks of gonorrhoea testing in specific populations and, where gonorrhoea testing is done, mitigate those risks. This document aims to inform decisions about the detection of gonorrhoea and recommends best practice for testing.

² Health Protection Agency. Guidance for gonorrhoea testing in England and Wales. February 2010.

<http://www.bashh.org/documents/2580.pdf>

³ Toby M, Saunders P, Ison CA. Survey of the laboratory diagnosis of gonorrhoea and chlamydial infection in the UK (submitted).

⁴ Field N, Kennedy I, Folkard K, Ison C A, Duffell S, and Hughes G. Use of dual nucleic acid amplification assays for chlamydia and gonorrhoea within the National Chlamydia Screening Programme (NCSP): Results from a national survey of local authority commissioners. Public Health England. © Crown copyright 2014.

⁵ Standards for the management of sexually transmitted infections (STIs).MEDFASH and BASHH. January 2014.

<http://www.medfash.org.uk/standards-for-the-management-of-stis>

⁶ Fifer H, Ison C. Nucleic acid amplification tests for the diagnosis of *Neisseria gonorrhoeae* in low-prevalence settings: a review of the evidence. Sex Transm Infect. 2014 Dec;90(8):577-9.

1.2 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 concerns the increased likelihood of false positive test results in low prevalence populations. Returning misdiagnoses risks direct harm at an individual level arising from incorrect and stigmatising diagnoses and partner notification, and at a population level through the unnecessary use of antibiotics (which may contribute to antimicrobial resistance developing) and avoidable financial costs. Although less common, false negative test results may also occur, leading to undue reassurance to patients with a treatable infection.

1.3 Background and rationale

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.^{7 8} Infection also occurs at extra-genital sites (the rectum or pharynx), which is usually asymptomatic.^{7 8} Undetected or inadequately treated gonorrhoea may lead to complicated infection of the upper genital tract. This presents as prostatitis or epididymitis in men and salpingitis or pelvic inflammatory disease (PID) in women. Complications include tubal infertility and ectopic pregnancy in women. Gonorrhoea is also known to facilitate the acquisition and transmission of HIV.⁹ The emergence of antimicrobial resistant gonococcal strains is identified as a particular threat to global public health.¹⁰

Unlike chlamydia, which is ten fold more common, gonorrhoea is concentrated in core risk groups, including men who have sex with men (MSM) and black Caribbeans. It is also highly geographically concentrated and infection is strongly associated with deprivation.¹¹ A recent population-based survey detected gonorrhoea only in those aged 20-24 years; in this age group the prevalence was 0.1% in men and 0.2% in

⁷ Sherrard J, Barlow D. Gonorrhoea in men: clinical and diagnostic aspects. *Genitourin Med* 1996;72:422 –26.

⁸ Barlow D, Phillips I. Gonorrhoea in women: diagnostic, clinical and laboratory aspects. *Lancet* 1978;i:761 –64.

⁹ Jarvis GA, Chang TL. Modulation of HIV transmission by *Neisseria gonorrhoeae*: molecular and immunological aspects. *Curr HIV Res.* 2012 Apr;10(3):211-7. Review.

¹⁰ World Health Organization (2012) Global action plan to control the spread and impact of antimicrobial resistance in *Neisseria gonorrhoeae*. Geneva: World Health Organization.

¹¹ Public Health England. Sexually transmitted infections and chlamydia screening in England, 2012. Health Protection Report Vol 7 No. 23 - 7 June 2013.

women.¹² Data from GUM clinics show that 42% of diagnosed gonorrhoea is among MSM.¹³ Transmission is perpetuated by higher rates of partner change and complex sexual networks, which can lead to localised outbreaks.¹⁴ Chlamydia co-infection is common, being found in half of those diagnosed with gonorrhoea in clinic studies,¹⁵ and all of those with gonorrhoea in a recent British population-based survey.¹²

Gonorrhoea detection

The key objectives when testing for any sexually transmitted infection (STI) are to diagnose infection, and ensure rapid and effective treatment to prevent onward transmission and serious sequelae, while promoting overall good sexual health. For gonorrhoea, localised interventions targeted at high risk groups are more likely to be cost effective than unselected screening in community-based settings.¹⁵ (See Box 1 for definitions of testing and screening used in the document).

Box 1: Definitions of testing and screening used in this document

‘Testing’ is an overarching term which refers to diagnostic and opportunistic testing for gonorrhoea in both symptomatic and asymptomatic individuals, in any setting.

‘Screening’ refers only to opportunistic testing for gonorrhoea in asymptomatic individuals, in any setting. Here, the term screening is used in its broadest sense and not in the context of a structured screening programme.

Like chlamydia, gonorrhoea diagnosis now routinely uses highly sensitive and specific NAATs. However, despite excellent specificity, high rates of false positive tests can occur due to low gonorrhoea prevalence in the population tested and the potential for cross reaction with non-gonococcal neisseria species.^{16 17}

¹² Sonnenberg P, Clifton S, Beddows S, et al. Prevalence, risk factors, and uptake of interventions for sexually transmitted infections in Britain: findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). *The Lancet* 2013; 382: 1795–806.

¹³ Public Health England. Sexually transmitted infections and chlamydia screening in England, 2012. Health Protection Report Vol 7 No. 23 - 7 June 2013.

¹⁴ Chen MI, Ghani AC, Edmunds J. Mind the gap: the role of time between sex with two consecutive partners on the transmission dynamics of gonorrhoea. *Sex Transm Dis.* 2008 May;35(5):435-44.

¹⁵ Fifer H, Ison C. Nucleic acid amplification tests for the diagnosis of *Neisseria gonorrhoeae* in low-prevalence settings: a review of the evidence. *Sex Transm Infect.* In press.

¹⁶ Palmer HM, Mallinson H, Wood RL, Herring AJ. Evaluation of the specificities of five DNA amplification methods for the detection of *Neisseria gonorrhoeae*. *J Clin Microbiol* 2003; 41:835-7.

¹⁷ Field N, Kennedy I, Folkard K, Ison C A, Duffell S, and Hughes G. Use of dual nucleic acid amplification assays for chlamydia and gonorrhoea within the National Chlamydia Screening Programme (NCSP): Results from a national survey of local authority commissioners. Public Health England. © Crown copyright 2014.

Gonorrhoea testing is essential for symptomatic patients, contacts of those infected and those with recognised risk factors. However, gonorrhoea prevalence is low in most areas and opportunistic screening is not recommended unless there is a clear public health need, for example in settings or specific geographical areas where gonorrhoea prevalence is high and during outbreaks to improve case detection. In all cases, robust care pathways should be in place to avoid high rates of false positive test results and consequent harm. This document provides guidance to inform the commissioning and clinical delivery of gonorrhoea testing in England and gives recommendations for best practice.

Section 2: Making decisions about gonorrhoea testing

This section is designed to help local authority commissioners and service providers decide whether testing for gonorrhoea using NAATs is appropriate and, where done, whether supplementary testing is recommended for confirmation. These decisions should be based on the public health need for gonorrhoea testing in the population to be tested, and should ensure an acceptable positive predictive value (PPV) of the testing algorithm used.

2.1 Establishing the need for gonorrhoea detection

Gonorrhoea testing is essential for symptomatic patients, contacts of those infected and those with recognised risk factors. Screening for gonorrhoea is recommended in high prevalence populations and settings, but there is limited evidence to provide a robust definition of this for use in practice. Test sensitivity and specificity varies by diagnostic platform used, but below a prevalence of 1%, the majority of initial positive test results are likely to be false positives, suggesting screening would be of limited public health benefit (see Box 2; Table). Screening may therefore be most beneficial in populations or settings where gonorrhoea prevalence is $\geq 1\%$. However, in almost all cases a supplementary test will be needed to confirm the result, even in settings where prevalence exceeds 1% (see Box 2; Table).¹⁸

Where there is little available information on local prevalence, for example where screening is being considered for a population, it is recommended that piloting is undertaken to evaluate the public health need for gonorrhoea testing. For example, this might involve the introduction of testing in selected settings with a review and analysis of initial and supplementary test results after a 3-6 month period.

2.2 What is the PPV?

The PPV is the likelihood that patients with an initial positive test result are subsequently confirmed to have the infection (see Box 2 below for an example calculation of PPV, the PPV tool below for a more detailed explanation, and further general information for commissioners on the [commissioning support website](#)). PPVs vary considerably with the prevalence of the infection being tested for, becoming lower

¹⁸ Whiley DM, Garland SM, Harnett G et al. Exploring 'best practice' for nucleic acid detection of *Neisseria gonorrhoeae*. Sexual health 2008;5:17-23.

as prevalence drops. If the estimated PPV is less than 90%, a care pathway including supplementary testing is strongly recommended (see Section 3.4).

Box 2: 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.

Calculation of PPVs requires data on gonorrhoea prevalence or test positivity in the local population.

2.3 Estimating the PPV

To meet this need, PHE has developed a tool to estimate PPVs in different population groups for each LA, using a statistical algorithm. This algorithm was developed by quantifying the relationship between the prevalence of gonorrhoea in GUM clinic and community based settings, using areas where data for both are available.^{19 20}

¹⁹ Town K, Furegato M Hughes G. Developing a method to estimate the prevalence of *Neisseria gonorrhoeae* in community based sexual health services to inform decisions on gonorrhoea testing. International Union against STIs; 2014 European conference, Malta.

²⁰ Fifer H, Ison C. Nucleic acid amplification tests for the diagnosis of *Neisseria gonorrhoeae* in low-prevalence settings: a review of the evidence. *Sex Transm Infect.* 2014 Dec;90(8):577-9.

Using simple data entered about each area, the tool estimates:

- the maximum likely prevalence of gonorrhoea, by population/service provider group
- the PPV associated with the initial test
- the PPV associated with the confirmatory test
- the number of false positive results in the absence of supplementary testing

The tool also indicates whether or not supplementary testing is recommended. It uses default values of test sensitivity and specificity to estimate PPVs, but these values can be varied if you have more accurate information from your local lab. The statistical algorithm and tool will be reviewed quarterly and refreshed when new data become available.

Access the PPV tool here:

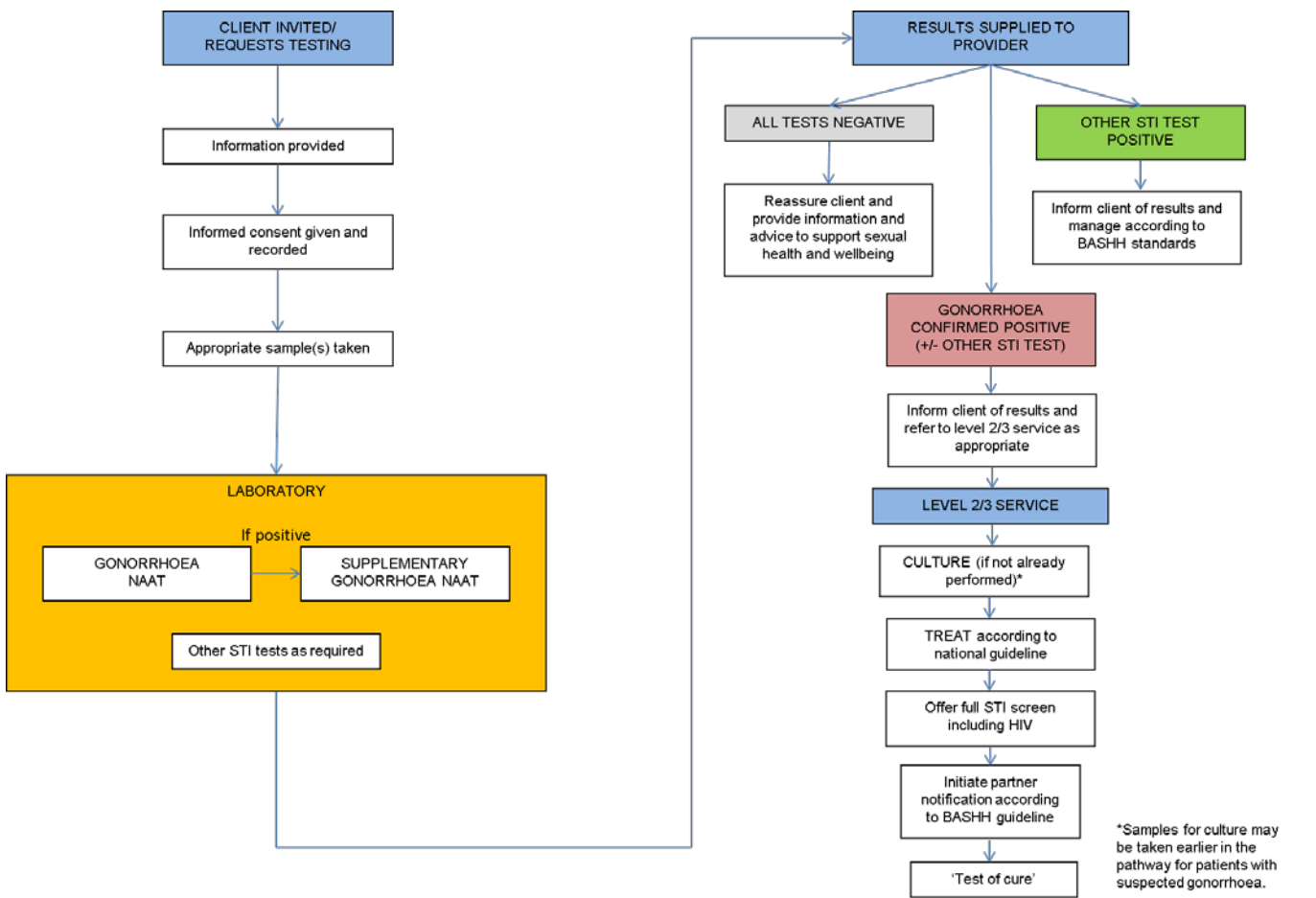
<https://www.gov.uk/government/publications/guidance-for-the-detection-of-gonorrhoea-in-england>

Section 3: Best practice for managing gonorrhoea testing

3.1 Care pathway

Any gonorrhoea-testing service should include a specific care pathway that sets out how to gain consent for the test, supplementary testing strategies, 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 3.

Box 3: Flow chart of best practice case management/patient pathway for gonorrhoea testing and case management



3.2 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.

It is best practice to provide written information, for example through patient information leaflets (PIL). Since gonorrhoea testing occurs in many different settings (including remotely 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 can be found here: <http://www.bashh.org/documents/4237.pdf>

3.3 Initial detection of gonorrhoea – specimens and type of test

The test used should be validated for the specimen type and sampling site (none of the commercial tests are approved for use on all sample types). Clinical pathology accreditation (which is currently being transferred to the United Kingdom Accreditation Service) requires that validation data are available and validation files are completed.²¹

There are a number of commercially available NAAT platforms with different nucleic acid targets and employing different amplification technologies (see Table). The sensitivity of these tests is high (>90%) for all specimens (endocervical swabs, self-taken vaginal swabs, urethral swabs and male urines), except for female urines, where the sensitivity can be as low as 30%.

²¹ Public Health England. (2014). Commercial and In-House Diagnostic Tests: Evaluations and Validations. UK Standards for Microbiology Investigations. Q 1 Issue 4.3. <https://www.gov.uk/government/publications/smi-q-1-commercial-and-in-house-diagnostic-tests-evaluations-and-validations>

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 in men who have sex with men and other high risk individuals. However, none of the commercial assays are approved for use at these anatomical sites and the test used should be validated to comply with any accreditation requirements.

Validation data are not available for samples taken from the conjunctiva.

Handling of the specimen

NAATs are extremely sensitive and will detect very small amounts of DNA or ribosomal RNA (rRNA). Note that detection of very small amounts of nucleic acid (DNA/rRNA) 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 rRNA 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.²²

3.4 Confirmation

Strictly, microbiological confirmation of gonorrhoea infection is only possible through culture and isolation of *N. gonorrhoeae* (see 3.5). However, culture has low sensitivity in comparison to NAATs and should not be considered as a first-line confirmation test, unless a culture-positive result is already available. Instead, supplementary testing using a second NAAT performed on the same sample, but which detects a different nucleic acid target, is recommended to reduce the risk of false positive test results. 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.

When to use supplementary testing

Testing algorithms should give a minimum PPV of 90% within the local setting or population group to minimise the proportion of false positives. In almost all cases, even in settings where prevalence exceeds 1% (as in many GUM clinics), it will be necessary

²² Ng LK, Martin IE. The laboratory diagnosis of *Neisseria gonorrhoeae*. *Can J Infect Dis Med Microbiol*. 2005 Jan;16(1):15-25.

to use a supplementary test to achieve an acceptable PPV (see Table). Where the PPV is greater than 90%, a supplementary test is not required. Section 2 provides more detail on estimating PPV to inform this decision.

For extra-genital specimens, cross-reactivity may occur with commensal neisseria species present at these sites, particularly in the pharynx. It is therefore essential that all initial positive test results from extra-genital specimens are confirmed by supplementary testing.

Methodology

Ideally the supplementary test will use the original patient sample. This avoids the need to take a further sample from the patient, reducing time to diagnosis and avoiding undue concern to the patient caused by being required to give a new sample.

Supplementary testing in most diagnostic laboratories is hampered by the lack of commercially available supplementary assays and difficulties in transferring clinical specimens between the different gonorrhoea NAAT platforms. A number of in-house tests have been published but only appear to be used by a few laboratories²³ and require validation and quality assurance to be in place. Caution needs to be taken in choosing a target for these tests following recent reports of *N. gonorrhoeae* which are negative for the *porA* pseudogene, which had previously been reported to be present in all isolates.^{24 25 26} Where supplementary testing is not available, residual clinical material may be sent to the reference laboratory for confirmation.²⁷

Issuing test results

Laboratories should only issue positive test results that are confirmed by supplementary testing or, for genital samples, where the PPV of the initial NAAT has been validated by the laboratory as being $\geq 90\%$.

²³ Toby M, Saunders P, Ison CA. Survey of the laboratory diagnosis of gonorrhoea and chlamydial infection in the UK (submitted).

²⁴ Whiley DM, Limnios A, Moon NJ, Gehrig N, Goire N, Hogan T, Lam A, Jacob K, Lambert SB, Nissen MD, Sloots TP. False-negative results using *Neisseria gonorrhoeae* *porA* pseudogene PCR - a clinical gonococcal isolate with an *N. meningitidis* *porA* sequence, Australia, March 2011. Euro Surveill. 2011 May 26;16(21). pii: 19874.

²⁵ Golparian D, Johansson E, Unemo M. Clinical *Neisseria gonorrhoeae* isolate with a *N. meningitidis* *porA* gene and no prolyliminopeptidase activity, Sweden, 2011 – danger of false-negative genetic and culture diagnostic results. Euro Surveill. 2012;17(9):pii=20102.

²⁶ Eastick K, Winter A, Jamdar S. Identification of *Neisseria gonorrhoeae* isolates with a recombinant *porA* gene in Scotland, United Kingdom, 2010 to 2011. Euro Surveill. 2012;17(9):pii=20101

²⁷ <https://www.gov.uk/stbru-reference-and-diagnostic-services>

Diagnostic samples should be processed promptly so that results can be conveyed in a timely fashion. Laboratories should provide final reports on supplementary testing to the clinician within 10 working days of the specimen being received.

A template service specification available on the website contains detailed requirements for supplementary testing for gonorrhoea:

<https://www.gov.uk/government/publications/guidance-for-the-detection-of-gonorrhoea-in-england>

3.5 Gonorrhoea culture for monitoring antimicrobial resistance (AMR)

Microbial culture is the process by which viable organisms are isolated from an infected patient and grown in a laboratory for identification and antimicrobial sensitivity testing. Culture techniques require specialist knowledge and skills.²⁸

Although culture for *N. gonorrhoeae* is less sensitive than NAATs, it is still required to detect clinical isolates with reduced antimicrobial sensitivity to inform individual patient management (especially where treatment failure is suspected) and for national public health surveillance. Current commercially available NAATs do not detect AMR. 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 is not a suitable sample for culturing for gonorrhoea.²⁹

3.6 Treatment

In most cases, gonorrhoea treatment should not be commenced until the result has been confirmed. However, unnecessary delays to treatment should be avoided to prevent onward transmission.

Providers and commissioners need to be aware that guidelines may change rapidly in response to emerging antimicrobial resistance and it is their responsibility to ensure treatment reflects the most recent treatment guidelines. Clinicians treating a patient with gonorrhoea should follow the latest evidence-based guidelines developed by the

²⁸ United Kingdom National Guideline for Gonorrhoea Testing 2012. Clinical Effectiveness Group, British Association of Sexual Health and HIV. (<http://www.bashh.org/documents/4490.pdf>)

²⁹ Cook RL, Hutchison SL, Østergaard L, et al. Systematic review: non-invasive testing for Chlamydia trachomatis and Neisseria gonorrhoeae. *Ann Intern Med* 2005;142:914–25.

BASHH and the Royal College of General Practitioners.^{30 31}

If services are not able to treat in line with national guidelines they should refer to a specialist service.

3.7 Ongoing management

Ongoing management of patients diagnosed with gonorrhoea should follow BASHH guidelines. The key considerations are outlined below.

Test of cure

Resistance to current treatments is likely to emerge in due course. A test of cure (TOC) is recommended for all cases of gonorrhoea to monitor treatment failure. Where TOC is not possible for all patients, those with persisting symptoms, signs of pharyngeal infection, or who were not treated according to first-line recommendations, should be prioritised.

Patients with persisting symptoms should be tested with culture at least 72 hours after completion of therapy. Asymptomatic patients should be tested with NAATs, followed by culture if positive, at least two weeks after completion of therapy.

Treatment failure

Any suspected cases of treatment failure should be reported to PHE using this link: <https://www.gov.uk/government/publications/reporting-gonorrhoea-treatment-failure>

Partner notification

Partner notification should be undertaken in all patients diagnosed with confirmed gonorrhoea, preferably by a trained health adviser in GUM. Male patients with symptomatic urethral infection should notify all partners with whom they had sexual contact within the preceding two weeks or their most recent partner. Patients with infection at other sites or asymptomatic infection should notify all partners within the preceding three months. Sexual partners should be offered testing (including culture) and treated epidemiologically for gonorrhoea.

³⁰ Bignell C, FitzGerald M; Guideline Development Group; British Association for Sexual Health and HIV UK. UK national guideline for the management of gonorrhoea in adults, 2011. Int J STD AIDS. 2011 Oct;22(10):5417.

<http://www.bashh.org/documents/3920.pdf>

³¹ Sexually Transmitted Infections in Primary Care 2013 (RCGP/BASHH) by Lazaro N. available at www.rcgp.org and www.bashh.org/guidelines

Full STI screen including HIV

Patients diagnosed with gonorrhoea are at high risk of other STIs and should be offered a full STI screen – including tests for syphilis and HIV (and chlamydia if not already performed). Patients diagnosed with gonorrhoea also require detailed assessment of future risk of repeat infection and other STIs (including HIV) and should be offered appropriate advice on risk reduction according to BASHH guidelines.³²

Referral for ongoing management

Where a service is not able to (i) confirm an initial positive test result, (ii) treat in line with current guidelines, (iii) offer further STI testing, or (iv) offer partner notification, patients should be referred to a specialist service for further management. This will usually be a GUM clinic, but may be a level 2 sexual health service (see Glossary for definition). If there is concern that referral risks the patient not receiving treatment, ie due to non-attendance, then the primary service should make every effort to treat the patient according to national treatment guidelines.

Where level 2 services manage gonorrhoea cases they are strongly advised to develop a close working relationship with the local GUM service, to provide clinical oversight and specialist advice as required.

Robust care pathways need to be in place for those with an initial positive test result to ensure prompt confirmatory testing, treatment and further management wherever possible. The referring service should actively follow up referred patients to ensure successful transfer of care.

³² Bignell C, FitzGerald M; Guideline Development Group; British Association for Sexual Health and HIV UK. UK national guideline for the management of gonorrhoea in adults, 2011. *Int J STD AIDS*. 2011 Oct;22(10):541-7. <http://www.bashh.org/documents/3920.pdf>

Section 4: Reporting data for public health surveillance

Public health surveillance data are collected and analysed to monitor trends in STI diagnoses and other sexual health problems and 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 level 2 commissioned sexual health services and level 3 specialist sexual health and HIV (or GUM) services (see Glossary for definition) are required to report data on all STI tests and diagnoses, including those for gonorrhoea, through the Genitourinary Medicine Clinic Activity Dataset (version 2 – GUMCADv2) to PHE.^{33 34}

Testing activity and diagnoses made through any testing service that does not submit data through GUMCADv2, eg community pharmacy, internet testing etc, will not be captured through national surveillance data collection unless patients are referred to a level 2 or level 3 service for ongoing management.

Commissioners' starter packs and guidance for providers for submitting GUMCADv2 are available here: <https://www.gov.uk/genitourinary-medicine-clinic-activity-dataset-gumcadv2>

³³ Standards for the management of sexually transmitted infections (STIs).MEDFASH and BASHH. January 2014.
<http://www.medfash.org.uk/standards-for-the-management-of-stis>

³⁴ Sexual health commissioning. Frequently asked questions. Local Government Association, February 2013.
http://www.local.gov.uk/c/document_library/get_file?uuid=de86daf2-19e3-42f4-95c8-29bb6cc80a65&groupId=10180

Section 5: Glossary of terms

BASHH	British Association for Sexual Health and HIV. A professional organisation for those working in sexual health. It produces guidance on best clinical practice.
<i>Chlamydia trachomatis</i>	The sexually transmitted bacterium that causes chlamydial infection, also known as chlamydia.
Confirmation	The process through which an initial screening test result is confirmed. Strictly microbiological confirmation of gonorrhoea requires culture but a supplementary NAAT test using a different nucleic acid target (ideally on the same sample) is usually acceptable as confirmation.
Culture	The process by which viable organisms are isolated from an infected patient and grown in a laboratory for further testing.
DNA/RNA	Deoxy-/ribonucleic acid (DNA/RNA) are molecules that encode the genetic instructions of all known living organisms. Dual NAATs identify pathogen-specific DNA/RNA targets to detect the presence of chlamydial and gonococcal infection.
Dual NAAT/Dual testing	Where testing for two different pathogens is carried out simultaneously on the same sample using a single assay. In this guidance it refers to testing for both chlamydia and gonorrhoea.
False negative	A test for an infection or disease is negative, but the patient does have that infection/disease.
False positive	A test for an infection or disease is positive but the patient does not have that infection/disease.
Incidence	The rate at which new cases of infection/disease occur within a specified period. Incidence is expressed as a proportion of the number of people at risk of the infection/disease in the population during that time period.
Initial positive test result	A positive test result from the initial gonorrhoea NAAT (sometimes known as a reactive test result) prior to any supplementary testing. An initial positive test result may not be confirmed as a true positive.

Level 1, 2 and 3 sexual health services	Three levels of care for the management of STIs - level 1 (asymptomatic), 2 (symptomatic) and 3 (complex/specialist). The levels were originally proposed in The National Strategy for Sexual Health and HIV (2001) to assist the commissioning process by indicating the elements of care that could be delivered by a range of providers in any setting. Only a service led by a consultant on the specialist register of the General Medical Council for Genitourinary Medicine (GUM) and offering a comprehensive range of STI services spanning all three levels can be defined as being a specialist GUM service (level 3) for the management of STIs. ³⁵
Misdiagnosis	An incorrect diagnosis. This may result in treatment or other care steps being carried out unnecessarily or missed. Misdiagnosis may occur following false positive or negative test results.
NAAT	Nucleic acid amplification test. A molecular test that detects the presence of genetic material (nucleic acid) for a particular pathogen in a clinical sample.
NCSP	National Chlamydia Screening Programme. A national public health programme that seeks to improve sexual health by encouraging screening of asymptomatic 16-24 year olds for chlamydia.
<i>Neisseria gonorrhoeae</i>	The sexually transmitted bacterium that causes gonococcal infection, also known as gonorrhoea.
NPV	Negative Predictive Value. The proportion of negative test results where the person tested has the infection/disease. It is usually expressed as a percentage.
PHE	Public Health England. An executive agency of the Department of Health. PHE provides expertise and advice to the NHS, local authorities and government.
PPV	Positive Predictive Value. The proportion of positive test results where the person tested has the infection/disease. It is usually expressed as a percentage.
Prevalence	The proportion of a population that are cases for an infection or disease at a fixed point in time. Prevalence is the number of people with the infection/disease expressed as a proportion of the population.
Sensitivity	The ability of a test to identify true positives. It is usually expressed as a percentage.
Specificity	The ability of a test to identify true negatives. It is usually expressed as a percentage.

³⁵ Standards for the management of sexually transmitted infections (STIs).MEDFASH and BASHH. January 2014.
<http://www.medfash.org.uk/standards-for-the-management-of-stis>

<p>Supplementary test</p>	<p>A second test done to confirm a diagnosis of infection/disease in an individual. For gonorrhoea testing, a supplementary test usually involves a second NAAT using a different nucleic acid target on the same sample, although different samples can also be used. Although supplementary testing reduces the risk of false positive results, it does not guarantee the final result is correct.</p>
<p>Test of cure</p>	<p>A test to confirm the absence of the original infection. Persistent infection may be due to reinfection or treatment failure.</p>
<p>True negative</p>	<p>A negative test result for infection/disease, where the patient does not have that infection/disease.</p>
<p>True positive</p>	<p>A positive test result for infection/disease, where the patient does have that infection/disease.</p>

Section 6: Additional supporting materials

Additional documentation that commissioners, providers and public health services may find helpful in implementing this guidance can be found at:

<https://www.gov.uk/government/publications/guidance-for-the-detection-of-gonorrhoea-in-england>

Table: Summary of commercially available FDA-approved gonorrhoea NAAT platforms

		Aptima Combo 2 [AC2] (Hologic)	Cobas Amplicor (Roche)	Probetec GC Qx Amplified DNA Assay (Becton Dickinson)	RealTime CT/NG (Abbott)
Target		16S rRNA	DR-9	Pillin	Opa gene
Amplification Technology		Transcription Mediated Amplification (TMA)	Real-Time PCR	Strand Displacement Amplification (SDA)	Real-time PCR
Sensitivity*		96.5% ⁺	100% [§]	99.3% [‡]	97.5% [!]
Specificity*		99.4% ⁺	99.8% [§]	99.3% [‡]	99.7% [!]
Positive predictive value[^]	0.1% Prevalence	13.9%	33.4%	12.4%	24.5%
	1% Prevalence	61.9%	83.5%	58.9%	76.7%
Alternative GC Assay and Assay Target		GC 16S rRNA (different region to the AC2)	Not applicable	Not applicable	Not applicable
Reported cross reaction with other <i>Neisseria</i> species[#]		None reported	None reported	Potential cross reaction with <i>N. cinerea</i> & <i>N. lactamica</i> . However this has not yet been reported *	None reported
Manufacturer approved specimen types		<ul style="list-style-type: none"> • PreservCyt liquid Pap specimens • Vaginal swabs • Cervical swabs • Urethral swabs (male) • Urine (male and female) 	<ul style="list-style-type: none"> • Cervical swabs • Vaginal swabs • Urine (male and female) • PreservCyt liquid Pap specimens 	<ul style="list-style-type: none"> • PreservCyt liquid Pap specimens • Cervical swabs • Urethral swabs (male) • Urine (male and female) • Vaginal swabs 	<ul style="list-style-type: none"> • Cervical swabs • Urethral swabs (male) • Urine (male and female) • Vaginal swabs

* As defined by the product insert: A combined figure for all validated specimen sites unless otherwise stated. Note that definition of patient infected status differs between inserts. See individual inserts for details.

⁺ The Aptima Combo Two data is based on the figure for a combined figure for all urine specimens (See table 9a, p57: <http://www.hologic.com/products/clinical-diagnostics-blood-screening/assays-and-tests/aptima-combo-2-ctng-assay>)

[§] Calculated from data presented in product insert when testing urine specimens (See table 6, p39: <https://dialog.roche.com/web/gb/elabdoc>)

[‡] Taken from data presented in product insert when testing a range of specimen types (See table 9A, p19: <http://moleculardiagnosics.bd.com/product/viperxtr/>)

[!] Data taken directly from kit insert of overall test performance when testing a range of specimen types (See page 6 text:

http://www.abbottmolecular.com/static/cms_workspace/pdfs/US/CTNG_8L07-91_US_FINAL.pdf)

[^] All PPVs are calculated from the sensitivity and specificity values presented in the package inserts. Note these data were not generated in a head to head evaluation of the different testing platforms and are consequently not intended to be used to compare the performance of the different platforms but merely to illustrate the influence of using each of the tests in low prevalence settings.

[#] Note that the cross reactivity of these tests with closely related *Neisseria* specie has only been demonstrated in analytical studies when presented with bacterial isolates.