Nucleic Acid Amplification Tests

Guidance on the use of the new Nucleic Acid Amplification Tests (NAATs) for joint Neisseria gonorrhoeae and Chlamydia trachomatis testing in the community

**Summary points:**

- There are multiple advantages to having gonococcal NAATs (as already exists for Chlamydia testing): improved sensitivity, the utilising of non-invasive samples and reduced storage and transport requirements.

- In Lothian, the lab will use a combined NAAT platform for testing for Chlamydia and Gonorrhoea. **THIS MEANS IN PRACTICE THAT ALL SAMPLES SENT TO THE LAB FOR CHLAMYDIA TESTING WILL ALSO BE TESTED FOR GONORRHOEA AND VICE VERSA** – this will happen even if the clinician taking the sample has not specifically requested the additional test.

- The only exception to this rule is the Chlamydia Postal Testing Kits (PTKs), which will continue to be tested for Chlamydia alone.

- The recommended sample for the dual Chlamydia and Gonorrhoea NAAT test is a first voided urine (FVU) sample for men and a self or clinician-taken vaginal sample for women. A clinician-taken cervical sample is also acceptable for women.

- **Please note that urine samples are suboptimal in women for Gonorrhoea NAAT testing due to decreased sensitivity.**

- The specific sample containers provided should be used for the transport of all swabs. A ‘universal container’ should be used for the transport of the first voided urine samples.

- All patients at high risk (e.g. sexual contacts), or diagnosed with gonorrhoea on NAAT testing should preferably be referred to Chalmers (Triage 0131 536 1070, then 9 for professional calls) for further management (including performance of culture tests for antibiotic sensitivities, comprehensive sexual risk assessment, full STI screening, treatment and partner notification). If a patient declines attendance at Chalmers, we would be very happy to offer telephone advice on further management (triage 0131-536 1070, then press ‘9’). Treatment is now with im ceftriaxone 500mg (from 2011), another reason to refer.

- Patients positive for Chlamydia alone can continue to be managed as before in the community (with advice from the specialist services if required).
Background to and benefits of GC NAATS:
Across the UK there is now a move towards introducing Nucleic Acid Amplification testing for Gonorrhoea. Nucleic Acid Amplification testing (NAAT) carries some significant benefits over culture for gonococcal testing:

- Improved sensitivity.
- Reduced requirements in terms of sample storage and transport: samples no longer need to be incubated or reach the lab within 24-hours (previously required to ensure organism viability for culture).
- Can utilise non-invasive and self-taken samples: with NAAT testing, men can provide a first void urine sample, and women a self (or clinician) taken blind vaginal swab (though cervical samples are still suitable if speculum examination is being performed). **Please note that most gonococcal NAAT platforms have lower sensitivity for urine samples from women and these are therefore not recommended.**
- Faster turn-around of tests in the labs with faster availability of results to clinicians.
- A single sample from an individual can be utilised for both Chlamydia and Gonorrhoea NAAT testing.

**Drawbacks of GC NAATS:**
As well as benefits, there are also potential drawbacks to GC NAATS. These include:

- GC NAATS do not provide organism antibiotic sensitivities. Thus, it is recommended that culture samples are also performed in all patients with suspected/ proven gonorrhoea (e.g. attending with symptoms, attending as a contact, positive on microscopy or positive on NAATs) **prior to initiating antibiotic therapy.** This is more difficult to perform in the community and these patients should therefore, as a general rule, be referred to Chalmers Sexual Health for this. **IN ADDITION, RECOMMENDED TREATMENT IS NOW IM CEFTRIAXONE 500MG, AGAIN BETTER GIVEN IN A SPECIALIST SETTING.**
  - Due to the high sensitivity of all NAAT testing, extra care must be taken in both the clinical and lab settings to prevent contamination of samples (and thus false positive results).
  - There is minimal data on the use of GC NAATS on specimen types such as eye swabs, or those taken in suspected disseminated infection (blood, joint fluid, skin vesicle fluid). These complex patients should usually be referred on to the specialist sexual health services rather than managed in the community.

**How to test:**
In Lothian, along with the majority of the UK, we plan to combine Chlamydia and Gonorrhoea NAAT testing in the lab: called ‘dual testing’. **Thus, any samples in Lothian sent for Chlamydia testing will also be tested for Gonorrhoea, and vice versa. The only exception to this will be the Chlamydia Postal Testing Kits (PTKs), which the Laboratory will continue to test for Chlamydia only.**

As discussed above, the sample of choice for combined NAAT testing is urine for men and vaginal (or cervical) samples for women. Urine samples are not recommended for women. The new NAAT sample containers provided should be used for the storage and transport of all swabs (instructions provided in the kit), while ‘universal containers’ can be used for transport of urine samples.
Who to test:

On a population level Gonorrhoea is generally restricted to some high risk populations: young adults (under-25s), black ethnicity and men who have sex with men (MSM). (For example, in Lothian in 2009, from over 1500 endocervical swabs sent to the lab from the community, there were only 10 culture proven Gonorrhoea diagnoses.) This makes it important that these new dual NAAT tests are targeted carefully, to prevent large numbers of tests being performed on low risk populations (resulting in a low positive predictive value for results and unnecessary expense for the laboratories).

So, outside a Sexual Health Clinic setting, who should you offer the new combined Chlamydia and GC NAAT testing to?

Patients who should definitely be tested include:

- Individuals with symptoms suggestive of Chlamydia or Gonorrhoea or their sequelae (e.g. PID, epididymo-orchitis)
- Individuals attending as contacts of either infection

You should also consider offering opportunistic testing to the groups below:

- Individuals with a previous diagnosis of either infection (especially within the preceding year)
- Young adults (under-25s)
- Men who have sex with men (MSM) – but please note that this patient group may also need sampling from pharyngeal and rectal sites, and additionally should routinely be tested for Syphilis, HIV and Hepatitis B. These tests can be done in general practice, but you may prefer to refer on to the local specialist Sexual Health Clinic.
- (Patients at risk on sexual history taking – 2 or more partners in preceding year)

Please do NOT do the dual NAAT test routinely in women >25 attending for a smear!

Note that the SIGN Guidelines on Chlamydia trachomatis gives further information on who to test for this infection (there is no SIGN guideline on Neisseria Gonorrhoea).
What to do with positive NAAT results:

If positive only for Chlamydia:

- Continue to manage these patients as before in the community: i.e. treat and perform partner notification.
- Consider offering these patients retesting at an interval of about 3-6 months, as these patients are at high risk of re-infection.

  You can contact Chalmers (0131-536 1070, then '9') if you wish for advice on the above. Chalmers also now offers a 48hr turnaround clinical e-mail advice service for queries at Chalmers.ClinicalAdv@nhslothian.scot.nhs.uk). **NOTE that the SIGN Guidelines on Chlamydia trachomatis gives further information on how to manage positive patients.**

If positive for gonorrhoea (alone or in combination with Chlamydia):

- Please refer these patients directly to Chalmers for the performance of culture testing (for antibiotic sensitivities) prior to treatment. They also require NAAT testing from other potential sites of infection. In addition, these patients are usually at higher risk of other STIs (including HIV), and require comprehensive sexual risk assessment and STI screening. They also require more rigorous partner notification.
- If the patient declines attendance at the specialist services, we would be very happy still offer telephone advice on further management.

Imali Fernando,
GUM Consultant,
Chalmers Sexual Health Centre,
Edinburgh

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