



Public Health
England

Use of dual nucleic acid amplification tests for chlamydia and gonorrhoea on samples collected for the National Chlamydia Screening Programme:

Results from a national survey of local
authority commissioners

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Executive summary

- this report summarises findings from a national survey of Local Authorities (LAs) in England undertaken in 2013 to understand the use of nucleic acid amplification tests (NAATs) which simultaneously detect both chlamydia and gonorrhoea (hereafter referred to as 'dual NAATs') on samples collected for chlamydia screening by the National Chlamydia Screening Programme (NCSP)
- an online questionnaire was delivered to commissioners of sexual health services, who were responsible for commissioning chlamydia screening in young people aged 15-24 years in the 152 local authorities (LA) in England;
- the aim of the survey was to:
 - understand the proportion of LAs currently commissioning the use of dual NAATs on samples collected for chlamydia screening by the NCSP
 - map the microbiological and clinical pathways used when gonorrhoea is identified through dual screening, including confirmation of diagnoses
 - provide an evidence base for clear and workable guidance to LA commissioners, clinicians and other decision-makers to ensure that the use of dual NAATs is clinically and ethically appropriate, and cost efficient
- 64% (98/152) of LAs responded to the survey, with no significant differences found between those responding and not responding
- 53% (52/98) of LAs reported currently using dual NAATs; gonorrhoea diagnosis rates based on genitourinary medicine (GUM) clinic data were significantly higher among LAs reporting use of dual NAATs
- where gonorrhoea screening was occurring alongside chlamydia screening, it was found:
 - the consent process for gonorrhoea was generally less clear than for chlamydia, with patients not always being informed that their sample would be tested for both infections
 - considerable variation in clinical pathways used to manage gonorrhoea
 - supplementary testing (using a second assay with a different nucleic acid target) is recommended, but was not universally delivered
 - patients were sometimes notified of the initial screening results, either prior to supplementary tests being performed or where no such tests were carried out, which increases the risk that false positive results are returned to patients, who may be given antibiotics and whose partners may be notified unnecessarily
- the British Society for Sexual Health and HIV (BASHH) treatment guidelines for gonorrhoea were followed in just over half of LAs where the NCSP-affiliated service provided treatment
- antimicrobials not recommended by BASHH are less likely to be effective and might result in selection pressures leading to antimicrobial resistance (AMR)

most LA commissioners received data about gonorrhoea diagnoses made through their local NCSP

- NCSP providers submitted gonorrhoea diagnoses to the national surveillance database for only half of LAs

Recommendations This survey found that use of dual NAATs on samples collected for chlamydia screening by the NCSP is already widespread, with the result that gonorrhoea screening is occurring alongside chlamydia screening in many areas in England. This has been introduced without any change in NCSP policy, nor any evidence that gonorrhoea screening is necessary or cost effective. There are no structured, systematic clinical and procedural arrangements in place to manage gonorrhoea screening of samples collected by the NCSP.

While gonorrhoea testing guidance maintains that there is no evidence to support widespread unselected screening for gonorrhoea in the UK, in practice it may be difficult to reverse the trend for using dual NAATs. To mitigate the potential harms associated with use of dual NAATs in low prevalence settings, the following public health messages should be emphasised to any LAs using or considering use of dual NAATs for asymptomatic, community-based screening:

- wherever dual NAATs are used for community-based screening, patients should be provided with appropriate information about gonorrhoea screening (in addition to chlamydia screening) to help ensure that testing is only performed with informed consent
- where the initial screening test is positive for gonorrhoea in low prevalence settings (as is likely to be the case for most community-based screening), a supplementary test, using a second assay with a different nucleic acid target, should be used on the same sample to prevent false positive results
- return of results, treatment and partner notification should only be undertaken following confirmation of gonorrhoea
- patients with confirmed gonorrhoea should be referred to level two or three sexual health services for further management
- clearly defined clinical pathways are required and should be followed to ensure the best care for patients and their partners
- data on gonorrhoea diagnoses should be reported through national surveillance systems (GUMCADv2) wherever possible so that national trends can be monitored
- national gonorrhoea testing guidance has been revised to inform and support commissioners of sexual health services in making decisions about use of dual NAATs

Introduction

The NCSP is a large national public health intervention designed to improve sexual health in young people in England. The programme offers sexually active, asymptomatic women and men, aged 15-24 years opportunistic screening to diagnose and control *Chlamydia trachomatis* (chlamydia) infection.¹ Testing for chlamydia, including through the NCSP, is undertaken using highly sensitive and specific NAATs. Technological advancements in NAATs make it possible and inexpensive to simultaneously test for *Neisseria gonorrhoeae* (gonorrhoea) alongside chlamydia in a single assay – called combined or ‘dual NAATs’.

Like chlamydia, gonorrhoea is a sexually transmitted infection (STI) primarily causing uncomplicated lower genital tract infection, which may lead to complicated or systemic infection in some cases. Unlike chlamydia, the prevalence of gonorrhoea is very low in the general population, instead being concentrated in specific groups: GUM attendees, men who have sex with men, black Caribbeans, and in some regions where outbreaks have occurred among young heterosexuals with high rates of partner change.² Screening of asymptomatic individuals in low risk populations with low gonorrhoea prevalence, and the potential for cross-reaction with non-gonococcal neisseria species,³ can result in high rates of false positive results, even when using highly sensitive and specific NAATs. False positive results may lead to incorrect and stigmatising diagnoses, partner notification, unnecessary use of antibiotics, and avoidable expense. Revised guidance from PHE, the British Society for Sexual Health and HIV (BASHH) and the Royal College of Pathologists (RCPATH), accepted by the NCSP, states that while testing for gonorrhoea is strongly recommended within specialist sexual health clinics targeting higher risk populations there is no evidence to support widespread unselected screening for gonorrhoea, and only sparse evidence for selective community screening in the UK.⁴ If screening is undertaken, the guidance recommends the positive predictive value (PPV) of the testing algorithm should be at least 90%, usually requiring supplementary testing using a second NAAT with a different nucleic acid target on the same sample.⁴

A survey of English laboratories in 2007 found that 29% of laboratories responding to the survey were already routinely using dual NAATs for chlamydia and gonorrhoea.⁵ A recent update of this survey suggests this proportion has increased (Ison, pers. comm.). However, the extent to which dual NAATs are used on samples collected by the NCSP for chlamydia screening, where gonorrhoea prevalence is likely to be low, is not known.

Aim

A survey was undertaken of LA sexual health commissioners to:

- understand the proportion of LAs currently commissioning the use of dual tests for chlamydia screening on samples collected by the NCSP
- map the microbiological and clinical pathways used to screen, confirm and manage patients diagnosed with gonorrhoea identified through the use of dual NAATs
- provide an evidence base for clear and workable guidance to LA commissioners, clinicians, and other decision-makers about the use of dual NAATs

Methods

During May to July 2013, an online questionnaire was delivered to commissioners of sexual health services in the 152 LA areas in England who were responsible for commissioning chlamydia screening in young people aged 15-24 years.

Questionnaire development

The questionnaire was deployed through the PHE web-based survey tool, 'Select Survey'. Such web-based surveys are easy to use and tend to maximise the number of respondents.⁶ The survey used adaptive questioning so that all participants completed basic information, with subsequent questions determined by their initial answers. Respondents who reported never commissioning dual NAATs went straight to a conclusion page, which provided an opportunity to give feedback as free-text comments. Respondents who currently or had previously commissioned dual NAATs were asked further questions.

The questionnaire was developed through an iterative process. Key areas were developed by consensus within the project team. These were: (1) service setting and sample types, (2) use of dual NAATs, (3) confirmation using supplementary NAAT tests^{*} and use of gonorrhoea culture, (4) patient information and consent processes, (5) clinical pathways for screening and management of gonorrhoea, (6) data management and surveillance, and (7) contractual arrangements and costs associated with use of dual NAATs. Specific questions were developed from these themes. Closed questions were used, with dropdown menus for local authority and laboratory names, to increase data quality. The questionnaire was initially screened by PHE staff members to test usability, understanding, clarity, and question flow. It was then tested by the eight NCSP sexual health facilitators (SHFs), who were asked to comment on clarity, content, and

^{*} Although true confirmation requires culture to identify *Neisseria gonorrhoea*, the survey questionnaire gave the following pragmatic definition for a 'confirmation test': 'a second test used to confirm the diagnosis of gonorrhoea where the initial screening test is positive for gonorrhoea.'

wording. The questionnaire was put into an online webpage format and piloted with commissioners in one area. The final questionnaire consisted of 29 questions and took approximately 20 minutes to complete (Appendix 1).

Sampling and recruitment

The sampling frame for this survey was the 152 upper tier LAs in England. Each of the NCSP SHFs wrote by email to their contact list of LA sexual health commissioners, which covered the whole of England. This email introduced and briefly explained the project and provided a web link to the survey. The survey was advertised in the quarterly NCSP newsletter (including the weblink). SHFs also wrote individually to commissioners not responding within three weeks to remind them of the survey, and contacted commissioners who they believed not to be using dual NAATs to ensure that this group was not under represented.

Data handling and statistical analysis

The survey data were extracted to Microsoft Excel and a descriptive analysis was undertaken to understand the proportion of respondents reporting each outcome. Using Stata (version 12.1), independent samples t-tests compared area-level characteristics between LA responders and non-responders and between LAs using dual NAATs and those not using dual NAATs. In some instances, more than one person responded for the same LA; where there were inconsistencies between answers or for other reasons, individual respondents were contacted to check the correct response. For descriptive analyses of the survey data, the denominator throughout the analysis is the number of LAs. Where an answer was missing, the LA was generally excluded from the denominator and the denominator therefore varies according to item non-response.

This work was undertaken as a service evaluation project, with data collected and held within the requirements of the data protection act and in accordance with PHE data sharing best practice.

Results

Survey response

Survey response was good; 64% (98/152) of LAs responded to the survey and stated whether or not they used dual NAATs (Figure 1). Although response varied by PHE centre area, the proportion of LAs responding was at least 50% in all but one area, suggesting good geographical coverage (Figure 1). The area-level characteristics of responding and non-responding LAs were compared (Table 1) and no significant differences were found in gonorrhoea diagnosis rates (estimated from diagnoses made in GUM clinics), area-level deprivation (index of multiple deprivation (IMD)),⁷ NCSP chlamydia positivity, chlamydia diagnosis rates, coverage, or service type (Table 1). From the data available, there was no evidence of participation bias.

Figure 1. Survey response showing the proportion of LAs responding in each PHE centre area (n=152)

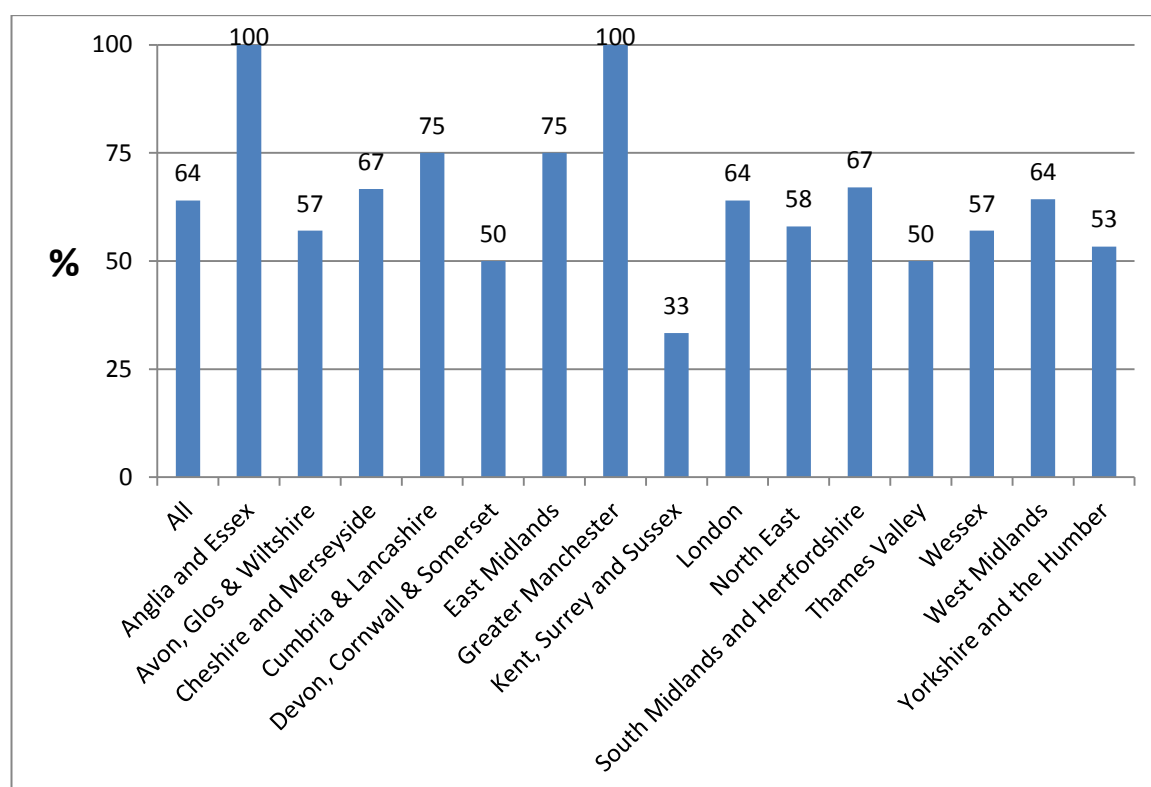


Table 1. Comparison of area-level characteristics between LAs responding and not responding to the web survey¹

	Number of LAs	Mean chlamydia diagnosis rate / 100,000 ²	Mean NCSP coverage ³	Mean gonorrhoea rate (GUM) / 100,000 ⁴
Responders	98	2151.9	27.3%	42.9
Non-responders	54	1869.8	24.2%	38.9
<i>p-value difference</i>	-	0.06	0.06	0.68

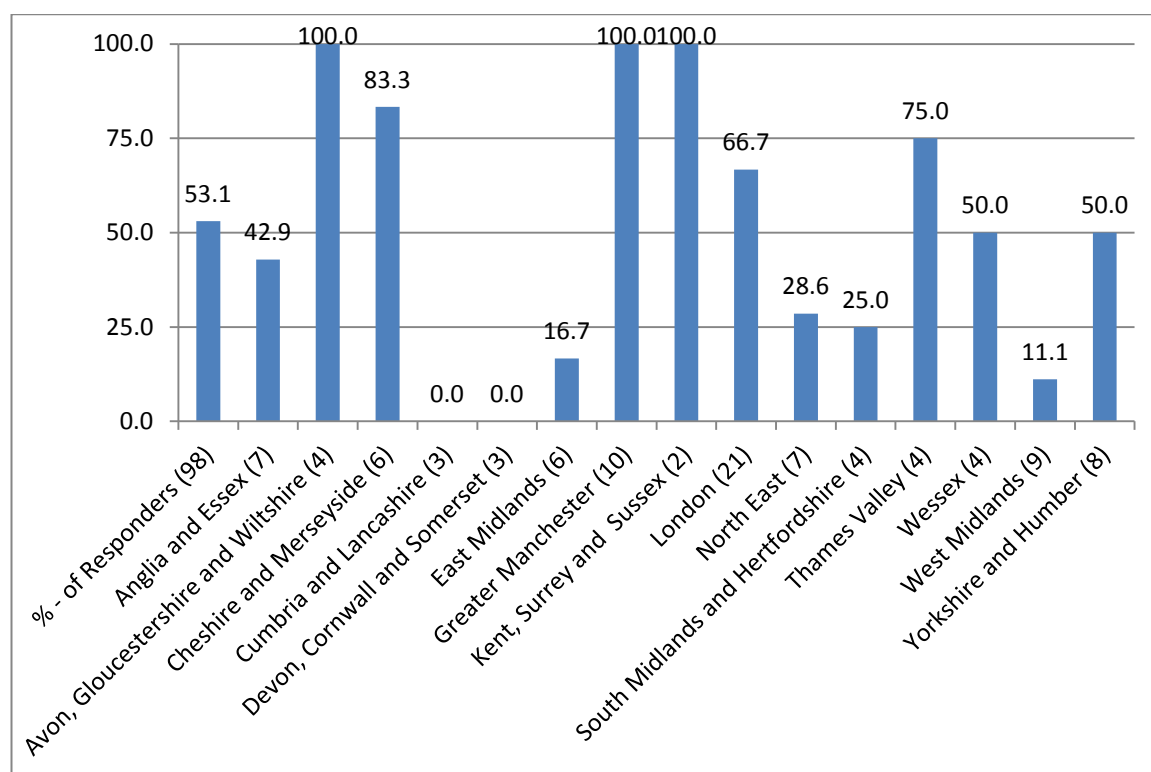
1. In addition, no significant difference was found by NCSP chlamydia positivity rate ($p=0.63$), service type (the proportion of NCSP services provided by GUM, primary care, or Sexual and Reproductive Health (SRH) in 2012) ($p=0.54$), or LA IMD ($p=0.89$)
2. Chlamydia diagnosis rates (per 100,000 population) include diagnoses made in community-based and GUM settings collected through the Chlamydia Test Activity Dataset (CTAD) and the GUM Clinic Activity Dataset (GUMCAD)
3. Chlamydia testing coverage includes tests done in community-based and GUM settings collected through CTAD and the GUMCAD
4. Gonorrhoea diagnoses (per 100,000 population) include diagnoses made in GUM clinics collected through GUMCAD.

Use of dual NAATs on NCSP samples

Over half (53% (52/98)) of LAs reported currently using dual NAATs on NCSP samples, 45% (44/98) reported never using dual NAATs, and 2% (2/98) reported previously using dual NAATs or did not know. Figure 1 shows that the proportion of LAs in each PHE centre area reporting current use of dual NAATs showed substantial geographical variation, with 100% of LAs using dual NAATs in some areas (Avon, Gloucestershire, and Wiltshire, Greater Manchester, and Kent, Surrey and Sussex) and no LAs using dual NAATs in two areas (Cumbria and Lancashire, and Devon, Cornwall and Somerset).

Comparing LAs by whether or not they reported current use of dual NAATs, there was no significant difference in IMD, NCSP chlamydia positivity, chlamydia diagnosis rate or coverage (Table 1). However, mean gonorrhoea diagnosis rates (estimated from diagnoses made in GUM clinics) were higher ($p=0.03$) and a higher proportion of services were provided by community sexual health services (CSHS) in LAs using dual NAATs on NCSP samples ($p<0.1$) (Table 1).

Figure 2. Proportion of LAs using dual NAATs on NCSP samples, by PHE centre area (n=98)



For 14% (7/52) of the LAs who reported using dual NAATs, no further answers were given to the survey and these LAs were excluded from further analyses.

LAs reporting use of dual NAATs on NCSP samples were asked in which settings this occurred. Dual NAATs were used in a wide range of venues across the country, including settings such as Contraception and Sexual Health and Sexual and Reproductive Health (CaSH/SRH) services (98% (44/45)) and primary care (91% (41/45)), as well as through remote testing by post or Internet (80% (36/45)) and termination of pregnancy (ToP) services (87% (39/45)) (Appendix 2). Most LAs reported using dual NAATs for samples collected in at least five different settings (82% (37/45)).

Respondents were asked to select their largest venue using dual NAATs as the setting to consider when answering the remaining questions in the survey. In 51% (23/45), this was CaSH/SRH, in 20% (9/45) this was primary care, in 13% (6/45) it was another setting and 16% (7/45) did not know the answer to this question.

Dual NAATs were used with all sample types, although less frequently with pharyngeal and rectal samples (24% (11/45)) and urethral samples (18% (8/45)) than with endocervical (56% (25/45)), urine (91% (41/45)) and vaginal samples (82% (37/45)) (Appendix 2).

Table 2. Comparison of area-level characteristics between LAs reporting current commissioning of dual NAATs and those not¹

	Number of LAs	Mean chlamydia diagnosis rate / 100,000 ²	Mean chlamydia testing coverage ³	Mean gonorrhoea diagnosis rate / 100,000 ⁴
Dual NAATs	52	2254.8	28.6%	52.7
No dual NAATs	46	2063.2	26.2%	32.4
<i>p-value difference</i>	-	<i>0.31</i>	<i>0.24</i>	<i>0.03</i>

1. No significant difference was found by NCSP chlamydia positivity rate ($p=0.93$), LA IMD ($p=0.88$), or the proportion of NCSP services provided by GUM or GP, but the proportion of services provided by CSHS was higher in those LAs using dual NAATs (19.4% vs 8.6%; ($p<0.01$))
2. Chlamydia diagnosis rates (per 100,000 population) include diagnoses made in community-based and GUM settings collected through the Chlamydia Test Activity Dataset (CTAD) and the GUM Clinic Activity Dataset (GUMCAD)
3. Chlamydia testing coverage includes tests done in community-based and GUM settings collected through CTAD and the GUM Clinic Activity Dataset (GUMCAD)
4. Gonorrhoea diagnoses (per 100,000 population) include diagnoses made in GUM clinics collected through GUMCAD

Patient information and consent

Informed consent is essential when undertaking clinical diagnostic tests and returning results to patients. The survey sought to understand whether and how patients were informed about, and consented to, gonorrhoea screening when undertaken alongside chlamydia screening. Overall, 36% (15/42) of LAs using dual NAATs provided gonorrhoea-specific patient information materials to patients, 45% (19/42) provided no gonorrhoea-specific information materials and 19% (8/42) did not know (Appendix 2). Of those LAs reporting no gonorrhoea-specific patient information materials, 84% (16/19) reported that gonorrhoea was discussed within their NCSP patient information leaflet, while only 5% (1/19) of these LAs provided no gonorrhoea information and 11% (2/19) did not know (Appendix 2). Informed consent for gonorrhoea testing was assumed on the basis that information was provided and the testing kit was returned in 71% (25/35) of LAs, and consent was taken in writing in 14% (5/35). Only 2% (1/52) of LAs reported that no informed consent was obtained for gonorrhoea testing, although this may underestimate the true proportion not obtaining consent, because 32% (17/52) of all LAs using dual NAATs did not answer this question and 4% (2/52) did not know whether consent was obtained.

Four LAs that included information on gonorrhoea in their NCSP leaflets uploaded copies of the documents to the survey website. Two leaflets were produced by NHS organisations and two by a third sector organisation (Terrence Higgins Trust). Three of the leaflets discussed chlamydia and gonorrhoea, and one leaflet discussed solely gonorrhoea. The leaflets mentioning both infections explained appropriately that testing with dual NAATs was performed on a single sample. Only one leaflet stated that gonorrhoea testing was optional and explained how to opt out.

Clinical care pathways

Of 52 LAs performing testing using dual NAATs, 41 provided sufficient information to understand their clinical care pathways in detail. Although confirmation testing[†] involving a supplementary test was used in 93% (38/41) of LAs, 63% (26/41) of LAs referred patients to higher level sexual health services on the basis of any initial reactive screening test results, 17% (7/41) referred only after supplementary testing, 15% (6/41) of LAs did not refer patients to another service (possibly because the initial service was level 2), and 10% (4/41) did not know when patients were referred in relation to the timing of supplementary testing. Where patients were referred, 8% (3/36) of LAs referred to level 2 sexual health services and the remaining LAs referred to Level 3 (GUM). Patients were informed of the initial reactive test result by the initial testing service prior to supplementary testing in 73% (29/40) of areas where confirmation was undertaken. Where patients were referred, the supplementary test results were provided to patients by the referral service for 75% (27/36) of LAs.

Partner notification was usually initiated by the referral service, with 60% (15/26) undertaking partner notification only after gonorrhoea was confirmed. This contrasts with LAs where the initial service provider undertook partner notification: 79% (11/14) initiated partner notification immediately following the initial reactive screening result.

Referral services performed treatment in 71% (29/41) of LAs. Treatment was delayed until the supplementary test result was known by 33% (4/12) of initial service providers and 52% (15/29) of referral services, but the difference was not significant. Seventy five per cent (9/12) of LAs where the initial service provided treatment reported on the treatment regimen used. All nine of these LAs prescribed combination treatment with azithromycin 1g; this was with intramuscular ceftriaxone 500mg in four cases, oral cefixime 400mg in another four cases, and with both ceftriaxone 500mg and doxycycline 100mg in the final LA.

[†] The survey provided the following definition for 'confirmation test': 'a second test used to confirm the diagnosis of gonorrhoea where the initial screening test is positive for gonorrhoea.' More complex definitions involving second DNA targets were thought not likely to be understood well.

LAs were assessed on whether they met three core criteria for using dual NAATs:

1. was a supplementary test performed?
2. were patients with gonorrhoea referred to level 2 or 3 sexual health services?
3. were the return of gonorrhoea results, treatment, and partner notification undertaken only after gonorrhoea was confirmed?

Overall, 12% (5/41) of LAs met all three criteria, 71% (29/41) met two criteria, 8% (3/41) met one criterion and 3% met none of the criteria. Eight per cent (3/41) provided insufficient data to fully assess the clinical pathways in this way.

Gonorrhoea data collection and reporting

For most LAs using dual NAATs their NCSP commissioners reported receiving data about gonorrhoea diagnoses (86% (36/42)), although 12% (5/42) received no data (Appendix 2). The survey asked whether gonorrhoea diagnoses made through NCSP services are submitted through the national STI reporting systems, called the genitourinary medicine clinic activity dataset (GUMCADv2). About half of LAs undertaking testing using dual NAATs reported that their NCSP gonorrhoea data are submitted to GUMCADv2 (52% (22/43)), 9% (4/43) did not submit data and 16% (7/43) did not know whether or not data were submitted (Appendix 2).

Costs of using dual NAATs

Commissioners were asked: 'Has the cost for your NCSP service changed due to the introduction of dual testing?' Seventeen per cent (7/42) reported that costs for their NCSP service had increased as a result of introducing dual NAATs, although most LAs (69% (29/42)) reported that costs had stayed the same and the remainder did not know (14% (6/42)) (Appendix 2). The survey also asked about the tariff for dual NAATs (if a fee per service or item was in place). However, item non-response was high for this question and the data are therefore difficult to interpret: 15% (8/52) reported paying less than £20 per dual test (the lowest price quoted was £7) and 4% (2/52) reported paying £20-59 per test, while the remaining LAs did not provide an answer.

Discussion

This is the first study to estimate the extent of testing using dual NAATs on samples collected for chlamydia screening by the NCSP. We found that just over half of LAs were already commissioning testing using dual NAATs, although it is likely that in many cases these arrangements will have been inherited by LAs from their predecessor Primary Care Trusts.

LAs which were using dual NAATs on NCSP samples were more likely to be areas with higher rates of gonorrhoea diagnosis made in GUM clinics. Whether this is an indication of evidence-based policy making, or whether the finding is associated with the introduction of dual NAATs in these areas, is not known. However, gonorrhoea rates have historically been high in these LAs, suggesting that some dual testing of NCSP samples may have been introduced to further improve case detection in areas with higher gonorrhoea prevalence.

Patient information material about gonorrhoea screening was provided (either specifically or as part of dual testing information) and consent was taken (implied, written or verbal) by at least 60% of LAs using dual NAATs. Although very few LAs reported not providing information or not taking informed consent, many of the remaining LAs did not answer or did not know the answer to these questions, suggesting that commissioners may not be including this level of detail in service specifications.

We found significant variation in care pathways between LAs, with 13 different pathways described by 41 LAs where data were available. In many LAs (73%), unconfirmed results were given to patients, and at least 4 LAs did not adhere to national guidance on first-line antimicrobial therapy for gonorrhoea. Three suggested standards for use of dual NAATs were adhered to by only 12% of LAs reporting clinical pathway data. These findings support the need for a standardised clinical pathway for use of dual NAATs.

Although data about gonorrhoea diagnoses made through testing of NCSP samples were received by commissioners in most LAs, providers submitted these data to national surveillance systems in less than half of LAs. There are currently limited data routinely available to monitor and evaluate the use of gonorrhoea screening in community-based settings, but this may improve as GUMCADv2 is rolled out across level 2 sexual health services.

Limitations

The survey response was high and similar across the geographical areas in England, and there was no evidence of participation bias associated with IMD or NCSP area-level

characteristics. It therefore seems reasonable to assume that the responding LAs are representative for England in their use of dual NAATs. However, the responses might be subject to reporting bias and were dependent on the respondents' full understanding of what was being asked, particularly where this required technical knowledge about molecular tests or clinical pathways. Most questions had item non-response rates of around 14%, which may reflect respondents' lack of understanding or knowledge about service specifications or a reluctance to answer questions that might reveal sub-optimal practice.

Use of dual NAATs in settings where gonorrhoea prevalence is low

Importance of supplementary testing

Overall, these data suggest that use of dual NAATs on samples collected by the NCSP is already widespread so that, in many areas, gonorrhoea screening is occurring through a programme that was only designed to diagnose and control chlamydia.

Gonorrhoea diagnoses were nearly ten fold lower than chlamydia diagnoses in England and Wales in 2012. Recent data from the third National Survey for Sexual Attitudes and Lifestyles (Natsal-3) shows that the weighted population prevalence of gonorrhoea was less than 0.1% among those aged 16-44 years, although the prevalence in community-based services, such as NCSP settings, is likely to be somewhat higher.^{8,9} Table 3 shows worked hypothetical examples of gonorrhoea screening in populations where the gonorrhoea prevalence is **0.1%** and **1.0%** using an assay with a sensitivity and specificity of **99%**. If prevalence is **0.1%**, this would result in the PPV being **9%** for an unconfirmed reactive screening test for gonorrhoea, equivalent to **91** unconfirmed gonorrhoea diagnoses for every **100** positive tests. A supplementary test would result in the PPV rising to **91%**. In fact, gonorrhoea prevalence needs to be greater than **8%** before the PPV reaches **90%** when using a single assay with 99% sensitivity and specificity. These data highlight the importance of adhering to testing guidance and using supplementary tests as part of the clinical diagnostic algorithm.^{3,10}

Table 3. Modelling the effect of prevalence on PPV and the number of false positives using a gonorrhoea test with 99% sensitivity and specificity

	Screening test PPV	No. patients with false +ve / 100 +ve tests	Supplementary test PPV	No. patients with false +ve / +ve 100 tests
Prevalence 0.1%	9%	91	91%	9
Prevalence 1.0%	50%	50	99%	1

Implications for patients

Where dual NAATs are used, it is important to mitigate the potential risks of screening for gonorrhoea. For example, there was considerable variation in the clinical pathways used to test patients and manage results, including that patients were sometimes notified of the initial screening results, either prior to supplementary tests being performed or where no supplementary tests were used. There were also several LAs where partner notification and treatment for gonorrhoea were based solely on the initial test results. Not undertaking supplementary testing and/or initiating treatment or partner notification prior to supplementary testing increases the risk of treating and managing patients on the basis of a false positive result, which may lead to harm and increase unnecessary antibiotic treatment, increasing risk of developing AMR.

A diagnosis of gonorrhoea may be highly stigmatising and might have considerable negative social and health consequences for patients and their partners. It is therefore important that patients are made aware that they are being tested for both infections. It is also important that the risk of gonorrhoea misdiagnosis is minimised, usually requiring supplementary testing. This survey found that patients were not always informed that their sample would be tested for both infections. Consent for both chlamydia and gonorrhoea screening should be obtained where dual testing is performed; assumed or opt-out consent may not be appropriate.

Gonorrhoea resistance

Over the last 50 years, *N. gonorrhoeae* has developed resistance to a wide range of antibiotic treatments in England and Wales. Treatment guidelines are based on known patterns of susceptibility and aim to reduce practices that increase the likelihood of resistance developing. In this survey, the treatment guideline (intramuscular ceftriaxone and oral azithromycin)¹¹ was followed in just over half of LAs where the initial service provided treatment. In the other LAs, cefixime/azithromycin combination treatment was used, which may reflect that cefixime can be administered orally and is therefore easier for patients to receive and practitioners to provide. However, cefixime is less likely to be effective and might result in selection pressures promoting AMR.¹²

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Appendix 1: dual testing survey

National Chlamydia Screening Programme – Chlamydia and Gonorrhoea Dual Testing survey

Introduction

National Chlamydia Screening Programme – Chlamydia and Gonorrhoea Dual Testing survey

Thank you for agreeing to participate in this survey, which we are asking all commissioners of sexual health services in England, including chlamydia testing programmes, to complete. It will take approximately 10-15 minutes. The survey will automatically save your responses, allowing you to complete the survey at a later time if necessary.

What is 'dual testing'?

The term 'dual testing', refers to the testing of two infections, chlamydia and gonorrhoea, at the same time using a single laboratory reaction. The survey is about 'dual testing' and gonorrhoea diagnosis in the NCSP (including chlamydia screening of 15-24 year olds which has been integrated into local services). We are not seeking information about GUM services.

What is the aim of the survey?

The data collected will be used to update current NCSP and other national guidelines on the use of 'dual testing':

[Link to BASHH guidance for gonorrhoea testing in England and Wales](#)

Please click next to begin the survey

Section A

This section asks some basic information about you and services in your area.

1. What is your job title/role?*

2. Which organisation do you work for?*

3. Which local authority areas do you cover?*

Please select each unitary/upper tier local authority you cover from the drop down menu. If you cover more than four local authorities, please enter the names of the other authorities in the comments box at the end of the survey.

	Local Authority 1	Local authority 2	Local authority 3	Local authority 4
Local authority	<div>-- Please Select --</div>	<div>-- Please Select --</div>	<div>-- Please Select --</div>	<div>-- Please Select --</div>

4 Please provide the names and locations of all the laboratories for your area that test chlamydia or 'dual testing' samples.*

. If a lab is not listed, please enter it in question 5.

	Lab 1	Lab 2	Lab 3
Laboratory	<div>-- Please Select --</div>	<div>-- Please Select --</div>	<div>-- Please Select --</div>

5. Please provide the names and locations of any laboratories for your area that were not included in question 4. Please include private laboratories, if applicable*

Please enter each lab name and location on a separate line

Lab 1 name

Lab 1 location

Lab 2 name

Lab 2 location

Lab 3 name

Lab 3 location

Lab 4 name

Lab 4 location

6. Has any 'dual testing', where samples are tested for chlamydia and gonorrhoea in the same reaction, been commissioned in your area outside of GUM clinic settings?*

- ☐ We currently commission 'dual testing' services
- ☐ We have previously commissioned 'dual testing' services but these have stopped
- ☐ We have never commissioned any 'dual testing' services

Please tell us the dates 'dual testing' ran between and briefly state why it was stopped. If you require more space please use the comments box at the end of the survey.

Section B

This section asks questions about some of the basic aspects of the service specification for 'dual testing' for chlamydia and gonorrhoea in settings outside of GUM clinics. If 'dual testing' is no longer commissioned in your area, please answer about the services that used to be commissioned.

7. In which settings does 'dual testing' for chlamydia and gonorrhoea currently occur (please select all that apply)?

Select at least 1.

- ☐ General Practice
- ☐ Pharmacy
- ☐ Termination of pregnancy services
- ☐ Contraception and Sexual Health /Sexual and Reproductive Health
- ☐ Remote (eg mailout, web based)
- ☐ Outreach/educational settings
- ☐ Other, please specify

8. **When responding to the remaining questions in this survey, we would like you to answer for the setting where the largest proportion of your 'dual testing' occurs.**

Please tell us the setting which undertakes the largest volume of 'dual testing' in your area (and therefore which the remaining questions relate to).

9. Please use the slider to indicate what percentage of your 'dual testing' occurs in the setting with the highest volume of testing?
This should be the same setting as for question 8.



10. What biological specimens are used for 'dual testing' (please select all that apply)?
Select at least 1.

- ☐ Urine
- ☐ Endocervical swab
- ☐ Urethral swab
- ☐ Vaginal swab
- ☐ Rectal swab
- ☐ Pharyngeal swab
- ☐ Don't know
- ☐ Other, please specify

11. How is consent taken for 'dual testing' ?

- ☐ A written consent form is required, which specifically mentions gonorrhoea testing
- ☐ People are informed that gonorrhoea testing will occur, and by completing and returning the test kit, it is assumed the patient has consented to gonorrhoea testing
- ☐ No specific consent for gonorrhoea testing is taken
- ☐ Other, please specify

12. Does the patient information leaflet that is provided to people undergoing 'dual testing' discuss gonorrhoea?

- ☐ Yes
- ☐ No
- ☐ Don't know

13. Select file to upload:
(click "Browse" button below to locate file)

File size restricted to: 4194304 KB

File type restricted to: no file type restrictions

File name: (limit 255 characters)

File description: (limit 255 characters)

Files uploaded:

14. Are any additional gonorrhoea specific patient information materials provided to people offered 'dual testing'?

- ☐ Yes
- ☐ No
- ☐ Don't know

15. Select file to upload:

(click "Browse" button below to locate file)

File size restricted to: 4194304 KB

File type restricted to: no file type restrictions

File name: (limit 255 characters)

File description: (limit 255 characters)

Upload

Files uploaded:

Section C

The next questions ask about the clinical care pathway for clients with a positive test result for gonorrhoea.

In this survey we are not collecting information about positive chlamydia test results.

A 'confirmation test' is a second test used to confirm the diagnosis of gonorrhoea where the initial screening test is positive for gonorrhoea.

The next questions ask about the clinical care pathway for clients with a positive test result for gonorrhoea.

In this survey we are not collecting information about positive chlamydia test results.

A 'confirmation test' is a second test used to confirm the diagnosis of gonorrhoea where the initial screening test is positive for gonorrhoea.

16. If a 'dual test' is positive for gonorrhoea, do local service specifications require further tests to be carried out to confirm the diagnosis of gonorrhoea?

- ☐ Further tests to confirm the diagnosis of gonorrhoea are performed on the original sample
- ☐ Further tests to confirm the diagnosis of gonorrhoea are performed on a new sample
- ☐ Further tests to confirm the diagnosis are performed, but it is not specified if this is on the same sample or a new sample
- ☐ Further tests to confirm the diagnosis are not included in the service specification
- ☐ Don't know
- ☐ Other, please specify

If no confirmation is carried out, what action occurs on the basis of the initial screening result? (for example: notification, treatment, referral?)

17. If confirmation tests are performed, do these occur at the same lab or a different lab to where the original screening test was carried out?

- ☐ Same commissioned lab
- ☐ Different commissioned lab
- ☐ National reference lab
- ☐ Don't know

18. Is culture carried out following a positive 'dual test'?

- ☐ Yes
- ☐ No
- ☐ Don't know

19. Who is responsible for the following care steps?
Please select the most appropriate box in each row.

	Initial 'dual testing' service provider	A different level 2/3 sexual health provider	Process does not happen	Don't know
Informing person of initial screening result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Informing person of diagnosis (confirmation test result)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Treatment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Partner notification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

20. When in the pathway do the following care steps occur?
Please select the most appropriate box in each row.

	When initial screening result is known	When confirmation test result is known	Process does not happen	Don't know
Person first notified of result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Treatment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Partner notification	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to other services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

21. Where are people referred if they are diagnosed with gonorrhoea through the 'dual test'?

- ☐ The initial service provider refers the person directly to Level 2 sexual health services
- ☐ The initial service provider refers the person directly to Level 3 sexual health services
- ☐ The initial service provider refers the person directly to primary care services
- ☐ The person is encouraged to self-refer to appropriate services
- ☐ Not referred
- ☐ Don't know
- ☐ Other, please specify

22. If someone is referred to other services, are any actions taken to confirm they attended the other service?

- ☐ The NCSP service contacts the person to confirm they have attended
- ☐ The NCSP service contacts the receiving service to confirm that the person has attended
- ☐ The NCSP service is contacted by the receiving service, who confirm that the person has attended
- ☐ The NCSP service does not confirm that the person has attended
- ☐ N/A - clients are not referred

23. If treatment is initiated as part of the 'dual testing' service, what treatment is given?

Section D

This section asks about the information on gonorrhoea cases that is collected in your area as part of NCSP services

24. What data on gonorrhoea diagnoses made through NCSP services is received by commissioners of NCSP services in your area?

Please tick all that apply

- ☐ Individual identifiable line listing
- ☐ Anonymised/pseudonymised line listing
- ☐ Aggregated summary usable data by patient demography (ie split by age group, gender or geography)
- ☐ Aggregate summary by testing venue
- ☐ Count of tests/positivity rates only
- ☐ None
- ☐ Other, please specify

25. How are data on gonorrhoea diagnoses through NCSP services held by providers in your area?

- ☐ Individual paper patient records
- ☐ Individual electronic patient records
- ☐ Combined electronic record (for example line listing)
- ☐ Don't know
- ☐ Other, please specify

26. Are data on gonorrhoea diagnoses made through 'dual testing' reported through GUMCAD/GUMCAD 2 (the national electronic STI reporting systems)?

- ☐ Yes
- ☐ No
- ☐ Don't know

Section E

This section asks about the contractual arrangements for any chlamydia and gonorrhoea 'dual testing' service commissioned in your area for the NCSP

27. Has the cost for your NCSP service changed due to the introduction of 'dual testing'?

- ☐ Costs have increased
- ☐ Costs have decreased
- ☐ Costs have stayed the same
- ☐ Don't know

28. Please inform us of the tariff if a fee per item/service is in place. These data will be used to generate aggregated national averages, and will not be reported individually.

There is no need to enter a "£" symbol. Please enter data for any option that applies

Cost per patient

Cost per 'dual test'

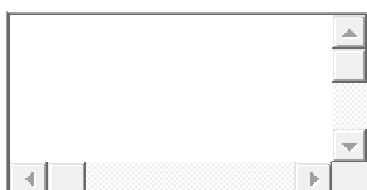
Cost per standard chlamydia only test

Cost per confirmation

Cost per treatment

Cost per referral to other services

29. Do you have any other comments on the use of 'dual testing' for chlamydia and gonorrhoea as part of the NCSP?



Finally

Thank you for taking the time to complete this survey. These data will be used to inform national guidelines about the future use of 'dual testing', and we hope the results of this project will help to support you in making future commissioning decisions.

Appendix 2: additional data table

Use of dual testing assays on samples collected for the National Chlamydia Screening Programme (NCSP):

Results from a national survey of local authority commissioners

Appendix 2 - additional data tables

Q7 In which settings does 'dual testing' for chlamydia and gonorrhoea currently occur?

Type of setting	CaSH/SH	GP	Outreach/Educational	Pharmacy	Remote (mail/web)	Top
No. LAs (%)	44 (88%)	41 (81%)	31 (69%)	32 (71%)	36 (80%)	39 (87%)

7 LAs did not answer; denominator is 45 LAs

Q8 Where does the largest proportion of your 'dual testing' occur? In which settings does 'dual testing' for chlamydia and gonorrhoea currently occur?

Type of setting	CaSH/SH	GP	Outreach/Educational	Other - not specified	Not known
No. LAs (%)	23 (51%)	9 (20%)	3 (7%)	3 (7%)	7 (16%)

7 LAs did not answer; denominator is 45 LAs

Q10 What biological specimens are used for 'dual testing'?

Type of specimen	Endocervical	Pharyngeal	Rectal	Urethral	Urine	Vaginal	Other	Not known
No. LAs (%)	25 (56%)	11 (25%)	11 (25%)	8 (18%)	41 (92%)	17 (38%)	1 (2%)	8 (18%)

7 LAs did not answer; denominator is 45 LAs

Q11 How is consent taken for 'dual testing'?

Method of consent	Information provided, consent for gonorrhoea testing is assumed by return of kit	Written consent is obtained, which specifically mentions gonorrhoea testing	Consent for gonorrhoea testing is opt out	Verbal consent is obtained for gonorrhoea testing	No consent is obtained for gonorrhoea testing	Not known
No. LAs (%)	25 (71%)	5 (14%)	1 (3%)	1 (3%)	1 (3%)	2 (6%)

17 LAs did not answer; denominator is 35 LAs

Q12 Does the patient information leaflet that is provided to people undergoing 'dual testing' discuss gonorrhoea?

LA answer	Yes	No	Not known
No. LAs (%)	15 (80%)	35 (45%)	8 (10%)

10 LAs did not answer; denominator is 42 LAs

Q14 Are any additional gonorrhoea specific patient information materials provided to people offered 'dual testing'?

LA answer	Yes	No	Not known
No. LAs (%)	16 (86%)	1 (5%)	2 (12%)

Denominator is 17 LAs without gonorrhoea-specific patient information materials

Q24 What data on gonorrhoea diagnoses made through NCSP services is received by commissioners of NCSP services?

Method of data receipt	Summary data obtained by patient demography (gender, age group etc)	Summary data obtained by testing venue	Anonymous/pseudonymised data obtained listing individual patient outcomes	Summary count of tests/positivity rates without further breakdown	Identifiable data obtained listing individual patient outcomes	Bespoke analyses are obtained	No data are obtained	Not known
No. LAs (%)	9 (17%)	5 (22%)	2 (5%)	8 (39%)	1 (2%)	11 (26%)	5 (12%)	1 (2%)

10 LAs did not answer; denominator is 42 LAs

Q26 Are data on gonorrhoea diagnoses made through 'dual testing' reported through GUMCAD/GUMCAD 2 (the national electronic STI reporting systems)?

LA answer	Yes	No	Not known
No. LAs (%)	22 (51%)	4 (9%)	7 (16%)

9 LAs did not answer; denominator is 43 LAs

Q27 Has the cost for your NCSP service changed due to the introduction of 'dual testing'?

LA answer	Increased	Stayed the same	Not known
No. LAs (%)	7 (16%)	29 (69%)	6 (14%)

10 LAs did not answer; denominator is 42 LAs