



Public Health
England

Protecting and improving the nation's health

National chlamydia screening programme standards (seventh edition)

Updated October 2016

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

Public Health England
133-155 Waterloo Road
Wellington House
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
[Twitter: @PHE_uk](https://twitter.com/PHE_uk)
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Erna Buitendam
For queries relating to this document, please contact: Erna.Buitendam@phe.gov.uk

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Introduction

This is the seventh edition of the 'National chlamydia screening programme (NCSP) standards' (previously titled 'NCSP core requirements'). Please replace all previous editions, published:

Edition 1	June 2003	Edition 4	January 2008
Edition 2	July 2004	Edition 5	June 2010
Edition 3	September 2006	Edition 6	September 2012

NCSP aims and objectives

The NCSP aims to:

- prevent and control chlamydia through early detection and treatment of asymptomatic infection
- reduce onward transmission to sexual partners
- prevent the consequences of untreated infection
- raise awareness and skills of health professionals to screen for chlamydia, and provide the information young adults need to reduce the risk of infection and transmission

High quality chlamydia screening is an integral part of the offer of sexual health care that all young people should receive. By regularly testing and treating young people the NCSP will interrupt transmission of chlamydia and ultimately prevent infections. It ensures access in a variety of settings, allowing young people to take responsibility for their sexual health regardless of their location or proximity to specialist clinics. Additionally the offer of a chlamydia test in a wide range of settings is well received by young people and helps to normalise sexually transmitted infection testing. For many young people the offer of a chlamydia test will be their first contact with sexual health services and as such provides an important opportunity to support young people by improving knowledge and attitudes.

Document purpose

The NCSP standards support an evidence-based and cost-effective approach to delivering chlamydia screening. This document outlines the minimum standards for local implementation and should be used by commissioners and providers to form the basis for local screening plans.

The document includes:

- programme mandatory requirements
- auditable outcome measures for service delivery and national and local monitoring (page 8)
- standards to inform local service level agreements (SLA), contracts specifications and monitor quality
- commissioning tips

The content allows appropriate flexibility to suit local infrastructure and demographics. The NCSP standards also support providers to deliver chlamydia screening in line with other relevant national standards and good practice. Relevant British Association for Sexual Health and HIV (BASHH) and Care Quality Commission (CQC) standards are referenced.

The NCSP standards document is supplemented by a technical appendix, referenced throughout this document. The standards document is available on the NCSP website.

Context

The [BASHH Standards 2014](#) for the Management of Sexually Transmitted Infections¹ cover all aspects of the management of sexually transmitted infections (STIs), including chlamydia, as well as the diagnosis, treatment and the broader public health role of infection control.

Criteria for screening

The NCSP includes:

- men and women under 25 who have ever been sexually active and who are offered, or request, a chlamydia test
- 15 and 16 year olds who meet Fraser criteria for consent to testing
- contacts of test positives, regardless of age
- people of all sexual orientations (see also section 2.5)

The NCSP does not include those who cannot give consent, anyone unwilling to give any means of contact for the purpose of result notification, and under 16s not deemed to meet Fraser criteria.

Screening roles and responsibilities

See next page for a diagrammatic representation of the roles and responsibilities for planning, commissioning and delivering chlamydia screening as we move into new structures for the NHS and PHE.

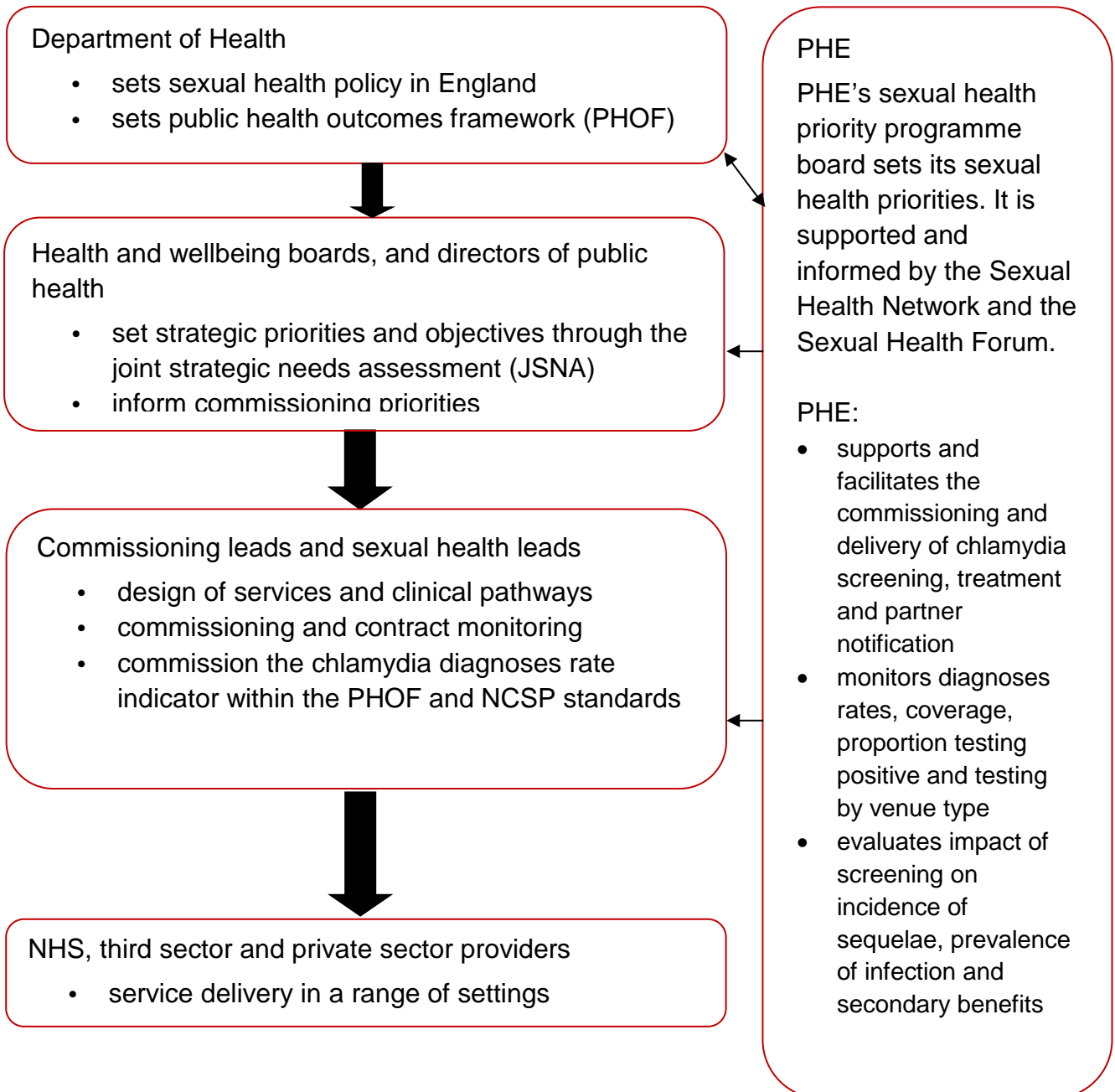
Commissioners are responsible for ensuring that quality assurance is built into contracts and SLAs, and that performance towards NCSP standards is monitored (e.g. by regular local audit). The NCSP also conducts regular national audits and surveys and recommends participation to be specified in contracts (see standard five).

Key stakeholders such as GPs, pharmacies, community sexual and reproductive health (SRH) services, abortion providers and genitourinary medicine (GUM) services should be remunerated for the parts of the care pathway they undertake. Clinical providers should complete the entire NCSP pathway including results management and partner notification (PN), where feasible.

Integrating chlamydia screening within existing services

As set out in the NCSP guidance on screening integration, chlamydia screening should be delivered within existing primary care, SRH and GUM services wherever possible. Standalone chlamydia screening offices should be avoided. Integration can deliver a range of benefits including cost reductions and improved patient access and care.

Chlamydia screening roles and responsibilities



NCSP standards: quick reference sheet for providers

<p>Chlamydia screening delivery</p> <ul style="list-style-type: none"> • directors of public health hold responsibility for ensuring local screening delivery • all screening to be in line with NCSP Standards (7th) 	<p>Testing practice</p> <ul style="list-style-type: none"> • self taken swab or urine sample • if cervical examination is taking place a cervical swab is acceptable • nucleic acid amplification tests (NAAT) must be used
<p>Chlamydia screening venues</p> <ul style="list-style-type: none"> • at least 70% of screening delivered via primary care, SRH and GUM services (per upper tier/unitary local authority) • targeted outreach screening can be considered for groups not engaged by healthcare services (if evidence of unmet need) • healthcare staff at all venues should be trained to provide results, treatment and initiate partner notification • high quality internet testing should be considered to supplement core service provision 	<p>Providing results</p> <ul style="list-style-type: none"> • young person to select preferred notification method • if test is positive, three contact attempts to be made (using more than one notification method) • where appropriate and agreed in local care pathways, the test result should be accessible to the test initiator for further action if required
<p>NCSP screening criteria</p> <ul style="list-style-type: none"> • opportunistic screening of all sexually active young people under 25 years old • testing of partners regardless of age 	<p>Management of positives</p> <ul style="list-style-type: none"> • advise full STI screen • arrange treatment • initiate partner notification • agree arrangements for partners to be managed • give safe sex advice • follow up two weeks post-treatment • offer of retest at around three months
<p>Offering the test</p> <ul style="list-style-type: none"> • offer test annually and on every change of partner • offer test via routine medicals, contraceptive / emergency hormonal contraceptive consultations, abortion referral and 'call' opportunities (eg, asthma check) 	<p>Treatment</p> <ul style="list-style-type: none"> • azithromycin (1gm) stat or doxycycline (100mg bd) seven days • treatment free for the young person • see BASHH guidance for treatment during pregnancy
<p>Test consent</p> <ul style="list-style-type: none"> • provider to obtain consent plus; • sample provided plus; • able to provide consent (Fraser criteria for under-16s) 	<p>Partner management</p> <ul style="list-style-type: none"> • patient-led PN (provider-led offered as required) • offer testing • empirical treatment (do not wait for test result) • ask about partners of partners and encourage testing

NOTES:

- Further detail on chlamydia screening in men having sex with men in section 2.5
- Those with symptoms should have a clinical assessment.

NCSP standards: quick reference sheet for commissioners

<p>Chlamydia screening delivery</p> <ul style="list-style-type: none"> • directors of public health and sexual health leads responsible for ensuring screening delivery, quality assurance and audit participation (national / local) • all screening to be in line with NCSP standards (seventh edition) 	<p>Commissioning</p> <ul style="list-style-type: none"> • integrate commissioning of chlamydia screening with other sexual health services and primary care • chlamydia screening can be commissioned as part of the public health contract as provided by the Department of Health, as well as its national template service specification • commission towards achieving recommended diagnosis rate of $\geq 2,300$ per 100,000 15-24 year olds p.a. (Public Health Outcomes Framework) • NCSP mandatory requirement/standards specified in provider contracts and reviewed regularly • Chlamydia Testing Activity Dataset (CTAD) data requirements included in laboratory contracts
<p>Chlamydia screening venues</p> <ul style="list-style-type: none"> • at least 70% of screening delivered via primary care, SRH health and GUM services (per upper tier/unitary local authority) • targeted outreach screening can be considered for groups not engaged by healthcare services (if evidence of unmet need) • healthcare staff at all venues should be trained to provide results, treatment and initiating partner notification • high quality internet testing should be considered to supplement core service provision 	<p>Testing practice</p> <ul style="list-style-type: none"> • nucleic acid amplification tests (NAAT) must be used • self-taken swab or urine sample • if cervical examination is taking place a cervical swab is acceptable • laboratories must have the capacity to meet CTAD data requirements and turnaround times • laboratory contracts should include a completion target for CTAD postcode of residence data item, to ensure tests accurately attributed to LA
<p>Service integration</p> <ul style="list-style-type: none"> • chlamydia screening integrated within primary care and sexual health services and embedded in existing sexual and reproductive health pathways 	<p>Providing results</p> <ul style="list-style-type: none"> • young person offered choice of notification method • direct text from laboratory or provider most cost effective • where appropriate and agreed in local care pathways, the test result should be accessible to the test initiator for further action if required
<p>NCSP screening criteria</p> <ul style="list-style-type: none"> • opportunistic screening of sexually active young people under 25 years old • testing of partners regardless of age 	<p>Treatment and partner notification</p> <ul style="list-style-type: none"> • testing and treatment free for the young person • test offered and treatment provided to all identified partners (includes partners of partners) free of charge
<p>Offering the test</p> <ul style="list-style-type: none"> • testing annually and on every change of partner • test offered via routine medicals, contraceptive/emergency hormonal contraceptive consultations, abortion referral and 'call' opportunities (eg, asthma check) • offer of re-test around three months after treatment of known positives 	<p>Value for money</p> <ul style="list-style-type: none"> • commission clinical venues to provide treatment and partner notification as a package with care pathways defined for provider notification • integrate screening into young person services, • develop capacity for testing, treatment and partner management in these services • consider collaborative commissioning across all sexual health service commissioners in an area

NOTES: Further detail on chlamydia screening for men having sex with men can be found in section 2.5. Those with symptoms should have a clinical assessment.

Auditable outcome measures

Per NCSP standard, this document sets out the mandatory programme requirements plus additional screening recommendations. For four of the standards auditable outcome measures are also defined, as key considerations to inform local programme design and performance monitoring:

Standard 1. Offering chlamydia testing
<ul style="list-style-type: none"> • key performance indicator: at least 70% of tests delivered in primary care, sexual and reproductive health (SRH) and genitourinary medicine (GUM) services (per upper tier/unitary local authority)* <p>* Primary care includes GP surgeries and community pharmacies. SRH includes sexual health clinics and abortion providers.</p>
Standard 4. Notification of results
<ul style="list-style-type: none"> • auditable outcome measure: all those tested notified of result within ten working days (from date of test)* • key performance indicator: at least 95% of those tested notified of result within ten working days <p>* Test date assumed as date on the test form. Notification date assumed as date provider sent text/left verbal message.</p>
Standard 4. Turnaround time for treatment
<ul style="list-style-type: none"> • auditable outcome measure: all those testing positive offered treatment within six weeks of test date* • key performance indicator: at least 95% of those testing positive treated within six weeks of test date <p>* Test date is assumed to be the date on the test form.</p>
Standard 5. Partner notification
<ul style="list-style-type: none"> • auditable outcome measure: % of index cases documented as offered ≥one PN discussion (including telephone discussion) with a healthcare worker with the appropriate documented competency • key performance indicator: at least 97% of index cases • auditable outcome measure: % of index cases for whom outcome of agreed contact action(s), or decision not to contact, documented for all contacts. • key performance indicator: at least 97% of index cases • auditable outcome measure: number of all contacts whose attendance at a level 1,2, or 3 sexual health service was documented <u>as reported</u> by index case or healthcare worker (HCW), within four weeks of first PN discussion* • key performance indicator: at least 0.6 contacts per index case for all clinics (in and outside London) and documented within four weeks of date of first PN discussion. <p>* This is the first discussion between the index case and a HCW (including telephone) for the purpose of PN, with the appropriate documented competency.</p>

Main changes in NCSP standards (seventh edition)

References to primary care trusts (PCTs), Health Protection Agency (HPA) and to changes that were planned from April 2013 (for example, references to ‘the new landscape’) have been removed as appropriate throughout the whole document. The former accompanying document has been incorporated into this standards document as a technical appendix. The table below sets out the main changes made to the NCSP standards in the seventh edition:

Location	Key changes
Introduction	1. New paragraph under ‘aims and objectives’ and updated diagram on page 5
Standard 1	<ol style="list-style-type: none"> 1. Inserted references to DH guidance on commissioning integrated sexual health services, the standard template contract specification 2. Inserted paragraph that reflects that providers expected to undertake results management should routinely receive a copy of their patients’ results via a secure data transfer system. With local agreement and where patient consent has been obtained, the test initiator should receive a copy of the patient’s results even when they are not responsible for results management. 3. Inserted reference to re testing of patients found to be positive 4. Inserted paragraph to reflect requirement to register with CQC 5. Removed paragraph with out of date financial information 6. Inserted paragraph with reference to services being young people friendly
Standard 2	<ol style="list-style-type: none"> 1. Updated paragraphs re obtaining consent 2. Updated paragraph 2.5 in relation to young people reporting symptoms 3. Updated with reference to recommendation to re test those found to be positive 4. Updated paragraph 2.6 in relation to extra genital testing
Standard 3	<ol style="list-style-type: none"> 1. Referred to new BASHH standards for the management of STIs (January 2014) re turnaround times 2. Updated with reference to CQC registration 3. Updated with reference to dual testing NAATS 4. Updated reference to UK Accreditation Service.
Standard 4	<ol style="list-style-type: none"> 1. Updated the section on management of positives with re testing recommendation 2. Included suggested guidance in relation to recurrent Ct infections 3. Changed standard on turnaround time from 90% to 95% being notified within 10 working days, in line with BASHH standards for the management of STIs 4. Inserted paragraphs on PN in here instead of Standard 5
Standard 5	<ol style="list-style-type: none"> 1. Amended with up to date CTAD guidance 2. Removed paragraphs on PN data collection 3. Removed reference to NCSP test request form
Standard 6	<ol style="list-style-type: none"> 1. Updated with reference to DH clinical governance guidance 2. Updated with reference to requirements for websites facilitating chlamydia screening
Standard 7	<ol style="list-style-type: none"> 1. Removed references to LINKs

Standard 1. Service delivery and development



1.1 Responsibilities for strategic direction and commissioning of sexual health services

From April 2013, local authorities have been mandated to commission comprehensive sexual health services, which includes open access testing and treatment for STIs.² A key principle of STI management is the 'open access' nature of services that allows people to use the service they choose, regardless of its location or their LA of residence. STIs remain stigmatised and in order to encourage people at risk of STIs to access care, this open access provision needs to remain. Further guidance in relation to open access and issues such as principles of cross charging can be found on the [DH's website](#).

Local health and wellbeing boards will set local priorities for public health outcomes through the JSNA and joint health and wellbeing strategies.³ Local commissioning of chlamydia services will need to reflect the sexual health commissioning priorities set out in these, with due consideration also given to the PHOF (2013-16).²

1.2 Integrated chlamydia screening

It is important that young adults have a choice of service available to them, and equitable standards of care in whichever setting they choose. Commissioners of sexual health services should ensure chlamydia screening is embedded within core healthcare services. Per upper tier/unitary local authority, 70% of all chlamydia tests should be delivered via:

- primary care services (GP surgeries, community pharmacies)
- SRH services (including abortion providers)
- GUM services

Auditable outcome measure: offering chlamydia testing

- at least 70% of tests delivered in primary care, SRH and GUM services (per upper tier/unitary local authority)*

* Primary care includes GP surgeries and community pharmacies. SRH includes sexual health clinics and abortion providers.

Chlamydia screening should be integrated within wider sexual health provisions for young adults, and offered at every opportunity (eg, consultations such as emergency hormonal contraception and abortion referrals). [National guidance on integrated care models](#) has been produced by the NCSP.

Providers expected to undertake results management should routinely receive a copy of their patients' results via a secure data transfer system. Where a clinician responsible for care of a patient initiates a test, a copy of the result should be made available, even if result management has been delegated to other providers. For example, a GP who initiates a test should, with the patient's consent, have access to results. Patients should be notified of their results: 'no news is good news' is not the recommended approach under the NCSP and BASHH guidance.

Consideration should be given to collaborative commissioning across all commissioners of sexual health services in an area. Commissioning parties are encouraged to stipulate BASHH and NCSP standards in relevant contractual agreements.

In general, providers of chlamydia screening and treatment are required to register with the Care Quality Commission (CQC). Two 'regulated activities' are particularly relevant to the NCSP:

1. Diagnostic and screening procedures
2. Treatment of disease, disorder or injury

Therefore only community pharmacies are currently exempt from registration. Providers such as GUM, SRH and CASH clinics, GPs, termination of pregnancy services and laboratories all require CQC registration. Internet-based chlamydia testing services need to register with CQC if the laboratory testing the sample is part of the same organisation.

Outreach chlamydia screening:

Latest data support the cessation of outreach services yielding a small proportion of infections amongst those tested. Resources disinvested in outreach services should be redirected into high quality, widely accessible, integrated chlamydia screening services.

Outreach testing to hard-to-reach groups not accessing healthcare services can be considered if there is evidence of unmet need available. This should be targeted to hard-to-reach groups that have limited access to primary care or SRH services based on local needs assessment and built into wider health initiatives in order to provide value and sustainability. Further [outreach guidance](#) is available on the NCSP website.

1.3 Remote chlamydia screening

Health service based screening services may also be supplemented by high quality services delivered using the internet. Remote testing is attractive to some sections of the population, especially men. It can provide automated reminders to test once a kit is registered and provides a low-cost option. As symptomatic patients can not be assessed remotely, they must be advised to attend a clinical service. Tests that do not include a face to face consultation should not be offered to young people under 16 years old, as Fraser competency cannot be assessed under these circumstances. The [NCSP's audit on internet based chlamydia screening](#) contains recommendations on how to ensure that standards are being met and how to optimise the use of the internet in the course of testing for chlamydia.

1.4 PHOF: chlamydia diagnosis rate

The PHOF includes a chlamydia diagnosis indicator as a new outcome measure to assess progress in controlling chlamydia in young persons less than 25 years old.² The diagnosis rate reflects both screening coverage and the proportion infected amongst those tested (positivity). It is linked to expected falls in prevalence, provided treatment and partner notification standards are met.

PHE recommends that local areas work towards an annual diagnosis rate of at least 2,300 per 100,000 15-24 year olds per year. Commissioners should examine historical diagnosis rates to inform local planning. A wealth of historical data and guidance available from both local and national sources can be found on the NCSP website. The [NCSP annual diagnosis rate calculator](#) can also be used to determine the coverage required to reach this rate.

Commissioners and providers should also emphasise the importance of retesting of patients with a positive test result (see paragraph 2.2), as well as repeat screening annually and on change of sexual partner for all patients. Effective treatment and partner notification remains crucial, and must continue to be fulfilled locally by trained and competent healthcare professionals.

Efforts to meet diagnosis rates should emphasise the importance of screening that is widely accessible in order to avoid undermining gains already made to normalise chlamydia screening and reduce stigma.

1.5 Delivering chlamydia screening cost-effectively

In costing evaluation work, the NCSP will engage with local and regional integrated sexual health services tariff development work. A tariff represents a more transparent, outcome-focussed payment mechanism than many current funding arrangements. It is anticipated that tariffs will drive the modernisation and integration of sexual health services and deliver efficiencies in service provision.

1.6 Ensuring services are young people friendly

Following the Department of Health 'young people friendly' criteria will assist in making screening services as accessible to young people as possible. A self-assessment tool can be used to identify if any improvements are needed. Further information can be found [here](#).

1.7 Local monitoring and evaluation

PHE publishes data on screening coverage, proportion infected and diagnosis rate by LA for commissioners and provides to use to monitor local progress to improve outcomes and compare their achievement with other areas. Any local requirements for additional activity reporting should be agreed and contracted with local providers.

Other quality assurance standards such as turn-around times and patient satisfaction surveys should continue. Local landscape knowledge can also be used to inform service provision. Patient, public and professional engagement exercises can also be used to understand local needs, service capacities and capabilities.

The NCSP plans to publish three local audit tools in 2014 to be used for local monitoring of:

- retesting rates
- partner notification rates
- turnaround times between test, result notification and treatment

Service development and delivery:

considerations for commissioning

- a) commissioning of young people's sexual health services should be informed by an up-to-date local sexual health needs assessment, under the JSNA
- b) chlamydia screening should be commissioned for delivery in core healthcare services, with at least 70% of tests via primary care, SRH and GUM services (per upper tier/unitary local authority). Consideration should be given to collaborative commissioning across all sexual health services in an area
- c) outreach services should be limited to hard to reach groups where there is evidence of unmet need. Funds released by reducing outreach should be redirected into high quality, widely accessible integrated chlamydia screening services
- d) commissioners should examine historical diagnosis rates to inform local planning towards achieving the recommended annual diagnosis rate of at least 2,300 per 100,000 15-24 year olds per year
- e) commissioners and providers should also emphasise the importance of effective treatment, repeat screening annually and on change of sexual partner and partner notification, and re testing of young people that are found to be positive at around three months following the initial test date
- f) efforts to meet diagnosis rates should emphasise the importance of screening that is widely accessible in order to avoid undermining gains already made to normalise chlamydia screening and reduce stigma

Standard 2. Offering chlamydia screening

Mandatory requirements

Consent for screening

The test is voluntary and young people must be given information to assist them in making an informed choice. This must include the fact that data collected as part of the programme will be used for national programme monitoring but the patient's name and address are not used. This information can, but does not need to be, given through a patient information leaflet (the NCSP's patient information leaflet can be found [here](#), available in a number of languages). Young people should understand that no test is 100% accurate and that regular screening is a part of good sexual health. Consent must be obtained prior to testing. It is the provider's responsibility to obtain a patient's consent to take a chlamydia test.

Consent is implied if:

- the patient has been informed about chlamydia testing and what test results will mean for them and has had the opportunity to ask questions about the test and the implications of infection, plus
- the young person has been told how data is used by PHE and given time to understand it prior to participating, plus
- a sample has been provided, plus
- the young person has competence to consent (see below)

A [general leaflet](#) is available for GP surgeries and clinics about the use of data by PHE for surveillance purposes. This is a generic document covering more than STI data. This may be supplemented with local information on chlamydia screening or other sexual health services.

The test initiator is responsible for ensuring that any under 16-year olds offered a test are competent to make an informed decision. Staff should adhere to national and local guidance on consent for the under 16 year olds.^{4, 5, 6} Further information is available in the technical appendix, page 46.

The Mental Capacity Act should be followed for adults (and young people aged 16-17 years) with learning difficulties or where there is impairment of decision making: [Mental Capacity Act](#).

Confidentiality

Patients have a right to confidentiality regardless of where testing and treatment take place.

BASHH Standards: 1, 2, 3
CQC Standards: 1, 2, 3, 4 and 5

2.1 Offering chlamydia screening

NCSP tests should be offered to men and women under 25 who have ever been sexually active, annually or on change of sexual partner.

Providers should use every opportunity to offer chlamydia screening across primary care, SRH and GUM services; routine medicals, contraceptive/emergency hormonal contraceptive consultations, abortion referral and 'call' opportunities (eg, asthma check).

Young adults should have a choice of service options with the right to confidentiality regardless of venue. Core healthcare service screening may be supplemented by high quality services delivered using the internet. However, remote testing should not be offered to young people under 16 years old, as Fraser competency cannot be assessed under these circumstances. If it appears that a person under 16 has accessed a test without a face to face consultation, a suitably trained HCW must liaise with them in line with local and national guidelines.^{4, 5, 6}

2.2 Frequency of screening

Young people should be offered the test annually and whenever there is a change in sexual partner. Additional repeat testing may be required according to risk assessment by clinical staff. If the young person is found to be positive, a re-test is recommended at around three months as the risk of re-infection is higher for positives compared to those with a negative test result. We recommend this is raised with the young person as early as possible in the care pathway.

2.3 Testing for other STIs

A number of local programmes offer dual testing for chlamydia and gonorrhoea (GC). In these cases specific information must be provided to patients and consent obtained for GC testing. Staff involved in offering tests, providing results, treatment and PN must be trained as appropriate.^{7, 8} PHE recently undertook a survey of local authority commissioners to ascertain the extent of dual CT/GC testing of the NCSP population of 15-24 year olds. The results from this survey will be available later in 2014 and the current HPA guidance referred to earlier will be updated to provide support to local areas in relation to dual testing. Further guidance on considerations for dual testing is provided in the technical appendix, and further guidance on testing for GC is available [here](#).

2.4 Sexual health advice

In line with good practice we recommend that effective sexual health advice is also offered at the point where a chlamydia test is initiated, whether this is in a clinical or non-clinical setting. This can be found for example [here](#).

2.5 Men who have sex with men

Men who have sex with men (MSM) should be advised, even if asymptomatic, to have a full STI screen, including a test for HIV and hepatitis B as required. There is evidence that urine testing alone misses possible asymptomatic rectal and pharyngeal infections in MSM. Non-clinical venue providers should ensure that MSM presenting for testing are aware of the need to attend a local clinical venue for appropriate testing.

2.6 Young people reporting symptoms

All those reporting symptoms should see a clinician (see box 1). Non-clinical venues should ensure that this happens. For example, websites offering test kits must advise those with symptoms to see a clinician, but may still offer testing. People with STI concerns should have a medical and sexual history taken and appropriate management given within a competent clinical service. The definitions of the levels of service competency are set out in the National Strategy for Sexual Health and HIV⁹.

Actions should follow according to level of service as below:

- Level 1 – CT specimen then refer conditions outside competence
- Level 2 – CT specimen + investigation. Refer conditions outside competence
- Level 3 – CT specimen + investigation and treatment

Box 1. Symptoms in males and females of possible STIs that warrant referral to a clinician

Symptoms/signs of possible STI, eg, itch, dysuria, development of ulcers or abnormal lumps in the genital area;

Females: non-physiological vaginal discharge, superficial dyspareunia, and or upper genital tract infection (UGTI) – deep dyspareunia fever, abnormal bleeding, dysuria, abdominal pain.

Males: urethral discharge, dysuria, testicular discomfort or swelling.

This is not a comprehensive list.

2.7 Specimen collection

Vulvo-vaginal swabs VVS (for women) and first-void urine samples (for men and women unable/unwilling to perform VVS) are the preferred method of specimen collection. Cervical swabs are acceptable *if a speculum examination is being carried out as part of routine clinical care* however there is evidence to suggest that these are less sensitive than VVS.^{10,11}

Providers should have procedures in place to ensure that all test kits issued are within their expiry date. Information on collection, transport, storage and handling of specimens should be available to healthcare professionals and young people as necessary.

Manufacturers' recommendations should be adhered to, including specimen type, volume and minimum time since last urine passed. Further details are available in the technical appendix, page 48.

In some individuals, such as MSM, extra genital testing (rectal and pharyngeal) may be indicated due to their sexual history. Extra genital testing is a routine component of the sexual health testing of MSM but should not be considered a tool for population screening within the NCSP. It should only be undertaken in settings with experienced sexual health service providers. Where indicated extra genital testing should be performed in line with BASHH management standards.

2.8 Minimum time between tests

A minimum of six weeks is recommended between tests. Repeat testing before this time may miss delayed therapeutic reaction to treatment or may detect non-viable organisms.¹² A series of clinical frequently asked questions concerning the timing of tests is available in the technical appendix, page 50.

2.9 Point of care tests

Point of care tests (POCTs, where the test result can be delivered to the patient without the sample being sent to a laboratory) are not currently used by the NCSP. This position will be reviewed following evaluation of POCTs within the programme, should the use of these tests be demonstrated to be effective, cost-effective, feasible and acceptable in clinical practice.

Offering chlamydia testing:

considerations for commissioning

- a)* HCWs across primary care, SRH and GUM services should be encouraged to use every opportunity to offer chlamydia screening, to ensure sexually active young adults are tested annually and on change of sexual partner, as well as offering a retest to a young person with a positive test result as early in the care pathway as possible
- b)* commissioners should ensure that services offering dual screening meet additional consent and information requirements
- c)* suitable facilities for specimen collection, and appropriate space for consultations, should be provided at each testing venue
- d)* there should be clear pathways and signposting for symptomatic patients, MSMs, under 16 year olds and those not deemed Fraser competent, towards appropriate services
- e)* commissioners should ensure that all providers can supply evidence that policies, training and staff checks for safeguarding children and vulnerable adults are in place and current

Standard 3. Laboratory testing procedures

Mandatory requirements

Nucleic acid amplification tests (NAATS) must be used.

Laboratories must be appropriately accredited with a nationally agreed accreditation scheme such as the United Kingdom Accreditation Service's (UKAS)'s Clinical Pathology Accreditation (CPA)¹³

Commissioned laboratories must have capability to submit Chlamydia Testing Activity Data (CTAD) extracts to PHE on a quarterly basis (see Standard Five).

3.1 Contracting laboratories

When contracting a laboratory, commissioners are advised to perform a baseline assessment of capacity and infrastructure across laboratories in the area. Laboratories need to have the capacity to meet NCSP standards on turnaround times. Transport networks should be factored into any decision. It is recommended that collaborative laboratory procurement is considered in order to minimise cost.

Only appropriately trained laboratory staff with suitable proof of fitness to practice should carry out testing and the laboratory UKAS accredited. Laboratories must be enrolled in a nationally recognised quality assurance scheme (eg, Quality Control for Molecular Diagnostics (QCMD) and National External Quality Assessment Service in laboratory medicine (NEQAS)). Where contracted to provide results directly to patients, the contract should include

standards of results notification time and information governance, and there should be clear pathways in process for treatment and partner notification (see Standard 4).

The CTAD variation letter and agreements are available from NCSP sexual health facilitators and the PHE [website](#). (See also Standard 5 for detail on laboratory commissioning for CTAD submissions, including accurate geographical data reporting).

To avoid delays, laboratories should not process any tests where information on the test request form is illegible or incomplete so that a result cannot be issued. The laboratory can refer these to the local programme for resolution and monitoring. Laboratories will also not process specimens which are not supplied in the correct format and condition according to requirements of the SOPs appertaining to their NAATs platform.

3.2 Test request forms

We recommend that local screening providers liaise with laboratories to obtain and use standard laboratory test forms, which contain the necessary items for CTAD (see standard five), rather than using old NCSP forms or amend these. This is the most cost-effective and sustainable solution.

The standard laboratory test request forms generally contain all the required CTAD data items. However, it may be that in some cases separate forms are required for patient management e.g. outreach screening (see NCSP [outreach guidance](#)), or for testing outside clinical services where patients are not registered with the provider and where a different provider is involved in results management. When separate forms are used for test requests, missing codes should be used if items such as *gender* or *ethnicity* are not recorded on the form.

In non-clinical settings where the standard lab form is not employed, test request forms should be formatted to facilitate ease of patient self completion. It is recommended that the young person completes their own personal information and staff complete venue specific details. Service providers must ensure that all relevant information is passed on to the laboratories to assist CTAD reporting.

All forms are should include the following fields for results management purposes:

- clinic ID
- patient ID or NHS Number
- patient forename and surname or initials
- sex
- date of birth
- date of attendance
- test result
- two methods of contact for results communication

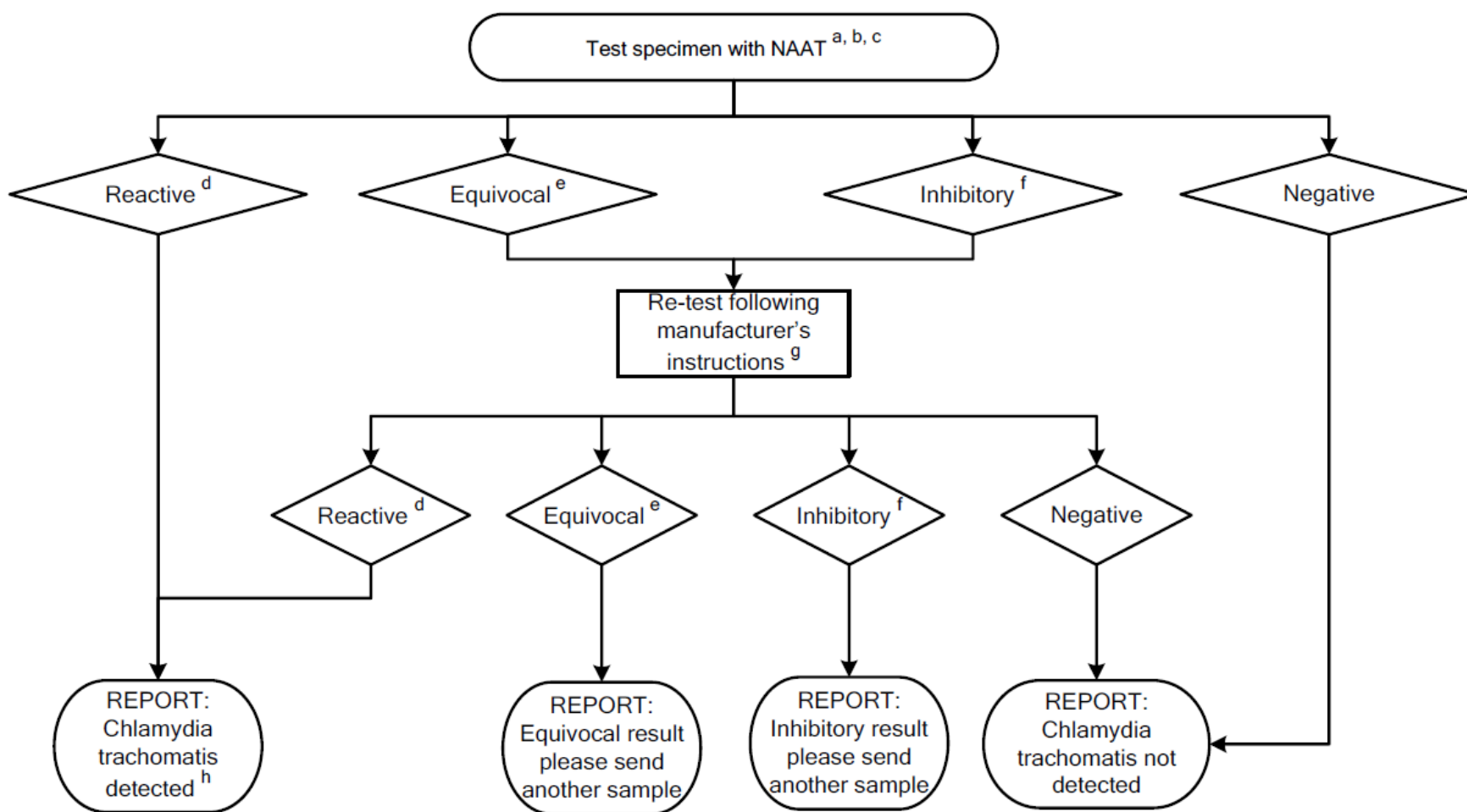
Programmes may also use a 'virtual test request form' or collect test request information through other means providing patient results can be communicated to both providers and patients in a swift and effective manner.

3.3 Confirming positive results

Testing should be carried out according to the algorithm below (Figure 2) from the [UK standards for microbiological investigations v37](#). Laboratories using platforms that specify inhibitory results should routinely monitor the inhibitory rate and demonstrate that action has been taken, should the rate exceed five percent.

Laboratories should ensure they meet the turnaround time standards as per the BASHH standards for the management of STIs (January 2014).

Figure 2. Chlamydia *trachomatis* infection – testing by nucleic acid amplification tests (NAATs)



Footnotes

- a. First catch urine or urethral swab for men and vaginal swab (which may be self-collected) or endocervical swab for women are the recommended specimen types. The testing of first catch urine specimens from women may result in lower sensitivity and is not recommended by national or European guidelines. Where extra-genital specimens are being tested, local validation should be carried out. In all cases laboratories should follow manufacturer's instructions regarding individual specimen types. Laboratories should ensure that their assay is capable of detecting the new variant *C. trachomatis* (nvCT).
- b. Laboratories using dual nucleic acid amplification tests (NAATs) capable of detecting both *C. trachomatis* and *N. gonorrhoeae* should follow nationally agreed algorithms and confirmatory strategy for the *N. gonorrhoeae* component of the test. In women, urine is not the optimal sample for *N. gonorrhoeae*/*C. trachomatis* combined NAATs.
- c. Laboratories should follow good laboratory practice in molecular testing. Good laboratory practice for *C. trachomatis* should include environmental swabbing.
- d. As per national and international guidelines, where the PPV is less than 90%, and for specimens from extra-genital sites (eg rectal swabs), confirmatory testing for persons with a positive *C. trachomatis* screening test should be considered, taking into consideration local evaluation and validation data. In laboratories where confirmatory testing results are found to be consistently concordant following audit, confirmatory testing may be deemed unnecessary.
- e. The term 'equivocal' may be different for various platforms eg 'indeterminate'.
- f. The term 'inhibitory' may be different for various platforms eg 'invalid'.
- g. Some manufacturers work to a consensus algorithm of the best of three results. This has reagent and staff cost implications.

- h. The primary sample container should be checked before reporting to ensure sample confirmation is not required.

Additional footnote for information not stated in the flowchart:

- i. Where results are likely to have medico-legal significance, specimens should be handled in accordance with Royal College of Pathologists' guidance. Legal precedent is limited, but laboratories should consider confirmatory testing with an assay of equal sensitivity and an alternative gene target in the case of a reactive result.
- j. The detection of *C. trachomatis* may be positive in patients with LGV. Definitive diagnosis of LGV to distinguish LGV serovars from non-LGV serovars is done by PCR.

Laboratory testing procedures.

considerations for commissioning

- a. All laboratories commissioned to perform NCSP testing should be appropriately accredited, registered with a nationally recognised quality assurance scheme, and CQC as appropriate, and have evidence of external and internal quality assurance
- b. Contracts should include the NCSP standards, and ensure laboratories are able to provide CTAD extracts to PHE in accordance with the information standards notice (ISN) and PHE protocols
- c. Consider economies of scale when commissioning laboratory services and consider collaborative laboratory arrangements
- d. Consider potential issues around communication and consistency caused by having multiple labs providing services, and ensure there is a contingency plan should the laboratory be temporarily unable to provide any element of the service scope
- e. Consider the information flows between laboratories and providers to ensure rapid and effective results notification. In those labs providing results direct to the patient, the contract should include standards of turnaround time and information governance. Links to PN and clinical services should be well defined
- f. Existing transport links should be taken into account when commissioning laboratory services.

[See Standard 5 for laboratory commissioning to ensure robust CTAD submissions, including accurate reporting of geographical data items].

Standard 4. Results notification and treatment

Mandatory requirements

All results should be reported confidentially and positive results should be provided by staff with appropriate clinical competencies.¹

Treatment must be in accordance with published clinical guidelines and standards (see 3.5).

Young people receiving treatment must also receive:^{1, 12}

- Information on treatment and the potential for re-infection
- Safer sex advice including details of local services
- Offer of a full STI screen (chlamydia, gonorrhoea, syphilis and HIV)
- Partner Notification.
- Offer of a re-test at three months

Treatment must be administered by either medical practitioners or other clinical staff legally covered to work under patient group directions (PGD), [per NICE guidance](#). Further information is available in the technical appendix, page 51-54.

4.1 Reporting results

At the time of testing, young people should be asked how they wish to receive their result, choosing from a text message, telephone call, letter (to any address of the young person's choice) or email. Two methods of contact should be provided to ensure that the result can be communicated to the young person. Providers considering emailing results should take appropriate advice from their provider Caldicott Guardians and data protection leads.

Providers should consider requesting consent to contact the young person's GP in the event that the young person cannot be contacted via the details provided on the test form. All participants must be notified of their result. **The NCSP does not endorse a policy of 'no news is good news'. A test should not be taken if there is no way of contacting the young person.**

There must be documented procedures and care pathways for patient management. Accountability structures for managing test negative and test positive young people must be clear. Staff involved in giving results should be aware of the possibility of false negative and false positive results, and should be able to convey this possibility to young people. Where appropriate and agreed in local care pathways, the test result should be accessible to the test initiator for further action if required.

Automated text result messages may be sent direct from the laboratory to the young person. This should be in addition to being sent to the agreed service provider who is deemed responsible for ensuring the 'follow through' care pathway is completed. All young people should be advised to seek a clinical consultation and full STI screen if they are symptomatic, even if they test negative.

The clinical governance lead for the commissioning organisation has responsibility for ensuring that policies and processes for the multiplicity of venues involved in the care pathway are robust. This includes following through test results (negative and positive) to the young person, and ensuring the process has high levels of confidentiality.

4.2 Management of test negatives

One documented attempt can be made to report a negative result. No further action is required.

4.3 Management of test positives

4.3.1 Contact

Three documented attempts to report positive results should be made. It is recommended that where possible more than one method of communication is obtained to attempt to contact the patient as a back-up in case the main means of contact fails.

4.3.2 Management

The system for managing positives should be sustainable. It is therefore recommended that clinical service providers are trained to provide results, treatment and PN. As those who test positive for chlamydia are at increased risk of subsequently testing positive, compared to those who test negative, we also recommend that case management for test positives includes routine offer of re-testing, around three months after treatment. Re-testing should be built into the care pathway at as early a stage as possible (i.e. discussed at the first screen). Discuss young person's preferred ways on how to be contacted for a new appointment at around three months.

4.3.3. Recurrent chlamydia infections

When an asymptomatic young person has been found to be positive three times in a 12 month period in a non-clinical setting, in line with good practice we recommend they are being referred to a trained sexual health professional for further consultation and management.

Auditable outcome measure: notification of results

- **auditable outcome measure:** all those tested notified of result within 10 working days (from date of test)*
- **key performance indicator:** at least 95% of those tested notified of result within 10 working days

* test date assumed as date on the test form. Notification date assumed as date provider sent text / verbal message left

Robust arrangements must be in place so that the person responsible for compiling local data is informed about the treatment of positive participants to ensure the accuracy and completeness of data on positives and their partners. To facilitate this, there may be an agreed 'follow through' process, contacting test positives two weeks after the result to verify that they have been treated and the PN process initiated. Roles and responsibilities should be clearly defined in order to avoid confusion or duplication in workload.

4.5 Treatment

All treatment should be in accordance with current BASHH clinical effectiveness group national guidelines.¹ Treatment and PN may take place across primary care and SRH venues.

Auditable outcome measure: turnaround time for treatment

- **auditable outcome measure:** all those testing positive offered treatment within six weeks of test date*
- **key performance indicator:** at least 95% of those testing positive treated within six weeks of test date

* test date is assumed to be the date on the test form

BASHH recommendations for treatment are summarised below:

Men and non pregnant women	<p>Azithromycin 1g in a single dose, or doxycycline 100mg bd for seven days</p> <p>For people intolerant of these regimes or for whom the treatment is contraindicated: Ofloxacin 200mg bd for seven days or 400 mg od for seven days, or erythromycin bd for 10-14 days</p>
Pregnant women	<p>Amoxycillin 500mg three times a day for 7 days</p> <p>Azithromycin 1g in a single dose. (The safety of azithromycin in pregnancy and lactating mothers has not been fully assessed, although available data indicate that it is safe. The British National Formulary currently recommends the use of azithromycin in pregnancy and lactation only if no alternative is available)</p> <p>Erythromycin 500 mg four times OD for seven days or 500mg bd for 14 days</p> <p>Doxycycline and Ofloxacin are contraindicated in pregnancy</p>

Staff responsible for treatment and PN must be suitably trained in line with the BASHH standards and professional guidance. Treatment must be administered by either medical practitioners or other clinical staff legally covered to work under patient group directions (PGD), [per NICE guidance](#).

All young people treated for chlamydia must be offered sexual health advice and be advised to notify their partners. The treatment interview is a key opportunity to:

- explore sexual history
- provide sexual health advice
- communicate the importance of PN in relation to preventing repeat infection for the individual
- encourage young people testing positive to abstain from sex until they, and all partners, have been treated (including the treatment period and the next seven days for all people)

Commissioners need to ensure processes in place so that this can be provided in all treatment locations, including considering accessibility and opening times for treatment sites.

Treatment should be free of charge, and advice on routes to free treatment is available from NCSP Sexual Health Facilitators. Individuals suspected of clinical treatment failure should be referred to appropriate sexual health services / managed according to the BASHH guidelines.^{1, 11}

4.6 Partner notification (PN)

PN is a key element in the identification, management and control of chlamydia. All HCWs providing PN should have documented competency, corresponding to the Society of sexual health advisers' National Sexual Health Advisers Competencies – Competency Record Book ([SSHA Manual](#)).¹⁴ Some individuals require active intervention by HCWs to complete PN (provider notification). Each area should have clear referral pathways for this activity.

At least one discussion (which may be a face-to-face or telephone discussion) should be offered to people found to have the infections listed below to begin the PN process. This discussion should be provided by a HCW with the appropriate documented competency. If the offer of discussion of PN is declined, the reason for this should be documented.

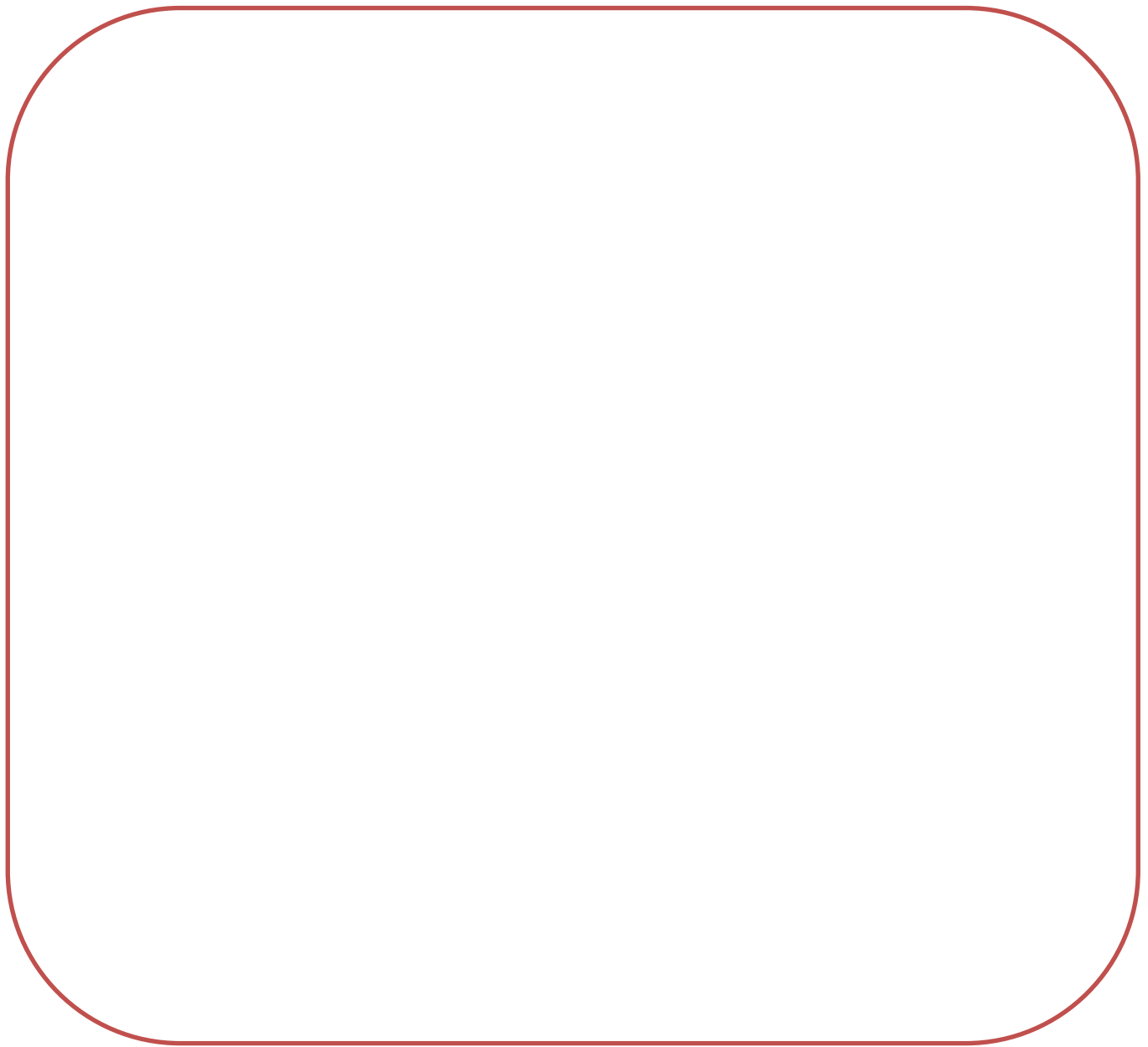
The appropriate look-back interval for PN should be used, as per the BASHH Statement (2012) 15. The look-back interval is the time during which the index case may have been infectious and transmitted infection, and should be applied to all contacts whether or not condoms were used:

- male index cases with urethral symptoms: all contacts since, and in the four weeks prior to, the onset of symptoms
- all other index cases (i.e. all females, asymptomatic males and males with symptoms at other sites, including rectal, throat and eye): all contacts in the six months prior to presentation

Local pathways should be in place to clarify roles and responsibilities for all aspects of PN, including interviews, provider referral, follow-up, verification and data reporting. Up to date protocols should be in place at each PN venue, which are acceptable to young people and partners. Close working relationships between all services offering PN and treatment are important to maximise effectiveness. If the provider is unable to fully undertake PN agreed care

pathways to another service should be utilised to ensure that it takes place in a timely fashion. Minimum requirements are set out in figure 3.

At a national level, the NCSP will use the GUMCAD V2 dataset to estimate PN rates by local area. It is recommended that systematic monitoring of local treatment and PN rates is continued at commissioner and/or provider level in the form of regular local audits. A national audit tool is planned to be available on the NCSP's website in 2014 and can be found [here](#).



BASHH uses the following definitions for index reported contacts:

- Contacts with attendance verified by a HCW, even if there is no record of attendance reported by an index case. Many contacts with verified attendance will also have reported attendance. However, it may be possible to record that a contact was verified as having attended the same clinic (or another clinic), without this being reported by an index case, provided that sufficient baseline contact information was obtained. Counting verified attendance in with reported attendance is intended to facilitate the counting of contacts for the purpose of audits and improve consistency between clinics. This means that the number of reported contacts should be greater than the number of verified contacts
- Contacts reported as attending by a HCW. A HCW may have received information, other than from the index case, that a contact has attended a service managing STIs, without verifying this by contacting that service

4.7 Follow-up

Follow up is an important part in the management of chlamydia, with the following objectives:

- repeating safer sex information including details of local SRH services
- ensuring compliance with treatment
- ensuring abstinence from sexual intercourse until partner(s) complete(s) antibiotics
- re-treating non-compliant and/or re-exposed individuals
- following up PN

There is evidence to suggest that follow-up by phone approximately two weeks after treatment may be more effective than asking the patient to re-attend. It is therefore likely that the former method is more cost effective.¹⁵

4.8 Test of cure

Test of cure is not routinely recommended. However, if the young person has been treated with erythromycin, test of cure should be considered six weeks after the original test date (or three weeks after the end of the 14 day course). A test of cure prior to five weeks may miss patients with delayed therapeutic reaction to treatment or may detect non-viable organisms. All pregnant women are advised to have a test of cure.¹⁰ Providers who suspect patient or partner non-compliance with therapy may consider repeat therapy.

Figure 3: Minimum PN pathway requirements

<p>PN discussion: agree a plan with index patient to identify and contact all partners in the look back period (or reason for not contacting a partner). If PN discussion declined, the reason for this should be documented.</p>	<p>At least one discussion (face-to-face or telephone) should be offered to all those diagnosed with chlamydia. Discussion should take place and be recorded without delay and may be by telephone (when the result is given) or face to face.</p> <p>Recommended look back period: six months for women and asymptomatic men; one month for symptomatic men.</p> <p>Details of all partners in the look back period should be sought, including those who have already attended or are presumed untraceable.</p>
<p>PN method: patients should be offered a choice of PN method</p>	<p>Possible contact actions are: patient, provider or contract methods of PN or no action. Patients should be offered the option of informing partners themselves (patient referral) or providing contact details for a health worker to notify the partner confidentially without mentioning the index patient's name (provider referral). Health worker notification may be delayed for an agreed period, to allow the index patient time to inform the partner (contract referral).</p>
<p>Contact action: agree contact action for each identified partner: patient- or provider-led, or no action.</p>	<p>No action is appropriate when a contact is considered untraceable, or has been verified as already seen. 'Untraceable' may include contacts that cannot be contacted by the patient, provider or contract methods because of lack of information, patient preference or welfare needs. However, there are circumstances where there may be a best interests obligation to break confidentiality (e.g. when the health of another person is at risk) and local policies should be followed.</p>

<p>Partner management: all partners should be offered a test and epidemiological treatment, in accordance with BASHH guidance⁸. Partners presenting as a contact of a case of chlamydia in organisations reporting through GUMCAD V2 should be coded appropriately (e.g. PNC).</p>	<p>Providers should link to venues competent to offer wider STI management for symptomatic patients if they do not provide this themselves.</p> <p>Partner treatment should ideally be confirmed by a clinician. If this is not possible, confirmation should be sought from the index patient.⁸</p>
<p>Information sharing: sharing confidential data within NHS networks has been agreed by BASHH/SSHA and NCSP. Provider referral requests may be passed to the local programme, or nearest GUM, to protect index patient confidentiality'. The index patient's service should be informed of partner tests/diagnosis/ treatment by phone or return of contact slip'.</p>	<p>See Section 11 of the BASHH PN Guideline.</p>
<p>Documentation: PN resolution (the outcome of an agreed action) for each contact documented within four weeks of the first PN discussion.</p>	<p>Documentation includes: attendance of a contact at service for the management of the infection, testing for the relevant infection, the result of testing and appropriate treatment of a contact.</p>

Results and treatment:

considerations for commissioning

- a) Commissioners should ensure that patient pathways, policies and guidance for testing, treatment and PN are in place, up to date, and available to all involved
- b) Test positives should be clearly signposted for treatment; there should be a variety of treatment venues available locally to enable patient choice
- c) Performance management of the number of attempts made to contact both test negative and test positive patients is recommended to ensure high standards of care
- d) PN is a key part of STI management to reduce risk of reinfection for the index patient and to reduce transmission risk across the community
- e) All services that give results, treatment or PN should adhere to the [BASHH guidelines](#) and standards
- f) Systematic monitoring of local treatment and PN rates should be continued at commissioner and/or provider level in the form of regular local audits

Standard 5. Data collection and submission to PHE

Mandatory requirements

Data submission

Laboratories must have the capability to submit the Chlamydia Testing Activity Dataset (CTAD) data items in the correct format through the Public Health England HIV & STI Web Portal

Data confidentiality

Confidential data (i.e. clinic or NHS number, date of birth, and postcode) must not be disclosed to anyone other than the provider of the data, provider responsible for results management and communication, local programme staff handling the data and the HPA. No data may be disclosed to any other parties unless in aggregate form and with the agreement of those responsible for their provision

5.1 Data collection

PHE collects data on all chlamydia tests undertaken in England from NHS laboratories and LA/NHS commissioned laboratories, to measure screening activity. These data are used to provide detailed reports at a national and local level, on screening coverage, the proportion of chlamydia tests that are positive, and the chlamydia diagnosis rate.

Chlamydia activity data reported by PHE are based on primary care and community service chlamydia data from Chlamydia testing activity dataset (CTAD), and GUM clinic chlamydia data from GUMCAD:

- CTAD became mandatory in April 2012, superseding the NCSP and the non-NCSP non-GUM (NNNG) data sources of primary care and community service chlamydia data
- GUMCAD, which reports GUM clinic activity including service user area of residence, continues to be used to ensure the most accurate attribution possible of GUM tests and diagnoses to local areas

Several significant changes in the way chlamydia data are reported were made from 2012, including the introduction of CTAD. These changes mean that data for 2012 onwards are not directly comparable with the data reported in earlier years.

5.2 Chlamydia Testing Activity Dataset (CTAD)

The purpose of CTAD is to enable collection of robust data from laboratories on all chlamydia testing carried out in NHS laboratories and LA/NHS-commissioned laboratories in England, in order to effectively monitor the NCSP through estimation of population screening coverage, proportion of tests that are positive and diagnosis rates.

PHE is responsible for CTAD implementation and collates CTAD data and GUMCAD chlamydia testing and diagnosis data for use by local programmes. CTAD is sponsored by the Department of Health and was adopted as a national NHS information standard by the NHS Information Standards Board (ISB 1538) in July 2011.

The CTAD dataset is comprised of all LA/NHS-commissioned chlamydia (NAATs) tests for all ages (with the exception of conjunctival samples), from all venues and for all reasons. Commissioned laboratories are required to submit these data on a quarterly basis to PHE via a secure web portal, the PHE [HIV & STI web portal](#). The dataset includes the following 20 data fields in a format specified by PHE:

1. Laboratory identifier	11. National general practice code
2. Test identifier	12. Postcode of testing service
3. Patient identifier	13. LA of testing service
4. NHS number	14. Specimen type
5. NHS number status indicator	15. Testing service type
6. Gender	16. NCSP clinic code
7. Date of birth	17. Specimen date
8. Ethnicity	18. Sample receipt date
9. Postcode of residence	19. Date result authorised
10. Postcode of general practice	20. Chlamydia test result

All CTAD dataset submissions must be checked thoroughly prior to submission to ensure technical specifications have been met ([CTAD guidance](#)). Of the 20 fields specified above, those in bold are **mandatory** and need to contain a valid code for the file to be accepted by the CTAD web portal. If the information is not held on the laboratory information systems or is missing or unknown the appropriate code should be used. The remaining fields are **required**; if the information is not held on the laboratory information system or is missing or unknown the data field can be left blank. All CTAD codes can be found in the CTAD standard specification on the [NCSP website](#).

5.3 Recommended CTAD quality and activity requirements

The [CTAD commissioning guidance; 2013 update](#), contains the standards that are recommended to be included in all commissioned laboratory contracts, which is presented in figure 4.

Postcode of residence data field:

To accurately attribute tests to the correct upper tier/unitary local authority of residence of a patient, the *postcode of residence* data item must be correctly completed. The NCSP estimates that it is feasible for this data field to be completed in ~75% of all tests; the only venue type for which postcode of residence is unlikely to be supplied is GUM clinics. As such, it is recommended that commissioners set a required completion level for this data item within CTAD laboratory contracts, at 95% for non-GUM tests, as per the above table.

If *postcode of residence* is not available, *postcode of GP* will be used to attribute LA codes. If *postcode of GP* is not available, *postcode of testing service* will be used to attribute LA codes. If *postcode of testing service* is not available, *GP code* will be used to attribute LA codes. If *GP code* is not available, *NCSP clinic code* will be used to attribute LA codes. Again, it is recommended that commissioners consider specifying expected completion rates for these data fields within laboratory contracts, as per the above table.

Venue data fields:

In line with the NCSP standards, 70% of all chlamydia tests should be delivered in primary care, SRH and GUM services. To enable commissioners to analyse local testing activity, and plan future services, accurate data on testing venues is needed. In addition, accurate identification of GUM clinic tests is essential to enable the correct combination of CTAD and GUMCAD chlamydia data.

The feasibility of the NCSP providing **venue-specific testing data**, is highly dependent on accurate completion of the data fields *testing service type*, *postcode of testing service* and *NCSP clinic code*, which is currently sub-optimal. Commissioners are encouraged to consider specifying expected completion rates for these data fields within CTAD laboratory contracts, as per the above table.

Further background information including guidance for laboratory staff on the CTAD data return, data items to be collected, data item format/coding and transmission of data to PHE, along with all other key reference material for CTAD can be found on the PHE website: [CTAD information](#). A list of frequently asked questions with responses can also be found at [CTAD FAQs](#).

5.4 Data protection

Testing providers are responsible for ensuring the quality of data collected and held locally. Confidential data (ie, clinic or NHS number, date of birth, and postcode) must not be disclosed to anyone other than the provider of the data, local programme staff handling the data and PHE. No data may be disclosed to any other parties unless in aggregate form and with the agreement of those responsible for their provision. Additional confidentiality measures include, but are not limited to the following:

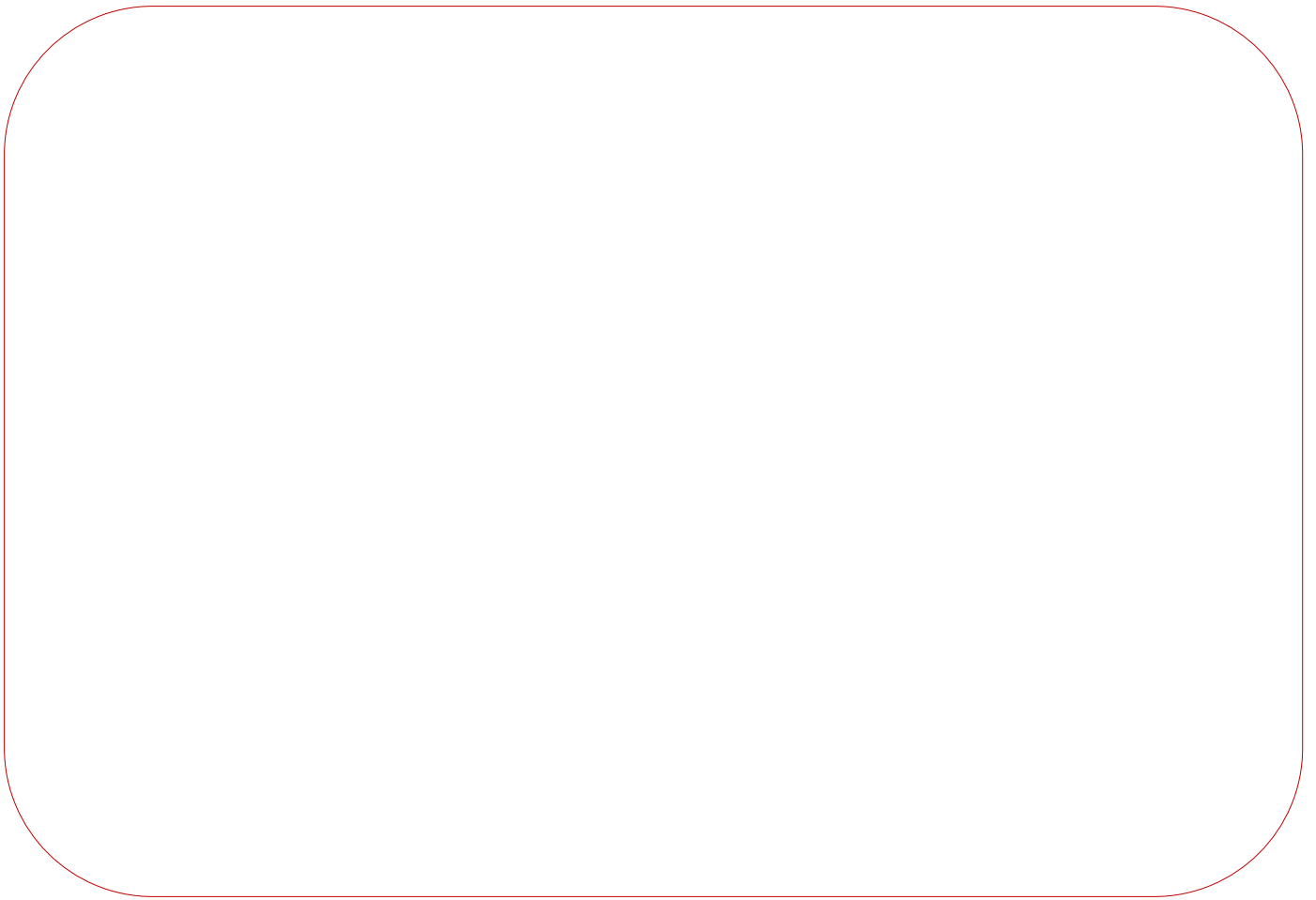
- while data are held locally, access to records should be restricted as part of the system security
- at no time should data be used for any purposes other than those for which they were specifically collected, unless the consent of the providers of that information has been confirmed

Figure 4. Completion standards for CTAD data fields

Quality requirement	Threshold	Responsible	Method of measurement	Consequence of breach
The first 3 requirements concern the timely submission of data by the laboratory in the correct format, with all available information included:				
Timely quarterly submissions of CTAD report extracts to PHE for and on the behalf of laboratories	100%	Laboratory	PHE Colindale confirmation	[As per local agreement]
Records within the CTAD data extract reports are error free	>90% or >250 records (whichever amounts to less) are to be completed, formatted and coded correctly	Laboratory	PHE Colindale: HIV/STI web portal confirmation and acceptance/ rejection report	[As per local agreement]
Reporting of all 20 data fields requested within CTAD Data extract reports	100% inclusion and completion where information is available on test request or from the provider requesting the test	Laboratory if information available on test request form Provider: responsibility for completing information on test request form	PHE with providers and labs (local SHF-convened teams)	[As per local agreement]

Quality requirement	Threshold	Responsible	Method of measurement	Consequence of breach
The following 3 requirements support accurate attribution of tests to local authority of residence:				
Reporting of patient postcode of residence (PCR) (1)	>95% of all non-GUM1 CTAD records must have a valid and known patient postcode of residence. If this proportion is lower than 95%, there must be an improvement of 5% per quarter	Provider must record PCR on all test request forms ² Laboratory must enter and extract data	PHE: HIV/STI web portal user generated reports PHE with providers and labs (local SHF-convened teams)	As per local agreement for the record will not be attributed to a LA if omitted
Reporting of patient postcode of residence (PCR) (2)	<5 records per CTAD extract with the same postcode of residence ³	Provider must record PCR on all test request forms Laboratory must enter and extract data	PHE with providers and labs (local SHF-convened teams)	[As per local agreement]
Reporting of patient postcode of residence (PCR) (3)	CTAD records with a patient postcode that is the same as either a testing venue or laboratory postcode	Provider must record PCR on all test request forms Laboratory must enter and extract data	PHE with providers and labs (local SHF-convened teams)	[As per local agreement]

Quality requirement	Threshold	Responsible	Method of measurement	Consequence of breach
Geographical attribution of tests where postcode of residence is not available; enables analysis of records by individual provider and type of testing service				
Reporting of geographical data fields relating to testing site and GP	>95% of records must have a valid Postcode of Testing Service4 OR Postcode of GP OR National GP code	Laboratory if information available on test request form Provider: responsibility for completing information on test request form	PHE with providers and labs (local SHF-convened teams)	[As per local agreement]



Standard 6. Quality assurance and governance

Mandatory requirements

Confidentiality

All staff involved with testing, providing results, treatment or PN must adhere to national and professional guidelines concerning patient confidentiality:

- BASHH (2014) Standards for the management of sexually transmitted infections (STIs)¹
- Department of Health, Information: To share or not to share? The Information Governance Review March 2013¹⁷
- Department of Health (2003) Confidentiality Code of Practice¹⁹
- UK National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People – 2010, BASHH Clinical Effectiveness Group¹⁶

Test request forms (where used) and treatment and PN notes must be retained in accordance with national and local guidelines (see records management section below).²⁰

The NCSP position regarding sharing of information between services and data protection can be found in the technical appendix, p.55.

Child protection

- anyone under 16 who has a test should be assessed for Fraser competency¹
- any cases of a child under 13 should be discussed with a nominated professional responsible for safeguarding in that service or locality¹
- it is recommended that all sexually active young people under 16 should have a risk assessment for sexual abuse or exploitation¹
- staff involved with regular, substantial and unsupervised contact with young people or vulnerable adults must be CRB checked²¹

Information governance

The use of websites, email and data storage must be approved by local Information governance leads and Caldicott Guardians. The confidentiality of patient information and contact details should be maintained at all times. Websites must be registered with the Information Commissioner's Office.

Mandatory requirements (2)

Clinical governance

The Department of Health has issued new guidance to assist local authorities in commissioning sexual health services ²³. This guidance should be adhered to when commissioning chlamydia screening as well and the guidance can be found [here](#).

Records retention period

GUM and sexual health records for people over 18 must be kept for a minimum of 10 years (both positive and negative) in either paper format or electronically by scanning original paper documents securely. For clients under 18 records should be kept until their 25th birthday or for 8 years after last entry, whichever is the longer i.e. records for clients aged 16-17 should be retained for 10 years and records for clients under 16 should be retained until age 25 (i.e. still retained for at least 10 years).

BASHH Standards: 2, 3, 6, 8
CQC Outcomes: 2, 5

6.1 Quality assurance

Quality assurance (QA) is the systematic action necessary to provide confidence that a service will meet given requirements. QA covers all areas of a service that affect the quality of the end product. The aim of QA in the NCSP is to maintain minimum standards and improve performance of all aspects of chlamydia testing, in order to ensure young people have access to a high quality service. NCSP auditable outcome measures for performance monitoring are set out on page eight.

There should be a local system for monitoring QA at least annually. Contracts/SLAs should specify participation in local and national QA audits, and specifications should be monitored quarterly.

Local programmes should use NCSP standards when:

- preparing SLAs / contracts with providers, and monitoring those SLAs / contracts
- monitoring quality at LA level
- devising measures to drive continual improvement
- training staff involved in delivery of the service

The national [NCSP QA framework](#) includes regular audits and surveys which should be completed in addition to ongoing local QA measures.

6.2 Clinical governance

Commissioning bodies like local authorities need to be sure that they are commissioning services from providers who have robust and effective clinical governance systems in place, (and that they commission services from providers who adhere to clinical and service standards set by relevant professional organisations). The guidance on clinical governance can be found [here](#).

6.3 Websites

Commissioning organisations should consider copyrighting the information on their websites, and should ensure there are clear privacy statements in place. Websites facilitating internet based chlamydia testing should be fully compliant with NHS information governance procedures and their suppliers should be registered with the Information Commissioner's Office (ICO).

6.4 Risk assessment

Commissioners and providers are advised to incorporate risk assessment processes into their testing plans and monitoring. Areas to be covered may include:

- staff cover in the event of sickness or other absence
- security of data held and transferred between venues, including paper, electronic and faxed data
- procedures to ensure everyone tested receives their result, and if necessary, treatment and PN
- local procedures are documented and do not rely on individual staff members
- continuity of service provision in the event of other emergency priorities within the NHS

6.5 Records management

Providers should have a records management policy authorised by medical records and governance leads (and in some cases Caldicott Guardians and safeguarding leads). See the mandatory requirements box above for retention periods. The DH Code of Practice for records management is available at: [Records Management Code of Practice](#).²⁰

6.6 Incident reporting

Providers are responsible for their own governance, and for investigation and resolution of incidents in order to provide assurance of governance and safety, to prevent recurrence, improve services and share learning.

Commissioning organisations should have oversight of serious incidents, and should ensure that they are managed properly. The NCSP also asks to be informed about all serious incidents related to the programme, in order to share learning and maintain an overview of any issues or problems surrounding the programme.

The full NCSP incident reporting policy will soon be available on the [NCSP website](#). In the meantime however, in addition to normal local reporting requirements, organisations are encouraged to inform the NCSP through sending reports to NcspTeam@phe.gov.uk as soon as key details of an incident become clear.

In addition, more general information is available here:

- Managing Incidents in National NHS Screening Programmes, Interim Guidance, Developed in collaboration between the UK National Screening Committee, the NHS Screening Programmes, the NHS Cancer Screening Programmes (all part of Public Health England) and NHS England, available here.²⁴
- Serious Incident Framework, NHS England, March 2013 (update from the 2010, National Framework for Reporting and Learning from Incidents Requiring Investigation, former National Patient Safety Agency), available [here](#)²⁵

Quality assurance and governance:

Considerations for commissioners

- a) QA should be an ongoing process, standards should be specified in SLAs / contracts, and performance managed accordingly
- b) Guidelines for confidentiality, safeguarding and child protection should be in place by all providers, and evidence of staff training and CRB checks should be kept
- c) Commissioners should ensure that requirements for governance and accountability are explicit in contracts with providers
- d) Commissioners should ensure that all providers comply with national requirements in relation to the recording, collection, sharing and reporting of data, including those relating to commissioned websites that facilitate internet based chlamydia testing
- e) All providers should be registered under the Data Protection Act and have a system in place to assess requests for research and audit data

Standard 7. Engaging users and professionals

Mandatory requirements

The Health and Social Care Act 2012 establishes Healthwatch England and local Healthwatch to ensure the views and experiences of the public and people who use health and social care services are taken into account in their commissioning, planning and delivery. Healthwatch is being developed as a statutory part of the Care Quality Commission. A representative of local Healthwatch has a seat on local Health and Wellbeing Boards.

7.1 Promotion and marketing

Communication strategies should be used to promote chlamydia screening to both professionals offering tests and the target population accepting or seeking a test. There are national resources, and further information, available for public health professionals to use to promote screening locally:

- <https://www.gov.uk/government/collections/national-chlamydia-screening-programme-ncsp>
- <http://www.nhs.uk/sexualhealthprofessional/Pages/index.aspx>
- <http://www.nhs.uk/Conditions/Chlamydia/Pages/Introduction.aspx>.

Public health professionals may opt to supplement these with local promotion and marketing strategies. Commissioners should consider collaborative arrangements at a regional or pan-regional level in order to maximise value for money and impact. Local services should be promoted in a way that is accessible to the target population.

When devising marketing materials and patient information all NHS organisations must adhere to NHS branding requirements: [NHS branding](#).

7.2 Engaging and training providers

Commissioners are responsible for ensuring that all staff involved in the delivery of NCSP are adequately trained and competent. Training should be refreshed and updated on a regular basis. The type of training required will depend on the location and roles of the individuals involved. Where third party organisations are involved in programme delivery, commissioners should ensure documented evidence of training specific to the local and national programme. NCSP sexual health facilitators can also support local training and education initiatives.

7.3 Healthwatch

The [Health and Social Care Act 2012](#) aims to put patients at the centre of the decision-making and for commissioner priorities to be informed by engagement with local communities. Healthwatch England and local Healthwatch are new organisations to help in ensuring that the views of the public and the people who use the services, are taken into account. Its role will be to champion service users/patients/carers across health and social care. A representative of local Healthwatch has a seat on local health and wellbeing boards, influencing joint strategic needs assessments and joint health and wellbeing strategies on which local commissioning decisions will be based.

Engaging users and professionals:

Considerations for commissioning

- a) The communications strategy targets both providers and young people, and will support current and potential service users to access services - consider regional or national marketing campaigns to save resources and make messages consistent and powerful
- b) A collaborative commissioning approach should be considered when planning service promotion and marketing
- c) Commissioners and providers should engage with young people when developing their JSNA and service planning to ensure that service provision is appropriate for and acceptable to young people, and taking into account the information and advice from Healthwatch
- d) Services commissioned to provide STI management should have an appropriate contract that states requirements in relation to education and training, assessment of competencies, ongoing maintenance of skills and clinical governance arrangements
- e) Commissioners should ensure that the local communication strategy will support current and potential service users to access services

Glossary of Abbreviations

BASHH British Association for Sexual Health and HIV	NAAT Nucleic acid amplification test
CQC Care Quality Commission	NCSP National Chlamydia Screening Programme
CRB Criminal records bureau	PGD Patient group direction
CTAD Chlamydia testing activity dataset	PPE Patient and public engagement
DH The Department of Health	PHE Public Health England
GC Gonorrhoea	PIL Patient information leaflet
GP General practice	PN Partner notification
GUM Genitourinary medicine	POCT Point of care test
ICO Information Commissioner's Office	QA Quality assurance
JSNA Joint strategic needs assessment	SLA Service level agreement
LARC Long acting reversible contraception	SRH Sexual reproductive health
LGV Lymphogranuloma venereum	STI Sexually transmitted infection
MSM Men who have sex with men	WSW Women who have sex with women

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24. Managing Incidents in National NHS Screening Programmes, Interim Guidance, Developed in collaboration between the UK National Screening Committee, the NHS Screening Programmes, the NHS Cancer Screening Programmes (all part of Public Health England) and NHS England, 2013
25. Serious Incident Framework, NHS England, March 2013 (update from the 2010, National Framework for Reporting and Learning from Incidents Requiring Investigation, former National Patient Safety Agency)

Technical appendix

This appendix provides further detailed information to support the NCSP standards (seventh edition). The page numbers listed in section titles in this document indicate the relevant NCSP standard.

NCSP standard 2

Consent from young people under 16 years old

The test initiator is responsible for ensuring that any young person under 16 being offered a test is competent to make an informed decision. Test venues must adhere to national and local guidance and ensure competency is assessed and documented.

Fraser Guidelines establish that young people under 16 years old can give consent provided that the healthcare worker (HCW) is convinced that:

- the young person understands the HCW's advice, including risks
- the health professional cannot persuade the young person to inform his or her parents or allow the doctor to inform the parents
- the young person is very likely to begin or continue having intercourse with or without contraceptive / sexual health treatment
- unless s/he receives contraceptive advice or treatment the young person's physical or mental health or both are likely to suffer
- the young person's best interests require the HCW to give contraceptive advice, treatment or both without parental consent

Further information:

- General Medical Council. 0-18 Years: Guidance for all doctors:²
http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp.
- UK National Guideline on the Management of Sexually Transmitted Infections and Related Conditions in Children and Young People – 2010, [BASHH Clinical Effectiveness Group](#)¹⁵
- NCSP Standard 2.3 (p.15)
- Dual Screening for Chlamydia and Gonorrhoea

The NCSP formal position statement on dual testing for chlamydia and gonorrhoea, August 2010.

There is limited evidence to support screening for gonorrhoea in unselected populations. Where individual programme areas are providing dual testing for chlamydia and gonorrhoea then information on both infections and consent for

both tests must be obtained prior to screening. Where a sample is tested for gonorrhoea as part of a dual test for chlamydia and gonorrhoea the gonorrhoea result must be reported and acted upon.

It is important that any additional activities do not negatively impact on the implementation and monitoring of the NCSP. The NCSP highlights the following implications of dual testing which should be considered by commissioners prior to the introduction of dual testing:

- evidence: there is no evidence to support widespread unselected screening for gonorrhoea, and evidence for selective community screening in UK settings is sparse (*Guidance for Gonorrhoea Testing in England and Wales*, 2010). Commissioners are advised to consider local prevalence rates and implications of investigating and treating potentially false positive diagnoses, before commencing a widespread screening programme
- patient consent to use of data for monitoring the NCSP: additional testing is not covered by the permissions sought and agreements made nationally for chlamydia testing
- patient information leaflet: the NCSP patient information leaflet does not cover any other test. Separate information will be required.
- staff training: knowledge of gonorrhoea, its treatment and implications for the young person must be disseminated to staff at appropriate levels of complexity
- laboratory accreditation and standards: Laboratories providing dual testing should be CPA-accredited. Laboratories should not test for infections for which a specific request has not been received
- treatment regimes and follow up recommendations will vary. Pathways should be reviewed to ensure that they are appropriate
- partner notification (PN) recommendations will vary and should be reviewed if dual testing
- interpretation of results may be needed (e.g. in an area of low overall prevalence of gonorrhoea, positive results will require formal confirmation since the positive predictive value of a positive test could be low). Supplementary testing with a second NAAT using a different target for confirmation is recommended. Repeat testing of the residual NAAT performed by many laboratories is not a confirmation. Test initiators should be prepared to explain test results and should have robust recall and re-test protocols. Those with positive results should be referred to a level two or three services in accordance with BASHH guidance for culture for antibiotic sensitivity testing, treatment and PN
- websites: where postal kits are sent out, it should be made clear on the website that the test will also be for gonorrhoea
- clinical risk for fail-safe for other infections needs to be delineated

- PHE recently undertook a survey of local authority commissioners to ascertain the extent of dual CT/GC testing of the NCSP population ie. 15-24 year olds. The results from this survey will be available later in 2014 and the current HPA guidance referred to earlier will be updated to provide support to local areas in relation to dual testing

Further information:

- 2010 HPA Guidance and 2012 [BASHH](#) Guidance on Gonorrhoea Testing in England and Wales, 2012^{3,4}
- Local and national advice should be sought from sexual and reproductive (SRH) service providers before considering dual testing

NCSP standard 2.7

Specimen collection

Testing may be undertaken using first-void urine samples (for men and women), self-taken vulvo-vaginal swabs, or cervical swabs if a speculum examination is being carried out as part of routine clinical care. The decision regarding which of these specimens to use will be made in collaboration with the local clinicians and microbiologists participating in the programme.

The following should be noted:

- first-void urine is the sample of choice for men and for women who decline other sampling^{5,6}
- MSM should be offered the option of attending a venue competent to offer rectal chlamydia and gonorrhoea swabbing since there is a high rate of asymptomatic rectal infection in those practicing anal sex⁷

Care must be taken with all samples to avoid cross contamination. After collection, samples (including self-taken samples obtained off site) should be placed in an individual specimen bag along with a completed request form. Information on collection, transport, storage and handling of specimens for both young people and staff should be provided. Disposable equipment should be handled according to local infection control policy.

Requirements for specimen collection

1. Urine specimens (for men and women)

- participants should be supplied with a labelled collection pot or kit and instructions
- a suitable toilet and hand-washing facilities will need to be available and instructions given to allow participants to provide the urine sample

Example instructions for collecting a sample:

- a) you should not have passed urine in the last hour. [Some platforms may require two hours.] If you have tell the person asking you to do this specimen **before** you do anything else
- b) wash and dry your hands
- c) as soon as you start, pass the **first** part of your urine into the bottle (about half full). Pass the rest of your urine into the toilet
- d) if you have been given a grey 'teabag'-shaped pouch, insert it into the urine now
- e) screw the cap back on tightly
- f) ensure your name and clinic identification number are on the specimen
- g) place the specimen into the plastic specimen bag and hand it back to the clinic staff

If the young person is unable to pass urine, or has voided urine outside the manufacturers' recommendations, they should be given specimen collection equipment and instructions, and asked to return another fresh sample as soon as possible. Women may also be offered a self-taken vulvo-vaginal swab or offered an alternative sample type. Information regarding manufacturers' recommendation, including specimen type (first void), quantity and time since last passed urine, should be adhered to. Additional information is needed for samples requiring the insertion of preservation pouches. Urine sample should be stabilised by refrigeration or by other means prior to transport to the lab (refer to manufacturers' recommendations for sample stability).

2. Vulvo-vaginal swabs

- a private area with hand-washing facilities will need to be made available for on site swabbing. Alternatively, after receiving instructions, specimens can be obtained off site and returned at a later stage
- an appropriate sterile swab and instructions should be provided

Example instructions:

- a) first, wash and dry your hands and then take the cotton wool swab out of the packing by twisting the cap
- b) rub the soft cotton-bud ends (not the plastic sticks) gently just inside the vagina opening
- c) rotate the cotton buds, pressing firmly on the moist part inside. Please make sure they touch the skin inside your vagina
- d) place the swab back into the small plastic tube
- e) press the cap on tightly
- f) ensure your name and clinic identification number are on the tube
- g) place the tube into the plastic specimen bag and hand it back to the clinic staff

3. Cervical specimens

- if a planned cervical examination is being undertaken, the opportunity should be taken for a cervical swab to be collected according to the manufacturers' recommendations
- if a cervical examination is not being performed, participants should be offered the choice of a urine sample or self taken vulvo-vaginal swab. Cervical examination should not be carried out for the sole purpose of obtaining a specimen sample for testing

Specimen storage and transport:

Providers should follow the test manufacturers' instructions and guidance from their laboratory service provider.

NCSP standard 2.8

Test timing clinical FAQs

How often can a test be repeated?

It is advised not to repeat a test within six weeks after treatment of a positive result.⁵ NAATs are very sensitive and may pick up chlamydial nucleic acids from non-viable organisms.^{8, 9}

How many days should pass after unprotected sex before a chlamydia test is undertaken?

The NCSP recommends that a test be given immediately and repeated in two to three weeks. If the first test is positive it may be because the index person already has chlamydia or, in the case of the female, that the test is picking up chlamydia in the partner's semen. The NCSP recommends that the individual should be treated on each occasion that the test is positive in this particular scenario, since there is the possibility that positive results on both occasions could indicate identification of an existing infection, followed by a new infection.

If a patient requesting a chlamydia test is currently taking antibiotics (for an unrelated infection), how many days should pass before a chlamydia test should be undertaken so that false negatives would not be a problem?

- Individuals should be tested regardless of antibiotic treatment.
- If the result is negative, the clinician should undertake a risk assessment to determine if this may represent a 'false negative', based on the action of the antibiotic used against chlamydia, clinical assessment, and the likelihood of detecting non-viable organisms given the sensitivity of NAATs tests. PN may be considered.
- If the result is positive and the antibiotic being used could also be used to treat chlamydia, a positive result could indicate either non-viable organisms from a treated infection, or a partially treated infection. The NCSP recommends that presumptive treatment for chlamydia infection should be given and partner notification undertaken.

What advice should be given to a woman who requests a chlamydia test but indicates that her period started today? How many days (if any) should elapse before swabs are undertaken?

When using NAATs this does not matter as there is no interference seen with blood. If a woman feels uncomfortable providing a lower vaginal or endocervical swab at this time, or if she is using a tampon (see below) a urine test can be used instead. Alternatively she can be advised to wait until after her period.

What advice should be given on the use of tampons?

A tampon may absorb chlamydia organisms and reduce the effectiveness of a lower vaginal swab. Clinicians are advised to use a urine test or an endocervical swab in this instance.

NCSP standard 4

Legal Framework for Supply and Administration of Medicines used by NCSP and Patient Group Directions (PGDs)

Treatment must be administered by either medical practitioners or other clinical staff legally covered to work under PGDs. Regardless of the treatment delivery method that local programme areas elect to use, they must comply with clinical governance standards. If PGDs are in use, there must be clear documentation of who is the authorising medical consultant. Special considerations will need to be put in place for practices that can prescribe but not administer therapy.

When developing and reviewing local PGD templates be aware of [NICE guidance](#), as well as the latest British National Formulary (BNF) guidance:

- addition to the exclusion criteria section:
 - myasthenia gravis
 - previous history of cardiac arrhythmia
 - any medicine known to interact with Azithromycin including drugs known to prolong the QT interval (see current [British National Formulary](#))

Types of licensed medicines

The Medicines Act 1968 regulates the sale, supply and administration of all medicines. Medicines are categorised in three - *Prescription-only medicines (POMs)*, which require a prescription to be written, usually by a doctor, dentist, nurse or other approved prescriber), *Pharmacy (P) medicines* (which can only be sold through a registered pharmacy under the personal supervision of a pharmacist, and *General Sales List (GSL) medicines* (which are deemed even safer than P medicines and can be sold in general shops as well as through pharmacies, albeit often in small quantities). Both GSL and P medicines can be known as over the counter (OTC) medicines.

For more information on the mechanisms available for the prescribing, supply and administration of medicines to support the development of new roles or service redesign, see:

- Department of Health. *Medicines Matter* (2006).¹⁰
- PGD website (<https://www.gov.uk/government/publications/patient-group-directions-pgds>), which contains and signposts to a wide selection of resources, including examples of PGDs such as national templates for emergency care, and which is supported by the National Knowledge Service.

Patient-specific directions and PGDs

Patient-specific directions

A patient-specific direction is the traditional written instruction, from a doctor, dentist or independent prescriber, for medicines to be supplied or administered to a named patient (e.g. an instruction on a ward drug chart or an instruction by a GP in medical notes for a practice nurse to administer an injection).

The majority of medicines are still prescribed, supplied or administered through this process. As a patient-specific direction is individually tailored to the needs of a single patient, it should be used in preference to a PGD wherever appropriate.¹⁰

Patient Group Direction (PGD)

A PGD is a written instruction for the supply or administration of a medicine (or medicines) to groups of patients who may not be individually identified before presenting for treatment. The supply and administration of medicines under PGDs should be reserved for the limited number of situations where this offers an advantage for patient care (without compromising patient safety).

Use of PGDs is appropriate when:

- the medicines to be given, and the circumstances under which they should be given, can be clearly defined in the written direction, and there is a robust evidence base
- there are 'high volume' groups of patients who present for treatment
- medicines are to be supplied and/or administered by one of the registered health professionals who are allowed to use PGDs

Where clear criteria are included within the PGD, the PGD can include a flexible dose range so that the healthcare professional can select the most appropriate dose for each patient. The majority of clinical care should be provided on an individual, patient-specific basis.

A PGD should be drawn up locally by doctors, pharmacists or other health professionals and must meet certain legal criteria. Each PGD must be signed by a senior doctor or dentist, as appropriate, and by a senior pharmacist, both of whom should have been involved in developing the PGD. Additionally the PGD must be authorised by an appropriate body (i.e. clinical service provider). Accountability for any PGD lies with the signatories to that PGD.

The employing organisations have a legal duty of care and are responsible for ensuring that the staff they employ are properly trained and competent, and that they undertake only those responsibilities specified in agreed job descriptions.

A list must be kept within each organisation detailing the individuals who approved the PGD and the individuals named as competent to use specific PGDs. A designated senior person in each profession locally should be responsible for ensuring that only fully competent, qualified and trained professionals operate within PGDs. For a PGD to be implemented, the signatures of all professionals who will be working within the PGD must be obtained, as well as the signatures of those giving organisational approval.

Professionals work under PGDs as named individuals, and no delegation of the supply or administration of medicines is permissible. Non-registered staff cannot administer medicines using a PGD, and cannot train others to prescribe medicines.

PGDs can only be used by the following registered healthcare professionals, acting as named individuals, including: nurses, midwives, health visitors, ambulance paramedics and pharmacists.

All professionals must act within their appropriate professional code of practice, and their own level of expertise and competence. The use of PGDs must also be consistent with appropriate professional relationships and accountability.¹⁰

Supply

Treatments should only be supplied pre-packaged ("patient-ready") in appropriately labelled packs. Pre-packaged treatments should be obtained from a licensed pharmacy pre-packing unit. The packs must either be supplied against a valid individual prescription or PGD or be supplied by a practitioner who is accredited to work with/under a PGD.

The exception to this is pharmacists, who will dispense treatment from bulk stock. This should be done in accordance with dispensing and labelling regulations. (Guidance is available from the [Royal Pharmaceutical Society of Great Britain](#), Medicines Act 1968 and [Medicines and Healthcare Products Advisory Agency](#)).

PGDs and those under 16 years old

There is no specific legislation regarding use of PGDs in those aged under 16 years. It is up to the clinical services provider, to ensure that the document includes the locally agreed policy for the management of under-16s. The signatories of the PGD will have ultimate responsibility for its use in this age group. Staff using the PGD in the under-16s must have received the appropriate training and be aware of local care pathways and the nominated person(s) responsible for child protection issues.

Off-label use in PGDs

A PGD can include an 'off-label use' (using a licensed product for an unlicensed use) provided that there is appropriate and robust (ideally national) evidence.¹⁰ As with any off-label use, adequate information needs to be made available to the patient. Such off-label use occurs in chlamydia screening with the use of azithromycin in children and pregnant women.

- **Azithromycin in children**

The summary of product characteristics (SPC) for the Pfizer product, [Zithromax®](#), does not specify what a child is, but there is discussion regarding weight needing to be >45kg (as of July 2012). Pfizer considers that persons aged 12 years or over have a sufficiently mature metabolic mechanism to deal with the stat dose, even if their weight is marginally less than 45kg. Guidance from the US Centers for Disease Control and Prevention states that children over the age of eight years, regardless of weight, can receive the adult stat dose.

At present there is no definitive guidance from the NCSP on this topic, and individual commissioners will need to agree locally what stance they wish to take on this and to document any associated decisions.

- **Azithromycin in pregnancy**

The safety of azithromycin in pregnancy and lactating mothers has not yet been fully assessed, although available data indicate that it is safe. The BNF recommends its use only if no alternative is available. WHO guidelines recommend a 1g stat dose in pregnancy. The alternative is erythromycin 500mg bd for 14 days. This drug has a significant side effect profile, and some individuals may find it unacceptable or be unable to tolerate the regime. The NCSP advises that clinicians follow the recommendations made by the BNF (www.bnf.org.uk/bnf/) and [BASHH](#).⁵

Note: The generic azithromycin produced by TEVA UK Ltd has a similar SPC to that of Pfizer's product regarding age, weight and pregnancy.

Presentation of azithromycin

Commissioners should be aware that azithromycin is available generically in both capsule and tablet presentations. When choosing the presentation commissioners should take into account:

- market availability
- drug tariff price

- ease of administration
- the fact that manufacturing SPCs vary between tablets and capsules, and consideration may need to be given to this during the patient consultation. Tablets are film-coated and unaffected by the intake of food, allowing individuals to take the treatment dose immediately at any time. Capsules, according to the manufacturing SPC, are affected by the intake of food and carry the recommendation to take on an empty stomach i.e. avoid food one hour before taking, or for two hours after taking. A literal interpretation could prevent some individuals from taking the treatment on site. This has multiple implications: Inability to verify treatment has been taken; risk of failure to take; treatment issued under PGD would become chargeable if taken away by person. This problem arises from the relatively low bioavailability of the drug in the plasma. Some clinicians have taken a pragmatic approach of giving the treatment immediately and requesting patients to avoid food for two hours after

NICE guidance on PGD

NICE published good practice guidance on PGD in August 2013. This can be found [here](#).

NCSP standard 5.4

Data protection

The following statement is a joint position statement by BASHH, SSHA and the NCSP clarifying the position regarding sharing of information between GUM services and the different healthcare professionals within the NCSP.

Purpose of statement

- to establish communication pathways between GUM and chlamydia screening programmes to enhance the care of people with chlamydia, and their partners, within a framework of confidentiality
- primarily this will be for the purpose of confirming index patient or partner treatment. Discussions for advice on clinical management, or for referral of complicated cases to GUM, may also be covered by this statement
- the information shared would be for the purpose of the treatment of the patient and/or the prevention of the spread of the disease. Information may also be shared for surveillance and agreed audit purposes

Statement

- information that allows individuals to be managed effectively for genital chlamydial infections may be exchanged between GUM and health care services delivering chlamydia screening programmes within the NCSP*
- information may include confirmation of tests taken, results, treatment given and follow-up arrangements for a named individual.
- information will be exchanged verbally where possible
- staff identities will be verified before information is exchanged
- information exchanged will be documented in the relevant patient record

*Clinical staff and administrative staff working under their direction working in GUM and core healthcare services undertaking chlamydia screening operating within the NCSP, encompassing primary care (GP practices and pharmacies) and SRH services (including abortion services).

This statement does not cover communication with non-clinical screening sites.

Further Information:

- Department of Health. Guidance for Access to Health Records Requests. 2010.¹¹
- Data Protection Act 1998.¹²
- NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000.¹³
- SSHA. The Manual for Sexual Health Advisers. London: SSHA, 2004.¹⁴
- Department of Health, Information: To share or not to share? The Information Governance Review March 2013¹⁵

References

1. Department of Health. Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health, 2004
2. General Medical Council. 0-18 Years: Guidance for all doctors, 2007
3. BASHH. UK National Guideline on Gonorrhoea Testing, 2012
4. HPA. Guidance on Gonorrhoea Testing in England and Wales 2010
5. BASHH Clinical Effectiveness Group. UK National Guideline for the Management of Genital Tract Infection with Chlamydia trachomatis, 2006
6. BASHH Chlamydia Trachomatis Screening and Testing Draft Guidelines, 2010
7. Annan et al. Rectal chlamydia—a reservoir of undiagnosed infection in men who have sex with men. *Sex Transm Infect* 2009;**85**:176-179
8. Gaydos et al. Molecular amplification assays to detect chlamydial infections in urine specimens from high school female students and to monitor the persistence of chlamydial DNA after therapy. *J Infect Dis* 1998;177:417-24
9. Morre et al. Monitoring of Chlamydia trachomatis infections after antibiotic treatment using RNA detection by nucleic acid sequence based amplification *J Clin Pathol: Mol Pathol* 1998;51:149–154
10. Department of Health. Medicines Matters, 2006
11. Department of Health. Guidance for Access to Health Records Requests, 2010
12. Data Protection Act, 1998
13. Department of Health. NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions, 2000
14. Society of Sexual Health Advisors. SSHA manual for sexual health advisors, 2004
15. Department of Health, Information: To share or not to share? The Information Governance Review March 2013