Syphilis

CDNA National Guidelines for Public Health Units

Revision history			
Version	**Date**	**Revised by**	**Changes**
1.0	June 2015		Original
1.1	June 2018	Public Health Laboratory Network, STI Enhanced Response Unit, Multijurisdictional outbreak working group (MJSO)	Document further updated for currency and revised formatting. Additional information provided for: - syphilis point of care testing (Page 15 of the SoNG and pp. 43-45 of Appendix D) - frequency of testing during pregnancy within the context of an outbreak (page 18 and 25)

The Series of National Guidelines ('the Guidelines') have been developed by the Communicable Diseases Network Australia (CDNA) and noted by the Australian Health Protection Principal Committee (AHPPC). Their purpose is to provide nationally consistent guidance to Australia's public health units (PHUs) in responding to a notifiable disease event.

These guidelines capture the knowledge of experienced professionals, and provide guidance on best practice based upon the best available evidence at the time of completion.

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1. Summary

Public health priority

Infectious syphilis, confirmed or probable case in a pregnant female: URGENT

Infectious syphilis, confirmed or probable case in a male or non-pregnant female:

HIGH

Congenital syphilis: HIGH

Non-infectious syphilis: ROUTINE

Priority Classification	Public health response timeline	Data entry timeline
Urgent	Act as soon as possible, respond within 24 hours	Within 1 working day
High	Act as soon as possible, generally within one working day	Within 3 working days
Routine	Action should be carried out as part of routine duties	Within 5 working days

Case management

Immediately on notification of a case of confirmed or probable infectious syphilis, begin follow up investigation and notify the state/territory public health authority or syphilis register in accordance with jurisdictional statutory requirements.

Cases who present with symptoms consistent with infectious syphilis (classically a relatively painless, indurated genital ulcer or symptoms / signs of secondary syphilis) must be treated at the time of first presentation.

Cases of infectious syphilis diagnosed on serology should be treated as soon as possible (and ideally within two days) of diagnosis.

For cases of syphilis of less than two years duration, one dose of benzathine penicillin 1.8g (2.4 million units) by intra-muscular injection (IMI) is required. For syphilis of more than two years or unknown duration, a course of three doses of benzathine penicillin 1.8g (2.4 million units) IMI, each dose 7 days apart, is required.

At the time of the first treatment dose, blood should be collected for non-treponemal tests RPR (rapid plasma regain) or Venereal Disease Research Laboratory (VDRL) to provide the baseline used to assess response to treatment and check for re-infection.

RPR testing, ideally by the same laboratory that undertook the baseline assessment, at 3-6 and 12 months following treatment, is important to determine the response to treatment.

Infectious cases are rendered non-infectious 5 days after one dose of benzathine penicillin and all symptoms are resolved (whichever is longer). Completion of adequate treatment for syphilis does not confer immunity and re-infection can occur, frequently in some risk groups, especially HIV infected men who have sex with men (MSM).

Particular care is required to ensure adequate treatment in pregnancy, because of the extreme risk

of in-utero infection of the fetus. Serological follow-up of the maternal RPR during and following the pregnancy is essential. Syphilis infection may occur after screening in early pregnancy or following reinfection after treatment. Specialist paediatric review is recommended for the children of all women treated for syphilis in pregnancy[1,2,3].

Contact management

The aim of identifying contacts of infectious syphilis is to prevent disease transmission by offering testing to identify infection before the onset of clinical symptoms and providing empirical treatment. Timely contact tracing lies at the heart of an effective public health response to syphilis and needs to be prioritised.

Anyone who has had sex (including oral sex) with a person who has confirmed or probable infectious syphilis is a contact. Unborn babies and infants of women with infectious syphilis are also contacts.

Stage of index case	Look-back period for sexual contacts	Management
Primary	Duration of symptoms plus 3 months	Perform syphilis testing Serology and PCR swab collection if a lesion is present Give 1.8g (2.4 million unit) benzathine penicillin without waiting for serology results
Secondary	Duration of symptoms plus 6 months	
Early latent and probable infectious	12 months	

2. The disease

Infectious agents

The causative agent is the spirochaete bacterium, *Treponema pallidum* subspecies *pallidum*. There are a number of other *Treponema pallidum* subspecies that cause non-venereal infections including: *pertenue* (yaws), *endemicum* (bejel or endemic non-venereal syphilis) and *carateum* (pinta).

Reservoir

Treponema pallidum subspecies *pallidum* is an obligate human parasite.

Mode of transmission

In the vast majority of cases, syphilis is spread by direct contact with skin lesions or mucous membranes of an individual with infectious syphilis during anal, oral or vaginal intercourse. Vertical transmission can occur at any time during pregnancy and at any stage of syphilis.

Less commonly, syphilis is transmitted by infected blood (transfusion, drug users), by non-sexual personal contact with infected lesions or by accidental direct inoculation.

Incubation period

The incubation period is 10 to 90 days with a median of 3 weeks to the onset of primary syphilis.

Infectious period

Syphilis is most infectious during the primary and secondary stages of the disease (refer section below) when moist mucocutaneous lesions are present, with transmission risk being up to 50% per sexual contact. The infectious period is defined as the first two years of infection, if untreated,

however the period of high infectivity lasts for 12 months from the onset of infection. Sexual transmission is uncommon after two years of infection.
The risk of maternal trans-placental transmission to the unborn baby is also highest in infectious syphilis. The risk of infection in the unborn baby of a pregnant woman with primary or secondary syphilis is extremely high, approaching 100%. If left untreated, the risk of vertical transmission diminishes over years but may never disappear.

Infected infants with moist mucocutaneous lesions are a potential source of infection.

Clinical presentation and outcome

Clinical presentation may be highly variable and many cases do not follow the classical stages listed below. Neurosyphilis can occur in any stage of syphilis.

Primary syphilis: The primary lesion, a chancre, begins as a papule 10-90 days after infection, soon ulcerating to form an indurated ulcer at the site of inoculation; this may be on external or internal genitalia or a non-genital site, e.g. lip, tongue, pharynx, anus, rectum. This is usually a single indurated and relatively painless lesion and accompanied by regional lymphadenopathy, however atypical multiple and painful lesions can occur. The ulcer heals spontaneously over the course of a few weeks[4]. Clinical suspicion of syphilis should be high for all presentations of a painless, indurated genital ulcer. However in an outbreak setting all genital ulcers should be considered to be potential primary syphilis cases.

Secondary syphilis usually occurs 4 to 10 weeks after onset of the primary lesion. Symptoms include headache, fatigue, lymphadenopathy, low grade fever, sore throat, rash, mucocutaneous lesions, condylomata lata (large, raised, whitish or grey, flat-topped lesions found in warm moist areas) and alopecia. Ocular and neurological symptoms may also occur. Secondary syphilis may commence prior to the resolution of the primary lesion. Untreated secondary syphilis symptoms persist for 3-12 weeks after which the patient enters the early latent phase. Symptomatic relapses of secondary syphilis occur in 25% of untreated cases, mainly in the first 12 months after infection.

Early latent syphilis refers to syphilis of less than two years duration (infectious syphilis) in a person who has no symptoms or signs of infection at the time of diagnosis.

Syphilis of more than two years duration, in the absence of clinical signs or history of treatment, is called late latent syphilis. People with late latent syphilis are asymptomatic for many years. Historically, between one quarter and one third of infected and untreated individuals will ultimately develop tertiary syphilis. The following timelines for development of tertiary syphilis were derived in the pre-antibiotic era and are a guide only. Bone and skin lesions at any time after 2 years but usually between 2 and 15 years, cardiovascular disease at 20-30 years and three types of central nervous system disease (meningo-vascular at 5-12 years, and general paresis and tabes dorsalis usually at 15-25 years).

Treponema pallidum crosses the placenta and infects the foetus at any time in the pregnancy. If untreated, this can result in intrauterine foetal death, stillbirth or a premature baby with congenital syphilis. In early congenital syphilis, the infected baby may be severely affected at birth (with hepatomegaly, ascites, hydrops, foetal anaemia) or more frequently, may not present any observable sign. If the diagnosis is not made then, the baby will present later with non-specific complaints (rhinitis, failure to thrive, pneumonia), nearly always within three months of birth. Neonates with severe disease have a worse prognosis. Late congenital syphilis corresponds to tertiary disease in the adult and can be prevented by early diagnosis and treatment of the infant.

Persons at increased risk of disease

Populations at highest risk of syphilis include Aboriginal and/or Torres Strait Islander people in remote Australia, men who have sex with men (MSM), female partners of MSM and people who have unprotected sex in overseas countries where syphilis is prevalent. Effective treatment of syphilis does not confer immunity against *Treponema pallidum*, and these high risk groups are at risk of reinfection. Clinical presentation of reinfection may be similar to primary or secondary symptomatic infection, but

often presents as asymptomatic (or pre-symptomatic) rises in serology parameters and is indistinguishable from early latent infection[1].

Particular issues of special relevance to MSM and Aboriginal and/or Torres Strait Islander people are discussed in section 12 and Appendix D, respectively, of this document.

Disease occurrence and public health significance

Syphilis is no longer rare in Australia with high rates in some communities, including MSM and Aboriginal and Torres Strait Islander people. The rate in the non-Indigenous female population is increasing, albeit from a low baseline. Syphilis rates declined among MSM with the onset of the HIV epidemic but have climbed consistently since the late 1990's. Rates in Aboriginal and Torres Strait Islander people have increased in recent years, especially those living in remote areas, after sustained periods of decline. Overall notification rates in Aboriginal and Torres Strait Islander people remain well above the general population and outbreaks continue to occur.

The public health significance of syphilis lies in its impact on the developing foetus in utero and the interaction of *Treponema pallidum* with the human immunodeficiency virus (HIV). Congenital syphilis is an entirely preventable disease and thus it is an event that represents a failure of the health system. Its occurrence reflects a failure of delivery systems for antenatal care and for syphilis control programs. In addition to shared transmission routes syphilis biologically enhances both the transmission and acquisition of HIV; hence syphilis control and HIV prevention are closely aligned.

3. Routine prevention activities

A combination of coordinated prevention activities is more effective than an isolated, single activity.

Sexual health promotion and education programs aim to increase awareness of syphilis and other sexually transmissible infections and empower people to adopt safe sex practices (e.g. condom use), thus reducing their risk of both acquiring and transmitting infection. These programs are targeted to priority groups including young people, MSM, Aboriginal and Torres Strait Islander populations, sex workers and prisoners.

4. Surveillance objectives

- Provide baseline data to enable detection of changes in disease trends including evaluation of intervention strategies
- Enable timely detection and identification of cases of infectious syphilis to facilitate rapid response to the management of cases and their contacts
- Enable timely detection of clusters and outbreaks to facilitate early intervention to control transmission
- Inform the prevention of congenital syphilis

5. Data management

Data for confirmed and probable cases of infectious (i.e. primary, secondary, early latent) syphilis and congenital syphilis should be entered into jurisdictional notifiable conditions databases within one day of confirmation.

Data for confirmed cases of non-infectious (i.e. late latent, tertiary) syphilis should be entered into jurisdictional notifiable conditions databases as soon as possible following confirmation.

[1] This is a problematic area – many reinfections in MSM & HIV MSM would not be detected[5] without regular screening as per STIGMA[16] guidelines.

Syphilis is a notifiable disease under the public health acts of all states and territories, and nationally. Cases of reactive serology are reported by pathology laboratories to public health authorities. In some jurisdictions the medical and/or nurse practitioner who diagnoses a case of syphilis is also required to notify the jurisdictional public health authority.

6. Communications

Notify confirmed and probable cases of infectious (i.e. primary, secondary, early latent) syphilis and congenital syphilis in accordance with jurisdictional statutory requirements; include the patient's date of birth, sex, indigenous status, address, date of onset, laboratory status, possible sources of infection, other people thought to be at risk and follow up action taken.

State/territory Communicable Disease Branches (CDB) should inform CDNA of outbreaks of infectious syphilis. Interjurisdictional outbreaks requiring national coordination may require support from the National Incident Room (NIR). See Appendix D for information about outbreaks in remote populations.

7. Case definition

Infectious Syphilis – less than two years duration (includes primary, secondary and early latent including reinfections)

Reporting

Confirmed and probable cases should be notified.

Confirmed case

A confirmed case requires either:

Laboratory definitive evidence

OR

Laboratory suggestive evidence **AND** clinical evidence.

Laboratory definitive evidence

Seroconversion in past two years: treponemal specific test reactive[2] when previous treponemal specific test non-reactive within past two years and the latest result is confirmed by either a reactive non-treponemal test[3] or a different reactive treponemal specific test

OR

A fourfold or greater rise in non-treponemal antibody titre compared with the most recently recorded titre within past two years, and a reactive treponemal specific test

Laboratory suggestive evidence

Demonstration of *Treponema pallidum* by dark field microscopy (not oral lesions), direct fluorescent

[2] Treponemal specific tests are: IgG or total Ab immunoassay (EIA or CLIA), *Treponema pallidum* haemagglutination assay (TPHA), *Treponema pallidum* particle agglutination assay (TPPA), Fluorescent Treponemal Antibody Absorption(FTA-Abs), 19S-IgM antibody test, or IgM immunoassay, Treponemal Ab specific immunochromatography (ICT) assay. See section 8 for further details

[3] Non-treponemal tests are; Rapid Plasma Reagin (RPR), Venereal Disease Research Laboratory (VDRL). See section 8 for further details.

antibody microscopy (direct antigen test), equivalent microscopic methods (e.g. silver stains), or DNA methods (e.g. nucleic acid testing)

OR

A reactive treponemal specific test confirmed by either a reactive non-treponemal test or a different reactive treponemal specific test

OR

A reactive non-treponemal test confirmed by a treponemal specific test

Clinical evidence

1. Presence of a primary chancre (or ulcer)

OR

2. Clinical signs of secondary syphilis.

Probable case

A probable case requires that the case does not meet the criteria for a confirmed case **AND**

Either:

a) In a person with no known previous reactive serology: no history of adequate treatment of syphilis, or endemic treponemal disease, and

1. Contact with an infectious case **AND** laboratory suggestive evidence.

OR

2. Laboratory suggestive evidence **AND** RPR ≥16.

OR

3. Positive syphilis IgM **AND** laboratory suggestive evidence.

OR

b) In a person with previous reactive serology: a fourfold or greater rise in non- treponemal antibody titre when the previous serology was done more than two years ago.

AND

1. Contact with an infectious case

OR

2. Positive syphilis IgM

Syphilis - Congenital

Reporting

Both **confirmed cases** and **probable cases** should be notified, including syphilis-related stillbirth[6].

Confirmed case

A confirmed case requires laboratory definitive evidence.

Laboratory definitive evidence

Mother and child both seropositive by a treponemal specific test.[7]

AND

One or more of the following:

Direct demonstration of *Treponema pallidum* by any of the following: nucleic acid amplification (NAA) test, dark field microscopy, fluorescent antibody or silver stain - in specimens from lesions, nasal discharge, placenta, umbilical cord, cerebrospinal fluid (CSF), amniotic fluid or autopsy material

OR

Detection of *Treponema pallidum* specific IgM in the child

OR

The child's serum non-treponemal[8] serology titre at birth is at least fourfold greater than the mother's titre.

Probable case

A probable case requires laboratory suggestive evidence AND clinical evidence.

Laboratory suggestive evidence

Direct demonstration of *Treponema pallidum* as described under laboratory definitive evidence (above), but without serological confirmation in the child.

OR

Child seropositive on non-treponemal testing in the absence of IgM testing

OR

A reactive CSF non-treponemal test (VDRL or RPR) in a child.

OR

A child who remains seropositive by a treponemal specific test at 15 months of age, which is confirmed either by another, different reactive treponemal specific test or a reactive non-treponemal test, in the absence of post-natal exposure to *Treponema pallidum* , including the non-venereal subspecies *Treponema pallidum* subsp. *pertenue* (Yaws) or subsp. *endemicum* (Bejel, endemic syphilis).

Clinical evidence

1. Any evidence of congenital syphilis on physical examination

OR

2. Any evidence of congenital syphilis on radiographs of long bones

OR

3. An elevated CSF cell count or protein (without other cause)

OR

4. The mother is seropositive in the perinatal period AND has no documented evidence of adequate treatment[9].

Notes:

1. A stillbirth where the foetal death has occurred after a 20 week gestation or in a foetus which weighs greater than 500g should be counted as clinical evidence towards a case where laboratory suggestive or definitive evidence exists.

2. Treponemal tests: see footnote 2 and section 8

   IgM assays should not be used for screening purposes.

   Treponema pallidum-specific rapid immunochromatography (ICT) assays for use as point-of-care tests are now becoming available, but their performance has not yet been fully established. Positive ICT results should be confirmed with a second treponemal specific assay.

3. Non-treponemal tests: see footnote 3 and section 8. Any positive sera should be tested by serial dilution to provide an end-titre. Non-treponemal tests may be used to monitor efficacy of treatment. Mother and child sera should be collected contemporaneously and tested in parallel and cord blood should not be used for the investigation of congenital syphilis.

4. Treatment is considered adequate if

   a. a stage-appropriate penicillin-containing regimen was used 30 days or more prior to delivery AND

   b. all antenatal and delivery pathology investigations were performed and results verified AND

   c. there is no evidence of reinfection.

5. Treatment with macrolides alone during pregnancy in penicillin-allergic women is no longer regarded as adequate therapy as resistance to macrolides in *T. pallidum* is increasingly common (now >50% in Australia) and may arise during therapy. Expert advice should be sought in such cases

6. Although the risk of congenital syphilis is much higher in early-stage disease, in the presence of untreated syphilis the birth of an unaffected child does not guarantee that subsequent children will not be affected.

Syphilis - more than 2 years or unknown duration

Reporting

Only **confirmed cases** should be notified.

Confirmed case

A confirmed case requires that the case does not meet the criteria for a case of infectious syphilis less than 2 years duration AND either:

Laboratory definitive evidence

OR

Laboratory suggestive evidence **AND** clinical evidence.

Laboratory definitive evidence

1. A reactive treponemal specific test which is confirmed either by a reactive non-treponemal or a different treponemal specific test

AND

2. a) In a person with no known previous reactive serology: no history of adequate treatment of syphilis, or endemic treponemal disease (e.g. Yaws)

OR

b) In a person with previously reactive serology: a fourfold or greater rise in non-treponemal antibody titre when the previous serology was done more than two years ago.

Note: In a high prevalence area, only one reactive treponemal specific test result is necessary.

Laboratory suggestive evidence

Demonstration of *Treponema pallidum* by dark field microscopy (not oral lesions), direct fluorescent antibody microscopy (direct antigen detection), equivalent microscopic methods (e.g. silver stains), or DNA methods (e.g. nucleic acid testing).

Clinical evidence

Clinical, radiological or echocardiographic signs of tertiary syphilis.

8. Laboratory testing

Laboratory case definitions for syphilis are available on the Department of Health web site (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-phln-syphilis.htm).

Culture is not available. Syphilis is principally diagnosed by serology (treponemal specific and non-treponemal tests), and sometimes (if lesions are present) by nucleic acid amplification techniques or direct demonstration of the organism by dark-field microscopy or direct fluorescent antibody techniques (direct antigen detection). Current NAA techniques cannot reliably detect *T. pallidum* in blood at any stage of infection.

Syphilis serology

There are two types of syphilis serology tests: treponemal specific tests and non-treponemal tests. Treponemal specific tests detect antibodies to antigens specific to pathogenic *T. pallidum*. They become reactive after infection with *T. pallidum* and usually remain reactive indefinitely regardless of adequate treatment, however partial or complete loss of treponemal specific antibodies over time occurs in a minority of patients, especially HIV-infected or those treated very early in infection. They do not necessarily indicate active infection. Non-treponemal tests detect antibodies to reagin (a combination of lecithin, cholesterol and cardiolipin), a substance similar to that generated in response to spirochaete-induced damage to cellular membranes. Tests based on detection of antibodies to reagin are a useful indicator of disease activity.

Treponemal and non-treponemal serology tests are less than 100% sensitive in primary syphilis so syphilis serology may be negative in the presence of a chancre.

Treponemal specific tests

- Agglutination assay tests: *T. pallidum* particle agglutination (TPPA), *T. pallidum* haemagglutination (TPHA), microhaemagglutination assay for antibodies to *T. pallidum* (MHA-

TPTPPA). These assays detect IgM well and show sensitivity in early syphilis roughly equivalent to IgM immunoassays.

- *T. pallidum* immunoassays: Immunoassays are suitable for automation and is favoured by many laboratories as a suitable screening test for infectious syphilis. The recombinant (IgG or total antibody) immunoassay antibody test is probably the most sensitive treponemal specific test post primary syphilis, and it is highly specific. There are a variety of different immunoassays in use; the most common tests in Australia are Enzyme immunoassays (EIA), Chemo-luminescent immunoassays (CLIA) and Chemiluminescent Microparticle Immunoassay (CMIA). Immunoblot assays are also used by a few laboratories. Sensitivity and specificity of different immunoassays at various stages of syphilis will vary with antigen type and concentration used.

- Fluorescent treponemal antibody absorption test (FTA-ABS). Sensitivity varies with disease stage: primary 86%, secondary 100%, early latent 98% and late latent 73%. Specificity is 97%.[7] This test is less commonly used as a confirmatory test since the introduction of EIAs and other immunoassays as it is technically difficult, labour intensive and subjective, but is still used with CSF.

- *T. pallidum* IgM EIA: this test is sometimes used in the investigation of congenital syphilis and early acquired syphilis. In primary syphilis sensitivity is 86.5% and specificity oscillates between 91 and 99.8% depending on the assay used.[8] Sensitivity is lower in later disease stages and in re-infections, but its presence indicates active disease. This test should not be used for screening purposes as occasional low-level false positive results occur.

Non-treponemal tests

- Non-treponemal tests do not detect antibody to *T. pallidum* but to reagin and are a useful indicator of disease activity. Other conditions (infections and autoimmune conditions) can also induce antibodies to reagin, leading to false positive results but with titres generally ≤ 8. Non- treponemal tests in use today are known as VDRL (venereal diseases research laboratory) and RPR (rapid plasma reagin).

- The VDRL test requires microscopy and is usually used only on cerebrospinal fluid, although it may also be used on serum (but not plasma).

- The RPR is performed on serum or plasma. Sensitivity varies according to disease stage: primary 86%; secondary 100%; early latent 98%, late latent 73%.[7] Specificity is 98% (if treponemal specific tests positive).[8]

Reporting and interpretation of tests

There is a period after infection when both treponemal specific and non-treponemal serology may be negative. Generally speaking the treponemal specific test (e.g. EIA) becomes reactive within 2-4 weeks and the RPR becomes reactive within 3-4 weeks post infection.

Most laboratories in Australia now use a treponemal specific test as the first (screening) test following a request for syphilis serology. If reactive, a non-treponemal test (e.g. RPR) and another treponemal specific test is performed.

Most laboratories report treponemal specific tests as reactive or non-reactive.

The RPR, if reactive, is reported as a titre – the endpoint of a serial dilution: 1 in 2, 1 in 4, 1 in 8, 1 in 16, 1 in 32 etc. which represents the highest dilution giving a reaction. A higher dilution suggests more active disease. The results are reported as the reciprocal of the highest dilution (ie. 2, 4, 6, 8 etc). Figure 1, developed by Gavin Hart, indicates the typical RPR response following syphilis infection.[10]

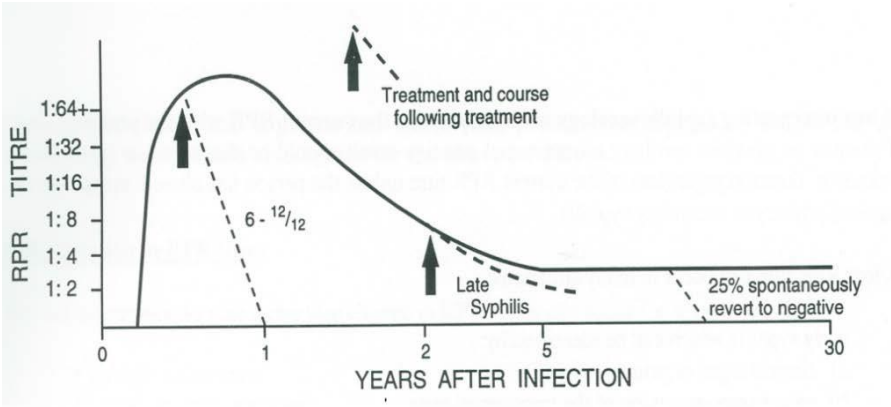

Figure 1: Variation in RPR titre after infection

The RPR test is also used to monitor response to treatment. An adequate response to treatment in infectious syphilis is defined as a four-fold (or two-dilution) drop in RPR e.g. 1 in 128 to 1 in 32 on parallel testing by 6 months, though the rapidity of this decline varies according to disease stage at treatment. This test becomes non-reactive in the majority of patients if infection is diagnosed and adequately treated early in its course. Patients with high RPR titres, late diagnoses and individuals who have been re-infected will be left with fixed reactive (serofast) RPR titres (e.g. 1 in 16) despite adequate treatment, in up to a quarter of patients.

Re-infection is generally diagnosed on the basis of changes in RPR titre. A four-fold or two-titre rise in RPR, e.g. 1 in 2 to 1 in 8, following previous adequate treatment is considered a re-infection. PCR may be useful if ulcerated or moist lesions are present.

The non-treponemal test results rely on subjective judgements by the operator reading the test. The reproducibility of the result will vary according to the skill of the operator and the antigen preparation used. Comparison of results on serial samples should always be done in parallel. Results from different laboratories for an individual patient should not be compared.

Treponemal specific and non-treponemal tests do not distinguish between sub-species of Treponemes. In some parts of remote Australia yaws and non-venereal endemic syphilis were common up until the late 1960s and yaws remains common in PNG, Indonesia, the Solomon Islands, Vanuatu and parts of central and west Africa.[11] It is possible that people from these regions who acquired these conditions as children will still have the antibodies giving them reactive treponemal serology without ever having had infectious syphilis.

Nucleic acid amplification techniques

If an individual has clinically observable lesions (e.g. genital ulcer, lesions of secondary syphilis), a dry swab, scrapings or biopsies for nucleic acid amplification (NAA) test such as a polymerase chain reaction (PCR) test for *Treponema pallidum* should be collected. This test can also be done on placental specimens (including paraffin embedded tissue), ocular fluids and CSF. These tests are highly sensitive and specific and are now available in most states, but are not recommended for testing blood.[12]

Point of care tests for syphilis[4]

There is currently only one syphilis point of care test registered by the Therapeutic Goods Administration in Australia, the Determine Syphilis TP™ manufactured by Alere, now Abbott. The Determine Syphilis TP™ is a treponemal specific immunochromatographic test that can be used with whole-blood samples from either finger-prick or venepuncture.

Point of care syphilis tests, used in combination with conventional syphilis serology and treatment

[4] See: *Appendix D. Guidelines for the Public Health Management of Syphilis Outbreaks in Remote Populations in Australia* for further discussion on the use of point of care testing in the current context

history data, can facilitate case identification and reduce time to treatment for infectious syphilis.[13,14,15] Interpretation requires access to the individual's previous syphilis serology and treatment history. If treatment is triggered on the basis of the point of care test alone, then over-treatment can result. In an outbreak situation, this may be considered an acceptable risk, especially for people who have no known history of past syphilis and where follow-up is uncertain.

There are a number of limitations with current syphilis point of care tests:

- currently tests cannot distinguish current from previous syphilis infection, due to either the absence of, or non-quantified nature, of a non-treponemal component;
- even in ideal use sensitivity and specificity are slightly lower than laboratory based assays;
- the tests are moderately complicated and require staff to be specifically trained in their use;
- there are quality control issues with the storage, tracking and QC validation of test batches and
- the results may not be captured by current notification and testing registries.

The following issues should be considered when implementing syphilis point of care tests:

- the prevalence of past syphilis infection (generally they should only be used in populations with low rate of past syphilis infection);
- development of clinical protocols, training and an appropriate clinical governance system;
- perform laboratory based testing in parallel for all reactive results and for negative results wherever feasible; and
- ensure there is a process to notify reactive results to public health authorities and, where applicable, notify all test results to the syphilis register.

Please refer to Appendix D for further consideration on the use of syphilis point of care tests in outbreak contexts.

9. Case management

Response times

Prioritisation of the public health response to a case of confirmed or probable infectious syphilis is HIGH. Infectious syphilis occurring in a pregnant woman requires URGENT public health response due to the risk of congenital infection.

Investigation

Immediately on notification of a case of confirmed or probable infectious syphilis, begin follow up investigation and notify the state/territory CDB.

Case investigation

The response to a notification will normally be carried out in collaboration with the case's health carers. Regardless of who does the follow-up, for confirmed and probable cases of infectious syphilis, PHU staff should ensure that action has been taken to:

- confirm results of relevant pathology tests
- confirm the onset date and symptoms of the illness
- obtain a full sexual history, including contact history; conduct a physical examination and testing for other STIs, including HIV, in accordance with local clinical guidelines
- find out if the case has had syphilis previously and if so, obtain details of previous syphilis tests and treatments & where these were carried out.
- find out if the case or relevant care-giver has been informed of their diagnosis and seek the doctor's permission to contact the case or relevant care-giver (where possible) before

beginning the interview; although this may not always be practicable it is included as a courtesy to the treating doctor

- review case and contact management to ensure they have been completed
- review the case history and test results to ensure that the correct syphilis stage has been recorded in notification data.

Who is the best person to conduct the contact tracing interview? This is a local decision best made on a case-by-case basis. The culture and gender of the interviewer and whether or not they are known to and trusted by the case are relevant factors to consider.

When to interview cases about their contacts? Symptomatic patients should be interviewed in relation to their contacts when they first present, while early latent cases diagnosed on serology findings should be interviewed when seen for treatment.

Interviewing cases about their sexual contacts must be undertaken on a voluntary basis. The cooperation of the case is critical. The interview must be conducted in a private space and without hurrying. It needs to be approached with care and sensitivity and accompanied by clear information in language the individual understands. The way syphilis is spread and the importance of tracing all sexual contacts who may have been exposed should be explained. The case should be assured of the confidential nature of these disclosures and that the contact/s will not be told the identity of the person who named them, only the type of infection to which they have been exposed.

A clinical review at one-week post-treatment is recommended and gives the health care provider the opportunity to ask again about contacts. Even if contact names were provided at the first interview, further careful inquiry would be appropriate, e.g. "….. Is there anyone else you think should be seen?"

When a case has named a contact, they should be asked whether this is their regular partner. If it is, then they should be asked "who else?" If the named contact is not a regular partner, then they should be asked about their regular partner/s. If the interviewer believes there are other contacts that remain un-named, the question may be asked differently. For example, the case may find it easier to remember their contacts if the inquiry is related to significant events: "where were you on your birthday? Did you have a party? Who were you with then?" or "what was happening at the rodeo? Who were you with then?"

The interviewer should always expect more than one contact, and never assume the gender of any contact. The interviewer should also consider asking the case about their friendship group: "who, in your group, do you think should also have a test?" (social contact tracing).

If a case has not named any contacts, or the named contacts do not have syphilis, or a case and contact name only each other, both case and contact must be re-interviewed. Consultation with a local health worker as to the appropriate approach may be helpful, but must not compromise confidentiality.

Case treatment

Cases who present with symptoms consistent with infectious syphilis (a painless or painful, indurated genital ulcer or symptoms / signs of secondary syphilis) must be treated at the time of first presentation.

Cases of infectious syphilis diagnosed on serology should be treated as soon as possible (and ideally within two days) of diagnosis. Rapid referral and confirmation of treatment is required if a case moves away from the location where they were diagnosed before undergoing treatment.

Cases of infectious syphilis who are known to be pregnant require urgent follow up and treatment to minimise the possibility of vertical transmission. Breast feeding does not result in the transmission of syphilis, unless an infectious lesion is present on the breast.

The treatment for syphilis generally recommended is long-acting benzathine penicillin.

For cases of confirmed infectious syphilis of less than two years duration, one dose of benzathine penicillin 1.8g (2.4 million units) IMI , OR procaine penicillin 1.5 g IM, daily for 10 days is required. For probable cases of infectious syphilis or syphilis of more than two years or unknown duration, a course of three doses benzathine penicillin 1.8g (2.4 million units) IMI, 7 days apart, OR procaine penicillin 1.5 g IM, daily for 15 days is required.

Cases of congenital syphilis should be treated in consultation with a specialist paediatrician. The recommended treatment is benzylpenicillin 50mg/kg IMI or IVI, 12 hourly for 10 days or procaine penicillin 50mg/kg IMI daily for 10 days.

For detailed information on therapeutic agents for tertiary syphilis see the current edition of Therapeutic Guidelines: Antibiotics (www.tg.org.au).

If penicillin is contraindicated, seek specialist advice from an infectious diseases, or sexual health, physician. Individuals who are allergic to penicillin should be considered for desensitization in the first instance (especially if pregnant). For non-pregnant patients who are hypersensitive to penicillins if desensitisation is not possible, doxycycline 100 mg orally, 12-hourly for 14 days can be used. Ceftriaxone may also be an option, but efficacy has not been formally proven. Do NOT attempt to treat syphilis with macrolides.

Monitoring response to treatment

At the time of the first treatment dose, blood should be collected for RPR to provide the baseline used to assess response to treatment and check for re-infection.

Treatment of infectious syphilis is considered to be adequate if there is a four-fold (two dilution) drop in RPR titre, e.g. 1 in 64 to 1 in 16, by 6 (up to 12) months. RPR testing, by the same laboratory that undertook the baseline assessment, at 3-6 and 12 months following treatment, is important to determine the response of treatment. Comparison of results on serial samples should always be done in parallel. Results from different laboratories for an individual patient should not be compared.

Testing too soon after treatment should be avoided as it may show an increase in RPR; this does not indicate treatment failure.

Infectious cases are rendered non-infectious 5 days after one dose of benzathine penicillin. Completion of adequate treatment for syphilis does not confer immunity and re-infection can occur.

Syphilis in pregnancy

Due to the extreme risk of vertical transmission of syphilis particular care is required to ensure adequate treatment in pregnancy, all case of syphilis in pregnancy should be discussed with a clinician with expertise in the area. Treatment of syphilis in pregnancy is according to disease stage and is usually the same as in the non-pregnant state. Contact tracing and treatment for the woman's partner/s are critical to minimise the potential for re-infection as this represents a particular threat to the unborn baby. Serological follow-up of the maternal RPR during and following the pregnancy is essential and should start at 3 months after the first dose of benzathine penicillin; this is important for monitoring the response to treatment and prompt detection and treatment of re-infection. For treatment of syphilis in pregnancy to be considered adequate, the first dose must be administered at a minimum of one month (30 days) prior to delivery. Ideally there should be a demonstrated four-fold (two-titre) drop in maternal RPR, e.g. 1 in 64 to 1 in 16, prior to birth. If these conditions have not been satisfied at the time of delivery, then the baby should be examined, investigated and treatment for congenital syphilis considered. Specialist paediatric review is recommended.

All cases of congenital syphilis must be consistently identified, reported and then investigated to identify factors for improvement at both clinical and system levels, with mechanisms made available to implement recommended changes to practice.

Education

Cases of infectious syphilis need to be informed of the infectious nature of their disease, even in the absence of visible lesions or symptoms, and to abstain from sexual activity for 5 days post-treatment or until symptoms have completely resolved (whichever is the longer). The importance of follow up and repeat syphilis serology testing to monitor the response to treatment should be emphasised. The case should be informed that they are likely to continue to have positive treponemal specific tests for life, even after successful treatment.

Isolation and restriction

Cases of infectious syphilis should abstain from sexual activity for five days after receiving treatment or until symptoms have completely resolved (whichever is longer)

Active case finding

Testing for syphilis is recommended when:

- There is a clinical presentation of a suggestive genital ulcer(s) (chancre of primary syphilis) or symptoms/signs of secondary syphilis
- A person is diagnosed with another STI – at the time of diagnosis and 3 months later
- A sexual contact of a person diagnosed with an STI is being evaluated
- A person requests an STI check, and

In pregnancy, according to national and local clinical guidelines, The Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommends syphilis testing of all pregnant women at the first antenatal visit and again at 28 weeks in those at high-risk. Women at high-risk includes all Aboriginal and Torres Strait Islander women. In the jurisdictions affected by an ongoing syphilis outbreak, most antenatal care guidelines for at-risk populations within the outbreak areas recommend syphilis serology screening 5 times around the pregnancy: at the booking visit, again at 28 weeks, at 36 weeks, at delivery, and 6 weeks post-partum. Local guidelines exist within those areas that might recommend different or additional times for testing; cross-reference with direction from local authorities is advised. In those areas where point of care tests are used, serology confirmation of current infection or stages is recommended. Syphilis testing in pregnancy is essential for early detection and treatment of new infections and re-infections.

Periodic syphilis testing is currently recommended for asymptomatic people in high risk groups, including:

- Young, asymptomatic Aboriginal and Torres Strait Islander populations in specific regions. Recommendations vary between regions and are based on local evidence and expert opinion. Health staff should be aware that the requirement of a blood sample for syphilis testing might deter some young people from participating. Outside of outbreak situations opportunistic syphilis testing of asymptomatic older Aboriginal and Torres Strait Islander people (>40 years) in pursuit of diagnoses of infectious syphilis should be actively discouraged because this group is not at increased risk of infectious syphilis and testing without a clinical indication is likely to result in unnecessary treatment of people with positive treponemal specific tests who were treated many years ago for venereal and/or non-venereal syphilis and/or yaws.
- MSM. The STIGMA (Sexually Transmissible Infections in Gay Men Action Group) guidelines[16] recommend annual STI testing, including syphilis testing, for all MSM who have had sex with a man in the past one year; 3-6 monthly testing for MSM who have had unprotected anal intercourse, more than 10 partners in the past 6 months, group sex or used recreational drugs during sex; and 3 monthly testing for MSM with HIV.

- Women whose sexual partner/s are MSM.

- Sex workers. STI prevalence in Australian sex workers is low. However, periodic 6-12 monthly testing is recommended.

10. Environmental evaluation

Not applicable

11. Contact management

It is recommended that jurisdictions ensure that primary health, sexual health and public health staff are made aware of their roles and responsibilities in relation to contact tracing for infectious syphilis. Roles may vary between jurisdictions and between different regions within a jurisdiction. It is also recommended that public health services maintain active oversight of contact tracing processes for infectious syphilis cases even where they do not provide staff to actively support the contact tracing effort. Contact tracing staff should be guided by the Australasian Contact Tracing Guidelines (www.contacttracing.ashm.org.au).

Identification of contacts

The aim of identifying contacts of infectious syphilis is to prevent disease transmission by offering testing to identify infection before the onset of clinical symptoms and providing empirical treatment.

Contact definition

Anyone who has had sex (including oral sex) with a person who has confirmed or probable infectious syphilis is a contact. Unborn and newborn babies of women with infectious syphilis are also contacts.

How far back to trace? The infectious period depends on the stage of infection.

- For cases with primary syphilis, contacts should be traced for the duration of the case's symptoms plus three months; if uncertain, contacts to six months prior to presentation are to be traced

- For cases with secondary syphilis, contacts should be traced for the duration of the case's symptoms plus six months; if uncertain, contacts to 12 months prior to presentation are to be traced

- For cases of probable infectious syphilis and early latent syphilis, contacts to 12 months prior to presentation are to be traced.

Contact management

In addition to empirical treatment, contact management should include:

- Obtaining a sexual history including inquiry for symptoms or a recent history of symptoms and a clinical examination for signs of syphilis and other STIs

- Investigations for other STIs, according to local clinical guidelines.

- Informing contacts of their test results at the earliest opportunity after the results of investigations become available.

- If it was difficult to locate the contact or if their follow-up is likely to be difficult or delayed, consider obtaining a full sexual history including a sexual contact history at the initial consultation.

Patient and provider referral are the two main methods of alerting contacts. In the former, the case notifies their contacts while in the latter, the health care provider organises the notification and treatment of contacts. In remote populations, provider referral is the principal method of contact tracing used. When patient referral is used, contact management as outlined above should occur within two weeks of case treatment and the health staff responsible should confirm with the patient that this has occurred. If delays in patient referral occur, the patient should be offered additional support to undertake patient referral and the option to change to provider referral.

Innovative contact tracing tools have been used in MSM settings. These include on-line patient referral tools such as The Drama Downunder's 'Let him know' website (www.thedramadownunder.info/notify/) and the WA AIDS Council M Clinic's peer-led service delivery. On-line partner notification services have been developed by the Australian Council of AIDS Organisations for Aboriginal people (www.bettertoknow.org.au/) and by the Melbourne Sexual Health Clinic (www.letthemknow.org.au/).

How much effort should be put into finding contacts of infectious syphilis? The highly transmissible nature of infectious syphilis, and specifically its capacity to spread rapidly through a population and to cause both fetal death and severe congenital complications if transmitted to a pregnant woman, demands an urgent response from primary care and public health/sexual health clinic staff. Tracing the contacts of early syphilis should be a high priority, higher than contact tracing for other STI (chlamydia, gonorrhoea) which can cause serious complications but not so acutely. Rigorous and immediate efforts are called for. Half-hearted attempts will result in further sexual transmission and potentially result in serious avoidable outcomes such as congenital syphilis. If contact tracing is not effective, the patient is at high risk of being re-infected after treatment.

Response times

Timely contact tracing lies at the heart of an effective public health response to syphilis and needs to be prioritised. Contacts of infectious syphilis who live locally should be seen and treated within two working days of the case's treatment. If the contacts are elsewhere and referral has been necessary, health staff should aim to ensure that all contacts are seen and treated within two weeks of the case's treatment.

Empirical treatment

Persons who were sexually exposed to a patient with primary, secondary, or early latent syphilis should be treated presumptively with one dose of benzathine penicillin 1.8g (2.4 million units) regardless of their syphilis serology results.

Education

Contacts of infectious syphilis need to be informed about the infectious nature of the disease, the possibility that they might be infected and infectious even in the absence of symptoms, and to abstain from sexual activity for 5 days after they have received empirical treatment or their syphilis serology shows that they have not been infected. The importance of follow up and repeat syphilis serology testing to monitor the response to treatment should be emphasised.

Isolation and restriction

Sexual contacts of infectious syphilis should abstain from sexual activity for five days after receiving treatment.

12. Special situations

Syphilis outbreaks are more likely to occur in particular populations. In Australia, recent outbreaks have occurred in MSM and Aboriginal and Torres Strait Islander populations (See Appendix 4 which comprises Guidelines for the Public Health Management of Syphilis Outbreaks in Remote Populations in Australia). Syphilis clusters may also occur in association with certain sexual networks. It is

important to pay attention to confidentiality and the sensitivities associated with sexually transmissible infections when managing syphilis clusters and outbreaks.

MSM who participate in highly sexually active subcultures are at increased risk of acquiring syphilis. Due to the diversity of the MSM population in relation to syphilis infection, any initiative developed must take into account the varying subpopulations, e.g. HIV positive and negative MSM; younger and older MSM (MSM <30 years contribute the highest number of syphilis notifications among HIV negative MSM whereas MSM aged 40-49 years contribute the highest number of syphilis notifications among HIV positive MSM); and those with differing stages of syphilis including symptomatic and asymptomatic infections. The *National Gay Men's Syphilis Action Plan* outlines priority actions to achieve a sustained reduction in the incidence of infectious syphilis in MSM.[16]

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14. Appendices

Appendix A. Syphilis fact sheet

Appendix B. Public Health Unit Checklist

Appendix C. Syphilis investigation form

Appendix D. Guidelines for the Public Health Management of Syphilis Outbreaks in Remote Populations in Australia

15. Jurisdiction specific issues

Links to State and Territory Public Health Legislation, the Quarantine Act and the National Health Security Act 2007
(www.health.gov.au/internet/main/publishing.nsf/Content/cda-state-legislation-links.htm).

Appendix A. Syphilis fact sheet

What is syphilis?

Syphilis is a very serious sexually transmissible infection. It is caused by the *Treponema pallidum* bacterium.

What are the symptoms?

The first signs of syphilis may not last long, so you can have it and pass it on without knowing.

You might get an ulcer or sore around the genital area or mouth, 3 to 12 weeks after infection. The sore can be any size or shape. It can be painful or painless, doesn't bleed, and feels like a hard button on the skin. Sometimes there can be more than one sore. This is called the primary stage of syphilis. If not treated, the sore heals and disappears after a few weeks, but the person is still infected.

Two to 6 months after getting infected, the secondary stage of syphilis occurs. Symptoms include a skin rash on the face, palms, and soles of the feet, swollen glands, lumps around the moist areas of the body, and hair loss. You can also get headaches, and pains in the bones, muscles and joints. This stage can last for 6 months or more.

What happens if syphilis is not treated?

Without treatment, there is a latent stage where there are no visible signs but you are still infectious and can pass on syphilis through sex for up to 2 years.

If untreated for more than 2 years, syphilis can progress to the tertiary stage which can affect your brain, heart, large blood vessels, the spinal cord, skin and bones, leading to disability and death.

If a pregnant woman has syphilis, her baby can be born dead or damaged (congenital syphilis).

How is it spread?

Syphilis is spread by unprotected vaginal, anal and oral sex. You can also be infected through intimate or skin to skin contact with an infected person. Syphilis also increases the risk of HIV transmission.

An infected mother can pass syphilis on to her baby via the placenta during pregnancy.

Who is at risk?

Everyone is susceptible to infection. In Australia, groups at particular risk of syphilis include:

- Men who have sex with men
- Female sexual partners of men who have sex with men
- Aboriginal and Torres Strait Islander people
- People who have unprotected sex with people who have syphilis
- Babies of mothers who have not had adequate antenatal care, including syphilis testing during pregnancy

In Australia, the risk of getting syphilis from a woman involved in sex work is very low.

You can get syphilis again, even if you have been treated for it in the past. Syphilis infection does not create immunity.

How it is prevented?

The safest ways to protect against syphilis are to:

- Always use condoms, dams and water based lubricant. Condoms and dams are the best way of protecting against syphilis and some other sexually transmissible infections (STIs).
- Avoid having sex with someone who has a visible ulcer or sore on their genitals.
- Have a long-term relationship where neither you nor your partner is already infected or has other sexual partners.
- Having fewer sexual partners lowers your risk of having sex with someone who has syphilis.
- Have regular STI check-ups.
- If you are diagnosed with an STI, complete the recommended course of treatment.

All women should have a syphilis test in the first 12 weeks of pregnancy or at the first antenatal visit. The earlier syphilis is treated during the pregnancy, the lower the risk of the baby becoming infected or being damaged by syphilis. Additional testing for syphilis in pregnancy may be recommended in areas affected by a syphilis outbreak and for certain at-risk populations. Please check directions from local health authorities on this matter.

There is no vaccine for syphilis.

How is it diagnosed?

Blood tests are used to diagnose syphilis. There is a short period after exposure to syphilis when the tests may not pick up the early stages of infection and repeat tests may be necessary. If you have contracted syphilis you will test positive by three months after infection, and usually much earlier.

How is it treated?

Syphilis is usually treated with penicillin injections. You should abstain from sexual activity until five days after completing your course of treatment and your doctor has informed you that you are no longer infectious.

It is important that you have regular blood tests at 3, 6 and 12 months after syphilis treatment to monitor the effectiveness of treatment.

Even after treatment, some of your blood tests might be positive for syphilis. This does not mean you are still infected. It just shows that you have had syphilis in the past.

Treatment of your sexual partners is important to prevent you from getting re-infected and to prevent the infection spreading in your community. You can help by advising your sexual partners to get tested and treated for syphilis. You can do this by talking with your partners or asking your doctor to inform your partners or you could use an on-line notification website such as "Let Them Know" (suitable for all people), "The Drama Downunder" (for gay men); and "Better to Know" (for Aboriginal and Torres Strait Islander people).

What are your doctor's responsibilities?

Your doctor is responsible for:

Providing you with appropriate tests, treatment and information about how to protect yourself from sexually transmissible infections.

Helping you to ensure that your sexual partners get tested and treated. Confidentially notifying cases of syphilis to the local health department.

Where can you find more information about syphilis?

Contact your GP, community health clinic, sexual health clinic or Aboriginal and/or Torres Strait Islander health worker.

Appendix B. Public health unit checklist

Contact the patient and/or the patient's doctor to:

- Obtain patient's risk exposure history
- Obtain patient's previous syphilis testing and treatment history (this information might be available from a state or regional syphilis register/database)
- Identify likely source of infection
- Confirm onset of symptoms (if any)
- Confirm results of relevant pathology tests
- Ensure that the patient is aware of diagnosis
- Ensure that contact tracing has been commenced.

Contact the laboratory to:

- Check samples received and obtain any outstanding results

Confirm case:

- Assess information against case definition
- Stage syphilis in consultation with specialist advice
- Enter data into jurisdictional infectious disease notification database

Other issues:

Infectious syphilis occurring in a pregnant woman requires a URGENT public health response due to the risk of congenital infection.

Appendix C. Syphilis case investigation form

Public Health Unit/Sexual Health Clinic undertaking case investigation:

…… Notification ID: ……..

Case details

Family name: ……..

Given names: ……..

Date of birth: d d / m m / y y y y

Sex: ☐ M ☐ F ☐ Indeterminate

Female patients: ☐ Pregnant ☐ Not pregnant ☐ Unknown

Note: Infectious syphilis occurring in a pregnant woman requires URGENT public health response due to the risk of congenital infection

Indigenous Status:

☐ Aboriginal but not Torres Strait Islander origin

☐ Torres Strait Islander but not Aboriginal origin

☐ Both Aboriginal and Torres Strait Islander origin

☐ Neither Aboriginal nor Torres Strait Islander origin

☐ Not stated/inadequately

described Address

……..

Postcode …….

Country of birth: ☐ Australia ☐ Other, specify ……

Language mostly spoken at home: ☐ English ☐ Other, specify ……. ☐ Unknown

Past history

Previous syphilis testing: ☐ Yes ☐ No ☐

Unknown If yes, provide details

	Date	**Result**
Last treponemal specific test	d d / m m / y y y y	
Last RPR	d d / m m / y y y y	

Previous syphilis diagnosis: ☐ Yes ☐ No ☐

Unknown Date of last syphilis notification: d d / m m / y y y y

Previous syphilis treatment: ☐ Yes ☐ No ☐

Unknown If yes, provide details

Date given	Drug	Dose	Route	Comments

Other relevant information .....

Disease details

Symptoms at time of diagnosis: ☐ Primary ☐ Secondary ☐ Tertiary ☐ No

symptoms If symptoms present, date of onset: d d / m m / y y y y

If primary syphilis, site of infection: ☐ Urogenital ☐ Anorectal ☐ Oropharyngeal
☐ Other ☐ Unknown

Laboratory results:

☐ Positive PCR/dark ground microscopy of lesion

☐ Reactive RPR/VDRL

☐ Reactive TPPA/TPHA

☐ Reactive EIA

☐ Other, specify

Stage of infection: ☐ Primary ☐ Secondary ☐ Early latent ☐ Late latent ☐ Tertiary

☐ Congenital

Health service where patient was diagnosed: ☐ Public hospital ☐ Private hospital
☐ Sexual health clinic ☐ Family planning ☐ GP ☐ Aboriginal health service

☐ Prison/detention centre ☐ Public/community health clinic

☐ Other, specify .....

Reason for presentation to health service: ☐ Symptoms ☐ Contact of syphilis
☐ Contact of other STI ☐ STI Screening ☐ Antenatal care, gestation ……../40
☐ Other, specify ……..

Risk information

Where was the infection most probably acquired? ☐ This state ☐ Interstate, specify……..
☐ Overseas, specify …… ☐ Unknown

Sex of partner from whom the infection was most probably acquired ☐ Opposite sex
☐ Same sex ☐ Either sex ☐ Unknown ☐ Not sexually acquired

Type of sex partner from whom the infection was most probably acquired

☐ Regular ☐ Casual ☐ Sex worker ☐ Client (of a sex worker)
☐ Other, specify …….. ☐ Unknown ☐ Not sexually acquired

Where did patient meet the sex partner from whom the infection was most probably acquired?
☐ Brothel ☐ Beat ☐ Internet ☐ Sex on premises venue
☐ Other, specify …….. ☐ Unknown
☐ N/A, regular partner or already known to patient

Most likely mode of transmission: ☐ Vaginal intercourse, insertive
☐ Vaginal intercourse, receptive ☐ Oral sex, insertive ☐ Oral sex, receptive
☐ Anal sex, insertive ☐ Anal sex, receptive ☐ Unknown ☐ Not sexually acquired

Management

Treatment details

Date given	**Drug**	**Dose**	**Route**	**Comments**

Other relevant information ……

Contact tracing: ☐ Patient agreed to notify partners
☐ Health service will notify partners, name of health service……..
☐ Other, specify ……

Appendix D. Guidelines for the Public Health Management of Syphilis Outbreaks in Remote Populations in Australia

Outbreak responses will be dictated by the constraints and opportunities within each jurisdiction. These recommendations aim to cover principles to ensure a comprehensive response. Experience has demonstrated that, unlike food-borne or respiratory disease outbreaks, a syphilis outbreak in remote Australia will require a community-wide approach and a sustained response lasting two or more years.[17]

A significant syphilis outbreak is a complex social challenge. The ideal response will be multi-strategic, informed by local knowledge, and attentive to detail in its execution. It will be enhanced where positive relationships already exist between the stakeholders.

Syphilis Outbreak Response Framework

A Syphilis Outbreak Response is divided into 4 phases, timelines are suggested as a guide only and may not be applicable to all situation:

Phase One: Outbreak identification
Phase Two: Early Response (0 – 1 month)
Phase Three: On-going Response: Part 1: (1- 12 months); Part 2: (12+ months)
Phase Four: Outbreak reporting and response evaluation

Considerations on the role of Syphilis Point of Care Testing (POCT) in outbreak response

Public health objectives and targets* for the outbreak response:

The aim of the response is to interrupt the further transmission of infectious syphilis and to prevent congenital syphilis.

The public health objectives are:

a) To increase testing in the "at risk" population:

Target: 100% of pregnant women are tested at first antenatal visit and thereafter according to regional clinical guidelines

Target: 100% of people diagnosed with chlamydia, gonorrhoea or HIV have a test for syphilis as part of the management of their infection

b) To achieve best practice management outcomes for cases of infectious syphilis:

Target: At least 80% of cases are treated and undergo public health investigation within two weeks of diagnosis

Target: At least 80% symptomatic cases are treated for syphilis on first presentation

Target: At least 80% cases of infectious syphilis cases have repeat syphilis serology at 3-6 months post-treatment

c) To achieve best practice management outcomes for contacts of infectious syphilis:

Target: 80% of named contacts are examined, tested and treated for syphilis at their first presentation to a health service

Target: 80% of named contacts are examined, tested and treated for syphilis within one month of being named

*The targets are based on discussion with stakeholders and clinical experience.

Phase One: Outbreak Identification: Is There a Problem?

It is not possible to provide a specific definition of a syphilis outbreak that can be universally applied. A working definition is: a greater than expected number of infectious syphilis cases diagnosed over a short period within a defined region or sexual network.[18,19] The cases may arise independent of each other or from a single contact tracing effort.

The relevant public health staff should alert their public health medical officer (PH MO) in the event of such an increase over the preceding 3 (up to 6) months.

The PH MO should investigate to determine whether the increase is real and whether there are increases in contiguous regions / jurisdictions. Please note that an increase in testing locally cannot explain away the finding of a cluster of cases of infectious syphilis given that syphilis is no longer an endemic condition in rural / remote populations in Australia.

The initial response requires an immediate re-prioritising of routine work and the allocation of existing staff and resources to address treatment and contact tracing. This situation occurs sporadically across remote Australia, and local services, working collaboratively with regional public health support and expertise, have been able to satisfactorily interrupt further transmission.

If this initial response fails to contain the incident, that is:

- new, un-linked cases continue to be diagnosed, the list of contacts who have not been evaluated increases
- a case of inadequately treated syphilis in pregnancy or congenital syphilis occurs, or
- existing resources are stretched

Then a more comprehensive response is called for.

- The relevant PH MO should alert their manager, the Director of the Public Health Unit and their jurisdiction's Director of Communicable Disease Control. A briefing should be prepared for the attention of the jurisdiction's Executive Director of Public Health and/or Director General of Health, and the Communicable Diseases Network of Australia (CDNA).
- Each jurisdiction will decide when a briefing to the Minister for Health is appropriate. A briefing should be considered when there are many cases, the outbreak crosses jurisdictional boundaries or involves cases with HIV infection; if an intrauterine fetal death (IUFD) from syphilis occurs, or the outbreak has other features that would attract media attention.

In summary, outbreak identification is a process. Early identification requires:

- A vigilant public health surveillance system including enhanced surveillance for all infectious syphilis cases
- Familiarity with the usual regional epidemiology of syphilis
- Communication between relevant public health staff across jurisdictions
- Clear protocols within public health units for clinical and public health management of infectious syphilis cases.

Phase Two: Early Response

Ideally, these tasks should be completed within the first month.

Phase Two: 0 - 1 month	Timeframe	Issues to consider
1. Public Health Medical Officer briefs their Manager, the Director of the Public Health Unit and their jurisdiction's Senior Director of Communicable Disease		
2. Form an outbreak response team (or ORT) to lead the response	2 weeks	Governance of outbreak response (Refer issue A below)
3. Complete an epidemiological and social assessment of the initial cases	2 weeks	Baseline community, health service and outbreak needs assessment report (Refer issue B below)
4. Communicate with the affected population and other relevant organisations in the region	2 weeks	Communication with the affected population (Refer issue C below)
5. Alert local health service providers (government and community-controlled) (by 2 weeks) and other regional health providers (by 4 weeks): general practitioners, hospital staff, visiting health services, health services in related regions where the affected population/s may travel	4 weeks	Communication between public health and clinical staff and services (Refer issue D below)
6. Liaise with relevant public health and primary health care staff across regions and jurisdictions		Cross-jurisdictional communications (Refer issue E below)
7. Manage media interest		Community communications and Media Management (Refer issue F below)
8. Identify additional resources (human, financial)		Additional resources – Staffing (Refer issue G below)
9. Review sexual health service delivery in health centres in affected locations to ensure: a. A confidential service delivered by informed health care providers b. Prompt treatment of cases c. Comprehensive contact tracing and timely contact evaluation and treatment d. Increased syphilis screening in the at-risk population presenting to the health service e. Adherence to syphilis screening guidelines in pregnancy and when another STI is diagnosed.		Ensuring best practice sexual health services for the at-risk population in health centres in affected locations (Refer issue H below)

Issues to consider

A. Governance of outbreak response

It is essential that an executive position is given explicit responsibility for meeting strategy implementation targets. This responsibility should be accompanied by a set of accountabilities – with consequences for not progressing strategies in a timely manner. At the same time, the accountable party must have the authority to re-prioritize routine service activities in the region. Access to specialist public health and sexual health advice, and the ability to marshal resources to achieve outbreak response targets, are also required.

An outbreak response team (ORT) can improve control efforts by providing leadership, facilitating a co-ordinated, multiagency, partnership approach and giving a central focus to response activities.[19] The partners would include the affected community, local / district health service/s (both government and community-controlled), and population health and sexual health experts. Ideally, each of these groups should be represented on the ORT.

The ORT should be appropriately skilled, authoritative and outcome oriented. It should be responsible for:

- Developing, implementing and evaluating strategies to control the outbreak
- Monitoring and reporting of the outbreak
- Communication with stakeholders and the media
- Attracting additional resources as needed

The agenda for the first ORT meeting should cover the items in the Phase Two: Early Response table. A standard agenda for subsequent ORT meetings should include:

- Updates on cases, contacts and their management, including feedback from other jurisdictions when appropriate
- A surveillance report on the outbreak and on syphilis serology testing in the affected population
- Report from senior public health officer (or other suitable officer) on progress in strategy implementation (including condom access) and problems arising
- Individual site reports (where relevant) including community liaison reporting - feedback from community
- Resource requirements: additional staff, funding for community screens

B. Baseline community, health service and outbreak needs assessment report

An informed epidemiological and social assessment of the initial cases is needed[20]: the context within which the cases live, the sub-populations most at-risk, the services they can access including local sexual health service capacity and the initial additional resources likely to be required. The report of this assessment should be provided to the first ORT meeting in order to inform intervention development.

C. Communication with the affected population[18]

Early face-to-face meetings with local community (and health service leaders) to begin a dialogue are required. These meetings have the following objectives: to inform and educate community (and health staff); to establish a trusting basis for on-going dialogue; and to seek advice and support for proposed control strategies. A one-on-one relationship between a community representative who

supports outbreak control and a suitable person nominated by the ORT, would facilitate on-going communication.

Communication with Aboriginal and Torres Strait Islander people about STI in their communities is always sensitive. Communities care about their health and about the health of unborn children, but the "shame" attached to this issue can overwhelm these sentiments and elicit a negative response.

Community leaders are necessary partners in addressing a syphilis outbreak. Their co-operation and support is critical to effective intervention. This situation calls for frank explanation and discussion. If the issue is ignored and allowed to fester, the impacts on those affected, and on babies infected in utero, will be felt for years to come. Addressing the situation involves discussion about how to achieve "best practice" in this setting. Sometimes, the most significant barriers to implementing appropriate interventions come not from affected communities but from health staff who, for a variety of reasons, feel challenged by the outbreak, and obstruct "best practice" with arguments about "community" or "cultural" acceptability. These arguments must be overcome.

Engaging early with the state-based peak Aboriginal and Torres Strait Islander community-controlled health organisations should also be considered, as their Board members are usually representative of a broad cross-section of the Indigenous communities in their jurisdiction. This may be particularly useful in opening up communication with difficult-to-reach communities without a community-controlled health service.

D. Communication between public health and clinical staff and services

Periodic communication between neighbouring clinical and public health services (both within and across jurisdictions) is important to quell rumours and enable remote staff to maintain clinical vigilance for their service populations. In addition to clinical communications about the follow up of individuals affected by the outbreak, neighbouring or related health services need updates about the size of the outbreak and where the majority of cases have arisen and/or been diagnosed.

E. Cross-jurisdictional communications

Cross-jurisdictional communication should occur at a number of levels where the affected population spans more than one jurisdiction:

At Public Health Unit level

Cross-jurisdictional communication at this level is a permanent feature of effective syphilis surveillance across Australia. Usually, it occurs by telephone and email as needed. In an outbreak, more frequent communications should be scheduled between the PHNs and PH MOs responsible for syphilis outbreak control. Minutes of these meetings should be tabled at the ORT meeting.

At ORT level

A representative from the affected jurisdictions should sit on (or regularly attend and be briefed by) the ORT of the other jurisdictions involved, so that up-to-date outbreak status information can be readily shared and strategy co-ordination across jurisdictions is made possible. Alternatively for large scale outbreaks a dedicated multi-jurisdictional team may be set up to share data and coordinate the response.

The ORT or multi-jurisdictional team should provide timely updates to CDNA.

F. Community communications and media management

The occurrence of a syphilis outbreak is distressing for the individuals affected and for their communities. As noted above, the burden of STIs is in itself a sensitive issue for remote populations who frequently feel judged and at the same time powerless to change the situation.

In the event of a significant syphilis outbreak, both on-going dialogue with community leaders and a

community level information campaign is needed to facilitate community co-operation and engagement in the necessary interventions. Communication should focus on the risk of syphilis to individuals and communities, the importance of getting tested, how to keep safe; and the effectiveness of treatment, especially to prevent pregnancy loss and damaged babies.

On the other hand, mainstream publicity about the syphilis outbreak occurring in identifiable Aboriginal and/or Torres Strait Islander communities e.g. regional town newspaper article, is another matter. It carries a significant risk for negative discrimination and will elicit a defensive, counterproductive response from the affected communities.

Hence, responses to mainstream media inquiries must be approached with great care. The language used should be matter-of-fact and the characterisation of the outbreak should not identify locations or particular populations (e.g. Indigenous) but should be framed in terms of risky behaviours, the importance of safe sex, the value of testing and the curable nature of the condition. Positive pre-existing relationships with a local journalist are always helpful.

Jurisdiction level approval processes for mainstream media messages and press releases should be followed.

G. Additional resources - Staffing

In large outbreaks, a number of locations and regions would be involved and the response will be on-going. In this case, additional staff are likely to be needed for an extended period.

- Skilled sexual health nursing and Indigenous health worker staff
- A senior sexual health promotion officer
- A senior public health officer to lead the on-going implementation of strategies and support outbreak staff. This position would be the link between the ORT and operational staff.

H. Ensuring best practice sexual health services for the at-risk population in health centres in affected locations

Effective, timely case management and contact tracing lie at the heart of controlling an outbreak of syphilis, and these, in turn, rest on sexual health service quality.

- Immediately offer sexual health/public health outreach assistance to the affected health service/s to assist in a review of work practices and information systems supporting sexual health care.
    - What clinical decision support is available?
    - Are data systems in place to support STI clinical management and contact tracing?
    - What STI testing takes place?
- If appropriate on the basis of the findings, offer early assistance to help manage the clinical caseload and address gaps in the service based systems that support sexual health care.
- Support local health service management to organise the delivery (as soon as possible) of a mandatory sexual health skills development package for local staff with review embedded in performance management plans for health workers, nurses and medical officers. The package should focus on confidentiality, respectful communication with patients, increasing testing in at-risk populations, timely treatment of cases and follow up of contacts.
- Inform and engage visiting care providers. This may include a personal letter conveying information about the outbreak, the importance of testing those at-risk and information about syphilis management. Assist these care providers with data feedback on their syphilis testing

practices and engage with them to address barriers to increasing syphilis testing.

- Closely monitor testing coverage among local youth, in pregnancy and when another STI is diagnosed, and investigate, if testing fails to increase and health staff insist that young people refuse testing.

- Consider the appointment of a sexual health portfolio holder within the primary care service to oversee STI data systems and to monitor progress against targets.

- Provide feedback to staff on progress in achieving clinical targets.

Phase Three: On-Going Response

Part 1: 1 - 12 months	**Issues to consider**
Communications	
1. Continue periodic minuted ORT meetings	refer issue A above
2. Establish on-going communication with community leaders of affected population/s	refer issue C above
3. Establish periodic communication with local and regional health care providers and stakeholders – syphilis factsheet and quarterly outbreak update	
4. Establish periodic cross-jurisdictional PHU teleconference (if other jurisdictions are likely to be affected)	refer issue E above
5. Seek additional expert advice: • Convene a meeting with national Aboriginal and Torres Strait Islander sexual health experts • Liaise with state-based peak Indigenous community-controlled health organisations re engaging community and utilizing their public health physician capacity and expertise	Expert advice for the ORT (refer issue I below)
Build clinical sexual health service capacity	
6. Implement on-going sexual health skills workforce development (face-to-face and/or video-conference) for primary care staff in affected regions	Refer issue H above
7. Ensure adequate STI data systems that facilitate clinical management and contact tracing, are in place in each primary care location	
8. Establish at least one point of reliable condom access 24/7 in each remote location	
Additional strategies to Increase syphilis testing in at-risk population/s	
9. To increase testing in the at-risk population, implement complementary STI (including syphilis) testing strategies that: a. Have community support b. Include an evaluation plan c. Are based on an understanding of the epidemiology of the outbreak and d. Where possible, co-ordinate strategy implementation for related communities within and across jurisdictions	Additional strategies to increase syphilis serology screening in at-risk populations (Refer issue J below)
Sexual health promotion	
10. Develop sexual health communications to support the outbreak response. Main messages: Communicate the Risk, Get Tested, Keep Safe (fewer partners, use condoms)	Sexual Health Promotion (Refer issue K below)
11. Develop strategies to disseminate these messages widely in affected populations, possibly in schools and among at-risk groups	

Data	
12. Report the following data for each ORT meeting: • Management outcomes for infectious syphilis cases and contacts • Number of new syphilis cases and their connections to known cases, review "outstanding contacts" list and review evaluated contacts' findings • If the outbreak is of a manageable size, map cases and contacts and their connections • Cumulative epidemiological report on outbreak numbers (cases by stage of disease) over time (and by location if multi-focal) • Syphilis serology test numbers by age group, gender and location • Syphilis screening guideline adherence (in pregnancy and when another STI is diagnosed) by location	
Part 2: 12+ months	
13. Continue 0-12 month activities as outlined above	
14. Consider the need for research: Outbreak persistence may indicate the need for new interventions informed by the findings of behavioural and social research on cases and their transmission context e.g. transactional sex among young adolescents	
15. Continue to build clinical sexual health service capacity and sexual health promotion capacity including: • Embedded school based age-appropriate, continuous, curriculum-based sexuality and reproductive health education from year 5 to 10 • Sexual health promotion including community engagement strategies, sexual health communications initiatives, events-based sexual health promotion and consistent condom access.	

Issues to Consider

I. Expert advice for the ORT

With respect to the health issue: expertise in population health and sexual health communications, STI epidemiology, remote Aboriginal and Torres Strait Islander primary health care and local health systems, are required.

With respect to the social and demographic context, local knowledge will be critical: an understanding of local sensitivities, local history and the relationships between the Aboriginal and Torres Strait Islander community and the health service.

Access to key individuals from community who are prepared to work with the ORT to negotiate with community how to achieve the outcomes required for an effective response is needed.

J. Additional strategies to increase syphilis serology screening in at-risk populations

In addition to high quality case management and contact tracing, syphilis

screening in at-risk populations is a core intervention in the event of an outbreak.[18,20,21,22] Syphilis screening strategies should focus on:

- Adherence to existing guidelines for syphilis screening (in pregnancy and when another STI is diagnosed)
- Increasing syphilis screening in the at-risk population (likely to be youth <30 years) – both opportunistically when they visit the health service and in-community, through outreach programs to achieve high coverage
- If the outbreak continues with on-going transmission evident in particular locations or networks, then social and behavioural research of cases and the context of transmission may be necessary in order to develop specific interventions to encourage screening for these core-transmitting groups.

In smaller more remote locations, additional syphilis screening strategies may take the form of age group targeted whole of community screening. If this community screening achieves satisfactory participation but the outbreak continues, consider repeating the screen. At-risk individuals in the affected communities will benefit from syphilis testing at a frequency that reflects their risk – more often than annually. Communities are often highly mobile and the resident at-risk population may shift significantly within a six-month period. Furthermore, repeat screens that achieve 70+% participation of the target population resident at the time of the screen may provide useful epidemiological data on the status of the outbreak. It is important to note that the population targeted for STI testing (including syphilis) in a community screen is defined by membership of a high-risk group (young people living in particular locations). In order to exclude a reservoir of infection, the target population for STI screening may include children aged 12-14 years. Performing STI tests for this age group in this context does not constitute grounds for notification to child protection authorities as the tests are provided on public health grounds with no knowledge of an individual's sexual activity. If the child returns a positive test for an STI, then jurisdiction-level child protection protocols would be followed.

In larger population centres, strategies to increase syphilis serology screening in young people attending primary care and sometimes, emergency departments of public hospitals, are utilised.

K. Sexual Health Promotion

The term sexual health promotion covers a broad range of activities that are best conceptualised using the Ottawa Health Charter Framework.[23] This approach emphasizes working with communities to improve the conditions that determine sexual risk for youth, and it includes: reorienting health services, community engagement strategies, population-wide sexual health communications, school-based sexuality and relationships education, and improvements in condom access. Building this broad sexual health promotion capacity will be critical for sustainable and continuing improvements in sexual health outcomes.

However, in the context of a syphilis outbreak, the immediate sexual health promotion priorities will be to implement effective youth screening recruitment strategies, to develop relationships that facilitate constructive community dialogue, to establish consistent condom availability, and sexual health communications. The latter is of the highest priority with the main messages being:

- Communicate the risk
- Get tested, and keep safe

Phase Four: Outbreak Reporting and Response Evaluation

Phase Four: reporting and evaluation	Issues to consider
16. Decide when the outbreak is over: • No strict criteria exist. Ideally, the number of new infectious cases reduces to pre-outbreak levels while at the same time the at-risk population testing coverage is high • Unfortunately, it may be that notifications reduce but only to a level that is higher than before the outbreak (indicating low level endemicity) • For the outbreak to be declared over, the caseload must be within a range that can be managed within permanently available sexual health resources.	
17. Develop a report that describes the epidemiology of the syphilis outbreak and the outbreak response	
18. Evaluate the outbreak response • Both process and outcome measures should be used in the evaluation • An outbreak evaluation report should be produced and disseminated so that lessons can be learned and these guidelines refined.	Outbreak evaluation(refer issue L below)

Issues to consider

L. Outbreak evaluation

Process measures will depend on the interventions employed and may include:

- Timeliness of outbreak identification and response development
- Satisfaction of community and other partners
- Condom access measures
- Assessment of testing coverage of specific at-risk populations, in pregnancy, and for those diagnosed with another STI, against targets (see Public Health Objectives and Targets for the Outbreak Response)
- Assessment of management outcomes for cases and contacts against targets (see Public Health Objectives and Targets for the Outbreak Response)
- Measures arising from specific interventions e.g. coverage of target population in community screens
- Measures arising from sexual health promotion interventions

Considerations on the role of Syphilis Point of Care Testing (POCT) in outbreak response[5]

The use of POC testing in outbreak contexts needs to be carefully considered by the ORT (refer to Issue A: Outbreak Governance) and, if utilised, integrated within the broader outbreak response as an additional tool and not a substitute for best-practice serology-based testing (please check limitation to the use of syphilis POCT). The World Health Organization[24] recommends that existing serology testing should be maintained and improved. Any increase in use of syphilis POCT should only be in specific contexts where it can be implemented with appropriate training and quality assurance and where the value compared with serology has been fully considered.

There is currently only one syphilis point of care test registered by the Therapeutic Goods Administration in Australia, the Determine Syphilis TP™ manufactured by Alere, now Abbott. The Determine Syphilis TP™ is a treponemal specific immunochromatographic test. Based on an independent laboratory based evaluation of 4 Syphilis POCTs the Determine Syphilis TP™ was the most sensitive at 97%, other tests ranged from 86-92%. Specificity was lower for Determine Syphilis TP™ (96.4%) than 2 other options tested but was similar for all tests (92-98%)[25]. Based on this, expert analysis has recommended that Determine Syphilis TP™ has a sensitivity deemed sufficient to be useful in community screening.

Generally, it is preferable not to use syphilis POCTs as stand-alone tests because of:

- their inability to differentiate new infection from previously treated infections;
- marginally inferior sensitivity and specificity compared with serology;
- no recognition of POCT in infectious syphilis national case definition (refer to Issue M);
- lack of a centralised mechanism to record POCT results; these are only recorded in individual patient records.

However, in an outbreak affected area, a positive POCT result can be used to reduce time to initiating treatment and contact tracing, minimise lost to follow-up, reduce follow-up burdens placed on primary care services and provide access to testing for those unwilling or unable to have venepuncture performed.

Syphilis POCT should be considered in an outbreak affected areas, for:

- Individuals for whom POCTs would facilitate greater access to testing in the community (e.g. people who do not engage with the health service regularly, etc.)
- Community-based screening and outreach settings
- Individuals for whom there is a high likelihood of being lost to follow-up on return of positive serology result (e.g. prison screening with early release, highly mobile people attending health services).
- Individuals attending health services where:
    1. There is a long wait for pathology results or
    2. People are unable or reluctant to have a venous blood sample for syphilis serology at the time of consult.

Immediate treatment and contact tracing should be performed after reactive POCT where a patient:

- has a known previous negative syphilis result OR
- has no known history of past syphilis infection AND
- belongs to a predefined at-risk group, if so indicated by local seroprevalence data (e.g. age-range, geographic location, etc.)

[5] These recommendations were developed in 2018 based on the work of the Syphilis POCT Working Group established by the Syphilis Enhanced Response Governance Group of the Australian Health Protection Principal Committee (AHPPC). The full set of recommendations, reported as 6 core areas, can be obtained directly from AHPPC.

Issues to consider

M. Reactive POCT results do not meet the laboratory or public health case definition

The current Communicable Diseases Network Australia (CDNA) and Public Health Laboratory network (PHLN) case definitions for syphilis classification do not include the use of syphilis POCT outside laboratories. Under the current CDNA surveillance case definition, serological confirmation is required, therefore a reactive POCT is not nationally notifiable.

Where it is not possible to confirm with serology in some settings, under the current conditions, reactive syphilis POCTs might not be notified unless additional arrangements are developed. Cross-reference with local jurisdictional guidelines on notification of results is recommended. This is a similar situation to HIV POCTs, where a reactive HIV POCT test is considered preliminary until confirmed by reference laboratory tests. Health services conducting syphilis POC testing should ensure any reactive syphilis test have parallel laboratory serology (see below), and HIV testing is recommended according to guidelines in this situation.

N. Importance of other STI testing, including serology

If an individual has had a previously treated syphilis infection, a positive POCT merely indicates the presence of treponemal antibodies, which usually persist for life; hence a POCT cannot distinguish between a reinfection and a past infection.

- It is recommended to perform parallel laboratory serology for all POCT tests where this does not impact on syphilis test uptake.
- Parallel testing should occur for all reactive syphilis POCTs.
- Consideration should be given to including chlamydia and gonorrhoea NAAT testing where the local health service is able to manage follow-up and facilities to collect urine or swabs are available.
- It is recommended to offer a full STI screening, including HIV serology, where venepuncture is being performed, and should also be performed for reactive POCT results.

O. POCT during pregnancy

Ideally pregnant women should receive comprehensive health care, which includes syphilis serology, however if the woman meets criteria for syphilis POCT as outlined above (concern about loss to follow-up post diagnosis, or engagement with care) then performance of syphilis POCT is better than not being tested at all.

P. Staffing models, training and quality assurance of sites using syphilis POCT

In addition to the considerations outlined previously on this Appendix (refer to Issue G – Additional Resources: Staffing), in the context of the implementation of syphilis POCT tailor staffing models to local context. It is recommended to use cultural brokers, health promotion and clinical staff familiar with local community, ideally peer-led. There is likely to be greater success where staff with a specialty portfolio is responsible for performing tests and responding to results. Consideration also needs to be given to staffing of syphilis surveillance services and/or registers if there is an expected significant increase in notifications from a 'surge' response. Regular engagement, training and feedback to staff and services is essential.[26]

POCT for syphilis should only be performed by health professionals who have undergone initial training and competency certification, and who participate in regular recertification. Quality management (Quality Control and/or External Quality Assurance) should be mandatory components of a quality system. All sites participating in POCT should be provided with a simple training resource package including a step-by-step guide for testing, troubleshooting support and risk management strategies. Consistent with routine procurement and stock management processes at the health services, the expiry dates of kits should be monitored, and regular stocktake of kit levels performed to ensure that stock outages do not lead to testing failures[27]. There should be flexible options for delivery of training (but with at least one operator from each site undergoing face-to-face training).

Q. Recording and reporting of POCT results

It is essential to document syphilis POCT results within clinical record systems, including reactive, non-reactive, or invalid. Development of standardised and consistent surveillance and monitoring systems within the outbreak region is also recommended. Issues such as integration in existing syphilis registries, the need for parallel laboratory serology for reactive POCT results (since they do not meet case definition, see Issue M above), and reporting non-reactive results to a centralised repository, need all to be carefully considered by the ORT and jurisdictional surveillance units.

R. Monitoring and evaluation of the use of syphilis POCT in outbreak contexts

In addition to the general recommendations on outbreak evaluation (see Issue L. – Outbreak evaluation) in areas where community-based syphilis POCT is undertaken, it is recommended that additional monitoring systems are developed. It is important to balance monitoring needs with on-the-ground clinical capacity if new systems need to be introduced.