



Guidelines for health service providers:

Use of syphilis point-of-care tests provided by the WA Department of Health

Revision History		
Version	Date	Changes
1.0	June 2020	Original
1.1	November 2020	1.1 Introduction Additional information, metropolitan and South West region inclusion. Attachment C Additional information, metropolitan and South West region inclusion.

Summary

This document is for government and non-government health service providers (HSP) to outline the conditions and requirements for expanded use of the syphilis Point of Care Tests (PoCT) in Western Australia (WA). The WA Department of Health (WA DoH) funded program aims to complement the roll-out of PoCT currently provided by the Australian Government to selected Aboriginal Community Controlled Health Services.

HSPs eligible to provide syphilis PoCT, supported by the WA DoH, include government health services (including community health, antenatal clinics and hospitals), Aboriginal community-controlled health services (not eligible under the Australian Government program), general practices and the Royal Flying Doctor Services, in the declared syphilis outbreak regions.

These Guidelines draw heavily on the *Guidelines for Program Managers: Use of Syphilis Point of Care Tests provided by the Australian Government in a 'Test and Treat' Model* (National Guidelines), developed by the Australian Government and the National Aboriginal Community Controlled Health Organisation. The WA Guidelines closely follow the National Guidelines, to ensure consistency across sites within WA. It is recommended that HSP are also familiar with the Australian Government's Guidelines.

This document includes information on the syphilis outbreak in WA, considerations for use of the syphilis PoCT, ordering and logistics for the PoCT, and training and programmatic planning considerations.

1. Background information on the syphilis outbreak and roll-out of syphilis PoCT

1.1 Introduction

An outbreak of infectious syphilis began in northern Queensland in January 2011, extending to the NT in July 2013, the Kimberley in WA in June 2014. In March 2017, SA declared an outbreak in the Far North and Western and Eyre regions.

In August 2018, WA declared that the outbreak had spread to the Pilbara region with the first syphilis notification in this region in February 2018. By April 2019, WA declared the outbreak had spread to the Goldfields region with the first notification in this region reported in January 2019.

In 2020 there has been increasing populations that are at-risk of syphilis in the metropolitan and South West regions.

More detailed information of outbreak cases in Western Australia can be found on the [WA Department of Health syphilis outbreak response web-page](#).

Syphilis is a highly contagious and serious infection caused by the bacterium *Treponema pallidum*. It has a complex disease progression and early symptoms are often unnoticed. Left untreated it can have significant health effects in several organ systems. In pregnant women it can lead to miscarriages, congenital syphilis, stillbirth and birth complications. It is treated with long-acting penicillin injections.

1.2 Australian Government funded 'Test and Treat' Model

The Australian Government commenced the use of the syphilis PoCT kits and training components of the enhanced response program to Aboriginal Community Controlled Health Services in outbreak-affected jurisdictions in August 2018. The 'Test and Treat' model was implemented to curb the syphilis outbreak in the affected Aboriginal populations in central and northern Australia, at selected Aboriginal community-controlled health services only, with high and emerging numbers of syphilis cases in their regions.

2. Use of point-of-care test in the WA Outbreak Response

2.1 Point-of-care test (PoCT)

The use of a rapid PoCT will enable immediate treatment, as compared to the up to two-week turnaround for a traditional blood test result in some areas (which could be complicated by the movement of people and the challenges of locating some patients once the test result has returned).

The *Determine Syphilis TP*TM immuno-chromatographic test manufactured by Alere/Abbott syphilis PoCT is currently used in the outbreak affected jurisdictions. The *Determine Syphilis TP*TM is currently the only syphilis PoCT registered by the Therapeutic Goods Administration in Australia.

Based on the model developed by the Australian Government, WA DoH will implement a compliance training and quality assurance program to support the use of syphilis PoCT.

2.2 Considerations

The use of PoCT in outbreak contexts needs to be carefully considered and, if utilised, integrated within the broader outbreak response as an **additional tool and not a substitute for best-practice serology-based testing**. The World Health Organisation 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. PoCT should not be considered an acceptable alternative to serology outside of an outbreak control context.

Generally, it is preferable not to use syphilis PoCT 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; or
- lack of a centralised mechanism to record PoCT results; these are only recorded in individual patient records.

However, in an outbreak affected area, a reactive PoCT result can be used to **reduce time to initiating treatment and contact tracing, minimise individuals lost to follow-up, reduce follow-up burdens placed on primary care services and provide enhanced access to testing**.

2.3 Target audience

Syphilis PoCT should be considered in outbreak affected areas, for:

- Individuals for whom PoCT would facilitate greater access to testing in the community (e.g. people who do not engage with the health service regularly);
- 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. highly mobile people, youth, homeless people, and healthy people who do not necessarily present to health clinics regularly); and
- 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 a 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, as outlined in the [Syphilis Series of National Guidelines for Public Health Units \(SoNG\)](#).

A reactive PoCT should always be confirmed by syphilis serology.

Ideally pregnant women should receive comprehensive antenatal care, which should include five syphilis serology tests during, intrapartum and after the antenatal period, however if the woman meets criteria for syphilis PoCT as outlined above (and there is 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.

PoCT can have an advantage in treating all pregnant women in regional areas due to potential delays in obtaining pathology results from syphilis serology. If PoCT is done alongside venepuncture for syphilis serology, women who have a positive PoCT result and have no prior history of syphilis can be treated on the same day of the test. Given the concerning potential of congenital syphilis, this is an advantageous approach for testing and treating pregnant women.

2.4 Comprehensive approach

When implementing syphilis PoCT, HSPs should tailor the roll-out and training of staff to local context and model of service.

It's recommended that a comprehensive programmatic approach is considered when planning and using syphilis PoCTs. This includes availability of culturally appropriate health promotion resources, peer-led education, accessible treatment and contact tracing. Ideally, Aboriginal health workers/practitioners and locally-based clinicians are central to planning and negotiating with local communities on access to and use of syphilis PoCT. Staff should be aware of the ['Talk Test Treat and Trace Manual'](#), to assist in planning, implementing and monitoring a comprehensive approach to the syphilis outbreak.

Consideration also needs to be given to staffing required to prepare paperwork for recording results and liaising with syphilis surveillance services and/or registers if there is a significant increase in notifications as expected from an enhanced syphilis program. Regular engagement, training and feedback to staff and services are essential.

Staffing considerations should take into account skill levels, confidence of staff involved and staff turnover. Staff involved in the development or implementation of syphilis PoCT should have access to clinical updates, including the South Australian Health and Medical Research Institute (SAHMRI) [Clinical Practice and Resource Manual](#), and the Syphilis Outbreak Training website that can be found on the [ASHM web-site](#).

Staff should also be aware of the WA DoH online ['Silverbook'](#) for clinical management of syphilis and other sexually transmitted infections.

Services need to have capacity to distribute the syphilis PoCT kits to their secondary or associated sites. Primary services will receive the syphilis PoCT kits and will have responsibility for ensuring testing kits are distributed to the secondary sites as needed. Additional syphilis PoCT kits can be ordered via the WA Department of Health Coordinator at syphilispoct@health.wa.gov.au

2.5 Settings

It is recommended that HSPs adapt a syphilis program that includes PoCT to the local context that is based on assessment of the target population and their utilisation of health services. This includes determining if additional outreach or expanded service settings are required e.g. antenatal clinics or out-station clinics.

Planning should include a review of where the target groups access health services already or where the target populations gather.

3. Approval procedures – Accessing the point-of-care test under the enhanced response

3.1 Criteria for assessing HSPS

HSPs that meet the following requirements are eligible to access the PoCT at no additional cost:

1. The HSP catchment area is within a designated outbreak region. The infectious syphilis outbreak case definition as per Attachment C. (Please refer to the [WA syphilis outbreak response](#) webpage for up-to-date information on the outbreak, with reference to the affected regions included as part of the monthly surveillance reports.)
2. The HSP employs at least two health professionals (Registered Nurse, Aboriginal Health Worker/Practitioner, or Medical Practitioner) who will commit to completing the training outlined in 4.2 and are willing to participate in quality management once the PoCT kits are received.
3. The HSP will complete quality management activities within the reporting timeframes outlined in 4.3.
4. The HSP agrees to adhere to the recommended storage of the PoCT, Quality Control (QC) kits and External Quality Assurance (EQA) kits, as outlined in 4.4.
5. The HSP will record patient PoCT results appropriately into its clinical information and recall system and report monthly on agreed PoCT data, as outlined in 4.5.

3.2 Training

The WA DoH is supporting access to a training package and quality assurance framework for participating HSP to complement the roll-out of the syphilis PoCT kits. Flinders University International Centre for Point-of-Care Testing (FUICPoCT), hereon to be referred to as 'Flinders University', has been engaged to deliver this training and quality framework.

PoCT for syphilis must only be performed by health professionals who have undergone appropriate training and competency certification. Participants must undergo recertification every two years to ensure up to date knowledge of PoCT procedures and quality management practices. Quality management practices (Quality Control [QC] and External Quality Assurance [EQA] testing) are mandatory components of the training package and routine testing for the project.

The training framework is designed around a train-the-trainer model whereby Flinders University provide Advanced Training to regional champions (via face-to-face or teleconference/videoconference), enabling them to deliver Basic Training to health service staff within their regions with FUICPOCT support.

All sites participating in PoCT training will be provided with a training resource package. This package will comprise a laminated poster set (containing step-by-step instructions for conducting patient, QC and EQA testing), and additional paperwork that supports testing (including a quality testing calendar and QC/QA result sheets).

3.3 Quality management

Consistent with best practice guidelines for PoCT in Australia, services are required to conduct **fortnightly QC testing and EQA testing four times per year**, using testing material provided by the project. These quality materials will contain samples with a known value of syphilis reactivity. Results for both QC and EQA testing must be sent immediately after testing to the Flinders University for review. Flinders University will provide regular feedback reports on quality testing to participating services.

QC testing

Each participating clinic within an enrolled HSP must conduct QC testing.

If PoCT testing is to be extended to additional clinics within an enrolled HSP (that is, clinics not specified in a program enrolment form sent to WA DoH), the key contact for the Program at the enrolled HSP must:

- notify WA DoH by completing and submitting a revised enrolment form at Attachment A to WA DoH; and
- notify Flinders University to arrange for the dispatch of the QC materials and the monitoring of new clinics, prior to any patient testing.

HSP must also notify WA DoH and Flinders University in writing as soon as possible if they cease or pause PoCT patient testing at one or more of their clinics.

EQA testing

EQA testing is only required to be conducted by one participating clinic within each enrolled HSP, unless otherwise agreed with Flinders University.

Compliance with quality testing requirements

Flinders University will provide HSP staff with a calendar with dates for QC testing and will provide a reminder five days in advance of those dates. If quality testing is not completed in accordance with these Guidelines, Flinders University and/or WA DoH may contact HSP staff to identify potential reasons for non-compliance and to encourage the resumption of regular and compliant quality testing.

The HSP must cooperate with, and comply with any directions issued by, Flinders University and WA DoH in relation to QC and EQA testing including:

- providing further information in relation to QC and EQA testing if required; and
- ceasing patient testing if directed to do so.

Telephone help desk support will be available Monday to Friday 9am-5pm CST to support services with patient testing, as well as QC and EQA testing and interpretation of their quality results. For support with patient or quality testing, result interpretation or general trouble shooting, call the **Flinders University Help Desk on 08 8201 7555**.

For further information on how to access the PoCT testing training, please contact WA DoH STI Program Officer, Phone: (08) 9222 2275 or syphilispoct@health.wa.gov.au or the FUICPOCT Help Desk Phone: 08 8201 7555 or SyphilisPOCT@flinders.edu.au

3.4 Logistics

Ordering and stock management

Approved HSP will work directly with the dedicated WA DOH Coordinator to order POC testing kits from the supplier, Abbott. Each kit will include:

1. DT7D2443- Determine Syphilis Tests (100/30 tests);
2. DT7D2243- Determine Chase Buffer (100/30 tests/bottle) - (for use with Determine Syphilis TP Rapid for WB); and
3. DT1050-100 Microsafe tubes 50µL tubes (100/30 tests) (this is used to transfer the blood from the patient's finger onto the test strip).

Transportation of the PoCT kits will be arranged by WA DoH.

Consistent with routine procurement and stock management processes at the health services, the expiry dates of kits should be monitored in consultation with WA DoH, and regular stocktake of kit levels performed to ensure that stock outages do not occur.

Storage

PoCT

The HSP must store the PoCT kits in a cool, dry area between 2 and 30 degrees Celsius, such as a service's medicines storage room (in accordance with current RACGP Standards).

External Quality Assurance (EQA)

EQA samples are shipped to each HSP once a year and there are four testing events each year. These samples are shipped at ambient temperature but must be frozen upon receipt until testing, to ensure sample stability and integrity.

If appropriate freezing arrangements are not available on site, HSP should consider exploring alternative storage arrangements, such as with a local pathology service or pharmacy.

Quality Control (QC)

Quality Control kits must be transported and stored between 2 and 8 degrees Celsius. QC kits will be provided to HSP every 6 months, and QC is to be conducted fortnightly. Kits are shipped at ambient temperature however must be stored between 2 and 8 degrees Celsius once received. Any subsequent transport of QC material within the health service must maintain cold chain. QC testing must be completed by all participating clinics within a health service. To enable sharing of QC material across clinics, Flinders will provide each HSP with appropriate numbers of pipettes and tubes for aliquoting of QC material. Instructions for this process will be provided by Flinders University as part of the training package (as per [National Vaccine Storage Guidelines: 'Strive for 5'](#) cold chain standards).

Refer to [Attachment B PoCT Logistical Flow Chart](#) for further information.

For further information on the logistical arrangements for the PoCT, please contact WA DoH STI Program Officer Phone: (08) 9222 2275 or syphilispoct@health.wa.gov.au

3.5 Recording and reporting of PoCT results

Development of standardised and consistent surveillance and monitoring systems within the outbreak region is required by the WA DoH. It is essential to document syphilis PoCT results on patients within clinical record systems, including reactive, non-reactive, or invalid. 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), and reporting non-reactive results to a centralised repository, need all to be carefully considered and will vary between regions.

With regard to the data requirements of participating HSP, the WA Department requires monthly reports with de-identified quantitative data on patient PoCT utilisation numbers and their results. Reporting requirements will only be enforced if there is an automatic extraction system within clinical record systems (such as provided reports for *Communicare*, *CHIS*, *MMeX* or other patient software) that reduces the burden to the service.

- a. If the HSP has an automatic extraction system within clinical record systems, it must provide monthly reports of de-identified quantitative data which includes overall syphilis testing (number of people within the previous month and proportion of regular client population within the target group who received a syphilis test within the previous 12 months).
- b. Within that group:
 1. Gender, age group, Aboriginality and number of people who received a PoCT and a serology test
 2. Gender, age group, Aboriginality and number of people who received a PoCT only
 3. Gender, age group, Aboriginality and number of people who received serology only
 4. Numbers and proportion of reactive and non-reactive PoCT.

Data provided by services will be de-identified and aggregated so whole of state aggregated region-level data reports can be reported to the Australian Government Department of Health as needed. Health services will retain full ownership of their data.

For further information on recording and reporting of patient PoCT results, please contact the WA Department of Health at syphilispoct@health.wa.gov.au.

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.

3.6 Application process

If the HSP meets the above criteria and would like to apply for access to the PoCT, the HSP must complete the Enrolment Form at [Attachment A](#) and the Quality Testing Enrolment Form at [Attachment D](#) and email to the STI Program Officer, Sexual Health and Blood-borne Virus Program, Communicable Disease Control Directorate, at WA DoH, at syphilispoct@health.wa.gov.au.

4. References

- i. *National strategic approach for an enhanced response to the disproportionately high rates of STI and BBV in Aboriginal and Torres Strait Islander people.*
- ii. *Action Plan: Enhanced response to addressing STI (and BBV) in Indigenous populations.*
- iii. Syphilis Series of National Guidelines for Public Health Units (SoNG).

Attachments

Attachment A: HSP PoCT Enrolment Form

Attachment B: PoCT Logistical Flow Chart

Attachment C: Infectious syphilis outbreak case definition

Attachment D: Quality Testing Enrolment Form



Enhanced Response to the Infectious Syphilis Outbreak Declared Regions within Western Australia

Access to the Syphilis Point of Care Tests (POCT)

Provided by the WA Department of Health

Enrolment Form for Health Service Providers (HSP)

HSP Name: _____ Region: _____

I agree that my service will meet the criteria to access the PoCT provided by the WA Department of Health. The criteria are outlined in *Guidelines for Health Service Providers: Use of Syphilis Point of Care Tests provided by the*

WA Department of Health (November 2020). This includes:

1. The HSP catchment area is within the designated outbreak region.
2. The HSP employs at least two health professionals (Registered Nurse, Aboriginal Health Worker/Practitioner, or Medical Practitioner) who will commit to completing the PoCT training and are willing to participate in quality management once the PoCT kits are received.
3. The HSP will complete quality management activities within the reporting timeframes.
4. The HSP agrees to adhere to the recommended storage of the PoCT, QC and EQA kits.
5. The HSP will record PoCT results appropriately into its clinical information and recall system and report monthly on agreed PoCT data.

Estimated Regular Client Population: _____

List Names and Addresses of Clinical Sites that will be participating in the PoCT program*:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

*Please advise WA DoH via an updated enrolment form if new clinical sites are added.

Clinical Information System: (please specify e.g. Communicare/MMEX/other): _____

Estimated Initial Number of PoCT Kits Required for the first three months of service delivery (1 PoCT kit = 1 Test): _____

PoCT Training:

Estimated Staff Numbers Requiring

1. Train-the-Trainer: _____ 2. Basic Training: _____

HSP Contact for PoCT Training
(Name/ Email/ Phone Number): _____

Authorised signatory

Name: _____

Position: _____

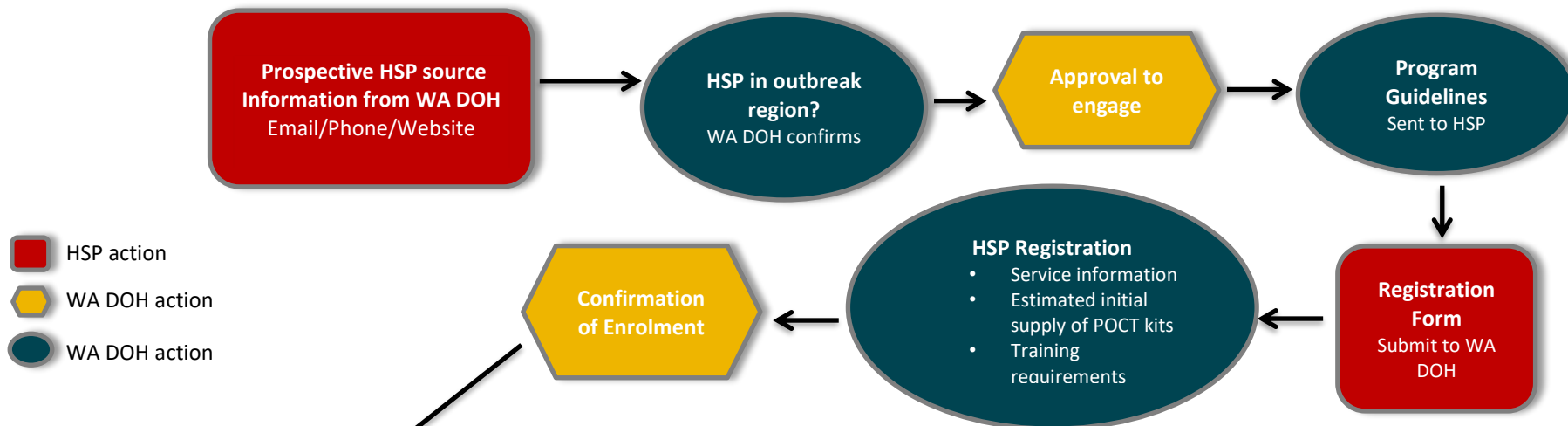
Signature: _____ Date: _____

Please email completed form to STI Project Officer WA DOH: syphilispoct@health.wa.gov.au

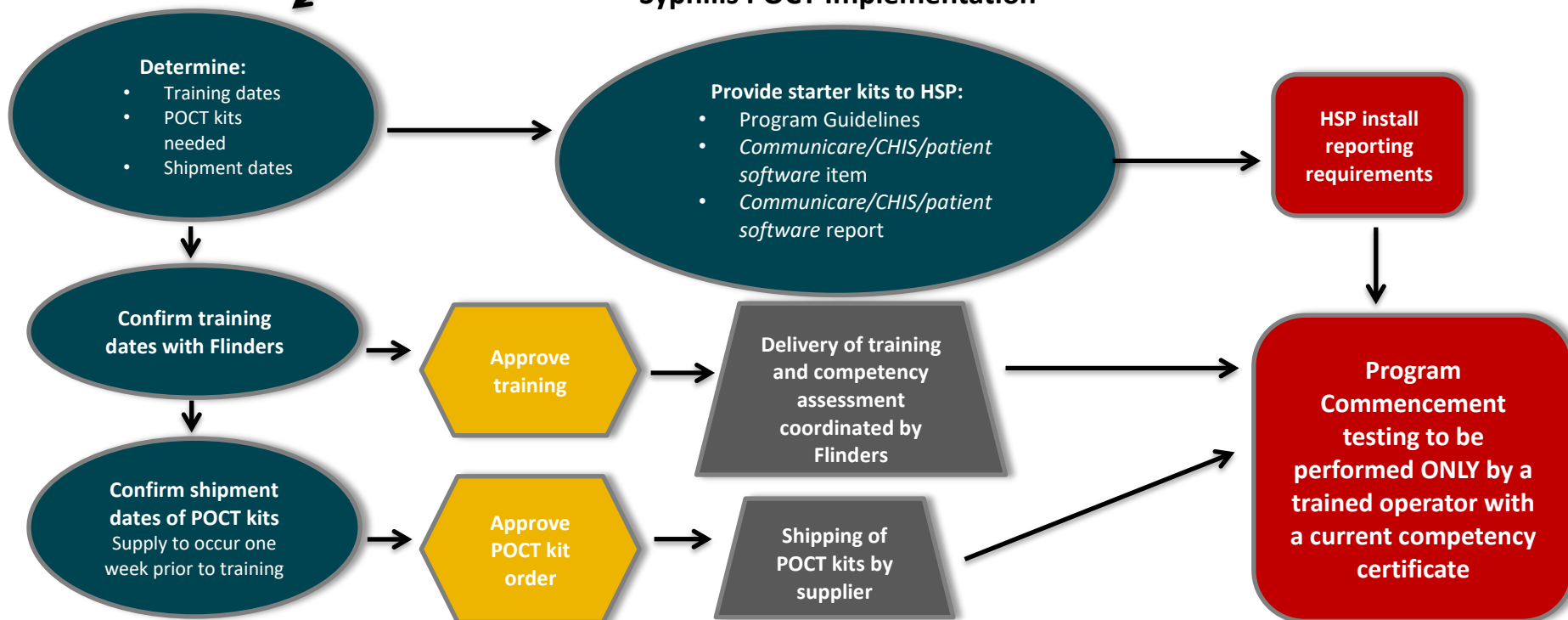
For any questions on the enrolment process, contact WA DoH on (08) 9222 2275

Syphilis POCT enrolment flowchart

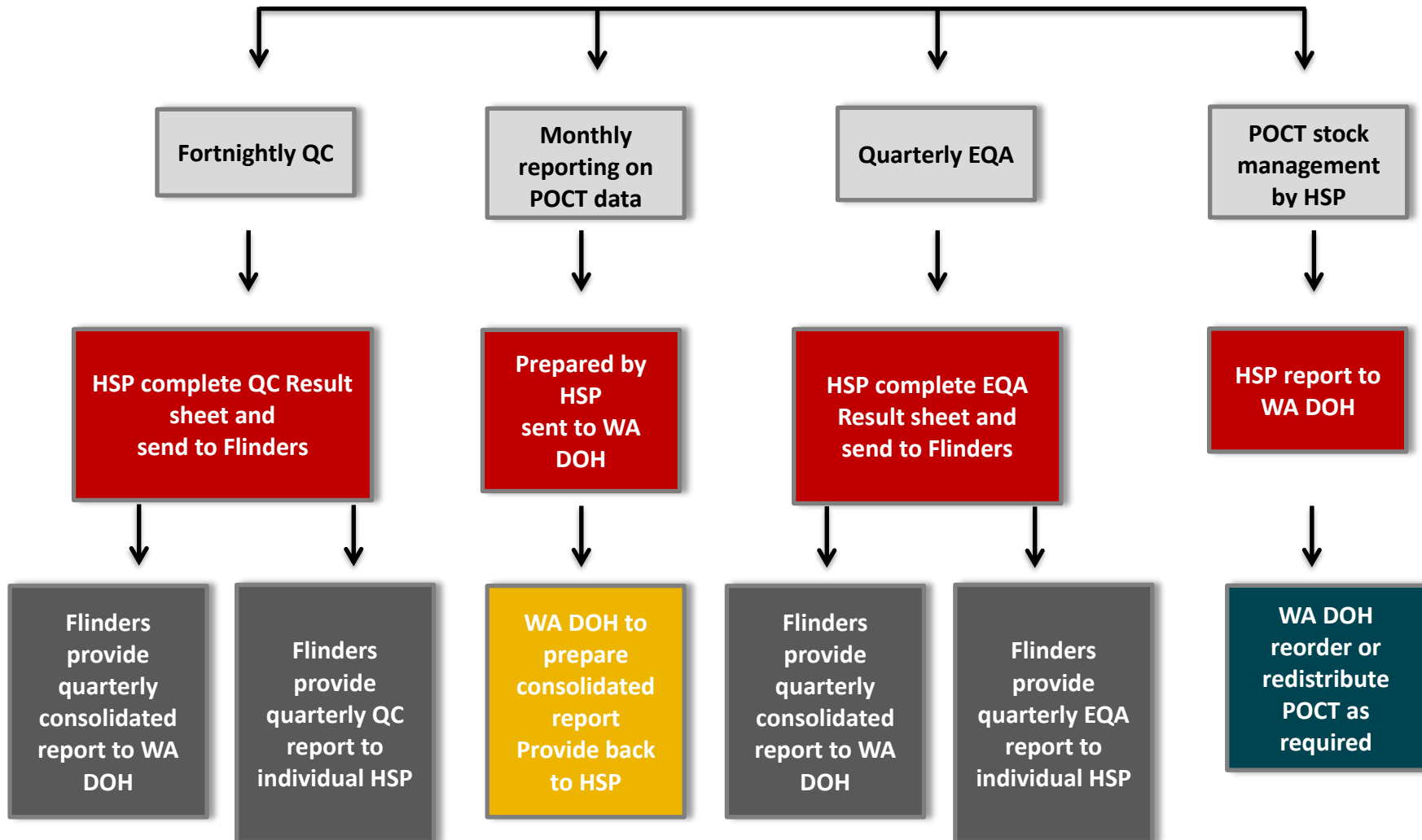
Attachment B



Syphilis POCT Implementation



Syphilis POCT reporting and restocking





Infectious syphilis outbreak case definition (November 2020)

In Western Australia, an infectious syphilis outbreak case is defined as:

any person who is newly diagnosed with confirmed or probable infectious syphilis according to the [CDNA national surveillance case definition](#) for infectious syphilis,

AND, is a part of an at-risk population that has been assessed based on epidemiology:

WA -

Kimberley – Aboriginal people

Pilbara – Aboriginal people

Goldfields – Aboriginal people

South West – young Aboriginal and non-Aboriginal heterosexual people, people who use methamphetamine and/ or inject drugs, people who have sex with men who have sex with men (MSM)

Metropolitan area – young Aboriginal and non-Aboriginal people, people experiencing homelessness, people who use methamphetamine and/ or inject drugs, culturally and linguistically diverse people, people who have sex with MSM

(category 1 outbreak cases)

OR, is a sexual contact of a confirmed outbreak case (category 2 outbreak cases).

Note: Outbreak cases are reported as either category 1 or category 2: category 1 cases include at risk populations residing in an outbreak declared region^β at the time of diagnosis, and; category 2 cases include people who are a sexual contact of a confirmed outbreak case which includes Aboriginal and Torres Strait Islander people who do not reside in an outbreak area at the time of diagnosis and non-Indigenous people regardless of where they reside.

Congenital syphilis outbreak case definition

Any newly diagnosed case of confirmed or probable congenital syphilis that meets the [CDNA national surveillance case definition](#) whose mother's syphilis infection prior to or during pregnancy meets the infectious syphilis outbreak case definition.



Syphilis point-of-care testing program

Quality testing enrolment form

Health service: _____

Please provide contact details for two (2) people at your health service who will be responsible for receiving and storing quality testing samples for the Syphilis Point-of-Care Testing program. These people will also receive regular QC and EQA testing reminder emails and be responsible for ensuring this testing is completed as required.

Primary contact

Name: _____

Position: _____

Email Address: _____

Phone number: _____

Secondary contact

Name: _____

Position: _____

Email Address: _____

Phone number: _____

Street Address for Delivery of Samples (samples will not be sent to PO Box addresses)

Number/Street: _____

Suburb: _____

State: _____ Postcode: _____

Please scan and email the completed form to:

SyphilisPOCT@flinders.edu.au and syphilisPOCT@health.wa.gov.au

If you have any queries regarding this form, please contact:

STI Project Officer (WA DoH) on 08 9222 2275 or the FUICPOCT Help Desk Phone: 08 8201 7555 or
SyphilisPOCT@flinders.edu.au

This document can be made available in alternative formats on request for a person with disability.

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