Appendix D. Standard Operating Procedures: Gonococcal infections with critical antimicrobial resistance or decreased susceptibility to ceftriaxone

Last updated: December 2022

Public Health Priority:
Urgent for gonococcal infection with critical antimicrobial resistance.
High for gonococcal infections with decreased susceptibility to ceftriaxone.
PHU response time:
Respond to any report of gonococcal infection with critical antimicrobial resistance on the day of notification.
Respond to any report of gonococcal infection with decreased susceptibility to ceftriaxone within one working day of notification.
Public health follow-up (incl. case and contact management):
Public health follow-up is a joint responsibility of the PHU, CDB, the specialist sexual health service and the treating doctor.

1. Scope of Standard Operating Procedures

These Standard Operating Procedures (SOPs) define the response procedures for gonococcal infections with critical antimicrobial resistance and those with decreased susceptibility to ceftriaxone identified in New South Wales. The purpose of the SOPs is to ensure a standardised response to notifications of gonococcal infections with antimicrobial resistance of concern across NSW, with the aim to prevent further spread of these strains through appropriate clinical management, and timely and comprehensive contact tracing.

The SOPs apply in conjunction with the NSW Health Gonorrhoea Control Guideline for Public Health Units and are implemented by the Communicable Diseases Branch (CDB) and NSW Public Health Units (PHUs) in collaboration with other key stakeholders, including the diagnosing medical practitioner and specialist sexual health services.

2. Surveillance of gonococcal antimicrobial resistance

Routine surveillance of gonococcal antimicrobial resistance consists of the following two components:

1. All laboratories undertaking antibiotic susceptibility testing or other resistance testing of gonococcal isolates for residents of NSW are requested to immediately notify cases with critical antibiotic resistance and cases with decreased susceptibility to ceftriaxone (see case definition in section 3) to the relevant PHU.
2. Results from antibiotic susceptibility testing performed by the Neisseria Reference Laboratory (SEALS) are uploaded to NCIMS on a weekly basis. Automatic alerts to flag notifications with isolates that are non-susceptible to ceftriaxone and/or azithromycin* are reviewed by the CDB STI/BBV team in the first instance before liaising with the relevant PHU for further investigation.

*Not all laboratories undertaking susceptibility testing report a test value (Minimum Inhibitory Concentrations (MICs) for E-test and agar plate dilution method) in addition to a categorical interpretation of the result. Also note that the Australian Gonococcal Surveillance Programme interpretative criteria used by SEALS for testing of NSW isolates do not currently (March 2019) distinguish between isolates with decreased susceptibility to ceftriaxone and resistance to ceftriaxone (generally MIC ≥ 0.5 in case reports). For the purpose of surveillance of *N. gonorrhoeae* antimicrobial resistance in NSW, all cases reported as resistant to azithromycin and/or having decreased susceptibility to ceftriaxone will be flagged in NCIMS and reviewed by the STI/BBV team to determine the degree of decreased susceptibility/resistance.

3. Case definitions

A case is considered to have critical antibiotic resistance if:

a) The case meets the CDNA national surveillance case definition for gonococcal infection; and
b) The isolate is found to be resistant in relation to current recommended treatment regimens on culture-based susceptibility testing (i.e. high-level resistance to azithromycin and/or resistance to ceftriaxone†) or NAAT resistance testing.

A case is considered to have decreased susceptibility to ceftriaxone if:

a) The case meets the CDNA national surveillance case definition for gonococcal infection; and
b) The isolate is reported by a laboratory to have decreased susceptibility to ceftriaxone[2] on culture-based susceptibility testing.

4. Response procedures for gonococcal infections with critical antimicrobial resistance

4.1. Notification procedure

Depending on the source of the initial alert, the following notification procedures apply following the detection of a case with critical antibiotic resistance:

1. If a PHU reviews a laboratory report or receives a laboratory alert:
   - The PHU notifies the CDB on call officer as soon as possible.
   - The CDB on call officer notifies the Director of CDB and/or the CDB STI/BBV Manager within one hour in line with the requirements for urgent public health responses.
   - The CDB STI/BBV Manager notifies the STI/BBV epidemiologists.
2. If a case is identified by the CDB STI/BBV team as part of routine surveillance:
   - The STI/BBV epidemiologists notify the CDB STI/BBV Manager and/or the Director of CDB.
   - The CDB STI/BBV team notify the relevant PHU.
3. If CDB on call receives a laboratory alert:
   - The CDB on call officer notifies the Director of CDB and/or the CDB STI/BBV Manager within one hour in line with the requirements for urgent public health responses.
   - The CDB STI/BBV Manager notifies the STI/BBV epidemiologists.
   - The CDB STI/BBV team notify the relevant PHU.

The Director CDB will notify the Executive Director Health Protection and the Chief Health Officer.

†For the purpose of surveillance of *N. gonorrhoeae* antimicrobial resistance in NSW, isolates with ceftriaxone MICs ≥0.125 mg/L-<0.5 mg/L are considered to have decreased susceptibility to ceftriaxone, and isolates with ceftriaxone MICs ≥0.5 mg/L are considered to be resistant to ceftriaxone. Isolates with azithromycin MICs ≥256mg/L are considered to have high level resistance to azithromycin. Where MIC values are not included on laboratory notifications, all cases reported to have at least decreased susceptibility to ceftriaxone are to be initially investigated as meeting the decreased susceptibility case definition pending confirmation of the test value (the current Australian Gonococcal Surveillance Programme interpretative criteria (March 2019) consider isolates with MICs≥0.06 to have decreased susceptibility, with no separate resistant category defined due to a lack of data regarding a clinically relevant cut-off).

4.2. Risk assessment and public health response

Response times
Once a PHU becomes aware of a case of gonococcal infection with critical antimicrobial resistance, an initial risk assessment should be commenced on the day of notification to enable the prompt initiation of control measures. The initial risk assessment should be based on any available information on the day of notification. The PHU should also assess the need for urgent referral to a sexual health service or other appropriate specialist service and arrange for the completion of the standard STI questionnaire (available on NCIMS) and the additional case investigation form (provided in this appendix and available on NCIMS) by the treating clinician. The information obtained forms the basis of the centrally coordinated response by the Incident Management Team (see below). The forms with the information ascertained to date or a synopsis thereof and any other documentation related to the case investigation should be provided to the CDB STI/BBV Manager or other nominated contact as soon as possible, ideally within one working day. A case summary using the CD on-call report should be sent to the CDB on-call officer and circulated to the NSW Public Health Network by CD on-call within one working day. The PHU should record all relevant information in the current question packages in NCIMS. Any details relevant to the public health management of the event that are not captured in current question packages should be documented in appropriate free text sections or as attachments.

Response procedure

The detection of one or more cases of gonococcal infection with critical antimicrobial resistance triggers the formation of an Incident Management Team to centrally coordinate the public health response in close collaboration with the PHU within the LHD of the case's residential address. The CDB STI/BBV Manager will convene a multidisciplinary Incident Management Team, including but not limited to the following membership:

- Director of CDB
- Representative(s) of the investigating PHU(s)
- Representative(s) of the Office of the Chief Health Officer
- Sexual health clinicians, including from the treating specialist service
- Representative(s) of the Neisseria Reference Laboratory (SEALS)
- Representative(s) of NSW Sexual Health Infolink (SHIL), if involved in the case investigation
- Representative(s) of the CDB STI/BBV team
- Representative(s) of NSW Health media & communications
- Representative(s) of the Centre for Population Health and the Centre for Aboriginal Health, as appropriate
- Representative(s) of third sector organisations as appropriate, e.g. Aboriginal, CALD, LGBTI, sex worker health services and community organisations
- Representative(s) of interstate laboratories involved in the case investigation, where relevant

Case management

Contact with the diagnosing and/or treating medical practitioner(s)
PHU staff should contact the diagnosing medical practitioner (i.e., the doctor who ordered the initial laboratory test confirming gonorrhoea) and/or the current treating medical practitioner to:

- Establish whether the medical practitioner is aware of the critical antibiotic resistance
- Discuss and agree actions regarding case and contact follow-up, including:
  - urgent referral to a specialist sexual health service wherever possible if the patient is not already under specialist care. If there are strong reasons (e.g., distance or patient

cultural/language background) not to refer to a sexual health service, refer to an infectious disease specialist or arrange for specialist advice;
    - ascertain testing and treatment history;
    - discuss requirements for additional testing of potential other sites of infection, tests of cure etc. and need for CDB assistance with exceptional urgent specimen transport on advice of specialist sexual health services as required;
    - obtain information on contact tracing already completed and still outstanding (see below)
- Gather any additional information about the case from the medical practitioner using the standard STI questionnaire and the additional case investigation form
- Establish whether the case is aware of the diagnosis and the critical antibiotic resistance
- Obtain permission to contact the case directly for interview, noting that direct case follow up is most likely to be conducted by the specialist sexual health service (see below)

Case follow-up

The specialist sexual health service and the relevant PHU determine responsibility for case follow-up collaboratively. The following items should be covered:

- Inform the case about the critical antibiotic resistance/need for immediate public health action, including additional testing and treatment as required and further contact tracing
- Arrange for additional testing, case management follow-up and additional contact tracing activities to be done as required. The PHU has the responsibility to check that all actions are completed.
- Interview the case using the case investigation form (re-confirm details obtained from diagnosing medical practitioner)
- Provide patient education regarding transmission; advise to avoid sexual contact until test of cure results are negative and contacts have been tested, treated and cured

Contact management

The specialist sexual health service and the relevant PHU determine arrangements for contact tracing collaboratively, recognising that the primary responsibility for contact tracing lies with the clinician managing the case. Complex contact tracing may involve referral of some or all contacts to the NSW Sexual Health Infolink (SHIL) partner notification service. Where the case was referred and the primary diagnosing practitioner had already initiated contact tracing prior to the finding of critical antibiotic resistance, the primary diagnosing practitioner should be consulted.

Additional epidemiological and laboratory investigations

The Incident Management Team (see below) decides on additional epidemiological and laboratory investigations and liaises with relevant stakeholders. This may include further characterisation of isolates with critical antibiotic resistance, including by whole genome sequencing.

Communications

Communications are overseen by the Incident Management Team and may include the following:

- Alert to the National Incident Room
- Liaison with key stakeholders relevant to the case investigation, including interstate and international stakeholders (via National Incident Room as appropriate)
- Information to CDNA as appropriate
- Information to the NSW Public Health Network (i.e., initial case summary and further information as appropriate)

- Information to Sexual Health Directors
- Alert to clinicians
- Media release(s)
- Information to community groups as appropriate
- Health promotion messaging as appropriate
- Dissemination of key information to professional audiences (e.g., letter to editor, short communication etc.)

5. Response procedures for gonococcal infections with decreased susceptibility to ceftriaxone

5.1. Notification procedure

Depending on the source of the initial alert, the following notification procedures apply following the detection of a case with decreased susceptibility to ceftriaxone:

1. <u>If a PHU reviews a laboratory report or receives a laboratory alert:</u>
   - The PHU notifies the CDB on call officer as soon as possible.
   - The CDB on call officer notifies the CDB STI/BBV Manager
   - The CDB STI/BBV Manager notifies the STI/BBV epidemiologists and the Director CDB
2. <u>If a case is identified by the CDB STI/BBV team as part of routine surveillance:</u>
   - The STI/BBV epidemiologists notify the CDB STI/BBV Manager
   - The CDB STI/BBV team notify the relevant PHU.
   - The CDB STI/BBV Manager notifies the Director CDB
3. <u>If CDB on call receives a laboratory alert:</u>
   - The CDB on call officer notifies the CDB STI/BBV Manager as soon as possible.
   - The CDB STI/BBV Manager notifies the STI/BBV epidemiologists.
   - The CDB STI/BBV team notify the relevant PHU.
   - The CDB STI/BBV Manager notifies the Director CDB.

5.2. Risk assessment and public health response

Response times

Once a PHU becomes aware of a case of gonococcal infection with decreased susceptibility to ceftriaxone, contact with the diagnosing medical practitioner should be initiated within one working day. A case summary using the CD on-call report should be sent to the CDB on-call officer and circulated to the NSW Public Health Network by CD on-call within one working day. The PHU should record all relevant information in the current question packages in NCIMS. Any details relevant to the public health management of the event that are not captured in current question packages should be documented in appropriate free text sections or as attachments.

Response procedure

The PHU within the LHD of the case's residential address has the primary responsibly for the public health response to sporadic cases of gonococcal infections with decreased susceptibility to ceftriaxone, in consultation with the CDB STI/BBV team as required. Case management and contact tracing is the responsibility of the clinician managing the case. The PHU is responsible for ensuring that appropriate case management and contact tracing has been initiated for cases with decreased susceptibility to ceftriaxone, or that referral have been made to specialist sexual health

services or other appropriate specialist service. The PHU is also responsible for obtaining relevant information from the treating clinician and ensuring this information is documented in NCIMS.

In a cluster involving multiple cases with decreased susceptibility to ceftriaxone in one or more PHUs, the CDB STI/BBV Manager may decide to convene an Incident Management Team and apply the standard operating procedures for the response to gonococcal infections with critical antimicrobial resistance as outlined in section 4.2.

Case management

Contact with the diagnosing medical practitioner

PHU staff should contact the diagnosing ***and/or treating medical practitioner(s)*** to:

- Establish whether the medical practitioner is aware of the antibiotic resistance
- Discuss and agree actions regarding case and contact follow-up, including:
  - referral to a specialist sexual health service where appropriate and the patient is not already under specialist care. Referral to a specialist sexual health service should occur wherever possible if treatment failure is suspected in response to guideline-adherent treatment. If there are strong reasons (e.g., distance or patient cultural/language background) not to refer to a sexual health service, refer to an infectious disease specialist or arrange for specialist advice;
  - ascertain testing and treatment history;
  - discuss requirements for additional testing of potential other sites of infection, tests of cure etc on advice of specialist sexual health services as required;
  - obtain information on contact tracing already completed and still outstanding (see below)
- Gather any additional information about the case from the diagnosing medical practitioner using the standard STI questionnaire and the additional case investigation form
- Establish whether the case is aware of the diagnosis and the antibiotic resistance
- Obtain permission to contact the case directly for interview, noting that direct case follow up is most likely to be conducted by the treating medical practitioner, specialist sexual health service (see below)

Case follow-up

The treating medical practitioner and the relevant PHU should discuss case follow-up, with the assistance of specialist sexual health services as required. The following items should be covered, noting that direct case contact should preferentially be undertaken by the treating medical practitioner or specialist sexual health service, with PHUs checking that actions are completed:

- Ensure the case is informed about the antibiotic resistance/need for public health action, including additional testing and treatment as required and further contact tracing
- Arrange for additional testing, case management follow-up and additional contact tracing activities to be done as required. The PHU has the responsibility to check that all actions are completed.
- Interview the case using the case interview form (re-confirm details obtained from diagnosing medical practitioner)
- Provide patient education regarding transmission; advise to avoid sexual contact until test of cure results are negative and contacts have been tested, treated and cured

Contact management

The treating medical practitioner has the primary responsibility for contact tracing. The relevant PHU should ensure that arrangements have been made for contact tracing, with assistance from

specialist sexual health services as required. Complex contact tracing may involve referral of some or all contacts to the NSW Sexual Health Infolink (SHIL) partner notification service.

Communications

Communications are overseen by the CDB STI/BBV Manager and may include the following:

- Alert to the National Incident Room
- Liaison with key stakeholders relevant to the case investigation, including interstate and international stakeholders (via National Incident Room as appropriate)
- Information to CDNA as appropriate
- Information to the NSW Public Health Network (i.e., initial case summary and further information as appropriate)
- Information to Sexual Health Directors
- Alert to clinicians

Case investigation form for gonococcal infections with critical antimicrobial resistance or decreased susceptibility to ceftriaxone

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CASE INVESTIGATION FORM FOR GONOCOCCAL INFECTIONS WITH CRITICAL ANTIMICROBIAL RESISTANCE OR DECREASED SUSCEPTIBILITY TO CEFTRIAXONE

NSW GOVERNMENT

This form is to be completed in conjunction with the SEXUALLY TRANSMISSIBLE INFECTIONS NOTIFICATION FORM. Please complete this form only for cases requiring enhanced public health follow-up under the Standard Operating Procedures for gonococcal infections with critical antimicrobial resistance or decreased susceptibility to ceftriaxone

NCIMS no: PHU: PHU Fax No:

CASE DETAILS

Last Name: First Name:

Date of birth: __ __/__ __/__ __ __ __

1. Is the case currently under the care of a specialist sexual health service?

☐ Yes (specify service)

☐ No- referral made or planned (specify service and referral date)

☐ No (state reasons)

2. Did the case report any signs or symptoms (select all that apply)?

☐ No symptoms ☐ Urethral discharge ☐ Vaginal discharge

☐ Dysuria ☐ Abdominal pain ☐ Cervical excitation/adnexal tenderness

☐ Proctitis/tenesmus ☐ Pharyngitis ☐ Other (please specify)

3. Diagnostic test results for current episode of infection (please include negative test results where known)

Specimen site	Specimen date	Test	Result	Testing laboratory

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CASE INVESTIGATION FORM FOR GONOCOCCAL INFECTIONS WITH CRITICAL ANTIMICROBIAL RESISTANCE OR DECREASED SUSCEPTIBILITY TO CEFTRIAXONE

NSW GOVERNMENT

CASE DETAILS

4. Gonorrhoea test results in the 12 months prior to current episode of infection (please include positive and negative test results)

Specimen site	Specimen date	Test	Result	Testing laboratory

5. Susceptibility test results for current episode of infection (please add additional antibiotics if results are available, and note any differences in susceptibility between sites of infection)

Antibiotic	Susceptibility category[1]	MIC value *(where known)*	Testing laboratory	Notes
ceftriaxone				
azithromycin				
ciprofloxacin				
penicillin				
gentamicin				
ertapenem				
spectinomycin				
tetracycline				

1 Susceptibility interpretative criteria are not currently available for all antibiotics.

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CASE INVESTIGATION FORM FOR GONOCOCCAL INFECTIONS WITH CRITICAL ANTIMICROBIAL RESISTANCE OR DECREASED SUSCEPTIBILITY TO CEFTRIAXONE

NSW GOVERNMENT

CASE DETAILS

6. Additional exposure details (at a minimum, cover all sexual contacts in the 2 months prior to symptom onset, date of diagnosis, or date of last sexual contact- whichever is later).

Note that in most cases, this information will be collected by specialist sexual health services during contact tracing conducted to enable partner notification and testing and treatment of all partners. The information collected for this purpose should include additional details such as contacts' addresses, DOB or age, Aboriginal status, and any social media handles that might assist with partner notification. This level of detail does not need to be provided in the summary table below, but should be documented and made available to aid the case investigation as required.

Contact	Type of sexual partner *(e.g. regular, occasional/ casual, one-night stand, sex worker)*	What is the gender identity of the partner? *(e.g. male, female, non-binary)*	If not a regular partner- where did the case meet this contact? (e.g. dating app or *website, bar/club, specific event, brothel, beat, massage, sex on premises venue)*	Where did the case have sex with this partner? *(e.g. NSW, interstate, overseas – please list all that apply and be as specific as possible)*	What type of sex did the case have with this partner? *(Vaginal intercourse, anal intercourse, giving oral sex, receiving oral sex, kissing – please list all that apply)*
Contact 1					
Contact 2					
Contact 3					
etc					

7. Has contact tracing been initiated (select all that apply)?

☐ Yes (specify all providers/services involved)

☐ No- referral made or planned (specify provider/service and referral date)

☐ No (state reasons)

Source of information (select all that apply)

☐ Diagnosing doctor (specify name of medical practitioner and date/s)

☐ Sexual health service (specify name of medical practitioner and date/s)

☐ Case (specify date/s of interview)

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CASE INVESTIGATION FORM FOR GONOCOCCAL INFECTIONS WITH CRITICAL ANTIMICROBIAL RESISTANCE OR DECREASED SUSCEPTIBILITY TO CEFTRIAXONE

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ADDITIONAL NOTES