Health Service Directive – Tuberculosis Management

Protocol for the Treatment of Tuberculosis

1. Purpose
This protocol describes the mandatory steps to be taken in the treatment of tuberculosis (TB) cases in Queensland. The goal of clinical management of a TB case is to interrupt TB transmission, prevent acquisition of drug resistance, and cure the patient.

2. Scope
This Protocol applies to all Hospital and Health Service (HHS) employees and organisations and individuals acting as an agent HHS’s (including Visiting Medical Officers and other partners, contractors, consultants and volunteers).

3. Process for the Diagnosis and Treatment of Tuberculosis

3.1 Case Management Model of Care
- Each metropolitan or regional Tuberculosis Control Unit (TBCU) is to manage each TB case diagnosed within their jurisdiction under a case management team model.
- The TBCU case management team is responsible for the overall management of the patient which involves the TBCU checking that treatment regimens are correct and that appropriate follow up has been performed, and that all essential data has been provided by the treating team.
- The medical officer of the relevant TBCU is responsible for review of TB treatment regimens, in collaboration with the treating doctor, to ensure therapy adheres to best practice principles provided case has been notified to the TBCU.

3.1.1 Case Management Team
- The case management team is comprised of the treating doctor, case management doctor and case management nurse. The treating doctor is responsible for ensuring compliance with approved processes outlined within this document regarding TB regimens, drug dosages and detection of variances from standard regimens.
- All patients treated for TB in Queensland (regardless if a public or privately treated patient) have an allocated TBCU nurse assigned for the duration of treatment as an integral part of the case management team.
The treating doctor is also responsible for providing clinical support for the nursing staff involved with the management of TB patients.

Further, the case management team must:
- monitor the TB treatment course and ensure health records are current;
- monitor microbiology conversions,
- ensure treatment adherence by regularly checking drug regimens and doses; through medical and nursing assessments,
- ensure completion of treatment with appropriate regimen,
- as appropriate, assist regions in clinical functions if there are gaps in service delivery for TB patients,
- determine clinical and bacteriological outcomes; and
- determine cause of death for TB patients.

3.1.2 Decision for Directly Observed Therapy (DOT)

Although the World Health Organization policy recommends Directly Observed Therapy (DOT) for all patients being treated for TB, Queensland’s approach differs. Specific high-risk patients are placed on supervised treatment when considered necessary. The decision for DOT is made in consultation with the treating doctor and the TBCU case nurse in consultation with the HHS as required, and includes assessment of patient’s knowledge of TB, drug resistance pattern of the infecting strain of *Mycobacterium tuberculosis*, social factors which may impact on treatment, understanding of English, increased risk of side effect or need for support for the duration of treatment.

DOT must be considered for patients who:
- are in a high risk category,
- have a history of previous TB treatment, and/or
- have demonstrated they are incapable, unreliable, or unwilling to take medication unsupervised.

The Centre for Healthcare related Infection Surveillance and Prevention & Tuberculosis Control (CHRISP & TB) support using this risk-assessment to determine the need for DOT in Queensland. This is considered to be the minimum standard for TB control in Queensland.

3.1.3 Administering DOT

- The responsible supervisor must fully supervise the timely and correct dose of anti-tuberculosis medication to ensure the successful treatment and cure of the disease for the patient
- DOT for TB is given daily or thrice weekly. DOT is mandatory for all thrice weekly regimens. All other regimens shall be discussed with the treating doctor
• DOT treatment should be administered and observed for ingestion at the same time each day. A place and an approximate timeframe (eg; 9 – 10am) should be negotiated that is acceptable and convenient to the patient and the supervisor

• Patients must be provided with information relating to TB disease and medication and educated about the importance of medication compliance and any side effects they may experience

• The DOT process should be seen as a support mechanism rather than a police-type action.

3.1.4 Prescribed Medications

• The prescribed drugs must be documented with medication dosages and expected dates of DOT, and signed by the treating doctor allowing each drug to be signed off when supervised by the designated and responsible supervisor

• The supervisor is to "initial, time and date" the DOT form directly following the patient’s ingestion of medication

• Medication side effects and adverse reactions should be documented and appropriately reported to treating doctor or case nurse for appropriate action. The continuation of DOT should be regularly reviewed by the TBCU case nurse in consultation with the HHS as required.

3.1.5 Eligibility for DOT Supervisor

The DOT supervisor may be any of the following but is not limited to:

• TBCU nurse,
• community nurse or member,
• family member,
• local doctor, or
• local pharmacist.

External DOT providers shall be provided with the standard information package regarding the delivery of supervision.

3.1.6 Non-Adherence to DOT

• Non-adherence should be reported immediately by the DOT supervisor to the case nurse and to the treating doctor

• If thrice DOT is administered then it should be clearly understood that one or two defaults from attendance for the DOT dose(s) would amount to a loss of efficacy disproportionate to the number of dosages missed

• Additionally, intermittent therapy should not routinely be given without both Isoniazid and Rifampicin. Such cases should be discussed with the Case Management team and treating doctor

• Even a single failure from attendance should be followed up. The case management team should attempt to locate any patient who may require the
assistance of other parties, identify the reason for non-attendance, ensure medication dosage has actually been supervised and document in the patient record as a non-adherence.

### 3.1.7 Notification

- The Tuberculosis Expert Advisory Group (TEAG) must be notified in a timely manner of all individual cases of multi-drug resistant Tuberculosis (MDR-TB) and/or extensively-drug resistant Tuberculosis (XDR-TB) as well as where rifampicin cannot be used in the regimen.
- Treatment and management decisions of complex TB cases will be as per Treatment Guidelines 1-5, and may be subject to further investigation as decided appropriate by the TEAG.
- TB is a notifiable disease and must be reported to the Notifiable Conditions System (NOCS).

### 3.2 Public Health Management

#### 3.2.1 Commencing Treatment for TB

- Upon initial notification to the Department of Health’s NOCS (as per the Public Health Act 2005) all patients diagnosed with TB shall be commenced on treatment (smear positive pulmonary TB patients should commence treatment within 7 days in most instances)
- Smear negative and extrapulmonary TB cases should commence treatment within 28 days in most instances
- Each TB patient is to have an allocated case nurse from a metropolitan or regional TBCU to provide a supportive partnership and advocacy role between the patient and treating doctor delivering a quality, timely and client focussed consultancy through home or hospital visiting and telephone correspondence. Excellent communication, counselling and interviewing skills are essential for optimal patient management and outcomes.

Initial actions from the case management team include:

- determining patient infectivity and the impact on public health,
- assessment of the need for hospitalisation or isolation, and
- assessment of the need to limit mobility, work, study or travel i.e. aircraft.

#### 3.2.2 Patient Movement

- Each newly notified TB patient must be questioned by the case management team about possible movements interstate or out of the country and complete information is be obtained on alternative sources for contact information to ensure the patient is contactable as far as possible should the need arise to quickly trace the patient across cities, borders or countries. Additionally, the patient must be reminded about the need to contact the TBCU prior to any travel as agreed to in the TB treatment consent form.
• Should the patient leave their address without notice, government and non-government agencies (e.g., Department of Immigration & Citizenship, Centre Link, banks) may be used to assist with the tracing of the patient.

• If a patient with infectious TB has left the state or country without giving notice to the treating doctor or TBCU, duty of care requires that alerts are to be provided to settings where infection may have been transmitted (e.g., airlines, conference venues, etc) and procedures must be put in place to trace patient.

• Additionally, if a patient has left Queensland, the transfer out of patients for TB treatment form should be utilised. In particular, information should be forwarded to the TBCU in the state or country to which patient has moved.

• When all normal liaison and correspondence regarding compliance with management and/or treatment of TB fail, invoking the Public Health Act of the Health Act Order shall be carried out as a last resort (See Public Health Act 2005).

3.2.3 Clinical Management

All treating doctors from TBCUs and all other medical officers (including paediatricians) in Queensland must adhere to:

• Treatment Guideline 1 – Treatment of TB which stipulates approved treatment regimens for TB in QLD including but not limited to standard Mycobacterium Tuberculosis (MTB), monoresistant TB, extended treatment in specific extrapulmonary TB cases, and indications for ethambutol use in children and intermittent treatment regimens.

• In the event that any deviation to the standard regimen is required, Treatment Guidelines 1-5 where appropriate must be adhered to. All deviations, although rarely indicated, must be discussed with the TEAG.

Treating doctors must adhere to the following treating principles:

• Never treat active TB with a single drug.

• Never add a single drug to a failing TB treatment regimen.

• Seek consultation with the TEAG for failure of sputum cultures to convert to negative following 2 months of therapy, resistance to rifampicin (with or without resistance to other drugs) and HIV co-infection, drug intolerance, pregnancy, or other situations requiring deviation from a standard treatment regimen.

• Test all TB patients for HIV after obtaining informed consent.

• Adhere to the TB patient state-wide clinical pathway and where appropriate, the Confirmation of drug-resistant TB state-wide clinical pathway.

• Monitor infectiousness and microbiological results for drug sensitivities. Quality mycobacteriological assessment is the only reliable index of effective TB treatment at:
  • Initial phase, conversion of sputum smear to negativity is indicates non-infectiousness although the persistence of smear positivity in an adherent patient with drug susceptible infection is not necessarily an indication of persistent infectiousness. All pulmonary TB cases who are smear positive at
the time of diagnosis, should be discussed with a TBCU clinician prior to hospital discharge and / or return to work.

- **Continuation phase**, sputum culture negativity confirms early effective bactericidal effect in pulmonary TB and can be compared to benchmarks established in international Randomised Control Trials of treatment

- **End of treatment**, culture negativity confirms bacteriological cure (best assessment for smear positive pulmonary TB not managed with full supervision of drug doses).

4. **Supporting and related documents**

   **Authorising Health Service Directive**
   - Health Service Directive – Tuberculosis Management

   **Legislation**
   - Public Health Act 2005

   **Queensland Department of Health Guidelines:**
   - Treatment of Tuberculosis
   - Treatment of Tuberculosis in Pregnancy
   - Treatment of HIV / Tuberculosis Co-infection
   - Treatment of Latent Tuberculosis Infection
   - Treatment of Tuberculosis in Renal Disease

   **State-wide Clinical Pathways**
   - Appendix 1: Diagnosed or Presumed TB Patient
   - Appendix 2: Confirmation of Drug-resistant TB

5. **Definition of Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition / Explanation / Details</th>
<th>Source</th>
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<tbody>
<tr>
<td>DoH</td>
<td>Department of Health</td>
<td>Queensland Health</td>
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<tr>
<td>DOT</td>
<td>Directly Observed Therapy</td>
<td>WHO</td>
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<td>MDR-TB</td>
<td>Multi-drug Resistant Tuberculosis</td>
<td>WHO</td>
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<td>MTB</td>
<td>Mycobacterium Tuberculosis</td>
<td>WHO</td>
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<td>NOCS</td>
<td>Notifiable Conditions System</td>
<td>Australian Govt.</td>
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<td>TB</td>
<td>Tuberculosis</td>
<td>WHO</td>
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<tr>
<td>TBCU</td>
<td>Tuberculosis Control Unit. These include the regional tuberculosis control units located in Cairns, Rockhampton, Toowomba and Townsville, as well as Metro South Clinical Tuberculosis Service.</td>
<td>Queensland Health</td>
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<tr>
<td>TEAG</td>
<td>Tuberculosis Expert Advisory Group</td>
<td>Queensland Health</td>
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<tr>
<td>XDR-TB</td>
<td>Extensively Drug Resistant Tuberculosis</td>
<td>WHO</td>
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6. Approval and Implementation

Protocol Custodian

Director
Centre for Healthcare Related Infection Surveillance and Prevention & Tuberculosis Control
Communicable Diseases Unit
Chief Health Officer Branch

Approving Officer:
Dr Michael Cleary
Deputy Director-General
Health Service and Clinical Innovation

Approval date:
01/07/2013

Effective from:
01/07/2013
Appendix 1: Diagnosed or Presumed TB Patient

Initial Clinical Assessment - MO
- Check HIV & Hepatitis serology
- Consider DOT if Smear pos
- Check sensitivities
- Refer to hospital if necessary
- Notify case
- Referral to TB Unit for Initial Nursing interview
- Consider Contact Tracing involved

TB Case Nurse Manager
- Initial Nursing interview
- Contact Tracing & Screening

Previously Treated

Drug resistance considered possible?

YES

Drug resistance

No

DOT if not already

YES

Drug Side effects

Variance

YES

NON-MDRTB
- Reassess regimen

NO

Interruption or Rx failure

MDRTB
- Add 2nd line drugs
- DOT if not already
- Consider hospitalisation
- Reassess contact tracing
- ?Surgical intervention

XDR TB
- All of above +
- Add 3rd line drugs
- Hospitalisation with strict respiratory precautions

Completed adequate Rx

YES

Reassess Treatment

F/U Clinical Assessment
3 – 5yrs or as appropriate

NO

F/U MDRTB & XDR TB
Statewide Clinical Pathways
Appendix 2: Confirmation of Drug Resistant TB

- Reassess Treatment if already commenced
- Consult with Expert TB Advisory Group
- Treat
- Check HIV status
- Ensure DOT is implemented
- Hospitalise if necessary e.g. co-morbidities
- Review Contact Tracing & Screening results to date and expand if necessary

XDRTB?

NO

Hospitalise with strict respiratory precautions

YES

Follow WHO guidelines for treatment of XDRTB

- MO Clinical Assessment – minimum monthly
  - Investigations as appropriate ensuring mycobacteriology check @ 2 or 3 & 6mths and thereafter to end of treatment i.e. 18mths +
  - Regular updates to TB Expert Advisory Group
- Monthly TB Unit Case Nurse follow-up

Drug Side Effects

- Continue
- Re-challenge
- Add other drugs

Interruption or

Completed adequate Rx

YES

YES

F/U Clinical Assessment

NO

Reassess Treatment

NO

Variance

YES

XDRTB?