

## COMMUNITY MEDICAL LIAISON GUIDELINES FOR TUBERCULOSIS USING THE COMMUNITY COOPERATION CLINICAL PATHWAY

—Medical Institution's Roles in Community DOTS—

### The Treatment Committee of the Japanese Society for Tuberculosis

The number of medical institutions that provide institutional care of tuberculosis has decreased for several reasons: the number of patients with tuberculosis has decreased; the length of hospitalization has been shortened; and medical care has become more efficient. In addition, the number of tuberculosis specialists has decreased. Patients with tuberculosis are currently treated by limited numbers of specialists under conditions such as limited hospital bed capacities. Physicians and medical institutions with little experience with tuberculosis are increasingly providing medical care. The creation of a community medical liaison for tuberculosis treatment is necessary to provide continuous appropriate medical care for tuberculosis including Directly Observed Treatment, Short-course (DOTS) from the initiation to the completion of treatment. It is important that community medical liaisons share roles and information among community medical institutions, for which the community cooperation clinical pathway is useful.

The guidelines here show the specific requirements for cooperation between the above tuberculosis medical institutions and other community medical institutions in the treatment of patients with tuberculosis. Such cooperation is expected to ultimately improve the level and results of tuberculosis treatment<sup>1)</sup>. However, major effort is required by each medical institution, tuberculosis medical institutions in particular, to construct and operate the cooperation system. Therefore, the promotion of systems such as fee for medical services, which consists of proper remuneration for labor, is also necessary.

The Committee on Health and Nursing of the Japanese Society for Tuberculosis is preparing the guidelines for community DOTS and focusing on the role of the public health center. DOTS is an indispensable element for tuberculosis treatment. "In-hospital DOTS" has been used widely in medical institutions that provide institutional care of tuberculosis<sup>2)</sup>, but DOTS is also required for the continuous treatment of patients after discharge or ambulatory treatment from the initiation of treatment. "Community DOTS" is proposed to encourage patients to continue medication and community medical care. However, for practicality, close cooperation among a public health center, tuberculosis medical institution, local medical institution, local social welfare institution, and dispensing pharmacy as well as other institutions is required. Although a public health center has the role of stimulating community

DOTS, medical institutions are also expected to play a major role. The guidelines for community DOTS developed by the Committee on Health and Nursing and the Guidelines for Community Medical Liaison for Tuberculosis, which are presented for medical institutions, are two sides of the same coin. We hope that these guidelines will help facilitate efficient delivery of appropriate tuberculosis treatment including community DOTS in both tuberculosis medical institutions and other medical institutions.

#### 1. Roles of medical institutions in community medical liaison and community DOTS

##### 1) Roles of a tuberculosis medical institution

To have adequate numbers of tuberculosis hospital beds that comply with the standards (or model hospital beds) and treat mainly infectious patients (e.g., positive sputum smear) and patients in whom standard treatment is difficult. A tuberculosis medical institution includes the following: a tuberculosis base hospital; a regional core tuberculosis hospital in each prefecture; a hospital with tuberculosis hospital beds; and a hospital in which tuberculosis/atypical mycobacterial infection specialists and preceptors certified by the Japanese Society for Tuberculosis work.

(1) Prepare a treatment plan and provide information to a cooperative medical institution (a designated tuberculosis medical institution) that continuously treats patients after discharge using a cooperation clinical pathway or other method.

(2) If side effects or other such things develop, review the treatment plan based on clinical practice to provide information if necessary when referred by a cooperative medical institution.

(3) Provide information regarding the patient's condition on admission and subsequent condition to the public health center.

(4) To perform community DOTS appropriately in preparation for discharge, perform a risk assessment of each patient and cooperatively create each patient's support program in a DOTS (or other) conference with the public health center. Follow the guidelines developed by the Committee on Health and Nursing when creating the individual support program.

##### 2) Roles of a general medical institution

Mainly to treat patients who were referred from tuberculosis specialty hospital to continue treatment and patients

who are non-infectious (e.g., patients with a negative sputum smear) for whom standard treatment is available when tuberculosis is diagnosed. This type of general medical institution must be designated a tuberculosis medical institution.

(1) Treat patients who were referred from a tuberculosis medical institution using the community cooperation medical program and provide treatment information to the public health center in which the patients are being treated.

(2) Treat non-infectious patients who do not need to be treated in tuberculosis medical institutions (e.g., patients in whom the standard treatment seems to be effective) using other programs such as a clinical pathway developed by a tuberculosis medical institution. In this case, the tuberculosis medical institution does not have to be directly involved in the patient's treatment.

(3) Patients in (1) and (2) above should be referred to a tuberculosis medical institution as needed to ask for a treatment plan change when side effects develop, symptoms are aggravated, or problems such as drug resistance occur.

(4) In cases such as a patient non-adherent to treatment, actively provide that information to the public health center.

### 3) Role of a pharmacy, home medical care, and social welfare institution in medication assistance

In the treatment of tuberculosis, the daily direct observation of medication ingestion is indispensable. For patients who require caregiving, the most effective and reliable observation of medication ingestion occurs in home medical care or in the care systems within welfare institutions. A patient's regular pharmacy is also an appropriate place to observe medication ingestion.

Medication ingestion should occur by individual methods appropriate for each patient based on the support program prepared at a DOTS or other conference. The observation of physical conditions and medication ingestion may help detect the side effects of the drugs or a possible early recurrence of tuberculosis. If a change is observed, advise the patient to consult their medical institution; otherwise, contact the public health nurse of the relevant public health center.

## 2. Basic treatment schedule (community cooperation clinical pathway)

In the guidelines, it is assumed that tuberculosis hospitals are directly involved in treatment in the community cooperation clinical pathway. It is desirable to treat a patient using the treatment pathway developed by a tuberculosis medical institution or others when treatment is initiated in a local designated tuberculosis medical institution.

### 1) Essential matters to be included in the pathway at the initiation of treatment

Pathways should include the matters in (1) to (4) below. These should be distributed to the designated tuberculosis medical institutions beforehand or at the time a notification of

patient is submitted.

(1) Procedures such as a case notification of tuberculosis and a medical certificate to make an application for the public subsidy of the medical treatment of tuberculosis

(2) Criteria for the necessity of hospitalization (including understanding the number and function of tuberculosis hospital beds in the region)

(3) Laboratory tests required at the time of diagnosis

(4) Education of patients and families: inform them that it is an infectious disease as prescribed by the law; instruct them about the preventive measures against infection

### 2) Continuous treatment pathway

A tuberculosis medical institution develops and provides a continuous treatment pathway to general medical institutions to which the patient has been referred. A new plan should be developed when discontinuation of treatment is inevitable because of drug resistance, side effects, or various reasons.

(1) The treatment plan should include therapeutic drugs, dosage and administration, planned treatment duration, side effects, bacteriological examinations, test schedule for understanding treatment course, necessary notifications.

(2) The treatment course table should include the treatment situation, bacteriological examinations, and drug sensitivity test results (if positive bacteria are noted).

(3) The relevant public health center, its contact information, and the need to consult the tuberculosis medical institution and its contact information (when treatment cannot be performed as scheduled) should be included.

### 3) Summary of the standard treatment of tuberculosis

Treatment should be administered according to the "Standards for Tuberculosis Care"<sup>3)</sup>. For more information, refer to the Clinical Practice Guidelines for Tuberculosis or other guidelines. Only the basic points are described here.

(1) Prescribe a combination of 4 drugs consisting of isoniazid (INH), rifampicin (RFP), pyrazinamide (PZA), and ethambutol (EB) or streptomycin (SM), or a 3-drug combination of INH, RFP, and EB or SM.

(2) Do not treat patients with  $\leq 2$  drugs at the initiation of treatment.

(3) Treatment duration: if PZA is used for the initial 2 months, 6 months (180 days) is standard; otherwise, 9 months (270 days) is standard. Another 3 months may be added as needed.

(4) In situations in which the standard treatment is unavailable, the treatment strategy should be changed when either INH or RFP resistance is seen or when it cannot be used because of complications, side effects, or drug interactions. When treatment other than the standard treatment is used, comply with the "Standards for Tuberculosis Care" and consult specialists as needed. In addition, to prevent discontinuation of the treatment because of the mild side effects or to prevent severe side effects by indiscriminate use, specialists should

be consulted.

(5) Medication assistance: because DOTS for continuous medication during the required period is an indispensable treatment element, medical institutions should provide explanation and instructions to patients and cooperate closely with the public health center.

Situations in which the standard treatment is unavailable or a consultation with specialists is necessary are explained in detail below.

–INH and/or RFP cannot be used because of resistance or severe liver disease.

–In liver function tests, an aspartate aminotransferase/alanine aminotransferase (AST/ALT) level of 200U or a  $\geq$  5-fold baseline AST/ALT level is seen.

–A patient has subjective symptoms that may be associated with liver damage as evidenced by an AST/ALT level of 100 U or a  $\geq$  3-fold baseline AST/ALT level.

–Of the symptoms that can be considered side effects, including widespread drug eruption, thrombocytopenia, and visual disturbances, serious symptoms or symptoms with difficulties in recovery are seen.

–Clinical deterioration during treatment or re-excretion of the organism after the culture results are negative.

–Alternatively, the standard procedures cannot be performed during the drug and dosage and administration process.

#### 4) Illustration of the community cooperation pathway

(1) Tuberculosis medical treatment pathway (Appendix 1)

(2) Standard treatment pathway

4-drug standard treatment with INH, RFP, PZA, and EB or SM (Appendix 2)

3-drug standard treatment without PZA (Appendix 3)

(3) Pathway when the standard treatment cannot be performed (Appendix 4)

Appendices 1–4 contain a pathway example. Such an example may be originally developed by each medical institution and each public health center to meet the requirements described in above 1), 2).

### 3. Other tools for sharing information in the community

#### 1) Liaison medication notebook

Patients receive the notebook from the public health center, tuberculosis medical institution, or a general medical institution in which treatment is initiated. Its main contents include a tuberculosis treatment schedule and a field in which to record medication ingestion. A person who checks medication ingestion records the daily medication. Patients bring the notebook when visiting the medical institution. The attending physician fills in the treatment course and the bacteriological examination results. Through these phases, a patient, a person who checks medication ingestion, the relevant medical institution, the public health center, the patient's regular pharmacy or caregiver can share information.

#### 2) Considerations for the development and use of a liaison medication notebook

Although the public health center often provides the notebook, tuberculosis medical institutions cooperatively prepare the notebook which is continuously available from admission to completion of treatment as needed. It is desirable that the contents include a field to record medication ingestion, a field to record test results, and a schedule of management and examination from the initiation to completion of treatment. The patients bring it when visiting the medical institution and when undergoing a check of medication ingestion. The attending physician, person who checks medication ingestion, pharmacist in the patient's regular pharmacy, and public health nurse or others complete the required fields every time and read the records provided by other persons to take them into account when examining the patient treatment and support.

### References

- 1) Shigeto E: Present and future of tuberculosis care in regions (in Japanese). *Kekkaku*. 2012 ; 87 : 789–794.
- 2) The Committee on Health and Nursing of the Japanese Society for Tuberculosis: Hospital DOTS guidelines (in Japanese). *Kekkaku*. 2004 ; 79 : 689–692.
- 3) The Treatment Committee of the Japanese Society for Tuberculosis: Review of "Standards for Tuberculosis Care" — 2008 (in Japanese). *Kekkaku*. 2008 ; 83 : 529–535.

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### Appendix 1 Tuberculosis manual and medical treatment pathway

<i>Symptoms that indicate tuberculosis should be also suspected</i>	Coughing continues for two weeks or more. On chest radiograph, a shadow that cannot be clearly diagnosed as other diseases exists. In particular, elderly patients who also have symptoms such as mild fever, general malaise, and loss of appetite in addition to respiratory symptoms should be considered as tuberculosis in all cases.									
<i>Actions when tuberculosis is suspected</i>	"Coughing etiquette" is recommended (wear a mask; during coughing, cover the mouth with towels). Perform tests and medical examination immediately when a patient is coughing (assign priorities of medical care to such a patient) to shorten the waiting time of patients with cough. It is ideal to allow such a patient to be waiting in a room separate from that in which other patients are waiting.									
<i>Tests to diagnose tuberculosis (pulmonary tuberculosis in particular)</i>	Sputum smear for acid-fast bacillus/cultivation (appropriate sputum, three times); Identification of <i>Mycobacterium tuberculosis</i> complex with nucleic acid amplification; Drug sensitivity test* (when positive for tuberculosis is reported by cultivation) *Taking account of the possibility that bacteria may not be collected at a hospital where a patient is transferred, perform the tests even if the patient is no longer admitted and send the bacterial strain to the hospital where a patient is transferred, if necessary. When sputum cannot be collected, use induced sputum, aspiration of sputum, and early-morning gastric juice as specimens. When it is difficult to diagnose because bacteria was negative, refer the results of Interferon Gamma Release Assay (IGRA) test (QuantiFERON TB® Gold, T-SPOT® TB; make a reservation with the laboratory). However, tuberculin test has priority in infants, children under 5 years old, children who have never undergone BCG vaccination.									
<i>*Diagnostic treatment</i>	Do not treat a patient with single agent even if it is diagnostic treatment, which may cause drug-resistance. Some fluoroquinolones in particular are effective against tubercle bacillus. However, do not use fluoroquinolone alone when tuberculosis is suspected.									
<i>Situation when notifications need to be submitted to the public health center</i>	Patients with a positive smear for acid-fast bacilli are a "confirmed tuberculosis case" (if it is found to be nontuberculous mycobacteria later, it is outcome at the time). Untreated patients with positive <i>Mycobacterium tuberculosis</i> complex by PCR, positive <i>Mycobacterium</i> culture, and identified <i>Mycobacterium tuberculosis</i> complex, are considered "confirmed cases." When active tuberculosis or its possibility is diagnosed, including unknown PCR results.									
<i>Procedures to submit notifications to the public health center</i> XXX public health center Tel: YYYYYY	Submit the "Case notification" promptly to the nearest public health center (the relevant public health center of the patient's or hospital's address). First make a call or send a notification form fax to the "Department of Infection of the Public Health Center."									
<i>Decision of necessity of hospitalization</i>	Patients with positive sputum acid-fast bacillus smear should be hospitalized as recommended by the public health center. Hospitalized depending on the situation: a patient showed negative sputum smear for acid-fast bacillus/cultivation or positive by PCR and negative bacteria but frequently coughs. Particularly for institutionalized or hospitalized patients. Basically outpatient treatment is acceptable: for patients with three negative results of sputum acid-fast bacillus smear and without frequent cough.									
<i>Instructions to patients in whom infectivity is still suspected</i>	Wear a mask (e.g., large gauze mask) when going out or to the hospital. Always cover the mouth with a mask or towel when coughing. Do not go out: in particular, do not use public transportation.									
<i>When a patient does not agree to hospitalization</i>	Submit a notification to the public health center and consult with the person in charge.									
<i>Request and referral of hospital treatment</i>	A call must be made for patients requiring hospitalization; a reservation is required for a treatment consultation.									
<i>Tuberculosis hospital beds in the region</i>	<table border="0"> <tbody> <tr> <td>YYY Hospital</td> <td>Address</td> <td>Tel:</td> </tr> <tr> <td>XY Hospital</td> <td>Address</td> <td>Tel:</td> </tr> <tr> <td>XYZ Center</td> <td>Address</td> <td>Tel:</td> </tr> </tbody> </table>	YYY Hospital	Address	Tel:	XY Hospital	Address	Tel:	XYZ Center	Address	Tel:
YYY Hospital	Address	Tel:								
XY Hospital	Address	Tel:								
XYZ Center	Address	Tel:								
<i>Summary of explanation to a patient and family at referral</i>	The patient is likely to have infectious tuberculosis, so hospitalization to a tuberculosis ward is necessary to prevent its spread to society. The time to discharge is determined in reference to the results of the periodical sputum tests; many patients are hospitalized for 1–4 months. If patients are hospitalized according to the public health center's hospitalization recommendation, after taking steps, then the entire treatment cost is paid by public subsidy as a general rule. Unless a patient has chronic tuberculosis and their overall status is poor, tuberculosis is a treatable disease if the patient receives appropriate treatment.									

<i>Instructions about transmission</i>	<p>If a patient is infectious and their overall status is poor: request emergency transport, and the fellow passenger wears a N95 mask.</p> <p>When the patient's overall status is tolerable for transfer: use a privately owned car.</p> <p>When the infectivity is high and a privately-owned car is unavailable: consult the public health center.</p>
<i>Explanation of infection to a family</i>	<p>The patient's "coughing etiquette" is the most important to prevent spread of infection to the neighborhood. Close contacts such as family members may be infected but the public health center may advise. Unless the contacts themselves become sick, infection is not spread from the contacts to the neighbors, and behavior restrictions are unnecessary.</p>
<i>Countermeasures against infection</i>	<p>Ventilation in the space (room, car, or others) where the patient stayed should be performed.</p> <p>The necessity and range of medical examinations of the contacts is judged by the public health center.</p> <p>When hospital infection is suspected, contact and cooperate with the public health center.</p>
<i>When ambulatory treatment is provided in the same hospital</i>	<p>The standard treatment pathway is shown in the attached sheet. *It is necessary to be a designated tuberculosis medical institution.</p>
<i>Precautions to treat a patient with tuberculosis in the same hospital</i>	<p>Follow the standard treatment.</p> <p>When the patient is very likely to have drug resistance and when the standard treatment is unavailable because of side effects or other reasons, consult a medical institution with tuberculosis hospital beds.</p>
<i>Source of information about tuberculosis</i>	<p>The Japanese Society for Tuberculosis, Homepage <a href="http://www.kekkaku.gr.jp">http://www.kekkaku.gr.jp</a> Japan Anti-Tuberculosis Association, Homepage <a href="http://www.jata.or.jp">http://www.jata.or.jp</a></p>
<i>The person in charge who prepared this information, contact and consultation information</i>	<p>XXX Public Health Center      Tel:</p>

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## Appendix 2 Tuberculosis treatment: Standard treatment A

Patient name: \_\_\_\_\_ Body weight: \_\_\_\_\_ kg Age: \_\_\_\_\_ years

Attending physician name: \_\_\_\_\_

Contact information of the relevant public health center:

Public health center: \_\_\_\_\_ TEL: \_\_\_\_\_

Public health nurse name: \_\_\_\_\_

Regimen

Standard treatment with 4 drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol)

Date of initiation of treatment: Day Month Year

Due date of completion of treatment: Day Month Year

Date of completion of treatment: Day Month Year

DOTS method

Standard regimen

Isoniazid (5 mg/body weight kg; Up to 300 mg/day) 100 mg \_\_\_\_\_ tablets for 6 months\*  
 Rifampicin (10 mg/body weight kg; Up to 600 mg/day) 150 mg \_\_\_\_\_ capsules for 6 months\*  
 Pyrazinamide (25 mg/body weight kg; Up to 1500 mg/day) Powder \_\_\_\_\_ mg for initial 2 months (56–60 days)  
 Ethambutol (15–20 mg/body weight kg; Up to 1000 mg/day) 250 mg \_\_\_\_\_ tablets  
 Until confirmation of initial INH/RFP-sensitive

(Instead of ethambutol, streptomycin can be used as follows:

–15 mg/body weight kg twice a week; Up to 1 g/day) Once a day \_\_\_\_\_ one dose package

\*Consider to extend treatment duration up to 9 months when the patient shows diabetes, pneumoconiosis, use of immunosuppressive drugs, immunodeficiency, or others and positive bacteria is reported at 3 months after the initiation of treatment.

Check items for side effects

Appetite, nausea, general malaise, jaundice, numbness, rash, visual acuity (EB), hearing ability, dizziness, tinnitus (SM)

\*When drugs are unavailable due to side effects, consult a specialist.

Other cautions

When combining with other drugs, it is required to pay attention to drug interactions. In addition, it is required to check it at the initiation of use and at the completion of tuberculosis treatment.

Test schedule

Perform sputum smear for acid-fast bacillus/cultivation, liver function tests, CBC, renal function tests, visual acuity (when EB is used), and hearing ability (when SM is used), one or more times per month.

Perform sputum smear for acid-fast bacillus/cultivation and liver function tests every 2 weeks for initial 2 months.

Chest radiography: At the initiation of treatment, 1 month after initiation, at the completion of treatment, and when necessary.

Notification documents

Submitted notification: Day Month Year

Application form of the public subsidy for medical treatment: Day Month Year

(Clause 2 of Article 37)

Comments

	On admission	After 2 weeks	4 weeks	6 weeks	8 weeks	After 3 months	4 months	5 months	6 months	7 months	8 months	9 months
Date												
Smear for acid-fast bacilli												
Cultivation												
Drug resistance												
Used drugs	RFP INH PZA EB											
Subjective symptoms												
Side effects												
Procedures	Application for public subsidy for medical treatment. According to the Clause 2 of Article 37, apply for public subsidy for medical treatment when hospitalization recommendation is released.								Apply for public subsidy for medical treatment at 6 months after the last time if necessary.			



**Appendix 4 Tuberculosis treatment: Case that the standard treatment is unavailable**

Patient name: \_\_\_\_\_ Body weight: \_\_\_\_\_ kg Age: \_\_\_\_\_ years

Attending physician name: \_\_\_\_\_

Contact information of the relevant public health center:

Public health center: \_\_\_\_\_ TEL: \_\_\_\_\_

Public health nurse name: \_\_\_\_\_

*Regimen*

Date of initiation of treatment: Day Month Year

Due date of completion of treatment: Day Month Year

Date of completion of treatment: Day Month Year

*DOTS method*

*Prescription*

\* Consult a specialist

*Check items for side effects*

Appetite, nausea, general malaise, jaundice, visual acuity, numbness, and rash

*Other cautions*

When combining with other drugs, pay close attention to drug interactions, especially at the initiation and completion of tuberculosis treatment.

*Test schedule*

Perform sputum smear for acid-fast bacillus/cultivation, liver function tests, renal function tests, CBC, and others, one or more times per month.

Chest radiography: At the initiation of treatment, 1 month after initiation, at the completion of treatment, and when necessary.

*Notification documents*

Submitted notification: Day Month Year

Application form of the public subsidy for medical treatment: Day Month Year

(Clause 2 of Article 37)

*Comments*

	On admission	After 2 weeks	4 weeks	6 weeks	8 weeks	After 3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months		
Date															
Smear for acid-fast bacilli															
Cultivation															
Drug resistance															
Used drugs															
Subjective symptoms															
Side effects															
Procedures	Application for public subsidy for medical treatment when the patient has the first medical examination and when hospitalization recommendation is released.							Apply for public subsidy for medical treatment at 6 months after the last time.							
	After 11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19 months	20 months	21 months	22 months	23 months		
Date															
Smear for acid-fast bacilli															
Cultivation															
Used drugs															
Subjective symptoms															
Side effects															
Procedures		Apply for public subsidy for medical treatment at 6 months after the last time							Apply for public subsidy for medical treatment at 6 months after the last time						