

## Reporting criteria for Tuberculosis (TB)

### (1) Definition

Infectious disease caused by *Mycobacterium tuberculosis* complex (excluding *M. bovis*, BCG).

### (2) Clinical manifestations

TB is caused by droplet nuclei infection through the respiratory tract. Majority of the sources of infection are patients with pulmonary TB whose sputum are smear-positive; less frequently, however, source of infection also include patients who are only culture-positive or those with extra-pulmonary TB. Once infected, there may be clinical manifestations, with occurrence ranging from several weeks after infection through the course of a lifetime, but such manifestations occur in approximately 30% of those infected. Among young patients, a history of contact with TB patient(s) within a few months to a few years of onset may be present.

The risk of symptomatic TB is high shortly after infection (especially within the first year), and in terms of age, is high among infants and adolescents. In addition, risk also increases for patients with complications (such as diabetes, chronic renal failure, AIDS, and pneumoconiosis), those with a history of gastrectomy, and for those receiving immunosuppressant therapy (such as adrenocortical hormone and TNF $\alpha$  inhibitor).

In many cases, given the entry site of *M. tuberculosis*, the most frequently affected organ is the lung (pulmonary TB), but extra-pulmonary organs may also be affected. Such organs that are frequently affected include pleurae, lymph nodes, vertebrae, bones, joints, kidneys, urogenital tract, central nervous system, and larynx. The systemic spread of the bacteria throughout the body results in miliary TB.

The typical symptoms of TB are cough, expectoration, and mild fever, which may be accompanied by chest pain, dyspnea, bloody sputum, general malaise, anorexia, etc. In the early phase of infection, the patient may be asymptomatic.

### (3) Reporting criteria

#### a) "Patients (confirmed cases)"

In compliance with Article 12 paragraph 1 of the Infectious Diseases Control Law, if a physician has examined a patient with clinical signs or symptoms as described in (2), has suspected TB, and has made a diagnosis of TB based on the results obtained by the laboratory method and specimen as described below, the physician shall notify the case immediately.

When laboratory diagnosis other than the detection of the pathogen or the pathogen's genome is applied, in addition to those examination results, the patient is notifiable only when the physician's diagnosis is warranted by patient interview or other means.

Diseases that should be considered in the differential diagnosis of TB include pneumonia caused by other agents, non-tuberculosis mycobacterial infection, lung cancer, bronchiectasis, and benign tumor.

**b) “Asymptomatic infections”**

In compliance with Article 12 paragraph 1 of the Infectious Diseases Control Law, if a physician has examined a person without clinical characteristics listed in (2), but has diagnosed that the person is an asymptomatic carrier of *M. tuberculosis* complex, based on the results obtained through the laboratory tests listed below (excluding imaging examination), and has judged that the patient requires treatment for TB (latent TB infection), the physician shall notify the case immediately.

For patients younger than 5 years of age, even if carriage could not be confirmed by the laboratory methods as described, the physician shall submit a notification if there is a high index of suspicion for infection based on the epidemiologic situation, such as being in contact with a patient, within droplet range, on a repeated or sustained basis.

**c) “Suspected cases”**

In compliance with Article 12 paragraph 1 of the Infectious Diseases Control Law, if a physician has examined a patient with clinical signs or symptoms as described in (2), and has a high index of suspicion for diagnosing him/her as “suspected TB”, the physician shall notify the case immediately.

When diagnosing suspected cases, information such as an occurrence of an outbreak and epidemiologic links should be considered.

**d) “Deceased person whose death was attributed to TB”**

In compliance with Article 12 paragraph 1 of the Infectious Diseases Control Law, if a physician has examined a deceased person with clinical signs as described in (2), and has diagnosed that the death was due to TB based on the results obtained by the laboratory methods and specimens as described below, the physician shall notify the case immediately.

**e) “Deceased person whose death was suspected to be due to TB”**

In compliance with Article 12 paragraph 1 of the Infectious Diseases Control Law, if a physician has examined a deceased person with clinical signs as described in (2), and has suspected the death was caused by TB, the physician shall notify the case immediately.

| Laboratory method  | Specimen   |
|--|--|
| Detection of the pathogen by smear microscope  | Sputum, gastric juice, pharyngeal/laryngeal swab, bronchoalveolar lavage, pleural fluid, pus, secretion, urine, stool, cerebrospinal fluid, tissue specimens |
| Detection of the pathogen by isolation and identification                                    |  |
| Detection of the pathogen’s genome by PCR  |  |
| TB-specific pathological findings  | pathology specimens  |
| Tuberculin reaction (reddening, induration, vesicles, necrosis)                              | skin   |
| Interferon $\gamma$ release assay from lymphocytes after stimulation by TB-specific antigens | blood  |
| Imaging examination  | e.g. chest X-ray, CT scan  |