

California Department of Public Health Tuberculosis Control Branch  
**Tool for Completing RVCT Item 15 and 44**

Death is the most serious outcome of tuberculosis and investigating deaths among TB patients is an essential component of TB control programs<sup>1</sup>. In order to further investigate deaths among patients with TB, the CDC has added questions in items 15 (Dead at Diagnosis\*) and 44 (Reason Therapy Stopped; If Died) of the revised Report of Verified Case of Tuberculosis (RVCT):

**15. Status at TB Diagnosis (select one)**

Alive     Dead \*

Month                      Day                      Year

If DEAD, enter date of death:

If DEAD, was TB a cause of death? (select one)

Yes     No     Unknown

**44. Reason Therapy Stopped or Never Started (select one)**

Completed Therapy     Not TB    If DIED, indicate cause of death (select one):

Lost     Died     Related to TB disease     Unrelated to TB disease

Uncooperative or Refused     Other     Related to TB therapy     Unknown

Adverse Treatment Event     Unknown

CDC guidance states that *Yes/Related to TB* should be selected if TB, or TB therapy, was the immediate cause of death, an underlying cause of death or another significant condition contributing to death. Because determining whether TB was a cause of death is often challenging, CDPH TB Control Branch is issuing this document to help with this determination and to bring consistency among local jurisdictions reporting TB cases in California.

**How to Use this Document:**

We recommend that this tool be used by a clinician.

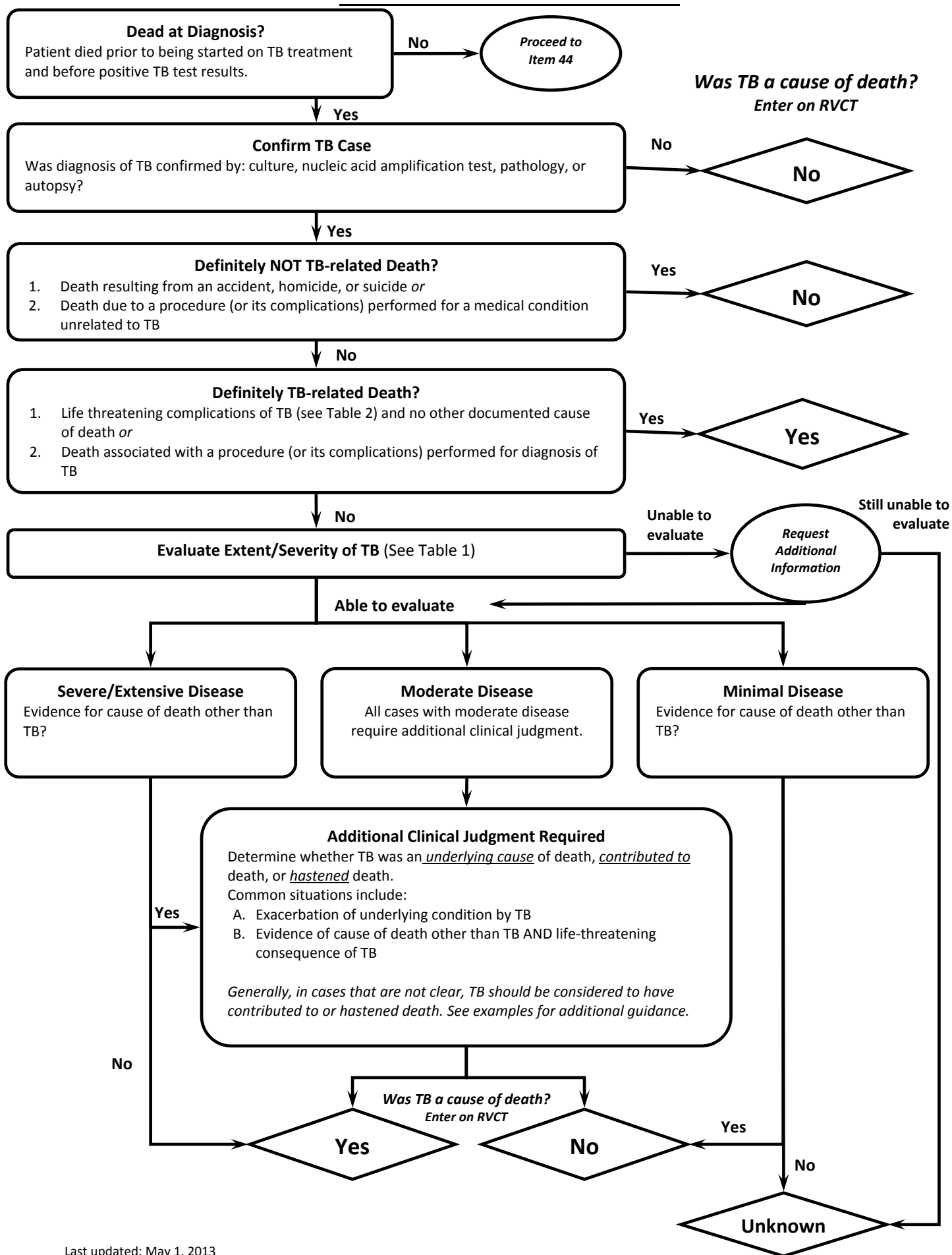
**Steps:**

1. Obtain relevant documents: a) death certificate, b) public health TB record, c) discharge summary and other relevant medical records.
2. Review documents above to evaluate extent of disease, other underlying conditions or possible causes of death, presence of life-threatening complications of TB and its treatment.
3. Proceed through appropriate algorithm on the next pages to guide answer.
4. If answer is still not clear, read through example cases for additional guidance.

This document is a framework and cannot anticipate all circumstances and cannot be a substitute for clinical judgment. Please answer *unknown* only if extent of disease cannot be determined or if there is no other reasonable cause of death but extent of tuberculosis is minimal. As a point of reference, prior detailed reviews of the cause of death among a small number of persons with active TB have found that approximately 70–80% of deaths were TB related (unpublished data).

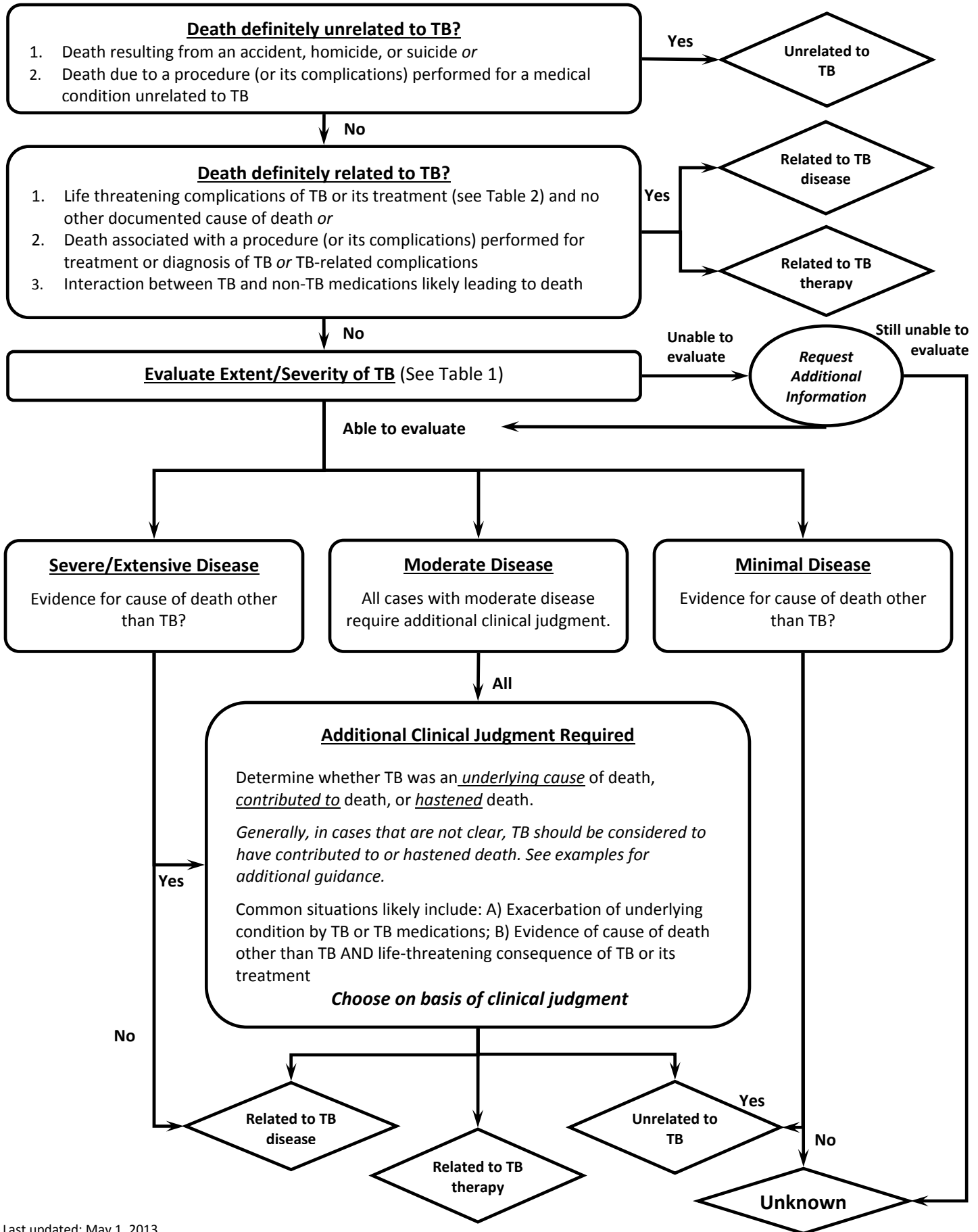
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\* Definition of Dead at diagnosis: Patient died prior to being started on TB treatment *and* before positive TB test results have been reported.



## RVCT Item 44 (If Died)

*Was TB a cause of death?  
Enter on RVCT*



**Table 1: Extent/Severity of Tuberculosis**

Pulmonary and/or Pleural TB Disease	
Extensive disease	<ul style="list-style-type: none"> <li>▪ Miliary pattern on imaging study, <i>or</i></li> <li>▪ Pathology report indicates extensive pulmonary TB disease, <i>or</i></li> <li>▪ Massive tubercular empyema or pleural effusion, <i>or</i></li> <li>▪ ≥2 of the following:                             <ul style="list-style-type: none"> <li>• Sputum smear positive disease</li> <li>• Failure to convert culture within 60 days of treatment initiation prior to death</li> <li>• Reversion of culture from negative to positive</li> <li>• Cavitory disease</li> <li>• Bilateral disease or multi-lobar disease</li> <li>• Large pleural effusion</li> <li>• Collapse of 1 or more lobes</li> </ul> </li> </ul>
Moderate disease	All patients with pulmonary disease that do not meet the criteria of <i>either</i> extensive disease or minimal disease
Minimal disease	All of the following: <ul style="list-style-type: none"> <li>▪ Sputum smear negative*</li> <li>▪ Non-cavitory disease</li> <li>▪ Limited disease (e.g., single lung lesion &lt;2 cm<sup>2</sup>, minimal pleural effusion)</li> </ul> * <i>If sputum smear is not available, patient has minimal disease if the other criteria for minimum disease are met.</i>
Extra-Pulmonary TB Disease	
Severe Extra-Pulmonary TB	<ul style="list-style-type: none"> <li>▪ CNS TB</li> <li>▪ Disseminated TB (&gt;1 non-contiguous site)</li> <li>▪ Pericardial TB</li> <li>▪ GI TB</li> <li>▪ Renal TB</li> <li>▪ Peritoneal TB</li> </ul>
Moderately Severe Extra-Pulmonary TB	All patients with extrapulmonary disease that do not meet the criteria of either severe or minimally severe disease
Minimally Severe Extra-Pulmonary TB	<ul style="list-style-type: none"> <li>▪ Skin TB</li> <li>▪ Mild peripheral lymphadenitis</li> <li>▪ TB uveitis</li> </ul>

**Table 2: Life threatening consequences of TB**

Site of Disease / Treatment	Life threatening consequence
CNS TB	<ul style="list-style-type: none"> <li>▪ Meningitis</li> <li>▪ Encephalitis</li> <li>▪ Mass or spinal cord lesion</li> <li>▪ Herniation</li> <li>▪ Coma</li> <li>▪ Other complications of CNS disease</li> </ul>
Disseminated TB	bacillemia
Pericardial disease	<ul style="list-style-type: none"> <li>▪ cardiac failure</li> <li>▪ myocarditis</li> <li>▪ cardiac tamponade</li> </ul>
GI TB	bowel perforation or hemorrhage
Renal TB	renal failure
Hepatic TB	hepatic failure
Peritoneal TB	disseminated TB or bowel obstruction
Pulmonary/Pleural TB	<ul style="list-style-type: none"> <li>▪ Respiratory failure (Not respiratory arrest occurring at the time of death)</li> <li>▪ Pulmonary hemorrhage with or without asphyxia</li> <li>▪ Extensive pulmonary destruction, with or without cavitations</li> <li>▪ Tension pneumothorax</li> </ul>
TB Medications	<ul style="list-style-type: none"> <li>▪ Anaphylaxis</li> <li>▪ Hepatitis (rising INR/falling albumin + encephalopathy)</li> <li>▪ Metabolic acidosis</li> <li>▪ Seizure</li> <li>▪ Severe dermatitis/Stevens-Johnson syndrome</li> <li>▪ Thrombocytopenia/Leukopenia</li> </ul>

**Table 3: Pathologic / Autopsy findings consistent with TB**

Pathologic Description
<ul style="list-style-type: none"> <li>▪ Caseating granulomas</li> <li>▪ Non-caseating granulomas</li> <li>▪ Granulomatous inflammation</li> <li>▪ Caseous necrosis</li> </ul>

Examples:

YES/RELATED TO TB DISEASE/THERAPY:

55 yo man with smear positive pulmonary TB and end stage liver disease dies in the hospital. He started TB medications (RIPE) four weeks prior to death. He was hospitalized three weeks later with hepatic encephalopathy and shortness of breath. Transaminases were elevated upon admission. CXR prior to death showed diffuse infiltrates or edema. No autopsy is performed. TB is not listed on his death certificate.

The timing of this patient's liver disease exacerbation is likely the result of TB medication side effects. As such, *Related to TB Therapy* should be chosen on item 44 of the RVCT. If this same patient had died of a massive variceal bleed without acute exacerbation of liver disease, then *Unrelated to TB* should be chosen.

67 yo man with baseline severe but stable CAD (planned for CABG) presents to his PMD with fevers, weight loss, and pleuritic chest pain. He is diagnosed with cavitary, smear-positive TB and starts on therapy. Over the next few days he becomes increasingly short of breath. He is found dead at home. Autopsy confirms cavitary TB and severe CAD (85% occlusion of the LAD) but no acute thrombus.

One reasonable explanation in this case is that in the setting of reduced cardiac perfusion, the increased work of breathing and stress from the tuberculosis resulted in ischemia induced arrhythmia. In this case TB likely contributed to death and *Related to TB Disease* should be chosen on item 44.

73 yo woman is admitted to the hospital with shortness of breath and found to have a large right sided pleural effusion with surrounding infiltrate. She is intubated and a chest tube is placed. Sputum culture is positive for *Staphylococcus aureus* and she is started on appropriate therapy for bacterial pneumonia. She also is found to have hematuria and a right lower extremity DVT. Two days later she becomes difficult to ventilate. CXR shows a tension pneumothorax on the left. Soon thereafter a code blue is called and she is not able to be resuscitated. Several weeks after death, 2 of 3 pleural fluid samples become culture positive for Mtb. *Stenotrophomonas maltophilia* also grew from 1 of 3 pleural fluid samples. No sputum was sent for AFB smear or culture.

This case should be classified as extensive disease even though no sputum was obtained (large effusion, bilateral disease). Although she had cultures that were positive for other bacteria, the fact that she had multiple pleural fluid specimens positive for Mtb and that she had life-threatening complications of TB (tension pneumothorax) make it unlikely that her disease was exclusively caused by staph or stenotrophomonas. TB very likely contributed to her death and *Yes* should be chosen on item 15.

33 yo woman with AIDS (CD4 count = 23) not on ARVs is admitted to the hospital with fevers, weight loss, and subacute headache. Cryptococcal meningitis is diagnosed on the basis of positive CSF cryptococcal antigen and treatment is initiated. However, her disease is slow to respond to therapy and 10 days after admission she suffers from cerebral herniation and dies. Subsequently, AFB culture of the CSF returns positive for Mtb. TB is not listed as a cause of death on the death certificate.

Although it is difficult to disentangle the effect of the cryptococcal infection from the tuberculosis, it seems likely that concomitant CNS TB played at least a contributing role in her death. *Yes* should be chosen on item 15.

NO/UNRELATED TO TB:

62 yo woman with DM is diagnosed with TB cervical lymphadenitis by FNA and culture. She begins on RIPE and does well. Two months following treatment initiation, she develops a fever and a cough. She is admitted to the hospital with a diagnosis of pneumonia. She worsens in the hospital and is intubated with ARDS and requires vasopressor therapy. Sputum and blood cultures grow MRSA. After 4 days without improvement, her family and medical team change her goals of care to comfort and she dies. No autopsy is performed.

There is a clear other cause of death and her TB disease should be classified as minimally severe extrapulmonary TB. *Unrelated to TB disease* should be chosen on item 44.

83 yo man previously healthy except for osteoarthritis and hypertension treated with a diuretic is diagnosed with smear positive TB during workup for a large pleural effusion. He starts on RIPE. Two weeks later, he is found dead at home. Autopsy reveals a large hemorrhagic stroke.

Although this is extensive pulmonary disease, the stroke is a cause of death that was not likely to have been hastened or contributed to by TB or TB treatment. Choose *Unrelated to TB disease* on item 44.

55 yo woman with poorly controlled diabetes is diagnosed with smear positive TB. CXR shows minimal lingular infiltrate. She is started on RIPE. She subsequently converts her smear and culture to negative. Her diabetes continues to be poorly controlled and she requires amputation of 4 toes. During her hospitalization, she develops MRSA pneumonia requiring intubation and vasopressors. She continues to deteriorate and she is made DNR/DNI. She dies in the ICU 2 days later.

This is moderate TB that responded to treatment. TB was not likely to have contributed to or hastened her death since that stemmed from complications of her diabetes. Choose *Unrelated to TB disease* on item 44.

UNKNOWN:

47 yo man with no significant past medical history is diagnosed with asymptomatic smear negative, culture positive pulmonary TB as part of a contact investigation. CXR findings are 2 small nodules in the left apex. He is treated for TB with RIPE. His 1 month evaluation had negative cultures and his CXR is slightly improved. He is found dead at home. Autopsy findings do not reveal another cause of death. TB is listed as a cause of death on the death certificate.

With minimal disease apparently responding to therapy, TB seems unlikely to have caused death, but in the absence of another cause in this otherwise healthy person, TB cannot be ruled out as a cause of death either. In this situation, the role of TB can be deemed to be unknown (despite the fact that TB was listed as a cause of death on the death certificate). *Unknown* should be chosen on item 44.

### Reference List

- (1) Essential components of a tuberculosis prevention and control program. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR Recomm Rep 1995; 44(RR-11):1-16.