

TO: Director, DTBE
FROM: Chair, NTIP Workgroup
DATE: July 15, 2013

SUBJECT: NTIP Decision Memo. Sputum culture conversion documented within 60 days of treatment initiation to be sustained.

Through: Chief, SEOIB, DTBE

Background

Monitoring culture conversion at 2 months is essential for assessing treatment progress and evaluating the effectiveness of the treatment regimen. According to the American Thoracic Society/CDC's guidelines on the treatment of tuberculosis, approximately 80% of patients with pan-susceptible pulmonary TB will have converted to culture-negative after 2 months of treatment. Closer monitoring of patient to ensure adherence, and extending treatment to a minimum of 9 months may be warranted for treatment success if conversion did not take place within 60 days of treatment initiation.

The national objective encourages programs to strive for increasing the proportion of culture-positive patients with culture conversion within 60 days of initiating treatment. Since becoming one of the national objectives, local TB programs have worked on this indicator, bringing the national average from 47.2% in 2008 to 56.4% in 2010.

A positive-culture result in the initial sputum specimen is the basis for assessing conversion. Sputum culture conversion is defined as two consecutive negative cultures with no positive culture thereafter. The guidelines recommend that sputum specimens be obtained at a minimum of monthly intervals until two consecutive specimens are culture-negative. The RVCT defines the date of conversion as the specimen collection date for the first consistently negative culture at least one week after the last positive culture, suggesting specimen collections at least 7 days apart.

NTIP users proposed the following changes to this indicator:

1. Remove the objective for attaining culture conversion within 60 days, and focus on the documentation of sputum culture conversion alone (i.e. culture conversion ever). Or change the objective of 60 days to 65, 70, or 75 days.
2. Revise the RVCT instruction on the "Sputum Culture Conversion" variable stipulating that the first consistently negative culture should be a least 7 days after the last positive culture (i.e., allow follow-up cultures to be obtained at shorter intervals).
3. Exclude patients with cavitory disease from the indicator cohort.
4. Exclude patients who moved out of the country from the indicator cohort.

NTIP Work Group Recommendations

- A. Agree to exclude patients who moved outside of the country within 60 days of treatment initiation from the indicator cohort to make it consistent with the change recently made to the Completion of Treatment calculation.

But --

- B. Not to remove or change the 60-days objective
- C. Not to change the RVCT instruction on the Sputum Culture Conversion variable, which defines the specimen collection date for the first consistently negative culture to be at least 7 days from the last positive.
- D. Not to exclude patients with cavitary disease from the indicator cohort.

Alternative option

If the NTIP Work Group recommendations are not approved, NTIP will continue to calculate the indicators as previously done (as described in the introduction above).

Operational details, if recommendations are accepted

Patients who moved outside of the country within 60 days of treatment initiation will be excluded. The exclusion criteria will be based on the RVCT variables, "Moved; Out of the U.S." and the "Date Therapy Stopped." The "Date Therapy Stopped" should reflect the date patient left the country and stopped treatment in the United States.

Arguments in favor of the recommendation

- A. Exclusion of patients who moved out of the country from the indicator cohort is consistent with the calculation for the Completion of Treatment indicator. Furthermore, sputum culture is usually not a standard practice in less developed countries. Even if an international contact can be established for a patient who moved outside of the U.S.; sputum culture conversion information are likely not available once a patient moved outside of the U.S.
- B. Specimen collection and testing for culture conversion before or at the 60-day mark is clinically significant and requires diligence in practice. Re-evaluation of the treatment regimen and case management strategy may be warranted if conversion does not take place within 60 days of a patient initiating treatment. While not all patients with positive sputum culture result will convert to culture-negative within 60 days after receiving anti-tuberculosis treatment, removing or changing this objective could create confusion among program staff.
- C. The reason RVCT instructions for Sputum Culture Conversion require the specimen collection date for the first consistently negative culture to be at least 7 days from the last positive is to discourage over-sampling of specimens. While it is possible for a conversion to occur overnight, daily collection of specimen is neither efficient nor cost-effective. Since the implementation of this indicator laboratories have reported

an increased volume of sputum specimens submitted for testing raising concerns of over-sampling in some programs.

- D. While patients with cavitory disease may take a longer time to convert, over 50% of cases converted within 60 days suggesting this objective is feasible.

Arguments against the recommendation

Some program staff are concerned that they will be judged as showing poor program performance if too many of their patients do not have culture conversion within 60 days. By obtaining multiple specimens within a 7-day period, they increase their chances of meeting this indicator.

Summary of NTIP Work Group recommendation:

- To exclude patients who moved out of the country from the indicator cohort.
- The objective of monitoring culture conversion within 60 days has practical significance in the treatment of TB patients. While not all patients will convert within 60 days, particularly those with cavitory disease and sputum smear-positive result, sputum collection and monitoring for culture conversion around 60-day period is essential.
- Although sputum specimen collection and monitoring for culture conversion is important in evaluating patient response to treatment, specimen collection and testing can be costly. Programs will need to balance between cost and optimize return in investment while striving for increased performance on this indicator.
- Additional training and education on the rational of this national objective and how to interpret and use this indicator is needed.

Decision:

Accept the exclusion of patients who moved out of the country from the sputum culture conversion indicator as recommended by the NTIP Workgroup:



Alternative: Do not accept the exclusion of patients who moved out of the country from the calculation of sputum culture conversion indicator:

Date: 26 July 2013

