

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Joe Manchin III
Governor

Patsy A. Hardy, FACHE, MSN, MBA

MEMO

Date: September 21, 2010

To: Local Health Department Personnel
Chris Curtis, MPH, Commissioner, BPH
Cathy Slemper, MD, MPH, State Health Officer
Loretta Haddy, PhD, Director, OEPS
Amy Atkins, Director, Division of Local Health

From: Carmen Priddy, RN, BSN, WV-DTBE Director

Re: Cohort Review

WV-DTBE is now required by CDC to have a Cohort Review process for all active tuberculosis cases, and in the future to include latent TB infection (LTBI) treatment. Please find enclosed information regarding the new cooperative agreement requirement from CDC. The information explains what a Cohort Review is and how WV will begin handling the process. After the first year of reviews, with input from participating LHDs and the WV-DTBE Advisory Committee, a decision will be made to determine the future process of cohort reviews.

You will find national and state TB program objectives, which will be used to help guide the focus of the reviews. The criteria for the Cohort Review presentation process, along with a form to help guide you, are also included. Keep in mind that any active case you handle will ultimately be scrutinized by cohort review. The first round will be any active TB cases that were identified January through June of 2010 and the second round will be the active cases identified July through December 2010. WV-DTBE will contact the case manager for each case, and assist with a mock review, prior to the actual Cohort Review being done.

WV-DTBE wants to thank, in advance, each LHD who will help with this initial process. The next year will be a learning experience for all.

TB COHORT REVIEW PROCESS IN WEST VIRGINIA

I. What is Cohort Review?

Cohort review has been an integral part of the TB control approach advocated by the *International Union Against Tuberculosis and Lung Disease* (IUATLD). Dr. Karel Styblo, who pioneered the approach in Tanzania, proposed the idea of a local management unit that would have the staff and resources necessary to diagnose disease, initiate treatment, monitor adherence, and report patient treatment progress. After Dr. Styblo visited and reviewed the New York City TB Program, the Medical Director of the program implemented a cohort review process in which the Medical Director himself personally reviewed every one of the thousands of cases for treatment details and completion. The implementation of cohort review in conjunction with other TB control measures resulted in a steep increase in completion rates and, beginning in 1993, a steep decline in the number of reported TB cases. More impressive was the even sharper decline in the number of reported cases of multidrug-resistant TB (MDR TB), from 441 cases in 1992, to just 38 cases in 1998.

The cohort review process can take many forms. In its most simplified form, TB control staff at the local level meets to review the treatment outcomes of every patient listed in a chronological patient register. Today, with computerized TB registries, multimedia projection, and cheaper long-distance communications, it can be adapted to a variety of settings.

Cohort review is a systematic review of the management of patients with TB disease and their contacts. A “cohort” is a group of TB cases counted over a specific period of time, usually 3 months. CDC allows low incidence states the option of a 6 month review period, and WV has opted to begin our Cohort Review Process with this model. The cases are reviewed approximately 6–9 months after they are counted; therefore, many of the patients have completed treatment or are nearing the end of treatment. Details regarding the management and outcomes of TB cases are reviewed in a group setting with the following information presented on each case by the case manager:

- Patient’s clinical status
- Patient’s treatment outcome
- Adequacy of the medication regimen
- Treatment adherence or completion
- Results of contact investigation
- Percentage of patients who did, or are likely to, complete treatment.

All TB patients should be assigned a case manager, whether they receive TB care in one of the health department clinics or from a private provider. During the cohort

review, case managers present the TB cases for which they are responsible, often assisted by staff involved in contact investigation, directly observed therapy, and initial patient evaluation. TB case managers know that their day-to-day case management efforts will be reflected in the cohort review several months later and that they are accountable for the services they provide. Information that is to be reported at the cohort review session, on each case, is found in Table 1.

Table 1: Case Information Reported in a Cohort Review

<ul style="list-style-type: none">• Patient's initials and case number• Age• Sex• Country of birth• HIV status• Smear and culture results• Chest radiograph (CXR) results• Drug susceptibility results• Status of treatment (completed therapy, currently taking TB medications, lost, died, moved, or case reported at death)• Directly observed therapy status• Results of the source case investigation, if the patient is a child• Number of contacts identified• Number of contacts evaluated• Number of contacts infected, but without disease• Number of contacts infected and having disease• Number of contacts started on treatment for latent TB infection (LTBI)• Number of contacts completing treatment for LTBI
--

The presentation of cases allows staff to detect potential problems in the way the case is being managed, such as the use of an inappropriate regimen or an inadequate number of contacts tested. It also allows clinicians, managers, and public health advisors to consult on difficult cases, especially those in which the patient is nonadherent, has MDR TB, or has numerous contacts in a congregate setting. Finally, it allows senior staff and managers to recognize the intensive efforts of staff in managing TB cases and contacts.

Overall, the cohort review process can benefit the TB program by:

- Increasing staff accountability for patient outcomes
- Improving TB case management and the identification of contacts
- Motivating staff
- Revealing program strengths and weaknesses
- Indicating staff training and education needs

II. DTBE Program Objectives

Increased accountability helps TB control programs meet their local and national program objectives. In order to assess progress in attaining objectives, TB control teams must clearly delineate the desired outcomes. At the national level, the Centers for Disease Control and Prevention provide objectives for all programs they support. The following are National TB Program Objectives, and then WV-Division of TB Elimination (WV-DTBE) Objectives, that may be monitored with the use of cohort review.

A. National TB Program Objectives

a. **Completion of Therapy:** For patients with newly diagnosed TB, for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 93.0% by 2015.

b. TB Case Rates

- **In U.S.-born persons:** Decrease the TB case rate in U.S.-born persons to less than 0.7 cases per 100,000 by 2015.
- **In foreign-born persons:** Decrease the TB case rate in foreign-born persons to less than 14 cases per 100,000 by 2015.
- **In U.S.-born non-Hispanic blacks:** Decrease the TB rate in U.S.-born non-Hispanic blacks to less than 1.3 cases per 100,000 by 2015.
- **In children younger than 5 years of age:** Decrease the TB rate for children younger than 5 years of age to less than 0.4 cases per 100,000 by 2015.

c. Contact Investigations

- Increase the proportion of TB patients with positive acid-fast bacillus sputum-smear results who have **contacts elicited** to 100.0% by 2015.
- Increase the proportion of contacts to sputum acid-fast bacillus smear-positive TB cases who are **evaluated** for infection and disease to 93.0% by 2015.
- Increase the proportion of contacts to sputum acid-fast bacillus smear-positive TB cases, with newly diagnosed latent TB infection, who **start treatment** to 88.0% by 2015.
- For contacts to sputum acid-fast bacillus smear-positive TB cases who have started treatment for the newly diagnosed latent TB infection, increase the proportion who **complete treatment** to 79.0% by 2015.

d. Laboratory Reporting

- Increase the proportion of culture-positive or nucleic acid amplification test-positive TB cases with a pleural or respiratory site of disease that have the identification of *tuberculosis complex* reported by laboratory within n days from the date the initial diagnostic pleural or respiratory specimen was collected to 75%.
- Increase the proportion of culture-positive TB cases with initial drug-susceptibility results reported to 100%.

e. **Treatment Initiation:** Increase the proportion of TB patients with positive acid-fast bacillus sputum-smear results who initiated treatment within 7 days of specimen collection to $n\%$.

f. **Sputum Culture Conversion:** Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 61.5% by 2015.

g. Data Reporting

- **Report of Verified Case of Tuberculosis (RVCT):** Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 99.2% by 2015.
- **Aggregate Reports for Tuberculosis Program Evaluation (ARPEs):** Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0% by 2015.
- **Electronic Disease Notification (EDN) System:** Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 87% by 2015.

h. **Recommended Initial Therapy:** Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 93.4% by 2015.

i. **Universal Genotyping:** Increase the proportion of culture-confirmed TB cases with a genotyping result reported to 94.0% by 2015.

j. **Known HIV Status:** Increase the proportion of TB cases with positive or negative HIV test result reported to 88.7% by 2015.

k. **Evaluation of Immigrants and Refugees**

- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiates medical evaluation within 30 days of arrival to 87%.
- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion that complete medical evaluation within 90 days of arrival to 87%.
- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to 87%.
- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S. and started on treatment, increase the proportion who complete LTBI treatment to 87%.

l. **Sputum Culture Reporting:** Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 95.7% by 2015.

B. WV State TB Program Objectives

- **Completion of Treatment:** For patients with newly diagnosed TB, for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to: 2010 - 93%, 2011- 94%, 2012 - 95%, 2013 - 96%, 2014 - 97%.
- **TB Case Rates**
 - Decrease the TB case rate (per 100,000 persons) in **U.S.-born persons** to: 2010 - 1.10; 2011 - 0.99; 2012 - 0.88; 2013 - 0.77; 2014 - 0.71.
 - Decrease the TB case rate (per 100,000 persons) for **foreign-born persons** to: 2010 - 32.5; 2011 -27.8; 2012 - 23.2; 2013 - 18.6; 2014 - 14.0.
 - Decrease the TB case rate (per 100,000 persons) in **U.S.-born non-Hispanic blacks** to: 2010 - 4.8; 2011 - 3.2; 2012 - 1.6; 2013 - 1.6; 2014 - 0.

- Decrease the TB case rate (per 100,000 persons) for **children younger than 5 years of age** to: 2010 – 0; 2011 – 0; 2012 – 0; 2013 – 0; 2014 - 0.

a. Contact Investigations

- Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to: 2010 - 93%; 2011- 95%; 2012 - 97%; 2013 - 99%; 2014 -100%.
- Increase the proportion of contacts to sputum AFB-smear positive TB patients who are evaluated for infection and disease to: 2010 - 93%; 2011- 94%; 2012 - 95%; 2013 - 95%; 2014 - 95%.
- Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to: 2010 - 83%; 2011- 85%; 2012 - 87%; 2013 - 88%; 2014 - 88%.
- For contacts to sputum AFB smear-positive TB patients, who have started treatment for the newly diagnosed LTBI, increase the proportion that complete treatment to: 2010 - 70%, 2011 - 73%; 2012 - 75%; 2013 - 77%; 2014 - 79%.

b. Laboratory Reporting

- Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of *M. tuberculosis complex* reported by laboratory within *n* days from the date the initial diagnostic pleural or respiratory specimen was collected to: 2010 - 35%; 2011 - 45%; 2012 - 55%; 2013 - 65%; 2014 - 75%.
- Increase the proportion of culture-positive TB cases with initial drug-susceptibility results reported to: 2010 - 95%; 2011 - 95%; 2012 - 100%; 2013 - 100%; 2014 - 100%.

- c. Treatment Initiation:** Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to: 2010 - 80%; 2011- 85%; 2012 - 85%; 2013 - 90%; 2014 - 90%.

d. Sputum Culture Conversion: Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to: 2010 - 25%; 2011 - 35%; 2012 - 45%; 2013 - 55%; 2014 - 62%.

e. Data Reporting

- **Report of Verified Case of Tuberculosis:** Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to: 2010 - 100%; 2011 - 100%; 2012 - 100%; 2013 - 100%; 2014 - 100%.
- **Aggregated Reports for Tuberculosis Program Evaluation:** Increase the completeness of each core Aggregated Report for TB Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to: 2010 - 100%; 2011 - 100%; 2012 - 100%; 2013 - 100%; 2014 - 100%.
- **Electronic Disease Notification (EDN) System:** Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreement announcement, to: 2010 - 74%; 2011 - 78%; 2012 - 82%; 2013 - 85%; 2014 - 87%.

f. Recommended Initial Therapy: Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to: 2010 - 80%; 2011 - 83%; 2012 - 86%; 2013 - 89%; 2014 - 93.4%.

g. Universal Genotyping: Increase the proportion of culture-confirmed TB cases with a genotyping result reported to: 2010 - 85%; 2011 - 90%; 2012 - 95%; 2013 - 100%; 2014 - 100%.

h. Known HIV Status: Increase the proportion of all TB cases with positive or negative HIV test result reported to: 2010 - 80%; 2011 - 83%; 2012 - 85%; 2013 - 87%; 2014 - 89%.

i. Evaluation of Immigrants and Refugees

- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within

30 days of arrival to: 2010 - 74%; 2011 - 78%; 2012 - 82%; 2013 - 85%; 2014 - 87%.

- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion that complete medical evaluation within 90 days of arrival to: 2010 - 74%; 2011 - 78%; 2012 - 82%; 2013 - 85%; 2014 - 87%.
- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to: 2010 - 74%; 2011 - 78%; 2012 - 82%; 2013 - 85%; 2014 - 87%.
- For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S. and started on treatment, increase the proportion who complete LTBI treatment to: 2010 - 74%; 2011 - 78%; 2012 - 82%; 2013 - 85%; 2014 - 87%.

j. Sputum Culture Reporting: Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to: 2010 - 80%; 2011 - 85%; 2012 - 90%; 2013 - 95%; 2014 - 95.7%.

C. Presentation

The Cohort Review sessions in WV will be held approximately every six months at the corresponding local health department (LHD). These sessions should include participation from the WV-DTBE Medical Director, Division Director and surveillance nurse. Also included should be the Local Health Department TB Clinician, Administrator, Director of Nursing, case manager, DOT administrator (if different from case manager) and Public Health Nurses.

During the presentation, the case manager will present the information that is required for all active/suspect cases identified during the Cohort Review period. Included in the presentation will be data on all contacts that were identified for each case. At the end of the presentation, discussion will be held as to the strengths and weaknesses of the cases reviewed. Recommendation will be made by all regarding changes needed in the LHD process and WV-DTBE process. WV-DTBE will assist the case manager in preparing their presentation by conducting a mock cohort review via telephone prior to the official review.

Each Cohort Review will be followed by a written report from WV-DTBE of findings and recommendations. After the first year of conducting cohort reviews, WV-DTBE will

review the findings and recommendations made during the reviews, and determine the future course of cohort reviews in WV.

The planned schedule for presentations is shown in Table 2.

Table 2

Cohort Review Period	Mock Presentation	Cohort Presentation
January - June 2010	October - December 2010	January - March 2011
July - December 2010	April - June 2011	July - September 2011

D. Ground Rules for Cohort Review Presentation

It is very important that everyone participating in the review process give their undivided attention to the task at hand. CDC has recommended that ground rules be determined prior to the start of the process. Therefore, it is asked that all who participate follow the guidelines as listed.

Ground Rules

1. The Director of WV-Division of TB Elimination (WV-DTBE) or her designee will facilitate the introduction of participants
2. The Director of WV-Division of TB Elimination (WV-DTBE) or her designee will re-state the "Ground Rules" before the presentation begins
3. Put cell phones on "silent" or "vibrate"
4. If you need to answer your cell phone, be sure to go out of the room **before** answering
5. Please be respectful and remain quiet during case presentations and when others are speaking
6. Save questions until the end of each case presentation
7. Please come prepared to share your viewpoints and opinions

Cohort Presentation for Active TB Patients in West Virginia

Patient Initials _____ County _____ Age _____ Gender _____ Case
Number _____

Country of Birth _____ Arrived in US _____ (date) Class A, B1, B2?

Initial Report of Case to LHD _____ (date) _____
(source)

Source of index case identified _____

TST _____ mm, read on _____ (date) Done by LHD **or** _____
(facility)

IGRA (positive, negative, indeterminate) (QFT, QFT-G, T-Spot) collected on _____
(date)
Reason for IGRA _____

CXR/Imaging study shows (WNL, cavitary, abnormal-non cavitary) done on _____
(date)

TB Case is pulmonary and/or extrapulmonary _____ site(s)
_____ culture confirmed _____ clinically confirmed _____ provider
diagnosed

Sputum collected on _____ (date) and received at _____ (lab) on _____ (date)

Sputum smear (___+ positive/negative) reported on _____ (date) LHD notified _____ (date)

MTD (negative / positive) reported on _____ (date) LHD notified _____ (date)

Sputum culture (positive/negative) reported on _____ (date) LHD notified _____ (date)

Sputum conversion within 2 months of treatment (occurred/did not occur/not obtained)
Explain: _____

Other specimen: source(s) _____ collected on _____ (date)
Received at _____ (lab) on _____ (date) (positive/negative) on _____ (date)
Culture results (positive/negative) reported on _____ (date) LHD notified _____ (date)

Sensitivity testing reported _____ (date) LHD notified _____ (date)
Results _____

Genotyping reported _____ (date)

HIV (positive/negative/refused/not offered) on _____ (date)

If no results, explain: _____

If yes, treatment regimen: _____

Patient Initials _____

Risks/Social factors (medical conditions, substance abuse, homeless, employments, other):

Diabetic ___yes ___no (IDDM, NIDDM)

TB Treatment started on _____ (date) Plan of treatment _____
(months)

Drug regimen _____

DOT (yes/no) for a total of _____ (weeks)

If no DOT, reason: (provider refused/patient refused/other)

Explain: _____

Completed _____ weeks of treatment on _____ (date), **or** still on therapy and is due to complete on _____ (date)

Did not complete treatment due to:

___ Refused treatment, explain: _____

___ Lost, explain: _____

___ Died (TB related/Non-TB related) explain: _____

___ Moved, jurisdictional referral _____ (date) to _____ (new state/country)

___ Reported at death

Treatment interruptions ___yes ___no

___ Medical/adverse reaction, explain: _____

___ Nonadherence, explain: _____

___ Provider issues, explain: _____

___ Lost for period of time, explain: _____

Completion of treatment CXR

Was done on _____ (date) and showed (improved/worsened/no change/not done).

If treatment ongoing, follow-up CXR was done _____ (date) and showed
(improved/worsened/no change/not done).

Patient Initials _____

Contacts

Number of Contacts identified	
Number of Contacts evaluated	
Number of Contacts evaluated at 3 month retest	
Number of Contacts with (+) TST	
Number of Contacts started on LTBI treatment	
Number of Contacts who completed LTBI treatment	
Number of Contacts diagnosed with active TB disease	
Number of Contacts currently being treated	
Number of Contacts who discontinued LTBI treatment	

Review all information on Contact Form 1001. Give explanation for any positive cases that did not receive or did not complete treatment. i.e.; refused, died, moved, adverse reaction, or lost to follow-up.

Items needing follow-up: _____

Notes, Definitions and Special Cases

1. Have copies of your form for each person participating in the Cohort Review.
2. Complete each section. Do not leave any areas blank. Mark non-applicable if indicated.
3. Specify the highest grade of smear, if known.
4. Be prepared to report the source case and associated contact investigation, if known.
5. If more than one TST was done, give complete information on each test.
6. Give CXR information on the initial report.
7. Give sputum information on the first positive report.
8. HIV results should be current, within 6 months of TB diagnosis.
9. Under “Risks/Social Factors” indicate anything that would indicate a high risk group and anything that would impact treatment. Think hard to determine that all important information is documented.
10. Under “Drug Regimen” indicate any changes that were made during the course of treatment, the date of change, and the reason for change.