Form Approved
OMB No. 0920-XXXX
Expiration Date XX/XX/20XX

Reporting Severe Adverse Events (Hospitalization or Death) Associated with Treatment of Latent Tuberculosis infection (Adverse Events to LTBI Treatment) Data Collection Form

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a persons is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (P920-XXXX)

State:________ ID:_____________

Form completed by:
CDC phone interview _____ CDC on-site investigator ______ On-site local staff _____

Part 1. To be completed by the physician, nurse or medical clerk, when a person's condition is suspected to be related to tuberculosis treatment.

**** The information requires input from the medical clerk by searching the records of the admitting hospital and other hospitals where the patient might have been evaluated in the past.***

SOURCE OF REPORT

Name of setting where TLTBI was prescribed: _____________________________
County/city/state: ____
Facility type: Health department _____ Private provider _____ HMO _____
Other (specify): ____
Name of person who reported the case: ____
Phone number: ____
Corresponding health department: ____
Name of contact in corresponding health department (if different than above):
___________________________ **Phone number:** _____________________________

Date CDC notified __________ **Reported to FDA/MedWatch (Yes/No)** _____

BASIC PATIENT AND ILLNESS DESCRIPTION

Assigned Case identification number: 2digit state abbreviation-5 digit county FIPS-001
Country of birth: United States _____Other country (specify) ___________________
Residence in other country/countries: (Yes/No) _____
Identify country/countries: ____ How long? ______
International travel history within the past two years: (Yes/No) _____ Unknown_____
If Yes, identify specific countries and dates: ____________________________________

Able to speak English? (Yes/No) ___
If No, what is the primary language?______________

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Part 2. To be completed by the physician

Adverse event leading to hospitalization or death associated with LTBI treatment:
Anaphylaxis ____ Metabolic acidosis ____ Other, specify __________________
Liver injury ____ Severe dermatitis ____

***Admission to hospital:** (Yes/No) _____ Unknown _____
If Yes: Date:___________ Date discharged:___________
Reason:______________________________

Severity of outcome illness: Still Sick _____ Full recovery _____ Pending _____
Recovery with residual effects _____ Liver transplant _____ Unknown _____
Death: (Yes/No) _____ Date died: __________

Comments of physician:

LTBI DIAGNOSIS AND TREATMENT

Reason(s) for tuberculin skin test (TST)/Quantiferon (QFT) test for LTBI (Check all that apply):
1. Contact with person with TB disease _____ Recently (past 2 years)? _____
2. Medical risk for TB

* information may be provided by medical clerk from hospital/ facility records.

HIV infection: _____ Unknown _____ HIV test date*: __________
Diabetes* _____ Renal failure* _____ Organ transplant* _____ Cancer or leukemia _____
Abnormal chest radiograph*_____ Chronic steroid administration* _____
Immunosuppressive therapy other than chronic steroid administration* ____, Specify________

TB DISEASE EVALUATION (OR EXCLUSION)

No symptoms _____ Cough _____ Fever _____ Weight loss _____
Other symptoms _____ Unknown _____
Comments of physician:

Date of chest radiograph*: __________
Result/ interpretation:

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EXCLUSIONARY TESTING

Serology testing done*: (Yes/No) _____ Unknown _____

A virus: Negative _____ Positive _____ Not done _____
Date: ________________ Test type: ________

B virus: Negative _____ Positive _____ Not done _____
Date: Test type: ____

C virus: Negative _____ Positive _____ Not done _____
Date: ________________ Test type: ______________________________

HEPATITIS/LIVER INJURY DIAGNOSIS

Symptoms of hepatitis: (Yes/No) _____ If Yes, symptom onset date: ___________
Describe symptoms: ____

Initial diagnosing provider: Unknown _____ Same as prescribing provider _____
Other provider _____ Identify other provider: ___________________________
Comments:

Reason for seeing provider: Routine check _____Symptoms of hepatitis _____ Other _____

Part 3. To be completed by the medical clerk from the medical records at the admitting hospital where the patient might have been evaluated and/or admitted previously. If this information is unavailable at the admitting hospital it will be provided by the nurse who will access the information from the clinics and other facilities where the patient has visited previously.

Date of chest radiograph: __________ (include all that are available at this and other hospitals and clinics)
Result/ interpretation:

Cultures for *M. tuberculosis*: Unknown _____ Cultures not done _____
Sputum: no growth for *M. tb*_____ Other specimen: no growth _____ Pending result _____

***Date of first abnormal blood test results:** ______________________

***Date of peak abnormal blood test results:** ______________________

HEPATITIS/LIVER INJURY DIAGNOSIS

Initial diagnosing provider: Unknown _____ Same as prescribing provider _____
Other provider _____ Identify other provider: ________________________
Comments:

Reason for seeing provider: Routine check _____Symptoms of hepatitis _____ Other _____

***Liver biopsy date:** __________ Result:____

***If the patient died prior to completing the investigations to confirm if the condition was a severe adverse event to TB treatment.**
Autopsy date: _____________

Result/ findings of the autopsy:

Part 4. To be completed by the nurse from interviews of primary care provider and/or clinics providing treatment for tuberculosis and other medical conditions.

RISK FACTORS FOR HEPATITIS

Injection drug use: (Yes/No) _____ Unknown _____
If Yes: Current _____ Previous use _____ For how long? ________________________
Specify drug(s) used, if known____
Comments:

Previous liver disease: (Yes/No) _____ Unknown _____
If Yes, specify diagnosis(es), if known____
Comments:

Date of chest radiograph: __________ (include all that are available at this and other hospitals and clinics)
Result/ interpretation:

Cultures for *M. tuberculosis*: Unknown _____ Cultures not done _____
Sputum: no growth for *M. tb*_____ Other specimen: no growth _____ Pending result _____

***Date of first abnormal blood test results:** ______________________

***Date of peak abnormal blood test results:** ______________________

MONITORING DURING TB THERAPY
Monitoring strategy:
Clinical observation only _____ Laboratory testing only _____ Combination _____
Comments:

Clinical monitoring:
Evaluated by a licensed medical professional (Yes/No) __
If yes, the licensed medical professional was a physician (Yes/No)____

Frequency of scheduled clinic appointment:
- Weekly _____
- Every two weeks _____
- Monthly _____

Frequency of actual evaluation:
- Weekly _____
- Every two weeks _____
- Monthly _____

Comments:

Frequency of laboratory testing:

Weekly _____
Every two weeks _____
Monthly _____

Comments:

Supervision of treatment:

Self supervised _____ Directly observed therapy (DOT)/supervised _____ Combination _____

Comments:

History of alcohol consumption: (Yes/No) _____ Unknown _____

If Yes: Excessive* (Yes/No) _____ Current _____
Previous use _____ For how long? _______

*Reliable indicators of excessive alcohol use include participation in Alcoholics Anonymous or alcohol treatment programs (e.g., outpatient, residential or inpatient, halfway house, prison or jail treatment, or other self-help. If Yes to excessive alcohol use, check all that apply below:

_____ A description by the patient, the patient's family or acquaintances, or healthcare provider of chronic, high intake of alcohol with behavior associated with alcohol abuse.

_____ Repeated visits to healthcare facilities during which alcohol intoxication was observed

_____ Report of alcohol use coupled with the existence of organic, alcohol-associated disease (e.g., pancreatitis, cirrhosis)

_____ A diagnosis of alcoholism on available medical records (e.g., discharge summaries or medical referral information)

Comments: