

1 **Attachment Ca. Instructions for Completing State and County Representative Spreadsheet**
 2 **Instrument**

3 XDR TB Contact Investigation: A Cost Assessment
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Form Approved
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9 **Introduction**

10 After arriving to the United States in April 2015, a person with infectious extensively drug
 11 resistant tuberculosis (XDR-TB) came into contact with people who were identified and followed
 12 across 14 states. While previous analyses have estimated the economic value of conducting
 13 contact investigations of TB after exposure during long airline flights [1], among refugee
 14 populations [2], and different models of conducting contact investigations [3]; and
 15 epidemiological studies on large contact investigations are available [4, 5]; studies on the costs of
 16 investigating large numbers of people having contact with XDR-TB patients across multiple
 17 jurisdictions are needed.
 18

19 This assessment is important for several reasons. Making estimates as setting-specific as possible
 20 can inform projections or evaluations of responding to XDR cases in the future for the jurisdictions
 21 involved [6]. Therefore, the Centers for Disease Control and Prevention (CDC) is gathering data to
 22 evaluate the cost of the contact investigation for this recent XDR-TB case from a 'bottom-up
 23 perspective', reflecting the cost of what actually occurred. In addition, this assessment can be used
 24 to check whether general estimates from previous studies can be used to predict costs accurately,
 25 or if 'bottom-up perspective' activities add value. We anticipate that both the research process and
 26 results will raise awareness about the cost of contact investigations, and activities will provide a
 27 spreadsheet template that can be used to estimate the cost of contact investigations in the future.
 28

29 **Objectives include:**

- 30 1. Collect or estimate the overall direct costs of investigating and following contacts of an imported XDR
 31 tuberculosis patient
 32 2. Collect or estimate the direct costs to tuberculosis programs in affected states and other entities involved
 33 3. Provide results that will be used by CDC, state, and local programs
 34

35 **Methods**

36 This assessment will use data on the costs to the health system of this contact investigation up to
 37 this point, and model the total cost up to two years for the remaining analytic horizon. Data
 38 collection will involve identifying types of resources used to conduct the investigation, quantifying
 39 the number of units or time consumed, and assigning a monetary value to each of them [7]. The
 40 total cost of the contact investigation will then be calculated, and state-specific and organization-
 41 specific subtotals will be generated.
 42

43 **Short description of questions**

1 CDC estimates the average public reporting burden for this collection of information as up to 2.5 hours per response per program
 2 manager and 1.5 hours per response per accountant, including the time for reviewing instructions, searching existing
 3 data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of
 4 information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it
 5 displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this
 6 collection of information, including suggestions for reducing burden to CDC/ATSDR Information Collection Review Office, 1600
 7 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0879).

44 Activities to be evaluated include the costs of organizing and managing the investigation, finding
 45 contacts, testing them, treating them, and following them up. We are asking for the following data
 46 about the contact investigation specific to your location:

- 47 • A few statistics describing investigation outcomes
- 48 • Number and types of tests administered for TB infection and disease and results
- 49 • Risk factors for developing TB disease after infection
- 50 • Costs of testing for TB infection and disease
- 51 • Costs of testing for other illnesses that are risk factors for TB
- 52 • Costs of treating latent tuberculosis infection (LTBI)
- 53 • Personnel costs
- 54 • Travel costs
- 55 • Training costs
- 56 • Costs of incentives and enablers
- 57 • Any other miscellaneous costs necessary for this XDR TB contact investigation

58

59 Please include all relevant items consumed regardless of who paid for them, although indicating
 60 who if information is available. If the item was donated, please include it in the total. We are not
 61 collecting data that identify specific people. However, we need the following aggregate data to
 62 compute costs and adequately describe the contact investigation that occurred.

63

64 **Excel worksheet**

65 An Excel worksheet with two tabs at the bottom is provided to record these costs **for two phases**
 66 **(1) preparatory and initial assessments in identifying and evaluating each contact up to**
 67 **their initial diagnosis and classification, and (2) follow-up costs to date.** We will use this
 68 information to project the costs that will be expected for the two-year time horizon of the
 69 investigation. If you expect any deviations from standard protocols between now and the two-year
 70 endpoint, please let me know. If more rows are needed to insert data anywhere on the
 71 spreadsheet to fit your data, please insert them. If an estimate is unknown or uncertain, please
 72 make your best estimate. If needed, you can indicate a range of values. If an item or category is ‘not
 73 known’, ‘not recorded’, or ‘not relevant’; please indicate with the appropriate phrase to indicate to
 74 us that nothing has been overlooked. Line numbers corresponding to the accompanying
 75 spreadsheet are included in parentheses; it may be helpful to save a blank copy of the spreadsheet
 76 for your records if you decide to fill in a copy.

77

78 **Actual data collection**

79 **Who should answer these questions?**

80 These questions are intended for anyone from the TB controller’s office who can collect and/or
 81 report data to the CDC. Potential respondents may include nurses, program managers,
 82 accountants, contact investigators, epidemiologists, interjurisdictional referral contacts, nurse
 83 consultants, nurse case managers, surveillance managers, public health program specialists, or
 84 anyone else who is delegated by the TB controller.

85

86 **Time burden**

87 Please review the accompanying spreadsheet and following questions about data that we will be
 88 collecting. This data collection should take about 1 hour to review instructions per person, 2 hours
 89 to collect data (or 1.5 hours for the first person, 30 minutes for the second), with another 1.5
 90 hours to transmit the data to the master CDC spreadsheet or discuss results with the analyst via

91 phone interview (1 hour for the first person, 30 minutes for the second). After all results are
 92 together, the analyst will schedule another call to follow-up for any new developments and ask
 93 any questions about the data (20 minutes each).

94

95 **Preparation and initial assessments page**

96 Please provide data for activities spent in preparation for the contact investigation and
 97 assessments of each contact to the point in which you determine results from preparation and
 98 initial assessments up to their initial diagnosis and classification. Before completing the form, it
 99 may be helpful to save a blank copy of the file to ensure that line numbers correspond to questions
 100 as you may need to add rows so that your data will fit.

101

102

1. I will already have **information describing your location** (lines 12-14)

103

104

2. Please tell us some **specifics about contact evaluation outcomes** (lines 18-25)

105

- How many hours in total were needed to identify contacts in your state?

106

- i. Please include time of personnel directly involved in contact investigation activities, in addition to administrative and support staff

107

- How many contacts were identified in your state?

108

- i. This response will validate my records

109

- ii. Please include both air and ground; and high, medium, low priority; or 'close and casual contacts' if you have used that classification

110

- By classification, how many high, medium, and low priority contacts were identified [8]?

111

- i. How many contacts were classified as either high priority [8] or 'close contacts' [9]?

112

- High-priority contacts include the following [8].

113

- Household contacts

114

- Under 5 years old

115

- With an immunosuppressive medical risk factor (HIV, diabetes, silicosis, gastrectomy or jejunoileal bypass surgery; or taking prednisone, chemotherapy, antirejection drugs, or TNF alpha inhibitors)

116

- Exposed during a medical procedure (bronchoscopy, sputum induction, autopsy)

117

- Exposed in a congregate setting

118

- Exposed for more than locally defined environmental duration limits for high priority

119

- Close contacts is an older, less specifically defined, classification, including contacts with prolonged, frequent, or intense contact with a TB case while infectious

120

- ii. How many contacts were classified as medium-priority contacts?

121

- Medium-priority contacts include the following [8].

122

- Between 5-15 years old

123

- Exposed for more than locally defined environmental duration limits for medium priority

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- iii. How many contacts were classified as low-priority or casual contacts?

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- Low priority contacts are all contacts that are not classified in the other two categories
 - Casual (other than close) contacts have less intense, less frequent, or shorter durations of contact with the TB case while they are infectious.
 - How many contacts in your state were evaluated for TB?
 - i. Please include both LTBI and TB disease evaluations
 - How confident are you that this number represents the total number of actual contacts exposed to the index case?
 - i. Please indicate high, moderate, or low, and comment on any areas of uncertainty
3. What were the results of **testing for tuberculosis infection and disease**, indicating the number of tests administered, and those whose result was positive, negative, and indeterminate? Please indicate any notes needed for explanation in column I, such as a borderline result (lines 29-41).
- Tuberculin skin testing*
- Initial tuberculin skin test (TST) placement with TB education
 - Reading of initial TST
- IGRA testing*
- QuantiFERON Gold In Tube (QFT-GIT) interferon gamma release assays (IGRA)
 - T-spot IGRAs
- Testing for TB disease*
- Physical examinations
 - Chest x-ray (CXR)
 - Sputum induction
 - Sputum smear microscopy and culture exams
 - Nucleic acid amplification (NAA) tests for TB disease
4. How many contacts had the following **risk factors for developing TB disease after infection**? Please include any explanatory notes as needed in column F (lines 45-82).
- How many contacts were born in the different regions listed?
 - i. Please indicate 'other' if the contacts were born in a low incidence region.
 - ii. There is a space for notes if any explanation is needed. For example, if the contact was born to at least one US born parent living in another country.
 - How many contacts have lived or travelled for more than one month in the different regions listed?
 - i. Please indicate 'other' if the contacts lived or travelled in a low incidence region.
 - ii. There is a space for notes if any explanation is needed.
 - How many contacts had **medical risk factors**?
 - i. How many contacts had a history of LTBI prior to investigation?
 - ii. How many contacts had a history of TB disease prior to investigation?
 - iii. How many contacts had received the BCG vaccine?
 - iv. How many contacts had diabetes?
 1. Please include both type I and type II diabetes.
 - v. How many contacts had HIV or AIDS?

- 184 1. Please include documented laboratory or clinical diagnosis, or
 185 indicate unknown. Self-report is not sufficient [10, 11].
- 186 vi. How many contacts had autoimmune disease or another immunosuppressive
 187 condition?
- 188 • How many contacts had **non-medical risk factors**?
- 189 i. How many contacts were close contacts of someone with TB disease other
 190 than the index case?
- 191 ii. How many contacts were under 5 years old?
- 192 1. If day, month, or year of birth are unknown, please report according
 193 to the level of information that is available [11].
- 194 iii. How many contacts were a resident of a correctional facility in the past year?
- 195 1. Please include prison, jail, juvenile, or any other type of correctional
 196 facility [11].
- 197 iv. How many contacts used injection drugs in the past year?
- 198 1. Please include having ever used injecting drugs including people
 199 classified by either documented and physical evidence [11].
- 200 v. How many contacts were homeless in the past year?
- 201 1. Homelessness is defined as having no fixed, regular, and adequate
 202 nighttime residence, or living in a shelter, temporary institution,
 203 unstable residence, or public or private place not designated for a
 204 regular sleeping accommodation of human beings [11].
- 205
- 206 5. What were the **costs of the testing for TB infection and disease**? (lines 86-94)
- 207 • *Please note that this and the following two blocks of questions ask about the costs*
 208 *according to the number of services provided, not data according to the number of*
 209 *contacts. In contrast, the previous three blocks of questions ask for data according to*
 210 *number of contacts.*
- 211 • Please indicate the unit costs for the following tests (Column E)
- 212 o Tuberculin skin tests (TST)
- 213 o QuantiFERON Gold In Tube (QFT-GIT) IGRAs
- 214 o T-spot IGRAs
- 215 o Physical examinations
- 216 o Chest x-rays (CXR)
- 217 o Sputum inductions
- 218 o Sputum smear and culture exams
- 219 o Nucleic acid amplification (NAA) tests
- 220 • Please indicate who paid for them (Column F)
- 221 • Please list any notes or specifications about the type of service (Column G)
- 222 o For example, different types of CXR may be used in different circumstances
- 223 o Different NAA tests may use different polymerase chain reaction (PCR)
 224 methods, probes, or sequencing methods.
- 225
- 226 6. What **testing was provided for illnesses that are risk factors for TB disease**, including
 227 HIV, diabetes, severe kidney disease, or any other condition? (lines 98-113)
- 228 o ELISA (HIV)
- 229 o Western blot (HIV)

- 230 o Rapid diagnostic test (HIV)
- 231 o Hemoglobin A1C test (Diabetes)
- 232 o Blood glucose test (Diabetes)
- 233 o Urinalysis (Kidney disease)
- 234 o Ultrasound (Kidney disease)
- 235 o Computerized tomography (Kidney disease)
- 236 o Biopsy (Kidney disease)
- 237 o Any other test
- 238 • How many tests were provided? (column E)
- 239 • What was the cost per service? (column F)
- 240 • Who paid for these services? (column G)
- 241 • Please give any explanatory notes at the end (column H)
- 242 • **Please repeat for each service provided, including any other tests**
- 243 **administered that are not listed.**
- 244 • Please note that counselling services provided to contacts about these conditions is
- 245 included as part of personnel costs.
- 246
- 247 7. What costs of **treating latent tuberculosis infection (LTBI)** were incurred? (lines 117-
- 248 121)
- 249 • How many contacts were initiated on treatment for potentially drug susceptible
- 250 tuberculosis with 6H, 9H, 4H, or 3HT? (column E)
- 251 i. What was the cost per dose? (column F)
- 252 ii. How many doses were taken? (column G)
- 253 iii. Who paid for it? (column H)
- 254 • How many contacts were treated incorrectly with Cycloserine (CYC)? (column E)
- 255 i. What was the cost per dose? (column F)
- 256 ii. How many doses were taken? (column G)
- 257 iii. Who paid for it? (column H)
- 258 • Please indicate any other notes in column I.
- 259
- 260 8. What investigative, clinical, administrative, laboratory, government, or other **personnel**
- 261 were involved in the contact investigation? (lines 126-161)
- 262 • Please provide aggregate data
- 263 • Please exclude clinician time used for physical examinations. These costs are
- 264 accounted for in Section 5.
- 265 • How many total personnel were involved in the contact investigation by category?
- 266 (column E)
- 267 o Please include personnel involved directly in the specific XDR-TB contact
- 268 investigation, and administrative or support personnel who also contributed
- 269 their time.
- 270 o If one person filled more than one role, please divide their time according to
- 271 role.
- 272 • How many total hours were spent on activities related to or supporting the contact
- 273 investigation? (column F)
- 274 o Please account for activities preparing for the investigation as well as
- 275 investigation activities themselves such as interviewing or counselling

- 276 contacts, coordinating with others in the contact investigation team, and time
 277 spent in training or self-study.
- 278 o Please also include donated time.
- 279 o Please round hours to the nearest quarter hour.
- 280 • What was the average gross annual salary (without benefits)? (column G)
- 281 • What was the percent fringe benefit involved from your jurisdiction? (column H)
- 282 • Who paid for the salaries? (column I)
- 283 • Please indicate any notes needed (column J)
- 284 • **Please add any other categories at the end**
- 285
- 286 9. What **travel costs** did your office incur in preparing for the investigation (e.g. meetings),
 287 and in locating, interviewing, and testing contacts? (lines 166-173)
- 288 • If travel included objectives external to activities related to the contact
 289 investigation, please indicate only the expenses that would have been incurred on
 290 the contact investigation activities alone. For example, do not include the costs of
 291 returning home if the contact investigator forgot something unrelated to the project.
 292 However, things that are necessary and typical for program activities to function,
 293 such as going to the gas station, should be included.
- 294 • What were the mileage costs?
- 295 • Were *per diem* costs incurred?
- 296 o Per diem costs include lodging, meals, incidental expenses incurred when
 297 traveling
- 298 • Were any other types of travel costs related to contact investigation activities
 299 incurred?
- 300 • Please list any notes in column H.
- 301
- 302 10. Did anyone involved in the contact investigation receive any **training** that contributed to
 303 their ability to perform this specific contact investigation [12]? (lines 177-185)
- 304 • Please list all trainings in column D that were specific to this contact investigation.
- 305 • Please list all personnel categories of participants who were involved in the contact
 306 investigation separately as subheadings in column D if any of the following
 307 information.
- 308 i. How many personnel of each category received the training in total? (column
 309 E)
- 310 ii. How many personnel receiving the training were involved in contact
 311 investigation activities, administration, or support? (column F)
- 312 iii. What was the cost of providing each training course? (column G)
- 313 • Each training course may involve multiple sessions. Please account for
 314 each course as one training
- 315 • Please include time and salary costs of the instructor and participants
 316 under personnel if all were in-house. If an external instructor
 317 provided the training, please include their time and salary costs here.
- 318 • Please include any food or materials consumed such as printed
 319 manuals, presentation materials, contact investigation supplies, or
 320 any other components
- 321 iv. How long is the training valid for before it would be renewed? (column H)

- 322 v. What proportion of the person's job responsibilities helped by this training is
 323 dedicated to the contact investigation or its support? (column I)
 324 vi. Who provided the training? Was it external or in-house? (column J)
 325 • Please indicate if the training was with a Regional Training and
 326 Medical Consultation Center, with the CDC, or other organization to
 327 help us avoid double counting.
 328 vii. Who paid for the training? (column K)
 329 viii. Please list any notes in column L
 330

331 11. Please indicate the types and quantities of **incentives and enablers** that were used for
 332 contact investigation activities, and how much they cost (lines 189-195)

- 333 • Incentives include things that encourage the person to keep their appointments
- 334 • Enablers include things to help the person keep their appointments
 - 335 o Please list specific items in column D
 - 336 o How many units were consumed? (column E)
 - 337 o What was the cost per unit? (column F)
 - 338 o Who paid for them? (column G)
 - 339 o Please add any notes in column H

340
 341 12. Please indicate any other **miscellaneous costs** incurred during preparation or for contact
 342 investigation activities and initial assessments that were not included in previous sections
 343 (lines 199-203)

- 344 • Please list specific items in column D
- 345 • How many units were consumed? (column E)
- 346 • What was their cost per unit? (column F)
- 347 • What percentage of each resource was dedicated to contact investigation activities?
 348 (column G)
- 349 • Who paid for each item? (column H)
- 350 • Please add any notes in column I
 351

352 **Follow-up activities conducted**

353 For the same categories listed above for the preparation period and initial assessment, please
 354 indicate what resources have been consumed in the follow-up phase to the current date on the
 355 second tab. This period includes cost of physical examinations and diagnostic testing (periodically
 356 and as needed), cost of LTBI treatment, personnel costs, travel costs, training costs, costs of
 357 incentives and enablers, and any other costs. I will use data from this page to make projections
 358 about what the contact investigation will cost across its two-year time horizon. On this page,
 359 please be specific in quantifying all components consumed. If valuations are the same as in the
 360 initial period, it is fine to simply indicate 'same', and I will transfer the valuations from the initial
 361 sheet.
 362

363 **Contact information**

364 If you need clarification about what any of these questions mean or what is needed, please do not
 365 hesitate to contact us (Samuel Shillcutt at 404-718-8963 sshillcutt@cdc.gov, and Suzanne Marks at
 366 smarks@cdc.gov). We would request that you contact us by (date TBD after decision by OMB) to

367 set up a call to record the data that you have collected. Thank you very much for your
368 collaboration!
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370
371

372 **References**

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