**Nonparticipation Reasons in a Randomized International Trial of a New Latent Tuberculosis Infection Regimen**

**Online Data Supplement**

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**Supplement Figure E1.** Nonparticipation log (Internet-based)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Site:  | Study 26 logo |

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| **Complete the Form below for patients that have declined to participate in Study 26.** |
| Top of Form

|  |  |
| --- | --- |
| **Local ID:** | Do not use a medical record number or other HIPAA Privacy Rule-defined Personal Identifier.Do not use a medical record number or other HIPAA Privacy Rule-defined Personal Identifier.  |
| **Data Entry Date:** |  |
| **Year of Birth:** |   Check if estimate  |
| **Gender:** | Male Female  |
| **Race:** |  |
| **Ethnicity:** |  |
| **Place of Birth:** |  |
| **Eligibility Group(s):** | Indicate the appropriate group(s) to which this candidate belongs, for one or more presumptive diagnosis, based on the best available information, even if the information is not verified. |
|  | Contact of infectious TB case |
|  | TST Converter |
|  | HIV positive |
|  | Fibrosis on chest X-tray |
|   |   |
| **Outside Treatment:** |  Did the candidate accept treatment for LTBI outside of study 26? Yes No Unknown  |
|   |   |
| **Non-enrollment Reason:** | Doesn't meet protocol eligibility criteriaEligible, but not enrolled, by site choice (eg: transient, lives too far, unable to reach for follow-up)Eligible, but not enrolled, by candidate's choice (follow-up question shows if chosen)  |
| **Reason Declined:** |   Do you know why patient declined enrollment?Yes No **(List shows if "Yes" is chosen)** |
|   |   |
|  | **Check all that apply:**  |
| **Research**  | Worried about enrolling in any clinical research studies ID  |
|  | Worried about efficacy of experimental arm  |
|  | Worried about DOT in one arm  |
|  | Worried about blood draw  |
|  | Length and/or complexity of obtaining informed consent  |
| **Communication**  | Does not understand language available for translation  |
|  | Understands English, but does not understand study  |
|  | Unable to communicate for other reasons (e.g. illiterate, mental or neurologic incapacity, etc)  |
| **Patient LTBI Beliefs**  | Not infected with TB  |
|  | BCG caused positive TST  |
|  | BCG will protect patient from TB  |
|  | Infected with TB, but not interested in LTBI therapy  |
|  | No risk of active TB perceived  |
|  | Everyone in patient's country has +TST, don't need medicine  |
| **Clinic/staff**  | Has trouble keeping medical appointments in general  |
|  | Travel to/parking at clinic not convenient  |
|  | Negative interaction with staff  |
|  | Does not trust information from staff  |
| **Work/School**  | Number of visits not convenient  |
|  | Only wants work clearance  |
|  | Worried about supervisor's/teacher's response to missed work/school  |
|  | Missing work or school could otherwise be a problem  |
|  | Worried about losing income  |
| **Medication/Health**  | Patient worried about medication side effects  |
|  | Worried about duration of medication required  |
|  | Worried about number of pills required per dose  |
|  | Worried about impact on other medical problems or medications  |
|  | Does not take any medicine in general  |
|  | Primary care or other physician’s concerns about TLTBI in this patient  |
| **Patient lifestyle, family, other**  | Family member against enrollment  |
|  | Worried about stigmatization due to TB or taking TB medicine  |
|  | Displeased with recommendation not to drink alcohol while on TLTBI  |
|  | Perceived potential conflict with recreational drug use  |
|  | Too much stress now  |
|  | Worried about impact on immigration status  |
|  | Worried about use of barrier methods of birth control  |
|  | Children or other dependents make clinic attendance difficult  |
| **Other Reason:** | Other Reason  |

Bottom of Form |

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|  |
| HHS/CDC/NCHSTP/PIO - [**TB Trials Consortium Portal Version 4.0.0 (Build 01)**](https://webappa.cdc.gov/TBTC/jsp/appmain?action=properties) For information, please contact Lorna Bozeman at 404.639.5342 or send e-mail to llb1@cdc.gov. For technical issues, please contact CCID Informatics Customer Support (CDC) at Toll Free 877-659-7725 or locally at 404-639-6480 or send email to ccidinformatics@cdc.gov.  |

**Supplement Table E1.** Characteristics of Patients Screened and Acceptance of Treatment Outside of Study

|  | **Total Not Enrolled** | **Not Enrolled Recorded as Having Accepted Treatment Outside of Study** |
| --- | --- | --- |
|  | **Yes** | **No** | **OR** | **(95% CI)†** | ***P* value\*** | **Unknown** |
|  | **No.** | **Col %** | **No.** | **Row %** | **No.** | **Row %** | **No.** | **Row %** |
|  | **3584** |  | **1979** | **(55.2)** | **1010** | **(28.2)** |  |  |  |  | **595** | **(16.6)** |
| **Sex** |  |  |  |  |  |  |  |  |  | 0.69 |  |  |
| Male | 1927 | (53.8) | 1085 | (56.3) | 546 | (28.3) | 1.0 |  |  |  | 296 | (15.4) |
| Female | 1657 | (46.2) | 894 | (54.0) | 464 | (28.0) | 0.97 | (0.83– | 1.13) | 0.69 | 299 | (18.0) |
| **Age group (yrs)\*** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| 2–17 | 277 | (7.7) | 176 | (63.5) | 62 | (22.4) | 1.0 |  |  |  | 39 | (14.1) |
| 18–35 | 1311 | (36.6) | 756 | (57.7) | 314 | (24.0) | 0.85 | (0.62– | 1.17) | 0.31 | 241 | (18.4) |
| ≥36 | 1995 | (55.7) | 1046 | (52.4) | 634 | (31.8) | 0.58 | (0.43– | 0.79) | 0.00 | 315 | (15.8) |
| Unknown | 1 | (0.0) | 1 | (100.0) | — | — | — | — | — | — | — | — |
| **Birthplace‡** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| Canada and United States | 977 | (27.3) | 575 | (58.9) | 260 | (26.6) | 1.0 |  |  |  | 142 | (14.5) |
| Africa | 157 | (4.4) | 92 | (58.6) | 41 | (26.1) | 1.02 | (0.68– | 1.51) | 0.94 | 24 | (15.3) |
| Americas-Other | 1066 | (29.7) | 536 | (50.3) | 376 | (35.3) | 0.65 | (0.53– | 0.79) | <.01 | 154 | (14.4) |
| Eastern Mediterranean | 87 | (2.4) | 66 | (75.9) | 10 | (11.5) | 2.98 | (1.51– | 5.90) | 0.00 | 11 | (12.6) |
| Europe | 131 | (3.7) | 95 | (72.5) | 26 | (19.8) | 1.65 | (1.05– | 2.61) | 0.03 | 10 | (7.6) |
| South-East Asia | 115 | (3.2) | 72 | (62.6) | 27 | (23.5) | 1.21 | (0.76– | 1.92) | 0.43 | 16 | (13.9) |
| Western Pacific | 705 | (19.7) | 432 | (61.3) | 209 | (29.6) | 0.94 | (0.75– | 1.17) | 0.55 | 64 | (9.1) |
| Non-WHO Region | 1 | (0.0) | 1 | (100.0) | — | — | — | — | — | — | — | — |
| Unknown | 345 | (9.6) | 110 | (31.9) | 61 | (17.7) | — | — | — | — | 174 | (50.4) |
| **Study site country‡** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| United States | 3047 | (85.0) | 1629 | (53.5) | 878 | (28.8) | 1.0 |  |  |  | 540 | (17.7) |
| Brazil | 143 | (4.0) | 42 | (29.4) | 96 | (67.1) | 0.24 | (0.16– | 0.34) | <.01 | 5 | (3.5) |
| Canada | 301 | (8.4) | 220 | (73.1) | 32 | (10.6) | 3.71 | (2.54– | 5.42) | <.01 | 49 | (16.3) |
| Spain | 93 | (2.6) | 88 | (94.6) | 4 | (4.3) | 11.84 | (4.34– | 32.34) | <.01 | 1 | (1.1) |
| **Race\*\*** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| White | 1520 | (42.4) | 781 | (51.4) | 521 | (34.3) | 1.0 |  |  |  | 218 | (14.3) |
| American Indian/Alaskan Native | 19 | (0.5) | 13 | (68.4) | 3 | (15.8) | 2.89 | (0.82– | 10.19) | 0.10 | 3 | (15.8) |
| Asian/Pacific Islander | 914 | (25.5) | 572 | (62.6) | 252 | (27.6) | 1.51 | (1.26– | 1.82) | <.01 | 90 | (9.8) |
| Black | 782 | (21.8) | 477 | (61.0) | 192 | (24.6) | 1.66 | (1.36– | 2.03) | <.01 | 113 | (14.5) |
| Other | 26 | (0.7) | 22 | (84.6) | — | — | — | — | — | — | 4 | (15.4) |
| Unknown | 323 | (9.0) | 114 | (35.3) | 42 | (13.0) | — | — | — | — | 167 | (51.7) |
| **Ethnicity††** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| Hispanic | 1084 | (30.2) | 525 | (48.4) | 353 | (32.6) | 1.0 |  |  |  | 206 | (19.0) |
| Non-Hispanic | 1967 | (54.9) | 1222 | (62.1) | 523 | (26.6) | 1.57 | (1.33– | 1.86) | <.01 | 222 | (11.3) |
| Non-US/Canada | 236 | (6.6) | 130 | (55.1) | 100 | (42.4) | — | — | — | — | 6 | (2.5) |
| Unknown | 297 | (8.3) | 102 | (34.3) | 34 | (11.4) | — | — | — | — | 161 | (54.2) |
| **Indications for LTBI Treatment‡‡** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| Contact | 2115 | (59.0) | 1213 | (57.4) | 604 | (28.6) | 1.0 |  |  |  | 298 | (14.1) |
| Contact and Converter | 103 | (2.9) | 64 | (62.1) | 19 | (18.4) | 1.68 | (1.00– | 2.83) | 0.05 | 20 | (19.4) |
| TST converter | 1006 | (28.1) | 522 | (51.9) | 247 | (24.6) | 1.05 | (0.88– | 1.26) | 0.58 | 237 | (23.6) |
| Fibrosis | 259 | (7.2) | 112 | (43.2) | 122 | (47.1) | 0.46 | (0.35– | 0.60) | <.01 | 25 | (9.7) |
| HIV positive | 70 | (2.0) | 54 | (77.1) | 9 | (12.9) | 2.99 | (1.47– | 6.09) | 0.00 | 7 | (10.0) |
| **Nonparticipation due to** |  |  |  |  |  |  |  |  |  | <.01 |  |  |
| Ineligible | 1469 | (41.0) | 742 | (50.5) | 508 | (34.6) | 1.0 |  |  |  | 219 | (14.9) |
| Not Enrolled, Site Choice | 358 | (10.0) | 265 | (74.0) | 44 | (12.3) | 4.12 | (2.94– | 5.78) | <.01 | 49 | (13.7) |
| Not Enrolled, Patient Choice | 1757 | (49.0) | 972 | (55.3) | 458 | (26.1) | 1.45 | (1.24– | 1.70) | <.01 | 327 | (18.6) |

*Definitions of abbreviations:* Birthplace: Americas–Other (Americas, not Canada or the United States); CI = confidence interval; Fibrosis = Fibrosis on chest radiograph; HIV = human immunodeficiency virus; LTBI = latent tuberculosis infection; LTBI Treatment Indications: Contact = Contact with infectious TB case, Contact and TST converter = Contact with infectious TB case and TST Converter; OR = odds ratio; TST = tuberculin skin test; WHO = World Health Organization.

\* Age group: "Unknown" (Total, n = 1; Not enrolled, n = 1): Among those not enrolled and not included in univariate analysis.

† Chi-square *P* values and odd ratios are statistically significant at <.05.

‡ Birthplace: "Non-WHO Region" (Total n=3, Not Enrolled n=1) and "Unknown” include not reported (Total, n = 346; Not enrolled, n = 345): Not included in univariate analysis.

§ One site in Canada only enrolled (n = 6) and did not provide information about patients who were screened but not enrolled.

\*\* Race: "Other" includes multiracial (Total, n = 124; Not enrolled, n = 26), and "Unknown” includes not reported (Total, n = 340; Not Enrolled, n = 323): Not included in univariate analysis.

†† Ethnicity: For the main PREVENT TB (Sterling NEJM 2011), ethnicity was evaluated only among patients screened in the United States and Canada. "Unknown” includes not reported (Total, n = 297; Not enrolled, n = 297): Not included in univariate analysis.

‡‡ Indications for LTBI treatment: Participants who had other combinations of risk factors (n = 49); not shown because of limited numbers

**Supplement Table E2. Incentives and Patients Screened**

|  |  |  |
| --- | --- | --- |
|  | **Sites** | **Patients** |
|  | **Total** | **Enrolled** | **Not Enrolled** |
|  | **Total** | **Ineligible** | **Site Choice** | **Patient Choice** |
|  | **No.** | **Col %** | **No.** | **Col %** | **No.** | **Row %** | **Col %** | **No.** | **Row %** | **Col %** | **No.** | **Row %** | **Col %** | **No.** | **Row %** | **Col %** | **No.** | **Row %** | **Col %** |
|  | 26 |  | 7,452 |  | 3,868 | (51.9) |  | 3,584 | (48.1) |  | 1,469 | (19.7) |  | 358 | (4.8) |  | 1,757 | (23.6) |  |
| **Incentive amount\*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <US$100 | 2 | (7.7) | 592 | (7.9) | 379 | (64.0) | (9.8) | 213 | (36.0) | (5.9) | 99 | (16.7) | (6.7) | 25 | (4.2) | (7.0) | 89 | (15.0) | (5.1) |
| US$100–199 | 9 | (34.6) | 2911 | (39.1) | 1213 | (41.7) | (31.4) | 1698 | (58.3) | (47.4) | 999 | (34.3) | (68.0) | 204 | (7.0) | (57.0) | 495 | (17.0) | (28.2) |
| US$200–299† | 4 | (15.4) | 1008 | (13.5) | 503 | (49.9) | (13.0) | 505 | (50.1) | (14.1) | 149 | (14.8) | (10.1) | 26 | (2.6) | (7.3) | 330 | (32.7) | (18.8) |
| US$300–399 | 7 | (26.9) | 1537 | (20.6) | 883 | (57.4) | (22.8) | 654 | (42.6) | (18.2) | 99 | (6.4) | (6.7) | 50 | (3.3) | (14.0) | 505 | (32.9) | (28.7) |
| US$500–599 | 1 | (3.9) | 229 | (3.1) | 194 | (84.7) | (5.0) | 35 | (15.3) | (1.0) | 20 | (8.7) | (1.4) | 1 | (0.4) | (0.3) | 14 | (6.1) | (0.8) |
| Not specified‡ | 3 | (11.5) | 1175 | (15.8) | 696 | (59.2) | (18.0) | 479 | (40.8) | (13.4) | 103 | (8.8) | (7.0) | 52 | (4.4) | (14.5) | 324 | (27.6) | (18.4) |

\*Maximum provided by site (some sites varied depending on regimen); international currency converted to U.S. dollars at the end of the screening period described in this paper (February 2008).

†This includes one site in Canada that did not record any nonenrolled patients during the specified period.

‡ This includes one site in both Brazil and Spain and one site in Canada that did not provide compensation.