World TB Day 2022

March 18, 2022

Dr. Joseph Burzynski
Assistant Commissioner
NYC Department of Health & Mental Hygiene
Bureau of TB Control

Agenda

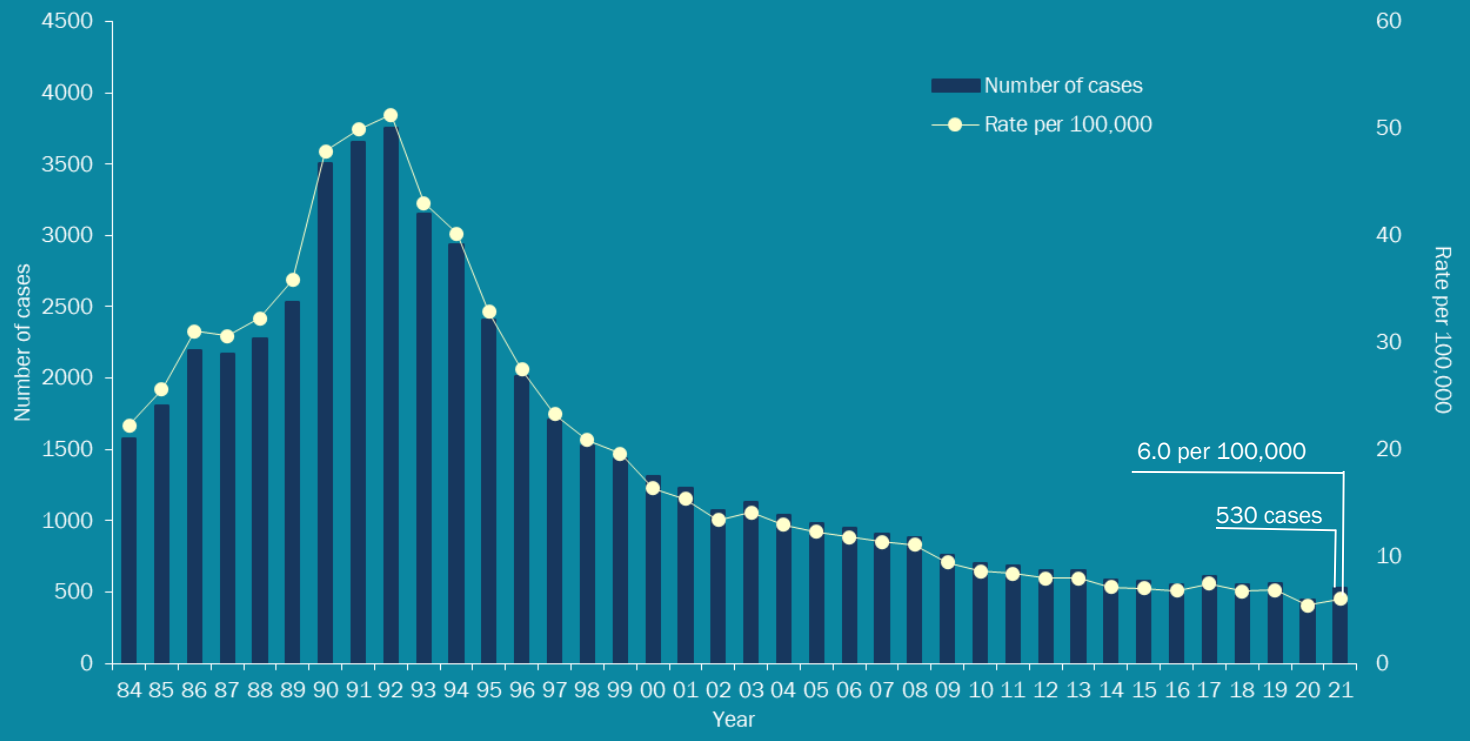
1. TB epidemiology in NYC
2. Impact of COVID-19 on:
    a. NYC TB patients
    b. NYC TB program
3. Other TB updates
    a. International
    b. NYC
4. Resources & partnership

NYC Health

TB epidemiology in NYC

NYC Health

TB cases and rates[1], NYC, 1984-2021

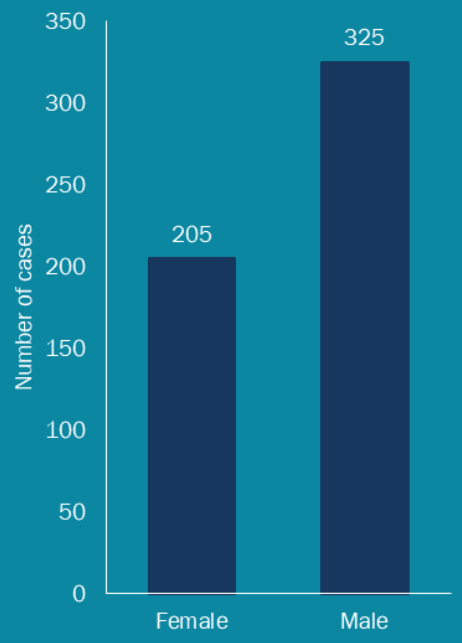


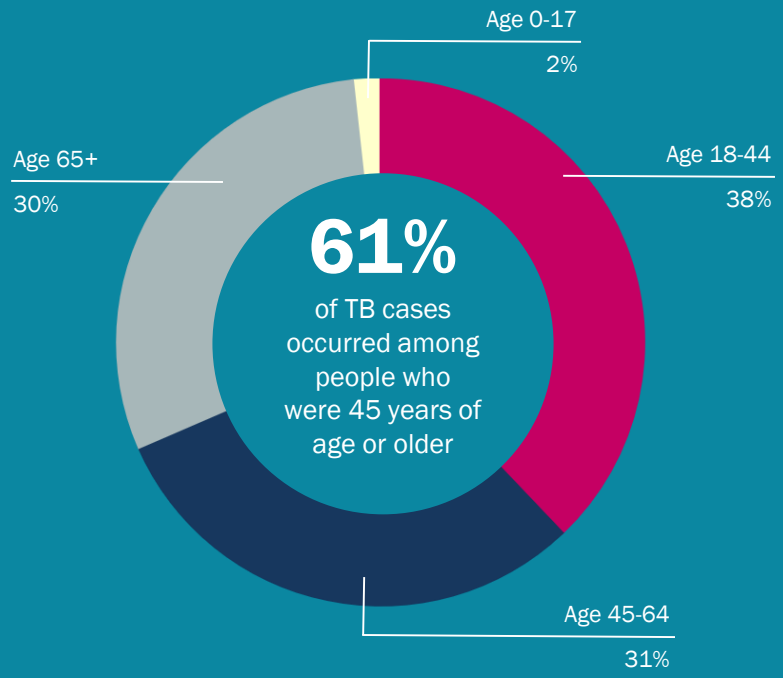
[1] Rates are based on decennial census data

TB cases and rates by birth in the U.S., NYC, 1992-2021

1 Rates prior to 2000 are based on 1990 U.S. Census data. Rates for 2000-2005 are based on 2000 U.S. Census data. Rates after 2005 are based on 1-year American Community Survey data for the given year or the most recent available data. 2. U.S.-born includes individuals born in the U.S. and U.S. territories.3. Excludes cases with unknown country of birth.

TB rates by gender[1] and age group in years, NYC, 2021





[1] Data on patient sex are currently collected and categorized as male, female, or transgender. In future reports, more expansive categories of gender identity will be presented to reflect changes in data collection methods.

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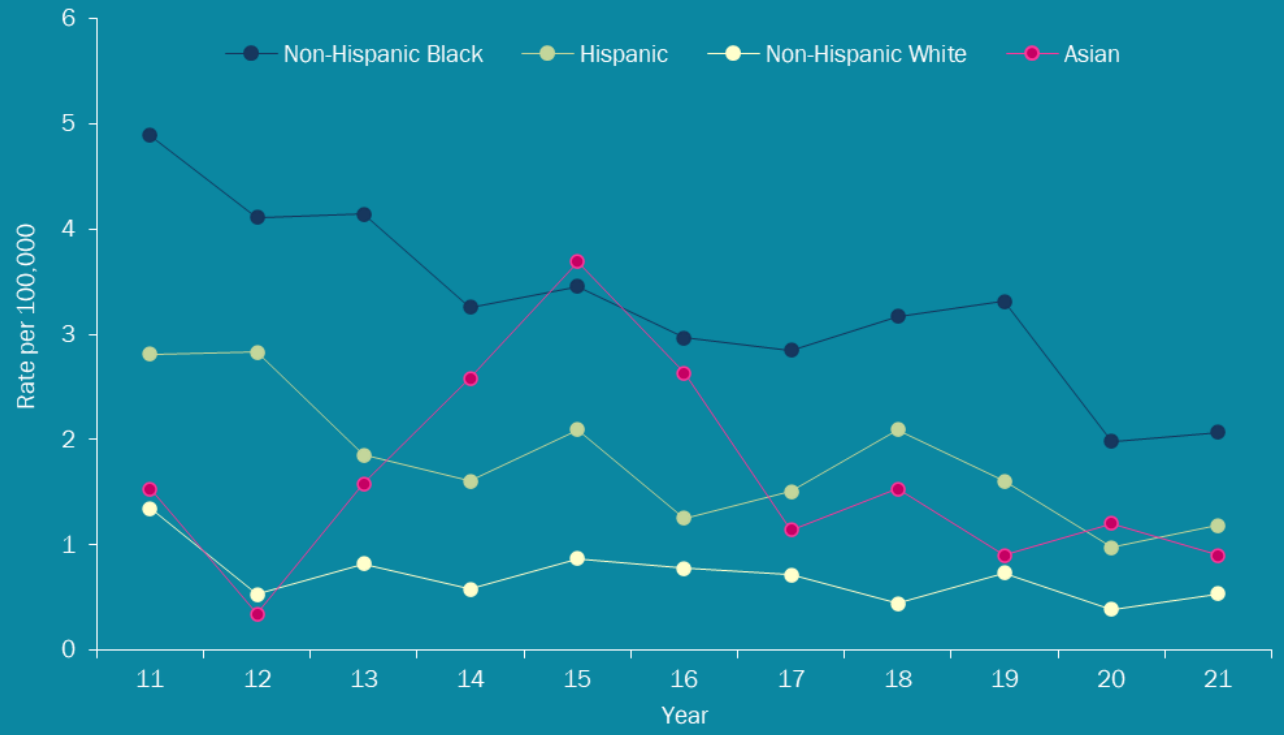
U.S.-born TB rates by race/ethnicity, NYC, 2021



1. Rates are based on 1-year American Community Survey Public Use Microdata Sample data for the given year or the most recent available data. 2. Data shown does not include patients with multiple, other, or unknown race/ethnicity 3. U.S.-born includes individuals born in the U.S. and U.S. territories. 4. Excludes cases with unknown country of birth

Top country of birth by NYC TB burden and incidence, 2021

COUNTRY OF BIRTH	# OF NYC CASES
China	104
USA	59
Ecuador	41
Bangladesh	36
India	32
Philippines	32
Mexico	23
Haiti	19
Dominican Republic	18
Guyana	18

COUNTRY OF BIRTH	NYC TB RATE (PER 100,000)[1]
Congo (2 cases)	597.0
Nepal (13 cases)	113.6
Senegal (5 cases)	77.5
Indonesia (3 cases)	74.0
Malaysia (5 cases)	68.7
Burma (4 cases)	64.1
Singapore (2 cases)	62.6
Armenia (1 case)	59.1
Philippines (32 cases)	53.4
Sierra Leone (1 case)	43.5

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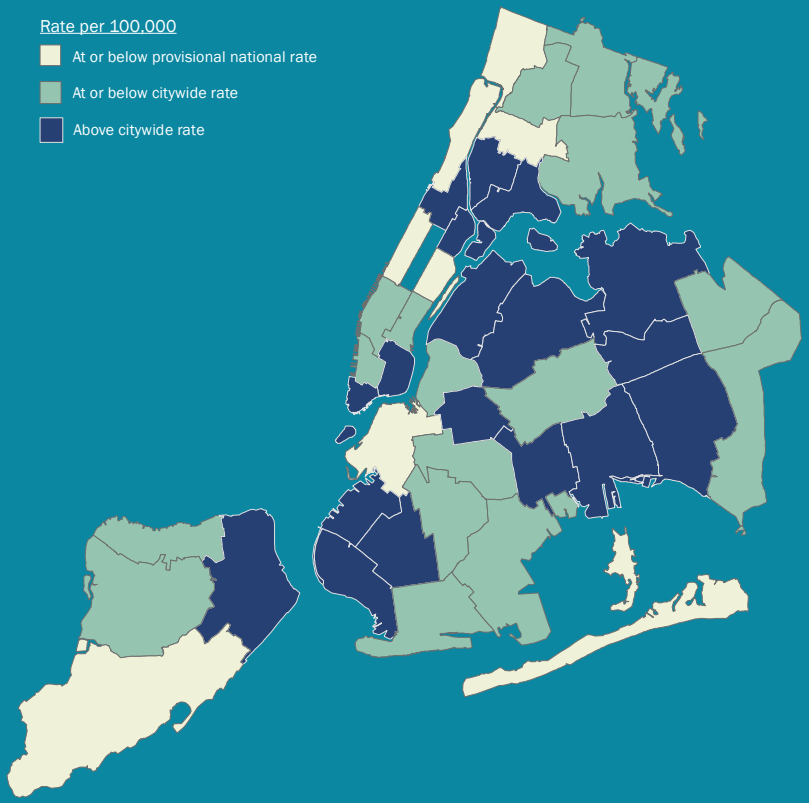
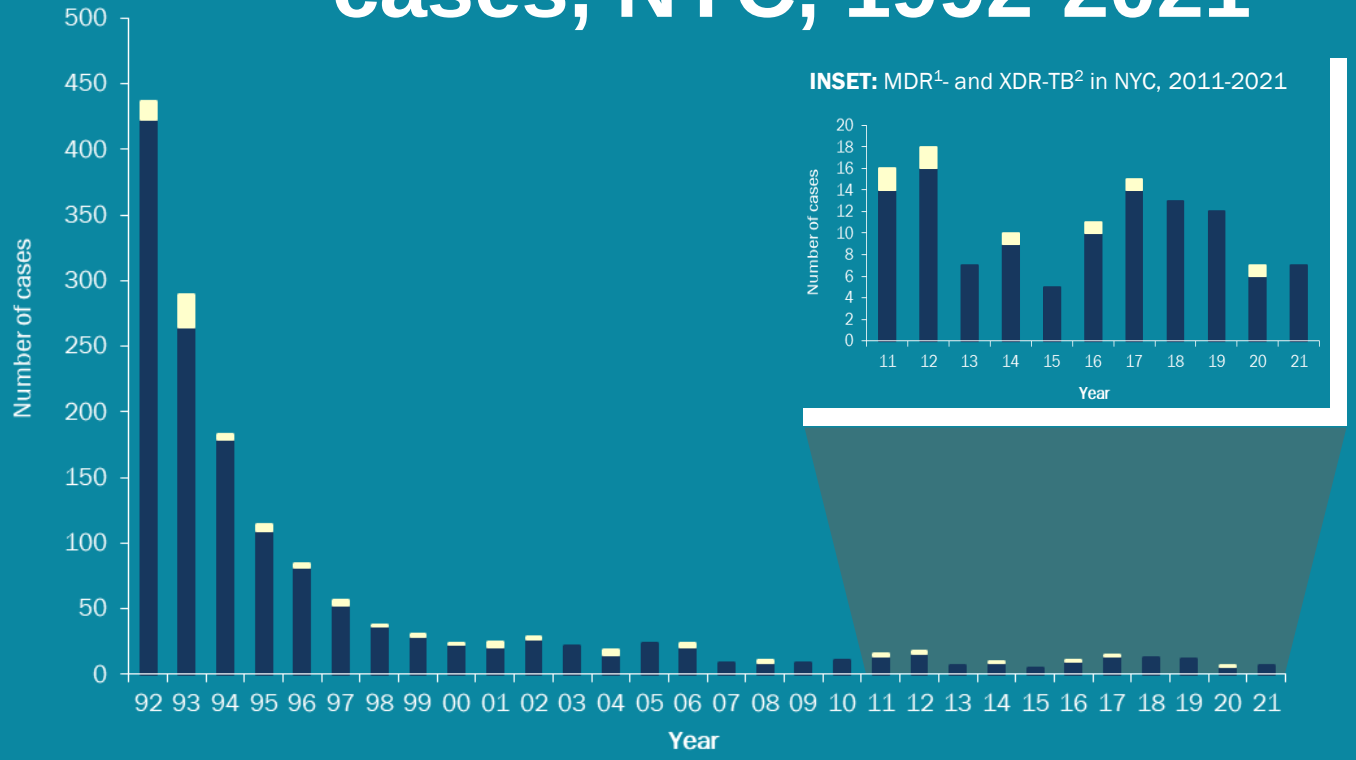
TB rates by United Hospital Fund neighborhood, NYC, 2021



Multidrug resistance among TB cases, NYC, 1992-2021



1. Multidrug-resistant (MDR) TB is defined as resistance to at least isoniazid and rifampin. 2. Extensively drug-resistant (XDR) TB is defined as resistance to at least isoniazid and rifampin plus a fluoroquinolone and a second-line injectable anti-TB medication.

Impacts of COVID-19 on TB patients

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TB/COVID-19 coinfection

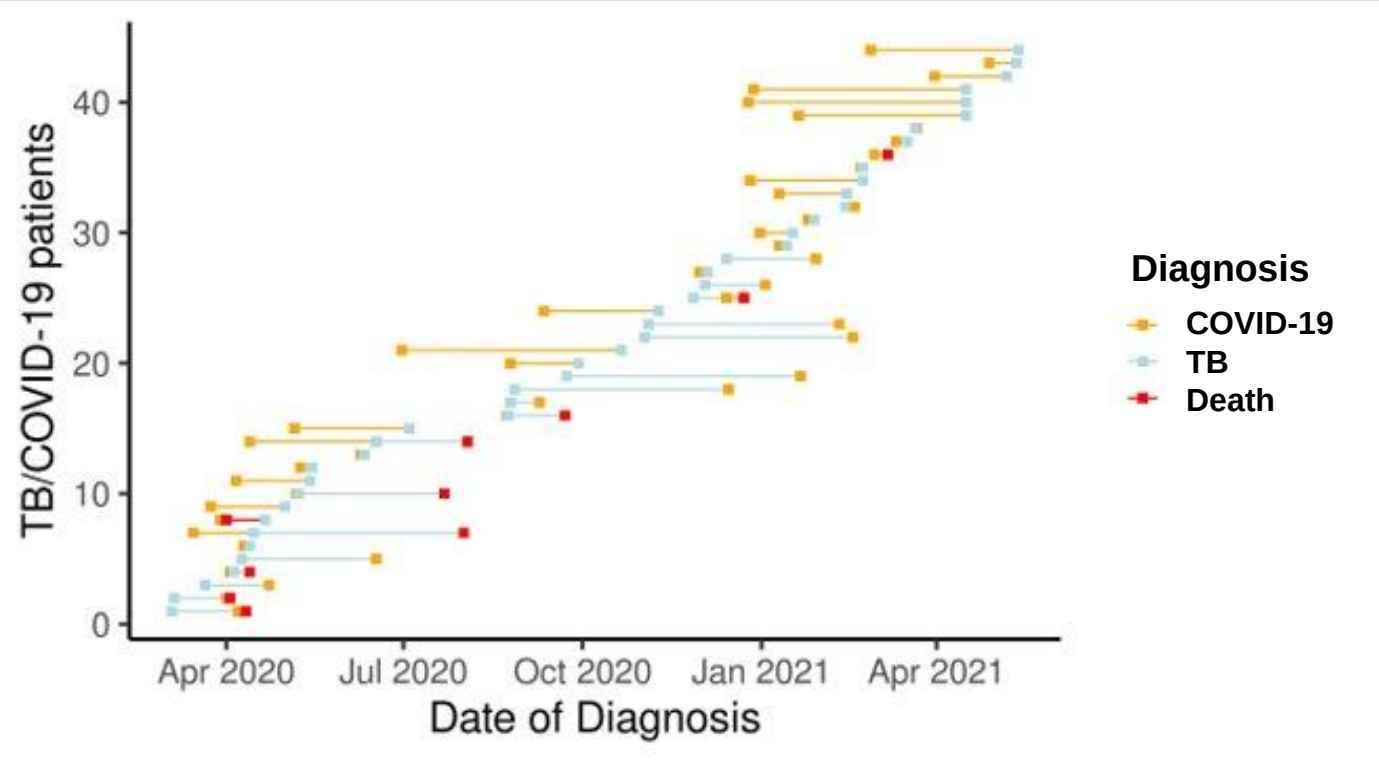
- TB patients with COVID-19 are at elevated risk for complications and should seek medical care.
- Existing literature suggests co-infected patients are at higher risk for severe COVID-19 outcomes.*

←As you see patients who may have COVID-19, you should also "think TB."

*Source: cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html

Date of TB diagnosis and positive COVID-19 test result, NYC

(March 2020-May 2021, N=44)



TB/COVID data are preliminary and not for distribution.

Demographics of NYC patients with TB alone and concurrent TB and COVID-19, March 2020-May 2021

	TB (N=422)	Concurrent TB/COVID-19 (N=44)	p-value
Median [Min, Max] age at diagnosis	50 [0, 93]	54 [18, 87]	0.89
Male sex	257 (61%)	24 (55%)	0.42
Race/ethnicity			0.83
Non-Hispanic White	20 (5%)	2 (5%)	
Non-Hispanic Black/African American	77 (18%)	7 (16%)	
Hispanic/Latinx	100 (24%)	9 (20%)	
Asian/Pacific Islander	190 (45%)	24 (55%)	
Other/Unknown	35 (8%)	2 (5%)	
Non-U.S. born	360 (85%)	39 (89%)	0.66

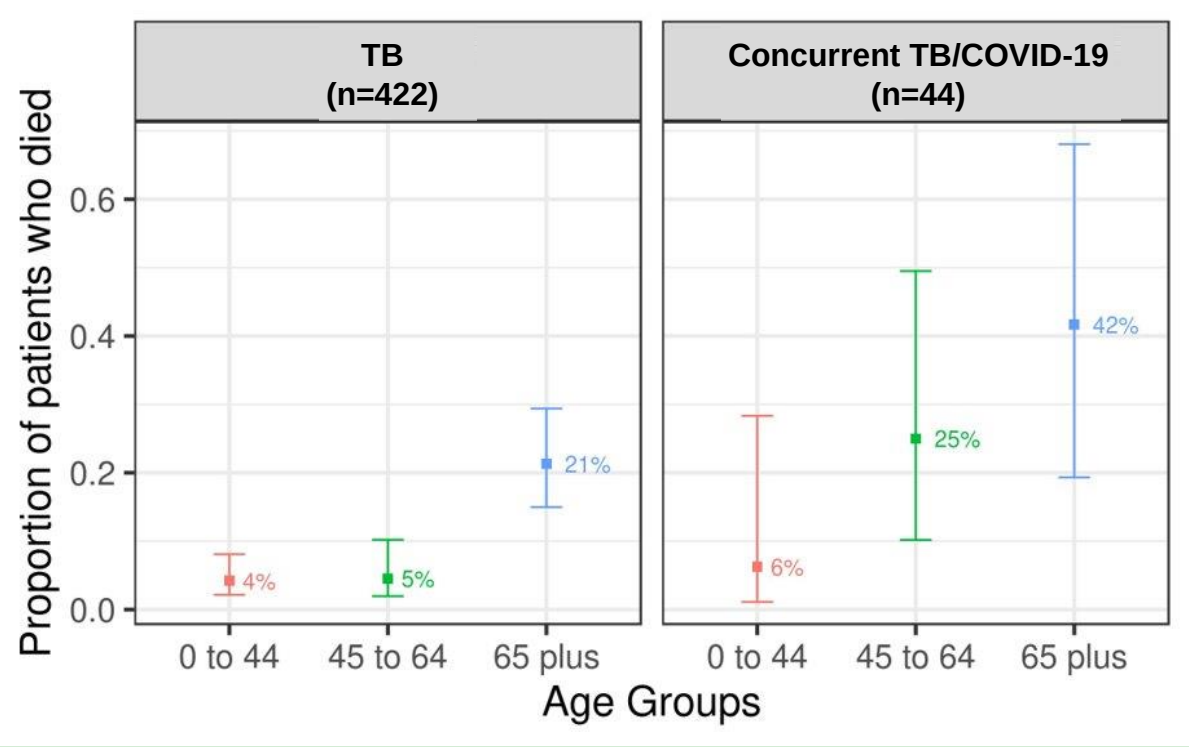
TB/COVID data are preliminary and not for distribution.

Clinical and social characteristics of NYC patients with TB only and concurrent TB and COVID-19, March 2020-May 2021

	TB (N=422)	Concurrent TB/COVID-19 (N=44)	p-value
Pulmonary involvement	351 (83%)	37 (84%)	1.00
Living with HIV	19 (5%)	2 (5%)	
Diabetes	90 (21%)	15 (34%)	0.06
Homeless within past year	15 (4%)	1 (2%)	1.00
MDR (out of culture positive)	3/360 (1%)	1/41 (2%)	0.35
Died	39 (9%)	10 (23%)	**<0.001**

TB/COVID data are preliminary and not for distribution.

Mortality of NYC TB patients with TB only and with concurrent TB and COVID-19, March 2020-May 2021



TB/COVID data are preliminary and not for distribution.

Impacts of COVID-19 on TB Program

NYC Health

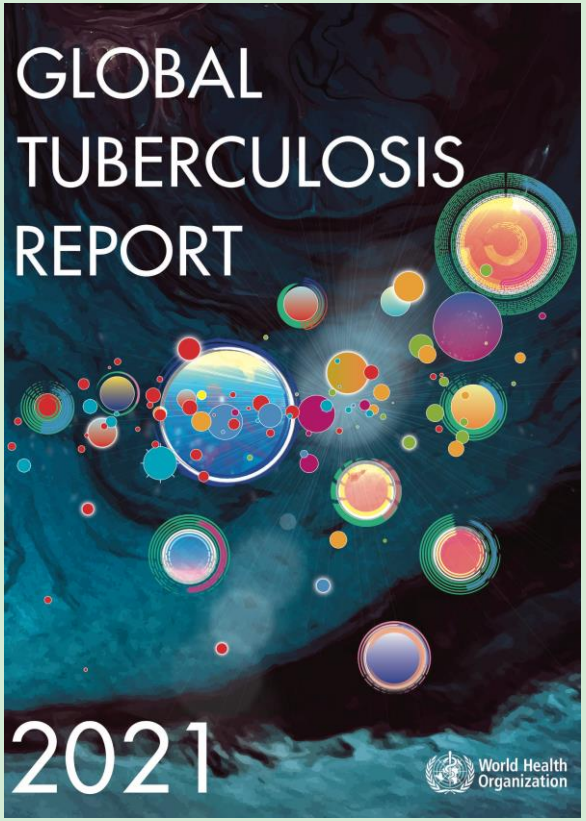
Programmatic adaptations in NYC

- Telehealth
- Virtual education and outreach events
- Case management: virtual patient interviews, video home assessments
- Staff wellness efforts

Other TB updates: International

WHO 2021 Report

- Main findings:
  - Big drop in TB case notifications, 5.8 million in 2020, down from 7.1 million in 2019
  - TB deaths increased to 1.3 million in 2020, up from 1.2 million in 2019
  - Declines in TB incidence slowed



New treatment regimen for drug-susceptible TB

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Four-Month Rifapentine Regimens with or without Moxifloxacin for Tuberculosis

S.E. Dorman, P. Nahid, E.V. Kurbatova, P.P.J. Phillips, K. Bryant, K.E. Dooley, M. Engle, S.V. Goldberg, H.T.T. Phan, J. Hakim, J.L. Johnson, M. Lourens, N.A. Martinson, G. Muzanyi, K. Narunsky, S. Nerette, N.V. Nguyen, T.H. Pham, S. Pierre, A.E. Purfield, W. Samaneka, R.M. Savic, I. Sanne, N.A. Scott, J. Shenje, E. Sizemore, A. Vernon, Z. Waja, M. Weiner, S. Swindells, and R.E. Chaisson, for the AIDS Clinical Trials Group and the Tuberculosis Trials Consortium

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 71 / No. 8
February 25, 2022

Interim Guidance: 4-Month Rifapentine-Moxifloxacin Regimen for the Treatment of Drug-Susceptible Pulmonary Tuberculosis — United States, 2022

Wendy Carr, PhD[1]; Ekaterina Kurbatova, MD[1]; Angela Starks, PhD[1]; Neela Goswami, MD[1]; Leeanna Allen, MPH[1]; Carla Winston, PhD[1]

ABSTRACT

BACKGROUND
Rifapentine-based regimens have potent antimycobacterial activity that may allow for a shorter course in patients with drug-susceptible pulmonary tuberculosis.

METHODS
In an open-label, phase 3, randomized, controlled trial involving persons with newly diagnosed pulmonary tuberculosis from 13 countries, we compared two 4-month rifapentine-based regimens with a standard 6-month regimen consisting of rifampin, isoniazid, pyrazinamide, and ethambutol (control) using a noninferiority margin of 6.6 percentage points. In one 4-month regimen, rifampin was replaced with rifapentine; in the other, rifampin was replaced with rifapentine and ethambutol with moxifloxacin. The primary efficacy outcome was survival free of tuberculosis at 12 months.

RESULTS
Among 2516 participants who had undergone randomization, 2343 had a culture positive for *Mycobacterium tuberculosis* that was not resistant to isoniazid, rifampin, or fluoroquinolones (microbiologically eligible population; 768 in the control group, 791 in the rifapentine–moxifloxacin group, and 784 in the rifapentine group), of whom 194 were coinfected with human immunodeficiency virus and 1703 had cavitation on chest radiography. A total of 2234 participants could be assessed for the primary outcome (assessable population; 726 in the control group, 756 in the rifapentine–moxifloxacin group, and 752 in the rifapentine group). Rifapentine with moxifloxacin was noninferior to the control in the microbiologically eligible population (15.5% vs. 14.6% had an unfavorable outcome; difference, 1.0 percentage point; 95% confidence interval [CI], −2.6 to 4.5) and in the assessable population (11.6% vs. 9.6%; difference, 2.0 percentage points; 95% CI, −1.1 to 5.1). Noninferiority was shown in the secondary and sensitivity analyses. Rifapentine without moxifloxacin was not shown to be noninferior to the control in either population (17.7% vs. 14.6% with an unfavorable outcome in the microbiologically eligible population; difference, 3.0 percentage points [95% CI, −0.6 to 6.6]; and 14.2% vs. 9.6% in the assessable population; difference, 4.4 percentage points [95% CI, 1.2 to 7.7]). Adverse events of grade 3 or higher occurred during the on-treatment period in 19.3% of participants in the control group, 18.8% in the rifapentine–moxifloxacin group, and 14.3% in the rifapentine group.

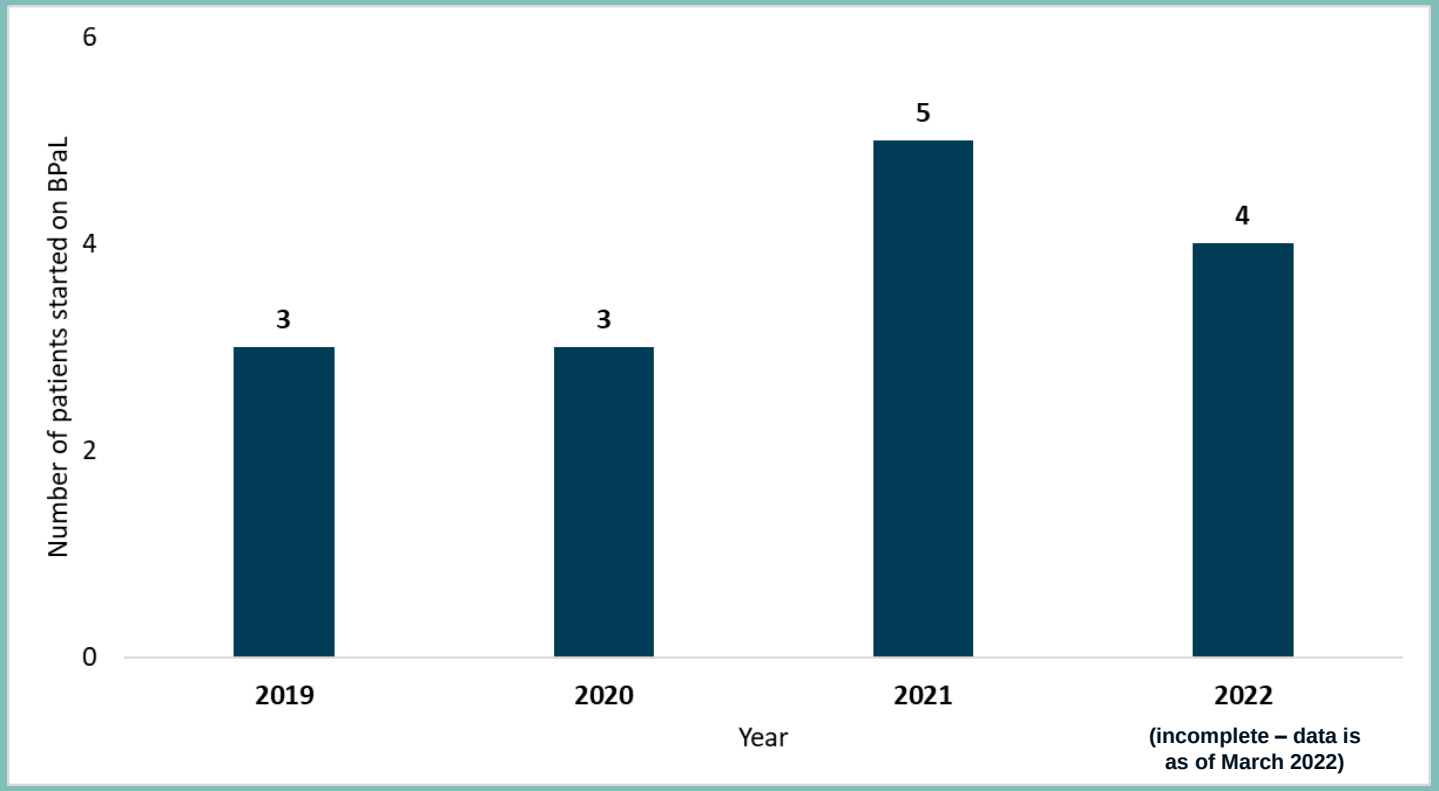
CONCLUSIONS
The efficacy of a 4-month rifapentine-based regimen containing moxifloxacin was noninferior to the standard 6-month regimen in the treatment of tuberculosis. (Funded by the Centers for Disease Control and Prevention and others; Study 31/A5349 ClinicalTrials.gov number, NCT02410772.)

Other TB updates: New York City

Active TB: BPaL for drug-resistant TB

- Approved by FDA in 2019
- 6 to 9-month treatment regimen of bedaquiline, pretomanid, and linezolid that appears to be well-tolerated
- 15 MDR/RR-TB patients have been placed on BPaL in NYC:
  - 9 have been treated by the NYC DOHMH
  - 6 treated by outside facilities (i.e., NYC HHC – Bellevue and Elmhurst; Mt. Sinai)

Patients started on BPaL, NYC, 2019-2022



Active TB: BPaL for drug-resistant TB

Treatment outcomes:

- 7 patients have finished BPaL
- 6 patients remain on BPaL
- 1 patient has refused treatment on BPaL and is lost to follow-up
- 1 patient moved before completing the BPaL regimen in NYC

Active TB: BPaL for drug-resistant TB

- Possible side effects/adverse events:
  - Prolonged QTc interval
  - Abnormal liver function
- DOT is strongly recommended

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LTBI: TBTC Study 37

- Randomized trial comparing 6 weeks Rifapentine to traditional therapy for treatment of LTBI
- Partnership with Veterans Affairs New York Harbor Healthcare System
- Enrollment to begin soon

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eDOT vs. in-person DOT

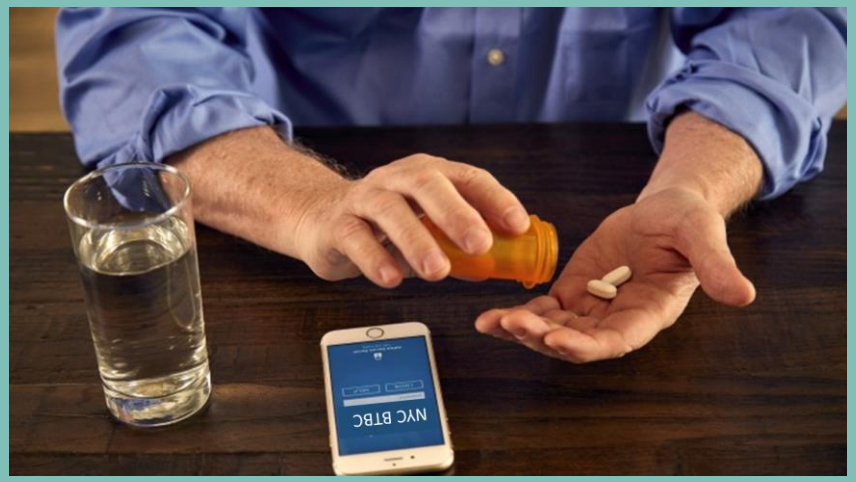
JAMA Network | Open.

Original Investigation | Public Health

In-Person vs Electronic Directly Observed Therapy for Tuberculosis Treatment Adherence

A Randomized Noninferiority Trial

Joseph Burzynski, MD, MPH; Joan M. Mangan, MST, PhD; Chee Kin Lam, MS, MPH; Michelle Macaraig, DrPH; Marco M. Salerno, MPH; B. Rey deCastro, ScD; Neela D. Goswami, MD, MPH; Carol Y. Lin, MPH, PhD; Neil W. Schluger, MD; Andrew Vernon, MD, MHS; for the eDOT Study Team



Key Points

Question Is electronic directly observed therapy (DOT) noninferior to in-person DOT in supporting medication adherence for tuberculosis treatment?

Findings In this randomized, 2-period crossover noninferiority trial of 216 patients with tuberculosis, the modified intention-to-treat analysis estimate of the percentage of medication doses staff observed patients ingest with in-person DOT was 87.2% vs 89.8% with electronic DOT. The percentage difference between DOT methods was −2.6%, which was less than the noninferiority margin of 10% at a statistically significant level.

Meaning These findings suggest that electronic DOT was noninferior to in-person DOT when employed by a tuberculosis program that has historically implemented in-person DOT successfully.

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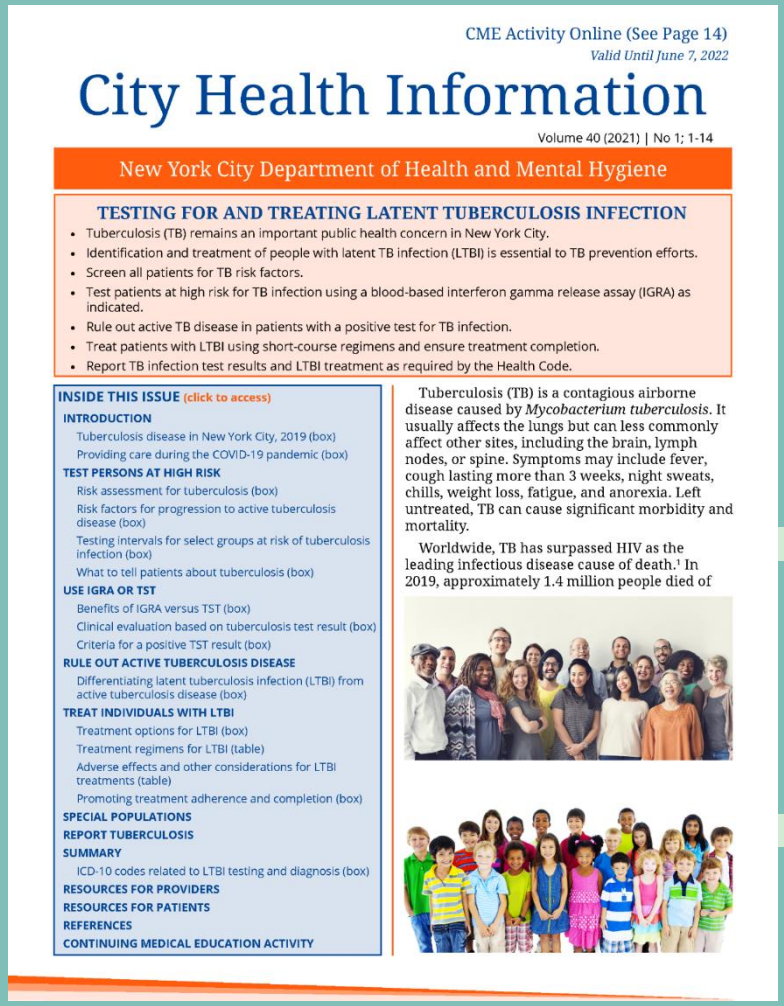
LTBI provider outreach

LTBI City Health Information Bulletin



CME Activity Online (See Page 14)
Valid Until June 7, 2022

City Health Information

Volume 40 (2021) | No 1; 1-14

New York City Department of Health and Mental Hygiene

TESTING FOR AND TREATING LATENT TUBERCULOSIS INFECTION

- Tuberculosis (TB) remains an important public health concern in New York City.
- Identification and treatment of people with latent TB infection (LTBI) is essential to TB prevention efforts.
- Screen all patients for TB risk factors.
- Test patients at high risk for TB infection using a blood-based interferon gamma release assay (IGRA) as indicated.
- Rule out active TB disease in patients with a positive test for TB infection.
- Treat patients with LTBI using short-course regimens and ensure treatment completion.
- Report TB infection test results and LTBI treatment as required by the Health Code.

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Testing intervals for select groups at risk of tuberculosis infection (box)
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Criteria for a positive TST result (box)
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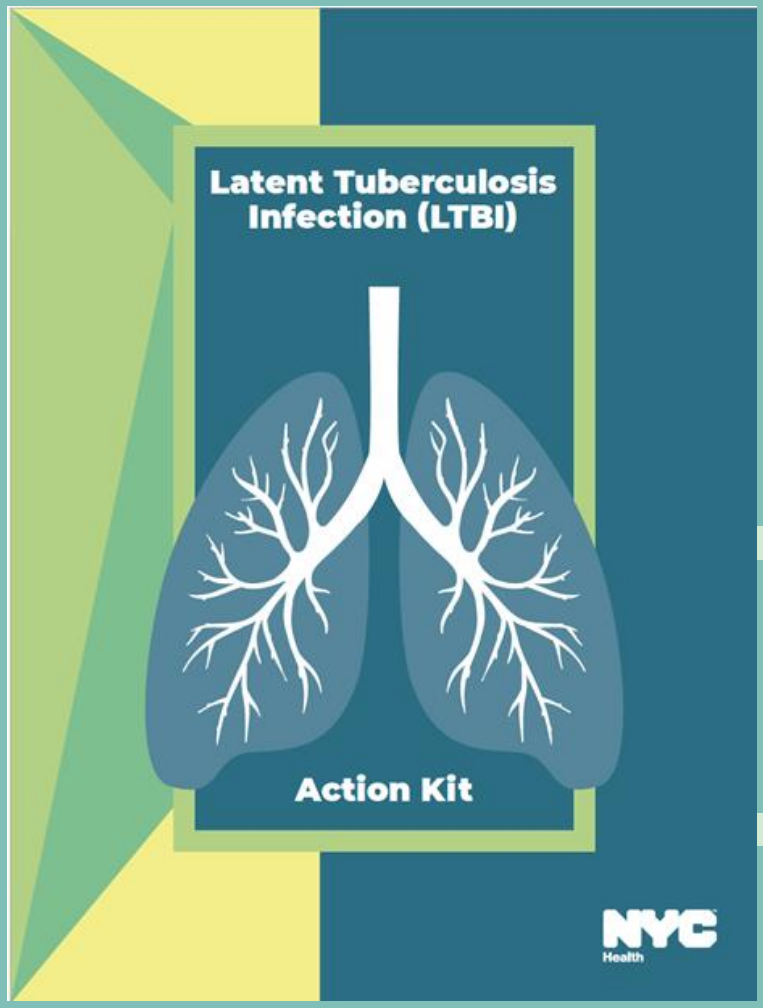
Tuberculosis (TB) is a contagious airborne disease caused by *Mycobacterium tuberculosis*. It usually affects the lungs but can less commonly affect other sites, including the brain, lymph nodes, or spine. Symptoms may include fever, cough lasting more than 3 weeks, night sweats, chills, weight loss, fatigue, and anorexia. Left untreated, TB can cause significant morbidity and mortality.

Worldwide, TB has surpassed HIV as the leading infectious disease cause of death.[1] In 2019, approximately 1.4 million people died of

LTBI provider outreach

LTBI public health detailing toolkit to be completed in Fall 2022



LTBI community outreach

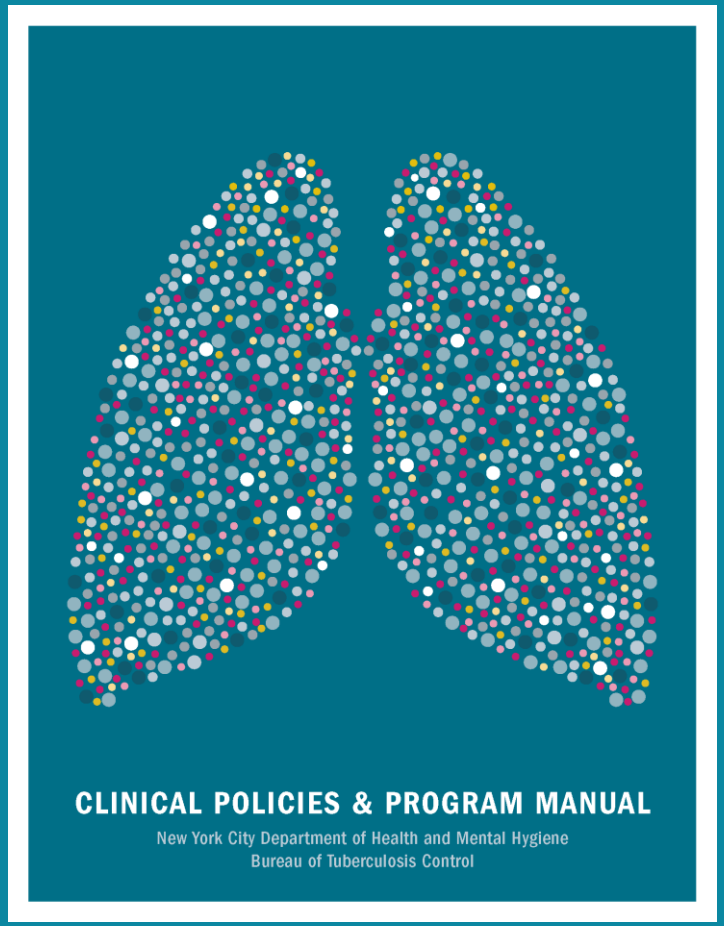
Grant to conduct LTBI Testing in Filipino community and connect to clinical care using patient navigator model

Resources & partnership

NYC Health

NYC BTBC Program Manual now available online

https://bityl.co/B9if



Join the Coalition for a TB-Free NYC

TB-Free NYC | Tuberculosis Elimination (tbfreenyc.wixsite.com)

Think TB!

Questions on reporting TB:
NYC MED / Call 844-713-0559 / TB-surv@health.nyc.gov

Medical consultation and clinic referral:
Call DOHMH TB Hotline at 844-713-0559

TB information:
Call 311 or access www.nyc.gov/health/tb

Request TB talks or join the coalition for a TB-Free NYC: tboutreach@health.nyc.gov

Thank you!

NYC Health