Finding TB in the crowd: testing strategies for today's skilled nursing facilities

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QIAGEN would like to thank our speaker, Evelyn Cook, for her presentation.

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FINDING TB IN THE CROWD

Get To Know You Questions

How many hours are you budgeted, weekly, to spend on infection prevention and control in your facility?

1. 5-10
2. 10-20
3. 20-30
4. 30-40

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Get To Know You Questions

Do you have oversight for your facilities *Mycobacterium Tuberculosis* control program?

1. Yes
2. No
3. Shared responsibility

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Get To Know You Questions

What TB screening test do you use for new employees at time of hire?

1. Tuberculin skin test-TST
2. Interferon-gamma Release Assay-IGRA-blood test
3. We don't test our employees at time of hire

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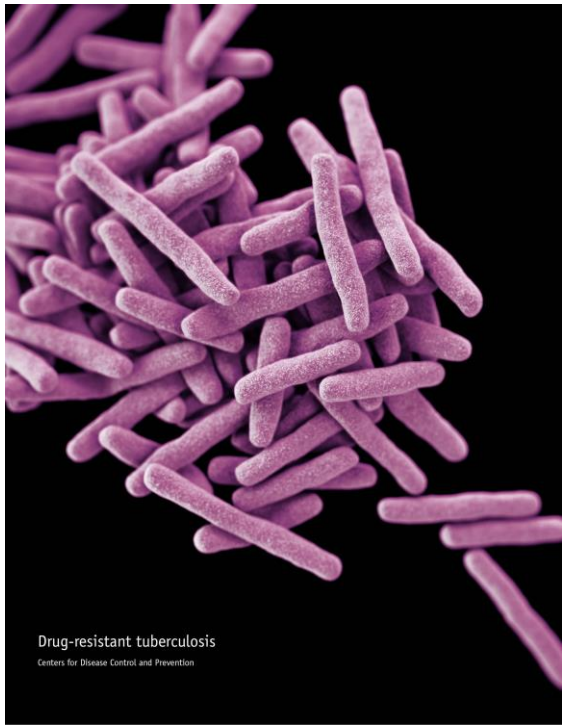
Objectives

- Present an overview of *Mycobacterium Tuberculosis* (TB)
  - Transmission
  - Epidemiology
  - Prevalence and Incidence
- Discuss TB infection versus TB disease
- Describe CDC recommendations for healthcare personnel
- Recognize differences in testing methodologies



https://phil.cdc.gov/details_linked.aspx?pid=16881

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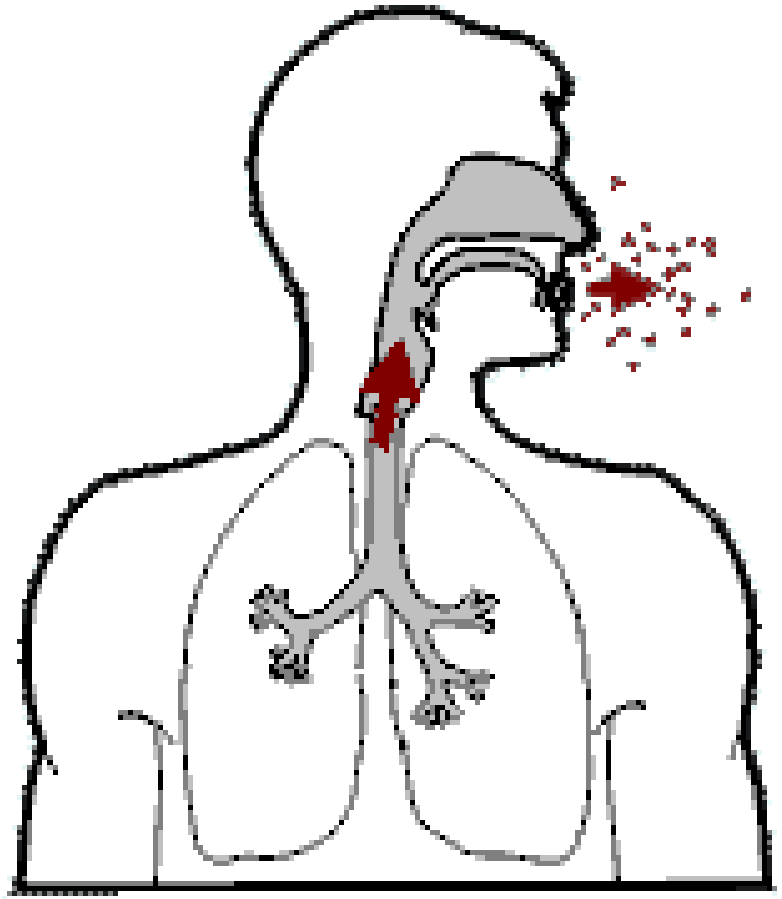
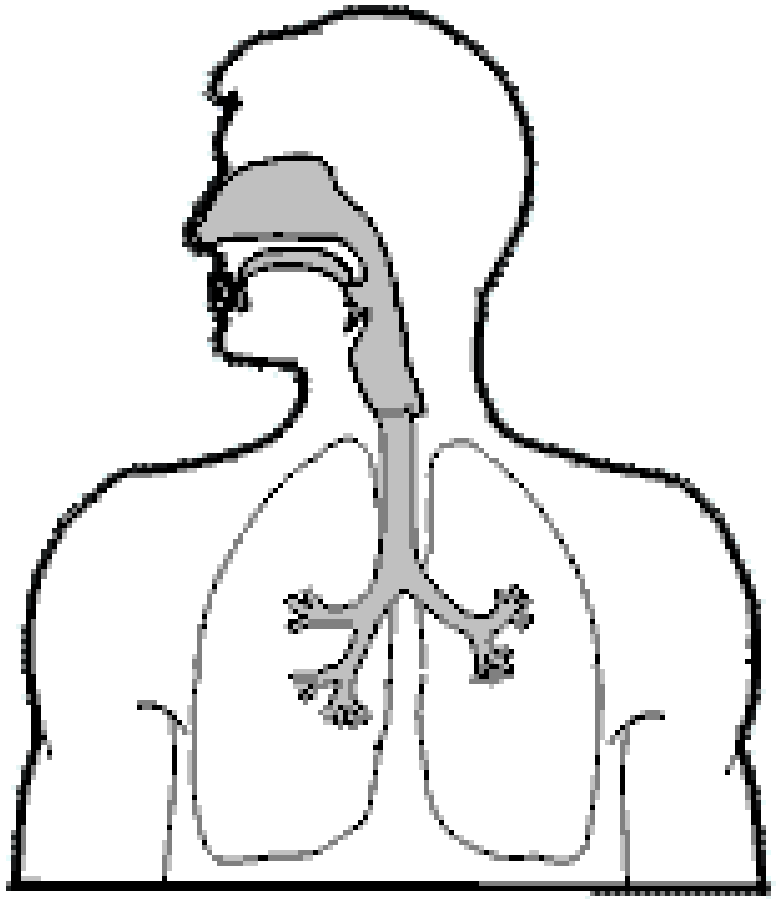
Transmission





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Transmission-Environmental Factors

Factor	Description
Concentration of droplet nuclei	The more droplet nuclei in the air, the more probable that Mtb will be transmitted
Space	Exposure in small, enclosed spaces
Air Circulation	Recirculation of air containing droplet nuclei
Air Pressure	Positive air pressure in infected patients room causes droplet nuclei to flow to other areas

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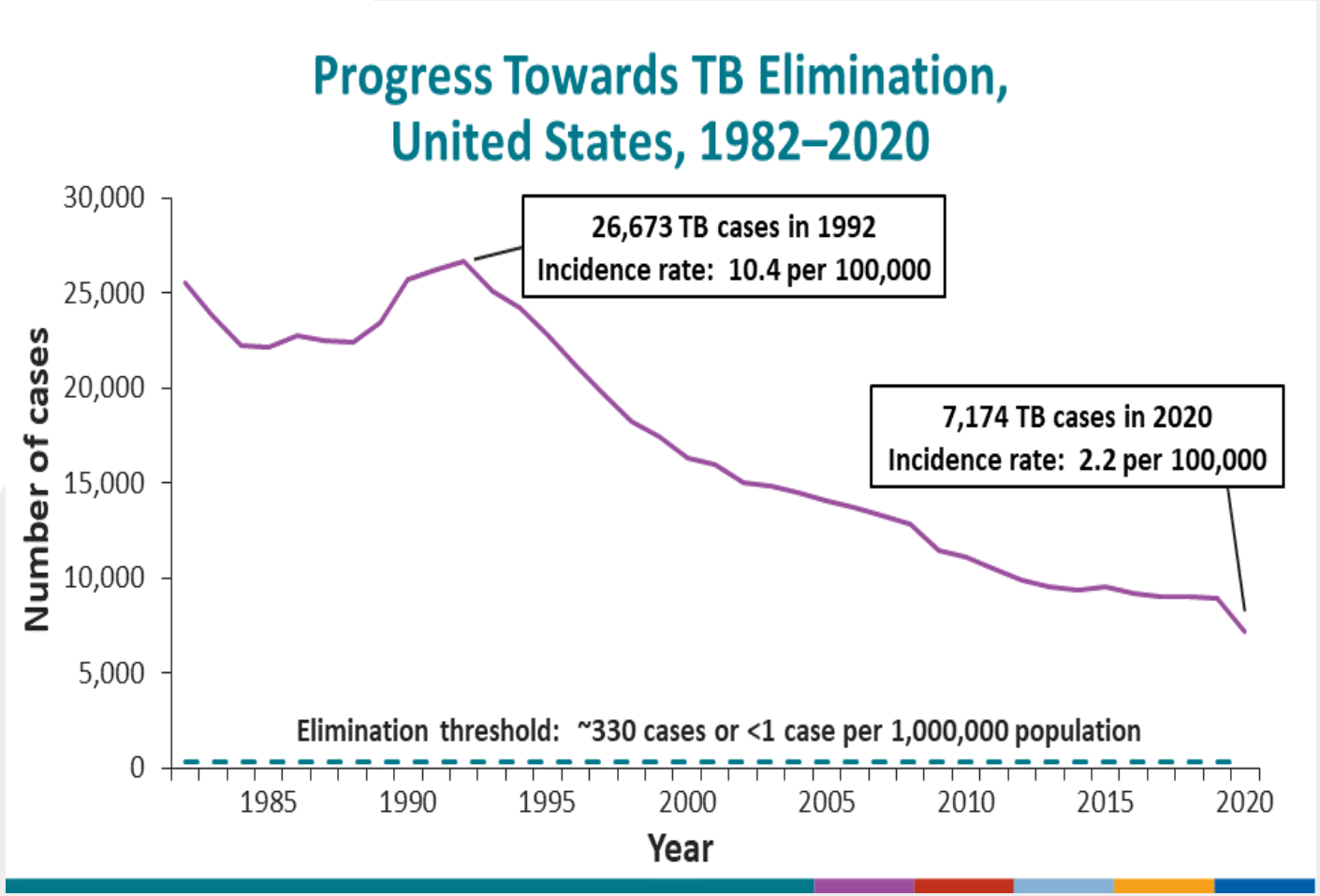
Epidemiology

- TB is one of the most common infections in the world
- Nearly 2 billion people (1/4th of the worlds population) are infected with TB
- Every year about 10 million people develop TB disease
- 1.6 million die
- 2015- the World Health Organization (WHO) reported TB disease as the leading cause of death due to infectious disease in the world

INCIDENCE OF TB

- In 2020 the U.S. reported an incidence of 2.2 cases per 100,000 population (7,174)
- Represents a 19.7% decline since 2019
- 0.2 deaths per 100,000 persons (526) TB related deaths-2019



https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm

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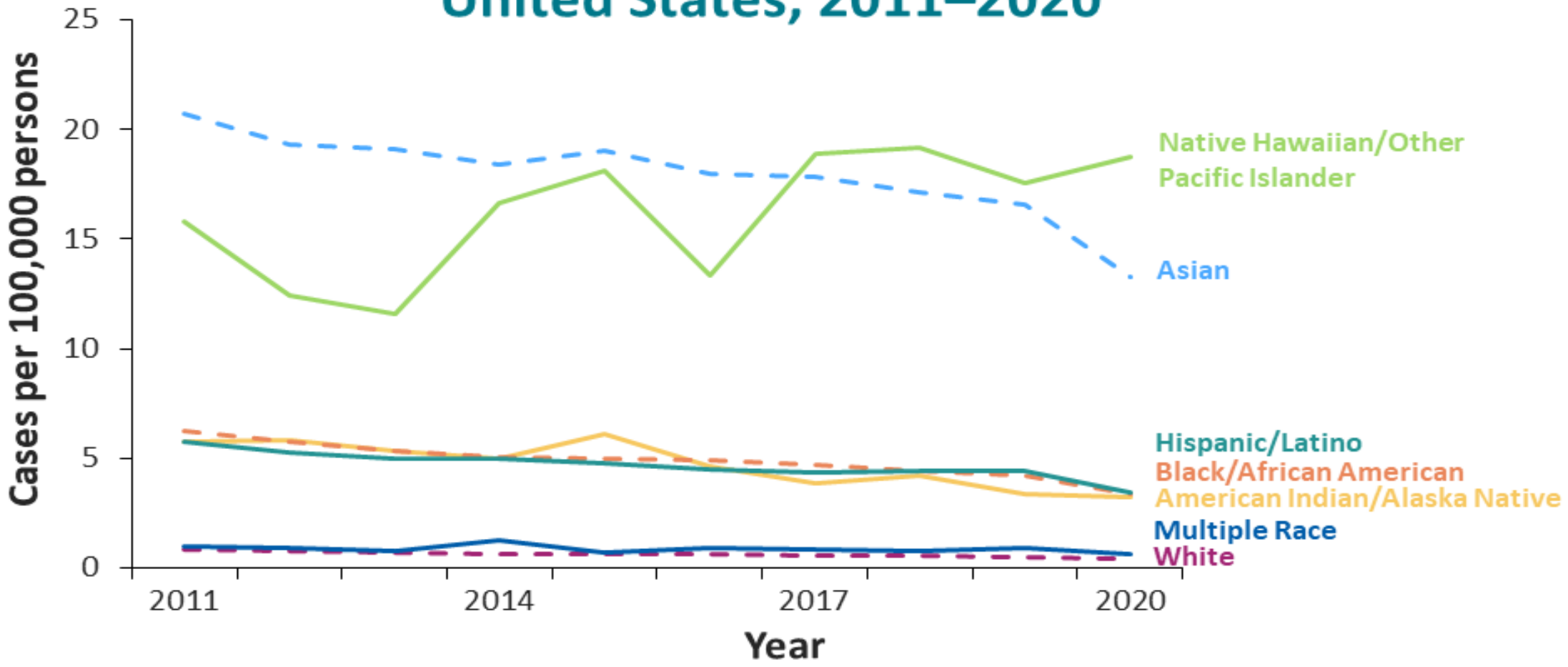
- [1]Despite this decline ongoing concerns exist-
  - TB cases reported in almost every state
  - > 80% of U.S. TB cases are believed to be associated with longstanding, untreated latent TB infection
  - > that 2/3 of cases in the U.S. are among non-U.S.-born person
  - Affects racial/ethnic minorities disproportionately
  - Drug-resistant TB (MDR TB) and extensively drug-resistant TB (XDR TB) remain a serious public health issue-In 2020 a total of 56 cases[2]

[1]Self-Study Modules on Tuberculosis Modules 2 Epidemiology of Tuberculosis

[2]https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/TB-in-the-US-508.pdf

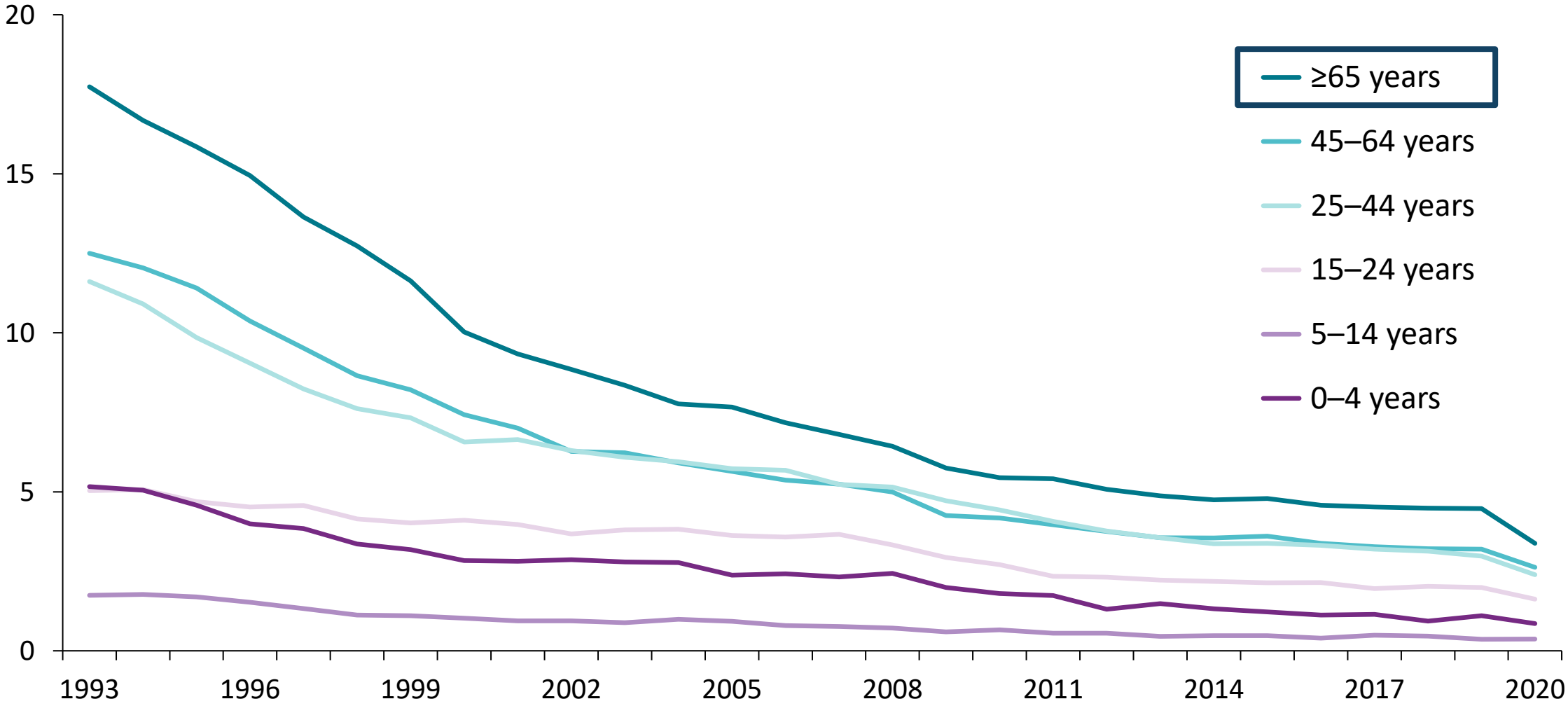
TB Incidence Rates by Race/Ethnicity,* United States, 2011–2020



*All races are non-Hispanic; multiple race indicates two or more races reported for a person but does not include persons of Hispanic or Latino origin.

https://www.cdc.gov/tb/statistics/reports/2020/demographics.htm

TB INCIDENCE RATES BY AGE GROUP, UNITED STATES, 1993–2020



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Risks-Congregate Care

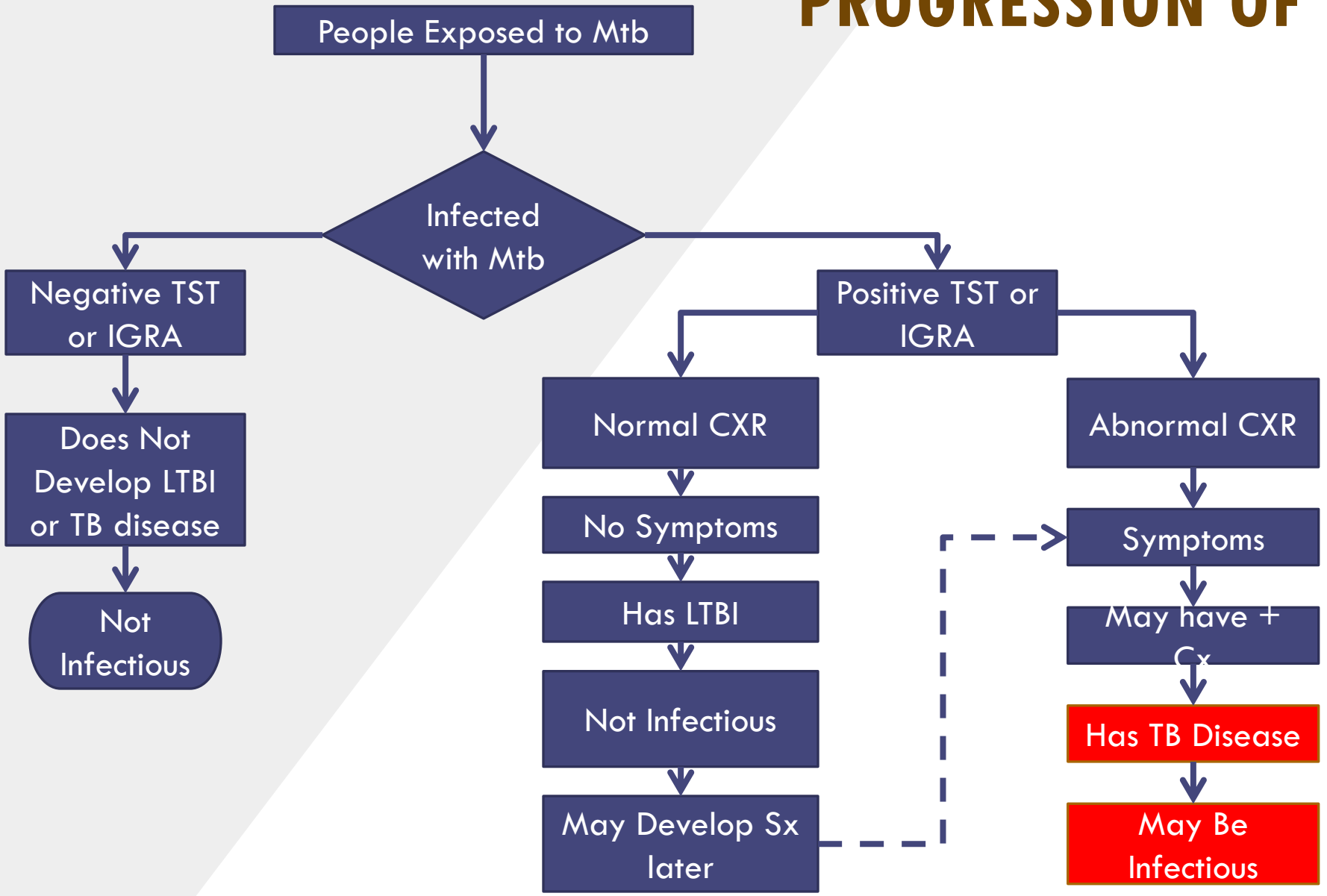
- 2017- 25% of TB cases were in adults aged ≥ 65 years even though this age group only made up about 16% of the population.
  - Exposed to and infected when younger and TB more common
  - A nursing home with concentration of elderly people, who may have weak immune systems, creates a high-risk setting for TB transmission[1]
- Each facility where there is a high risk of TB transmission (i.e., nursing homes) should ensure appropriate measures are in place to protect residents and staff.
  - Testing
  - Treatment

[1]Self-Study Modules on Tuberculosis Modules 2 Epidemiology of Tuberculosis

- ADULTS AGED ≥65 YEARS HAD THE HIGHEST TB INCIDENCE IN 2020-LARGEST % OF DECREASE FROM 2019

- Deaths associated with COVID-19 disproportionately affects older adults-increased mortality among older adults in 2020 might have reduced the number of TB cases diagnosed in this age group

PROGRESSION OF TB



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Infection versus Disease

Latent TB Infection

- Infected with TB but do not have disease
- Usually have a positive skin test
- Negative chest x-ray and a negative sputum test
- Do not feel sick
- Cannot spread TB to others-needs treatment-refer to local health department
- Staff can work

TB Disease

- Symptomatic with unexplained weight loss, loss of appetite, night sweats, fever, chills and fatigue
- Cough for 3 weeks or longer and coughing up blood
- Can spread disease and should not work-until approved to return by local health department

Without treatment approximately 5% of persons will develop disease in the first year or 2 after infection and another 5% sometime late in life (latent TB)

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CDC Recommendations

- U.S. health care personnel should be screened for TB upon hire (i.e., preplacement).
- TB screening is a process that includes:
  - A baseline individual TB risk assessment,
  - TB symptom evaluation,
  - A TB test (e.g., TB blood test or a TB skin test), and
  - Additional evaluation for TB disease as needed.

https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm

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CDC Recommendations

Category	2005 Recommendation	2019 Recommendation
Baseline (preplacement) screening and testing	TB screening of all HCP, including a symptom evaluation and test (IGRA or TST) for those without documented prior TB disease or LTBI.	TB screening of all HCP, including a symptom evaluation and test (IGRA or TST) for those without documented prior TB disease or LTBI **(unchanged)**; individual TB risk assessment **(new)**.
Postexposure screening and testing	Symptom evaluation for all HCP when an exposure is recognized. For HCP with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8–10 weeks after the last exposure.	Symptom evaluation for all HCP when an exposure is recognized. For HCP with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8–10 weeks after the last exposure **(unchanged)**.
Serial screening and testing for HCP without LTBI	According to health care facility and setting risk assessment. Not recommended for HCP working in low-risk health care settings. Recommended for HCP working in medium-risk health care settings and settings with potential ongoing transmission.	Not routinely recommended **(new)**; can consider for selected HCP groups **(unchanged)**; recommend annual TB education for all HCP **(unchanged)**, including information about TB exposure risks for all HCP **(new emphasis)**.
Evaluation and treatment of positive test	Referral to determine whether LTBI treatment is indicated.	Treatment is encouraged for all HCP with untreated LTBI, unless medically contraindicated **(new)**.

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CDC Recommendations

BOX. Indicators of risk* for tuberculosis (TB) at baseline health care personnel assessment†

Return

Health care personnel should be considered to be at increased risk for TB if they answer "yes" to any of the following statements.

1. Temporary or permanent residence (for ≥1 month) in a country with a high TB rate (i.e., any country other than Australia, Canada, New Zealand, the United States, and those in western or northern Europe)

Or

2. Current or planned immunosuppression, including human immunodeficiency virus infection, receipt of an organ transplant, treatment with a TNF-alpha antagonist (e.g., infliximab, etanercept, or other), chronic steroids (equivalent of prednisone ≥15 mg/day for ≥1 month), or other immunosuppressive medication

Or

3. Close contact with someone who has had infectious TB disease since the last TB test

Abbreviation: TNF = tumor necrosis factor.

* Individual risk assessment information can be useful in interpreting TB test results. (Lewinsohn DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children. Clin Infec Dis 2017;64:111–5).
https://academic.oup.com/cid/article/64/2/111/2811357

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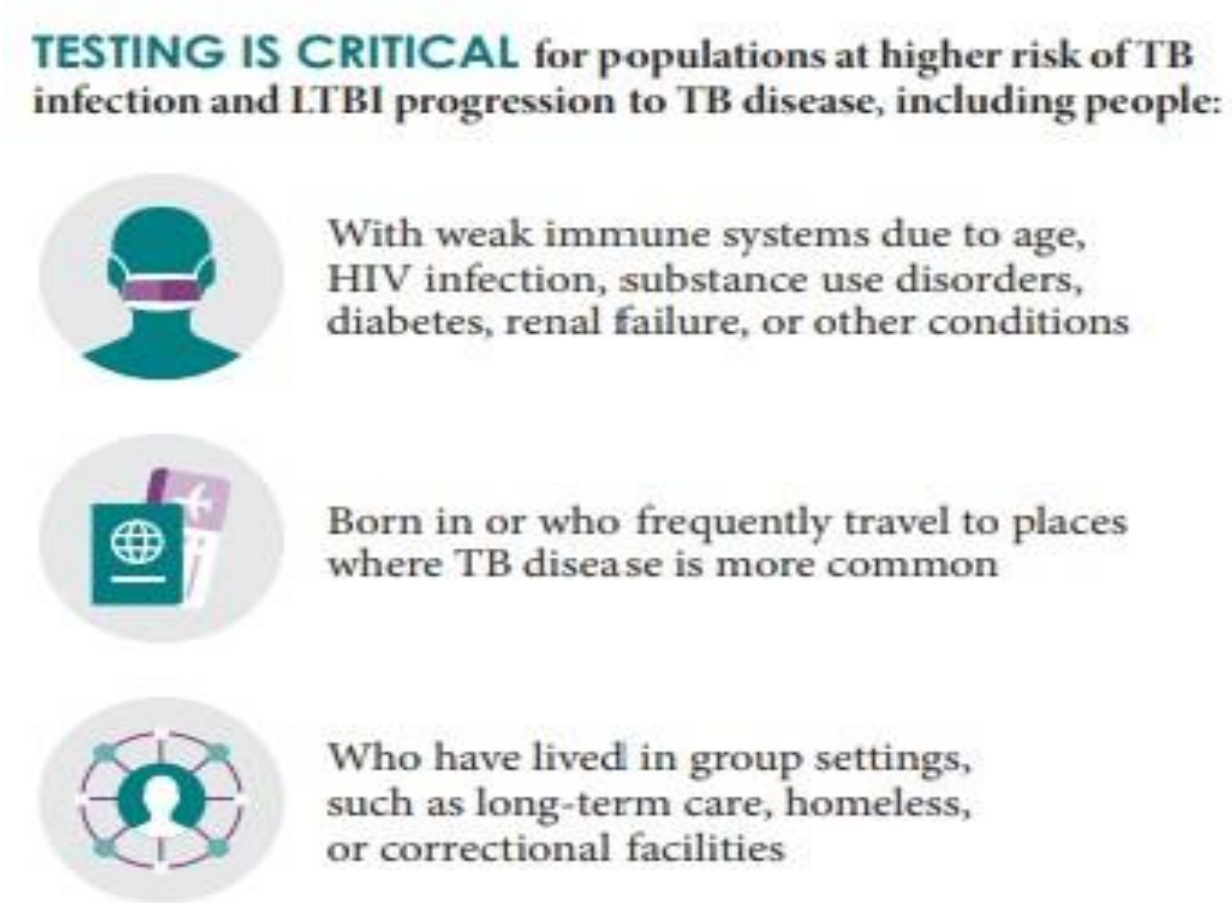
Testing

Easy to administer
Minimal discomfort
Reliable (consistent)
Valid
Inexpensive



https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/TB-in-the-US-508.pdf

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Screening Test

- Simplest form screening test has only two outcomes- positive or negative
- Generally performed on defined asymptomatic population to assess likely of having infection
- Most do not diagnose the illness-rather identify those who are positive and need additional **diagnostic testing**
- Major objective is to reduce morbidity or mortality from the disease by early detection-reduces risk of transmission and treatment may be more successful.

Disease or Condition	**Screening Tests**	**Diagnostic test/Gold Standard**
TB	Tuberculin Skin Test (TST) Interferon Gamma Release Assays (IGRA)	Chest x-ray and a sputum sample, detection of *Mycobacterium tuberculosis* (MTB)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389712/

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Available Methods of Testing-IGRAs

- Interferon-Gamma Release Assays (IGRAs) are blood test that help diagnosis *M. tuberculosis* infection
- Two test available:
  - QuantiFERON®-TB Gold Plus (QFT-Plus)
  - T-SPOT®.*TB* test (T-SPOT)
- Requires drawing a sample of blood and arrange for delivery to laboratory
- Laboratory conducting analysis of the IGRA will submit a report of the results
- If results positive likely person has *M. tuberculosis* infection
- If results negative likely person does not have *M. tuberculosis* infection

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Interferon-Gamma Release Assay (IGRAs)

- Recommended for
  - Groups of people who might be less likely to return for TST reading and interpretation
  - People who have received BCG vaccine
  - People who are likely to be infected with M. Tuberculosis and at low to intermediate risk of progression
- Advantages:
  - Requires a single visit to conduct the test
  - Results can be available within 24 hours
  - Does not cause a booster phenomenon which can happen with repeat TSTs
  - Previous BCG vaccination does not cause a false- positive result
- Disadvantages:
  - Samples must be processed with 8-32 hours after collection
  - Tests may be expensive

Figure 3.1 Health care worker collecting a blood sample for an IGRA.

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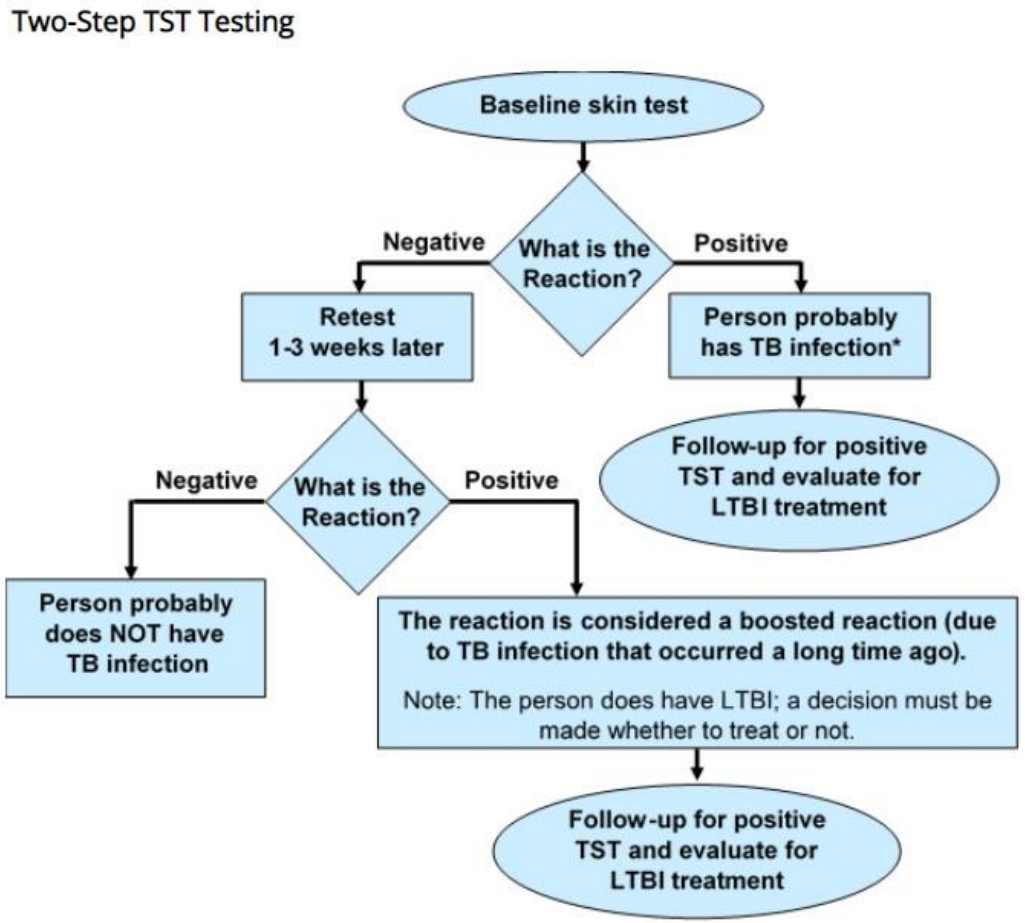
Available Methods of Testing-Tuberculin Skin Test (TST)

- Recommended for ages 5 and under
- Requires a two-step process
- Skill in administering
- Skill in reading/ interpretation
- Interpretation depends on (HCWs) the risk of exposure to TB at work and individual risk factors for TB
- May have a false-positive reaction
- May have a false-negative reaction



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Tuberculin Skin Test

- Administration:
  - The TB skin test is performed by injecting a small amount of fluid (called tuberculin) into the skin on the lower part of the arm.
  - A person given the tuberculin skin test must return within 48 to 72 hours to have a trained health care worker look for a reaction on the arm.
  - The result depends on the size of the raised, hard area or swelling.

Figure 3.2 Administering the Mantoux TST.

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Tuberculin Skin Testing

- CDC recommends a trained healthcare personnel read and interpret the reaction to the TST
- Some states have requirements for HCP to complete a training course to validate competency
- Interpretation is also based on the size of the induration and the person's risk factors for TB
  - Person with HIV an induration of 5 millimeters or more is considered positive
  - Persons with other risk factors (born outside the U.S) an induration of 10 millimeters or more is considered positive
  - Persons with no risk factors an induration of 15 millimeters or more is considered positive

Figure 3.3 Only the induration is being measured. This is CORRECT.

Figure 3.4 The erythema is being measured. This is INCORRECT.

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Booster Phenomenon

- Can affect the accuracy of the baseline TST
- Occurs mainly in older adults
- 2-step TST is recommended for HCP at time of hire with some exceptions:
  - Have had a previous documented negative 2-step
  - Have had a single documented negative TST within past 12 months
  - A single baseline required in these situations
- IGRAs do not boost subsequent test results-no 2-step process necessary

Criteria	Test Type	
	IGRAs	TST
Easy to administer	Requires a single blood draw and deliver to lab	Requires administering a skin test with knowledge and skill, for intradermal (between the skin layers) placement of the needle
Minimal Discomfort	Puncture of the skin, into the vein	Puncture between the skin layers
Reliable	Test results are read as positive, negative, indeterminate by the laboratory	Test results are read as positive or negative based on a visual reading and employee's underlying risk factors. **Reliable administration and reading of the tuberculin skin test involves standardization of procedures, training, supervision, and practice**[1]
Valid	Lab reports findings to the facility.	Trained competent HCP must read and interpret the findings-based on a determination of induration and underlying risk factors
Inexpensive	Test cost more but no other associated cost	Test cost less but facilities must administer the test-ensure employee return in 48-72 hours to have the test interpretated. If they do not return the test should be repeated
Timely results	Can be available in 24 hours	At a minimum 48-72 hours

[1]https://www.cdc.gov/tb/publications/posters/images/mantoux_wallchart.pdf

Table 3.4 – Advantages of using an IGRA compared to using the TST.

IGRA	TST
Requires one patient visit to conduct the test	Requires at least two patient visits to conduct the test
Results can be available in 24 hours	Results are available 48 to 72 hours later
Does not cause booster phenomenon	Can cause booster phenomenon
Previous BCG vaccination does not cause false-positive result	Previous BCG vaccination may cause false-positive result

https://www.cdc.gov/tb/education/ssmodules/pdfs/Module3.pdf

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Recommendations from the American Thoracic Society/Infectious Disease Society of America/CDC

- Preform an IGRA rather than a TST in individual 5 years or older who meet the following criteria:
  - Are likely to be infected with *Mtb*
  - Have a low or intermediate risk of disease progression
  - Testing for LTBI is warranted
  - History of BCG vaccination
  - Person unlikely to return for TST to be read (at the appropriate time)

Remarks:

A TST is an acceptable alternative, especially in situations where an IGRA is not available, too costly, or too burdensome.

FINDING TB IN THE CROWD

Recommendations from the American Thoracic Society/Infectious Disease Society of America/CDC

- Suggest performing a TST rather than an IGRA in healthy children < 5 years of age for whom it has been decided that diagnostic testing for LTBI is warranted.

Remarks:

In situations in which an IGRA is deemed the preferred diagnostic test, some experts are willing to use IGRAs in children over 3 years of age.

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Summary

- All facilities, including nursing homes, should have a Tuberculosis Control Policy in place
- All HCP at time of hire should be:
  - Screened with an individual risk assessment questionnaire
  - Screened for any signs and or symptoms of TB
  - Screened and tested for TB infection
- All HCP should receive TB education annually
- Facilities should adhere to all state and federal regulations governing control and reporting of ***Mycobacterium Tuberculosis***

CDC IS COMMITTED TO MAKING TB A DISEASE OF THE PAST. ELIMINATING TB WOULD PROTECT THE HEALTH OF AMERICANS AND REDUCE COSTS TO THE HEALTH CARE SYSTEM. REACHING THE GOAL OF ELIMINATION IN THE UNITED STATES, DEFINED AS LESS THAN ONE CASE PER ONE MILLION PEOPLE, REQUIRES A DUAL APPROACH OF MAINTAINING AND STRENGTHENING CURRENT TB CONTROL PRIORITIES WHILE INCREASING EFFORTS *TO TEST AND TREAT LATENT TB INFECTION AMONG POPULATIONS AT RISK*.

https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/TB-in-the-US-508.pdf