EVALUATING THE USE OF AN EVIDENCE-BASED TEST FOR TUBERCULOSIS SCREENING

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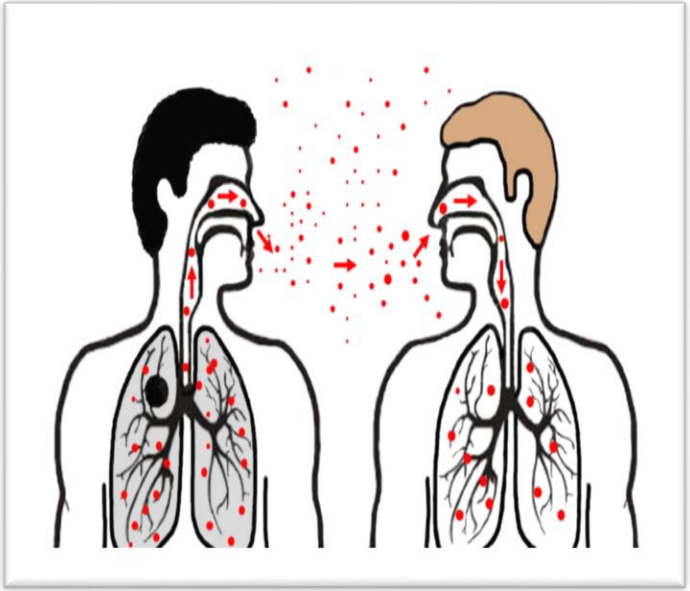
Tuberculosis (TB)

- Caused by *Mycobacterium tuberculosis*
- TB is spread via droplet nuclei
- The best way to stop transmission is to:
  - Isolate infectious persons
  - Provide effective treatment to infectious persons as soon as possible



Adopted from http://www.cdc.gov/tb/publications/slidesets/corecurr/default.htm

Latent TB Infection vs. TB Disease

Latent TB Infection (LTBI)	TB Disease (in the lungs)
Inactive, contained tubercle bacilli in the body	**Active**, multiplying tubercle bacilli in the body
TST or blood test results usually positive	TST or blood test results usually positive
Chest x-ray usually **normal**	Chest x-ray usually **abnormal**
Sputum smears and cultures **negative**	Sputum smears and cultures may be **positive**
No symptoms	**Symptoms** such as cough, fever, weight loss
Not infectious	**Often infectious** before treatment
Not a case of TB	**A case** of TB

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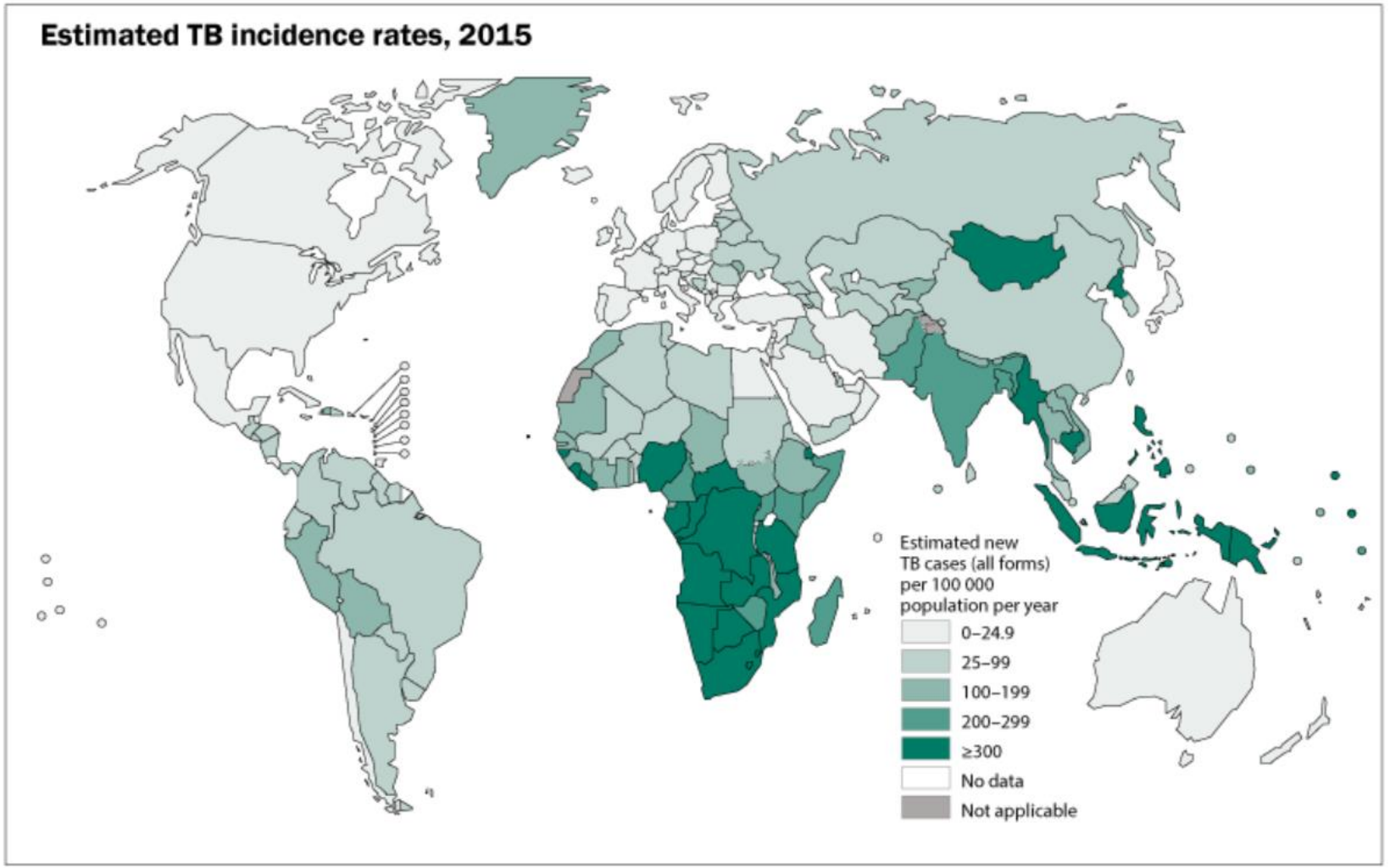
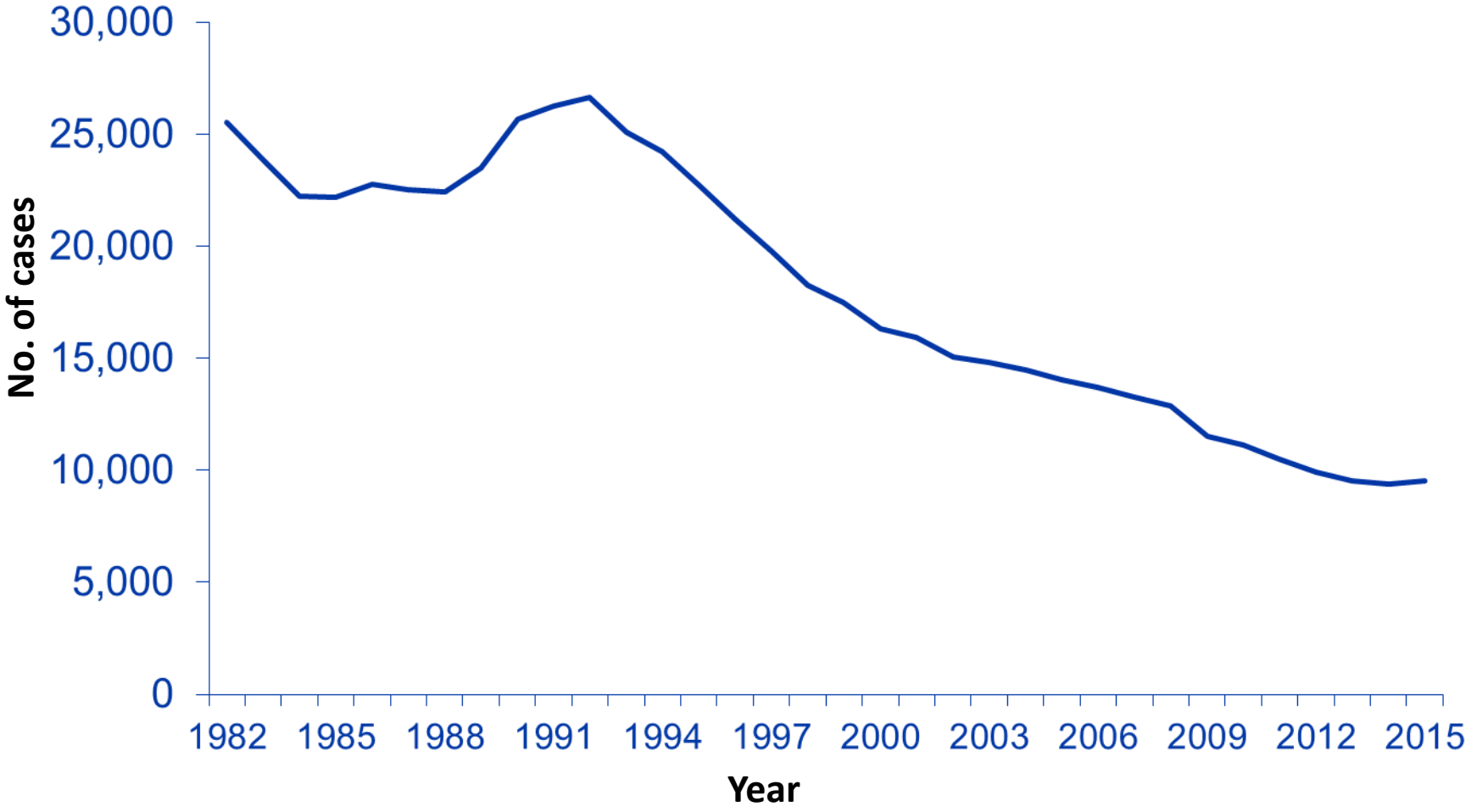


The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: *Global Tuberculosis Report 2016*. WHO, 2016.

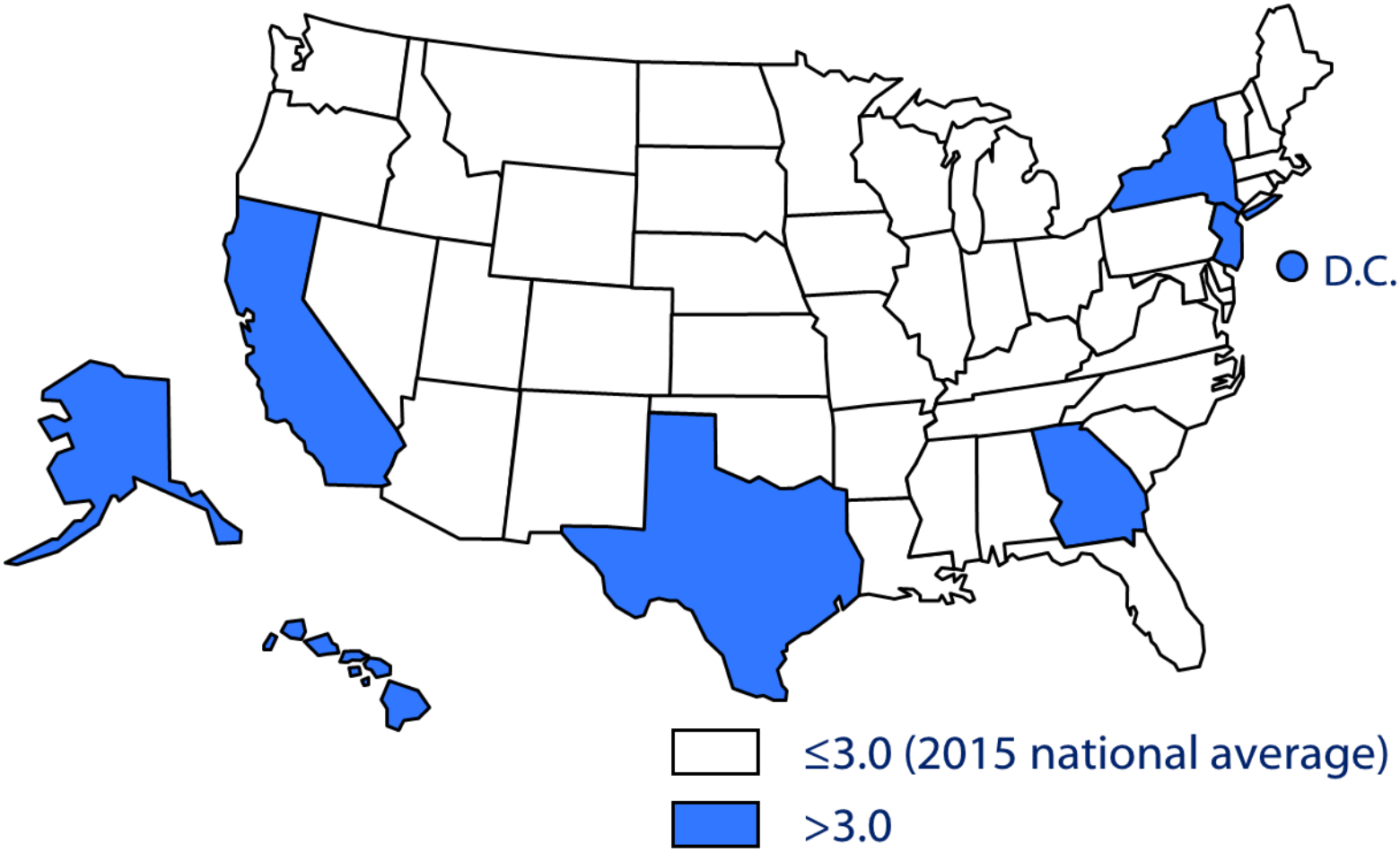
World Health Organization

Reported Tuberculosis (TB) Cases United States, 1982–2015*



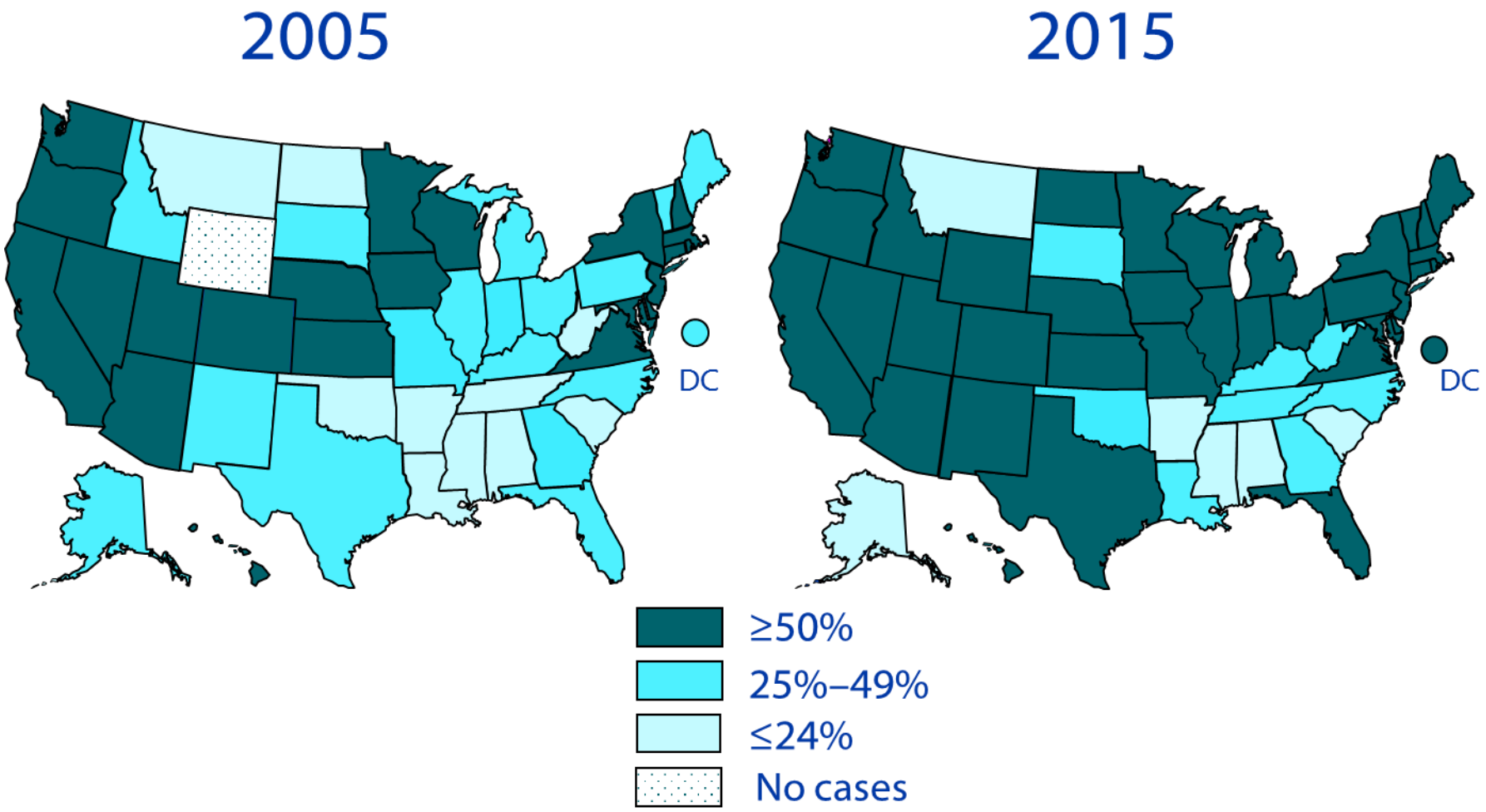
*As of June 9, 2016. Centers for Disease Control

TB Case Rates,* United States, 2015



*Cases per 100,000 population; as of June 9, 2016. Centers for Disease Control

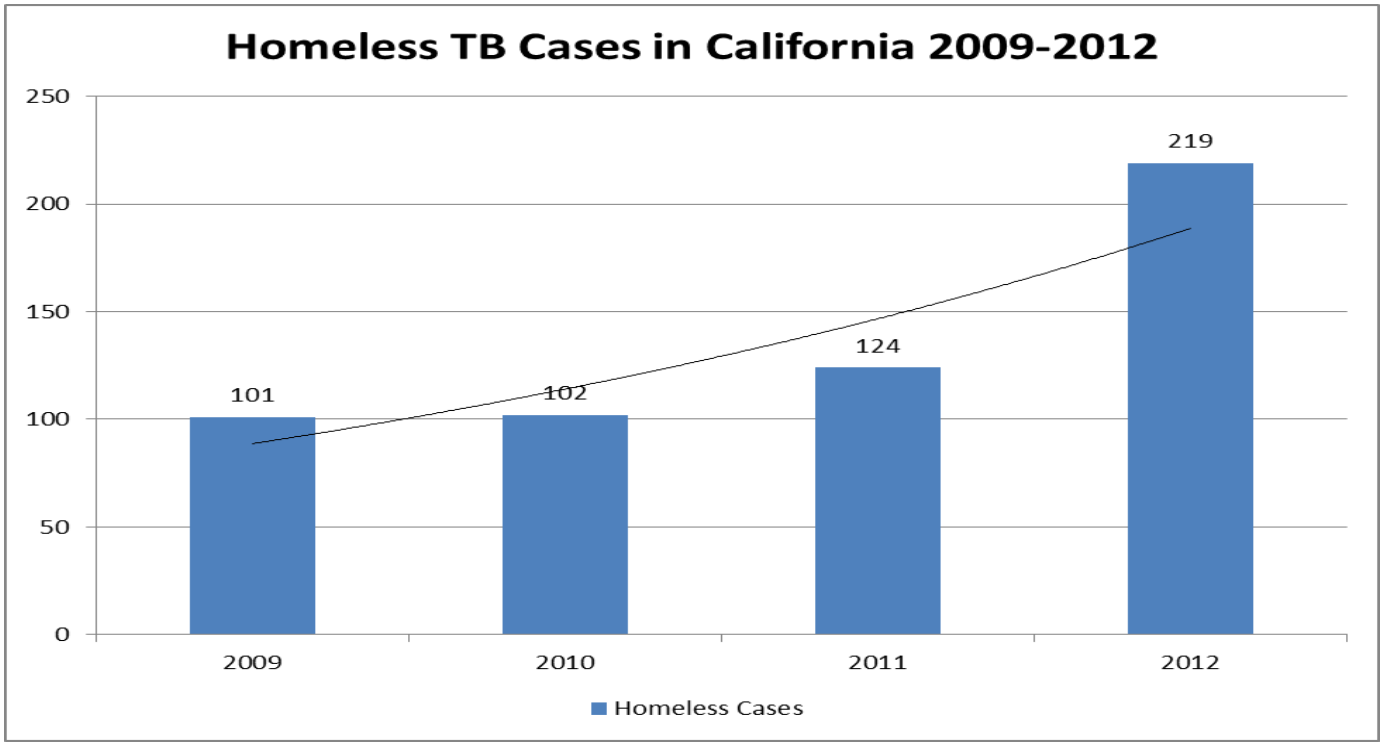
Percentage of Foreign-Born Persons Among TB Cases, United States,* 2005 and 2015



* As of June 9, 2016. Centers for Disease Control

Assessment

- In 2012, California reported the highest number of tuberculosis (TB) cases in the United States
  - Largest groups are Foreign born (79%) and homeless (5.9%)

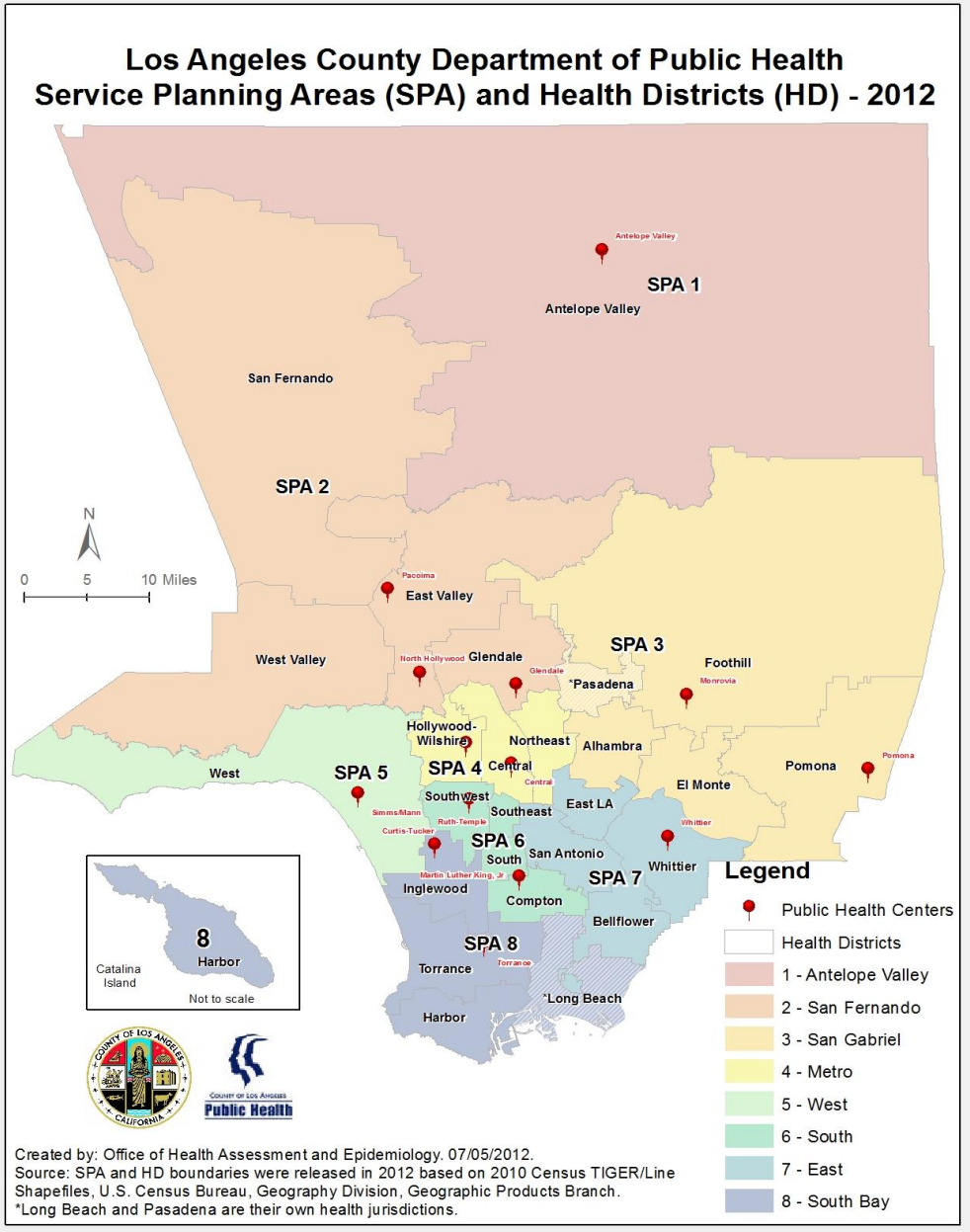


- In December 2012, CDC identified a TB homeless outbreak in Los Angeles County

Adopted from http://www.cdph.ca.gov/data/statistics/Pages/TuberculosisDiseaseData.aspx

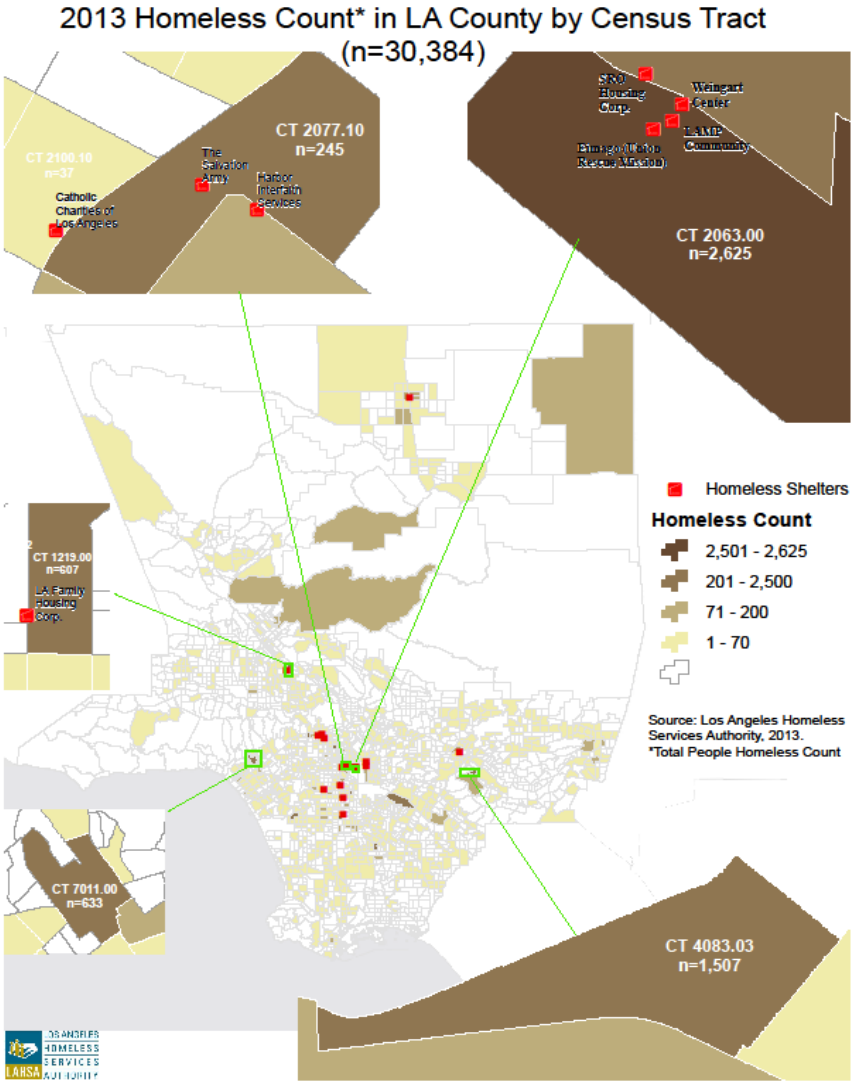
Los Angeles County

- 10 million residents
- 88 cities
- 4,000 square miles
- 14 Public Health Centers
- ~165 Public Health Nurses (generalist)
- Investigate over 3,000 TB suspects



Homeless in Los Angeles County

- 39,463 (2013) homeless
- L.A. second to New York City in homeless
- Nationwide decline of homeless, but an increase in LA County



Assessment

Current practice in LA County 2012:

- Using TST as the only method for screening for TB
- Since 1907 Tuberculin Skin Test (TST) has been the test of choice for TB screening
- New technology offered an evidence based practice alternative to TST called IGRA

Screening for TB: Tuberculin Skin Test

Of this first class, Sister M. Euphrasia, C.S.A. went on to become principal of the nursing school from 1915-23. Photographer: Unknown

1907

Tuberculin Skin Test (TST)

- Advantages
  - Using it since 1907
  - Intradermal
  - Low cost
- Disadvantages
  - Return visit for reading
  - Lacks accuracy
  - Interacts with BCG vaccine an other mycobacterium (that are not TB)

Technology Advancing Medicine

- In 2001 a new blood test was developed to screen for TB

Interferon-Gamma Release Assay

(IGRA)

Blood test that is specific to Mycobacterium Tuberculosis

2 vendors:

Quantiferon (QFT) Gold

TSPOT

Screening for TB: Interferon-Gamma Release Assay

2001

IGRA Test

- Advantages
  - No return visit necessary
  - Accuracy
  - Does not interact with BCG vaccine or other mycobacterium
  - Lower cost in the long run
- Disadvantages
  - Higher cost for test (lower cost on the long run!)
  - Venipuncture
  - Incubation or laboratory processing is necessary

Evidence Based

	Sensitivity		
	QFT	TSPOT	TST
Schluger & Burzynski (2010)	76%	88-90%	71%
Menzies, Madhukar & Comstock (2007)	76%	88%	63%
Sadatsafavi et al. (2010)	64.2%	50%	70.9%

Sensitivity : True Positive
Ability to yield a positive result when person actually has that condition

Specificity : True Negative
Ability to yield a negative result when the person does not have that condition

	Specificity		
	QFT	TSPOT	TST
Schluger & Burzynski (2010)	97%	88-92%	66%
Menzies, Madhukar & Comstock (2007)	97.7%	92.5%	66%
Sadatsafavi et al. (2010)	99.6%	90.6%	68.3%
Diel et al. (2011)	100%	98%	88.7% (55-95%)

CDC Recommendations

Using an IGRA in the following populations:

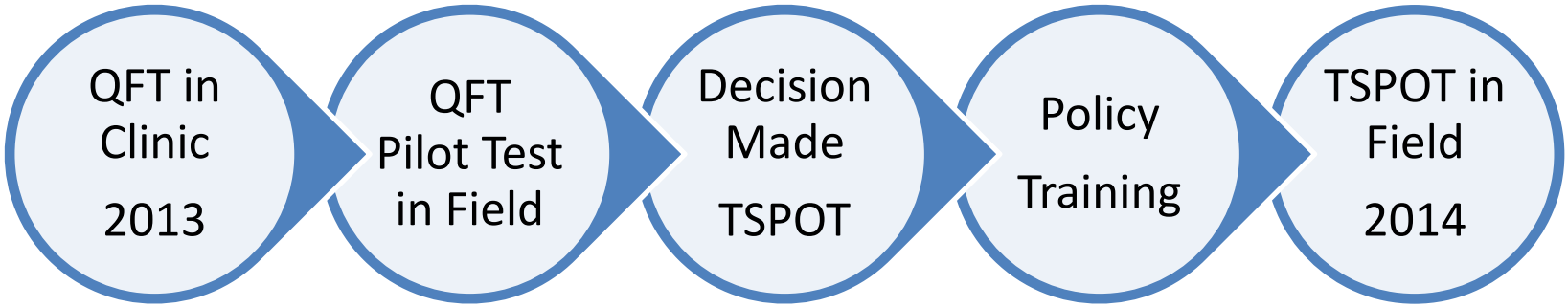
- Persons who have received BCG (either as a vaccine or for cancer therapy); and
- Persons from groups that historically have poor rates of return for TST reading.
- For those 5 years old or older

GOAL: Screen contacts, homeless and foreign born with IGRA

Plan

- February 2013 Policy Implementation to use IGRA in the *clinics* only using QFT
  - Field Testing for Contact Investigation
    - Integral part of stopping the spread of TB
    - Key role of public health departments
    - Occur in the field setting (home, workplace, schools, etc.)
- In February 2014 expanded the policy to include IGRA testing in the *field* using TSPOT
- ***Evaluate***

Implementation



Evaluation

1. Compared TB Control data for
   - Contact investigation screening completion rates
   - Latent TB infection rate

2. Cost Analysis
   - Cost
   - Cost impact analysis

3. Track usage of IGRA in the field

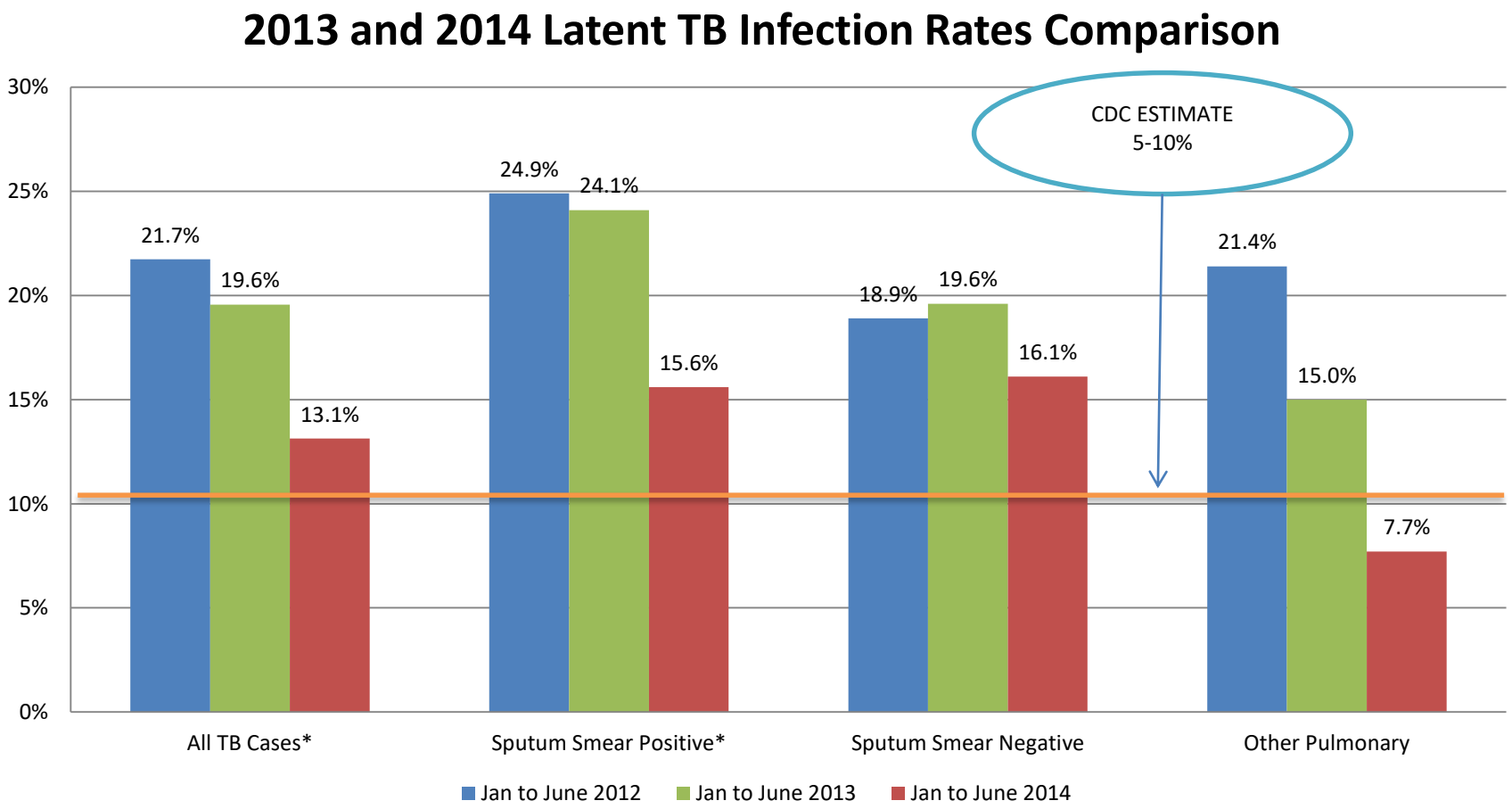
Results: Screening Completion

Screening completion includes:

- Negative TST or IGRA
- Positive TST or IGRA and Negative CXR

	Number of TB Cases Investigated	Number of Contacts	Number of Contacts Screened	Percent completed Screening	LTBI Positivity Rate
Jan to June 2013	178	3223	3146	97.6%	19.6%
Jan to June 2014	143	1383	1337	96.6%	13.1%

Results: Latent TB Infection Rate



X^2 (1,*N*= 3731) = 31.85, *p*= .0000

Results: Cost-Analysis

LTBI Screening Cost in the field

ITEM	TST	IGRA
Test	0.28	46.50
PHN Time 15 min visit 1	13.28	13.28
PHN Time 15 min visit 2	13.28	0.00
Screening Total	$26.84	$59.78

LTBI Treatment Cost for 9 month course

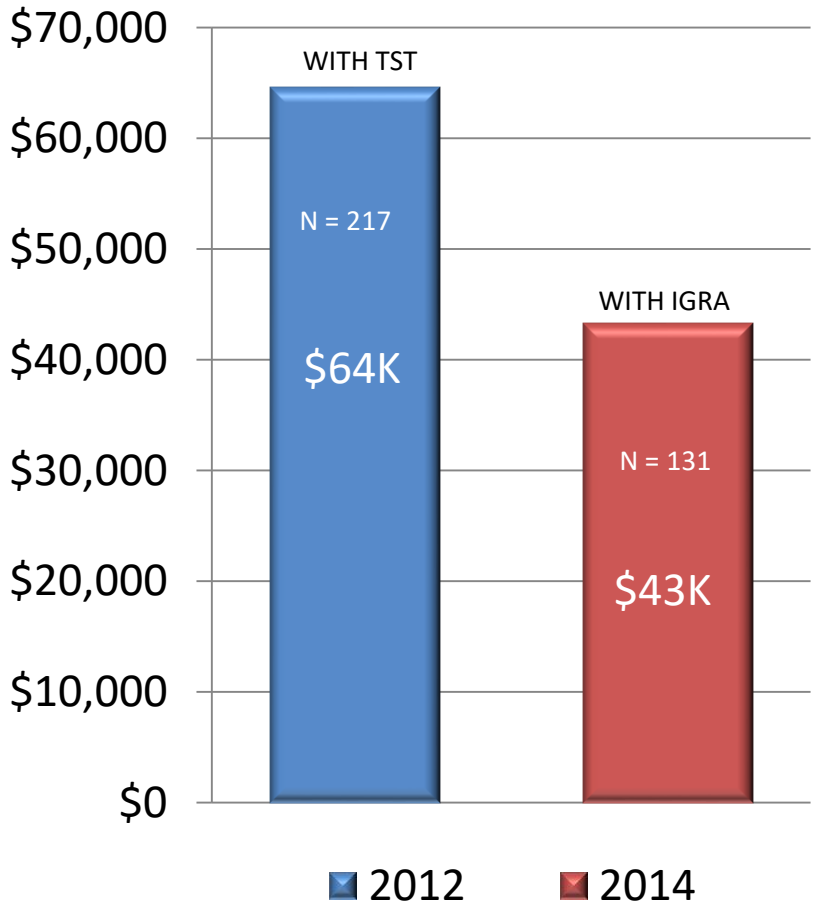
Xray 1 view	5.60
Radiology Technician 15 min	7.32
Radiologist MD 15 min	56.25
Xray Total	$69.17
INH 300mg x9 mos	18.90
B6 50mg x9 mos	2.70
Prescription Total	$21.60
Baseline Liver Function test x1	7.50
Follow up AST/ALT x9	2.20
RN blood draw 10 min	8.10
MD visit 15 min x1	24.41
RN visit 15 min x9	109.37
Clerk 10 min x9	28.53
Clinic Visits for 9 months Total	$180.11
TOTAL COSTS FOR 9 MOS LTBI TX	**$270.88**

Results: Cost Impact Analysis

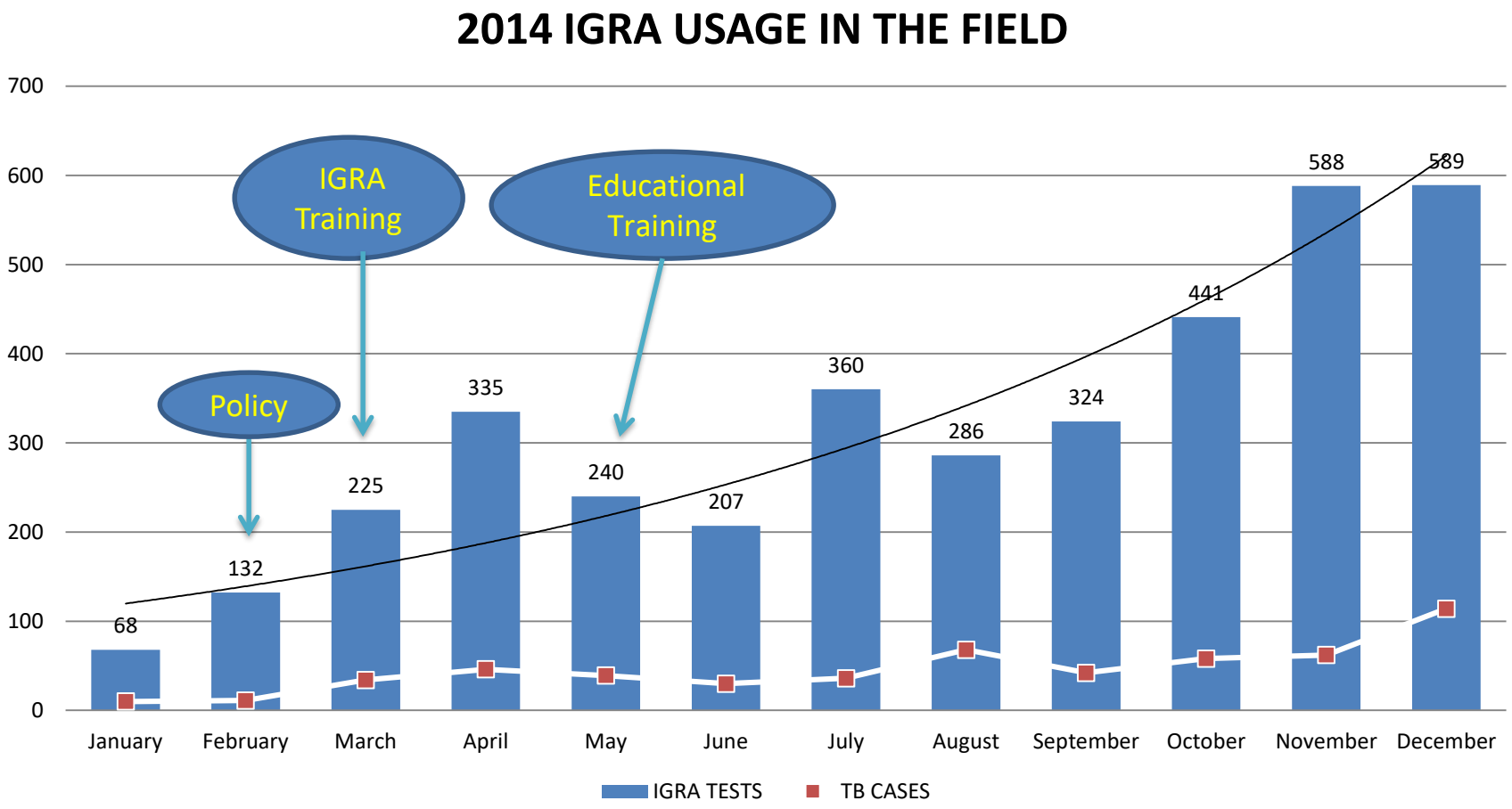
	TST	IGRA
Test	26.84	59.78
9 month LTBI Treatment	270.88	270.88
Screening Total	**$297.72**	**$330.76**

For 1,000 contacts screened, there is an estimated cost savings of $21,288.78.

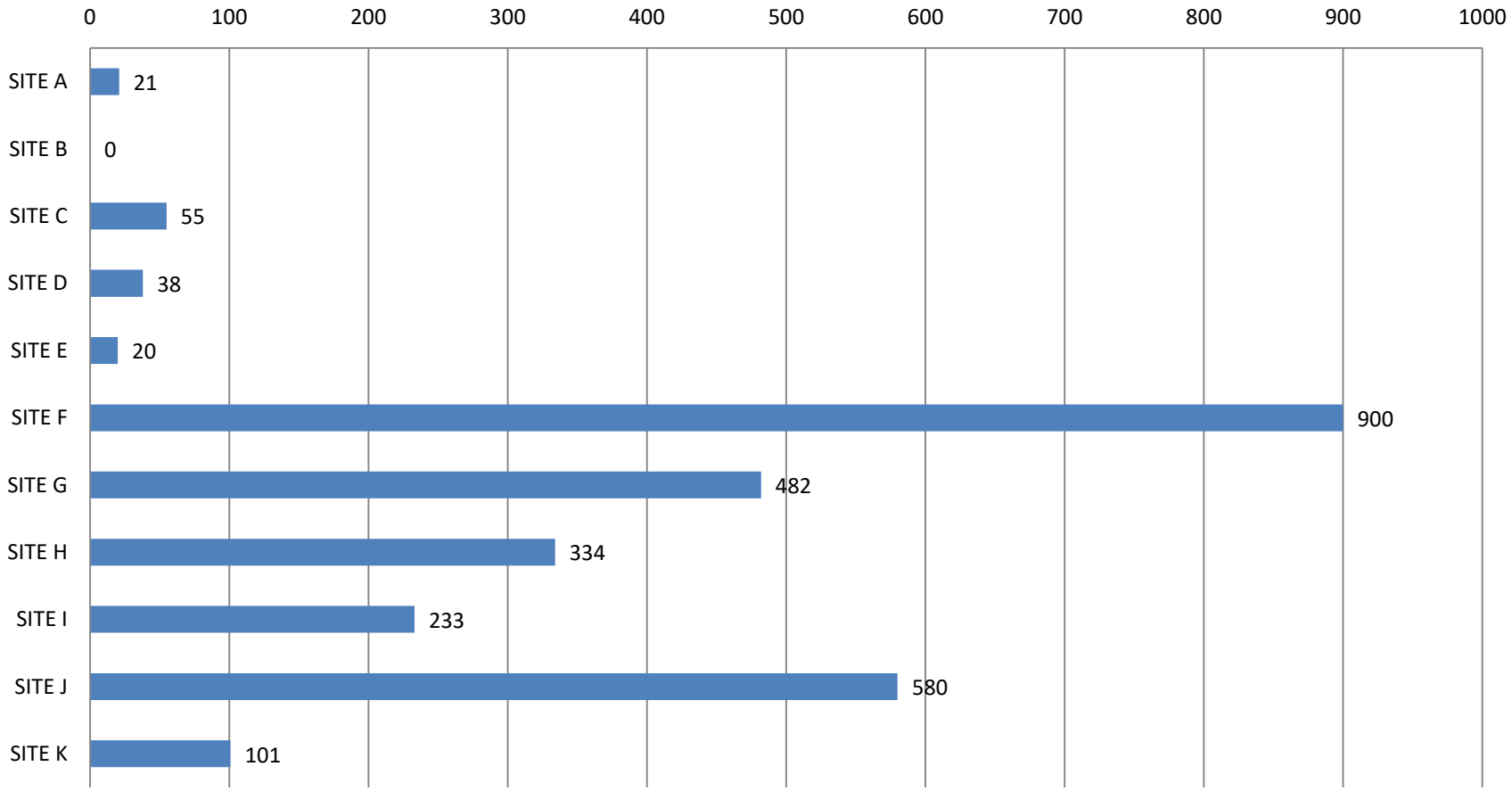
1,000 Contacts Screened	TST	IGRA
LTBI RATE	21.7%	13.1%
# Estimated Contacts with LTBI	217	131



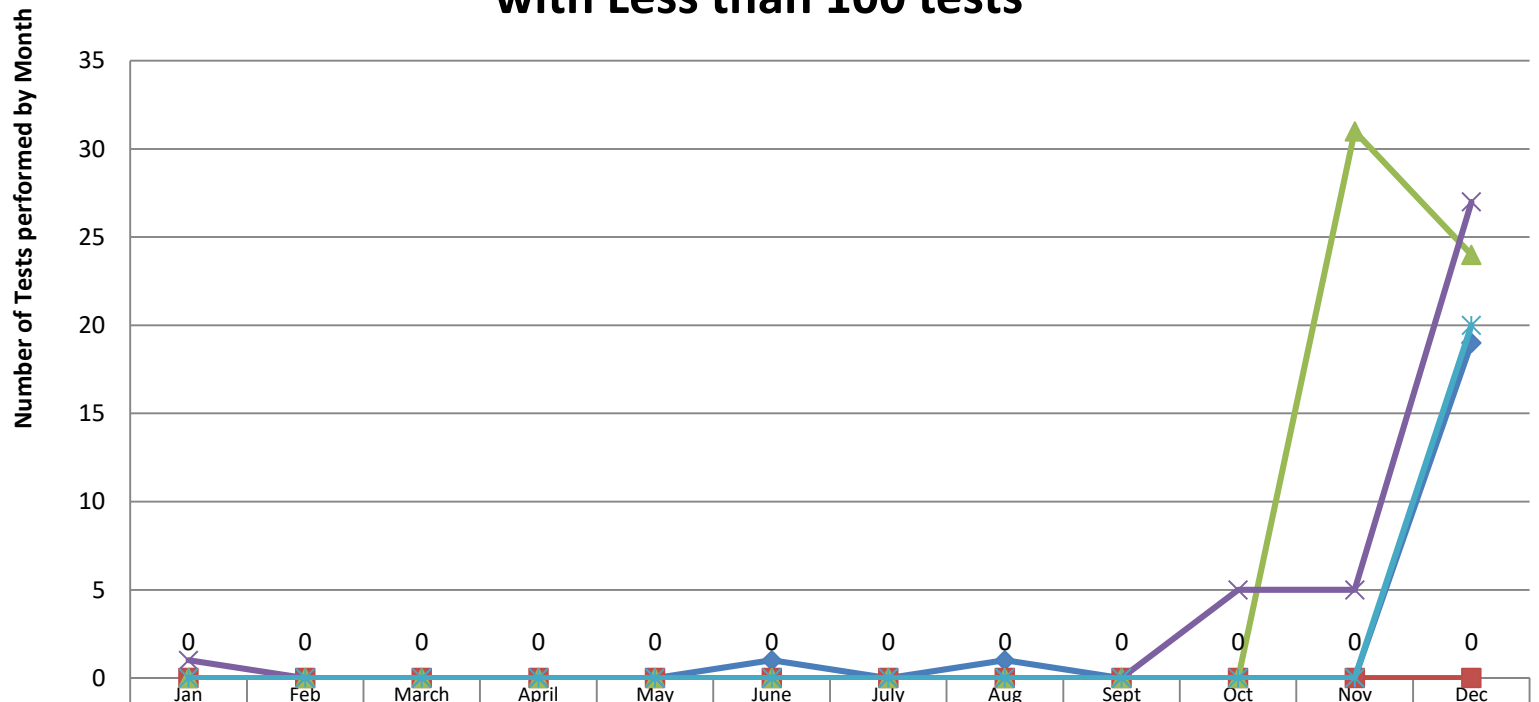
Results: Usage of IGRA



IGRA USAGE IN FIELD SETTING BY SITE JAN-DEC 2014

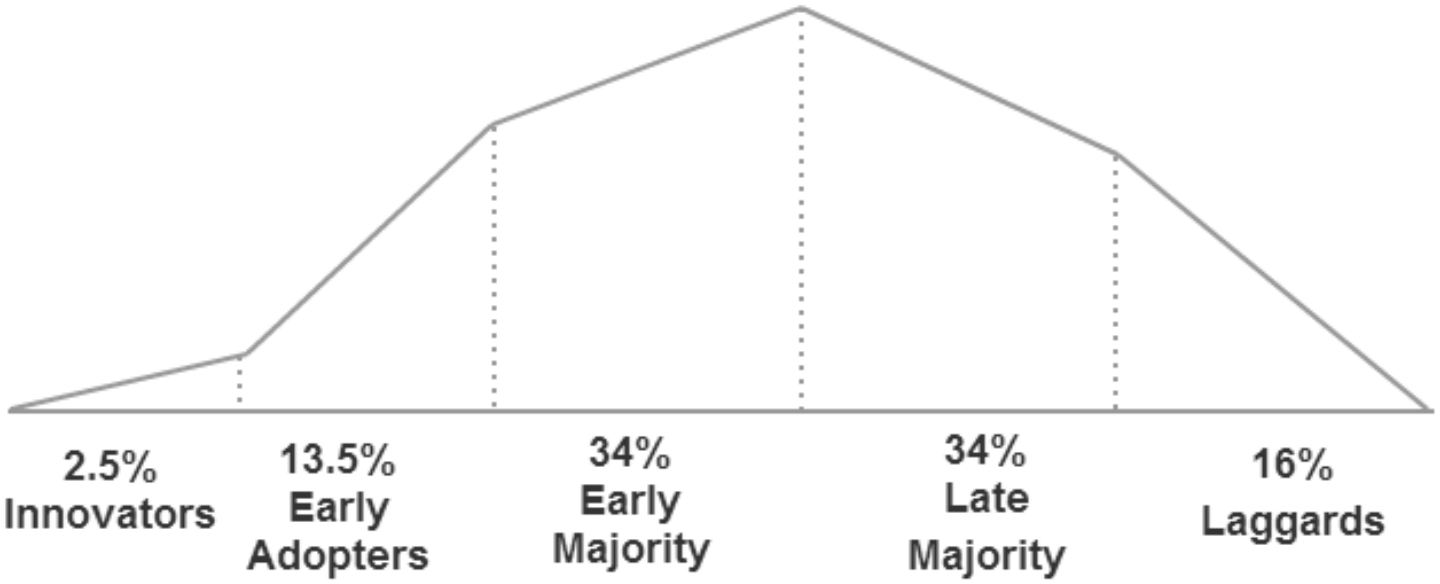


2014 IGRA Usage in the Field by Sites with Less than 100 tests

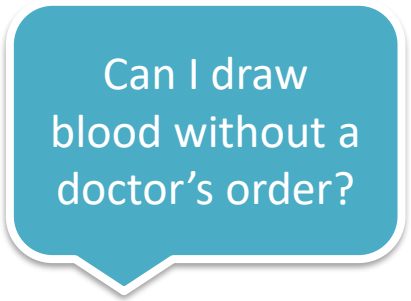


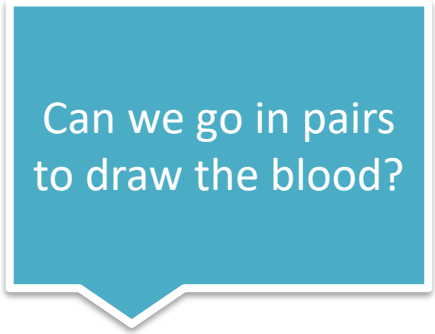
	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
SITE A	0	0	0	0	0	1	0	1	0	0	0	19
SITE B	0	0	0	0	0	0	0	0	0	0	0	0
SITE C	0	0	0	0	0	0	0	0	0	0	31	24
SITE D	1	0	0	0	0	0	0	0	0	5	5	27
SITE E	0	0	0	0	0	0	0	0	0	0	0	20

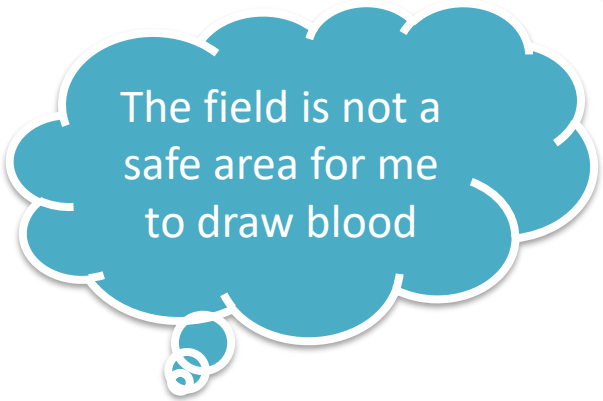
Innovation Adoption Lifecycle

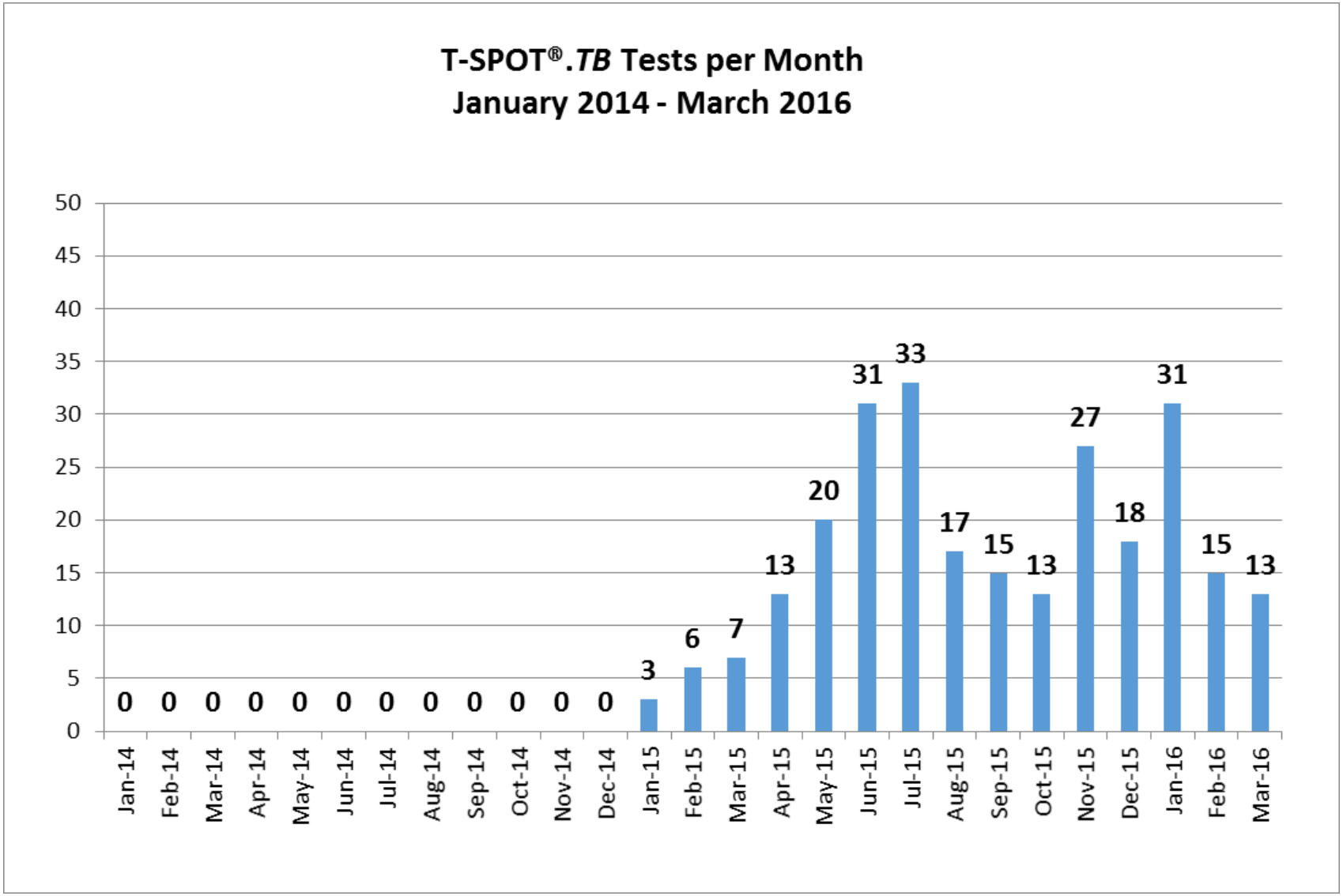


BARRIERS TO IMPLEMENTATION

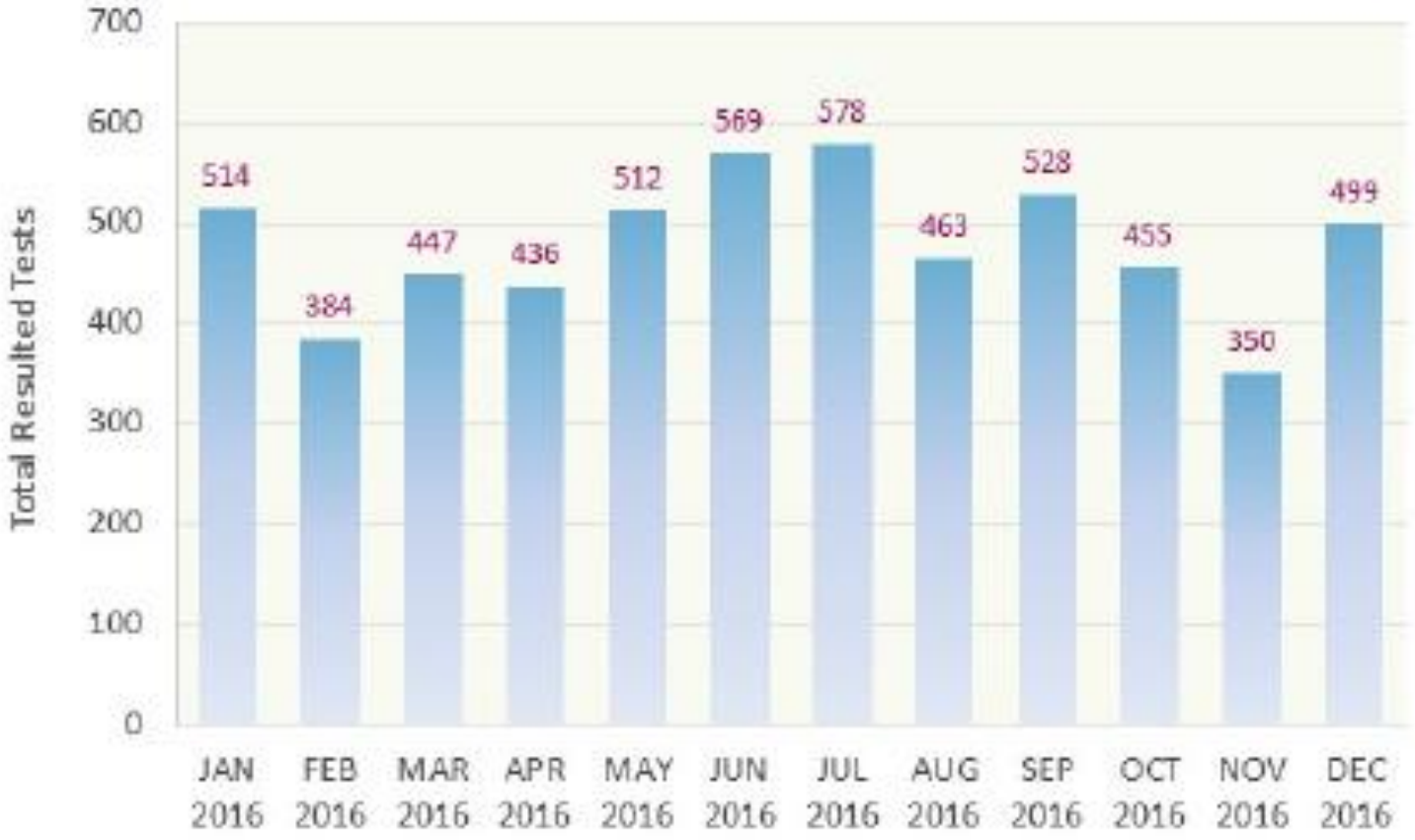







T-SPOT®.TB Tests per Month
January 2014 - March 2016
50
45
40
35
30
25
20
15
10
5
0
0 0 0 0 0 0 0 0 0 0 0 0 3 6 7 13 20 31 33 17 15 13 27 18 31 15 13
Jan-14
Feb-14
Mar-14
Apr-14
May-14
Jun-14
Jul-14
Aug-14
Sep-14
Oct-14
Nov-14
Dec-14
Jan-15
Feb-15
Mar-15
Apr-15
May-15
Jun-15
Jul-15
Aug-15
Sep-15
Oct-15
Nov-15
Dec-15
Jan-16
Feb-16
Mar-16

The T-SPOT®.*TB* Test Results per Month
January 2016 – December 2016



Benefits of IGRA

- Less false positives!!

- Reduce unnecessary exposure to patient:
  - Chest x-ray
  - LTBI treatment with INH

- More accurate results!!

Lesson Learned

- **Change is not easy**
- A policy does not mean nurses will change their practices
- Training does not mean nurses will change their practices
- Looking at overall data doesn’t mean everyone has adopted the change
- Cost-analysis are important in the evaluation of changes in nursing practice
- The outcomes of the patient should drive change

Screen for TB with an IGRA

County of Los Angeles Public Health