

Tuberculosis Exposures at Santa Clara Valley Medical Center

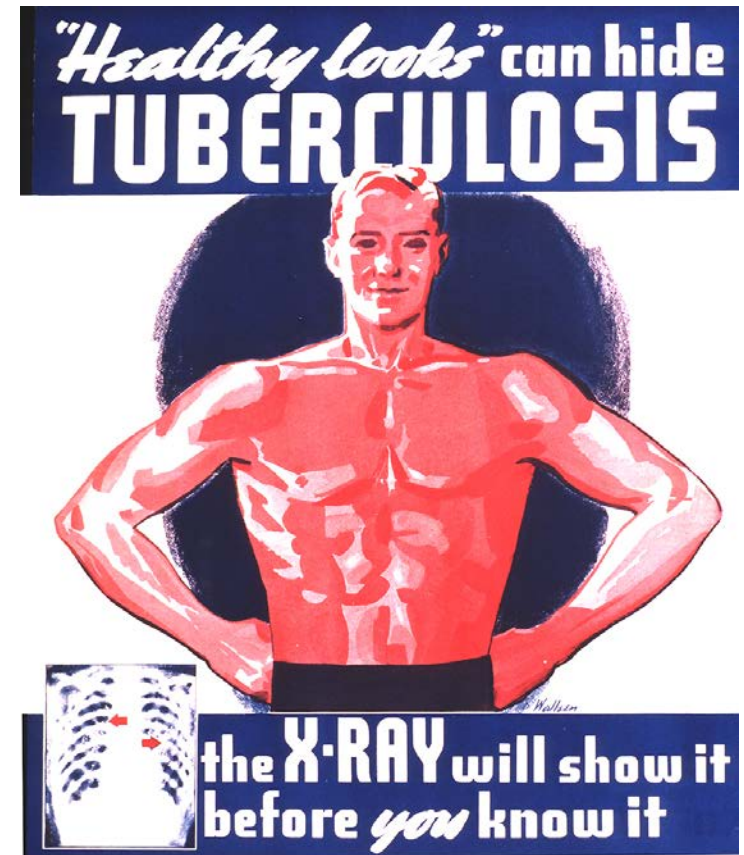


May 11, 2016

Objectives

- ❖ To provide basic definitions of tuberculosis including differentiation between active tuberculosis disease and latent tuberculosis infection.
- ❖ To provide the framework for Santa Clara Valley Medical Center's response to two tuberculosis exposures:
 1. An employee in the Mother Infant Care Center
 2. A patient in the Infusion Oncology Center

Background Information on Tuberculosis



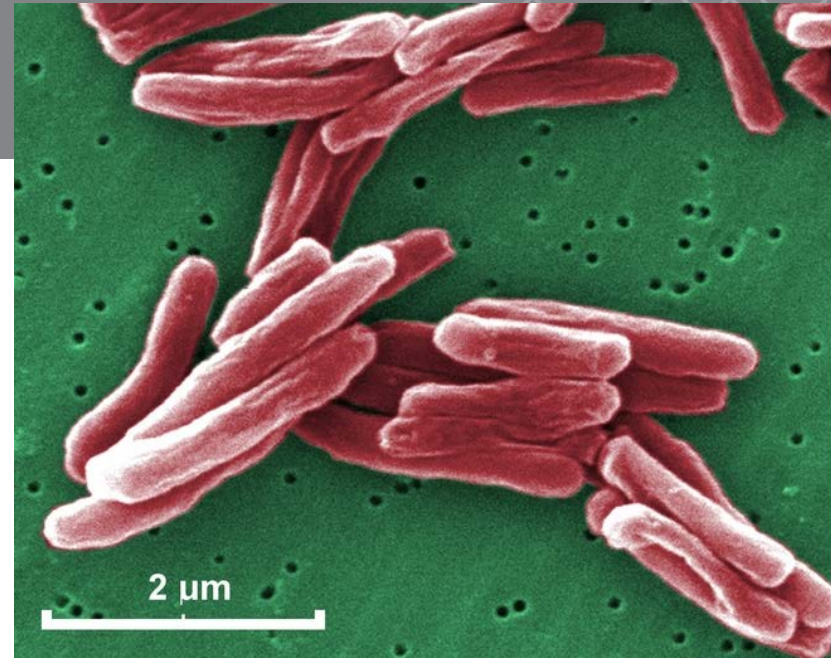
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Better Health for All

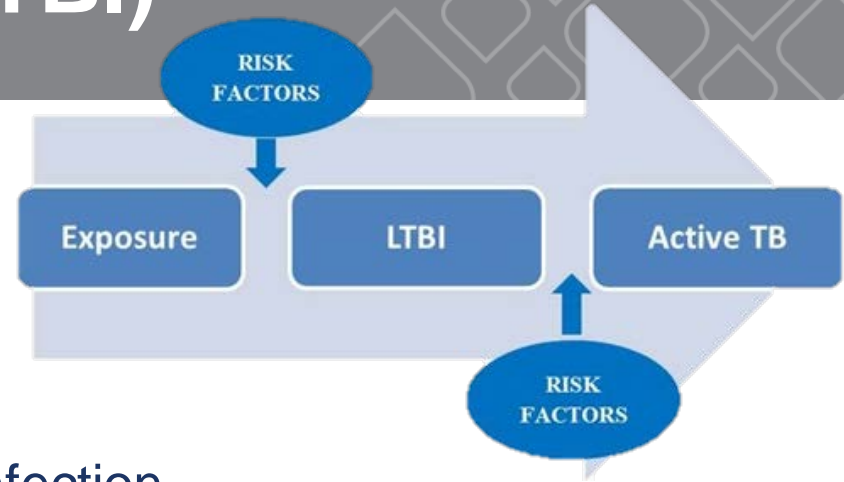


Tuberculosis (TB)

- Spread by airborne route; droplet nuclei
- Transmission affected by:
 - Infectiousness of individual
 - Environmental conditions
 - Duration of exposure
- Most exposed persons do not become infected
- Once inhaled, bacteria travel to lung alveoli and establish infection
- 2-12 weeks after infection, immune response limits activity; infection is detectable
- Some bacteria survive and remain dormant but viable for years (LTBI)



Latent TB Infection (LTBI)



- Persons with LTBI are
 - Asymptomatic, do not feel sick
 - Non infectious
- LTBI progresses to TB disease in
 - Small number of persons soon after infection
 - 5%-10% of persons with untreated LTBI sometime during lifetime
 - About 10% of persons with HIV and untreated LTBI per year
- Persons at high risk for LTBI progressing to TB disease
 - Coinfected with HIV (highest risk)
 - Recent *M. tuberculosis* infection (within 2 years)
 - Children under 4 years of age
 - Persons with certain clinical conditions or other conditions of compromised immunity
 - History of untreated or poorly treated TB

Risk Factors for LTBI to TB Disease

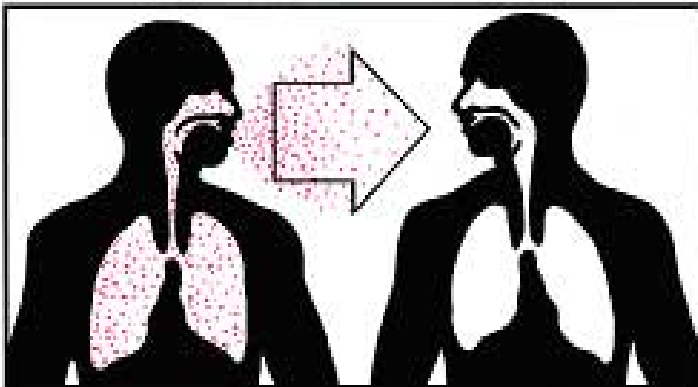
Relative risk reactivation of TB in various clinical settings

AIDS	110–170 times
HIV infection	50–110
Solid organ transplant	20–74
Silicosis	30
Recent TB infection (<2 years)	15
Chronic renal failure	10–25
Carcinoma of head and neck	16
Abnormal chest radiograph with upper lobe fibro nodular disease typical of healed TB infection	6–19
TNF Alpha inhibitor therapy	1.7–9
Glucocorticoid therapy	4.9
Children less than 4 years old	2.2–5
Diabetes mellitus	2–3.6
Underweight (BMI <20)	2–3
Smoker (1 pack/day)	2–3
Normal healthy individual	1

TB Disease

Characteristics of infectiousness

- Cough \geq 3 weeks
- Coughing up blood or sputum
- Weakness or fatigue
- Weight loss, loss of appetite
- Chills, fever, sweating at night
- Cavitation on chest radiograph
- Positive sputum smear results



LTBI	TB Disease
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 are negative	Sputum smears and cultures may be positive
No symptoms	Symptoms such as cough, fever, weight loss
Not infectious – cannot spread TB bacteria to others	Often infectious before treatment – may spread TB bacteria to others
Should consider treatment to prevent TB disease	Needs treatment for TB disease

* The absence of significant physical findings does not exclude active TB. Classic symptoms are often absent in high-risk patients, particularly those who are immunocompromised or elderly.

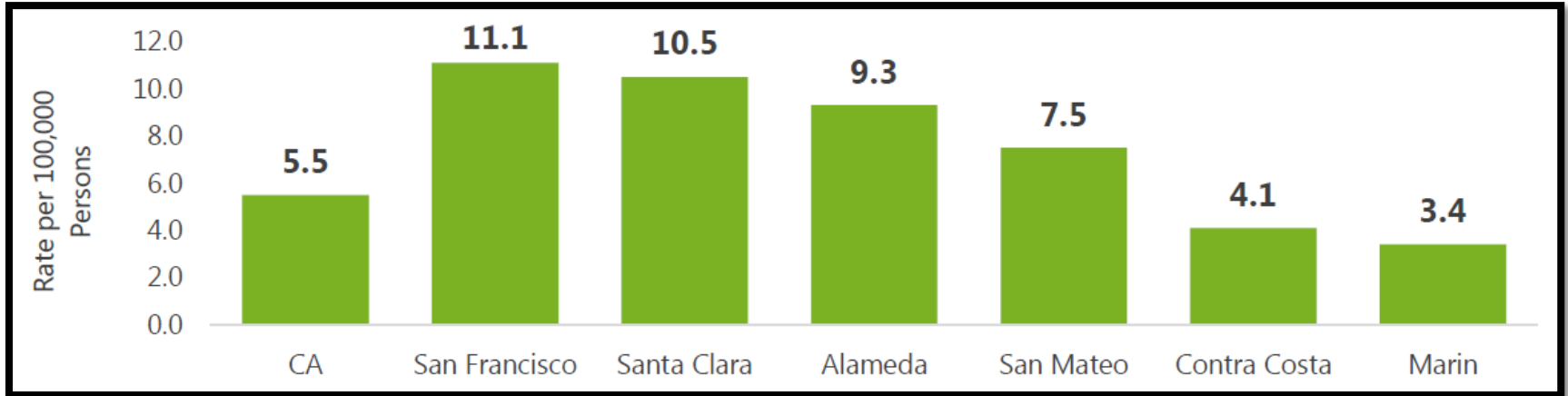
QuantiFERON-TB Gold test (QFT-G)

- Approved by FDA in 2005
- QFT-G is a type of blood assay for *M. tuberculosis*
 - Measures the patient's immune system reaction to *M. tuberculosis*
 - Blood samples must be processed within 12 hours
 - Interpretation of QFT-G results is influenced by the patient's risk for infection with *M. tuberculosis*
 - An alternative to TST, QFT-G
 - ◆ Requires only one visit
 - ◆ Interpretation is less subjective
 - ◆ Probably less affected by BCG vaccination
- QFT-G is not recommended for children < 5 years of age

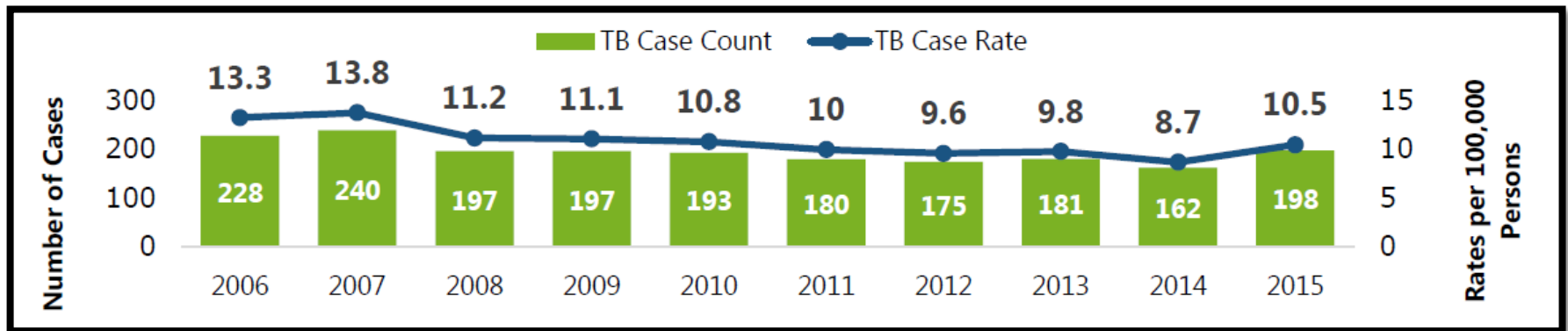


TB in California

TB Case Rates: California and San Francisco Bay Area



Trends in TB Case Counts and Rates: Santa Clara County



SCVMC TB Protocol for HCWs



- Initial TB screening for employees
 - 2 step TST screen or IGRA (interferon gamma release assay)
 - Chest x-ray for those with significant reaction on TST test or positive IGRA
- Follow-up TB screening
 - All employees complete a yearly symptom review questionnaire
 - If previous negative TST/IGRA, complete an annual or semi-annual TST (based on employee's department)
- HCWs must be excluded from duty if has, or suspected to have, TB pending sputum results or evaluation of suspicious chest x-ray.
 - Confirmed cases: Duration of exclusion is until HCW on therapy for at least 2 weeks, clinical improvement, and clearance by Employee Health in conjunction with Infectious Disease, Pulmonary, or county TB Controller.
 - Suspected cases: Can return to work if suspected TB is ruled out.

Tuberculosis Exposure – MICC



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Better Health for All



MICC Exposure Determination

- Notified by SCC TB Controller of employee with suspected TB disease
- Infection Prevention investigation includes
 - Confirm active TB
 - Inform key stakeholders (Department Management, Risk Management, Leadership, etc.)
 - Notification of Employee Health so that employee excluded from work effective immediately
 - Determination of classification of patient and/or employee exposures
 - ◆ Determine exposure period
 - ◆ Define what qualifies as an exposure
 - ◆ Identify exposed patients and employees



TABLE 2. Guidelines for estimating the beginning of the period of infectiousness of persons with tuberculosis (TB), by index case characteristic

TB symptoms	Characteristic		Recommended minimum beginning of likely period of infectiousness
	AFB* sputum smear positive	Cavitary chest radiograph	
Yes	No	No	3 months before symptom onset or first positive finding (e.g., abnormal chest radiograph) consistent with TB disease, whichever is longer
Yes	Yes	Yes	3 months before symptom onset or first positive finding consistent with TB disease, whichever is longer
No	No	No	4 weeks before date of suspected diagnosis
No	Yes	Yes	3 months before first positive finding consistent with TB

SOURCE: California Department of Health Services Tuberculosis Control Branch; California Tuberculosis Controllers Association. Contact investigation guidelines. Berkeley, CA: California Department of Health Services; 1998.

* Acid-fast bacilli.

Definition of Exposure

An exposure shall be defined as:

- Patients who received direct patient care in MICC during the time the source employee was working scheduled shifts. When employee worked in a relief or resource role, all patients currently inpatient on the unit are included.
- Healthcare workers who worked with the employee in MICC during the time the source employee was working scheduled shifts or attending classes/training.
- Exposure period was the time the exposed patients or employees shared the same air space with the source employee during the infectious period --

Mid August to Mid November



Media Coverage

CBS NEWS / December 12, 2015, 2:48 PM

Hundreds potentially exposed to tuberculosis at hospital

Hundreds of Newborn Babies Need Antibiotics for Tuberculosis After Santa Clara Valley Medical Center Employee Tests Positive

To prevent infection, doctors are recommending all 350 newborns who may have been exposed receive antibiotic treatment for the next six months, as a precaution.

By Michelle Roberts

NBC  **BAY AREA**

The Washington Post

Nurse may have exposed hundreds of babies to TB

SFGATE <http://www.sfgate.com/bayarea/article/Nurse-s-infection-causes-TB-warning-at-San-Jose-6693088.php>

San Jose nurse's active TB infection prompts warning at hospital

By Jenna Lyons Updated 3:00 pm, Saturday, December 12, 2015

San Jose Mercury News

San Jose: Valley Medical Center tuberculosis risk means hundreds of babies, moms need treatment or tests

By Tracy Seipel | tseipel@mercurynews.com

POSTED: 12/11/2015 01:32:20 PM PST | UPDATED: 3 MONTHS AGO

The New York Times | <http://nyti.ms/1jXrB2t>

U.S.

Nurse With Tuberculosis May Have Exposed Over 1,000, Including 350 Infants

By LIAM STACK DEC. 13, 2015



Employee Notification



Infection Prevention notified managers. Managers notified their employees to complete post-exposure follow-up:

- If History of Negative TST/IGRA → TST 8-10 weeks after last date of exposure to source employee
- If History of Positive TST/IGRA → Symptom screen 8-10 weeks after last date of exposure to source employee

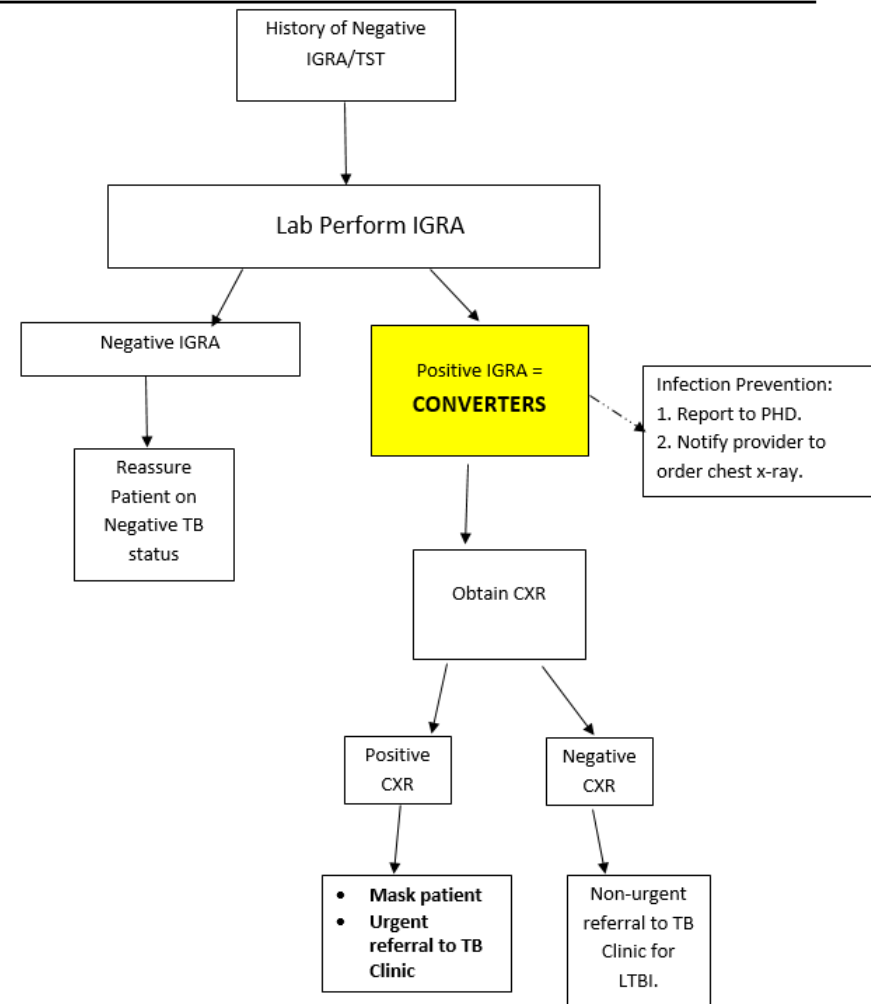
Follow-Up Plan for Patients

Algorithms developed after collaboration with Infection Prevention, Hospital Epidemiologist, SCC TB Controller, Pediatric Infectious Disease, CDPH TB Control, and national experts.

Women:

- All MICC patients are screened for TB prior to delivery at SCVMC.
- If history of negative TB screen → QFT-TB testing 8-10 weeks post-exposure

Algorithm for Negative TB Screen (Adult): Post TB Exposure

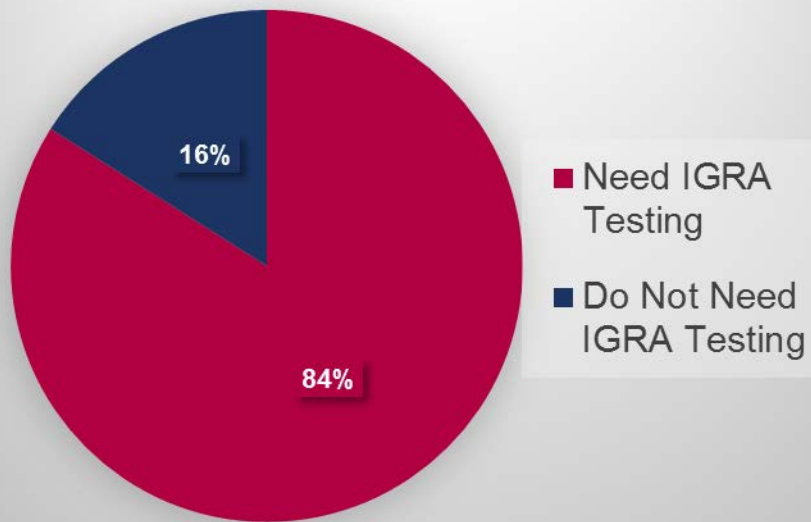


Follow-Up Plan for Patients

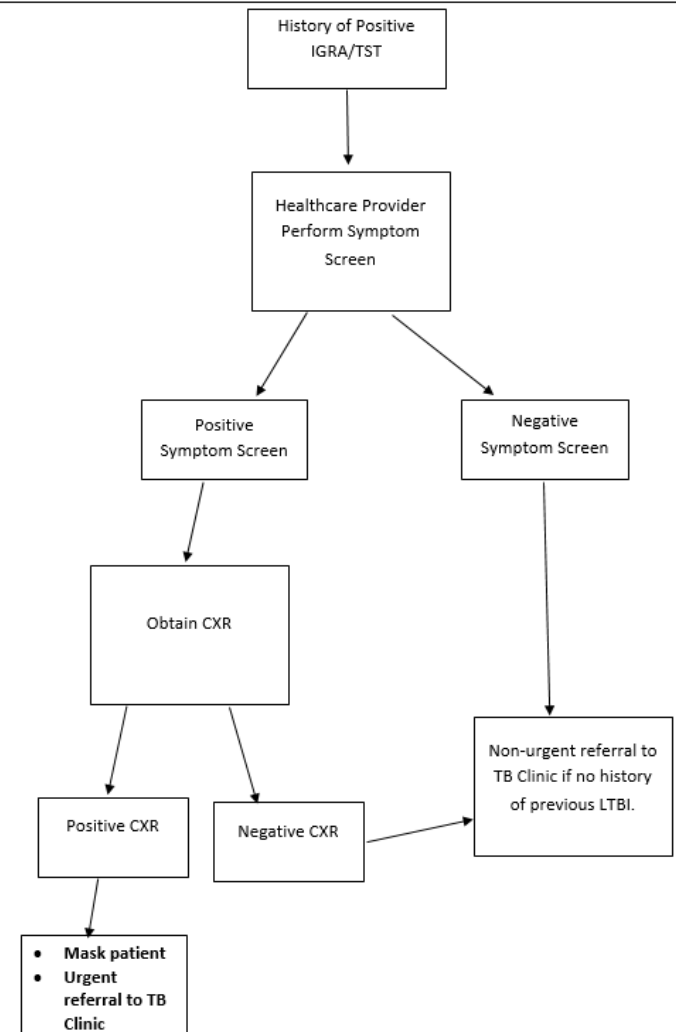
Women:

- If history of positive TB screen → Symptom screen and chest x-ray if indicated

84% (309/368) of Women Exposed Need IGRA Testing



Algorithm for Positive TB Screen (Adult): Post TB Exposure

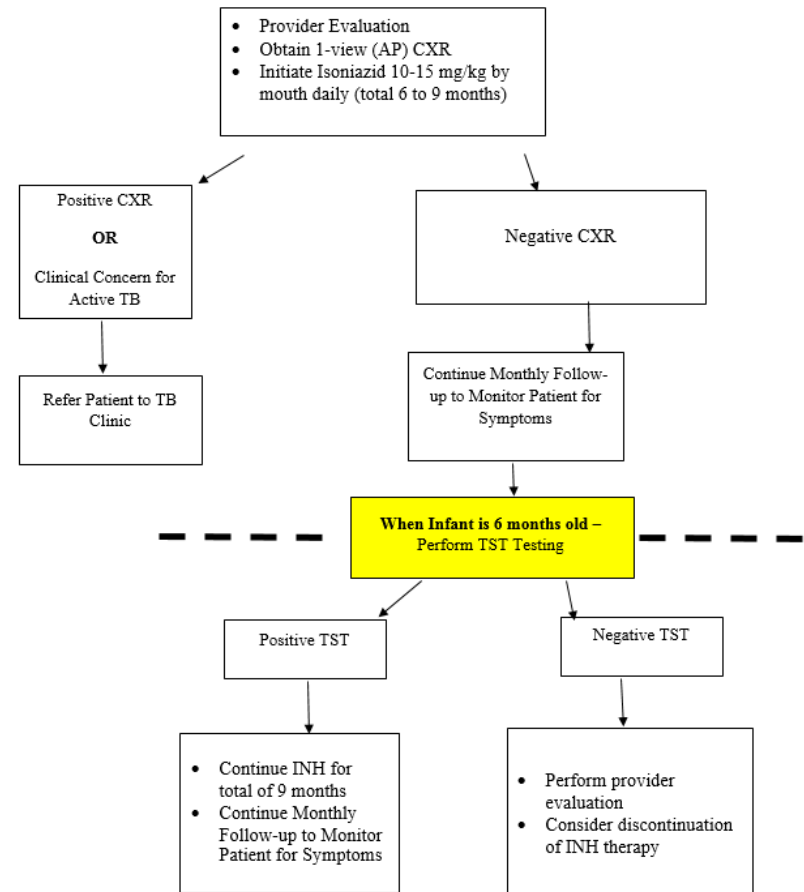


Follow-Up Plan for Patients

Infants:

- Baseline chest x-ray and medical evaluation
- Initiate Isoniazid (INH) therapy
- Monthly follow-up to monitor patient for symptoms
- TST testing at 6 months of age (QFT not reliable < 5 years of age)
 - ◆ If positive TST → continue INH for 9 months and continue monthly follow-up
 - ◆ If negative TST → perform medical evaluation and consider discontinuation of INH therapy

Algorithm for Infants: Post TB Exposure



Patient Notification

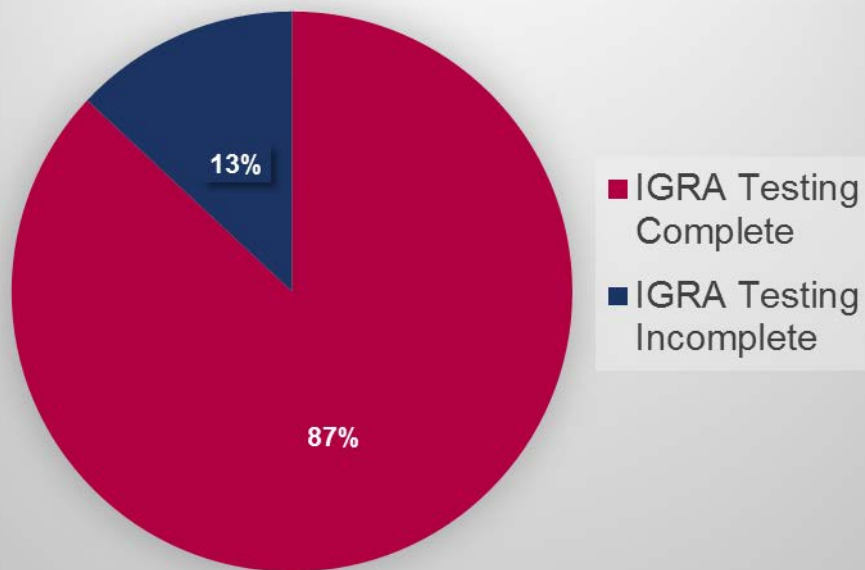
- Infection Prevention developed letters to women (based on TB screen history) and infant caregivers.
 - Reviewed by multidisciplinary team and County Council.
 - Translated into Spanish and Vietnamese.
 - Letters mail to all patients and included frequently asked questions about TB specific to that patient population.
- Ambulatory Staff began phone notification of infant caregivers and scheduling appointments for infant evaluation.
- Infection Prevention developed letters to all patient's providers with algorithms for recommended follow-up procedure.
- All SCVMC providers notified of exposure via email with copies of patient letters, provider letters, algorithms for care.
- Press release issued by SCVMC.



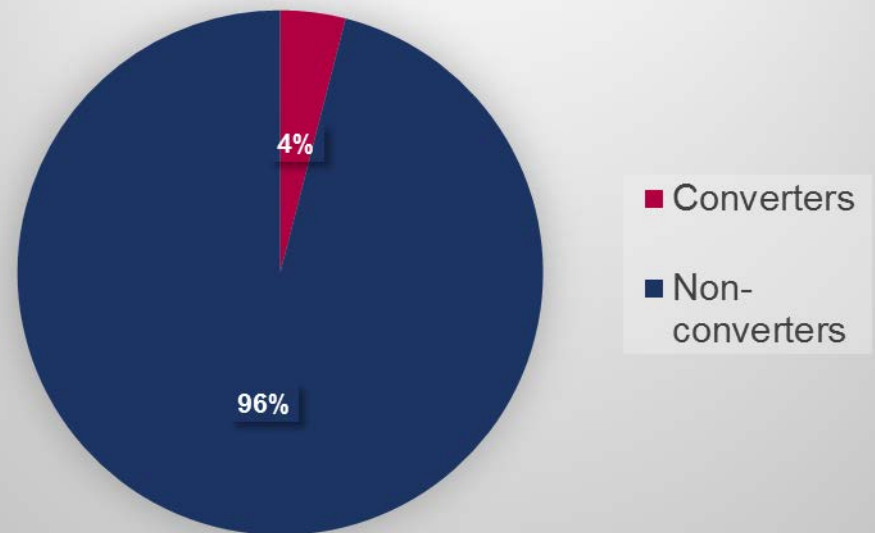
Status of Follow-Up: Women

As of 4/11/2016

87% (270/310) of Women that Need IGRA Testing Have Been Tested



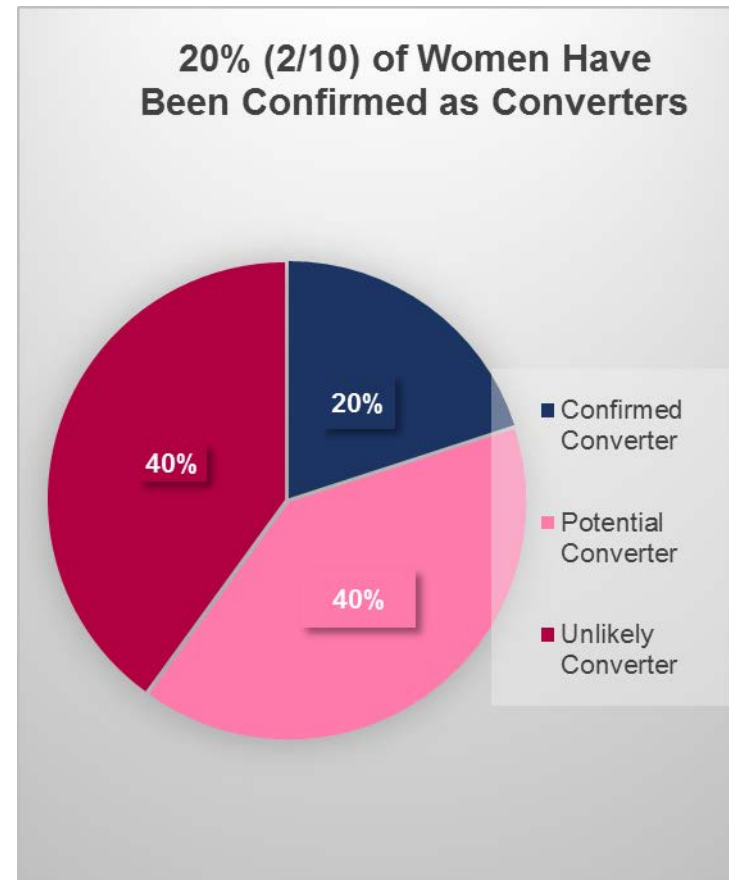
4% (10/270) of Women have Converted (Negative to Positive TB Screen)



Status of Follow-Up: Women

As of 4/11/2016

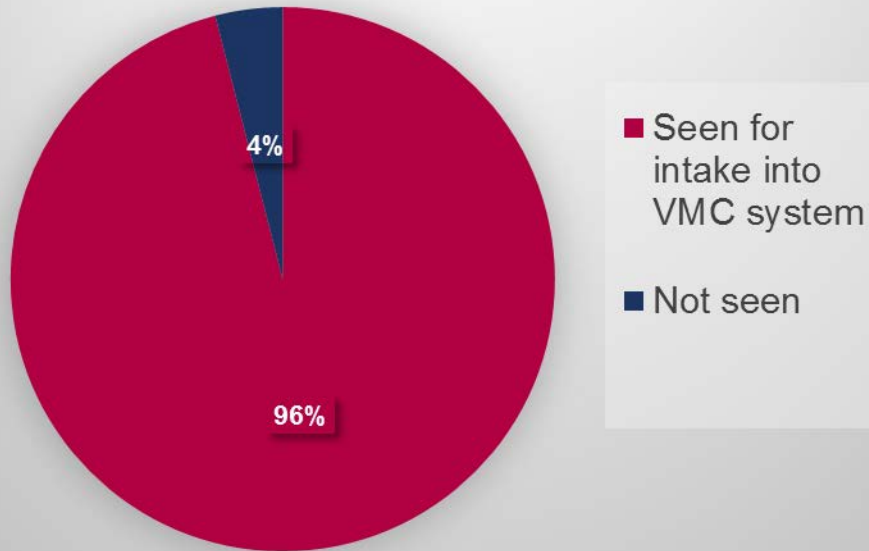
- After testing complete, providers notified by Infection Prevention of test results and any additional recommendations for treatment and/or follow-up care based on algorithms.
- Potential converters reported to SCC TB Control.
- Referrals placed with SCC TB Control on potential converters for further investigation and testing:
 - 2/10 (20%) have been confirmed as a converter
 - 4/10 (40%) have been determined to be potential converters
 - 4/10 (40%) have been determined to unlikely be converters
- Conversion is defined as a patient with a confirmed negative to positive TB test (QFT or TST). No patients have been diagnosed with active TB disease at this time.



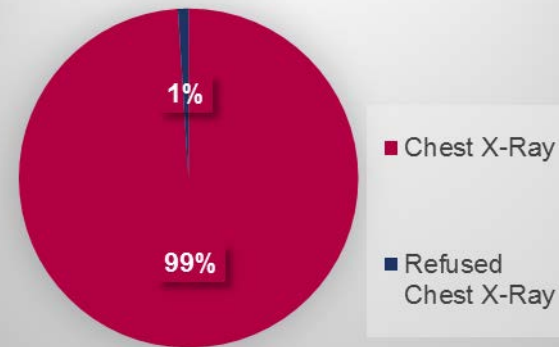
Status of Follow-Up: Infants

As of 4/11/2016

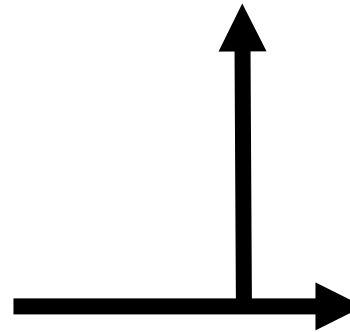
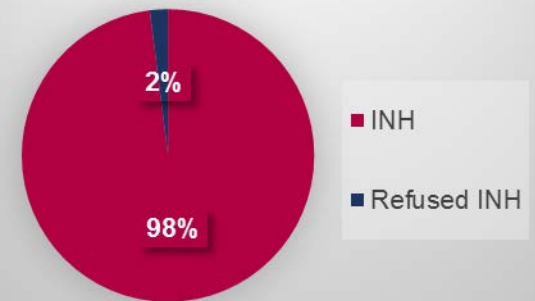
96% (335/349) of Exposed Infants were Seen for Intake into VMC System for Follow-Up



>99% (334/335) of Infants had Baseline Chest X-Ray



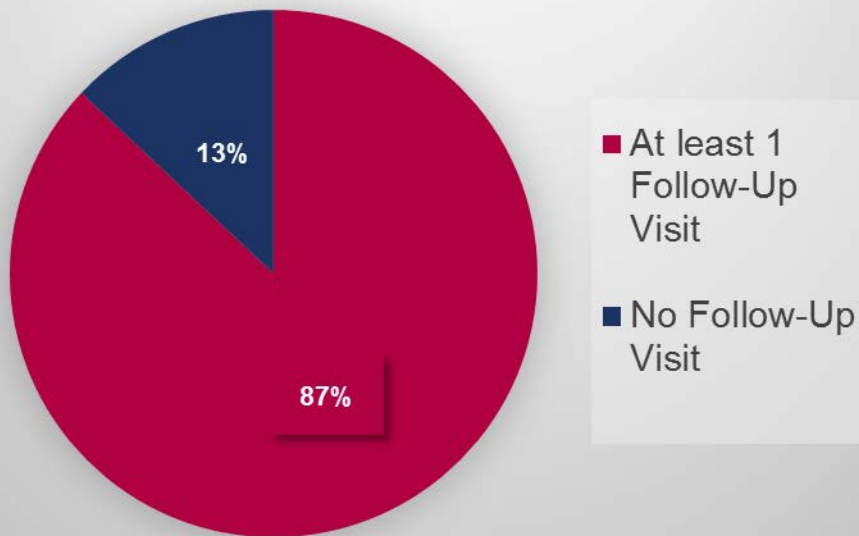
98% (327/335) of Infants were Started on INH



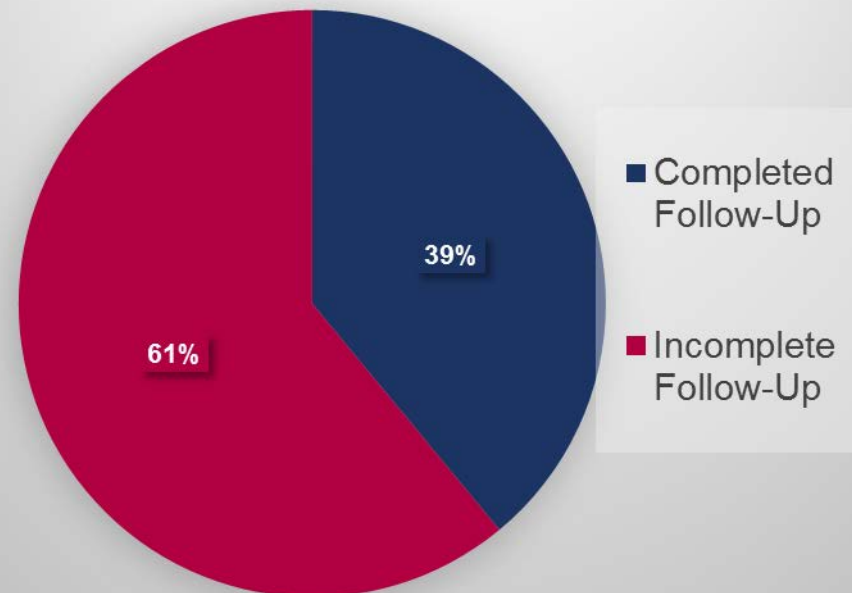
Status of Follow-Up: Infants

As of 4/11/2016

87% (293/335) of Exposed Infants had at least ONE Follow-Up Visit



39% (135/349) of Exposed Infants had Reached 6 Months of Age, Received TST, and INH was Stopped



All infants TST tested have resulted 0 mm at this time.

SCC Public Health Department

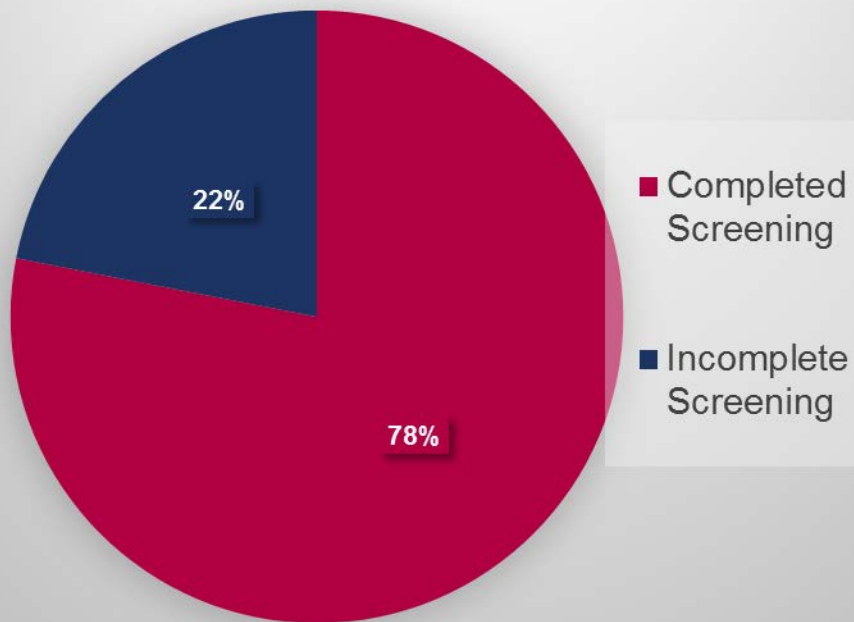
- Referrals sent to SCC PHD for:
 - Any patient that is unreachable by phone and mail.
 - Any patient that has moved out of the county.
 - Any patient who has chosen to receive testing and/or follow-up care outside of SCVMC.
 - Women who have not completed QFT testing.
 - Infants that have not completed follow-up testing or care as recommended.
- PHD process:
 - 2 phone calls to patient
 - 2 home visits (morning and evening)
 - Additional letter



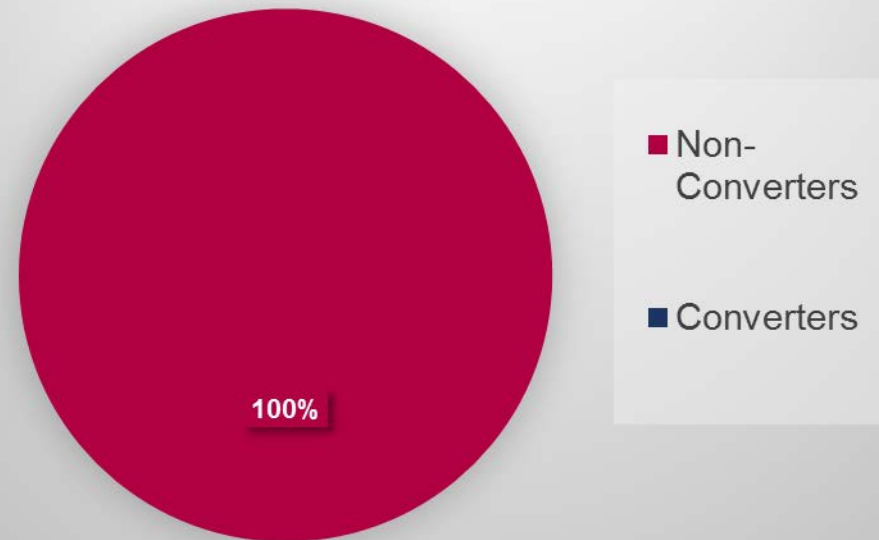
Status of Follow-Up: Employees

As of 4/5/2016

**78% (166/212) of Exposed Employees
Have Completed Post-Exposure
Screening at Employee Health**

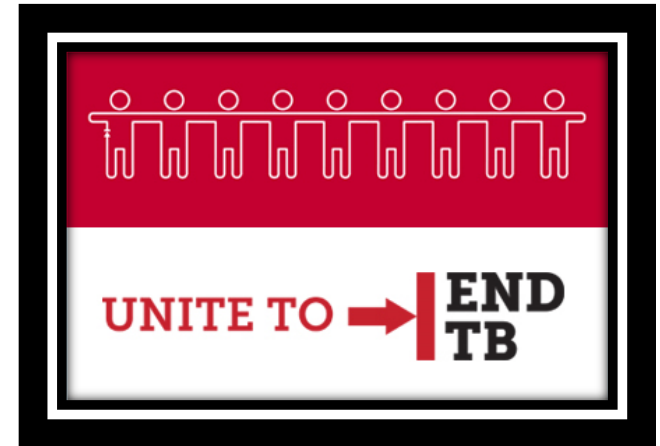


**0% (0/166) of Exposed Employees
Tested that Have Converted (Negative to
Positive TB Screen)**



Current Status

- Continue testing and follow-up of all employees and patients.
- Continued meetings of multidisciplinary team to evaluate progress and identify additional needs and challenges.
- Implement new methods for employee education on LTBI, TB Disease, Employee Health screenings and exclusions from work.
- Evaluate current recommendations/practices for employees to receive LTBI treatment, when applicable.
- Update Infection Prevention policies and procedures to reflect lessons learned during this exposure event.
- Publish findings in order to globally contribute to best practices for TB exposures.



References

- Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005; 54 (No. RR-17).
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=r5417a1_e
- Newsy. 350 infants potentially exposed to tuberculosis at California hospital, 2015. https://www.youtube.com/watch?v=BQQMr8s_jnU
- Quiagen. Frequently asked questions QuantiFERON®-TB Gold: Health Professionals, 2013.
http://usa.quantiferon.com/irm/content/pdfs/FAQ_QFT_HCP-US_EN_1113_H_LR.pdf
- Santa Clara County Public Health. Tuberculosis in Santa Clara County: A summary, 2016. <https://www.sccgov.org/sites/sccphd/en-us/Residents/TbResources/Documents/tb-factsheet-3-24-16.pdf>

Tuberculosis Exposure – Infusion Oncology Center



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Infection Prevention Department

Better Health for All



Case study background (1)

65 yrs old male

- New immigrant from Vietnam
- Seeking medical attention for suspected gastric cancer
- Had abnormal chest CT scan
- Came to SCVMC ED after discharge from local hospital
- Was referred to VHC Infusion-Oncology clinic

Case study background (2)

Clinical Follow-up

- Diagnosed with gastric cancer (Jan 2015)
- Started on chemo tx (Feb 2015)
- Suspected mets to lung
 - chest CT shows lung mass (Jan 2015)
- Admitted to SCVMC (May 2015)
 - increasing dyspnea, chest discomfort, significant weight loss, fatigue
 - AFB smears positive
 - cxr RUL nodularity possibly cavitary lesion

Patient Identification

- Medical history
- Clinical history
- When patient entered SCVMC healthcare system
- Which SCVMC locations patient had encounters

Period of Infectiousness

- AFB smears positive (May 2015)
- Symptoms
 - Medical chart indicated occasional cough
 - Chest discomfort
 - Dyspnea
 - Fatigue
 - Weight loss
 - fever

Findings

- Pt was hospitalized at local hospital (Jan 2015)
 - 4 days inpatient
 - Work-up indicated gastric cancer
 - Chest CT showed lung mass
- Pt seen in SCVMC ED (Jan 2015) same day after discharge
 - Abdominal pain
 - Was referred to VHC Infusion-Oncology clinic for further f-u

CSI (4)

Findings

- Pt seen in VSC Infusion-Oncology clinic starting(Feb 2015)
- Pt had multiple scans done from Jan-June 2015
- Also seen at Valley Health Clinic with PCP in June 2015



Was there an exposure?

Indicators for a potential exposure

- Infectivity of the index case
- Symptoms that warrant potential transmission
- Location of encounters
 - Shared air space
 - Air exchanges/min
 - Ventilation pattern



Was there an exposure?

Indicators for a potential exposure

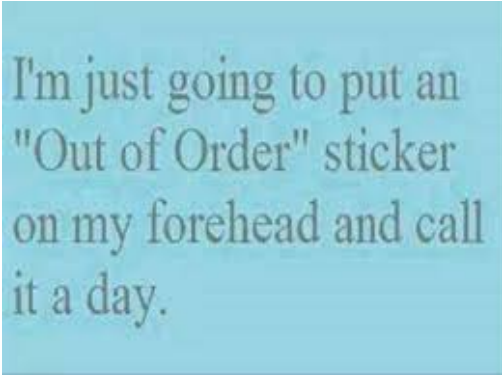
- AFB smears positive (June 2015)
- Sputa positive MTB PCR (June 2015)
- Pt was seen in Infusion-Oncology clinic setting

When was the period of infectiousness?

- Jan 2015—June 2015
 - From entrance into SCVMC healthcare system until hospital admission date

Locations

- Pt seen in VSC Infusion-Oncology clinic starting(Feb 2015)
 - Over 700 patients identified
- Pt had multiple scans done from Jan-June 2015
 - Unaccounted for
- Also seen at Valley Health Clinic with PCP in June 2015
 - About a dozen
- Healthcare workers identified
 - Over 80 staff

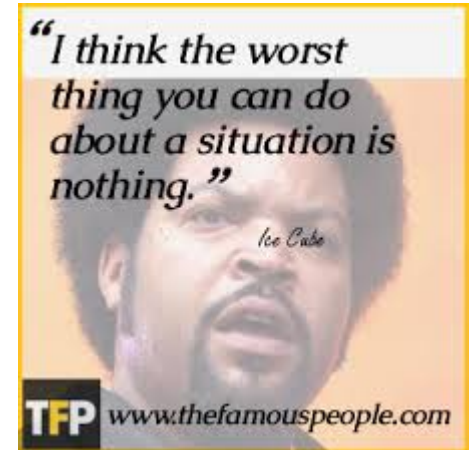


I'm just going to put an
"Out of Order" sticker
on my forehead and call
it a day.

Who is considered most at risk?

Risk Stratification Criteria

- Most high risk medical diagnoses
- Number of encounters in correlation with index case
- Those who have documented baseline TB screening
- All identified patients categorized into 1 of 3 tiers
- Those with documented previous positive TB screenings were not included in any Tiers



Tier 1

Tier 1 Criteria

- 3 or more encounters and or has the following medical diagnoses/conditions
 - HIV
 - Lymphoma
 - Leukemia
 - Renal Disease
 - Immunosuppressive conditions (DM, RA ...)
 - Provider considers highest risk due to immunocompromised conditions

Tier 2

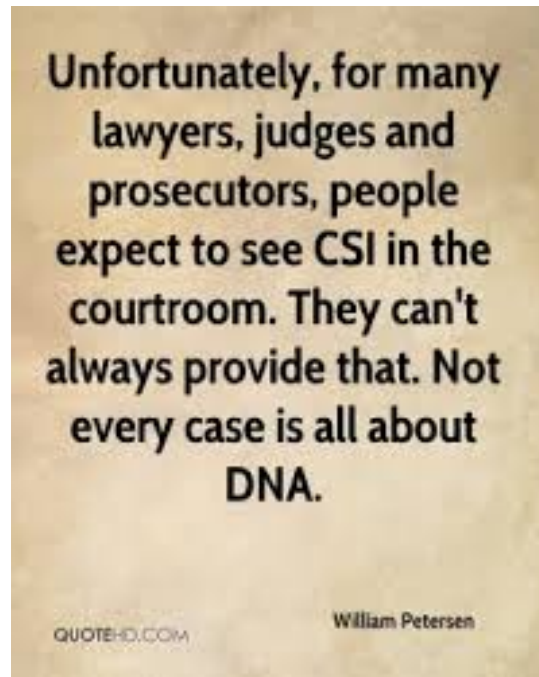
Tier 2 Criteria

- Other diagnoses not listed in Tier 1
- High risk medical conditions
- Those with 3 or less encounters in correlation with index case

Tier 3

Tier 3 Criteria

- Remaining patients not listed in Tier 1 or Tier 2



Determination of the follow-up screening

No documented baselines

Interferon Gamma Release Assay

- Quantiferon Gold
- Symptoms screen

Documented positive baselines

- Symptoms screen
- cxr

Potential exposure notification

Method of Notification

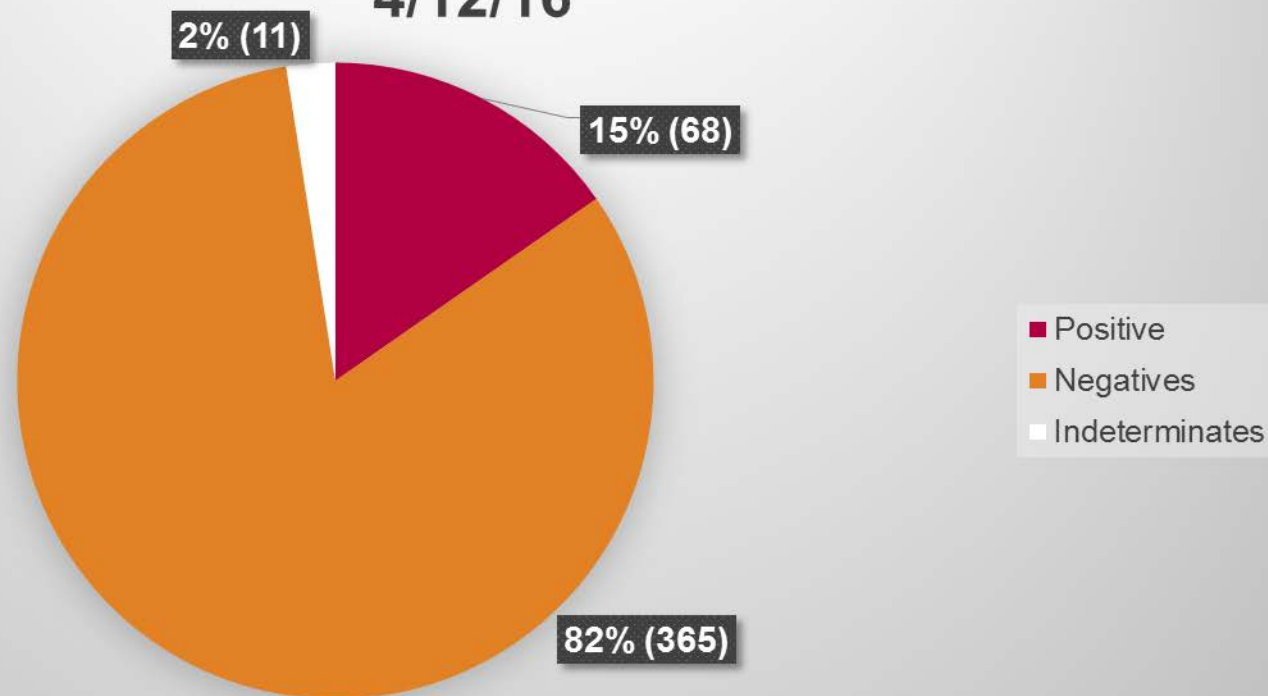
- Individual letters to potentially exposed patients
 - Explanation letter (language specific)
 - FAQs
 - Lab Hours
 - Symptoms Review form
- Letters to Providers
 - Explanation letter
 - FAQs for providers

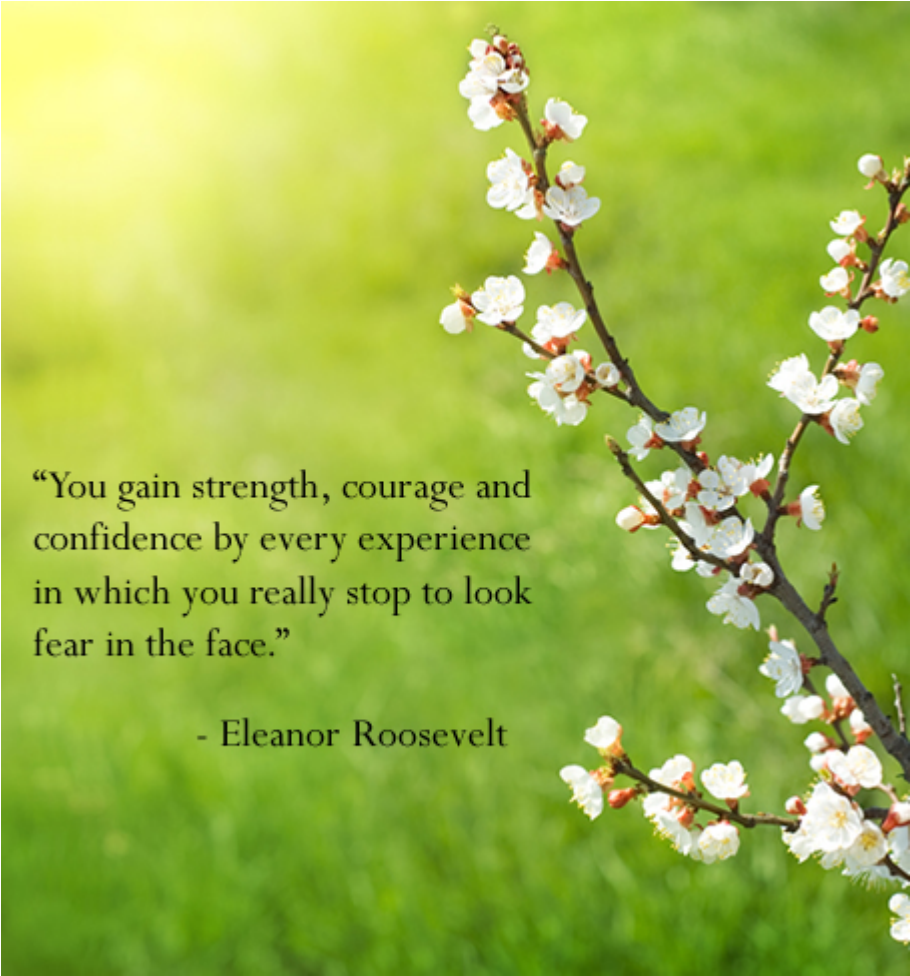


Results of patient screenings

VSC Infusion-Oncology Clinic TB Exposure May-Oct 2015

Quantiferons Completed= 444 / 622 (71%)
4/12/16





“You gain strength, courage and confidence by every experience in which you really stop to look fear in the face.”

- Eleanor Roosevelt



SANTA CLARA
VALLEY
HEALTH & HOSPITAL SYSTEM

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