

DEVELOPING A TUBERCULOSIS PROTOCOL MANUAL FOR THE SALINE COUNTY HEALTH DEPARTMENT

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2017

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Chapter 1: Scope of Work

Saline County Health Department (SCHD)

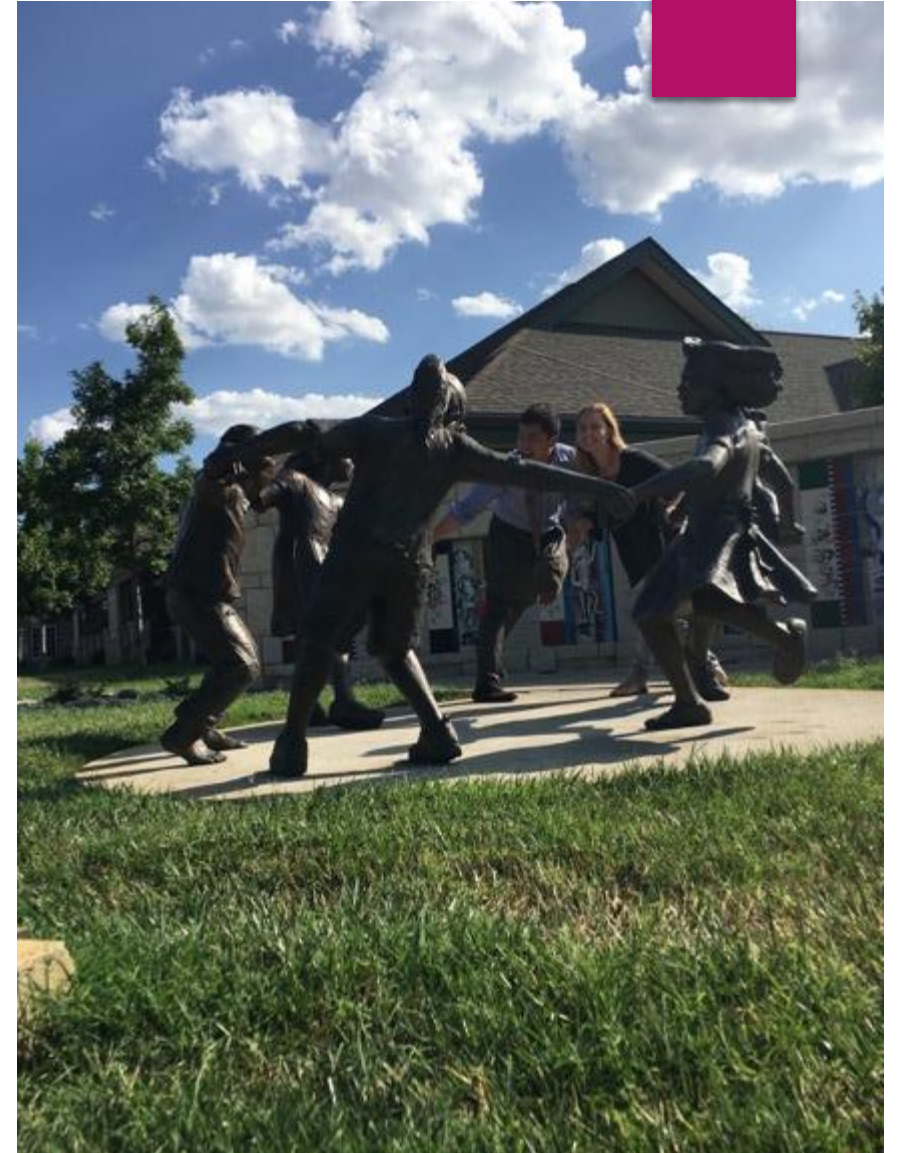
Saline County Health Department (SCHD)

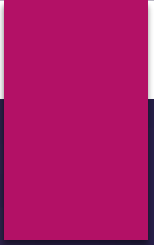


- ▶ **Mentor:** Jason Tiller, M.S. (Director, SCHD)
- ▶ **Population (*Saline County*):** ~55,000
- ▶ **Cities Served:** Assaria, Brookville, Gypsum, New Cambria, Salina, Smolan, Solomon (partly in Dickinson County)
- ▶ **Departments (*SCHD*):** **1)** WIC, **2)** MCH, **3)** Home Health, **4)** Child Care Licensing, **5)** Health Education, **6)** Nursing Clinic, **7)** PHEP

Scope of Work:

- ▶ *Become familiar with all aspects of a local health department*
- ▶ *Enrich knowledge of public health and infectious disease/zoonoses*



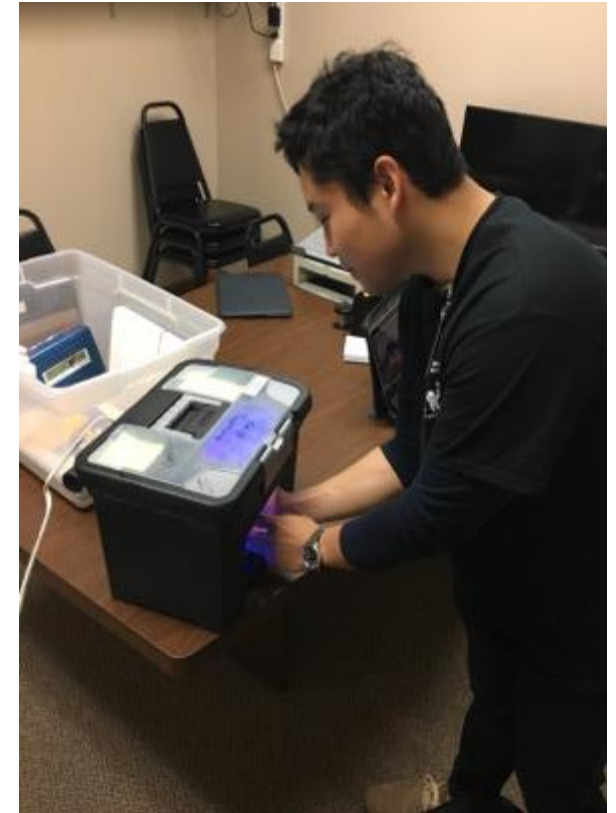


Chapter 2: Objectives, Activities, & Products

Learning Objectives, Activities Performed, & Products Developed

Learning Objectives and Activities Performed:

- ▶ *Became better acquainted with different aspects of public health by attending meetings and conferences*
- ▶ *Learned about how the different branches of a health department work together to improve the health of the community it serves*
- ▶ *Broadened knowledge pertaining to infectious diseases/zoonoses while working on tuberculosis protocol*



Meetings

- ▶ “LiveWell Saline County” Meeting
- ▶ “Kansas Healthy Living” Meeting
- ▶ “Central KS Region for Public Health Emergency Preparedness” Meeting
- ▶ “Becoming a Mom” Session





Lectures:

- Bioinformatics
- Public Health 3.0
- Effective Health Communication



Conference: KALHD (Kansas Association of Local Health Departments)

Saline County Health Department Staff

(Director, WIC, MCH, Home Health, Child Care
Licensing, Health Education, Clinic Services, PHEP)

**SALINE COUNTY
HEALTH DEPARTMENT**



We are good for your health!

Director (*Jason Tiller, M.S.*)

- ▶ Oversees health department branches
- ▶ Meets with Advisory Council
- ▶ Works with Finance Department to ensure grants/funding
- ▶ “Wears many hats”



1) Women, Infants, & Children (WIC)

- ▶ Offers nutrition support:
 - ▶ Pregnant women
 - ▶ Breastfeeding women
 - ▶ Postpartum women
 - ▶ Children up to 5 years of age
- ▶ Prevent or correct health problems caused by poor nutrition
- ▶ Free to qualifying parents/legal guardians



2) Maternal and Child Health (MCH)

- ▶ Special Health Care Needs (SHCN)
- ▶ Maternal & Infant Program (M&I)
- ▶ Becoming a Mom
- ▶ Maternal & Child Health (MCH) Home Visitor Program
- ▶ Breastfeeding Coalition



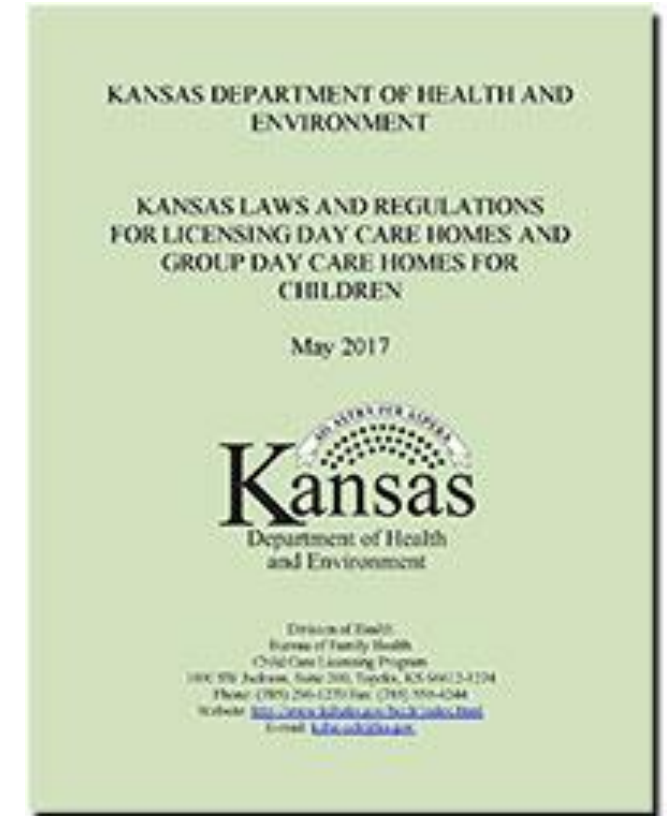
3) Home Health

- ▶ Medicare certified & Kansas State Licensed Agency
- ▶ Provides intermittent professional home health care
- ▶ RN on call 24 hours a day
- ▶ Patients receiving home health:
 - ▶ A recent hospitalization
 - ▶ Outpatient surgery
 - ▶ A temporary or long-term disability
 - ▶ A chronic illness
 - ▶ Aging
 - ▶ Special needs



4) Child Care Licensing

- ▶ Inspects (for 3 counties- Saline, Ottawa, & McPherson)
 - ▶ Family child care homes
 - ▶ Preschools
 - ▶ Child care centers
 - ▶ School age facilities
- ▶ Protecting the health, safety, and welfare of children receiving care away from their parents



5) Health Education

- ▶ Chronic and Infectious Disease Prevention
- ▶ Why Wellness?
- ▶ Tobacco Use Prevention
- ▶ *Pictured: HYPE (Helping Youth Pursue Excellence)*



6) Clinic Services

- ▶ Family Planning Services
- ▶ Pregnancy Testing
- ▶ STI Testing
- ▶ Immunizations
- ▶ Foreign Travel Immunizations
- ▶ Communicable Disease Prevention
- ▶ TB Testing & Treatment
- ▶ Lead Poisoning Prevention
- ▶ HIV/AIDS Case Management



7) Public Health Emergency Preparedness (PHEP)

- ▶ Central KS Region for Public Health Emergency Preparedness Meeting
- ▶ Disaster Preparation
 - ▶ Earthquakes
 - ▶ Floods
 - ▶ Tornadoes
 - ▶ Infectious Disease Outbreaks



Product Developed:

► Saline County Health Department Guidelines for the Prevention, Diagnosis, and Treatment of Tuberculosis (2017)

*(written for use by the Saline County Health Department
and other local health departments in Kansas)*



Saline County Health Department
125 W. Elm St. Salina, KS 67401
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Fax (785) 826 - 6605
<http://www.sachd.org>

SALINE COUNTY HEALTH DEPARTMENT

GUIDELINES FOR THE PREVENTION, DIAGNOSIS,
AND TREATMENT OF TUBERCULOSIS

2017

*Written and adapted for use by the Saline County Health
Department and other local health departments in Kansas*

Chapter 3: Developing a Tuberculosis Protocol Manual for the SCHD

MPH Competencies

3.1) *Introduction*

3.2) *Methods*

3.3) *Results/Discussion*

MPH Competencies

- 1) BIOSTATISTICS
- 2) ENVIRONMENTAL HEALTH SCIENCES
- 3) EPIDEMIOLOGY
- 4) HEALTH SERVICES ADMINISTRATION
- 5) SOCIAL AND BEHAVIORAL SCIENCES

3.1) Introduction

3.1.1) DISCUSSING NEEDS OF THE SCHD

3.1.2) CAPSTONE PROJECT OBJECTIVE

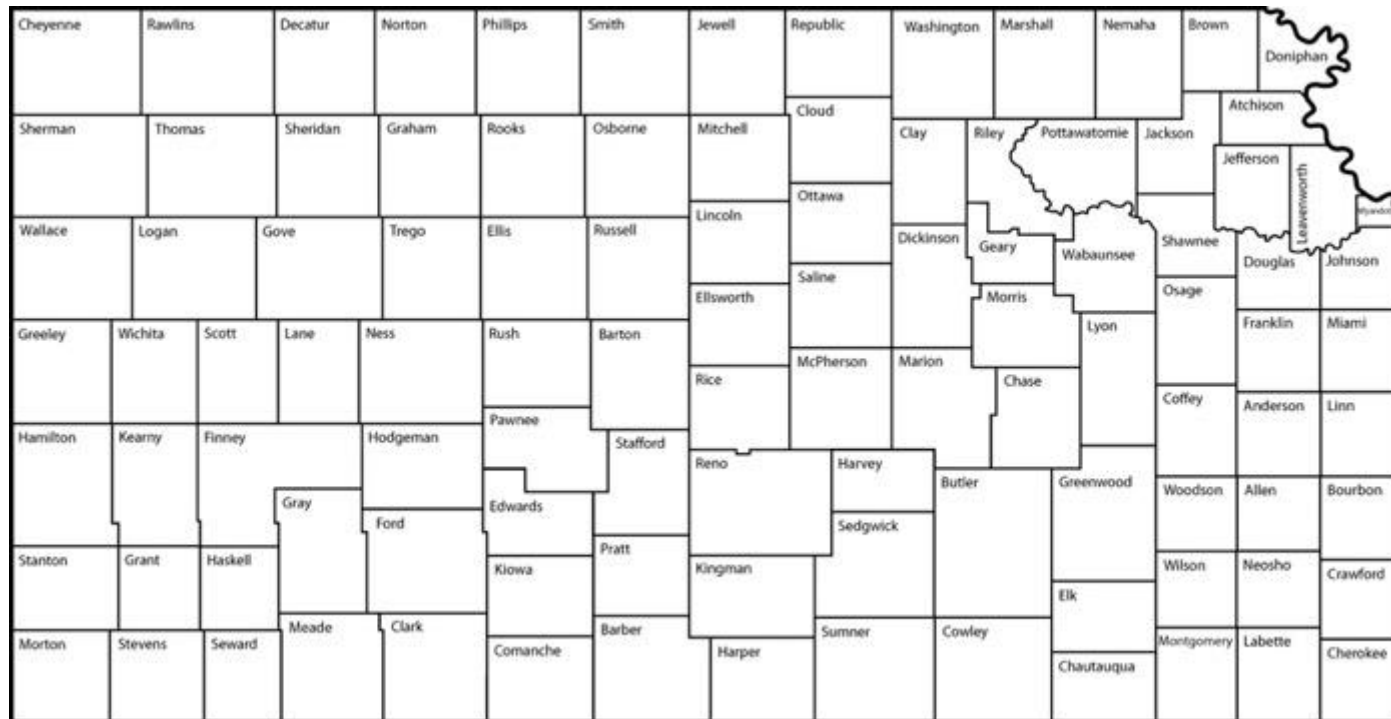
3.1.1) Discussing Needs of the SCHD:

- ▶ **Communicable Disease / TB Program Manager**
 - ▶ Maria Shoultys, RN
- ▶ **Kansas Department of Health and Environment (KDHE)**
 - ▶ Currently has a TB control program and offers helpful links on webpage
 - ▶ Does not offer a standard TB protocol



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3.2) Methods

3.2.1) QUALITATIVE RESEARCH

3.2.2) RESEARCH QUESTION

3.2.3) QUANTITATIVE RESEARCH

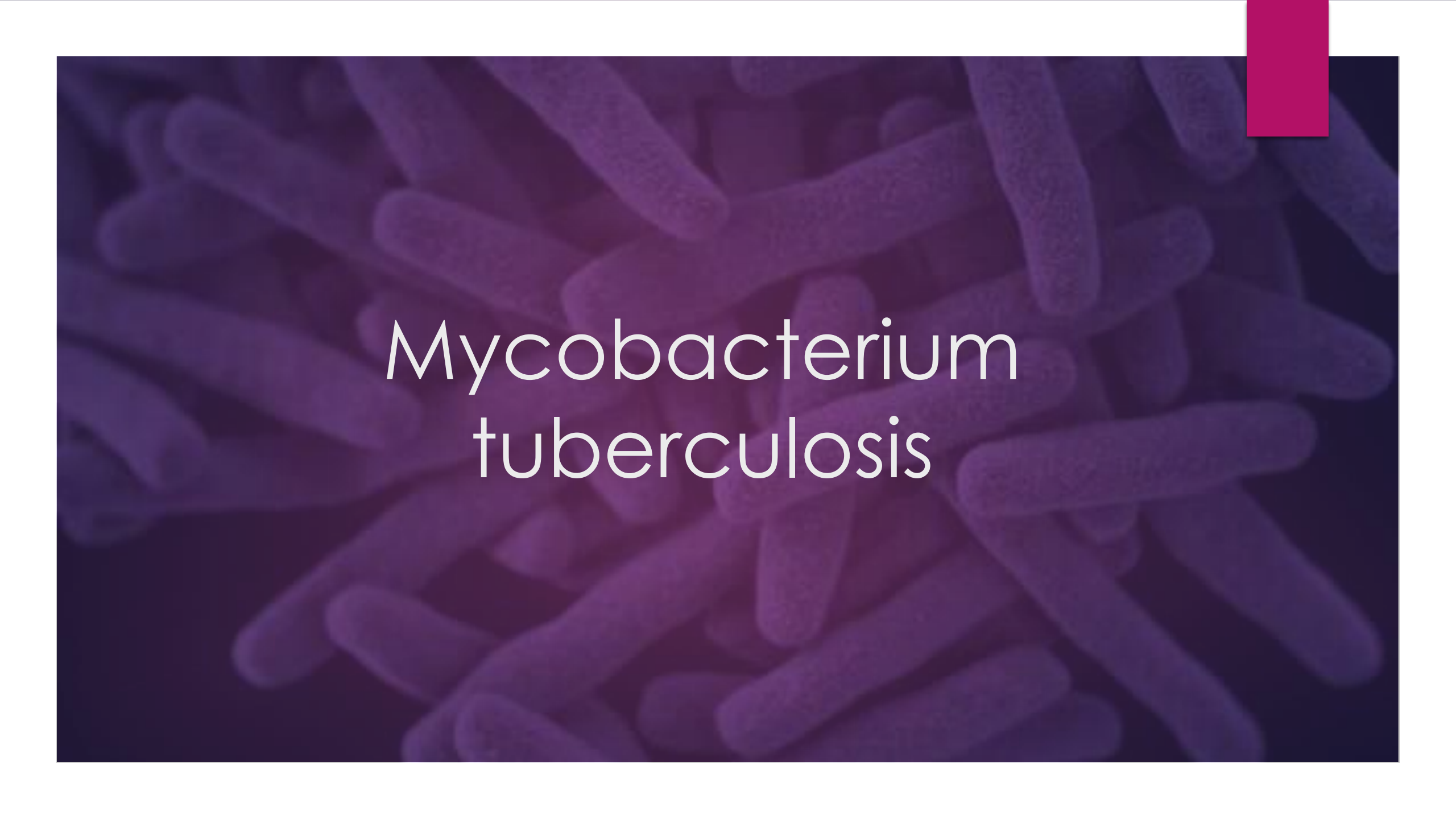
3.2.4) PRODUCING THE PRODUCT

3.2.5) EXTERNAL REVIEW

3.2.1) Qualitative Research:

- ▶ Tuberculosis Literature Review
- ▶ Review of TB Protocol Manuals from Other States
- ▶ Economic Impacts of TB Treatment
- ▶ CDC-Recommended Guidelines for TB Management/Control
- ▶ MPH Competency (Epidemiology):
 - ▶ Epidemiological triad
 - ▶ Host, Agent, & Environment
 - ▶ EpiTrax
 - ▶ Electronic disease surveillance system for Kansas





Mycobacterium tuberculosis

TB – Background

▶ Agent

- ▶ *Mycobacterium tuberculosis*
- ▶ *M. Africanum*, *M. bovis*, *M. microti*, etc⁽³⁰⁾

▶ Discovery

- ▶ German microbiologist, Robert Koch
 - ▶ Discovered microbial cause of TB in 1882

▶ Impact

- ▶ ~9 million people get sick with TB
- ▶ ~2 million lives are claimed yearly –WHO⁽⁴⁾



WORLD TB DAY
MARCH 24



TB – Transmission

- ▶ **Primary mode of transmission**

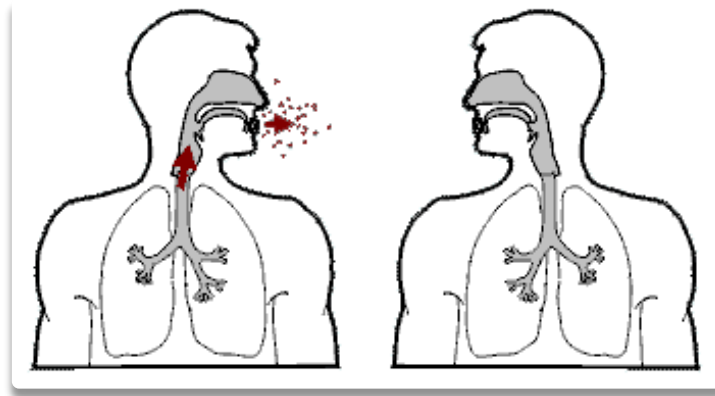
- ▶ Airborne (droplet nuclei) particles

- ▶ Expelled (via coughing, sneezing, etc.) by a person with infectious, or active TB

- ▶ **Size & Hardiness**

- ▶ 1-5 microns in diameter

- ▶ Depending on the environment, may remain suspended in the air for hours



TB – Transmission (Continued)

- ▶ TB transmission probability directly increases with an increase in:
 - ▶ **Susceptibility**
 - ▶ Of exposed individual
 - ▶ **Infectiousness**
 - ▶ Of the person with TB disease
 - ▶ **Environmental factors**
 - ▶ That affect the concentration of *M. tuberculosis* organisms
 - ▶ **Level of exposure**
 - ▶ E.g. Proximity, frequency, & duration of exposure to the infected individual⁽³⁰⁾

TB – Prevention/Management

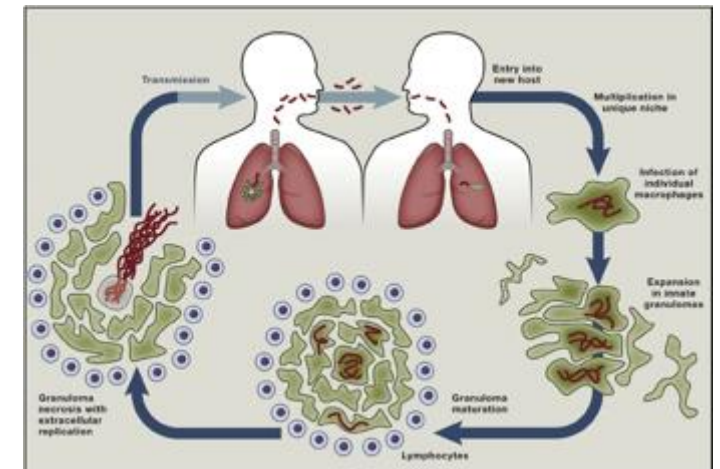
- ▶ **Stopping transmission of TB**
 - ▶ Promptly identifying and isolating patients with infectious TB and starting appropriate treatment
 - ▶ The level of infectiousness will decrease with treatment
- ▶ **Directly Observed Therapy (DOT)**
 - ▶ Health care worker physically observing a TB patient ingest his or her medication



Every day, tuberculosis patient Siti (not her real name) visits Bukit Batok Polyclinic to take her medication under a treatment regimen called "directly observed therapy", where a nurse watches as she finishes her cocktail of nine pills. This is the optimal form of TB care, according to the World Health Organisation.

TB – Pathogenesis

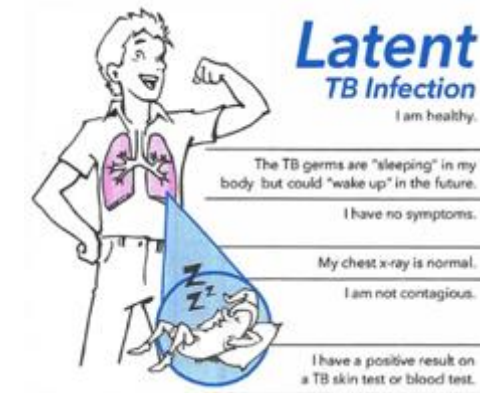
- ▶ Person ingests air with droplet nuclei containing tubercle bacilli
 - ▶ Alveolar macrophages ingest tubercle bacilli
 - ▶ Intracellular replication
 - ▶ Bacilli released with macrophage death
 - ▶ **Lymphatic channels → regional lymph nodes**
 - ▶ **Bloodstream → other locations**
 - ▶ E.g. kidneys, brain, and bone
 - ▶ **Most cases → remains localized**
 - ▶ Apices of the lungs⁽³⁰⁾



LTBI vs. Active TB

▶ Latent TB Infection (LTBI)

- ▶ Infected with TB bacilli
- ▶ **Asymptomatic** and **not contagious**
- ▶ Returns a positive reaction on the tuberculin skin test (TST)



Active TB Disease

I have a serious illness that could kill me if left untreated.

The TB germs have "woken up".

I may have symptoms – cough, fever, weight loss, night sweats.

My chest x-ray may be abnormal.

I may be contagious and could infect other people when TB germs are spread through the air when I cough, laugh or speak.

I may have a positive result on tests of my phlegm.



The illustration shows a man in a white shirt and pants, looking sick and holding his head. He has a speech bubble that says "I am healthy." and a thought bubble that says "The TB germs are 'sleeping' in my body but could 'wake up' in the future." Below the thought bubble, there is a small illustration of a person sleeping with "Z"s above their head. To the right of the man, there is a list of statements: "I have no symptoms.", "My chest x-ray is normal.", "I am not contagious.", and "I have a positive result on a TB skin test or blood test."

▶ Active TB Disease

- ▶ Without treatment, 5 to 10% of those with LTBI eventually develop active TB disease
- ▶ Characterized by **morbidity, contagiousness, and indicative chest x-ray (CXR)** findings or positive TB diagnostic tests
- ▶ Immunocompromised individuals (e.g. HIV/AIDS patients)
 - ▶ Have a higher risk of developing active TB disease⁽²⁹⁾

LTBI Treatment

LATENT TB INFECTION TREATMENT REGIMENS:				
DRUG(S)	DURATION	DOSE	INTERVAL	DOSES
Isoniazid (INH)	9 months	Adults: 5 mg/kg Children: 10-20 mg/kg** Max dose: 300 mg	Daily	270
		Adults: 15 mg/kg Children: 20-40 mg/kg** Max dose: 900 mg	Twice weekly DOT (Directly Observed Therapy)	76
	6 months	Adults: 5 mg/kg Children: NOT RECOMMENDED Max dose: 300 mg	Daily	180
		Adults: 15 mg/kg Children: NOT RECOMMENDED Max dose: 900 mg	Twice weekly DOT (Directly Observed Therapy)	52
Isoniazid (INH) & Rifapentine (RPT)	3 months	Adults & Children (12+ Years): INH*: 15 mg/kg rounded up to nearest 50 or 100 mg Max dose: 900 mg RPT* (by weight): 10.0-14.0 kg → 300 mg 14.1-25.0 kg → 450 mg 25.1-32.0 kg → 600 mg 32.1-49.9 kg → 750 mg ≥50.0 kg → 900 mg (Max dose)	Once weekly DOT (Directly Observed Therapy)	12
Rifampin (RIF)	4 months	Adults: 10 mg/kg*** Max dose: 600 mg	Daily	120
* INH is formulated as 100 & 300 mg tablets. RPT is formulated as 150 mg tablets in packs that should be kept sealed until usage. ** The American Academy of Pediatrics recommends an INH dosage of 10-15 mg/kg for daily regimen and 20-30 mg/kg for the twice weekly regimen. *** The recommended regimen for LTBI treatment in children is a 9-month course of INH. For LTBI treatment in infants, children, and adolescents with INH intolerance or a child with contact with a patient infected with an INH-resistant but rifamycin-susceptible organism, the American Academy of Pediatrics recommends 6 months of daily RIF (180 doses) at a dosage of 10-20 mg/kg.				

Table 4: Latent TB Infection Treatment Regimens⁽¹³⁾

STANDARD DRUG-SUSCEPTIBLE TB DISEASE TREATMENT REGIMENS

INITIAL PHASE (8-9 WEEKS)		CONTINUATION PHASE**** (18 WEEKS)		TOTAL DOSES	COMMENTS
REGIMEN # & DRUGS	INTERVAL***/DOSE (MINIMUM DURATION)	REGIMEN # & DRUGS	INTERVAL/DOSE (MINIMUM DURATION)		
(1) INH, RIF*, PZA, EMB**	7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks) *****	(1) INH, RIF	7 days/week for 126 doses (18 weeks) OR 5 days/week for 90 doses (18 weeks)	130- 182	- Preferred regimen for patients with newly diagnosed Pulmonary TB. - Most effective regimen.
(2) INH, RIF*, PZA, EMB**	7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)	(2) INH, RIF	3 times weekly for 54 doses (18 weeks)	94- 110	- Preferred alternative regimen in situation in which frequent DOT during continuation phase proves difficult.
(3) INH, RIF*, PZA, EMB**	3 times weekly for 24 doses (8 weeks)	(3) INH, RIF	3 times weekly for 54 doses (18 weeks)	78	- Use regimen 3 with caution in patients with HIV and/or cavitary dz. Missed treatments can lead to treatment failure, relapse, and drug resistance.
(4) INH, RIF*, PZA, EMB**	7 days/week for 14 doses, then twice weekly for 12 doses	(4) INH, RIF	Twice weekly for 36 doses (18 weeks)	62	- Do NOT use 2x-weekly regimen in HIV patients or patients w/ smear (+) and/or cavitary dz. - Least effective.

* HIV-infected patients on certain antiretroviral drugs may need medication adjustment because of drug interactions with rifampin. HIV-infected patients with <100 CD4+ cells/μl should be given daily therapy for the first 8 weeks and daily or three times weekly for the remaining 18 weeks. Consult a HIV/TB expert.

** EMB can be discontinued (prior to 8 weeks) once sensitivity to INH, RIF, & PZA are known.

*** ALL Regimens (1x, 2x, & 3x weekly and 5 days/week) must be administered via DOT (Directly Observed Therapy).

**** Treatment should be extended in certain circumstances. (See "Minimum TB Treatment Duration by Case Characteristics" below.)

***** The weekend doses are supplied to the patient to take on his or her own self. They are self-administered, so they are not really considered a part of the DOT.

MINIMUM TB TREATMENT DURATION BY CASE CHARACTERISTICS

TB Diagnosis (Case Characteristics)	Minimum Months of Treatment
Standard drug sensitive TB disease	6
Culture negative (abacillary) pulmonary disease	4
Drug resistance / Intolerance	
Without INH	6
Without PZA (pregnancy & M. bovis)	9
Without RIF	9-12
Without INH / RIF & other drugs	18-24
Cavitary Chest X-ray / Culture Positive @ 2 months	9
Extrapulmonary	
CNS	9
Bone Joint	9
Miliary	9
Other	6

Table 6: Standard TB Disease Treatment Regimens⁽²²⁾

FIRST-LINE TB DRUGS DOSAGE (MAXIMUM DOSE IN PARENTHESIS)

DRUGS	DAILY		WEEKLY					
			1x		2x		3x	
	CHILD	ADULT	CHILD	ADULT	CHILD	ADULT	CHILD	ADULT
INH	10-15 mg/kg (300 mg)	5 mg/kg (300 mg)	N/A	15 mg/kg (900 mg)	20-30 mg/kg (900 mg)	15 mg/kg (900 mg)	N/A	15 mg/kg (900 mg)
RIF	10-20 mg/kg (600 mg)	10 mg/kg (600 mg)	N/A	N/A	10-20 mg/kg (600 mg)	10 mg/kg (600 mg)	N/A	10 mg/kg (600 mg)
PZA*	15-30 mg/kg (2000 mg)	15-30 mg/kg (2000 mg)	N/A	N/A	50 mg/kg (4000 mg)	50-70 mg/kg (4000 mg)	N/A	50-70 mg/kg (3000 mg)
EMB*	15-20 mg/kg (1000 mg)	15-25 mg/kg (1600 mg)	N/A	N/A	50 mg/kg (4000 mg)	50 mg/kg (4000 mg)	N/A	25-30 mg/kg (2400 mg)
RBT	N/A	5 mg/kg (300 mg)	N/A	N/A	N/A	5 mg/kg (300 mg)	N/A	5 mg/kg (300 mg)
RPT	N/A	N/A	N/A	(600 mg) (10 mg/kg if >60 kg)	N/A	N/A	N/A	N/A

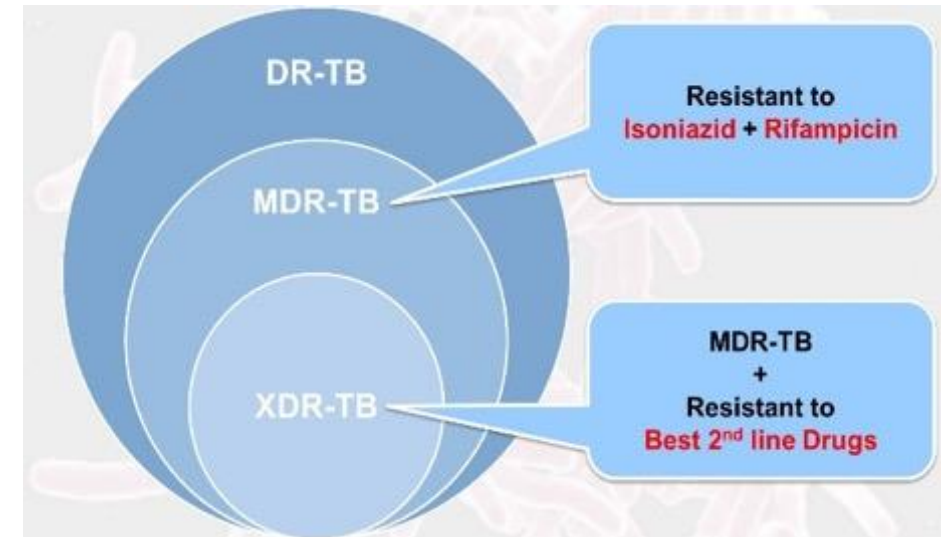
* The CDC recommends dosing based on weight ranges for PZA and EMB.

Table 7: First-Line TB Drug Dosage (Maximum Dose in Parenthesis)^(44, 47)

Active TB Treatment

Multi-Drug Resistant TB

- ▶ **Multi-Drug Resistant TB (MDR-TB)**
 - ▶ Resistant to:
 - ▶ ***At least isoniazid and rifampin*** (two most potent TB drugs)
- ▶ **Extensively Drug Resistant TB (XDR-TB)**
 - ▶ Resistant to:
 - ▶ ***Isoniazid and rifampin***
 - ▶ And ***any fluoroquinolone***
 - ▶ And ***at least one of three injectable second-line drugs*** (e.g. amikacin, kanamycin, or capreomycin)
 - ▶ ***High chance of developing TB disease***
 - ▶ ***High mortality rates***⁽¹⁶⁾



Contact Investigations

- ▶ **Who is a Contact?**

- ▶ Anyone who has been exposed to someone with infectious TB
 - ▶ *Measuring level of exposure: **Duration, proximity, and intensity of shared time***

- ▶ **Contact Investigations**

- ▶ Interviewing TB patient and visiting locations where patient spent time
 - ▶ Identify/screen contacts & find source or environmental factors

- ▶ **The health department is legally responsible for:**

- ▶ Identifying and evaluating contacts
- ▶ Offering treatment to any infected contacts
- ▶ Monitoring adherence to prescribed regimens
- ▶ Ensuring accessibility to completion of treatment

Infection Control

▶ AIRBORNE INFECTION ISOLATION (AII)⁽¹⁷⁾

- ▶ All should be initiated for all hospitalized TB suspects
 - ▶ Until a thorough medical evaluation is conducted
- ▶ TB patient should remain in isolation if infectious
 - ▶ Until the treatment renders the patient noninfectious
- ▶ Facilities without an AII room
 - ▶ Should have a written plan for referring patients to an equipped facility



▶ All Discontinuation⁽¹²⁾

- ▶ TB patients may be discontinued from AII when they meet **at least one** of the following criteria:
 - ▶ 1) Another diagnosis assigned
 - ▶ 2) **3 consecutive, negative AFB smears**
 - ▶ 3) At least 2 weeks of treatment with a known, strain-susceptible TB treatment regimen

Infection Control (Continued)

- ▶ **MPH Competency (Environmental Health Sciences):**

- ▶ **Unique KS Infection Control Requirements for:**

- ▶ **1)** Adult care homes
 - ▶ **2)** Correctional/detention facilities
 - ▶ **3)** Hospital-based care settings

- ▶ **Central Kansas PHEP meeting in Lyons, KS**

- ▶ Health directors from 5 different counties
 - ▶ Purchasing certain Personal Protective Equipment (PPE)
 - ▶ Expired PPE that could no longer serve its purpose
 - ▶ Medical waste

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Nebraska TB Manual

Maryland TB Guidelines for Prevention and Treatment of Tuberculosis 2007

Maryland Department of Health and Mental Hygiene

Martin O'Malley, Governor
Anthony G. Brown, Lt. Governor
John M. Colson, Secretary, DHMH

Maryland TB Manual

Review of TB Protocol Manuals from Other States

Four Manuals Referenced:

1. Nebraska Department of Health and Human Services
2. Maryland Department of Health and Hygiene
3. Washington State Department of Health
4. County of Los Angeles Tuberculosis Control Program

Review of TB Protocol Manuals from Other States

Table 1. Comparison of Pros & Cons for TB Manuals for Nebraska & Maryland			
<u>Nebraska</u>		<u>Maryland</u>	
<u>Pros:</u>	<u>Cons:</u>	<u>Pros:</u>	<u>Cons:</u>
<i>Logical order of presentation.</i>	<i>No graphics, figures, tables, or cover page.</i>	<i>Some graphics and includes cover page.</i>	<i>No Tuberculin Skin Test instructions.</i>
<i>Includes very detailed TB Skin Test instructions.</i>	<i>Some aspects are not explained in enough detail (e.g. "Treatment of TB" section- had little to no explanation.</i>	<i>Very thorough and includes a logical order of presentation that is easy to follow.</i>	<i>Some of the guidelines are too study-focused instead of practice-focused. Not ideal for a health care worker to follow and implement.</i>
<i>Brevity of Information where it is needed.</i>	<i>Small font and no distinguishable spacing between the sections.</i>	<i>Includes many customizable factors that relate to Maryland.</i>	<i>No graphics to help in understanding certain procedures.</i>

Review of TB Protocol Manuals from Other States

► Upon Review:

- **Emphasis on brevity without compromising content**
- CDC-based instructions and graphics
 - Tuberculin Skin Test procedure
- Logical order for the different parts of the CDC manual
 - 1) Introduction to TB
 - 2) Latent TB Infection Management
 - 3) Active TB Management
 - 4) Adherence Promoting Strategies
 - 5) Contact Investigations / Infection Control
 - 6) References and Appendices

SCHO GUIDELINES FOR THE PREVENTION, DIAGNOSIS, AND TREATMENT OF TUBERCULOSIS (2017)

- **Filling the Syringe:**
 - Wipe the top of the vial with a new alcohol swab and allow it to dry thoroughly.
 - Fasten the needle tightly on the syringe by holding the cap and twisting it onto the tip of the syringe. Remove the needle cap and make sure that the needle bevel is facing upwards.
 - Hold vial between your thumb and fingers and insert the needle through the stopper. Inject air into the empty space in the vial. **(Step A)**
 - Invert vial and draw out slightly over 0.1 mL of solution. **(Step B)**
 - Remove needle from vial. Hold syringe upright and gently tap to break up any air bubbles. Expel air from syringe and excess solution, leaving exactly 0.1 mL of tuberculin solution. **(Step C)**



Figure 2.3: Filling the SyringeTM

- **Injection of Tuberculin PPD Solution:**
 - Stretch the skin taut over the injection site to provide a surface that is easy for the needle to penetrate. (Stretch skin between thumb and index finger with the hand not used to administer injection or grasp patient's forearm and gently pull skin towards you.)
 - Hold syringe between your thumb and index finger with the needle bevel facing up and the syringe parallel to the forearm.
 - With needle against the patient's skin, barely insert the needle slowly at a 5-15 degree angle, just below the surface of the skin. **(Step A)**
 - Release the stretched skin and hold the syringe in place. Slowly inject the tuberculin solution, forming a 6-8mm wheal (pale, raised area with distinct edges and orange peel appearance).
 - If no wheal forms, repeat on opposite arm.
 - Slowly withdraw needle from patient without massaging area and immediately discard syringe in sharps container. **(Step B)**
 - If minor bleeding occurs, use a 2x2 gauze pad or cotton ball to dab gently at injection site.
 - Do not cover the site with an adhesive bandage as it could cause irritation.



Figure 2.4: Injection of Tuberculin PPD SolutionTM

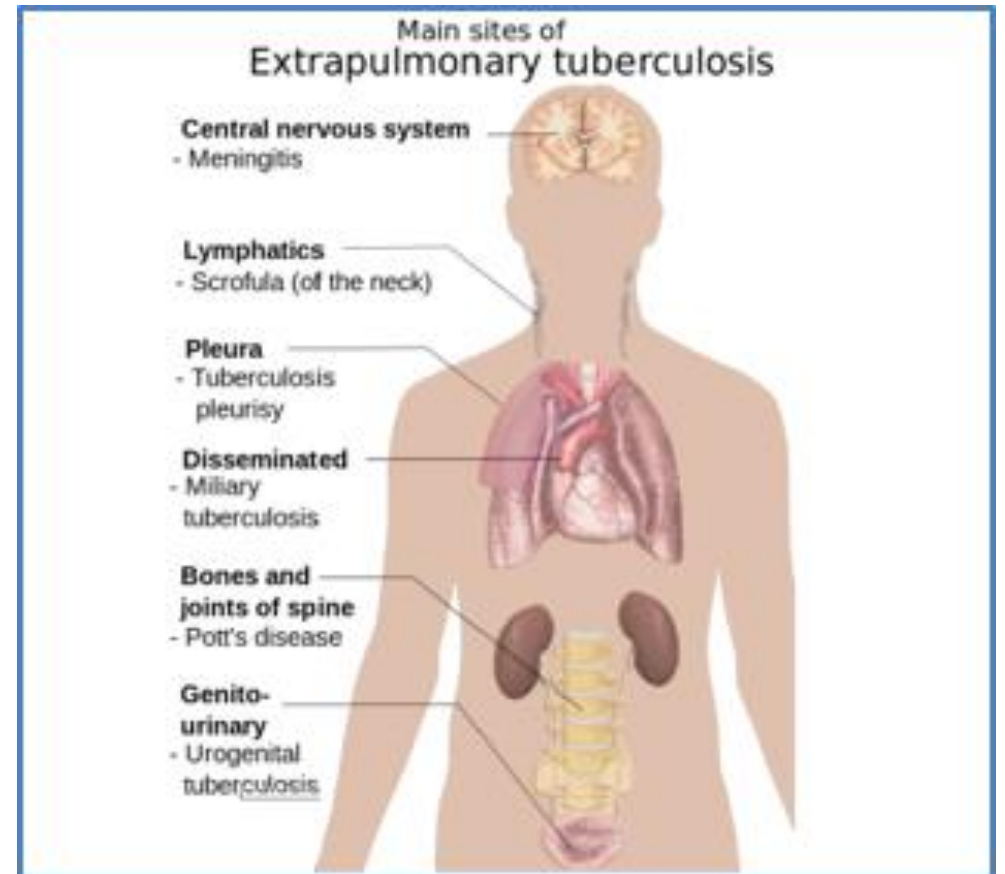
- **Post-Administration:**
 - Record the following information on the patient's form:
 - Date, time, and location of injection site
 - Name of manufacturer and lot number
 - Expiration date of PPD solution
 - Name of manufacturer, lot number, and expiration of PPD solution

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Shadowing Experience (Extrapulmonary TB Case Treatment)

▶ Extrapulmonary TB Case Management

- ▶ Observe the process of treating an elderly patient with extrapulmonary tuberculosis
 - ▶ Managed every day
 - ▶ Travelled to patient's house daily to provide DOT
- ▶ **Total time (including travel): ~30 minutes**



Economic Impacts of TB Treatment

- ▶ The treatment of TB is mostly covered by the public sector.
- ▶ Total monthly costs of treating a LTBI case were as follows:
 - ▶ 9H: **\$26.37**
 - ▶ 9H-DOT: **\$204.56**
 - ▶ 3HP (with DOT): **\$167.82**
 - ▶ 4R: **\$53.07**
- ▶ Toxicity costs, which included lab monitoring: **\$158.36**
- ▶ 7-day hospitalization average cost estimate: **\$5,320.77**
 - ▶ Range: **\$4250-\$8000** –American Thoracic Society⁽⁵⁸⁾



Economic Impacts of TB Treatment (Continued)

- ▶ **Active TB** case management costs:
 - ▶ 6-month treatment regimen, total cost average: **\$12,511.71**
 - ▶ 9-month treatment regimen, total cost average: **\$13,246.57**
- ▶ **Drug Resistant TB** direct costs of treatment –CDC⁽⁵⁸⁾:
 - ▶ Per MDR-TB patient: **\$134,000**
 - ▶ Per XDR-TB patient: **\$430,000**
- ▶ **MPH Competency (Health Services Administration):**
 - ▶ **Costs of TB treatment**
 - ▶ “Managing Non-Adherence”
 - ▶ State ordinances (**Kansas State Statutes**)
 - ▶ **Obtaining Grants and Grant Allocation**
 - ▶ Community Health Assessments
 - ▶ Need-based reports for grants to support effective health outcomes



Blue Cross Blue Shield (Breakdown of Healthcare Spending)

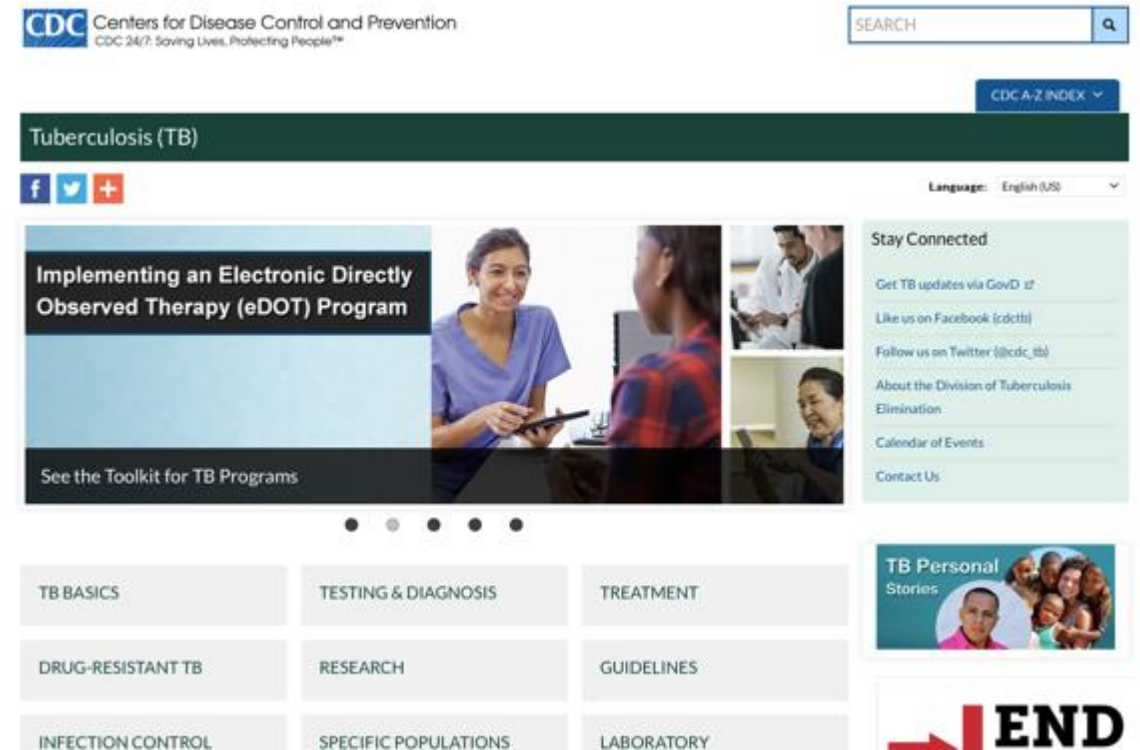
CDC-Recommended Guidelines for TB Management/Control

► CDC Website

► <https://www.cdc.gov/tb>

► Electronic Directly Observed Therapy (e-DOT)

► Remote administration of DOT via use of electronic video-sharing devices



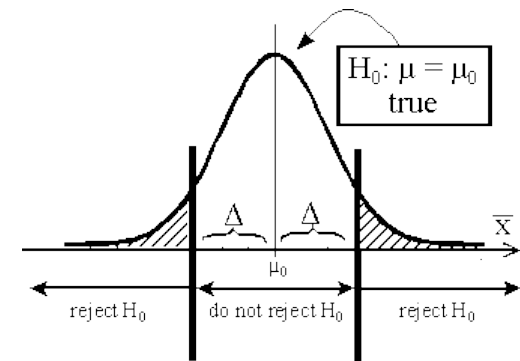
3.2.2) Research Question

- ▶ *What are the specific needs of Saline County or Kansas local health departments as it relates to TB management and control?*



3.2.3) Quantitative Research

- ▶ **KS Active TB Case Data (2012-2017)**
 - ▶ Demographic & Risk Factor Visualizations
- ▶ **CDC WONDER Active TB Case Data (1993-2015)**
 - ▶ Question Formulations
 - ▶ Testing of Questions
 - ▶ Results, Conclusions, and Discussion
- ▶ **Additional Data Collection Via SurveyMonkey**
 - ▶ e-DOT
 - ▶ Google Translate
- ▶ **MPH Competency (Biostatistics):**
 - ▶ Descriptive and inferential statistical methods
 - ▶ Hypothesis Testing / Odds Ratio Calculations
 - ▶ Statistical analysis tools: SAS / R



KS Active TB Case Data (2012-2017)

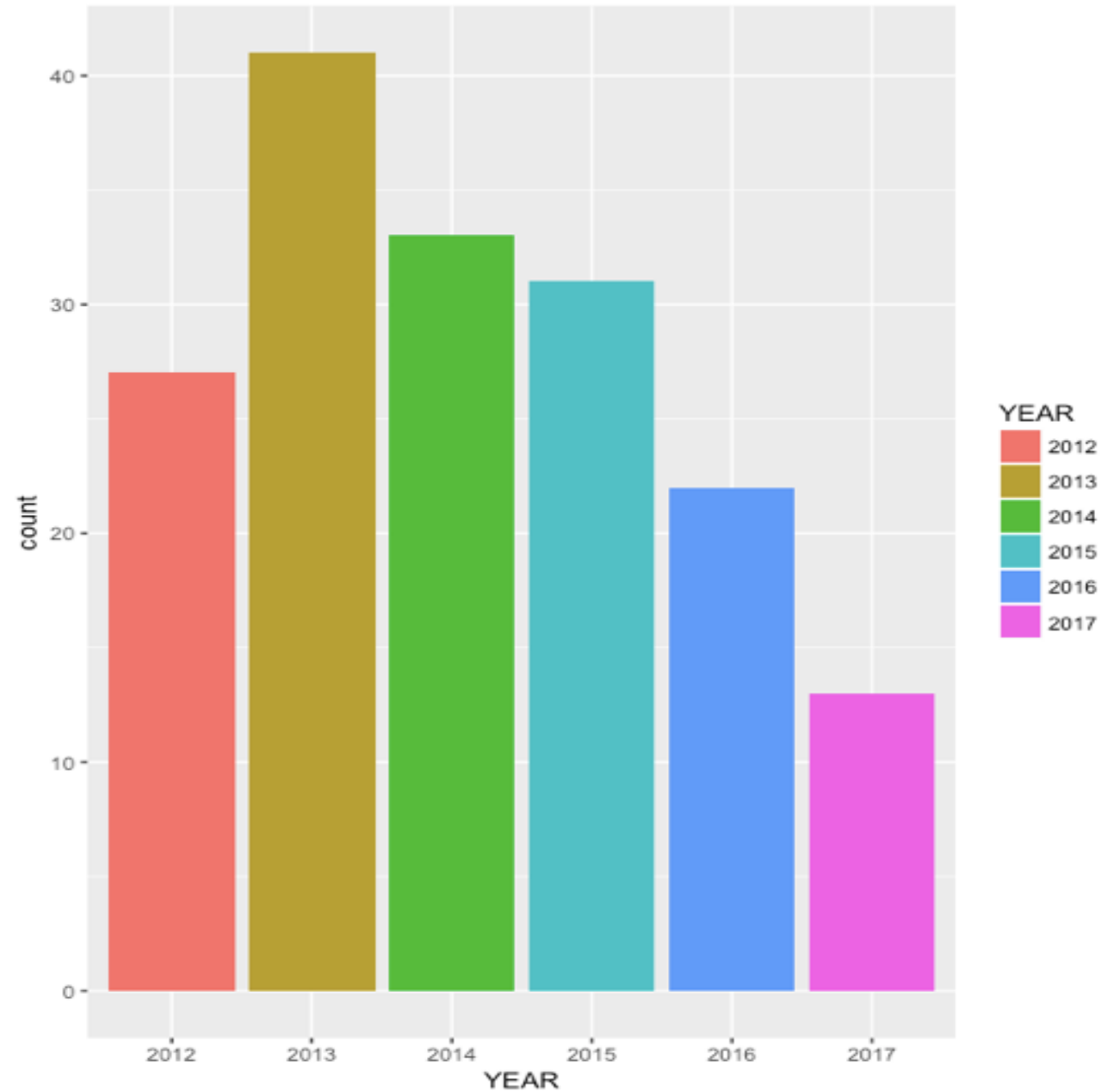
- ▶ 167 Case files (Doctor's Notes) for all Kansan active TB cases from 2012- 2017
 - ▶ Demographic information
 - ▶ Risk factors
- ▶ Visualization
 - ▶ Package 'ggplot2' in R

RISK FACTORS FOR TARGETED TESTING IN ADULTS & CHILDREN/ADOLESCENTS	
<u>ADULTS</u>	Foreign-Born from / Recent-Traveler to High-Prevalence Countries (e.g. Mexico, the Philippines, Vietnam, India, China, Haiti, etc.) <i>(See List of HBCs in Appendix B.)</i>
	Close Contact with Someone with Infectious TB Disease
	Resident/Employee of High-Risk Congregate Setting in Places at High Risk for TB Transmission (e.g. Long-Term Care Facility, Correctional Facility, Hospital, Homeless Shelter)
	The Immunosuppressed: HIV Patients, Organ Transplant Recipients, Substance Abusers (e.g. Smoking, Alcohol Abuse, Injection Drug Use), and those with Secondary Immunosuppression Due to Prednisone Usage (≥ 15 mg/day for One Month) or TNF-α antagonists)
	Medical Conditions Associated with Risk of Progressing to TB Disease if Infected (e.g. Diabetes Mellitus, Silicosis, Cancer (Head & Neck), Hodgkin's Disease, Leukemia, End-Stage Renal Dz, Intestinal Bypass/Gastrectomy, Chronic Malabsorption Syndrome, & Low Body Weight)⁽²⁶⁾
	Chest Radiographs with Fibrotic Changes Suggesting Inactive or Past TB
	Signs and Symptoms of TB Disease
<u>CHILDREN/ADOLESCENTS</u>	Children ≤ 5 Years Old
	Annual Testing for: HIV-Infected Children and Incarcerated Adults
	Testing Every 2-3 Years for: Children Exposed to HIV-Infected, Homeless, Nursing Home Residents, Institutionalized, Illicit-Drug Users, Incarcerated, or Migrant Farm Workers, & Foster Children Exposed to Adults in Above Categories
	Testing Consideration at 4-6 and 11-16 Years of Age for: Children whose Parents or Household Contacts (w/ Unknown TST Status) Immigrated from High-Prevalence Countries & Children with Continued Potential Exposure by Travel to these Counties

Table 2: Risk Factors for Targeted Testing in Adults & Children/Adolescents^(14, 26, 46)

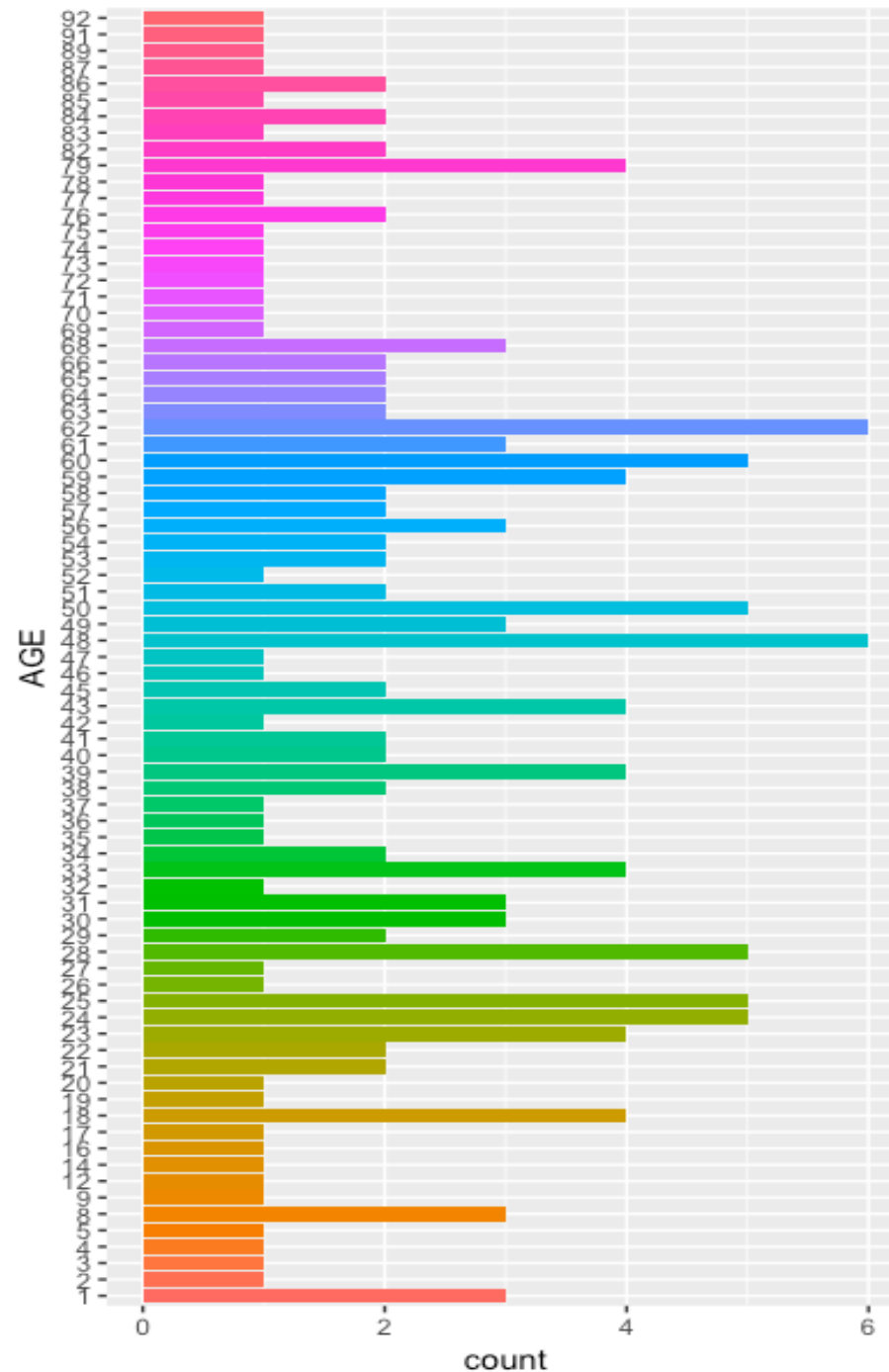
Year

- ▶ NOTE: 2017 is half-year
- ▶ Observed hike in 2013
- ▶ Steady drop in concurrent years



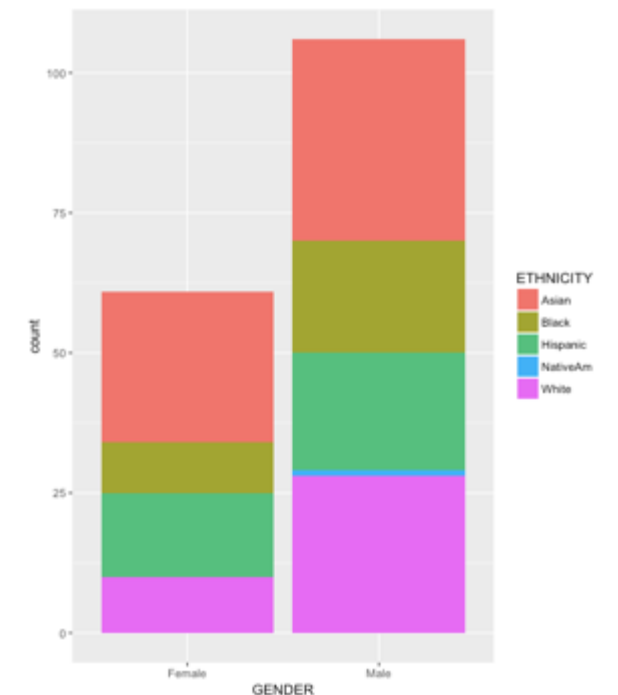
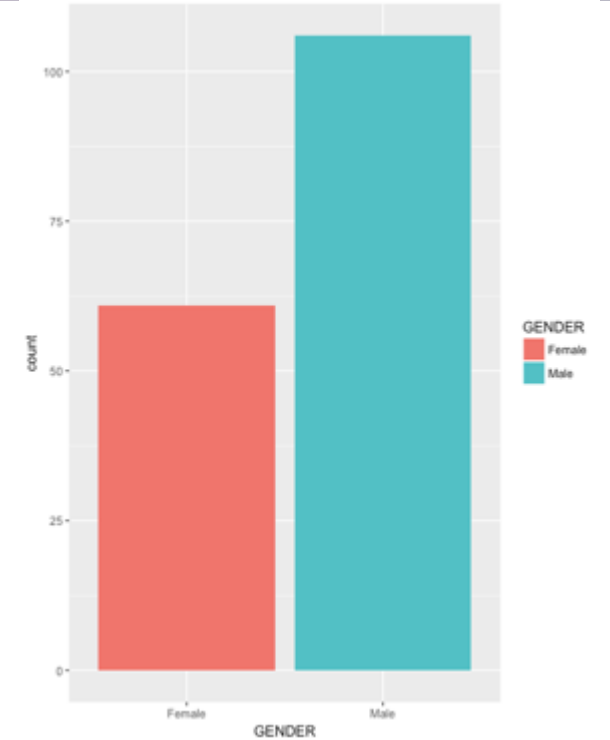
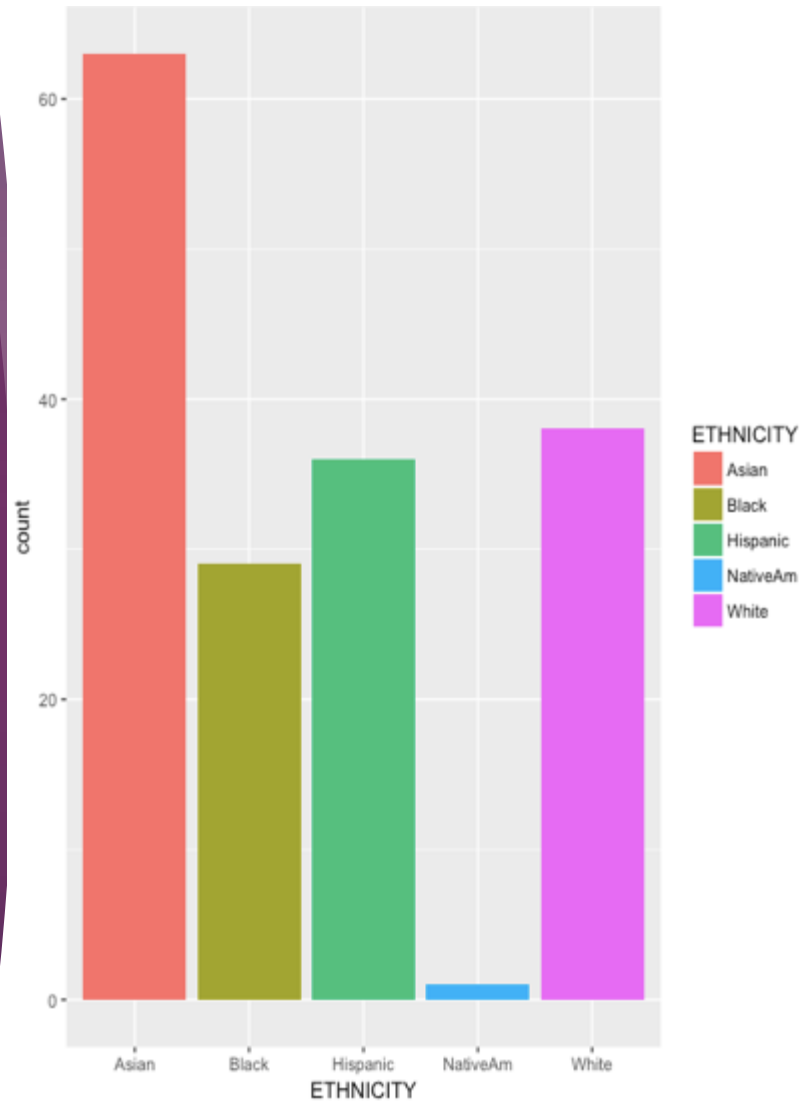
Age Distribution

- ▶ Age range appears to be fairly uniformly distributed
- ▶ Upon age group stratification, distribution may appear to be normally distributed



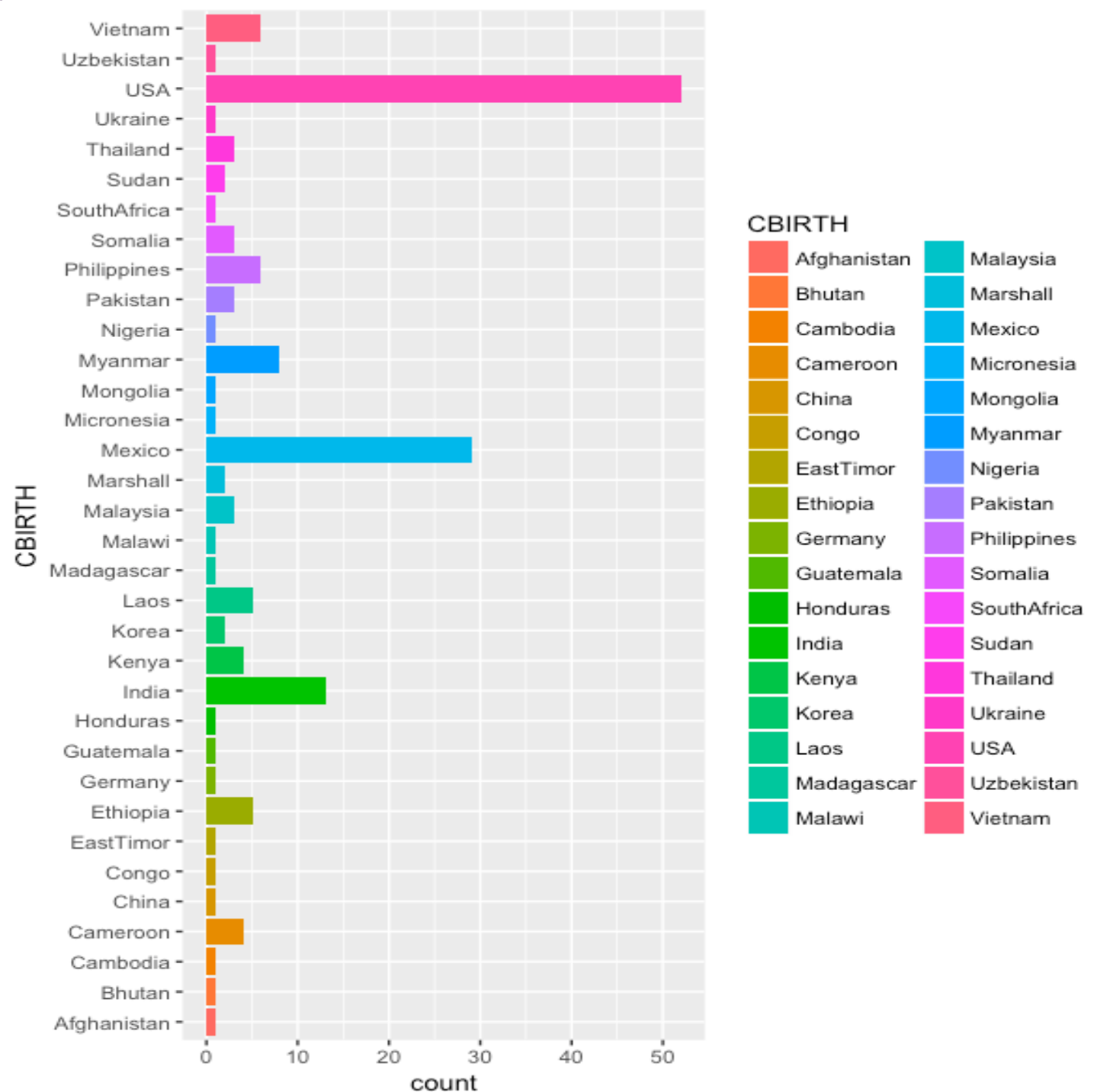
Ethnicity, Gender, & Ethnicity by Gender

- ▶ Ethnicity
 - ▶ Asian
 - ▶ White
 - ▶ Hispanic
 - ▶ Black
 - ▶ Native American
- ▶ Gender
 - ▶ Roughly 2 in 3 cases of active TB are male



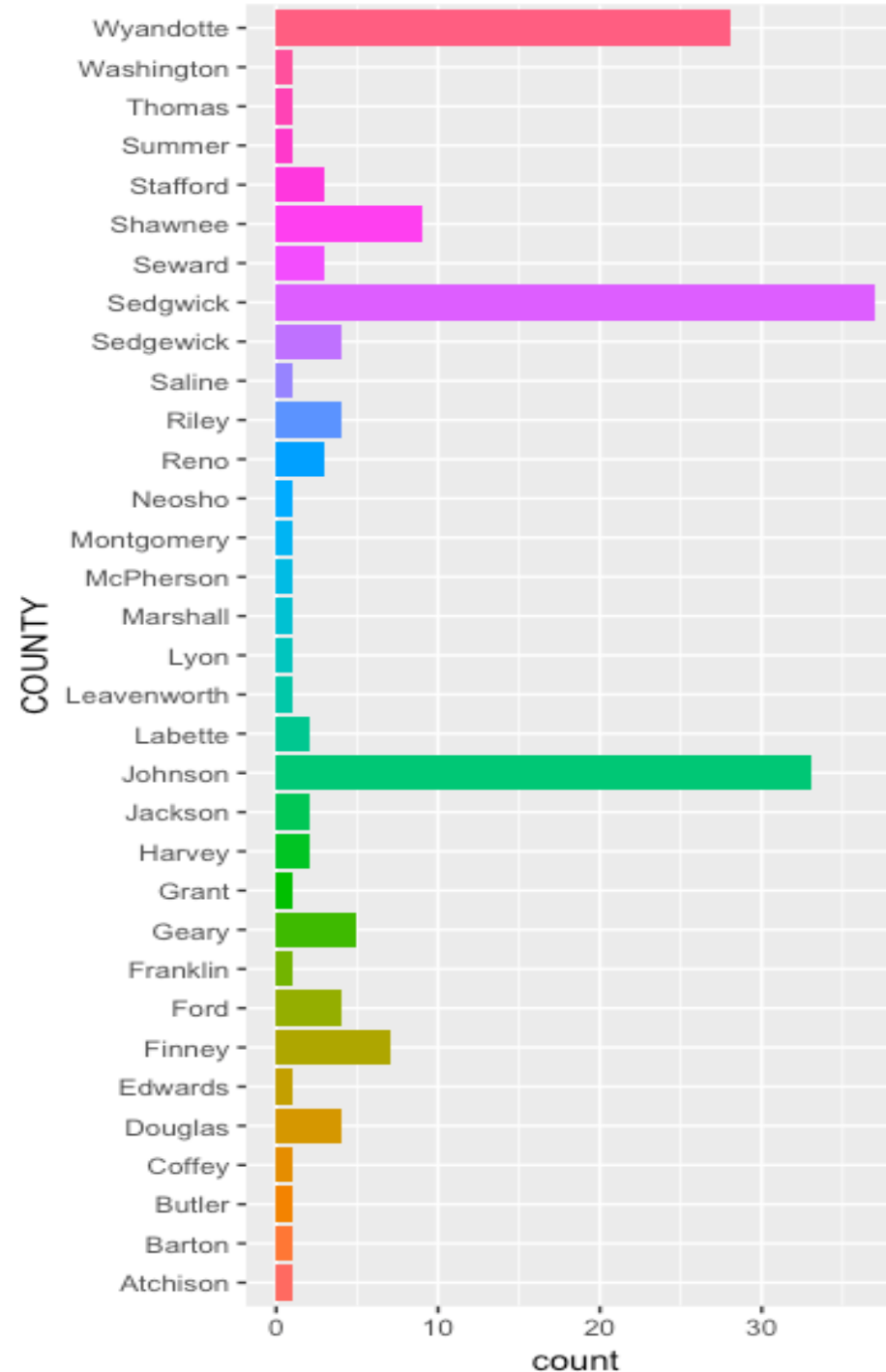
Country of Birth

- ▶ Top 3:
 - ▶ USA
 - ▶ Mexico
 - ▶ India
- ▶ Other Countries:
 - ▶ Myanmar (Burma)
 - ▶ Vietnam
 - ▶ Philippines
 - ▶ Ethiopia
 - ▶ Laos
 - ▶ Somalia



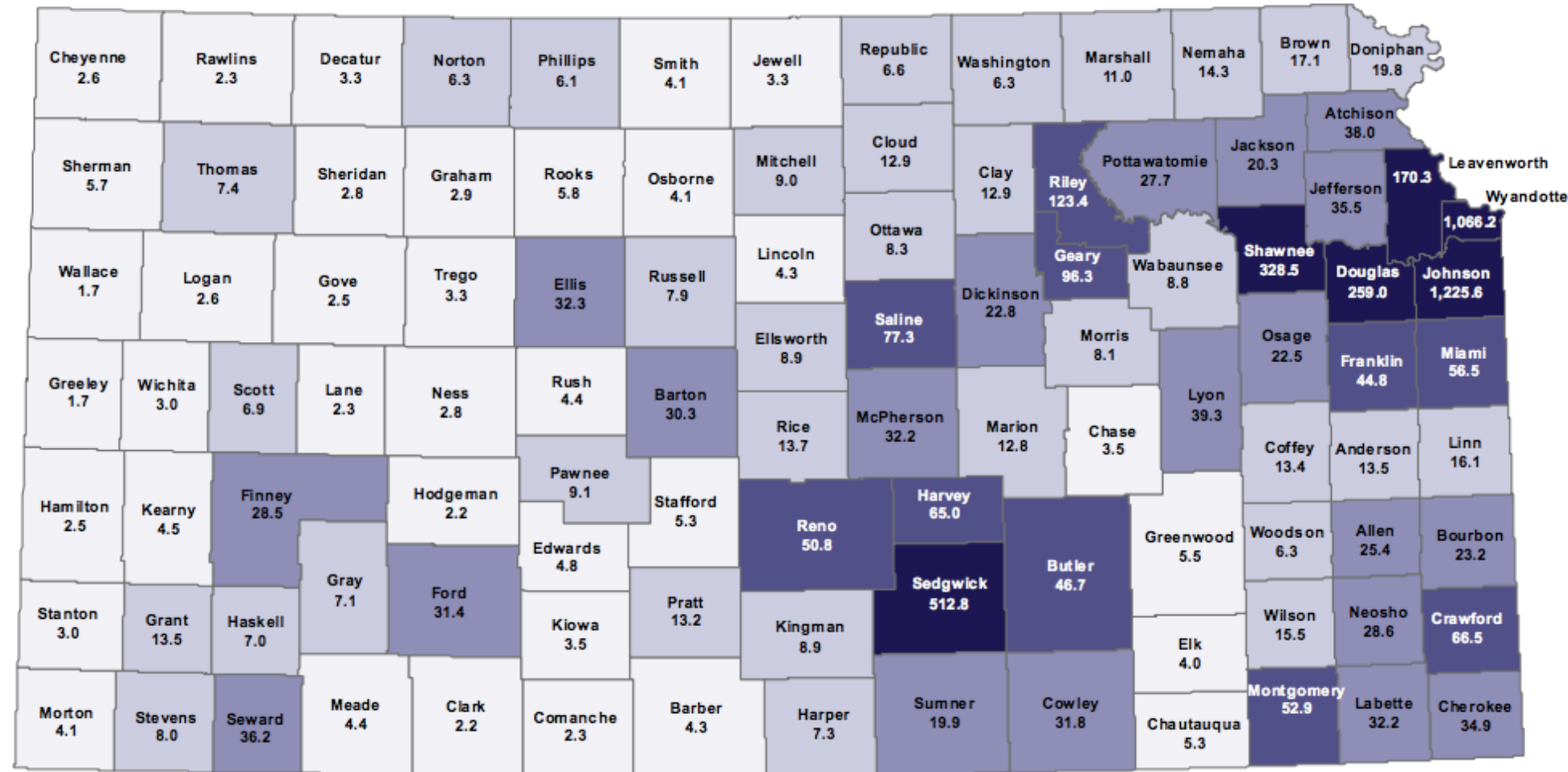
County of Occurrence

- ▶ Top 3:
 - ▶ Sedgwick
 - ▶ Johnson
 - ▶ Wyandotte
- ▶ Other Counties:
 - ▶ Shawnee
 - ▶ Finney
 - ▶ Geary
 - ▶ Ford
 - ▶ Douglas
 - ▶ Riley



Population Density Classification

by County, 2015



Source: Institute for Policy & Social Research, The University of Kansas;
data from the U.S. Census Bureau, Population Estimates, Vintage 2015.

Population Density by Classification*
(persons per square mile)

- Frontier (less than 6.0 ppsm)
- Rural (6.0 - 19.9 ppsm)

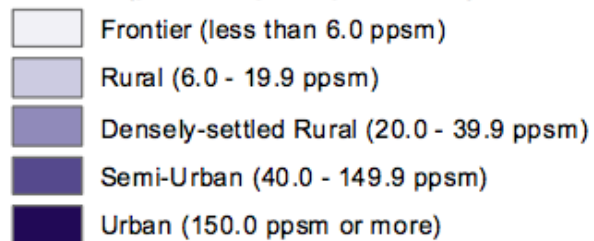
State: 35.6

Population Density Classification

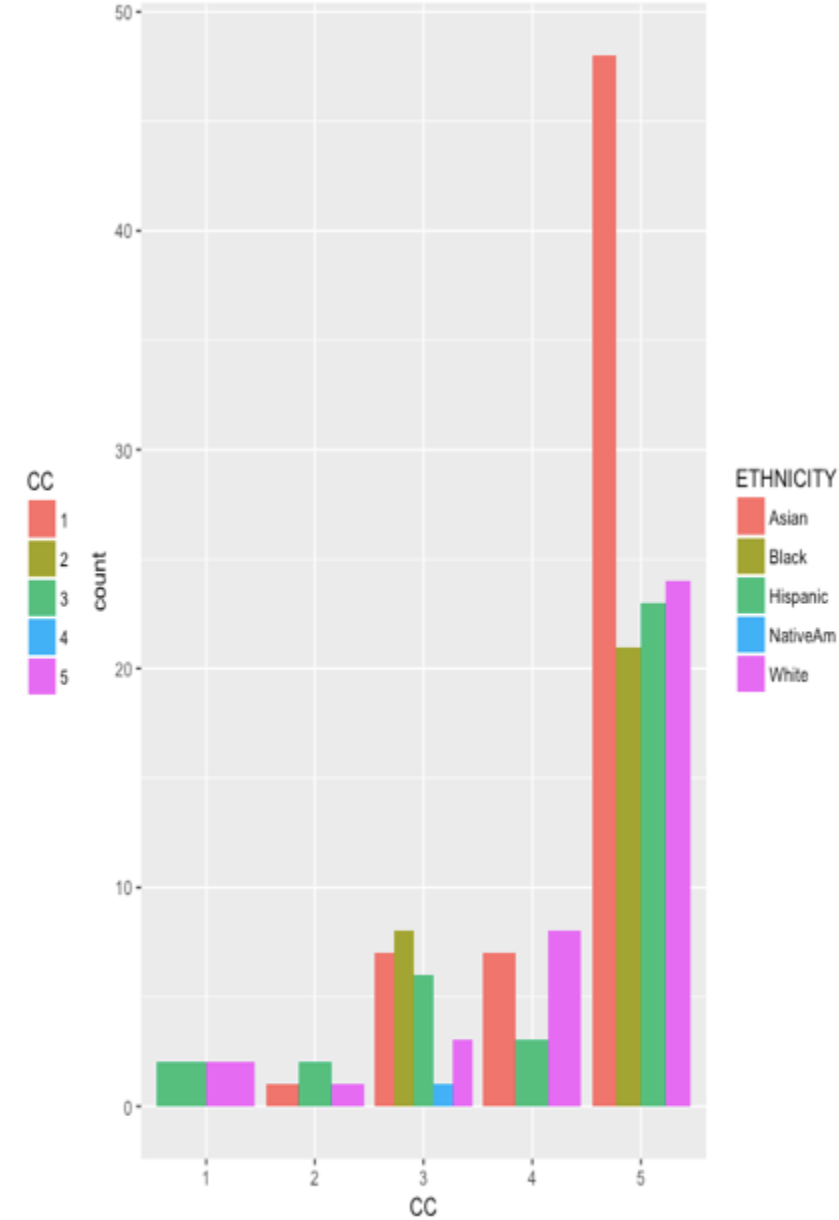
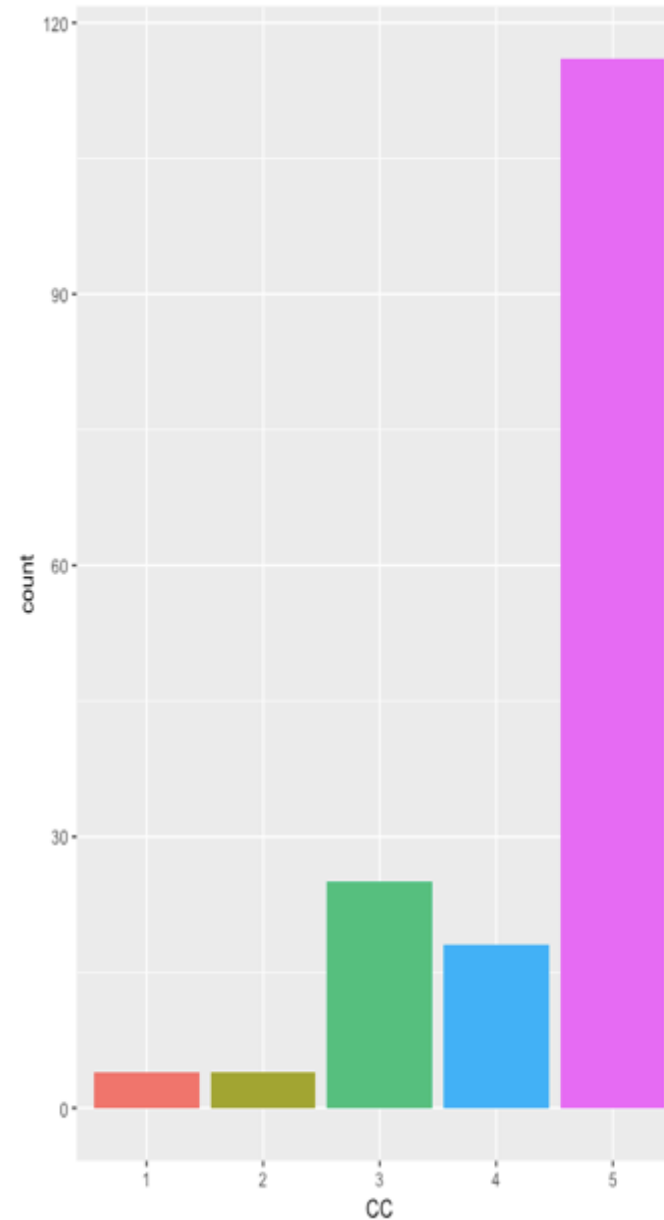
► KDHE Classifications:

- 1) Frontier (<6.0 ppsm)
- 2) Rural (6.0-19.9 ppsm)
- 3) Densely-Settled Rural (20.0-39.9 ppsm)
- 4) Semi-Urban (40.0-149.9 ppsm)
- 5) Urban (150+ ppsm)

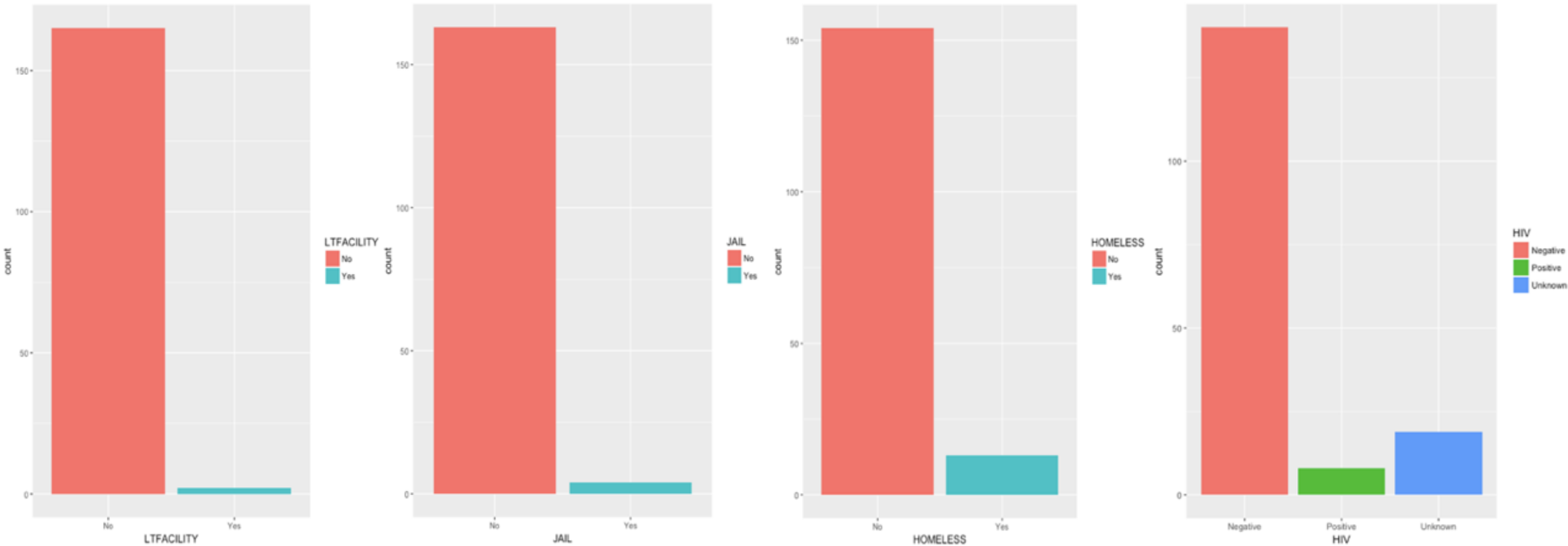
Population Density by Classification* (persons per square mile)



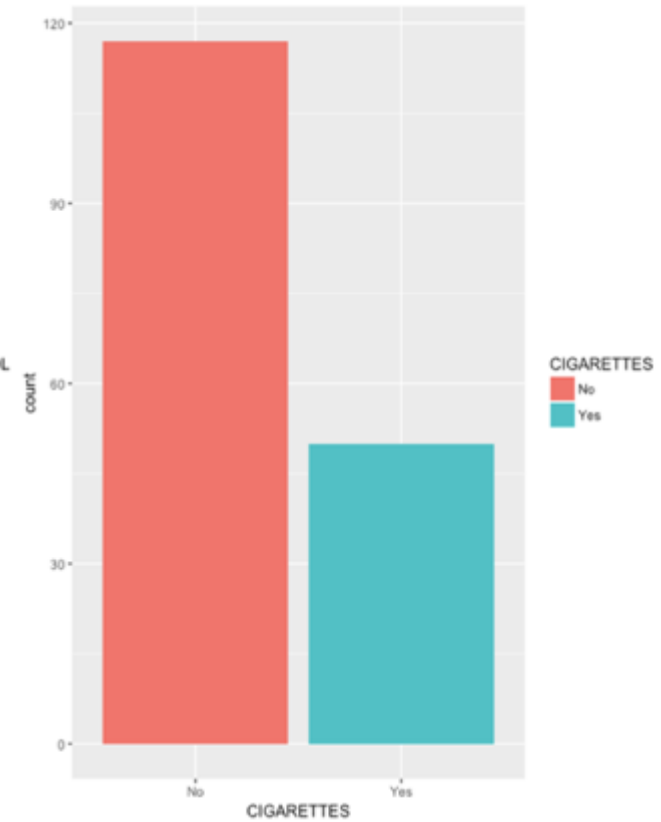
* Kansas Department of Health and Environment classifications.



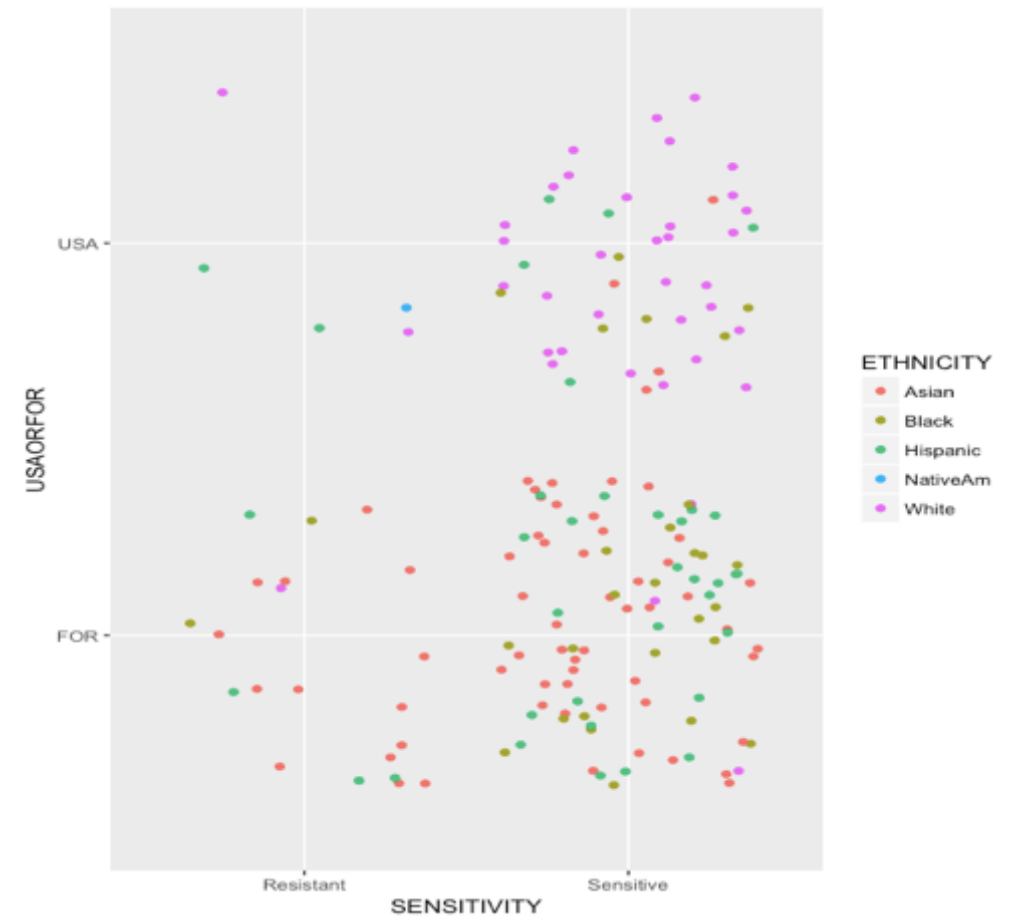
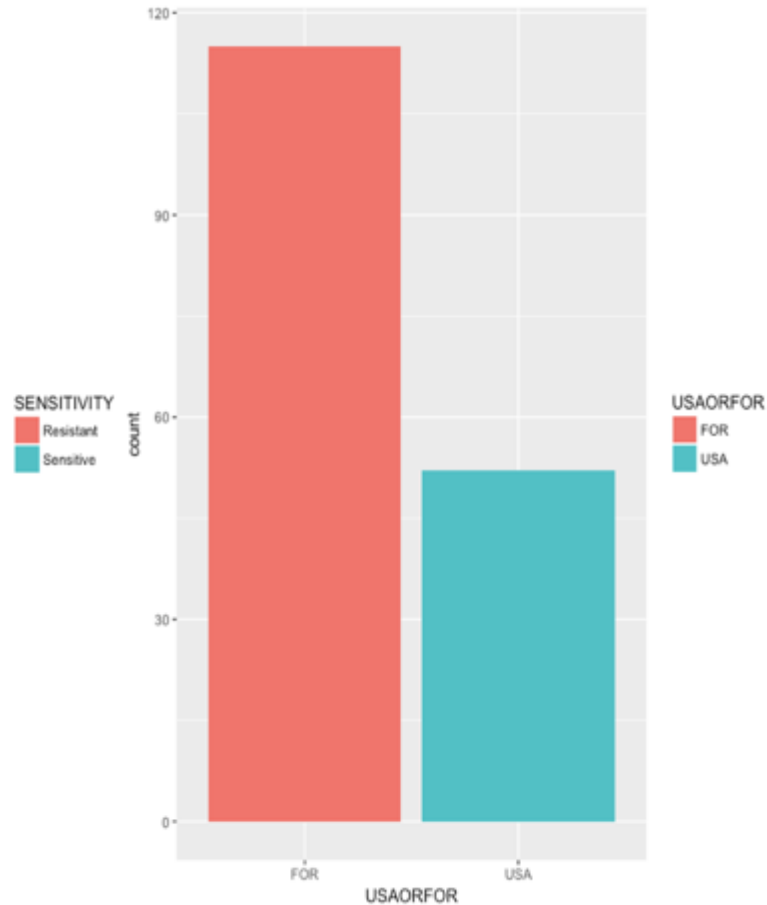
Risk Factor Visualization



Risk Factor Visualization (Continued)



Risk Factor Visualization (Continued)



Kansas TB Risk Factor Visualization

► Observations:

- Active TB in Kansas
 - Greater proportion of foreign-born cases
- When a foreign-born immigrant, traveler, student, or refugee arrives in the U.S. from a TB high-burden country, they have a significantly higher rate of developing active TB than those who are born in the U.S.
- **TB drug resistance cases**
 - More commonly seen in *foreign-born individuals*

CDC WONDER Active TB Case Data (1993-2015)

▶ **CDC WONDER**

- ▶ Online ad-hoc query system
- ▶ Utilized for disseminating public health data and information for analysis
- ▶ WONDER's Online Tuberculosis Information System (OTIS)
 - ▶ Kansas and USA active TB data from years 1993-2015



Question Formulation / Testing:

▶ QUESTIONS:

- ▶ 1) Is the relative proportion of **foreign-born cases** of active TB greater in Kansas than the true proportion or **overall burden of foreign-born cases**?
- ▶ 2) Is **country of birth** (U.S. vs foreign-born status) independent of **multi-drug resistance**?
- ▶ 3) Is **TB therapy administration method** (self-administered vs. DOT vs. both) independent of **completion of therapy** in Kansas TB cases?

▶ TESTING:

- ▶ **Test 1** – A one-sample Z-test to compare proportions
- ▶ **Tests 2 & 3** – Chi-square tests to test independence of categorical variables with associated odds ratio calculations.

Test 1 (One-Sample Z-test for Proportions):

- ▶ **Question:** Is the relative proportion of foreign-born cases of TB greater in Kansas than the true proportion or overall burden of foreign-born cases (proportion of foreign-born cases in the U.S.)?
- ▶ **H_0 :** $\mu_{KS} \leq \mu$, (where μ represents the true proportion of active TB Cases that are foreign-born)
- ▶ **H_a :** $\mu_{KS} > \mu$
- ▶ **Significance Level:** $\alpha = 0.05$
- ▶ **Decision Rule:** Reject H_0 if $Z > \text{Critical Value (1.645)}$.
- ▶ **Test Statistic:** $n = 1471$
 - ▶ $\hat{p} = \frac{\text{\# of Foreign-Born Cases of Active TB in KS}}{\text{Total \# of Active TB Cases in KS}} = \frac{764}{1471} = 0.5194$
 - ▶ $p_0 = \frac{\text{\# of Foreign-Born Cases of Active TB in the U.S.}}{\text{Total \# of Active TB Cases in the U.S.}} = \frac{169,127}{351,029} = 0.4818$
 - ▶ $Z = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}} = \frac{0.5194 - 0.4818}{\sqrt{\frac{(0.4818)(1-0.4818)}{1471}}} = \mathbf{2.8861} > 1.645 \text{ (Critical Value)}$
 - ▶ From Standard Normal Table: $P(Z \leq 2.8861) = \Phi(2.9) = 0.9984$
P-Value: $1 - \Phi(2.9) = 1 - 0.9984 = \mathbf{0.0016}$

Test 1 (Continued):

- ▶ **Decision:** Reject H_0 in favor of H_a .
- ▶ **Conclusion:** The proportion of active TB cases that are foreign-born is greater in Kansas than the proportion of active TB cases that are foreign-born in the U.S (0.4818). (*P-Value: 0.001962*)



```
> prop.test(x=764, n=1471, p=0.4818, correct=FALSE, alternative="greater")
```

1-sample proportions test without continuity correction

```
data: 764 out of 1471, null probability 0.4818
X-squared = 8.3183, df = 1, p-value = 0.001962
alternative hypothesis: true p is greater than 0.4818
95 percent confidence interval:
 0.4979315 1.0000000
sample estimates:
      p
0.5193746
```

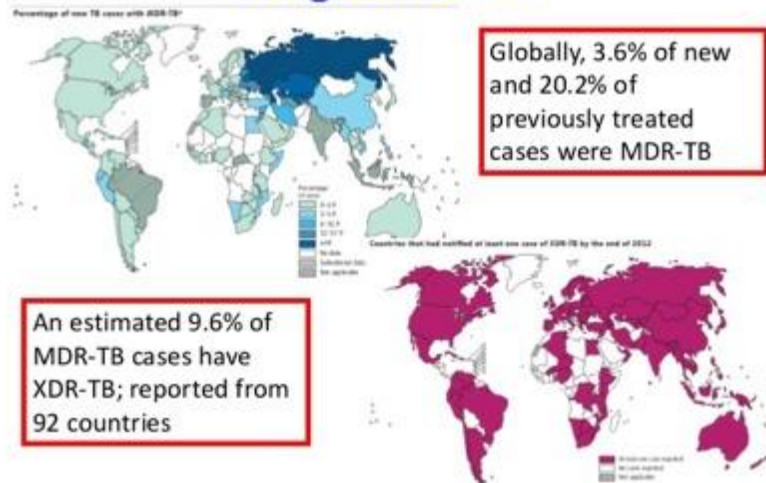
Test 2 (Chi-Square Test of Independence):

- ▶ **Question:** Is U.S./foreign-born status independent of multi-drug resistance?
- ▶ **H_0 :** U.S./Foreign-Born Status is independent of Multi-Drug Resistance Status
- ▶ **H_a :** U.S./Foreign-Born Status is not independent of Multi-Drug Resistance Status
- ▶ **Significance Level:** $\alpha = 0.05$
- ▶ **Decision Rule:** Reject H_0 if $\chi^2 > \text{Critical Value}$
- ▶ **Test Statistic:** $df = (r-1)(c-1) = (2-1)(2-1) = 1$
 - ▶ From χ^2 Distribution Table: $\chi^2_{(df=1, \alpha=0.05)} = 3.84$ (Critical Value)
 - ▶ $\chi^2 = \sum \frac{(|\text{Observed} - \text{Expected}| - 0.5)^2}{\text{Expected}}$ (With Yates' Continuity Correction)
 - ▶ $= \frac{(|13.5 - 7.4866| - 0.5)^2}{7.5} + \frac{(|586.5 - 592.5134| - 0.5)^2}{592.5} + \frac{(|0.5 - 6.5134| - 0.5)^2}{6.5} + \frac{(|521.5 - 515.4866| - 0.5)^2}{515.5}$
 - ▶ $= \mathbf{8.84} > 3.84$ (Critical Value)

Test 2 (Continued):

- ▶ **Decision:** Reject H_0 in favor of H_a .
- ▶ **Conclusion:** U.S./foreign-born status is not independent of MDR status (P-Value: 0.002951).

WHO Global Tuberculosis Report 2013 Drug Resistance



```
> ForeignBorn = c(13.5, 586.5)
> USBorn = c(0.5, 521.5)
> as.numeric(c(ForeignBorn, USBorn))
[1] 13.5 586.5 0.5 521.5
> mdrtb = as.data.frame(rbind(ForeignBorn, USBorn))
> names(mdrtb) = c('Yes', 'No')
> mdrtb
```

	Yes	No
ForeignBorn	13.5	586.5
USBorn	0.5	521.5

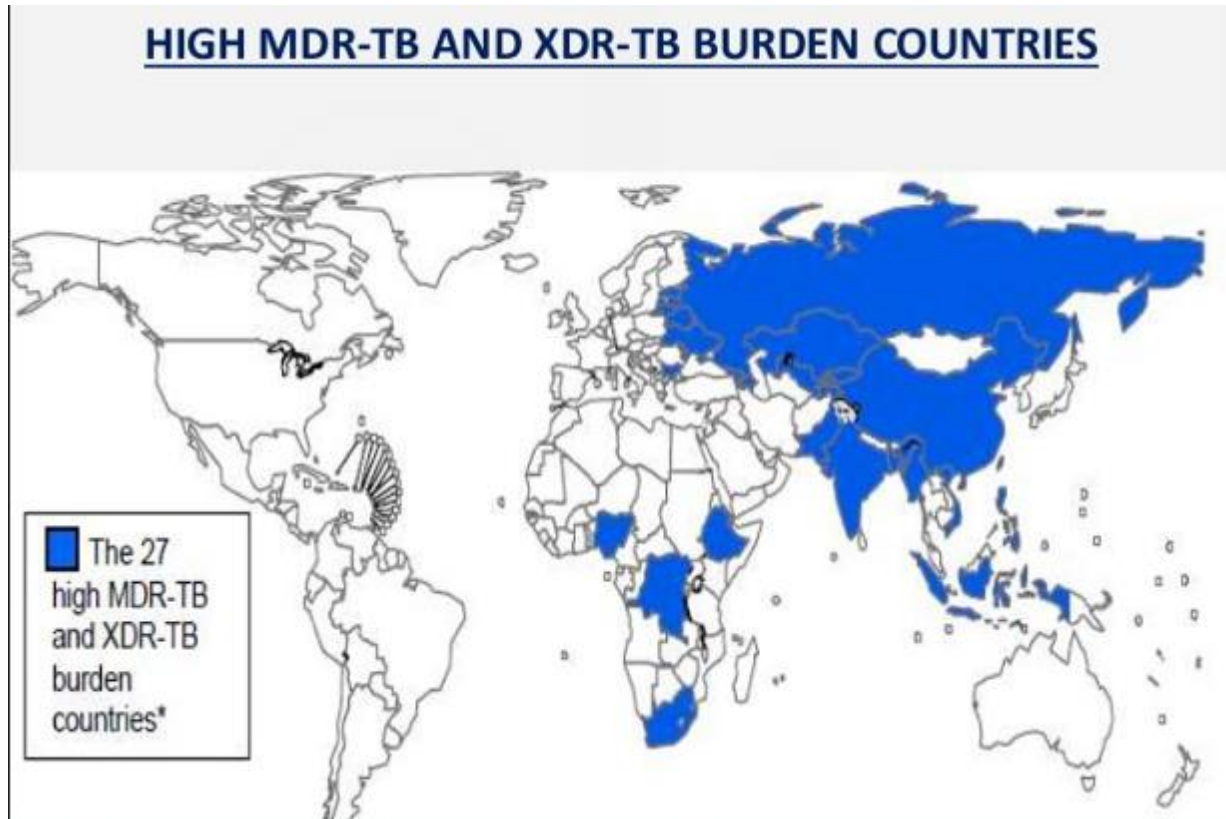
```
> chisq.test(mdrtb)
```

Pearson's Chi-squared test with Yates' continuity correction

```
data: mdrtb
X-squared = 8.8374, df = 1, p-value = 0.002951
```

Test 2 (Odds Ratio Calculation):

- ▶ **ODDS RATIO CALCULATION (Test 2):**
 - ▶ Odds of Risk Factor (MDR-TB) in Foreign Born: $13.5/586.5 = 0.2302$
 - ▶ Odds of Risk Factor (Foreign-Born) in Controls (Not MDR-TB): $0.5/521.5 = 0.0009588$
 - ▶ **Odds Ratio:** $(13.5/586.5) / (0.5/521.5) = \mathbf{24.0077}$
- ▶ **Conclusion:** *The foreign-born TB cases in Kansas were **24 times** more likely to be MDR-TB cases than U.S.-born TB cases in Kansas.*



Test 3 (Chi-Square Test of Independence):

- ▶ **Question:** Is TB therapy administration method (self-administered vs. DOT vs. both) independent of completion of therapy in cases of active TB in Kansas?
- ▶ **H_0 :** Treatment Administration Method is independent of Therapy Completion Status.
- ▶ **H_a :** Treatment Administration Method is not independent of Therapy Completion Status.
- ▶ **Significance Level:** $\alpha = 0.05$
- ▶ **Decision Rule:** Reject H_0 if $\chi^2 > \text{Critical Value}$
- ▶ **Test Statistic:** $df = (r-1)(c-1) = (3-1)(2-1) = 2$
 - ▶ From χ^2 Distribution Table: $\chi^2_{(df=2, \alpha=0.05)} = 5.9915$ (Critical Value)
 - ▶
$$\chi^2 = \sum \frac{(\text{Observed} - \text{Expected})^2}{\text{Expected}} = \frac{(812-799.45)^2}{799.45} + \frac{(71-77.48)^2}{77.48} + \frac{(86-92.07)^2}{92.07} + \frac{(65-77.55)^2}{77.55} + \frac{(14-7.52)^2}{7.52} + \frac{(15-8.93)^2}{8.93}$$
 - ▶ = **12.887** > 5.9915 (Critical Value)

Test 3 (Continued):

- ▶ **Decision:** Reject H_0 in favor of H_a .
- ▶ **Conclusion:** Treatment method is not independent of therapy completion (P-Value: 0.001591).



```
> DirectOnly = c(812, 65)
> SelfOnly = c(71, 14)
> Both = c(86, 15)
> DOTvsCompletion = as.data.frame(rbind(DirectOnly, SelfOnly, Both))
> names(DOTvsCompletion) = c('Yes', 'No')
> DOTvsCompletion
```

	Yes	No
DirectOnly	812	65
SelfOnly	71	14
Both	86	15

```
> chisq.test(DOTvsCompletion)
```

Pearson's Chi-squared test

```
data: DOTvsCompletion
X-squared = 12.887, df = 2, p-value = 0.001591
```

Test 3 (Odds Ratio Calculation):

- ▶ **ODDS RATIO CALCULATION (Test 3):**
 - ▶ Odds of Therapy Completion in Cases with some sort of DOT: $898/80 = 11.2250$
 - ▶ Odds of Therapy Completion in Cases without any sort of DOT: $71/14 = 5.0714$
 - ▶ **Odds Ratio:** $(898/80) / (71/14) = \mathbf{2.2134}$
- ▶ **Conclusion:** *The active TB cases in Kansas who had some sort of DOT were **2.2 times** more likely to finish therapy within 1 year than those who only self-administered their TB therapy.*



Results, Conclusions, and Discussion:

▶ MPH Competency (Social and Behavioral Sciences):

▶ **Promoting Cultural Sensitivity**

- ▶ TB is a highly stigmatizing disease in many cultures
- ▶ Promoted cultural awareness for health care workers utilizing the TB manual
 - ▶ CDC's *Promoting Cultural Sensitivity* series

▶ **Google Translate**

- ▶ Better **health communication** and **treatment adherence** by foreign-born individuals
 - ▶ May reduce foreign-born cases of TB in Kansas
 - ▶ Mitigate state spending on TB treatment

▶ **E-DOT**

- ▶ **Some form of DOT** is better than none



Additional Data Collection via SurveyMonkey

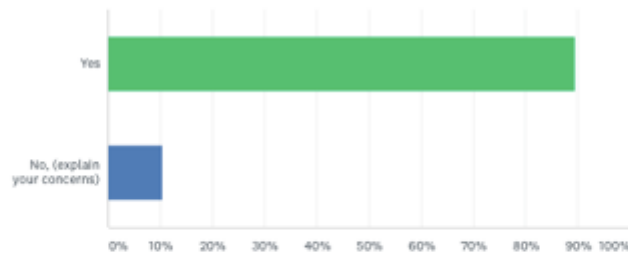
▶ **SurveyMonkey Online Survey**

- ▶ Saline County Health Department Staff
- ▶ Assess general knowledge and gain feedback
 - ▶ Video-communication and translation services



e-DOT (Electronic DOT) is a relatively new, CDC-recommended implementation plan for DOT. (Using video chat via smartphones, tablets, or webcam computers to directly observe the patient swallowing the medication and to provide education. The patient would still be met with physically on occasion for check ups.)(Assume that you and your patient know how to use Skype, FaceTime, etc...) In real practice, would you think that implementation of this plan would be a good way of providing DOT care to these patients? (The alternative would be to go out to see some of these patients daily to observe them taking their medicine physically.)

Answered: 19 Skipped: 0



ANSWER CHOICES	RESPONSES
Yes	89.47% 17
No, (explain your concerns)	10.53% 2

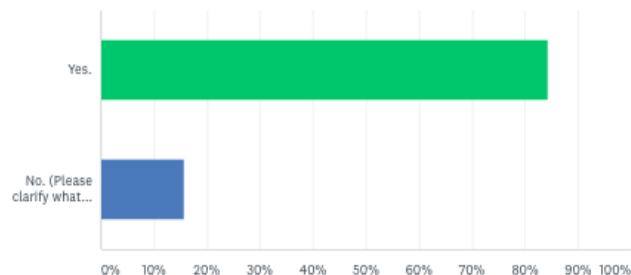


Regarding e-DOT:

- ▶ **7/19 (37%)**
 - ▶ Never used video-communication before
- ▶ After introduction to **DOT**, **associated time & monetary costs**, and **e-DOT**,
 - ▶ **17/19 (89.5%)**
 - ▶ Thought that e-DOT would be a good way of providing remote therapy
 - ▶ Concerns of 2 respondents:
 - ▶ **1) Manipulation of e-DOT observation**
 - ▶ **2) Lost client-caregiver connection and other observations without direct contact**

*You will need a smartphone, tablet, or computer for this portion.*Pick one. (Countries of most frequently observed foreign-born TB cases in the U.S.): Mexico (Spanish), Guatemala (Spanish), Vietnam (Vietnamese), China (Chinese), India (Hindi- most commonly spoken, Tamil, Punjabi, etc.), Haiti (Haitian Creole) You encounter a patient who has a language barrier. There is no family member to translate your message for you and you need to provide the patient with this message: "You need to finish this medication, even if you feel better, or you will become severely sick." The patient nods (as if he understands you), but you have your doubts about whether he understands the gravity of the message.1) Open an internet browser on your device and type "google translate" on the browser.2) On the left hand (or top) column, type your message: "You need to finish this medication, even if you feel better, or you will become severely sick." (English should automatically be detected.)3) On the right hand (or bottom) column, from the drop down menu, select the language of your patient. The translation should automatically occur.4) Press the Speaker icon (if it is available) on the right-hand side (bottom) of the translate module and turn up your volume. The computer should speak the translation. Did you find these instructions easy (and useful) to follow and implement?

Answered: 19 Skipped: 0



ANSWER CHOICES	RESPONSES
▼ Yes.	84.21% 16
▼ No. (Please clarify what part was confusing or any concerns.)	15.79% 3

Regarding Google Translate:



- ▶ **17/19 (90%)**
 - ▶ Familiar with using a smartphone to seek answers to questions
- ▶ **11/19 (58%)**
 - ▶ Familiar with Google Translate before survey
- ▶ **16/19 (84%)**
 - ▶ Found the instructions “easy and useful” to follow/implement

3.2.4) Producing the Product:

▶ **MANUAL CUSTOMIZATIONS:**

- ▶ *Use of graphics and visually pleasing tables to accompany procedures*
 - ▶ *(e.g. Tuberculin Skin Test section)*
- ▶ *Electronic DOT (e-DOT) Implementation*
- ▶ *Promoting Cultural Sensitivity*
- ▶ *Translator Services & Google Translate Implementation*
- ▶ *Other Relevant SCHD/KS Customizations*
 - ▶ *(e.g. KS State Statutes, KS TB Infection Control Measures, SCHD TB forms).*

SCHD TB Protocol Manual Navigation:

Part 1: An Introduction to Tuberculosis Control

- I. Introduction
- II. Effective TB Control Programs
- III. Pathogenesis of Tuberculosis

Part 2: Latent Tuberculosis Infection Management

- IV. Targeted Tuberculin Skin Testing & IGRA
 - **CUSTOM:** Graphics accompanying procedures (e.g. Tuberculin Skin Test section)
- V. Treatment of Latent TB Infection

SCHD TB Protocol Manual Navigation (Continued):

Part 3: Active Tuberculosis Disease Management

- VI. Diagnosis of Tuberculosis
- VII. Treatment of Tuberculosis
 - **CUSTOM:** *Colorful TB Treatment Regimen Tables*

Part 4: Adherence Promoting Strategies

- VIII. Promoting Treatment Adherence
 - **CUSTOM:** *Electronic DOT (e-DOT) Implementation Instructions*
- IX. Managing Non-Adherence
 - **CUSTOM:** *Kansas State Statutes*
- X. Promoting Cultural Sensitivity
 - **CUSTOM:** *Promoting Cultural Sensitivity (CDC series adaptation)*
 - **CUSTOM:** *Translator Services & Google Translate Implementation Instructions*

SCHD TB Protocol Manual Navigation (Continued):

Part 5: Contact Investigations & Infection Control

- XI. Contact Investigations
- XII. Infection Control
 - **CUSTOM:** *Kansas TB Infection Control Measures*

Part 6: References & Appendices

- XIII. References
- XIV. Appendices
 - **CUSTOM:** *SCHD TB Forms (SCHD Treatment Agreement Forms, SCHD Medication Administration Record (MAR) Form, SCHD Contact Investigation Form, & KDHE Interpreter/Translator Vendor List)*

3.2.5) External Review:

- ▶ Saline County Health Department Communicable Disease / TB Program Manager
 - ▶ *Maria Shoultys, RN*
- ▶ Stanford University, School of Medicine (Department of Radiology) Resident Physician
 - ▶ *Joseph Tseng, MD*
- ▶ MPH Report Review:
 - ▶ *Robert Larson, PhD (KSU CVM)*

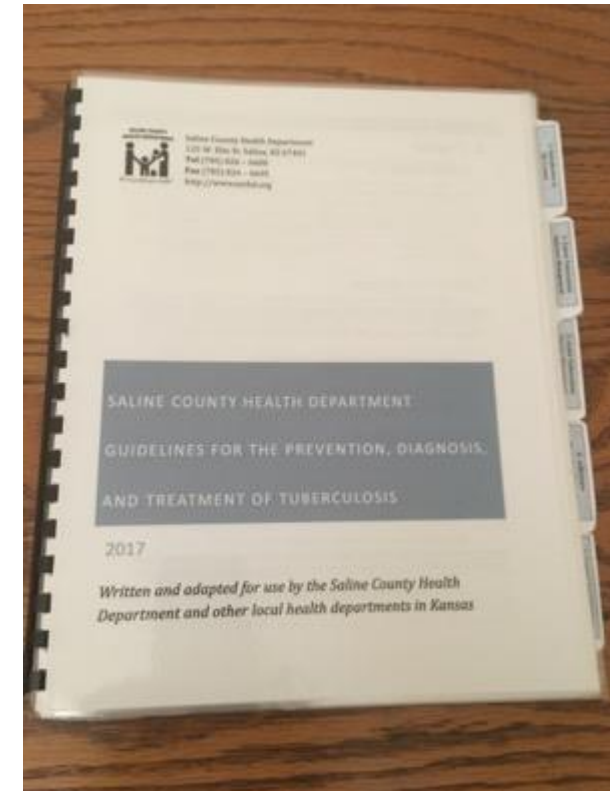
3.3) Results/Discussion

3.3.1) DOCUMENT PRODUCED

3.3.2) POTENTIAL AREAS OF IMPROVEMENT

3.3.1) Document Produced

- **Saline County Health Department Guidelines for the Prevention, Diagnosis, and Treatment of Tuberculosis (2017)** (written and adapted for use by the Saline County Health Department and other local health departments in Kansas)



3.3.2) *Potential Areas of Improvement*

- ▶ **Areas of Potential Improvement**
 - ▶ **1) More picture graphics to aid in procedural instructions**
 - ▶ e.g. Contact Investigation and Infection Control sections
 - ▶ **2) Additional information on Second-Line TB drugs**
 - ▶ Ways to implement anti-TB drugs in the case of MDR-TB or XDR-TB

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60) All images from powerpoint courtesy of Google Images

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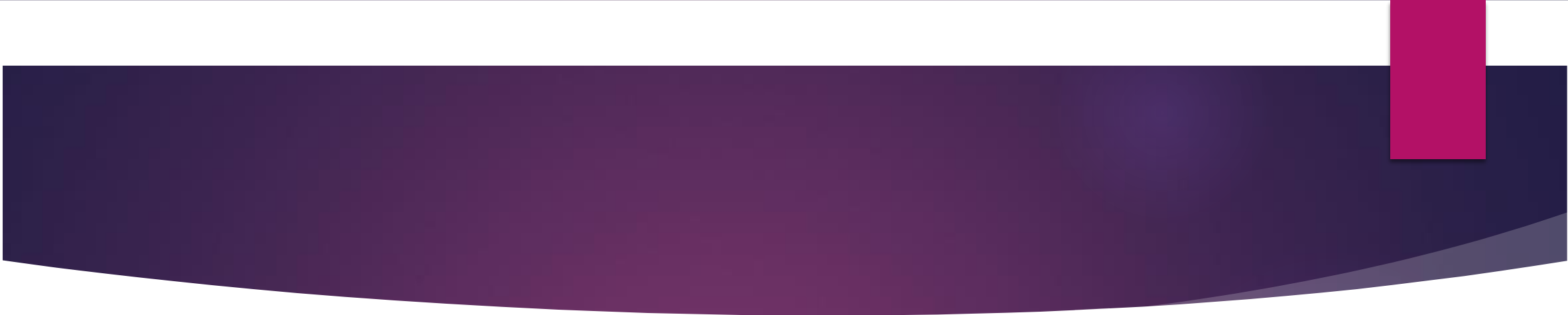
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Thank you!

Questions?