Tuberculosis Pharmacy Reporting

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Learning Outcomes

- Determine a pharmacy/pharmacist role in Tuberculosis (TB) prevention and control
- Discuss rationale for the development of TB reporting requirement for pharmacies and pharmacists
- Identify new TB reporting requirements for pharmacies/pharmacists
- Identify the appropriate treatment regimens utilized for active TB disease
- Discuss multi-drug resistant (MDR), extensively drug resistant (XDR), and totally drug resistant TB (TDR)
- Identify the benefits of meaningful partnership between pharmacies and public health entities

Background

- Ten to Fifteen million persons in the United States are infected with *M. tuberculosis*
- TB cases are reported in every state on an annual basis
- Without treatment, 5% of persons who have been infected with *M. tuberculosis* will develop active disease
  - Typically with in 2 years of becoming infected
- Approximately, 10% of persons with competent immune systems who don't receive treatment will develop TB at one point in their lifetime
- TB infection and diabetes increases your risk of developing disease to 30% in your lifetime
- TB and HIV infection increases your risk of developing TB disease 7-10% per year that you have both diagnoses (very high lifetime risk)
- Drug-resistant cases have been reported in almost every state

Background

- Patient may be discharged from the hospital or sent to the pharmacy by their provider with prescriptions for TB medications
  - May or may not be referred to the TB clinic for outpatient follow-up
- ***Patients should not be sent to pharmacies to pick up their prescriptions (following hospitalization)***
  - ***Especially if there is a possibility of contagiousness***
- This accounts for a small percentage of cases with active TB disease (managed by private providers)
  - On average this trends between 2-5 patients per year
  - 4 cases have been identified from pharmacies in 2012
- Pharmacists are the most accessible healthcare worker that the patient will see

Rationale

- Appropriate treatment is key to success and curing the infection and disease
  - Inappropriate treatment can lead to multi-drug resistance and exposure of infection to more individuals
- Active TB disease is typically treated with a 4 drug regimen for a minimum of 6 months of therapy
  - If the organism is sensitive to all active first line TB medication
- These medications have varied side effects and drug-drug interactions
- Co-morbid conditions such as diabetes, rheumatoid arthritis, psoriasis, and HIV put patients had a high risk of developing disease as well as a delayed response to therapy
- Knowing the patients full medical picture is imperative to achieving optimal drug therapy and treatment success

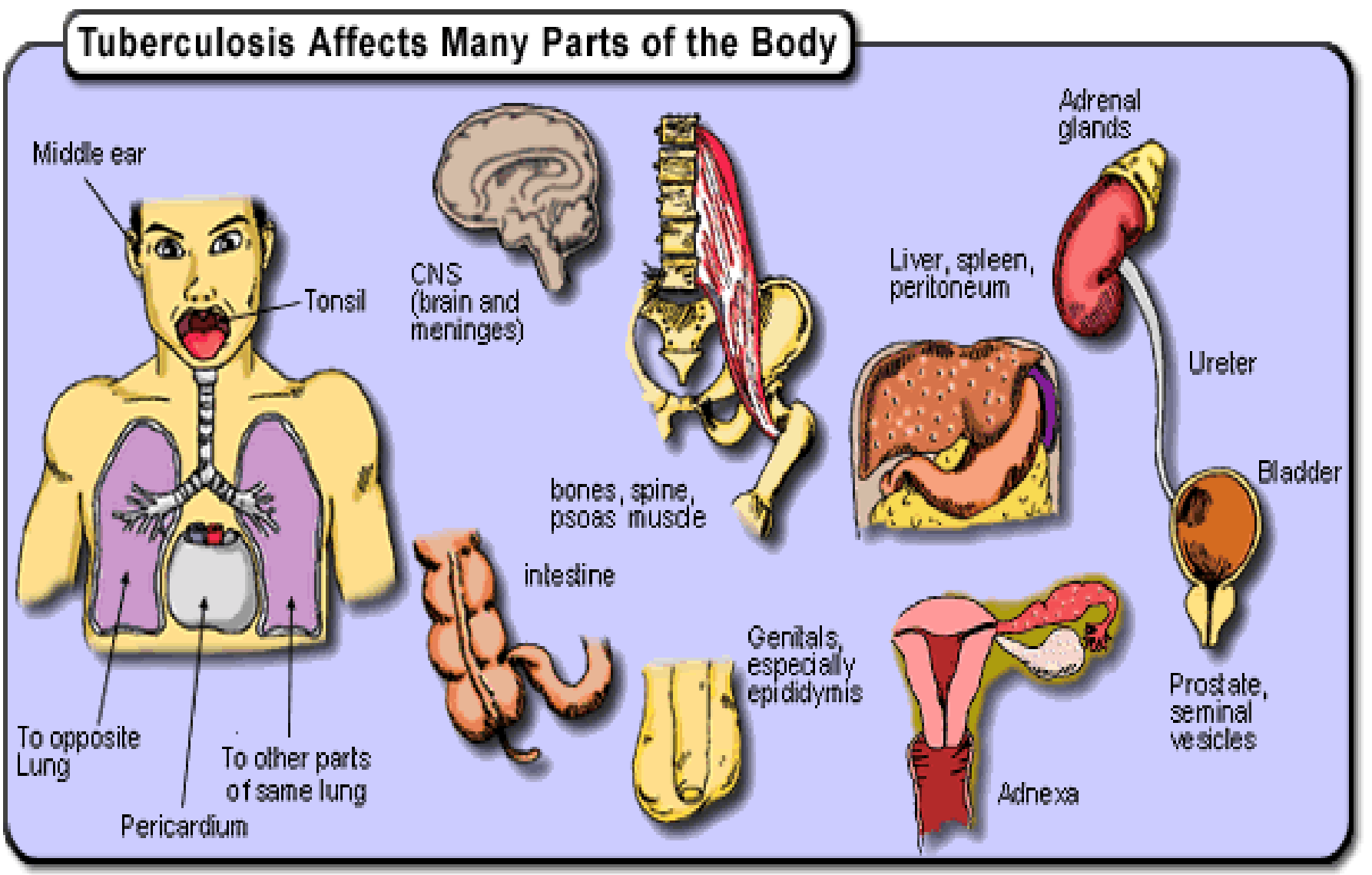
Rationale

- Pharmacies and pharmacist are uniquely positioned to know a patients full medication history
  - Chronic conditions can be identified by drug therapy being received
- Based on the Center for Disease Control and Prevention (CDC) recommendations
  - All patients identified with suspected or diagnosed active TB should be treated under directly observed therapy (DOT)
- Most providers do not have the ability to have a patient come to their office on a daily basis to receive medication
- Treatment of active TB disease via a private practitioner can be difficult
  - For both the patient and provider

Rationale

- Alerting the health authority that a patient is receiving 2 or more TB medications (INH/RIF/PZA/EMB) is another way to identify possible active case in our community
  - 2 or more drugs can be used to treat active TB disease (initiation phase vs. maintenance phase)
  - LTBI therapy can also be treated with 2 drugs but for a period of 3-4 months
- Reporting these cases to the health authority will allow the patient to receive additional monitoring and follow up that may not be available at their providers office
- This is also another way to identify those cases of active TB disease that have not been reported
  - Early identification allows for appropriate contact investigation and decreases the spread of disease

Sites of Tuberculosis Disease



TB Reporting

- Nevada Administrative Code (441A) was recently updated to including registered pharmacist or intern pharmacist
  - Dispensing two or more prescription drug used for the treatment of TB
  - As one of the health professionals, laboratorians, and others responsible for reporting TB required to report the occurrence of a communicable disease to the health authority
    - NRS 441A.150, NAC 441A.290, NAC 441A.295
  - Effective January 1st, 2011
- By law these cases must be reported because Tuberculosis is a communicable disease that can be transmitted in the air via respiratory droplets

TB Reporting

- Other health care providers are also required to report this communicable disease but there have been instances when individuals were not report by a private physician managing their care
- In some cases incorrectly, which can lead to prolonged infectiousness and acquired drug resistance
- Treatment via (DOT) based on the current CDC guidelines is done on a regular basis at the Health Department
  - Patients will also receive their medications free of charge

TB Reporting

- In Southern Nevada the Health Authority that you will be reporting to is the Southern Nevada Health District TB clinic located at 625 Shadow Lane, LV, NV 89106
- Fax # is 702 759-1414
- The information needed is as follows:
  - Name of Pharmacy – including address and contact phone number
  - Name of Pharmacist or Pharmacy Intern reporting the patient
  - Patient demographic information
  - Medications being prescribed
  - Prescribing physician or other licensed health professional- including address and contact phone number

TB Reporting

- Pharmacies frequency as the question – “Is this a HIPPA violation?”
- As a provider you are authorized, under HIPAA Section 164.512b
- “Disclosures for Public Health Activities”, to release protected health information without patient consent to ensure public health and safety

TB Reporting Form Example

***Mycobacterium tuberculosis* (TB) Medication Dispensing Report**

Pursuant to NAC 441A this form may be used whenever a registered pharmacist or intern pharmacist dispenses two or more prescription drugs used for the treatment of TB requiring them to report to the Local Health Authority. As a provider you are authorized, under HIPAA Section 164.512b "Disclosures for Public Health Activities", to release protected health information without patient consent to ensure public health and safety.

TB DRUG DISPENSING REPORT

FACILITY REPORTING

NAME OF PHARMACY:

ADDRESS OF PHARMACY:

NAME OF PHARMACIST OR INTERN PHARMACIST:

FIRST NAME LAST NAME PHONE NUMBER:

DATE PRESCRIPTION FILLED: MONTH DAY YEAR MILITARY TIME

DATE AND TIME THE LOCAL HEALTH AUTHORITY WAS NOTIFIED: MONTH DAY YEAR MILITARY TIME

PROVIDER INFORMATION

NAME OF PRESCRIBING HEALTH CARE PROVIDER:

FIRST NAME LAST NAME

PHONE NUMBER: DATE PRESCRIPTION WRITTEN: MONTH DAY YEAR

ADDRESS:

COMMENTS:

PATIENT INFORMATION

PATIENT NAME:

FIRST NAME LAST NAME

ADDRESS: DATE OF BIRTH: MONTH DAY YEAR

CITY: STATE:

PHONE NUMBER:

COMMENTS:

Check All That Apply

Only report if two or more boxes are checked and a report has not previously been submitted for this person

MEDICATION DISPENSE

- ☐ Ethambutol
- ☐ Pyrazinamide
- ☐ Rifampin
- ☐ Isoniazid
- ☐ Streptomycin
- ☐ Rifabutin
- ☐ Other:

FAX COMPLETED FORMS TO YOUR LOCAL HEALTH AUTHORITY AT:

Treatment Regimens

Initial Phase			Continuation Phase			
Regimen	Drugs	Interval and Doses	Regimen	Drugs	Interval and Doses	Range of Total Doses
1	INH RIF PZA EMB	7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)	1a 1b 1c	INH RIF INH RIF INH RPT	7 days/week for (18 weeks) 126 doses OR 5 days/week 90 doses 2 days/week for 36 doses (18 weeks) 1 day/week for 18 doses (18 weeks	182-130 (26 weeks) 92-76 (26 weeks) 74-58 (26 weeks)
2	INH RIF PZA EMB	7 days/week for 14 doses (2 weeks), then 2 days/week for 12 doses (6 weeks) OR 5 days/week for 10 doses (2 weeks, then 2 days/week for 12 doses (6 weeks)	2a 2b	INH RIF INH RPT	2 days/week for 36 doses (18 weeks) 1 day/week for 18 doses (18 weeks)	62-58 (26 weeks) 44-40 (26 weeks)

Drug Resistance

- Multi-drug resistant (MDR) TB
  - Resistant to at least INH and RIF (or rifamycin class)
- Extensively drug resistant (XDR) TB
  - Resistance to INH and RIF
  - FQN (fluroquinolones)
    - Levofloxacin and moxifloxacin
  - At least one 2nd line injectable agent
    - Aminoglycoside
      - Streptomycin, Amikacin, Kanamycin
    - Capreomycin (polypetide – aminoglycoside "like")

Drug Resistance

- Totally Drug Resistant (TDR)
  - Resistant to ALL 10 drugs with know activity against TB
  - First case identified in Europe in 2006
    - Cases have been identified in Italy (2007), Japan (2008), Iran (2009), and India (2012)
  - Seen in young otherwise healthy patients
  - Also know as Extremely Drug Resistant (XXDR) TB
- *A drug resistant organism can be passed on from person to person* ***OR***
- ***Drug resistance can be acquired due to inappropriate treatment***

Summary

- As of January 1st, 2011 all Nevada pharmacies are required to report a patient receiving 2 or more TB medications to the health authority
  - Nevada Administrative Code (441A)
- Drug therapy is one of the **MOST** important part of effective TB infection and control
- Pharmacists are uniquely qualified to assess the patient for medication side effects and possible drug-drug interactions
- Pharmacists involvement
  - Will help to obtain treatment goals
  - Assist in management of other chronic medical conditions
  - Maintain the health and wellness of the patient

Summary

- Appropriate management of active TB disease is imperative to treatment success and decreasing the spread of disease
- Patients being treated for active TB disease should be treated under DOT
- This is routinely done at the Health Department and is free of charge to the patient
- When in doubt contact the Health Department with question regarding Tuberculosis!!!!!


POSITIVE SKIN TEST
coughing up blood
Weight Loss
Night Sweats
WEAKNESS
MALAISE
CHILLS
FEVER
Loss of Appetite
HEMOPTYSIS
THINK
Chest Pains
difficult breathing
TB!
Exposure to Tuberculosis
fatigue
ANOREXIA
cough
Significant Skin Test
failure to thrive
Abnormal X-Ray
Shortness of Breath
Recognize positive signs and symptoms of tuberculosis.
Early diagnosis and treatment reduces spread.
Contact your Health Department or Physician for more information.
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
CDC

Contact Information

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- Phone: 702 759-1639 office

References

- Centers for Disease Control and Prevention. Treatment of Tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003;52(No. RR-11)
- Core Curriculum on Tuberculosis: What the Clinician Should Know Fifth Edition 2011; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention – Division of Tuberculosis Elimination
- National Tuberculosis Surveillance System Highlights from 2010. CDC
- www.cdc.gov
- www.who.int