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
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 within 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
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 at 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 patient's 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

Tuberculosis Affects Many Parts of the Body

- Middle ear
- Tonsil
- CNS (brain and meninges)
- To opposite Lung
- To other parts of same lung
- Pericardium
- Bones, spine, psoas muscle
- Intestine
- Genitals, especially epididymis
- Liver, spleen, peritoneum
- Adrenal glands
- Ureter
- Bladder
- Prostate, seminal vesicles
- Adnexa
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 reported 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 [NAC441A](#), this form may be used when 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 164.512(b) “Disclosures for Public Health Activities”, to release protected health information without patient consent to ensure public health and safety.

## TB Drug Dispensing Report

<table>
<thead>
<tr>
<th>Field Reporting</th>
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<tbody>
<tr>
<td><strong>NAME OF PHARMACY:</strong></td>
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<tr>
<td><strong>ADDRESS OF PHARMACY:</strong></td>
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</tr>
<tr>
<td><strong>NAME OF PHARMACIST OR INTERN PHARMACIST:</strong></td>
<td>[ ]</td>
</tr>
<tr>
<td><strong>PHONE NUMBER:</strong></td>
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<tr>
<td><strong>DATE PRESCRIPTION FILLED:</strong></td>
<td>[ ]</td>
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<tr>
<td><strong>DATE AND TIME THE LOCAL HEALTH AUTHORITY WAS NOTIFIED:</strong></td>
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<table>
<thead>
<tr>
<th>Provider Information</th>
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<tbody>
<tr>
<td><strong>NAME OF PRESCRIBING HEALTH CARE PROVIDER:</strong></td>
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<tr>
<td><strong>FIRST NAME:</strong></td>
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<td><strong>ADDRESS:</strong></td>
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<tr>
<td><strong>COMMENTS:</strong></td>
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<table>
<thead>
<tr>
<th>Patient Information</th>
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<tr>
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<tr>
<td><strong>COMMENTS:</strong></td>
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</tbody>
</table>

**Check All That Apply**

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

- [ ] Ethambutol
- [ ] Pyrazinamide
- [ ] Rifampin
- [ ] Isoniazid
- [ ] Streptomycin
- [ ] Rifabutin

**Fax completed forms to your local health authority at:**
## Treatment Regimens

<table>
<thead>
<tr>
<th>Initial Phase</th>
<th>Continuation Phase</th>
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<tr>
<td>2</td>
<td>INH RIF PZA EMB</td>
</tr>
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</tbody>
</table>
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 (fluoroquinolones)
    • Levofloxacin and moxifloxacin
  – At least one 2\textsuperscript{nd} line injectable agent
    • Aminoglycoside
      – Streptomycin, Amikacin, Kanamycin
    • Capreomycin (polypeptide – aminoglycoside “like”)
Drug Resistance

• Totally Drug Resistant (TDR)
  – Resistant to ALL 10 drugs with known 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 known 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!!!!!
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
Contact Information

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• E-mail: madison@snhdmail.org
• 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](http://www.cdc.gov)
- [www.who.int](http://www.who.int)