TB Intensive
San Antonio, Texas
December 1-3, 2010

TB & Diabetes
Barbara Seaworth, MD; HNTC
December 3, 2010

Dual Epidemic
Diabetes - Tuberculosis

Barbara J. Seaworth MD
Medical Director, Heartland NTBC
Professor of Medicine, UT Tyler
Objectives

- Provide quick overview of diabetes
- Describe the epidemiology of TB and diabetes noting important areas of overlap
- Discuss the impact of diabetes on TB
  - Increased risk
  - Clinical presentation
  - Treatment outcomes
- Identify impact of rifampin on blood sugar and oral agents for treatment of diabetes
- Identify management strategies

Diabetes

- Group of diseases marked by high blood glucose

- **Type 1:** Insulin Dependent diabetes mellitus (IDDM)
  - 5 – 10% of all diagnosed cases
  - Destruction of insulin producing pancreatic beta cells by body’s immune system - these individuals require insulin for survival
  - Risk factors may be auto-immune, genetic, environmental
Diabetes

**Type 2:** Non-insulin dependent diabetes (NIDDM)

- 90 – 95% of all diagnosed cases
- Usually begins as insulin resistance
- Associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and race/ethnicity.

Diabetes

**Gestational diabetes**

- Glucose intolerance diagnosed during pregnancy
- Occurs more often in African Americans, Hispanics, and Native Americans
- More common among obese women and women with a family history of diabetes
- Following pregnancy 5 – 10% have diabetes, usually Type 2
- During next 5 – 10 years, 40 – 60% develop diabetes
Diabetes

• Diabetes can lead to serious complications
  – Blindness
  – Kidney failure resulting in dialysis
  – Cardiovascular disease
    • High blood pressure, stroke, heart attack
  – Neuropathy – burning, tingling numbness in feet and hands
    • Lower limb amputations
  – Tuberculosis

• Complications can be Prevented!

Diagnosis of Diabetes

• Fasting blood glucose ≥ 125

• Blood glucose ≥ 200, 2 hrs after an oral glucose tolerance test (GTT)

• Hemoglobin A1C ≥ 6.5%

• Symptoms plus a random blood glucose of ≥ 200

• Impaired glucose tolerance:
  – Fasting glucose 100-125 or glucose 140-199 2 hrs after GTT
  – Increased risk of developing Type 2 diabetes, heart disease, strokes and tuberculosis?
## Treating Diabetes

Type 2 diabetes can often control blood glucose with healthy diets, exercise, weight loss along with oral medications
- Some may need insulin

- Type 1 diabetics must have insulin to survive
- Many need medications for cholesterol and BP
- Diabetic educators are key to self management and improving health outcomes for diabetics.

- **TB case managers?**

## Type 2 Diabetes

- Increased risk has been noted in many racial and ethnic populations
  - African Americans
  - Hispanic/Latino Americans
  - Native Americans
  - Asian Americans

- Globally urbanization has fueled an increasing incidence in Africa, India, Asia
  - Areas of world with high rates of tuberculosis
Type 2 Diabetes and Native Americans

- Highest prevalence of Type 2 diabetes of any population in world

- Rates increasing at epidemic proportions

- Incidence of Type 2 diabetes is rising faster among children and young adults than in any other ethnic population
  - Am Academy Pediatrics, 2002

CDC National Diabetes Fact Sheet, 2007
Mortality in Native Americans

- Increased risk compared to other Americans including white and minority populations
  - 650 percent more likely to die from TB
  - 420 percent more likely to die from diabetes,

Prevalence of Diabetes by Ethnicity

- 16% of adults (> 20) who received care from the IHS had a diagnosis of diabetes
  - 6.0% Alaska natives
  - 23.9% in Native American in southern Arizona
    - Indian Health Service Database – 2005

- 14.7% of all non-Hispanic blacks ages 20 years or older have diabetes

9.8% of all non-Hispanic whites ages 20 years or older have diabetes.

National Diabetes Statistics 2007
Prevalence of Diagnosed Diabetes by Race/Ethnicity and Age in Persons 18 & Older

<table>
<thead>
<tr>
<th>AGE</th>
<th>White non-Hispanic</th>
<th>Black, non-Hispanic</th>
<th>Hispanic</th>
<th>Other</th>
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<td>18 – 44</td>
<td>2.9</td>
<td>3.0</td>
<td>4.3</td>
<td>1.4</td>
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<td>45 – 64</td>
<td>10.4</td>
<td>23.8</td>
<td>20.9</td>
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<tr>
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<td>17.0</td>
<td>33.5</td>
<td>34.8</td>
<td>28.7</td>
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<tr>
<td>Overall</td>
<td>8.3</td>
<td>13.0</td>
<td>11.1</td>
<td>8.1</td>
</tr>
</tbody>
</table>

» Texas Diabetes Fact Sheet, 2009

Does Diabetes Predispose to TB?

DOES TB INCREASE THE RISK OF DIABETES?
Diabetes: a Moderate to Strong Risk Factor for TB

- 2008 Meta analysis
  - 13 studies many areas of world showed increased risk of TB in persons with diabetes
    - 3 prospective cohort studies showed RR 3.1
    - 8 case-control studies and 2 other types- OR 1.2-7.8
  - Association of Diabetes and TB stronger
    - With higher background TB incidence
    - In younger age groups
    - In Central America, Asia, Europe
    - Among North Americans the RR for Hispanics 2.69

Jeon, PLoS Medicine, 2008

Diabetes Predisposes to TB

- Hong Kong prospective study of 4661 close contacts of active TB cases
  - RR 3.4 in diabetics for both
    - early – primary progressive disease (3month)
    - and late- reactivation (within 5 years) disease

Lee MS, Int J Tuberc Lung 2008
Risk of TB Related to Degree of Diabetic Control

1592 diabetics in Chili followed prospectively from 1959-1982
- Actuarial probability of developing TB was 24% in IDDM and 4.8% in NIDDM

Prospective study in Tanzania, diabetic patients followed 1 – 7 years
- 9.0% IDDM versus 2.7% NIDDM developed pulmonary TB

Incidence of Tuberculosis and Diabetes in the United States, 2007-2008

Tuberculosis
4.2 per 100,000 persons

Diabetes Mellitus
9.1 per 1,000 persons

(Source: Centers for Disease Control and Prevention, 2008)
Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2008


Age-adjusted percentage of adults aged ≥20 years with diagnosed diabetes, 2007

MMWR 58:1259-1263, 2009
Age-adjusted Percentage of U.S. Adults Who Were Obese or Who Had Diagnosed Diabetes

<table>
<thead>
<tr>
<th>Year</th>
<th>Obese (BMI ≥ 30 kg/m²)</th>
<th>Diabetes</th>
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<tbody>
<tr>
<td>1994</td>
<td>No Data</td>
<td>No Data</td>
</tr>
<tr>
<td>2000</td>
<td>&lt;14.0%</td>
<td>&lt;4.5%</td>
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<tr>
<td>2008</td>
<td>14.0-17.9%</td>
<td>4.5-5.9%</td>
</tr>
<tr>
<td></td>
<td>18.0-21.9%</td>
<td>6.0-7.4%</td>
</tr>
<tr>
<td></td>
<td>22.0-25.9%</td>
<td>7.5-8.9%</td>
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<tr>
<td></td>
<td>≥ 26.0%</td>
<td>&gt;9.0%</td>
</tr>
</tbody>
</table>

Global Prevalence of Tuberculosis and Diabetes, 2008

- **Tuberculosis**: 12.7 million people (9.4 WHO 2010) 95% in developing countries
- **Diabetes Mellitus**: 171 million people (285 WHO 2010) 70% in developing countries

(Source: World Health Organization, 2008)
Projected prevalent DM incidence & TB Incidence

Dooley, & Chaisson, Lancet ID, Dec, 2009

Linkage Between Tuberculosis and Diabetes

- Patient diagnosed with Diabetes
- Immune Response is weakened
- Exposure to M. Tuberculosis
- Increased susceptibility for LBTI or TB Disease
Population Risk factors for Latent TB Infection

• Foreign born
• Prisoners
• Homeless/marginally housed
• Injection Drug Users
• Racial/ethnic minorities
• Recent contact to TB

Risk Factors for Progression to Active TB

• HIV
• Diabetes
• Other medical conditions:
  • Renal failure
  • Smoking
  • Immunosuppression (transplant, steroids. Anti-TNF)
  • Gastrectomy/ jejuno-ileal bypass
  • Silicosis
  • Malnutrition
At Risk Populations and Behaviors for TB and Diabetes

- Native Americans
- Hispanics
- Asian / Pacific Islanders
- Blacks
- Older Age
- Unhealthy Diet
- Smoking
- Vitamin D deficiency

- Overweight / Obesity
- Cardiovascular Disease
- Family History
- Polycystic Ovary Syndrome (PCOS)

Relative Risk of TB by BMI

Figure. Hazard function curves of active tuberculosis for different body mass index categories in the overall Cox model. Leung Arch Internal Med, 2007
Other risk factors for TB and Diabetes

- **Smoking**
  - Active smoking associated with significant increase in risk of diabetes RR 1.4
    - Will, JAMA 2007
  - Exposure to passive smoke increases RR 1.81
    - Hayashino, Diabetes Care, 2008
  - Asia 50-60% of male population smokes

- **Vitamin D deficiency**
  - Increases risk of type 1 and type 2 diabetes
  - Also associated with active TB
    - Odds ration 2.9
    - Deficiency may lead to TB and vice versa
      - Wilkinson, Lancet 2000

TB and Diabetes: Is Vitamin D the Missing Link?

- 1 billion people worldwide are Vitamin D deficient due to decreased sun exposure or inadequate intake

- Vitamin D is thought to affect pancreatic β cell function and immune response
  - Low concentrations associated with insulin resistance and glucose intolerance
  - Deficiency increases risk of type 1 & type 2 diabetes
  - Supplementation is protective against both types

- Vitamin D deficiency is associated with active TB
  - Actions of monocytes and phagocytes on M TB dependent on Vitamin D
    - Handel & Ramagopalan, Sept 2010, Lancet Inf Dis
Vitamin D Deficiency in Adults

- CDC notes decline in adults who have \textit{adequate} levels of Vitamin D
  - 30% whites, 5-10% blacks

- Who should be tested?
  - Decreased intake (poor nutrition)/Limited sun exposure
  - Gastrointestinal illness with malabsorption
  - Hepatic disease
  - Chronic renal disease (GFR < 60%), nephrotic syndrome
  - Aging
  - Diabetics?

  » Kennel et al, Mayo Clinic Proc; August 2010

Pathogenesis of TB Progression to Disease

Exposure (LTBI)

No Disease (90%)

~0.1% per year thereafter

2-3% Second Year

5% First Year

Disease
Latent TB Infection (LTBI) in Diabetic Patients

- Persons with diabetes should be screened for TB with an IGRA or TST
  - Communicate risk of progression to disease to community physicians caring for diabetics
  - If LTBI is found, treat for latent infection
  - INH for 9 months is best approach
  - Be sure to include Vitamin B6
    - Neuropathy is complication of diabetes and a side effect of INH

Presentation of TB in Diabetics

- Various reports of more severe disease
- Varying findings as to the radiographic presentation
  - ? More cavities
  - ? Isolated lower lung involvement
### Classic Article Prior to Availability of TB Medications

Howard Root MD, Deaconess Hospital, Boston  
NEJM, 1934

- Autopsy series of 126 patients: no pathological findings unique to "the tubercular diabetic"
- 245 TB cases in diabetic patients, "no special insidiousness" of signs or symptoms and similar CXR findings to non-diabetics
- Noted that TB developed most frequently in patients with poor diabetic control

Dooley, & Chaisson, Lancet ID, Dec, 2009

### TB and Diabetes, CXR Findings

<table>
<thead>
<tr>
<th>Year</th>
<th>Study location</th>
<th>Participants</th>
<th>With diabetes</th>
<th>Without diabetes</th>
<th>Lower lung more commonly involved</th>
<th>More cavitation</th>
<th>More diffuse involvement</th>
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<td>2001</td>
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<td>2000</td>
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<td>2005</td>
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<td>2008</td>
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<td>2009</td>
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<td>57</td>
<td>78</td>
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</table>

Table 2: Studies assessing chest radiographic findings in patients with tuberculosis, comparing diabetic to non-diabetic patients

Dooley, & Chaisson, Lancet ID, Dec, 2009
Does Diabetes Impact TB Treatment and Cure?

- Previously thought not to affect treatment

- Four new studies from Baltimore, Texas, Taiwan and Indonesia reveal:
  - Delayed culture conversion
  - Higher mortality
    - Dooly, 2009; Restrepo 2008; Wang 2008; Alisahlanda, 2007

Response to Treatment

- Relapse may be more frequent
  - Recent Shanghai study 203 diabetics with TB followed for 2 years after standard treatment
    - 20% relapse rate in patients with DM (most Type 2)
    - 5% relapse rate in patients without DM

  Zhang et al. Jpn J Infect Dis, 2009
Hyperglycemia in Patients with TB

- Blood glucose control may worsen while patients are taking Rifampin
  - Rifampin augments intestinal absorption of glucose
  - Does so in both diabetics and non-diabetics

- Infections impair glucose tolerance early in disease in both diabetics and non-diabetics
  - Independent of rifampin, infection can lead to poor glucose control

Does Diabetes Predispose to TB?

DOES TB INCREASE THE RISK OF DIABETES?
No evidence to suggest that having tuberculosis or taking medications for tuberculosis increases the risk for diabetes

Increased hyperglycemia with active disease and with rifampin-induced medicine interactions, does not lead to development of diabetes

Low Blood Levels of Rifampin in Diabetics: Indonesia

- 17 Patients with Diabetes and Tuberculosis

- Rifampin levels decreased 50%
  - Perhaps related to higher BMI in diabetics

- Is a different dose of rifampin needed?
  - Mg/kg?

  Hanneke M. J. Nijland *Clinical Infectious Diseases*, 43 2006
Treatment Issues – Rifampin

• Rifampin induces CYP450 enzyme system increasing production of enzymes that metabolize many drugs

  – Increased metabolism results in lower blood levels of drug (20 – 40+%)  

  – Affects many classes of diabetic medications
### Effects of Rifampin on Anti-diabetic Drugs

<table>
<thead>
<tr>
<th>Interacting drug</th>
<th>Subjects (n), study design</th>
<th>Rifampin (mg/d)</th>
<th>Results</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Glibenclamide (glyburide)*</td>
<td>Healthy (10), randomized crossover</td>
<td>600 x 5d</td>
<td>39% ↓ in AUC, 22% ↓ in C_{max}, 17% ↓ in t_{1/2}; 44% ↓ in blood glucose decremental AUC; 36% ↓ in maximum ↓ of blood glucose</td>
<td>Monitor blood glucose carefully and increase dosage as necessary</td>
</tr>
<tr>
<td>Gliptide*</td>
<td>Healthy (10), randomized crossover</td>
<td>600 x 5d</td>
<td>34% ↓ in AUC, 25% ↓ in t_{1/2}</td>
<td>Monitor blood glucose carefully and increase dosage as necessary</td>
</tr>
<tr>
<td>Glipizide*</td>
<td>Healthy (10), randomized crossover</td>
<td>600 x 5d</td>
<td>22% ↓ in AUC, 18% ↑ in C_{max}, 36% ↓ in t_{1/2}</td>
<td>Monitor blood glucose carefully and increase dosage as necessary</td>
</tr>
<tr>
<td>Repaglinide*</td>
<td>Healthy (10), randomized crossover</td>
<td>600 x 5d</td>
<td>57% ↓ in AUC, 41% ↓ in C_{max}, 21% ↓ in t_{1/2}; blood glucose decremental AUC↓ by 1.2 mmol·h/L, 37% ↓ in maximum ↓ of blood glucose</td>
<td>Monitor blood glucose carefully and increase dosage as necessary</td>
</tr>
</tbody>
</table>

AUC = area under the concentration-time curve; C_{max} = peak concentration; d = days; t_{1/2} = elimination half-life; ↑ indicates increase; ↓ indicates decrease.

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### TB and Diabetes - Treatment Issues

- **Diabetic neuropathy** at baseline complicates therapy due to INH-related neuropathy
  - Baseline assessment of neuropathy
  - Vitamin B 6 (pyridoxine) to all diabetics on INH or ethionamide
  - Careful follow up and education

- **Renal insufficiency** is associated with diabetes, especially long standing or poorly controlled diabetes
  - Adjust dose and dosing interval of EMB & PZA in those with Creatinine CI < 30
TB and Diabetes - Treatment Issues

• Diabetics have an increased risk of hepatotoxicity
  – Multiple medications
  – Fatty liver

• Monitoring and education are very important
  – Baseline and monthly liver enzymes
  – Educate regarding risk of liver toxicity, symptoms to watch for, and what to do should these occur
    • Contact provider
    • Hold TB medications until liver injury excluded

Impact of Diabetes on TB Epidemic

• A transition is occurring in many countries as development increases -- the most common cause of morbidity and mortality is changing from “Infectious” to “Chronic” diseases
  – The impact of diabetes on TB threatens to cause an overlap that adds infectious disease to an increasing tide of chronic disease
  – Urbanization increases risk of both TB and diabetes
How Big?

- TB has never been big enough to really grab the world’s interest except for outbreaks of MDR in the 1990’s and now XDR TB in recent years

- HIV is really big as it affects many more people but-----

- Diabetes is huge and it’s impact on TB incidence and control may be greater than the impact of HIV

Diabetes cases may double by 2050

And perhaps triple, with 1 in 3 having the disease

—By Mary Brophy Marcus, USA TODAY

October 22, 2010

The future of diabetes in America looks bleak, according to a new Centers for Disease Control and Prevention report out today, with cases projected to double, even triple, by 2050. According to the report, one in 10 U.S. adults have diabetes now. The prevalence is expected to rise sharply over the next 40 years with as many as one in three having the disease, primarily type 2 diabetes, according to the report, published in the journal *Population Health Metrics*.

“There are some positive reasons why we see prevalence going up. People are living longer with diabetes due to good control of blood sugar and diabetes medications, and we’re also diagnosing people earlier now,” says Ann Albright, director of the CDC’s Division of Diabetes Translation.

A more diverse America — including growing populations of minority groups such as African Americans and Hispanics, who are more at risk for the disease — factors into the increase as well, Albright says. But an increasing number of overweight Americans is also fueling the stark predictions for diabetes, which should be taken seriously, Albright says.
Diabetes and Tuberculosis: Mexico

- Prospective population based evaluation of pulmonary TB in Veracruz Mexico, using molecular epidemiological data
  - Risk of TB in diabetics was increased 7 times
  - Risk was increased in both reactivation and new infection

- Authors concluded that:
  - Increased risk due to diabetes is comparable to that found in other studies attributable to HIV
  - “When HIV prevalence in the study area was estimated based on national HIV prevalence, tuberculosis-attributable risk due to HIV was 2% compared with 25% due to diabetes”

  » Ponce-de-Leon, 2004 “TB and Diabetes in Southern Mexico”, Diabetes Care

Impact of Diabetes Epidemic on TB Incidence

- Epidemiological model to assess potential impact of diabetes as risk factor for incident pulmonary TB using India as example

- 2000 there were 20.7 million adults with diabetes and 900,000 with pulmonary TB
  - Model suggests diabetes accounted for 14.8% of pulmonary TB
  - And for 20.2% of smear positive TB

  - Increased TB in urban areas
    - is associated with a 15.2% greater smear + TB incidence vs rural

  » Stevenson et al, BMC Public Health, 2007
Impact of Diabetes Epidemic on TB Incidence

• “In India, HIV accounts for 3.4% of adult tuberculosis incidence, the proportion we estimate to be attributable to diabetes is 14.8%”

• “The current diabetes epidemic may lead to a resurgence of tuberculosis in endemic regions, especially in urban areas”

• “It is time that the “unhealthy partnership” of tuberculosis and diabetes receives the attention it deserves”

  » Stevenson et al, BMC Public Health, 2007

Meeting Report

Consultation meeting on tuberculosis and diabetes mellitus: meeting summary and recommendations


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SUMMARY

The steadily growing epidemic of diabetes mellitus (DM) poses a threat for global tuberculosis (TB) control. Previous studies have identified an important association between DM and TB. However, these studies have limitations: very few were carried out in low-income countries, and none in Africa, raising uncertainty about the strength of the DM-TB association in these settings, and many critical questions remain unanswered. As a result of these questions and uncertainties, the International Union Against Tuberculosis and Lung Disease (The Union), the World Diabetes Foundation and the World Health Organization Stop TB Department undertook a series of consultations as of January 2009. A systematic review and meta-analysis was undertaken by the Department of Epidemiology, Harvard School of Public Health between May and August 2009, and a consultation meeting inviting the experts who reviewed the report took place at The Union Headquarters in Paris on 6 and 7 November 2009. This paper constitutes a summary report of the findings, the research gaps and prioritised areas of research, and the recommendations from that meeting.

KEY WORDS: diabetes mellitus; tuberculosis; meeting report; screening; treatment outcomes
Expert Meeting November 2009
Research Agenda for TB & DM

- IF and when to screen for TB in patients with DM and vice versa
- Impact of DM and non diabetes hyperglycemia on TB treatment outcomes and deaths
- Implementation and evaluation of the TB DOTS model for diabetes management
- Development and evaluation of better point of care diagnostic and monitoring tests for diabetes

Recommendations from 2009
Consultation Meeting TB and DM

- Collaboration between diabetes and TB care and control initiatives
- Screening diabetics for active TB
  - Screening for LTBI benefit unclear
  - Screening for LTBI for increased risk
- Screening TB patients for diabetes
  - At initial diagnosis and repeat at 3 months
- Management of TB and diabetes co-morbidity
  - Optimize case management, education, monitoring for adverse outcomes
What Can We Offer in TB Clinics?

• Include glucose on blood work.
• Educate on need to follow a healthy eating plan.
• Encourage physical activity for 30 to 60 minutes/day.
• Stress the importance of taking medicines as directed.
• Encourage patients to quit smoking.
• Refer for regular physician visits
• Educate on need for daily foot check
  – for cuts, blisters, sores, swelling, redness, or sore toenails.

TB and Diabetes

• DM growing in prevalence world-wide
• Uncontrolled DM increases risk of TB
• TB often presents in more advanced stage in DM
• Treatment time may need to be longer in DM patients
• Implications in populations with high prevalence
• Screening across clinics for DM and TB is needed