Making the Case for TB Continuity of Care Planning for Homeless Patients

2015 National Health Care for the Homeless Conference and Policy Symposium

May 7, 2015

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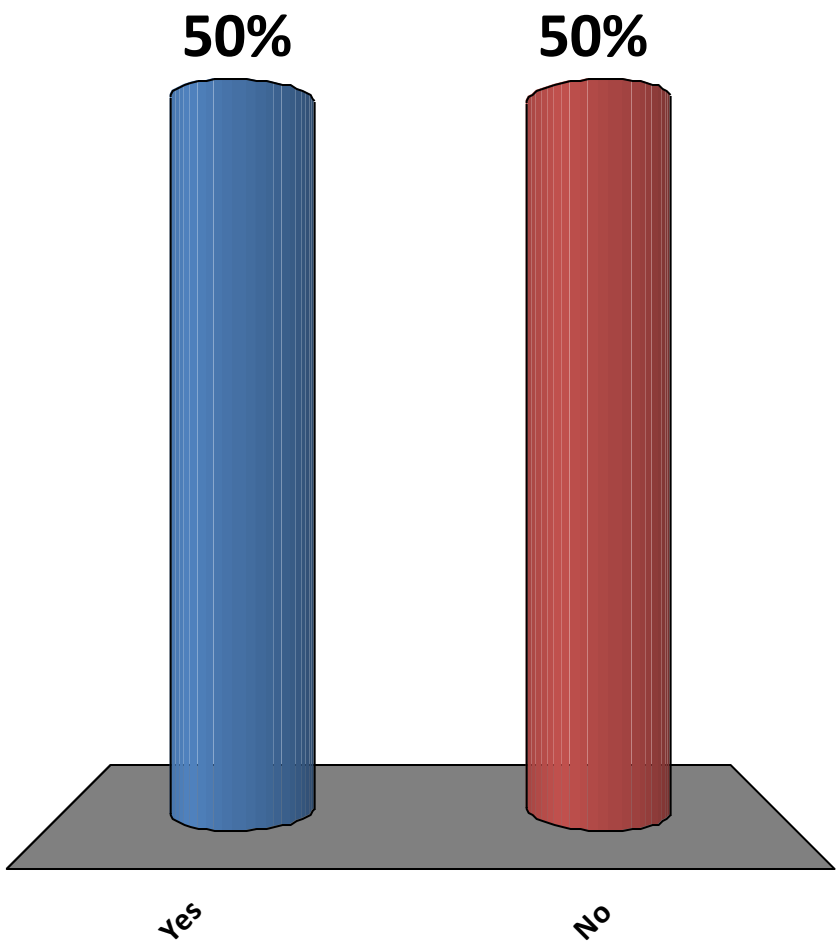
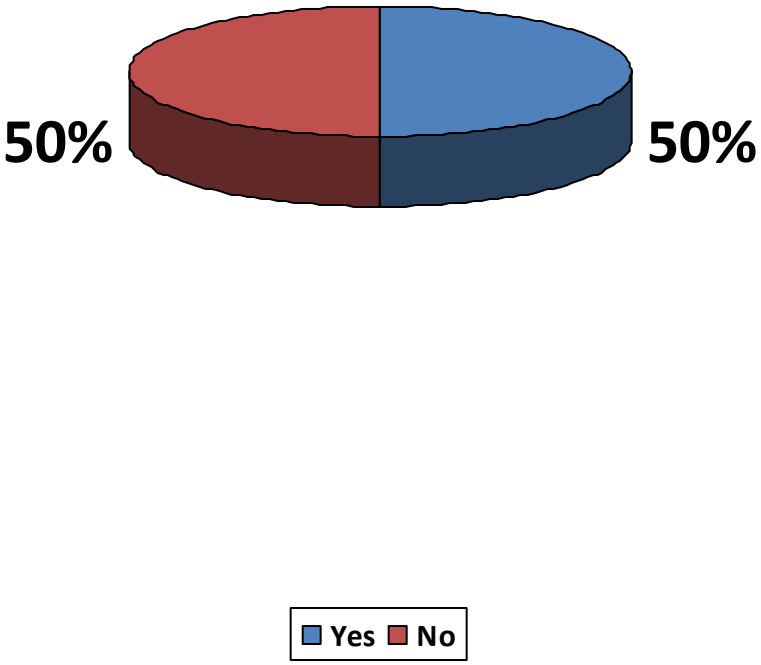
Do you regularly test for TB infection?

A. Yes
B. No
C. Sometimes

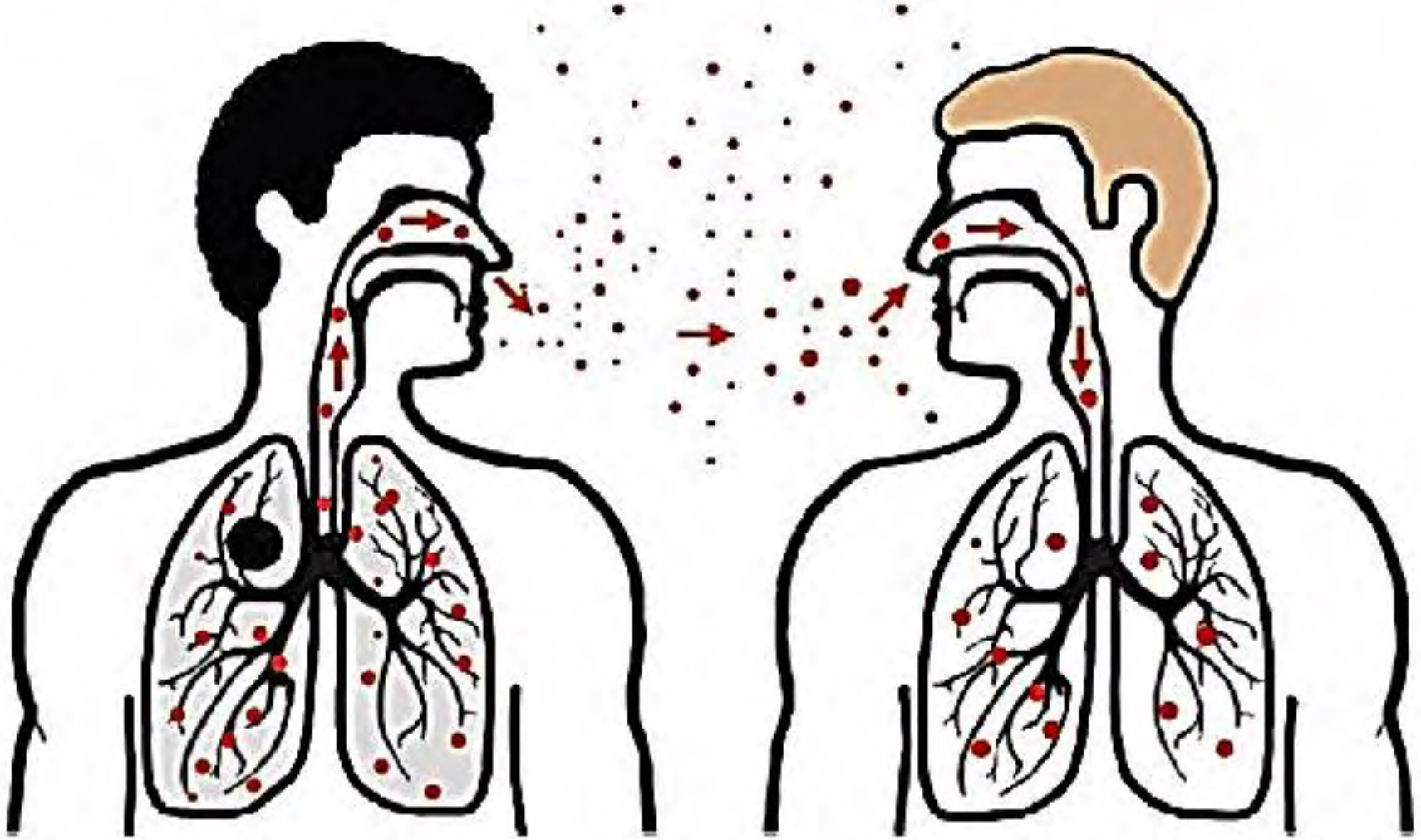


Do you actively treat TB infection once found positive skin or IGRA test?

A. Yes
B. No
C. Sometimes

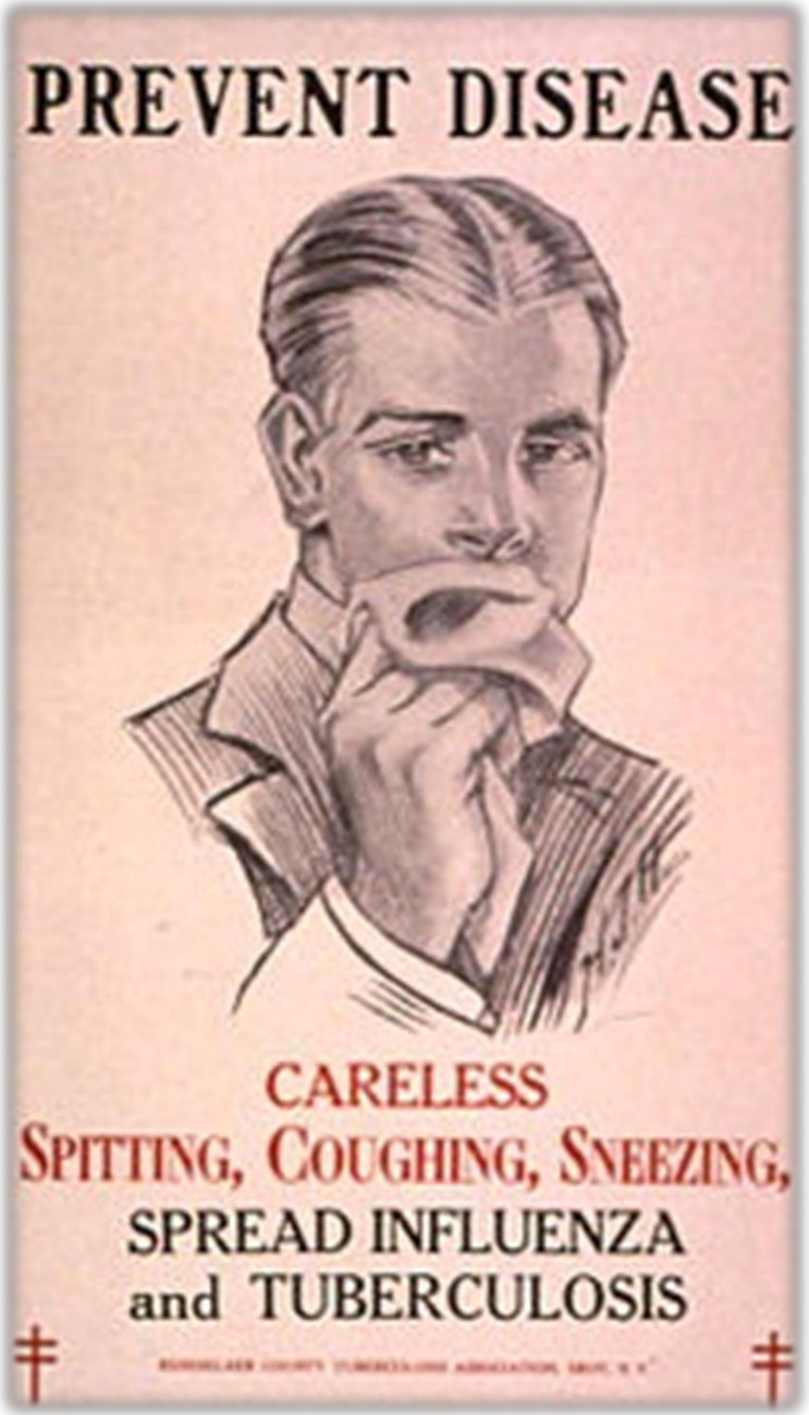


Transmission and Pathogenesis



Transmission of *M. tuberculosis*

- Infectious disease caused by a bacteria, *M. tuberculosis*
- Transmitted through the air on water droplets
- Primarily affects the lungs (85%), though it can affect any organ



- Spread when someone who is sick with TB disease of the lungs coughs or sneezes, releasing bacteria – **and a person nearby breathes in these infected droplets**
- Untreated, a person with active TB can infect 10 to 15 people a year on average

What is the probability that TB will be transmitted?

It depends on…

- Infectiousness of person with TB
- Environment in which exposure occurred
- Duration of exposure
- Virulence of the organism

Lifetime Risk of Active Disease

Global Burden of TB, 2014

WHO Global TB Report, 2014

	Estimated Number of Cases	Estimated Number of Deaths
All forms of TB	9 million	**1.5 million***
HIV-Associated TB	1.1 million (13%)	**360,000**
Multidrug-resistant TB (MDR-TB)	480,000	~150,000

- Approx. 1/3 of the world (2 billion people) is infected with *M.tb*
- Estimated that 37 million lives were saved between 2000 and 2013 through effective diagnosis and treatment
- ***Fewer than 25% of those thought to have MDR TB were detected*

*including deaths among PLHIV

TB Morbidity

United States, 2002-2014

Year	No. of Cases	Rate (per 100,000)
2003	14, 837	5.1
2004	14, 501	4.9
2005	14, 065	4.7
2006	13, 754	4.6
2007	13, 299	4.4
2008	12, 898	4.2
2009	11, 540	3.8
2010	11, 181	3.6
2011	**10, 521**	**3.4**
2012	**9,951**	**3.2**
2013	**9,588**	**3.0**
2014	**9,412***	**2.95**

2.2% decline

****Lowest since 1953***

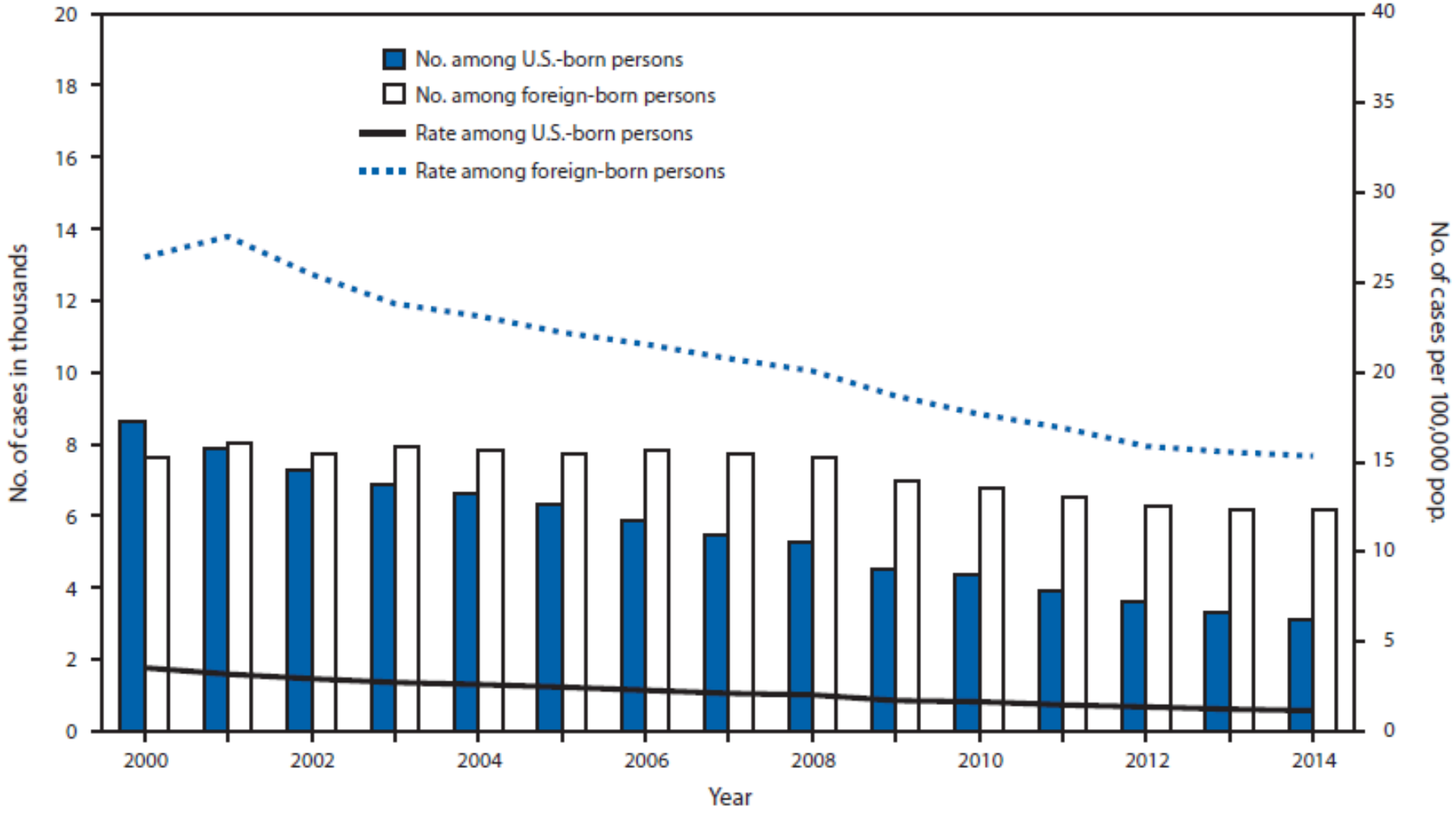
TB Morbidity

United States, 2002-2013

- TB disproportionately affects foreign-born persons (13.4 times higher than among U.S.-born persons), Asians, blacks, and people with HIV
- Compared with whites, **TB is 29 times higher for Asians**, 8 times higher for blacks and 8 times higher for Hispanics.
  - More TB cases reported among Asians than any other racial/ethnic group in the US in 2014
- Multidrug-resistant TB (MDR TB) cases accounted for 86 of all US TB cases in 2013 (1.2% of all cases)
  - 2 cases of extensively drug resistant (XDR TB) (2013), all among foreign-born persons (2 cases in 2012; 5 cases in 2011)
- HIV status known for 85% of TB cases
  - 6.8 % co-infected with HIV

TB Cases in US-born vs Non-US-born Persons

United States, 2000-2014*



*Updated March 21, 2015 with provisional 2014 data

66.5% Foreign-born

What are the "Hidden Stats" on TB

- Active TB cases 9,588
- Contact investigation* identifies average of 17.9 contacts/active case; 1% new active case identified; 20% LTBI; estimated over 170,000 individuals that need to be evaluated, tested and offered preventive treatment if infected.
- TB Infection (LTBI) at least 11,000,000
  - ~ 10% risk of active TB in lifetime

*ARPE Report US, 2010 (CDC data 2/1/2013)

The burden of tuberculosis infection, the reservoir for active TB

WHO estimates that 2 billion persons (1/3 of the world's population) have tuberculosis infection

- From this reservoir, millions of people will have active tuberculosis (TB) in coming decades

In the U.S., it is estimated by a recent NHANES survey that there are at least 11 million persons with TB infection

- >70% of TB disease in the US are re-activation TB

Table 1. Prevalence of Latent Tuberculosis Infection among U.S. Residents, as Assessed by Tuberculin Skin Testing.*

Group and Study	Expected Prevalence (95% CI)
	%
Foreign-born persons	
Bennett et al.[4]	18.7 (13.5–25.2)
Close contacts of persons with infectious tuberculosis†	
Marks et al.[8]	37.1 (35.7–38.5)
Homeless persons	
Kong et al.[9]	12.8 (12.2–13.5)
Moss et al.[10]	32.4 (30.5–34.4)
Injection-drug users	
Riley et al.[11]	16.1 (12.5–22.4)
Grimes et al.[12]	27.7 (19.3–37.5)
Brassard et al.[13]	22.4 (17.7–28.5)
Salomon et al.[14]	14.0 (11.4–17.1)
Prisoners	
Lobato et al.[15]	17.0 (16.8–17.1)
U.S.-born, no other risk	
Bennett et al.[4]	1.8 (1.4–2.1)

Horsburgh and Rubin
NEJM 2011

Table 2. Common Risk Factors for Increased Likelihood of Progression from Latent Tuberculosis Infection to Active Disease.*

Risk Factor and Study	Relative Risk (95% CI)
	%
Advanced, untreated HIV infection	
Moss et al.[10]	9.9 (8.7–11)
Pablos-Méndez et al.[16]	9.5 (3.6–25)
Close contact with a person with infectious tuberculosis†	
Ferebee[17]	6.1 (5.5–6.8)
Radiographic evidence of old, healed tuberculosis that was not treated	
Ferebee[17]	5.2 (3.4–8.0)
Treatment with ≥15 mg of prednisone per day‡	
Jick et al.[18]	2.8 (1.7–4.6)
Chronic renal failure	
Pablos-Méndez et al.[16]	2.4 (2.1–2.8)
Treatment with TNF-α inhibitor	
Askling et al.[19]	2.0 (1.1–3.5)
Poorly controlled diabetes	
Pablos-Méndez et al.[16]	1.7 (1.5–2.2)
Weight ≥10% below normal	
Palmer et al.[20]	1.6 (1.1–2.2)
Smoking	
Bates et al.[21]	1.5 (1.1–2.2)

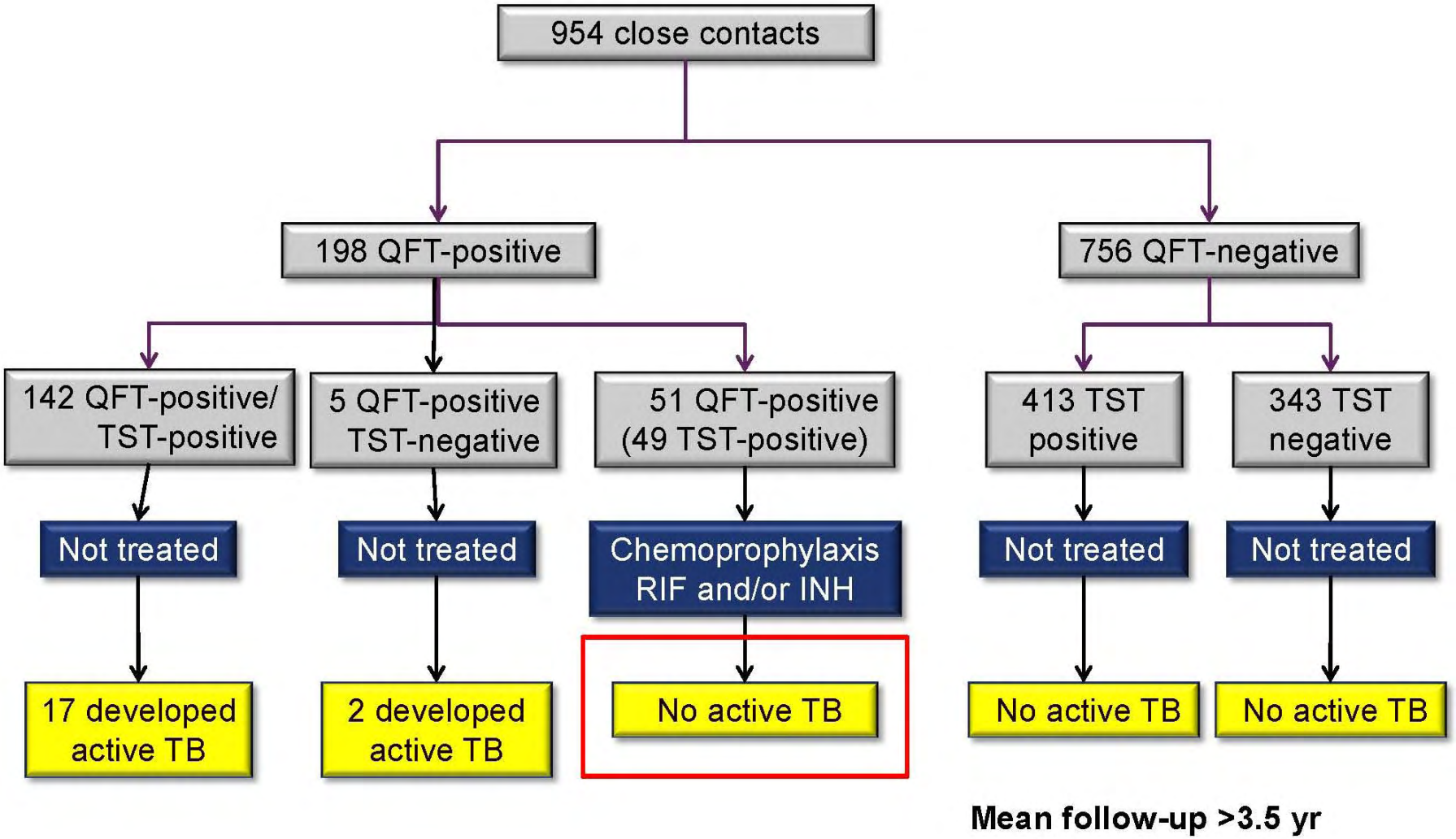
Horsburgh and Rubin
NEJM 2011

US 2010 IGRA CDC Guidelines

- “An IGRA may be used in place of (but not in addition to) a TST in all situations in which CDC recommends TSTs”
- **IGRAs preferred:**
  - BCG vaccinated persons
  - Persons unlikely to return for a TST reading
  - Low risk individuals
- Like the TST, clinical judgment required when interpreting IGRA results in children <5yrs, immunocompromised persons, and TB suspects
- When maximum sensitivity needed → acceptable to use both TST and IGRA
- Lab should report quantitative results

Predictive power of QFT for development of active TB

Diel, Loddenkemper et al., AJRCCM, 27 August 2010



Mean follow-up >3.5 yr

Interferon Gamma Release Assays vs. Tuberculin Skin Test

IGRA

- In vitro
- Single antigens
- Can be fully Automated
- Not affected by BCG
- Result with one patient visit
- Minimal inter-reader variability
- Outstanding surveillance tool if results electronic
- Results confidential

TST

- In vivo
- Multiple antigens
- Manual reading and entry
- BCG may affect results
- Two patient visits required
- Significant inter-reader variability
- Poor surveillance tool
- Results not confidential

PUBLIC HEALTH: San Francisco TB Control
QFT+ results 2008-2011 vs historical TST+ rates

	TST*	IGRA†
Clinic for immigrants	1050/2825 (37%)	750/3391 (22%)
Clinic for homeless people	1726/6231 (28%)	506/7548 (7%)

TST=tuberculin skin test. IGRA=interferon-γ release assay. *January 2001–December 2003. †January 2008–May 2011.

Table: **Positive results for tuberculosis tests in San Francisco, CA, USA**

Kawamura et al, Lancet ID Correspondence, Volume 12, No. 8, p584, August 2012

Before initiating treatment for LTBI…

- ✓ Rule out TB disease
  - CXR (if abnormal—obtain sputum)
  - Assess/evaluate for symptoms (sputum)
  - Wait for culture result if specimen obtained
- ✓ Prior history of treatment for TB infection or TB disease?
- ✓ TB exposure?
- ✓ Assess risks and benefits of treatment
  - ✓ Active liver disease (LFTs if indicated)
- ✓ Ascertain current and previous drug therapy and side effects

Treatment Regimens for TB Infection

Drugs	Months of Duration	Interval	Minimum Doses	Rating/ Evidence
INH	9*	Daily	270	AII
		2x wkly**	76	BII
INH	6	Daily	180	BI
		2x wkly**	52	Avoid: HIV infected, children (CII)
RIF	4	Daily	120	BII

Preferred ** Intermittent treatment only with DOT

INH=isoniazid; RIF=rifampin

Rifampin Regimens

- ✓ RIF daily for 4 months is an acceptable alternative when treatment with INH is not feasible (BII for HIV-, BIII for HIV +)
  - INH resistant or intolerant
  - Patient unlikely to be adherent for longer treatment period
- ✓ In situations where RIF cannot be used (e.g., HIV-infected persons receiving protease inhibitors), rifabutin may be substituted

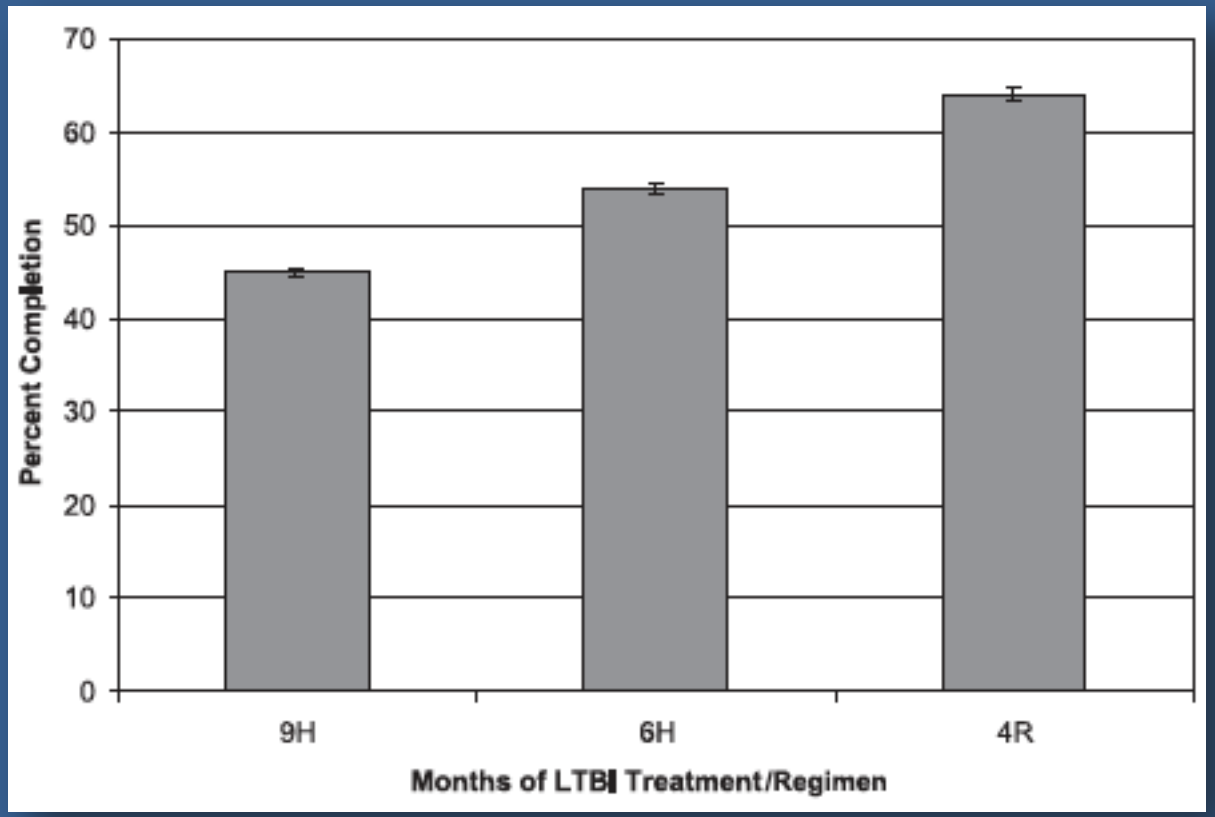
Comparison of INH vs. RIF For Treatment of TB Infection

Regimen Feature	9H	4R
High efficacy	X	*
Lower hepatotoxicity		X
Lower overall cost		X
Higher adherence / completion		X
More effective against INH-resistant strains *(e.g., among foreign-born persons)*	X	
Shorter duration	X	
Fewer drug-drug interactions	X	

** Good evidence that 3R is at least as efficacious as 6H. Inferential reasoning from other evidence suggests that efficacy of 4R may approach that of 9H.*

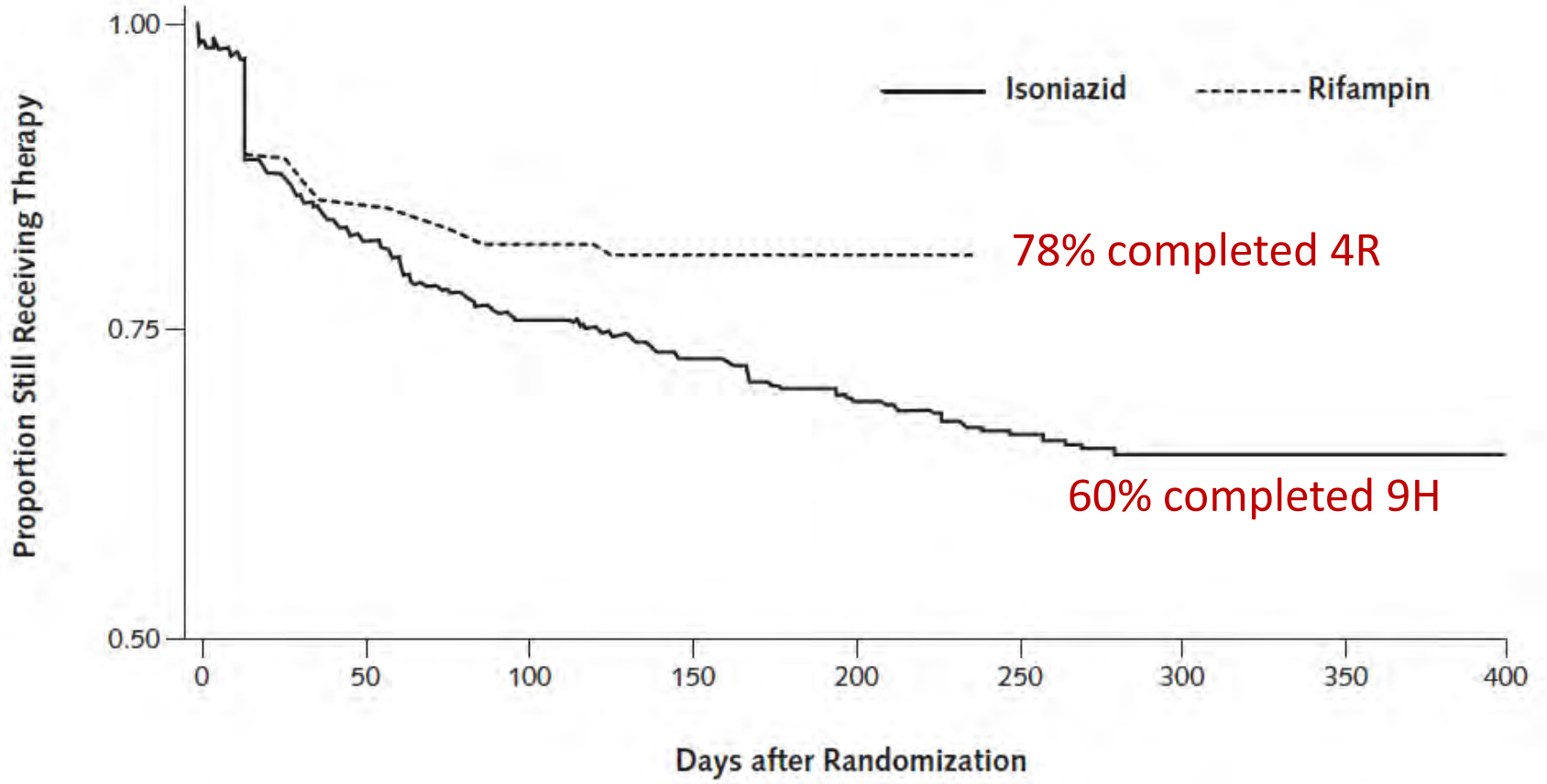
Reichman LB, *Am J Respir Crit Care Med* 2004:170;832-835,

Shorter regimens appear to be associated with increased completion rates



Horsburgh CR *Chest* 2010:137:401-09

Completion with 4R compared to 9H: a randomized trial of 847 patients



Menzies et al. *Ann Int Med* 2008;149:689-697

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 8, 2011 VOL. 365 NO. 23

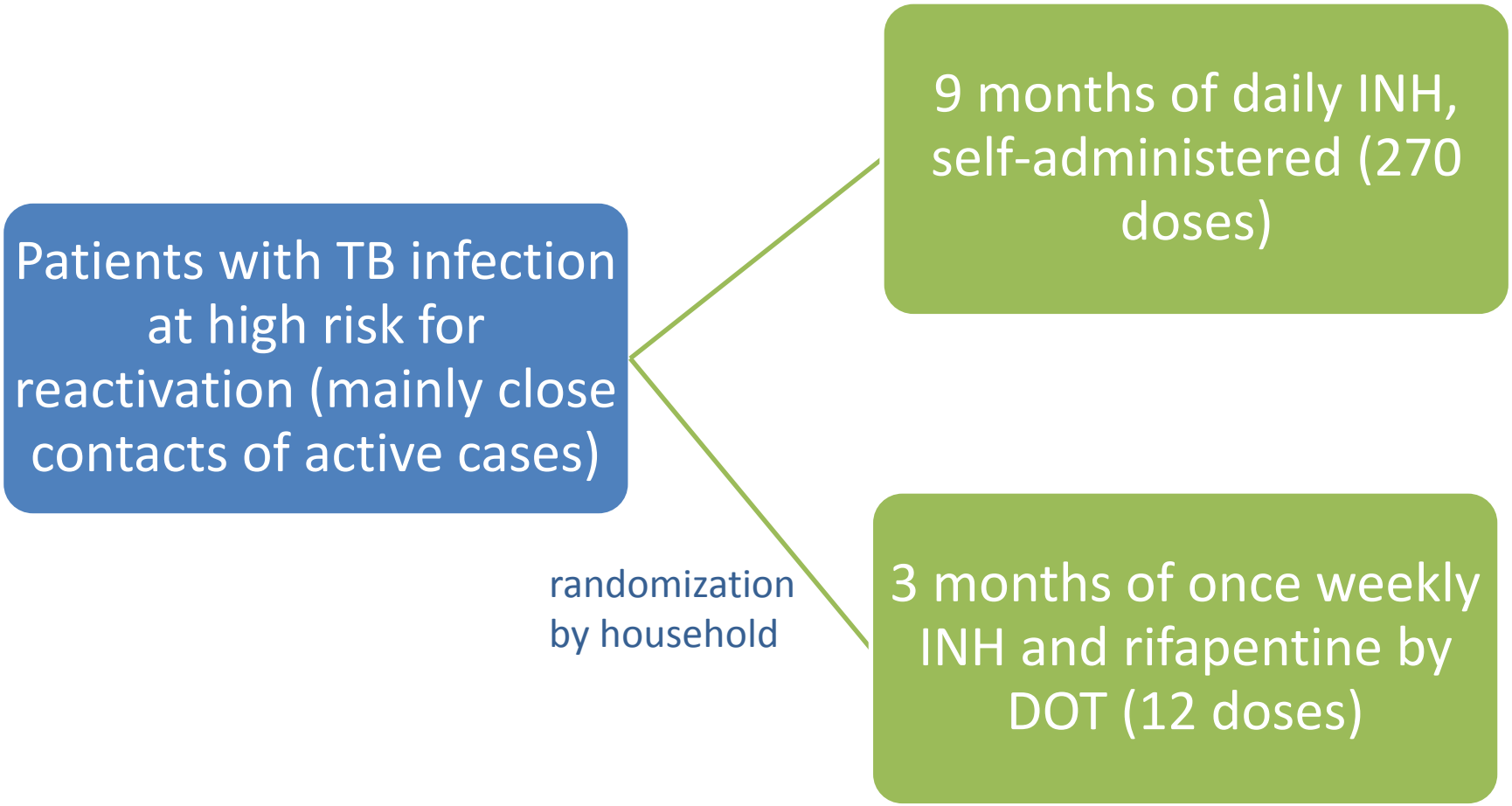
Three Months of Rifapentine and Isoniazid for Latent Tuberculosis Infection

New Option for TB Infection Treatment

- ✓ 12 weekly doses of Isoniazid/Rifapentine (INH/RPT) with directly observed therapy (DOT)
- ✓ Based on review of randomized clinical trial and two other studies:
  - ✓ As effective as INH for 9 months
  - ✓ More likely to be completed
- ✓ CDC Recommendations as of December 9, 2011

MMWR 2011; Vol 60 No. 48

TBTC Study 26, PREVENT-TB:
A randomized, controlled trial of two regimens for treatment of LTBI



Study endpoint: development of active TB at 2 years

Primary Aim

- Evaluate the effectiveness of weekly INH-RPT vs daily 9H
- Primary endpoint:
  - Culture-confirmed TB in persons ≥ 18 y.o. and culture-confirmed or clinical TB in persons < 18 y.o.

Hepatotoxicity

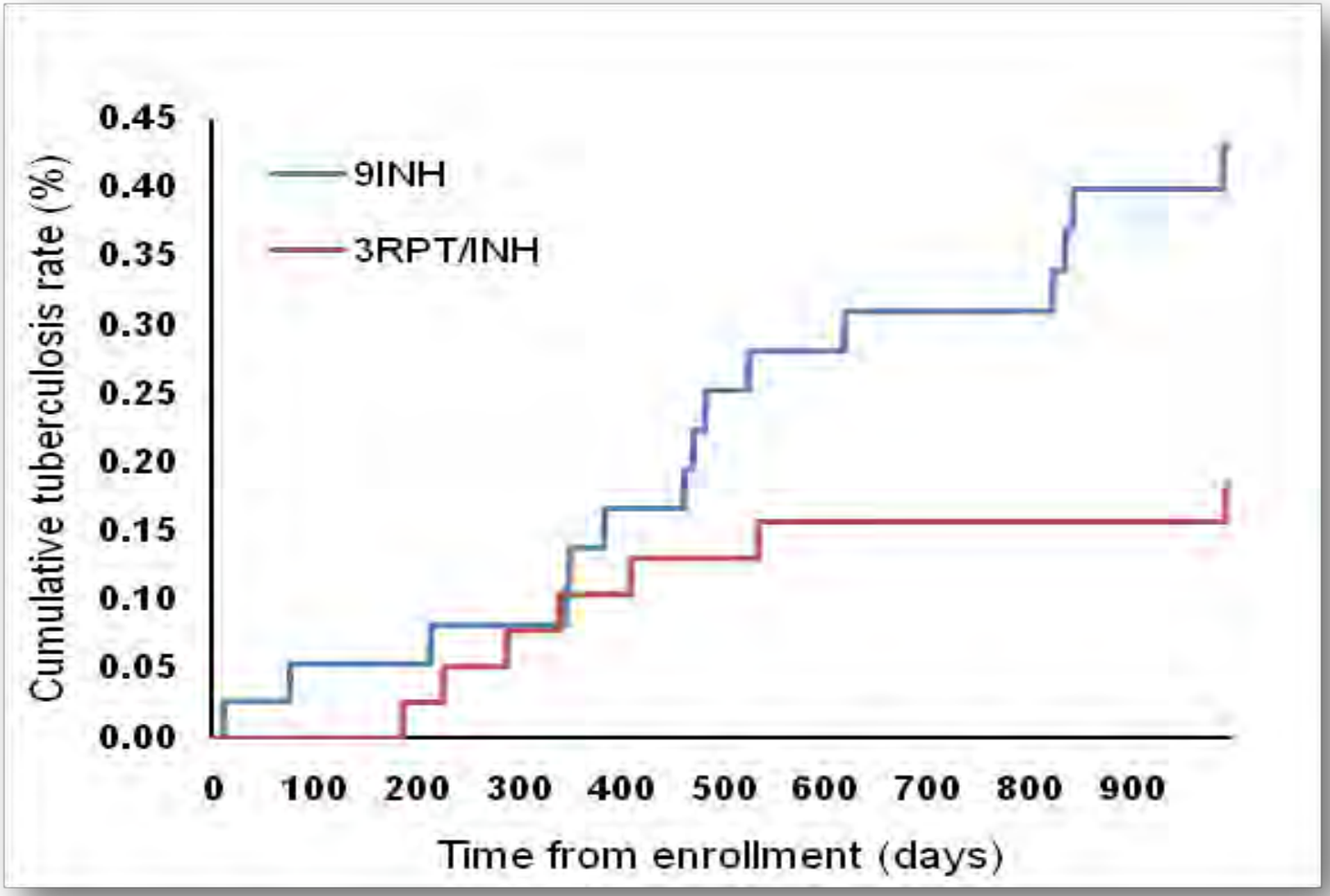
Among persons receiving ≥ 1 dose
During treatment or within 60 days of the last dose

Toxicity	9H N=3,759	INH-RPT N=4,040	P-value
All hepatotoxicity	113 (3.0)	24 (0.6)	<0.0001
Related to drug	103 (2.7)	18 (0.5)	<0.0001
Not related	13 (0.4)	6 (0.2)	0.08

TBTC Study 26, PREVENT-TB: Outcomes

Population and Study Group	No. of Subjects	Subjects with Tuberculosis		
		no.	*no. per patient-yr*	*cumulative rate*
Modified intention-to-treat analysis				
Isoniazid only	3745	15	0.16	0.43
Combination therapy	3986	7	0.07	0.19
Per-protocol analysis				
Isoniazid only	2585	8	0.11	0.32
Combination therapy	3273	4	0.05	0.13

Cumulative TB Rate
33 months from enrollment—MITT



INH/RPT – Recommended Groups

- ✓ Healthy persons ≥12 years old with at least one risk factor for TB progression
  - Recent known contacts to TB
  - Conversion from negative to positive on a TST or IGRA
  - Radiographic findings of healed pulmonary TB
  - HIV-infected patients NOT on anti-retroviral therapy
- ✓ Case by case basis for other patients (individuals unlikely to complete longer regimens “migrant farmworkers” “homeless individuals”)

INH/RPT – Groups Not Recommended

- Children < 2 years old
- HIV-infected patients on antiretroviral therapy
- Pregnant women
- Patients exposed to TB resistant to either INH or rifampin

INH/RPT – Dosing/Cost

BOX 1. Dosage for a combination regimen of isoniazid and rifapentine in 12 once-weekly doses under direct observation for treating latent *Mycobacterium tuberculosis* infection.

Isoniazid

15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum

Rifapentine

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 maximum

Isoniazid (INH) is formulated as 100 mg and 300 mg tablets. Rifapentine (RPT)is formulated as 150 mg tablets packed in blister packs that should be kept sealed until usage. New formulations with larger dosage per tablet and fixed-dose INH-RPT combinations are in development.

Source: Three months of weekly rifapentine and isoniazid for *Mycobacterium tuberculosis* infection (PREVENT TB). Information available at http://clinicaltrials.gov/ct2/show/nct00023452?term=rifapentine&rank=9.

Drug costs (CT DOH; Lynn Sosa, MD)
INH/RPT- **$112 for 12 wk**
INH- **$14 for 9 month**

Limitations

- Few HIV-infected participants
  - Tolerability and effectiveness data pending
- Complete tolerability assessment in young children also pending

TBTC Study 26, PREVENT-TB Conclusions

- ✓INH-RPT was at least as effective as 9H
  - The INH-RPT TB rate was less than half that of 9H
- ✓INH-RPT completion rate was significantly higher than 9H
  - 82% vs. 69%
- ✓INH-RPT was safe relative to 9H
  - Lower rates of:
    - Any adverse event
    - Hepatotoxicity attributable to study drug

Do we *really* need DOT for INH-RPT?

- **Once a week regimen**
  - Ensure compliance
  - Standard for all intermittent TB or LTBI treatment regimens
  - Impact of missed doses on regimen effectiveness?
  - Monitor for adverse effects
- **Self-administered INH-RPT is being studied**
  - TBTC Study 33 to address this: roughly 1100 patients randomized to DOT or self-administration with SMS reminders
    - Study is ongoing
  - Safety
- **CDC LTBI treatment adverse effects surveillance system**
  - (ltbidrugevents@cdc.gov, http://www.fda.gov/medwatch or 1-800-FDA-1088)

Completion of Therapy

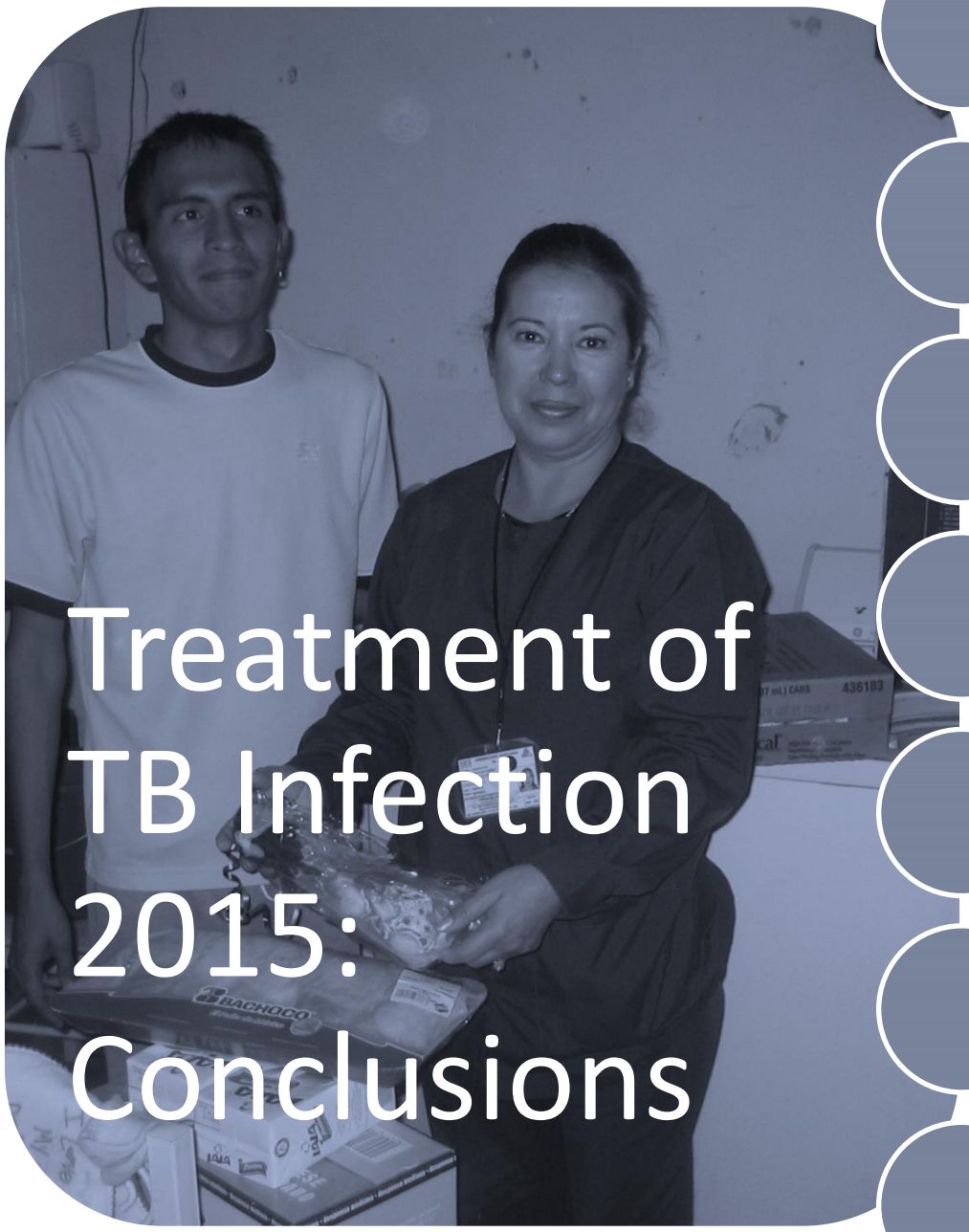
Regimen	Duration	Doses	Complete Within
Daily INH	9 months	270	12 months
Twice weekly INH	9 months	76	12 months
Daily INH	6 months	180	9 months
Twice weekly INH	6 months	52	9 months
Rifampin	4 months	120	6 months
INH-RPT	3 months	11-12	16 weeks

Priorities in Screening and Treatment of TB Infection

Photo: Bertha Almendariz

- ✓ With new tools for the diagnosis and treatment of TB infection, we now have a chance to improve the effectiveness of TB control in the US by focusing on cost-effective priorities
- ✓ IGRA was cost saving compared with TST in certain groups
- ✓ TB Infection screening guidelines could make progress toward TB elimination by screening close contacts, HIV infected, foreign born regardless of time living in the US

Linas BP. *Am J Respir Cri Care Med*. 2011;184:590-601

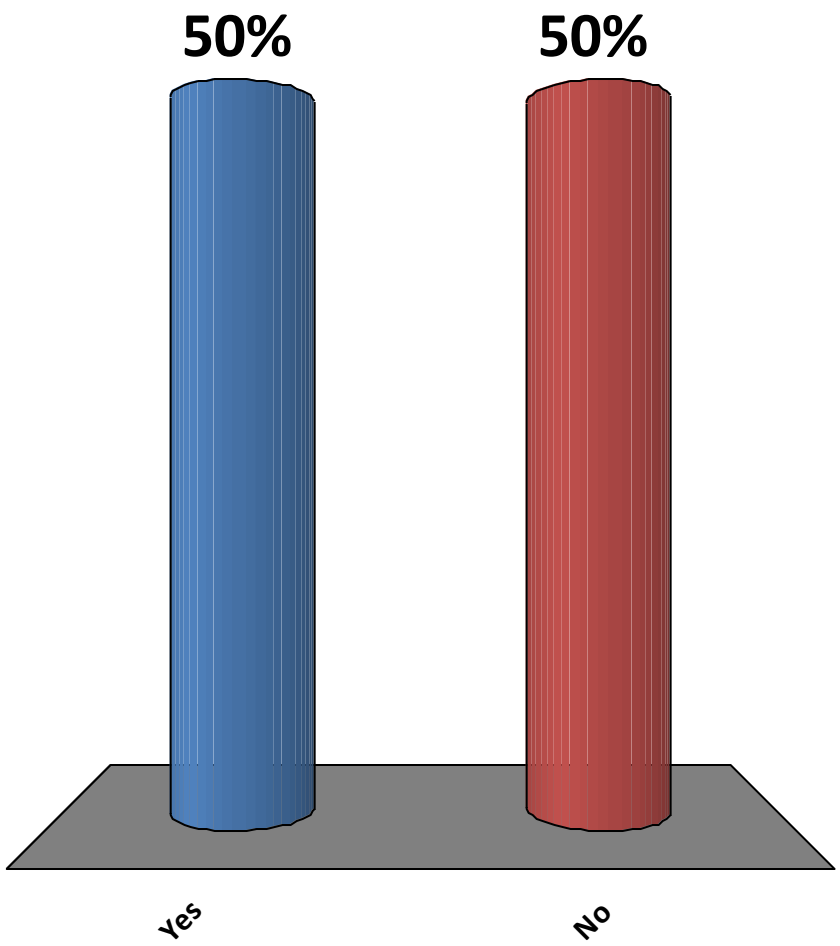


Treatment of TB Infection 2015: Conclusions

- TB Infection is common in the U.S.
- Treatment of TB Infection is an important component of TB elimination strategies
- Important to choose treatment regimen based on individual circumstance of each patient
- Treatment with the standard regimen of 9H is associated with very low adherence and significant rates of adverse events
- Treatment with 4 months Rif is associated with much higher adherence and fewer serious side effects when compared to 9H
- Regimen of INH-RPT is as efficacious as 9H, and when administered by DOT
- Self-administration of INH-RPT will be tested in a randomized controlled TBTC trial

Have you ever lost a patient to follow up?

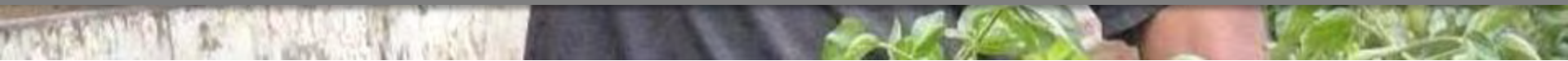
A. Yes
B. No



MCN Health Network

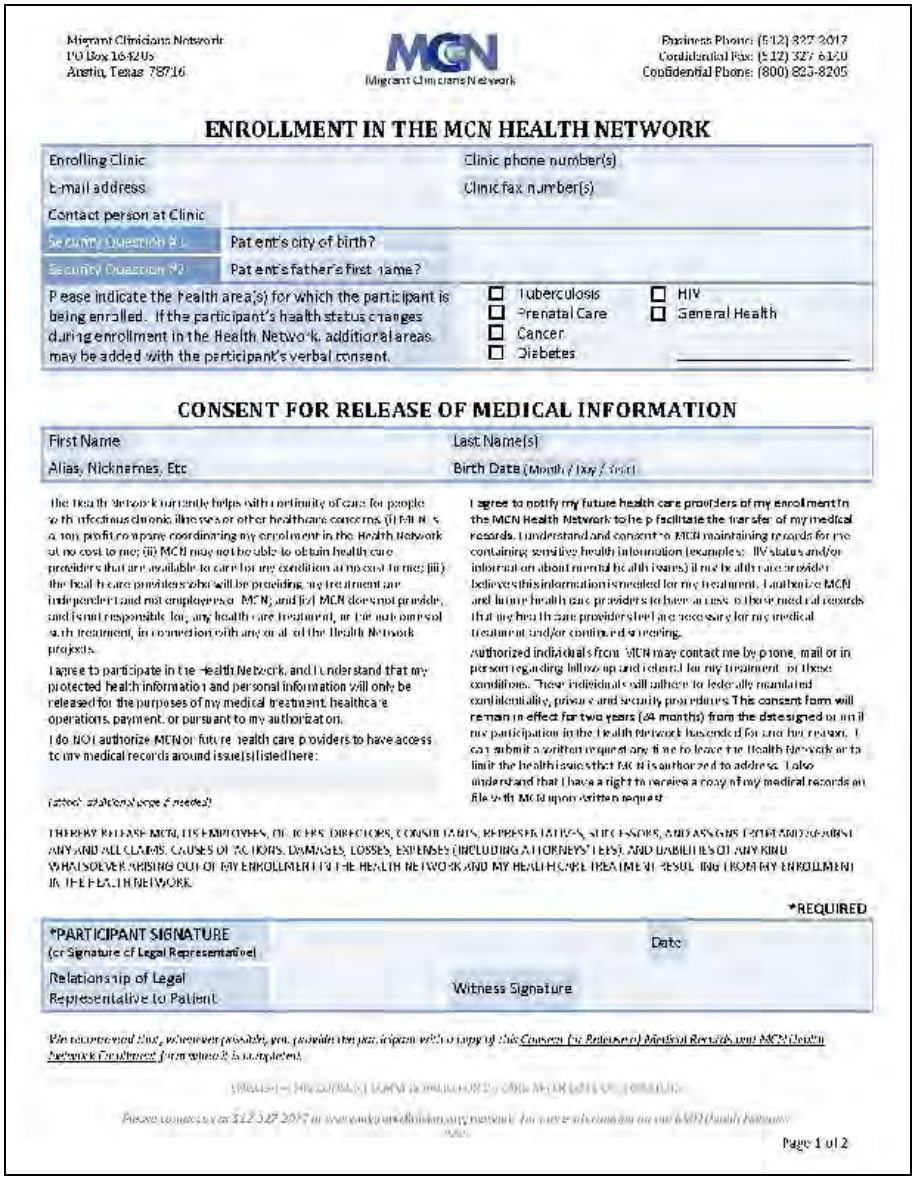
Goal: Eliminate health disparities due to patient mobility

Responds to challenges in providing continuity of care through patient navigation; medical record transfer and bridge case management program




HEALTH NETWORK
Bridge Case Management
Ongoing communication
Health education
Care coordination services
Toll-free access
Expert, bilingual, culturally-competent staff
Store & transfer medical records

Forms Required for Enrollment



Migrant Clinicians Network
PO Box 164285
Austin, Texas 78716

Migrant Clinicians Network

Business Phone: (512) 327-2017
Confidential Fax: (512) 327-6140
Confidential Phone: (800) 825-8205

ENROLLMENT IN THE MCN HEALTH NETWORK

Enrolling Clinic	Clinic phone number(s)
E-mail address	Clinic fax number(s)
Contact person at Clinic	
Security Question #1:	Patient's city of birth?
Security Question #2:	Patient's father's first name?

Please indicate the health area(s) for which the participant is being enrolled. If the participant's health status changes during enrollment in the Health Network, additional areas may be added with the participant's verbal consent.

☐ Tuberculosis ☐ HIV
☐ Prenatal Care ☐ General Health
☐ Cancer
☐ Diabetes

CONSENT FOR RELEASE OF MEDICAL INFORMATION

First Name	Last Name(s)
Alias, Nicknames, Etc	Birth Date (Month / Day / Year)

The Health Network currently helps with continuity of care for people with infectious/chronic illnesses or other healthcare concerns. (i) MCN is a non-profit company coordinating my enrollment in the Health Network at no cost to me; (ii) MCN may not be able to obtain health care providers that are available to care for my condition at no cost to me; (iii) the health care providers who will be providing my treatment are independent and not employees of MCN; and (iv) MCN does not provide, and is not responsible for, any health care treatment, or for non-universal health treatment, in connection with any or all of the Health Network projects.

I agree to participate in the Health Network, and I understand that my protected health information and personal information will only be released for the purposes of my medical treatment, healthcare operations, payment, or pursuant to my authorization.

I do NOT authorize MCN or future health care providers to have access to my medical records around issue(s) listed here:

(attach additional page if needed)

I agree to notify my future health care providers of my enrollment in the MCN Health Network to help facilitate the transfer of my medical records. I understand and consent to MCN maintaining records for me containing sensitive health information (examples: HIV status and/or information about mental health issues) if my health care provider believes this information is needed for my treatment. I authorize MCN and future health care providers to have access to these medical records that my health care providers feel are necessary for my medical treatment and/or continued screening.

Authorized individuals from MCN may contact me by phone, mail or in person regarding follow-up and referral for my treatment or these conditions. These individuals will adhere to federally mandated confidentiality, privacy and security procedures. This consent form will remain in effect for two years (24 months) from the date signed or until my participation in the Health Network has ended for any reason. I can submit a written request any time to leave the Health Network or to limit the health issues that MCN is authorized to address. I also understand that I have a right to receive a copy of my medical records on file with MCN upon written request.

I HEREBY RELEASE MCN, ITS EMPLOYEES, OFFICERS, DIRECTORS, CONSULTANTS, REPRESENTATIVES, SUCCESSORS, AND ASSIGNS FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTIONS, DAMAGES, LOSSES, EXPENSES (INCLUDING ATTORNEYS' FEES), AND LIABILITIES OF ANY KIND WHATSOEVER ARISING OUT OF MY ENROLLMENT IN THE HEALTH NETWORK AND MY HEALTHCARE TREATMENT RESULTING FROM MY ENROLLMENT IN THE HEALTH NETWORK.

*REQUIRED

*PARTICIPANT SIGNATURE (or Signature of Legal Representative)	Date
Relationship of Legal Representative to Patient	Witness Signature

We recommend that, whenever possible, you provide the participant with a copy of this Consent for Release of Medical Records and MCN Health Network Enrollment form when it is completed.

Please contact us at 512-327-2017 or www.migrantclinician.org/network for more information on the MCN Health Network.

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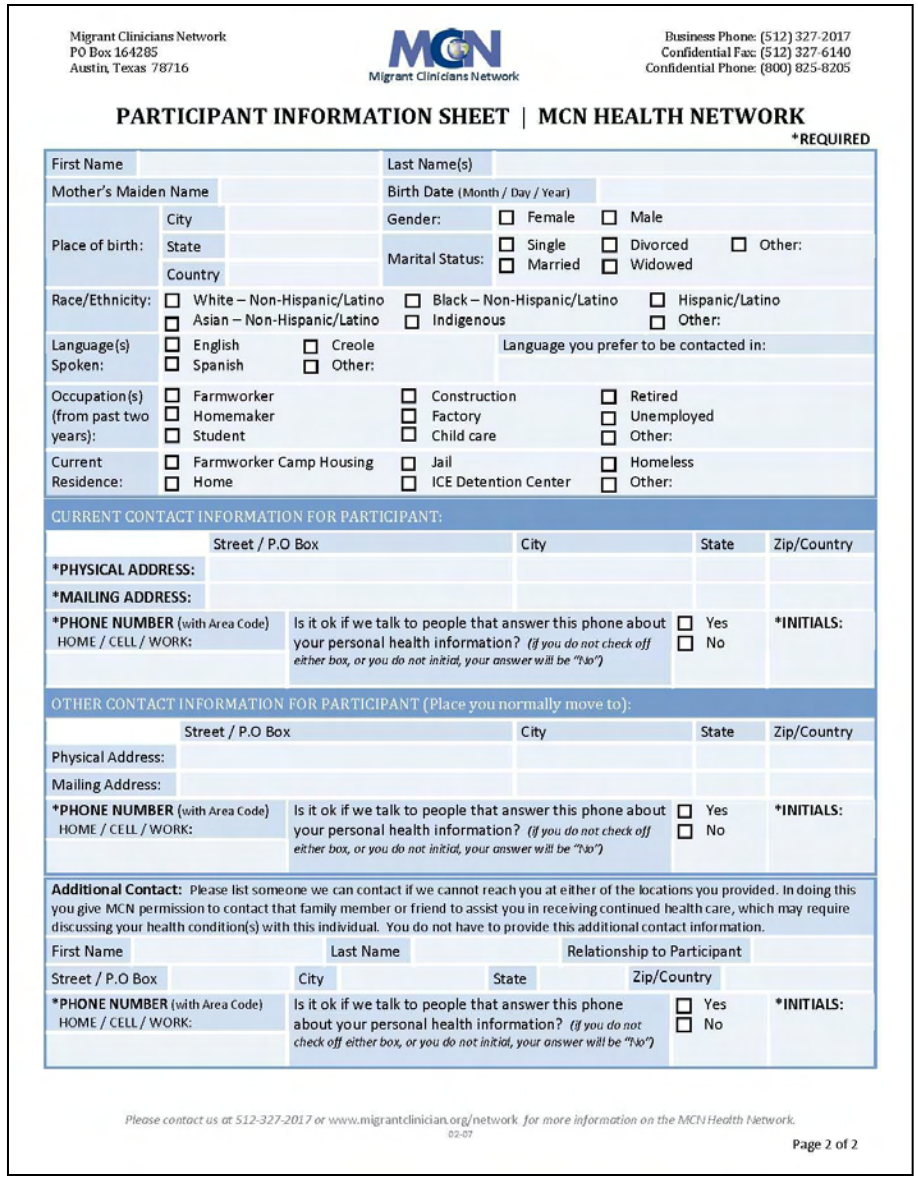

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Confidential Fax: (512) 327-6140
Confidential Phone: (800) 825-8205

PARTICIPANT INFORMATION SHEET | MCN HEALTH NETWORK

*REQUIRED

First Name		Last Name(s)	
Mother's Maiden Name		Birth Date (Month / Day / Year)	
Place of birth: City		Gender:	☐ Female ☐ Male
Place of birth: State		Marital Status:	☐ Single ☐ Divorced ☐ Other: ☐ Married ☐ Widowed
Place of birth: Country			
Race/Ethnicity:	☐ White – Non-Hispanic/Latino ☐ Black – Non-Hispanic/Latino ☐ Hispanic/Latino ☐ Asian – Non-Hispanic/Latino ☐ Indigenous ☐ Other:		
Language(s) Spoken:	☐ English ☐ Creole ☐ Spanish ☐ Other:	Language you prefer to be contacted in:	
Occupation(s) (from past two years):	☐ Farmworker ☐ Construction ☐ Retired ☐ Homemaker ☐ Factory ☐ Unemployed ☐ Student ☐ Child care ☐ Other:		
Current Residence:	☐ Farmworker Camp Housing ☐ Jail ☐ Homeless ☐ Home ☐ ICE Detention Center ☐ Other:		

CURRENT CONTACT INFORMATION FOR PARTICIPANT:

	Street / P.O Box	City	State	Zip/Country
*PHYSICAL ADDRESS:				
*MAILING ADDRESS:				

*PHONE NUMBER (with Area Code) HOME / CELL / WORK:	Is it ok if we talk to people that answer this phone about your personal health information? *(if you do not check off either box, or you do not initial, your answer will be "No")*	☐ Yes ☐ No	*INITIALS:

OTHER CONTACT INFORMATION FOR PARTICIPANT (Place you normally move to):

	Street / P.O Box	City	State	Zip/Country
Physical Address:				
Mailing Address:				

*PHONE NUMBER (with Area Code) HOME / CELL / WORK:	Is it ok if we talk to people that answer this phone about your personal health information? *(if you do not check off either box, or you do not initial, your answer will be "No")*	☐ Yes ☐ No	*INITIALS:

Additional Contact: Please list someone we can contact if we cannot reach you at either of the locations you provided. In doing this you give MCN permission to contact that family member or friend to assist you in receiving continued health care, which may require discussing your health condition(s) with this individual. You do not have to provide this additional contact information.

First Name		Last Name		Relationship to Participant	
Street / P.O Box		City	State	Zip/Country	
*PHONE NUMBER (with Area Code) HOME / CELL / WORK:	Is it ok if we talk to people that answer this phone about your personal health information? *(if you do not check off either box, or you do not initial, your answer will be "No")*		☐ Yes ☐ No		*INITIALS:

Please contact us at 512-327-2017 or www.migrantclinician.org/network for more information on the MCN Health Network.

02-07

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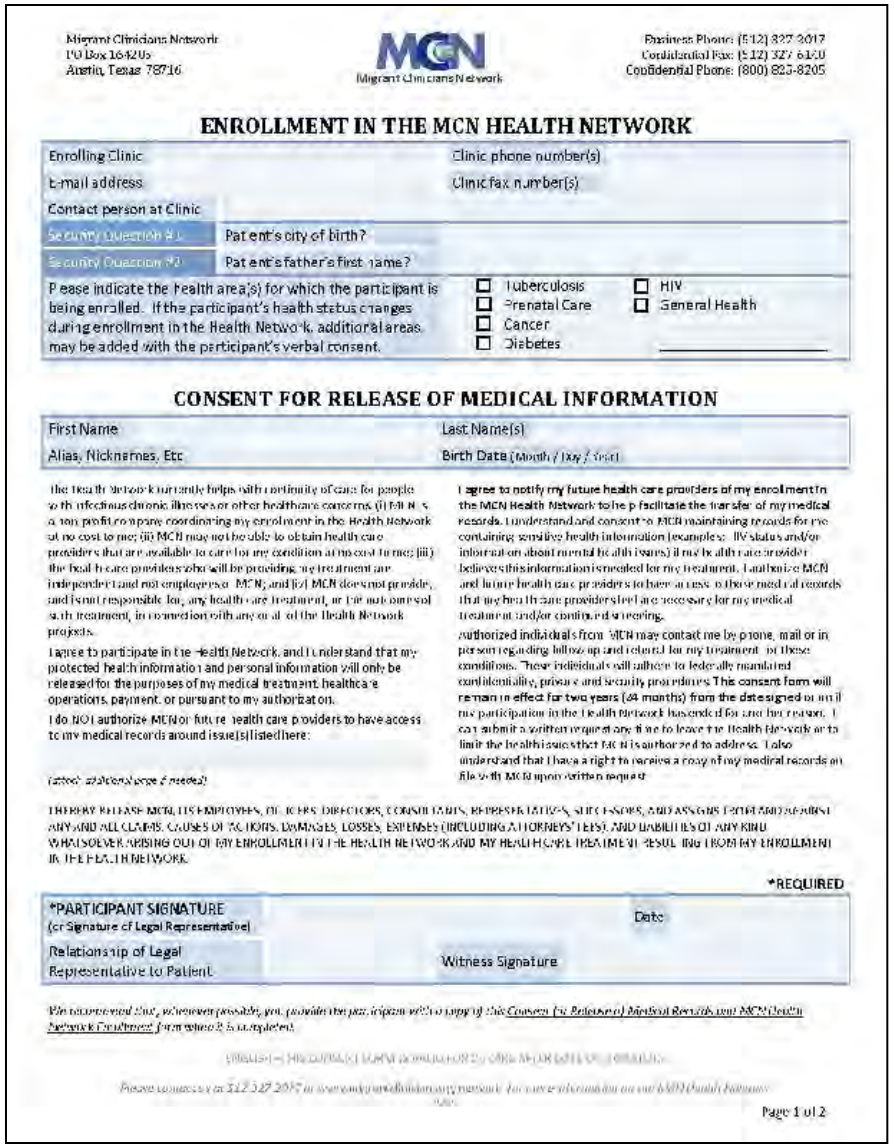
Consent Form

- Gives MCN staff legal permission to transfer participants' medical records and contact participants
- This form **must have** the participant's signature
- Valid if sent to HN staff within 5 business days of being signed by patient, and remains valid for 24 months from the date signed
- Participants may renew their consent after it expires if they still need assistance



Migrant Clinicians Network
PO Box 164205
Austin, Texas 78716

MCN
Migrant Clinicians Network

Business Phone: (512) 327-2017
Confidential Fax: (512) 327-6430
Confidential Phone: (800) 823-8205

ENROLLMENT IN THE MCN HEALTH NETWORK

Enrolling Clinic	Clinic phone number(s)
E-mail address	Clinic fax number(s)
Contact person at Clinic	
Security Question #1	Patient's city of birth?
Security Question #2	Patient's father's first name?

Please indicate the health area(s) for which the participant is being enrolled. If the participant's health status changes during enrollment in the Health Network, additional areas may be added with the participant's verbal consent.

☐ Tuberculosis ☐ HIV
☐ Prenatal Care ☐ General Health
☐ Cancer
☐ Diabetes
_____

CONSENT FOR RELEASE OF MEDICAL INFORMATION

First Name	Last Name(s)
Alias, Nicknames, Etc	Birth Date (Month / Day / Year)

The Health Network currently helps with continuity of care for people with infectious/chronic illnesses or other healthcare concerns. (i) MCN is a non-profit company coordinating my enrollment in the Health Network at no cost to me; (ii) MCN may not be able to obtain health care providers that are available to care for my condition at no cost to me; (iii) the health care providers who will be providing my treatment are independent and not employees of MCN; and (iv) MCN does not provide, and is not responsible for, any health care treatment, or the outcome of such treatment, in connection with any or all of the Health Network projects.

I agree to participate in the Health Network, and I understand that my protected health information and personal information will only be released for the purposes of my medical treatment, healthcare operations, payment, or pursuant to my authorization.

I do NOT authorize MCN or future health care providers to have access to my medical records around issue(s) listed here:

(attach additional pages if needed)

I agree to notify my future health care providers of my enrollment in the MCN Health Network to help facilitate the transfer of my medical records. I understand and consent to MCN maintaining records for me containing sensitive health information (examples: HIV status and/or information about mental health issues) it may be all I can provide believes this information is needed for my treatment. I authorize MCN and future health care providers to have access to these medical records that my health care providers feel are necessary for my medical treatment and/or continued screening.

Authorized individuals from MCN may contact me by phone, mail or in person regarding follow up and referral for my treatment for these conditions. These individuals will adhere to federally mandated confidentiality, privacy and security procedures. This consent form will remain in effect for two years (24 months) from the date signed or until my participation in the Health Network has ended for any other reason. I can submit a written request any time to leave the Health Network or to limit the health issues that MCN is authorized to address. I also understand that I have a right to receive a copy of my medical records on file with MCN upon written request.

I HEREBY RELEASE MCN, ITS EMPLOYEES, OFFICERS, DIRECTORS, CONSULTANTS, REPRESENTATIVES, SUCCESSORS, AND ASSIGNS FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTIONS, DAMAGES, LOSSES, EXPENSES (INCLUDING ATTORNEYS' FEES), AND LIABILITIES OF ANY KIND WHATSOEVER ARISING OUT OF MY ENROLLMENT IN THE HEALTH NETWORK AND MY HEALTHCARE TREATMENT RESULTING FROM MY ENROLLMENT IN THE HEALTH NETWORK.

*REQUIRED

*PARTICIPANT SIGNATURE (or Signature of Legal Representative)	Date
Relationship of Legal Representative to Patient	Witness Signature

We recommend that, whenever possible, you provide the participant with a copy of this Consent for Release of Medical Records and MCN Health Network Enrollment form when it is completed.

Please contact us at 512.327.2017 or www.mcn.org with additional questions, comments, or concerns about MCN Health Network.

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Health Network Enrollment Criteria

1

Patient is:

- Already mobile OR
- Likely to move

2

Patient has:

- In need of a clinic for follow-up of ANY health condition

3

Clinic Must:

- Complete Enrollment Registration
- Have patient sign Consent/Send
- Send Medical Records

Health Network Maintain a Patient in Care

- Contacts patients on a scheduled basis, TB patients monthly
- Contacts TB clinics monthly
- Assists patients in locating clinics for services and resources (transportation)
- Reports back to the enrolling clinic and notifies them of patient status and final outcomes

Maintaining a Patient in Care

The Patient's Role…

1. Provide HN with as many phone numbers as possible
2. Contact HN after arriving to new area
3. Stay on treatment until indicated
4. Inform HN of address / Phone changes

MCN Health Network

- An innovative approach for over 19 years (1996-2015)
- 8,221 total HN enrollments
  - 6,137 TB
  - 962 Diabetes
  - 421 Prenatal
  - 339 General Health
  - 275 Cancer
  - 87 HIV
- 2,951 total clinics in U.S. and over 91 countries

Nationality TBNet 2005-2013

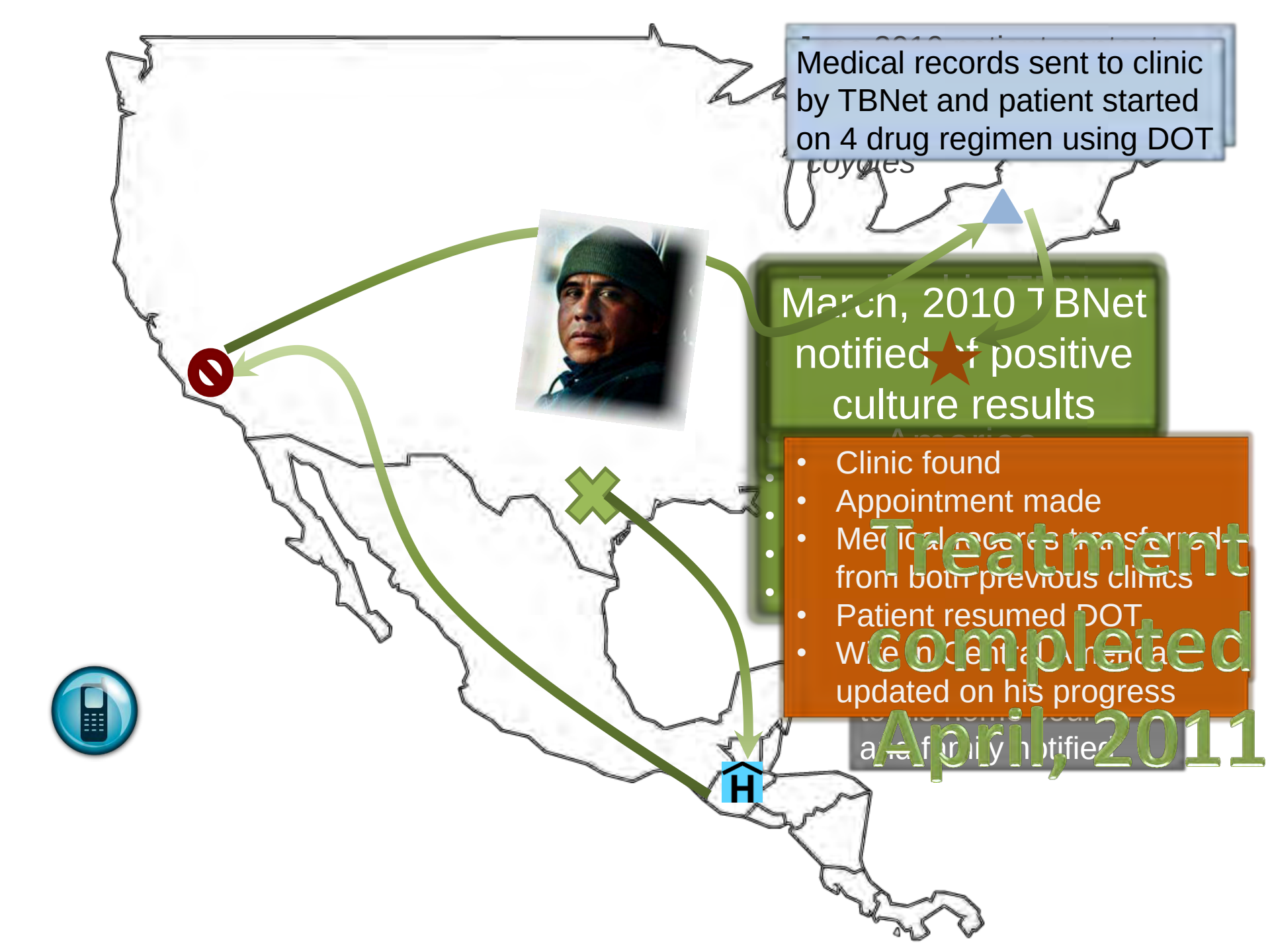
Country (91Total Countries)	Total Class 3 patients (1,512 total patients)	Percent of total patients
Honduras	446	29.5%
Mexico	318	21.0%
Guatemala	245	16.2%
El Salvador	143	9.5%
India	35	2.3%
China	30	1.9%
Peru	29	1.9%
Nicaragua	28	1.9%
Phillipines	26	1.7%
United States	23	1.5%
Ecuador	23	1.5%
Haiti	21	1.4%
Viet Nam	12	0.8%
Honduras; Mexico; Guatemala; El Salvador	**1,152**	**76.2%**

Class 3 Active TB:
TBNet Treatment Success (2005-2013)

(91 Total Countries)

- ✓ 1,512 Class 3 Active TB Cases Referred
  - – 37 not recommended by country
- ✓ 1,475 Treatment Recommended
  - – *24 deceased*
- ✓ 1,451 Followed by TBNet for Active TB
  - – *147 lost to follow up*
  - – *87 refused treatment*

1,217 Complete Treatment = 83.9%

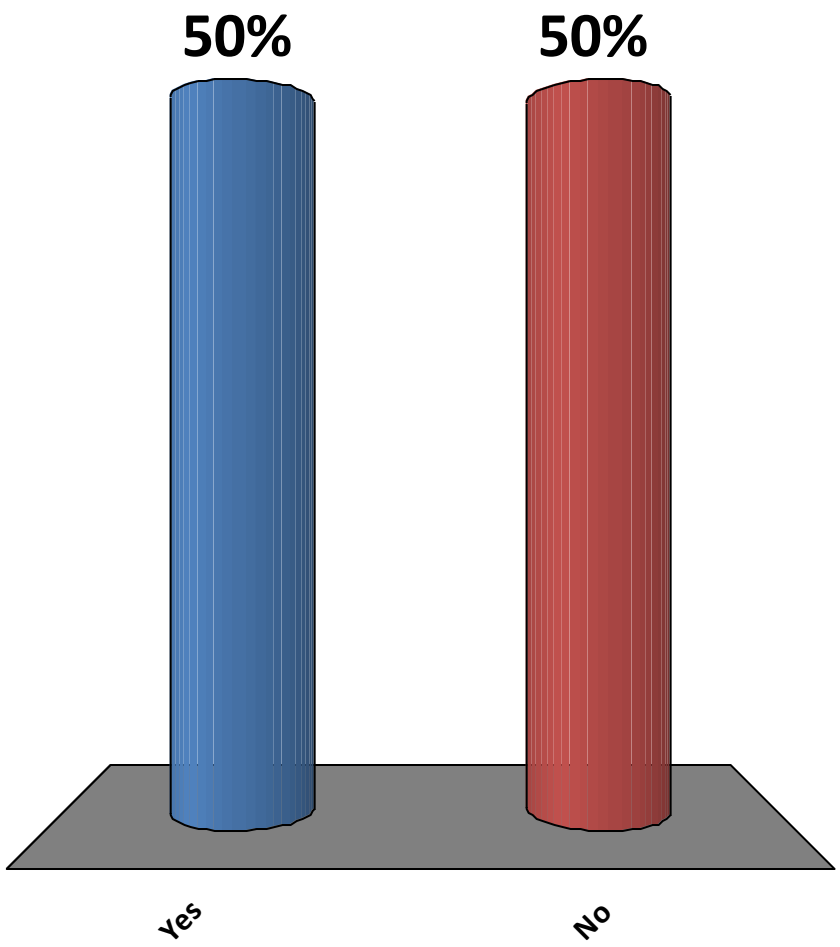

Medical records sent to clinic by TBNet and patient started on 4 drug regimen using DOT
March, 2010 TBNet notified of positive culture results
Clinic found
Appointment made
Medical records transferred from both previous clinics
Patient resumed DOT
updated on his progress
Treatment completed April, 2011

TBNet Successes

- Treatment equal to that among geographically stable populations
- Disease surveillance role
- Consistency between international protocols
- Policy recommendations – identify difficult to treat populations
- Model for management of other diseases in mobile populations

Is "cost-effective" the same thing as ”cost-saving"?

A. Yes
B. No



Quick Primer: CEA

- Way to value cost per health outcome
- Cost-effectiveness is not the same as cost-saving
- All things being equal, cost-saving > CE
- Combined with "quality adjusted life year" or QALY, it can be a useful way to compare health interventions across the health/public health spectrum
- WHO guidelines: 3x gross national income (GNI) per capita = CE, 1x or less = highly CE

Cost-effectiveness of bridge case management for tuberculosis infection treatment for mobile patients within the United States

Aims & Population

Aim 1: Modeled incremental health benefits of BCM

- TB cases averted
- QALYs saved

Aim 2: Determined the cost-effectiveness of the BCM, compared to the status quo (ICERs)

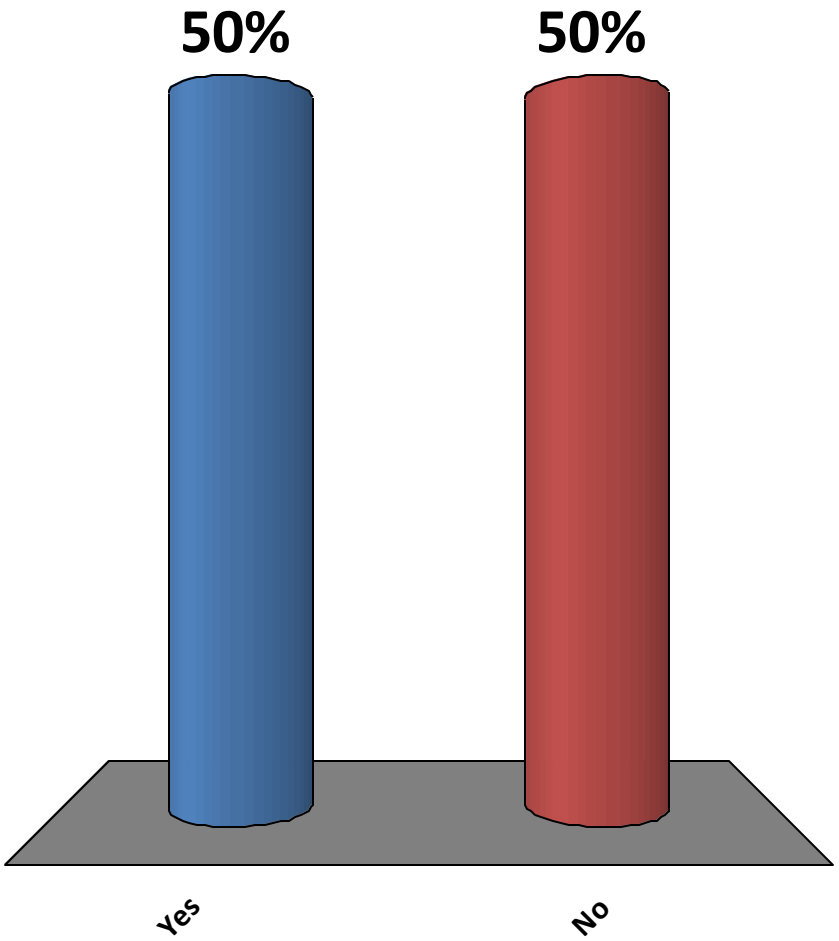
Population: 162 individuals referred for LTBI treatment with BCM, 2005-2012; counterfactual cohort calculated using the literature

Findings

- Incremental benefits of BCM cohort (n=162):
  - 2 TB cases averted and 2.7 QALYs saved
- Incremental costs of BCM:
  - $480 per unique client enrolled or about $97 per client per year
- BCM for LTBI patients highly cost-effective
  - $28,662 per QALY gained; $39,629/averted case (1x GNI per capita = highly cost-effective, i.e., $50,120)
  - Sensitivity analyses: $33,009 (CI: $6,625-$90,056) per QALY saved; $45,678 (95% CI: $9,160-$124,514) per TB case averted

Would a system like the one just described work for your patient population?

A. Yes
B. No
C. A subgroup of my patients



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