

3HP Evaluation & Implementation Under a Programmatic Setting in New Mexico

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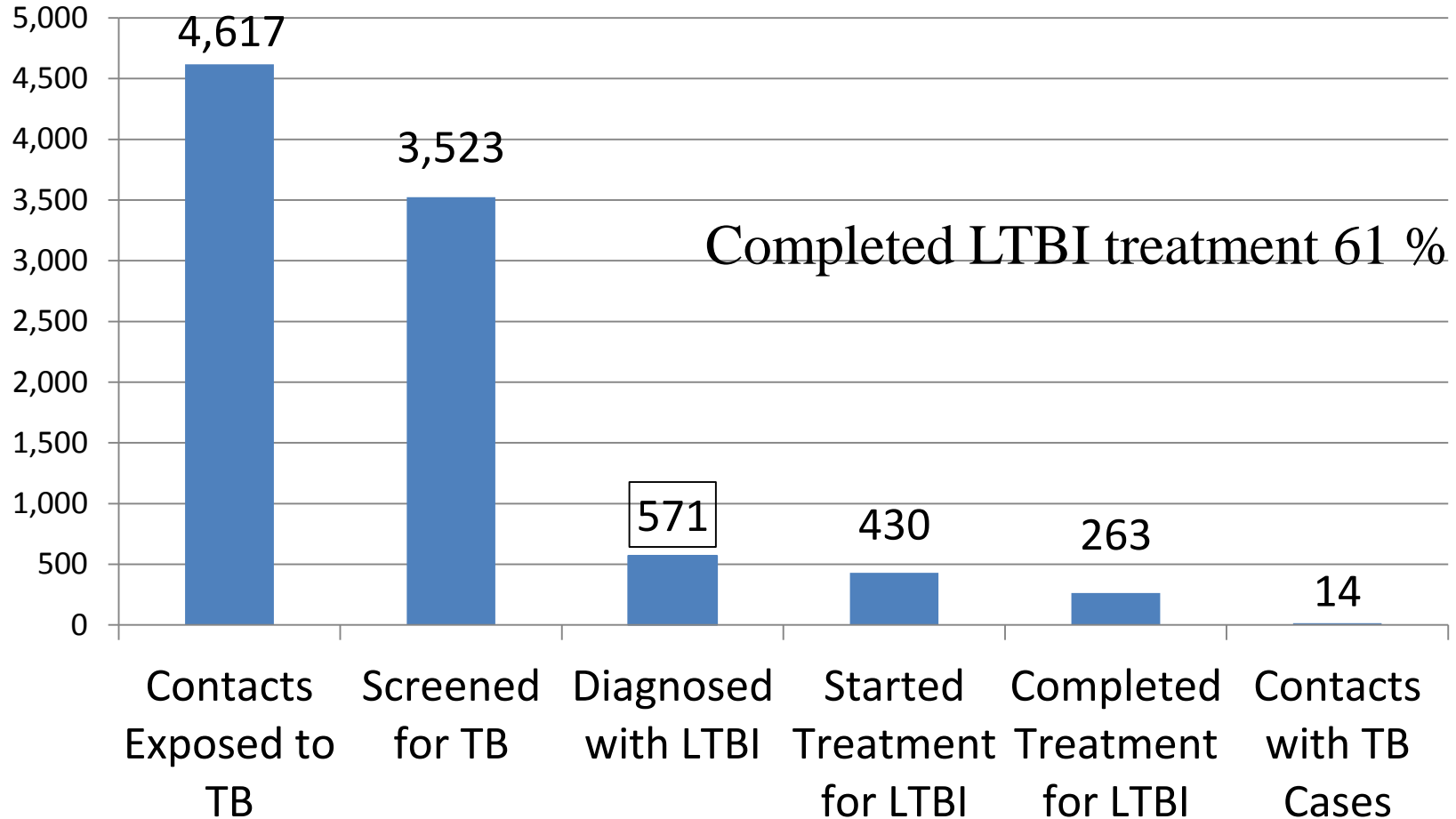
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Treatment Regimens for Latent TB Infection

Drug(s)	Duration	Interval
Isoniazid	9 months	Daily
		Twice weekly
	6 months	Daily
		Twice weekly
Isoniazid & Rifapentine	3 months	Once weekly
Rifampin	4 months	Daily

TB infection & treatment

Among Contacts to Smear Positive TB Cases: NM, 2004-2011



Reasons for Not Completing LTBI among contacts: New Mexico, 2004-2011

Risk factors	Percent
Lost to follow up/ moved	47%
Side effects	6%
Non adherence/ refused further treatment	37%
Other	10%

Prevent TB study 26

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Three Months of Rifapentine and Isoniazid for Latent Tuberculosis Infection

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3HP vs. 9 month INH

Outcome	9H N=3,745	3HP N=3,986	P-value
Treatment completion	2,585 (69.0%)	3,362 (82.0%)	< 0.0001
Permanent drug d/c- any reason	1,160 (31.0%)	624 (18.0%)	< 0.0001
Permanent drug d/c- due to an adverse event	135 (3.6%)	188 (4.7%)	0.004
Death	39 (1.0%)	31 (0.8%)	0.22

Study objectives

- Assess the use of 3HP in a programmatic setting
- Determine 3HP treatment completion rates
- Evaluate rate of side effects
 - Serious side effects
 - Side effects that resulted in discontinuation of treatment

Method

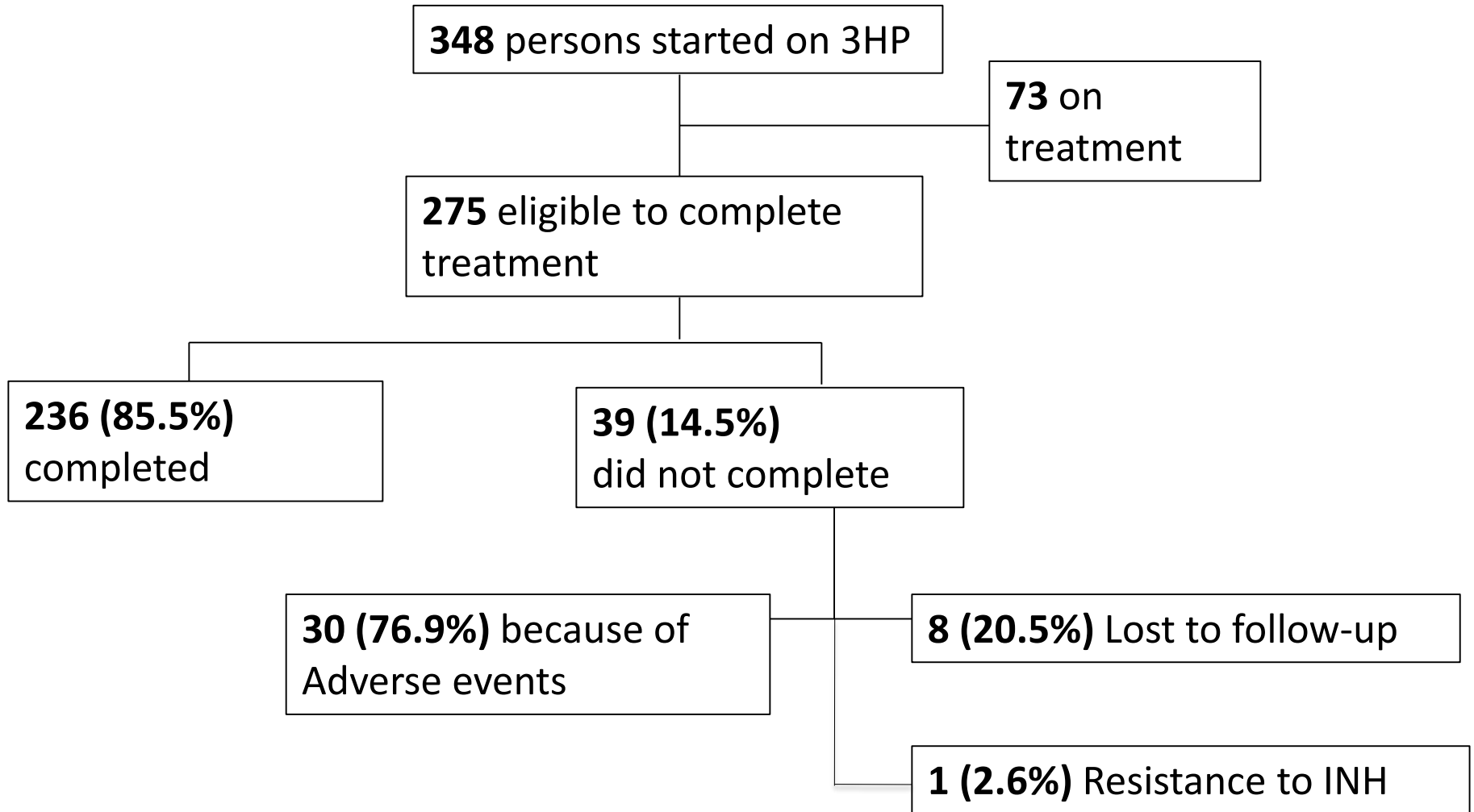
- Observational cohort study of LTBI treatment with 3HP as a public health activity
- Testing and treatment protocols were carry out by NM DOH nurses
- Clearance and review of cases before initiation of treatment was done by TB physicians
- Data was collected from electronic medical records and DOH forms
- Completion of therapy 11 of 12 doses

Enrollment

- Dates of enrollment: 3/16/2012 to present
- Inclusion criteria
 - Age > 12 year old
 - HIV positive not on HAART
 - LTBI identified by;
 - contacts to TB cases
 - refugees, foreign born
 - referrals from HCP, Rheumatologists, Dialysis Centers, Immigration, Occupational Health, other
- Exclusion criteria
 - HIV positive on HAART
 - Pregnant women
 - Major drug interaction to isoniazid and rifamycins

Results

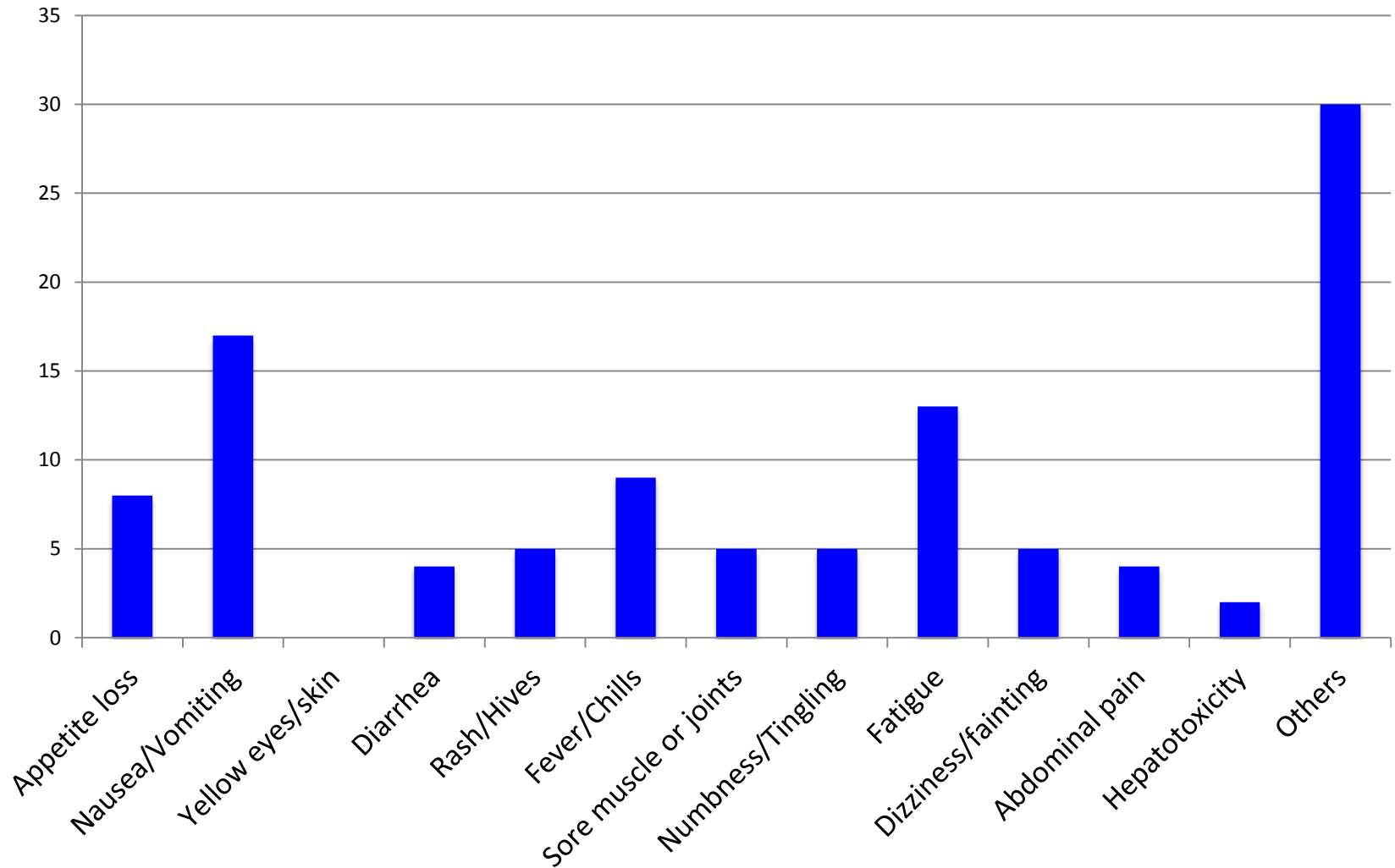
Enrollment



3HP regimen for LTBI in NM

- Completion rate : 85.8% (236/275)
- Non-completion rate: 14.2% (39/275)
- Reason for non-completion:
 - adverse effects : 76.9% (30/39)
 - lost to follow-up : 20.5% (8/39)
 - resistance to INH : 2.6% (1/39)

Patients that reported any symptoms at any time during treatment*

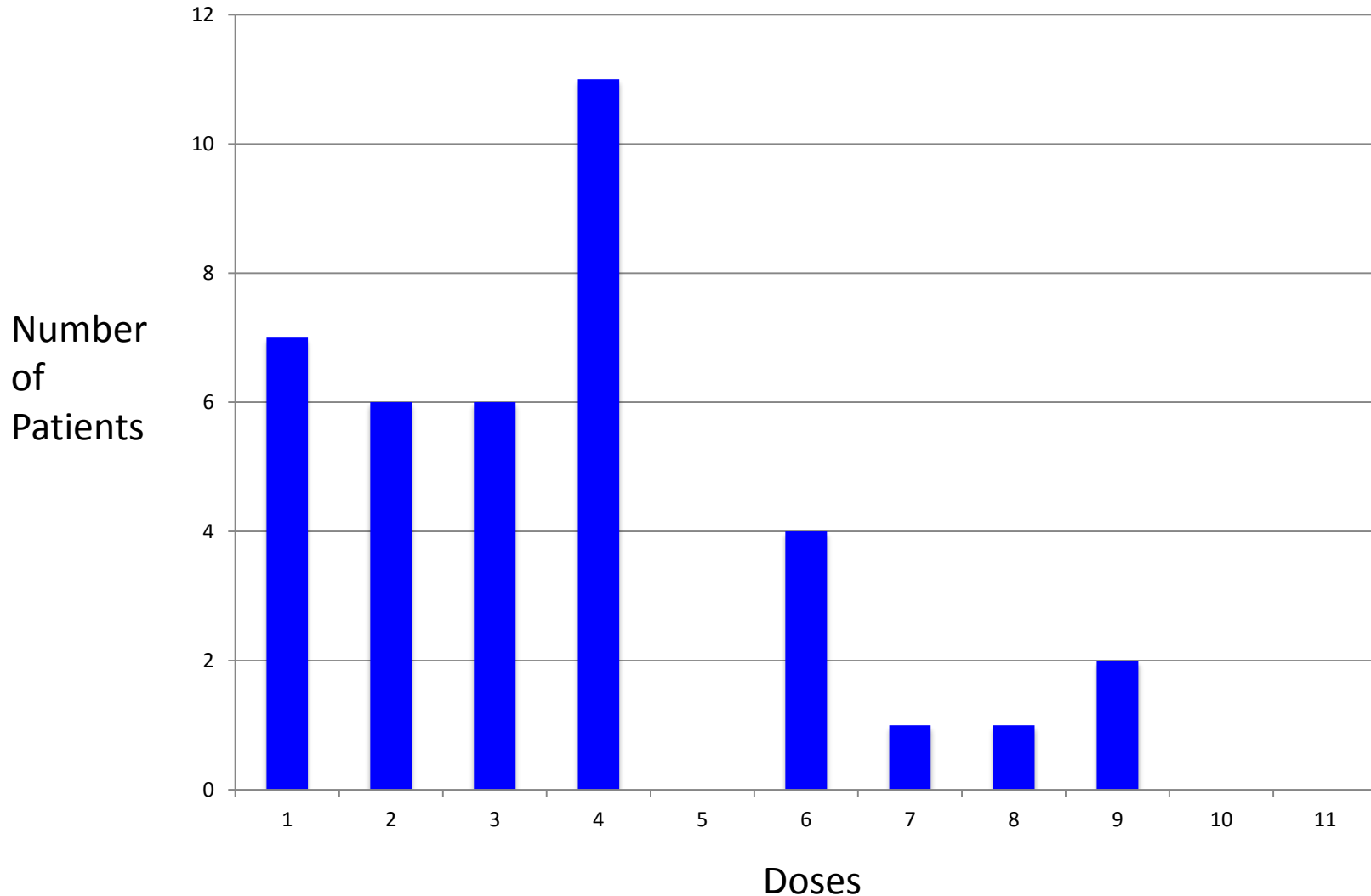


*Patients could report more than one symptom

Other symptoms reported

- 5 instances of headache
- 3 instances of weight loss
- 2 instances of persistent cough
- The following instances were reported in 2 or less events
 - joint pain, muscle aches, chest pain, hypotension, night sweats, leukopenia, dark urine, swollen mouth, swollen

Number of doses associated with discontinuation of 3HP in NM



Patient Completion Rates by Risk Factors

Risk factors for Treatment	Eligible to complete	Completed (%)	Discontinued With symptoms (%)
Contact	76	65 (85.5)	11 (14.5)
Rheumatologic disease	53	46 (86.8)	7 (13.2)
HD/Transplantation	12	9 (75.0)	3 (25.0)
Foreign born	105	91 (86.7)	14 (13.3)
HCW	22	17 (77.3)	5 (22.7)
Refugee	15	13 (86.7)	2 (13.3)
Other	13	12 (92.3)	1 (7.7)

* Patients could have more than one risk factor for treatment

Historical NM 9 months of INH vs. 3HP NM Study

	Cohort 9 mo INH	%	3HP NM Study	%	
Completion rate	263/430	61.2	236/275	85.5	P<0.001

Conclusion

- Treatment completion significantly higher with 3HP than historical LTBI treatment cohort with daily INH
- Similar completion rates of 3HP treatment as Prevent TB study 26
- The percentage of patients that stopped 3HP due to AE was higher than in the Prevent TB study 26
- There were no serious AE
- Most adverse events occurred within the first 4 doses

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Patients with hepatotoxicity

Pt	Age	Gender	Race	PMH	Meds	Outcome
1	84	M	W, Hispanic	RA, HTN, HLD	Lovastatin Terazosin Metoprolol Famotidine	Symptomatic (Dark urine, pruritis w/ rash)
2	28	F	W, non-Hispanic	No significant PMH	None	Symptomatic (nausea/vomiting, appetite loss, chills)

Patients with hepatotoxicity

Pt 1	AST	ALT	ALP	T. bil
Baseline	64	65	103	0.9
After the doses	58	66	89	0.7

Pt 2	AST	ALT	ALP	T. bil
Baseline	20	25	63	0.5
After the doses	37	120	129	1.0

LTBI Detection and Treatment of Contacts to Sputum AFB + Pulmonary Cases: New Mexico 2004-2011

- Contacts evaluation & outcomes

Outcomes	N. (%)
Contracts exposed to an infectious TB case	4617
Contacts evaluated	3523 (76%)
Diagnosed with LTBI	571 (16%)
Started Treatment	430 (75%)
Completed Treatment	263 (61%)

- Reasons for not completing treatment

Risk factors	Percent
Lost to follow up/ moved	47%
Side effects	6%
Non adherence/ refused further treatment	37%
Other	10%