

# A prospective study into the impact of Xpert MTB/RIF on the management of tuberculosis in a low-resource high-burden Indian setting.

## Introduction

- Xpert MTB/RIF is more sensitive than conventional smear microscopy for the diagnosis of tuberculosis.
- It is also more expensive, costing approximately 20 USD, as compared to just 0.15 USD per smear examination.
- In low-resource settings Xpert MTB/RIF use must be directed in the manner that will have the greatest impact on patient care.
- We set out to evaluate the impact of Xpert MTB/RIF on patient-management in our high-burden Indian setting where empirical TB treatment is commonplace.

## Method

- Between February-July 2017 clinicians completed one questionnaire at the time of an Xpert MTB/RIF request and another when reviewing the result.
- Form 1 concerned pre-test treatment status and clinician confidence in the diagnosis.
- Form 2 concerned post-result management.

## Results

- 45.9% of patients were on TB treatment empirically.
- Of 100 Xpert MTB/RIFs analysed, 60(60%) were positive for MTB.
- 17/55 (30.9%) of positive Xpert MTB/RIF results led to TB treatment being initiated in a patient not already on so empirically.
- Following a positive MTB result, all 17 patients not on treatment started and all 38 on so already continued.
- Following a negative MTB result, most patients not yet on treatment remained so (26/27 – 96.3%) but few already on treatment stopped (2/12 – 16.7%).
- Even where the clinician's pre-test confidence in TB was low, 9/30(30%) of Xpert MTB/RIF results were positive.

“If positive Xpert MTB/RIF results merely confirm TB in those already on Treatment empirically, and negative results are not relied upon to cease treatment then is it a cost-effective intervention?”



**Table 2. Xpert MTB/RIF result by sample type, prior-treatment status and pre-test confidence in diagnosis of MTB**

	Total, n (%)	MTB Not Detected n (%)		MTB Detected n (%)		rpoB mutation(s) n (%)		
		Included	No Form 1	Included	No Form 1	Included	No Form 1	
<b>All</b>	100	85	40 (40)	50 (58.8)	60 (60)	35 (41.2)	3/60 (5.0)	5/35 (14.3)
<b>Sample</b>								
Pulmonary	76 (76)	34 (40)	26 (34.2)	13 (38.2)	50 (65.8)	21 (61.8)	2/50 (4.0)	2/21 (9.5)
Extra-pulmonary	22 (22)	51 (60)	14 (63.6)	37 (72.5)	8 (36.4)	14 (27.5)	1/8 (12.5)	3/14 (21.4)
Unclear	2 (2)	0						
<b>Treatment</b>								
Previously treated	14 (14)	17 (20)	8 (57.1)	10 (58.8)	6 (42.9)	7 (41.2)	0/6 (0)	2/7 (28.6)
Treatment naive	84 (84)	68 (80)	32 (38.1)	40 (58.8)	52 (61.9)	28 (41.2)	3/52 (5.8)	3/28 (10.7)
Unclear	2 (2)	0 (0)						
<b>Pre-test Confidence All (n=100)</b>								
Almost certain	41 (41)		34 (82.9)		5 (12.2)			
Confident	19 (19)		12 (63.2)		7 (36.8)			Correlation* 0.47 (p<0.001)
Not confident	30 (30)		10 (33.3)		20 (66.7)			
Unsure/blank	10 (10)							
<b>Pre-test Confidence Post positive smear excluded (n=74)</b>								
Almost certain	17 (23.0)		14 (82.4)		3 (17.6)			
Confident	17 (23.0)		10 (58.8)		7 (41.2)			Correlation 0.44 (p<0.001)
Not confident	30 (40.5)		9 (30)		21 (70)			
Unsure/blank	10 (13.5)							

\*Spearman Rank correlation of pre-test confidence to MTB Detected where confidence converted to ordinal scale 'Not Confident' = 1, 'Confident' = 2 and 'Almost certain' = 3.

**Table 3. Xpert MTB/RIF result impact on treatment status, All (n=94)**

Treatment pre-result?	MTB Detected (n=55)		MTB Not Detected (n=39)	
	Treatment post-result?		Treatment post-result?	
	Yes	No	Yes	No
Yes	38	0	10	2
No	17	0	1	26

Figure 1. Exclusion flow diagram

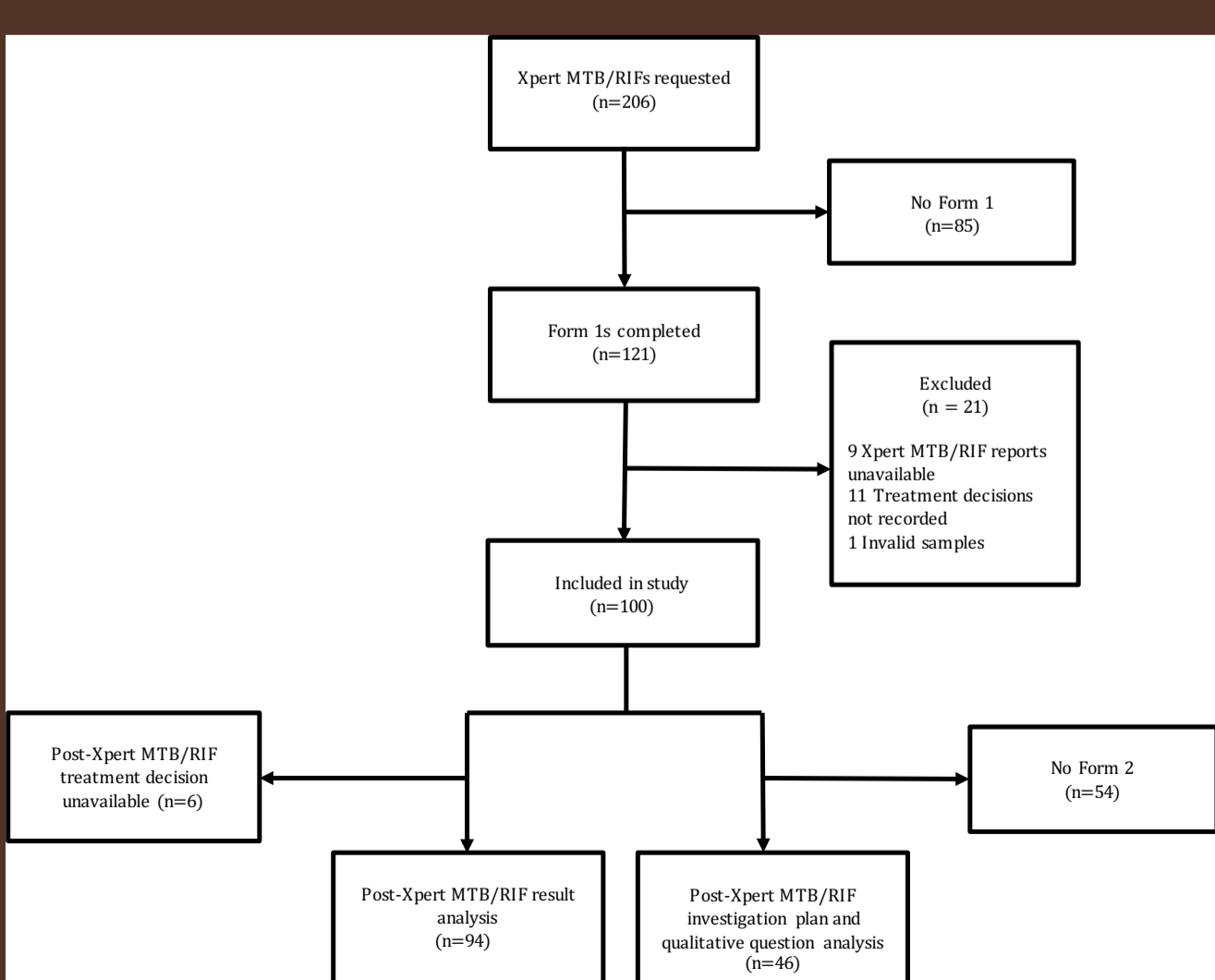
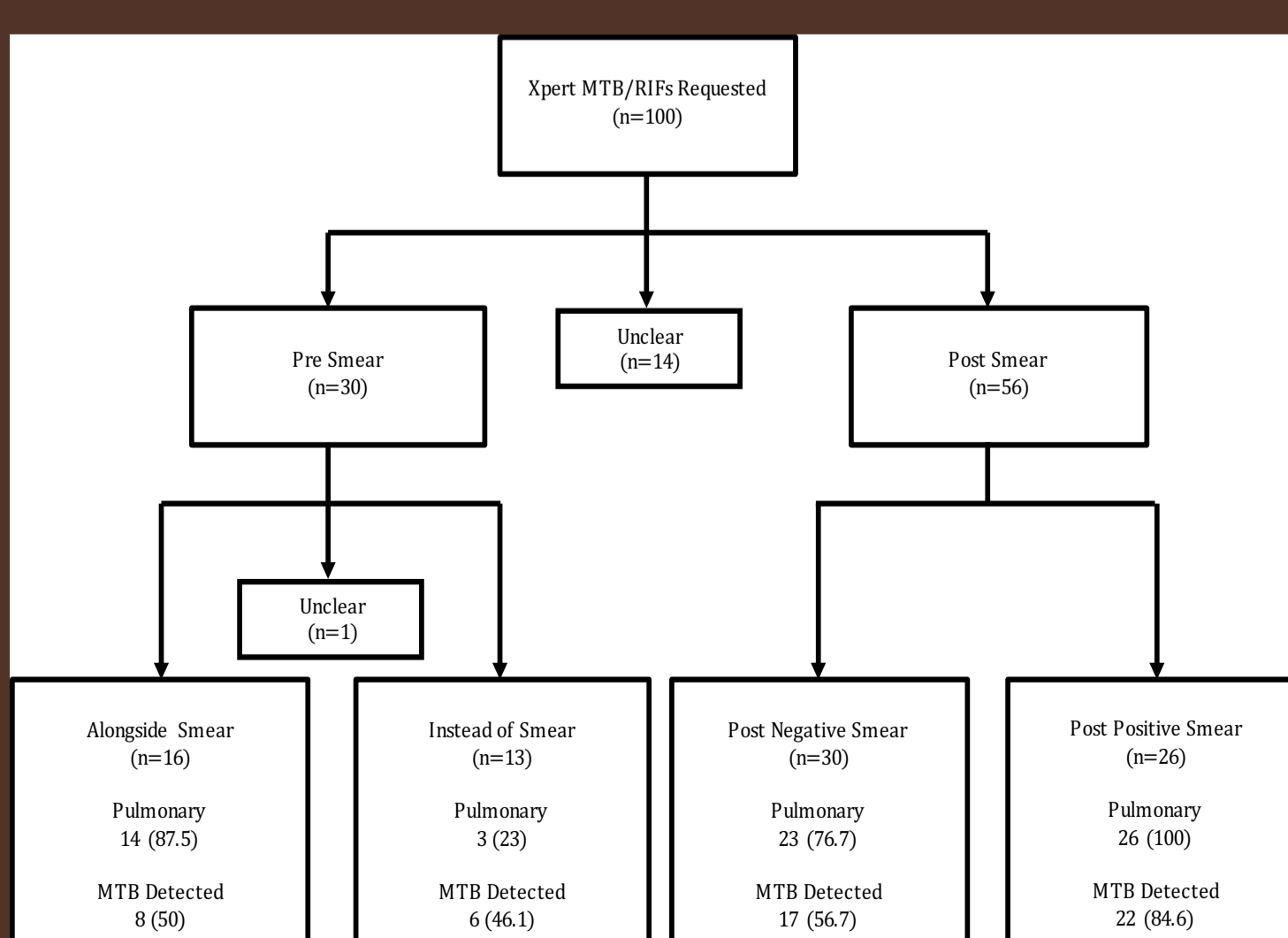


Figure 2. Result by relation to smear



## Conclusions

- Despite empirical treatment being common, a substantial proportion of Xpert MTB/RIF results prompted treatment initiation.
- Negative results rarely prompted treatment cessation.
- Assuming drug resistance is not a concern, Xpert MTB/RIF may have the greatest impact where the clinician's pre-test confidence in TB is lower such that empirical treatment is not being considered.
- This means positive results will lead to appropriate initiation of treatment and negative results are more likely to be relied upon to hold-off treatment.