

Table 3: Treatment Outcomes Assessed in Clinical Trials Designed to Estimate Xpert Impact on Patient Outcomes

Study, author, date	LTFU before TB treatment among Microbiologically-Confirmed TB Patients			TB Treatment Outcomes				LTFU and Mortality among all Study Enrollees				Mortality predictors
	Micro	Xpert	p	Outcome	Micro	Xpert	p	Outcome	Micro	Xpert	p	
TB-NEAT ⁹	15%	8%	0.03	LTFU	32%	29%	0.55	3m Mortality	8%	8%	0.71	Multivariable analysis: - HIV-positive vs. HIV-negative - Lower baseline TB score.
				2m TB score ^a	2	2	0.85					
				2m KPS ^a	80	90	0.23					
XTEND ^{10,20,29}	14.9% ^b	17% ^b	0.91	Composite ^c	12.5%	11.7%	0.8	6m Mortality	5.0%	3.9%	0.43	Multivariable analysis: - Known HIV-positive and not on ART vs. HIV-negative - Not knowing HIV status vs. HIV-negative - BMI <18.5 vs. 18.5-24.9 - Age <30 vs. ≥50 years - Higher number of TB symptoms
Brazil Stepped Wedge ^{11,21}	NA	NA	NA	Composite ^d	31.7%	29.6%	NS ^e	NA	NA	NA	NA	Multivariable analysis (predictors of unfavorable TB treatment outcome): - Male sex - HIV positive vs. HIV-negative - HIV unknown vs. HIV-negative - Rio vs. Manaus
				LTFU	16.2%	15.9%	NS ^f					
				TB-mortality	3.8%	2.3%	SS^g					
Zimbabwe RCT ¹⁴	NA	NA	NA	NA	NA	NA	NA	6m Mortality	10%	6%	0.19	Multivariable analysis: - Male sex - Low CD4 count (<100) vs. >100 - TB diagnosed at enrollment before ART start.
								6m LTFU	18%	15%	0.38	
								6m TB incidence	4%	3%	0.92	
								6m Death or TB	12%	9%	0.39	
South Africa Single Clinic CRT ¹²	NA	NA	NA	Composite ^h	12.5%	12.7%	0.750	6m Mortality	3.8%	3.4%	0.52	NA
Uganda Pre-post Trial ¹³	NA	NA	NA	2m Mortality	17%	14%	0.80	2m Mortality	17%	17%	0.96	NA
								2m LTFU	10%	2%	<0.001	
SA ICU RCT ¹⁵	NA	NA	NA	NA	NA	NA	NA	1m Mortality	34%	27%	0.26	Mortality predictors among all ICU enrollees (N=341), not just those randomized: - Age 24-39 vs. <24 years - HIV-positive and ART unknown vs. HIV-positive not on ART. - Inotrope use - APACHE-II score >25 vs. <20.
								3m Mortality	42%	32%	0.15	
Indonesia Pre-post trial ¹⁶	52.4% ⁱ	31.0% ⁱ	<0.001 ¹	NA	NA	NA	NA	NA	NA	NA	NA	NA

Abbreviations: TB, tuberculosis; LTFU, loss to follow-up; KPS, Karnofsky Performance Score; NA, not available; BMI, body mass index; NS, not statistically significant; SS, statistically significant on the basis of an odds ratio with 95% confidence interval excluding 1 (p-value not provided); m, month; ART, antiretroviral treatment; ICU, intensive care unit; OR, odds ratio; CI, confidence interval; SA, South Africa

^a Both median TB score (2 vs. 2, p=0.85), and median Karnofsky Performance Score (KPS) (80 vs. 90, p=0.23) in culture-positive patients, who had started TB treatment, did not differ at 2 months post randomization, or at 6 months.

^b In XTEND, the percentages reported here represent those not starting TB treatment by 28 days after bacteriological TB confirmation.

^c Composite poor outcome was death, LTFU, and treatment failure.

^d Composite poor outcome was incidence of LTFU, TB-attributable death, other deaths, change of diagnosis, transfer out, or resistance.

^e P-value was not provided. Instead, the 95% confidence interval was provided and included 1: 29.6% versus 31.7%, OR=0.93; 95% CI=0.79-1.08

^f P-value was not provided. In the text, the paper states "loss to follow-up was not changed by the intervention (16.2% vs. 15.9%)".

^g No p-value was provided. The text states that "Adjusted for HIV status, age group and city, the intervention resulted in a 35% decrease in TB-attributed deaths (OR=0.65, 95%CI=0.44-0.97)"

^h Composite poor outcome was LTFU, death, or TB treatment failure.

¹ The percentage of rifampicin resistant (RR) TB patients with missing information on RR treatment initiation declined from 52.4% in the baseline phase to 31.0% in the Xpert phase, p<0.001. No differences in the percentage of enrollees documented to be LTFU before RR treatment (0.9% pre- vs. 2.3% post-Xpert, p=0.30), or documented to be dead before RR treatment (2.4% pre- vs. 1.0% post-Xpert, p=0.50) were noted.