

Annex 1: Standard tool to perform the clinical survey

1 per patient

Part I		Result/comment
General Information	Name of the Unit audited	
	Location	
	Country	
Country information	Notified incidence (overall x 100.000)	
	Notified incidence (SS+ x 100.000)	
	Notified number of MDR	
	Notified number of XDR	
	Estimated number of MDR	
	Estimated number of XDR	
Department Administrative Information	Kind of Department	
	Overall number of beds	
	Number of TB beds	
	Total number of TB cases admitted in 2008	
	How many cases from OPD?	
	How many cases referred from External Health Units?	
	Total number of MDR cases admitted in 2008	
	Total number of XDR cases admitted in 2008	
	Total number of TB/HIV cases admitted in 2008	
	Average proportion (%) of bed used (average n. of patients day/ average n. of beds day)	
	Total number of physicians in 2008	
	Total number of nurses in 2008	
	Total number of rooms	
	Total number of rooms with 1 bed	
	Total number of rooms with 2 beds	
Total number of rooms with ≥ 3 beds		
Department Infection Control information	Negative pressure ventilation available	
	Negative pressure ventilation available (specify details)	
	Are ACH (Air Changes per Hour) measured?	
	Are infection control administrative measures in place?	
	Describe which administrative infection control measures are in place	
	Are patients wearing surgical masks?	
	Are staff wearing FP2 respirators?	
	Are visitors wearing FP2 respirators?	
	Did staff undergo respirator fit testing?	
	Was an infection control training organized for all staff?	
	When was an infection control training organized for all staff?	
	Is an infection control committee in place?	
	How many staff had TB in the last 10 years?	
	How many staff had MDR in the last 10 years?	
	Number of Respiratory isolation room	
	Total number of single rooms	
	Total number of double rooms	
Laboratory information	How many SS are managed in one year? (2008)	
	How many SS are positive in one year? (2008)	

	How many Cultures are positive in one year? (2008)	
	How many DST are done in one year? (2008)	
	How many DST are pan-susceptible in one year? (2008)	
	How many DST are mono-resistant in one year? (2008)	
	How many DST are poly-resistant in one year? (2008)	
	How many DST are MDR in one year? (2008)	
	How many DST are XDR in one year? (2008)	
	Is the laboratory:	
	Is an external Quality Assurance (QA) in place?	
	QA Under NRL	
	(QA) Under WHO SRL	
	Location SRL	
	Culture methods	
	Type of liquid technology	
	NAAT	
	NAAT methodology	
	NAAT frequency	

1 per patient

Part 2		Result/ comment
Identification	Institution patient number	
	Date of admission in the hospital	
	Case definition	
Current TB diagnosis	Date of current TB diagnosis	
	Date of current MDR/XDR-TB diagnosis	
	Duration of symptoms till diagnosis	
	Type of pulmonary TB	
	Extra-pulmonary TB	
	Microscopy material examined	
	Result microscopy: neg or # positive	
	Culture material examined	
	Result culture: Neg /N. of days (lower of 3) liquid/ N. of colonies (higher of 3) solid	
	Chest X-ray result:	
	Bronchoscopy	
	CT scan	
	NAAT	
	Mantoux done	
	Mantoux type (RT23, other specify)	
	Mantoux dose (5IU, other specify)	
	Mantoux reading method (induration mm, average 2 diameters; other specify)	
	Result of the Mantoux	
	IGRAs done	
	IGRA type(ELISPOT, Quantiferon, Quantiferon GOLD, other specify)	
	IGRAs result	
	Other examination/s	
	Describe other examination/s	
	Isolation room (days)	
Surgical mask adopted by the patient		
Respirator adopted by the patient		
Patient characteristics and medical history	Date of birth	
	Gender	
	Country of birth	
	Country of residence	
	Province of residence	
	Year of entry in the country	
	Employment status	
	Homeless	
	IV drug user	
	Current smoker	
	Ex-smoker	
	Pack/yr: cigarettes/day x years	
	Current alcohol abuser	
	EX-alcohol abuser	
	Alcohol/day x time	
Incarcerated		

	Known contact of a TB case	
	Resistance status contact	
	Resistance status contact, if yes specify DST	
	BCG vaccinated	
Previous history of TB	Previous diagnosis of TB	
	Previous DST results (in case of multiple ones, specify)	
	Previous result of Tuberculin Skin Testing	
	Previous result of IGRA	
	Previous Chest X-ray result	
	Treatment following previous diagnosis (regimen)	
	N. of previous anti-TB treatment > 1 month	
	N. of months between last treatment > 1 and current diagnosis	
	Treatment outcome of last TB treatment before current diagnosis	
	Previous pulmonary surgery	
	Drug resistance	Current DST (N° resistance detected)
Date of DST result 1° line available:		
Date of DST result 2° line available		
At current diagnosis resistant to isoniazid		
At current diagnosis resistant to rifampicin		
At current diagnosis resistant to ethambutol		
At current diagnosis resistant to streptomycin		
At current diagnosis resistant to pyrazinamide		
At current diagnosis resistant to ethionamide /prothionamide		
At current diagnosis resistant to kanamycin		
At current diagnosis resistant to cycloserine		
At current diagnosis resistant to capreomycin		
At current diagnosis resistant to PAS		
At current diagnosis resistant to amikacin		
At current diagnosis resistant to rifabutin		
At current diagnosis resistant to ciprofloxacin		
At current diagnosis resistant to moxifloxacin		
At current diagnosis resistant to ofloxacin		
At current diagnosis resistant to levofloxacin		
At current diagnosis resistant to linezolid		
At current diagnosis resistant to clarithromycin		
At current diagnosis resistant to amoxi/clavulanate		
	At current diagnosis resistant to Clofazimine	
	At current diagnosis resistant to azithromycin	
Comorbidities	HIV test offered	
	HIV test performed	
	HIV status at current diagnosis	
	CD4-cell count at current diagnosis	
	Plasma HIV-RNA at current diagnosis	
	Diabetes	
	Silicosis	
	Chronic hepatitis B	
Chronic hepatitis C		
	Others: specify	
Hospital stay (total n. of	Hospital stay	

days)	Total n. of days in hospital	
Prescribed drugs	Anti-TB regimen	
	Adverse events of anti-TB drugs	
	Adverse events of anti-TB drugs: specify which drug	
	Notes on treatment	
	Body weight at admission (kg)	
	Isoniazid, dose prescribed in mg	
	Rifampicin, dose prescribed in mg	
	Ethambutol, dose prescribed in mg	
	Streptomycin, dose prescribed in mg	
	Pyrazinamide, dose prescribed in mg	
	Ethionamide /Prothionamide, dose prescribed in mg	
	Kanamycin, dose prescribed in mg	
	Cycloserine, dose prescribed in mg	
	Capreomycin, dose prescribed in mg	
	PAS, dose prescribed in mg	
	Amikacin, dose prescribed in mg	
	Rifabutin, dose prescribed in mg	
	Ciprofloxacin, dose prescribed in mg	
	Moxifloxacin, dose prescribed in mg	
	Ofloxacin, dose prescribed in mg	
	Levofloxacin, dose prescribed in mg	
	Linezolid, dose prescribed in mg	
	Clofazimine, dose prescribed in mg	
	Meropenem, dose prescribed in mg	
	Imipenem, dose prescribed in mg	
	Amox/Clavul, dose prescribed in mg	
	Other...dose prescribed in mg	
	Describe any deviation form Standard dosages of anti-TB drugs	
	Anti-HIV regimen	
	Adverse events of anti-HIV drugs	
Dosages of anti-HIV drugs adequate		
Dosages of anti-HIV drugs adequate: specify which drug		
Pharmacokinetics performed for anti-TB drugs		
Pharmacokinetics performed for anti-HIV drugs		
Surgery at current diagnosis	Surgery at current diagnosis	
Treatment monitoring	Month 2 SS	
	Month 2 C	
	Month 5 SS	
	Month 5 C	
	Month 7 SS	
	Month 7 C	
	End SS	
	End C	
	If MDR, Laserson's criteria	
Outcome	Time to SS conversion (days from start treatment)	
	Time to culture conversion (days)	
	Final outcome (Laserson) : Ongoing	

Follow-up	Plan of follow-up in an out-patient setting	
	Notes	

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Part 3		Result/comment
	Institution patient number	
Medical history	Investigation previous TB diagnosis	
	Investigation previous DST	
	Investigation previous treatment	
	Investigation contacts	
Diagnosis	Diagnostic algorithm	
	Microbiology	
	Other examinations	
	Final decision	
Treatment	TB regimen choice (4 active drugs ensured)	
	Dosage	
	Duration	
	Management adverse events TB treatment	
	HIV regimen choice	
	Management adverse events HIV treatment	
Treatment monitoring	Necessary examinations performed	
Outcome	Correct outcome assigned	
Infection control	Administrative measures adequate	
	Environmental measures adequate	
	Infection control committee	
	Surveillance system for drug-resistance in the setting	
	Staff personal protective measures adequate	
	Cough etiquette	
	Availability of respirators	
	Training of the staff on infection control	
	Remarks	