

Drug Safety

Adverse drug reactions reported to a National HIV and Tuberculosis Health Care Worker Hotline in South Africa: description and prospective follow up of reports

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Electronic Supplementary Material 1. MIC Data Capture Forms: General queries and ADR follow-up.

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Name:		 Address/Facility:		Taken by:	Answer provided:	
 Tel:				Date:	1 Immediate	4 1 - 8 hrs
 Cell:					2 < 30 min	5 Next day
 Other:				Time:	3 30 min –1hr	6 2 - 5 days
Origin:	Region:	Profession:	Topic:	HIV/AIDS/TB Sub-Topics:		
1 Private Sector	01 W. Cape	01 GP/Specialist	01 ADR – other drugs	01 Adherence		
2 Public Sector	02 N. Cape	02 Pharmacist	02 Availability/Supply	02 ADR – ARV/TB drugs		
3 Groote Schuur	03 E. Cape	03 Intern/Student	03 Foreign Product ID	03 Dosage		
	04 Gauteng	04 Nurse	04 Tablet ID	04 Failure		
Contact method:	05 Mpumalanga	05 NIMART Nurse	05 Interaction	05 Initiating Therapy		
1 Telephone (default)	06 Limpopo	06 Medical Aid	06 HIV/AIDS/TB	06 Interactions		
2 E-mail	07 North West Prov	07 Industry	07 Lactation	07 IRIS		
3 SMS / PCM	08 Free State	08 Other HCW	08 Malaria	08 Lactation		
4 Other:	09 Kwazulu Natal	09 Lay Person	09 Medicolegal	09 Medicolegal		
	10 Other (outside	10 Wholesaler	10 Other	10 Ols other than TB		
Demographics of the patient			11 Pharmaceutical	11 Other		
*Age:	1 *Male	Y Pregnant	12 Pharmacokinetics	12 Paediatrics		
Weight:	2 *Female	Gestation wks:	13 Pharmacology/MOA	13 PEP		
Clinical Scenario/Problem statement			14 Poisoning	14 Pharmacology		
			15 Porphyria	15 PMTCT		
			16 Pregnancy	16 Poisoning/OD		
			17 Psychopharmacology	17 Porphyria		
			18 Therapy	18 Pregnancy		
				19 Resistance		
				20 Second-line Regimen		
				21 Switching Therapy		
				22 TB		
				23 TDF Renal ADR		
				24 TDM		
			Reference sources:			
			01 AHFS			
			02 Briggs			
			03 BNF			
			04 Drugdex			
			05 Consultant			
			06 Industry			
			07 Internet:			
			08 Journal			
			09 Martindale			
			10 Medline			
			11 Meyler's SE			
			12 MIMS			
			13 NDOH guidelines			
			14 Package insert			
			15 SAMF			
			16 Stockley			
			17 Other:			
Question:						
			Y Clinical HIV Query			
Answer:			Reply			
			1 Oral – telephonic			
			2 Email / Fax			
			3 Literature supplied			
			Answer by		Peer reviewer	
			Date		Time	

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HIV & CURRENT REGIMEN DETAILS:						
*Status 1 Negative 2 Positive 3 Unknown	Regimen 1 FDC (TDF+3TC/FTC+EFV) 6 AZT+3TC+LPV/r 4 ABC+3TC+EFV 5 ABC+3TC+LPV/r	Individual drugs (other regimens): 01 ABC 02 ATV 03 AZT 04 d4T 05 EFV 06 FTC 07 LPV/r 08 NVP 09 TDF 10 3TC 11 Other:	On co-trimoxazole? 1 Yes → 2 No 3 Unknown	Date started:		
Treatment status 1 HAART (default) 2 PMTCT 3 PEP 4 Not on ARVs	Hepatitis B 1 Negative 2 Positive 3 Unknown		Disease markers CD4:	Date:		
			VL:			
			*Regimen start date:			

TB & CURRENT REGIMEN DETAILS:						
*Status 1 No TB 2 No TB – on prophylaxis 3 TB – on treatment 4 Unknown TB status	Diagnosed by: 1 Gene Xpert 2 AFB 3 Culture 4 Clinical 5 Unknown	Individual drugs (other regimens): 01 Amikacin 02 Capreomycin 03 Cycloserine 04 Ethambutol 05 Ethionamide 06 INH 07 Kanamycin 08 Levofloxacin 16 Other:	09 Moxifloxacin 10 Ofloxacin 11 PAS 12 PZA 13 RIF 14 Streptomycin 15 Terizidone			
Type of TB 1 P-TB 2 Extra P-TB 3 DR-TB 4 XDR-TB	Regimen 1 RHZE 2 RH 3 INH prop. 4 Not on TB meds					
# TB Episode:				*Treatment start date:		

SUSPECTED ADR DETAILS:						
*Short description of suspected ADR:				*Date of onset of AE:		
Known allergies/ Previous similar reactions?				*Suspect drug(s):		

DRUG HISTORY (PAST MONTH) NOT INDICATED ABOVE						
Drug & dose (& route if not per os)	Date of first dose		Date of last dose		*Indication	
INVESTIGATIONS:	Date:	Date:	Date:	Date:	Date:	Date:
Relevant Labs						

ADR MANAGEMENT & FOLLOW-UP:	
*Plan for management (select <u>all</u> that apply) 1 Continue drug 2 Stop drug 3 Decrease dose 4 Substitute with: 5 Rechallenge 6 Monitor: 7 Gave information 8 Other:	*Current status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:
We are following up on all patients with a suspected ADR. *When would be appropriate to follow-up?	Never
*Reference for the call-back (E.g. folder number if state hospital, age, sex and initials if private sector)	None

Query number		Date:
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	Actions taken 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	Patient's condition... 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown
		Needs to be called again Yes No

Query number		Date:
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	Actions taken 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	Patient's condition... 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown
		Needs to be called again Yes No