



Rapid Pharmacovigilance Implementation in Developing Countries

Assessing Pharmacovigilance (PV) Capacity in Public Health Programs

HIV/AIDS and ART Programs

Country: _____

Date : _____

I.	Respondent: Background Information	
	Name	
	Designation	
	Department, Ministry	
	Address	
	Email	
	Phone; Mobile; Fax	

II.	Country and Public Health Information	
	Country Population	
	Estimated number of HIV/AIDS cases in country	
	Estimated number of patients taking ARVs	
	Percent pediatric patients taking ARVs	

III.	HIV/AIDS Treatment Information				
	Drug name(s) (include generic names)	First Line		Second Line	
		Adults	Pediatrics	Adults	Pediatrics
	First option				
	Second option				
	Compliance: What is the estimated Drop Out Rates of the Patients: (if possible, distinguish between pediatric vs adult drop out rates)				



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<p>Number of ART centers in the country</p> <p>In Public sector</p> <p>In NGO sector</p> <p>In Private sector</p>			
<p>What is the estimated number of DAILY visits to the ART centers in:</p> <p>- Large and busy centers</p> <p>- Small and less busy centers</p>			
<p>What are the operating hours of the ART centers?</p> <p>- Which days of the week?</p> <p>- Typical hours of work each day?</p>			
<p>Human Resources for Treatment Delivery at ART centers:</p> <p>- How many staff is usually present in ART centers? (large vs. small ones)</p> <p>- What types of staff are operating the ART centers? (large vs. small ones) [Admin, IT, nurses, pharmacists, doctors, etc.]</p> <p>- Estimated percent of posts that is vacant</p>			
<p>- What is the estimated number and type of ARVs purchased by MoH in the past year?</p> <p>- What is the projected ARV procurement for current year?</p>	<p><i>Indicate ARV Name</i></p>	<p>Last year</p>	<p>Current year</p>
	<p>Adults:</p> <p>First line</p> <p>Second line</p>		
	<p>Pediatric</p> <p>First line</p> <p>Second line</p>		
<p>Which international organizations are involved in ARV procurement and /or distribution in the country?</p>			



IV.	PV Process for HIV/AIDS	
	<p>Is there a nationally approved ADR form?</p> <p>If yes, is the same form being used in the HIV/AIDS program?</p>	
	<p>What system of PV is used for HIV/AIDS?</p>	<p>Circle one or more:</p> <p>Passive PV</p> <p>Active research (e.g. Cohort event Monitoring)</p> <p>Prescription event monitoring</p> <p>Case control studies (phase IV)</p> <p>Any other</p>
	<p>Is reporting mandatory or voluntary or both?</p> <p>If mandatory, as part of which health program?</p>	
	<p>Who fills out the reports – Doctor/Nurse/Pharmacist/other?</p>	
	<p>Is data being processed?</p> <p>What method is used? (Manual, computerized)</p> <p>What software? (e.g. Vigiflow, Aris G, other?)</p> <p>Is there any outside source involved in data processing?</p>	
	<p>Is there a pharmacist working in ART center (even if the person is not involved with pharmacovigilance).</p>	
	<p>What pharmacovigilance specific training has this pharmacist received? By whom?</p>	
	<p>Are there specific target population in HIV/AIDS program for pregnant women, children, and patients with concomitant infections, e.g. TB, malaria, other?</p>	



V.	PV Efficiency and Outcomes for HIV/AIDS-ARVs	
	<p>How many HIV/AIDS specific ADR/AE reports have been collected during the past 12 months?</p> <p>What is the total number of reports that you have?</p> <p>How many have been analyzed?</p> <p>Is there any outside source involved in data analysis, causality assessment/signal detection?</p>	
	For ARVs, have any ADR problem/s been detected? Any other drug related problem/s?	
	How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]	
	<p>How is ADR information disseminated to policy makers, doctors, pharmacists, nurses and other paramedics, health system, institutions, other – confidential letters/conferences/mass media?</p> <p>How soon and how often?</p>	
	Is there any policy decision as a result of Pharmacovigilance?	

VI.	Challenges and Future Scale Up	
	What are the challenges in implementation of Pharmacovigilance including capacity constraints for data entry/processing, assessing events, severity, causal relationship, etc, responding to signals of ADRs	



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	Suggestions for improving and scaling up Pharmacovigilance Type/s of assistance required to establish an efficient and effective Pharmacovigilance system	
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VII.	Other Contacts/Information		
	Name of Head of National HIV/AIDS Program		
	Name of Head of National Drug Authority		
	Name of Head of Pharmacovigilance		
	Name of WHO Officer in charge of Pharmacovigilance		

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