



SAARC GUIDELINES FOR PARTNERSHIP  
WITH

# PHARMACISTS

IN  
PREVENTION & CONTROL OF  
TUBERCULOSIS & HIV/AIDS



**SAARC Tuberculosis & HIV/AIDS Centre**

Thimi, Bhaktapur, GPO Box 9517, Kathmandu, Nepal

Tel: 00977-1-6631048, 6632601, Fax: 00977-1-6634379

E-mail: [saarcib@mos.com.np](mailto:saarcib@mos.com.np), Website: [www.saarcib.com.np](http://www.saarcib.com.np)

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E-mail: [saarctb@mos.com.np](mailto:saarctb@mos.com.np)

Website: [www.saarctb.com.np](http://www.saarctb.com.np)

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## FOREWORD

TB is considered as a global public health problem with 8.9 million of new cases and 1.7 million deaths each year. While the world comes together to tackle this major public health emergency on war footing, the challenges remain daunting. The SAARC Region with 22.4% of global population bears over 27.9% of the global burden of TB.

All Member Countries of the Region have adopted DOTS strategy, the best available and cost-effective strategy for control of Tuberculosis by 1996. Since then, considerable progress has been made in the Region. Overall cure rate in the Region is very near to global target but case detection rate is still low. The Member Countries are strengthening their TB control activities, initiating new approaches and developing partnership to curb the epidemic.

In order to sustain the achievements and expand the partnership activities, the SAARC Tuberculosis Centre has identified **PHARMACISTS** as one of the potential partners to be involved in this mission along with others like media, industry workers, students, medical colleges and private sector. Pharmacists are largely accessible in this medical world. In low-income countries patients first visit the pharmacists or retail drug seller to take the advice about their illness and treatment. The trust between patients and pharmacists is great. They talk to patients in language they can understand in an informal setting. Pharmacists and clinicians are very close partners on managing the patients. If medicines are used safely, effectively and cost-effectively, society will benefit. In this context the partnership with pharmacist might yield great benefit to TB & HIV/AIDS control programme of the country.

I would like to appreciate the efforts made by Dr. Lochana Shrestha, Epidemiologist, STC for revising the “**SAARC Guidelines for Partnership with Pharmacists in Prevention & Control of TB & HIV/AIDS**”. I also would like to acknowledge the input rendered by Dr. Rano Mal Piryani, then TB & HIV/AIDS Consultant of STC, Mr. Kailash Bdr. Karki, Training Officer & all other Staff of STC for providing valuable inputs to bring this document in revised form.

I hope this document will provide updated information on TB and HIV/AIDS & will also help to accelerate partnership with pharmacists in prevention and control of TB & HIV/AIDS.

We look forward to your valuable comments/suggestions and urge to collaborate in fight against TB and HIV/AIDS.

Dr. Kashi Kant Jha  
Director, STC

## **Abbreviations:**

AIDS – Acquired Immunodeficiency Syndrome

ARV- Anti-Retroviral

BCC- Behaviour Change Communication

BCG- Bacillus Calmette Guerin

DOTS- Directly Observed Treatment Short-course

EP- Extra pulmonary

GPO – General Post Office

GS – General Services

HIV – Human Immunodeficiency Virus

IEC- Information, Education and Communication

INGOs – International Non-governmental Organizations

MDR – Multi-Drug Resistance

NGOs – Non-governmental Organizations

NTP – National TB Control Programme

PTB – Pulmonary Tuberculosis

SAARC – South Asian Association for Regional Cooperation

STC – SAARC Tuberculosis and HIV/AIDS Centre

TB - Tuberculosis

WHO – World Health Organization



SECTION - I

Tuberculosis

&

HIV/AIDS Control

# CHAPTER - I

## **Situation of Tuberculosis HIV/AIDS**

### **1. Introduction:**

Dr. Robert Koch announced his discovery of the TB bacillus on 24<sup>th</sup> March 1882 in Berlin, TB was raging through Europe and the Americas, killing one in every seven people. Koch's discovery paved the way for the potential elimination of this fearsome disease.

Since that landmark discovery, many great technological developments like invention of BCG vaccine, tuberculin, and many anti-TB drugs, implementation of principles of National TB Control Programme as well as Directly Observed Treatment Short-course (DOTS) have taken place. However, TB is still the leading killer among curable infectious diseases and has claimed the lives of millions of people.

### **2. Situation of TB**

#### **Global:**

An estimated 8.9 million new cases of TB occurred in 2004 at the rate of 140/ 100000 population, of which 3.9 million (62/100000 pop) were smear positive and 741000 were in adults infected with the human immunodeficiency virus (HIV). 14.6 million were estimated to be prevalent TB cases at the rate of 229/100000 pop, of which 6.1 million were smear positive (95/100000 pop). More than 80% of all new TB patients in 2004 was in the African, South East Asia and Western Pacific Region. An estimated 1.7 million people (27/100000 pop) died from TB in 2004, including those co infected with HIV (248000).

A total of 183 countries and territories were implementing the DOTS strategy during 2004. By the end of 2004, 83% of the World's population lived in countries, or parts of countries, covered by DOTS.

DOTS programs notified 4.4 million new and relapsed TB cases in 2004, of which 2.1 million were new smear positive. In total, 21.5 million TB patients, and 10.7 million new smear positive patients, were treated in DOTS programs over the 10 years 1995-2004.

The 2.1 million smear-positive cases notified by DOTS program in 2004 represent 53% of the estimated incidence. The increment in smear-positive cases notified under DOTS between 2003 and 2004 (350000) was greater than ever before (the average annual increment from 1995 to 2000 was 134000).

Treatment success in the 2003 DOTS cohort of 1.7 million patients was 82% on average, edging closer to the 85% target. As in previous DOTS cohorts, treatment success was substantially below average in the African Region (72%) and the European Region (75%). The relatively poor outcomes in these two Regions can be attributed, in part, to the complications of HIV co infection and drug resistance, respectively.

Based on case reports and WHO estimates, 26 countries had reached the targets for case detection and treatment success by the end of 2004.

### **SAARC Region:**

Almost 50% the adult population of this Region has already been infected with Mycobacterium tuberculosis and is at risk of developing tuberculosis disease. In the year 2004 an estimated 2.5 million people newly developed TB disease (174/100 000 population), of which about 1.11 million (78/100000) were smear positive and capable for spreading the disease to others.

According to this estimate SAARC Region was bearing 27.9% of the total global new TB cases (with 22.4% of population share). India, Bangladesh and Pakistan are occupying the 1<sup>st</sup>, 6<sup>th</sup> and 7<sup>th</sup> position in the list of 22 high burden nations {*according to estimated incidence (absolute number) of TB: high burden countries.2004*} with India revealing the highest (20.45%) global absolute burden of TB. These 3 SAARC nations account for 27.18% of the total global new TB cases.

An estimated 470888 people (36/ 100 000) died from TB in 2004, including those co-infected with HIV (20912). More than 75% of these cases and deaths occur among 15-54 years age group, economically the most productive age group. As a result the social and economic losses due to TB are huge.

### **TB Burden in SAARC Region**

- 50% the adult population infected with MTB 2004
- India, Bangladesh & Pakistan (Rank 1st, 6th & 7th) are among high burden countries
- An estimated 2.5 million people developed TB disease (174/100 000 population)
- About 1.11 million (78/100000) smear positive
- An estimated 470,888 people (36/100000) died from TB including those co-infected with HIV (20,912) 4.4%

TB notifications and case Detection rate in SAARC Region, 2004 (**DOTS & Non DOTS Area**)

Countries	Population	No. of Notified TB cases		No. of Estimated TB		Case detection rate (%)	
		All cases	New SS+	All cases	New SS+	All cases	New SS+
Bangladesh	139215000	98234	62500	319252	143637	31	44
Bhutan	2116000	1002	356	2265	1019	44	35
India	1087124000	1275998	489031	1824395	814570	70	60
Maldives	321000	119	66	157	71	76	93
Nepal	26591000	32678	14614	48834	21868	70	67
Pakistan	154794000	104842	33746	280597	126155	37	27
Sri- Lanka	20570000	8952	4302	12445	5597	72	77
<b>Region</b>	<b>1430731000</b>	<b>1530825</b>	<b>604615</b>	<b>2487945</b>	<b>1112917</b>	<b>62</b>	<b>54</b>

Source: Global Tuberculosis Control-WHO Reports 2006

### **3. Situation of HIV/AIDS:**

#### **Global:**

In just 25 years, HIV has spread relentlessly from a few widely scattered “hot spots” to virtually every country in the world, infecting 65 million people and killing 25 million. Nearly twenty-five years of experience with HIV prevention and ten years of experience with effective antiretroviral therapy have produced mountains of evidence about how to prevent and treat HIV.

Current estimates suggest that at the end of 2005, 38.6 (33.4-46.0) million people around the world were living with HIV. An estimated 4.1 (3.4-6.2) million people acquired the HIV virus (infection) in 2005. The AIDS epidemic claimed 2.8 (2.4-3.3) million lives in 2005 (The UNAIDS & WHO estimates published in 2006 Report on the Global AIDS Epidemic are lower than those published in the AIDS epidemic update-December 2005).

The epidemic remains extremely dynamic, growing and changing character as the virus exploits new opportunities for transmission. There is no room for complacency anywhere. Virtually no country in the world remains unaffected. Overall, the HIV incidence rate (the proportion of people who have become infected with HIV) is believed to have peaked in the late 1990s and to have stabilized subsequently, notwithstanding increasing incidence in several countries.

**Table I: Adults (15+) and children living with HIV, end 2003 and end 2005 globally by region (according to new estimate) <sup>8</sup>**

Region	2005		2003	
	Adults (15+) and children living with HIV	Adult (15-49) Prevalence (%)	Adults (15+) and children living with HIV	Adult (15-49) Prevalence (%)
Sub-Saharan Africa	24.5 (21.6-27.4) million	6.1 (5.4-6.8)	23.5 (20.8- 26.3 million)	6.2 (5.5-7.0)
North Africa & Middle East	440 000 (250 000-720 000)	0.2 (0.1-0.4)	380 000 (220 000- 620 000)	0.2 (0.1-0.3)
Asia	8.3 (5.7-12.5) million	0.4 (0.3-0.6)	7.6 (5.2-11.3) million	0.4 (0.2-0.6)
Oceania	78 000 (48 000- 170 000)	0.3 (0.2-0.8)	66 000 (41 000-140 000)	0.3 (0.2-0.7)
Latin America	1.6 (1.2-2.4) million	0.5 (0.4-1.2)	1.4 (1.1-2.0) million	0.5 (0.4-0.7)
Caribbean	330 000 (240 000-420 000)	1.6 (1.1-2.2)	310 000 (230 000-400 000)	1.5 (1.1-2.0)
Eastern Europe & Central Asia	1.5 million (1.0 – 2.3 million)	0.8 (0.6-1.4)	1.1 million (790 000-1.7 million)	0.6 (0.4-1.0)
North America Western & Central Europe	2.0 (1.4-2.9 million)	0.5 (0.4-0.7)	1.8 (1.3-2.7 million)	0.5 (0.3-0.6)
<b>Total</b>	<b>38.6 (33.4-46.0) million</b>	<b>1.1 (0.9-1.2)</b>	<b>36.2 (31.4-42.9) million</b>	<b>1.0 (0.8-1.2)</b>

Source: 2006 Report on the Global AIDS Epidemic

Note: The ranges around the estimates in this table define the boundaries (low to high estimates) within which the actual numbers lie, based on the best available information. These ranges are more precise than those of previous years' estimate. These are all according to latest estimate.

## **SAARC Region:**

All the SAARC countries are reporting cases of HIV and AIDS and the epidemic is spreading rapidly in most of the countries. India has the single largest proportion of HIV positive cases within its border. On the basis of available information it can be assumed that around 6 (5.87) million estimated HIV infected people are living within the region second highest after Sub Saharan Africa. <sup>1</sup>

The danger for SAARC region rests in the low ‘general population’ prevalence rates, which may be undermining the gravity of the situation. Such low rates conceal dangerously elevated ‘concentrated’ infection rates within high-risk groups such as CSW, MSM, IDU etc. The fact is that despite the low prevalence rates within this region, the factors are in place to spread HIV epidemic farther and faster than in any other region globally. The existence of high-risk group behaviours, migrant workers, truckers, mobile populations in search of sexual pleasure, drugs, and commerce, the unequal status of women, the lack of population awareness of ‘basic’ risks and prevention strategies, the trafficking of women and young girls within the sex trade, the high rates of STIs etc., all make for an explosion of HIV epidemic within the region.

The country specific HIV/AIDS estimates are given in Table 2:

### **HIV/AIDS Burden in SAARC Region**

- Over 5.87 million estimated HIV infected
  - Second highest after Sub-Saharan Africa
  - Over 1.6 are women above aged 15 years
  - Adult HIV prevalence < 1% (concentrated epidemic)
-

**Table 2. Estimated number of people living with HIV in SAARC Region, end 2005**

Country	Estimated Population (Approximately)	HIV Prevalence Rate (%) among Adults	No. of PLWH	Adult (15+) PLWH	Women (15+) PLWH	AIDS Deaths
Bangladesh	141822000	<0.1 (<0.2)	11000 (6400– 18000)	11000 (6400– 18000)	1400 (710– 2500)	500 (<1000)
*Bhutan	2163000	<0.1 (<0.2)	500 (<2000)	500 (<2000)	100 (<200)	100 (<200)
**India	1103371000	0.9(0.5– 1.5)	5700000 (3400000– 9400000)	5600000 (3400000– 9300000)	1600000 (820000– 2800000)	(270000– 680000)
Maldives	329000	<0.2	***60	60	12	12
Nepal	27133000	0.5(0.3– 1.3)	75000 (41000– 180000)	74000 (40000 – 180000)	16000 (7500 – 40000)	5100 (2800– 8400)
Pakistan	157935000	0.1(0.1– 0.2)	85000 (46000– 210000)	84000 (45000– 210000)	14000 (6600 – 36000)	3000 (1700 – 4900)
Sri- Lanka	20743000	<0.1 (<0.2)	5000 (3000 – 8300)	5000 (3000– 8300)	1000 (<1000)	500 (<1000)
Regional	1453496000	< 0.9	5876560	5774560	1632512	-



# CHAPTER - II

## **National TB Control Programme:**

### **1. What is National TB Control Programme (NTP)?**

The NTP is an approach within the National Health System to control TB.

### **2. What are the aims of NTP?**

The Aims of National Tuberculosis Control Programme are;

- (i) to decrease the spread of TB infection in the community, thereby expediting the elimination of TB from society.
- (ii) to cure the individual patients effectively, restore their capacity for activities of daily living, and to allow them to remain within their family and community enabling them to lead a active productive life.

### **3. What is the goal of NTP?**

The goal of NTP is to reduce the mortality, morbidity and transmission of tuberculosis, until it is no longer a public health problem.

### **4. What are the activities of NTP?**

- ✓ Establish a network of *microscopy* centres, and a system of quality control of sputum smear examination.
- ✓ Promote early diagnosis of patient with infectious pulmonary TB by *sputum smear examination*.
- ✓ Organize and expand *DOTS treatment centres* within the existing primary health care system.
- ✓ Provide effective *chemotherapy* to all diagnosed TB patients, in accordance with national treatment policies.

- ✓ Provide a continuous *drug supply* to treatment centres.
- ✓ Maintain a standard system for *recording and reporting*.
- ✓ Monitor the results of the treatment and evaluate progress of the programme.
- ✓ Provide regular training and supervision for all staff involved in the NTP, at different level.
- ✓ Develop IEC materials and methods to improve community awareness about TB.
- ✓ Strengthen cooperation between INGOs & NGOs.
- ✓ Carry out research activities regarding TB.
- ✓ Develop partnership with other sectors.

## **National HIV/AIDS Control Programme (NACP):**

### **1. What is National AIDS Control Programme (NACP)?**

The NACP is an approach within the National Health System to control and prevent HIV and AIDS

#### **1. What are the aims of NACP?**

**The aims of NACP are:**

1. To control the spread of HIV in the community and country.
2. To provide treatment, care and support services to PLWHA.

#### **2. What are the activities of NACP?**

##### **➤ Prevention aspect;**

- Advocacy and Raising Awareness
- Behavioral change communication
- Condom promotion
- STI diagnosis and treatment

- Voluntary Counseling and Testing (VCT)
- PMTCT programme
- Mobilizing and unifying national and international efforts
- Surveillance
  - **Treatment:**
    - ART programme
    - Interrupted drug supply with good logistic management
    - Effective and efficient monitoring and evaluation
  - **Care and support:**
    - Community based Organization-care and support
    - Development of good Network and Linkages
  - **Others:**
    - Regular training and supervision
    - Strengthen coordination and cooperation with INGOs and NGOs
    - Carry pout research activities
    - Develop partnership with other sectors.

# CHAPTER - III

## General Information on TB

### 1. What is Tuberculosis (TB)?

Tuberculosis is a communicable disease caused by an organism called *Mycobacterium tuberculosis*. This organism is also called as **tubercle bacilli**. Usually they affect the lungs.

### 2. How does TB spread?

When a person with pulmonary TB coughs, sneezes, laughs, or talks tubercle bacilli are spread into the air in tiny droplets. People who are in close contact can breathe in these droplets and become infected.

### 3. What is a case of TB?

A patient in whom TB has been bacteriologically confirmed or diagnosed by a clinician.

### 4. How many types of TB are there?

There are two types of TB (according to organ/parts of the body affected):

#### ***Pulmonary TB-***

When tuberculosis occurs in the lungs then it is called as pulmonary TB.

#### ***Extra-Pulmonary TB-***

If TB affects organs other than lungs, such as lymph nodes, bones and joints, genitourinary tract, meninges, pleura, intestines etc. it is called as Extra Pulmonary TB.

## **5. What are the symptoms of pulmonary TB?**

### **Symptoms of pulmonary TB include:**

- Cough more than two weeks
- Chest pain
- Low-grade fever, especially in the evening.
- Loss of weight
- Loss of appetite
- Blood stained sputum
- Night sweat

## **6. Who are vulnerable to TB?**

Following individuals are at risk of contracting infections and developing the disease because of their exposure to a patient with TB.

- ❑ Family and close contacts of the patients
- ❑ The elderly
- ❑ People who inject illicit drugs
- ❑ People who live or work in certain setting, such as nursing homes, prisons, shelters for the homeless or TB treatment centres
- ❑ People with HIV infection
- ❑ People addicted to alcohol
- ❑ Malnourished people
- ❑ People with poorly controlled Diabetes
- ❑ People having chronic lung diseases
- ❑ Smokers
- ❑ People suffering from cancers

## **7. How is TB detected/diagnosed?**

Pulmonary TB can be detected by sputum examination. At present, microscopic examination of sputum is the best method for diagnosis of pulmonary TB. Chest X-ray may help in diagnosis of TB of the lungs. The smear microscopy is better method of diagnosis than X-ray because it is simple, easy to perform; less expensive and more reliable. **Microscopy services are provided free of cost.**

# CHAPTER - IV

## General information on HIV/AIDS

### 1. What is HIV?

HIV stands for “Human Immunodeficiency Virus” which infects cells of the human immune system and impairs their function.

### 2. What is AIDS?

AIDS stands for ‘Acquired Immune Deficiency Syndrome’ and describes the collection of symptoms and infections associated with acquired deficiency of the immune system.

Infection with HIV has been established as the underlying cause of AIDS and it applies to the most advanced stage of HIV infection.

### 3. What are the symptoms of HIV (infection)?

Most people infected with HIV do not know that they have become infected, because no symptoms develop immediately after the initial infection. Some people have a glandular fever-like illness (with fever, rash, joint pains and enlarged lymph nodes), which can occur at the time of sero-conversion. Sero-conversion refers to the development of antibodies to HIV and usually takes place between 45 and 90 days after an infection has occurred.

The only way to determine whether HIV is present in a person’s body is by taking an HIV test.

### 4. How HIV is Transmitted?

**The main modes of HIV transmission are:**

- *Unprotected sexual intercourse (anal and vaginal) and oral sex;*



- Contaminated blood and blood products, tissues and organs;



- Mother to child transmission (MTCT).



## 5. How HIV is not transmitted?

The following activities will not transmit the virus:

- Shaking hands, hugging or kissing;
- Coughing or sneezing;
- Sharing food, eating or drinking utensils;
- Visiting a hospital;
- Using common toilets or swimming pools;
- Getting bites of mosquitoes or other insects.
- Caring of AIDS patients also does not carry risk of HIV transmission.<sup>5, 6, 7</sup>

## 6. Prevention of HIV Transmission

### HIV and AIDS can be PREVENTED

- By being mutually faithful to sex partner
- By using only HIV screened blood or blood products when required
- By using new Needles, Syringes, Blades, Razor
- By avoiding inject able drugs and needle sharing

- By using a condom ( consistently and correctly) for safer sex
- By participating in PMTCT program for delivery of baby from HIV infected mother

## **Things to remember regarding condom use**

⇒ Use good quality condoms properly and consistently

⇒ Avoid using condoms which are dry/brittle, sticky, discolored or date expired

⇒ Store condoms in a cool and dry place out of direct sunlight.

**It is not the condom on its own- it is the appropriate use of condom that produces benefit to the users.**

## **7. How HIV is detected or diagnosed?**

HIV is diagnosed by clinical assessment and HIV testing. The usual HIV test is one that detects antibodies to HIV in the blood. Rarely, a single HIV test for an individual person may not be reliable. The usual recommendation in diagnosing HIV infection is therefore to perform two tests. Both should be positive for a diagnosis of HIV infection.

When a person gets infected with HIV, the virus will start to attack his/her immune system. After exposure, there is a 2-4 week period of intense viral replication before onset of an immune response ( i.e. antibody production) and clinical illness. This period is called window period; in this period HIV testing will be negative.

In high prevalence, as many as 5% of those testing HIV antibody negative will actually be in the window phase and are really infected with HIV. People in these settings who test HIV negative should be counseled strongly to return in three months for repeat testing.

### **Diagnostic tests available for the diagnosis of HIV:**

- a. ELISA (enzyme-linked immunosorbent assay)
- b. Rapid Tests



# CHAPTER -V

## **HIV and TB-relation**

HIV is the most potent risk factor for progression to active TB both in people with recently acquired infection and those with latent MTB infection. The annual risk of developing TB in HIV infected individuals co-infected with MTB is 5-10 %. Lifetime risk of development of active TB among co infected people (latent MTB and HIV) is 60% and among latent MTB infected individuals is 10%. HIV-positive TB patients also suffer increased morbidity from other HIV related diseases.

Increasing TB cases among PLWHA augment the risk of TB transmission to the general community whether or not HIV infected.

TB is the most common causes of HIV related illness and death. HIV not only increases the number of TB cases, but also alters the clinical course of TB disease.

TB notifications have increased in population where both HIV infection and M. tuberculosis are common.

### **1. Impact of HIV/AIDS on TB control:**

- ❖ Increased case load of active TB attributable to HIV
- ❖ Increased HIV related morbidity and mortality in TB patients
- ❖ Increased emergence of drug resistance
- ❖ Higher default rates and lower cure rates
- ❖ High rates of adverse drug reactions during TB treatment
- ❖ Increased risk of TB transmission (including nosocomial transmission)
- ❖ Increased burden on TB services
- ❖ Delay of access to health services for TB suspects due to the stigma of HIV/AIDS

### **2. Impact of TB on HIV:**

- Increased case load of active TB among PLWHA
- TB may accelerate the progression of HIV-related immuno-suppression
- Increased morbidity and mortality from TB among PLWHA

- Difficulties with diagnosing TB among PLWHA owing to the different clinical presentations of HIV related TB
- Increased burden on HIV services

**Sub-Populations at higher risk (PHR) of getting HIV infection:**

- IDU
- Sex workers : street based and Non-street (institute) based
- Clients of sex workers
- Labor migrant / Transport workers
- MSM
- Partners of migrants / house wives
- Street children
- Uniform service

# CHAPTER - VI

## Treatment of Tuberculosis:

### 1. How TB disease is treated?

Tuberculosis is a curable disease and treated with the oral drugs & sometimes together with injections. **TB drugs are available at free of cost in all government health facilities.** The total duration of treatment is 6 to 8 months. It is essential to complete full course of treatment. If treatment is interrupted before completion of full course the drug resistance will develop which is dangerous to patient as well as to the community. Drug resistance TB is difficult to treat.

### 2. What are the effective anti-TB drugs?

Following are the main anti -TB drugs available everywhere. (in all TB treatment Centres)

#### Oral Drugs

- Isoniazid (INH)
- Rifampicin ( RFP)
- Pyrazinamid (PZA)
- Ethambutol (EB)

#### Injection

- Streptomycin (SM)

### 3. What are the adverse effects of anti-TB drugs?

Drugs used in the treatment of tuberculosis may sometimes cause side effects/adverse effects, such as loss of appetite, nausea, abdominal pain, joint pains, etc. These may cause the patients to stop taking medicines. Most TB patients complete their treatment without any significant adverse effects of drugs. However, a few patients do experience adverse effects. It is therefore important that patients need to be clinically

monitored during treatment so that adverse effects can be detected promptly and managed properly. Health personnel can monitor adverse effects of drugs by teaching patients how to recognize symptoms of common adverse effects.

<i>Drugs</i>	<i>Common Side Effects</i>	<i>Rare Side Effects</i>
Isoniazid	<ul style="list-style-type: none"> <li>• Peripheral neuropathy</li> <li>• Hepatitis</li> </ul>	Convulsion, pellagra, joint pains, agranulocytosis, lupoid reactions, skin rash
Rifampicin	<ul style="list-style-type: none"> <li>• Gastrointestinal, anorexia, nausea, vomiting, abdominal pain</li> <li>• Hepatitis</li> <li>• Reduced effectiveness of oral contraceptive pill</li> </ul>	acute renal failure, shock, thrombocytopenia, skin rash, "fly syndrome" pseudomembranous colitis, pseudoadrenal crisis
Pyrazinamide	<ul style="list-style-type: none"> <li>• Joint pains</li> <li>• Hepatitis</li> </ul>	gastrointestinal symptoms, skin rash, sideroblastic anaemia
Streptomycin	<ul style="list-style-type: none"> <li>• Auditory and vestibular nerve damage</li> <li>• Renal damage</li> </ul>	skin rash
Ethambutol	<ul style="list-style-type: none"> <li>• Optic neuritis</li> </ul>	skin rash, joint pains, peripheral neuropathy

#### **4. Prevention of side effects:**

Pharmacists should be aware of the special situations, which influence the choice and dose of anti-TB drugs. It is possible to prevent the peripheral neuropathy caused by isoniazid. This neuropathy usually shows as a burning sensation of the feet. It occurs more commonly in HIV-positive individuals, in alcoholic, and in patients with diabetes. These patients should receive preventive treatment. For the proper management refer the patients at hospital/TB clinic.

#### **5. When to stop anti-TB drugs:**

When a patient has minor side effects, explain the situation, offer symptomatic treatment and encourage to continue treatment. When a patient has a major reaction, stop the suspected drug(s) responsible at once. A patient who develops one of the following reactions must never receive that drug again.

## 6. Management of side effects:

Refer chart – symptom based approach to management of side effects.

### Symptom-based approach to management of drug side effects

Side Effects	Drug(s) Probably Responsible	Management
<b>Minor</b> <span style="float: right;"><b>continue anti-TB drugs</b></span>		
Anorexia, nausea, abdominal pain,	Rifampicin	Give tablets at night
Joint pains	Pyrizinamide	Aspirin
Burning sensation in feet	Isoniazid	Pyridoxine 100mg daily
Orange/red urine	Rifampicin	Reassurance
<b>Major</b> <span style="float: right;"><b>stop anti-TB drugs</b></span>		
Skin itching/rash	Thiacetazone (streptomycin)	stop anti TB drugs, refer patients to hospital/TB clinic
Deafness (no wax in auroscopy)	Streptomycin	-do-
Dizziness (vertigo and nystagmus)	Streptomycin	-do-
Jaundice (other causes excluded)	Most anti-TB drugs	-do-
Vomiting and confusion (suspected drug-induced pre-icteric hepatitis)	Most anti-TB drugs	-do-
Visual impairment	Ethambutol	-do-
Generalized, including shock and purpura	Rifampicin	-do-

**Some practical points:**

- Rifampicin reduces the effectiveness of the oral contraceptive pill. Advise a woman to choose between the following two options. Following consultation with a physician, she could take an oral contraceptive pill containing a higher dose of oestrogen (50mcg). Alternatively, she could use another form of contraception.
- Refer patients with severe drug reactions to specialist centres.
- Never attempt desensitization in TB/HIV patients.

## **7. How one can help TB patients understand more about their disease?**

Patients are more likely to successfully complete their treatment if they understand about their disease and treatment. Patients are often afraid when they learn of their diagnosis, because they harbor misbeliefs such as TB is an incurable disease. Reassure them and provide them with proper and relevant information;

- TB is caused by an organism/bacillus
- TB spreads by air through coughing, sneezing.
- TB is a curable disease and not a hereditary disease.
- Investigation of TB suspects and treatment of TB cases are free of cost.
- If there is a side effect, inform Health workers as soon as possible.

Talking to an individual patient or patients in groups and distribution of pamphlets and brochures containing basic TB information should help to improve the patients' knowledge on TB.

# CHAPTER - VII

## Treatment of HIV/AIDS-ARV

### 1. Antiretroviral Therapy (ART) on HIV and AIDS

*ART is the available treatment for HIV/AIDS with following purpose:*

- a. Reduce the viral load as much as possible
- b. Achieve immune reconstitution
- c. Reduce HIV-related morbidity and mortality
- d. Prolong and improve the quality of life for PLHA
- e. Reduce mother-to-child transmission
- f. Reduce post exposure transmission of HIV

### 2. When and who need ARV therapy:

HIV positive individual needs ART when he or she is symptomatic and/or there is evidence of significant immune system damage on clinical assessment.

### 3. What ART are available:

There are currently 20 approved ART agents for the treatment of HIV-1 infection.

Approved antiretroviral drugs are grouped into four categories:

1. A. Nucleoside analog reverse transcriptase inhibitors (NsRTIs).  
B. Nucleotide analog reverse transcriptase inhibitors (NtRTI).
2. Non-nucleoside analog reverse transcriptase inhibitors (NNRTIs)
3. Protease inhibitors (PIs)
4. Fusion inhibitors (FI)

Complete cure of HIV infection is not possible with presently available ARV drugs. Therefore, the aim of the treatment is to prolong and improve the quality of life by suppressing viral replication as long as possible.

The only regimens potent enough to reduce viral replication drastically and to prevent the emergence of resistance and treatment failure for a significant amount of time involve a *combination of at least three antiretroviral drugs*.

In co-infection with other diseases, treatment of Tuberculosis and other opportunistic infection may be more important than antiretroviral therapy



# CHAPTER - VIII

## DOTS:

### ➤ **Directly Observed Treatment Short-course**

#### **1. What is DOTS and why DOTS?**

Tuberculosis is entirely curable and Directly Observed Treatment Short-course (DOTS) is the best ever known available strategy to cure TB patients and control TB.

Under this strategy TB suspects **are tested free of cost**. The diagnosed TB patients receive free treatment with recommended standard drugs and are observed taking every single dose at least for the intensive phase (first 2 to 3 months) of their 6-8 months treatment regimens. For the rest of the treatment course, patients are kept under strict supervision. This ensures that TB patients take all their drugs regularly in proper doses for the full-recommended period of treatment course, which ultimately ensures their cure.

#### **2. What are the elements of DOTS strategy?**

The DOTS strategy consists of five elements:

- ① Political Commitment
- ② Good quality case detection using sputum smear microscopy in person who have cough of more than two weeks duration.
- ③ Short-course chemotherapy using standardized regimens and recommended case management protocols including direct observation of treatment
- ④ Regular supply of good quality anti-TB drugs, and
- ⑤ A standardized recording and reporting system that allows an objective assessment of individual patient outcomes as well as overall programme performance.

### **3. Why it is necessary to have directly observed treatment?**

At least one third of the patients receiving self-administered treatment do not adhere to treatment. It is impossible to predict which patients will take medicines regularly. Therefore, directly observed treatment is necessary at least in the initial phase of treatment to ensure adherence and achieve sputum smear conversion. A TB patient missing even one attendance can be traced immediately and counseled. No method other than directly observed treatment has been able to achieve 85% cure rate of new smear positive cases.

### **4. What are the evidences that DOTS works?**

In areas where DOTS was implemented, cure rates of up to 95% have been recorded, even in very poor countries. More over DOTS prevents transmission of new infections and the development of multi-drug resistant TB. The DOTS strategy has been ranked by the World Bank as one of the most cost-effective of all health interventions.

### **5. What are the benefits of DOTS?**

The benefits for patients themselves are the increasing treatment completion resulting in rapid cure. Furthermore, case management under DOTS strategy can prevent death, sequel & relapse. Moreover, DOTS can reduce community transmission of tubercle bacilli as well as emergence of drug resistance strains.

DOTS is the internationally recommended cost-effective strategy for TB control. DOTS cures patients, saves lives, prevents the development and spread of drug resistance, and reduces disease transmission.

#### **DOTS can:**

- Prolong life and improve its quality
- Stop the spread of TB
- Prevent emergence of multi-drug resistance TB
- Reverse the trend of multi-drug resistance TB

Treatment of TB under DOTS strategy is very effective, if a patient takes treatment:

- with right combination of drugs
- with correct dose
- regularly for full period of the course (6-8months) as advised by physician.

# CHAPTER - IX

## Drug resistance to anti TB drugs & MDR-TB

### 1. What is drug resistance & MDR-TB?

Drug resistant bacilli are the Mycobacterium tuberculosis bacilli, which are resistant to anti-tuberculosis drugs. Multi-Drug resistant (MDR) bacilli are the bacilli that are resistant to at least INH & Rifampicin. MDR is currently the most severe form of bacterial resistance.

### 2. Treatment of MDR-TB

Treatment of patients with MDR tuberculosis may have to involve second-line (reserve) drugs. These are drugs other than the standard essential anti-TB drugs. These reserve drugs are much more expensive, less effective and have many more side effects than standard drugs. They should only be made available to a specialized unit and not in the free market. It is the responsibility of National Health authorities to establish strong pharmaceutical regulations to limit the use of second-line drugs in order to prevent the emergence of drug resistance tuberculosis.

### 3. Priority is prevention

A country with limited resources may reasonably decide that its resources should be concentrated on ensuring that all patients complete the standard National treatment and are thereby cured. With good standard treatment meticulously administered, multi-drug resistance should not occur.

The most common assumption is that the emergence of **MDR-tuberculosis is always due to medical error** prescribing an unavailable regimen, using unreliable regimen, using unreliable drugs, or failing to ensure (by directly observed treatment and education of the patients and the family) that the patients takes the drug as prescribed and for the full period prescribed. **MDR tuberculosis should always be regarded as a result of failure of effective implementation of the National TB control programme.** Top priority should be given to preventing such failure.

## 4. MDR TB a consequence of poor treatment

In some countries MDR tuberculosis has arisen from poor treatment before the introduction of the National Programme or because some patients received poor treatment outside the National Programme. As a wide variety of different poor regimens may have been used for such patients, the MDR tuberculosis cases, which arise, will require detailed assessment by the specialized unit.

## 5. How MDR TB is produced?

As with other forms of drug resistance, the phenomenon of MDR tuberculosis is entirely man-made.

Drug resistant bacilli are the consequences of human error in any of the followings:

- Prescription of chemotherapy —→ wrong combination, inadequate dosages
- Management of drug supply —→ irregular supply
- Case management —→ Irregular treatment, lack of monitoring & supervision.
- Process of drug delivery to the patient —→ Irregular delivery, lack of supervisory visits

## 6. What is DOTS PLUS Programme

The drugs used in the Directly Observed Therapy Short Course (DOTS) programme are the best for tuberculosis and called *First Line Drugs*. The name of the drugs being used in DOTS programme is mentioned in Chapter V. Most patients are cured using these drugs. However there are some **very few patients** who do not get cured using DOTS drugs. At the end of the Category-II (Cat-II) re-treatment regimen these patients sputum is still smear positive for TB.

The DOTS PLUS Programme offers drug treatment to patients who have failed first line Drug re-treatment (CAT-II) or who have culture proven MDR –TB, with drug

sensitivity Testing (DST) showing resistance to at least Rifampicin and Isoniazid. The national Tuberculosis Control Programme provides these drugs as a last resort after DOTS treatment with CAT-I and CAT-II. DOTS PLUS is-a **second line of treatment**, after patients have failed on fully observed DOTS treatment and re-treatment or for patients, who have smear and culture positive with DST proven MDR Tuberculosis. This is why this treatment programme is called the **DOTS PLUS programme**.

#### ➤ **Policies of DOTS PLUS Programme**

The DOTS PLUS programme like the DOTS programme has policies plans and activities to achieve good case holding and treatment.

The drugs in the DOTS PLUS programme will be given free to patients. The DOTS PLUS programme is a part of the National Tuberculosis Programme and is integrated within the general health services.

#### ➤ **Goal of the DOTS PLUS Programme**

The Goal of the DOTS PLUS is to reduce the mortality, morbidity and the transmission of tuberculosis from these CHRONIC patients.

**The aim of the DOTS PLUS Programme is to reduce MDR-TB transmission by curing;**

- ❖ Any smear positive CAT-II failure
- ❖ Any CAT -I Failure with culture & Drug Sensitivity Testing (DST) confirmed MDR-TB
  - Any MDR-TB patient house hold contact who is smear positive, with culture & DST confirmed MDR TB.
- ❖ Any MDR TB patient who is smear positive, with culture & DST confirmed MDR-TB.

# CHAPTER - X

## Facts about TB & HIV/AIDS

### 1. TB:

- TB kills more youth and adults than any other curable infectious disease.
- TB is a contagious disease but only people that are sick with pulmonary tuberculosis are infectious.
- Poverty increases the risk of tuberculosis; impoverishes its victims.
- DOTS restore health to young and adult people who are in their most economically productive years.
- More than 90% of TB cases and deaths occur in low and middle-income countries.
- TB carries a direct cost to the health services (diagnosis, treatment and control)
- DOTS can add two year of life to an HIV positive person and 25-30 years to an HIV negative person.
- TB is the leading cause of death among people who are HIV positive.
- Late diagnosis, inadequate treatment, over crowding, poor ventilation and repeated prison transfer encourage the transmission of TB infection.
- TB can be readily and inexpensively cured with DOTS.
- Every infectious patient cured reduced the risk to everyone of contracting TB.
- DOTS prevents new infections and the development of MDR-TB.
- From a public health prospective, poorly supervised, incomplete treatment of TB is worse than no treatment at all.

- In some parts of the world, the stigma attached to TB leads to isolation, abandonment and divorce of women.

## 2. HIV/AIDS:

- AIDS Kills more than 8000 people every day world wide.
- More than 5000 people die form TB every day.
- TB is the leading killer of people infected with HIV.
- TB causes at least 11% of AIDS deaths and possibly as many as 50%.
- Up to 50% of people with HIV or AIDS develop TB.
- World wide, 14 Million people are co-infected with TB and HIV-70% of them are concentrated in Africa.
- Treatment of TB can prolong and improve the quality of life for HIV-positive people newly infected, 200 million will develop the disease, and 35 million will die of it.
- More people are dying of TB today than ever before.
- TB is the biggest curable infectious killer of young people and adults in the world today.
- TB is an opportunistic disease that preys on weakened immune systems.

With effective treatment Tuberculosis can be cured,  
& HIV can be managed to prolong lives

# SECTION - II

Guidelines for

Partnership Programme



# CHAPTER - XI

## **TB & HIV Control a Shared Responsibility**

### **1. Partnership is most essential to stop TB & HIV/AIDS**

21<sup>st</sup> century begins with more people dying of TB & HIV/AIDS than ever before. Developing countries are worst hit accounting for as much as 95% of all new cases and 98% of all TB deaths. TB & HIV/AIDS, are not only public health problem, it is the developmental problem, as its impact worse in all sectors. Worldwide experiences, shows that individual effort is not sufficient to tackle this problem. There is a need of combined effort from all sectors with partnership approach.

### **2. Why do TB patients go to Pharmacists?**

- Pharmacy is accessible
- Available on their favorable time.
- Low trust in government TB treatment centre or fear of hidden costs
- Feel free to talk
- Feel less stigmatized

### **3. Why do we need partnership with Pharmacists?**

Pharmacists can play a significant role in control of TB & HIV/AIDS in the community. They can contribute a lot in disseminating TB/HIV related information to the public and promoting the understanding of the people about the disease. The Pharmacists are the first patient contact point in our society and can be utilized to provide education to the public. Pharmacies are the places where the general public could access easily in their favorable time. Pharmacists see a lot of people from different walks of life and therefore could be distributors of informative materials to the public at large. Educating the public in this way could assist in reducing the stigma often associated with TB and HIV. The pharmacists can also improve accessibility for diagnosis and treatment of TB in right and proper place. In other words they can provide information and advice on rational drug use patients on a one-to-one basis as

well as through campaigns and workshops. Treatment of TB can be improved by using pharmacies as centres for the Directly Observed Treatment Short-course (DOTS) Centre & Pharmacists as DOTS providers & VCT Counselors. Finally, the pharmacists can emphasize the importance of completing the total course of drugs for total cure of diseases (TB and HIV). It is therefore; the pharmacists are the forefront group whose support always benefited to control of TB/HIV in the community. Their valuable advice to the people regarding proper treatment schedule will help to prevent the emergence of drug resistance in both cases. Their partnership always be helpful in TB control programme.

On the background SAARC TB Centre has identified Pharmacists as one of the most potential group to be involved in this mission along with the others partners like medical/nursing colleges, industry workers, media school students, travel, man power agency and pharmacists can do a collaborative effort between the TB and HIV infected people and TB/HIV control programme. Outbreak information on TB/HIV can be obtained from the pharmacists.

#### **4. Objectives of the partnership with Pharmacists:**

##### **General objectives:**

Enhancement of public awareness on TB/HIV and its prevention and control

##### **Specific objectives:**

- To disseminate update information on TB/HIV.
- To seek coordination and cooperation for control efforts on TB /HIV

#### **5. Strategy to fulfill the objectives:**

- Organize interaction programme with Pharmacists

#### **6. Role of Pharmacists on TB/HIV control efforts?**

Pharmacists are largely accessible to the public. They are becoming more involved in drug therapy decision making and patients counseling. They dispense drugs prescribed

by physicians and other health practitioners and provide information to patients about medications and their use. They talk to patients in language they can understand in an informal setting. They also monitor the health and progress of patients in response to drug therapy to ensure safe and effective use of medication. Medicines are likely to remain a core element of health care. If medicines are used safely, effectively and cost-effectively, society will benefit. In this context Pharmacists have to perform their professional role wisely. Pharmacists should have a deep understanding of the proper use of medicine.

Pharmacists can propagate the information about availability of DOTS centre, the risks of inappropriate use of anti-TB and ARV drugs.

Hence, then the role is to aware the public on update information on TB and HIV with advising proper use of drugs, which in turn enhance the control efforts implemented by TB/HIV programmes.

## **7. How to develop partnership with Pharmacists?**

To develop partnership with pharmacists, it is necessary to organize a brief interaction programme for pharmacists in collaboration with the association of pharmacist, chemist or druggist. If there is no existence of such organization, all the pharmacists/chemists/ druggists or salesman on the medical stores should inform individually or collectively for gathering in one proper venue for interaction programme. In the interaction objectives of partnership programme should be explained clearly.

## **8. How to organize partnership programme with Pharmacists?**

### **Responsibility:**

The primary responsibility in organizing partnership programme with pharmacists goes to the National TB & HIV/AIDS Control Programmes, Director/Manager of the country.

The Director/Manager should appoint a programme officer for overall organization of partnership programme in the country.

At the periphery these programme may be organized at the district level and main responsible person would be the district TB & HIV/AIDS coordinator.

## **Programme**

### **Participants:**

- Pharmacists or the people who are working as a salesman on drug retail shops
- Pharmacists working in hospitals (government and private sector)
- Pharmacists working in pharmaceutical companies

### **Interactive programme:**

Talk programme with multimedia presentations on TB & HIV/AIDS problem, its prevention and control with emphasis on importance of partnership programme with pharmacists in TB/HIV control. In this regard the following points may be explained:

- Information on TB/HIV with historical background
- Magnitude of TB/HIV burden in World, Region, Country and Local level
- Causative agent and its mode of transmission
- Symptoms of pulmonary TB/HIV
- Diagnosis of TB/HIV
- DOTS and its importance
- Complications of irregular drug taking
- Inappropriate doses or combinations of TB drugs
- Impact of HIV/AIDS on TB disease
- Preventive measures
- ARV and its implications
- Role of Pharmacists in TB/HIV control programmes

During the interaction programme IEC/BCC materials/publications should be distributed to the participants.

## CHAPTER - XII

### **Partnership Programme with Pharmacists Organized by STC**

#### **1. Initiative to develop partnership &/or strengthening partnership**

SAARC Tuberculosis & HIV/AIDS Centre (STC) has been supplementing to Member States in their efforts to response towards TB/HIV epidemic by taking initiative to develop partnership and /or strengthening partnership with various stakeholders like Pharmacists.

#### **2. List of the activities organized by STC**

The Centre has organized Partnership- Programme with Pharmacists on Tuberculosis and HIV/AIDS Prevention and Control in SAARC Member States are as under;

1.	Partnership Programme with Pharmacists –August 25, 2003 STC, Kathmandu
2.	Partnership Programme with Pharmacists –December 2, 2004 STC, Kathmandu
3.	Partnership Programme with Pharmacists –August 18, 2005 Colombo, Sri –Lanka
4.	Partnership Programme with Pharmacists – June 24, 2006, Thimphu, Bhutan

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*The medicine on its own does not have  
any benefits,  
it is the appropriate use of medicine that  
produces therapeutic benefit to the patients,  
it is therefore, the Pharmacists have  
important roles to play*