TRAINING MODULE
FOR
Medical Officers
ON TB/HIV

Central TB Division & National AIDS Control Organization
New Delhi

August 2005

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Contents

Note: Training on chapter 8 only for DTOs, DNOs, MO-TCs, and MO-VCTCs

Preface

TB is one of the leading infectious causes of death, accounting for over 2 million deaths per year worldwide. Globally, 8.8 million new cases of TB occur every year, of which 1.8 million occur in India. TB control in INDIA is a daunting task for which India is making concerted efforts which are very well appreciated internationally. Globally, the RNTCP is the largest DOTS Programme in terms of patients treated. The programme is demonstrating to the world how effectively the principle of DOTS can be implemented while maintaining the quality.

It is estimated that 40% of the Indian population is infected with Mycobacterium tuberculosis. Considering that above 5.1 million people are infected with HIV in India, an estimated 2 million persons are co-infected with Mycobacterium tuberculosis & HIV.

HIV infected individuals co-infected with TB have an annual risk of 5-15% of developing active TB as compared with 10% lifetime risk in HIV negative. Active TB disease is the commonest opportunistic infection amongst HIV-infected individuals and is also the leading cause of death in PLWHA (People living with HIV/AIDS).

HIV/AIDS poses a major threat to TB Control in India, with a potential to increase the incidence of TB in some parts of the country. The need of the hour is to establish a package of services for TB-HIV that reach out to PLWHA and addresses their needs for TB diagnostic and treatment services.

Though an action plan has been jointly laid down by both the programmes in 2001, effective and optimum implementation of the plan still remains a challenge.

Training of staff is very crucial to the scaling–up of TB/HIV activities. To streamline the training, both the programmes have come up with Modules which address the training needs of various categories of staff. It is envisaged, that uniform, standardised modular training shall be imparted to all the Programme and general health staff through out the country.

I hope this module would act as a useful tool for further expanding the implementation of TB/HIV Coordination activities in the country.

Dr.L.S.Chauhan
Deputy Director General,
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Preface

TB and HIV tend to fuel each other. HIV infection makes an individual more prone to TB. HIV epidemic has the potential to worsen the TB scenario because HIV increases the risk of disease re-activation in people with latent TB infection. The scenario becomes grimmer since these people can further spread TB to other persons.

HIV is the most powerful risk factor for the progression of TB infection to TB disease. This is further substantiated by the fact that an HIV positive person has 50-60% lifetime risk of developing TB disease as compared to an HIV negative person who has a risk of just 10% of developing the TB disease in a lifetime.

In a developing country like India, the potential extra burden of new TB cases attributable to HIV could overwhelm the budgets and support services. Though, a low cost cure exists for TB and is provided through the internationally accepted DOTS strategy, there is no cure for HIV. With ART however, the scourge of HIV can be converted into a chronic manageable illness. ART, by virtue of improving the immunity of PLWHA's, reduces the incidence of opportunistic infections thereby improving the quality of life and reducing the cost on treatment of OI's.

Effective treatment of TB disease can improve the quality of life and prevent transmission of both, TB and HIV in the community.The basic purpose of HIV-TB coordination is to ensure optimal synergy between the two programmes for the prevention and control of both diseases. Key areas include:

1. Commitment to HIV-TB coordination, through sensitisation;
2. Service delivery coordination and cross-referral, through training, provision of additional services, and coordination at the local level;
3. Optimal and comprehensive use of the community reach of both programmes through the sensitisation and involvement of NGOs and private practitioners who are involved in both programmes;
4. Infection control to prevent spread of TB in facilities caring for HIV-infected persons, and to prevent spread of HIV through safe injection practices in the RNTCP;
5. Joint efforts at IEC particularly with regard to de-stigmatisation, TB being treatable; HIV being preventable; DOTS prolongs life of HIV infected persons and ensuring confidentiality of HIV- and TB-related information.
6. Monitoring and evaluation at district, State and National level to assess the co-ordination between both these programmes.

In view of the consideration discussed above, a strategy for TB-HIV Care was considered and a Joint Action Plan for TB-HIV developed in 2001 by the Revised National Tuberculosis Control Programme and the National AIDS Control Programme.

Phase I of the programme which was launched in 2001, the co-ordination was initiated to cover the population residing in the six high HIV prevalence states, namely- Andhra Pradesh, Karnataka, Tamil Nadu, Maharashtra, Nagaland & Manipur. Whereas, in 2003, the Phase II of the co-ordination saw similar activities being extended to eight additional states of moderate HIV prevalence. These states are- Delhi, Gujarat, Himachal Pradesh, Kerala, Orissa, Punjab, Rajasthan and West Bengal.

In order to deliver services properly it becomes imperative that we train the service providers about all the nuances of both the diseases and their managements. Though Training material had been developed earlier, individually by both the National Programmes, yet due to the progressively turbulent dynamics in the arena of HIV-AIDS, reflecting proportionally on the quantum of TB-HIV co-ordination activities, there was a dire need for the technical update/revision of the existing training modules.

To streamline the process of trainings and in order to make it a uniform standard and task specific procedure for the various categories of staff working in both the National programmes, throughout the country, it was proposed to develop common training modules at the Central level, jointly by both the National Programmes.

This training module is one amongst a series of such developed specifically for the purpose of making the health service provider aware of the delicate inter-relation between both the diseases and the devastating impact of their individual or combined effects, which if not treated properly and timely can be lethal.

The module covers all the relevant aspects of both the diseases comprehensively, and will be a valuable guide for the health service provider towards discharging their duties optimally.

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Additional Project Director
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Learning objectives

At the end of the training participants will be able to:

- Understand the burden of TB/HIV
- Understand the diagnostic and treatment issues related to TB/HIV
- Understand the TB/HIV Programme coordination and the related operational issues
- Understand the issues related to confidentiality and counselling on TB/HIV
- Understand infection Control Measures
- Understand the role of service providers in TB/HIV coordination

METHODOLOGY

- Modular Training
- Individual work exercises
- Field visit to VCTC, ART Centre, District TB Centre, DMC

MATERIALS REQUIRED

- Course material- Module for Medical Officers on TB/HIV
- White writing board / flip charts with marker pens

DURATION

- One day
- Two days for DTOs, DNOs, MO-VCTC, MO-TC (including field visit).

1. Introduction

HIV/AIDS

Acquired Immune Deficiency Syndrome (AIDS) is the name given to a group of potentially life threatening conditions caused as a result of progressive decrease in body's immunity consequent to infection by the Human Immune-deficiency Virus (HIV). It was first reported in the *Morbidity and Morality Weekly* Report as "Pneumocystic Pneumonia – Los Angeles," in 1981. Since then AIDS has become the most devastating disease that mankind has ever faced. The HIV/AIDS epidemic continues its expansion across the globe with approximately 14,000 infections a day. Till date, there is no vaccine to protect an individual from this dreadful virus. Since the first description of AIDS in 1981, researchers have identified two serotypes of HIV. HIV-1 is the predominant serotype worldwide. HIV-2 occurs most commonly in West Africa. Both HIV-1 and HIV-2 cause AIDS and the routes of transmission are the same. However, HIV-2 is less efficiently transmitted that HIV-1 and progresses to AIDS at a comparatively slower rate.

Once the individual is infected, the virus gradually weakens the immune system and makes him/her vulnerable to multiple opportunistic infections. These manifest in the form of a syndrome as various signs and symptoms. This syndrome is called AIDS. People infected with HIV may take 7-10 years to develop AIDS. In developing countries like India, the progression to AIDS may be faster because of malnutrition and a poorer state of health and may be a different strain of virus/genetic factors.

HIV is present in certain body fluids of infected human being like blood, semen, vaginal fluids, breast milk, cerebrospinal fluids, synovial fluids, amniotic fluids etc. That is why HIV is transmitted through the routes associated with these fluids. However HIV is not known to be transmitted through saliva, tear, urine, faeces, sweat etc. Once HIV enters the human body, it selectively invades the white blood cells which bear the necessary viral receptor on their surfaces called CD4 receptor. Eventually, the infected cell dies. This process goes on ultimately leading to destruction of more and more of CD4 cells causing deficiency of these cells – a condition known as immunodeficiency; which renders the person unable to fight infection and tumours. The micro organisms which can not produce infections or diseases in a person with normal immune system now take full advantage of the weakened immune system and start producing infections (opportunistic infections) in the person.

According to UNAIDS, there are 34-46 million HIV infections in the world by the end of December 2004 of which 90% are in the developing countries, 19.2 million are women, 11.8 million are young people below 25 years, 3.2 million are children below 15 years. 14000 infections are occurring everyday and 8000 death are occurring every day. International agencies have reported that there will be 45.4 million new cases by the year 2010 of which 12.8 million can be averted by our expanded response. AIDS has already produced 27.9 million deaths and 13.4 million orphans. The number of orphans is likely to increase to 41 million orphans by 2010.

Today, it has spread from the high risk to the low risk general population and from urban to rural areas. It has invaded communities that previously had little to do with the epidemic.

The first HIV positive case in India was reported from Madras (now Chennai) in May 1986 from among a cluster of commercial sex workers. Today according to NACO, there are already 5.134 million people living with HIV/AIDS (end of December, 2004) which is about 0.8% of the adult population in India. India is having about 11% of the global HIV/AIDS burden and 65% of the Asia's HIV/AIDS burden. All States and Union Territories have reported HIV/AIDS cases. No state or union territory is free from AIDS. By the end of May, 2005 NACO has reported 109349 AIDS cases in India. This may be under reported because of special nature of disease, its mode of transmission and stigma attached to it.

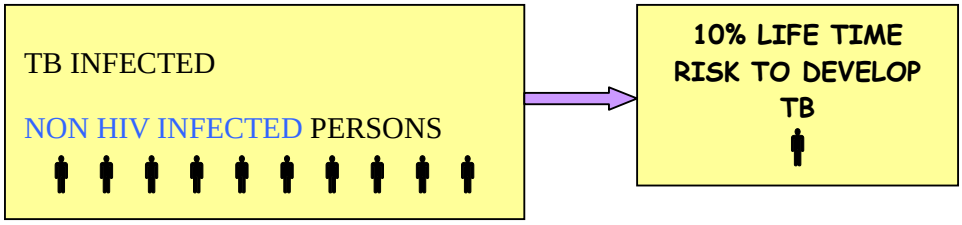
The epidemic pattern shows great variance across the country. The worst affected states are Andhra Pradesh, Karnataka, Manipur, Maharashtra, Nagaland and Tamil Nadu. In these six states, the HIV sero prevalence rate among the pregnant women is 1% or more. These six states have reported more than 75% of all the AIDS cases in India and are classified as category-I states or High Prevalence States. Another three states namely Gujarat, Goa and Pondicherry have reported HIV sero prevalence among the pregnant women below 1 %. These three states are taken as highly vulnerable. The remaining states including big states like Delhi, UP, M.P., Bihar, West Bengal, Punjab, Haryana, Gujarat, Rajasthan, Kerala etc. have reported HIV sero prevalence rate of below 5% among the high risk groups and below 1% among the pregnant women. These remaining states are taken as vulnerable.

Tuberculosis

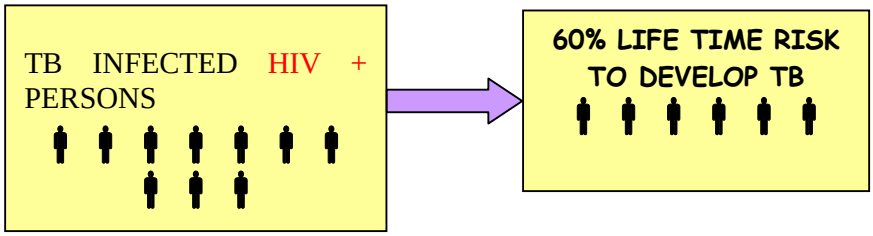
Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis* and, less commonly, by other organisms of the 'tuberculosis complex'. Globally, it is estimated that 1.8 million people die from TB each year—the majority of them in developing countries. The annual incidence of new cases of all forms of TB (pulmonary and extra-pulmonary) worldwide is estimated to be approximately 8.8 million, of which about 95% occur in developing countries. Many TB cases in developing countries remain undetected. India, alone accounts for one fifth of the Global incident TB cases.

Almost 40% of the Indian population has TB bacilli present in their body (infected). However, only a small proportion of these persons actually go on to develop TB disease. The life-time risk of developing TB is 10% in non-HIV infected persons. This means that a large number of persons do not develop the disease in spite of having TB bacilli in their body.

Tuberculosis is one of the earliest opportunistic diseases to develop amongst the HIV infected person. The risk of developing TB is higher amongst HIV infected person as compared to a HIV non-infected person. The higher risk to develop TB in HIV positives is because of decrease in immunity.



If the person harbouring the TB bacilli is also HIV infected, then there is higher risk of developing TB disease. Life-time risk of developing TB in HIV infected person is 60%. This means that at least 60% of those who are HIV infected and TB infected will develop active TB disease. The risk of recurrent TB is slightly higher in HIV infected persons. Thus with an increase in number of TB cases in PLWHA, there may be an increase in the risk of transmission of TB to the general community, as the cumulative number of infectious cases increases .



An HIV infected person who is newly infected with TB bacilli, is also more likely to develop the TB disease as compared to an HIV negative person. The rate of progression from infection to disease is also higher; ten to thirty times higher among individuals infected by both TB and HIV as compared to those infected with only TB.

EFFECT OF HIV INFECTION ON TB DISEASE

Risk of developing TB is higher in HIV infected persons.

Life-time risk of developing TB is 60% in persons infected with both HIV and TB.

HIV infected person develops the disease rapidly as compared to HIV negative.

The rate of progression to disease is 10-30 times higher in HIV infected person.

In a TB/HIV co-infected person; the immune response to TB bacilli increases HIV replication. As a result of the increase in number of viruses in the body, there is rapid progression of HIV infection. The viral load can increase by six-seven folds. As a result, there is a rapid decline in CD4 count and patient starts developing symptoms of various opportunistic infections. Thus the health of the patient who has dual infection deteriorates much more rapidly than with a single infection.

Amongst the AIDS cases, TB is most common opportunistic infection. The mortality due to TB in AIDS cases is also high.

EFFECT OF TB DISEASE ON HIV INFECTION

Increases the risk of developing other Opportunistic infections.

Increases the rate of progression from HIV to AIDS.

Shortens the life span of patients with HIV infection.

TB is a common cause of death in AIDS patients.

Impact of HIV on TB Control

The principles of TB control are the same even when there are many TB/HIV patients. Treatment with DOTS (Directly Observed Treatment, Short course) is the accepted standard even for HIV positive TB patients. Treatment with DOTS improves the quality of life and increases the life span of an HIV infected TB patient. The following consequences are likely to be seen wherever there is high prevalence of HIV and TB.

- Increased load of TB cases, including smear positive cases
- Increased morbidity in TB patients due to HIV related opportunistic infections.
- Increased death rates leading to low cure rates.
- HIV stigma may lead to inadequate supervision of anti-TB chemotherapy and delay in seeking care by TB suspects.
- Over-diagnosis of sputum smear-negative Pulmonary TB (PTB) (Due to difficulties in diagnosis).
- High default rates because of adverse drug reactions.
- In a developing country like India, the potential extra burden of new TB cases attributable to HIV could overwhelm budgets and support services, as has already happened in countries most heavily affected by the HIV epidemic.

Impact of TB on AIDS Control programme

- Increased case load of active TB disease among PLWHA (People Living with HIV/AIDS)
- TB accelerates the progression of HIV related immunosuppression
- Increased morbidity and mortality from TB among PLWHA
- Difficulties in diagnosing TB in PLWHA due to atypical clinical presentation of TB
- Increased burden on HIV services

The number of people having dual infection with HIV and TB has markedly risen globally. In 2000, the revised estimates for global TB/HIV indicate that 9% of the total 83 lakh new cases are attributable to HIV. Of the 18 lakh deaths from TB, 12% were attributable to HIV. Amongst the AIDS cases reported so far in India, more than 50% had developed TB. It is estimated by WHO that about 5% of the adult TB cases are HIV positive.

EXERCISE

1. **What is the effect of HIV infection on the status of TB infection/disease?**

2. **What is the effect of TB disease on HIV infection?**

3. **What is the effect of HIV on TB Control programme?**

4. **What is the effect of TB on AIDS Control programme?**

2. Natural history of infection

Tuberculosis

TB infection occurs when a person carries the tubercle bacilli inside the body, but the bacteria are in small number and are dormant. These dormant bacteria are kept under control by the bodies defences and do not cause disease. Many people have TB infection however all are well. TB disease is a state in which one or more organs of the body become diseased as shown by clinical symptoms and signs. This is because the tubercle bacilli in the body have started to multiply and become numerous enough to overcome the body's defences.

Sources of infection

The most important source of infection is the patient with TB of the lung, or pulmonary TB (PTB), and who is coughing. This person is usually sputum smear-positive. Coughing produces tiny infectious droplet nuclei (infectious particles of respiratory secretions usually less than $5^{\mu m}$ in diameter and containing tubercle bacilli). A single cough can produce 3000 droplet nuclei. Droplet nuclei can also be spread into the air by talking, sneezing, spitting and singing, and can remain suspended in the air for long periods. Direct sunlight kills tubercle bacilli in 5 minutes, but they can survive in the dark for long periods. Droplet nuclei are so small that they avoid the defences of the bronchi and penetrate into the terminal alveoli of the lungs, where multiplication and infection begin. Two factors determine an individual's risk of exposure: the concentration of droplet nuclei in contaminated air and the length of time he or she breathes that air.

TB is not transmitted through food and water or by sexual intercourse, blood transfusion, or mosquitoes.

An individual's risk of infection depends on the extent of exposure to droplet nuclei and his or her susceptibility to infection. The risk of infection of a susceptible individual is high with close, prolonged, indoor exposure to a person with sputum smear-positive PTB. The risk of transmission of infection from a person with sputum smear-negative PTB is low, and negligible from someone with extrapulmonary TB (EPTB).

Infection with M. tuberculosis can occur at any age. Once infected with M. Tuberculosis, a person can stay infected for many years, even for life. The vast majority (90%) of people without HIV infection who are infected with M. tuberculosis do not develop TB disease. In these, asymptomatic but infected individuals, the only evidence of infection may be a positive tuberculin skin test. Infected persons can however develop TB disease at any time. The disease can affect most tissues and organs, but especially the lungs. The chance of developing disease is greatest, shortly after infection and steadily lessens as time goes by. Infected infants and young children are at greater risk of developing disease than older people because they have an immature immune system. TB is also more likely to spread from the lungs to other parts of the body in this age group. Children who develop disease usually do so within two years following exposure and infection. Most do not develop disease in childhood but may do so later in life.

Various physical or emotional stresses may trigger progression of infection to disease. The most potent trigger is weakening of immune resistance, especially by HIV infection.

Natural history of untreated TB

Without treatment, by the end of 5 years 50% of PTB patients will be dead, 25% will be healthy (self-cured by a strong immune defence) and 25% will remain ill with chronic infectious TB.

Pathogenesis of TB

Primary infection

Primary infection occurs in people who have not had any previous exposure to tubercle bacilli. Droplet nuclei, which are inhaled into the lungs, are so small that they avoid the mucociliary defences of the bronchi and lodge in the terminal alveoli of the lungs. Infection begins with multiplication of tubercle bacilli in the lungs. The resulting lesion is the Ghon focus. Lymphatic drain the bacilli to the hilar lymph nodes. The Ghon focus and related hilar lymphadenopathy form the primary complex. Bacilli may spread in the blood from the primary complex through out the body. The immune response (delayed hypersensitivity and cellular immunity) develops about 4–6 weeks after the primary infection. The size of the infecting dose of bacilli and the strength of the immune response determine what happens next. In most cases, the immune response stops the multiplication of bacilli. However, a few dormant bacilli may persist. A positive tuberculin skin test would be the only evidence of infection. In a few cases the immune response is not strong enough to prevent multiplication of bacilli, and disease occurs within a few months.

Post-primary TB

Post-primary TB occurs after a latent period of months or years following primary infection. It may occur either by reactivation of the dormant tubercle bacilli acquired from a primary infection or by reinfection. Reactivation means that dormant bacilli persisting in tissues for months or years after primary infection start to multiply. This may be in response to a trigger, such as weakening of the immune system by HIV infection. Reinfection means a repeat infection in a person who has previously had a primary infection. The immune response of the patient results in a pathological lesion that is characteristically localized, often with extensive tissue destruction and cavitations. Post-primary TB usually affects the lungs but can involve any part of the body. The characteristic features of post-primary PTB are the following: extensive lung destruction with cavitations; positive sputum smear; upper lobe involvement; usually no intrathoracic lymphadenopathy. Patients with these lesions are the main transmitters of infection in the community.

Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is the name of the virus that causes AIDS. The

HIV invades selectively the cells which bear the necessary viral receptor on their surfaces. This site is called CD4 antigen. Chief among these cells are white blood cells, the CD4 or T4 –Helper Cells. Infection with HIV leads to destruction of more and more of CD4 cells causing immunodeficiency, which renders the person unable to fight infections and tumours. The micro-organisms which can not produce infection or disease in a person with normally functioning immune system now take full opportunity of the weakened immune system and start producing infections (opportunistic infections) in the person such as tuberculosis, oral candidiasis, Herpes Zoster, Pneumocystis Carinii Pneumonia and cancers like Kaposi's Sarcoma. The course of the disease is marked by increasing levels of viral replication, emergence of more virulent viral strains and progressive destruction of immune system. However, the natural history of HIV infection is changing with better diagnosis, anti-retro-viral (ARV) therapy, and early treatment and prophylaxis of various opportunistic infections.

People infected with HIV remain infectious lifelong. On average, it takes about 7 -10 years for the HIV infected person to develop AIDS. Even during this relatively silent asymptomatic period they are infectious. Some HIV-infected individuals progress more quickly than others to HIV-related disease and AIDS. The rate of progression depends on the virus and host characteristics. Virus characteristics include serotype and strain: HIV-1 and certain HIV strains may cause faster progression. Host characteristics that may cause faster progression include age less than 5 years, age more than 40 years, concurrent infections and possibly genetic factors.

Natural history of HIV infection

Acute HIV infection

Acute HIV infection is also called "primary HIV infection" or "acute seroconversion syndrome". Between 40% and 90% of new HIV infections are associated with symptomatic illness. The time from exposure to onset of symptoms is usually 2–4 weeks. Some people present with a glandular-fever -like illness (fever, rash, arthralgia and lymphadenopathy). Occasionally acute neurological syndromes may occur, which are often self-limiting. These include aseptic meningitis, peripheral neuropathy, encephalitis and myelitis. A severe illness may predict a worse long-term outcome. Most symptomatic patients seek medical help. However, the diagnosis is infrequently made, for several possible reasons. First, the clinician may not consider HIV infection. Secondly, the nonspecific clinical features may be mistaken for another cause, e.g. malaria. Thirdly, standard serological tests at this stage are usually negative. Serological tests first become positive about 4–12 weeks after infection, with over 95% of patients "seroconverting" within 6 months of HIV transmission. The diagnosis of acute HIV infection is best established by demonstration of HIV RNA in plasma.

Asymptomatic HIV infection

In adults, there is a long, variable, latent period from HIV infection to the onset of HIV-related disease and AIDS.A person infected with HIV may be asymptomatic for 10 years or more. The vast majority of HIV-infected children are infected in the perinatal period. The period of asymptomatic infection is shorter in children than in adults. A few infants become ill in the first few weeks of life. Most children start to become ill before 2 years of age. A few children remain well for several years.

Persistent generalized lymphadenopathy (PGL)

PGL is defined as enlarged lymph nodes involving at least two sites other than inguinal nodes. At this time, the lymph tissue serves as the major reservoir for HIV. PGL occurs in about one-third of otherwise healthy HIV-infected people. The enlarged lymph nodes are persistent, generalized, symmetrical, and non-tender. PGL has no particular prognostic significance.

Progression from HIV infection to HIV-related disease and AIDS
Almost all (if not all) HIV-infected people, if untreated, will ultimately develop HIV-related disease and AIDS. Some HIV-infected individuals progress more quickly than others to HIV-related disease and AIDS. The rate of progression depends on virus and host characteristics. Virus characteristics include type and subtype: HIV-1 and certain HIV-1 subtypes may cause faster progression. Host characteristics that may cause faster progression include: age less than 5 years; age more than 40 years; concurrent infections; and genetic factors.

Advancing immunosuppression
As HIV infection progresses and immunity declines, patients become more susceptible to infections. These include TB, pneumonia, recurrent fungal infections of the skin and oropharynx, and herpes zoster. These infections can occur at any stage of progression of HIV infection and immunosuppression. Some patients may develop constitutional symptoms (unexplained fever and weight loss), previously known as "AIDS-related complex" (ARC). Some patients develop chronic diarrhoea with weight loss, often known as "slim disease".
Certain specific HIV-related diseases occur predominantly with severe immunosuppression. These include certain opportunistic infections (e.g. cryptococcal meningitis) and certain tumours (e.g. Kaposi sarcoma). At this late stage, unless patients receive specific therapy for HIV infection, they usually die in less than 2 years. This late stage is sometimes known as "full-blown AIDS".

One can keep tract of the progress of the infection by physical examination and two laboratory tests.

- First test is the “CD4 Cell count” in the blood. The normal CD4 count is 700-1300 per mm^3 of blood. In a person with HIV the CD4 count may decrease on an average by 40-80 cells per mm^3 per year. Most people do not develop symptoms until the CD4 count is below 300. CD4 cell count below 200 is diagnostic of AIDS.
- A second method of keeping tract of infection is through blood count. The blood count must be lowered severely before symptoms occur. Thus, there may be leucopenia, thrombocytopenia, altered serum transaminase level and polyclonal activation of immune cells.

Spectrum of Opportunistic Infections

AIDS is the late stage of HIV infection which is marked by the appearance of a variety of illnesses, labelled as opportunistic infections (OIs). *Mycobacterium tuberculosis* is the commonest opportunistic infection seen in India and other developing countries of Africa, South and Southeast Asia. Atypical mycobacteria (mycobacterium avium intracellular), which is commonly seen in AIDS cases in the Western hemisphere, is uncommon in India. The fact that persons co-infected with HIV and TB are six times

more likely to develop active TB, may cause an even further increase in the number of TB cases. Details of TB/HIV co infection are discussed separately.

Oral and oesophageal candidiasis is the second most common opportunistic infection reported from India, seen in about 58% of cases. Oral candidiasis is characterised by the presence of whitish, grey-white, or light brown plaques on mucosa. These plaques are located on the palatal or buccal mucosa and can be easily removed. Candidiasis can spread to the oesophagus and cause difficulty (dysphagia) and/or pain (odynophgia) on swallowing.

Chronic diarrhoea is a common manifestation in AIDS cases. The most common causative pathogens are Cryptosporidium, (found in 35% of cases), Giardia, E. histolytica and Strongyloides.

Some of the other OIs seen in India are Herpes zoster, Toxoplasmosis, Pneumocystis Carinii Pneumonia (PCP), CMV retinitis and Cryptococcal meningitis. Certain infections like Herpes simplex, coccidiomycosis, lymphoid interstitial pneumonia (LIP), and oral hairy leukoplakia are also reported. Certain newer infections like Penicillium marneffei are being reported quite frequently from north-eastern part of our country.

Malignancies such as Kaposi's sarcoma and Non-Hodgkin's lymphoma are also reported among PLWHA. However, Kaposi's sarcoma is not reported frequently in India.

The occurrence of the various opportunistic infections broadly correlates with CD4 lymphocyte count in the majority of cases; For example, TB tends to develop when the CD4 Count has just started declining and is between 200-500/cmm. Candidiasis also appears at around the same time and may be the first indication of immune deficiency. PCP occurs when CD4 count falls below 200/cmm, CMV and Cryptococcal infections occur when the CD4 count has fallen below 150/cmm.

As regards the presenting signs and symptoms of AIDS cases, fever is seen in 88%, weight loss in 89%, chronic diarrhoea in 86%, cough in 68%, asthenia in 72% and lymphadenopathy in 28%.

The Clinical staging for HIV infection and HIV-related disease is given at Annex1.

It is important to distinguish between being infected with HIV and having AIDS. People infected with HIV may take 7-10 years to progress to AIDS stage.

EXERCISE:

1. **What are the routes through which TB may be transmitted?**

2. **What are the common opportunistic infections seen in HIV/AIDS?**

3. **How does CD4 count co-relate with the progression of HIV disease?**

3. Programme objectives

Revised National Tuberculosis Control Programme

In developing countries, such as India, the fight against TB can be successfully carried out only within the setting of a National TB Control Programme. The programme is integrated with the country's general health services.

The goal of The Revised National Tuberculosis Control Programme (RNTCP) is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem. The goal is achieved through the programme's objectives.

The objectives of RNTCP are:

- To achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear positive) cases, and
- To achieve and maintain detection of at least 70% of such cases existing in the population

However, additional efforts towards meeting the objective for case detection should be attempted once the cure rate of 85% is achieved among new sputum smear positive patients. Despite the focus on the new sputum smear positive patients, RNTCP detects and treats all forms of TB, including smear negative and extra-pulmonary TB.

The RNTCP is based on the WHO-recommended DOTS (Directly Observed Treatment, Short course) strategy. DOTS is a systematic strategy which has 5 components:

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of good quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

Political and administrative commitment: Since TB can be cured and the epidemic reversed, it warrants the topmost priority, which has been accorded by the Government of India. This priority must be continued and expanded at state, district, and local levels.

Good quality diagnosis: Case detection is done primarily by sputum microscopy among chest symptomatic patients attending health facilities. This policy allows effective diagnosis and appropriate prioritization of efforts.

Good quality drugs: An uninterrupted supply of good quality anti-TB drugs must be available. In RNTCP, a box of medications for the entire course of treatment is earmarked for every patient registered, ensuring the availability of the full course of treatment to the patient the moment he/she is diagnosed to be suffering from TB disease. Hence, in RNTCP the treatment never fails on account of non-availability of medicines.

Short-course chemotherapy given in a programme of direct observation: RNTCP uses the best anti-TB medications available but unless patients adhere to treatment, it will fail. This is why the heart of the DOTS programme is “directly observed treatment (DOT)” in which a health worker or another trained person who is not a family member, watches the patient swallow the anti-TB medicines in his/her presence.

However, directly observed treatment (DOT) is not just supervised swallowing but a service to the patient. It helps to develop a human bond between the patients and the treatment observer, which increases the probability of the patient completing treatment. With short-course chemotherapy it is easier to prevent drug resistance by using directly observed treatment, and achieve high cure rates.

The DOTS strategy is very important for HIV infected TB patients to promote adherence to therapy which cures TB and improves their quality of life. A worsening of the HIV epidemic could lead to a increase in TB cases. The DOTS strategy can cure HIV infected TB patients and thus reduce mortality and morbidity associated with TB in HIV infected individuals.

Systematic monitoring and accountability: There are two means of monitoring the success of treatment. First, sputum is examined during the course of treatment to monitor the progress and cure of patients. Second, a revised recording and reporting system rigorously monitors and evaluates the outcome of every patient treated at the different levels of the health system, and if any area is not achieving 90% sputum conversion rate at the end of 3 months and 85% cure rate, supervision is intensified. For effective programme implementation, having well-trained and motivated staff is essential.

RNTCP shifts the responsibility for cure from the patient to the health system. When cure rates are high, health facilities will attract more patients due to the good results obtained in the cases already treated.

National AIDS Control Programme

The second phase of the National AIDS Control programme commenced in November, 1999 and has been extended up to March, 2006. The NACP-II has two key project objectives:

- To reduce the growth of HIV infection in India; and
- To strengthen India’s capacity to respond to HIV/AIDS

NACP has the following main services/ activities:

- Voluntary Counselling and Testing Centre (VCTC): VCTC provides an opportunity for a person to learn about his/her HIV status in a confidential manner. The individual undergoes counselling enabling the person to make an informed decision about HIV testing. VCTC are located generally at district level hospital, and medical colleges.

- Prevention of Parent to Child Transmission (PPTCT): Prevention of HIV transmission from parent to child is done through the PPTCT centres, located in antenatal clinics of medical college hospitals and district hospitals. PPTCT centres provide counselling services, HIV testing and administration of the anti-retroviral drug Nevirapine to the HIV infected mother at the time of delivery and to the newborn within 72 hours of birth.

- Targeted Interventions: Targeted interventions aim to interrupt transmission of HIV among highly vulnerable populations like sex workers and their clients, truckers, migrants, men who have sex with men, street children, injecting drug users, etc.

- Sexually Transmitted Infections (STI) Management services: On account of the strong co-relation between HIV and STI, the treatment, control and prevention of STI is a key strategy. STI Clinics provide consultations, investigation, treatment & some counselling to the clinic attendees. These clinics are located in almost all district hospitals and all Medical colleges

- Blood Safety: For ensuring blood safety, all the blood samples are screened for HIV before transfusion.

- Prophylaxis and Treatment of Opportunistic Infections. (Discussed in chapter 5)

- Provision of Anti Retroviral Therapy. (Discussed in chapter 5)

- Post Exposure Prophylaxis (PEP): For the management of needle stick injury, drugs for PEP are provided (Details in separate chapter) free of cost to all health care providers and available at all Government hospitals and Medical colleges.

- Care and Support Centres: These centres act as a bridge between hospital and home care. These centres provide psychological support for HIV infected persons and his family; assist the HIV infected persons to avail of existing health care facilities; helping the patients and the families to prepare for coping with life after HIV. They render advice on proper care and nutrition, helping them to be as independent as possible, etc. Providing advice and assistance for legal matters is also one of the areas in which drop-in care centres are active. There are two types of Care and Support Centres:
    - Drop-in Centres
    - Community Care Centres, which in addition, provide residential/ institutional care, medical treatment
- IEC and Social Mobilisation

The outcomes envisaged in the second National AIDS Control Project are to keep the HIV seroprevalence below 5 percent of the adult population in high prevalence states, below 3 percent in the moderate prevalence states, and below one percent in the low prevalence states

TB- HIV Programme Coordination

The overall goal is reduction in TB related morbidity in people living with HIV/AIDS while preventing further spread of HIV and TB through collaboration between NACP and RNTCP.

The objectives of TB-HIV co-ordination programme are:

- To reduce the burden of TB among the PLWHA
- To decrease the burden of HIV in TB patients

Key areas for coordination include:

1. Commitment to TB/HIV coordination, through sensitization;
2. Service delivery coordination and cross-referral, through training, provision of additional services, and coordination at the local level;
3. Optimal and comprehensive use of the community reach of both programmes through the sensitisation and involvement of NGOs and private practitioners who are involved in both programmes;
4. Infection control to prevent spread of TB in facilities caring for HIV-infected persons, and to prevent spread of HIV through safe injection practices in the RNTCP;
5. Coordination for the dissemination of IEC material of individual programmes
6. Monitoring and evaluation at district, State and National level to assess the co-ordination between both these programmes. Co-ordinators would be posted in all the states identified for implementing the TB/HIV action plan.

EXERCISE:

1. What are the main objectives and components of RNTCP?

2. What are the main objectives and activities of NACP?

3. What is the objective of TB-HIV co-ordination and what are the main areas of coordination?

4. Diagnosis

Diagnosis of HIV

As access to antiretroviral treatment is scaled up in the country, there is an opportunity to simultaneously expand access to HIV prevention, which continues to be the mainstay of the response to the HIV epidemic. Without effective HIV prevention, there will be an ever increasing number of people who will require HIV treatment making the scale-up difficult to sustain. Among the interventions which play a pivotal role both in treatment and in prevention, voluntary HIV testing and counselling stands out as paramount. The conditions of the **'3 Cs**', advocated since the HIV test became available in 1985, continue to be the principles for conducting of HIV testing of individuals.

Such testing of individuals must be:

- **Confidential**
- Accompanied by **counselling**
- Only be conducted with informed **consent**, meaning that it is both informed and voluntary. All suspected cases of HIV/AIDS should be encouraged to go to the Voluntary Counselling and testing centres (VCTCs) for confirmation of diagnosis and necessary counselling.

Diagnosis of HIV infection in TB patients:

When a clinician is treating a patient with TB disease the following are the situations under which s/he should be alert to the possibility of HIV co-infection:

- Patients with TB giving history of high risk behaviour for HIV.
- Patients with opportunistic infections like coexistent oral/oesophageal candidiasis, herpes zoster especially multidermatomal, recurrent pneumonias, Pneumocystis Carinii pneumonia, oral hairy leukoplakia, present or past genital ulcerations, Kaposi's sarcoma or generalized dermatitis.

Patients with TB suspected to have HIV co-infection should be counselled by the attending physician and referred to the VCTC. The same policy of HIV testing which is applied to people without TB should be followed. A well coordinated HIV/AIDS Control Programme and Revised National TB Control Programmes at each level is the cornerstone for the effective management of patients with dual TB/HIV co-infection.

Voluntary Counselling and Testing

HIV voluntary counselling and testing (VCT) has been shown to have a role in both HIV prevention and as an entry point to care. It provides people with an opportunity to learn and accept their HIV status in a confidential environment. VCT has become an integral part of HIV prevention programs as it is a relatively cost effective intervention in preventing HIV transmission. As of 2005, there are 804 VCTCs across the country. Along with improving accessibility and availability of HIV testing, it is necessary to improve the counselling services. The guidelines clearly state that no HIV testing is to be undertaken without an informed consent, and pre-test and post-test counselling. HIV

testing services should be designed to address the multiple needs and rights of individuals at risk or already infected. The concept of VCT is based on a more humane and client oriented approach to HIV testing, by moving from HIV testing alone to Voluntary Counselling and Testing where primary emphasis is to reach individuals with effective counselling, condom supplies and peer and community support, rather than focus on HIV testing alone. Such efforts to reduce stigma and discrimination seek to 'normalise' community perceptions of HIV infection and AIDS, and make counselling services available to all who seek them, regardless of their willingness to be tested.

Voluntary HIV counselling and testing is the process by which an individual undergoes counselling enabling him or her to make an informed choice about being tested for HIV. This decision for testing must be the choice of the individual and he or she must be assured that the process will be confidential. However, in concurrence with the Supreme Court decision, partner notification is necessary and this makes it imperative for the attending physician to disclose the HIV status to the spouse or sexual partner of the person. In-spite of this, all efforts must be made to counsel the person for voluntary disclosure of HIV status to the spouse or sexual partner.

Benefits of VCT

The potential benefits of VCT are:

- Awareness about HIV, the modes of transmission and methods of personal protection
- Earlier access to care and treatment
- Prevention of HIV related illness
- Emotional Support
- Better ability to cope with HIV related anxiety
- Awareness of safer options for reproduction and infant feeding
- Motivation for behavioural change
- Safer blood donation
- Improved health status through good nutritional advice

HIV testing

The diagnosis of HIV testing has traditionally been made by detecting antibodies against HIV. There has been rapid evolution in diagnostic technology since the first HIV antibody tests became commercially available. Besides ELISA, newer rapid and simple tests are available which are comparable to ELISA on sensitivity and specificity. In addition they are easy to perform in limited resource settings like district hospitals and more cost-effective than ELISA.

The success of the voluntary counselling and testing strategy largely depends on the availability of low cost testing facilities that give results in the shortest possible time. This makes the rapid tests an attractive option where the client can be subjected to a pre-test counselling, test result and post-test counselling in a single day, thereby minimizing both, the inconvenience to the patient and at the same time the loss of patients.

Strategies of HIV testing in India

Because of the enormous risk involved in transmission of HIV through blood, safety of

blood and blood products is of paramount importance. WHO/GOI have evolved strategies to detect HIV infection in different population groups and to fulfil different objectives. The various strategies, so designated, involve the use of categories of tests in various permutations and combinations.

1. ELISA/Simple/Rapid tests (E/R/S) used in strategy I, II & III
2. Supplemental test like Western Blot and Line Immunoassay and used in problem cases e.g in cases of indeterminate/discordant result of E/R/S.

Strategy I: Serum is subjected once to E/R/S for HIV, if negative, the serum is to be considered free of HIV and if positive, the sample is taken as HIV-infected for all practical purposes. This strategy is used for ensuring donation safety (blood/blood products, organ, tissues, sperms etc.). The unit of blood testing reactive (Positive) is discarded. Donor is not informed.

Strategy II: A serum sample is considered negative for HIV if the first ELISA report is so, but if reactive, it is subjected to a second ELISA which utilizes a system different from the first one, it is reported reactive only if the second ELISA confirms the report of the first. This strategy is used for surveillance and for diagnosis only some AIDS indicator disease is present.

Strategy III: It is similar to strategy II, with the added confirmation of a third reactive ELISA test being required for a sample to be reported HIV positive. The test to be utilized for the first ELISA is one with the highest sensitivity and for the second and third ELISAs, tests with the highest specificity are to be used.

Strategy II & III are to be used for diagnosis for HIV infection. Strategy III is used to diagnose HIV infection in asymptomatic individuals indulging in high risk behaviour.

When to declare a person HIV positive?

In voluntary counselling and testing centres, the following procedures should be practiced-

- The serum sample is first tested with a Rapid test.
- Any reactive sample is retested using a different assay
- Serum found reactive on the second assay is repeated for the third test.
- Serum found reactive on all the three tests is considered HIV antibody positive. .
- Indeterminant result, i.e. serum that remains discordant in the second assay or reactive on the 1st and 2nd test but non-reactive on the 3rd test is considered to be indeterminate. In such cases, the person must be asked to report for a re-test after a minimum period of 2 weeks and if still indeterminate may be subjected to a confirmatory assay like Western Blot or Line Immunoassay. In some cases, the person may be followed up for 3, 6 or 9 months

Counselling Process

The VCT process consists of the following:

- Pre test Counselling
- Post test counselling
- Follow-up counselling

The contents and approach of each type of counselling may vary and should be adapted to the needs of the clients and may be different for individuals, couples, families, men, women etc. Contents and approaches may also reflect the context of intervention, e.g. counselling associated with specific interventions like PPTCT. Counselling as part of VCT ideally involves at least two sessions (pre-test and post-test counselling). More sessions can be offered before and after the test or during the time the client is waiting for the test result.

1) Pre test Counselling

HIV counselling should be offered before taking an HIV test. In this process, the counsellor prepares the client for the test by explaining what an HIV test is and also by correcting myths and misinformation about HIV/AIDS. In certain situations like Ante Natal Clinic, this counselling can also be provided to groups to reduce costs and can be backed up by providing printed information. However, group counselling must be followed by individual sessions before the HIV test is undertaken. Persons refusing pre-test counselling should not be prevented from taking a voluntary HIV test. But informed consent from the person being tested is usually the minimum requirement before an HIV test.

2) Post test Counselling

Post-test counselling should always be offered. The idea is to help clients to understand their test results and initiate adaptation to their sero-positive or sero-negative status. When the test is sero-positive, the counsellor tells the client the result clearly and sensitively, providing emotional support and discussing how he/she will cope with the information. The counsellor must ensure that the person has immediate emotional support from a partner, relative or friend. Sharing one's HIV status with a sexual partner is important to enable the use of safer sexual practices and should be encouraged.

Counselling is also important when the test result is negative. While the client is likely to feel relieved, the counsellor needs to discuss changes in behaviour that can help the client to stay negative. The window period of HIV testing means that the patient may not be truly negative and the client may be asked to undertake the test again in 3 months time, depending on the history of risk behaviour.

3) Follow-up Counselling

Most clients may require follow-up counselling immediately after post test counselling or anytime between 1 to 5 years following post test counselling. This often coincides with a crisis or change in personal circumstances. VCT services should therefore be flexible

and either be able to provide ongoing counselling or have close links with other organizations for referral like community based organizations, spiritual groups or health facilities.

As part of follow-up counselling, the VCT services should offer the opportunity of ongoing care and support for sero-positive cases and should act as an entry point to medical care. Collaboration and cross referral can ensure that people with HIV receive appropriate medical care, including home care and supportive palliative care.

For counselling of women in antenatal settings for PPTCT, special consideration is given to:

- Counselling about infant feeding.
- Counselling about PPTCT options.
- Family planning counselling.
- Counselling about partner notification.
- Involvement of partner in decision making.
- Information on Care and support services.

A comprehensive manual on Counselling on HIV/AIDS is developed by NACO and counsellors are required to be in tune with the procedures as laid down in this manual.

Confidentiality

Confidentiality may be defined as a protection of personal data and test results to ensure the rights and welfare of the individual from whom such data is collected. This information is not to be furnished under any circumstances to any other person without the individual's explicit consent. However, as stated earlier, this information should be disclosed to the spouse of the person. The VCT services should always preserve individuals' records for confidentiality. Loss of confidentiality may lead to increased stigma and discrimination against HIV positive individuals.

Diagnosis of Tuberculosis

All outpatients with a cough of 3 or more weeks are to be considered as TB suspects. Using the RNTCP laboratory form for sputum examination, the attending medical officer sends the suspects for sputum examination to the nearest Designated Microscopy Centre (DMC).

In the laboratory the patient receives sputum containers with instructions to provide sputum samples, which are then subjected for sputum examination. If the health facility is not a DMC, then the patient should be referred to the nearest DMC or else the patient's sputum is collected and transported to the nearest DMC.

Three sputum samples are collected over two consecutive days:

- Spot sample on the first day;
- One early morning sample on second day; and
- One spot sample on the second day.

Sputum examination and anti-TB treatment are available FREE of charge at all RNTCP facilities.

The MO / health worker / laboratory technician (LT) should instruct the patient for proper sputum collection. If sputum is not collected in a correct manner and the patient has smear-positive pulmonary TB, the diagnosis may be missed, and the patient may continue to spread the infection to others.

The LT should properly label the sputum container by writing the patient's Laboratory Serial Number on the side of the sputum container and not on the lid.

- 3 sputum specimens (spot—morning—spot) should be collected over 2 consecutive days
- Sputum should be at least 2 ml in quantity and preferably mucopurulent
- Sputum samples should be examined as soon as possible, and not later than seven days after collection
- Results of sputum tests should be reported within a day
- Sputum smears are stained with Ziehl-Neelsen staining procedure and examined under the binocular microscope. All RNTCP DMCs are quality assured using the standard RNTCP quality assurance protocol.

More than 10 AFB per oil immersion field	**Pos**	**3+**	**20**
1-10 AFB per oil immersion field	**Pos**	**2+**	**50**
10-99 AFB per 100 oil immersion fields	**Pos**	**1+**	**100**
1-9 AFB per 100 oil immersion fields	**Pos**	**Scanty-B***	**100**
No AFB in 100 oil immersion fields	**Neg**		**100**

The above table describes how to enter the results and grading in the grading column of the form according to the number of acid fast bacilli (AFB) seen while examining the slide:
*Record actual number of bacilli seen in 100 fields – e.g. "Scanty 4"
LTs must write all smear-positive (including scanty) results only in red ink in the TB Laboratory Register.
Grading improves the laboratory technician's attention and facilitates supervision. It also helps to assess the load of disease. Patients who have 3+ or 2+ sputum smear examination results are less likely to convert to smear-negative by the end of the initial intensive phase, although these patients have equally high cure rates.

LTs should have little or no difficulty in reading slides that contain many AFB. However, when there are less than 10 AFB per 100 oil immersion fields, the laboratory technician may have difficulty in reading the slide. Results should be reported to the treating physician within one day after receipt of specimens.

RNTCP has a standard diagnostic algorithm. If the standard diagnostic algorithm (given below) is not followed, patients not having TB may be treated unnecessarily on the basis of abnormal X-rays.

Patients with three, or at least two out of three, sputum positive smear results are diagnosed by the physician as having pulmonary sputum smear-positive TB. They are further classified as a new or retreatment case based on their previous treatment history as per the RNTCP case definition, and appropriate therapy is prescribed.

Patients with only one positive result out of three sputum smear examinations will be subjected for chest X-ray examination. Patients, who have one smear positive and a chest X-ray compatible with TB, as diagnosed by an MO, are considered to be having pulmonary sputum smear-positive TB.

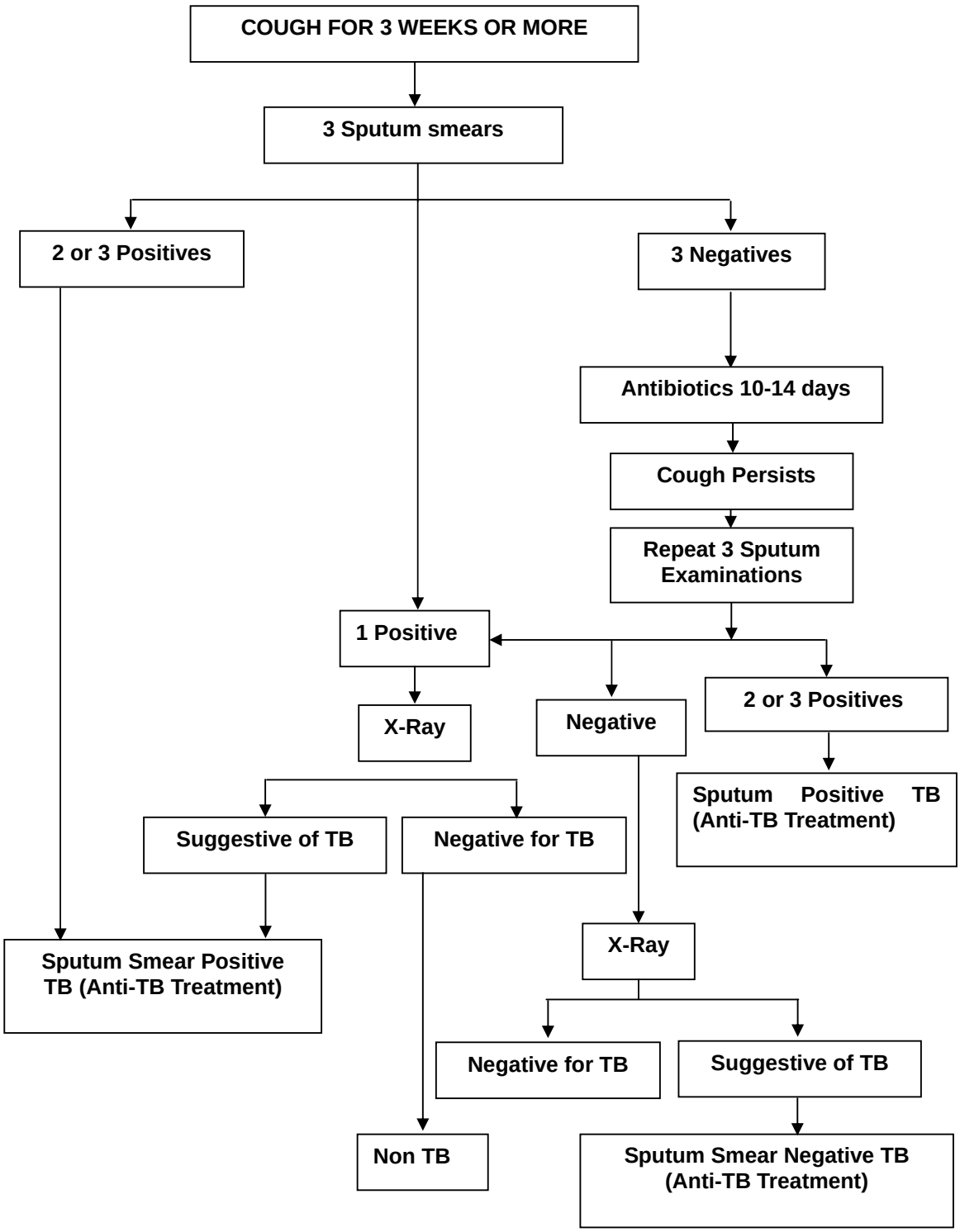
If good diagnostic practices are followed it is expected that among the new pulmonary TB cases, at least 50% will be sputum smear positive cases. Patients in whom all 3 samples are smear negative should be prescribed broad-spectrum antibiotics for 10 -14 days. Care must be taken to prescribe antibiotics (such as Cotrimoxazole, Doxycycline, Amoxycillin) which do not have anti-tuberculous activity. It must be ensured that antibiotics such as fluoroquinolones (Ciprofloxacin, Ofloxacin, etc.), Rifampicin or Streptomycin, which are active against TB, are not used in such cases.

Most patients are likely to improve with a course of antibiotics if they are not suffering from TB. But if symptoms persist, the patient is re-evaluated on the basis of repeat sputum examination and X-ray examination. Thereafter, if in the opinion of the treating physician, patient is having TB, treatment is initiated accordingly.

Patient suspected of having extra-pulmonary TB, and patients who are contacts of sputum smear positive patients, should have their sputum examined for AFB if they have cough of any duration. Procedures undertaken to arrive at the diagnosis of extra pulmonary TB must be mentioned in the Treatment Card.

Patients suspected of having pulmonary TB may be referred by private practitioners to the nearest DMC for diagnosis. In such cases, the MO at the DMC will have 3 sputum smears examined to arrive at a diagnosis and then, if diagnosed to be suffering from TB, would refer the patient to an appropriate peripheral health institution for treatment. Feedback on the patient’s diagnosis and treatment should be provided to the referring physician. Patients diagnosed at large tertiary care hospitals may have come from long distances and in such cases diagnosed TB cases are referred for start of treatment at a peripheral health institution close to the patient’s place of residence. This process is facilitated by the use of standard referral for treatment mechanism

Diagnostic Algorithm for Pulmonary TB



Diagnosis of TB in HIV positive patients

Pulmonary TB is the most common manifestation of TB in adults infected with HIV. The clinical pattern of TB correlates with the patient's immune status. If TB occurs in the early stages of HIV infection when immunity is only partially compromised, the features are typical of adult forms of TB. As immune deficiency advances, HIV-infected patients present with atypical pulmonary disease resembling primary TB or extra-pulmonary or disseminated disease.

Clinical Features

Generally both HIV positive and HIV negative patients manifest similar clinical features, namely cough, fever, night sweats, haemoptysis and weight loss. However among HIV infected patients, cough is reported less frequently, probably because of: (i) weak cough reflex due to debilitated condition of patients in advanced disease, and (ii) absence of cavitations, dominant interstitial/ miliary lesions which do not communicate with the bronchi and less endobronchial irritation. In tertiary care settings induction of sputum with hypertonic saline or bronchoalveolar lavage (BAL) may increase the yield of AFB. Similarly, haemoptysis, which results from caseous necrosis of the bronchial arteries, is less common in HIV- infected patients.

Sputum Microscopy

Sputum microscopy is the cornerstone for the diagnosis of TB even in HIV infected patients. Patients suspected of having TB should have three sputum specimens examined for AFB. Even in HIV-infected patients, pulmonary TB is still the commonest form of TB. HIV-infected, smear positive patients tend to excrete significantly fewer organisms per ml of sputum than HIV-negative patients, which can lead to AFB being missed if the appropriate number of sputum samples as well as high power fields are not examined by microscopy. The sputum negativity tends to increase as the HIV disease and immune suppression progress. The AFB yield could be increased by induction of sputum with hypertonic saline or bronchoalveolar lavage. However both these procedures are not used in routine practice.

Mantoux test

Though useful for measuring the prevalence of tuberculous infection in a community, it has limited value for individual adult diagnosis. Furthermore, with progression of immuno-compromise and decrease in CD4 counts, cutaneous anergy to Mantoux test increases. It can however be used as an adjunct to diagnose childhood TB.

Chest X-Ray

Needed for persons suspected of having TB who are smear- negative and who do not respond to 10-14 days of antibiotics. No radiographic pattern is pathognomic of TB, although the classical hallmarks of the disease are cavitation, apical distribution, pulmonary fibrosis, shrinkage and calcification. HIV infected persons with a relatively well preserved immune function will show these typical features. However, as immune

suppression worsens, chest X-rays more often show atypical findings such as pulmonary infiltrates affecting the lower lobes, intrathoracic lymphadenopathy and sometimes even a normal chest radiograph. Diseases other than TB can cause both the Classical and Atypical chest X-ray findings of TB, and if sputum smears are negative, other conditions have to be considered in the differential diagnosis. Important HIV-related pulmonary diseases which may be confused with pulmonary TB are bacterial pneumonia, Pneumocystic carinii pneumonia, Kaposi's sarcoma, fungal infections and Nocardiosis.

The following table shows how the clinical picture, sputum smear result and chest X-ray appearance often differ in early and late HIV infection:

Features of PTB	**Stage of HIV Infection**	
	Early	**Late**
Clinical Picture	Often resembles post-primary TB	Often resembles primary TB
Sputum Smear Result	Often positive	Often negative
Chest X-Ray Appearance	Often cavities	Often infiltrates with no cavities

Extra-pulmonary TB

Extra-pulmonary disease has been reported in up to 70% of HIV-related TB cases when the CD4 lymphocyte count is less than 100. The main types of extra-pulmonary TB seen in HIV-infected patients are lymphadenopathy, pleural effusion, pericardial effusion, and miliary TB. The definitive diagnosis of extra-pulmonary TB is often difficult because of the scarcity of diagnostic facilities. Presentation of extra-pulmonary TB is generally no different in HIV-infected compared with HIV-negative patients. However, HIV-related TB lymphadenopathy can occasionally be acute and resemble an acute pyogenic bacterial infection. Diagnosis can be made using simple techniques such as fine needle aspiration cytology and histopathological study of biopsied lymph nodes, and examination of direct smears from the cut surface. It is important to differentiate between TB lymphadenopathy and PGL. PGL occurs in about one-third of otherwise healthy HIV-infected people. In PGL, the enlarged lymph nodes are persistent, generalized, symmetrical, and non-tender. In TB meningitis, the CSF may be completely normal in HIV-infected persons. Disseminated TB may be difficult to diagnose. Pericardial TB is rare and may be diagnosed presumptively based on the characteristic balloon-shaped appearance of cardiac shadow on chest X-ray.

Paediatric TB

Similar to adults, pulmonary TB is the most common manifestation of TB in HIV-positive children. The diagnosis of pulmonary TB in children less than 4 years old has always been difficult and HIV-infection further compounds the problem. Mantoux test may be negative in later stages of HIV infection. The management is as per the RNTCP diagnostic algorithm for Paediatric TB (Annex 2.).

Implications of diagnostic difficulties

The advent of HIV has made the diagnosis of TB more difficult, and false diagnosis of TB probably occurs frequently among patients affected by other HIV-related illnesses. These false-positive diagnoses in most cases, however account for a very small proportion of all forms of TB notified, and thus do not negate the huge increases observed in TB notifications in HIV-endemic areas.

Sputum smear remains the gold standard of diagnosis in identifying infectious patients so that transmission can be stopped.

EXERCISE:

1. **List the principle of the 3 C's that must be followed before conducting testing for HIV.**

2. **Enlist the various steps of the diagnostic algorithm for TB patients (adults and paediatric) on the black board/ flip chart?**

3. **When do we declare a patient HIV sero-reactive/ positive?**

5. Treatment services

I. Treatment for Tuberculosis

Once the diagnosis of TB is established, the patient should be treated effectively. The objectives of treatment are:

- To decrease mortality and long-term morbidity by ensuring permanent cure, minimizing relapses and preventing development of drug resistance
- To decrease transmission of infection
- To achieve the above whilst minimizing side effects due to drugs

These objectives are achieved in RNTCP through intermittent (three times a week) treatment regimens given under direct observation for both pulmonary and extra-pulmonary TB patients. Treatment regimens for TB have emerged as a result of controlled clinical trials in India and other parts of the world. It has been proven that thrice-a-week (intermittent) treatment is as effective as daily treatment with lesser side effects.

Originally it was believed that anti-tuberculosis drugs needed to be given every day to maintain drug concentrations continuously at inhibitory levels. However, animal experiments and in vitro studies demonstrated that certain drugs were also effective when the drug concentration dropped temporarily below that level and even after the drug had disappeared completely from the lesion or the medium. In vitro experiments demonstrated that after a culture of mycobacterium tuberculosis is exposed to certain drugs, in certain concentrations, for certain lengths of time, it takes several days (the so called “lag period”) before new growth occurs. This lag period demonstrated by mycobacterium is the basis of intermittent treatment regimens. A series of experiments in an animal model demonstrated that intermittent dosing actually increased the efficacy of treatment. This is presumably because intermittent dosages allow organisms to re-enter the active metabolic phase in which the bactericidal drugs are more effective.

Studies throughout the world and in India have shown that if treatment is not given under direct observation, at least one third of the patients do not take medicines as prescribed. The key principle for treatment of TB worldwide, and in RNTCP, is protocol-based treatment, wherein short-course standardized chemotherapy regimens are given under a programme of direct observation. Before administering treatment, we need to classify the patient as per the following RNTCP definitions:

New: A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month.

Relapse: A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear-positive.

Transferred in: A TB patient who has been received for treatment in a TB Unit, after starting treatment in another unit where s/he has been registered.

Treatment after default: A TB patient who received anti-TB treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear-positive.

Failure: Any TB patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear-positive during treatment.

Chronic: A TB patient who remains smear-positive after completing a re-treatment regimen.

Others: TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.

According to the case definition the patients are categorized into the following categories:

Category I: This category is generally prescribed to new sputum smear-positive patients. They have a high bacillary population with higher chances of having naturally occurring drug resistant mutants. Therefore, four drugs are prescribed during the intensive phase. In addition, seriously ill smear negative and extrapulmonary TB cases are also given Category I treatment. Any new TB patient, pulmonary or extra-pulmonary, who is known to be HIV positive based on voluntary sharing of results and / or history of anti-retroviral therapy, is considered as seriously ill and given Category I treatment. For the purpose of categorization, HIV testing should **NOT** be done. Also, HIV status should **NOT** be revealed / recorded in any RNTCP documents.

Category II: These are cases that have had previous anti-TB treatment. Therefore, the chances of harbouring resistant bacilli are higher. Hence, a 5 drug regimen is prescribed in the intensive phase, and the total duration of treatment is 8 months.

Category III: These are sputum smear-negative cases with a low bacillary population. There is a lower chance for drug-resistant mutants. Therefore, a 3 drug regimen is prescribed.

The RNTCP treatment regimens are as follows:

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill** new sputum smear-negative Seriously ill** new extra-pulmonary	$2H_3R_3Z_3E_3+$ $4H_3R_3$
Category II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default Others***	$2H_3R_3Z_3E_3S_3+$ $1H_3R_3Z_3E_3+$ $5H_3R_3E_3$
Category III	New Sputum smear-negative, not seriously ill New Extra-pulmonary, not seriously ill	$2H_3R_3Z_3$ + $4H_3R_3$

**The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows: H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh 60 kg or more receive additional Rifampicin 150 mg. Patients who are more than 50 years old receive streptomycin 500 mg. Patients who weigh less than 30 kg, receive drugs as per body weight. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.*

*** Seriously ill also includes, any patient, pulmonary or extra-pulmonary who is HIV positive and declares his sero-status to the categorizing/ treating medical officer. For the purpose of categorization, HIV testing should not be done*

**** In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be categorized as 'Others' and given Category II treatment.*

Role of Nutrition in the Treatment of Tuberculosis

In pre-chemotherapeutic era, the treatment of TB was directed mainly at strengthening patient's immunity by nutrition. With the advent of chemotherapy, this has lost its relevance. Pioneering studies in India have shown that diet has no discernible influence on the recovery of the patients in the presence of potent chemotherapeutic drugs

II. Clinical Management of HIV/AIDS

For the clinical management of HIV/AIDS guidelines have been prepared by NACO. Clinical management of HIV/AIDS basically comprises of A) Antiretroviral Therapy and B) Prophylaxis and Management of opportunistic infections (For management of Opportunistic Infections refer to NACO publications or website, www.nacoindia.org).

Antiretroviral Therapy (ART)

The advent of antiretroviral drugs in the late 1980s began a revolution in the management of HIV. The primary aim of antiretroviral treatment strategy is to suppress

viral replication to undetectable levels. Successful outcomes on this parameter restore the balance within the immune system, slow or halt disease progression, prevent drug resistance and improve quality of life. The anti retroviral drugs act on various stages of the life cycle of the virus in the human body and stop the replication of the virus, but do not eradicate the virus out of the human cell. The antiretroviral drugs fall into the following five broad categories:

1. Nucleoside Reverse Transcriptase Inhibitors (NRTIs);
2. Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs);
3. Nucleotide Reverse Transcriptase Inhibitors (NtRTIs) and
4. Protease Inhibitors (PIs);
5. Fusion Inhibitors (FIs)

The use of only one or even two drugs in combinations promotes rapid development of resistant strains of HIV and renders the therapy ineffective and is not recommended. Ideal antiretroviral treatment regimen consists of using three drug combinations from these groups. Ideally two drugs from NRTI group and one from NNRTI group or PI group should be included in the regimen. Compelling epidemiological and clinical evidence demonstrates that with strict adherence, the use of three drugs in combination will achieve sustained viral suppression for several years leading to improvement in quality of life and prolongation of life.

WHO recommends adoption of a public health approach to the administration and distribution of antiretroviral therapy. This implies that antiretroviral therapy regimens should be standardized, and that only a single first line, and a limited number of second line regimens should be made available through the public sector for large scale use. Standardization and simplification of ART regimens facilitate the effective implementation of HIV treatment programmes. Effective implementation means maximum benefit for individual patients, with minimum risk of drug resistance.

Presently the following regimens are being provided by the NACO:

1. Stavudine+Lamivudine+Nevirapine, taken as a twice a day (BID) fixed dose combination

Advantages: It is well tolerated in most cases, has few contra-indications and is appropriate for use in women of child bearing age. It has proven efficacy under actual field conditions, is affordable, and is easy to take.

Limitations: Stavudine can have side effects like neuropathy and lipoatrophy. Nevirapine has suspected negative interaction with Rifampicin, has a resistance risk (especially in women receiving Nevirapine–based PPTCT) and can cause skin hypersensitivity and hepatic disorders. It is ineffective for HIV-2 infection.

2. Zidovudine + Lamivudine + Nevirapine taken twice daily in fixed dose combination.

Advantages: largest experience is with Zidovudine use, easy to take, well tolerated. Can be used where Stavudine is contraindicated/ not tolerated.

Limitations: Major potential toxicities with Zidovudine are anaemia and neutropenia. In resource poor settings where anaemia is common, it may be a cause for concern. The

treatment requires regular Haemoglobin monitoring. Zidovudine is slightly more expensive than Stavudine and therefore this combination is also more expensive.

3. Stavudine + Lamivudine + Efavirenz / Zidovudine + Lamivudine + Efavirenz:

Efavirenz (600 mg) one tablet once per day plus Stavudine + Lamivudine OR Zidovudine + Lamivudine as BID fixed dose combination.

Advantages: Can be used with Rifampicin especially for **patients on ATT**.

Limitations: Efavirenz has suspected teratogenicity, and is therefore not indicated in pregnant women. It has certain neuropsychiatric manifestations.

The programme envisages that Efavirenz be used in place of Nevirapine in patients who are on ATT and ART simultaneously or have sensitivity to Nevirapine.

Fixed dose combinations are considered important tools for scaling up in resource-poor, high prevalence settings. They are preferable because they are easy to use and have distribution advantages (procurement and stock management), and effect on adherence and resistance (impossible to take partial dose). As of now Govt. of India is providing first line regimen(s), consisting of following fixed does combination:

i. Stavudine(30mg) + Lamivudine(150mg) + Nevirapine(200 mg)
ii. Stavudine(40mg) + Lamivudine(150mg) + Nevirapine(200 mg)
iii. Stavudine(30mg) + Lamivudine(150mg)
iv. Stavudine(40mg) + Lamivudine(150mg)
v. Zidovudine(300mg) + Lamivudine(150mg)
vi. Nevirapine(200 mg) for lead in dosage and combination with(v)
vii. Efavirenz (600 mg) for single dose

Criteria for starting ARV therapy in adolescents and adults:

Confirmed HIV infection and CD4 testing facility available:

- WHO **clinical state IV** HIV disease irrespective of CD4 counts
- WHO clinical stage III HIV disease, with CD4 cell counts< 350/mm^3
- WHO stage I or II disease with CD4 cell count < 200/ mm^3

Confirmed HIV infection but CD4 testing facility **not** available:

- WHO clinical state IV HIV disease irrespective of total lymphocyte count
- WHO clinical stage III disease irrespective of total lymphocyte count
- WHO stage II disease with total lymphocyte count = or < 1200/ mm^3

Starting Antiretroviral Therapy

(i) Pre-requisites

It is desirable to have certain specific services and facilities before starting ART due to the complexity of the therapy, the need for monitoring and the cost of therapy.

These services include:

1. Access to HIV voluntary counselling and testing services (VCT) and institution of follow up counselling services.
2. Medical services capable of identifying and treating common HIV-related illnesses and opportunistic infections.
3. Reliable laboratory services capable of doing routine laboratory investigations such as complete blood count and bio-chemistry. Access to a referral laboratory capable of doing CD4 lymphocyte count is desirable to monitor therapy.
4. Reliable and affordable access to quality antiretroviral drugs, and drugs to treat opportunistic infections and other related illness.

(ii) Patient education:

It is imperative that following issues are clearly explained to and understood by the patient before ART is instituted

- ART does not cure HIV infection, but prolongs life. Patients must be counselled regarding the risks and benefits of initiating ART 'early' and 'delayed' and it simplications for 'salvage therapy'.
- Treatment is lifelong, is expensive.
- High level of adherence is critical (>95%).
- Drug-drug and food-drug interactions are common.

(iii) Clinical evaluation

Prior to starting therapy, it is essential to have a detailed clinical evaluation, so as to assess the present stage of HIV infection, presence of any Opportunistic Infection (Present or Past) and identifying co-existing medical conditions. The patient should have a detailed physical examination and should undergo investigations like complete blood count, CD4 count (or total lymphocyte count), chest X-Ray, renal and liver function, lipid levels, VDRL, Hepatitis B & C serology, pregnancy testing and urine for routine and microscopic examination.

(iv) Factors to consider while initiating Antiretroviral Therapy:

Some important factors that must be considered while starting ART are:

1. The patients' willingness and readiness to begin therapy;
2. the assessment of adherence potential;
3. The patients' preference regarding pill burden, dosing frequency, and food & fluid considerations;
4. Severity of HIV diseases according to the baseline CD4 cell count, viral load, and presence or history of AIDS-defining conditions;
5. potential adverse drug effects;
6. Co-morbidity or conditions such as tuberculosis, liver disease, depression or mental illness, cardiovascular disease, chemical dependency, pregnancy, and family planning status; and
7. Potential drug interactions with other medications.

Prophylaxis for Opportunistic infection

Antiretroviral therapy is the most effective approach to reduce various opportunistic infections in HIV-infected patients, but should not replace efforts to provide antimicrobial prophylaxis. E.g. Cotrimoxazole reduces the risk of bacterial infections: Pneumocystic carinii pneumonia and toxoplasmosis and is recommended for all patients who meet indications for antiretroviral therapy. In areas with a high prevalence of Cryptococcal disease, Fluconazole prophylaxis could be considered for patients within less than 100 CD4 cells/mm^3. Based on observations in patients in developed countries, patients responding to antiretroviral therapy with a sustained elevation in CD4 cell counts above 200 cells/ mm^3 for 3-6 months may discontinue prophylaxis. INH prophylaxis for Tuberculosis is not recommended in India as discussed later in this chapter.

Immune Reconstitution Syndrome

For many opportunistic infections including TB, there can be a transient worsening of the infection 2-3 weeks after ART initiation. This is referred to as the “immune reconstitution syndrome”. For patients with TB, this syndrome has been reported to occur in as many as 30% of patients in the developed world. The syndrome is characterized by fever, lymphadenopathy, worsening pulmonary lesions (on X-ray examination) and expanding central nervous system (CNS) lesions. These reactions are typically self-limiting, although may require the use of a brief course of corticosteroids to reduce inflammation for sever respiratory or CNS symptoms. Initiation of ART can also unmask previously undiagnosed infections by augmenting the inflammatory response. In general, ART should not be interrupted for immune reconstitution syndromes.

Patients with HIV-related TB may experience a temporary exacerbation of symptoms, signs or radiographic manifestations of TB after beginning anti-TB treatment. This paradoxical reaction in HIV–infected patients with TB is seen as a manifestation of immune reconstitution. This occurs as a result of the simultaneous administration of ART and anti-TB drugs. Signs and symptoms may include high fever lymphadenopathy, expanding central nervous system lesions and worsening of CXR findings.

A thorough evaluation is necessary to exclude other causes, particularly TB treatment failure, before diagnosing a paradoxical reaction. For severe paradoxical reactions due to immune reconstitution, prednisone (1-2mg/kg for 1-2 weeks, then gradually decreasing doses) may help.

III. Treatment of TB in HIV-Infected Patients

Early diagnosis and effective treatment of TB among HIV-infected patients is critical for controlling the disease, minimizing the negative effects of TB on the course of HIV, and interrupting the transmission of TB to other persons in the community. Even in the absence of antiretroviral therapy, proper case management of active TB disease can significantly prolong the lives of HIV positive persons with TB. Delays in the diagnosis of TB have been associated with worse outcomes, so initiation of treatment as soon as TB is suspected is very important.

Anti-TB treatment is the same for HIV-infected persons as it is for HIV-negative TB patients, and all patients should be treated with RNTCP regimens under the DOTS

strategy. All new TB cases known to be HIV positive should be treated with Category I regimen since they are more likely to be seriously ill. The re-treatment cases are to be treated with Category II regimen. RNTCP regimens, if supervised properly are as effective in HIV positive as in HIV negative patients.

Use of Thioacetazone is contraindicated because it is associated with a high risk of severe and sometimes fatal skin reactions in HIV-infected individuals. However, Thioacetazone is not used under RNTCP.

Effectiveness of DOT in TB/HIV

Direct observation of treatment is even more important for HIV-infected TB patients. Self-administration of treatment is associated with higher case fatality rates. Hence DOT strategy that promotes adherence to therapy should be used for all patients with HIV-related TB.

Survival rate with DOTS is significantly higher compared to non-DOTS. Life span increases by an average two years. The case fatality of TB/HIV patients is higher than TB patients without HIV infection. This is partly due to other HIV-related problems like septicaemia, diarrhoea, pneumonia, anaemia, Kaposi's sarcoma, Cryptococcal meningitis etc. Case fatality is less in TB/HIV patients treated with DOTS than with unsupervised treatment.

Although a higher rate of TB relapse has been observed in HIV-infected patients, the relapse rate in HIV-positive TB patients who complete a directly observed Rifampicin containing regimen is still low. Treatment interruptions due to drug reactions and inter-current opportunistic infections are associated with an increased risk of relapse of TB.

Failure to use DOTS in the face of HIV can lead to explosive spread of TB with cases and drug resistance increasing rapidly.

Treatment of TB cases with HIV co-infection:

a. For Outdoor patients:

For out door patients drug supply will be as per RNTCP policies, with supply provided by the DTC so that the patient can receive directly observed treatment from the most conveniently located DOTS centre.

b. For Indoor patients:

- All indoor patients are to be treated with RNTCP regimens;
- Prolongation pouches which contain strips, each of which contains Rifampicin, INH, Ethambutol and Pyrazinamide and are to be used under RNTCP DOTS strategy, will be supplied by RNTCP for these patients;
- The DOTS Centre of the respective Medical College must be informed of the patient's admission at the earliest, to enable seamless transfer of the patient to their respective DOTS Centre on discharge from the Medical college indoor ward;
- All indoor patients treated in this way under RNTCP, should be registered under the local TU in which the hospital is located;
- The drug requirements needed to operationalise this system, to be assessed by the respective DTOs and STOs, and CTD;

- Consideration of a supply of, at maximum, 1 weeks drug supply (i.e. maximum of three doses) on discharge to patients who have commenced RNTCP treatment as indoor cases, to cover intervening period prior to continuation of treatment at their respective DOTS Centre, hence ensuring no interruption in treatment;

c. For patients receiving anti-retroviral treatment:

- Anti-retroviral (ARVs) drugs are effective in reducing viral replication and prolonging life.
- Some of the ARVs have adverse drug interaction with ATT, therefore, appropriate drug choices becomes imperative. NRTIs like Zidovudine (AZT), Didanosine (ddI), Stavudine (d4t), Lamivudine (3TC) and Abacavir can be safely co-administered with anti TB drugs.
- Co-administration of PIs or NNRTIs with Rifampicin is not recommended due to drug interactions. Rifamycins induce cytchrome P-450 and PIs/NNRTIs may induce/inhibit the iso-enzyme resulting in non-reliable serum concentrations of Rifamycins. Rifabutin is a less potent inducer of cytochrome P-450 and thus can be concurrently used with NNRTIs and certain PIs (e.g. Indinavir, Nelfinavir). However, Rifabutin is presently not available in India.
- If a protease inhibitor (PIs) or NNRTI is to be started after giving Rifampicin, then at least two weeks should elapse after the last dose of Rifampicin. This time gap is necessary for reduction of the enzyme inducing activity of Rifampicin prior to commencement of ARVs.
- ATT for patients on ARVs: If a patient already on ART develops active TB, then the antiretroviral therapy (ART) should be suitably modified to be compatible with RNTCP regimens.
- Treatment of TB patients co-infected with HIV cannot be envisaged without Rifampicin. In TB patients co-infected with HIV, treatment should be first administered for TB under the DOTS strategy and if the patient's clinical condition allows, ART should be started after completion of TB treatment. In patients with very low CD4 counts requiring concomitant administration of ART and anti-TB treatment, the ARV regimen should be modified by replacing Nevirapine with Efavirenz. On completion of TB treatment, such patients can be switched back to Nevirapine.
- Efavirenz is contra-indicated in pregnant women due to its teratogenicity. Rifampicin reduces drug exposure to Nevirapine and dose adjustments for Nevirapine co-administered with Rifampicin has not been established

Chemoprophylaxis for TB

Preventive therapy for TB (i.e. treatment for latent TB infection) reduces the risk of development of active TB disease in HIV infected individuals, although the durability of this effect may be limited by high rates of re-infection with TB in high TB burden countries like India.

WHO recommends TB preventive therapy if possible in areas where diagnostic testing, such as chest –X rays, is available to exclude active TB disease and where PPD skin testing is feasible. In such situations, Isoniazid therapy for 6 months in tuberculin skin test reactors could be given after exclusion of active disease.

In India however, INH prophylaxis is not recommended due to:

- Difficulty in excluding active TB disease in those with TB/HIV co-infection
- As the burden of TB is high in India, chemoprophylaxis may not be able to prevent the re-infection
- Widespread use of INH for chemoprophylaxis without a system to ensure adherence to treatment, may contribute to further increase in the INH resistance.
- PPD skin test may not be feasible and is also not reliable in severely immuno-compromised.

AS A POLICY, INH PROPHYLAXIS IS NOT RECOMMENDED IN INDIA

BCG and HIV

WHO and UNICEF recommend that asymptomatic HIV infected children should receive BCG vaccination as per the immunization policies, but should be withheld in a child having symptomatic HIV infection. BCG when given to a symptomatic HIV positive will lead to disseminated BCG disease.

Exercise

1. **What are the benefits of giving DOTS to an HIV infected person?**

2. **Which group of anti-retroviral drugs can be safely administered with Rifampicin?**

3. **What are the indications for giving anti-retroviral drugs simultaneously with anti-TB treatment?**

4. **What is the role of Nutrition in the treatment of TB?**

6. Prevention, biosafety & infection control

Prevention of HIV

In order to understand the ways and means to prevent HIV infection, it is important to understand the various modes of transmission, their efficacies and then understand preventive measures.

The main modes of transmission of HIV identified are:

- Unsafe sexual contact with an HIV-infected partner
- From an HIV infected mother to child
    - Intrauterine or perinatal stage of pregnancy
    - Breast feeding
- Blood borne
    - Injecting drug use
    - Blood and clotting factor transfusions contaminated with HIV
    - Occupational exposure (needle stick injury)
- Organ and tissue donations from an HIV-infected person

HIV transmission through various routes

Exposure route	Efficiency of Transmission (%)	Contribution to the total number of cases (World over) (%)	Contribution to the total number of cases (in India) (%)
Blood transfusion	90-95	5	3
Perinatal	20-40	10	3
Sexual intercourse	0.1 to 1	75	84
Vaginal	----	(60)	
Anal	----	(15)	
Injecting drug use	0.5-1.0	10	3
Needle stick exposure	<0.5	0.1	
Others	----	----	7

Sexual transmission of HIV

All over the world, the maximum transmission and acquisition of HIV is through the sexual route. Unsafe heterosexual and homosexual sexual practices lead to transmission of HIV. Sexual transmission of HIV is a significant but low probability event i.e. the efficiency of transmission through the route is low, though maximum infections (84%) are transmitted/ acquired through this route. This transmission depends on many factors such as-plasma viral load, presence of sexually transmitted infections at the time

of contact, behavioural issues like use of condom, multiple sexual partners, men having sex with men, stage of HIV infection, and circumcision,

The higher the viral load i.e. no. of copies of HIV RNA in plasma, the higher is the risk of HIV transmission from an infected to a non-infected partner. STI's increase the risk of HIV transmission due to breakdown in mucosal barriers, recruitment of activated target cells, enhanced cytokine environment, elevated cervico-vaginal viral load, higher level of seminal HIV-RNA, and recovery of HIV in genital ulcers.

Prevention of HIV transmission through sexual route

Methods to decrease source of infection:

i) Treat STIs;
ii) Decrease genital tract inflammation;
iii) Condom promotion – always use condom and lubrication with penetrative sex;
iv) Celibacy – stop or delay sexual activity;
v) Practice safe non-penetrative sex;
vi) Avoid combining sex with alcohol and drugs;
vii) Discuss sexual issues with partner;
viii) Take personal responsibility for sexual health;
ix) Counsel at risk populations like commercial sex workers, client with multiple sexual partners, immigrant workers, adolescents, etc. about sexual hygiene and health;

Mother to child transmission of HIV

(Through pregnancy and breastfeeding)

The transmission of HIV from infected mother to infant varies between 15-25% in industrialized countries to 25-45% in developing countries in the absence of antiretroviral drug intervention. HIV can be transmitted from mother to child either in-utero, during parturition or post-partum during breastfeeding.

Infants born to a HIV-infected mother can be HIV-exposed but may or may not be HIV infected. Early in-utero transmission of HIV is rare. Evidence indicates that HIV transmission probably occurs during the third trimester of pregnancy. If virological tests (detection of HIV DNA or RNA by PCR and of virus by culture) are positive within 48 hours of birth, the transmission of HIV is considered to have occurred in-utero. If the virological tests are negative 48 hours after birth but become positive 7 to 90 days after birth, timing of HIV transmission is considered to be intra-partum in the absence of breast-feeding. There is an approximate additional 14% risk of HIV transmission amongst women with established HIV infection and 29% in women who develop primary HIV infection during lactation. Most of lactation associated HIV infections occur after 4-6 months of age of the infant. So, if a child is negative by serological and virological tests initially, and is being breastfed by the HIV-infected mother, the tests have to be repeated to rule our lactation associated transmission of HIV. Recent data indicates that as much as 62% to 85% of perinatal transmission may occur in the intra-partum or neonatal period.

The risk of postpartum infection from breast-feeding is estimated to be approximately 15% in women who are infected with HIV prior to delivery, and 30% in women who acquire HIV following delivery. WHO and health authorities recommend, that if safe, alternative feeding methods are available, HIV-infected women should be advised not to breastfeed.

The risk factors can be related to the mother e.g. high viral load, advanced disease, vaginal delivery, breast-feeding, and to the infant e.g. breast feeding, the obstetric procedures like Invasive procedures, episiotomies etc.

Maternal viral load is an important determinant of HIV transmission to the infant. Other maternal risk factors include advanced HIV disease, decreased CD4 T-cell counts, lower serum vitamin A level in the mother, abnormalities of placenta, vaginal delivery, and premature rupture of membranes and have also been associated with increased transmission of HIV-1 to the baby.

Blood borne transmission of HIV

Blood borne transmission of HIV can occur due to transfusion of an infected unit of blood/blood product, use of unsafe syringes needles and sharps, accidental occupational exposure to infected blood/sharp instruments.

Unsafe injections and transmission of HIV

The likelihood of acquiring a blood borne pathogen depends upon the prevalence of the pathogen in the population and the transmissibility of the pathogens. HIV prevalence is still low in the general population of India, and also the transmissibility of HIV is low as compared to HBV and HCV on account of the low plasma levels of HIV. HBV is ten times more transmissible than HCV and more that 20 times more transmissible than HIV.

Injecting drug use is another situation where HIV is transmitted through contaminated injection equipment. However, this mode of transmission is prevalent in identified groups of population among the World's urban poor. Sexual contact permits the spread of HIV from this group to general population. The risk factors include heterosexual contact with IDUs, sharing injection equipment, where needles and syringes can be rented and reused. Exchange of unprotected sex with multiple partners for money or drugs is another common risk factor among IDUs as it increases the risk of acquiring and transmitting HIV and other STIs. IDUs are mostly a socially marginalized group, which increases the vulnerability to acquire HIV.

Prevention of HIV transmission through injecting drug use

Targeted interventions devised specifically for IDUs keeping in view the risk factors given above can reduce transmission of HIV among IDUs. These strategies include free needle/syringe exchange, harm-reduction, de-addiction, education about HIV transmission and safer sex, voluntary confidential testing and use of disinfectants like

full strength household bleach to decontaminate the injection equipment. However, the above strategies should not be viewed by policy makers as programs encouraging drug use.

Blood and clotting factor transfusions

The first case of transfusion associated AIDS was reported in the US in 1982 in an infant who received an exchange blood transfusion in 1981. Subsequently cases of blood and blood products transfusion/injection associated with HIV/AIDS were reported from all over the world, particularly among the multiply transfused individuals, frequent recipients of blood products e.g. haemophiliacs, etc. Routine testing of donated blood for HIV-antibodies started in 1985 in the industrialized world and in 1989-1990 in India. Transfusion (blood and blood products) associated transmission has been markedly reduced all over the world after the institution of National Blood Transfusion Policies. Prevalence of transfusion associated transmission of HIV reduced from 8.72% (of total HIV infected) in 1992 to 2.7% in 2004 in India (NACO report).

Today the blood supply is safer than it has ever been at any other time in recent history. Though, this mode of transmission of HIV has > 90% efficiency, still the risks associated with blood transfusion today are extremely small. However, the major threats that still remain are in the donation of blood by seronegative donors during an infectious window period which is approximately 3 months for HIV, transmission of hitherto unknown types/subtypes/ variants of HIV not detectable by the existing test systems, and the immuno-silent individuals. This can also be due to laboratory errors in testing and labelling.

Prevention of transfusion associated transmission of HIV

In India, the risk of transfusion-associated transmission of HIV has been minimized (<2.7% or total HIV-infected) by mandatory screening of blood units and blood products. Rational use of blood by clinicians may further enhance the safety of the transfusion process. As far as clotting factors are concerned, efficient methods have been developed to inactivate HIV in pooled plasma and strict quality management of the end product is enforced.

Transmission of HIV through organ and tissue donation

Transplantation of organ/ tissue such as kidney, liver, heart and bone graft, etc., has been implicated in transmission of HIV. NACO has made recommendations to prevent transmission of HIV through this route. These include interviewing the donors and testing their blood for HIV antibodies.

Occupational exposure

The most likely mode of HIV transmission in a health care setting is through a per-cutaneous injury with needles or other sharp instruments contaminated with HIV-infected blood. The percentage of sero-conversions following HIV-contaminated needle-stick accidents is reported to vary between 0.2 and 0.5 %, with a median of 0.3%. Rate of transmission following accidental exposure varies and is determined by the type of instrument causing injury, volume of blood involved in the exposure, period of contact with blood, stage of HIV disease of the source patient viral load, CD4 count and whether PEP is taken within the prescribed time after the accident.

The risk of transmission through muco-cutaneous exposure is 0.05 percent. This low rate of transmission is on account of the low concentration of HIV in the blood (10-100 infectious doses/ml) and low survival of HIV in the environment as compared to HBV and HCV.

With the introduction of PEP by NACO in Government hospitals, such injuries are managed promptly and efficiently. Practice of bio safety measures at all times, safe disposal of waste and institution of PEP, has gone a long way to allay the fears of health care workers as far as occupational transmission of HIV is concerned.

Management of an occupational exposure to HIV

Immediately following an exposure:

- Needle stick injuries and cuts should be washed with soap and water;
- Pricked finger should not be put into mouth reflexly;
- Splashes to the nose, mouth or skin, should be flushed with plenty of water; and
- Eyes should be irrigated with clean water; saline or sterile irrigants.

No scientific evidence exists to show that the use of antiseptics for wound care or squeezing the wound, will reduce the risk of transmission of HIV. However, use of antiseptics is not contraindicated. The use of a caustic agent such as bleach, is however, not recommended.

Post exposure prophylaxis (PEP)

Various animal studies have been done over the years and these have provided encouraging evidence of post exposure chemoprophylactic efficacy. It has also been shown that delaying initiation, shortening the duration or decreasing the antiretroviral dose of PEP, individually or in combination, decreased its prophylactic efficacy.

Also the experience in HIV infected patients has shown that a combination of different anti retroviral agents is superior to mono-therapy regimen. So a combination of two or three drugs in a PEP regimen should be more beneficial than a single drug. One needs to consider toxicity of a combination regimen vis-à-vis risk of transmission.

NRTI combinations being considered for PEP include ZDV and 3TC, 3TC and d4T, and ddI and d4T. In previous regimens ZDV and 3TC were considered as the first line

regimen but emergent resistance to ZDV and 3TC in certain geographical areas, may demand different initial combinations.
The addition of a third drug for PEP in high risk exposures is based on their demonstrated effectiveness in reducing viral burden in HIV infected persons. Previously Indinavir or Nelfinavir were recommended as first choice agents in "expanded PEP regimens". But now with chances of PI resistance, particularly on exposure to blood/blood fluid of patients who are already on triple therapy, Efavirenz (EFV) and Abacavir (ABC) are being considered as alternatives. Nevirapine has not been recommended for use in PEP regimen.

Most occupational exposures do not lead to HIV infection. The chances of possible serious side effects (toxicity) from the drugs used for PEP may be much greater than the chance of HIV infection from such exposures. Both risk of infection and possible side effects of drugs should be carefully considered when deciding whether to give post-exposure prophylaxis or not.

The decision to start PEP is made on the basis of extent and severity of exposure to HIV (Exposure Code) and the HIV status of the source (HIV Status Code) with whose blood/body fluids the exposure has occurred. The Exposure Code and HIV Status Code are then collated to arrive at a decision regarding initiation of PEP. Algorithm for determining exposure code and HIV status code and recommended drugs for PEP are annexed (Annex 5)

Due to the relatively lesser number of HIV infected individuals on triple therapy and an overall low prevalence of HIV in India, presently the above guidelines are being followed. The physicians dealing with HIV medicines may modify these guidelines depending on the source, risk and their experience.

If the source individual cannot be identified or tested, decisions regarding follow up should be based on the exposure risk and whether the source is likely to be a person who is HIV positive. Follow up HIV testing should be available to all workers who are concerned about possible HIV infection through occupational exposure.

Testing and counselling following exposure

The exposed health care worker is tested for HIV immediately following exposure, at six weeks following exposure and again at twelve weeks after the exposure. On all occasions, the health care worker must be provided with pre and post-test counselling. HIV testing should be carried out as per the strategies of testing described elsewhere. A complete blood count, renal function and liver function tests should be done 2 weeks after starting treatment. The health care worker should be advised to report any flu like illness, fever, rash, muscle aches, swollen glands etc. He/She should be advised to refrain from donating blood, semen or organs/tissues, and should abstain from sexual intercourse. In case, sexual intercourse is undertaken, a latex condom should be used consistently. In addition, women health care workers should not breast-feed their infants during the follow up period.

Bio safety Precautions

Transmission of blood borne pathogens in the health care setting

Transmission of these pathogens to health care workers in health care settings predominantly occurs through per cutaneous or mucosal exposure to the blood and body fluids of infected patients. Per cutaneous exposures include needle stick and other sharp injuries and direct inoculation of virus through compromised skin (scratches, abrasions, open lesions and burn wounds). Mucosal exposures include inoculation of virus onto mucosal surfaces of eyes, nose and mouth through accidental splashes. HIV, HBV and HCV cannot penetrate intact skin and are not transmitted through air. There is no report of transmission of these agents from contaminated surfaces, may be because these viruses survive for only a limited period outside the body, and the practice of standard precautions by health care workers.

HIV and the environment

- CDC, USA studies have shown that drying causes a 90-99% reduction in HIV concentration within several hours.
- In tissue culture fluid, cell free HIV could be recovered up to 15 days at room temperature, up to 11 days at 37^0C and up to 1 day if HIV was cell associated.
- No one so far has been HIV infected as a result of contact with an environmental surface.
- HIV cannot reproduce outside the living host except under laboratory conditions and cannot spread or maintain infectiousness outside its host.

Prevention and control of occupational exposure to blood and body fluids

Health care workers in a health care setting must have the correct knowledge about the risk areas, risk procedures in the setting, and take the standard precautions to prevent the acquisition of microbes from patients, environment and fomites. Health care workers must also be vaccinated against HBV. As far as possible, high risk techniques should be replaced by procedures, which have no risk or low risk e.g. giving tablets instead of injections. Health care workers must regard all patients/clients and specimen as potentially infectious, until proved otherwise.

High risk areas in the hospital include: Haemodialysis unit, diagnostic laboratories (pathology, microbiology, biochemistry, etc.), blood bank, emergency room, all surgical disciplines, dentistry and oral surgery, gynaecology and obstetrics and other areas where invasive procedures are being performed, and where there is high frequency of contact with blood, body fluids and tissues, etc.
However, success of universal precautions is not 100%, due to accidents (tearing of glove, needle stick injury through gloves), and cost of materials and educational efforts required. Still, diligent practice of standard precautions goes a long way in minimizing the risk to health care workers.

Various prevention and control measures are:

- Practice of standard blood and body fluid precautions
- Effective use of sterilization and disinfection
- Safe disposal of waste
- Immunization of health care workers
- Education of health care workers

Core elements of standard precautions are:

- Hand washing after each patient contact
- Careful handling of sharps
- Use of personal barriers like gloves, gowns, masks, protective eye and foot covers, etc.
- Practice of safe techniques
- Sterilization and dis-infection
- Education of health care workers
- Safe disposal of waste
- Safe handling of spills
- Immunization against HBV
- Engineering controls

Hand washing is mandatory after direct patient care; immediately after contamination with blood/body fluids; after removing gown / coat and gloves; before eating, drinking and leaving the workplace. Never regard gloves as a substitute to hand washing.

While handling sharp, take care so as to prevent autoinoculation. Do not handle broken glass with bare hands. Do not bend, manipulate, recap, and remove needles from the syringe. Always discard sharp disposable items in a colour coded puncture resistant container. Discard all clipped and cracked glassware in the appropriate container.

Protective barriers are needed to minimize the exposure of skin and mucous membranes to potentially infectious blood and body fluids. Gloves should be worn for all those activities during which contact with blood/body fluids and hazardous material is expected (e.g. per vaginal examination, invasive procedures, disposal of waste etc.) Gowns/coats made of water resistant material should be used whenever splashing of blood is expected during laboratory activities, performing other invasive procedures.

Simple deflector masks and protective eye glasses (zero power) goggles or eye cover should be worn wherever splashing of blood and body fluids is expected e.g. during surgical operations, vaginal deliveries, handling accident patients etc. Eye protection is necessary as HIV can pass through intact conjunctiva.

Health care workers must cover all cuts, scratches, and abrasions unexposed areas with waterproof dressing before providing patient care.

Details of sterilization and disinfection are annexed (Annex 6)

Infection Control measures against TB

It is now mandatory that any Infection Control Plan of the facility should include infection control for TB as well as HIV. Broadly, infection control needs to be addressed at three different levels: administrative, environmental and personal.

Administrative control normally relies on the extent of complete implementation of RNTCP diagnostic and treatment guidelines in the health care facility. The infection control plan should include the following:

- Giving priority for patients with cough for clinical and laboratory investigations for early detection of smear-positive pulmonary TB patients;
- Reducing delay in starting appropriate RNTCP treatment once diagnosed; and
- Avoiding unnecessary admission for inpatient care

Sputum collection should ideally be done outside the facility and away from other people. It should not be done in closed areas such as toilets or in ill-ventilated rooms. Processing specimens for smear microscopy (after sputum collection) has not been documented to cause any increased risk to laboratory personnel. However, TB suspects amongst health care workers should be subjected to screening procedures.

Second priority is environmental control, which is used to reduce the generation and concentration of droplet nuclei in the air in high-risk areas. High-risk areas that increase transmission include exposure in relatively small, enclosed rooms in health facilities, which lack adequate cross ventilation in the form of open windows and doors to “clean” the environment through dilution or removal of infectious droplet nuclei. Hence, the IC plan should also include educating the patients regarding cough hygiene e.g. covering the face while coughing and avoiding indiscriminate spitting, frequent identification of risk areas within the facility, and providing good cross-ventilation to the area.

Wearing of masks for personal protection does not protect the person who is wearing the mask from inhaling the droplet aerosols. Hence this is not recommended as a means to prevent hospital infection. As mentioned above, early identification and prompt initiation of RNTCP treatment under direct observation would protect all health care workers from hospital TB infection.

An Infection Control plan for TB may include precautions to be observed for HIV, in addition to that observed for TB, especially when streptomycin injections are being provided. Disposable/ adequately sterilized needles and syringes should be used for streptomycin injection. Following the streptomycin injection, the needles should be destroyed using needle cutters/ destroyers wherever available. Needles and syringes should be then disposed following the prevailing hospital waste management systems.

There is the risk of transmission of TB infection occurring in health care facilities and congregate settings where people with TB and HIV are frequently crowded together and when patients remain undiagnosed and untreated for TB. Such a situation should be generally avoided.

This may be curtailed to a large extent by early diagnosis and immediate initiation and adherence to RNTCP treatment regimens. This prompt and timely action will make infectious TB patients rapidly non-infectious.

Exercise

1. **What steps are to be taken when a person has been exposed to a potentially infectious source (of HIV)?**

2. **What are the various modes of transmission of HIV?**

3. **How can we prevent the transmission of HIV infection from mother to child?**

4. **Please enlist the various components of Universal Precautions**

7. Counselling a TB/HIV patient

An HIV positive TB patient needs to be counselled on the various aspects of both TB and HIV some of which are enlisted below:

- What is TB?

TB is a disease that can affect any part of the body except hair and nails, and is completely curable if treatment is taken appropriately.

- Modes of spread of TB

TB is an airborne infection. A sputum positive patient discharges the bacilli in his/her cough and spreads the infection to others

- Treatment of TB

Diagnostic facilities and treatment facilities are available at all the government health centres free of cost.

- Necessity of doing sputum smear examination

Three sputum smear examination are necessary for diagnosis of TB. Even after the start of treatment, follow up sputum examinations need to be done every two months till the end of the treatment.

- Necessity of taking treatment

TB can only be cured by taking complete and regular treatment.

- Completion of treatment

Even though patient starts feeling better after taking anti-TB treatment for few months, he should complete the full course so as to be completely cured of TB

- Contact screening

Any contact of sputum positive patient with chest symptoms of any duration should be evaluated for TB.

- Sputum disposal by patient

Avoid indiscriminate spitting

- What is HIV/AIDS?

AIDS is a life threatening condition caused by Human Immuno–deficiency Virus (HIV)

- Modes of spread

More than 80% of the HIV infections are acquired through sexual intercourse with an infected person. Abstinence, single mutually faithful sexual partner and use of condom will help to prevent the spread of HIV infection.

- Maintaining good immune system, by taking a nutritious diet will help to delay the onset of opportunistic infections.

- Anti-retroviral therapy

Anti-retroviral therapy prolongs life and delays the onset of opportunistic infections. Some of the anti-retroviral drugs cannot be concomitantly given with Rifampicin and therefore may be necessary to withhold anti-retroviral drugs till the completion of TB treatment.

8. Guidelines for operationalisation of VCTC-RNTCP cross-referral linkages

Service linkages between VCTC and RNTCP diagnostic and treatment centres are the most important area of co-ordination between the HIV/AIDS and TB Control programme. RNTCP visualizes VCTC as a PHI referring TB suspects irrespective of their sero-status. VCTC's will identify and refer suspected TB cases to the RNTCP Designated Microscopy Centres. Whereas Designated Microscopy Centres/ OPD/ wards may refer TB patients for counselling and diagnosis of HIV infection, they could also refer known HIV positive TB patients to the VCTC for Counselling.

Steps for Operationalisation

- Ensure that the VCTC, DMC and DOT centre are in the same campus. In case they are not in the same campus, establish referral linkages between them
- Ensure that all the VCTC and RNTCP staff, including the LT of the DMCs and VCTC, are trained in TB/HIV
- Provide RNTCP Laboratory Forms of sputum examination for referral of patients from VCTC to RNTCP DMCs
- Provide a DMC and DOT centres directory to all the VCTCs
- Ensure posters on TB are displayed at the VCTC's and provide any other IEC material on TB that is available for distribution to clients
- Confidentiality of HIV status must be ensured at all levels by all staff. Remember that the HIV status of a patient should not be mentioned in the Treatment card, TB lab Register or any other document. Do not use any symbols/codes for identification of HIV positive persons
- The VCTC Counsellors are to visit the DMCs, and the STSs are to visit the VCTCs to follow-up on referred cases.
- Monthly RNTCP Review meetings are to be attended by the VCTC staff.
- State TB Officer, State VCTC Programme Officer, District TB Officer and District Nodal Officers (HIV/AIDS) to review TB/HIV co-ordination activities during their periodic field visits.

There are two types of Referrals: VCTC to RNTCP and RNTCP to VCTC

Referral of Persons from VCTC to RNTCP

The Process at VCTC

VCTC Counsellors will identify persons with symptoms suggestive of TB disease amongst the clients. The Counsellor will ask each and every client for history of cough for more than three weeks and other associated symptoms of TB. These patients depending on their symptoms will be referred for appropriate investigation. Patients, irrespective of their serostatus, having cough will be referred to Designated Microscopy

Centre (DMC) for sputum examinations and in case of symptoms of extrapulmonary TB, the patient should be referred to the appropriate doctor. The RNTCP sputum examination form will be filled in by the Counsellor. On the sputum examination form, the Counsellor should fill in all the required details including the name of VCTC, and take special care in obtaining and recording correct residential address. The counsellor will not mention the HIV status of patient on the form or elsewhere, but shall encourage the patient to disclose his HIV status (if known) to the treating physician, in the interest of better case management. The sputum examination form is given to the patient with specific instructions on the location and timings of the DMC. The Counsellor should make a detailed note of the referral in the Counselling Register.

The counsellor should impart information / counselling on TB to all VCTC clients and should document the same in the counselling register, irrespective of whether they have signs or symptoms of TB or not. Either a column can be added in the Counselling register to document the information on persons who received information / counselling on TB or record it in the 'Remarks column' of Counselling Register. During counselling, encourage voluntary disclosure of HIV status by the client to the treating physician in those referred.

The Process at Designated Microscopy Centre

Once the patient reaches the Designated Microscopy Centre, the patient will undergo the same process as any other TB suspect, i.e. the diagnostic algorithm of RNTCP will be followed. The Laboratory Technician will enter the details of the patient, including correct residential address, in the TB Laboratory Register and clearly mention the name of VCTC as the referring unit in TB laboratory register. After all the three sputum examinations are done, the results of the test are given to the patient. Patient will go to the Medical Officer, who will decide on further management.

In case of Extrapulmonary TB, the VCTC will refer the patient to the Medical Officer, who will further refer the patient for necessary investigations. After obtaining the test results, the Medical Officer will decide further course of management.

If the patient is having TB (Pulmonary or Extrapulmonary TB), treatment categorization is done as per the RNTCP treatment algorithm. Known HIV positive persons, diagnosed with TB disease for the first time (new TB cases) will receive RNTCP Category I regimen whereas retreatment TB cases will receive Category II regimen. Voluntary disclosure of the HIV status by the client should be encouraged. Based on patient's area of residence, these patients are referred for treatment to the nearest DOT centre. A home visit is done to confirm the patient's address. Once the address verification is over and the patient is convinced to take DOTS for the required duration, the treatment is started. Patient's treatment card is made. Once the patient is started on treatment, the Senior Treatment Supervisor (STS) will enter the patient's information in the TB register and give a TB number, which is mentioned in the treatment card. In cases of referral for treatment to another district / TU, special care must be taken to obtain a feedback from the receiving district / TU about the start of treatment. STS and VCTC counsellor will coordinate to check how many of the referred patients did reach DMC and record the outcome of the referral.

Please note that HIV **status of the person should NEVER be mentioned** in the TB treatment card, TB Register or any other RNTCP document. Neither should any symbol be used to identify HIV infected TB patients. No separate record is to be maintained for recording the information on TB/HIV patients.

Recording Information on TB Status of Persons Referred by VCTC

If the patient comes back to VCTC after attending the TB OPD, the information regarding the diagnosis should be recorded in to the Counselling Register. For the remaining patients, at the end of the next month, when the information about the TB suspects referred from VCTC is provided in the Line-List by STS, this information is transferred onto the Counselling Register.

Referral of TB Patients to VCTC for HIV-Testing

Process at RNTCP Unit

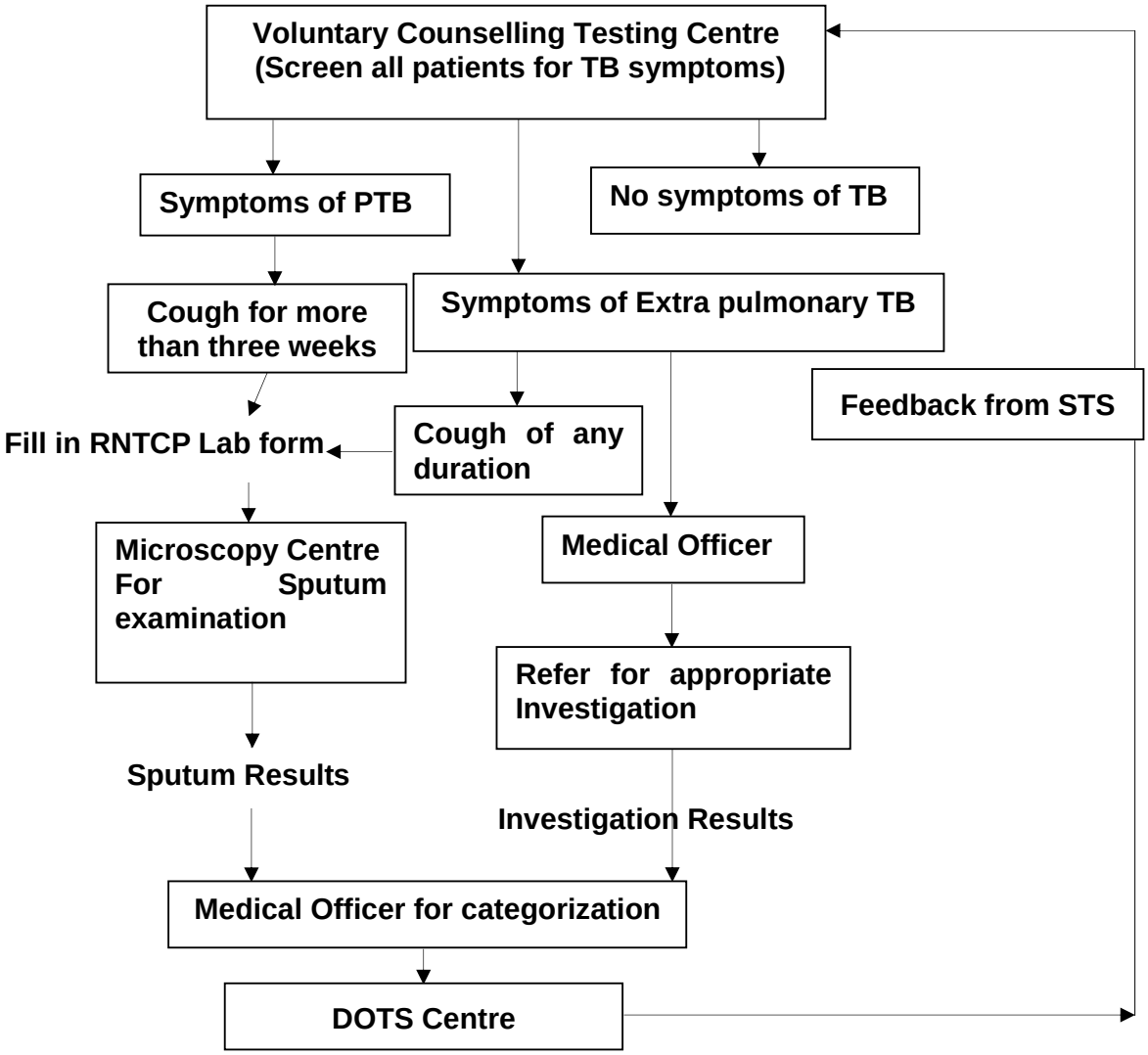
Diagnosed TB patients who have symptoms/signs suggestive of HIV infection will be referred by the medical officer to the VCTC. Thus, these diagnosed TB patients may be referred from DMC, DOT Centre, Out-patient clinics, TB ward, TB Clinic etc. Sometimes the patient may simultaneously be investigated for TB and HIV. The doctor should first complete the investigations for TB and then refer for HIV investigations. While referring to the VCTC, the doctor should write a referral note to VCTC in which the TB status of the person is mentioned. The referral of the TB patients to the VCTC for eliciting the HIV status for the sake of categorisation should **never** be done.

Process at VCTC

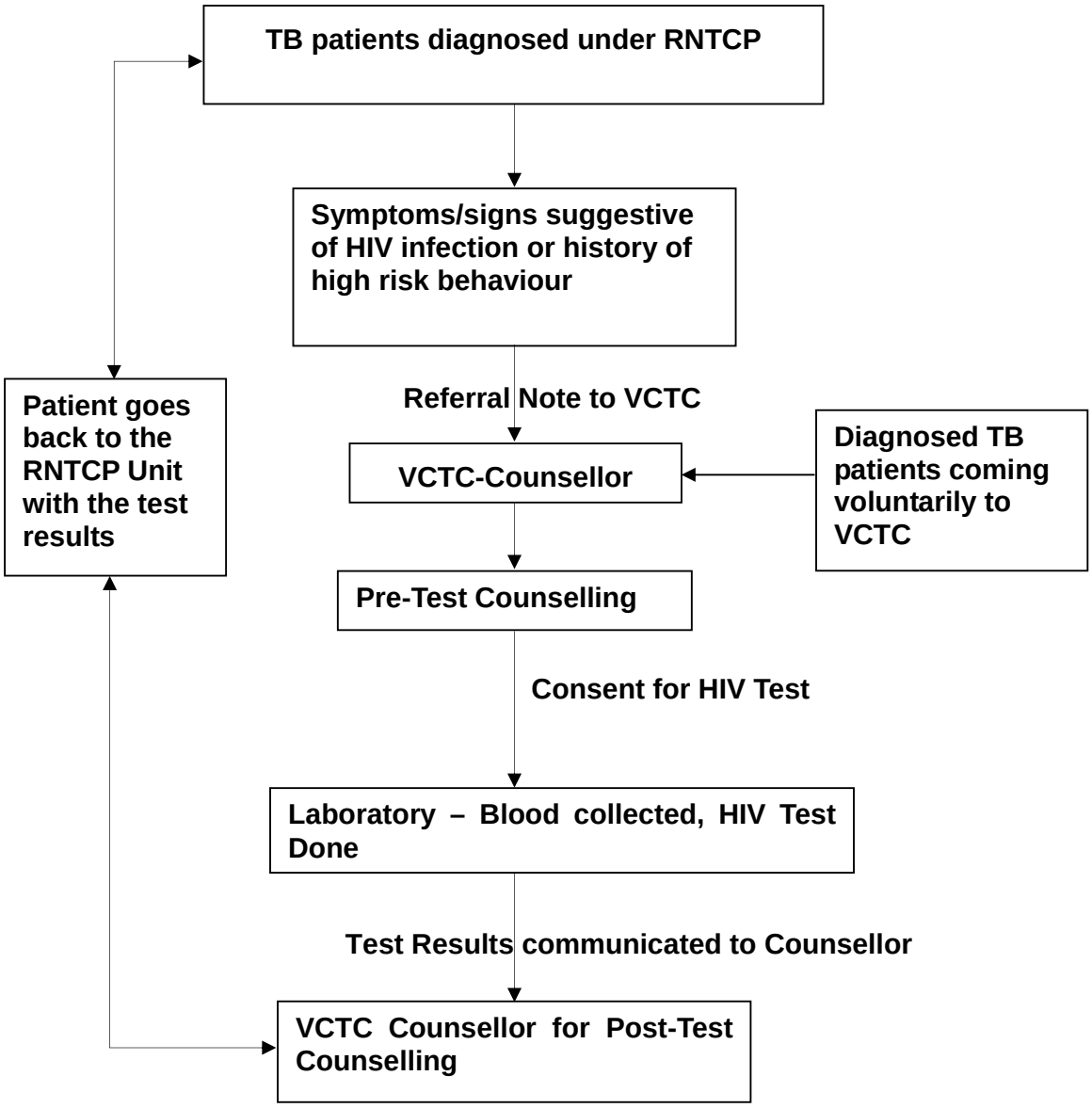
Once the referred TB patient reaches VCTC, the same procedure will be followed as that for any other client attending VCTC. Some TB patients may come on their own for HIV Testing (Direct Walk-In).

At the VCTC, the patient/client will undergo pre-test counselling. HIV testing is done after obtaining informed consent. The details of the patient/client will be entered into the PID register and Counselling Register. HIV testing is done and the test results are handed over by the Laboratory Technician to the Counsellor. The counsellor reveals the HIV test result to the patient/client with post-test counselling. The HIV test results are not revealed to any other person other than the individual himself.

Referrals from VCTCs to RNTCP diagnostic and DOT Centres



Process of Referral from RNTCP to VCTC



Monthly Report

VCTC-RNTCP co-ordination is monitored with the help of the monthly report on TB/HIV activities. In order to prepare the monthly report, the first step will be to make the Line-List (Annex 3). Preparing the Line–List will be the joint responsibility of the VCTC and RNTCP. The Line List for patients referred in the month of January, will be completed in the first week of March (fifth of the month) by the Counsellors and STS. Once the Line-List is completed, the monthly report will be prepared by the VCTC. The completed Line List and the Monthly Report will be compiled and submitted by the VCTC to all the concerned Officials (State AIDS Control Society, DTO) by the 10th of the month. The time taken for diagnosis and initiation of TB treatment may take up to 7 days and registering the patient in the TB register may take another few days and a maximum up to 1 month. Therefore, there will be a delay of one month in reporting of TB/HIV cross-referral. It means that the report of January will be submitted in March, that of February in April and so on.

At the SACS, the information on TB/HIV activities will be compiled and centre-wise report along with the monthly report for the entire state will be sent to NACO, State TB Office and Central TB Division by the 20th of every month

Line-List of Persons Referred From VCTC to RNTCP

The Line-List is prepared for each VCTC in the district separately. On the Line-List, the name of the VCTC, the district and the reporting month/year is to be filled in by the VCTC counsellor. The Line List has two parts. Part A, i.e. columns 1 to 8 contains information on the persons referred by VCTC to RNTCP. Part A is to be completed by the VCTC Counsellors and signed by the VCTC Counsellors and the In-charge of VCTC. Below the signature, date of completion of Part 'A' is to be mentioned. Note that only those persons who have been sent from VCTC to RNTCP are included here.

PART A of LINE-LIST

COLUMN NO.	COLUMN TITLE	WHAT SHOULD BE WRITTEN
1	Sr. No.	This is the serial number that you will write as you are making the line-list
2	PID No.	PID No. (Person Identification Digit No) is the number that the VCTC Counsellor has given to the client.
3	Complete Name and Complete Address	It is important to have the complete name and address of the person, otherwise it is difficult to trace out whether these persons have reached RNTCP Unit, whether they have been investigated and put on treatment. Therefore the VCTC Counsellor should write the complete name of the person.
4	Age	Age of the person should be mentioned
5	Sex	Male, Female or Transgender (Eunuch) should be mentioned

6	New or Follow Up Patient	Those patients who have come for the first time are labelled as 'new patients'. This includes those patients who have come for pre-test and post-test counselling. Follow Up Patients are those who have come to the VCTC after post-test counselling. This includes both HIV positive and HIV negative persons who come for follow up counselling.
7	Date of Referral	The date when the client is referred to the RNTCP Unit
8	Name of RNTCP Unit referred to	RNTCP Unit includes DTC, DMC, TB OPD, TB Clinic etc i.e. any health facility where the facility for sputum investigation for TB under RNTCP is available. In case the patient is referred to a doctor/OPD, the name of the OPD should be mentioned. For sputum examination, the counsellor should identify the Microscopy Centre that is convenient for the patient. The Counsellor should record the name of the centre the person has been referred to.

The Counsellor will meet the STS with the line list on the 1st or 2nd of the next month, i.e. the Line List for patients referred in the month of January, will be completed (Columns 1-8) in the first week of February by the Counsellors and handed over to the STS. The Counsellor should remember that HIV status should not be mentioned in the Line-List.

The STS/STLS will scan through the TB laboratory register to find out whether these patients have undergone the sputum microscopic examination. If the patient is sputum positive, then the TB number as mentioned in TB laboratory register will tell whether the patient has been started on DOTS and the treatment category. If the patient is sputum negative, then look for the patient in the TB register of the concerned Tuberculosis Unit. If patient was suspected of having Extrapulmonary TB, referring to the TB register would be helpful. For diagnosed TB patients referred out for DOTS treatment to another TU, the STS of the corresponding TU should be consulted, and for referrals for treatment outside the District the 'referral for treatment' register at the DMC should be scrutinized.

Once the Line-List is completed, the STS will sign the list and write the date of completion of Line-List. The STS will then take the signature of the concerned DTO/CTO or MO-TC. This Line List is handed over to the VCTC Counsellor by the fifth of the month.

Part B of LINE-LIST

COLUMN NO.	COLUMN TITLE	WHAT SHOULD BE WRITTEN
9	Has person reached RNTCP Unit (Yes/No)	To know whether the patient has reached the RNTCP Unit, refer to the TB Laboratory Register of the DMC where the patient has been referred. If the patients name is located in the TB Laboratory register, write 'YES' in the Line-List. If the patient has not reached DMC, write 'NO'. In case of extrapulmonary TB, where the patient has been referred to a doctor, asking the concerned doctor would be helpful. This information should be obtained from the concerned doctor immediately after referral and recorded in the Counselling register by the Counsellor. If the patient has reached the OPD and examined by the doctor, write "YES' in the Line-List. If patient has not reached the centre, mention 'NO'. Counsellor should ensure all such patients are referred to RNTCP treatment unit, once diagnosis is established.
10	Has Patient undergone three sputum Examination – (Yes/No)	If patient has undergone complete sputum examinations, then mention 'YES' If patient's only one sputum examination is done, mention 'NO' in the Line-List. Sometimes, after the patients name is entered in the TB Laboratory Register, the patient does not give sputum sample. In such a case mention 'NO' in this column. In case of EP TB, where the patient does not require sputum examination, write 'not applicable'
11	Date of Sputum Examination	The exact date on which the sputum examination was done
12	Sputum Result – Sputum Positive/Sputum Negative (If three sputum examinations are done)	Record the result of sputum examination for all those patients who have undergone complete sputum examinations. The sputum result is mentioned as sputum positive or sputum negative. In case of sputum positive do not mention the grade, only mention sputum positive
13	Date and Investigation Report for Extrapulmonary TB	In case where the patient has been referred for Extrapulmonary Investigations like FNAC, X-ray etc, the date of investigation and the results of investigation should be mentioned.
14	Is patient diagnosed as TB – Yes or No	If the patient is diagnosed as TB mention 'YES' and if non-TB mention 'NO'. For getting this information, the STS will need to check the TB Laboratory Register, Treatment Referral Register and the TB Registers

15	If diagnosed as TB, specify whether patient is sputum positive TB, sputum negative TB or Extrapulmonary TB	If the patient is diagnosed as TB, the STS should mention whether the patient is sputum positive TB, sputum negative TB or extrapulmonary TB.
16	Is patient receiving DOTS or Non-DOTS	Once diagnosed, the patient should be started on treatment. From the TB register, find out whether the patient is receiving RNTCP DOTS or non-DOTS. Mention DOTS if patient is being treated under RNTCP regimen and 'Non-DOTS' if under any other regimen
17	Treatment Category	If patient is receiving treatment, mention the treatment Category. Category I/II/III for DOTS regimen Or the NTCP regimen if non-DOTS
18	Date of Starting Treatment	The date of starting treatment as mentioned in the TB register should be recorded in the Line-List.
19	TB No.	From the TB register, write the TB no.
20	Remarks	The following information can be entered in the remarks column. • Name of the DOT centre to which patient has been referred to; • Name of the district, if the patient is from another district • If patient has died, date when expired • Reason for placing the patient on Non-DOTs regimen • If patient is from the district and has not been started on treatment, mention the reason. • any other

Monthly Report of TB/HIV activities at VCTC

The monthly report (Annex. 4) contains information on TB/HIV activities of the VCTC; no. of referrals made by VCTC to Microscopy Centre and no. diagnosed as TB amongst them; information about TB patients referred for HIV testing and their HIV status and no. of clients receiving information on TB.

Once the line list is completed, the VCTC Counsellors prepares the monthly TB/HIV report which has only aggregate numbers and no reference to any individual patients.

Section I: TOTAL NUMBER OF CLIENTS ATTENDING VCTC:

INDICATOR	WHAT SHOULD BE WRITTEN
a) No. of clients who received Pre-test Counselling	Refer to the Counselling Register and count the number of clients who have received pre-test counselling for the month. The reporting period is from day one of the month to the last day of the month
b) Out of above (a), No. detected to be HIV Positive	Out of the clients who received pre-test counselling, count the number of clients who are HIV positive. Those clients who are sero-positive by three different test kits/principle are counted as HIV sero-positive.
c) No. of HIV Positive and HIV Negative Follow-up Clients who attended VCTC	Count the number of HIV positive persons (I) who came for Follow Up Counselling in the month Count the number of HIV negative persons (II) who came for Follow UP Counselling in the month Add (I) and (II) to get the total no. of clients who came for follow up counselling

Section II: REFERRAL OF SUSPECTED TUBERCULOSIS CASES FROM VCTC TO RNTCP

INDICATOR	WHAT SHOULD BE WRITTEN
a) No. of persons suspected to have TB referred to RNTCP Unit	From the Line-List count the total number of persons suspected to have TB who were referred to RNTCP Unit. Referring to the Counselling register, count how many of these persons are HIV sero-positive and how many are HIV sero-negative. Mention accordingly under the appropriate columns in the monthly report. In case the person has not undergone HIV test, but still has been referred to RNTCP he will not be included in this indicator even though his name is there in the line-list. Similarly in case of indeterminate HIV test results, the person will not be counted.
b) Out of above (a) referred cases, No. who have reached RNTCP Unit	Out of the HIV sero-positive persons referred count the number of persons who reached the RNTCP Unit. Similarly count the HIV sero-negative persons who reached the RNTCP Unit. The information on whether the person has reached the RNTCP Unit is available in the column no. 9 of the Line-List
c) Out of above (b) no. who have undergone complete Investigation	Now count the number of HIV sero-positive persons who have undergone complete investigation. Now count the number of HIV sero-negative persons who have undergone complete investigation. The information on whether the person has undergone complete investigation is available in the column no. 10 and 13 of the Line-List. In case of suspected pulmonary TB check column no. 10. If three sputum examinations are done, it means the patient has undergone complete investigations. In case of suspected Extrapulmonary TB check column no. 13. If the patient has undergone relevant investigation for Extrapulmonary TB, it means the patient has undergone complete investigations.

d) Out of the above persons undergoing complete investigation(c), No. diagnosed as having:	Count the total number of HIV sero-positive persons diagnosed as TB. Count the total number of HIV sero-negative persons diagnosed as TB. The information on the persons diagnosed as TB is available from column no. 14 of the Line-List.
(i) Sputum Positive TB	Out of the HIV sero-positive TB patients count the number of sputum positive TB. Out of the HIV sero-negative TB patients count the number of sputum positive TB. The information on whether the person is diagnosed as sputum positive TB is available from column no. 15 of the Line-List.
(ii) Sputum Negative TB	Out of the HIV sero-positive TB patients count the number of sputum negative TB. Out of the HIV sero-negative TB patients count the number of sputum negative TB. The information on whether the person is diagnosed as sputum negative TB is available from column no. 15 of the Line-List.
(iii) Extra-Pulmonary TB	Out of the HIV sero-positive TB patients count the number of extrapulmonary TB. Out of the HIV sero-negative TB patients count the number of extrapulmonary TB. The information on whether the person is diagnosed as Extrapulmonary TB is available from column no. 15 of the Line-List.
e) Out of above (d), diagnosed TB patients, number receiving DOTS	Out of the HIV sero-positive TB patients count the number of persons receiving DOTS. Out of the HIV sero-negative TB patients count the number of persons receiving DOTS Include only those persons who are being treated with DOTS and whose TB number is available. Referring to column no. 16 and 19 of the Line-List will give this information.

Section III: REFERRAL OF DIAGNOSED TB PATIENTS FROM RNTCP TO VCTC

INDICATOR	WHAT SHOULD BE WRIITEN
a) No. of TB patients attending VCTC (referred or Direct Walk-In)	Referred Patients Referring to the Counselling register, count the number of persons who have been referred from RNTCP Unit (I). Direct Walk-In Clients Check column no. 3 and 11 of the Counselling register to see whether any diagnosed TB patient came on his own to VCTC. Count these known diagnosed TB patients who came as direct walk-in clients to the VCTC (II). Add (I) and (II) to get the total number of TB patients (a) attending VCTC. Note that those persons who have been referred from VCTC to RNTCP are excluded in this section
b) Out of above (a), No. Tested for HIV	Count the number of persons who consented for the HIV test(b) out of the above mentioned diagnosed TB patients

c) Out of above (b), No. detected to be HIV Positive	Now count the number of persons who were found to be HIV positive out of (b)

Section IV: IEC ACTIVITIES

No. of clients/patients receiving information / counselling on TB	There is no column in the Counselling register to record the information about the persons receiving counselling on TB. The Counsellor can add an extra column, after remarks column, titled as 'Information/Counselling on TB'. If the Client has been given information on TB, write 'YES'. Count the number of persons who received information/counselling on TB from the column 'Information/Counselling on TB' of the Counselling Register. Remember to include not only new patients, but also follow up patients who have come for counselling and have been imparted information on TB again.

The monthly report signed by the In-charge VCTC should be completed by the 5th/6th of the month and sent to District Nodal Officer for HIV/AIDS, District TB Officer and the SACS office so as to reach latest by 10th of the month. The District TB Officer compiles the reports of all VCTC in the district reports monthly to the state and reports quarterly in the RNTCP Quarterly report to the Centre and the State. The reports are dispatched by the DTO with a gap of one quarter i.e. TB/ HIV report for the first quarter of 2005 will be reported in the RNTCP programme management report of the second quarter, 2005

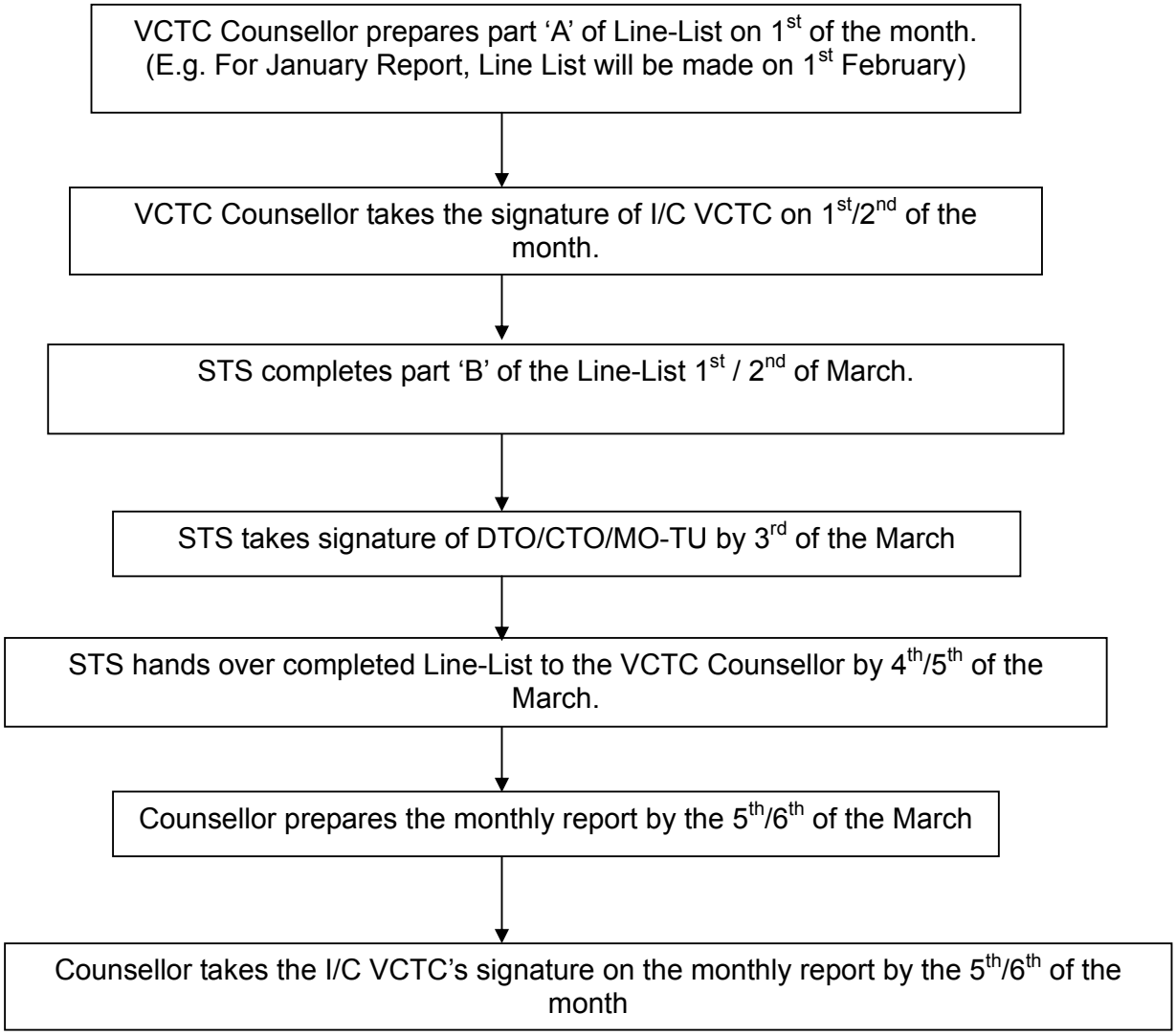
At District Level

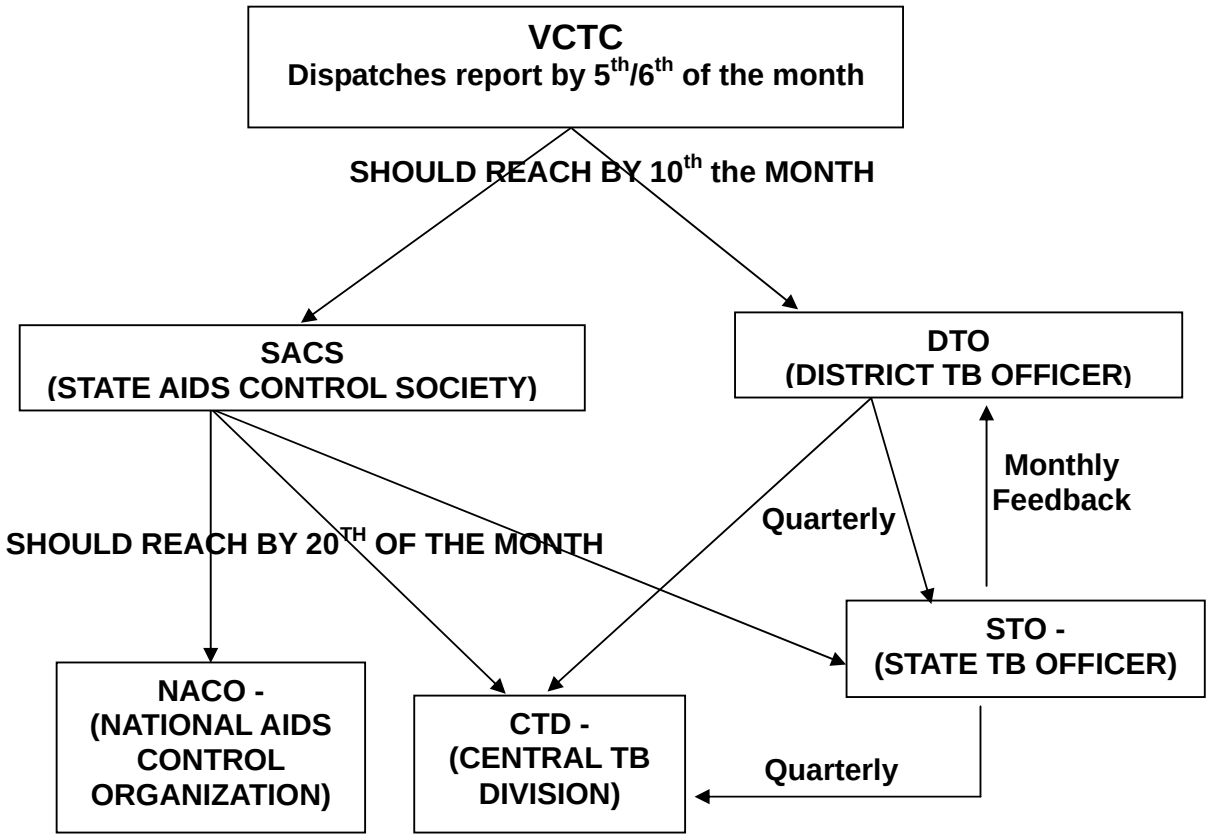
The report will be sent by the VCTC to the District Nodal Officer for HIV/AIDS, District TB Officer and the State AIDS Control Society. The report should reach State AIDS Control Society by 10th of the month. A copy the TB/HIV report is given to the concerned District Tuberculosis Officer/City TB Officer who in turn compiles the reports and reports quarterly in the RNTCP programme management report. The Counsellor also sends a copy of the Line-List to the SACS

At State Level

At the state level, at the SACS the information on TB/HIV activities will be compiled and a centre-wise report along with the monthly report for the entire state will be sent to NACO and CTD by the 20th of every month. A copy of this report will also be sent by SACS to the **State TB Office**.

Process of Preparing the Monthly Report





Role of VCTC and RNTCP Staff

Role of Counsellor

1. Referral of suspected TB patients to microscopy centre
2. Impart information on TB to all the VCTC Clients.
3. Maintain confidentiality, follow-up of drop-outs partner counselling and testing, creating community awareness
4. Know where to refer patient for sputum microscopy
5. Educate HIV positive persons about the symptoms and signs of TB and importance of reporting to the Counsellor/ DMC centre at the earliest.
6. Encourage HIV positive clients with TB to reveal their HIV status to the treating physician
7. Provide VCT services to patients referred from RNTCP
8. Send the report of TB/HIV activities regularly to State AIDS Control Society, District Nodal Officer of AIDS and District TB Officer every month
9. Send a copy of Line-List to the State AIDS Control Society every month

Role of STS/STLS

1. Ensure that the Lab Tech of DMC, mentions name of VCTC in TB Lab Reg.
2. Ensure and maintain strict confidentiality in dealing with all cases of TB/HIV.
3. If asked by TB patients, provide information about HIV/AIDS and the facilities available for HIV Counselling and testing.
4. Ensure availability of Sputum Laboratory forms and DOTS directory at the VCTC.
5. Give feedback to the VCTC counsellors regarding the TB status of persons referred from VCTC to Microscopy Centres.
6. Co-ordinate with the VCTC counsellors for preparing and completing the line-list.

Role of MO-VCTC

1. Ensure Counsellors screen VCTC clients for symptoms of TB
2. Ensure Counsellors are attending the monthly review meetings of RNTCP
3. Check the counsellors registers to verify if documentation is being done properly
4. Ensure Counsellors prepare the line-list and monthly report
5. Ensure that the report is complete and correct
6. Ensure the timely submission of reports.

Role of MO-TU

1. Ensure Lab Technician records referrals received from VCTC in TB Lab. register.
2. Ensure STS completes the line-list and hands it over to the Counsellor on time.
3. Ensure confidentiality of HIV status is maintained.
4. Ensure the prevention of spread of HIV through safe injection practices
5. Refer TB patients suspected to have HIV to VCTC
6. Refer known HIV positive patients to VCTC for Counselling

Role of DTO

1. Facilitate the Quarterly meetings of District TB/HIV Co-ordination Committee.
2. Ensure the availability of the logistics to all the VCTC's in the district
3. Ensure Lab Technician records referrals received from VCTC in TB Lab. register.
4. Ensure the STS coordinates with the Counsellor for completing Line-List
5. Conduct regular monthly meetings between VCTC and RNTCP staff
6. Ensure confidentiality of HIV status is maintained.
7. Ensure VCTC and RNTCP staffs are trained in TB/HIV.
8. Ensure appropriate measures are taken to prevent spread of TB in facilities caring for HIV-AIDS
9. Ensure the prevention of spread of HIV through safe injection practices
10. Timely submission of TB/HIV report to CTD and STO. DTO reports quarterly in the programme management reports. The reports are dispatched with a gap of one quarter i.e. TB/ HIV report for the first quarter of 2004 will be reported in the RNTCP programme management report of the second quarter

Annex 1.

Clinical staging for HIV infection and HIV-related disease

A clinical staging system (originally for prognosis), based on clinical criteria (and a past HIV positive test result) has been developed by WHO. The definition of symptoms, signs and diseases is according to clinical judgement. Clinical condition or performance score, whichever is the higher, determines whether a patient is at clinical stage 1, 2, 3 or 4. Clinical stage is important as a criterion for starting antiretroviral therapy (ARV)

WHO clinical staging system for HIV infection and related disease in adults (13 years or older)

Stage 1:

- Asymptomatic
- Persistent generalized lymphadenopathy
- **Performance scale 1**: asymptomatic, normal activity

Stage 2:

- Weight loss < 10% of body weight
- Minor mucocutaneous manifestations (e.g. oral ulcerations, fungal nail infections)
- Herpes zoster within the last 5 years
- Recurrent upper respiratory tract infections (e.g. bacterial sinusitis)
- and/or **Performance scale 2**: symptomatic, normal activity

Stage 3:

- Weight loss > 10% of body weight
- Unexplained chronic diarrhoea for more than 1 month
- Unexplained prolonged fever for more than 1 month
- Oral candidiasis (thrush)
- Oral hairy leukoplakia
- Pulmonary TB
- Severe bacterial infections (pneumonia, pyomyositis)
- and/or **Performance scale 3**: bedridden < 50% of the day during the last month

Stage 4:

- HIV wasting syndrome (i.e. weight loss > 10% of body weight, plus either unexplained diarrhoea for more than one month or chronic weakness and unexplained fever for more than one month),
- *Pneumocystic carinii* pneumonia
- Toxoplasmosis of the brain
- Cryptosporidiosis with diarrhoea, for more than 1 month
- Cryptococcosis, extrapulmonary
- Cytomegalovirus (CMV) disease of an organ other than liver, spleen, lymph nodes
- Herpes virus infection, mucocutaneous for more than 1 month, or visceral any duration
- Progressive multifocal leukoencephalopathy (PML)
- Any disseminated endemic fungal infection (e.g. histoplasmosis).

- Candidiasis of the oesophagus, trachea, bronchi or lungs
- Atypical mycobacteriosis, disseminated
- Non-typhoid salmonella septicaemia
- Extrapulmonary TB
- Lymphoma
- Kaposi sarcoma
- HIV encephalopathy (i.e. clinical findings of disabling mental or motor dysfunction, interfering with activities of daily living, progressing over weeks and months, in the absence of a concurrent illness or condition other than HIV infection which could explain the findings),
- and/or **Performance scale 4**: bedridden > 50% of the day during the last month

WHO clinical staging system for HIV infection and related disease in children

Stage 1:

- Asymptomatic
- Persistent generalised lymphadenopathy

Stage 2:

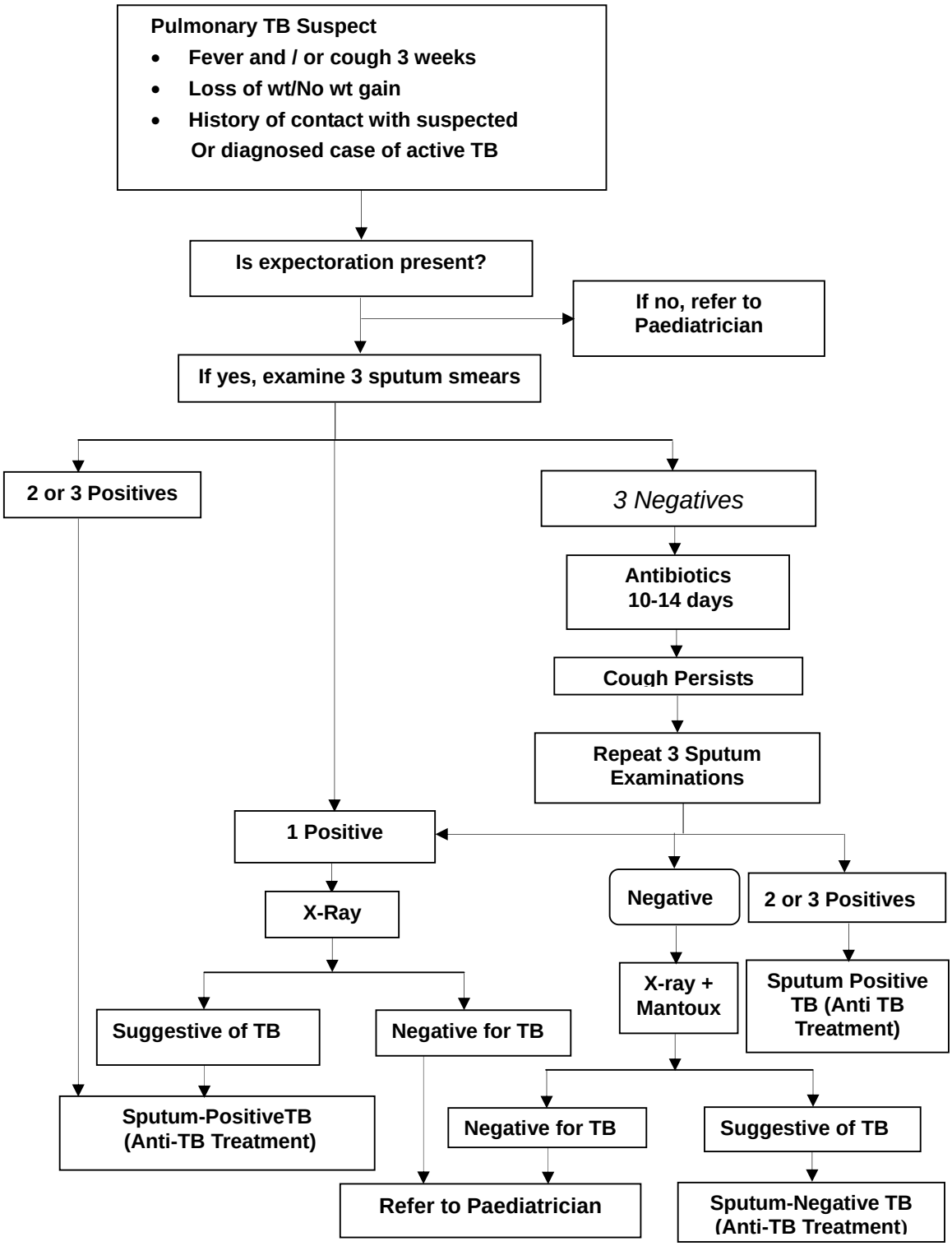
- Unexplained chronic diarrhoea
- Severe persistent or recurrent candidiasis outside the neonatal period
- Weight loss or failure to thrive
- Persistent fever
- Recurrent severe bacterial infections

Stage 3:

- AIDS-defining opportunistic infections
- Severe failure to thrive
- Progressive encephalopathy
- Malignancy
- Recurrent septicaemia or meningitis

Annex 2.

Diagnostic Algorithm for Paediatric Pulmonary TB



Annex 3.

LINE-LIST OF PERSONS REFERRED FROM VCTC TO RNTCP

REPORTING MONTH: _____ YEAR _____

NAME OF VCTC: **NAME OF DISTRICT:**

TO BE COMPLETED BY VCTC COUNSELLOR								*TO BE COMPLETED BY STS*											
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
Sr.No.	*PID NO.*	*Complete Name & Complete Address*	*Age*	*Sex*	*New or Follow Up Patient*	*Date of referral*	*Name of RNTCP Unit referred to*	*Has Person reached RNTCP Unit (Yes/No)*	*Has Patient undergone three sputum Examination –(Yes/No)*	*Date of Sputum Examination*	*Sputum Result - (Sputum Positive/Sputum Negative) (If three sputum examinations are done)*	*Date and Investigation Report for Extrapulmonary TB*	*Is patient diagnosed as TB - Yes or No*	*If diagnosed as TB, specify whether patient is sputum positive TB, sputum negative TB or Extrapulmonary TB*	*Is patient receiving DOTS or Non-DOTS*	*Treatment Category*	*Date of Starting Treatment*	*TB No.*	*Remarks*

Sign of Counsellor Sign of Counsellor Sign of MO- VCTC
Date of completion:

Signature of STS *Signature of DTO/CTO/MO-TU*
Date of Completion:

Annex 4.

REPORT OF TB/HIV ACTIVITIES AT VOLUNTARY COUNSELLING TESTING CENTRE

FOR THE MONTH OF _____ YEAR _____

Name of VCTC: *Name of the District:*

I. TOTAL NUMBER OF CLIENTS ATTENDING VCTC:

a) No. of clients who received Pre-test Counselling	
b) Out of above (a), No. detected to be HIV Positive	
c) No. of HIV Positive and HIV Negative Follow-up Clients who attended VCTC	

II. REFERRAL OF SUSPECTED TUBERCULOSIS CASES FROM VCTC TO RNTCP

	HIV positive	*HIV Negative*
a) No. of persons suspected to have TB referred to RNTCP Unit		
b) Out of above (a) referred cases, No. who have reached RNTCP Unit		
c) Out of above (b) no. who have undergone complete Investigation		
d) Out of the above persons undergoing complete investigation(c), No. diagnosed as having:		
(i) Sputum Positive TB		
(ii) Sputum Negative TB		
(iii) Extra-Pulmonary TB		
e) Out of above (d), diagnosed TB patients, number receiving DOTS		

III. REFERRAL OF DIAGNOSED TB PATIENTS FROM RNTCP TO VCTC

a) No. of TB patients attending VCTC (referred or Direct Walk-In)	
b) Out of above (a), No. Tested for HIV	
c) Out of above (b), No. detected to be HIV Positive	

IV. IEC ACTIVITIES

No. of clients/patients receiving information / counselling on TB	

Signature of Medical Officer – Incharge VCTC

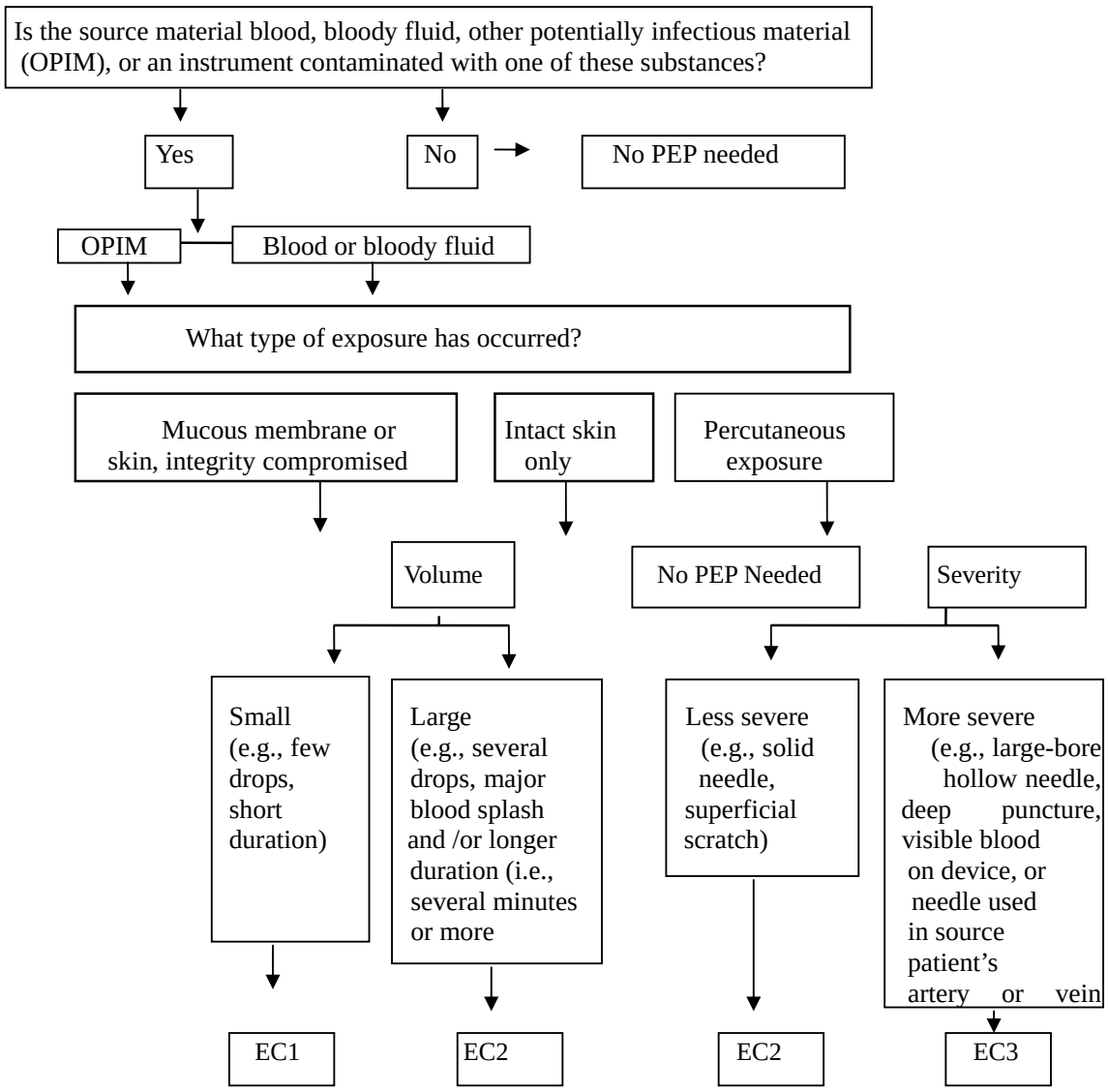
Name of Medical Officer– Incharge VCTC

Annex 5.

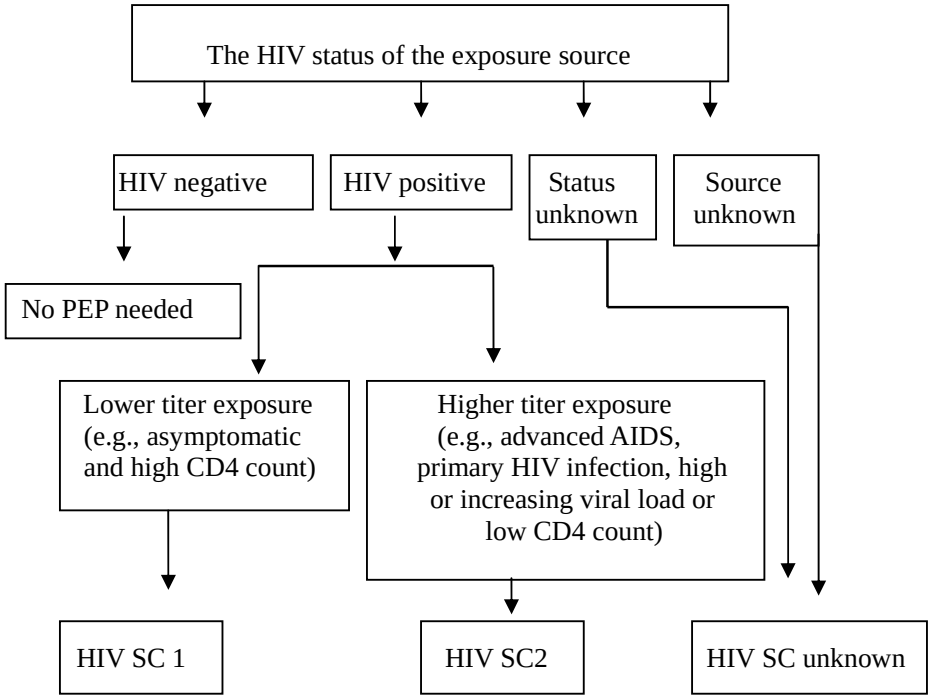
Determination of the Exposure Code (EC)

Exposure code can be defined as per the flow chart given below. It may be classified into three categories, EC-1, EC-2 and EC-3, depending upon the severity of exposure.

Exposure Code (EC)



HIV Status Code (HIV SC)



Determine the PEP recommendation

EC	HIV SC	PEP recommendation
1	1	PEP may not be warranted
1	2	Consider **basic regimen** (Exposure type poses a negligible risk for HIV transmission).
2	1	Recommend **basic regimen** (Most HIV exposures are in this category; no increased risk for HIV transmission has been observed but use of PEP is appropriate).
2	2	Recommend **expanded regimen** (Exposure type represents an increased HIV transmission risk.)
3	1 or 2	Recommend **expanded regimen** (Exposure type represents an increased HIV transmission risk.)
	UNKNOWN	If the source, (in the case of an unknown source), the setting where the exposure occurred suggests a possible risk for HIV exposure and the EC is 2 or 3, consider PEP basic regimen.

Specific drugs recommended for PEP

Basic Regimen: (4 weeks therapy)		Zidovudine (AZT/ZDV) – 300mg twice a day is used for all types of exposure + Lamivudine (3TC) – 150 mg twice a day is added to increase the effectiveness of ZDV and to prevent resistance to ZDV
Expanded Regimen: (4 weeks therapy)		Basic Regimen (AZT/ZDV + 3TC) + Indinavir – 800 mg/thrice a day or any other protease inhibitor is added for higher risk categories.

Annex 6.

Sterilization and Disinfection

Standard sterilization and disinfections procedures recommended for patient care equipment are adequate to sterilize or disinfect items contaminated with blood or other body fluids from people infected with blood borne pathogens including HIV, HBV and HCV. Instruments like endoscopes should be cleaned and then disinfected.

Sterilization methods

Sterilization is a process, which destroys all microorganisms (bacterial, viral, parasitic and fungal) including the resistant spore forms. Dry and moist heat, certain gases and chemicals are used for sterilization.

- Autoclaving at 121^0C at 15 lbs pressure for 20 mins.
- Dry heat 170^0C for 1 hour (holding time)
- Boiling for 20-30 minutes

Chemical disinfectants:

Disinfection is a process, which destroys the infectious microorganisms. High-level dis infection destroys all pathogenic organisms and most of other microorganisms but spores may survive. Intermediate and low level of disinfection destroys the pathogenic organisms. Decontamination is the same as low level of disinfection, this process gets rid of visible, contamination of surfaces, equipments etc. Some of the commonly used available disinfectants are listed below:

- Sodium hypochlorite : 1gm/L
- Calcium hypochlorite : 1.4 gm/L
- Chloramine : 20 gm/L
- Available chlorine 0.1% Chloramine most stable of the above three disinfectants
- Ethanol 70%
- Povidone iodine (PVI)
- Formalin : 3-4%
- Glutaraldehyde: 2% for 30 minutes

Safe handling of spills:

Cover the area of spill with adsorbable material (may be gauze, cotton, etc.) Wearing gloves. Flood the area with freshly prepared bleach 1% or some other appropriate disinfectant and leave for 30 minutes. The whole material is than lifted with clean dry gauze or cotton and area is washed with soap and water. All the contaminated materials are disposed off as infectious waste. Gloves should be worn throughout this activity.

Safe disposal of wastes

Hospital wastes are potential hazards. Infectious waste can transmit numerous diseases in the community and put those who handle waste and live in proximity, at risk. Besides, the increasing use of disposables in health care is also posing an additional burden on the waste management facility. It is extremely important that the recycling of these items is prevented. Only a small percentage (<10%) of the waste generated in health care settings is infectious while another 5% is non-infectious but hazardous. The most practical approach to the management of biomedical waste is to identify and segregate infectious and hazardous waste (with a potential for causing infection and or injury during handling and disposal), for which some special precautions appear prudent. This will drastically reduce the cost of the disposal methods in health care settings.

Setting up of a biomedical waste facility

Every hospital, nursing home, veterinary institution, animal-house, blood bank, research institute generating biomedical waste should install an appropriate biomedical waste facility in the premises or should set up a common facility in accordance with the directions given by the regulatory appropriate authority. Biomedical waste should not be generated without authorization. Every hospital should have a waste management programme. Waste survey is an important part of the waste management programme and helps in determining both the type and quantity of waste being generated in the hospital including the laboratory and determine the feasible methods of disposal.

Containing waste at generation point

At the generation point i.e. the laboratory, waste is managed in the following way :

- Collection
- Segregation and weighing
- Storage

Waste segregation is the key to any waste management scheme. It consists of placing different types of waste in different containers or colour-coded-bags at the site of generation. This helps in reducing the bulk of infectious waste and contains spread of infection to general waste. This practice reduces the total treatment cost, the impact of waste in the community and the risk of infecting workers. Proper segregation should identify waste according to source and type of disposal/ disinfection.

Segregate waste at source into

- **Solid non-infectious household type waste** e.g. paper, fruit peels etc.and dispose off in the routine dustbin/black bags and finally the MCD bin.
- **Infected sharp disposable waste** e.g. disposable syringes -needles and other sharps $\rightarrow$ place in a puncture resistant blue container containing disinfectant (0.1%-

0.5% bleach solution). The container should be placed near the activity place. Needles may be destroyed by using needle destroyer.

- Alternatively autoclave microwave, treat chemically and shred. Needles, lancets, blades, etc. can be buried or smelted and recycled.
- **Infected non sharp disposable waste** e.g. catheters, gloves etc.→ place in a container containing 0.1.-0.5% sodium hypochlorite solutions. Mutilate and or shred to avoid recycling.
- **Infected reusable instruments e.g. endoscopes , speculum** etc. → in a container containing 2% glutaraldehyde for 30 minutes → wash and autoclave or place in 2% glutaraldehyde for 6-8 hours as per the specifications of the instrument.
- **Swabs-** should be chemically disinfected followed by incineration.
- **Disposable items** include single use products (syringes, gloves, sharps etc.)- As these items are often recycled and have the risk of being reused illegally, these should be disinfected by dipping in freshly prepared 1% Sodium hypochlorite for 30 minutes to 1 hour. Containers which can be used for this purpose are a set of twin containers, one inside the other with the inner one being perforated and easily extractable. This minimizes contact when the contents are being removed.
- **Liquid wastes** generated by the laboratory are either pathological or chemical in nature and are disposed of as follows:
  - **Non-infectious chemical waste** should first be neutralized with relevant reagents and then flushed into conventional sewer system. Liquid infectious waste should be treated with a chemical disinfectant for decontamination then neutralized and flushed into the sewer.
- Disposable items like gloves, syringes etc. should be shredded, cut or mutilated before disposal followed by deep burial or properly accounted before disposal.
- **Collection bags:** Solid wastes are collected in leak-resistant single heavy duty bags or double bags. Bags having different colour codes (Table) with red labels mentioning date and details of waste are recommended. The bags are tied tightly after they are three-fourths full.

Packing, storage and transport

- All segregated and disinfected waste should be packed in proper containers and colour-coded bags (Table) with red labels mentioning details of biomedical waste and biohazard signs. All containers used for storage of such waste should be provided with a properly covered lid.
- Such containers should be inaccessible to scavengers and protected against insects, birds, animals and rain.
- There should not be any spillage during handling and transit of such waste.
- The sharp wastes, after pre-treatment should be broken before packing in the container.
- The waste should be transported in vehicles authorised for this purpose only.
- No such waste should be stored in the place where it is generated for a period of more than two days.