Islamic Republic of Afghanistan
Ministry of Public Health
General Directorate of Health Care Provision
Directorate of Communicable Diseases
National Tuberculosis Control Program

Standard Operational Procedures (SOPs) to improve the quality of care for TB patients in treatment

March.08.2009

Supported by USAID/TB CAP

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Acknowledgement

In developing of this SOPs to improve the quality of care for TB patients in treatment in Afghanistan under the Ministry of Public Health of Afghanistan would like to thank and acknowledge the inputs and contributions of the following organization and individuals;

H.E Deputy Minster Dr. Faizullah Kakar, General Director of Health Care Provision Dr. Ahmad Shah Shokohmanm and Dirctore of Communicable Disease Dr. Sayeed Habib,

WHO, JICA, MSH, TB CAP, USAID.

We especially wish to thanks the designated committee for the elaboration of the document: Dr. Pedro G Suarez (MSH/TB CAP Director), Dr. Konrad Juszkiewicz (WHO STB Medical Officer) Dr. Isono Mitsuo (Senior Advisor for JICA), Dr. Lailuma Nuzhat (WHO STB National Medical Officer), Dr. M.K Rashidi (TB CAP country team leader) , Dr. Faridullah Atiqzai (TB CAP provincial TB coordinator) and Dr. Abdul Qader(TB CAP Monitoring and Evaluation Coordinator). Dr. Mohmmad Salim Rasooli (NTP National TB Coordinator), Dr. Habibullah Habib(NTP, Head of New Initiative Department) and Dr. Sayeed Daoud Mahmmodi(NTP, Head of Surveillance and M&E Department).

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Date: 08 March, 2009

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LIST OF ACRONYMS/ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
HIV	Human Immunodeficiency Virus
CHW	Community Health Worker
CHS	Community Health Supervisor
cm	centimeter
DH	District Hospital
DOT	Directly Observed Treatment
E	Ethambutol
FDC	Fixed-dose combination
H	Isoniazid
HR	Heart Rate
HIV	Human immunodeficiency virus
inj	Injection
JICA	Japan International Cooperation Agency
kg	Kilogram
MDR TB	Multidrug-resistant tuberculosis
MTB	Mycobacterium tuberculosis
MSH	Management Science for Health
NTP	National Tuberculosis Program
M&E	Monitoring and Evaluation
mg	Milligram
PH	Provincial Hospital
PTC	Provincial Tuberculoses Coordinator
PR	Pulse Rate
R	Rifampicin
S	Streptomycin
SOPs	Standard Operational Procedures
SR	Symptomatic respiratory case
SS+	Sputum smear positive
SS-	Sputum smear negative
STB	Senior Tuberculosis
TB	Tuberculosis
TB SS+	Pulmonary tuberculosis sputum smear positive
TB SS-	Pulmonary tuberculosis sputum smear negative
TBCAP	Tuberculosis Control Assistance Program
USAID	United States Agency for International Development
WHO	World Health Organization
Z	Pyrazinamide

Standard Operational Procedures (SOPs) to improve the quality of care for TB patients in treatment

Introduction

I. General principles

1. Rationale

Tuberculosis (TB) disease can be treated successfully in almost all cases. Effective drugs are available, and the correct regimens and durations of treatment are well established. The efficacy of the standard treatment of 6 months in new pulmonary tuberculosis sputum smears positive (TB SS+) should be 99%. Treatment regimens for extrapulmonary TB generally are the same as for pulmonary TB.

Criteria to apply the correct TB treatment include the following conditions:

- Type (pulmonary/extra pulmonary)
- Bacteriological diagnosis (SS+ or SS-)
- Gravity of TB and antecedent (new or previously treated)

A critical factor in TB treatment is adherence of the patient to the prescribed regimen for the full duration of treatment. If treatment is stopped early or is interrupted for several weeks, some Mycobacterium tuberculosis (MTB) organisms at the site of infection survive. These bacteria can then resume their growth in the patient and cause TB disease to relapse. Also, if the number of TB medicines taken by a patient is inadequate or the medicines are taken in inadequate doses, MTB is likely to become resistant to the drugs and will continue growing and causing multidrug-resistant tuberculosis (MDR TB) in the patient. The drug-resistant MTB organisms can then be transmitted to other persons and cause disease that will not be cured by routine TB treatment.

To ensure that patients with TB disease receive correct and adequate treatment, standard treatment regimens have been developed. These regimens involve combinations of the following drugs: isoniazid (H), rifampicin (R), pyrazinamide (Z), ethambutol (E), and streptomycin (S).

Basic principles of TB treatment are the following:

- The treatment regimen should be safe, effective, and require the shortest duration of treatment
- Adherence to the regimen is critically important, and special measures should be taken to ensure compliance
- The patient should always be taking 2 or more medicines against which the infecting MTB organisms are susceptible
- If a treatment regimen is failing, the new regimen should contain new medicines

TB treatment is given in two phases, Phase I is called initial phase and Phase II the continuation phase. During the initial phase, when treatment is first started, the number of MTB organisms is greatest. In order to rapidly reduce the number of organisms and minimize the chance that organisms resistant to one or two drugs will survive, treatment with 4 medicines is given daily. During the subsequent continuation phase when the number of MTB organisms has been reduced, fewer drugs can be used, and the doses can be given daily.

Quality care of TB patients is a key component for guarantee successful treatment, for this reason definition on roles and responsibilities of health workers and Community Health Worker (CHW) on this process should be an important component in the National Tuberculosis Program (NTP) policy for TB control in the country.

2. Standard treatment regimens in Afghanistan

The NTP guideline recommended 8 months treatment of adult TB cases with three categories of treatment:

- **Category I:** 2RHZE/6HE. In the first phase of treatment the DOT is mandatory and for second or continues phase the DOT is required when ever possible. This indicates that new TB SS+ and other newly diagnosed seriously ill patients with severe forms of TB (meningitis, milliary TB and tubercular pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications, bone TB, smear negative pulmonary TB with extensive parenchyma involvement, intestinal and genitor urinary TB etc).
- **Category IA:** 2RHZ/4RH. Indicated for TB in children less than five years
- **Category II:** 2SRHZE/1RHZE/5RHE. In both phases treatments are under supervision. This indicates for relapses, treatment after interruption and failures
- **Category III:** 2RHZ/6HE. In first phase treatment is supervised and second phase self administration at home. This indicates pulmonary tuberculosis sputum smear negative (TB SS-) cases, extra pulmonary TB and other cases.

NTP is planning to start 6 months TB treatment for Category I, with following regimen RHZE/4 RH. For Category II there is 8 months treatment regimen.

- **Category I:** 2RHZE/4RH. DOT is mandatory for both phases. This indicates all new TB cases including children (Pulmonary, extra pulmonary, SS + and SS-)**.**
- **Category II:** 2SRHZE/1RHZE/5RHE. The DOT is mandatory for both phases of treatments. The duration of treatment is 8 months. This applied to all re treatment cases (relapses, treatment after interruption, failure and others).

3. Anti-TB medicines doses

Standard medicine doses are based on body weight. The full dose of each drug should be taken at one time on the assigned day (see Table 1). Some oral drugs are available in fixed dose combinations (FDC). FDCs reduce the number of pills that a patient must take and ensure that full doses of all drugs are taken (see Table 2 and Table 3).

Table1: Category 1 regimen

Patient Body weight (Kg)	**Initial Phase (2 months)**	Continuation phase	
	2 months	4 months	6 Months
	Daily	Daily	Daily
	RHZE 150mg+ 75mg+ 400mg+ 275mg	RH 150 mg + 75 mg	EH 400 mg + 150 mg
30-39	2	2	1.5
40- 54	3	3	2
55- 70	4	4	3
71 and more	5	5	3

Table2: Category 2 regimen

Patient Body weight (Kg)	**Initial Phase (3 months)**		**Continuation Phase (5 months)**	
	3 months	2 months	5 Months	
	Daily	Daily	Daily	
	RHZE 150mg+ 75mg+ 400mg+ 275mg+	S inj. (1000 mg)	RH (FDC) (150mg+75mg)	E (400mg)
30-39	2	500	2	1 + 1/2
40- 54	3	750	3	2
55- 70	4	1g *	4	3
71 and more	5	1g *	5	3

Table3: Doses of first-line anti-TB drugs for children

Drug	**Recommended dose**	
	Daily	
	Dose and range (mg/kg body weight)	**Maximum (mg)**
Isoniazid (H)	5 (4–6)	300
Rifampicin (R)	10 (8–12)	600
Pyrazinamide (Z)	25 (20–30)	–
Ethambutol (E)	20 (15–25)	–
Streptomycin (S)	15 (12–18)	–

Note: R = rifampicin; H = isoniazid; Z = pyrazinamide; E = ethambutol.
4RH may be replaced by 6EH daily when supervision of treatment is not possible. However, preliminary data from a recent clinical trial have shown that 6EH is much less effective than 4RH in terms of cure, with higher failure and relapse rates.
Maximum recommended daily dose of rifampicin in FDCs is 750 mg

4. TB treatment in special circumstances

4.1 Tuberculosis treatment during pregnancy and breast feeding

Active tuberculosis presents a special problem in pregnant women or in mothers who have small children. Pregnant women with active tuberculosis should start or continue their anti-tuberculosis treatment. Streptomycin administration must be avoided in pregnant women for the fear of ototoxicity for the fetus.

Situations in which tuberculosis is diagnosed in the mother only after delivery are most likely to occur in populations where environmental conditions are generally very poor and health risks to the infant are greatest. Under these conditions, breastfeeding the infant is even more important.

4.2 Treatment for women taking the oral contraceptive pill

Rifampicin interacts with the oral contraceptive pill, increasing the risk of decreased protection against pregnancy. A woman who usually takes the oral contraceptive pill may choose between the following two options while receiving treatment with Rifampicin: After consultation with a physician, taking an oral contraceptive pill containing a higher dose of estrogens (50mcg), or, alternatively, using another form of contraception.

4.3 Treatment for patients with liver disorders

Provided no clinical evidence exists of chronic liver disease, hepatitis virus carriage, a past history of acute hepatitis, or excessive alcohol consumption, patients with the following conditions can receive the usual short-course chemotherapy regimens:

4.4 Established chronic liver disease

Isoniazid plus Rifampicin plus one or two non-hepatoxic drugs, such as Streptomycin and Ethambutol, can be used for a total treatment duration of eight months. An alternative regimen is Streptomycin plus Isoniazid plus Ethambutol in the initial treatment phase followed by Isoniazid and Ethambutol in the continuation phase for a total treatment duration of 12 months. Patients with liver disease should not receive Pyrazinamide; therefore, recommended regimens are as follows: 2SHRE/6HR or 2SHE/10HE.

4.5 Acute hepatitis (e.g., acute viral hepatitis)

Rarely, a patient has TB and, at the same time, acute hepatitis unrelated to TB or anti-TB treatment. Determining the course to follow requires clinical judgment, in some cases; TB treatment can be deferred until the acute hepatitis has been resolved. In cases in which TB must be treated during acute hepatitis, the safest treatment option is a combination of Streptomycin and Ethambutol for up to a maximum duration of three months, until the hepatitis has been resolved. The patient can then receive a continuation treatment phase of six months of Isoniazid and Rifampicin (3SE/6HR).

4.6 Treatment of patients with renal failure

Isoniazid, Rifampicin and Pyrazinamide are either eliminated almost entirely by biliary excretion or metabolized into non-toxic compounds; therefore, patients with renal failure can take normal dosages of these drugs. Patients in severe renal failure should receive pyridoxine with Isoniazid in order to prevent peripheral neuropathy.

Streptomycin and Ethambutol are excreted by the kidney. Where facilities are available to monitor renal function closely, it may be sensible to give Streptomycin and Ethambutol in reduced doses.

2HRZ/6HR is the safest regimen for patients with renal failure.

5. Adverse effects of anti-TB medicines and how to manage them

Adverse reactions to TB medicines are common and the patient and his/her family should be educated about them. In general, adverse reactions can be classified as Minor, Moderate, and Serious. Minor reactions can generally be handled with a reduction in dose and symptomatic treatment. Moderate reactions often require temporarily stopping the culprit medicine, treating symptomatically, and then trying the medicine again. Serious reactions usually involve stopping the medicine definitively and referring the patient to a specialty hospital. See table 4 for management of adverse effects

Table 4

MINOR TO MODERATE ADVERSE EFFECTS		
Medicine	Adverse Reaction	Management
Rifampicin	Stomach pains, nausea. Flu-like symptoms	Symptomatic treatment, try reducing dose for 7 days and then increase to normal dose. Change to daily dose.
Isoniazid	Euphoria, Insomnia Gastritis. Neuropathy	Decrease dose and add Pyridoxine 100 mg/day Try antihistamine drugs such as ranitidine. Give the minimum dose and add Pyridoxine 50 – 100mg/day
Pyrazinamide	Nausea, Anorexia	Decrease dose.
	Joint aches	Temporarily stop medicine and give trial of aspirin.
Ethambutol	Nausea.	Temporarily stop medicine and treat symptomatically
Streptomycin	Vertigo	Decrease or stop dose.
	Hearing loss	Decrease or stop dose, audiometric evaluation.

SERIOUS ADVERSE EFFECTS		
Medicine	Adverse Reaction	Management
Any TB medicine	Hypersensitivity, Stevens-Johnson Syndrome	1. Stop all medicines 2. Refer to DH/ PH
Ethambutol	Optical neuritis	1 - Stop all medicines 2- Refer to DH/ PH
Rifampicin	Purpura, Hemolysis, and Renal Insufficiency	1- Stop all medicines 2- Refer to DH/ PH
Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	Jaundice	1. Stop all medicines 2. Refer to DH/PH

Isoniazid	Epilepsy and Psychiatric symptoms	1- Stop all medicines 2- Refer to DH/PH
The primary responsibility of the health provider is to recognize the possibility of serious reaction, diagnose the most likely cause, and follow-up closely with the patient.		

5.1 Re-introduction of anti-TB drugs following a drug reaction

Drug challenges can identify the drug responsible for a reaction. Drug challenges begin by using the anti-TB drugs least likely to be responsible for the reaction (for example, Isoniazid). A small challenge dose is used so that any reaction that occurs will be weaker than one that would result from a full dose. The dose is then gradually increased over a period of three days. The procedure is repeated, adding in one drug at a time. A reaction that occurs after the addition of a particular drug identifies that drug as responsible for the reaction. No evidence exists that the challenge process can cause drug resistance (see Table 6, below).

Table 6: Re-introduction of anti-TB drugs following drug reaction

Drugs	**Likelihood of causing a reaction**	**Challenge doses**		
		Day 1	**Day 2**	**Day 3**
Isoniazid	Least likely	50 mg	300 mg	300 mg
Rifampicin	↓	75 mg	300 mg	Full dose
Pyrazinamide		250 mg	800 mg	Full dose
Ethambutol		100 mg	800mg	Full dose
Streptomycin	Most likely	125 mg	400 mg	Full dose

6. Child contacts of adults with TB SS+

Active tracing of household contacts of adults with TB SS+ disease is desirable to identify newly infected children under 5 years aged. If they are symptom - free should receive preventive treatment with isoniazid 5 mg/kg daily for 6 months.

II. Treatment management

Adherence by the patient to the full treatment regimen is a critical factor in curing TB. This can be especially difficult when the patient no longer feels ill or if the anti-TB medicines cause side effects. Adherence is best when the treating facility has a patient-centered approach which facilitates access to treatment, cooperates with the patient in arranging supervised administration of drug doses, and provides support services, such as food or transportation.

1. Directly Observed Treatment (DOT)

DOT means that an observer watches the patient swallowing his or her anti-TB medicines. This ensures that the patient takes the right anti-TB medicines in the intended doses at the scheduled times. The observer must be a health worker or a trained and supervised CHS/CHW and TB treatment supporter. Direct observation must be maintained during the initial phase of 8 months

treatment. For continuation phase of 8 months treatment the DOT is required, whenever possible (see Picture 1).
For 6 months treatment the DOT is mandatory for both initial and continuation phases.
DOT is the standard method of TB treatment in both developing and industrialized countries recommended by WHO.

Picture 1

2. Sputum smear follow up

Patients with TB SS+ and TB SS- should be monitored by sputum smear examination and clinical response, while patients with extrapulmonary TB must be monitored clinically.

In new TB SS+ cases in treatment category I the sputum smear follow up should be as follow:
For 8 months treatment:

- Sputum smears should be performed at the end of the second month, end of the fifth month, and at the end of the 8-month
- If sputum smears are positive at the end of the second month, the initial phase of treatment with 4 drugs should be extended for a third month, and sputum smear examination should be performed once again at the end of the third month. The continuation phase should then be started regardless of sputum smear examination results.
- If smears are still positive during the fifth month, the patient should be classed as a treatment failure and changed to a full course of the re-treatment regimen

For TB SS- cases when the patient completes two months of the intensive initial phase of treatment, a sputum smear should be collected for smear examination. If the smear is negative, the continuation phase of treatment will begin. If the smear is positive, reconfirm the result with a second smear examination and then begin the re-treatment regimen

For 6 months treatment:

- Sputum smears should be performed at the end of the second month, at the beginning of fifth month and at the end of the 6th -month
- If sputum smears are positive at the end of the second month, the initial phase of treatment with 4 drugs should be extended for a third month, and sputum smear examination should be performed once again at the end of the third month. The continuation phase should then be started regardless of sputum smear examination results.
- If smears are still positive at the beginning of fifth month, the patient should be classed as a treatment failure and changed to a full course of the re-treatment regimen and re register the patient.

For TB SS- cases when the patient completes two months of the intensive initial phase of treatment, a sputum smear should be collected for smear examination. If the smear is negative, the continuation phase of treatment will begin. If the smear is positive, reconfirm the result with a second smear examination and then begin the re-treatment regimen

Perform sputum smear examination	Treatment regimens	
	6-month	8-month
At the end of the initial phase	The end of the second month	The end of the third month
During the continuation phase	The start of the fifth month	The end of the fifth month
At the end of treatment	The end of the sixth month	The end of the eighth month

III. Role in treatment by health cadre

Below are some suggested specific roles and responsibilities for the health professionals.

1. Physician

- Educate and to advice the TB patient
- Establish an appropriate relationship physician-patient
- Determine the treatment according to the standardized NTP guidelines
- Calculate the dose of anti-TB medicines according to the weight and the patient's age
- Follow up TB cases in treatment, through the medical consultation
- Carry out a minimum of three medical consultations to TB patient:
    - At the beginning of the treatment
    - At the end of the initial phase
    - When concluding the treatment
- Carry out the control of contacts
- Prescribe the chemoprophylaxis to the contacts of TB SS+ under 5 years of age
- Check the condition of the patient's treatment outcome
- Manage the adverse effects to the anti-TB medicines
- Determine the initial seriousness, risk of dying of TB, and attention of complications
- Refer complicated TB patients to the hospital
- Timely reporting to PTCs
- Organize tracing of defaulters

2. Nurse

- Organize the treatment to be administered
- Establish a monitoring and evaluation system for treatment
- Educate and advise the TB patient and treatment supporter
- Carry out the reporting and recording system of treatment
- Administer the treatment, according to the medical indication and standardized treatment outlines
- Guarantee the supervised treatment
- Use the TB treatment card
- Carry out the patient's monthly weight
- In the event of non-attendees of 48 hours inform the health facility in charge, CHS/ CHWs to proceed to the domiciliary visit
- Guarantee the appropriate use and conservation of anti-TB medicines
- In coordination with the physician, request the control sputum smear exam under NTP guidelines
- In the event of received transfers, communicate the outcome condition to the establishment of origin health
- In places of difficult access or in case the patient has physical limitations to go to the health facility, the treatment will be able to be administered by a CHS/CHW for such an end, under the personnel's of health supervision
- During the treatment, the nurse will be carried out as minimum three interviews to TB patient:
    - At the beginning of the treatment (using flipchart)
    - At the end of the first phase
    - When concluding the treatment
- Investigate on treatment antecedents
- Contribute an appropriate study of contacts
- Identify in the patient behaviors of risk, in order to avoid the abandonment
- Organize domiciliary visits
- Organize the TB treatment card box
    - It will be placed dividers for first phase and second phase, and inside each one of them per day.
    - The cards will be placed in the space corresponding to the day of administration.
    - To place dividers for the patients considered as absent, hospitalized and according to the outcome conditions.
    - Keeping in mind the cohort study, the cards will remain for one period of up to two years.
- Organize the referral/transfer system of TB patients

3. Laboratory technician

- Coordinate with physician and nurse for the reception of the sputum samples for follow up of TB patients in treatment.
- Carry out the necessary sputum smear exam for follow up of TB patients in treatment
- Inform the nurse about the result of the sputum smear exam in the format for bacteriological exam.
- Coordinate with the intermediate laboratory the derivation of samples of sputum that require culture *(if available)*

- In the event of being samples of another health facilities will send the results in a term than 48 hours
- Carry out the reporting and recording system of TB lab

4. Role of CHS

- Can be a treatment supporter if living close to patient. If so he/she will follow treatment supporter TOR
- Give instructions to CHW and other treatment supporter during supervisory visit monthly and review how the patient is doing and discuss any problems
- Before initially supplied drugs finish, re-supply anti TB drug (monthly base) to other treatment supporter and CHW (if CHW doesn't get drugs at the monthly meeting at health facility).
- Update original treatment card monthly referred from copied treatment card which other treatment supporter keep. After update original treatment card, return it to health facility.

5. Community Health Worker (CHW)

- Monitor treatment under the supervision of the CHS and nurse
- Notified each case of active TB in the community and set up a schedule of regular visits to the home to provide medications and observe the patient taking them
- Keep TB treatment cards, under the supervision of the nurse
- Participate in the domiciliary visits to the TB patients and families; and sensitize the community about the importance of the supervised treatment providing health education (see Picture 2)

Picture 2

IV. Main activities to be carried out in the medical consultation to TB patients

Below are some suggested specific activities;

1. First consultation: at the beginning of the treatment

- Establish a physician-patient appropriate relationship to clarify doubts and the sick person's concerns
- Elaborate the complete patient's clinical history
- Determine the stage of the TB case (location of the TB, previous treatment, bacteriological condition and graveness of the TB)
- Determine the treatment according to the NTP guideline
- Educate and advice the patient regarding their illness, treatment, sputum follow up, importance of not interrupting the treatment and the possibility of the presence of adverse effects to the anti-TB medicines or other complications
- Advice women of reproductive age with TB disease, about the importance of the use of family planning methods, and to avoid pregnancy during the TB treatment. Coordinate this activity with the midwives
- Carry out the control of contacts according NTP guideline

2. Second consultation: at the end of the initial phase

- Follow up the clinical and bacteriological evolution
- Explain the patient the results of the sputum smear obtained in their controls
- Reinforce the physician-patient relationship and their sanitary education.
- Update the patient's clinical history
- Verify the appropriate control of contacts.
- Authorize the change to second phase

3. Third consultation: at the end of the treatment

- Verify the complete treatment and the result of the treatment, in order to determine the condition of the patient
- Explain to the patient the necessity to go to the health facility if he or she presents reappearance of disease symptoms

4. Special medical evaluations

They can be necessary other additional consultations in the following cases;

- Unfavorable clinical, bacteriological evolution or other complications (Hemoptysis, etc).
- Irregularity in the treatment.
- Risk of abandonment to the treatment.
- Presentation of adverse effects to anti-TB medicines
- Presentation of other illnesses associated to the TB
- Carry out the study of contacts

5. Good practices for the medical attention to TB patients

Frequently the health facilities have a general form for recording a patient's clinical history; however, under operational conditions it is often incomplete. For this reason to improve the quality DOTS it is important that the physicians should include the following specific information, at a minimum, on the usual form of clinical history See Annex (1), focusing in the first medical consultation.

V. Main activities to be carried out in the nursing counseling to TB patients

Below are some suggested specific activities;

1. First interview: at the beginning the treatment

- Verify that the patient knows his/her diagnosis and to evaluate the grade of understanding about his/her illness
- Research on treatment antecedents
- Research about time of permanency in the place and possible home changes or work, to coordinate his/her referral in opportune form
- Offer education on TB treatment, control exams and possible reactions to the anti-TB medicines, with simple words and using the available educational material (using flipchart)
- Advice women of reproductive age with TB disease, about the importance of the use of family planning methods, and to avoid pregnancy during the TB treatment. Coordinate this activity with the midwives
- Inscribe the patient in the tuberculosis register
- Fill the TB treatment card and TB patient identification card
- Carry out the recording and reposting of contacts and coordinate an appointment with the physician for the exam of the contacts
- In patient with TB SS+ to identify the contacts under 5 years aged
- Inform to the patient on the realization of the domiciliary visit, explaining in simple form the reasons

2. Second interview: at the end of the initial phase

- Follow up the patient's evolution, exams and analysis
- Inform the patient about the continuation of the treatment in second phase and the importance of the sputum smears exam of control
- Verify the execution of the sputum smear exam of control and each patient's monthly weight.
- Reinforce the sanitary education, asking to the patient on their illness, like he/she feels and to clarify possible doubts. It is important to know some aspects of their family and social life, as well as their opinion on the attention that he/she receives in the health facility
- Explain to the patient about the bacteriological conversion to the end of the first phase and the importance of continuing their treatment.
- Revise of the study of contacts.
- Ask the patient on the appearance of adverse effects to the anti-TB medicines
- Coordinate the second medical consultation of evaluation.

3. Third interview: at the end of the treatment

- Follow up the result of the last sputum smear exam of control
- Verify the complete treatment and the result of the treatment, to determine the outcome of the patient
- Recommend that the patient go to the health facility in the event of presenting disease symptoms
- Offer education about sanitation
- Coordinate the third medical consultation of evaluation

4. Other interviews during the treatment

- If there is irregularity to receive treatment, the nurse asks the patient about the causes of their nonattendance and the orientation will be reinforced about the importance of not abandoning the treatment
- In the event of presenting some adverse effects to anti-TB medicines
- To contribute to the study of contacts
- If the patient will change home, the nurse will be guided to carry out the transfer to another health facility, near to her new home
- Other reasons that it considers necessary

5. Domiciliary visit

It is consists on going to the home of the TB patient, with the purpose of educating the patient and their family with relationship to the TB. It is suggested to carry out the visit in the first 48 hours of having the diagnosis.

The reasons should be;

- To locate the TB patient, to begin the treatment
- To verify if the TB patients are living in the coverage area of the health facility
- To offer education to the patient and family about the importance of the supervised treatment
- To offer sanitary education to the family group, guiding to the family on the TB prevention, requesting their participation in the care of the TB patient with tuberculosis
- To verify the number of contacts, in order to detect cases of TB and to prevent the risk of TB
- To gather sputum samples, in the event of finding symptomatic respiratory cases (SR) among the contacts and to recommend to go to the health facility
- To recover the patient that it misses the treatment, in the 24 following hours, to the lack or absence to the administration of the treatment

VI. Good uses and practices to guarantee the conservation of anti – TB medicines

For improve the quality of the treatment in the health facility should be organized the supervision to the nursing personnel, in the appropriate conservation of the drugs.

Following are some suggested specific activities;

- Respect the indications of conservation of the drugs, they will protect of the sunlight, humidity, to avoid the exhibition to excessive heat
- Correct manipulation of the medications; to extract the medications of the original container, only to the moment that leaves to administer the treatment
- Guarantee an appropriate place for the storage of the medications in use (see Pictures 2 and 3)
- Use syringes and needles not reusable

1. Technical basis for the use of TB Patient Kits (TB PK)

A TB PK contains the full course of treatment for a single patient. There are two variations depending on where packs are constituted:

- Packs constituted in health facilities
- Pre-packed TB patient kits (by manufacturers or suppliers)

The same basic principles are behind the constitution of a TB PK system: a complete course of treatment should be assured for each patient, and furthermore, treatment should not be started if there is no assurance that it will be completed.

From the provider point of view, the TB PK allows health workers to use a container that has all required medicines, strengths, and quantities, limiting confusion and wastage, making it easier to monitor the regularity of treatment and preventing supply breakdowns for individual patients.

The TB PK also increases patient adherence. Since medicine stock outs cause patients to lose confidence in the health system, the TB PK assures the TB patient that his or her medicines will be available from start to finish of the treatment. In addition, the patient may feel ownership of the patient kit and with the likelihood of completing the full course of treatment since he/she can see the quantity of medicines needed to be taken to achieve cure during visits to the health center or dispensary.

It is important to mention that the TB PK does not eliminate the need for directly observed treatment (DOT) as proscribed by the WHO. The fifth main components of the DOTS scheme require strict DOT at least during the intensive phase of TB treatment.

2. Constitution of TB-Patient Packs in health facilities

All medicines for a 6 month (category I) or 8 month (category II) treatment should be included in one plastic container (see Picture 3).

All packs should be labeled with the name of the patient, treatment category and the date the treatment was initiated. The security stock is usually kept as loose medicines.

Picture 3

The constitution of TB patient packs in health facilities has some of the most significant features:

- Assurance that the treatment is being followed since the health worker does not have to select which drug to use.
- Less preparation time by the health worker at the time of dose administration to the patient
- Improves patients' adherence.
- Easier to monitor the treatment when comparing the treatment card with the number of doses remaining in the container.

VII. Determination of the initial seriousness, risk of dying of TB, and attention of complications

The main risk to die occurs when the TB patient has not been diagnosed and treated. Around 50% of TB patients without treatment die after 2 to 4 years beginning of the disease and around 75 % die after 5 years. In consequence the main cause of death is the late TB diagnosis and start of treatment.

However when the TB patient has been early diagnosed and treated the main cause of death is not attributed to the same illness, but to associate conditions.

Severe malnutrition, serious co-morbid disease, and immunodeficiency (such as HIV/AIDS or late-stage diabetes) are risk factors which make a diagnosis of TB much more serious and require that this TB patient being hospitalized for treatment.

The following signs and symptoms should also cause providers to refer patients to the hospital:

- Respiratory insufficiency,
- Hemoptysis,
- Serious adverse effects to anti-TB medicines,
- Strong suspicion of serious extra-pulmonary TB (milliary TB, meningitis TB multisystemic TB)

Annex (1)

Personal social history

Name: _____ age:_____ sex: _____

address:_____ educational level:_____ job:_____

other:_____

Medical history

Drug addiction and tobacco use ☐
Family and personal medical antecedents: diabetes ☐ renal insufficiency☐
chronic liver disease ☐ others ☐

Current medications : _____
Allergies to drugs: _____
Last menstrual period and method of contraception: _____

TB History

Family medical antecedents including TB: ☐
Sputum smear exam and culture results:
Positive ☐ Negative ☐
Localization of the TB: pulmonary TB ☐ extra pulmonary TB ☐ or both ☐ (if extra pulmonary, indicate site) _____.

Graveness of the TB: _____
Treatment antecedents: new ☐ relapse ☐ failure ☐ treatment after interruption ☐ transfer in ☐ or other: _____

Date of initial diagnosis (/ /1387)
Start and end date of all previous treatments: _____
compliance with treatment regimens:_____
outcomes:_____
History of adverse effects to anti-TB medicines

Complications (pneumothorax ☐ Hemoptysis ☐ others :_____)
History of household contacts:

Review of symptoms

Cough: _____

Expectoration:_ _____

Fever night sweats: _____

Weight loss: _____

Dyspnea: _____

Appetite loss: _____

Others: _____

Physical Examination

Height: (cm) weight: (kg)

Vital signs:

BP: (mmHg) PR: (/min) RR:(/min) HR: (/min)

Physical examination of systems and organs:

skin: ( )

Head ( )

Neck ( )

Oropharynx ( )

cardiovascular system: _____

Pulmonary system : _____

Abdominal organs: _____

Extremities_____

Nervous system:_____

Tentative Diagnostic

TB and other diseases

Treatment

Category 1 ☐ 2 ☐ other: _____

Date: (/ /1387) **Signature: _____**