महानिदेशक सशस्त्र सेना चिकित्सा सेवा चिकित्सा ज्ञापन क्रमांक 178
DGAFMS MEDICAL MEMORANDUM NO. 178

क्षयरोग
TUBERCULOSIS

(यह ज्ञापन महानिदेशक सशस्त्र सेना चिकित्सा सेवा चिकित्सा ज्ञापन क्रमांक 167 को स्थगित करता है)
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वितरण :--

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(ख) एक प्रति प्रत्येक चिकित्सा यूनिट एवं फार्मेशन मुख्यालयों की चिकित्सा शाखाओं को।

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(a) One copy per medical officer.

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महानिदेशक सशस्त्र सेना चिकित्सा सेवा के प्राधिकार से जारी किया गया
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Revised Draft DG MEMORANDUM on 'Tuberculosis' 178

INTRODUCTION

1. Tuberculosis(TB) is a curable infection and its management requires prompt diagnosis, supervised regular drug therapy and periodic monitoring. The cure rates achieved in Armed Forces are much better and relapse rates are much lower as compared to general population. However, in view of alarming increase in the prevalence of drug resistance tuberculosis and emergence of HIV epidemic, it becomes imperative for all physicians to strictly follow standard treatment guidelines.

OBJECTIVE

2. This DG Memorandum is being brought out to give guidelines to treating physicians for management of tuberculosis in Armed Forces keeping in mind the national and international guidelines given by RNTCP and WHO.

CASE DEFINITIONS

For uniform reporting & data analysis, treating physicians must use following standard definitions:-

3. ***Tuberculosis suspect***. This term refers to any person with cough for more than two weeks with or without other respiratory symptoms (haemoptysis, pleuritic chest pain, shortness of breath) or constitutional symptoms (fever, anorexia, weight loss, night sweats, generalized weakness).

4. ***Tuberculosis—New case***. Patients who have never taken treatment for TB or have taken ATT for less than one month. Patient may be sputum positive/negative with pulmonary/ extrapulmonary tuberculosis.

5. ***Tuberculosis—Relapse***. Patient who was declared cured or had completed treatment but reports back to health services with recurrent disease and is found to be sputum smear positive.

6. ***Tuberculosis—Treatment Failure***. Any TB patient who is smear positive at five months or more after starting treatment or a sputum negative patient who becomes positive while on treatment.

7. ***Tuberculosis—Treatment Default***. TB patient who has received ATT for more than one month and subsequently has not taken ATT for two months or more and presently is found to be sputum smear positive.

8. ***Chronic Tuberculosis***. A TB patient who remains smear positive after completing a retreatment regimen.

9. ***Pulmonary tuberculosis***. Pulmonary tuberculosis is tuberculosis of lung parenchyma including miliary tuberculosis. Patient with pulmonary tuberculosis with associated intrathoracic involvement e.g. pleural effusion, mediastinal lymphadenopathy will still be classified as pulmonary tuberculosis (not disseminated tuberculosis). Associated intrathoracic involvement should be clearly mentioned in final diagnosis e.g. pulmonary tuberculosis with tubercular pleural effusion.

10. ***New sputum smear positive pulmonary tuberculosis***. One or more sputum smear positive and chest x-ray suggestive of pulmonary tuberculosis at start of treatment.

11. ***New sputum smear negative pulmonary tuberculosis***. Patient with clinical features of tuberculosis with at least two sputum smear examinations negative for AFB and radiographic abnormalities consistent with active pulmonary tuberculosis. A patient with positive culture but negative AFB sputum smear examination will also be classified as smear negative pulmonary tuberculosis. Pulmonary TB cases without smear results should be classified as smear not done (and not as smear negative).

12. ***Extrapulmonary tuberculosis***. Case of TB involving organ other than lung e.g. isolated pleural effusion, lymphnodes including isolated mediastinal lymphadenopathy, abdomen, genitourinary tract, skin, joint, bones, meninges. Diagnosis requires at least one specimen with confirmed MTB growth or histopathological evidence and strong clinical evidence of disease.

13. ***Disseminated tuberculosis***. Involvement of two or more non contiguous organs with tubercular disease will be termed as disseminated tuberculosis. The sites of involvement should be clearly mentioned in final diagnosis e.g. disseminated tuberculosis (Pulmonary and abdominal).

14. ***Tuberculosis—Cured***. A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.

15. ***Tuberculosis—Treatment completed***. A patient who completed treatment but who does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion.

16. ***Tuberculosis—Drug resistance***. Tuberculosis patient whose TB is due to Mycobacterium tuberculosis showing in vitro resistance to at least one of the anti tubercular drugs.

17. ***Multidrug resistant tuberculosis (MDR-TB)***. A patient whose TB is due to Mycobacterium tuberculosis showing in vitro resistance to at least Isoniazid and Rifampicin.

18. ***Extensively Drug-resistant tuberculosis (XDR-TB)***. A patient with MDR-TB who is found to be resistant to quinolones and also to any one of aminoglycosides (Kanamycin, Capreomycin, or Amikacin).

RECORDING OF DIAGNOSIS.

19. The diagnosis should include anatomical site (pulmonary, extrapulmonary, disseminated), type (new, relapse), smear status (positive / negative) and outcome (cured, treatment completed). In extrapulmonary, site should be mentioned & in disseminated, all sites involved should be mentioned. For example; pulmonary tuberculosis (New smear positive - cured), pulmonary tuberculosis (New smear negative - treatment completed), extrapulmonary (cervical lymph node), disseminated tuberculosis (pulmonary + abdominal).

DIAGNOSIS OF TUBERCULOSIS

20. A patient having cough of more than two weeks duration with or without systemic features like fever, night sweats, anorexia and weight loss and haemoptysis must be evaluated for pulmonary tuberculosis as tuberculosis suspect.

21. Initial investigation will include chest x-ray and examination of two sputum specimen with at least one early morning sputum for

acid fast bacillus (AFB). Any patient showing one or more sputum smear positive for AFB at start of treatment will be classified as smear positive case. Smear negative are patients with sputum smear negative for AFB, with clinical features suggestive of tuberculosis and evidence of radiological abnormalities consistent with active pulmonary tuberculosis. All serving officers and PBORs who are smear positive with or without chest x-ray abnormalities or smear negative with chest x-ray abnormalities will be transferred to a respiratory centre with TB beds. ***Smear positive patients should be put on ATT & then transferred without delay***. The patients will be further evaluated as follows:-

(a) Mycobacterium culture along with drug sensitivity testing (DST) will be obtained for all patients.

(b) Wherever available, rapid molecular based drug sensitivity test will guide choice of regimen in previously treated patients.

(c) Smear negative cases will be subjected to fibreoptic bronchoscopy and analysis of BAL for AFB and MTB culture.

(d) Other investigation like tuberculin test, polymerase chain reaction (PCR) may be complementary to diagnostic work up but they do not have definitive diagnostic value.

(e) Investigations including blood counts, ESR, liver function tests, serum transaminases, alkaline phosphatase, uric acid, blood sugar and HIV serology will be carried out for all patients at the onset of treatment.

TREATMENT.

22. Cure rate in pulmonary tuberculosis in Armed Forces during last quarter century has remained 98-100% with relapse rate below 1%. All efforts must be directed to maintain this record and if possible to improve upon it.

(a) **Aims of treatment** :-

(i) To cure the patient of TB.

(ii) To prevent death from active TB or its late effects.

(iii) To prevent relapse of TB.

(iv) To decrease transmission of TB to others.

(b) **Antitubercular drugs**. These are divided into 5 groups :-

(i) Group 1 (First-line oral antitubercular drugs):-

(aa) lsoniazid (H).

(ab) Rifampicin (R).

(ac) Ethambutol (E).

(ad) Pyrazinamide (Z).

(ae) Rifabutin (Rfb).

(ii) Group 2 (lnjectables)

(aa) Kanamycin (Km).

(ab) Amikacin (Amk).

(ac) Capreomycin (Cm).

(ad) Streptomycin (S).

(iii) Group 3 (Fluoroquinolones)

(aa) Levofloxacin (Lfx).

(ab) Moxifloxacin (Mfx).

(ac) Ofloxacin (Ofx).

(iv) Group 4 (Oral bacteriostatic second-line drugs) :-

(aa) Ethionamide (Eto).

(ab) Protionamide (Pto).

(ac) Cycloserine (Cs).

(ad) Terizidone (Trd).

(ae) P-aminosalicylic acid (PAS).

(v) Group 5 Antituberculosis drugs with unclear efficacy or unclear role in MDR-TB treatment (not recommended by WHO for routine use in MDR-TB patients) :-

(aa) Clofazimine (Cfz).

(ab) Linezolid (Lzd).

(ac) Clarithromycin (Clr)

(ad) Amoxicillin/clavulanate (Amx/C1v).

(ae) Imipenem (Ipm).

(af) Thioacetazone (Thz).

DAILY VERSUS INTERMITTENT THERAPY

23. The optimal dosing frequency for patients with pulmonary TB is daily throughout the course of therapy, since resistance rate is much higher in intermittent therapy as compared to daily regimen.

DOTS TREATMENT

24. Supervised drug therapy as an indoor patient is not entitled and feasible for families and ex-servicemen, they should be advised and encouraged to take treatment from nearest DOTS centre. **Community medicine needs to play an important role in spreading awareness about DOTS programme & should work in close association with DOTS centre.**

STANDARD TREATMENT REGIMEN

25. Standard regimens for new TB patients (presumed, or known, to have drug-susceptible TB) comprises of Intensive phase treatment with HRZE of **minimum 2 months extendable to 3 months** duration followed by continuation phase with HR of 4 months duration. Because of high levels of Isoniazid resistance, families and ex-servicemen in whom DST has not been performed, continuation of HRE in the continuation phase is an acceptable and justifiable alternative to HR. However, in case of serving personnel if DST does not reveal resistance to Isoniazid and Rifampicin, switch to HR only.

26. ***Drug resistant cases in new patients***. If sputum conversion does not occur at 2 months in a new smear positive case or sputum becomes positive in a smear negative case at 2 months and if there is no satisfactory clinco-radiological response, possibility of drug resistance should be considered and intensive phase should be extended by one more month. At the same time, repeat sputum culture and DST should be performed preferably by rapid culture methods like liquid cultures & molecular assays. Susceptibility testing for Isoniazid, Rifampicin, Fluroquinolones and the injectable agents is fairly reliable. It is less reliable for other drugs and basing individualized treatments on DST for these agents should be avoided. Since clinical effectiveness or ineffectiveness of a drug cannot be predicted by DST with 100% certainty, formulation of regimen should be based on clinical, radiological & microbiological co- relation and also on the duration of usage of drug. If repeat sputum is still positive at 3 months with unsatisfactory clinico-radiological response, patient should be started on empiric MDR regimen consisting of Z + Km + Mfx + Eto + Cs and regimen to be modified later depending on DST report and clinico-radiological response.

Note: Since microbiological support is mandatory for confirmation of diagnosis, drug susceptibility testing & monitoring especially in drug resistance tuberculosis, all respiratory centres should have conventional & rapid MTB culture & DST facilities. In view of significant number of cases having clinic-radiological & microbiological discordance (37% of cases in a study done at MH CTC) , all microbiologists/ pathologists should ensure good quality control of these facilities. Moreover, micobiological laboratories at MH CTC, MH Namkum & MH Dehradun should be accredited.

27. ***Drug resistance in previously treated patients***:—In these patients, first line ATT to be started & culture & DST, preferably rapid culture should be done at the start of treatment. Since incidence of MDR-TB is quite high in these patients, they need to be monitored closely. MDR-regimen to be started after DST results which is to be co-related with clinico-radiological profile.

28. **General principles for designing MDR-TB regimens**:—

(a) Use at least 4 drugs certain to be effective as found by DST or if the drug has not been used before for more than a month.

(b) Do not use drugs for which there is possibility of cross resistance.

(c) Include drugs from Gp 1-5 in a hierarchical order.

(d) Use any of the first line oral agents (Group 1) that are likely to be effective.

(e) Use one injectable drug (Gp-2).

(f) Use a fluoroquinolone (Gp-3).

(g) Use the remaining Gp 4 drugs to complete a regimen of at least four effective drugs.

For regimen with fewer than 4 effective drugs, consider adding two Gp 5 drugs. The total number of drugs may be 5–7.

29. ***Monitoring and duration of treatment for MDR-TB***:—

(a) The injectable drug should be continued for a minimum of 6 months or for at least 4 months after the patient first becomes and remains smear or culture negative.

(b) Patient will be monitored monthly by sputum smear, MTB culture preferably rapid culture methods, clinically & radiologically. If three cultures are negative and there is satisfactory clinico-radiological response at 6 months, total duration of therapy will be for 18 - 24 months. In case culture positivity persists along with unsatisfactory clinico-radiological response at 6 months, the patient should be re-evaluated for possibility of XDR-TB & may be invalided out of service.

TREATMENT REGIMENS IN SPECIAL SITUATIONS

30. ***Pregnancy***:—

(a) A pregnant woman should be treated with the standard regimen of ATT.

(b) With the exception of aminoglycosides, the first line anti-TB drugs are safe for use in pregnancy.

31. ***Breastfeeding***:—

(a) A breastfeeding woman who has TB should receive a full course of TB treatment.

(b) Mother and baby should stay together and the baby should continue to breastfeed.

(c) Mother should be advised to use surgical mask and frequent hand washing until she becomes sputum negative.

(d) After active TB in the baby is ruled out, the baby should be given BCG vaccination.

(e) Pyridoxine supplementation should be given to all pregnant or breastfeeding women taking isoniazid.

32. ***Treatment for Women taking the Oral Contraceptive Pills***.

Rifampicin interacts with the oral contraceptive pill with a risk of decreased protective efficacy against pregnancy. A woman who usually takes the oral contraceptive pill may choose:

(a) Following consultation with a physician, she could take an oral contraceptive pill containing a higher dose of estrogen (50 mcg).

(b) Alternatively she could use another form of contraception

33. ***Renal failure*** :—

(a) The recommended initial TB treatment regimen for patients with renal failure or severe renal insufficiency is 2 months of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol, followed by 4 months of Isoniazid and Rifampicin.

(b) Doses remain same for all first line drugs. However, three times per week administration of these two drugs at the following doses is recommended: Pyrazinamide (25 mg/kg), and Ethambutol (15 mg/kg).

(c) While receiving Isoniazid, patients with severe renal insufficiency or failure should also be given pyridoxine in order to prevent peripheral neuropathy.

34. ***Treatment for patients with liver disorders***.

The patients with the following conditions can receive the standard short-course chemotherapy regimens provided that there is no clinical evidence of chronic liver diseases: hepatitis virus carriage, a past history of acute hepatitis, excessive alcohol consumption. Since hepatotoxic reactions to ATT may be more common among these patients, they should be regularly monitored clinically & with LFT.

(a) ***Established chronic liver disease***.

In these patients, LFT should be done at the start of treatment & if serum aminotransferase level is more than three times normal, the following regimes should be considered. The more unstable or severe the liver disease is, the fewer hepatotoxic drugs should be used.

(i) For significant liver disease with decompensation: Regimen with no hepatotoxic drugs i.e. 18-24 months of streptomycin, ethambutol and a fluoroquinolone.

(ii) For compensated liver disease: Regimen with one hepatotoxic drug i.e. 2 months of isoniazid, ethambutol and streptomycin, followed by 10 months of isoniazid and ethambutol.

(iii) For doubtful liver disease one may start with regimen involving upto two hepatotoxic drugs (rather than the three in the standard regimen). Some examples are:

(aa) 9 months of isoniazid and rifampicin, plus ethambutol (until or unless isoniazid susceptibility is documented);

(ab) 2 months of isoniazid, rifampicin, streptomycin and ethambutol, followed by 6 months of isoniazid and rifampicin;

(ac) 6-9 months of rifampicin, pyrazinamide and ethambutol.

(b) ***Acute hepatitis (e.g. acute Viral hepatitis)***

It is a rare eventuality that a patient has TB and also at the same time acute hepatitis unrelated to TB or anti TB treatment. In some cases it is possible to defer TB treatment until the acute hepatitis has resolved. In other cases when it is necessary to treat TB during acute hepatitis, cautious use of non-hepatotoxic drugs with frequent monitoring of hepatic parameters needs to be done.

35. ***Extra pulmonary tuberculosis***.

(a) ***Lymph node tuberculosis***. It is the commonest form of extra pulmonary tuberculosis. All attempts should be made to obtain a tissue diagnosis prior to starting ATT. Though the recommended treatment for lymph node tuberculosis is for six months, it has been seen that in most cases the treatment has to be extended for 09-12 months. One third of cases of lymph node tuberculosis may show apparent increase in size and aggravation of lesions while on treatment (paradoxical reaction). However, they do not necessarily suggest failure of treatment and 1st line ATT should be continued. However in cases where the lymph nodes either do not regress or persistently increase in size or new nodes appear after 3-4 months of ATT, possibility of drug resistance or NTM infection should be considered and all these cases should be referred to a respiratory centre for further management.

(b) ***Bone and joint tuberculosis***. The recommended duration of ATT for bone and joint tuberculosis is 9 months. However difficult cases should be managed in consultation with a chest physician.

(c) ***CNS TB***. The recommended duration of ATT is for 9-12 months in cases of CNS tuberculosis. In view of better CNS penetration Ethambutol should be replaced with Inj Streptomycin for the intensive phase of treatment in TB meningitis. Systemic steroid therapy is added to reduce meningeal inflammation and prevent any obstruction to CSF flow in cases of TB meningitis where drug resistance is not suspected. Difficult to treat cases should be managed in consultation with a chest physician.

(d) ***Genito urinary tuberculosis***. A six month regimen with present short course therapy seems to be adequate except in cases where there has been involvement of prostate and seminal vesicles wherein the treatment may be extended to 9 - 12 months.

(e) ***Abdominal tuberculosis***. Gastro intestinal involvement is a fairly common occurrence. The tubercular lesions involving intestinal lumen and peritoneum may heal quickly but those involving intra-abdominal lymph nodes may take more time. A total duration of treatment of 9-12 months is recommended and the involvement of intra abdominal lymph nodes should be monitored by abdominal ultrasonography.

36. ***HIV and Tuberculosis.***

(a) All suspected and confirmed cases of tuberculosis should be tested for HIV.

(b) In all HIV-positive TB patients, co-trimoxazole preventive therapy should be initiated as soon as possible and given throughout TB treatment.

(c) ART should be initiated for all people living with HIV with active TB disease irrespective of CD4 cell count. TB treatment should be started first, followed by ART as soon as possible and within the first 8 weeks of starting TB treatment.

(d) DST should be performed at the start of TB therapy in all HIV-positive TB patients to avoid mortality due to unrecognized drug-resistant TB.

(e) TB patients with known positive HIV status should receive daily supervised TB treatment to reduce incidence of relapse and failure.

37. ***Treatment of tuberculosis in solid organ transplant patients***. These patients are on immunosuppressive drugs. Rifampicin decreases the levels of calcineurin inhibitor family (Cyclosporine and Tacrolimus) and Rapamycin (Sirolimus). Drug level should be monitored if rifampicin is being used with CNI and Rapamycin.

MANAGING SIDE-EFFECTS OF ANTI-TB DRUGS

38. ***Management of cutaneous reactions*** :—

(a) ***Itching without a rash***. Symptomatic treatment with antihistaminics, skin moisturizing agents and continue TB treatment with close observation of patient for development of skin rash.

(b) ***Skin rash*** :-

(i) All anti-TB drugs must be stopped.

(ii) Once the reaction has resolved, anti-TB drugs are reintroduced one by one.

(iii) Start with the drug least likely to be responsible for the reaction (Rifampicin or Isoniazid) at a small challenge dose, such as 50 mg Isoniazid or 150 mg of Rifampicin. The dose is gradually increased over 3 days.

(iv) This procedure is repeated, adding one drug at a time.

(v) A reaction after adding a particular drug identifies that drug as the one responsible for the reaction and that drug should be avoided.

39. ***Management of drug-induced hepatitis*** :—

(a) All drugs should be stopped. Start non hepatotoxic drugs (Streptomycin, Ethambutol and a Fluoroquinolone).

(b) Wait for liver function tests to revert to normal and clinical symptoms (nausea, abdominal pain) to resolve before reintroducing the anti-TB drugs.

(c) If the signs and symptoms do not resolve and the liver disease is severe, the non-hepatotoxic regimen consisting of Streptomycin, Ethambutol and a Fluoroquinolone should continue for a total of 18-24 months.

(d) Once drug-induced hepatitis has resolved, the drugs are reintroduced one at a time. Start with Rifampicin at about one third of total dosage for three days. Repeat LFT after 3 days. If LFT is normal, isoniazid may similarly be reintroduced gradually over

3 days and if LFT is normal start Pyrazinamide in a similar dosage schedule.

(e) If symptoms recur or liver function tests become abnormal as the drugs are reintroduced, the last drug added should be stopped and ATT to be continued with the introduced drugs. If Rifampicin and Isoniazid have been introduced but Pyrazinamide has not been re-introduced, then duration of therapy should be extended to 8 months. If either of Isoniazid or Rifampicin has not been included then therapy should be continued with non hepatotoxic regimen with either Rifampicin or Isoniazid for a minimum period of one year.

DISPOSAL OF CASES OF PULMONARY TUBERCULOSIS

40. All suspected cases suffering from pulmonary tuberculosis are to be transferred to respiratory centres with TB beds for establishing diagnosis and Attributability Medical Board (AMB). After detailed evaluation, the diagnosis must be confirmed and an AMB should be held within 60 days of transfer to respiratory centre with TB beds.

Note:- **The respiratory centers with TB beds are MH (CTC), MH Namkum & MH Dehradun. The respiratory centers without TB beds are AH (R&R), BHDC, CHs Lucknow, Kolkata, Chandimandir, CH (AF) Banglore & INHS Asvini. The dependency of TB beds is as under :—**

(a) **Officers**:

i. From all commands except Eastern, Western & Central Command (less UB Area) to MH (CTC), Pune.

ii. From Eastern, Western & Central Command (less UB Area) to MH Namkum.

(b) **JCOs/ORs**

i. From Southern Command, Southwestern Comd, and 14 & 15 Corps Z of Northern Command to MH (CTC) Pune.

ii. From Eastern, Western & Central Command (less UB Area) to MH Namkum.

iii. From UB Area and other sectors of Northern Command to MH Dehradun.

41. ***Duration of hospitalization***. The intensive phase of treatment should be under supervision of chest physician in a respiratory centre with TB beds and the patient should remain hospitalized till sputum becomes negative, DST reveals sensitivity to first line ATT and there is satisfactory clinico-radiological response. Subsequently they should be transferred to the nearest military hospital under the care of medical specialist for the remaining period till declared cured or treatment completed. If the patient, during continuation phase does not show satisfactory clinical/ radiological/ bacteriological response or develops complications he/ she should be transferred back to the respiratory centre where he/she had completed his/her intensive phase.

42. **Discharge from the hospital and Disposal**.

(a) ***Drug susceptible tuberculosis***.

(i) If the patient of pulmonary tuberculosis has been declared cured or treatment completed he should be placed in LMC P3 (T-24) and discharged to unit. The patient should remain in medical category P3 until he has been declared cured or treatment completed or maximum of one year.

(ii) ***Subsequent categorization***. In case treatment is completed & cure achieved before one year and there is no relapse of disease, no residual significant structural or functional deficit, he can be considered for up gradation to P2 (T-24) category and subsequently to P1.

(iii) If the individual cannot be upgraded to category P2 after remaining in category P3 for one year he will be transferred to nearest respiratory centre for detailed evaluation. If he is found unfit for up gradation to category P2, he may be considered for invalidment .

(b) **Drug resistant cases**.

(i) All cases of pulmonary tuberculosis suspected to be suffering from drug resistant pulmonary tuberculosis should

be transferred to nearest respiratory centre with TB beds for management by a Pulmonologist.

(ii) All cases of drug resistant tuberculosis (mono, poly, MDR and XDR) who show poor response to ATT after 6 months of starting 2nd line ATT in the form of persistence of sputum smear and culture positivity for AFB, should be invalidated out of service.

43. ***Treatment and disposal of recruits/cadets***. The treatment and disposal guidelines for recruits and cadets will be as per RMSAF–2010 (Revised).

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