Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

August 1, 2015

DEPARTMENT MEMORANDUM
No. 2015 - 0294

TO: **ALL DOH REGIONAL OFFICE DIRECTORS, SECRETARY OF HEALTH OF AUTONOMOUS REGION OF MUSLIM MINDANAO, AND DIRECTORS OF HOSPITALS WITH PROGRAMMATIC MANAGEMENT OF DRUG-RESISTANT TUBERCULOSIS (PMDT) TREATMENT FACILITIES**

SUBJECT: **Revised Clinical and Laboratory Baseline and Follow-up for Drug-resistant Tuberculosis (DR-TB) Patients**

According to the results of the "*Evaluation of Reasons for Patients' Loss to Follow-up during MDR-TB Treatment in the Philippines*", one of the reasons that contributes to a high proportion of patients being loss to follow-up during MDR-TB treatment is adverse drug reaction (ADR) or fear of ADR. One of the recommendations of the study is to do aggressive monitoring of ADR. This can be done by symptom assessment or through regular laboratory screening to detect occult adverse events. Hence, to be able to detect early and properly manage adverse events during the entire duration of treatment, there is a need to revise the current guidelines on the baseline and follow-up monitoring for all patients enrolled in PMDT as follows:

1. Once a patient has been diagnosed with Rifampicin Resistant Tuberculosis (RR-TB)/Multi Drug-resistant Tuberculosis (MDR-TB), the patient shall be properly evaluated and initiated on treatment while awaiting the result of the Drug Susceptibility Testing (DST).

2. Initial evaluation shall be done by the Satellite/Treatment Center (S/TC) Physician.

3. Pretreatment assessment shall be done on all patients to be enrolled in PMDT. This will serve as the baseline condition of the patient and to identify patient who is at high risk for developing adverse event.

4. Pretreatment assessment shall include a thorough medical history, complete physical examination and request baseline examinations/tests.

5. All patients started on MDR-TB therapy shall have the following baseline tests.
   - Direct Sputum Smear Microscopy (DSSM), TB Culture (TBC) and DST
   - Blood chemistry: Fasting Blood Sugar (FBS), Blood Urea Nitrogen (BUN), Creatinine, Uric Acid, Serum Glutamic Pyruvic Transaminase (SGPT)/Alanine

Aminotransferase (ALT), Serum Glutamic Oxaloacetic Transaminase (SGOT)/Aspartate Aminotransferase (AST), Potassium (K), Calcium (Ca), Magnesium (Mg)

- HIV Testing through Provider Initiated Counseling and Testing (PICT)
- Chest X-ray (CXR): Posterioranterior (PA) view for ambulatory patients; Anteriorposterior (AP) view for bedridden and very young patients

6. **The following <u>additional baseline tests</u> shall be requested:**
    - Complete Blood Count (CBC), if anemia is suspected
    - Pregnancy Test for women of childbearing age
    - Thyroid Stimulating Hormone (TSH)
    - Audiometry
    - 12 lead ECG if patient is receiving QT prolonging drugs such as Moxifloxacin (Mfx), Clofazimine (Cfz)

7. The patient shall be considered as Bacteriologically Confirmed RR/MDR-TB at the start of second-line anti-TB treatment if the following criteria are met:
    1. Molecular Test Positive or Phenotypic DST Positive (MTB Detected, Rifampicin Resistance Detected)
    2. **The collection date of the specimen shall be less than 30 days before or seven days after the initiation of DR-TB treatment.** (Reference: Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis 2014)

8. Monitoring of patient's response to treatment shall be done through regular consultation, physical examination and follow-up of laboratory tests/examinations as shown in the table below:

Table 1. Schedule of clinical and laboratory baseline and follow-up examinations for MDR-TB patients during the intensive phase and continuation phase of treatment. (New provisions are printed in bold).

Test/Examination	Intensive Phase	Continuation Phase
Clinical Evaluation by the S/TC Physician	Baseline, Monthly	Monthly
DSSM[1]	Baseline, Monthly	Monthly
TBC[1]	Baseline, Monthly	Every 3 months
DST[1]	Baseline, Month 4 if culture-positive	Anytime if culture-positive
CXR	Baseline, Month 6	Every 6 months
Audiometry	**Baseline, Monthly while receiving injectable agent**	
FBS	Baseline, Every 3 months if 50 y/o or more, Every 6 months if less than 50 y/o	Every 3 months if 50 y/o or more, Every 6 months if less than 50 y/o
BUN		
Serum Creatinine	Baseline, **Monthly while receiving injectable agent**	
Blood Uric Acid	Baseline, Every 3 months if 50 y/o or	

[1] For baseline and post-treatment follow-up, two (2) sputum specimens shall be collected for DSSM, TBC and DST while for treatment follow-up, only one (1) sputum specimen shall be collected.

SGPT, SGOT	more, Every 6 months if less than 50 y/o	Every 3 months if 50 y/o or more, Every 6 months if less than 50 y/o
Serum Potassium (K)	Baseline, **Monthly while receiving injectable agent**	
Serum Magnesium (Mg) Serum Calcium (Mg)	Baseline, Every 3 months if 50 y/o or more, Every 6 months if less than 50 y/o or **any time if there is hypokalemia**	
CBC	**Baseline if anemia is suspected**	
HIV Rapid Antibody Test	Baseline, Repeat if warranted	Repeat if warranted
TSH	**Baseline, Every 3 months if receiving both Prothionamide (Pto) AND Para-aminosalicylic Acid (PAS), Every 6 months if receiving Pto OR PAS**	**Every 3 months if receiving both Pto AND PAS, Every 6 months if receiving Pto OR PAS**
Pregnancy Test	**Baseline, Repeat if warranted**	**Repeat if warranted**
12-L ECG	**Baseline and Monthly if with QT prolonging drugs such as Mfx, Cfz**	**Monthly if with QT prolonging drugs such as Mfx, Cfz**

9. The monitoring of treatment shall be more frequent and intensive for patients with pre-existing condition or co-morbidity.

10. Post-treatment follow-up shall be done every 6 months for two years. This includes clinical evaluation by the S/TC Physician, CXR, DSSM, TBC and DST.

For your information and compliance.

By Authority of the Secretary of Health

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