Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 02 2020

ADMINISTRATIVEORDER
No.~~2019~~ 2020 - 0026

Subject: **Guidelines onIntegrating Existing Protocols on Tuberculosis (TB) and Diabetes Mellitus (DM) Case Finding and Management Activities**

I. RATIONALE

Systematic reviews of researches done in 2011 by the World Health Organization (WHO) showed that: (a) DM is associated with increased risk of active TB; (b) DM increases the time to culture conversion and the risk of death and relapse among TB patients; and (c) there is consistently higher TB prevalence and incidence in people with DM than in the general population or those in non-DM controls.

In the Philippines,five local studies showed an increased association between TB and DM. These include: (i) the 2016 National TB Prevalence Survey whichshowed that among the self-reported patients with DM, the risk of having TB is 1.7 times (95% CI 1.1-2.6); (ii) the 2012 Drug Resistance Survey which revealed that the risk of having multidrug resistant TB is 2.2 times (95% CI 1.03-4.07) among new patients with DM compared to patients without DM and 2.64 times (95% CI 1.26-5.53) among the previously treated patients with DM compared to previously treated TB patients without DM; (iii) the 2012 Bidirectional Screening on TB-DM by E. Baja et al. which claimed that 10.3% of TB patients had a diagnosis of DM in their medical records and 15.6% of patients with DM had current or past TB from selected DM clinics and TB-DOTS facilities;(iv) the 2012 study by C. Roa, et al. which reported 43 TB cases (2.6%) among 1,650 DM patients in the DM clinics of four public hospitals in Metro Manila; and(v) the 2014 study by Pablo-Villamor et. al. which showed that 18.4% (95% CI 7.7-34.3) diagnosed with PTB and enrolled in PTSI DOTS were diagnosed with DM.

Given the strong evidence on the TB-DM correlation, both the Department of Health (DOH) National Tuberculosis Control Program (NTP) and the Diabetes Mellitus Program (DMP) had initiated strategies of screening DM patients for TB and TB among DM. In the Training Manual on the Philippine Package of Essential Non-communicable (PhilPEN) Disease Intervention published on 2016, it was indicated that people with TBbelong to the list of individuals that should undergo risk screening for DM. On the other hand,the 5th edition of the NTP Manual of Procedures (MOP) categorized DM patients as one of the high-risk clinical groupsconsidered as presumptive TB when they experience unexplained cough of any duration. Consequently, all presumptive TB who could expectorate – whether pulmonary or extra-pulmonary – shall undergo aTB diagnostic test prior to treatment initiation.

Despite the existence of these guidelines, provision of integrated services for patients with TB-DM co-morbidities were limited based on the 2015 situational assessment by WHO. The NTP and DMP remain to function in parallel with each other -- hindering an integrated service delivery system. Hence, in support of the Fourmula 1 Plus goal of having better health outcomes and to ensure collaborative and prompt detection and management of patients with TB-DM and, ultimately, to achieve both Programs' goals and vision of alleviating the double burden brought by the TB-DM comorbidity,technical guidelines for TB-DM is deemed necessary.

II. OBJECTIVE

This Order aims to:

1. Integrate theexisting protocols on the screening and management of cases with TB and DM; and
2. Define the roles and responsibilities of various stakeholders.

III. SCOPE AND COVERAGE

This Order shall apply to all public and private health facilities that are implementing the NTP andthe PhilPEN interventionsand concerned offices of DOH and local government units (LGUs).

IV. DEFINITION OF TERMS

1. Fasting blood sugar – A test to determine how much glucose (sugar) is in a blood sample after an overnight fast.

2. Polydipsia - is excessive or an abnormally large production or passage of urine (greater than 2.5 Lor 3 L over 24 hours in adults).

3. Polyphagia - is excessive hunger and abnormally large intake of solids by mouth.

4.Polyuria - is excessive passage of urine (at least 2.5 liters per day for an adult) resulting in profuse urination and urinary frequency (the need to urinate frequently).

5. Oral glucose tolerance test - is a medical test in which glucose is given and blood samples taken afterward to determine how quickly it is cleared from the blood.

6. Random blood sugar –a test that measures the levels of glucose in the blood at any given point in the day.

V. GENERAL GUIDELINES

1. Algorithms for the screening of TB among DM and DM among TB shall be followed to ensure an integrated management of the comorbidity.
2. All DM patients shall be screened for TB in accordance with the NTP protocol.
3. All registered TB patients 20 years old and above shall be screened for DMin accordance with the PhilPEN protocol.
4. Patients with TB-DM comorbidity shall be managed and followed-up in accordance with the existing guidelines of bothPrograms.
5. Capacity building for health staff that will manage patients with TB-DM comorbidity shall be conducted.
6. Infection control plans shall be in place and implemented in all concerned facilities.
7. Health promotion activities shall be conducted to increase awareness and knowledge about TB-DM comorbidity and the available services among the general population.
8. Existing records and reports of both programs shall be utilized and enhanced, if deemed necessary, to include provisions to reflect identification and management of cases with TB-DM comorbidity.

9. A referral system shall be instituted for co-management andtransfer of service to address the heath care needs of DM and TB patients.

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VI. SPECIFIC GUIDELINES

These guidelines shall be followed by the health workers at the rural health units, private clinics, TB DOTS units at the hospitals and other health facilities that will provide TB services based on the NTP guidelines.

A. Procedures

1. Screening and Management of DM among TB patients. Since DM is considered a risk factor for TB, and the optimal treatment of DM has an impact on the outcomes of TB, routine laboratory screening for DM is recommended for all registered TB patients aged 20 years old and above.

1.1. Do laboratory testing for DM at the initiation of TB treatment.

1.1.1. For TB patients who already have the classical or typical symptoms of DM such as polyuria, polydipsia, polyphagia, and/or increased thirst, request for either Random Blood Sugar (RBS) or Fasting Blood Sugar (FBS) through venous blood extraction to screen for DM. If any of the tests is positive (FBS of $\geq$ 126 mg/dl or RBS of $\geq$ 200 mg/dl), consider as having DM.

1.1.2. For TB patients without symptoms of DM, any of the 3 tests shall be requested for routine screening: FBS, RBS or 75g Oral Glucose Tolerance Test (OGTT) through venous blood extraction. If any of the tests is positive (FBS of $\geq$ 126 mg/dl, RBS of $\geq$ 200 mg/dl or 75g OGTT of $\geq$200mg/dl), repeat the test on another day at the soonest possible time for confirmation.

1.1.2.1. If the abovementioned tests through venous blood extraction are not immediately available, then a capillary determination may be done after 8-10 hours of fasting or randomly without regard for the last meal.

1.1.2.2. If capillary test showed FBS of $\geq$ 126 mg/dl or RBS of $\geq$ 200 mg/dl, do confirmation through venous blood extraction in accordance with the DM Program guidelines.

1.1.3. If with DM, manage according to DM Program guidelines. The physician and patient shall mutually agree where DM treatment shall be provided and followed-up in accordance with the spirit of patient-centeredness. An option for the TB patient with DM is to also take the DM medications simultaneously with anti-TB drugsin consideration of other comorbidities and drug interactions which may complicate the treatment. If with incidental finding of abnormal kidney function tests such as serum creatinine level of >150μmol/L, refer patients to DM specialist for further evaluation and management.

1.2. Follow the algorithm illustrated in Annex A on screening and management of DM among TB patients 20 years old and above.

1.3. If the laboratory tests and services for DM are not available in the facility, refer to a quality assured laboratory or DM specialist.

1.3.1. Receiving facility shall provide feedback to the referring facility, and likewise, the referring facility shall actively follow-up the status of the referred patient. This is to ensure that all referred patients are accepted and provided with appropriate management.

2. Screening and Management of TB among DM patients

2.1.For DM patients 15 years old and above:

2.1.1. Screen for TB symptoms at every visit e.g. cough of any duration with or without significant and unintentional weight loss, fever, hemoptysis, chest/back pains, easy fatigability or malaise, night sweats, and shortness of breath or difficulty of breathing.

2.1.1.1.If with TB symptoms, collect sputum specimen for rapid TB diagnostic (RTD) test.

2.1.1.1.1. If RTD test shows positive result for TB, manage according to NTP policies and guidelines.

2.1.1.2.If without TB symptoms, screen for TB using chest radiography (CXR).

2.1.1.2.1. If with CXR findings suggestive of TB, do RTD test.

2.1.1.2.2. If RTD test shows positive result for TB, manage according to NTP policies and guidelines.

2.2.For DM patientsbelow 15 years old:

2.2.1. If the child can expectorate, do RTD test at once.

2.2.2. If the child cannot expectorate, assess the child using the following 5 criteria for diagnosing TB in children:

2.2.2.1. Presence of at least 3 out of 6 signs and symptoms:

a. Coughing/wheezing of two weeks or more, especially if unexplained;
b. Unexplained fever of two weeks or more after common causes such as malaria or pneumonia have been excluded;
c. Loss of weight/failure to gain weight/weight faltering/loss of appetite;
d. Failure to respond to two weeks of appropriate antibiotic therapy for lower respiratory tract infection;
e. Failure to regain previous state of health two weeks after a viral infection or exanthema (e.g. measles); and
f. Fatigue, reduced playfulness or lethargy (e.g. child has lost his/her normal energy).

2.2.2.2. History of exposure to an adult/adolescent with active TB disease

2.2.2.3. Positive tuberculin test

2.2.2.4. Abnormal CXR findings suggestive of TB

2.2.2.5. Laboratory examinations suggestive of TB

2.2.3. If the child meets at least any three of the five criteria, manage according to NTP policies and guidelines.

2.2.4. Follow the algorithm illustrated in Annex B on screening and management of TB among all DM patients.

2.2.5. If laboratory tests and services for TB are not available in the facility, refer to the nearest RTD laboratory or health facility providing TB services.

2.2.5.1. Receiving facility shall provide feedback to the referring facility, and likewise, referring facility shall actively follow-up the status of referred patients. This is to ensure that all referred patients are seen by the receiving facility and provided with appropriate management.

3. **Follow-up Screening for DM among non-diabetic TB patients under treatment**

3.1. Screennon-diabetic TB patients for DM at the start of treatment andmaybe repeated under the following situations:

3.1.1. Sputum non-conversion of a bacteriologically-confirmed TB case during treatment. Check FBS or RBS level using the capillary method. If FBS of ≥ 126mg/dl or RBS of ≥ 200 mg/dl, repeat the test in another day at the soonest possible time for comparison. If still positive, do confirmation of DM through venous blood extraction FBS or RBS.

3.1.2. If with incidental finding of abnormal kidney function tests such as serum creatinine level of >150μmol/L, refer patients to DM specialist for further evaluation and management.

3.2. Perform screening annually.

4. **Follow-up screening for TB among DM patients**

4.1. Screen all DM patients for signs and symptoms of TB every follow-up check-up.

4.2. If with TB signs and symptoms, follow the algorithm as illustrated in Annex B.

4.3. If without TB signs and symptoms, perform CXR annually.

4.4. Perform screening annually.

B. Joint Capability Building for Health Personnel Involved in TB and DM Collaborative Activities

1. All health workers in facilities providing TB-DM screening and/or management shall be oriented on TB – DM collaboration and referral of cases.
2. Health care providers of DM clinics shall be capacitated on Infection Prevention and Control (IPC), TB management, and referral of TB cases.
3. Continuous capacity-building on TB-DM program management (Program Planning, Implementation, Monitoring and Evaluation, and Documentation) shall be conducted.

C. Infection Control (IC)

All facilities shall implement an infection control plan based on the "DOH Standards for Infection Control" and the NTP "Guidelines on Infection Control for Tuberculosis and other Airborne Infectious Diseases in Healthcare Facilities, Congregate Settings, and Households."

D. Health Promotion

The National TB Control Program in coordination with the Health Promotion and Communication Service shalldevelopculturally sensitive IEC materials that includes TB and DM for the general population and shall provide a prototype for the use of the regional health offices and partners.

The Health facilities shall actively involve the community in the implementation of TB-DM through social mobilization and shall provide health education to all patients with TB-DM comorbidity to ensure that desired blood glucose level is maintained through healthy lifestyle and to prevent transmission of TB bacilli among other patients and their families through infection control measures.

E. Recording and Reporting

Existing recording and reporting forms shall be utilized to document and monitor the progress of patient management and program implementation.

1. NTP Records and Reports that will be utilized are the following:
    1.1. Form 7. NTP Referral Form
        1.1.1. The Form shall be used by health facilities and providers engaged in providing TB management services to refer to other health facilities.
        1.1.2. For registered TB patients, tick "For laboratory testing"at the "Reasons for Referral" section and write on the blank space"FBS," "RBS," or "OGTT" – whichever is available.
        1.1.3. For DM patients referred for screening to another facility providing TB services, on the "For Screening," specifically on the "High Risk Clinical Group" section, indicate "DM" as the risk factor of presumptive TB. Whereas,
        1.1.4. For patients with unknown TB and/or DM status, accomplish appropriately all fields deemed necessary.
    1.2. Form 1. Presumptive TB Masterlist and Referral Logbook
    The Masterlist is used to record all Presumptive TB, both Drug-Susceptible (DS) and Drug-Resistant (DR), seen at the health facility. Accomplished and maintained by the health care provider, the form serves as a tracking tool to ensure that all screened presumptive TB have a diagnosis and all diagnosed cases are started on treatment. Reflect "DM" in the "High Risk Clinical Group" column to classify the patient appropriately based on self-report or, preferably, on laboratory results for DM diagnosis provided. Laboratory results or medications for DM taken may be reflected in the "Remarks" column.
    1.3. Form 6a. DS-TB Register, Form 6b. DR-TB Register, and Form 6c. TB Register for Referring Hospital
    Record the action taken such as "referred to DM clinic" in the "Remarks" column. If registered TB cases are received from DM clinics, reflect in the "Remarks" column as "from DM clinic."For the purpose of identifying DM cases among registered TB cases based on self-report or, preferably, on laboratory results for DM diagnosis provided, write "DM" in the "DM status" column of Forms 6a and 6b, otherwise, write "nDM." Laboratory results or medications for DM taken may be reflected in the "Remarks" column. All registered TB patients 20 years old and above with Unknown DM status shall be referred and followed-up to DM clinics for confirmation.
    1.4. Report 3c. Quarterly Report on All TB Cases
    Include in Table L: "DM Status of TB Cases Started on Treatment Among 20 Years Old and Above" the number of cases tested or with known DM status during the quarter, the number of TB cases diagnosed with DM, and the number of TB-DM patients started on DM treatment. These shall be included in the Integrated TB Information System (ITIS).
    1.5. Submit TB quarterly reports to the DOH through channels (health facility to PHO/CHO to CHD, to DPCB) based on the agreed timeline.

2. DOH Hypertension & DM Registry
    2.1. Record the action taken such as "referred to DOTS facility" and diagnosis of TB as comorbidity as "Diagnosed TB" in the "Remarks" column of the DM

Masterlist for purpose of identification of TB cases among DM cases. Reflect in the "Remarks" column as "from DOTS facility" registered DM cases received from the DOTS facility.

2.2. Include in the reporting and recording forms columns for DM cases screened for TB and number of DM cases who are diagnosed with TB. The latter shall be included in the DOH Hypertension and DM Registry System.

2.3. Submit semi-annual reports to the DOH through channels (DM Clinics to PHO/CHO to CHD, to DPCB) based on the agreed timeline.

2.4. Use the existing DM Program referral form to indicate in the "Remarks" section the referral to DOTS facility.

3. Health facilities outside NTP and DM Program are encouraged to implement a recording and reporting system for TB-DM.
4. System shall be in place to respect patient confidentiality and ensure compliance with the Data Privacy Act of 2012 (RA 10167).
5. Report all detected TB cases as per Republic Act No. 10767.

F. Referral System

1. Existingreferral forms of the Programswill be accomplished by the health workers in the referring facility and be brought by the patient to the receiving facility where further evaluation and management shall be conducted.
2. The receiving facility shall contact the receiving facility for proper coordination and to minimize inconvenience for the patient.
3. The receiving facility shall provide feedback to the referring facility through the reply slip of the referral form, telephone call, SMS, email, or other modalities available.
4. If the patient did not report to the facility within five days, exert efforts to retrieve the patient through the help of barangay health workers, local officials, or community groups. Ensuring successful referral is a shared responsibility of the referring and receiving facilities.
5. In cases where the patient has no referral form, the receiving facility will contact/communicate with the referring facility for proper coordination and validation

G. Monitoring and Evaluation

1. Detailed mechanism and tools shall be jointly developed by NTP and DM Program to monitor and evaluate the implementation of the TB-DM collaboration.
2. The core indicators shall be assessed to determine the progress of implementation and extent of accomplishment of the TB-DM collaboration at the national, regional, and provincial/city levels.
    2.1. Number and proportion of RHUs/HCs and hospitals trained on TB-DM collaboration
    2.2. Number of DM screened for TB and Number of TB screened for DM
    2.3. Number of TB-DM patients detected and being managed
    2.4. Treatment outcome of TB-DM patients (i.e., cured, treatment completed, treatment failed, died, lost to follow-up, not evaluated)
3. Regional coordinators of NTP and DM Program shall jointly conduct the monitoring and evaluation in their respective catchment areas.
4. DPCB through the NTP Management Office and Degenerative Disease Office-Lifestyle Related Disease Division shall conduct quarterly analysis of all regional reports for use in succeeding M & E activities and to guide in updating policies and plans.

VII. ROLES AND RESPONSIBILITIES

1. The Department of Health through:

   The **Disease Prevention and Control Bureau** shall:
   i. Develop policies, guidelines and plans for the implementation of the TB-DM collaboration;
   ii. Develop capacity building plan for health workers and conduct training of trainers regarding TB-DM collaboration;
   iii. Procure and distribute equipment (i.e., blood sugar meters, Xpert MTB/Rif machines), medicines, and laboratory supplies;
   iv. Develop and provide prototype of TB-DM IEC materials to the regions;
   v. Provide technical support to program coordinators at the regional level in the conduct of TB-DM collaborative activities;
   vi. Conduct joint monitoring and evaluation of NTP and DM Program collaboration; and
   vii. Advocate and coordinate with professional groups to support the implementation of the TB-DM collaboration.

   The **Centers for Health Development** shall:
   i. Disseminate the policies, guidelines and plans for the implementation of the TB-DM collaboration to Provinces and Cities;
   ii. Conduct capacity building activities of health workers TB-DM collaboration;
   iii. Allocate equipment (i.e., blood sugar meters, Xpert MTB/Rif machines), medicines, and laboratory supplies;
   iv. Reproduce TB-DM IEC materials and distribute to the Provincial Health Offices (PHO) and City Health Offices (CHO);
   v. Advocate to local government units, non-government organizations, professional societies in their respective areas to support the initiative;
   vi. Gather, consolidate and analyze reports from the provinces and cities implementing the TB-DM collaboration;
   vii. Join the DOH - Central Office in the conduct of monitoring and evaluation activities; and
   viii. Include TB-DM concerns in the annual TB and DM Program Review.

2. **Local Government Units** through the Provincial/City and Municipal Health Offices shall:
   i. Formulate local policies to support and finance the TB-DM collaboration;
   ii. Ensure availability of human resources to support the collaboration;
   iii. Allow concerned health workers to undergo capacity building activities on the TB-DM collaboration; and
   iv. Participate during regional monitoring and evaluation activities of NTP and DMP collaboration;

3. **Health facility** shall:
   i. Implement policies, guidelines and plans of the TB-DM collaboration.

VIII ~~VII.~~ **FUNDING**

Funds for the implementation of the collaboration including human resources, capacity building, provision of equipment and commodities, monitoring and evaluation shall be shared between the two Programs. Sources of funds shall come from the DOH, CHDs, LGUs, Donors, and Development Partners.

IX ~~VIII.~~ **REPEALING CLAUSE**

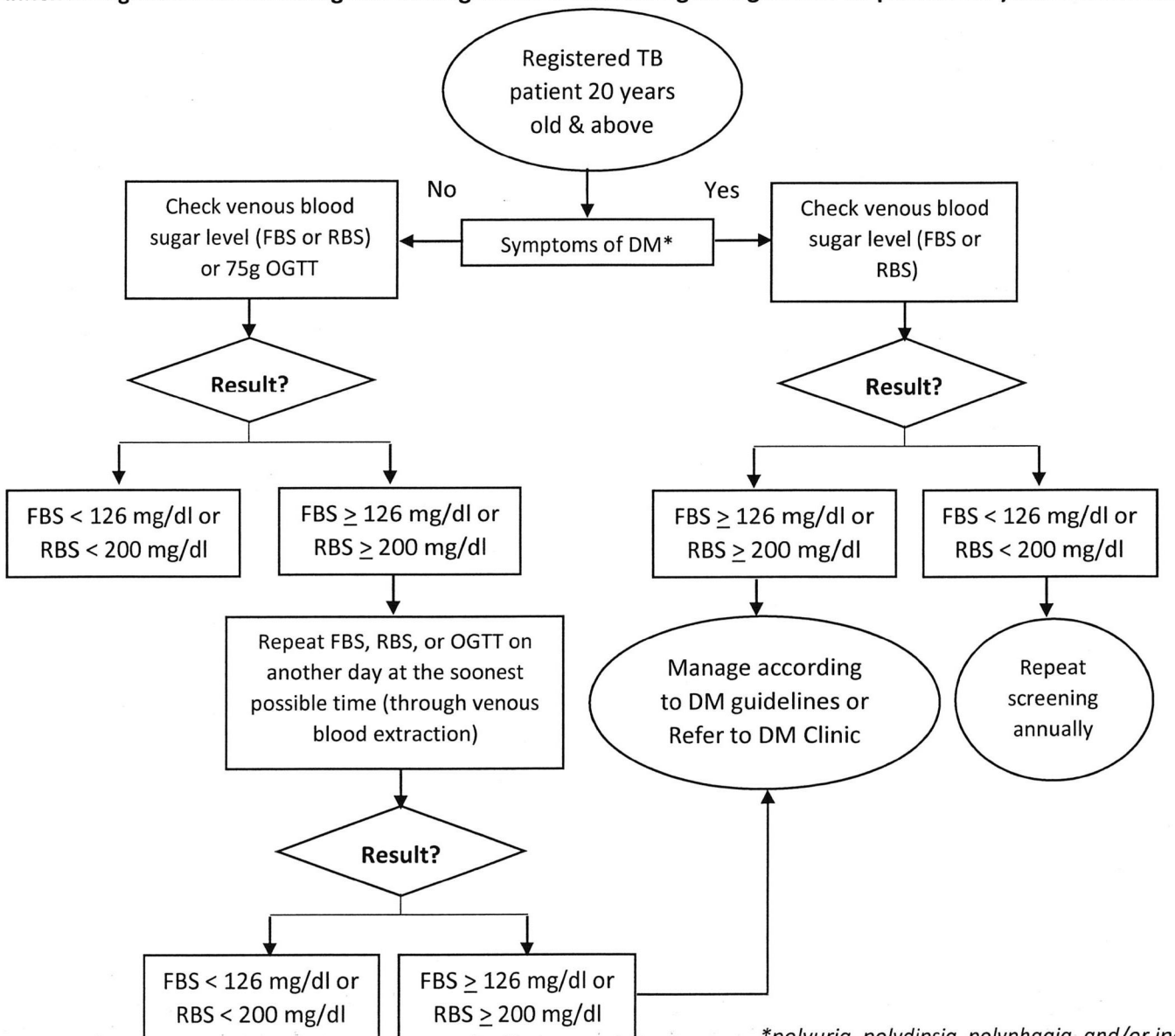
The provisions of previous Orders and other related issuances inconsistent or contrary with the provisions of this Department Order are hereby revised, modified, repealed or rescinded accordingly. All other provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

X ~~IX.~~ **EFFECTIVITY**

This Order shall take effect immediately upon approval.

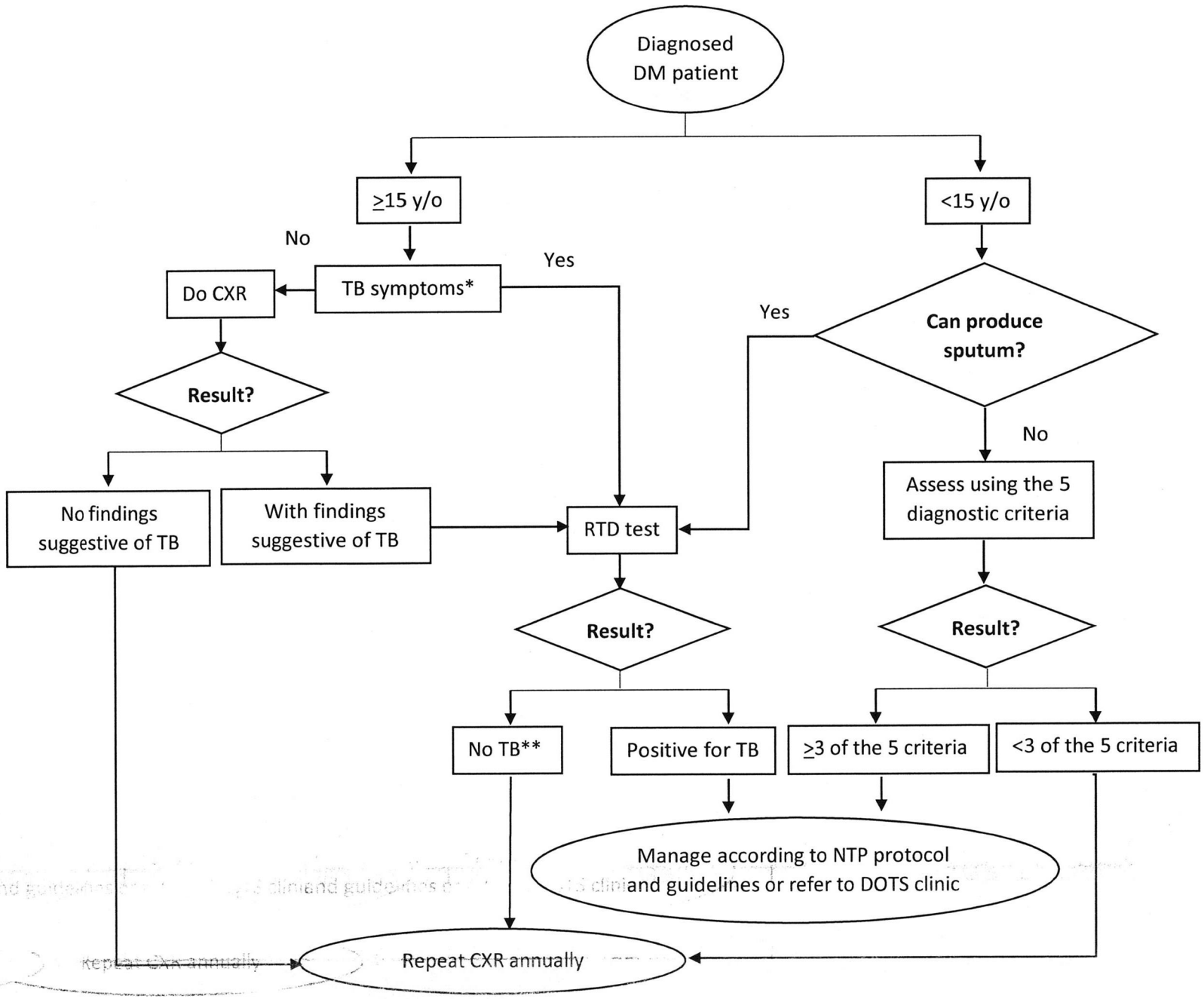
FRANCISCO T. DUQUE III, ~~MD,~~ MSc
Secretary of Health

Annex A. Algorithm on Screening and Management of DM among all registered TB patients 20 years old and above



**polyuria, polydipsia, polyphagia, and/or increased thirst*

Annex B. Algorithm on Screening and Management of TB among all DM patients



**unexplained cough of any duration*
***correlate clinically especially for children; if there is high index of suspicion of active TB, appropriate treatment should be given*