Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

11 January 2016

DEPARTMENT MEMORANDUM
No. 2016 - 0034

TO: **ALL REGIONAL OFFICE DIRECTORS, AND CHIEFS OF MEDICAL CENTERS AND HOSPITALS WITH PROGRAMMATIC MANAGEMENT OF DRUG-RESISTANT TB (PMDT) TREATMENT FACILITIES**

SUBJECT: **Classification of Tuberculosis (TB) Disease Based on Bacteriological Status of Drug-Resistant Cases**

Upon consultation with local and international TB experts, such as the World Health Organization (WHO) and Innovations and Multisectoral Partnerships to Achieve Control of TB (IMPACT), the following definitions of classification of TB disease based on bacteriological status of drug-resistant cases in support to the National TB Control Program (NTP) Manual of Procedures, 5th ed., shall be used in NTP reporting:

1. **Bacteriologically-confirmed Rifampicin-resistant TB (BC RR-TB)** – a patient with sputum from pulmonary site or biological specimen from extra-pulmonary site that is positive for MTB complex using rapid diagnostic modalities (i.e., Xpert MTB/RIF) with resistance to Rifampicin from a GeneXpert machine regardless of date of collection, with or without radiographic abnormalities. If patient had previous successful treatment, resistance should be from specimen collected after successful treatment.

2. **Bacteriologically-confirmed Multidrug-resistant TB (BC MDR-TB)** – a patient with sputum from pulmonary site or biological specimen from extra-pulmonary site that is positive for MTB complex with resistance to at least both Isoniazid and Rifampicin from an NTP-recognized laboratory regardless of date of collection, with or without radiographic abnormalities. If patient had previous successful treatment, resistance should be from specimen collected after successful treatment.

3. **Bacteriologically-confirmed Extensively Drug-resistant TB (BC XDR-TB)** – a patient with sputum from pulmonary site or biological specimen from extra-pulmonary site that is positive for MTB complex with resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin), in addition to multidrug resistance, from an NTP-recognized laboratory regardless of date of collection, with or without radiographic abnormalities. If patient

had previous successful treatment, resistance should be from specimen collected after successful treatment.

4. **Clinically-diagnosed Multidrug-resistant TB (CD MDR-TB)** – A patient with at least one of the following:
    i. specimens tested in an NTP-recognized laboratory that is negative for MTB Complex but with clinical deterioration and/or radiographic findings consistent with active TB, or
    ii. specimen/s with other resistance pattern (ie., Mono-DRTB or Poly-DRTB) with clinical deterioration and/or radiographic findings consistent with active TB, or
    iii. laboratory diagnosis not done due to specified conditions but with clinical deterioration and/or radiographic findings consistent with active TB, or
    iv. diagnosis showing resistance to both Isoniazid and Rifampicin from a non-NTP-recognized laboratory;

    and there has been no response to a course of empiric antibiotics and/or symptomatic medications; and who has been decided by the Medical Advisory Group (Consilium) to have TB disease requiring a full course of second-line anti-TB chemotherapy similar to BC MDR-TB.

5. **Other TB on Second Line Anti-TB Dugs (Other TB on SLD)** – The following are considered as Other TB on SLD:
    a. **Monoresistant-TB** – resistance to one first-line anti-TB drug except Rifampicin whether bacteriologically-confirmed (regardless of date of collection, with or without radiographic abnormalities) or clinically-diagnosed (ie., severe adverse drug reaction to anti-TB drugs except Rifampicin) and who has been decided by the Medical Advisory Group (Consilium) to have TB disease requiring a course on monodrugresistant-TB regimen
    b. **Polydrug-resistant TB** – resistance to more than one first-line anti-TB drug, other than both Isoniazid and Rifampicin, whether bacteriologically-confirmed (regardless of date of collection, with or without radiographic abnormalities) or clinically-diagnosed (ie., severe adverse drug reaction to anti-TB drugs except Rifampicin) and who has been decided by the Medical Advisory Group (Consilium) to have TB disease requiring a course on polydrugresistant-TB regimen
    c. **Serious adverse drug reaction to Rifampicin** – a patient with at least one of the following:
        i. positive for MTB complex but no resistance to any anti-TB drugs, or
        ii. negative for MTB complex but has been decided (either by the physician and/or the MAG) to have TB disease

        and has serious adverse drug reaction to Rifampicin thereby requiring a full course of second-line anti-TB chemotherapy similar to BC MDR-TB

The NTP-recognized laboratories are Drug Susceptibility Testing (DST) Laboratories that are under supervision of the National TB Reference Laboratory (NTRL) or with supranational laboratory outside the country and Xpert sites, public or private, that are using GeneXpert machines. Also note that in case patient has differing conventional DST results, worse case is considered.

This memorandum hereby directs all Regional Office-NTP Coordinators to advise all PMDT Treatment Facilities, both public and private, and respective Provincial/City Health Offices to apply these definitions to all cohorts reportable in 2015 (i.e., 2011 for 36th month outcome, 2012 for 24th month outcome, 2014 for interim outcome and 2015 for enrollment) and onwards.

Furthermore, this memorandum supersedes all previously issued related memorandum discussing definitions of drug-resistant TB.

For your information and compliance.

By Authority of the Secretary Health:

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