Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JAN 12 2021

ADMINISTRATIVE ORDER
No. 2020~~3~~ 0004
2021

SUBJECT: Updated Guidelines on the Treatment and Prevention of Leprosy in the Philippines

I. BACKGROUND AND RATIONALE

Leprosy is a chronic communicable disease that affects the peripheral nerves and skin. It causes permanent disabilities of the eyes, hands and feet especially in the occurrence of late detection and treatment of the disease. It appears through single or multiple white or red skin patches in different parts of the body that lead to definite loss of sensation. The disease is caused by bacteria called *Mycobacterium leprae* that is transmitted via respiratory tract through inhalation like Tuberculosis. The main reservoir of infection is the untreated leprosy patients (Multibacillary) who infect other members in the household due to prolonged exposure or contact to the untreated patients. Early detection of cases and Multidrug Therapy treatments are necessary to prevent the transmission of the diseases.

Leprosy has been eliminated in the Philippines as a public health problem since 1998. However, the country reported an average of 1,500 – 2,000 new leprosy cases from 2008-2018, showing that local transmission is still ongoing. The Department of Health (DOH) – National Leprosy Control Program (NLCP) is continuously faced by detection and reporting challenges because of the current limitations in the health system.

This Administrative Order is formulated to adopt the World Health Organization (WHO) guidelines on the recommended treatment for patients and on chemoprophylaxis for contact of index cases. This guideline will sustain leprosy services to further reduce the leprosy burden in the Philippines and will enable the National Leprosy Control Program to attain its targets as follows: (1) Zero Transmission; (2) Zero Disability due to leprosy and (3) Zero stigma and discrimination as support to the global target of Sustainable Development Goal (SDG) 3.3 particularly the roadmap of the Global Leprosy Program 2030.

Thus, updates on the policy include the following: guidance on improved management of leprosy cases, preventing disabilities among newly diagnosed cases and practical steps on attaining program targets in a devolved set-up. These guidelines are anchored to the Universal Health Care Law through the FOURmula One Plus (F1+) for Health Framework. The framework focuses on service delivery by ensuring accessibility of essential quality health services at all levels, thereby preventing the spread of leprosy through the treatment of existing cases and chemoprophylaxis for contact of index cases.

AMENDED by
No. 2021-0004-A
Date MAY 21, 2021
Posted on/by: MAY 25, 2021

II. OBJECTIVE

To update the guidelines on treatment and prevention of leprosy in line with the goal to achieve the global target of zero leprosy transmission, zero disability and zero stigma by 2030.

III. SCOPE AND COVERAGE

This Order shall apply to all offices and attached agencies of the DOH, Centers for Health Development, Local Government Units, the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of RA 11054 or the "Bangsamoro Organic Law" and subsequent rules and policies issued by the Bangsamoro government, and to both government and private national and local health facilities, health care providers and all others concerned.

IV. DEFINITION OF TERMS

A. **Chemoprophylaxis** - refers to the administration of drug to prevent the development of a disease.
B. **Household Contact** - refers to any person who has had direct contact or exposure with a leprosy case and has been living in the same household with the leprosy case for more than 30 days in the past 2 years.
C. **Index Case** - refers to a person who is on active treatment for leprosy Multi drug therapy (MDT) or those who have received or finished MDT treatment (RFT – Release from Treatment), Post - Dapsone Mono-therapy, or have been declared cured or negative for a certain period.
D. **Information System (IS)** - refers to a database evolved for the purpose of providing information support for decision -making process. The system is used to analyze data and generate knowledge-that is useful information in facilitating strategic and operational activities.
E. **Leprosy Elimination** - refers to reduction in the prevalence of registered leprosy cases to below 1 case per 10,000 populations.
F. **Leprosy Case** - refers to a patient infected with Mycobacterium leprae needing treatment or presently under Multi drug therapy treatment.
G. **Multi-Drug Therapy (MDT)** - refers to a regimen made up of a combination of three (3) drugs for both Multibacillary (MB) and Paucibacillary (PB) leprosy patients with difference only in duration.
H. **Multibacillary or MB Leprosy** - refers to a case of leprosy with more than five skin lesions; or with nerve involvement (pure neuritis, or any number of skin lesions and neuritis); or with the demonstrated presence of bacilli in a slit-skin smear, irrespective of the number of skin lesions.
I. **Paucibacillary or PB Leprosy** - refers to a case of leprosy with one (1) to five (5) skin lesions, without demonstrated presence of bacilli in a slit-skin smear.
J. **Post-Exposure Prophylaxis (PEP)** - refers to the intervention or actions to prevent infection and other harmful effects of the disease after someone has been exposed to the disease.
K. **Recording** - refers to the process of capturing the data of patient/client management. over time. It reflects/ gives the health-related services provided to an individual patient.

L. **Reporting** - refers to the routine tracking of information intended to aggregate outcome data at the local health facility, district and national (Central/local) level.
M. **Single-dose rifampicin (SDR)** - refers to the treatment regimen to be used as leprosy post-exposure prophylaxis for contacts of leprosy patients (adults and children aged 2 years and above), after excluding leprosy and tuberculosis (TB) disease, and in the absence of other contraindications.
N. **Zero Transmission** - refers to the total disappearance of the disease-causing organism resulting to total and complete interruption of disease transmission (zero disease).

V. GENERAL GUIDELINES

A. A detection, diagnosis, treatment and prevention of leprosy, including provision of Multi- Drug Therapy (MDT), chemoprophylaxis through Post- Exposure Prophylaxis (PEP) and other supportive drugs shall be a joint responsibility of the Department of Health (DOH) and the Local Government Units (LGUs).

B. Program strategies and activities shall be integrated with the regular public health services and shall be provided by health facilities as a measure for the prevention and control transmission of leprosy.

C. Funding requirements needed for detection, diagnosis, treatment, leprosy care and for operational systems shall be planned, secured and allotted by the Department of Health (DOH) and encourage Local Government Units (LGUs) for the support.

D. Advocacy through tri-media information dissemination campaign and ground activities such as Interpersonal Communication Campaign (IPCC) shall be conducted to the public to stop stigma and discrimination against Person Affected by Leprosy (PAL).

E. Training of healthcare providers on basic leprosy prevention and management shall be conducted at all levels for early detection and to end stigma and discrimination against Person Affected by Leprosy (PAL).

F. Collaboration and coordination among government agencies, non-government and private organizations shall be strengthened and sustained through Service Delivery Network to ensure successful implementation.

G. Provision of selective treatment for Neglected Tropical Diseases (NTD) patients and implementation of routine leprosy services shall be guided by provisions of DOH Administrative Order (AO) No. 2017-0007: "Guidelines in the Provision of the Essential Health Service Packages in Emergencies and Disaster" and DOH Department Circular No. 2020-0167: "Continuous Provision of Essential Health Services During the COVID-19 Epidemic".

H. Recording and reporting shall be joint responsibility of Department of Health and encourage the Local Government Units utilizing the NLCP forms and online reporting system.

VI. SPECIFIC GUIDELINES AND PROCEDURES:

A. Diagnosis and New Treatment Protocol

1. Active case finding and contact tracing strategy shall be conducted for early detection, diagnosis and treatment. This will reduce the chance of patients infecting others and developing nerve damage that results in paralysis and disabilities.

2. Diagnosis of leprosy shall be established through the following methods: clinical examination with or without slit-skin smear or pathological examination of biopsies. Under field conditions, leprosy can be diagnosed using clinical examination of the skin and nerves. However, in other health facilities and training institutions, clinical examination can be augmented with slit-skin smears or histopathology (skin or nerve biopsies).

3. The diagnosis of leprosy shall be based on the presence of at least one of the three cardinal signs: (i) Definite loss of sensation in a pale (hypopigmented) or reddish skin; (ii) Thickened or enlarges peripheral nerve with loss of sensation and or weakness of the muscles supplied by the nerve; and (iii) Presence of acid fast bacilli in a slit-skin smear.

4. In a routine leprosy program, the field classification of leprosy shall be Multibacillary and Paucibacillary, this will continue to be used based on the number of skin and nerve lesions and the presence or absence of acid-fast bacilli in skin specimens (see Annex A, Table 1: Field Classification of leprosy according to number of skin lesion and nerves affected). The three-drug treatment regimen composed of rifampicin, clofazimine, and dapsone will be used for all leprosy cases, with MB cases required to complete 12 monthly packs and PB cases required to complete 6 monthly packs (see Annex A, Table 2: Recommended treatment regimens).

5. Leprosy patient with drug-resistance shall be treated using at least two of the following second-line drugs (see Annex A, Table 3: Recommended regimens for drug-resistant leprosy).

6. The physician (or any authorized) shall make use of the Disability grading of the hands, feet, and eyes during diagnosis. (see Annex A, Table 4: Disability Grading of Hands, Feet and Eyes).

7. Persons Affected by Leprosy (PAL) shall be responsible for informing their family and household members about the need for them to consult a health facility for skin and nerve check-ups in the event that a PAL refuses to inform his/her household contact/s about the need to seek consultation and treatment, it is important to emphasize the importance of early detection to prevent further transmission in the family and in the community.

B. Prevention of Leprosy Through Chemoprophylaxis

1. The new leprosy control strategy shall aim at reducing clinical leprosy in household contacts of new cases (See Annex B).
2. The chemoprophylaxis shall be given to all household contacts of index case by the Department of Health and the Local Government Units.
3. The recommended dosage schedule for Single Drug Rifampicin shall be followed (See Annex B, Table 5).

C. Integration of Leprosy Alert and Response Network System (LEARNS)
LEARNS is a mobile health (mHealth) tool that enables health care practitioners nationwide especially in remote areas to refer suspected leprosy patients promoting early case finding and helping reduce delay in diagnosis and treatment.

1. The LEARNS shall be utilized in conducting active case finding to enhance early detection and diagnosis of leprosy disease.
2. The LEARNS shall be utilized for screening suspected leprosy cases and close contacts of persons affected by leprosy (PAL).

D. Policy, standards and regulations shall be observed to ensure equitable access to health services, essential medicines and technologies of assured quality, availability and safety in line with the goals of Universal Health Care (UHC).

E. Adapting and Implementing Activities during New Normal

1. Infection Prevention and Control (IPC) measure through physical distancing, proper wearing of mask, face shield and handwashing (hand sanitizing) shall be observed strictly by the health worker and patient.
2. Telephone hotline and SMS services shall be developed to provide essential information about leprosy (e.g. management of symptoms and referrals to be needed health services) to Persons Affected by Leprosy (PAL) and Household Contact (HC).

VII. ROLES AND RESPONSIBILITIES

A. DOH

1. Disease Prevention and Control Bureau (DPCB) shall:
   a. Manage, coordinate and monitor the NLCP including the assessment, introductory phase and nationwide implementation;
   b. Facilitate the yearly donation of Multi-Drug Therapy (MDT) from the World Health Organization.
   c. Facilitate the convening of meetings and orientations on treatment and prevention implementation in coordination with key partner organizations;
   d. Facilitate annual assessment of treatment and prevention implementation as part of the regular NLCP Program Implementation Review;

e. Consult with key stakeholders on program implementation, monitoring and evaluation such as WHO, Technical Working Group and Centers for Health Development (CHDs) and professional medical societies and organizations.
f. Allocate funds for monitoring and on the nationwide implementation and allocation of commodities in the region.

2. Health Promotion Bureau (HPB) shall develop Information Education and Communication (IEC) materials for advocacy campaign, implementation and guidelines for training including but not limited to information materials for index cases and household members, field user guides and references.

3. Centers for Health and Development (CHDs) shall:
   a. Provide direct support to localities in adopting and implementing Chemoprophylaxis/PEP and 3-drug regimen including training and other relevant technical support.
   b. Designate an immediate referral health facility for each province for appropriate management of leprosy patients.
   c. Monitor and evaluate implementation to inform Chemoprophylaxis/PEP and 3-drug regimen improvement and provide reports to the NLCP.
   d. Facilitate conduct of training of LGUs and other partners on Chemoprophylaxis/PEP and 3-drug regimen implementation.
   e. Facilitate allocation of donated Multi drug therapy (MDT) and other commodities in the Local Government Unit.
   f. Consolidate preparation of reports and facilitate resolution of implementation issues and challenges of provinces, cities and municipalities within the region.

B. Provincial Health Offices, City Health Offices and Municipal Health Offices shall encourage to:
1. Formulate and issue policy supporting the implementation
2. Coordinate with the Leprosy Control Program Coordinator at the CHD for identification and mobilization of available resources for LGUs.
3. Provide technical support such as training and advocacy materials to adopt procedures and control measure in the treatment and prevention of leprosy.
4. Monitor and evaluate implementation at the local level and submit reports to the DOH CHDs through the Provincial and Regional Leprosy Program Coordinator

C. Philippine Dermatological Society (PDS), Sanitaria and selected Medical Centers as partners who support the National Leprosy Control Program shall provide technical expertise, clinical and training support, and be part of the referral network.

D. Non-Government Organizations (NGOs) shall be highly encouraged to support the social preparation, implementation of the treatment and prevention depending on their resources.

E. **World Health Organization (WHO)** shall provide technical assistance in the implementation of the guidelines and its introductory phase of the Post-Exposure Prophylaxis.

VIII. REPEALING CLAUSE

Administrative Order No. 6-A S. 1999 entitled "Treatment Protocol for Leprosy" and all other issuances inconsistent or contrary to the provision of this order are hereby repealed or modified.

IX. EFFECTIVITY

This order shall take effect fifteen (15) days after publication to Official Gazette or newspaper of general circulation.

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

Annex A:

Table 1: Field Classification of leprosy according to number of skin lesion and nerves affected

Characteristics	Paucibacillary (PB)	Multibacillary (MB)
Skin Lesions *(Includes: macule – flat lesion Papule – raised lesion & nodule)*	✓ 1-5 lesions ✓ Asymmetrically distributed ✓ Definite loss of sensation	✓ More than 5 lesions ✓ Symmetrically distributed ✓ Definite Loss of sensation
Nerve Damage *(Resulting in loss of sensation or weakness of muscles supplied by the affected nerve)*	None or one nerve trunk	Many nerve trunks
Presence of Acid Fast Bacilli (SSS and Biopsy) *For facilities who has a capacity to perform the tests	Negative	Positive

Table 2: Recommended treatment regimens

Age Group	Drug	Dosage and frequency	Duration	
			MB	PB
Adult	Rifampicin	600 mg once a month	12 months (12 blister packs within 18 months)	6 months (6 Blister packs within 9 months)
	Clofazimine	300 mg once a month and 50 mg daily		
	Dapsone	100 mg daily		
Children (10- 14 years old)	Rifampicin	450 once a month	12 months (12 blister packs within 18 months)	6 months (6 Blister packs within 9 months)
	Clofazimine	150 mg once a month and 50 mg daily		
	Dapsone	50 mg daily		

Children <10 years old or 40kg	Rifampicin	10 mg/kg once a month	12 months (12 blister packs within 18 months)	6 months (6 Blister packs within 9 months)
	Clofazimine	6 mg/kg once a month and 50 mg daily		
	Dapsone	2 mg/kg daily		

Note: *The treatment for children with body weight below 40 kg requires single formulation medications since no MDT combination blister packs are available. For children between 20 and 40 kg, it would be possible to follow the instructions of the Operational Manual, Global Leprosy Strategy 2016–2020 on how to partly use (MB-Child) blister packs for treatment (60).*

Dosage and frequency	
Supervised dose	600 mg Rifampicin 300mg Clofazimine 100 mg Dapsone
Unsupervised Dose	100 Daily

**** Very rarely, it may be considered advisable to treat a patient with a high bacillary index (BI of 4 pluses and above) for more than twelve (12) month.*

Table 3: Recommended regimens for drug-resistant leprosy

Recommended regimens for drug-resistant leprosy Resistance type	Treatment	
	First 6 months (daily)	Next 18 month (daily)
Rifampicin resistance	Ofloxacin 400 mg* + Minocycline 100 mg + Clofazimine 50 mg	Ofloxacin 400 mg* OR minocycline 100 mg + clofazimine 50 mg
	Ofloxacin 400 mg* + Clarithromycin 500 mg + Clofazimine 50 mg	Ofloxacin 400 mg* + clofazimine 50 mg
Rifampicin and ofloxacin resistance	Clarithromycin 500 mg + Minocycline 100 mg + Clofazimine 50 mg	Clarithromycin 500 mg OR minocycline 100 mg + clofazimine 50 mg

*Ofloxacin 400 mg can be replaced by levofloxacin 500 mg OR moxifloxacin 400 mg

Table 4: Disability Grading of Hands, Feet and Eyes

DISABILITY GRADING	
Hands and Feet	Grade 0 - No anaesthesia, no visible deformity or damage Grade 1 = Anaesthesia, but no visible deformity or damage Grade 2 = Visible deformity or damage present
Eyes	Grade 0 = No eye problems due to leprosy; no evidence of visual loss Grade 1 = Eye problem due to leprosy present, but vision not severely affected (vision 6/60 or better; can count fingers at six meters) Grade 2 = Severe visual impairment (vision worse than 6/60; inability to count fingers at 6 meters), lagopthalmos, iridocyclitis, corneal opacities

Annex B

Prevention of leprosy through chemoprophylaxis

A new leprosy control strategy should aim at reducing clinical leprosy in household contacts of new cases. *Contacts* are key to future leprosy control strategy since population-based approaches are no longer cost-effective and the risk of exposure in the general community is very low. The focus of Post Exposure Prophylaxis (PEP) on contact management will be centered on Household Contacts (HHC) only.

There is a strong evidence that leprosy Post-Exposure Prophylaxis (PEP) can reduce incidence and thereby transmission of the infection by about 60 - 70%. Recent field study has demon strated that chemoprophylaxis with Single Dose Rifampicin (SDR) is safe and operationally feasible. PEP will now be integrated in the routine case finding activities of the leprosy program in the Philippines, as a new approach in reducing further leprosy burden towards leprosy free - Philippines.

The PEP-SDR offer the following advantages: a) it is feasible (it is not a complicated intervention), b) Cheap (it is not an expensive intervention), c) Cost-effective (investment to reduce disease burden over time , d) contacts are likely to accept intervention, e) Drug resistance with Single Dose Rifampicin is negligible, e) useful in every endemic situation like in the Philippines. (Annex b)

The Guidelines Development Group (GDG) recommends the use of single-dose rifampicin (SDR) as preventive treatment for contacts of leprosy patients (Table 4), after excluding leprosy and TB disease, and in the absence of other contraindications. This intervention shall be implemented by programs that ensure: (i) adequate management of contacts and (ii) consent of the index case to disclose his/her diseases.

Table 5: Recommended dosage schedules for SDR

Age/Weight	Rifampicin single dose
15 years and above	600 mg
10-14 years	450mg
Children 6-9 years (weight ≥20 kg)	300 mg
Children <20 kg (≥2 years)	10-15 mg/kg