SDR-PEP IMPLEMENTATION

Standard Operating Procedures (SOPs)

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1. Introduction

Since 2018, the World Health Organization (WHO) recommends the use of single-dose rifampicin as post-exposure prophylaxis (SDR-PEP) in their Guidelines on diagnosis, treatment and prevention of leprosy (1). A single dose rifampicin can effectively reduce the risk of developing leprosy in contacts of index patients. A randomised controlled trial in Bangladesh has demonstrated a risk reduction of 57% in the 2 years after SDR-PEP administration (2). Additionally, implementation of SDR-PEP as part of routine programme activities has been shown to be generally safe, acceptable and cost-effective (3,4).

There are various intervention approaches for SDR-PEP implementation. For example, a close-contact approach involves the screening of close contacts of leprosy index patients, after which eligible contacts are provided with SDR-PEP. Blanket approaches target an entire population and are mainly recommended for defined geographic areas with known high transmission. A skin camp approach involves the organisation of community health camps to screen contacts of index patients for signs and symptoms of multiple skin diseases, including leprosy, and distribute chemoprophylaxis to those eligible (5). The suitability of the different approaches depends on the context in which the intervention is being implemented. The decision tool for SDR-PEP implementation can support the selection of the most suitable approach.

Scale up of preventive chemotherapy is recognized as a key component in the Global Leprosy Strategy 2021–2030 "Towards zero leprosy" (6). Building upon the WHO's guide on contact tracing and post-exposure prophylaxis (7), these Standard Operating Procedures (SOPs) provide a structured approach to support the implementation of SDR-PEP interventions. This package of SOPs can be helpful for leprosy programme managers, health care workers, and organisations involved in implementing chemoprophylaxis for leprosy prevention.

2. Contact details

Any questions related to these SOPs may be directed to: NLR, sdr-pep@nlrinternational.org.

3. Content

The SOPs are subdivided into a **core package** and a **complementary package**. The core package includes key procedures that are essential for the implementation of any SDR-PEP intervention. The complementary package contains SOPs that can be considered optional for SDR-PEP implementation; the relevance of these procedures depend on the type of intervention (e.g., SOPs related to integrated skin diseases interventions). Two additional documents are included, the *SDR-PEP Green Card* and the *SDR-PEP Voucher*. All SOPs and additional documents are listed below.

Core package SOPs	
1	Informing index patients and obtaining their consent
2	Informing contacts and obtaining their consent
3	Eligibility criteria for SDR-PEP and screening of contacts
4	SDR-PEP administration
5	Referral of contacts in case of (possible signs or symptoms of) tuberculosis or leprosy
6	Pharmaceutical product procurement and storage: rifampicin and allergy medication

Complementary package SOPs	
7	Referral in case of suspicion of skin diseases (other than leprosy)
8	Skin medication
9	Use of the NLR SkinApp
10	Siilo usage (app for secured messaging between health professionals)
11	Organisation of a skin camp

Additional documents	
SDR-PEP Green Card	Contacts receiving SDR-PEP can receive this card, which includes (1) a statement that the person has received a single dose rifampicin for leprosy prevention, (2) the date SDR-PEP is provided, and (3) a statement that such person is not eligible to receive SDR-PEP again within 2 years counting from the administration date.
SDR-PEP Voucher	This voucher allows pregnant women and children <2 years of age and/or weighing <10kg who are not eligible for SDR-PEP to collect SDR-PEP when they have become eligible (after the pregnancy, or in case of young children: after turning 2 years of age and weighing ≥10kg).

4. Definitions

Adverse events	Any unfavourable medical occurrence in a patient or clinical investigation subject who has received a pharmaceutical intervention. It does not necessarily have a causal relationship with this treatment.
App	Application / software programme to be used on a mobile device.
Blanket approach	Situation where the entire population of a defined geographic area is provided with an intervention (in this context: post-exposure prophylaxis for leprosy prevention).
Chemoprophylaxis	Chemical agents/drugs used for the prevention of an infectious disease
Close contact (of index patient)	Refers to household contact and/or neighbours and/or social contact who has been in contact with a leprosy index patient for at least 20 hours per week over a period of at least 3 months in the year before the patient was diagnosed.
Community contacts	People living in the same community and in close contact with a leprosy index patient for at least 3 months in the year before the patient was diagnosed.
Contact screening registration form	A document or a digital form to record all information about the contacts.
Efflorescence	Generally used clinical descriptions for skin disease symptoms (like: 'bullae = large blisters').
Eligibility criteria	A list of criteria used to decide whether participants are eligible to participate in the intervention.
Exclusion criteria	A list of criteria that disqualify participants from inclusion in the intervention.
Guardian	An individual who is authorized by law to consent on behalf of a child or (mentally) impaired person.

Household contact	A person living in the same house as the leprosy index patient (sharing the same roof for at least 20 hours per week over a period of at least 3 months in the year before the patient was diagnosed).
Incidental findings	Medical findings that are discovered unintentionally during an intervention or medical evaluation and are unrelated to the objectives of the evaluation, but they have a potential health, well-being or reproductive importance for an individual.
Inclusion criteria	A list of requirements that participants must meet in order to be eligible to participate in the intervention.
Index patient	The first medically identified patient in a group with a particular condition, which triggers a line of investigation, for example a person diagnosed with leprosy.
Informed consent	A process by which a subject voluntarily confirms his/her willingness to participate in an intervention, after having been informed of all aspects of the intervention that are relevant to his/her decision to participate. Informed consent can be taken verbally or is documented by means of a written, signed (or thumb printed) and dated informed consent form (depending on the rules and regulations in the area of implementation).
Leprosy patient	Someone who has been diagnosed with leprosy according to the national guidelines and who is in need of/on treatment.
Macule	A flat, non-palpable lesion with well-defined edges that is different to the surrounding skin. It can be any colour or shape.
Nodule	Swelling or bump in or under the surface of the skin.
Papule	Superficial small, solid bump.
Parent	A child's biological, adoptive, foster parent or caregiver.
Plaque	A palpable lesion with well-defined edges. Plaques are flat but elevated.
Post-exposure prophylaxis (PEP)	Post-exposure prophylaxis is a preventive antibiotic treatment given after exposure to an infectious pathogen (in this context: a(n) (combination of) antibiotic(s) provided against *Mycobacterium leprae*).
Screening	The evaluation or investigation of someone to methodologically assess their status to suspect disease, for example, the presence of any signs of leprosy or other skin diseases. Information is always collected after consent has been obtained.
Siilo	A secured medical messenger (conversational) app.
Single-dose rifampicin chemoprophylaxis (SDR-PEP)	Post-exposure prophylaxis in which a single dose of rifampicin is given to contacts of a leprosy patient.
Skin camp	Skin camps are health camps focusing on dermatological (skin) conditions, held in the community. The purpose of a skin camp (in the context of SDR-PEP implementation) is to screen people living in a community where a new leprosy patient resides and distribute chemoprophylaxis to those eligible, and to diagnose and treat people with skin diseases. It brings (specialised) dermatological care and leprosy screening/prevention closer to communities, improving health care access.

SkinApp / NLR's SkinApp	Mobile phone application to help diagnosing and treating skin diseases.

5. Abbreviations

MDT	Multidrug therapy
NGO	Non-governmental organisation
NTD	Neglected tropical disease
OS	Operating system
PEP	Post-exposure prophylaxis
SDR	Single-dose rifampicin
SOP	Standard Operating Procedure
TB	Tuberculosis
WHO	World Health Organization

6. References

1. World Health Organization. Regional Office for South-East Asia. Guidelines for the diagnosis, treatment and prevention of leprosy. 2018.
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3. Richardus JH, Tiwari A, Barth-Jaeggi T, Arif MA, Banstola NL, Baskota R, et al. Leprosy post-exposure prophylaxis with single-dose rifampicin (LPEP): an international feasibility programme. Lancet Glob Health. 2021 Jan 1;9(1):e81–90.
4. Tiwari A, Blok DJ, Arif M, Richardus JH. Leprosy post-exposure prophylaxis in the Indian health system: A cost-effectiveness analysis. PLoS Negl Trop Dis. 2020 Aug 1;14(8):e0008521.
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6. World Health Organization. Towards zero leprosy: Global Leprosy (Hansen's disease) Strategy 2021-2030. New Delhi; 2021.
7. World Health Organization; Regional Office for South-East Asia. Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. Technical guidance. 2020.