

# Eligibility criteria for SDR-PEP and screening of contacts

## 1. Purpose

This Standard Operating Procedure (SOP) describes the procedures to assess whether household and other close contacts of index patients are eligible to receive single dose rifampicin as post-exposure prophylaxis (SDR-PEP), and the way contacts are screened during a visit to the index patient's household and/or community.

## 2. Justification

SDR-PEP is advised by the World Health Organization (WHO) in their 2018 [Guidelines on diagnosis, treatment and prevention of leprosy](#) (1).

## 3. Scope

This SOP applies to all aspects of the intervention that involve checking of eligibility criteria for SDR-PEP administration and screening of contacts of index patients.

## 4. Target group

This SOP applies to all (health) staff / volunteers involved in contact screening. The screening of close contacts should be done by staff that is normally involved in screening for signs and symptoms of leprosy and other (skin) diseases.

## 5. Procedure

### 5.1. Eligibility criteria for SDR-PEP

To assess the contact's eligibility to receive SDR-PEP, the medical history of the contact should be taken (i.e. ask contact about any sign or symptom, particularly the ones suggestive of tuberculosis, leprosy and other skin diseases, as well as other relevant clinical conditions, such as liver/kidney disease, pregnancy or allergies to drugs, particularly rifampicin), and a physical examination should be performed.

The exclusion criteria for SDR-PEP administration provided below are broad enough to fit any contact screening approach. The inclusion criteria depend on the intervention approach that is used.

*Inclusion criteria for SDR-PEP (2):*

- Consent to participate in the intervention (see '**SOP 2: Informing contacts and obtaining their consent**');
- Age  $\geq 2$  years and weight  $\geq 10$ kg. Children below the age of 18 should be accompanied by a parent or legal guardian.
- Intervention-specific inclusion criteria, depending on the approach used (e.g. a close contact approach, skin camp approach or blanket approach all have different inclusion criteria (2,3)).

*Exclusion criteria for SDR-PEP (2,4):*

- Refusal to participate in the intervention;
- Inability of the contact or parent/legal guardian to understand the benefits and risks of participating in the intervention;
- Pregnant women (will be provided with a '**SDR-PEP voucher**' to receive SDR-PEP after the delivery);

- People with a history of liver disorders (e.g. jaundice);
- People with a history of renal disorders;
- People with known allergy to rifampicin;
- People receiving or having received rifampicin for any reason in the last 2 years (e.g. for tuberculosis/leprosy treatment, or SDR-PEP as contact of another leprosy index patient);
- Known leprosy or tuberculosis (TB) disease;
- People who are suspected to have leprosy or TB. These people should be referred to the nearest (leprosy/TB) clinic for confirmation of diagnosis and should not receive SDR-PEP (they need full treatment, which often also includes rifampicin), until the diagnosis is ruled out.

## 5.2. Screening

Close contacts of index patients are screened for signs and symptoms of leprosy and TB, and may also be screened for other skin diseases. Standard patient registration forms/health records (aligned with context-specific procedures), in addition to specific contact registration forms, should be utilized during the screening procedure. For more information on and examples of contact screening forms, see the 2020 WHO Technical Guidance on [Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis](#) and Richardus et al.'s [Minimal essential data to document contact tracing and single dose rifampicin \(SDR\) for leprosy control in routine settings: a practical guide](#) (2,5).

**Screening should take place according to WHO guidelines (1,2,6,7):**

- Be respectful: treat a person the way you would want to be treated
- Use a gender sensitive approach: ensure that females are examined by females if possible, where not possible a female chaperon should be present.
- Take privacy and confidentiality into account (e.g. use curtains, separate rooms)
- Examine in a room with good lighting
- Wash your hands before you start, use anti-septic solution and put on gloves if needed
- Examine the **entire** body (ask the patient to undress) for signs and symptoms, do not forget to look at the back/bottom/back of the legs/chest/breasts/abdomen.
- Ask 5 important questions when you see a skin lesion:
  - **Since when** was the skin abnormality noticed?
  - Are there **other symptoms** (itchiness, pain, numbness, etc.)?
  - Are **relatives** affected?
  - What do you [the contact] think is the **cause** of the skin lesion?
  - What **treatments** did you try?
- Test for sensation (with cotton wool or a suitable mono-filament) when you see a skin lesion lighter than surrounding skin (1,8)
- Look for enlarged peripheral nerves (1,8)
- Look for any wounds and/or visible deformities
- Wash your hands with soap and where available use hand sanitizers after examining each contact/patient. Use gloves in case of ulcers.

Use the lists provided below to assess suspected skin lesions to increase the sensitivity and specificity of screening.

**A person suspected to have leprosy may appear with one or multiple of the following signs and symptoms (1,2,6,9):**

- Hypo-pigmented (pale), erythematous (reddish) or copper-coloured skin patches/lesion (the most common sign of leprosy). The lesion can be flat (macule), raised (plaque), papules or nodular;
- Loss or impairment of sensation (feeling) in the skin patch;
- Infiltration of skin (thickened skin lesion which is smooth and shiny);
- Numbness (decreased sensation) or tingling of hands/feet or loss of sensation (temperature, touch, pain), especially in fingers tips and foot soles and located at skin lesions;
- Weakness or paralysis of the hands, feet or eyelids of unknown cause;
- Palpably thickened or enlarged, painful or tender peripheral nerves; especially behind the ear, around the elbow, wrist, knee and ankle joints;
- Very dry hands/feet (impaired sweating) with cracks in the skin;
- Blisters, wounds or ulcers on hands/feet;
- Shortening of toes and fingers due to reabsorption;
- Painless swelling or lumps on the face or earlobes;
- Deformity and/or chronic wounds/ulcers (painless), especially on hands and feet;
- Loss of eyebrows or eyelashes;
- Eye problems that may lead to blindness (when facial nerves are affected).

**People having any of the following signs or symptoms should be referred for TB screening (2,10):**

- A cough for 2 weeks or more in immune-competent persons, but cough of any duration (current cough) in people living with HIV;
- Night sweats;
- Unexplained fever;
- Unexplained weight loss;
- Chest pain, or pain with breathing or coughing;
- Extreme tiredness without clear reason;
- Coughing up blood;
- Loss of appetite;
- Enlarged lymph nodes (usually painless/non-tender).

Record the eligibility status in a designated contact screening register.

- If the person does not meet the eligibility criteria, explain why the person is (currently) not eligible and do not administer SDR-PEP.
- If after screening, the contact is suspected to have leprosy or TB, she/he is not eligible to receive SDR-PEP and should be screened further for diagnosis, or referred to a health facility for leprosy or TB diagnosis and treatment (see ***'SOP 5: Referral of contacts in case of (possible signs or symptoms of) tuberculosis or leprosy'***).
- Contacts who are not eligible to receive SDR-PEP at the time of screening (e.g. because of pregnancy or children <2 years of age and <10 kg) can receive an ***'SDR-PEP Voucher'***. With this voucher they can receive SDR-PEP at the local health facility after their pregnancy or when aged ≥2 years and weighted ≥10kg.
- The intervention may also involve the screening for other skin diseases. Contacts with suspected skin diseases (other than leprosy) are eligible to receive SDR-PEP. See ***'SOP 7: Referral of contacts in case of suspicion of skin diseases (other than leprosy)'*** and ***'SOP 11: Organisation of a skin camp'***.

The screening and diagnosis pathway is presented in the figure below.

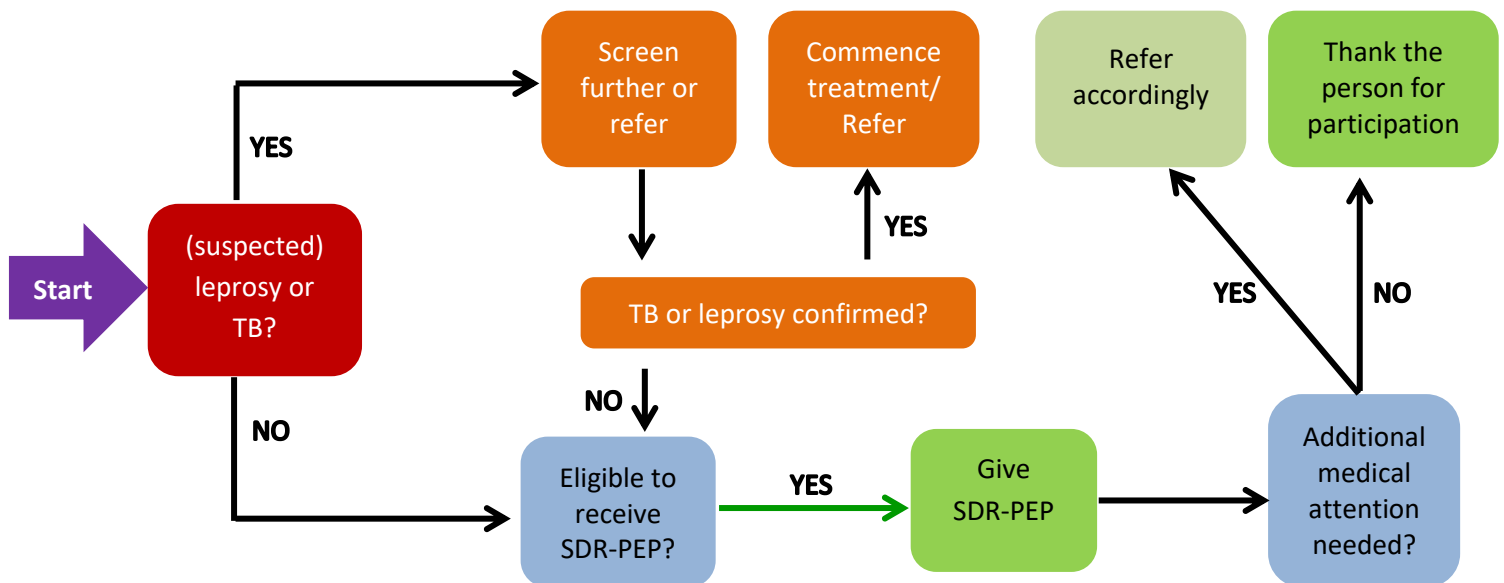


Figure 1: Contact screening pathway

### 5.3. Referral

Based on the outcomes of the screening procedure, some contacts may need to be referred to a specialized health facility (e.g. in case other skin diseases are seen, or when TB, leprosy, HIV/AIDS or other diseases [incidental findings] are suspected). Referral is done according to national guidelines. More information can be found in '**SOP 5: Referral of contacts in case of (possible signs or symptoms of) tuberculosis or leprosy**' and '**SOP 7: Referral in case of suspicion of skin diseases (other than leprosy)**'.

### 5.4. SDR-PEP administration

The administration of PEP should be directly observed. Do not provide tablets for absent contacts, and use a '**SDR-PEP Voucher**' for pregnant women or children <2 years of age and weighing <10kg. Refer to '**SOP 4: SDR-PEP administration**' for more details.

Contacts receiving SDR-PEP can be given an '**SDR-PEP Green Card**'. On this card will be stated that the person has received a single dose rifampicin for leprosy prevention and the date of administration. The person is not eligible to receive SDR-PEP again within 2 years of administration. The Green Card is to be saved at home, where it can be kept together with general medical files.

### 5.5. Other medication

Besides SDR-PEP, medications against allergy should be made available, and possibly also topical medication for skin diseases. Refer to '**SOP 6: Pharmaceutical product procurement and storage: rifampicin and allergy medication**' and '**SOP 8: Skin medication**' for details.

### 5.6. Adverse events

Refer to '**SOP 4: SDR-PEP administration**' for information on adverse events related to SDR-PEP.

## 6. Definitions and abbreviations

An overview of all definitions and abbreviations can be found in the document *‘Introduction, content and definitions’*.

## 7. Related SOPs and other documents

- SDR-PEP Voucher
- SDR-PEP Green Card
- *SOP 1: Informing index patients and obtaining their consent*
- *SOP 2: Informing contacts and obtaining their consent*
- *SOP 4: SDR-PEP administration*
- *SOP 5: Referral of contacts in case of (possible signs or symptoms of) tuberculosis or leprosy*
- *SOP 7: Referral in case of suspicion of skin diseases (other than leprosy)*
- *SOP 9: Use of the NLR SkinApp*
- *SOP 10: Siilo usage*

## 8. References

1. World Health Organization; Regional Office for South-East Asia. Guidelines for the diagnosis, treatment and prevention of leprosy. 2018.
2. World Health Organization; Regional Office for South-East Asia. Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. Technical guidance. 2020.
3. Ellen F Ter, Tielens K, Fenenga C, Mieras L, Schoenmakers A, Arif MA, et al. Implementation approaches for leprosy prevention with single-dose rifampicin: A support tool for decision making. *PLoS Negl Trop Dis*. 2022 Oct 1;16(10):e0010792.
4. Barth-Jaeggi T, Steinmann P, Mieras L, Van Brakel W, Richardus JH, Tiwari A, et al. Leprosy Post-Exposure Prophylaxis (LPEP) programme: study protocol for evaluating the feasibility and impact on case detection rates of contact tracing and single dose rifampicin. *BMJ Open*. 2016;6:13633.
5. Richardus JH, Kasang C, Mieras L, Anand S, Bonenberger M, Ignotti E, et al. Minimal essential data to document contact tracing and single dose rifampicin (SDR) for leprosy control in routine settings: a practical guide. *Lepr Rev*. 2018 Mar 1;89(1):2–12.
6. World Health Organization. Guide to eliminate leprosy as a public health problem. 2000.
7. World Health Organization. WHO guidelines on hand hygiene in health care : a summary. 2009.
8. World Health Organization. Leprosy/Hansen Disease: Management of reactions and prevention of disabilities. Technical Guidance. New Delhi; 2017.
9. Centers for Disease Control and Prevention (CDC). Signs and Symptoms - Hansen’s Disease (Leprosy) [Internet]. 2017 [cited 2023 May 11]. Available from: <https://www.cdc.gov/leprosy/symptoms/index.html>



10. Mayo Clinic. Tuberculosis - Symptoms and causes [Internet]. 2023 [cited 2023 May 11]. Available from: <https://www.mayoclinic.org/diseases-conditions/tuberculosis/symptoms-causes/syc-20351250>