

# Informing contacts and obtaining their consent

# 1. Purpose

This Standard Operating Procedure (SOP) describes the procedures to recruit contacts of index patients, to inform them about post-exposure prophylaxis (PEP) implementation, and to help protect their rights, safety and welfare.

## 2. Justification

PEP is advised by the World Health Organization (WHO) in their 2018 <u>Guidelines on diagnosis,</u> <u>treatment and prevention of leprosy</u> as single dose rifampicin (SDR) (1).

## 3. Scope

This SOP applies to all aspects of informing contacts of index patients about the intervention and obtaining their consent.

# 4. Target group

This SOP applies to all (health) staff involved in informing the close contacts of an index patient and obtaining their consent.

## 5. Procedure

The following steps guide the procedures of informing and obtaining consent of close contacts of index patients. All subjects approached should be documented, including the ones refusing to participate in the intervention (note the reason for refusal). For more detailed information on contact tracing approaches, see the 2020 WHO Technical Guidance - Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis (2). Once contacts have given consent, their eligibility for SDR-PEP is assessed and their skin is examined; see 'SOP 3: Eligibility criteria for SDR-PEP and screening of contacts' and 'SOP 4: SDR-PEP administration'.

Informing of contacts and obtaining their consent can only start when the index patient has given permission to include his/her close contacts in the intervention and disclose his/her disease status to the close contacts (see '*SOP 1: Informing index patients and obtaining their consent'*).

#### Procedure

Contacts will be approached in the household/community (neighbours) of the index patient or will be invited to a health centre, aiming to include at least the closest contacts (household contacts and neighbours) of index patients.

- Before any screening of contacts begins, the contact should be informed about the facts of leprosy (including the mode of transmission), the importance of early detection, possibility (with limitation) for reducing the risk of developing leprosy through PEP, and the overall aim of reducing the transmission of the disease (2). It is important to highlight that PEP is not 100% effective, and to explain about recognising the early signs/symptoms of leprosy. In addition, side-effects of rifampicin (e.g. flu-like symptoms, temporarily red colouring of body fluids) should be mentioned.
- The 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). A sample informed consent form for contacts is included in the



2020 WHO Technical Guidance - Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis.

- For children under the age of 18, or persons with mental impairment who are unable to understand the information provided, a parent or legal guardian should give consent on their behalf.
- If the contact has fully understood the information and all possible questions have been answered, her/his (un)willingness to participate must be indicated on the contact screening registration form. For more information on and examples of contact registration forms, see the 2020 WHO Technical Guidance 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 (2,3).

#### Follow up of missing contacts

If some targeted contacts are not around during the first visit, a revisit should be scheduled.

## 6. Definitions and abbreviations

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

## 7. Related SOPs

- SOP 1: Informing of index patients and obtaining their consent
- SOP 3: Eligibility criteria for SDR-PEP and screening of contacts
- SOP 4: SDR-PEP administration

## 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. 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.