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Informing index patients and obtaining their consent

1. Purpose

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

2. Justification

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

3. Scope

This SOP applies to all aspects of informing index patients about the intervention (contact screening and PEP implementation), their rights and obtaining their consent.

4. Target group

This SOP applies to key personnel involved in informing index patients and obtaining their consent.

5. Procedure

Staff involved in the implementation of chemoprophylaxis for leprosy should ensure that the index patient has completed or at least started multidrug therapy (MDT) treatment before his/her contacts are being screened and SDR-PEP is administered (2,3). Otherwise, re-infection by the index patient is possible.

- If the index patient is still under treatment: the patient can be contacted in the health facility during routine MDT treatment follow-up visits.

- If the index patient has completed MDT treatment: organise a visit to the index patient's house. If possible, a phone call should be made before the visit to ascertain the presence of the patient. Ensure that potential issues related to stigma or disease concealment are taken into account when visiting the index patient.

Procedure:

- Inform the index patient about the intervention.
- Ask the index patient for permission to visit his/her home/community to disclose his/her diagnosis to the household contacts and/or other close contacts, and conduct contact tracing and administer PEP.
- The index patient should voluntarily confirm his/her willingness to participate in the intervention, after having been informed of all aspects of the intervention. 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 index patients is included in the 2020 WHO Technical Guidance - Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis (3).
- For children under the age of 18, or for persons with mental impairment who are unable to understand the information provided, a parent or legal guardian should decide and give consent on their behalf.

- Check and enter demographic data of the index patient on a designated index patient registration form and/or their medical file.

6. Definitions and abbrevations

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

7. Related SOPs

- *SOP 2: Informing contacts 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. 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.

3. World Health Organization; Regional Office for South-East Asia. Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. Technical guidance. 2020.