






## STUDY PROTOCOL

# Definition of 'close contacts' in leprosy studies: protocol for a scoping review [version 1; peer review: 2 approved, 1 approved with reservations]

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## Abstract

Despite difficulties to document transmission pathways (assumed to be airborne), increased risk of leprosy infection has been shown for individuals living in close contact with patients. However, variations in the concept of 'close contacts' are used in different settings and studies. We conduct this review to identify criteria of space (location, geographical variables, distance, indoor vs outdoor), time (including frequency and duration), physical exposure (skin to skin, sexual), and relationship (familial, occupational, social) involved in the definition of 'close contacts' in leprosy studies. We expect this review to provide an overview of the (lack of) conceptualization of this term and its variations across settings. Primary studies and reviews are eligible for inclusion in this review. The main source of records will be the PubMed interface. Secondary searches will be conducted in Google Scholar, as well as through the reference lists of selected publications. The search strategy is based on the combination of the condition of interest (leprosy) and the concept under study ('contact'). The findings of this review will be presented using thematic narrative synthesis, tables, and figures. The protocol is written in line with the Prisma Extension for Scoping reviews (PRISMA-ScR).

## Keywords

Leprosy, close contacts, scoping review.

## Open Peer Review

### Approval Status



	1	2	3
<b>version 1</b> 20 Jul 2022	? view	✓ view	✓ view

### 1. Millawage Supun Dilara Wijesinghe ,

Health Promotion Bureau, Colombo, Sri Lanka

### 2. Vimal Kumar, National JALMA Institute for

Leprosy and Other Mycobacterial Diseases, Agra, India

### 3. Veronica Schmitz, Oswaldo Cruz Foundation,

Rio de Janeiro, Brazil

Any reports and responses or comments on the article can be found at the end of the article.

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**Author roles:** **Ronse M:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Software, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Nieto-Sanchez C:** Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Software, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **De Coninck S:** Formal Analysis, Investigation, Software, Writing – Original Draft Preparation; **Verdonck K:** Conceptualization, Formal Analysis, Funding Acquisition, Investigation, Methodology, Resources, Software, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Peeters Grietens K:** Conceptualization, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

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## Introduction

Despite difficulties to document transmission pathways (assumed to be airborne), increased risk of leprosy infection has been shown for individuals living in *close contact* with patients. The World Health Organisation (WHO) defines *close contact* as “a person having close proximity to a leprosy patient for a prolonged duration. Such persons are considered ‘exposed’ to leprosy and may or may not have been infected. ‘Prolonged duration’ is typically defined as having been in contact with an untreated patient for 20 hours per week for at least three months in a year, e.g. family members, neighbours, friends, school children in same class; co-workers in same office, etc”.<sup>1</sup> However, variations of this definition are used in different settings and studies.

Clustering of leprosy cases within households (often referred to as ‘household contacts’) has been documented,<sup>2–4</sup> as well as occurrence of new cases at close geographical distance from previous leprosy cases.<sup>5</sup> People living in the same household or at close distance are frequently linked through either social activities or networks,<sup>6</sup> raising the question whether the “distance” someone lives from an index case determines the risk of infection or whether it acts as a proxy for other explanatory variables that are more directly associated with leprosy risk, such as types and conditions of close human contacts.<sup>7,8</sup> Similar to other infectious diseases,<sup>9</sup> duration of contact has also been considered a criterion to determine risk of exposure.

We conduct this review to identify criteria of space (location, geographical variables, distance, indoor vs outdoor), time (including frequency and duration), physical exposure (skin to skin, sexual), and relationship (familial, occupational, social) involved in the definition of ‘close contacts’ in the context of risk of leprosy. We expect this review to provide an overview of the conceptualization of this term and its variations across settings.

This review is part of the study “Improving leprosy prevention strategies by integrating social network analysis with spatial and molecular epidemiology data of *Mycobacterium leprae* in the Comoros”, supported by ITM’s Structural Research Funding, and funded by the Flemish Ministry of Economy, Sciences and Innovation (EWI).

## Objectives

The central goal of this review is to identify definitions of ‘close contacts’ used in the description of risk for leprosy transmission, as well as specific criteria of space, time, physical exposure, and relationship employed in these definitions.

## Methods

### Eligibility criteria

Records will be included in the review if they meet all the following criteria:

- Reports of primary studies or review articles (not opinion papers); and
- Using the word ‘contact’ in relation to risk of leprosy, and
- Including a definition of ‘contact’ in relation to risk of leprosy infection

Inter and extra-domiciliary exposures will be included. We expect definitions of contacts to include different criteria to establish risk in relation to space, time, physical contact, and relationships.

The review will consider persons of any age and sex, residing in leprosy-endemic areas. Definitions might include participants recruited in the community (active case finding) or in health establishments (passive case finding); they may be symptomatic or asymptomatic.

### Information sources

PubMed interface will be used for the primary search, without any a priori restrictions to language or date. A limited search of Google Scholar as a secondary source will also be conducted. We intend to screen the reference lists of included records (especially review papers) and contact experts in the field to check if we have missed any potentially relevant records.

### Search strategy

The search strategy is based on the combination of two concepts: the condition of interest and the concept of ‘contact’. The Boolean operators “AND” and “OR” will be used to combine search terms. [Table 1](#) summarizes the planned search syntax for PubMed. The same general strategy will be used to search in Google Scholar.

**Table 1. Planned search syntax for PubMed.**

<pre> "leprosy"[All Fields] OR "leprosy"[MeSH Terms] OR "leprosy"[All Fields] OR ("mycobacterium leprae"[MeSH Terms] OR ("mycobacterium"[All Fields] AND "leprae"[All Fields]) OR "mycobacterium leprae"[All Fields]) OR ("mycobacterium leprae"[MeSH Terms] OR ("mycobacterium"[All Fields] AND "leprae"[All Fields]) OR "mycobacterium leprae"[All Fields]) OR "m leprae"[All Fields]) OR ("mycobacterium lepromatosis"[Supplementary Concept] OR "mycobacterium lepromatosis"[All Fields] OR "mycobacterium lepromatosis"[All Fields]) OR ("m"[All Fields] AND "lepromatosis"[All Fields]) </pre>
AND
(contact)

**Table 2. Categories of data items to be considered in the preliminary data extraction form.**

Category	Data items
Record	Journal and year of publication, first author and affiliation
Setting	Study aim, location, type of setting (urban, rural)
Conceptual frame	Definition of 'contact'
	Methods used for the identification of index cases and contacts
	Parameters of space (location, distance, geographical, intra/extra domiciliary, in/out-door)
	Parameters of time (frequency, duration)
	Parameters of relationship (genetic, familial, occupational, other social types)
	Parameters of physical contact (skin to skin, sexual)
Other conditions	
Intervention (if existing)	Contact tracing, screening, prevention, treatment, prophylaxis, active case detection, passive case detection

### Data extraction (selection and coding)

All retrieved records will be imported into **COVIDENCE**. Duplicate records will be identified and excluded using **COVIDENCE** and Mendeley. Two reviewers will independently select full-text papers to be included in this review. Discordances will be solved through discussion with the review team. Two reviewers will extract data items into a data extraction form in **COVIDENCE** that will include the categories included in **Table 2**. This table will be pilot tested on five papers, and then refined based on the results of the pilot. Data extraction will only consider published records; no contact with authors is planned.

### Strategy for data synthesis

Thematic narrative synthesis will be our main method of data reporting. Results will be inserted in each one of the categories specified in the final data extraction form. Information extracted from each manuscript will be indicated in summary tables. If considered useful, additional figures will be created.

### Registration

This protocol is registered in F1000Research. The protocol has been developed in line with the Prisma Extension for Scoping reviews (PRISMA-ScR) recommendations.<sup>10</sup>

### Planning

#### Timeframe

- Protocol publication: July 2022
- Search, selection, data extraction and synthesis: July 2022 – October 2022
- Writing of review paper: November 2022 – January 2023

### Study status

In preparation of this protocol, preliminary searches have been conducted (mostly to grasp the extent of the available literature). However, formal reviewing activities had not started yet.

### Data availability

No data are associated with this article.

### References

1. World Health Organization (WHO): *Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis*. World Health Organization; 2020. Regional Office for South-East Asia.
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[Publisher Full Text](#)
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[PubMed Abstract](#) | [Publisher Full Text](#)
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[PubMed Abstract](#) | [Publisher Full Text](#)
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[PubMed Abstract](#) | [Publisher Full Text](#)
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[PubMed Abstract](#) | [Publisher Full Text](#)
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[PubMed Abstract](#) | [Publisher Full Text](#)

# Open Peer Review

Current Peer Review Status: ? ✓ ✓

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## Version 1

Reviewer Report 13 July 2023

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### Veronica Schmitz

Oswaldo Cruz Foundation, Rio de Janeiro, Brazil

The manuscript entitled "Definition of 'close contacts' in leprosy studies: protocol for a scoping review" by Ronse et al. describes the literature review that the authors plan to carry out with a highly relevant topic which is the definition of contacts in leprosy. The close contact for leprosy is defined by WHO, however many different authors provide different definitions and found different results of what is a close contact or household contact."

The article has straightforward question and a search strategy defined.

Minor points:

Methods:

1. The eligibility criteria: I would suggest to define study inclusion and exclusion criteria separately.
2. Why don't you also use EMBASE, Web of Science, Scopus, LILACS, Virtual Health Library or Cochrane Library databases?
3. It is not clear if the development process will include the characterization of each selected study, evaluation of their quality, identification of important concepts, and comparison of statistical analyses used.
4. Is the planning/Timeframe updated?

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.**Reviewer Expertise:** Immunology of leprosy, clinical research**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Reviewer Report 13 June 2023

<https://doi.org/10.5256/f1000research.136014.r172157>

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**Vimal Kumar**

National JALMA Institute for Leprosy and Other Mycobacterial Diseases, Agra, Uttar Pradesh, India

## Summary:

The authors conducted this review to identify criteria of space (location, geographical variables, distance, indoor vs outdoor), time (including frequency and duration), physical exposure (skin to skin, sexual), and relationship (familial, occupational, social) involved in the definition of 'close contacts' in the context of risk of leprosy. They expect that this review will provide an overview of the conceptualization of this term and its variations across settings.

The proposal has good scientific and technical merit as the definition of contacts must be accepted in similar sense worldwide as still some ambiguity persists with the term 'contacts'.

## Comments:

a. Is the rationale for, and objectives of, the study clearly described?

Comment: Yes, the rationale for, and objectives of, the study clearly described.

As the objective is to conceptualize the term on the different criteria of space, time, physical exposure, and relationship the correlation of the above facts will help in reaching the final conclusion in a better way.

b. Is the study design appropriate for the research question?

Comment: Yes the study design is appropriate for the research question. The idea is innovative and has good novelty sense.

c. Are sufficient details of the methods provided to allow replication by others?

Comment: Yes, sufficient details of the methods have been provided to allow replication by others. As the assay will be evaluated on the different criterion, it will be very beneficial for the leprosy experts to come to a common conclusion for the leprosy contacts.

d. Are the datasets clearly presented in a useable and accessible format?

Comment: The datasets have been presented in a useable and accessible format but I have one suggestion regarding improvement of the same.

Suggestion: Instead of two, three reviewers should independently select full-text papers to be included in this review for the significant results.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Leprosy, tuberculosis, animal experimentation

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Reviewer Report 05 December 2022

<https://doi.org/10.5256/f1000research.136014.r155569>

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**Millawage Supun Dilara Wijesinghe** 

Health Promotion Bureau, Colombo, Sri Lanka



Thank you for the opportunity to review this paper, focusing on a crucial topic. This protocol for a scoping review is well-written and provides adequate details about the proposed methods. Furthermore, the methods seem well justified.

I have a few minor suggestions which will improve the paper further.

### **Abstract**

- The abstract should be structured as mentioned in the PRISMA-ScR guidelines<sup>1</sup>.
- It is always better to have MeSH terms as keywords.

### **Introduction**

- In the introduction section, it is better to have what are the problems associated with not having a proper definition of 'close contact'.
- It is also best to describe current discrepancies in the definition of contact in leprosy.
- The authors can further justify the rationale for undertaking this review in the present context.

### **Methods**

- Search strategy
  - What about grey literature? Are you planning to include them?
- Table 2 - Setting - location - at what level (country level or below)?
- Intervention (If existing) - is this for identification of the index case or identification of contacts?

### **Protocol and Registration**

- Please include the protocol's web address or registration number.

### **References**

1. Tricco AC, Lillie E, Zarin W, O'Brien KK, et al.: PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018; **169** (7): 467-473 [PubMed Abstract](#) | [Publisher Full Text](#)

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Leprosy, Public Health, Health Promotion, Occupational Health

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

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