PEP4LEP research and its contribution to capacity building

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Introduction

One of the important challenges in leprosy control is formed by the long incubation period of *Mycobacterium leprae* (*M. leprae*), that can last up to twenty years, during which it is generally assumed that transmission of the bacterium already occurs. Those most at risk of becoming infected with *M. leprae* are close contacts of leprosy patients: household contacts, neighbours and social contacts. The traditional approach to this problem has been to try various methods of active case finding in order to identify patients early, start treatment and thus reduce the potential for further transmission. A more recent supplementary intervention proven to be effective in reducing the risk of developing leprosy in contacts of leprosy patients, is the administration of post-exposure prophylaxis (PEP) with single-dose rifampicin (SDR). The World Health Organization (WHO) recommends the use of SDR-PEP as chemoprophylaxis in their “Guidelines for the Diagnosis, Treatment and Prevention of Leprosy”.

**PEP4LEP**

PEP4LEP is an SDR-PEP implementation study in Ethiopia, Mozambique and Tanzania aiming to identify an effective and feasible integrated skin screening method targeting people at risk of developing leprosy, and administrating SDR-PEP to contribute to stopping the transmission of *M. leprae*. Two interventions are compared: a community-based intervention, using skin camps to screen approximately 100 community contacts per leprosy patient, and to administer SDR-PEP when eligible; and a health centre-based intervention, inviting household contacts of leprosy patients to be screened in a local health centre and to subsequently receive SDR-PEP when eligible. The effectiveness is assessed by comparing the differences in the leprosy case detection delay (CDD) between the health centre-based and community-based intervention, and the CDD at baseline. The feasibility is determined by the cost-effectiveness of the interventions and the level of acceptability among the main stakeholders.
The CDD as the main outcome measure is defined as the period (in months) between the onset of the first sign and/or symptom of leprosy and the moment of diagnosis, encompassing both ‘patient delay’ and ‘health system delay’. A practical tool was recently developed to determine the delay in diagnosis of leprosy patients. The development was based on a literature review and consultation with experts. Country specific versions were piloted by health workers in Ethiopia, Mozambique and Tanzania and were shown to be administered quickly and easily. The Case Detection Delay tool (available at infolep.org) includes a questionnaire and several supporting documents: a context specific calendar to translate the patient’s indication of time to a number of months; a set of pictures of signs of leprosy; a body map to locate the signs, and a ‘question-by-question guide’.

In each of the three countries a baseline assessment was performed to describe the national/governmental leprosy control programmes, the epidemiological trends in leprosy over the past five years in the areas in which the PEP4LEP study will be implemented, and to report the mean detection delay in diagnosing leprosy patients. The findings of these baseline assessments are presented in the three papers that can be found in this edition of Leprosy Review. They show that leprosy transmission is continuing in the PEP4LEP study areas in Ethiopia, Mozambique and Tanzania, with significant numbers of new patients identified and high percentages of children among new patients. In Mozambique for example, case detection in the period 2015 to 2019 was on average 226 patients per million population per year. The child percentage was 11.0 on average and a high disability grade two percentage (16.3% on average) was found. In the study areas in the three countries the mean patient detection delay was significant, ranging from 22.4 months in Ethiopia to 28.1 months in Tanzania. These data underline the importance of sustained efforts to detect, treat and prevent leprosy.

**Capacity building**

**STUDY IMPLEMENTATION**

*Increased knowledge and skills for improved diagnosis and management*

An additional objective of the PEP4LEP study is related to increasing health workers’ capacity in diagnosing leprosy and other neglected tropical diseases (NTDs) that manifest with skin lesions, as well as common skin diseases, with the support of a mobile phone application: the SkinApp. Several studies have shown that there is a reason for concern about health workers’ knowledge related to leprosy. This is aligned with the WHO Global Leprosy Strategy 2021–2030, in which ‘Increasing capacity for diagnosis, treatment and management’ is identified as one of the critical actions for this decade on the path towards zero leprosy. PEP4LEP addresses this challenge, and WHO recommends capacity building as part of an integrated approach for skin NTDs in their road map for NTDs 2021–2030.

The capacity of health workers to diagnose leprosy and other skin diseases will be assessed: before (baseline) and after PEP4LEP health worker (refresher) training, during the implementation and towards the end of the study period. The training consists of interactive modules given over a period of several days and provides participants with knowledge on the PEP4LEP study protocol, the standard operating procedures, integrated skin screening, the use of the SkinApp, leprosy and its management, and the administration of SDR-PEP. The paper-based assessment methodology was developed with the support of an educational specialist.

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1The overall study period was October 2018 until January 2023, but a study extension is expected due to the impact of COVID-19.
In addition, qualitative methods such as semi-structured interviews, focus group discussions and ethnographic field observations will be used to get a better understanding of enablers and barriers for capacity building.

**Increased community engagement**

The other capacity building component of PEP4LEP is increasing the awareness of the community through involving patients, community leaders and representatives of organisations of persons affected by leprosy and organizations for disabled people in PEP4LEP related activities. This component contributes to monitoring activities and support community participation. Study findings will be reported back to the communities through community meetings. Results, lessons learned and recommendations will be actively disseminated to relevant stakeholders in Ethiopia, Mozambique and Tanzania, and to other leprosy endemic countries.

**Research Partnership**

**Balanced and justified engagement of partners**

The study is a collaboration of mutually reinforcing consortium members: Ministries of Health (MoH) and universities/knowledge institutes in the three countries in which the study is implemented, two international NGOs working on leprosy and a university in the Netherlands. The governance and meeting structures of the PEP4LEP study are set-up in a way that facilitates discussions on challenges and experiences and enables mutual learning. All consortium members are represented in the International Project Management Committee that oversees the study progress and makes decisions jointly. There is also an independent Scientific Steering Committee, which comprises scientists and experts from various countries and advises on all scientific aspects of the study. The study is set up in such a way that it encompasses the research development skills of young career professionals under the guidance of the universities that are part of the consortium: there is one PhD student in each of the Sub-Sahara African countries involved, plus one in Europe (an epidemiologist), with the aim to enable them to continue working in this field in the future. The PhD students in Ethiopia, Mozambique and Tanzania work with the PEP4LEP teams on the frontline of the implementation. They are a researcher with a Master of Public Health in Epidemiology, a Medical Doctor with a Master in Tropical Medicine and Hygiene, and a Dermatologist and they focus on different scientific aspects of the study. The implementing countries each have a taskforce with representation of the MoH, the university or knowledge institute and the NGO to monitor the quality and progress of the study.

There are several international, online meetings with a varying composition of participants to discuss operational aspects of the study as well as data collection, management and analysis.

One of the international NGOs is responsible for the overall coordination of the project in close collaboration with the consortium members. This Project Coordinator is the intermediary between the members of the consortium and the donors.

**Reflection**

Capacity building for the people involved in the implementation of the study has multiple positive effects that include generation of quality data for the study, creating trained and skilled health workers and researchers, and strengthening the health system, which results in improved patient care and management.
Increasing capacity within research partnerships is necessary in order to continue to meet long term public health and innovation needs and it leads to evidence based practice.\textsuperscript{12} The way in which capacity building is integrated in international studies requires critical consideration.\textsuperscript{13} One of the basic requirements is a balanced involvement of partners in low-, middle- and high-income countries from the development phase of the study until the phase of disseminating results. A model in which the coordination is assigned to an institute in a high-income country may create a power imbalance contributing to scientific inequity. This requires a research partnership that fosters open communication, critical reflection and sharing of experiences, so that researchers from low-, middle- and high-income countries will increase their research capabilities in a collaborative manner.

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**References**