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WORKSHOP REPORT

Towards integration of leprosy post-exposure prophylaxis into national programme routines: report from the third annual meeting of the LPEP programme

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Context

The Leprosy Post-Exposure Prophylaxis (LPEP) programme is designed to establish evidence of the feasibility and impact of tracing contacts of recently diagnosed leprosy patients, followed by their screening for signs of leprosy and administration of single dose rifampicin (SDR) to eligible contacts. The aim is to improve leprosy case finding among contacts of index patients, and reduce the risk to contacts of developing leprosy.[1,2] The programme has been designed by Novartis Foundation in close collaboration with the leprosy control programmes of eight countries, and their International Federation of Anti-Leprosy Association (ILEP) partners as well as other institutions. A steering committee provides strategic guidance. Novartis Foundation funds the programme activities, and ensures the central coordination of the programme.

Each year in November, since fieldwork began (2015), the Novartis Foundation has hosted an annual meeting to review progress and exchange insights between the programme partners. The annual meeting brings together representatives of the eight national leprosy programmes and their international partners, Novartis Foundation, the WHO Global Leprosy Programme, the CDC bacterial special pathogen branch, people affected by leprosy, and academic partners. Traditionally, one of the two annual LPEP Steering committee meetings is also held during these annual meetings.

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Meeting Objectives

The objectives of the 3rd LPEP programme annual meeting held in Bangkok, Thailand from 21–23 November 2017 were three-fold: (i) to review progress made to date; (ii) to discuss the completion and dissemination phase of the operational research programme; and (iii) to stimulate discussions and anticipatory planning regarding the eventual integration of the key programme features into national leprosy control programme routine processes.

The agenda was characterised by a high level of interactive elements intended to promote exchange and joint identification of key issues and the best way forward towards integration. Following a review of the LPEP programme achievements to date from a global and individual country perspective, a moderated discussion focused on the identification of common themes and general insights. A historical review of the leprosy control programme of the Kingdom of Thailand was offered by the Director of the Raj Pracha Samasai Institute, Department of Disease Control, the institution charged with the coordination of leprosy control in the country. This country perspective provided insights into the defining features of the programme, and made the subsequent discussions even more relevant by offering a positive experience. The following breakout and feedback sessions were dedicated to specific topics. Presentations focusing on complementary studies including perception of the intervention and economic studies, complemented the programme.

LPEP Programme Progress Update

The six initial countries participating in the LPEP programme, namely India, Indonesia, Myanmar, Nepal, Sri Lanka and Tanzania, have already completed between 2 and 2·5 years of field work. In 2016, two additional countries, Brazil and Cambodia, joined the programme. Data from all countries except Cambodia (which follows a slightly different protocol) are available up to summer 2017. A total of 6,646 index patients who were diagnosed in the study areas after the start of the field work, or up to 2 years prior to the start of the field work, depending on the country protocol, were registered. Among them, 48 (0·7%) refused the disclosure of their status to their contacts and hence participation in the study. After excluding other non-eligible index patients, e.g. due to residency in a non-LPEP district or absence of contacts meeting the local contact definition, a total of 5,941 index patients were included in the study across the seven countries. Cumulatively, 123,311 contacts were listed, or an average of 21 per enrolled index patient. Note that the country protocols for Tanzania and Sri Lanka only targeted household contacts while the other countries also targeted neighbours or even social contacts. Among the listed contacts, 99% could be traced and screened, the other 1,074 contacts being absent or otherwise unavailable for screening. A total of 406 contacts (329/100,000) were diagnosed with leprosy and immediately started on standard multidrug therapy (MDT) in accordance with standard protocols.[3] A total of 10,509 contacts were ineligible for SDR administration according to the exclusion criteria (age, pregnancy, suspected TB or recent treatment against this disease, liver or renal conditions, other reasons). Also, 427 contacts refused the administration of SDR. The other 89·9% of the listed contacts received SDR according to the established protocol.

It was concluded that this preliminary evidence suggested the feasibility of the intervention under different conditions. Specifically, the intervention appeared to be well accepted both in terms of agreement to contact tracing and SDR administration. Further,

based on feedback from the field, an invigoration of local leprosy control efforts has been noted in all settings, supported by increased motivation resulting from the availability of a preventive intervention, and strengthened training and supervision.

The results of the perception study embedded into the programme and implemented in India, Indonesia and Nepal confirmed this positive impact on the local leprosy control staff. It further documented the appreciation of the target population for the intervention, and an impressive increase in knowledge about leprosy, accompanied by an important decline in measured stigma against leprosy-affected individuals despite the absence of a dedicated leprosy information arm of the study.

Insights Regarding Integration into National Programme Routines

The general progress update was followed by structured presentations from all participating countries focusing on the individual achievements made to date, and the key challenges encountered in the implementation of the intervention including a subjective appraisal concerning which challenges are likely attributable to start-up issues, as opposed to those that are likely to be of a more permanent nature. Last, countries provided an update on their current leprosy control strategy with a focus on whether it already includes contact tracing and SDR administration, and which changes are needed in terms of local policy and protocols in order to eventually introduce an LPEP-like intervention into the national routine leprosy control programme.

The key issues identified by the countries were then synthesised in a structured discussion, and stratified into achievements, challenges and needs to be addressed for integration (Table 1). A list of participants is given in Table 2.

Key achievements noted are: all participating countries report a positive impact of their participation in the LPEP programme on their activities, specifically introduction or strengthening of contact tracing, the validation of the technical part of the protocol, and a sense of ownership of the intervention. In terms of challenges, the difficulties to adequately train field-level staff and retain them in the face of rapid turnover and political change was noted, access to sufficient amounts of rifampicin in appropriate formulations poses challenges in certain countries, and the issue of stigma and disclosure of leprosy status requires careful consideration in view of socio-cultural sensitivities regarding the disease.

The needs that must be addressed to ensure sustainability of the intervention are directly linked to the above-mentioned challenges. In addition, a formal recommendation by the World Health Organization (WHO) to offer SDR to contacts of leprosy patients to reduce their risk of developing the disease was identified by several country representatives as a basic requirement to include the intervention into the standard armamentarium of their national leprosy control strategy. Last, the minimal amount of data that needs to be collected and reported to properly document the intervention requires careful consideration. The meeting participants were informed that recommendations for minimal data have already been developed by a dedicated working group in close consultation with national programme representatives and their technical partners and fully considering the current monitoring and evaluation guide accompanying the Global Leprosy Strategy 2016–2020,[4] and can soon be made available.[5]

Table 1. Achievements, challenges and needs to be addressed for integration of key LPEP activities into leprosy control programme routines

	Essence/Trends
ACHIEVEMENTS	- All countries report a positive impact of LPEP on existing activities of national programmes - The technical protocol in general can be adhered to, and accepted by national programmes - Many NLPs in LPEP countries have already started taking ownership of the LPEP approach

CHALLENGES	- HR challenges:
	  - Continuity and resilience: HR turnover and political change
	  - Competence: training and experience
	- Availability of rifampicin (acquisition, pediatric form, access)
	- Stigma and disclosure: different LPEP countries demonstrate different ways of managing this challenge

NEEDS TOWARDS SUSTAINABILITY	- Continuity and resilience: HR turnover and political influence - Keeping up priority/visibility at National level despite epidemics/target diseases - Advocacy to non-leprosy stakeholders - Scaling-up: management and information - Protocol: Data recording, reporting and supervision need to be adapted to the routine context - WHO recommendations are needed as support for countries to take up LPEP into national programmes - Involving the affected community at an early stage can be beneficial for uptake and rollout, for example through requests by neighbors asking for PEP

Breakout Sessions

Following the LPEP programme progress update, breakout and feedback sessions for each LPEP country were organised to discuss specific issues in more detail. During each breakout session, the national programme representatives and their international partners discussed a given topic, summarised the key insights into a presentation and then shared them with the other countries in a subsequent plenary session. The feedback from each plenary session partially informed the topic for the next breakout and feedback session. The first breakout session focused on the needs and tools of individual countries to transition the LPEP intervention from an operational research project to a routine programme activity. In the frame of the feedback session, the identified issues were stratified into five core areas (Figure 1).

Strategy/Advocacy: Inclusion of LPEP into a country's national leprosy strategy is fundamental towards its transition to being a routine programme activity. At the global level, publications on LPEP impact and feasibility and a WHO recommendation were cited as powerful tools for countries to engage top decision makers. At the country level, developing a multi-partner strategic plan with interdepartmental and inter-ministerial cooperation (Ministry of Health, Ministry of Finance) was considered a requirement for a successful transition. There was a general sense of urgency to establish appropriate communication packages for each key LPEP stakeholder group (decision makers, health staff, the community and the target population).

Human Resources: An initial training (training of trainers), a curriculum for public health staff, an operational manual, job descriptions with clear division of roles and responsibilities

Table 2. List of participants

Last Name	First Name	Company/Organisation	Country
Ay	Sao Sarady	Swiss Tropical Health Institute	Indonesia
Aye	Tin Maung	LPEP Supervisor - Myanmar	Myanmar
Banstola	Nand Lal	Netherlands Leprosy Relief Nepal	Nepal
Bhatta	Madhav Raj	Netherlands Leprosy Relief Nepal	Nepal
Blaney	David	Centers for Disease Control and Prevention - USA	USA
Bonenberger	Marc	FAIRMED	Germany
Budiawan	Teky	Netherlands Leprosy Relief Indonesia	Indonesia
Cavaliero	Arielle	Novartis Foundation	Switzerland
Cholapand	Arjin	Raj Pracha Sanasai Institute, DDC, Thailand	Thailand
Dara	Sunil Anand	American Leprosy Missions	India
Gani	Zaahira	Novartis Foundation	Switzerland
Greter	Helena	Swiss Tropical Health Institute	Switzerland
Ignotti	Eliane	Universidade do Estado de Mato Grosso UNEMAT	Brazil
Iswandi	Alfinella Izhar	Ministry of Health of Indonesia	Indonesia
Kamara	Deusdedit Vedastus	National Leprosy Program Tanzania	Tanzania
Kasang	Christa	DAHW/GLRA	Germany
Kömm	Burkard	DAHW/GLRA	Germany
Kumar	Anil	Government of India	India
Lay	Sambath	National Leprosy Elimination program	Cambodia
Manglani	Pratap Rai	NLR India	India
Mieras	Liesbeth	Netherlands Leprosy Relief India	Netherlands
Narsappa	Vagavathali	Association of People affected by Leprosy	India
Njako	Blasdus Franz	DAHW/GLRA	Tanzania
Pemmaraju	Venkata Ranganadha Rao	WHO GLP	India
Richardus	Jan Hendrik	Erasmus MC, University Medical Center Rotterdam	Netherlands
Saunderson	Paul	American Leprosy Missions	USA
Sermrittirong	Silatham	Raj Pracha Sanasai Institute, DDC, Thailand	Thailand
Shwe	Tin	American Leprosy Missions	Myanmar
Soe	Oke	Dpt of Public Health, MoH and Sports - Myanmar	Myanmar
Staeheli	René	FAIRMED	Switzerland
Steinmann	Peter Jacob	Swiss Tropical Health Institute	Switzerland
Suriyarachchi	Nayani	FAIRMED	Sri Lanka
Thapa Kshetry	Mitharam	Leprosy Control Division - Nepal	Nepal
Tiwari	Anuj	Erasmus MC, University Medical Center Rotterdam	India
van Berkel	Jan	Netherlands Leprosy Relief	Netherlands
van Brakel	Wim	Netherlands Leprosy Relief	Netherlands
Viaud	Florent	MCI	Switzerland
Virmond	Marcos	Instituto Lauro de Souza Lima - Brazil	Brazil
Wijesinghe	Supun	Anti-Leprosy Campaign - Sri Lanka	Sri Lanka

and the involvement of people affected by leprosy were all considered essential for enabling a successful expansion of LPEP into a routine activity.

Rifampicin Procurement: Rifampicin availability as well as arrangements for how to manage adverse events is essential. A WHO recommendation or a White Paper from key stakeholders could assist countries seeking in-country registration.

Integration: Consideration of the LPEP approach, its implementation as well as its data management, monitoring and surveillance requirements need to be reviewed and properly integrated into a country's routine approach.

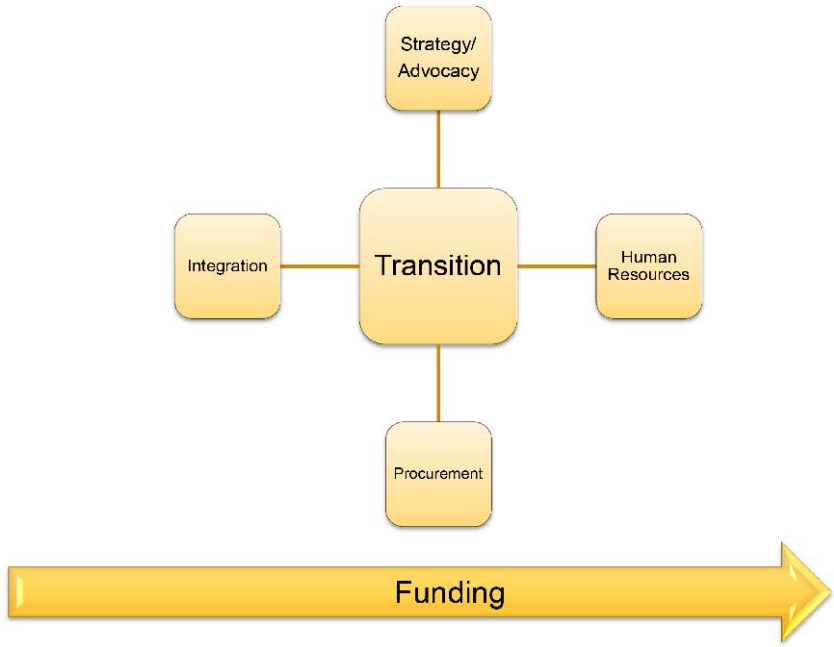

Figure 1. Evolution *from* operational research project *to* a routine program activity – core areas.

Funding: Transition from a project to a routine programme activity will require new sources of funding.

The second breakout session was dedicated to the identification of individual end products required to ensure the transition into national programme routines, and the identification of indicators for success. The third breakout session established the sequence and timelines to address the needs, identified responsibilities and concluded that to complement the planning, dedicated budgets were required to support these activities.

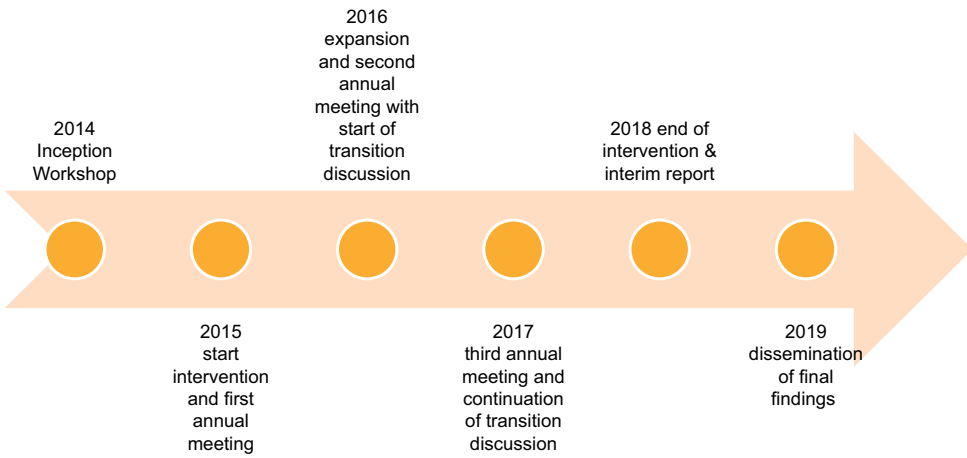

Figure 2. LPEP programme timeline – past and projected.

Appreciation of Meeting

The third LPEP annual meeting was designed to facilitate and promote a discussion initiated at the second annual meeting: comprehensive planning to facilitate the transition of the LPEP intervention **from project mode to routine programme activity**. The time horizon of 2 years from initial discussions until the end of the programme and uptake of key elements by national programmes only underscores the considerable time needed to successfully plan and introduce a public health intervention at national level. To facilitate further policy discussions, an interim progress report will be made available to all participating countries in 2018. The funder of the LPEP programme also committed to closely accompany and facilitate future discussions regarding the transition of the intervention from project to routine programme intervention in interested countries. Thus, interested countries will be able to decide on the uninterrupted continuation of the intervention based on programme findings even before the release of the consolidated final results of the LPEP programme, currently scheduled for the International Leprosy Congress in 2019. The results of the efforts to introduce the intervention into national programme routines will also be reassessed on that occasion. Figure 2 summarises the timelines of the LPEP programme.

The meeting also underscored the added value of bringing together all stakeholders of a large and diverse operational research programme such as LPEP. It not only facilitated the exchange between national programme managers and their international partners but also between country programmes and partners. The presence of a representative of WHO's Global Leprosy Programme also provided ready access to first-hand insights from the premier normative agency in global health policy. The meeting also promoted accountability and continued relevance of the programme objectives and activities, and fostered a sense of belonging through experience sharing and a demonstration of the size, international relevance of the endeavor and the agenda-setting power of the programme. Together, the experience was found to act as a potent motivator for all participants.

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Conflicts of interest

Novartis Foundation provided technical input in the design phase of the LPEP programme and ensures overall programme coordination. All authors are either staff of the Novartis Foundation or work as paid consultants for the programme described here.

The funder had no role in the interpretation of findings or decision to publish this manuscript.

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