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INTERIM REPORT

The Leprosy Post-Exposure Prophylaxis (LPEP) programme: update and interim analysis

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Summary Innovative approaches are required to further enhance leprosy control, reduce the number of people developing leprosy, and curb transmission. Early case detection, contact screening, and chemoprophylaxis currently is the most promising approach to achieve this goal. The Leprosy Post-Exposure Prophylaxis (LPEP) programme generates evidence on the feasibility of integrating contact tracing and single-dose rifampicin (SDR) administration into routine leprosy control activities in different settings.

The LPEP programme is implemented within the leprosy control programmes of Brazil, Cambodia, India, Indonesia, Myanmar, Nepal, Sri Lanka and Tanzania. Focus is on three key interventions: tracing the contacts of newly diagnosed leprosy patients; screening the contacts for leprosy; and administering SDR to eligible contacts. Country-specific protocol adaptations refer to contact definition, minimal age for SDR, and staff involved. Central coordination, detailed documentation and rigorous supervision ensure quality evidence.

Around 2 years of field work had been completed in seven countries by July 2017. The 5,941 enrolled index patients (89·4% of the registered) identified a total of 123,311 contacts, of which 99·1% were traced and screened. Among them, 406 new leprosy patients were identified (329/100,000), and 10,883 (8·9%) were excluded from SDR for various reasons. Also, 785 contacts (0·7%) refused the prophylactic treatment with SDR. Overall, SDR was administered to 89·0% of the listed contacts.

Post-exposure prophylaxis with SDR is safe; can be integrated into the routines of different leprosy control programmes; and is generally well accepted by index patients, their contacts and the health workforce. The programme has also invigorated local leprosy control.

Introduction

The introduction of multidrug therapy (MDT) in 1981 to treat leprosy patients and the following reduction of the registered number of patients encouraged the World Health Assembly in its resolution WHA44.9 adopted in 1991 to set the goal of global elimination of leprosy as a public health problem by the year 2000.[1] The goal was indeed achieved in 2001. Unfortunately, as a consequence of this success, control activities were rapidly scaled back in the early years of the millennium. This resulted in a much quicker reduction of the number of newly diagnosed patients than anticipated based on long-term trends, likely a result of the cessation of active case detection and suggesting the build-up of a considerable number of undetected cases in the community.[2] Over the past decade, the annual leprosy case detection rate has nearly plateaued yet every year, 200,000–250,000 new leprosy patients are diagnosed and receive MDT.[3]

Against this background, it became evident that there is a need for innovations to enhance the effectiveness of leprosy control at global level by improving early case detection and reducing the risk of infection and disease.[4] The ultimate goal of such interventions is to reduce morbidity and to finally achieve true interruption of human *M. leprae* transmission.[5] Consequently, the Global Leprosy Strategy 2016–2020 has identified early case detection and targeted case finding among high-risk groups as two of five key strategic operational changes.[6] Early case detection is best achieved through contact tracing and their repeated screening as well as awareness raising activities targeting the general public and medical community to reduce delays in presentation and diagnosis of leprosy patients.[7–9] Targeted mass screening in higher-risk groups is also revisited as a strategy to identify new leprosy patients.[10,11] Currently, no leprosy-specific immuno-prophylactic intervention is available: although Bacille Calmette Guérin (BCG) vaccination confers some level of protection,[12] there is no vaccine on the market that specifically targets *M. leprae*.[13] The most effective approach to reducing the risk of developing leprosy among individuals exposed to *M. leprae* over extended periods is chemoprophylaxis, usually with single-dose rifampicin (SDR) given to asymptomatic close contacts of recently diagnosed leprosy patients.[14–16] The combination of immuno- and chemoprophylaxis is also explored.[17,18] Combining case detection approaches with chemo- and/or immunoprophylaxis in integrated and sustained interventions promises to be particularly effective.[18,19]

Evidence on the feasibility of integrating contact tracing and SDR administration into routine leprosy control activities in different settings and populations is required by the Global Leprosy Programme and national health authorities to assess the benefits, costs and risks of such interventions.[6] Based on such data from the field, programme managers could more easily take informed decisions and ultimately introduce contact tracing combined with SDR administration to screening-negative contacts as a new routine into their national strategic plans for leprosy control.[20] To generate evidence on feasibility and explore the potential of the intervention under various epidemiological, cultural and health system

conditions, the comprehensive Leprosy Post-Exposure Prophylaxis (LPEP) Programme has been established in 2014, with implementation starting in 2015 in most sites.[21]

Here, we provide an update of the LPEP programme progress based on the available data reflecting the field work completed up to July 2017 in the seven countries where the standard LPEP programme is implemented, namely Brazil, India, Indonesia, Myanmar, Nepal, Sri Lanka and Tanzania. Since field work activities in Cambodia only started recently, no results pertaining to that country are reported here.

Methods

The LPEP programme explores the feasibility and impact of combining three key interventions: (i) to systematically trace the contacts of newly diagnosed leprosy patients; (ii) to screen the traced contacts for signs of the disease; and (iii) to administer SDR to eligible contacts. The activities are implemented through established structures of the national leprosy control programmes with support from the LPEP programme. The aim is to generate evidence and explore the feasibility of the intervention package to (i) improve leprosy case finding among contacts of index patients and thus enhance early case detection; and (ii) reduce the risk among contacts of developing leprosy.[21] The intervention package is based on available evidence, most notably the benefits of contact tracing[7,22] and the results of the COLEP trial on the benefits of chemoprophylaxis with SDR.[14,23] It combines these technical solutions with locally-adapted strategies to deploy them under varying programme conditions and socio-cultural contexts.

The strategic document underlying the LPEP protocol has been developed by Netherlands Leprosy Relief (NLR), Erasmus MC and Novartis Foundation in close collaboration with other international partners and in consultation with national leprosy control programme representatives.[21] Based on the strategic document, country LPEP protocols were defined by the leprosy control programmes of eight participating countries (Brazil, Cambodia, India, Indonesia, Myanmar, Nepal, Sri Lanka, Tanzania), in close collaboration with their designated International Federation of Anti-Leprosy Association (ILEP) partners.[24] Two academic partners determined the minimal sample size needed to demonstrate the impact of the intervention and developed the data recording and reporting system. They also conduct half-yearly quality assurance missions to all countries throughout the implementation period in close coordination with ILEP partners and leprosy control programme managers, and support data analysis and results dissemination. A steering committee representing independent academic advisors and observers from the WHO Global Leprosy Programme in addition to key LPEP programme stakeholders provides strategic guidance. Novartis Foundation funds the programme activities, and ensures the central coordination (Figure 1).

The basic design of the LPEP intervention is similar in all participating countries: the intervention is piloted in purposively selected administrative units of the health system based on the following criteria: a sufficiently high new case detection rate (NCDR) to achieve the calculated sample size, accessibility, and availability of basic leprosy control infrastructure. The main characteristics of the selected districts have been described previously.[21] Leprosy patients diagnosed within a defined period prior to the start of the field work and throughout a 3-year implementation term are invited by local health staff or by trained volunteers to participate in the study. Upon written or oral informed consent, their disease status can be disclosed to their contacts, which are then traced and screened for signs and symptoms of

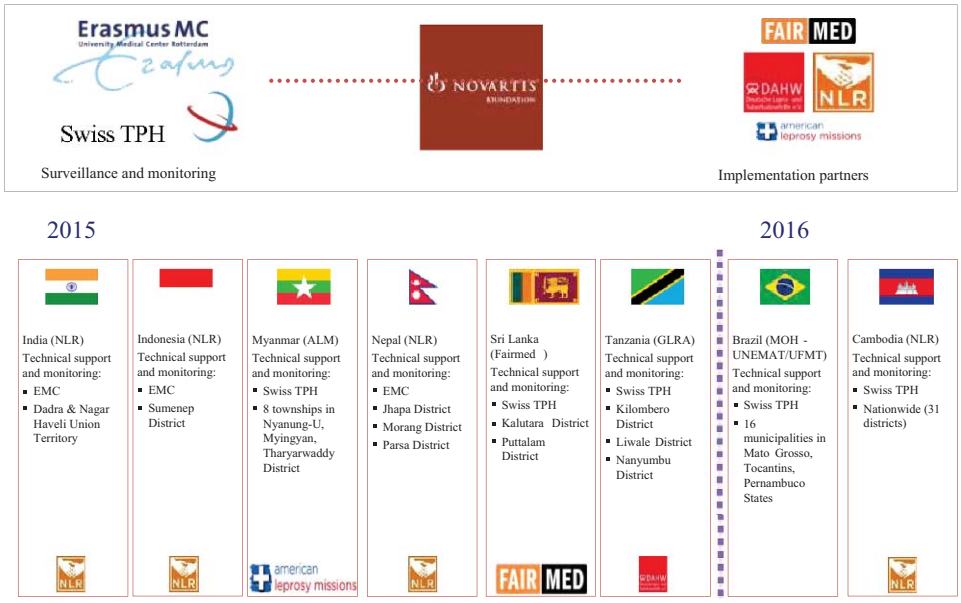

Figure 1. Leprosy Post-Exposure Prophylaxis (LPEP) programme partners, and year when field work started.

leprosy disease no earlier than 1 month post initiation of the MDT treatment of the index patient. In the absence of any evidence of leprosy and other exclusion criteria such as TB and pregnancy, SDR is offered.[21] Contacts identified with signs of active leprosy are evaluated as per routine leprosy control programme procedures and, if the diagnosis is confirmed, receive MDT treatment. No incentives are paid to patients, contacts, health staff or volunteers but the latter are entitled to reimbursement of costs associated with contact tracing. Country-specific LPEP protocol adaptations refer to the retrospective contact tracing period (typically 1–2 years), the contact definition (Sri Lanka and Tanzania: household contacts only; Indonesia, Myanmar and Nepal: household and neighbour contacts; Brazil and India: household, neighbour and social contacts), and the age limit above which children are eligible to receive SDR (2 or 6 years). Also, the approach for screening differs between countries, with Indonesia piloting a self-screening protocol whereby contacts receive simple pictorial and text aids to detect leprosy and then identify themselves if they detect possible signs or symptoms of leprosy disease on their own or their family members' bodies. In other countries, medical doctors, nurses, midwives, community health workers or volunteers support the screening effort. The data recording and reporting system was adapted to local conditions to minimize duplication with the routine leprosy programme documentation, reporting channels and preferred data entry locations. Of note, a specific LPEP protocol has been developed for Cambodia where contacts of leprosy patients diagnosed since 2011 are traced retrospectively, and tracing and screening are integrated into 'drives', which are implemented only once per targeted district.[25] Additional in-country manpower to manage the programme was limited to a national coordinator, sometimes supported by regional coordinators, and data entry staff. Rifampicin is procured by national programmes, in some countries with financial support of their ILEP partner.

In all participating countries except Indonesia where chemoprophylaxis had already been included in the list of standard interventions for leprosy control at the time the field work was planned, clearance for the study was obtained from the appropriate ethical review committees.

The data collection to document the activities focuses on the individual characteristics of the index patients and their contacts, and the reasons for exclusion at every stage of the process in order to provide data on the coverage achievable in different settings. Other variables of interest include the number of new leprosy patients identified in the frame of the field work. Data are regularly shared with the academic partners and analysed at least once a year. Interim results are then shared with all partners as part of the annual LPEP meeting.[20] Further, interim findings are regularly shared in the frame of scientific conferences including the European Congress on Tropical Medicine and International Health,[26] and the International Leprosy Congress (ILC, 2016).

As part of the programme design process, the risk of introducing rifampicin resistance in *Mycobacterium tuberculosis* by providing SDR to contacts of leprosy patients has been assessed systematically, and found to be very small even in individuals suffering from active TB.[27] Consequently, contacts were screened for signs of active TB so SDR is only given to contacts without suggestive symptoms. Extending the argumentation to *M. leprae*, it can be concluded that it is highly improbable that the development of resistant variants would be encouraged by SDR.

Integral parts of the LPEP programme are side studies to establish the perception, acceptability and health economic parameters in different contexts.[21] While relevant in all settings, financial and logistical constraints meant that the full set of ancillary studies could only be implemented in India. The first results are already available, namely the findings from a study on household expenditures on leprosy outpatient services in India[28] and the perception study conducted in India, Indonesia and Nepal under a unified protocol.[29] Insights from further studies will be published in appropriate fora as they become available.

Results

Field work related to the LPEP programme started in a step-wise arrangement in India, Indonesia, Myanmar, Nepal, Sri Lanka and Tanzania in 2015 and in Brazil in 2016. With each country completing the field work after 3 years, the integration of the programme into national leprosy strategies will follow the same sequence. Thus, between 1·5 and over 2 years of field work had been completed in the different countries by 1st July 2017, and the results presented here cover this timeframe. Within this period index patients diagnosed since 2013 (India, Nepal), 2014 (Myanmar, Tanzania) or 2015 (Brazil, Indonesia, Sri Lanka) were contacted and asked for permission to trace their contacts. The number of new leprosy patients registered in the project districts across the 7 countries stands at 6,646, with a range between 437 (Myanmar) and 1,613 (Nepal). The epidemiological profiles of the country index patient cohorts differed markedly: the rate of multibacillary (MB) leprosy among the index patients varied between 30% (India) and 77% (Tanzania), the Grade 2 disability rate was between 1% (Nepal) and 17% (Myanmar), and the fraction of females was between 38% (Brazil and Sri Lanka) and 54% (India). Last, between 3% (Tanzania) and 22% (India) of the index patients were children. No relevant data are yet available for the Brazil index patient cohort.

Overall, 89·4% of the registered index patients could be enrolled for participation in the study (Table 1).

Table 1. Number of leprosy patients diagnosed in the leprosy post-exposure prophylaxis (LPEP) programme districts since the start of the field work until July 2017, stratified by country, demographic and disease indicators, and enrolment status

	Brazil (Q1 2016)		India (Q2 2015)		Indonesia (Q3 2015)		Myanmar (Q2 2015)		Nepal (Q3 2015)		Sri Lanka (Q4 2015)		Tanzania (Q3 2015)		Total	
Country (start quarter-year)	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Population sub-national area (in thousands)	815		374		1,059		1,825		2,379		812		655		7,919	
Number of index patients registered	920		1,398		902		437		1,613		648		728		6,646	
Average annual New Case Detection Rate prior to the study (per 100,000)	135		98		45		9		23		14		46		NA	
New cases of MB leprosy	421	45·8	419	30·0	687	76·2	319	73·0	858	53·2	314	48·5	561	77·1	3,579	53·9
New cases with G2D	48	5·2	47	3·4	40	4·4	73	16·7	22	1·4	38	5·9	29	4·0	297	4·5
New female cases	310	33·7	753	53·9	430	47·7	184	42·1	676	41·9	248	38·3	319	43·8	2,920	43·9
New child (<15 years) cases	47	5·1	313	22·4	70	7·8	19	4·4	131	8·1	54	8·3	24	3·3	658	9·9
Number of index patients not enrolled	23		14		124		4		56		299		185		705	10·6
Number of index patients enrolled	897	97·5	1,384	99·0	778	86·3	433	99·1	1,557	96·5	349	53·9	543	74·6	5,941	89·4

Q1: quarter 1; Q2: quarter 2. . .

Among the 10·6% ($n = 705$) who were not enrolled, 48 (0·7% of the patient cohort) refused the disclosure of their status to contacts. Other reasons for exclusion from the study were living outside of the LPEP district (1·1%), absence of contacts according to the local contact definition (1·1%) and unstated reasons. Across countries, between 0·9% (Myanmar) and 46·1% (Sri Lanka; mainly retrospective cases) of the index patients could not be enrolled.

A total of 123,311 contacts were registered of the 5,941 index patients enrolled in the study (Table 2).

In countries targeting only household contacts, i.e. Sri Lanka and Tanzania, on average 6·6 contacts per index patient were listed while in the other five countries, the average was 23·3 contacts per index patient (range: 11·4 in Brazil to 38·9 in Indonesia). No reliable data are available for some countries about the number of contacts absent on the day when contact screening took place. Among the listed contacts, 99·1% could be traced and screened. The remaining 0·9% ($n = 1,074$ contacts) were absent at the time of screening ($n = 903$). Among the 122,237 screened contacts, 842 were suspected to have leprosy. The leprosy diagnosis was confirmed for 406 individuals (329/100,000). The highest rate of new leprosy patients among screened contacts was observed in Brazil (1,521/100,000) while the lowest was in India (73/100,000). All newly diagnosed leprosy patients were immediately offered MDT according to national leprosy treatment protocols while contacts found to be negative upon re-examination were offered SDR. Another 10,883 contacts (8·9% of the screened contacts) were not eligible for SDR administration according to the exclusion criteria (in descending order of frequency: age, medical reasons including liver or renal conditions, reported rifampicin allergy, pregnancy, suspected TB ($n = 94$) or recent rifampicin treatment for TB or any other reason, including previous MDT to treat leprosy). Across the seven countries, 785 contacts or 0·7% (range: 0% in Myanmar, Nepal and Tanzania – 3·8% in Brazil) of the eligible individuals refused the prophylactic treatment with SDR. Overall, SDR was administered to 89·0% of the 123,311 listed contacts or 89·8% of the 122,237 screened contacts (Figure 2).

Leprosy control programmes were actively encouraged to report adverse events related to the administration of SDR, both through the provision of a reporting form and regular reminders during monitoring visits. Across the seven countries, a single adverse event was reported, namely from Brazil where a 39 years old man developed a severe allergic reaction to rifampicin following SDR administration.

Discussion and Conclusions

The evidence so far available from the LPEP programme from seven leprosy endemic countries emphasizes that the tested approach of contact tracing followed by screening and the provision of SDR is generally feasible. We documented a high level of acceptance of contact tracing and SDR administration across vastly different socio-cultural, epidemiological and health system settings. Nevertheless, considerable efforts were necessary to implement contact tracing in those settings that had not yet implemented it in their routine practice although it was part of the national protocol for leprosy control. Of critical relevance are the quality, logistics and documentation of contact tracing, and maintaining the capacity of field workers to reliably detect those suspected of having leprosy (and TB) who can then be referred to medical personnel for confirmation of the diagnosis. Specific issues are encountered in settings such as Sri Lanka where the protocol suggests contact screening in

Table 2. Number of contacts of leprosy patients enrolled in the leprosy post-exposure prophylaxis (LPEP) programme districts since the start of the field work until July 2017, stratified by country, screening status, demographic indicators, and single-dose rifampicin administration status

	Brazil (Q1 2016)		India (Q2 2015)		Indonesia (Q3 2015)		Myanmar* (Q2 2015)		Nepal (Q3 2015)		Sri Lanka[1] (Q4 2015)		Tanzania[1] (Q3 2015)		Total	
Country (start quarter-year)	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Total listed contacts	10,192		31,503		30,291		7,985		37,471		1,317		4,552		123,311	
Number of listed contacts/ index patient	11·4		22·8		38·9		18·4		24·1		3·8		8·4		19·0	
Excluded from screening																
Absent[2]	0	–	199	0·6	277	0·9	47	0·6	139	0·4	205[3]	15·6	36	0·8	903	0·7
Refused screening	NA	–	NA	–	NA	–	23	0·3	NA	–	73	5·5	75	1·6	171	0·1
Total screened	10,192	100	31,304	99·4	30,014	99·1	7,915	99·1	37,332	99·6	1,039	78·9	4,441	97·6	122,237	99·1
Age Groups																
Children (<15 years)	2,339	22·9	10,280	23·8	4,857	16·2	2,007	25·4	11,093	29·7	328	31·6	1,727	38·9	32,631	26·7
Adolescents and adults (≥15 years)	7,725	75·8	21,024	67·2	25,155	83·8	5,908	74·6	26,239	70·3	708	68·1	2,714	61·1	89,473	73·2
Age unknown	127	1·2	0	–	2	<0·1	0	–	0	–	3	0·3	0	–	132	0·1
Type of contact																
Household contact	2,219	21·8	8,336	26·6	2,782	9·3	1,675	21·2	9,235	24·7	1,039	100·0	4,441	100	25,286	24·3
Neighbor contact	6,101	59·9	22,669	72·4	27,126	90·4	6,240	78·8	27,769	74·4	NA	–	NA	–	89,905	73·5
Social contact	1,872	18·4	299	1·0	104	0·3		0·0	328	0·9	NA	–	NA	–	2,603	2·1
Unspecified	0	–	0	–	2	<0·1	0	–	0	–	NA	–	NA	–	2	<0·1
Exclusion from SDR administration (other than suspected leprosy)																
Possible TB	10		NA		32		17		24		1		10		94	
Pregnancy	90		195		79		70		90		8		49		581	
Other medical reason(s)	505		723		21		101		321		32		22		1,725	
Other reason (min. age,. . .)	50		6476		367		229		749		101		511		8,483	
Suspected leprosy	155		101		184		13		207		33		149		842	
Confirmed leprosy (among suspected)	155	100	23	22·8	NA	–	13	100	171	82·6	4	12·1	40	26·8	406	48·2
Confirmed leprosy/ 100,000 contacts screened	1521		73		–		164		458		385		901		332	

Table 2. *Continued*

Country (start quarter-year)	Brazil (Q1 2016)		India (Q2 2015)		Indonesia (Q3 2015)		Myanmar* (Q2 2015)		Nepal (Q3 2015)		Sri Lanka[1] (Q4 2015)		Tanzania[1] (Q3 2015)		Total	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Total eligible SDR	9,382		23,809		29,331		7,485		35,941		864		3,700		110,512	90·4
Refused SDR	358	3·8	392	1·6	23	0·1	0	–	0	–	12	1·4	0	–	785	0·7
Total exclusions	1168	11·5	7,887	25·2	706	2·4	430	5·4	1,391	3·7	187	18·0	741	16·7	12,510	10·2
Received SDR of total eligible	9,024	96·2	23,417	98·4	29,308	99·9	7,485	100	35,941	100	852	98·6	3,700	100	109,727	99·3
Received SDR of total screened		88·5		74·8		97·6		94·6		96·3		82·0		83·3		89·8
Received SDR of total listed		88·5		74·3		96·8		93·7		95·9		64·7		81·3		89·0

Q1: quarter 1; Q2: quarter 2. . .

NR: Not relevant; NA: Not available.

[1]In Sri Lanka and Tanzania, only household contacts were eligible for inclusion. In Myanmar, only household and neighbor contacts were eligible for inclusion. In all other countries, household, neighbor and social contacts were eligible for inclusion.

[2]Initially, absent contacts were not systematically registered in all instances. Hence, the total number of absent contacts might be higher than indicated by the available numbers.

[3]In Sri Lanka, contacts were invited to present to the Medical Officer of Health (MOH) office for leprosy screening and SDR administration.

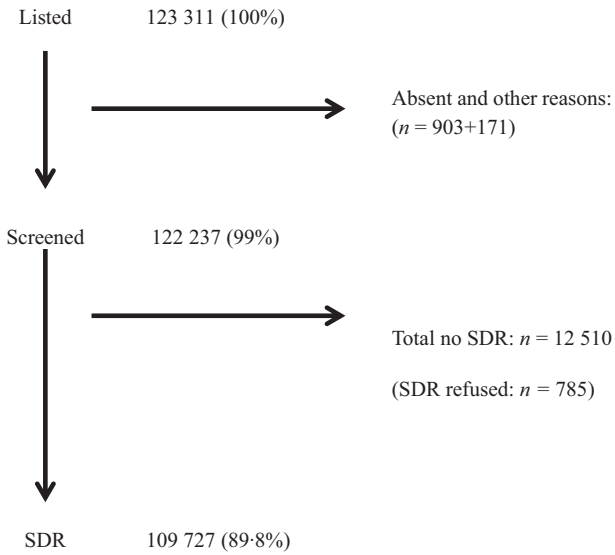

Figure 2. Flow-diagram of the registration, screening and single dose rifampicin (SDR) administration to contacts of leprosy patients recruited into the Leprosy Post-Exposure Prophylaxis (LPEP) programme across seven countries (Brazil, India, Indonesia, Myanmar, Nepal, Sri Lanka, Tanzania).

health facilities rather than in the house of the contacts. On the other hand, the administration of SDR was relatively easily integrated into the field routines.

Regular supervision visits ensured the quality of the field work and the integrity of data. Of note, doctors or health workers experienced in leprosy diagnosis periodically accompanied less experienced staff to supervise the screening process and provide practical training. Restrictions on rifampicin availability in some health systems may complicate the logistics required to maintain an adequate stock of the drug in peripheral health centres. Other issues specifically related to SDR administration include the need for liquid rifampicin formulations if young children are targeted for SDR administration. Also, for young children and underweight contacts scales are required to determine the correct rifampicin dose since available guidelines suggested standard doses for different age groups except in the case of very young children and underweight individuals. The directly-observed administration of SDR to contacts of leprosy patients diagnosed in the frame of the contact tracing, as well as individuals initially suspected of having leprosy but later found to be negative, also poses logistical challenges in settings where field workers do not routinely visit the homes of leprosy patients.

There is generally good acceptance of SDR by contacts and health care workers and a smooth integration of chemoprophylaxis into contact tracing procedures was observed. Not with standing, it remains crucial that the approach to identify contacts is carefully tailored to local contexts. In particular, in certain populations a marked reluctance of index patients to disclose their disease status to neighbours and sometimes even to household members must be considered. In such situations, alternative approaches to contact tracing should be explored. Specifically, protocols not requiring the disclosure of the disease status, and therefore also no consent for identification of the index patient, should be developed. This may be achieved by e.g. defining contact tracing perimeters around the index patient that

cover more than just a few households, allowing to mask the index patients' identity and guarding confidentiality. Community-wide screening, often termed blanket screening, has also been suggested as an option to achieve good coverage in highly endemic communities.[30] The feasibility study has revealed that contact tracing in urban settings, during particular times of the day (school, office hours) or seasons such as planting and harvest, or in communities with a high proportion of migrant workers, is associated with particular challenges related to reduced probability to meet contacts at home. In such instances, repeat visits might be necessary to enrol a high proportion of the contacts. Another important finding is that facility-based screening as it is practised in Sri Lanka appears to be much less efficient in terms of coverage compared to a home-based screening approach.

In view of contact tracing and screening being resource-intensive interventions, there is a need to balance the target number of contacts per index patient with the benefits expected in terms of leprosy prevention and burden reduction. It is likely that the incremental benefit of adding ever more distant contacts at one point becomes negative as resource needs for contact tracing are likely to increase near-linearly with the number of households and contacts traced and screened.[31] The ideal number of contacts probably also depends on the local epidemiological situation, household size and health system characteristics, and remains to be determined. Chemoprophylaxis with SDR has already been shown to be cost-effective in close contacts in Bangladesh.[32] As alternative options, self-screening (explored in the frame of the LPEP programme in Sumenep district, Indonesia) and mass or blanket SDR administration (Lingat village, Indonesia,[33] should be further explored. Complementary explorations by means of mathematical modelling to determine the optimal number and distance of contacts to be screened, and of prophylactic strategies in general, are on-going.[8,22] Further down the road towards leprosy elimination, a paradigm shift might gain importance: currently, leprosy interventions are generally evaluated for their efficacy by the number of newly identified cases. As numbers will drop, including as a result of the here presented interventions, leprosy programmes might also need to be evaluated by the number of cases prevented. This trend is already evident for certain neglected tropical diseases.[34]

For the evaluation of the LPEP programme, high-quality documentation of the field work was particularly important. National leprosy control programmes integrating contact tracing, screening and SDR PEP into their routine activities will need to document these activities. Taking into consideration the practical experience as well as standard leprosy documentation and reporting needs, a set of minimal essential data on contact tracing, screening and SDR to be recorded locally and reported to national and ultimately international agencies has been proposed.[35,36] Public health benefits of improved early case detection, and a reduced risk of developing leprosy among SDR recipients, are evident. However, it is obvious that the strategy will only have a long-term impact if it is embedded in a robust case detection system, as index patients need to be diagnosed before contact tracing can follow up on the at-risk persons in their vicinity. Of note, the NCDR among contacts in India (73/100,000) was lower than among the general population (98/100,000), indicating a high-quality routine case detection system with intensive contact screening.

An important positive effect of the intervention was widely noted in the participating countries: an invigoration of local leprosy control efforts. This positive impact on morale and efforts has been observed in all settings irrespective whether contact tracing and screening had already been integrated into the routine activities prior to the start of the LPEP programme, and was reported by staff at different levels, from the periphery to the central leprosy control programme coordination. The increased motivation was mainly associated

with the availability of an easily administered preventive intervention, and strengthened training and supervision. The perception study implemented in India, Indonesia and Nepal appears to confirm this finding based on preliminary results.[29] A common challenge in several LPEP programme countries is the scarcity of health staff with a good command of leprosy-related knowledge and skills, particularly the capacity to suspect and diagnose leprosy. This lack of expertise is particularly evident among younger staff generations. It remains to be seen if the LPEP programme and similar activities might motivate younger health staff at all levels to improving their leprosy knowledge and capacity to suspect the disease. The perception study also found that the intervention was widely appreciated by the target population, and documented important increases in knowledge about leprosy along with a decline in reported stigma against leprosy-affected individuals.[20] Of note, the LPEP programme does not include specific information, education and communication activities other than those related to informed consent procedures and regular communication.

Based on the findings available to date from screening over 120,000 contacts across seven countries, we conclude that post-exposure prophylaxis with SDR is (i) safe; (ii) can be integrated into the routines of different leprosy control programmes; and (iii) is generally well accepted by index patients, their contacts and the health workforce. Besides the protective effect, the programme reportedly has also invigorated local leprosy control through the introduction or strengthening of contact tracing, increased motivation through the availability of an easily administered preventive tool, and more frequent training and supervision. The last two points were particularly emphasized by health workers directly involved in contact tracing. Together, these effects have translated into improved programme implementation quality and documentation. While the LPEP programme field work is in its final year, multiple countries have already engaged in the planning of the transition from the project phase to integration of the approach into routine activities. The Novartis Foundation, coordinator and funder of the LPEP programme, has committed to actively support this transition process. It also engages with the Global Leprosy Programme of WHO to support the eventual official endorsement of the intervention, and facilitates the in-country processes for adoption of the intervention and its integration into routine programme protocols.[20] A critical aspect of the transition will be the replacement of programme funding to support contact tracing and supervision as the availability of such funds is likely to have facilitated the positive outcomes of the LPEP programme. In all participating countries except Cambodia, data collection for the LPEP programme will be completed by the end of 2018. Following a data verification, cleaning and validation process, country-specific analyses will be performed. Final programme results will become available in mid-2019 and are scheduled to be presented that year in the frame of the International Leprosy Congress (ILC) in the Philippines.

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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

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