

A **Start-Up Package** for the integration of SDR-PEP into leprosy control

**Main Goal: Starting with the embedment of
contact screening and SDR-PEP administration in routine leprosy control**

SDR-PEP integration framework



LEPROSY RESEARCH INITIATIVE

Global Partnership for
Zero Leprosy

PEP Country Profile Packages

There are three packages:

- A. Start-up package
- B. Scale-up package
- C. Last mile package

PEP integration phases

All packages have three phases for integration:

- I. Preparation phase
- II. Implementation phase
- III. Evaluation phase

SDR-PEP integration framework

Preparation phase

1. Advocate for stakeholders' commitment
2. Develop Operational Guidelines
3. Identify implementation area(s)
4. Prepare logistics
5. Develop training
6. Set up monitoring and supervision
7. Inform the community

SDR-PEP integration framework

Implementation phase

8. Leprosy patient identified
9. Informed consent (index patient)
10. List contacts
11. Informed consent (contact)
12. Examination by health worker
13. Eligibility criteria
14. Administration of SDR-PEP

SDR-PEP integration framework

Evaluation phase

15. Evaluate, involving all main stakeholders
16. Analyse data
17. Share lessons learned, document best practices
18. Take action on lessons learned
19. Ensure sustainability



Preparation phase 7 steps

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
1.	Advocate for stakeholders' / actors' commitment		
1.1a	List all stakeholders/actors	<ul style="list-style-type: none"> Which stakeholders/actors play a role in achieving start-up of SDR-PEP integration? <ul style="list-style-type: none"> international/ national/ local level group/ organization/ institution/ individual/ network/ company private/ public sector/ civil society current/ future/ potential/ active/ passive ➤ List all stakeholders/actors and write each one on a sticky note 	Relevant Documents: <ul style="list-style-type: none"> WHO leprosy Guideline SDR-PEP Toolkit: <ul style="list-style-type: none"> Slide deck SDR-PEP policy

Theory - How does change occur - actors

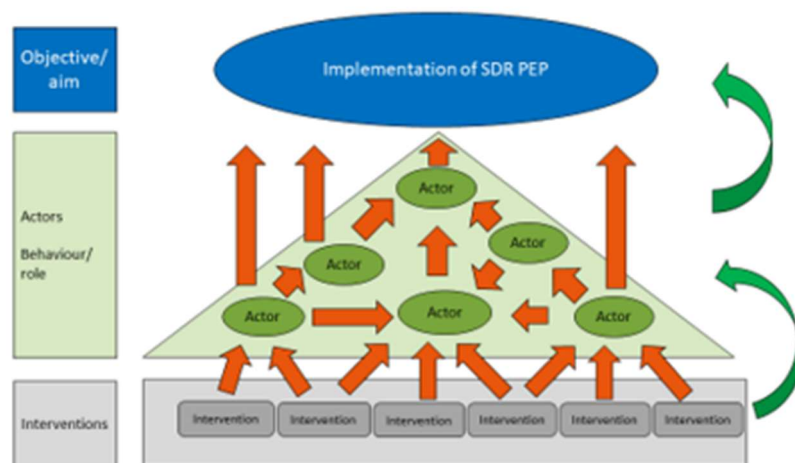


Fig. 1: How does change occur – actors influence

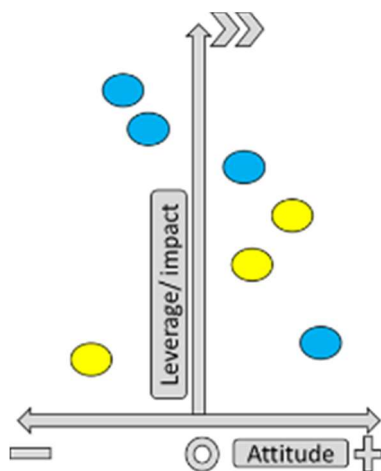


Fig. 2: Leverage/impact and Attitude

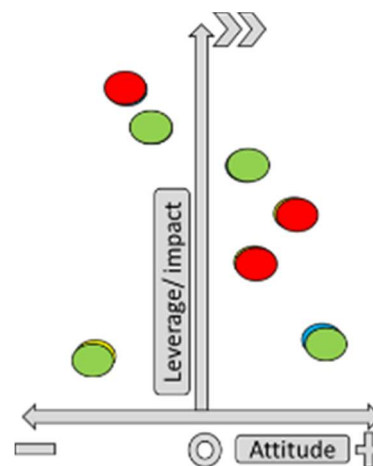


Fig. 3: ‘Our’ influence on stakeholders’ behavior

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
1.1b	Leverage and attitude of stakeholders/actors	<ul style="list-style-type: none"> What is their leverage/impact on achieving the situation? What is their attitude towards achieving the situation? What is “our” control over these stakeholders; in other words to what extent can “we” influence them? <ul style="list-style-type: none"> ➤ Position all actors in a diagram as shown above and indicate level of influence Blue = stakeholders we can influence Yellow = stakeholders we cannot influence (figure 2) 	
1.1c	Role of the main stakeholders	<ul style="list-style-type: none"> Prioritize stakeholders based on leverage/impact, attitude and the possibility to control them. <ul style="list-style-type: none"> ➤ Prioritize stakeholders Green = Prioritized stakeholder Red = Stakeholder with no/low priority (figure 3) What should be the role of these stakeholders so that the aimed situation can be achieved? What should we do to support this role/behavior? 	
1.2	Ensure sustainability	<ul style="list-style-type: none"> What resources are available? What kind of additional resources are needed? Who can make these resources available? How can sufficient resources be ensured? (note that an initial investment is most likely needed, which will lead to a reduction of costs in the long-term) 	Scientific Publications: <ul style="list-style-type: none"> - 2010 Idema Cost effectiveness

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
2.	Develop Operational Guidelines		
2.1	Describe selected approaches	<i>For the start-up package it is suggested to select a high endemic district to start building up experience working with the 'Standard Approach' = SDR-PEP for the ~20 closest contacts around every newly detected leprosy patient.</i>	Relevant documents: <ul style="list-style-type: none"> - Indonesia extended contract tracing with self-screening and blanket approach Scientific Publications: <ul style="list-style-type: none"> - 2005 Bakker et al Prevention of leprosy - 2008 Moet et al Effectiveness of single dose rifampicin - 2016 Barth-Jaeggi et al LPEP program study protocol - 2018 Furst et al Cambodia drive - 2018 Tiwari and Dandel et al Population wide administration
2.2	Define index patients	<ul style="list-style-type: none"> • Are retrospective leprosy patients going to be included? If so: <ul style="list-style-type: none"> ▪ How many years retrospectively? 	Scientific Publications: <ul style="list-style-type: none"> - 2016 Barth-Jaeggi et al LPEP program study protocol SDR-PEP Toolkit: <ul style="list-style-type: none"> - SDR-PEP field guide generic, chapter 3 – Enrolment of index patient

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
2.3	Define contacts	<ul style="list-style-type: none"> Is contact examination currently part of routine leprosy control? If so: <ul style="list-style-type: none"> Is this limited to household contacts, or does it go beyond household contacts? Are contacts asked to come to the health centre or are house visits made? Are the 20 closest contacts limited to household and neighbour contacts? Will social contacts such as class mates, colleagues etc. be included? If so: <ul style="list-style-type: none"> How will that be organized logistically? How will (the fear of) stigmatization be dealt with? 	Best practices: <ul style="list-style-type: none"> 1 – HH Contact Examination 2 – Quality screening of contacts 4 – Quality Counseling by GHC staff SDR-PEP Toolkit: <ul style="list-style-type: none"> SDR-PEP field guide generic, chapter 4 – Tracing and enrolment of contacts, and 5 – Screening of contacts
2.4	Determine roles and responsibilities	<ul style="list-style-type: none"> Which staff will be responsible for the overall management? Which (health) staff will be involved in contact tracing, screening of contacts and SDR-PEP administration? Which staff will be involved in monitoring and supervision? Which staff can refer suspected cases and which staff can diagnose leprosy? 	SDR-PEP Toolkit: <ul style="list-style-type: none"> Field guide generic, chapter 2 – Overall roles, responsibilities and timelines Scientific Publications: <ul style="list-style-type: none"> 2016 Barth-Jaeggi et al LPEP program study protocol
2.5	Develop recording and reporting system	<ul style="list-style-type: none"> How is recording and reporting on leprosy organized? Can the minimal essential data for the introduction of SDR-PEP be integrated into the national health information system? Do other/additional data need to be collected? Which stakeholders should be involved to make this happen? What steps are needed to bring the recording and reporting of the minimal essential data into practice? 	Scientific Publications: <ul style="list-style-type: none"> 2018 Richardus et al Minimal essential data SDR-PEP Toolkit: <ul style="list-style-type: none"> Field guide generic, chapter 8 – Data Recording and Reporting

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
3.	Identify implementation area(s)		
3.1	Collect epidemiological data	<ul style="list-style-type: none"> • Are good quality epidemiological data available over the last 10 years? (# of new patients; % disability grade 2; % children) 	Relevant documents: <ul style="list-style-type: none"> - WHO Global Leprosy Strategy 2016–2020 – Monitoring and Evaluation Guide
3.2	Set up or use epidemiological mapping	<ul style="list-style-type: none"> • Are mapping data available? • Have high endemic areas, clusters / hotspots been identified? 	Relevant documents: <ul style="list-style-type: none"> - 2019 Taal et al ILC Abstract Mapping India vs Indonesia PEP++ - 2019 Taal et al ILC Abstract Mapping India PEP++
3.3	Select the most suitable approach See Prep 2.1: Describe selected approaches	The selected approaches were described for step 2.1 <i>It is suggested to start with piloting the standard approach in the start-up package.</i>	Relevant documents: <ul style="list-style-type: none"> - Indonesia extended contract tracing with self-screening and blanket approach Scientific Publications: <ul style="list-style-type: none"> - 2005 Bakker et al Prevention of leprosy - 2008 Moet et al Effectiveness of single dose rifampicin - 2016 Barth-Jaeggi et al LPEP program study protocol - 2018 Furst et al Cambodia drive - 2018 Tiwari and Dandel et al Population wide administration

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
4.	Prepare logistics		
4.1	Human- and financial resources See Prep 1.2: ensure sustainability See Prep 2.4: roles and responsibilities	Keep in mind which resources were listed for step 1.2 and the roles and responsibilities as described for step 2.4. Human resources <ul style="list-style-type: none"> • Is staff available to manage, monitor, supervise and implement contact screening and SDR-PEP administration? • How are the added responsibilities and tasks going to be embedded in their work? Financial resources <ul style="list-style-type: none"> • How are additional costs going to be covered? Especially costs for training and fieldwork: <ul style="list-style-type: none"> ▪ Training costs ▪ Staff costs, including per diems ▪ Transportation costs (what means of transportation will be used?) • Is combination with other health programmes possible to increase cost-efficiency? 	SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 2 – Overall roles, responsibilities and timelines
4.2	Sufficient MDT	<ul style="list-style-type: none"> • Is there a functional MDT supply chain? • Is MDT sufficiently available? (Taking into account that the increased active case finding through contact examination will lead to an increased need of MDT) 	

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
4.3	Procurement of rifampicin	<ul style="list-style-type: none"> • Is loose rifampicin available? • Can rifampicin be used as chemoprophylaxis (for leprosy) according the current pharmacovigilance guidelines? • Is there a supply/distribution chain to which rifampicin can be linked? • How are costs for rifampicin supply going to be covered? 	
4.4	Surveillance for rifampicin resistance	<ul style="list-style-type: none"> • Is surveillance for leprosy resistance set-up in the country? <ul style="list-style-type: none"> ▪ If not, why not? • Is there a lab in the country or in the region that could do resistance testing? • Can the surveillance for leprosy resistance be set-up / intensified in areas where SDR-PEP is implemented? 	Relevant documents: <ul style="list-style-type: none"> - WHO A guide for surveillance of antimicrobial resistance in leprosy 2017
5.	Develop training		
5.1	Develop a training plan See Prep 2.4: Roles and responsibilities See Prep 4.1: Human – and financial resources	Keep in mind the roles and responsibilities as defined for step 2.4 and the necessary human resources as described in step 4.1. <ul style="list-style-type: none"> • Will the training for SDR-PEP implementation be embedded in leprosy training? If so: <ul style="list-style-type: none"> ▪ How will this be done? • Which staff will need to be trained? • How are costs for training going to be covered? 	Best practices: <ul style="list-style-type: none"> - 2.1 Training Module LPEP

	Steps	Guiding questions for the preparation phase	Available tools, documents, materials, best practices
6.	Set up monitoring and supervision		
6.1	On the job training See Prep 2.4: Roles and responsibilities See Prep 4.1: Human – and financial resources	<p>Keep in mind the roles and responsibilities as defined for step 2.4 and the necessary human resources as described in step 4.1.</p> <ul style="list-style-type: none"> • Who will monitor and supervise the implementation and give on the job training when needed? • How will costs for transportation and field visits be covered? 	<p>SDR-PEP Toolkit:</p> <ul style="list-style-type: none"> - Field guide generic, chapter 9 – Quality Control and Supervision
6.2	Quality assurance	<ul style="list-style-type: none"> • What kind of methods/tools will be used to help ensure the quality of the implementation? 	<p>SDR-PEP Toolkit:</p> <ul style="list-style-type: none"> - Field guide generic, chapter 9 – Quality Control and Supervision
6.3	Documentation of lessons learned	<ul style="list-style-type: none"> • How to ensure that lessons learned during the implementation will be addressed, documented and widely shared? • How will it be ensured that research questions that come up during the pilot phase will be taken up? 	
7.	Inform and involve the community		
7.2	Inform and involve community leaders and other community members	<ul style="list-style-type: none"> • Which key community persons need to be informed? • How will they be involved in the different phases: preparation, implementation and evaluation phase? 	<p>Relevant documents:</p> <ul style="list-style-type: none"> - 2019 Budiawan et al ILC Abstract Leprosy Friendly Village <p>Scientific Publications:</p> <ul style="list-style-type: none"> - 2018 Tiwari and Dandel et al Population wide administration

Implementation phase 7 steps

	Steps	Available tools, documents, materials, best practices
	ALL	Relevant documents: <ul style="list-style-type: none"> - 2017 example of pocket book for field work-Indonesian language Scientific Publications: <ul style="list-style-type: none"> - 2016 Barth-Jaeggi et al LPEP program study protocol
8.	Leprosy patient identified	SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 3 – Enrolment of index patient
9.	Informed consent (index patient)	Relevant documents: <ul style="list-style-type: none"> - WHO Leprosy Guidelines SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 3 – Enrolment of index patient
10.	List contacts	SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 4 – Tracing and enrolment of contacts
11.	Informed consent (contact)	SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 4 – Tracing and enrolment of contacts
12.	Examination by health worker	Best practices: <ul style="list-style-type: none"> - 1 – HH Contact Examination - 2 – Quality screening of contacts - 2.2 LPEP_Exclusion-criteria-for SDR - 2.3 LPEP_Exclusion-criteria-CARD-DND 4 – Quality Counseling by GHC staff SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 5 – Screening of contacts

		<ul style="list-style-type: none"> - Field guide generic, chapter 6 – Referral and Examination of contacts with suspected leprosy and/or TB
13.	Eligibility criteria	Best Practices: <ul style="list-style-type: none"> - 2.2 LPEP_Exclusion-criteria-for SDR - 2.3 LPEP_Exclusion-criteria-CARD-DND SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 7 – Administration of SDR to eligible contacts
14.	Administration of SDR-PEP	Scientific Publication: <ul style="list-style-type: none"> - 2018 Richardus et al Minimal essential data SDR-PEP Toolkit: <ul style="list-style-type: none"> - Field guide generic, chapter 7 – Administration of SDR to eligible contacts
	Repeat step 11 – 14 for contacts that were absent during the intervention, or not eligible at the time of intervention	<ul style="list-style-type: none"> • Contacts who were absent during the time of the intervention because of work/travel/school etc. should be re-visited for screening and SDR-PEP administration if eligible. • Children < 2years of age at the time of the intervention can be screened and given SDR-PEP after reaching the age of 2. • Women who are pregnant at the time of the intervention can be screened and given SDR-PEP after delivery.

Evaluation phase 5 steps

	Steps	Guiding questions for the evaluation phase	Available tools, documents, materials, best practices
15.	Evaluate, involving all main stakeholders See Prep 1.1 Involve main stakeholders	Keep in mind that involvement of main stakeholders was already described for step 1.1 <ul style="list-style-type: none"> How will stakeholders remain involved and informed during the implementation? 	Scientific Publications: <ul style="list-style-type: none"> 2016 Steinman et al LPEP Program progress 2017 Steinman et al LPEP Program update 2018 Richardus et al Minimal essential data
16.	Analyze data See Prep 1.1 Involve main stakeholders See Prep 2.6 Develop recording and reporting system	Keep in mind that involvement of main stakeholders was already described for step 1.1. For step 2.6 a recording and reporting system was described. <ul style="list-style-type: none"> Which information do stakeholders need from the SDR-PEP (pilot) implementation to ensure their continued support? Which information and data needs to be collected other than those routinely collected in the leprosy control programme and the minimal essential data? 	Scientific Publications: <ul style="list-style-type: none"> 2016 Steinman et al LPEP Program progress 2017 Steinman et al LPEP Program update 2018 Richardus et al Minimal essential data
17.	Share lessons learned, document best practices See Prep 1.1 Involve main stakeholders	Keep in mind that involvement of main stakeholders was already described for step 1.1 <ul style="list-style-type: none"> Who are the stakeholders that you want to inform? Can additional stakeholders be identified that need to be informed about the (preliminary) results and lessons learned? How are results going to be presented and lessons learned shared? How will it be ensured that research questions that have come up during the start-up phase are taken up? 	

	Steps	Guiding questions for the evaluation phase	Available tools, documents, materials, best practices
18.	Take action on lessons learned See Prep 1.1 Involve main stakeholders	Keep in mind that involvement of main stakeholders was already described for step 1.1 <ul style="list-style-type: none"> Who / which stakeholder will be responsible to ensure follow-up on lessons learned? 	
19.	Ensure sustainability See Prep 1.2 Ensure sustainability	Keep in mind that the sustainability was also already addressed in step 1.2 <ul style="list-style-type: none"> Is there anything else that would need to be done during the preparation phase to ensure sustainability? 	