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

Main Goal: Contact screening and SDR-PEP administration embedded in routine leprosy control
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

**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

**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

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<th>Available tools, documents, materials, best practices</th>
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<tr>
<td>1. Advocate for stakeholders’ / actors’ commitment</td>
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</table>
| 1.1a List all stakeholders/actors | - Which stakeholders/actors play a role in achieving scale up of SDR-PEP integration?  
  - 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:  
  - WHO leprosy Guideline  
  - SDR-PEP Toolkit:  
  - Slide deck SDR-PEP policy |
Fig. 1: How does change occur – actors influence

Fig. 2: Leverage/impact and Attitude

Fig. 3: ‘Our’ influence on stakeholders’ behavior
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| 1.1b  | - 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?  
      > 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  | - Prioritize stakeholders based on leverage/impact, attitude and the possibility to control them.  
      > 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   | - What resources are already 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:  
<p>|       | | - 2010 Idema Cost effectiveness |</p>
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<tr>
<td>2. Develop Operational Guidelines</td>
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<td>Relevant documents:</td>
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</table>
| 2.1 Describe selected approaches     | - Which approaches have been used?  
- Are any new approaches planned for that need to be piloted?  
- If so, which approaches and why?                                                                                     | - Indonesia extended contract tracing with self-screening and blanket approach                                                                                             |
|                                      | Scientific Publications:                                                                                                                                              | - 2005 Bakker et al Prevention of leprosy                                                                                                                                     |
|                                      | - 2008 Moet et al Effectiveness of single dose rifampicin                                                                                                              | - 2008 Moet et al Effectiveness of single dose rifampicin                                                                                                                     |
|                                      | - 2016 Barth-Jaeggi et al LPEP program study protocol                                                                                                                 | - 2016 Barth-Jaeggi et al LPEP program study protocol                                                                                                                        |
|                                      | - 2018 Furst et al Cambodia drive                                                                                                                                     | - 2018 Furst et al Cambodia drive                                                                                                                                           |
|                                      | - 2018 Tiwari and Dandel et al Population wide administration                                                                                                         | - 2018 Tiwari and Dandel et al Population wide administration                                                                                                                    |
| 2.2 Define index patients            | For the different approaches:  
- Are retrospective leprosy patients going to be included?  
If so:  
  - How many years retrospectively?                                                                                   | Scientific Publications:                                                                                                                                                       |
<p>|                                      |                                                                                                             | - 2016 Barth-Jaeggi et al LPEP program study protocol                                                                                                                         |
|                                      | SDR-PEP Toolkit:                                                                                                                                                      | - SDR-PEP field guide generic, chapter 3 – Enrolment of index patient                                                                                                         |</p>
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| 2.3       | Define contacts For the different approaches:  
• Which contacts are going to be targeted  
• How are they going to be approached (e.g. house visits, campaigns, invited to health centre)?  
• Will social contacts such as class-mates, colleagues etc. be included? If so:  
  ▪ How will that be organized logistically?  
  ▪ How will (the fear of) stigmatization be dealt with?                                                                                                                                                                                                                                                                                                                                 | - Best practices:  
  - 1 – HH Contact Examination  
  - 2 – Quality screening of contacts  
  - 4 – Quality Counseling by GHC staff  
SDR-PEP Toolkit:  
- SDR-PEP field guide generic, chapter 4 – Tracing and enrolment of contacts, and 5 – Screening of contacts  
Scientific Publications:  
- 2016 Barth-Jaeggi et al LPEP program study protocol  
SDR-PEP Toolkit:  
- Field guide generic, chapter 2 – Overall roles, responsibilities and timelines  
Scientific Publications:  
- 2016 Barth-Jaeggi et al LPEP program study protocol  |
| 2.4       | Determine roles and responsibilities  
• Which staff is / will be responsible for the overall management?  
• Which (health) staff is / will be involved in contact tracing, screening of contacts and SDR-PEP administration?  
• Which staff is / will be involved in monitoring and supervision?  
• Which staff can refer suspected cases? Which staff can diagnose leprosy?                                                                                                                                                                                                                                                                                                                | SDR-PEP Toolkit:  
- Field guide generic, chapter 2 – Overall roles, responsibilities and timelines  
Scientific Publications:  
- 2016 Barth-Jaeggi et al LPEP program study protocol  
Scientific Publications:  
- 2018 Richardus et al Minimal essential data  
SDR-PEP Toolkit:  
- Field guide generic, chapter 8 – Data Recording and Reporting  |
| 2.5       | Develop recording and reporting system  
• How is recording and reporting on leprosy organized?  
• Is SDR-PEP already embedded in routine recording and reporting? If so: How?  
• Are the minimal essential data for the introduction of SDR-PEP already integrated into the national health information system? If not, is there a plan to make this happen?  
• Do other/additional data need to be collected?  
• Are steps still needed to bring the recording and reporting of the minimal essential data into practice? If so, which steps?                                                                                                                                                                                                                           | Scientific Publications:  
- 2018 Richardus et al Minimal essential data  
SDR-PEP Toolkit:  
- Field guide generic, chapter 8 – Data Recording and Reporting  |
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<td>3.1 Collect epidemiological data</td>
<td>• Are good quality epidemiological data available over the last 10 years in the areas to which the SDR-PEP implementation will be scaled up? (# of new patients; % disability grade 2; % children)</td>
<td>Relevant documents: - 2019 Taal et al ILC Abstract Mapping India vs Indonesia PEP++</td>
</tr>
</tbody>
</table>
| 3.2 Set up or use epidemiological mapping | • Are mapping data available?  
• Have high endemic areas, clusters / hotspots been identified? | Relevant documents: - 2019 Taal et al ILC Abstract Mapping India PEP++ |
| 3.3 Select the most suitable approach     | The selected approaches were described for step 2.1  
• What is the most suitable approach for each of the areas to which SDR-PEP implementation will be scaled-up? | Relevant documents: - Scientific Publications:  
- 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 all Cambodia drive  
- 2018 Tiwari and Dandel et al Population wide administration |
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<td>4. Prepare logistics</td>
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<tr>
<td>4.1 Human- and financial resources</td>
<td>Keep in mind which resources were listed for step 1.2 and the roles and responsibilities as described for step 2.4.</td>
<td>SDR-PEP Toolkit:</td>
</tr>
<tr>
<td></td>
<td>Human resources</td>
<td>- Field guide generic, chapter 2</td>
</tr>
<tr>
<td></td>
<td>• Is staff available to manage, monitor, supervise and implement contact screening and SDR-PEP administration?</td>
<td>- Overall roles, responsibilities and timelines</td>
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<td></td>
<td>• Are operational guidelines available for staff to add the responsibilities and tasks to their daily work?</td>
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<td></td>
<td>Financial resources</td>
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<td></td>
<td>• How are additional costs going to be covered for scale-up?</td>
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<td>Especially costs for training and fieldwork:</td>
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<tr>
<td></td>
<td>▪ Training costs</td>
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<td></td>
<td>▪ Staff costs, including per diems</td>
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<td></td>
<td>▪ Transportation costs (what means of transportation will be used?)</td>
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<td></td>
<td>• Is there any experience combining activities with other health programmes, to increase cost-efficiency?</td>
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<tr>
<td>4.2 Sufficient MDT</td>
<td>• Is there a functional MDT supply chain?</td>
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<tr>
<td></td>
<td>• Is MDT sufficiently available? (Taking into account that the increased active case finding through contact examination will lead to an increased need of MDT)</td>
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| 4.3 Procurement of rifampicin | • How has loose rifampicin been made available in the pilot projects?  
• Can rifampicin be used as chemoprophylaxis (for leprosy) according the current pharmacovigilance guidelines?  
• Is rifampicin purchase already embedded in the supply/distribution chain?  
• How have costs for rifampicin supply been covered so far? Are funds available for rifampicin in the scale-up areas? | |
| 4.4 Surveillance for rifampicin resistance | • Is surveillance for leprosy resistance set-up in the country?  
  ▪ If not, why not?  
• Is there a lab in the country or in the region that could do resistance testing?  
• Has surveillance for leprosy resistance been set-up in areas where SDR-PEP has been implemented? If not: Can that be done in the scale-up areas? | Relevant documents:  
- WHO A guide for surveillance of antimicrobial resistance in leprosy 2017 |
| 5. Develop training | | |
| 5.1 Develop a training plan | Keep in mind the roles and responsibilities as defined for step 2.4 and the necessary human resources as described in step 4.1.  
• Has training for SDR-PEP implementation been embedded in leprosy training?  
  ▪ Will this be done? How?  
• Which staff has been trained in the pilot areas?  
• How are costs for training going to be covered? | Best practices:  
- 2.1 Training Module LPEP |
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<td>6. Set up monitoring and supervision</td>
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<td>SDR-PEP Toolkit:</td>
</tr>
<tr>
<td>6.1 On the job training</td>
<td>Keep in mind the roles and responsibilities as defined for step 2.4 and the necessary human resources as described in step 4.1.</td>
<td>- Field guide generic, chapter 9 – Quality Control and Supervision</td>
</tr>
<tr>
<td></td>
<td>• Who has monitored and supervised the implementation and gave on the job training in the pilot areas? Can this continue in the same way in the scale-up areas?</td>
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<tr>
<td></td>
<td>• How have costs for transportation and field visits been covered in the pilot areas? Can this be done in the same way in the scale-up areas?</td>
<td></td>
</tr>
<tr>
<td>6.2 Quality assurance</td>
<td>• What kind of methods/tools have been used to help ensure the quality of the implementation in the pilot areas? Can these also be used in the scale-up areas?</td>
<td>SDR-PEP Toolkit:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Field guide generic, chapter 9 – Quality Control and Supervision</td>
</tr>
<tr>
<td>6.3 Documentation of lessons learned</td>
<td>• How have lessons learned been documented, shared and addressed during the pilot phase? Should this process be adapted in the scale-up phase?</td>
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<tr>
<td></td>
<td>• How will it be ensured that research questions that have come up during the pilot phase or that will come-up during the scale-up phase are or will be taken up?</td>
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<tr>
<td>7. Inform and involve the community</td>
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</table>
| 7.2 Inform and involve community leaders and other community members | • Which key community persons have been involved in the pilot areas? Will this be done in a similar way in the scale-up areas?  
• Can other key community persons be identified that should be involved?  
• How will they be involved in the different phases: preparation, implementation and evaluation phase? | Relevant documents:  
- 2019 Budiawan et al ILC Abstract Leprosy Friendly Village  
Scientific Publications:  
- 2018 Tiwari and Dandel et al Population wide administration |
# Implementation phase 7 steps

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</table>
| ALL  | Relevant documents:  
  - 2017 example of pocket book for field work-Indonesian language  
Scientific Publications:  
  - 2016 Barth-Jaeggi et al LPEP program study protocol |
| 8. Leprosy patient identified | SDR-PEP Toolkit:  
  - Field guide generic, chapter 3 – Enrolment of index patient |
| 9. Informed consent (index patient) | Relevant documents:  
  - WHO Leprosy Guidelines  
SDR-PEP Toolkit:  
  - Field guide generic, chapter 3 – Enrolment of index patient |
| 10. List contacts | SDR-PEP Toolkit:  
  - Field guide generic, chapter 4 – Tracing and enrolment of contacts |
| 11. Informed consent (contact) | SDR-PEP Toolkit:  
  - Field guide generic, chapter 4 – Tracing and enrolment of contacts |
| 12. Examination by health worker | Best practices:  
  - 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:  
  - Field guide generic, chapter 5 – Screening of contacts  
  - Field guide generic, chapter 6 – Referral and Examination of contacts with suspected leprosy and/or TB |
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</table>
| 13. Eligibility criteria | Best Practices:  
- 2.2 LPEP-Exclusion-criteria-for SDR  
- 2.3 LPEP-Exclusion-criteria-CARD-DND  
SDR-PEP Toolkit:  
- Field guide generic, chapter 7 – Administration of SDR to eligible contacts |
| 14. Administration of SDR-PEP | Scientific Publication:  
- 2018 Richardus et al Minimal essential data  
SDR-PEP Toolkit:  
- 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**

- 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 < 2 years 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

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</table>
| **15.** Evaluate, involving all main stakeholders  
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  
- How will stakeholders remain involved and informed during the scale-up? | Scientific Publications:  
- 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.  
- Which information do stakeholders need from the SDR-PEP scale-up 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:  
- 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  
- 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 scale-up phase are taken up? | |
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<td><strong>18.</strong></td>
<td>Take action on lessons learned  &lt;br&gt;See Prep 1.1 Involve main stakeholders</td>
<td>Keep in mind that involvement of main stakeholders was already described for step 1.1  &lt;br&gt;• Who / which stakeholder will be responsible to ensure follow-up on lessons learned?</td>
</tr>
<tr>
<td><strong>19.</strong></td>
<td>Ensure sustainability  &lt;br&gt;See Prep 1.2 Ensure sustainability</td>
<td>Keep in mind that the sustainability was also already addressed in step 1.2  &lt;br&gt;• Is there anything else that would need to be done during the preparation phase to ensure support for the scale-up and sustainability?</td>
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</tbody>
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