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Minimal essential data to document contact tracing and single dose rifampicin (SDR) for leprosy control in routine settings: a practical guide

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Summary In leprosy control there is a renewed interest in active case finding, which is increasingly being combined with chemoprophylactic interventions to try and reduce *M. leprae* transmission. The Leprosy Post-Exposure Prophylaxis (LPEP) programme, currently ongoing in eight endemic countries, pilots the provision of single-dose rifampicin (SDR) to eligible contacts of leprosy patients. LPEP has developed a surveillance system including data collection, reporting and regular monitoring for every participating country. This system is still largely programme-specific to LPEP. To facilitate continuity after completion of the project phase and start-up in other interested countries, we aim at identifying the minimal set of data

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required to appropriately document contact tracing activities and SDR administration for leprosy control in a routine setting.

We describe four indicators for the index case (plus four already routinely collected) and seven indicators for household/neighbour screening, and community surveys. We propose two generic forms to capture all relevant information required at field and district level to follow-up on individuals or data if needed, provide guidance on the sequence of tasks, provide quality control by listing key questions to assess SDR eligibility, and facilitate reporting. These generic forms have to be adapted to local requirements in terms of layout, language, and additional operational indicators.

Introduction

Leprosy control is currently benefiting from a renewed interest in active case finding.[1,2] These efforts are increasingly being combined with chemoprophylactic interventions[3] in the context of a push to reduce *Mycobacterium leprae* transmission.[4] The tracing of contacts of newly identified leprosy patients, their screening for signs and symptoms of the disease and the provision of single-dose rifampicin (SDR) to eligible contacts, are the key activities related to chemoprophylaxis in the context of leprosy control, and of the Leprosy Post-Exposure Prophylaxis (LPEP) programme.[5] For the purpose of this programme, a surveillance system including data collection, reporting and regular monitoring has been developed for every participating country. While this system is aligned with the routine leprosy data collection, it is still a programme-specific system to satisfy the needs of the programme in terms of reporting and evidence generation to document the feasibility and impact of the LPEP approach.

The LPEP programme includes 3 years of field work in each of the eight participating countries (Brazil, Cambodia, India, Indonesia, Myanmar, Nepal, Sri Lanka, and Tanzania). After completion of the field work phase, countries are encouraged to continue contact tracing and SDR administration in the project area. A country may opt to extend the project phase, expand the intervention to additional pilot areas, or roll out the intervention nationally, depending on the strength of the evidence resulting from the programme, the confidence the national leprosy control programme has in the possible impact of the intervention, and the availability of resources. While some countries have already integrated chemoprophylaxis into their national strategy to control leprosy,[6] other countries may also require a specific endorsement of the intervention by the World Health Organization (WHO) and the Global Leprosy Programme. Currently, the Global Leprosy Programme recommends contact tracing to facilitate early case detection, while calling for further research to determine the value of prophylactic treatment.[2]

To facilitate continuity after completion of the project phase and start-up in other interested countries, here, we aim at identifying the minimal set of data required to appropriately document contact tracing activities and SDR administration for leprosy control in a routine setting. Our recommendations are based on experience from the LPEP programme and are designed to satisfy standard data needs, but we recognise that countries may want to collect additional data to satisfy specific purposes or interests.

DEFINITIONS AND CONSIDERATIONS

The definitions, indicators and generic forms presented below are together referred to as the minimal essential data to document contact tracing and SDR for leprosy control in a routine setting ('minimal essential data'). They have been identified and designed based on standard principles for public health data collection and reporting, practical experience from the LPEP programme,[5] and available guidance from the Global Leprosy Programme.[7] In an iterative process, the minimal essential data set has been reviewed by stakeholders in endemic countries, different non-governmental organisations (NGOs) supporting leprosy control in these countries, donor organisations, and members of the LPEP steering committee. A subgroup of the Technical Advisory Group (TAG) of the Global Leprosy Programme, which reports on information systems and monitoring annual progress towards targets, was also consulted.

Household and neighbour contacts

In line with the available evidence, we encourage and advise a broad definition of household contacts to maximize the impact of contact tracing and SDR.[8] When identifying household contacts, a definition should be chosen that is appropriate for the local conditions (e.g. people living in the same apartment/house/compound, extended family unit/sharing essential resources, etc.). Neighbour contacts include the households (typically around five) living immediately adjacent to the household where the index patient resides. As with household contacts, a definition for neighbour contacts should be chosen that is appropriate for the local situation. A focus on household and neighbour contacts requires disclosure – and therefore consent – of the index patient.[9] Operationally, an effort to trace household and neighbour contacts and screen them follows the diagnosis of an individual case. While available evidence does not point towards an 'optimal' time point to trace household and neighbour contacts,[10] all epidemiological and operational considerations suggest that contact tracing should be done between 1 and 6 months after the index patient started multi-drug therapy. While early contact tracing reduces the risk that contacts themselves develop leprosy and thereby also helps reducing delays in diagnosis and the risk of developing disabilities, operational considerations may favour a periodic effort to trace the contacts of all index patients diagnosed over a certain period (e.g. a quarter or half a year) in a campaign-style effort, sometimes labelled a 'drive'.[10]

Community contacts

Under certain conditions (e.g. a child leprosy case with disability, a child leprosy case in a low burden setting, populations that are hard to reach, high case detection rate in a small geographical setting), a full community screening should be considered.[9] A community may be defined as a neighbourhood, village, island population, school, workplace, etc., depending on the local conditions and the socio-demographic characteristics of the new leprosy case(s) (e.g. school child, factory worker, etc.). The size of the targeted community needs to be carefully defined for each individual community screening effort, taking into consideration the epidemiological situation, resources (funding, personnel, and time), logistics and acceptability by the community of the intervention. A focus on community contacts means that there is no need for disclosure and consent of the index patient. Rather, the community

members should be informed that their area is endemic for leprosy or that leprosy cases have been found in the community over the past years, and that a survey is planned to find any remaining hidden cases.

The decision to screen a community should always take into account the number of index patients in an area, over time. An ideal basis for such a decision is continuous mapping of historical and current patients,[11] and a periodic review of the spatial distribution of cases that have emerged over a certain period, typically 1-5 years. Furthermore, every community screening must be accompanied by an information campaign to raise awareness for leprosy and the cardinal signs of the disease, and to address stigma.

Data

The focus of the effort described here, namely to define the minimal essential data required to appropriately document contact tracing and SDR for leprosy control in a routine setting, is on reporting to the national and international level. Underlying documentation at field level must be more detailed to facilitate the work of the field staff and satisfy local operational, reporting and follow-up needs, which usually implies that the current place of residence and detailed contact information is recorded. This distinction is also reflected in the difference between the generic forms and the suggested indicators for reporting.

Index patient (case)

With regard to the index patient, often referred to as the index case, we assume that basic indicators are collected as required for reporting to the WHO Global Leprosy Programme (age, sex, leprosy classification, and disability grade).[7] In addition to these standard indicators, we propose the collection and reporting of the following four key indicators:

1. Mode of detection.
   This indicator is highly relevant as it is the only measure of contact tracing effectiveness in terms of new leprosy patients detected.
   - Passive (includes self-reported, referral – by medical service or from outside the health district, etc.).
   - Active (includes household and neighbour screening, community survey/ leprosy elimination campaigns (LEC), etc.).
2. Previous SDR.
   This indicator is of key relevance to (indirectly and retrospectively) measure SDR effectiveness. It refers to SDR previously given, e.g. after a household screening or in the frame of a community survey, irrespective of the time when SDR had been given. It can be reported in a simple Yes/No manner.
3. Presence of contacts in the current place of residence.
   'Current place of residence' of the newly diagnosed leprosy patient can refer to the household, but also a dormitory, boarding school etc., irrespective of the duration of residency. The intention is to identify patients without household contacts in the health district who therefore do not require follow-up or are difficult to trace. This is an operational indicator, but should be reported as it contributes to the calculation of the denominator to determine contact tracing coverage (% of new patients followed up by contact tracing). It can be reported in a simple Yes/No manner.

4. Index patient consent to disclosure and household/neighbour contact screening.
   This is an operational indicator but should be reported as it contributes to the calculation of the denominator to determine contact tracing coverage (% of new patients who agreed to follow up by contact tracing). Also, it is an indicator for acceptability of household/neighbour contact tracing. It can be reported in a simple Yes/No manner.

To facilitate data collection, these indicators should be integrated into the basic leprosy cards/forms used in nearly all programmes to summarise the basic information about a leprosy patient.

Household and neighbour contact screening

We propose the collection and reporting of seven indicators related to household and neighbour contact screening (Table 1):

1. Contacts listed/enumerated.
   This is the denominator to calculate the contact tracing rate (% of reported contacts actually traced).
2. Contacts traced.
   This is the numerator to calculate the contact tracing rate. The denominator is the number of contacts listed/enumerated (1) – the difference is due to absence of contacts, and may be used to monitor the coverage of the contacts.
3. Contacts screened.
   This is the numerator to calculate the contact screening rate. The denominator is the number of contacts traced (2) – the difference is due to refusal to be screened, and may be used to monitor the acceptability of the intervention.
4. Leprosy cases confirmed or suspected.
   This indicator quantifies the outcome of the screening in terms of the number of contacts that are confirmed or suspected of having leprosy. The number of confirmed

Table 1. Summary of the proposed minimal set of indicators to document contact tracing and post-exposure prophylaxis in leprosy control. All indicators are to be reported as totals and can be stratified by sex

Index case	Household and neighbour screening	Community survey
Age (child/adult)	Number listed/enumerated*	Number estimated[0]
Sex (M/F)	Number traced	Number traced
Leprosy classification (PB/MB)	Numbers screened[+]	Numbers screened[+]
Disability grade (G2D)	Number confirmed or suspected	Number confirmed or suspected
Mode of detection (passive/active)	Number SDR excluded	Number SDR excluded
Previous SDR (yes/no)	Number SDR refused	Number SDR refused
Presence of contacts (yes/no)	Number SDR received	Number SDR received
Consent to disclosure (yes/no)		

*Contacts listed = contacts screened + (contacts absent + screening refused + contacts receiving MDT or have received in the past 2 years)

[0]Ideally based on available listing. If no listing available, then estimate

[+]Contacts screened = Leprosy suspects + SDR refused + SDR excluded + SDR received

or suspected leprosy cases may be used to calculate additional indicators for in-depth analysis of contact tracing (e.g. new confirmed or suspected cases per x contacts screened, new confirmed or suspected cases per index case etc.). Confirmation is sometimes made on the spot during screening if a qualified health worker is present, but very often follows later, when the suspected contact is seen in a health clinic and further examined. Under such circumstances, the final diagnosis of each suspected leprosy case should be retrieved from the leprosy register. Finally, it is assumed that all known leprosy cases among the targeted contacts that are currently on MDT are exempted from screening.

5. SDR excluded/contraindicated.
   This is the numerator to calculate the SDR exclusion rate. Denominator is the number of contacts screened (3). This indicator may be used to monitor the coverage of this high-risk population with preventive chemotherapy.
6. SDR refused.
   This is the numerator to calculate the SDR refusal rate. Denominator is the number of contacts screened (3) minus the number of SDR excluded/contraindicated (5). This indicator may be used to monitor the coverage of this high-risk population and the acceptability of the intervention.
7. SDR received.
   This is the numerator to calculate the SDR coverage rate. Denominator is the number of contacts screened (3). This indicator may be used to monitor the coverage of this high-risk population with preventive chemotherapy.

Community survey

We also propose the collection and reporting of seven indicators related to community surveys (Table 1):

1. Community members estimated.
   This is the denominator to calculate the tracing rate (% of estimated population actually traced).
2. Contacts traced.
   This is the numerator to calculate the contact tracing rate. The denominator is the estimated number of community members (1) – the difference is due to absence of community members, and may be used to monitor the coverage of the contacts.
3. Contacts screened.
   This is the numerator to calculate the contact screening rate. The denominator is the number of contacts traced (2) – the difference is due to refusal to be screened, and may be used to monitor the acceptability of the intervention.
4. Leprosy cases confirmed or suspected.
   This indicator quantifies the outcome of the screening in terms of the number of contacts that are confirmed or suspected of having leprosy. The number of confirmed or suspected leprosy cases may be used to calculate additional indicators for in-depth analysis of contact tracing (e.g. new confirmed or suspected cases per x contacts screened, new confirmed or suspected cases per index case etc.). Confirmation is sometimes made on the spot during screening if a qualified health worker is present, but very often follows later, when the suspected contact is seen in a health clinic and

further examined. Under such circumstances, the final diagnosis of each suspected leprosy case should be retrieved from the leprosy register. Finally, it is assumed that all known leprosy cases that are currently on MDT in the area are exempted from screening.

5. SDR excluded/contraindicated.
   This is the numerator to calculate the SDR exclusion rate. Denominator is the number of community members screened (3). This indicator may be used to monitor the coverage of the population with preventive chemotherapy.
6. SDR refused.
   This is the numerator to calculate the SDR refusal rate. Denominator is the number of community members screened (3) minus the number of SDR excluded/contraindicated (5). This indicator may be used to monitor the coverage of the population and acceptability of the intervention.
7. SDR received.
   This is the numerator to calculate the SDR coverage rate. Denominator is the number of community members screened (3). This indicator may be used to monitor the coverage of the population with preventive chemotherapy.

The indicators suggested above are collected at field level. Summary data per household are usually reported to the district/municipality, where they are then aggregated for the district and either directly submitted to the central level or to further intermediate levels (e.g. province/state) where aggregation may happen again before submission to the national level.

In the case of a community survey, there is no equivalent to a contact list and there is no need to embark on a census if no register data is available. Instead, the number of individuals in the target community should be estimated. However, in many cases a list that can be used will be available (e.g. for schools and factory workers, in some countries village lists are maintained, etc.). Thus, community survey activities can be documented on a form that is derived from the form used for household screening. Of note, that form is best used for the lowest unit of organisation of the community that is surveyed (e.g. household, school class, work team, etc.). Summary data for each community survey are reported to the district/municipality, which may then be aggregated for the district and province/state etc., as appropriate, before submission to the national level.

Forms

We propose two generic forms for the recording of household/neighbour contact screening activities and community surveys, respectively. The forms are inspired by the LPEP contact forms,[5] and designed to capture all relevant information required at district/municipality level to follow-up on individuals or data in case this is needed, provide guidance on the sequence of tasks, provide quality control by listing key questions to assess SDR eligibility, and facilitate reporting. See Figures 1 (household and neighbour contacts) and 2 (community screening) for generic versions of these forms, which need to be adapted to local requirements in terms of layout, language, additional operational indicators, etc.

Index patient registration number: |_____| **Date** |___|___|_____| **(day | month | year)**

Physical address and mobile phone number of index case household:
|_____|

Contacts

	Name	Sex		Absent	Refused screening	Age (years)	Suspected leprosy	If screening negative: SDR exclusion criteria (check if yes)							SDR dose given**
		M	F					Age <2 years	Pregnancy	TB treatment within last 2 years	Suspected TB*	Liver or renal disease	Other	Refused SDR	
1															
2															
3															
4															
5															
6															
…															
	Total:							**Total:**							

*According to TB screening protocol [12]

** Recommended SDR dosage: [*add recommended dosage*] (justify any deviation from recommended dose)

Figure 1. Generic Contact Screening Form (household and neighbour screening).

Date |____|____|_____| **(day | month | year)**

Target community: |_____|

Contacts

	Name	Sex		Refused screening	Age (years)	Suspected leprosy	If screening negative: SDR exclusion criteria (check if yes)							SDR dose given**
		M	F				Age <2 years	Pregnancy	TB treatment within last 2 years	Suspected TB*	Liver or renal disease	Other	Refused SDR	
1														
2														
3														
4														
5														
6														
…														
	Total:						**Total:**							

*According to TB screening protocol[12]

** Recommended SDR dosage: [*add recommended dosage*] (justify any deviation from recommended dose)

Figure 2. Generic Contact Screening Form (community screening)

Discussion

Contact tracing should be a cornerstone of the leprosy control strategy of leprosy endemic countries. Several countries have also integrated chemoprophylaxis into their national leprosy elimination strategy, or are in the process of doing so, while others are piloting the approach.[6] Consequently, countries may already have integrated a part or all of these indicators into their data collection system. For example, countries already implementing contact tracing usually have a system to capture relevant data.

Pilot interventions often operate stand-alone recording and reporting systems. Every country proceeding to integrate an intervention that resembles LPEP in its routine leprosy control activities will need to modify its leprosy recording and reporting system to capture relevant activities and report key programmatic and outcome indicators to the national level. Also, monitoring activities will need to be adjusted to cover these additional activities. As it is the case with every reporting system, a balance must be found between the desire for detail and the burden created by recording and reporting. The resulting recording and reporting system for contact tracing and SDR administration should be fully integrated into the national leprosy reporting system, as the intervention has been integrated into the national strategy to control and eliminate leprosy. This will avoid duplication of efforts, reduce costs and signal the routine character of the activities to the field staff and the health system at large.

Ideally, the leprosy data collection system is updated to collect the additional indicators required for the surveillance of contact tracing and chemoprophylaxis along with the introduction of the actual activities in the field-level routine. The parallel updating of the activity protocols and data collection system allows for integrated training and avoids confusion about recording and reporting needs pertaining to the new activity. Also, integration from the outset allows the use of system-generated data to monitor the acceptability of the new interventions among the population and health workers through, for example, time trends in coverage and participation.

Governments may be reluctant to incorporate more information into their national disease control reporting system. An important argument in favour would be that if a government actually decides to add contact surveys and any other (prophylactic) interventions to their leprosy control programme, quality control dictates that these activities are monitored adequately. In addition, there may be other arguments specific for a country that should be addressed separately. If the Global Leprosy Programme proceeds to officially endorse or recommend preventive chemotherapy,[7] changes in the final list of indicators may occur. However, such changes will likely be minor and tweaking an established data collection system should be easier than establishing a new one under the pressure of international reporting demands.

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Conflicts of interest

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Contributorship

All authors contributed to the planning, conducting, and reporting the work. JHR and PS wrote the paper and carry final responsibility for this publication.

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