Evaluation of Leprosy Surveillance System in the Amazon region, Brazil, 2001–2007

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Summary
Objectives: We evaluated the leprosy surveillance system in the Amazon region, Brazil, 2001–2007, using evaluation guidelines from the US Centers for Disease Control and Prevention.
Results: We found that the leprosy surveillance system in the Amazon region is simple, presents good data quality and is representative in describing the socio-demographic profile and clinical classification of cases. The predictive value positive is high and its sensitivity is unknown. The grade two disability artificially increased in 2007 during the transition to a new version of the information system. The cases are reported, receive treatment and are discharged from the system in a timely fashion. Nevertheless, the dermatological and neurological examination introduces complexity to the system, which may account for the irregular data quality related to the evaluation of the disability degree, the system’s lack of representativeness to describe mild neurological manifestations and low proportion of household contacts investigated.
Conclusions: Despite its limitations, the leprosy surveillance system proved to be useful. Recommendations for its improvement were issued based on the results found. More data on surveillance systems in endemic countries are needed to facilitate valid comparisons between country indicators.

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Introduction

Despite the decline of leprosy cases in recent years, there were more than 200,000 new cases reported to the World Health Organization (WHO) in 2009 worldwide.¹ Sixteen countries accounted for 93% of all new leprosy cases, including Brazil, which is the second, after India, in number of cases. In 2009, Brazil reported 37,610 new leprosy cases, corresponding to 87% of all new cases in the Americas.¹

In Brazil, leprosy detection rates increased until 2003, which is believed to have been associated with the health system reform, in 1990. This provided universal health care for the whole Brazilian population, increasing diagnosis and detection in the most remote and impoverished areas.² Since 2003, the detection rates have decreased.³

Geographically, leprosy affects Brazil unevenly: 72.8% of the 29 clusters of the disease described in the country are located in the Amazon region, while the rest are located in the neighbouring savannah area.³,⁴ The Amazon region of Brazil is a large but sparsely populated area. It comprises 773 municipalities within nine states, a population of 24.7 million inhabitants in 2009 (12.9% of the Brazilian population) in an area of 5.08 million km² (59.8% of Brazil area), thus a demographic density ten times less than the national average (Figure 1).⁵

The region is characterised by low levels of social development, with waves of migration associated with agricultural activities, mineral extraction and more recently, a rapid process of urbanisation and deforestation. Leprosy detection rates in this region have been associated with social conditions and land settlement, in particular with indicators

Figure 1. A. Map of Brazil located in South America. B. Map of Brazil divided by states, showing the Amazon region in grey. C. Map of Brazil showing the new case detection rate per 100,000 inhabitants in 2005 and the limits of the Amazon region states.
such as deforested area, low human development index and proportion of households with rudimentary septic tanks.\textsuperscript{6}

An effective and reliable surveillance system for leprosy is essential to inform, monitor and guide disease control activities.\textsuperscript{7,8} The World Health Organization publishes annual data with leprosy figures from most countries. However, there is little information about their surveillance systems, which is fundamental to interpret and make comparisons between countries. In order to ensure the effective monitoring of the disease, to make recommendations to improve the system, and to enhance transparency in the data provided to WHO, we conducted an evaluation of the leprosy surveillance system in the Amazon region, Brazil, from 2001 to 2007.

\textbf{Material & Methods}

This analysis of the leprosy surveillance system was performed using a guideline for evaluating surveillance systems that was issued by the US Centers for Disease Control and Prevention in 2001.\textsuperscript{9} We present a description of the leprosy surveillance system in Brazil’s Amazon region: an analysis of its attributes as a public health surveillance system (simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness and stability); a summary of its level of usefulness; a discussion of its strengths and weaknesses; and recommendations for its improvement.

We applied a questionnaire to seven of the nine state leprosy surveillance coordinators of the Amazon region when they attended a regional meeting in Belém, Pará State, in July 2009. The questionnaire addressed quantitative and qualitative information about the routine work of the surveillance system and the main obstacles to achieve its objectives.

We used the national database of leprosy cases updated in February 2010 to conduct the analysis. We included all cases diagnosed between 2001 and 2007 with residence in the Amazon region.

We used the software RecLink 3.1.6 to identify duplicate records, on the basis of the following variables: name of the patient, name of the patient’s mother, sex, city of residence and date of birth, but excluding the cases classified as relapse. For further analysis, we used the software Epi-Info Windows 3.5.1.

\textbf{Results}

\textbf{SYSTEM DESCRIPTION}

Leprosy has been on the list of compulsory notifiable diseases since its first version in 1975, when it was created by the law that established the National Epidemiological Surveillance System in Brazil.\textsuperscript{10} The leprosy surveillance system is passive and universal. Its data are managed by a national information system for notifiable diseases (\textit{Sistema de Informação de Agravos de Notificação} – SINAN), a system that also manages other compulsory infectious diseases, such as dengue fever, meningitis, tuberculosis, aids, measles and many others.\textsuperscript{11}

The leprosy case definition used in the surveillance system is an individual who presents with one of the following characteristics and requires multidrug therapy (MDT): (1) skin lesions with abnormal sensitivity; (2) involvement of nerves with neural thickening; and/or (3) positive bacilloscopy skin smear.\textsuperscript{12,13} The cases are detected mainly through self reporting
to health care centres and referrals to specialised services. Active detection occurs sporadically through contact examination, community campaigns and surveys. Every new case, which is defined as a case of leprosy that has never received treatment, must be reported by the health care centre where the diagnosis was made, in the same epidemiological week of diagnosis, using a standard leprosy report form. Relapse cases must be reported by the referral centre that confirmed the diagnosis using the same standardised report form. The leprosy report form collects socio-demographic, clinical and laboratory data, and also the number of household contacts. Over the course of treatment, the health care centres report monthly updated information through a patient monitoring report form. The monitoring report updates the data on actual residence, leprosy operational classification, number of MDT doses, therapeutic regimen, and number of household contacts investigated, and it reports any reactional episode in that month.

Health centres transfer the data to the municipality surveillance coordinator, who consolidates them, checking for duplications, completeness and inconsistencies, and who then sends the data to the state level weekly. The state surveillance coordinator consolidates the data from its municipalities in the same manner and sends them every 15 days to the Ministry of Health (MoH). The data are typically transferred through the internet, but municipalities that are unable to transfer the data electronically send the data to states via mail.

Patients who complete treatment must have their situation reported in the system within 9 months for the paucibacillary (PB) cases and 18 months for the multibacillary (MB) cases. From 2001 to 2006, the cases registered in the system for more than 2 years if PB or 4 years if MB since the date of diagnosis with no updated situation were classified as abandoned treatment. Since 2007, any patient who does not attend the health care service in 12 months, despite the operational classification, must be classified as having abandoned treatment in the system.

From 2001 to 2006, the national database was managed by a version of the information system known as SINAN Windows; in 2007, a new version of the information system was introduced, known as SINAN Net. In order to maintain patients’ confidentiality, a system of password registration protects the access to the information system, according to the type of work to be performed. The MoH divulges the leprosy indicators every year in a national meeting with the state leprosy surveillance coordinators. These data are available for the public in the MoH website without personal identifiers.

The municipality is responsible for immediate control measures: delivery of MDT free of charge for every detected case of leprosy (every patient receives a monthly supervised dose at the health care centre until the end of treatment), investigation of signs and symptoms of leprosy and application of a dose of BCG vaccine to household contacts.

A summary of the leprosy surveillance system’s flow of information is presented in Figure 2.

**SYSTEM ATTRIBUTES**

**Simplicity**

This attribute reflects both the simplicity of the structure of the surveillance system and its ease of operation. The leprosy case definition does not require laboratory confirmation and can be confirmed with clinical criteria only. The leprosy report form has 43 fields and all the
data, except for the result of the skin smear, can be obtained during the patient’s first appointment at the health care centre.

The clinical portion of the form includes information from a detailed dermatological and neurological exam, which can represent a difficulty in primary care health centres in the most remote areas of the Amazon. Furthermore, the system requires monthly update through the patient monitoring report form, which has 16 fields. The data are transferred through multiple levels of reporting (the data generated by health care provider should pass through the municipality and state health department before going to the MoH).

Flexibility

This attribute is evaluated retrospectively observing if the system adapted to changing information needs or operating conditions. This evaluation was based on the process of database migration from a former information system version, SINAN Windows, to a new version, SINAN Net, which occurred in January 2007. From 2001 to 2006, there were 131,494 records in the SINAN Windows database and 129,764 records in the SINAN Net database, a difference of 1,730 (1.3%) records that did not migrate to SINAN Net database. The national leprosy surveillance coordinator decided to exclude certain variables from the leprosy report form during the period of the database migration: ‘number of nerve trunks involved,’ ‘bacilloscopy’ and ‘alternative therapeutic regimens.’ Although these variables eventually returned to the leprosy report form later in 2007, the information related to them from 2001 to 2006 in SINAN Windows database did not migrate to SINAN Net.

Another important change occurred in the evaluation of disability grading. From 2001 to 2006, the disability level was graded in four categories (zero, one, two or three); in 2007, it was reduced to three categories (zero, one or two). A new coding to the disability degree was introduced in this period (Figure 3A); this led to the overestimation of grade two disability in
2007 because of a typing error in the system. The estimates of grade two disability have gradually returned to levels similar to those before 2007 (Figure 3B).

Data Quality

This attribute reflects the completeness and validity of the data recorded in the surveillance system. There were 148,403 records in the database from 2001 to 2007, including 4,273 (2.8%) duplicates. Regarding completeness of the information among the key variables, we classified as excellent (above 90%): ‘mode of detection’ (99.3%), ‘initial therapeutic regimen’ (99.6%), ‘current therapeutic regimen’ (99.4%), ‘type of discharge’ (97.4%) and ‘date of last attendance’ (99.9%). However, we classified the level of completeness for the variable ‘evaluation of disability degree’ as regular (86.5%) at time of diagnosis and poor at the time of discharge for treatment completion (49.0%). We evaluated consistency comparing the operational classification versus the number of lesions registered (< five lesions = PB; ≥ five lesions = MB). We found 40% of MB cases among those reported with less than five lesions and 3% of PB cases among those reported with five or more lesions. The data were more consistent comparing the operational classification with the Madrid Classification (indeterminate and tuberculoid = PB; borderline and lepromatous = MB) and the number of MDT doses (six doses = PB; 12 doses = MB). We found 5% of MB cases among those reported as indeterminate and tuberculoid and 1% of PB cases among those reported as borderline and lepromatous Two percent of MB cases were reported as receiving six doses and 1% of PB were reported as receiving 12 doses of MDT.

Acceptability

This is a measure of the willingness to participate in the surveillance system. We evaluated the acceptability indirectly by the data quality and emphasising two important actions to disease control: the evaluation of disability degree and proportion of household contacts investigated. The system’s overall data quality was good; however, the evaluation of disability degree was irregular, in particular at the moment of discharge as treatment completion, as presented previously. The proportion of household contacts investigated during the whole period of study was 46%.
The main obstacles to evaluate the disability degree and to investigate the household contacts, as reported by the state leprosy surveillance coordinators, are presented in Table 1.

**Sensitivity**

This refers to the proportion of all cases that are detected by the system. We were not able to assess the sensitivity of the system because there is no other system capturing leprosy cases in Brazil for comparison.

**Predictive Value Positive**

This refers to the proportion of the cases reported that actually had leprosy. The proportion of cases that left the system with a different diagnosis during the period was 1%, which represents a predictive value positive of 99%.

**Representativeness**

This attribute refers to the ability of a surveillance system to describe accurately the occurrence of events both over time and as they are distributed in the population by place and person. Due to the lack of another system capturing leprosy cases in Brazil, the assessment of system representativeness is difficult. We compared the data on 749 cases from 2001 to 2006 in the municipality of Buriticupu, state of Maranhão, in the national database with a study performed by Aquino et al. in the same municipality from August 1998 to November 2000 that did not use secondary data from the national database to describe the profile of 207 cases. In both datasets, male sex, brown skin colour, age group of 15–44 years and illiteracy predominated and the proportion of PB and MB operational classification and Madrid classification were similar. The only significant difference observed was the proportion of disability found: the national database had 17% of disability while Aquino et al. found 76% of disability ($P$ value < 0.01). However, no difference was found in the proportion of grade two disability; there were 5% of grade two disability in the national database and 8% of grade two disability in Aquino et al. study ($P$ value = 0.12) (Table 2).

<table>
<thead>
<tr>
<th>Evaluation of disability degree</th>
<th>N = 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of professional training for neurological examination</td>
<td>5</td>
</tr>
<tr>
<td>The assessment is not performed on the day of the last dose</td>
<td>5</td>
</tr>
<tr>
<td>Lengthy examination, lack of time due to overload service</td>
<td>4</td>
</tr>
<tr>
<td>The examination is not registered in the report form</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Household contacts investigation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no active search of contacts</td>
<td>5</td>
</tr>
<tr>
<td>It is not registered correctly on the monitoring report</td>
<td>2</td>
</tr>
<tr>
<td>Lack of patient’s perception of the importance of bringing the contacts to the health centre</td>
<td>1</td>
</tr>
<tr>
<td>Fear of revealing the diagnosis because of social stigma</td>
<td>1</td>
</tr>
<tr>
<td>Patients living far from the health center</td>
<td>1</td>
</tr>
</tbody>
</table>
Timeliness

This attribute reflects the speed between steps in the surveillance system. During the period of study, 86% of the new cases were diagnosed and reported on the same date. Among those 14% presenting date of diagnosis different from the date of notification, the median period between these two steps was 7.5 days. Regarding treatment, 77% received MDT on the same date of the diagnosis. Among the 23% with date of diagnosis different from the date of treatment, the median period between these two steps was 6 days.

Among the PB cases, the median period in the system for those discharged as treatment completion was 193 days (6.4 months) and 81% of those cases were timely discharged as treatment completion (in up to 9 months). From 2001 to 2006, the median period of discharge as abandoned treatment was 747 days (24.9 months) and 44% of those cases were timely discharged as having abandoned treatment (in up to 24 months). In 2007, the median period of discharge as abandoned treatment was 369 days (12.3 months) and 38% of those cases were timely discharged as having abandoned treatment (in up to 12 months).

Among the MB cases, the median period in the system of those discharged as treatment completion was 390 days (13 months) and 80% of the cases were timely discharged as treatment completion (in up to 18 months). From 2001 to 2006, the median period of discharge as having abandoned treatment was 926 days (30.9 months) and 76% of those cases were timely discharged as abandoned treatment (in up to 48 months). In 2007, the median period of discharge as abandoned treatment was 367 days (12.2 months) and 42% of those cases were timely discharged as having abandoned treatment (in up to 12 months).

Stability

This attribute refers to the ability of the system to collect, manage and provide data properly without failure and to be operational when it is needed. None of the state leprosy surveillance
coordinators reported any failure in the system and all considered their material resource (computer, telephone, fax, etc) satisfactory. However, six out of the seven considered the human resource working with leprosy in their states to be insufficient. We did not evaluate the process of data transfer among municipalities, states and MoH.

USEFULNESS

During the evaluation, we did not find the system’s objectives clearly stated, yet the system is useful and has been used to (1) detect trends that signal changes in the occurrence of the disease;\(^3,19\) (2) establish priorities areas for health intervention;\(^3,4\) (3) describe the epidemiological profile of cases;\(^17\) (4) provide health indicators to estimate the magnitude of the disease;\(^17\) (5) assess the effectiveness of control measures (e.g. the proportion of household contacts investigated); and (6) stimulate research as evident in the number of peer reviewed articles published using data from the system.\(^20\)

Discussion

The leprosy surveillance system in the Amazon region, Brazil, from 2001 to 2007 proved to be simple with good data quality for most of its key variables and representative for its socio-demographic profile and clinical classification. It had a high predictive value positive, and was timely for reporting cases, treatment delivery, and patient’s discharge as treatment completion. Nevertheless, the dermatological and neurological examination introduces complexity to the system, mainly in the most remote areas in the Amazon region where it is difficult to maintain a qualified health workforce. This fact may reflect the irregular data quality related to the evaluation of the disability degree, low representativeness of the system to mild neurological manifestations (grade one disability) and low proportion of household contacts investigated.

The system presented regular flexibility during the transition to a new version of the information system. Although most of the information migrated to the new database, a few variables did not and the analysis of this information can only be done retrospectively using the old database. Moreover, the proportion of grade two disability increased in 2007 because of a typing mistake in coding the disability degree; effects of this fact may still be present, as the grade two disability gradually decreases towards levels reported before 2007.

The system presented good data consistency, except for the number of lesions and the operational classification, as 40% of cases reported with less than 5 lesions were classified as MB. Multibacillary cases presenting with widespread lesions are sometimes reported as a single lesion case. Data consistency was better between the Madrid classification and the MDT regimen compared to the operational classification, questioning the utility of number of lesions to determine MDT. Galvão et al. found similar results in the state of Pernambuco, an endemic area outside the Amazon region in Brazil.\(^21\)

This is the only system capturing leprosy case data in Brazil, and thus it was not possible to assess the system’s sensitivity. However, MDT is dispensed only after filling the leprosy report form; therefore the under reporting of detected cases in Brazil is likely to be very low. The high predictive value positive of the system may be explained by the system’s case definition: a patient presenting skin lesions with abnormal sensitivity can be confirmed as a
new case of leprosy with no additional laboratory test. It is not possible to know if every case reported was investigated with a skin biopsy for a differential diagnosis.

We performed an analysis of representativeness based only in one municipality in the Amazon region and comparing different periods between the study conducted by Aquino et al. and the national database. When interpreting these results, these limitations should be considered since we cannot extrapolate to the whole Amazon region. Nevertheless, it is worth noting that the demographic profile and clinical classification were similar. The only significant difference was the proportion of disability, although there was no difference in the proportion of grade two disability. The higher proportion of disability found by Aquino et al. was probably associated with more accurate assessment of disability degree by researchers. These data suggest that the neurological examinations have not been performed carefully in the Amazon region and the more subtle neurological manifestations are not being detected (Grade I disability), whereas grade two disability is detected because it already presents with clinical deformities. The state leprosy surveillance coordinators mentioned that lack of qualified professional workforce and overload of service work in the health centres as the main obstacles to performing a detailed neurological examination.

The proportion of households contacts investigated was low, 46%, the same proportion found by Galvão et al. in Pernambuco in 2005. The limited priority given to contact examination and lack of active search has already been noted in the Amazon region in the last decades.

This study had limitations; we did the analysis using secondary data from the national database and we could not evaluate their reliability against alternative sources of primary data. Moreover, we did not evaluate the data transferring among the different levels of the surveillance system (municipality, state and MoH). In the evaluation of SINAN performed by Galvão et al. in Pernambuco in 2005, despite the claims of software problems in transferring the data, this could not be confirmed, but memory limitations of computers used at municipal level could be responsible for problems in updating data transferred to states. We did not estimate the costs of the surveillance system because it would involve a much more complex analysis, but the costs are an important feature in a surveillance system evaluation.

In conclusion, the leprosy surveillance system in the Amazon region provides useful information that can guide public health interventions to the effective control of the disease. System limitations were identified and resulted in the following recommendations: (1) strategies should be developed to strengthen household contact investigation; (2) health workers should receive training for the grading of disabilities; and (3) local surveillance teams should be encouraged to timely report defaulters as abandoned treatment in the system. Future evaluations would be helpful for the optimal monitoring in the process of surveillance and leprosy control. More data about the national leprosy surveillance systems are needed in endemic countries, so stakeholders involved in leprosy control worldwide could make valid comparison between country’ indicators.

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Competing interest statement: There were no competing interests.
Authors Contributions
Felipe T M Freitas, Maria A F Grossi and Eduardo M Macário conceived and designed the study. Felipe T M Freitas and Sebastião A S Neto analysed the data. Felipe T M Freitas wrote the paper. Felipe T M Freitas, Maria A F Grossi and Aglaêr A Nóbrega reviewed the paper.

Ethical statement
This study is part of national surveillance routine work and only secondary data were used; no personal identifiers were disclosed. The national law that established the National Surveillance System in Brazil warrants that data collected are used for surveillance purpose only and every patient’s confidentiality is protected.

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References


