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Technical Note nº.10/2007 PNCEH/DEVEP/SVS/MS Preliminary Document

Subject: Indicators for Monitoring the Behavior of Leprosy in Brazil

1. Leprosy control is based on the early diagnosis of cases, its treatment, and cure, aiming at eliminating sources of infection and preventing sequels.
2. The multi-drug therapy (MDT) was introduced in the 1980s and resulted in the cure of many cases under mono-therapy treatment with dapsona since diagnosis. The implementation of the treatment, leading to the discharge of cured patients, who were previously under health care, with a significant reduction of the prevalence of cases under treatment, was the first goal of the leprosy elimination strategy. Cases still pending diagnosis and treatment are, however, chiefly responsible for spreading the disease, and thus control depends on early diagnosis.
3. The key epidemiological indicator for the control of leprosy is the detection coefficient in youth under 15 years of age, which shows the recent strength of transmission and trend. The detection coefficient for all ages is also important, as it expresses the relationship between new cases and the general population, and the cure rate of cases diagnosed, which is the key indicator of the results of control activities.

Detection Coefficient

4. As of 2004, the procedure to calculate the detection coefficient was altered by PNCEH, and began including as new cases of leprosy only those present in the database of the federal government's notifiable diseases information system (Sinan) on January 15th of the following year, instead of March 31st as was previously done. Since the Sinan is not a real time system, it is clear that it is not possible to include all cases diagnosed in the previous year in the database, even dismissing the possibility of problems in the system's operation, such as delay in notification and/or flow of information from the local to the federal level. The operational change introduced a modification in the structure of the historical series producing an artificial drop in the number of new cases detected.
5. The consequence of this decision is the existence of conflicting data in the Ministry of Health's official web pages. For example, due to the continuous input of new cases from the previous year, the SVS database shows the existence of some 51,000 new cases detected in 2004 (2.88 new cases / 10,000 inhabitants), while the RIPSAs shows 38,423 (2.14), which corresponds to the official figure announced and presented as the actual result of leprosy control efforts (graph 1).

It should also be noted that this is the figure used in programming for drugs and the underestimation could lead to shortage of drugs in the following years.

Recommendations

- Use the existing federal-level database on July 31st of the following year to calculate and announce the detection coefficient.
- Use the existing federal-level database on March 31st of the following year to estimate detection data and to send to the WHO in April. The data sent should be recorded as preliminary and, if possible, be followed by an estimate of under-registration¹.
- Leprosy cases can be included in the Sinan only in the first two years after diagnosis².

Rate of cure of new cases diagnosed (indicator of the Pact for Health and the Multi-Year Plan as of 2008)

6. The rate of cure after the first treatment is an indicator of the treatment's effectiveness and of results in leprosy control. This rate should be based on the cohort of new cases diagnosed, since the objective is to ensure timely cure of cases detected; it should also be based on the municipality of residence, because leprosy control is a primary health care activity.

7. Excluding only cases with mistaken diagnoses, the outcome of the treatment should be analyzed in the 12th month after diagnosis for paucibacillary (PB) cases and on the 24th month for multibacillary (MB) cases.

8. The possible outcomes at the time of assessing the treatment results are the following:

- Cure, patients with a medical assessment of disease inactivity after 6 doses taken in up to 9 months for PB patients or 12 doses taken in up to 18 months for MB patients.
- Treatment Completed, patients after 6 doses taken in 9 months for PB or 12 doses taken in 18 months for MB, but who were not assessed for disease activity.
- Death
- Transfer, when it implies in patient leaving scope of responsibility which geographical base defined the cohort.
- Under treatment, patients that restarted the therapy scheme for irregularity and are still under health care.
- Abandonment, patients who did not complete the number of doses in the treatment within the period established and who did not come to the health center in the last 12 months.

Note: cases that returned to the same or to another health center after abandoning the treatment should be notified as *other reentries*.

¹ A study of the time distribution in case entries may produce the estimate of under-registration in the months prior to July 31st, which is recommendable.

² This takes into account that according to data, in a period of two years, over 99% of cases have already been included in the Sinan database, making the cost-benefit of greater accuracy very high.

Prevalence

9. As of 2004, the calculation of punctual prevalence coefficient was modified and began considering cases *under treatment*, which included only PB patients with up to 6 months and MB patients with up to 12 months, counting from the date of diagnosis. This criterion excluded from prevalence all PB and MB patients under treatment with over 6 and 12 months respectively; cases that restarted treatment; cases under treatment with alternative schemes; and cases *in abandonment* of treatment, before meeting the criteria for *administrative exit*. This change resulted in the reduction of prevalence from 4.52 (2003) to 1.59 (2004).

10. The punctual prevalence of cases under treatment is an indicator that undergoes operational influences and is largely modified by changes like, for example, the duration of treatment. The detection coefficient and the outcomes of cohorts in cases diagnosed show more clearly the endemic situation and the effectiveness of treatment, making punctual prevalence a dispensable indicator to assess these aspects. It is, however, useful simply to estimate the average duration of treatment, that is, how much time the patient remains under health care for the specific treatment, by dividing the number of prevalent cases by the number of cases detected.

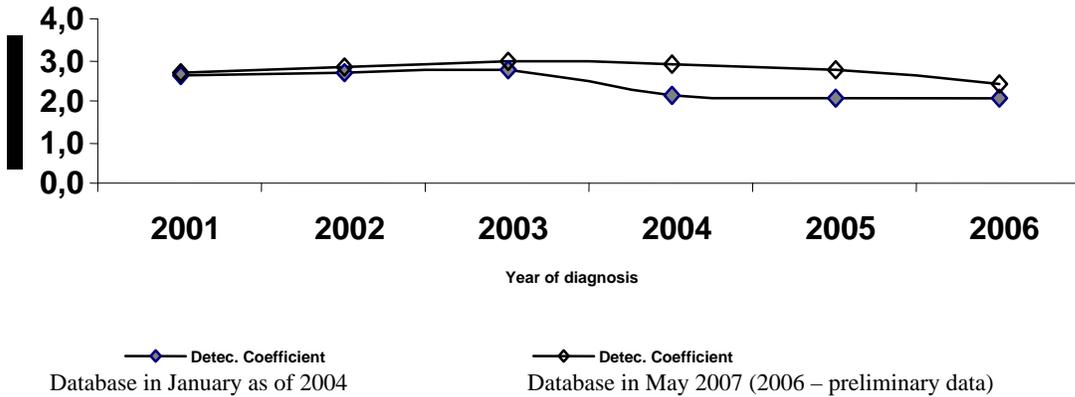
11. In this sense, the prevalence indicator will be considered a secondary or complementary one, in order to attend special or external evaluation and to compare with other countries or the regions. Therefore, the elimination term linked to the elimination target will be not adequate to nominate the programme. In this sense it will be called the National Hansen's Disease Control Programme.

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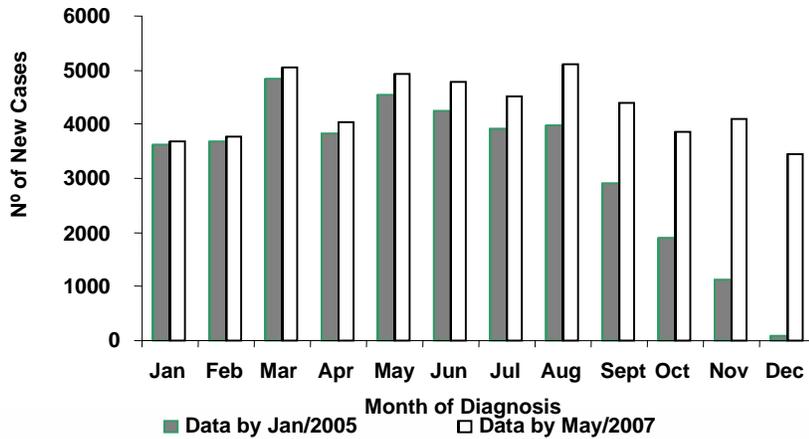
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Document prepared by the work groups meeting in Brasília and Fortaleza (May/07) and approved by the National Health Surveillance System's Monitoring and Assessment Committee on June 18th, 2007.

Graph 1 – Leprosy detection coefficient per 10,000 inhabitants – new cases registered in the Sinan, Brazil, 2001 to 2006



**New leprosy cases registered in the Sinan, per month of diagnosis, 2004, Brazil
Comparison of Sinan databases updated in January 2005 and in May 2007**



Brasília, 21 de agosto de 2007.

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Aprovo o parecer técnico.
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