

## EVALUATION OF THE IMPORTANCE OF RAPID TESTS IN THE EARLY DIAGNOSIS OF LEPROSY AND THEIR ROLE IN PROMOTING PUBLIC HEALTH

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**Abstract: INTRODUCTION:** Leprosy still represents a serious public health problem in Brazil and the delay in detection can be attributed to the lack of diagnostic capacity and the absence of rapid tests. With this, Brazil became the first country to incorporate the rapid immunochromatographic test into the Unified Health System (SUS) for the early detection of leprosy – technology that plays a crucial role in promoting health, reducing the burden of the disease in the community, preventing disabilities and improving the quality of life of affected patients. This study aims to discuss the main scientific evidence about the importance of early detection of leprosy and the impact of rapid tests on the current epidemiological scenario of the disease. **METHODS:** This integrative review was based on 13 studies on the importance of rapid tests in the early diagnosis of Leprosy. The PICO strategy was used to construct the research question and articles were selected from databases such as MEDLINE/PubMed, SCIELO and LILACS. **RESULTS:** To advance the fight and achieve the global strategy towards zero leprosy, it is necessary to invest and advance in research and distribution of rapid tests, overcome infrastructural obstacles, in addition to improving the quality of clinical services for diagnosis and monitoring of leprosy complications. illness. Furthermore, psychological support for affected people and families is essential, ensuring their longitudinal approach. **CONCLUSION:** In short, this review highlights the persistence of leprosy in developing countries, identifying a succession of failures in the process of combating this disease. This way, the relevance of early diagnosis and the importance of implementing rapid testing in this investigation and reducing the burden of the disease in the community were highlighted.

**Keywords:** leprosy; rapid tests; early detection; epidemiology.

## INTRODUCTION

Leprosy, known in religious narratives as leprosy, is a chronic and infectious disease, caused by *Mycobacterium leprae*, transmitted by droplets from the nose and mouth during close and prolonged contact in untreated leprosy patients (BRASIL, 2017). With this, it is important to highlight that, in the period from 2017 to 2021, 119,698 new cases of leprosy were diagnosed in Brazil – in addition to preliminary data from 2022, which demonstrated that Brazil diagnosed 14,962 new cases of leprosy, of which 645 (4.3 %) in children under 15 years of age (BRASIL, 2023).

In this context, it is worth noting that this disease is part of the list of neglected diseases, representing a serious public health problem, being associated with low socioeconomic status (BRASIL, 2021). It is worth noting that leprosy is endemic in 127 countries, in which Brazil is the country with the 2nd highest number of cases in the world, behind only India, revealing a high burden of the disease (BRASIL, 2021). From this perspective, it is important to highlight that its incubation period can vary from two to seven years, which, in most cases, compromises early diagnosis, and, when manifested, mainly affects the skin and peripheral nerves (BRASIL, 2009). Furthermore, if not treated in its initial form, it becomes transmissible, affecting people of any sex or age and can lead to sometimes irreversible physical disabilities (BRASIL, 2017). Based on the historical roots of the disease's stigma, the presence of injuries, in addition to making work activities difficult, also leads to restrictions in the personal, family and social spheres.

The diagnosis of leprosy cases is essentially clinical and epidemiological, carried out through anamnesis, general dermatological and neurological examination to identify lesions or areas of skin with altered sensitivity,

motor, autonomic or involvement of peripheral nerves (SILVA; SOUSA; MOURA, 2022). Furthermore, the delay in detection is also evidenced by the exponential proportion of new cases and the causes may include lack of capacity to diagnose, the absence of technologies such as a rapid test to detect the infection early and the population's lack of knowledge regarding the signs and symptoms.

Furthermore, Brazil is the first country in the world to incorporate, into the Unified Health System, a rapid test for early detection of leprosy – in accordance with Ordinance No. 189, published by the Ministry of Health (BRASIL, 2022). Under this analysis, the implementation of rapid tests in the diagnosis of leprosy plays a crucial role in promoting public health, since, by speeding up diagnosis and treatment, it is possible to reduce the burden of the disease in the community, prevent disabilities and improve health quality of life of affected patients.

## METHODOLOGY

The study is an integrative review in which the PICO strategy (Souza et al., 2010) was used to construct the research question. Thus, the first element (P = population) was limited to patients with leprosy, the second element (I = intervention) corresponded to the diagnosis of leprosy by rapid test, the third element (C = control) was composed of patients diagnosed late diagnosis of leprosy and the fourth element (O = outcome) aimed to evaluate the relevance of rapid tests in the early diagnosis of leprosy. The research question established “What is the importance of rapid tests in the early diagnosis of Leprosy?” was used to guide the search for articles and to structure a clear and specific research objective. This study aims to discuss the main scientific evidence about the impact of rapid tests on the current epidemiological scenario of leprosy.

The research was carried out through an electronic search for articles in the USA National Library of Medicine (MEDLINE/PubMed), Scientific Electronic Library Online (SCIELO) and Latin American and Caribbean Literature in Health Sciences (LILACS) databases. The descriptors used, associated with Boolean operators, were: (serologic test OR serological test AND leprosy) and (late diagnosis OR delayed diagnosis AND leprosy AND epidemiology).

As inclusion criteria, articles available in full were selected, published between 2019 and 2023, in English or Portuguese and that addressed the guiding question defined in this review. As exclusion criteria, duplicate articles and those that did not meet the inclusion criteria were defined. The selection of articles was represented in the flowchart in Figure 1.

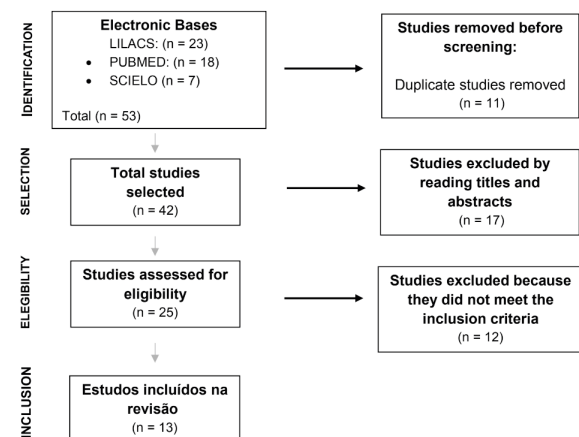


Figure 1. Flowchart for articles selected for the integrative review

Source: Authors (2023)

## RESULTS AND DISCUSSION

The epidemiology of leprosy indicates a slight reduction in the overall detection rate of the disease in the years evaluated from 2012 to 2021, with 2021 having the lowest percentage of new cases of this disease, which may be related to the effects of COVID 19, as there was an overload of health services due to the pandemic (BRAZIL 2023). This decreasing

trend in the general detection of Leprosy was also evidenced in previous years in the Northeast, from 2001 to 2015 (Leano, 2019), and in Goiás, from 2006 to 2015 (Silva et al., 2020). Furthermore, despite this reduction, other indicators point to the persistence of transmission of the bacillus, late diagnoses and underreporting of Leprosy cases (Leano, 2019). In line with these other results, *M. leprae* infection remains endemic in several regions in Brazil, constituting a serious public health problem, as it affects a wide variety of people (BRASIL, 2023).

Analyzing the epidemiological profile of leprosy in the regions of Brazil, the majority of leprosy diagnoses fell on males, individuals who identified themselves as belonging to the brown race/color, in the economically active age group and with up to eight years of schooling (Ferreira et al., 2020; Lanza et al., 2022; Santos et al., 2020). Furthermore, the results indicate greater vulnerability in children aged between 8 and 14 years, associating it with precarious housing conditions, with the increase in cases in a younger age group suggesting a greater prevalence of *M. Leprae*, as it highlights the transmission of the disease in all age groups (Rodrigues et al., 2020; Araújo et al., 2020). According to Montanha et al. (2023) and Rodrigues et al. (2020), the occurrence of leprosy is closely related to unfavorable socioeconomic factors, precarious living conditions and waste disposal. This is due to the fact that people with limited resources often face challenges when seeking access to appropriate healthcare. Furthermore, crowding in overpopulated environments and malnutrition, which often accompanies scarcity of financial resources, increase the organism's vulnerability to *M. leprae* infection (Lanza et al., 2022). This information is in line with studies that pointed out that personal factors associated with late diagnosis of leprosy include advanced age, multibacillary

Author	Title	Goal	Main results
Leandro, 2019.	Epidemiological analysis of leprosy in the Brazilian Northeast: individual, programmatic and social vulnerability	Analyze the epidemiological behavior of leprosy in the Northeast	Northeast presents a decreasing annual trend for general detection, but stationary for children under 15 years of age
Silva et al., 2020	Epidemiological trends of leprosy in Goiás, Brasil	Analyze the temporal trends of leprosy indicators in Goiás between 2006 and 2015	Significant downward trend for the detection coefficient, increase in cases of patients with physical disabilities in almost all macro-regions of the state and increase in cases in patients under 14 years of age
Ferreira et al., 2020	Leprosy in the North and Northeast regions of Brazil: an integrated spatiotemporal approach	Analyze spatio-temporal patterns of Leprosy occurrence in the North and Northeast regions of Brazil between 2001 and 2017	Of the 396,987 cases, 9.2% were children under 15 years of age, 5.4% individuals had grade 2 disability and the majority of cases were men aged 15 to 59, mixed race/black
Rodrigues et al., 2020	Factors associated with leprosy in children contacts of notified adults in an endemic region of Midwest Brazil	To analyze the factors associated with leprosy in children and household contacts of adults reported with the disease in an endemic municipality, Mato Grosso, Brazil.	The associated factors were: age, area of residence, waste destination, family history of the disease and length of residence.
Araújo et al., 2020	Hanseniasis in the municipality of Western Amazon (Acre, Brazil): are we far from the goal of the World Health Organization? Hansen and Western Amazon	To analyze the epidemiological profile and trends of leprosy between 2005 and 2018 in the city of Cruzeiro do Sul, Acre, Brazil.	Reduction in the detection rate of new cases among children under 15 years of age and stable trend in the proportion of new cases with grade 2 disability
Lanza et al., 2022	Epidemiological profile of leprosy in the municipality of Divinópolis, Minas Gerais, 2011 to 2019	To analyze the epidemiological profile of leprosy in the municipality of Divinópolis, Minas Gerais, between 2011 and 2019.	Of the 57 cases reported, all were in people over 20 years of age, the majority were men (50.9%), mixed race (49.1%), with incomplete primary education (26.3%) and 7% of cases had a high school diploma. 2 of physical disability
Santos et al., 2020	Clinical-epidemiological profile of leprosy in a hyperendemic municipality	Characterize the clinical and epidemiological profile of leprosy cases in the hyperendemic municipality of São Luís do Maranhão, Brazil.	Of the 2,166 reported cases, a higher frequency was observed in females (53.4%) and in the 15-59 age group (69.4%), 32% had some degree of disability
Amaral et al., 2023	Factors associated with delayed diagnosis in people with leprosy in primary health care: an integrative review	Identify the factors involved in late diagnosis in people with leprosy in PHC, from the perspective of current literature.	The fragility of the professional body in relation to the management of leprosy and the population's lack of knowledge regarding the signs and symptoms are factors linked to the process of delay in diagnosis
Lima et al., 2021	Therapeutic itinerary of people with leprosy: paths, struggles, and challenges in the search for struggles and challenges in search of care	Understand how the therapeutic itineraries of people affected by leprosy are processed	Leprosy control actions require reformulations that look for risk factors
Francisco et al., 2019	Estimates of the hidden prevalence of leprosy in a municipality in the State of São Paulo	Analyze the leprosy situation in a municipality in the interior of the State of São Paulo in light of the global situation and calculate the hidden prevalence.	A high rate of people diagnosed with leprosy with some physical disability was identified, as well as multibacillary cases, and a hidden prevalence of 23.90 cases per 10,000 inhabitants.

Montanha et al., 2023	ML Flow serological test: complementary tool in leprosy	Correlate the results of the ML Flow test with the clinical characteristics of the patients, evaluate their positivity in household contacts and describe the epidemiological profile of both.	The ML Flow test can speed up diagnosis, helping to prevent the physical disabilities still observed in people affected by leprosy in this region.
Silva et al., 2022	The use of the ML flow test between newly diagnostic leprosy cases and in-home contacts	Identify the ML Flow test result among newly diagnosed leprosy cases and household contacts.	Of the 38 newly diagnosed cases, the ML Flow test was negative in 7 of the 8 paucibacillary cases and positive in 21 of the 30 multibacillary cases, both in agreement with the smear microscopy of the intradermal scraping. 30 positive cases were also identified among the 324 household contacts at high risk of becoming ill.
Froes et al., 2022	Leprosy: clinical and immunopathological characteristics	Discuss immunological responses involved in each leprosy presentation	Multibacillary individuals produce large quantities of anti-PGL-1 IgM antibodies in quantities proportional to the bacterial load, suggesting the usefulness of positive serology for the diagnosis of early suspected multibacillary cases.

clinical presentation, male sex and lack of knowledge about the symptoms of the disease (Lanza et al., 2022).

In this discursive aspect, leprosy is a disease that presents significant obstacles in its diagnosis, treatment and prevention, corroborating negative impacts on public health (BRASIL, 2021). The complexity of the symptoms, as well as the lack of effective diagnostic methods, result in many patients only receiving adequate treatment when the disease is already in its most advanced stage (Lima et al., 2021). Furthermore, the population's lack of knowledge about the signs and symptoms of the disease is another obstacle to interrupting the transmission of the disease and early diagnosis (Amaral et al., 2023). In line with this reality, the lack of training of health professionals compromises the early and reliable diagnosis of leprosy, leading to underdiagnosis of the disease (Amaral et al., 2023; Lanza et al., 2022). For example, when characterizing the clinical and epidemiological profile of leprosy cases in the hyperendemic municipality of São Luís do Maranhão, in Brazil, it was found that the diagnosis of leprosy was being made late due to the detection of the multibacillary

classification and dimorphic clinical form, in addition the presence of physical disability of the patient at the time of clinical assessment (Santos et al., 2020). It must be added that there is still a stable trend of new cases with grade 2 physical disability (Araújo et al., 2020).

Furthermore, one of the problems is the spread of leprosy to children and adolescents under 15 years of age. The prevalence of leprosy at this age indicates active transmission and early exposure to the bacillus, being considered a consequence of the late diagnosis of this disease (Araújo et al., 2020; Santos et al., 2020). This occurrence may be related to the immunopathological response of individuals, genetic factors and the long incubation period, as these people have direct contact with infected patients. (Santos et al., 2020). Therefore, when analyzing the temporal trends of leprosy indicators in endemic regions in Brazil, a worse epidemiological situation is perceived due to the prevalence of cases of patients under 15 years of age and an increase in patients with physical disabilities (Leano, 2019; Silva et al., 2020).

In line with this reality, the design of health technologies is related to health promotion, prevention and treatment of

diseases, combined with the rehabilitation of people, including the provision of medicines, equipment, procedures and organizational and support systems through of which health care and attention are provided to the population (WHO, 2021). In this sense, investment in actions aimed at early diagnosis and protection of populations at risk becomes essential to meet the WHO Global Strategy for Leprosy 2021–2030, which reflects the need to provide a change in the global epidemiological picture, in order to outline a strategy aimed at interrupting transmission and obtaining zero indigenous cases.

From this perspective, when analyzing the available technologies, it was possible to realize that the implementation of the rapid immunochromatographic test for the qualitative determination of IgM anti *Mycobacterium leprae* antibodies in the complementary diagnosis of Leprosy in the SUS (Unified Health System) helps to reduce the time between the appearance of symptoms and the beginning of treatment, in order to reduce the risk of permanent disabilities and the spread of the disease. Among the serological tests available, ML Flow is considered a quick, individual, easy-to-perform test, with sensitivity and specificity similar to ELISA, in addition to providing a better cost-benefit ratio (Montanha et al., 2023).

Added to this, it is understood that the use of sensitive techniques, such as ML Flow, makes it possible to detect the presence of antibodies against the *M. leprae* specific antigen (PGL-I) in a less invasive way compared to sputum smear microscopy. intradermal smear, providing less discomfort to the patient (Francisco et al., 2019). Furthermore, according to Montanha et al. (2023), when comparing the results of sputum smear microscopy and the ML Flow test, there was an agreement of 75% between the positives and 100% between the

negatives, with these results being considered satisfactory and promising for the rapid test.

From this perspective, it is known that leprosy is classified as paucibacillary (PB), with the existence of up to five skin lesions with negative intradermal scraping smear microscopy, or multibacillary (MB), with the presence of six or more skin lesions or smear microscopy of positive intradermal scraping, the latter being considered the transmissible form of the disease, in addition to having the potential to cause greater damage (BRASIL, 2017). Multibacillary individuals produce large quantities of anti-PGL-1 IgM antibodies in an amount proportional to the bacterial load, suggesting the usefulness of positive serology for the diagnosis of early suspected multibacillary cases (Froes Junior, 2022). This way, the relevance of ML Flow can be seen once again, since Montanha et al. (2023) and Francisco et al. (2019) point out that the test demonstrates greater sensitivity in detecting MB cases, therefore enabling the reduction of transmissibility and worsening of the disease. Accordingly, its applicability is reiterated by its low cost, thus enabling its wide distribution by the SUS (Unified Health System), especially to the neediest regions.

## CONCLUSION

This review highlights the persistence of leprosy in developing countries, identifying a succession of failures in the process of combating this disease – thus causing a significant challenge for public health. Its persistent prevalence, especially in areas with unfavorable socioeconomic conditions, highlights the continued need for effective prevention, diagnosis and treatment strategies. This way, the relevance of early diagnosis and the importance of implementing rapid testing in this investigation and reducing the burden of the disease in the community were highlighted.

In this context, the incorporation of diagnostic technologies by the Brazilian Unified Health System (SUS), such as the ML Flow rapid immunochromatographic test, is a crucial advance for the development of public health. This implementation helps to reduce the time between the appearance of symptoms and the start of treatment, minimizing the risk of permanent disabilities and the spread of the disease. Furthermore, ML Flow proved to be an accessible and effective tool for detecting multibacillary cases, which are the most worrying types in terms of transmission and worsening of the disease.

In view of the above, when considering the exponential growth that the disease has been presenting, it is necessary to direct

resources and investments to carry out effective planning, in order to expand the mass implementation of rapid testing in Basic Health Units, aiming to prevent, respectively, the worsening and spread of leprosy.

Leprosy therefore continues to be a neglected disease, affecting not only physical health, but also the family, personal and social spheres of patients. To effectively combat this disease, a multidisciplinary approach that includes early diagnosis, effective treatment, public education and actions to reduce socioeconomic disparities is crucial. Only with coordinated efforts and continuous investments can we aim for a society free from leprosy and its debilitating consequences.

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