



## CUTANEOUS LEISHMANIASIS: URGENT NEED TO DEVELOP MORE EFFECTIVE AND USER-FRIENDLY POINT-OF-CARE DIAGNOSTIC TOOLS

Leishmaniasis is a complex vector-borne disease involving in its transmission several species of protozoan parasites called *Leishmania*, a wide variety of animal reservoirs and phlebotomine sandflies vectors. Cutaneous Leishmaniasis (CL) is the most common form of the disease, and its clinical manifestations vary from few papules to multiple ulcers affecting the skin but also the mucous membranes, leaving permanent scars and serious disability. It is a disfiguring and stigmatizing disease that often has a devastating psychosocial and economic impact on the affected resources limited communities.

An estimated 600,000 to 1 million new cases occur every year in approximately 90 countries around the world and more than 1 billion people are at risk of infection. In 2020 over 85% of new CL cases occurred in 10 countries: Afghanistan, Algeria, Brazil, Colombia, Iraq, Libya, Pakistan, Peru, the Syrian Arab Republic and Tunisia<sup>1</sup>.

Diagnosis is one of the major challenges for the control of the disease as public health problem. The availability of CL diagnostic tools is critical for reaching the targets set for CL in the WHO Roadmap for NTDs, 2021-2030, that 85% of all CL cases are detected and 95% of reported cases are treated<sup>2</sup>.

Traditional methods, i.e detection of *Leishmania* by direct microscopy, remain the reference standard in diagnosis of CL and is often the only available method in endemic areas. Though highly specific, its sensitivity varies depending on multiple factors such as type of parasite causing the lesion, duration of the lesion, procedure used for sample collection, and examiner. Therefore, in many places diagnosis is made based only on clinical and epidemiological criteria. Other diagnosis methods like culture of *Leishmania* parasites or molecular diagnosis (PCR-based methods) are costly, technically demanding, and done only in specialized facilities.

Simpler tests for detection of leishmanial DNA, that are easy to use and require limited infrastructure, such as Loop-mediated Isothermal Amplification (LAMP) tests, are yet to be

---

<sup>1</sup> <https://www.who.int/news-room/fact-sheets/detail/leishmaniasis>

<sup>2</sup> Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240010352>



implemented. Rapid immunochromatography tests that detects *Leishmania* antigens are other potential candidates. Currently, the only rapid diagnostic test available is CL Detect™ (InBios International Inc., Seattle, WA, USA), however its sensitivity varies greatly across regions, limiting its use and adoption.

The lack of appropriate tools for CL diagnosis results in delayed diagnosis and treatment with increasing risk of morbidity for the patients. Therefore, the development of effective rapid diagnostic tools, easy to use at community level, from samples collected in a minimally invasive way, is a gap that needs to be addressed urgently.

To guide the development of rapid diagnostic tools, the Foundation for Innovative New Diagnostics (FIND), together with experts from endemic regions, proposed a Target-Product-Profile (TPP), establishing the requirements for a point-of care diagnostic test for early diagnosis of dermal leishmaniasis (including CL and PKDL)<sup>3</sup>, this TPP has been reviewed recently and endorsed by the WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases<sup>4</sup>.

Nevertheless, adequate investments are cruelly lacking: according to G-Finder report, in 2020 only 0.1 million US\$ were invested in diagnosis for leishmaniasis, representing less than 0.5% of the total funding for the disease (45 M US\$)<sup>5</sup>.

Acknowledging these challenges, the investigators present at the 6<sup>th</sup> redeLEISH meeting that took place during the WorldLeish 7 Congress, in Cartagena das Índias, Colombia, on August 3<sup>rd</sup>, agreed that, in line with critical actions for CL of the WHO-NTD Roadmap 2030, there is an urgent need to:

1. Adopt and disseminate the TPP concept as a guide for structuring technological development and incorporation of new, rapid, non-invasive, easy to use and affordable diagnostic tests for CL;
2. Increase incentive and funding for all stages of development, validation, production and implementation of new diagnostic tests for LC, as a priority action, in line with the requirements agreed upon in the TPP;
3. Enhance commitment and concerted efforts of the different stakeholders (scientific community, governments, research funding agencies) to a common strategic agenda

<sup>3</sup> Israel Cruz, Audrey Albertini, Mady Barbeitas, Byron Arana, Albert Picado, Jose A. Ruiz-Postigo, Joseph M. Ndung'u, Target Product Profile for a point-of-care diagnostic test for dermal leishmaniasis, *Parasite Epidemiology and Control*, Volume 5, 2019, e00103, ISSN 2405-6731, <https://doi.org/10.1016/j.parepi.2019.e00103>.

<sup>4</sup> <https://www.who.int/publications/i/item/9789240045224>



aiming at enabling successive stages of development, validation in real-world conditions, production and implementation of new adequate diagnostic tools for CL;

4. Encourage initiatives for a better access of the patients with CL to early diagnosis and treatment.

In view of the enormous challenge that contrasts with the limited resources, the participants in the meeting expressed their commitment to make all efforts to contribute to the improvement in the diagnostic approach for CL, supporting and encouraging the priority strategies defined above.

Cartagena de Indias, August 3<sup>rd</sup> 2022