

Using a Consensus Technique for Improving the Methodology of Clinical Trials Assessing Treatments for Cutaneous Leishmaniasis



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Cutaneous Leishmaniasis (CL) :

- Most common of three forms of Leishmaniasis caused by the protozoan *Leishmania* parasites, which are transmitted by the bite of infected sandflies.
- Causes lesions on exposed parts of the body, which will potentially leave life-long scars.
- Approximately 95% of CL cases occur in the Americas, the Mediterranean basin, and the Middle East and Central Asia, and over two-third of new CL cases occur in six countries: Afghanistan, Algeria, Brazil, Colombia, the Islamic Republic of Iran and the Syrian Arab Republic^{1,7} (Fig. 2).
- An estimated 0.7 million to 1.3 million new cases occur worldwide annually⁸.

Recommendations on the treatment of CL currently have a weak evidence base:

- Treatment options are limited and potentially toxic.
- Cochrane Collaboration Systematic Reviews have pointed to a general poor quality and lack of methodological standardization in the conduct and analysis of clinical trials of CL interventions^{2,3,6}.
- In order for both current and newer treatments to be adequately assessed, standardised methodologies are needed which can be applied generally, while at the same time allowing the flexibility required to cover the diverse disease manifestations.

A first guidance document on the methodology of clinical trials assessing CL interventions was developed and published⁵ and will provide the basis for further refinement.

The aim of this project is to engage with stakeholders in order to agree on key methodological questions regarding whom to treat and how to measure treatment effects, so that results can later be shared and combined for meta-analysis so as to generate a robust evidence-base for treatment recommendations and policy decisions.

Stakeholders are:

- Researchers
- Health care providers (nurses and physicians) treating CL patients
- CL patients

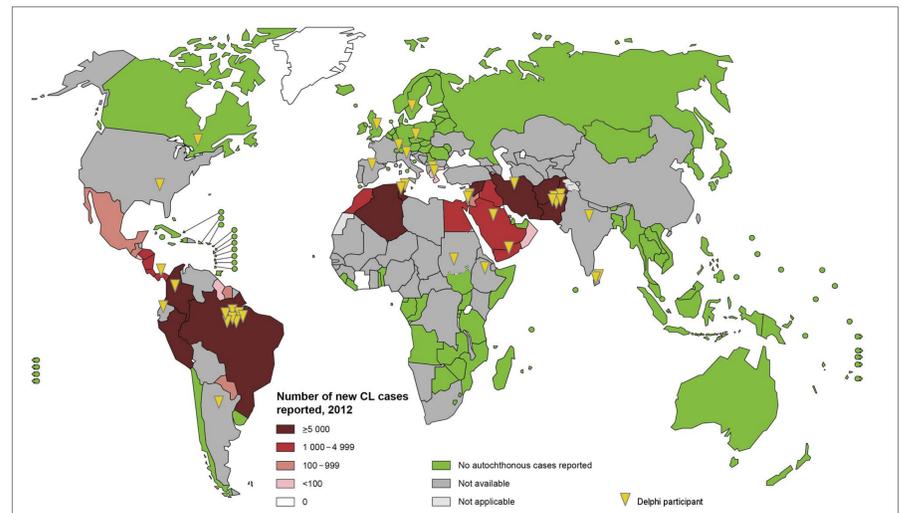


Fig. 2 Status of endemicity of cutaneous leishmaniasis worldwide (2012), and origin of Delphi participants (modified from 7)

The main questions that this study tries to answer are:

- Who should be treated/wants to be treated? (Eligibility criteria)
- What are the outcomes that we want to see/experience or not to see/suffer from? (Outcome measures)

Study design: A mixed-methods study, using a Delphi consensus technique for expert consultation, and integrating patient interviews (Fig. 1):

1. Delphi consensus technique (online):

- Anonymous, structured communication technique using 3 rounds of questionnaires
- Separate but converging questionnaires for researchers (clinical trial context) and nurses/doctors (treatment context), intended to cover all *Leishmania* species
- Participants are given the chance to modify own response from previous round in view of group's response
- So far, around 40 participants worldwide, most from CL endemic countries, have agreed to contribute to the study (Fig. 2).

2. Patient interviews:

- Conducted by 6 selected panellists, around 10 patients each
- Intended to cover specific *Leishmania* species: *L. (Viannia) braziliensis*, *L. panamensis*, *L. tropica* and *L. major*, and a broad patient spectrum
- Training in qualitative research techniques and grants will be provided
- Thematic analysis of interviews to obtain eligibility criteria and outcomes important from a patient perspective

Currently, the Call for Expression of Interest is available in English (http://www.who.int/entity/tdr/grants/CL_Call_for_Expression_of_Interest.pdf?ua=1), as well as translations into Spanish, Arabic, Farsi/Dari and Turkish. Participation in the survey is also offered in these languages or nurses and doctors.

Aim:

At the end, we hope to achieve a certain degree of consensus regarding eligibility criteria and outcomes for CL intervention trials amongst stakeholders.

The Global Health Network (www.tghn.org) is an online science park that allows researchers to work together without geographical, institutional or financial barriers.

The Global NTD Research platform (www.globalntdresearch.tghn.org) within The Global Health Network is a dedicated web space for research collaborations in Neglected Tropical Diseases.

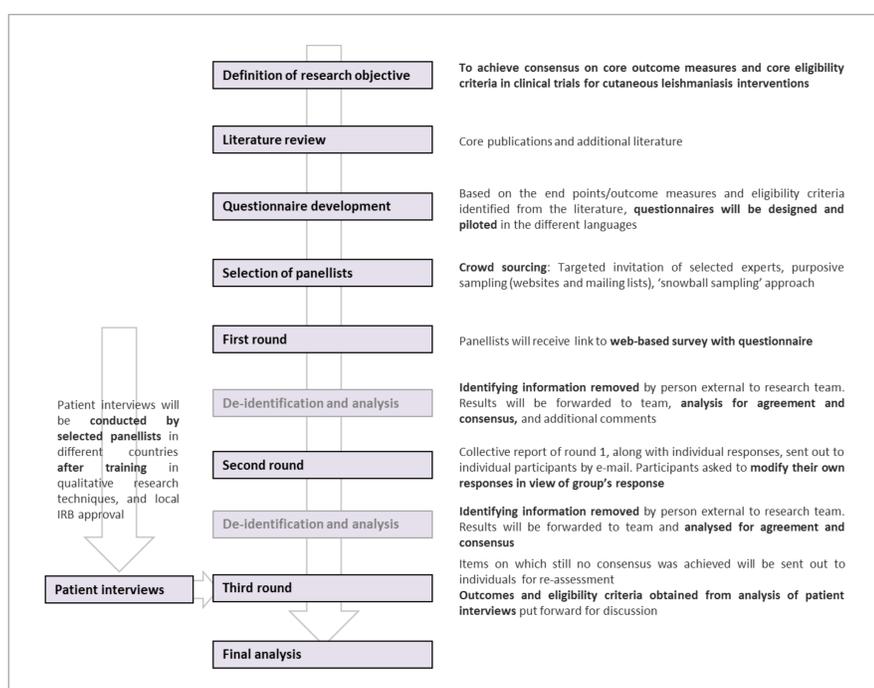


Fig. 1 Overall process: Delphi consensus technique with patient interviews (modified from 9)

Are you a researcher or health care provider (doctor or nurse) working on cutaneous leishmaniasis (CL) or seeing CL patients?

If yes, Are you interested in joining a collaborative initiative on CL clinical trial methodology to improve the way treatments for CL are tested?

Cutaneous Leishmaniasis (CL) will be used as a case-study to assess whether key stakeholders can be identified and encouraged to participate in consensus building to answer key questions regarding clinical trial methodology using an innovative, participatory approach. The stakeholder groups that are targeted are researchers and health care providers (doctors and nurses) as well as patients.

This project is designed as a proof-of-concept towards a broader coverage of clinical trial methodological questions using expert consensus methods.



www.who.int/entity/tdr/grants/CL_Call_for_Expression_of_Interest.pdf?ua=1