Review

# Ethical considerations in research during visceral leishmaniasis outbreaks in low- and middle-income countries: a narrative review

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### Ethical considerations in research during visceral leishmaniasis outbreaks in low- and middle-income countries: a narrative review

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## Abstract

*Visceral leishmaniasis (VL) is a neglected tropical disease with significant public health implications, especially in low- and middle-income countries (LMICs). Ethical challenges often emerge during outbreak research in such settings, where limited resources, power imbalances, and cultural differences complicate decision-making. Despite increased research interest, there is limited synthesis on how to ethically navigate VL outbreaks in LMICs. A systematic review was conducted using PRISMA guidelines to identify literature published between 2019 and 2024 that addressed ethical dimensions of VL research in LMICs. Databases searched included PubMed, Scopus, and Web of Science. Articles were selected based on inclusion criteria emphasizing ethical challenges, stakeholder perspectives, and research conduct in outbreak settings. Thematic analysis was employed to identify recurrent ethical concerns and proposed strategies. Fifty-four articles met the inclusion criteria. The major ethical themes identified included informed consent in emergency contexts, community engagement, fair participant selection, risk-benefit analysis, and data sharing. Several studies emphasized the need for context-specific ethical frameworks and culturally grounded approaches to stakeholder engagement. Resource constraints and weak regulatory oversight were also cited as compounding ethical risks. Addressing ethical challenges in VL research requires a proactive, inclusive approach grounded in local realities. Strengthening research ethics capacity, fostering community trust, and integrating ethical preparedness into outbreak response plans are essential. A tailored ethical framework could significantly improve both the quality and acceptability of VL outbreak research in LMICs.*

## Introduction

Visceral leishmaniasis (VL), also known as kala-azar, is a vector-borne parasitic disease that remains a significant public health challenge in low- and middle-income countries (LMICs). Caused by the leishmania donovani complex and transmitted by infected phlebotomine sandflies, VL is characterized by prolonged fever, hepatosplenomegaly, weight loss, and anemia. Without treatment, it has a case fatality rate of over 90% [1]. Endemic regions include South Asia, East Africa, and parts of Latin America, where the disease disproportionately affects impoverished and marginalized populations [2]. Outbreaks of VL are often exacerbated by fragile health systems, displacement, and poor infrastructure. Research during these outbreaks is essential to advancing diagnostics, therapeutics, and vector control interventions. Notably, VL outbreak research has contributed to innovations such as shorter treatment regimens and liposomal amphotericin B therapy [3,4]. However, the urgency of outbreak response introduces complex ethical challenges, particularly in settings marked by low literacy, linguistic diversity, and limited regulatory oversight.

In LMICs, ethical risks are heightened by the vulnerability of participants, weak research ethics capacity, and limited access to post-trial benefits. Challenges include obtaining valid informed consent, ensuring equitable community engagement, and safeguarding data governance. In outbreak contexts, participants may struggle to distinguish between research and clinical care, a phenomenon known as therapeutic misconception [5]. Standard consent processes often fail when time is short, or when participants are unfamiliar with biomedical research protocols [2]. Community engagement is crucial but frequently neglected. Ethical frameworks emphasize the importance of trust, participatory decision-making, and respect for local norms [6]. Where engagement has been prioritized-such as in India and Ethiopia-research outcomes have shown improved community participation and greater social acceptability [3,7].

Another pressing issue is post-trial access to beneficial interventions. Although international guidelines, including the Declaration of Helsinki and CIOMS 2016, mandate continued access to effective treatments, implementation in resource-constrained settings is inconsistent [5]. Studies show that unless built into trial design, sustainable access to new tools remains elusive [8]. Moreover, ethical oversight mechanisms in many LMICs remain under-resourced. During emergencies, local ethics review boards (ERBs) may lack the capacity to conduct timely reviews or apply outbreak-specific considerations. This has prompted calls for emergency review protocols and regional ethics networks to bolster responsiveness [7,9]. Given these concerns, it is imperative to analyze and synthesize the ethical dimensions of VL research during outbreaks in LMICs. This review focuses on informed consent, community engagement, post-trial obligations, data equity, and the strengthening of local ethics infrastructures. Through this lens, the paper aims to provide practical and context-sensitive recommendations that align with global standards while addressing the unique realities of outbreak-prone LMIC settings (Figure 1).

## Methods

**Study design:** this study employed a structured narrative review methodology to synthesize literature on ethical considerations in conducting research during visceral leishmaniasis (VL) outbreaks in LMICs. The review included peer-reviewed publications, global and national ethical guidelines, institutional reports, and case studies relevant to the topic (Figure 2).

**Source of information and search strategy:** relevant literature was identified through electronic databases including PubMed, Scopus, Web of Science, and Google Scholar. Grey literature was also included, drawing on sources such as WHO publications, CIOMS guidelines, Médecins Sans Frontières (MSF) field reports, and DNDi case documents. The search used keyword combinations such as “visceral leishmaniasis,” “ethics,” “outbreak research,” “LMICs,” “informed consent,” “community engagement,” “post-trial access,” “data sharing,” and “research oversight.” Articles published between 2000 and 2024 were considered.

**Inclusion criteria:** publications that discuss ethical dimensions of biomedical or public health research conducted during VL outbreaks. Studies or reports based in LMIC contexts as defined by the World Bank. Documents published in English.

**Exclusion criteria:** articles focused solely on clinical treatment without ethical discussion; non-human studies; commentaries lacking substantive ethical content.

**Selection of studies:** an initial pool of publications was generated from database and grey literature searches. Titles and abstracts were screened, and full-text articles meeting the inclusion criteria were reviewed independently by two researchers. Discrepancies were resolved through consensus.

**Quality appraisal:** studies were appraised for relevance, clarity of ethical discussion, contextual specificity, and contribution to ethical debate in outbreak research. Considerations included transparency in reporting, inclusion of LMIC perspectives, and alignment with international ethical guidance.

**Ethical considerations:** as this review is based on publicly accessible literature, formal ethical approval was not required. Nonetheless, all analyses were conducted in line with ethical research standards, ensuring accuracy and acknowledgment of all sources (Figure 3).

## Results

The thematic analysis of 54 articles and reports yielded six core ethical domains. A total of 54 studies published between 2000 and 2025 were included in the final synthesis. The majority were conducted in East Africa (Ethiopia, South Sudan, Sudan), South Asia (India, Bangladesh, Nepal), and Brazil. These studies comprised empirical research, ethical guidelines, implementation reports, and conceptual analyses focusing on ethical issues during visceral leishmaniasis (VL) outbreak research in LMICs. Study designs included observational research, randomized trials, and qualitative studies, often embedded within humanitarian response frameworks. Common themes spanned from participant vulnerability to institutional preparedness, with emphasis on the urgent, resource-limited nature of outbreak contexts.

**Informed consent challenges:**a consistent challenge across studies was ensuring truly informed consent in populations with low literacy and high vulnerability. Research participants in VL-endemic regions often misunderstood the distinction between clinical care and research, a phenomenon termed therapeutic misconception. Although this concept has earlier roots, recent studies reaffirm its persistence in LMIC settings [2,10]. Several studies stressed the importance of using local languages, culturally sensitive metaphors, visual aids, and involving community intermediaries to bridge comprehension gaps [6,9]. Outbreak settings compounded the challenge, with limited time and constrained resources undermining full consent processes. In response, some initiatives trialed verbal consent protocols with audio-visual documentation, particularly during COVID-19 co-epidemics where direct contact was minimized [11].

**Community engagement and cultural sensitivity:** effective community engagement was found to be essential for ethical legitimacy. Participatory models involving traditional leaders, women´s groups, and village health volunteers were associated with improved study acceptance and retention [3,12]. In contrast, studies that adopted top-down approaches faced delays, mistrust, or outright rejection by communities. Several programs emphasized the co-creation of study materials, early dialogue with religious leaders, and feedback loops to ensure transparency. The WHO guidance on community engagement in public health emergencies (2022) was frequently cited as a benchmark for ethical engagement, particularly in multi-ethnic and linguistically diverse settings.

**Risk-benefit assessment:** emergency timelines often skewed risk-benefit assessments. Many studies highlighted the ethical tension between expedited implementation and participant protection. For example, during VL flare-ups in South Sudan [13], investigational therapies were deployed under compassionate-use frameworks without formal trial registration, prompting ethical debate [13]. Researchers were urged to contextualize risk perceptions. In communities accustomed to daily survival threats, experimental treatments were often viewed as their only chance, amplifying coercive dynamics [14]. Several articles advocated that tangible, sustainable benefits-such as infrastructure investment or healthcare access-be integrated into research protocols.

**Post-trial access and benefit sharing:** post-trial access remained a critical ethical gap. Although global ethics guidelines call for continued access to beneficial interventions, implementation was inconsistent. Studies noted that VL therapies validated through trials were not always included in national formularies or procured at scale [2,15]. Positive examples included the rollout of liposomal amphotericin B in Bihar, India, which was scaled through a government-NGO partnership post-trial [16]. However, in several African settings, treatments demonstrated to be effective during research were not maintained post-project, frustrating participants and undermining trust. Calls were made for funders and sponsors to commit to benefit-sharing agreements, including medicine donation programs, technology transfer, and integration into essential medicines lists [5].

**Data ownership and authorship equity:** many studies criticized the continued marginalization of LMIC researchers in authorship and decision-making. Articles published in high-impact journals frequently excluded local investigators from lead authorship, despite their central roles in field access, data collection, and community engagement [6,8]. This pattern, described as "helicopter research," was flagged as a form of ethical injustice. Positive trends were seen in co-creation models that included Memoranda of Understanding (MoUs) on data sharing, co-authorship, and acknowledgment. The Nagoya Protocol and FAIR data principles were referenced in 2022-2024 literature as ethical imperatives for global research equity.

**Ethics review capacity and timeliness:** the review found that ethics review boards in most VL-endemic LMICs lacked the capacity for rapid assessment of outbreak-related research. While international collaborations sometimes secured ethics approvals through northern institutions, local committees struggled with outdated protocols, limited staff, or lack of emergency frameworks [9,17]. Efforts to establish expedited review pathways were reported in Ethiopia and Nepal, where generic outbreak protocols and ethics preparedness workshops were trialed. Still, the majority of studies called for more investment in national ethics infrastructure, including training, digital systems, and regional ERB networks (Table 1).

## Discussion

This review provides a critical synthesis of the ethical challenges in conducting research during visceral leishmaniasis (VL) outbreaks in low- and middle-income countries (LMICs). It highlights persistent gaps in ethical infrastructure, community engagement, and equitable collaboration, despite increased global attention to ethics in public health emergencies. The six thematic domains-ranging from informed consent to ethics review capacity-reveal not only structural vulnerabilities but also opportunities for reform and innovation.

**Informed consent in crisis contexts:** the informed consent remains one of the most ethically complex aspects of outbreak research. Although the principle of respect for persons is universally acknowledged, its practical application in VL-endemic LMICs is constrained by linguistic, educational, and cultural barriers [2]. Studies published between 2019 and 2025 reaffirm that traditional consent models often fail in these settings, where populations may have limited understanding of research processes or the distinction between clinical care and investigational activities [9,6]. Innovative approaches-such as the use of culturally adapted visual tools, audio-recorded consent, and trusted local intermediaries-have shown promise in enhancing comprehension and autonomy [18]. However, these strategies require time, training, and resources that are often unavailable during emergencies. Some researchers have proposed tiered consent models or advanced community authorization mechanisms to reduce individual burdens during crisis research [10]. These models should be rigorously evaluated for ethical soundness and cultural appropriateness.

**Community engagement as an ethical imperative:** effective community engagement is a cornerstone of ethical outbreak research. It not only improves participant recruitment and retention but also fosters trust, mutual respect, and transparency. Studies in Ethiopia and India demonstrated that early involvement of traditional leaders, women's groups, and youth networks led to better communication and ethical legitimacy [3,12]. Despite this, many outbreak studies still employ top-down, externally driven models that risk reinforcing historical power imbalances and paternalism [6]. WHO (2022) emphasizes that engagement should be continuous, context-specific, and co-designed with affected populations. Without meaningful engagement, researchers risk eroding community trust, compromising data quality, and causing unintentional harm. Engagement should be viewed not only as a tool for project success but also as an ethical obligation. Communities involved in research deserve a voice not only in implementation but also in research prioritization, feedback, and dissemination. Institutionalizing community advisory boards (CABs) and training local researchers in participatory methods are important next steps.

**Reframing risk-benefit assessment in LMICs:** outbreaks necessitate urgent responses, but this urgency should not override ethical obligations to participants. Research conducted during VL outbreaks frequently involves investigational treatments or diagnostics with limited prior testing in similar populations. While this can accelerate access to innovations, it also exposes participants to unknown risks [13]. Risk assessment must go beyond biomedical criteria to include participants´ lived experiences, socio-economic status, and access to health care. For example, in regions affected by both VL and malnutrition, risk-benefit trade-offs must account for compounding vulnerabilities [14]. Research protocols should incorporate mechanisms to minimize harm, monitor adverse events, and provide psychological support. Moreover, ethical committees should ensure that communities are not disproportionately bearing the risks of innovation without sustainable benefits.

**Post-trial access and the ethics of sustainability:** the failure to ensure post-trial access to successful interventions continues to undermine the ethical integrity of outbreak research. This issue is particularly acute for VL, where effective treatments like liposomal amphotericin B remain unaffordable or unavailable in many endemic regions despite being validated in earlier research [16]. Without clear access plans, communities may be disillusioned by what is perceived as extractive research. Strengthening partnerships with national health authorities, committing donor support beyond the trial period, and embedding post-trial plans in ethics protocols are necessary for ethical compliance. Examples from India and Sudan illustrate that long-term access is possible when governments, NGOs, and sponsors collaborate from the outset. Building VL interventions into universal health coverage schemes, and using local manufacturing or pooled procurement, may help address cost barriers sustainably.

**Data ownership, authorship, and global research equity:** concerns about inequitable data access and authorship in North-South collaborations were recurrent in the studies reviewed. Local researchers, despite managing fieldwork, were often relegated to middle or omitted authorship positions. This practice, referred to as "parachute" or "helicopter research," perpetuates neocolonial hierarchies in global health science [6,8]. Ethical research partnerships require transparency and recognition. Tools such as authorship agreements, data sharing policies, and training in publication ethics should be standardized. Moreover, funding agencies can play a role by requiring equitable authorship and capacity-building as grant conditions. Emerging guidelines, including the TRUST Global Code of Conduct (2020) and WHO´s 2022 research ethics roadmap, emphasize mutual respect and fair benefit sharing. Adopting these principles could accelerate the decolonization of global health and enhance the ethical legitimacy of collaborative research.

**Strengthening ethics oversight and preparedness:** the review found widespread concern about the lack of emergency-ready ethical review processes in many LMICs. Although most countries have functioning national ethics committees, few have protocols for expedited review during emergencies, nor training in outbreak-specific ethical issues [9]. Developing emergency ethics protocols, establishing regional ethics support networks, and investing in digital review infrastructure are critical steps. The Africa CDC and WHO-AFRO have initiated regional platforms for this purpose, but sustained investment and national uptake remain uneven. It is also important to include ethics preparedness in national disaster risk management plans. Simulation exercises, training programs for IRB members, and stockpiled generic protocols could help improve readiness. Without such preparation, research risks bypassing ethical scrutiny when it is most urgently needed. This review confirms that ethical challenges in VL outbreak research are multifaceted, deeply contextual, and often under-addressed. Informed consent, community engagement, equitable authorship, and post-trial access are not only moral obligations but essential components of research quality and public trust. As public health emergencies become more frequent and complex, ethical preparedness must be elevated alongside biomedical readiness. National governments, global funders, and academic institutions all share responsibility in ensuring that the most vulnerable are not merely participants in science, but partners in defining its priorities and benefits.

**Study limitations:** this review has some limitations. First, although a systematic search strategy was applied, the study did not conduct a full systematic review with meta-analysis; instead, it adopted a scoping/narrative synthesis approach, which may introduce interpretive bias. Second, only articles published in English were included, which may have excluded relevant evidence published in other languages from VL-endemic regions. Third, grey literature was selectively accessed, meaning some unpublished or local-level ethical reflections may have been missed. Finally, as the review focused on publications up to 2024, emerging guidance and practices developed after this period were not captured. Despite these limitations, the review provides a comprehensive synthesis of key ethical issues in VL outbreak research in LMICs and proposes context-relevant strategies.

**Study limitations:** this review did not employ a full systematic review with meta-analysis, which may limit reproducibility. Only English-language publications were included, potentially excluding relevant studies from non-English-speaking VL-endemic regions. Grey literature inclusion was selective, and recent guidance published after 2024 may not have been captured.

## Conclusion

Ethical challenges in conducting visceral leishmaniasis outbreak research in low- and middle-income countries are closely linked to participant vulnerability, emergency pressures, and structural health system limitations. This review highlights persistent gaps in informed consent processes, community engagement, post-trial access to benefits, and emergency ethics oversight. Strengthening ethical preparedness, fostering meaningful community participation, and investing in local research ethics capacity are essential to ensure ethically sound and socially responsive outbreak research. Integrating these measures into outbreak response frameworks can enhance research quality, community trust, and the sustainability of public health interventions in VL-endemic settings.

### *What is known about this topic*

- *Visceral leishmaniasis (VL) outbreaks primarily affect vulnerable populations in LMICs where ethical oversight and research capacity are often limited;*
- *Ethical dilemmas in outbreak research include challenges in obtaining informed consent, community engagement, and post-trial access to interventions;*
- *Global ethical frameworks exist, but their application in resource-limited settings is inconsistently implemented.*

### *What this study adds*

- *Synthesizes the key ethical challenges encountered in VL outbreak research conducted between 2000-2024 and provides a focused review of empirical and policy literature;*
- *Identifies context-specific strategies that improve ethical compliance, such as community-based consent models and equitable authorship frameworks;*

- *Proposes recommendations to strengthen emergency ethics review preparedness and long-term research partnerships in LMICs.*

## Competing interests

The authors declare no competing interests.

## Authors' contributions

Sadam Abdi Maalim: conceptualization, literature review, writing - original draft. Joseph Nguta: Methodology, supervision, writing - review and editing. All authors have read and approved the final version of this manuscript.

## Table and figures

**Table 1**: summary of ethical challenges and proposed strategies in low- and middle-income countries (LMICs) visceral leishmaniasis (VL) research

**Figure 1**: map of leishmaniasis (VL)-endemic low- and middle-income countries (LMICs) and research activity

**Figure 2**: the process of identifying and selecting papers for the systematic review

**Figure 3**: ethical decision-making flowchart in leishmaniasis (VL) outbreak contexts

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**Table 1:** summary of ethical challenges and proposed strategies in LMIC VL research

| **Ethical challenge** | **Description** | **Proposed strategies** |
|---|---|---|
| **Informed consent** | Low literacy, cultural barriers, and language differences may limit true understanding. | Use culturally appropriate materials; visual aids; verbal explanations in local languages; community mediators. |
| **Community Engagement** | Risk of tokenism or superficial consultation with affected populations. | Early and continuous engagement; co-design of research; use of local leaders and community advisory boards. |
| **Participant vulnerability and exploitation** | Participants may be from marginalized or desperate communities. | Equitable selection criteria; ensure voluntary participation; avoid coercive incentives. |
| **Risk-benefit assessment** | Tension between urgent data collection and ensuring participant safety. | Strengthen local IRBs; expedited but thorough review processes; real-time monitoring of adverse effects. |
| **Justice in access to benefits** | Interventions may not be made available to host communities post-research. | Plan for post-trial access; communicate results locally; build local capacity for follow-up care. |
| **Ethical oversight capacity** | Weak or under-resourced ethics committees in some LMICs. | Capacity building for local IRBs; promote regional ethics networks; international mentorship programs. |
| **Cultural sensitivity and local norms** | Standard protocols may conflict with local beliefs or customs. | Adapt protocols to local contexts; involve local anthropologists or cultural mediators. |
| **Data ownership and benefit sharing** | Communities may be excluded from ownership of data or outcomes. | Ensure transparent data sharing agreements; involve local institutions in data analysis and dissemination. |

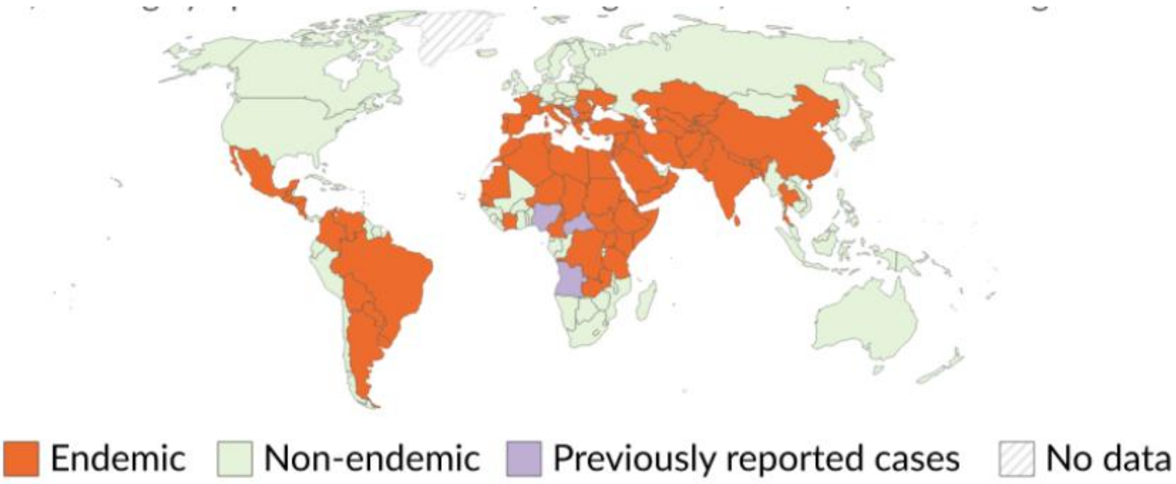

**Figure 1**: map of leishmaniasis (VL)-endemic low- and middle-income countries(LMICs) and research activity

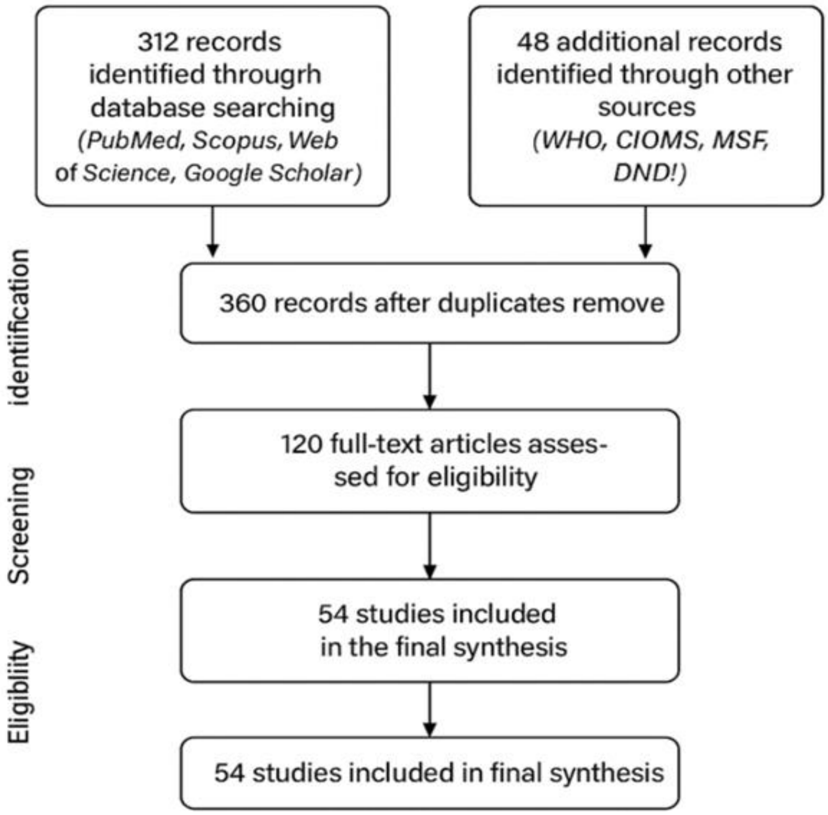

Figure 2: the process of identifying and selecting papers for the systematic review

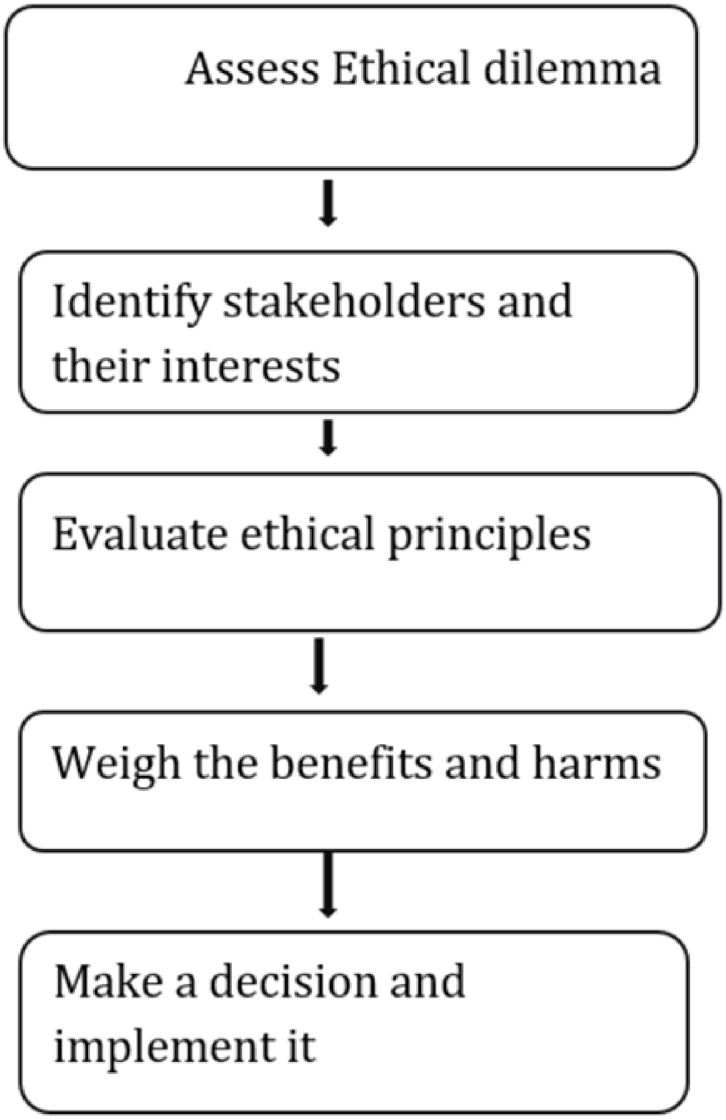

**Figure 3**: ethical decision-making flowchart in leishmaniasis (VL) outbreak contexts