# Intranasal delivery of a synthetic entamoeba histolytica vaccine containing adjuvant

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**Abstract:**

The National Institute of Allergy and Infectious Diseases (NIAID) Category B priority pathogen entamoeba histolytica is a causative agent of amebiasis. Amebiasis is responsible for about 50 million infections every year, including up to 100,000 deaths. E. histolytica is also of significant interest in biodefense since it has an extremely low infectious dose (less than 10 cysts), is resistant to chlorination, can be easily disseminated, and the infection can be difficult to diagnose. No vaccine exists for amebiasis, nor are there any vaccines in clinical development. Thus, there is an urgent need for an amebiasis vaccine that can stimulate protective mucosal immunity.

Intranasal delivery of vaccines offers the potential of non-invasive, needle-free administration, with devices that are easy to use and require minimal training. In the present work, the potential for intranasal delivery of a synthetic entamoeba histolytica vaccine candidate using a syringe-based liquid atomization device was explored. Comprehensive *in vitro* testing was done to evaluate spray pattern, plume geometry, droplet size distribution, and deposition patterns within adult and infant nasal geometries. Collectively, *in vitro* results demonstrated the feasibility of delivering the vaccine candidate to target sites with the nasal airways. Penetration through the nasal airways that could lead to deposition in the lungs was below the limit of quantification for both adults and infant geometries, indicating a low likelihood of adverse events due to lung exposure.

These results support continued investigation of intranasal delivery of the synthetic entamoeba histolytica vaccine.