

## **Aerosolized Vaccines**

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#### Technology description

Vaccine delivery to humans by mucosal routes may offer some operational and immunological advantages over intramuscular administration by needle-and-syringe. Potential targets include the oral, nasal, rectal conjunctival, and vaginal surfaces with the oral and nasal routes being the most practical to consider for infants, children and adults of both sexes. Needle-free delivery methods may improve compliance, reduce discomfort, and improve safety of vaccines; particularly in the developing world, needle-free delivery could mitigate the risk of blood-borne pathogen transmission by unsafe injection practices or inadequately sterilized equipment, and be easier and safer to deploy by non-medical personnel.

Mucosal vaccination may offer a potential immunological advantage of recruiting mucosal lymphoid tissues that are important in mediation of immune responses, particularly at the entry site for infectious pathogens. Optimally formulated and delivered antigens may elicit a variety of responses in these tissues including secretory IgA, serum IgG capable of neutralizing toxins or viruses, and cell-mediated immunity as measured by cytotoxic T-cell responses and cytokine production.

In the case of respiratory delivery, specific particle sizes can target particular microenvironments within the lung. Efficient penetration of the lung parenchyma depends upon optimizing the size of the droplet in relation to the diameter of the respiratory airways. It has been recommended that school age children and adults be immunized with respiratory particles that are between 3 and 5  $\mu$ m in diameter, since a larger particle cannot effectively penetrate deep into the lung.

This application claims aerosolized immunogenic compositions comprising aerosolized immunogenic particles between 0.01  $\mu$ m and 15  $\mu$ m. The application also claims methods for delivering immunogenic compositions, methods for generating immune responses, and methods for treating infections by producing and administering aerosolized immunogenic compositions. More specifically, the invention claims replication-defective recombinant adenoviruses encoding human immunodeficiency virus (HIV), simian immunodeficiency virus (SIV) and tuberculosis (TB) genes delivered by aerosolization into the lung. The inventors have shown that this regimen induces very high, stable cellular immune responses localized to the lung, as well as humoral responses in the lung, systemically, and, importantly, at distal mucosal sites. This regimen may prove highly useful for

vaccination against respiratory infections such as TB, influenza, and respiratory syncytial virus, and provide a platform for generating mucosal antibody responses against other pathogens.

### Application area

Improved immunogenic compositions and vaccine formulations, delivery of viral vectors, plasmid DNA, proteins, and adjuvants.

#### Institution

NIH - National Institutes of Health

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