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## Needle-free Biojector injection of a dengue virus type 1 DNA vaccine with human immunostimulatory sequences and the GM-CSF gene increases immunogenicity and protection from virus challenge in Aotus monkeys.

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### **Abstract**

A dengue-1 DNA vaccine containing sequences encoding premembrane and envelope proteins (DIME) was previously shown to elicit virus neutralizing antibodies in rhesus and Aotus monkeys, and the primates were partially protected from viremia upon challenge. To increase the neutralizing antibody levels and subsequent protection from virus challenge, four strategies were evaluated: (a) coimmunization with a plasmid expressing Aotus GM-CSF gene; (b) coimmunization with a plasmid containing human immunostimulatory sequences (ISS); (c) coimmunization with both the GM-CSF gene and ISS; and (d) delivery of vaccine using the needle-free Biojector system. Vaccination with the mixed formulation containing DIME, GM-CSF gene, and ISS, by either needle injection or Biojector, led to neutralizing antibody titers that were stable for up to 6 months after vaccination. Furthermore, 6 of 7 monkeys (85%), and 7 of 8 monkeys (87%) receiving this formulation were completely protected from viremia when challenged 1 and 6 months after vaccination, respectively. This is a significant improvement compared to our previous study in which one of three monkeys (33%) receiving just the DIME vaccine was completely protected from viremia at 6 months after immunization.

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