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Eliminating the vaccine cold-chain distribution hurdle

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Statement of the Problem: The requirement for vaccines to be kept sufficiently cold (unbroken cold chain) during transport makes vaccine distribution to some populations (where the vaccines are greatly needed) extremely challenging, if not impossible. Thus, various strategies are being explored to eliminate the need for the expensive cold chain. We have designed a versatile *Vibrio Cholerae* Ghost (VCG) vaccine delivery platform that eliminates the need for the expensive cold chain and thus alleviate cold chain-associated constraints on global vaccine access. Moreover, this platform is self-adjuvanting and capable of simultaneously delivering multiple vaccine antigens to the immune system. It also offers an attractive approach for developing combination vaccines, especially against diseases with epidemiological overlap. Here, we present data showing a VCG-based chlamydial vaccine protects against infertility in mice.

Method: Groups of mice were Immunized Rectally (IR) with VCG expressing the *Chlamydia trachomatis* porin B and polymorphic membrane protein D proteins (rVCG-PmpD/PorB) or glycoprotein D from HSV-2 (rVCG-gD2 or gD2) as antigen control. Vaccine efficacy was assessed by evaluating the intensity and duration of genital chlamydial shedding following intravaginal challenge with live chlamydiae. Protection against upper genital tract pathology was determined by assessing infertility and tubal inflammation. Analysis of Variance (ANOVA) was used to compare differences between groups.

Finding: We demonstrated that elicited immune effectors following immunization cross-reacted with the serovar E chlamydial antigen and reduced the length and intensity of genital chlamydial shedding. Moreover, immunization with the VCG-vaccine reduced the incidence of tubal inflammation and protected mice against *Chlamydia*-induced infertility.

Conclusion: These results highlight the potential of the VCG platform for eliciting immunity in the female genital tract and preventing the sequelae of chlamydial infection such as infertility and upper genital tract inflammation.

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