Implications And Future Research Regarding Oral Cholera Vaccine At Elevated Temperatures

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A health worker makes a home visit to vaccinate children in Sucre, Bolivia. ACPalomino, Courtesy of Photoshare, 2005.

The recent study, *The oral cholera vaccine Shanchol when stored at elevated temperatures maintains the safety and immunogenicity profile in Bangladeshi participants* [4], published in Vaccine, is the first of its kind to show the safety and immunogenicity of oral cholera vaccine (OCV) at elevated temperatures in vaccinated individuals. The study, which reviewed antibody responses among 4 groups of adult participants who received the vaccine at varying temperatures ranging from the standard 2-8°C up to 42°C for 14 days, found the vaccine remained stable. These findings have several implications for vaccine campaigns moving forward and lay the foundation for future research regarding the use of OCV within a controlled temperature chain (CTC).

**Implications**

First, these findings show promise for increased ability to vaccinate hard to reach populations with endemic cholera or during emergency situations with limited cold chain capacity. Without having to
transport heavy volumes of ice-packs, larger doses of vaccine could potentially be transported. These findings could potentially also allow a different cadre of health workers to implement vaccine campaigns as transportation mechanisms can be shifted to transport mediums that don’t necessitate a cold chain, such as bicycles or motorcycles.

Second, the results have implications for self-administration of the vaccine. The current standard is to provide the second dose 14 days after the first. Depending on how restrictive the CTC is, the vaccine could potentially be stored for a 14 day period at health clinics or in people’s homes. However, it is also essential to keep in mind local ambient temperatures before the decision to take the vaccine outside of the cold chain is made.

**Future research**

These findings have also led to future research and implementation questions. First, there is a lack of concordance between the current vaccine vial monitor (VVM) and the current research. The VVM is a time- and temperature-sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It is meant to warn those providing the vaccine that the vials exposure to heat is likely to have degraded the vaccine beyond an acceptable level. Currently, the VVM indicates the vaccine should be discarded if left at temperatures of 37°C for 14 days. Therefore, in order for those implementing the vaccine to have confidence in the immunogenicity of the vaccine, a new VVM would need to be developed to take full advantage of the findings of the study.

Finally, given that the findings showed no loss of potency or reduced immunogenicity of the vaccine when exposed to 42°C or less over a 14 days period, it is likely that the vaccine can be further heat-stressed without losing potency and immunogenicity. Therefore, future studies should be conducted to determine the temperature time and thresholds that could reduce potency.

Overall, this study provides a first and important look into the stability of the vaccine at elevated temperatures and provides the field with future research questions regarding implementation strategies and vaccine thresholds.

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