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Can thermostable vaccines help address cold-chain challenges? Results from stakeholder interviews in six low- and middle-income countries

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ABSTRACT

Introduction: This study captures the perspectives of stakeholders at multiple levels of the vaccine supply chain regarding their assessment of challenges with storing vaccines within recommended temperature ranges and their perceptions on the benefits of having vaccines with improved stability, including the potential short-term storage and transport of vaccines in a controlled-temperature chain.
Methods: Semi-structured interviews were undertaken with 158 immunization stakeholders in six countries. Interviewees included national decision-makers and advisors involved in vaccine purchasing decisions, national Expanded Programme on Immunization managers, and health and logistics personnel at national, subnational, and health facility levels.
Results: Challenges with both heat and freeze-exposure of vaccines were recognized in all countries, with heat-exposure being a greater concern. Conditions leading to freeze-exposure including ice build-up due to poor refrigerator performance and improper icepack conditioning were reported by 53% and 28% of participants, respectively. Respondents were interested in vaccine products with improved heat/freeze-stability characteristics. The majority of those involved in vaccine purchasing indicated they would be willing to pay a US$0.05 premium per dose for a freeze-stable pentavalent vaccine (68%) or a heat-stable rotavirus vaccine (59%), although most (53%) preferred not to pay the premium for a heat-stable pentavalent vaccine if the increased stability required changing from a liquid to a lyophilized product. Most respondents (73%) were also interested in vaccines labeled for short-term use in a controlled-temperature chain. The majority (115/158) recognized the flexibility this would provide during outreach or should cold-chain breaks occur. Respondents were also aware that possible confusion might arise and additional training would be required if handling conditions were changed for some, but not all vaccines.
Conclusion: Participating immunization stakeholders recognized the benefits of vaccine products with improved stability characteristics and of labeling vaccines for controlled-temperature chain use as a means to help address cold-chain issues in their immunization programs.

1. Introduction

The challenge of transporting and storing vaccines at refrigerated temperatures (2–8 °C) is being addressed on many fronts. The need to address this challenge has become increasingly important because of the introduction of new and more expensive vaccines that are at risk of damage from heat and/or freeze exposure [1–4] and that cumulatively may overwhelm the already insufficient cold-chain capacities of many countries [5–8].

Efforts to increase the heat and freeze stability of some vaccine products have been quite successful [9], and in 2012 the World Health Organization (WHO) proposed new programmatic-suitability requirements for vaccines purchased by United Nations agencies that set mandatory minimum stability standards and signaled a preference for vaccines that are heat- and freeze-stable and that can be stored for extended periods of time above 8 °C [10]. In 2013, MenAfriVac® became the first WHO-prequalified vaccine labeled for controlled-temperature chain (CTC) use, allowing a single excursion of up to four days at 40 °C [11,12]. Over the years, a number of countries have piloted or adopted protocols permitting several vaccines to be kept at ambient temperatures for a defined

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