Virol Mycol 2018, Volume 7
DOI: 10.4172/2161-0517-C3-030

Safety profile of the cuban implementation a new pneumococcal vaccine after community intervention in the preschool children

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Background and Aims: A new pneumococcal conjugate vaccine is currently undergoing advanced clinical evaluation in Cuba. We present the safety profile of the vaccine candidate (PCV7-TT) administered in real life conditions in children 1-5 years as part of the planned introduction strategy.

Methods: The implementation Cuban strategy has been designed with consideration of the need to maximize the effects of vaccination. Cluster non-randomized trial stepped wedge design is currently being implemented through a massive campaign high coverage (≥90%) with PCV7-TT. The inclusion criteria or the first stage of the intervention (October-November 2017) were children 1-5 years' local resident whose parents signed the informed consent for the vaccination and the follow-up study. The main endpoint defined was the proportion of adverse events attributable to vaccination at 7 and 30 days after the immunization.

Results: 4138 children were vaccinated (672 of 12-23 months and 3466 of 3-5 years). 4810 dose were administered. 15 (0.31%) serious adverse events were reported after the immunization (hospitalization required), none causal related with vaccination. 77 vaccinated children report 126 adverse events. The local adverse events (71.5%) dominated: Increase local volume (19.6%), redness (17.6%), induration (12.7%), and pain at the injection site (8.8%). The most common systemic adverse event was fever <39°C (16.6%). Rate of systemic and local adverse events per dose applied (x 1000) was the 15.1 and 6.4, respectively.

Conclusions: The Cuban pneumococcal vaccine candidate is safe. The contribution of the introduction strategy could support the decision-making to introduce the new vaccine in Cuba and shift of paradigm from the individual protection to population effect based on scientific evidences.

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