

tion. The cohort of new births, indicative of interventions' impact, had significantly lower mean ages at administration for DPT 2 and DPT 3 ($p < 0.0001$). Statistically significant trend in decline was observed for mean age at DPT 1, DPT 2 and DPT 3 from first to sixth quarter of study period ($p < 0.0001$).

Conclusion: Better programme management can improve performance levels. Community volunteers can increase outreach services. Government of India's recent health sector reforms of decentralization which provide flexibility at the district level and below to hire contractual staff and introduction of community volunteer called Accredited Social Health Activists (ASHA) under the National Rural Health Mission (NRHM) is likely to strengthen immunization program enhancing the age-appropriate immunization coverage.

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19.038

A New Mammalian Cell Culture-Derived Influenza Vaccine is as Safe as, and Immunogenically Non-Inferior to, an Egg-Based Influenza Vaccine

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Background: Influenza vaccines are currently produced using embryonated chicken-eggs for influenza virus propagation. Mammalian cell cultures have been employed as an alternative technology, primarily to overcome some limitations of current influenza vaccine manufacture from embryonated eggs. This study aimed to evaluate the safety and tolerability of a new cell culture-derived trivalent inactivated influenza vaccine (CCIV) (OPTAFU®, Novartis Vaccines), produced using Madin-Darby canine kidney cell culture, and demonstrate its immunological non-inferiority to an egg-based trivalent inactivated influenza vaccine (TIV) (Agrippal 51®, Novartis Vaccines).

Methods: In a Phase III study, 1300 adult (18–60 years of age) and 1354 elderly (≥ 61 years of age) subjects were randomized (1:1) to receive one dose of either CCIV or TIV. Solicited local and systemic reactions within 7 days, all adverse events (AE) up to Day 22, and all serious AE and AE leading to withdrawal up to 6 months were evaluated. Immunogenicity was assessed 3 weeks after vaccination, in compliance with European Committee for Medicinal Products for Human Use (CHMP) criteria, using the hemagglutination-inhibition (HI) assay.

Results: Solicited local or systemic reactions experienced in both vaccine groups were mostly mild or moderate in severity. There were no differences in the immune responses induced by either of the two vaccines for each of three influenza strains (A/H1N1, A/H3N2 and B). In adults, post-vaccination seroprotection rates (HI titer ≥ 40 IU) were 90–99% and 91–99% for CCIV and TIV groups, respectively. In elderly subjects, post-vaccination seroprotection rates were 85–97% and 85–98% for CCIV and TIV groups, respectively.

Both vaccines met all three CHMP criteria in both age groups and the CCIV met predefined criteria for non-inferiority.

Conclusion: The CCIV was as safe and well tolerated as the TIV, and was immunologically non-inferior to the TIV. The CCIV offers a valuable alternative to egg-based influenza vaccines.

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From Inactivated to Live Japanese Encephalitis Vaccine: A Synopsis of Sri Lankan Experience of Controlling Japanese Encephalitis

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The first recorded major outbreak of Japanese Encephalitis (JE) in Sri Lanka occurred in 1985–86 with 385 cases and 64 deaths in the North Central province. Outbreaks occurred in 1986–87, 1987–88, the latter being the largest with 812 cases and 192 deaths with the spread to three adjoining districts. The affected were rice cultivating areas with a network of irrigation canals supported by seasonal, moderate to heavy rainfall. Children in the age group 5–9 and young adults in 20–24 years were predominantly affected.

Though JE was prevalent in endemic districts, it was spreading to newer areas of previous low transmission. To cope with this emerging challenge, immunization against JE was initiated on phase basis in 1988. Children aged 1–10 years were offered three primary doses and a booster of inactivated vaccine in the interpandemic period in a campaign approach. Over the years, immunisation coverage increased with the reduction of JE incidence. However, cases and occasional outbreaks were reported in other districts where immunization was not carried out resulting in extension of the immunization to 18 districts.

Simultaneously, there was an increasing trend of adverse events following JE vaccine partly attributable to the change of the product with possible adverse repercussions on the JE immunization programme. The other obstacle was the increasing cost of the inactivated vaccine which amounted to US\$4.50 per a dose in 2006. The high vaccine cost was a prohibitive factor to sustain the programme of JE immunization. Therefore, an affordable, safe and immunogenic vaccine alternative was a high priority.

Against this background, live JE vaccine (LJEV) SA 14-14-2 appeared to be an appropriate, low cost, safe and potent alternative. To ascertain the safety and immunogenicity of LJEV, with the support of the PATH in 2007, a clinical trial was conducted by the Epidemiology Unit. Based on preliminary results of the trial, Sri Lanka has now decided to introduce LJEV in place of the inactivated vaccine to the JE Immunization Programme and hopefully to the EPI very soon.

Currently, the Ministry of Health is negotiating to receive a public price for procurement of LJEV. Details of the suggested schedule are yet to be decided. However, cost savings from LJEV will enable the introduction of benefits of new vaccines to Sri Lankan children and, on an optimistic note, LJEV to adults in high endemic areas in the future.

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