



Applicant Information

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Abstract Details

Title:

An evaluation of the cluster-randomised pilot implementation of RTS,S/AS01 through routine health systems in sub-Saharan Africa: A Post-Authorization Observation Study: Month 46 analyses

Category:

Communicable diseases (Malaria, TB, HIV, NTD)

Authors:

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Objectives:

In 2021, WHO recommended the RTS,S/AS01E (RTS,S) malaria vaccine for children living in endemic areas after a planned analysis 24-months after pilot introduction in Ghana, Kenya and Malawi demonstrated that RTS,S had an acceptable safety profile and reduced severe malaria hospitalizations. Here we report results during 46 months of evaluation

Method:

150 clusters randomized to introduce RTS,S in 2019 or later. National immunization programs delivered four-dose schedule beginning at 5-months of age. Vaccine uptake was monitored through routine administrative data. Vaccine coverage was measured through three household surveys. Impact and safety were measured through community-based mortality and sentinel hospital surveillance among children aged 1-59 months. Incidence rate ratios compared event rates in vaccine age-eligible and age-ineligible populations in implementing versus comparison clusters

Results:

During 46-months of implementation, 1.29 million first RTS,S doses were administered. Approximately 30-months post-introduction, dose-3 coverage was 74%, 69%, 62%, and dose-4 coverage was 52%, 34% and 32%, in Ghana, Kenya, and Malawi, respectively. Among children age-eligible to have received at least three doses, there were 5,706 deaths in implementing and 6,286 in comparison clusters; RTS,S was associated with 13.0% (95% Confidence Interval [CI]: 2.7%-21.2%) reduction in all-cause mortality, excluding injury. There was no evidence of an association between RTS,S and cerebral malaria (IRR 0.94, 95%CI 0.63-1.39), meningitis (IRR 0.98, 95%CI 0.63-1.52), or sex-specific mortality (interaction term 1.04, 95%CI 0.93-1.15).

Conclusion:

RTS,S introduction through national immunization programs is associated with significant reductions in all-cause child mortality despite suboptimal coverage of dose-4

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