

Study Protocol and Analysis Plan

Study 1. Cost-effectiveness of TAK-003 Dengue Vaccination in Thailand

Study Design

Model-based economic evaluation using a Markov model combined with decision trees from a societal perspective.

Study Population

No human participants. Model inputs from published literature and national databases.

Intervention

Simulation of routine TAK-003 vaccination in children (9–14 years) and young adults (15–24 years) versus no vaccination.

Primary Outcome

- Incremental cost-effectiveness ratio (ICER)

Secondary Outcomes

- Severe dengue cases prevented
- Deaths prevented
- Incremental costs
- Life-years gained
- Budget impact

Analysis Plan

Base-case analysis estimating lifetime costs, QALYs, ICER, severe dengue cases and deaths by age group and serostatus.

One-way sensitivity analysis and probabilistic sensitivity analysis (1,000 Monte Carlo simulations).

Budget impact analysis over 5–10 years.

Software: Microsoft Excel and IBM SPSS Statistics 29.

Study 2. Dengue Vaccine Acceptance among Thai Adults and Parents

Study Design

Sequential explanatory mixed-methods study:

Phase 1: Cross-sectional quantitative survey.

Phase 2: Qualitative in-depth interviews.

Study Population

240 Thai adults and 110 parents (total n=350).

Purposive sample of 25–30 participants for interviews.

Eligibility Criteria

Population 1: General Adults

Inclusion Criteria

- Thai adults (male or female).
- Aged ≥ 18 years.
- Able and willing to provide written informed consent.
- Never received any dengue vaccine.
- Single or married without biological or adopted children.
- Have an independent source of income.

Exclusion Criteria

- Healthcare personnel (all professions).
- Visiting the hospital because of suspected or confirmed dengue infection.
- No prior knowledge or awareness of dengue or dengue vaccines.

Population 2: Parents

Inclusion Criteria

- Thai adults (male or female).
- Aged ≥ 18 years.
- Able and willing to provide written informed consent.
- Parent or legal guardian of at least one dengue vaccine-naïve child aged 4–18 years.
- Have an independent source of income.

Exclusion Criteria

- Healthcare personnel (all professions).
- Visiting the hospital because of their child's suspected or confirmed dengue infection.
- No prior knowledge or awareness of dengue or dengue vaccines.

Primary Outcome

Dengue vaccine hesitancy measured using the 7C-model

Dengue vaccine hesitancy will be assessed using an adapted version of the validated 7C Model of Vaccine Readiness questionnaire. The questionnaire will be adapted to the context of dengue vaccination while retaining the seven psychological antecedents of vaccination: Confidence,

Complacency, Constraints, Calculation, Collective Responsibility, Compliance, and Conspiracy.

Analysis Plan

Descriptive statistics (mean $\pm$ SD, median[IQR], frequency/%).

Chi-square tests for categorical variables.

Independent t-tests for continuous variables.

Univariable and multivariable logistic regression for vaccine acceptance.

Qualitative thematic analysis with constant comparative method for mixed-methods integration.