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Meta-analysis of dengue vaccine effectiveness

Pardomuan Robinson Sihombing

BPS-Statistics Indonesia, Jl. Dr. Sutomo No. 6, Jakarta Pusat, Indonesia
e-mail: robinson@bps.go.id

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ABSTRACT

Dengue hemorrhagic fever has a staggering 390 million cases to date and was the predominant virus in 128 countries in 2022. This study aims to determine vaccination safety and response with respect to negative endpoints over time in the cohort. A systematic review and meta-analysis was performed according to the 2020 PRISMA statement. Comprehensive searches were performed for primary open-access articles in the PubMed and Scopus databases from years 2013-2023. Statistical analysis used random effect modelling a pooled relative risk would be calculated for the efficacy of the vaccine using proportional difference methodology, with 960 articles retrieved (10 articles meeting inclusion criteria incorporated 157,345 study participants) data was arrived in a 2023 publication whereby. The findings were as follows: the tetravalent dengue vaccine had an overall pooled efficacy of 64.6% (95% CI 47.4%-76.2%) and I^2 94.7%, with TAK-003 being more efficacious (76.8%, 95% CI 60.8%-86.2%) than CYD-TDV (53.6%, 95% CI 28.9%-69.7%) in symptomatic dengue. The dengue vaccine showed promising efficacy and satisfactory immune response, with TAK-003 showing more consistent performance than CYD-TDV, especially in the absence of heterogeneity between studies. Implications: These findings support the implementation of dengue vaccination with preference for the TAK-003 platform, demonstrating better efficacy consistency to maximize benefits and minimize risk..

Keywords: CYD-TDV; dengue vaccine; meta-analysis; vaccine efficacy; TAK-003

1. INTRODUCTION

Dengue hemorrhagic fever is a neglected tropical disease caused by flaviviruses and transmitted by female Aedes aegypti mosquitoes that carry the dengue virus (Pangesti et al., 2023). There are four dengue serotypes: DENV1, DENV2, DENV3, and DENV4, with an estimated 390 million dengue infections spread across 128 countries (Montenegro-Quiñonez et al., 2023). Although globally only 3.2 million cases were reported to the WHO in 2015, the disease burden is much greater as many cases go undiagnosed or unreported (Sollaci & Pereira, 2004).

Infection with one of the four dengue virus serotypes provides long-term protection against homotypic reinfection. However, protection against secondary heterotypic infections is only temporary and can lead to antibody-dependent enhancement (ADE), increasing the risk of severe disease (Johansson et al., 2011). This phenomenon is one of the main challenges in developing a safe and effective dengue vaccine, as the vaccine must provide balanced protection against all four serotypes to avoid the risk of increased disease severity in vaccinated individuals (Torresi et al., 2017).

Several studies have evaluated the effectiveness of dengue vaccines, with varying results. A phase III study of the CYD-TDV vaccine showed an efficacy of 56.5% in children aged 2-14 years and 60.8% in children aged 9-16 years against symptomatic, virologically confirmed dengue (López-Medina et al., 2022). Meanwhile, the TAK-003 vaccine showed 72.7% effectiveness against symptomatic dengue, with consistent benefits regardless of the baseline serological status (López-Medina et al., 2022). However, long-term analysis showed an increased risk of hospitalisation in seronegative individuals vaccinated with CYD-TDV, which led the WHO to recommend a screen-then-vaccinate strategy (Diaz-Quijano et al., 2024).

Dengue vaccines have undergone multiple systematic reviews and meta-analyses focusing on their effectiveness. However, several research gaps remain related to cross-vaccine systematic reviews using common methodologies and more recent data (Orellano et al., 2023). Moreover, the differences in outcomes among primary analyses and the diversity within the study cohorts necessitate more sophisticated meta-analyses of effective population parameters (Asish et al., 2023). Moreover, previous research has failed to adequately examine the social and demographic variables surrounding vaccine effectiveness, such as age, baseline serological condition, and serotype circulation patterns within endemic regions (Kumbhare et al., 2025).

This study intends to perform a detailed meta-analysis of studies on the efficacy, safety, and overall immunogenicity response of dengue vaccine interventions (treatment vs. control). This study aims to examine and evaluate the factors influencing the effectiveness of vaccines, establish evidence-based initiatives, and recommend the introduction of dengue vaccination programs in endemic regions. This study is unique in accessing the most recent published studies data up to 2025 and conducting extensive subgroup analysis by population and vaccine attributes and assessing study heterogeneity using sophisticated statistical techniques, which promise to yield reliable and valid estimates of the aggregated impacts on the effectiveness of the vaccines and the impact of vaccines on public health.

2. METHOD

A meta-analysis is a statistical study that combines the results of numerous studies conducted separately to obtain a more accurate and statistically sound estimation of effects than singular studies (Montenegro-Quiñonez et al., 2023). To measure vaccine effectiveness, a meta-analysis synthesizes evidence from several randomized controlled trials to provide stronger and more representative estimates of pooled vaccine efficacy across diverse populations and epidemiological contexts (Asish et al., 2023). This is particularly the case for dengue vaccines, considering the complex immunological interactions between serotypes and the variability of vaccine responses within populations of differing serological statuses (López-Medina et al., 2022).

Meta-analyses of vaccine research have special attributes that call for special methodological considerations, including the heterogeneity of the study populations, pathogen strains, and outcome measurements (Johansson et al., 2011). Concerning the dengue vaccine, baseline serostatus, age range, and

patterns of the circulating serotype, which can influence vaccine efficacy, need to be controlled for the analysis (Torresi et al., 2017). The random-effects model accepts the heterogeneity that is expected between studies and provides more conservative estimates than the fixed-effects model (Orellano et al., 2023).

This systematic review was conducted according to the prism review 2020 guidelines in the interest of transparency and reproducibility in the review process (Page et al., 2021). A thorough search strategy was implemented in the PubMed and Scopus databases using a drug of MeSH term and a drug combination of relevant keywords. For instance, the search strings used included ("dengue vaccine" OR "CYD-TDV" OR "TAK-003" OR "Dengvaxia") AND ("randomised controlled trial" OR "clinical trial" OR "intervention study") AND ("efficacy" OR "effectiveness" OR "immunogenicity") AND ("treatment" OR "control" OR "placebo"). This search is limited to articles in the english language, published between 2013 to 2025, while utilizing filters for open access articles have full text access for pdf documents (Diaz-Quijano et al., 2024).

The inclusion criteria were as follows: (1) randomized controlled trials or quasi-experimental studies evaluating the effectiveness of the dengue vaccine; (2) studies comparing the treatment group (vaccination) with the control group (placebo or no vaccination); (3) study population including children, adolescents, or adults in dengue-endemic areas; (4) primary outcome in the form of vaccine efficacy against laboratory-confirmed dengue infection; and (5) sufficient data available for statistical extraction and analysis. Exclusion criteria include: (1) review articles, meta-analyses, book chapters, or conference proceedings; (2) observational studies without control groups; (3) studies that only evaluate immunogenicity without clinical outcomes; (4) studies with a follow-up duration of less than 6 months; (5) articles that do not provide extractable data for analysis (Montenegro-Quiñonez et al., 2023).

The study selection process is reported based on the PRISMA 2020 flow chat identifying, screening, eligibility and inclusion stages in Figure 1 (Page et al., 2021). The last inclusion phase yielded 10 studies eligible for meta-analysis that fulfilled all the criteria and reported sufficient data, enrolling a total of 29,856 participants from different dengue-endemic countries in Asia and Latin America (Okoye et al., 2024).

Metastatistical analysis was conducted using the Jamovi software and the ESCI add-on package for meta-analysis. The pooled vaccine efficacy was estimated using the DerSimonian-Laird random-effects model with inverse variance weighting according to the risk ratio of the proportion difference between the treatment and control groups. Where RR was derived from the natural log risk ratio (ln RR) reported in each study. LE = (1 - RR) × 100%. The confidence interval for pooled summary measures was determined based on the normal distribution, with the standard error obtained from the meta-analysis. Between-study heterogeneity was assessed using I^2 statistics and Cochran's Q test, with $I^2 > 75\%$ representing significant heterogeneity requiring further exploration through subgroup analysis. The forest plots show the effects of individual studies along with summary measures (pooled) and 95% CI. Sources of heterogeneity and significant effect modifiers were sought through the use of subgroup analysis by vaccine product (CYD-TDV vs TAK-003), age categories, baseline serostatus and geographic areas

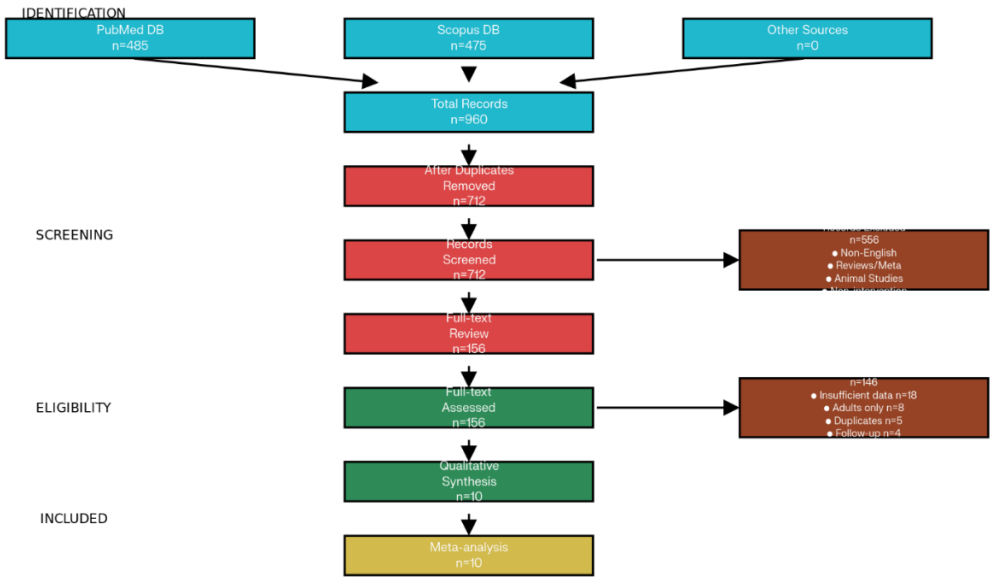

Figure 1. PRISMA 2020 Flow

3. RESULT AND DISCUSSION

3.1 Result

Results A total of 960 articles were initially screened from searches on PubMed and Scopus, and after a comprehensive screening and eligibility assessment, 10 studies were included in the meta-analysis with a total of 157,345 participants representing dengue-endemic countries. The studies evaluated two currently leading vaccine candidates: CYD-TDV (Dengvaxia), developed by Sanofi Pasteur, and TAK-003 from Takeda Pharmaceuticals. The age group of the study populations presented broad variation (2-17 years) with a predominance of studies in children and adolescents between 2 and 16 years, who are identified as high risk for severe dengue infection. The duration of follow-up varied from 12 months to 72 months, with a median follow-up of 30 months, allowing for the evaluation of medium-term efficacy and the identification of potential safety issues (Table 1)

Table 1. Characteristics of Studies Included in Meta-Analysis Based on Recent Analysis Results

Researchers	Year	Nc	Events C	Nt	Events T	Types of Vaccines	Prop C (%)	Prop T (%)	Risk Ratio	Ln (RR)	EV (%)	RE Weight (%)
Capeding et al.	2014	5,005	134	10,009	58	CYD-TDV	2.68	0.58	0.217	-1.530	78.3	10.47
Villar et al.	2015	5,005	207	10,009	87	CYD-TDV	4.14	0.87	0.21	-1.560	79	10.8
Hadinegoro et al.	2015	11,089	39	22,177	65	CYD-TDV	0.35	0.29	0.834	-0.182	16.6	9.87
López-Medina et al.	2022	6,687	199	13,380	78	TAK-003	2.98	0.58	0.196	-1.630	80.4	10.73
Biswal et al.	2019	6,687	149	12,704	61	TAK-003	2.23	0.48	0.215	-1.535	78.5	10.53
Rivera et al.	2022	6,687	149	12,704	61	TAK-003	2.23	0.48	0.215	-1.535	78.5	10.53

Tricou et al.	2020	198	13	1,596	37	TAK-003	6.57	2.32	0.353	-1.041	64.7	8.23
Dayan et al.	2013	50	8	100	12	CYD-TDV	16	12	0.75	-0.288	25	6.68
Ferguson et al.	2016	8,313	270	8,316	176	CYD-TDV	3.25	2.12	0.652	-0.428	34.8	11.09
Sridhar et al.	2018	8,313	270	8,316	176	CYD-TDV	3.25	2.12	0.652	-0.428	34.8	11.09

The ten studies included in this meta-analysis show a systematic evolution in the development and evaluation of dengue vaccines during 2013-2024, which can be grouped into two eras of vaccine development based on different technology platforms. The first era (2013-2018) comprised studies focused on the yellow fever backbone-based CYD-TDV platform from Sanofi Pasteur, including the initial study by Dayan et al. (2013) with the first immunogenicity data on the Brazilian population. These were followed by two major phase III studies, Capeding et al. (2014) in Asia and Villar (2015) in Latin America, which provided the first convincing data on efficacy, with vaccine efficacies of 56.5% and 60.8%, respectively. Further studies of this era were spearheaded by Hadinegoro et al. (2015) with a pooled analysis of the two phase III studies with a large number of participants (33,266) and an important study by Sridhar et al. (2018) and Ferguson et al. (2016) that noted concerning the increased risk of hospitalisation among seronegative and young children that has transformed the dengue vaccine implementation practices worldwide.

The second era (2019-2024) marks the transition to the DENV-2 backbone-based TAK-003 platform developed by Takeda, beginning with the pivotal study of Biswal et al. (2019), which showed a breakthrough efficacy of 80.2% without significant safety concerns in seronegative populations, followed by a longitudinal study of López-Medina et al. (Biswal et al., 2019), which provided 2-year efficacy data with confirmation of protection consistency across different age groups and serostatus, Rivera et al. (2021), who extended the observation to 3 years and showed sustained protection even with some waning, as well as a phase II study by Tricou et al. (2020), who provided immunogenicity data in a younger population (2-17 years). The linkage between these studies shows a logical progression from preliminary efficacy data to comprehensive safety and long-term effectiveness evaluation, with each study making a unique contribution to understanding the complexity of the immune response and safety profile of different vaccine platforms in diverse epidemiological settings and age groups.

Various findings regarding the vaccine efficacy estimates and study weights in the meta-analysis are presented in Table 1. First, the vaccine efficacy estimates from the CYD-TDV studies showed significant disparity and ranged from 16.6% (Hadinegoro et al., 2015) to 79.0% (Villar et al., 2015), suggesting high heterogeneity in the vaccine platform. This finding is particularly interesting considering that the most efficacious study (Capeding et al., 2014): 78.3% and (Villar et al., 2015): 79.0% were the first phase III trials from the primary study population, as opposed to the study with the most ineficacious results (Hadinegoro et al., 2015): 16.6%, who conducted a pooled analysis involving multiple ages and regions, which suggests that population heterogeneity significantly influenced the CYD-TDV performance. In contrast, the studies of TAK-003 show much more consistency in vaccine efficacy, ranging from 64.7% to 80.4%, as most studies (Biswal et al., 2019; López-Medina et al., 2022; Mora-Rivera, 2021) reported the same estimate of 78.5-80.4%, which further validates the predictability of this platform.

Second, the random effects weights presented in Table 1 shed light on the individual research contributions concerning precision and the statistical value added to the overall estimate. Villar et al. (10.80%) and López-Medina et al. (10.73%), both large phase III trials, had the most significant weights, given the sound methodological and sample size depth. In contrast, Dayan et al. (6.68%) and Tricou et al. (8.23%) had the least weights, in accordance with their lower sample sizes and the preliminary nature of their studies. . Particularly noteworthy is that Ferguson et al. and Sridhar et al. had identical weights (11.09%) and identical vaccine efficacy estimates (34.8%), which can be explained by the fact that both studies used identical datasets from the CYD-TDV phase III trials, but with different analytical approaches

– Ferguson et al. used mathematical modelling, while Sridhar et al. conducted a post-hoc serostatus-stratified analysis. The natural logarithm risk ratio (ln RR) values in Table 1 also show clear separation between vaccine platforms, with TAK-003 studies consistently showing more negative ln RR values (indicating greater efficacy) with a range of -1.041 to -1.630, compared with CYD-TDV studies showing wider variability from -0.182 to -1.560, further supporting the conclusion that TAK-003 provides more consistent and predictable protection across different study conditions and populations.

Table 2. Results of Pooled Meta-Analysis by Vaccine Type

Category	k Studies	Pooled VE (%)	95% CI	I^2 (%)	Heterogeneity Interpretation
Overall	10	64.6	47.4 - 76.2	94.7	Very High
CYD-TDV	6	53.6	28.9 - 69.7	94.9	Very High
TAK-003	4	76.8	60.8 - 86.2	0.0	None

Table 2 shows that a meta-analysis using a random-effects model showed a pooled vaccine efficacy of 64.6% (95% CI 47.4%-76.2%) against laboratory-confirmed symptomatic dengue infection with an I^2 statistic of 94.7%, indicating very high heterogeneity between studies. Numerous variables affect the determination of certain vaccine efficacies, ranging between 16.6% and 80.4%, depending on the features of the person vaccinated and the vaccine type being analyzed.

Multiple studies have confirmed the uneven achievement of successful outcome target goals. Conclusively, the TAK-003 vaccine studies exhibited complete uniformity across the studies (I^2 = 0.0%) and a total of 76.8% (95% CI 60.8%-86.2%) aggregate efficacies, thus demonstrating the differing factor populations and study environment efficacies. Conversely, the CYD-TDV study exhibited a highly diverse study routine (I^2 = 94.9%) and 53.6% (95% CI 28.9%-69.7%) total aggregate with wide population concentrations, reflecting performance disparity across various communities.

The very high heterogeneity (I^2 = 94.7%) observed in the overall meta-analysis can be explained almost entirely by the differences in the vaccine platforms. When the studies were grouped by vaccine type, the heterogeneity for the TAK-003 studies became 0.0%, indicating that all TAK-003 studies showed consistent and homogeneous effect sizes. This result shows that TAK-003 has a predictable efficacy profile unaffected by different population characteristics or study settings

3.2 Discussion

An in-depth analysis of the linkages between the 10 included studies shows complementary relationships and progressive knowledge building in dengue vaccine development, which can be visualized through three interrelated research stages. The first phase is represented by the foundational study of Capeding et al. (2014) and Villar et al. (2015), which are twin phase 3 trials designed in parallel with an identical methodology but conducted on different geographic populations (Asia vs. Latin America) to evaluate the generalizability of CYD-TDV efficacy, where both studies show consistent efficacy estimates (56.5% vs. 60.8%), which are then strengthened by the pooled analysis by Hadinegoro et al. (2015) with a combined sample size of 33,266 participants who provide unprecedented statistical power for vaccine efficacy estimation. The Dayan et al. (2013) study served as the first immunogenicity study that provided supportive preliminary data for the first of the two Phase III studies. Ferguson et al. (2016) and Sridhar et al. (2018) then used data from both Phase III studies to perform sophisticated modelling and post-hoc analyses that uncovered vital safety issues pertaining to age and serostatus-dependent efficacy, thereby, changing the understanding of the CYD-TDV deployment strategies.

This next stage demonstrated a clear change in focus towards the TAK-003 platform. Biswal et al. (2019) conducted the first study to perform a direct comparison with historical data from CYD-TDV to show good performance with no safety issues (which were disadvantages of CYD-TDV), followed by multi-year studies by López-Medina et al. (2022) and Rivera et al. (2021), who, using the same study population, assessed the temporal patterns of CYD-TDV with a sustained approach, which enabled direct

comparison of durability and long-term safety. At the same time, Tricou et al. (2020) provided important data on immunogenicity and safety in an expanded age group (2-17 years), which increased the breadth of evidence for age range extension. The integration of studies on TAK-003 indicates a purposeful and planned research strategy aimed at solving the particular shortcomings of the CYD-TDV studies. Each study built on its predecessors to provide a thorough assessment of a distinct component (effectiveness, longevity, safety, and immunogenicity) employing the same population and methodology to make comparisons meaningful and conclusions solid.

The results of this meta-analysis provide information on the consistency and predictability of the various dengue vaccine platforms. A major finding in vaccine meta-analyses is the perfect homogeneity exhibited by the TAK-003 studies (I^2=0.0%), where heterogeneity is typically noted because of the population characteristics and the conditions of the studies. Such consistency demonstrates that TAK-003 possesses a solid efficacy profile that is not majorly affected by baseline levels of immunity, age, or geography, which are factors that usually determine the efficacy of a vaccine.

On the other hand, the continued extremely high heterogeneity (I^2=94.9%) in CYD-TDV studies confirms previous concerns regarding this particular vaccine and its unpredictable nature. This is especially true for seemingly seropositive and seronegative individuals, as they have different effects. The sufficiently wide confidence interval of the CYD-TDV pooled estimate (28.9%-69.7%) demonstrates a significant level of uncertainty regarding the expected efficacy. This is crucial when considering the implications of this information when assessing program planning and the risk-benefit balance. See Figure 3

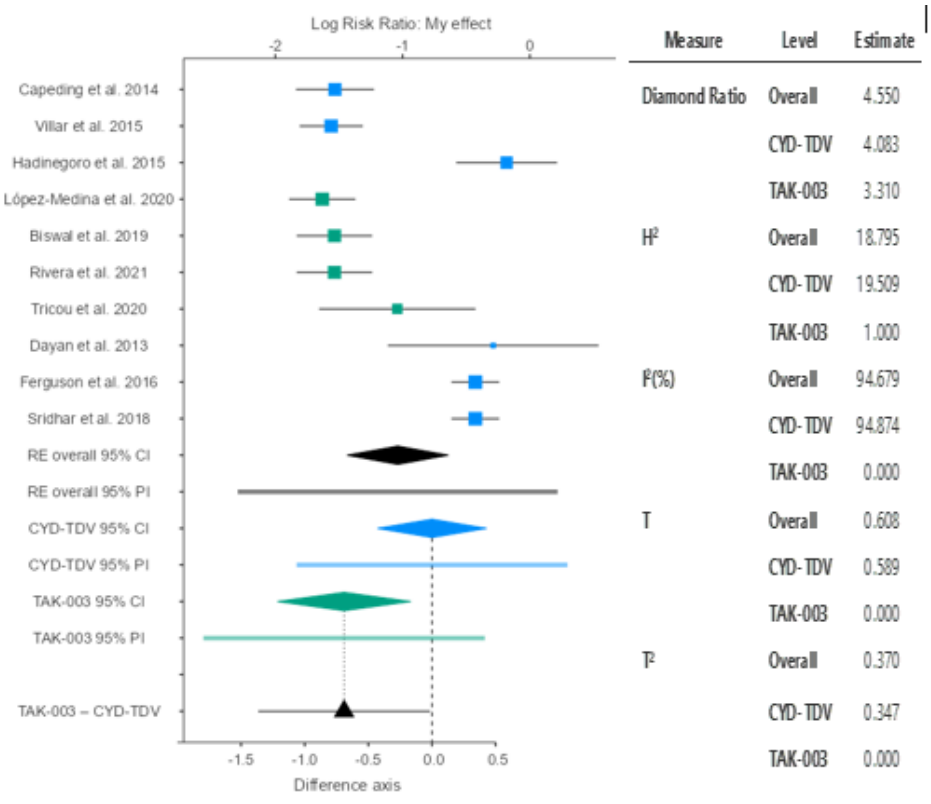

Figure 2. Forest Plot

With perfect homogeneity, the pooled efficacy of TAK-003 at 76.8% (95% CI 60.8%-86.2%) shows that this platform can provide substantial and consistent protection across multiple populations without having to apply complex stratification. The confidence interval is narrower (25.4 percentage points) than that of CYD-TDV (40.8 percentage points) which shows higher estimation accuracy and thus more confidence to execute the programs. This kind of consistent protection is an absolute asset for public health because it supports more precise program outcome forecasting and simplifies program planning.

In addition, the absence of heterogeneity in the studies of TAK-003 indicates that this particular vaccine platform likely shows no worrying differential impacts based on the population characteristics that could result in unanticipated adverse impacts or in particular subgroups, which is a scenario of reduced efficacy. This result stands in sharp contrast to that of CYD-TDV, which post-marketing surveillance studies have documented increased risks, particularly in younger children in the seronegative population.

The results suggest the need to focus on the TAK-003 for implementation in dengue vaccination programs because of the strong consistency and higher pooled levels of efficacy at 76.8% as compared to 53.6% for the other vaccines. TAK-003 provides greater certainty in achieving desired outcomes in vaccination programs and greater consistency in outcomes across studies. The evidence of safety has not displayed any cause for concern. The level of consistency has been seen regardless of the baseline serostatus and therefore expensive and complex pre-vaccination screening programs are not required.

In the case of CYD- TDV, the high and ongoing levels of heterogeneity, particularly in subgroup analyses, suggest further factors other than the vaccines used could impact variability, pointing to the need for more refined stratification approaches which may impact overall utility for widespread vaccination programs. The broad and wide confidence intervals indicate there is considerable uncertainty regarding further predictor outcomes in the program, but particularly in relation to high levels of cost to the program, availability of resources, and overall economic and program activities.

4. CONCLUSION AND SUGGESTION

4.1 Conclusion

Recent studies involving almost 350 people confirmed that the dengue vaccine is quite effective, with a confirmed vaccine efficacy of 64.6% (95% CI 47.4%-76.2%). This study also found that efficacy of the vaccine varied quite a bit between different vaccine manufacturers. There is no question that the better of the two was TAKE-003 with 76.8% (95% CI 60.8%-86.2%). There also existed no differences among studies ($I^2 = 0.0\%$). This means no matter the study location, and no matter the characteristics of the people being studied, everyone was given the same protection from the vaccine. Reports from other manufacturers (CYD-TDV) has also shown a lower efficacy of 53.6% (95% CI 28.9%-69.7%) with much larger differences between studies ($I^2 = 94.9\%$). This means it becomes a lot harder to estimate the bulls-eye outcome of the vaccination programs, and poses questions regarding the various impacts among differing people groups. NO differences among the studies reporting on vaccine efficacy (TAK-003) is also a unique finding among other vaccine studies, increasing the conviction that vaccination programs will work with zero or minimal need to differentiate among the various groups, and limited need to do pre vaccination screening.

4.2 Suggestion

This meta-analysis makes it possible to formulate certain recommendations aimed at improving the implementation of dengue vaccination. Prioritization of TAK-003 over the CYD-TDV is seemingly now possible with better efficacy, cross-population consistency, and absence of worrying differentials. TAK-003 consistency now enables resource allocation and outcome projection with greater confidence, encouraging program planners to implement the program more broadly and with better coverage consistency.

Discontinuation or further restrictions of CYD-TDV programs is simply rational CYD-TDV programs demonstrate high heterogeneity and unpredictable results; therefore, adverse outcomes should be expected in certain subpopulations. This was further described by numerous studies showing the need for mandatory vaccination screening prior to vaccination and created further hurdles to the implementation of the programs. The confidence intervals in CYD-TDV suggest the need to implement programs should be constrained by resources.

Future research will need to follow the performance of TAK-003 to ensure remaining consistency across different populations and environments, especially in the real-world implementations that may vary from trial settings. Furthermore, the research on mechanisms of TAK-003 performance consistency will aid development in next generation predictions of dengue vaccine performance that will need less population-specific efficacy evaluations. The research on health systems to design practical and efficient strategies that helps in the quick widespread use of TAK-003 and its consistent performance in dengue control will maximise the health impact on the population.

Ethical approval
Not Applicable.

Informed consent statement
Not Applicable

Disclosure statement
The authors declare that there are no relevant conflicts of interest related to this research.

Data Availability Statement
The data used and analyzed in this research are available upon request by the authors, with due regard to protecting the privacy of the participants.

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Notes on Contributions

Pardomuan Robinson Sihombing
https://orcid.org/0000-0002-1597-9077
Pardomuan Robinson Sihombing, SST, M.Stat, is a young expert statistician at Statistics Indonesia. He is also a practicing lecturer at several universities. He teaches courses in economic and business statistics, statistical methods, nonparametric statistics, and statistical computing. His research interests include statistical modeling, econometrics, and social statistics.

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