

Surveillance of Adverse Events Following Immunization (AEFI) of the RTS,S/AS01 Malaria Vaccine in Three Pilot Districts of the Littoral Region, Cameroon, 2024–2026: A Cross-Sectional Descriptive Study

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Abstract

Background

Cameroon was the first African country to introduce the RTS,S/AS01 malaria vaccine into its Expanded Programme on Immunisation on 22 January 2024, using a four-dose schedule (6, 7, 9 and 24 months). Surveillance of adverse events following immunization (AEFI) is essential to assess vaccine safety under real-world conditions. This study describes AEFI notified in three pilot districts of the Littoral Region.

Methods

We conducted a descriptive cross-sectional analysis of routine DHIS2 data from Monthly Activity Reports of health facilities, from January 2024 to August 2026, in the districts of Edea, Japoma and Mbanga. The variables analysed were serious and non-serious AEFI, as well as doses administered used as denominator. Notification rates per 1,000 doses were calculated with 95% confidence intervals using the exact Poisson method.

Results

A total of 295 AEFI were notified, of which 288 were non-serious (97.6%) and 7 were serious (2.4%). The Japoma district accounted for 210 AEFI (71.2%), including 124 non-serious cases in 2025. The overall AEFI rate ranged from 1.13 to 12.06 per 1,000 doses administered depending on district and year. Serious AEFI were rare and dispersed (Edea: 1; Mbanga: 3; Japoma: 3), with no temporal or spatial clustering.

Conclusions

The safety profile of RTS,S/AS01 in the three pilot districts appears favourable. The increase in non-serious AEFI in Japoma in 2025 suggests improved sensitivity of the surveillance system rather than a safety signal. Strengthening causality assessment and standardizing notifications remain necessary.

Background

Malaria remains a major public health problem in sub-Saharan Africa. According to the WHO World Malaria Report 2025, an estimated 282 million cases and 610,000 deaths occurred worldwide in 2024, with Africa concentrating about 95% of this mortality, children under five years being the most affected [1]. This increase compared with previous estimates underscores the persistence of challenges in malaria control.

In October 2021, based on favourable results from the malaria vaccine implementation programme (MVIP), conducted since 2019 in Ghana, Kenya and Malawi, the World Health Organization (WHO) recommended the large-scale use of the RTS,S/AS01 malaria vaccine in children living in areas of moderate to high transmission [2]. This recommendation followed the results of the phase 3 trial, which showed a reduction of approximately 39% in clinical malaria episodes and 29% in severe forms after administration of the four doses of the vaccine schedule [3].

On 22 January 2024, after receiving an initial delivery of 331,200 doses in November 2023, Cameroon became the first African country to integrate RTS,S/AS01 into its Expanded Programme on Immunisation (EPI) outside a pilot framework, in 42 high-risk health districts across the ten regions of the country [4]. The selected schedule includes four doses administered at 6, 7, 9 and 24 months. The health districts of Edea, Japoma and Mbanga, in the Littoral Region, are among these first introduction sites.

Surveillance of adverse events following immunization (AEFI) is an essential pillar of any vaccination programme; it allows early detection of potential safety signals, maintains population trust and guides programmatic decisions [5]. During the phase 3 trial, three safety signals were identified for RTS,S/AS01: a transient increase in the risk of febrile seizures in the days following vaccination, an excess of meningitis and cerebral malaria cases, and all-cause mortality in vaccinated girls compared with girls in the control group [6]. Safety analyses conducted within the MVIP, using routine pharmacovigilance data and sentinel hospital surveillance in Ghana, Kenya and Malawi, did not show an excess of meningitis, cerebral malaria or differential mortality by sex in vaccinated children [7], although some authors continue to discuss the robustness of these conclusions, particularly regarding the female mortality signal [8].

Despite these reassuring data from the pilot context, AEFI data under real-world conditions of large-scale routine vaccination remain limited, particularly in the Cameroonian context. The present study uses routine DHIS2 data to describe AEFI related to RTS,S/AS01 notified in the three pilot health districts of the Littoral (Edea, Japoma, Mbanga), from January 2024 to August 2026.

Methods

Study design

This was a descriptive cross-sectional study, based on the analysis of routine data from the national health information system.

Study setting

The study covers the three pilot health districts of the Littoral Region that introduced RTS,S/AS01 on 22 January 2024: Edea, Japoma and Mbanga. The study period extends from January 2024 to August 2026, representing 32 months of implementation.

Data sources

Data were obtained from the District Health Information Software 2 (DHIS2). This software is used by the Ministry of Public Health of Cameroon and some African countries for the collection, transmission and monthly aggregation of vaccination data [4]. Raw data come from vaccination registers and AEFI notification forms kept at health facility level, aggregated in Monthly Activity Reports (MAR) and transmitted in the DHIS2 software.

Study population

The study population includes all children who received at least one dose of the RTS,S/AS01 malaria vaccine in the three pilot districts (Edea, Japoma, Mbanga) between 22 January 2024 and 31 August 2026, and for whom an AEFI was notified in DHIS2.

Inclusion criteria:

- Children aged 0 to 59 months at the time of vaccination
- Residing in one of the three pilot districts at the time of vaccination
- Having received at least one dose of RTS,S/AS01 during the study period
- AEFI notified in DHIS2 during the study period

Exclusion criteria:

- Children whose vaccination or notification data were incomplete or missing in DHIS2
- AEFI occurring outside the study period
- AEFI notified in districts other than the three pilot districts

Definition of variables

AEFI (main variable). According to the WHO classification [5], an adverse event following immunization (AEFI) is defined as any untoward medical occurrence following vaccination, without prejudice to a causal relationship with the administered vaccine. An AEFI is classified as serious when it meets at least one of the following criteria: death, life-threatening condition, hospitalization or prolongation of hospitalization, persistent incapacity or disability, or congenital anomaly [5]. Any AEFI not meeting any of these criteria is classified as non-serious. These two categories (serious AEFI / non-serious AEFI) correspond to the standardized DHIS2 fields used in this study; no data on the precise clinical nature, time of onset after vaccination or causality assessment were available in the system.

Doses administered (denominator). The denominator used corresponds to the total number of doses administered, all doses combined (1st dose at 6 months, 2nd dose at 7 months, 3rd dose at 9 months,

4th dose at 24 months) and all age groups combined (0–11 months, 12–59 months, vulnerable populations), in order to reflect all vaccine exposures over the period.

Statistical analysis

Data were presented as frequencies and proportions (distribution of AEFI by district, year and severity), as well as notification rates per 1,000 doses administered, calculated as follows:

$$\text{AEFI rate (/1,000 doses)} = (\text{Number of AEFI notified} / \text{Total number of doses administered}) \times 1000$$

The 95% confidence intervals (95% CI) of the rates were calculated using the exact Poisson method, particularly appropriate for rare events. For rates with a zero numerator, the upper limit of the 95% CI was estimated by the "rule of three" (3/n), in accordance with recommendations for estimating confidence intervals in the absence of observed events [5].

This rate was calculated separately for serious AEFI, non-serious AEFI and all AEFI, by district and by year. As 2026 data were partial (January–August, i.e., 8 months, versus 12 months for 2024 and 2025), inter-annual comparisons were interpreted with caution, without formal statistical adjustment for observation duration. The analysis was purely descriptive, without hypothesis testing or modelling, in accordance with the nature of routine surveillance data. The writing of this article follows the STROBE recommendations for the presentation of observational studies [9].

Ethical considerations

This study relies on routine data, anonymized and aggregated at health facility level before entry into DHIS2: no identifying individual data were used. As a secondary analysis of programmatic surveillance data, no formal ethical approval was required. Authorization to use the data was obtained from the competent health authorities of the districts of Edea, Japoma and Mbanga.

Results

Overview of AEFI

Between January 2024 and August 2026, the three pilot districts notified 295 AEFI, of which 288 were non-serious (97.6%) and 7 were serious (2.4%) (Table 1). The Japoma district alone accounted for 210 AEFI, i.e., 71.2% of all notifications in the study, mainly driven by the 124 non-serious AEFI recorded in 2025. The districts of Edea and Mbanga notified 53 and 32 AEFI respectively over the entire period.

The distribution of serious AEFI differed markedly from that of non-serious AEFI. Mbanga, although the district with the fewest total AEFI notifications, had the highest severity proportion (9.4% of its notifications), with 3 serious cases concentrated in 2026. No serious AEFI were recorded in Edea in 2024 and 2025 (only one case in 2026), nor in Japoma in 2025 and 2026 (the 3 serious cases in this district all dating from 2024). Notably, no serious AEFI were notified in any of the three districts during 2025, while

this same year concentrated the highest number of non-serious AEFI of the entire study period (151 cases, i.e., 52.4% of the total non-serious cases) (Table 1).

Table 1

Distribution of AEFI by district and year, Littoral Region, Cameroon, January 2024 – August 2026.

District	Year	Serious AEFI	Non-serious AEFI	Total AEFI	Proportion of serious AEFI (%) [95% CI]
Edea	2024	0	33	33	0.0 [0.0–10.6]
	2025	0	10	10	0.0 [0.0–30.8]
	2026*	1	9	10	10.0 [0.3–44.5]
	Subtotal	1	52	53	1.9 [0.05–10.1]
Mbanga	2024	0	11	11	0.0 [0.0–28.5]
	2025	0	17	17	0.0 [0.0–19.5]
	2026*	3	1	4	75.0 [19.4–99.4]
	Subtotal	3	29	32	9.4 [2.0–25.0]
Japoma	2024	3	33	36	8.3 [1.8–22.5]
	2025	0	124	124	0.0 [0.0–2.9]
	2026*	0	50	50	0.0 [0.0–7.1]
	Subtotal	3	207	210	1.4 [0.3–4.1]
Total		7	288	295	2.4 [0.96–4.8]

*Partial period: January–August 2026 (8 months). 95% CI calculated by the exact Poisson method; for proportions with a zero numerator, upper limit by the rule of three (3/n).

Notification rate per 1,000 doses administered

The overall AEFI rate, relative to the number of doses administered, ranged from 1.13 to 12.06 per 1,000 doses depending on district and year (Table 2). The highest rate of the entire study was observed in Japoma in 2025 (12.06/1,000 doses; 95% CI: 10.0–14.4), driven by the 124 non-serious AEFI that year over a volume of 10,279 doses administered, the highest recorded in the study. Conversely, the lowest rate was recorded in Edea in 2025 (1.13/1,000 doses; 95% CI: 0.5–2.1).

Serious AEFI rates remained, regardless of year or district, clearly lower than those of non-serious AEFI, with a maximum of 1.08/1,000 doses in Mbanga in 2026 (95% CI: 0.2–3.2). No serious AEFI were recorded in Edea in 2024 and 2025, nor in Japoma in 2025 and 2026, regardless of the volume of doses administered in those years (Table 2).

Table 2
AEFI rate per 1,000 doses administered, by district and year [95% CI].

District	Year	Total doses	Total AEFI	Overall rate [95% CI]	Serious AEFI rate [95% CI]
Edea	2024	9,015	33	3.66 [2.5–5.1]	0.00 [0.0–0.33]
	2025	8,873	10	1.13 [0.5–2.1]	0.00 [0.0–0.34]
	2026**	6,254	10	1.60 [0.8–2.9]	0.16 [0.0–0.64]
Mbanga	2024	3,063	11	3.59 [1.8–6.4]	0.00 [0.0–0.98]
	2025	4,120	17	4.13 [2.4–6.6]	0.00 [0.0–0.73]
	2026**	2,767	4	1.45 [0.4–3.7]	1.08 [0.2–3.2]
Japoma	2024	6,736	36	5.34 [3.7–7.4]	0.45 [0.1–1.3]
	2025	10,279	124	12.06 [10.0–14.4]	0.00 [0.0–0.29]
	2026**	8,142	50	6.14 [4.6–8.1]	0.00 [0.0–0.37]

*Sum of 1st, 2nd, 3rd and 4th doses administered, all age groups combined. **Partial period: January–August 2026 (8 months). 95% CI calculated by the exact Poisson method; for rates with a zero numerator, upper limit by the rule of three (3/n).

Annual evolution of AEFI

The annual number of non-serious AEFI evolved from 77 cases in 2024 to 151 cases in 2025, then to 60 cases over the first eight months of 2026. This progression in 2025 was almost exclusively driven by Japoma (124 of the 151 non-serious cases that year), while the other two districts saw their notifications decrease or remain stable over the same period (Edea: 33 → 10; Mbanga: 11 → 17).

Serious AEFI, conversely, did not follow any clear temporal trend: 7 cases were notified over 32 months, i.e., an average of 0.22 cases per month across all localities combined, with a distribution dispersed over time (3 in 2024, 0 in 2025, 4 in 2026 for the first eight months of the year) and in space (Edea: 1; Mbanga: 3; Japoma: 3), without evident temporal or geographical clustering (Fig. 1).

Discussion

AEFI profile and safety of RTS,S/AS01

The routine DHIS2 data from the three pilot districts of the Littoral indicate a favourable safety profile for RTS,S/AS01: 97.6% of notified AEFI were non-serious, and the proportion of serious AEFI (2.4%) was very low. These results are consistent with data from clinical trials and the WHO tripartite pilot programme (Ghana, Kenya, Malawi), which did not show an excess of meningitis, cerebral malaria or differential mortality by sex in vaccinated children [6]. These conclusions remain debated by some authors, who

consider that the methodological robustness of the MVIP does not allow formal exclusion of the female mortality signal observed in phase 3 [8]. The African Advisory Committee on Vaccine Safety (AACVS), for its part, concluded that there was no new safety signal and judged the MVIP safety data robust and sufficiently diversified [11].

It should be emphasized that, in our context, we were unable to establish a causal link between the observed AEFI and the RTS,S/AS01 vaccine. The notified AEFI are events occurring after vaccination, but nothing proves that these effects are due to the vaccine rather than to other underlying causes. This limitation is inherent to passive surveillance systems, which record events temporally associated with vaccination without systematic causality assessment according to WHO criteria. Other studies conducted in Cameroon as part of the introduction of RTS,S/AS01 also reported adverse events without establishing a formal causal link, limiting themselves to a description of their frequency and distribution [12]. A similar study conducted in the Soa district (Cameroon) described parent-reported AEFI without causality assessment, reporting that 27% of vaccinated children presented minor events, mainly fever (93%) and injection site swelling (10%) [12]. These contextual data are consistent with the profile observed in our three districts, although the methodologies differ (community study versus routine surveillance).

Reasons for the increase in non-serious AEFI in Japoma in 2025

Several hypotheses can be advanced concerning the marked increase in non-serious AEFI in Japoma in 2025 (124 cases, i.e., 43% of all non-serious AEFI in the study): (i) improved sensitivity of the notification system; (ii) a mechanical effect of the scale-up of vaccination, Japoma having administered 10,279 doses in 2025, the highest volume in the study; (iii) real variations in reactogenicity, unlikely in the absence of documented lot change; (iv) a simple notification artefact. The rate of 12.06/1,000 doses observed in Japoma in 2025 (95% CI: 10.0–14.4) nevertheless remains within acceptable orders of magnitude for an adjuvanted vaccine. It would be advisable to verify whether specific vaccine lots or particular vaccination sessions are associated with this increase.

Serious AEFI and absence of safety signal

The 7 serious AEFI notified over 32 months do not allow conclusion of a safety signal. Their geographical dispersion (Edea: 1; Mbanga: 3; Japoma: 3) and temporal distribution (3 in 2024, 0 in 2025, 4 in 2026) do not suggest any clustering. However, the absence of data on the exact nature of these AEFI and on the time of onset relative to vaccination limits interpretation: causality assessment according to WHO criteria [5] is not documented in DHIS2, which prevents determining whether these 7 cases are coincidental events or authentic vaccine reactions.

Strengths and limitations of the study

This study uses national routine data reflecting real-world implementation conditions, over a 32-month period and in three pilot districts, making it one of the first descriptions of AEFI related to RTS,S/AS01

outside the MVIP pilot framework. Several limitations must nevertheless be highlighted: (i) probable under-notification of AEFI, inherent to any passive surveillance system; (ii) absence of data on the nature, clinical severity and time of onset of AEFI; (iii) impossibility of establishing a causal link in the absence of assessment according to WHO criteria; (iv) absence of distinction, in DHIS2, of the dose after which each AEFI occurred; (v) a partial period in 2026 (8 months), limiting comparability of annual data; (vi) probable heterogeneity of notification practices between districts; (vii) possible changes in DHIS2 definitions or fields in 2026 (introduction of the 4th dose).

Recommendations and implications of the findings

Although limited to three pilot districts and based on routine data, the findings of this study provide useful insights that may inform the design of strategies to strengthen AEFI surveillance and maintain confidence in the malaria vaccine in Cameroon.

First, health authorities at district and central levels should strengthen causality assessment of notified serious AEFI, by systematically documenting the clinical nature, time of onset and outcome according to WHO criteria. The study identified 7 serious AEFI over 32 months, whose exact nature and causal link with the vaccine could not be established due to lack of data in DHIS2. The absence of this information prevents any conclusion on a possible safety signal. This recommendation is feasible in the Cameroonian context, as it relies on existing pharmacovigilance structures of the EPI. Although feasible, this recommendation faces the reality of passive surveillance systems in resource-limited settings, where priority is often given to detection rather than in-depth investigation. A progressive approach, targeting serious AEFI first, would be more realistic.

Second, the Ministry of Health and related stakeholders, such as the Expanded Programme on Immunisation and the national pharmacovigilance unit, should investigate the increase in non-serious AEFI in Japoma in 2025 (124 cases; rate of 12.06/1,000 doses) by analysing vaccine lots, vaccination practices and notification procedures. The study highlighted a marked increase in non-serious AEFI in Japoma in 2025, representing 43% of all non-serious AEFI in the study. This increase could reflect improved notification, a volume effect (10,279 doses administered), or a real variation in reactogenicity. This investigation is feasible in the short term, as it relies on data already collected in DHIS2 and vaccination registers. It requires collaboration between districts, the EPI and the national pharmacovigilance unit. This recommendation is relevant, but requires cautious interpretation: an increase in notifications is not necessarily a safety signal, and too intensive an investigation could divert limited resources from other public health priorities.

Third, a detailed case review of the 7 notified serious AEFI should be conducted to document their clinical nature and assess their causality, mobilizing the competent pharmacovigilance committees. The 7 serious AEFI are dispersed over time (3 in 2024, 0 in 2025, 4 in 2026) and in space (Edea: 1; Mbanga: 3; Japoma: 3), without evident clustering. Their small number and the absence of detailed clinical data prevent any conclusion. This recommendation is feasible in the medium term, as it relies on existing pharmacovigilance committees at national and regional levels. It nevertheless requires access to the

medical records of the cases, which can be complex in low-resource health facilities. This case review is an essential step to distinguish coincidental events from authentic vaccine reactions. However, with only 7 cases over 32 months, statistical power remains limited to detect a safety signal, even after detailed review.

Conclusion

The routine DHIS2 data from the three pilot districts of the Littoral indicate that the RTS,S/AS01 malaria vaccine has a favourable safety profile, with a very low proportion of serious AEFI (2.4%) over the period January 2024 – August 2026. The increase in non-serious AEFI in Japoma in 2025 is more likely related to improved notification than to a safety signal. The 7 notified serious AEFI, dispersed over time and space, do not suggest a clustering evocative of a safety problem, but their exact nature and causal link with vaccination remain to be documented. Strengthening causality assessment and standardizing notifications are essential to maintain confidence in the malaria vaccine and to guide programmatic decisions as the vaccine is scaled up nationally.

Abbreviations

AACVS

African Advisory Committee on Vaccine Safety

AEFI

Adverse Events Following Immunization

CI

Confidence Interval

DHIS2

District Health Information Software 2

EPI

Expanded Programme on Immunisation

MAR

Monthly Activity Reports

MVIP

Malaria Vaccine Implementation Programme

STROBE

Strengthening the Reporting of Observational Studies in Epidemiology

WHO

World Health Organization

Declarations

Ethics approval and consent to participate

This study relies on routine, anonymized and aggregated data. No formal ethical approval was required. Authorization to use the data was obtained from the competent health authorities of the districts of Edea, Japoma and Mbanga.

Consent for publication

Not applicable.

Availability of data and materials

The data supporting the findings of this study are available from the health authorities of the districts of Edea, Japoma and Mbanga, but restrictions apply to their public availability, as they were used under authorization for this study. Aggregated data are included in the article and its supplementary files.

Competing interests

The authors declare that they have no competing interests.

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No specific funding was received for this study.

Authors' contributions

ASNN designed the study and study materials, coordinated implementation, conducted data analysis and wrote the first draft of the manuscript.

SRS supervised all study activities and provided administrative authorisation for data collection in the Health District.

PTD revised the manuscript.

CT revised the manuscript.

JVL revised the manuscript and approved the final version of the manuscript.

All authors reviewed and approved the final manuscript.

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Figures

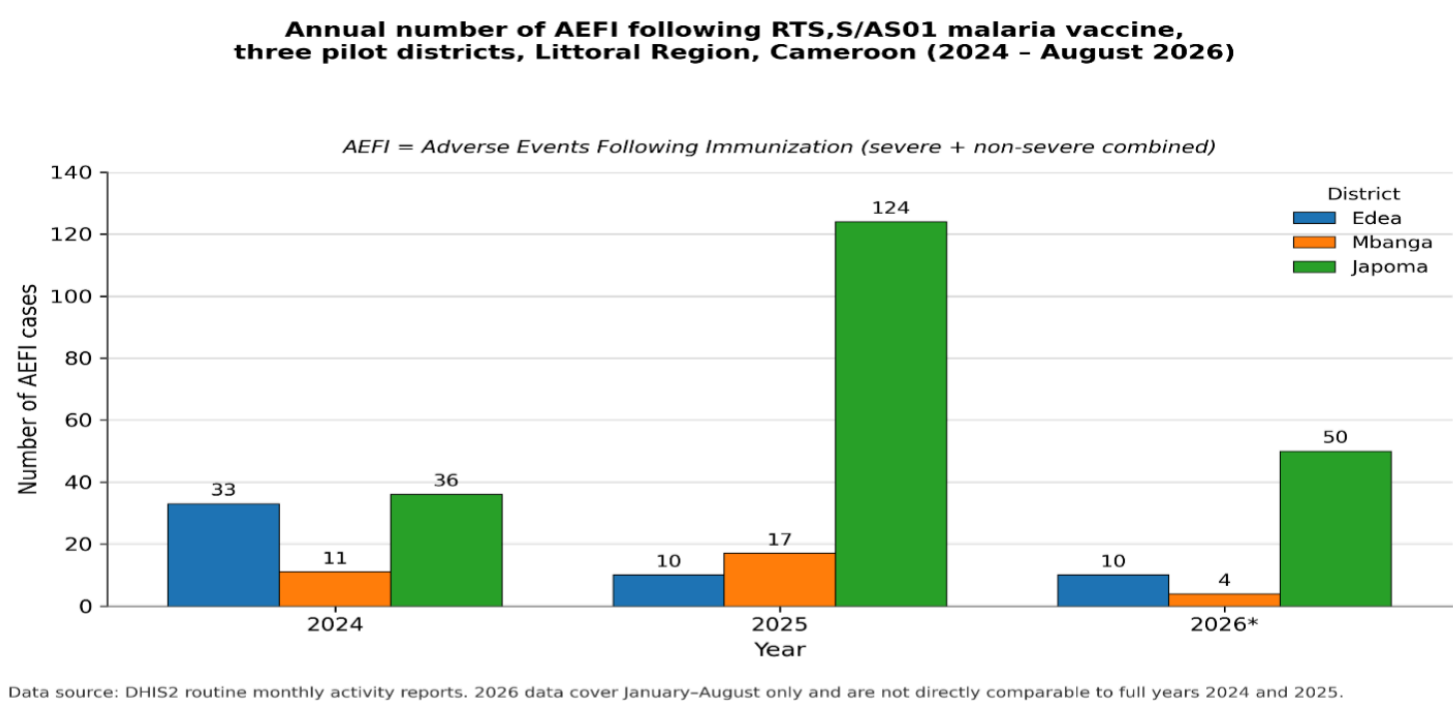


Figure 1

Annual evolution of the number of AEFI by district, Littoral Region, Cameroon, 2024 – August 2026. AEFI = Adverse Events Following Immunization (serious and non-serious AEFI combined).