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The Role of Mobile Technology in Surveillance of Adverse Events Following Immunization during New Vaccines Introduction in Cameroon: A Cross-Sectional Study

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***Abstract*—**Vaccines serve a great deal in protecting the population globally. Vaccine products are subject to rigorous quality control and approval before use to ensure safety. Even if all actors take the required precautions, some people could still have adverse events following immunization (AEFI) caused by the vaccine composition or an error in its administration. AEFI underreporting is pronounced in low-income settings like Cameroon. The Country introduced electronic platforms to strengthen surveillance. With the introduction of many novel vaccines, like COVID-19 and the novel Oral Polio Vaccine (nOPV) 2, there was a need to monitor AEFI in Cameroon. A cross-sectional study was conducted from July to December 2022. Data on AEFI per region of Cameroon were reviewed for the previous five years. Data were analyzed with MS Excel, and the results were presented in proportions. AEFI reporting was uncommon in Cameroon. With the introduction of novel vaccines in 2021, the health authorities engaged in new tools and training to capture cases. AEFI detected almost doubled using the open data kit (ODK) compared to previous platforms, especially following the introduction of the nOPV2 and COVID-19 vaccines. The AEFI rate was 1.9 and 160 per administered 100,000 doses of nOPV2 and COVID-19 vaccines, respectively. This mobile tool captured individual information for people with AEFI from all regions. The platform helped to identify common AEFI following the use of these new vaccines. The ODK mobile technology was vital in improving AEFI reporting and providing data to monitor the use of new vaccines in Cameroon.

***Keywords*—**Adverse events following immunization, AEFI, Cameroon, COVID-19 vaccines, novel oral polio vaccine 2, open data kit

I. Background

AEFI are elements requiring particular attention post-vaccination. AN AEFI is any health problem that follows immunization and might not necessarily have a causal link with the vaccine used [1]. Indeed, despite the mammoth benefits of vaccines in global disease control and eradication, there is a risk of undesirable side effects [2]. Vaccines contain antigens (the active ingredient) and other components, including adjuvants, preservatives, stabilizers, buffers, surfactants, and antibiotics to prepare the immune system to fight specific infections. These constituents have the potential to create an adverse event. Therefore, even if all vaccine actors take the required precautions, consumers could still have AEFI caused by the vaccine composition or an error in its administration [3].

There are no perfect vaccines – all vaccines potentially create undesirable effects on healthy individuals despite their effectiveness [1]. Although severe forms like anaphylactic shock could occur in rare cases, most effects are mild and clear up quickly. However, it could undermine vaccine confidence if not rapidly identified and effectively managed. More so, conspiracy theorists could leverage poorly managed AEFI to drive anti-vaccine agendas. This issue could lead to a significant drop in vaccination coverage, reversing global efforts in disease eradication and control – ultimately leading to the sprouting of vaccine-preventable diseases (VPDs) globally. It is, therefore, of utmost importance to report all cases of AEFI to allow for additional research and appropriate action.

Although most events following immunization are coincidental or due to human or programmatic errors and not due to the vaccine itself, a sound surveillance system must be established to identify and report all cases [1]. That is why most countries employ passive and active surveillance and reporting of AEFI. However, spontaneous reporting of AEFI is the primary approach to monitoring the vaccinated post-licensure. This passive AEFI surveillance is practiced in many countries

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[4], while active surveillance is reserved for the follow-up of specific cases of interest [5]. Despite several approaches employed in capturing and reporting data on AEFI, underreporting is still a significant challenge worldwide. This challenge is more pronounced in low-income settings [6].

Cameroon is one of such countries in sub-Saharan Africa with critically under-reported AEFI during routine childhood immunization. Indeed, before the introduction of new vaccines, many health districts routinely vaccinate children without surveying and reporting cases of AEFI, except during national immunization campaigns. In recent years, the Country's vaccination program has faced an increasing infodemic challenge that preceded the introduction of new vaccines [7]. These newly introduced vaccines (COVID-19 and nOPV2) are based on novel technology, such as genetically modified ribonucleic acid or recombinant viral vectors and new delivery systems, with little past human experience [8]. This observation prompts the need to adequately identify, manage, and transparently communicate on AEFI. This study, therefore, focuses on sharing up-to-date information on the AEFI burden in Cameroon during the introduction of new vaccines and the role played by mobile technology in enhancing AEFI reporting. This study will therefore be resourceful in strengthening AEFI surveillance and serve as a platform for further AEFI investigation in Cameroon.

II. Methodology

Study Design and Setting

We conducted a descriptive cross-sectional study using 2018-2022 aggregated AEFI surveillance data from Cameroon's weekly and annual epidemiological reports of the Expanded Program on Immunization (EPI), the District Health Information System (DHIS)-2, and the ODK.

Cameroon is a country in sub-Saharan Africa with an estimated national population of over 27 million inhabitants in 2022, 25% of whom are aged less than 15 years, unequally distributed in 10 regions and 197 districts [9]. Therefore, to effectively survey and report AEFI, each vaccinating health facility has staff in charge of the follow-up of AEFI. Vaccinators educate caregivers, and the vaccinated on AEFI and then monitor and report AEFI to these focal persons, who do a comprehensive report using a predesigned reporting tool. In the past three decades, reports were usually paper-based or using MS Excel-based AEFI reporting tools. However, early in 2019, DHIS-2 was used to capture aggregated AEFI data. Generally, the staff entered the data in the DHIS-2 at the end of the month using a computer and internet access. Later in 2019, the ODK was employed to capture real-time individual-level data of cases of AEFI. The staffs use a mobile phone with the ODK application to report AEFI. The actors enter the data even without internet access but use the internet to transmit the reporting form. Today, the DHIS-2 reports monthly aggregated data, while the ODK is used for routine individualized AEFI data collection in the field.

Traditionally, none-severe AEFI cases are noted and reported in the DHIS-2 monthly [9], while severe cases are managed and immediately reported to the hierarchy. The information on severe and none-severe AEFI is usually assessed at the national level by a team of experts. The task includes classifying the cases and conducting further investigations to establish causality. This expert committee meets when there are reported cases following the invitation of its president.

Key Operational Definitions

In this study, AEFI considered all cases reported in the DHIS-2, ODK; and weekly and annual epidemiological reports of AEFI cases. The classification of AEFI severity was strictly based on established classifications in the databases.

Sampling and Data Collection

The secondary data on AEFI from 2018 to 2022 in all districts were extracted from DHIS-2, ODK, and epidemiological reports; and cleaned for analysis. Data on weekly and annual reports smaller than that found in the DHIS-2 or ODK were excluded.

Data Management and Analysis

The data were exported and analyzed using a Microsoft Excel 2019 worksheet, and summary statistics were used to estimate the incidences of AEFI. We used a quantum geoinformation system to report the data on maps.

Ethical Considerations

This study mainly used secondary aggregated data and did not involve individual-level data, so ethical clearance and participant consent were not required.

III. Results

All 197 health districts in Cameroon were included in the study.

Evolution of AEFI Cases

Considering the surveillance platform of Cameroon, before 2020, at least 40% of districts did not report a case of AEFI yearly. In 2018, the EPI captured 1,172 cases of AEFI across Cameroon, including 202 severe cases. The incidence was 1.6 per 100,000 vaccine doses administered. A similar trend occurred in 2019 when the EPI captured 1 942 cases of AEFI (AEFI rate of 1.8 per 100,000 vaccine doses administered), including 50 severe cases, following the data reported in the DHIS-2. In 2020, Cameroon captured 1,221 cases of AEFI in the district health information software. The reporting forms were rarely available at the national level before 2020. From 2021 and 2022, the DHIS-2 reported less than 400 AEFI per year. The ODK captured more AEFI instances than the DHIS-2 (Fig. 1) and transmitted individualized data for review. From 2020, the ODK reported more AEFI than any other platform.

Types of AEFI with Novel Vaccines

New vaccines against COVID-19, including Sinopharm BBIBP, Oxford AstraZeneca vaccine, Covishield™, and Johnson & Johnson's Janssen COVID-19 vaccine, were introduced in April 2021 for people aged 18 years and older in Cameroon. In June, July, and November 2022, nOPV2 was

used to mass vaccinate children under five.

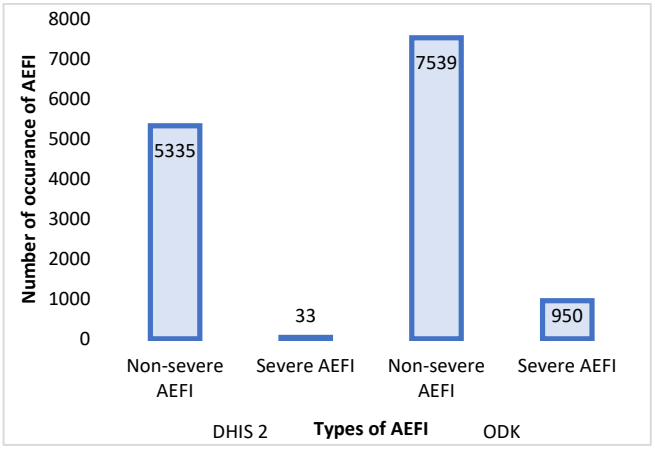

Fig. 1 AEFI reported per platform from 2018 to 2022

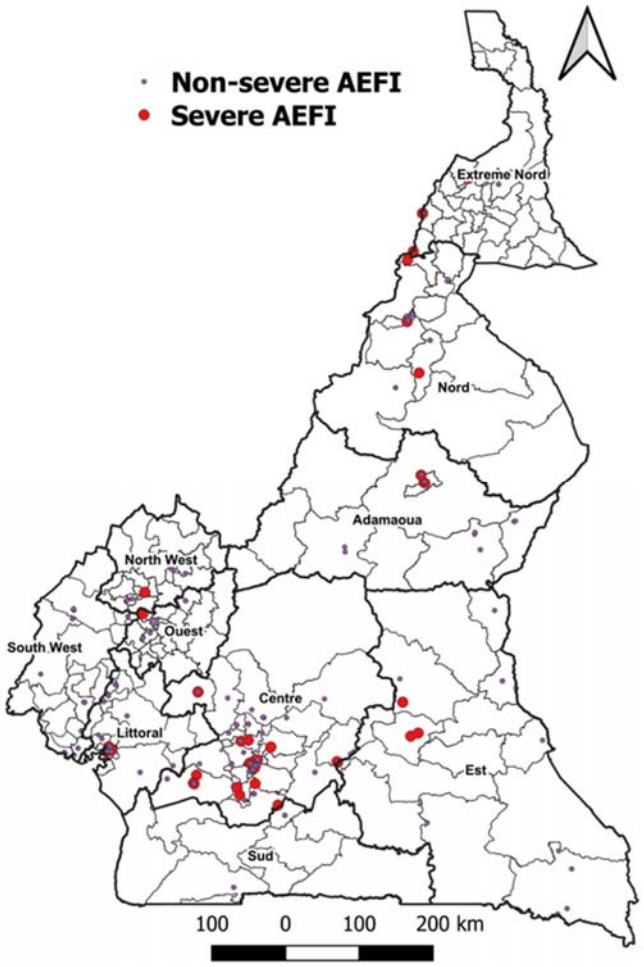

Fig. 2 Distribution of AEFI following nOPV2 vaccination June - December 2022

Following the COVID-19 vaccination, an AEFI rate of 160 per 100 000 vaccine doses administered, including 126 severe cases. On the other hand, with nOPV2, an AEFI rate of 1.9 per 100 000 vaccine doses were administered, including 47 severe cases.

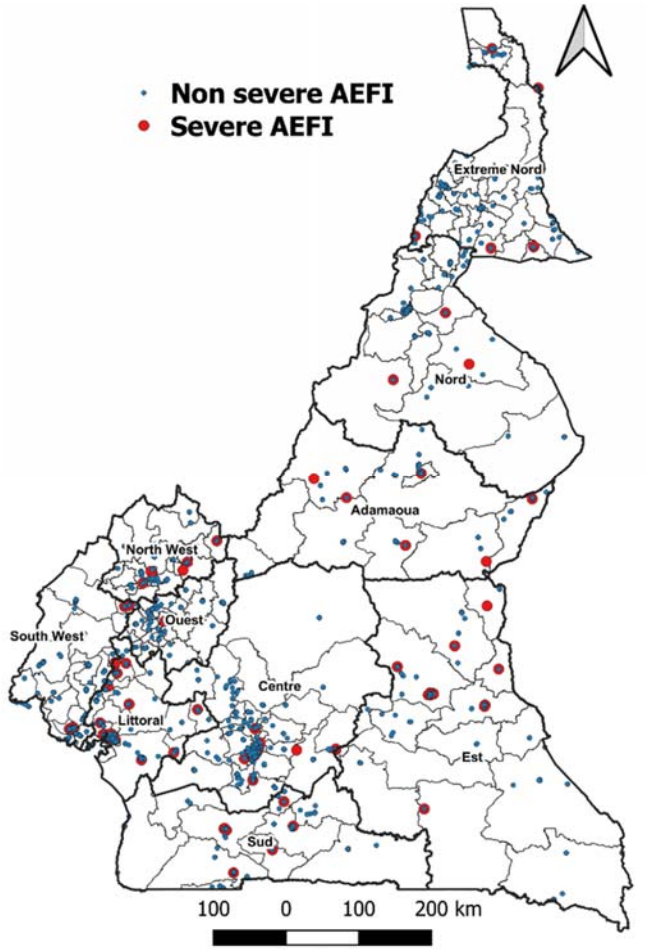

Fig. 3 Distribution of AEFI following COVID-19 vaccination April 2021 - December 2022

During the new vaccine introduction, health workers reported non-severe and severe AEFI from all 10 regions of Cameroon (Figs. 2 and 3).

The AEFI were mainly flu-like (Figs. 4 and 5) with the new vaccines. The common AEFI following nOPV2 vaccination were fever, diarrhea, vomiting, prostration, and cough (Figs. 4). Rare presentations with nOPV2 included convulsion, anemia, rash, headache, dehydration, dyspnea, hives, agitation, anaphylactic shock, and edema (Fig. 4). People who received COVID-19 vaccines reported pain at the injection site, headache, fever, and prostration (Fig. 5). Rare AEFI were palpitations, agitation, anaphylactic shock, epigastralgia, altered consciousness, asthmatic crisis, pelvic pain, erectile dysfunction, rash, anemia, loss of balance, ocular disorders, dehydration, erythema, respiratory distress, edema, cardiovascular conditions, and paralysis (Figs. 5).

Individualized data for severe AEFI cases helped the national adverse event following immunization expert committee classify. The people affected by severe AEFI benefitted from medical care and funding at the closest health facility for case management through the Ministry of Public Health.

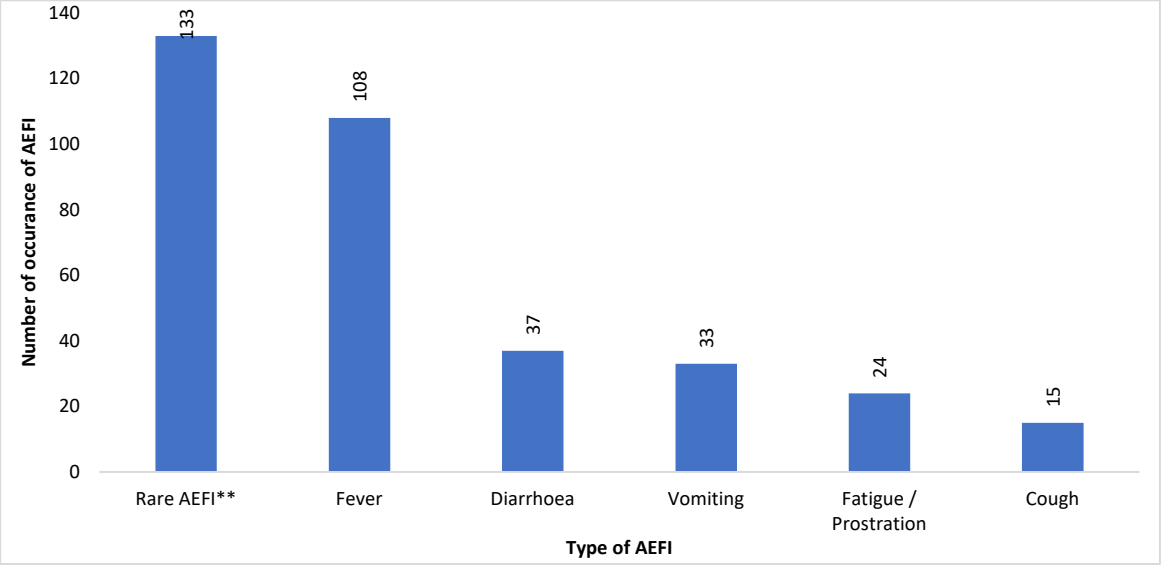

Fig. 4 Common AEFI reported with nOPV2 vaccination June - December 2022

Key: ** Any AEFI with less than 10 occurrences was considered Rare: convulsion (9), anemia (8), rash (6), headache (5), dehydration (5), dyspnea (5), hives (5), agitation (4), motor weakness(4), nausea (4), anorexia (4), abscess at the injection site (3), pain (3), acute flaccid paralysis (3), loss of balance (3), allergic reaction (3), refusal to suck (3), anaphylaxis (2), coryza (2), chills (2), jaundice (2), persistent crying (>3 hours) (2), dizziness (2), anuria (1), hot flashes (1), anaphylactic shock (1), conjunctivitis (1), respiratory distress (1), pain at the injection site (1), joint pain (1), muscle pain (1), pelvic pain (1), erythema (1), inflammation (1), insomnia (1), lethargy (1), heaviness of the limbs (1), limb edema (1), eye edema (1), facial edema (1), oliguria (1), mouth sores (1), itch (1), cold (1), tachycardia/palpitations (1), difficulty breathing (1), blurred vision (1), hoarse voice (1)

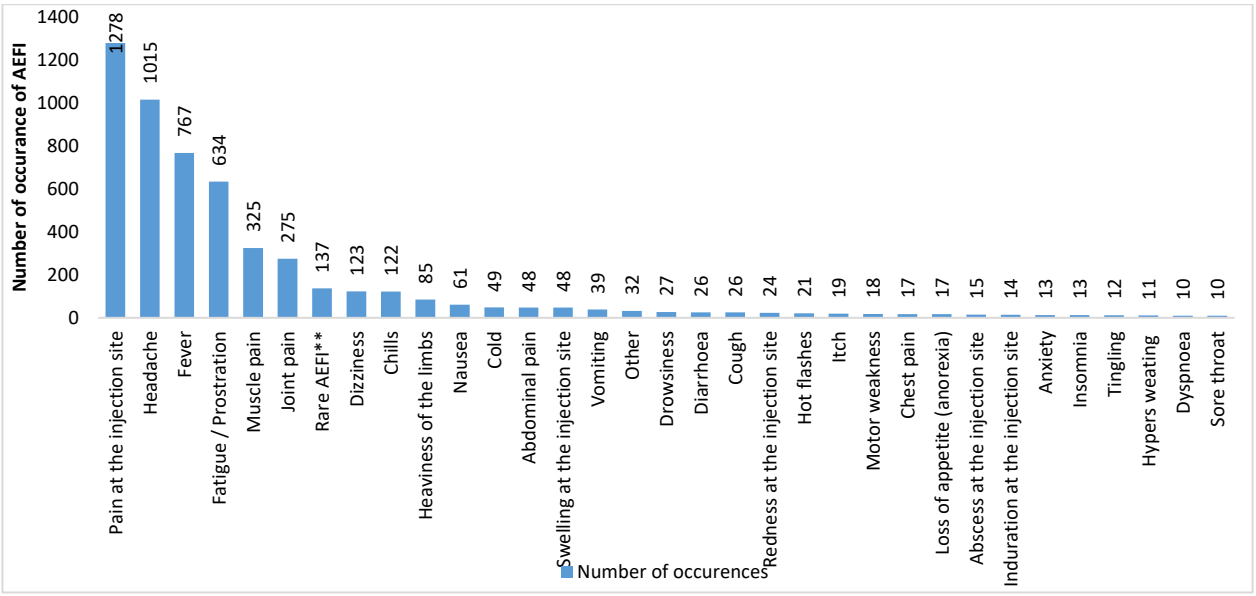

Fig. 5 Common AEFI reported with COVID-19 vaccination April 2021 - December 2022

Key: ** Any AEFI with less than 10 occurrences was considered Rare: palpitations (9), agitation (8), anaphylactic shock (7), epigastralgia (7), fainting/syncope (7), asthmatic crisis (6), pelvic pain (6), lethargy (6), erectile dysfunction (6), rash (5), anemia (4) loss of balance (4), decreased or no eye contact (3), conjunctivitis (3), coryza (3), visual field deficit (3), dehydration (3), erythema (3), hypertension (3), loss of consciousness (3), angioedema (2), convulsions (2), respiratory distress (2), jaundice (2), edema (2), bleeding (2), blurred vision (2), hoarse voice (2), blindness (2), limb paralysis (3), blink (1), altered consciousness (1), encephalopathy (1), whimper (1), hypersalivation (1), hypotension (1), change in tendon reflexes (1), cerebellar nystagmus (1), eye edema (1), facial edema (1), facial paralysis (1), phlyctens (1), mouth sores (1) ocular pruritus (1), allergic reaction (1), redness of the eyes (1), capillary refill time >3s(1), hives (1)

IV. Discussion

Vaccination provides the most efficient way to protect against infectious diseases globally. Vaccine products are subject to rigorous quality control and approval to ensure safety. Notwithstanding, some people could still have AEFI. Unfortunately, reporting AEFI in Cameroon was not common

with routine childhood vaccines. Following the introduction of new vaccines with novel technologies, it became crucial to strengthen AEFI surveillance and closely follow up with the vaccinated people in the Country. This vaccine introduction prompted us to review AEFI in Cameroon from various reporting platforms.

Although active and passive surveillance approaches are vital tools used to monitor AEFI in Cameroon, the Country reported few cases in the past. Until 2020, the routine platform captured fewer cases due to limited attention paid to this surveillance indicator. In addition, transmitting individualized reporting sheets was challenging, rendering the classification by the national expert committee complex.

The ODK platform's introduction experienced a marked increase in AEFI-reported cases (Fig. 1). The system captured most of the AEFI from 2021 following the introduction of COVID-19 vaccines and nOPV2 in 2022. This smartphone application made it possible to keep records and quickly identify cases of AEFI in communities across the country [10]. This increased case detection could be linked to the urge to verify the safety of the new vaccines coupled with active disease surveillance. This approach strengthened the system of governance for vaccine safety monitoring. Consequently, the National AEFI Expert Committee was able to follow up on AEFI cases and establish causality and vaccine safety in Cameroon [4]. This progress helped identify and address instances of AEFI, which could hamper vaccine uptake [11].

Following a vaccine introduction, there is a need to monitor the vaccinated population. In Cameroon, the identified AEFI (Figs. 4 and 5) was similar to other settings and routine childhood vaccines. In addition, ODK technology helped enhance reporting rates in the country from 2021 and reduced delays in reporting. Furthermore, the tool immediately made available individualized data of people affected by AEFI during the nOPV2 and COVID-19 vaccine introduction. This system improved community-based AEFI reporting rates [6]. Moreover, with patients' complete medical records, it was easier for the national expert committee to do an adequate case review and established causality.

V. Conclusion

Although vaccines undergo rigorous control before introduction for use, it is crucial to monitor AEFI. Adequate follow-up of AEFI indicates vaccine safety and guides health actors to manage and communicate on vaccination adequately. We observed AEFI in Cameroon after introducing new vaccines like nOPV2 and those against COVID-19. Before this period, reporting on AEFI was limited. Using a mobile-electronic platform like the ODK captured a considerable number of AEFI and reported individualized data on people vaccinated with these new vaccines. It was observed that the associated AEFI with these new products was common to other vaccines used in the population. This paper gives initial information on the state of AEFI before and after using ODK and following the use of vaccines with a new technology in Cameroon. However, the research did not report data on the causalities of AEFI following these vaccines. It is vital to establish a link between the adverse outcomes following the use of vaccines to associate the reported AEFI with the corresponding vaccines.

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Availability of Data and Materials

The datasets used during this study are available from the corresponding author upon reasonable request. These data can also be directly obtained from the Dhis-2, ODK platform, and the weekly and annual reports of the EPI for the corresponding periods.

Contributions

Andreas Ateke Njoh conceived the idea of the study, interpreted the data, and drafted the paper. Laurent Cleenewerck De Kiev supervised the work. Shalom Tchokfe Ndoula, Amani Adidja, and Germain Nguessan Menan participated in the data collection. All authors reviewed and approved the final copy of the manuscript.

Ethics Declarations

This secondary study used data abstracted from existing Ministry of Health databases. So, no ethics approval and consent to participate were required.

Consent for Publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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