



Vaccines safety; effect of supervision or SMS on reporting rates of adverse events following immunization (AEFI) with meningitis vaccine (MenAfriVacTM): A randomized controlled trial



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ABSTRACT

Background: To ensure vaccines safety, given the weaknesses of the national pharmacovigilance system in Cameroon, there is a need to identify effective interventions that can contribute to improving AEFI reporting.

Objective: To assess the effect of: (i) sending weekly SMS, or (ii) weekly supervisory visits on AEFI reporting rate during a meningitis immunization campaign conducted in Cameroon in 2012 using the meningitis A conjugate vaccine (MenAfriVacTM).

Methods: Health facilities that met the inclusion criteria were randomly assigned to receive: (i) a weekly standardized SMS, (ii) a weekly standardized supervisory visits or (iii) no intervention. The primary outcome was the reported AEFI incidence rate from week 5 to 8 after the immunization campaign. Poisson regression model was used to estimate the effect of interventions after adjusting for health region, type of health facility, type and position of health workers as well as the cumulative number of AEFI reported from weeks 1 to 4.

Results: A total of 348 (77.2%) of 451 health facility were included, and 116 assigned to each of three groups. The incidence rate of reported AEFI per 100 health facility per week was 20.0 (15.9–24.1) in the SMS group, 40.2 (34.4–46.0) in supervision group and 13.6 (10.1–16.9) in the control group. Supervision led to a significant increase of AEFI reporting rate compared to SMS [adjusted RR = 2.1 (1.6–2.7); $p < 0.001$] and control [RR = 2.8 (2.1–3.7); $p < 0.001$] groups. The effect of SMS led to some increase in AEFI reporting rate compared to the control group, but the difference was not statistically significant [RR = 1.4 (0.8–1.6); $p = 0.07$].

Conclusion: Supervision was more effective than SMS or routine surveillance in improving AEFI reporting rate. It should be part of any AEFI surveillance system. SMS could be useful in improving AEFI reporting rates but strategies need to be found to improve its effectiveness, and thus maximize its benefits.

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1. Background

The major goal of immunization safety surveillance is to detect and respond appropriately to adverse events following

immunization (AEFI) in order to reduce its potential negative impact on the success of immunization programs [1].

An AEFI is medical incidence occurring after immunization and believed to be caused by immunization [2]. Types, seriousness and frequency of AEFI depend on the product and the medical history of the vaccine recipient [3,4]. AEFI are susceptible to cause minor or serious harm to individuals, as well as negatively affect the national immunization program, including a reduction in the population's use of the program [5]. During vaccination campaigns,

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risk of AEFI occurring is higher since a very large number of people are vaccinated at the same time and rumors can have damaging consequences on vaccine uptake [6,7].

In Cameroon, AEFI surveillance is an integral part of the EPI [8]. It is part of the national pharmacovigilance system which is based in the Directorate of Pharmacy, Medicine and Laboratories [9]. Weaknesses in this system include insufficient motivation and training of personnel at different levels; limited coordination and resources; and low AEFI and ADR (adverse drug reactions) reporting, investigation, completeness and timeliness rates. The system is implemented within routine EPI activities but is much more active and supported during immunization campaigns. For example, all immunization campaigns conducted in the last four years included AEFI surveillance [10,11]. Reports from these activities highlighted the same weaknesses as the national pharmacovigilance activities as well as a positive effect of supervision on these parameters. For example, during a yellow fever immunization campaign that took place in 2009 in 62 health districts in Cameroon, 362 AEFI were reported, including 53 serious cases. Ninety-two of the cases or 25% of all reported AEFI were detected as a result of supervision conducted in only 20% of the target health districts during the last week of AEFI surveillance. These included eight serious cases (28.8% of all serious AEFI reported).

Supervision is the standard recommended intervention in Cameroon to ensure that AEFI monitoring, reporting, and cases investigation take place [8]. However, the efficiency of supervision is limited since it requires a lot of resources in terms of personnel, coordination, funding and logistics to sustainably contribute to the monitoring of field activities [12–14]. Short Messages Services (SMS) has been shown to improve health outcomes among patients in African countries by increasing health workers' adherence to guidelines [15–17]. It is therefore a potentially valuable tool to remind health professionals to identify and report AEFI. The coverage of mobile phone networks in Cameroon was estimated in 2011 to be more than 90% [18].

This paper describes research conducted in conjunction with meningitis A immunization campaign that took place from 3rd to 16th December 2012 in two health regions in Cameroon (Adamaoua and North West) that are part of the African meningitis belt [19]. The campaign used the new conjugate vaccine against group A Meningococcus (MenAfriVac™) produced by Serum Institute of India. This vaccine has been shown to be efficacious and extremely safe [20–23].

The aim of the study was to assess the effect on AEFI reporting, after the meningitis vaccination campaigns, of sending a weekly standardized SMS to health workers in charge of AEFI surveillance in health facilities or conducting standardized supervision of these personnel using skilled supervisors. We hypothesized that either of these interventions would result in higher AEFI reporting rates than the routine AEFI surveillance activities (i.e., "no intervention").

2. Methods

2.1. Registration

The study was approved by the Cameroon National Ethics Committee and registered in the Pan African Clinical Trial Registry (www.pactr.org) database with PACTR201201000454298 as the unique identification number.

2.2. Study design

The study used an open randomized controlled design with three arms. All health facilities that were registered in health districts targeted in the 2012 meningitis A campaigns and that met

the inclusion criteria were randomly assigned to receive: (i) a weekly standardized SMS asking them to report all medical events occurring during the intervention period in persons immunized during the campaign, (ii) a weekly standardized supervisory visit by trained health district focal points for AEFI detection and reporting processes, or (iii) no intervention besides routine training and sensitization of health facility teams during health districts coordination meetings (the control group). The primary outcome was the incidence of AEFI per 100 health facilities per week reported to the Regional Delegation of Public Health. Informed consents of all health workers were obtained after the nature and possible consequences of the studies had been fully explained to them.

2.3. Participating health facilities

Inclusion criteria for health facilities in the study included the existence of at least one health professional appointed or accepting to be the health facility focal point for AEFI during the meningitis A campaign surveillance period, their ownership of a mobile telephone and their commitment to be present during the study period. Non-functional health facilities, those not covered by at least one of national mobile telephone networks, those with AEFI focal point who expected to be absent for at least one week or during one of interventions were excluded from the study.

The study targeted health facilities that were officially registered in all 27 health districts of the health regions of Adamaoua (8 health district) and North West (19 health districts). The official document mapping out Cameroon's health facilities indicates that there were 468 health facilities in these two health regions in 2011, including 136 in the Adamaoua region, and 332 in the North West region [24].

2.4. Interventions

2.4.1. Pre-intervention procedures

Field activities conducted in all health districts before intervention are shown in Fig. 1.

2.4.2. Interventions

(i) **SMS:** Mobile phone numbers of AEFI focal points in health facilities in the SMS groups were cross-checked by calling each owner. Messages to be sent were typed, crosschecked and saved onto a mobile telephone. Each week for four consecutive weeks, standardized SMS were sent to all AEFI focal points in the SMS group at 8:00 a.m. on Monday in one language (French or English) and on Tuesday in the other language (the order was alternated from one week to the other) to all AEFI focal points in SMS health facility group at 8:00 AM. The content of the messages was the same each week and included a reminder of the MenAfriVac™ AEFI surveillance period, case definition of an AEFI and a recommendation to actively detect and report all occurring AEFI on a daily basis. The "delivery report" function of the mobile phone was used to verify if the message was received and opened.

(ii) **Supervision:** Each week, a nurse trained in supervision and AEFI surveillance visited on Monday or Tuesday each health facility to supervise the focal point on AEFI detection and reporting using a standardized grid. This grid included structured questions to check if the supervisor had included AEFI surveillance in his or her daily time table and if he/she knew the AEFI case definition, the AEFI surveillance period, how to detect and report a case and what to do with a serious AEFI case. Weaknesses were corrected by supervisors using standardized guidelines. The supervisory visits were verified by checking the stamps and signatures of the head of the health facility on supervisor's mission orders.

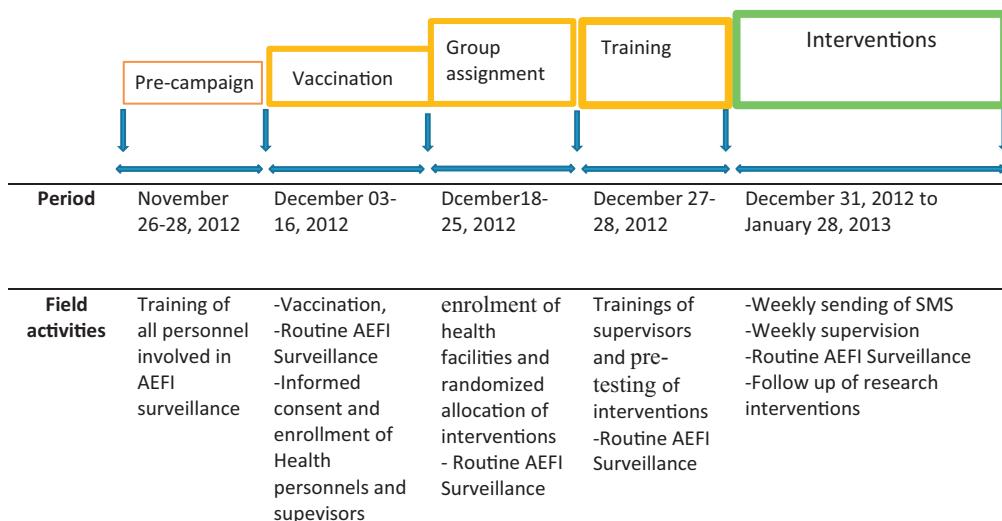


Fig. 1. Flow diagram of field activities during the implementation of the study.

2.4.3. Control

Health facilities in the control group received no additional AEFI-related interventions apart from what all health facilities normally receive during a vaccination campaign, namely pre-campaign training on AEFI surveillance, passive AEFI monitoring during the campaign and 42 days after and monthly sensitization of health facility teams during health district coordination meetings.

2.5. Outcomes

The primary outcome was the incidence rate of reported AEFI per 100 health facility per week during the intervention period, (week 5–8 after immunization, 31 December 2012 to 27 January 2013). The numerator was the sum of reported AEFI and the denominator was the number of health facilities multiplied by the number of weeks of the intervention. The secondary outcome was the reported incidence rate of serious AEFI.

For each health facility, baseline information was collected on the health region, health district, category of health facility (e.g., integrated health center vs. other), and type and position of health professionals designated as the AEFI focal point. In addition, the number of AEFI reported before the interventions were implemented was collected at North West and Adamaoua Regional Delegations of Public health.

2.6. Sample size

The sample size calculation was based on the test of the null hypothesis that there is no difference between supervision or SMS on AEFI reporting rate compared to no intervention. The level of significance was set at 0.05 with 2-tailed test. The sample size was calculated using the WHO publication on Sample Size Determination in Health Studies [25]. Assuming equal numbers of health facilities in each of the three groups, 150 health facilities or 50 per group were needed to give 80% power to detect a 5% increase in reported AEFI per health facility per week. To account for a compliance rate of 80% and 20% drop-out rate, the sample size was increased to 300 health facilities.

2.7. Randomization

Health districts that had health facilities included in the study were ranked in alphabetic order from A to Z using the filter function of Excel 2010. The health facilities were also ranked in the same

order per health district. All its key variables (health region, health district, type of health facility, type and position the focal point) except its name were hidden during the assignment process. The facilities were then randomly assigned to the SMS, supervision and control arms in blocks of three following a 1:1:1 allocation ratio. All combinations of blocks were listed and a number assigned to each combination. Numbers were generated from Table XXXIII of Yates and Fisher [26] as follow: an arbitrary starting point was chosen in the table and from that point; numbers were read row by row across pages.

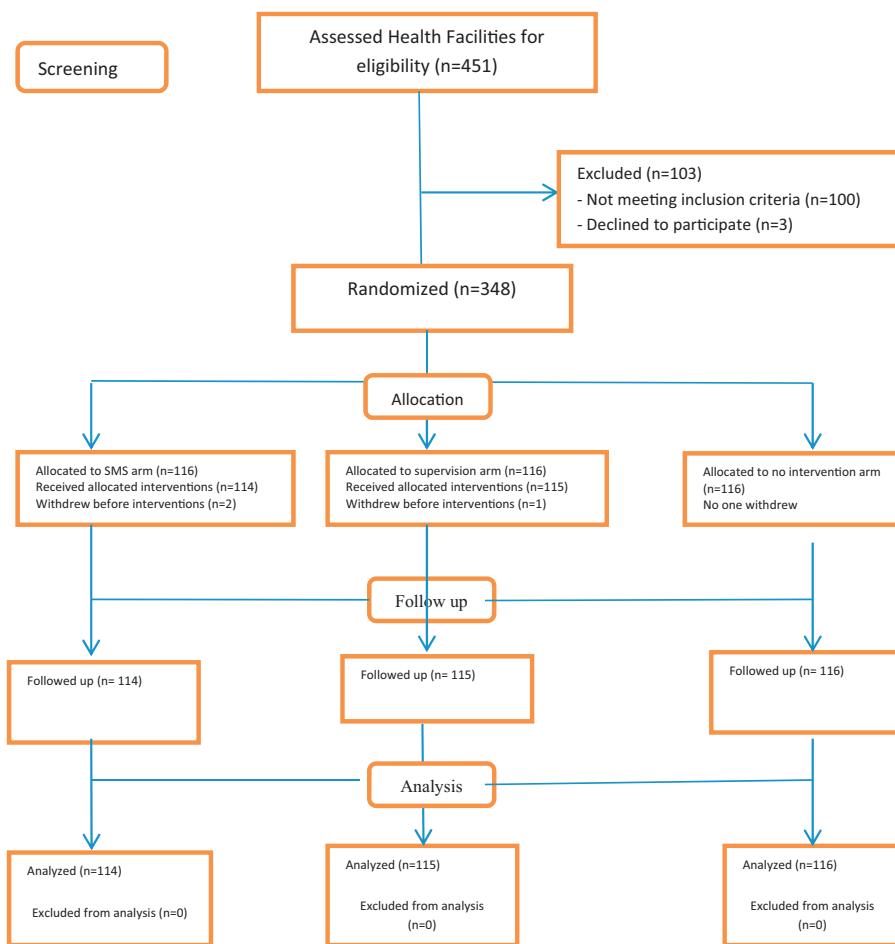
2.8. Statistical analysis

An intention-to-treat approach was used to assess outcomes. All missing values were crosschecked and data were retrieved from the regional delegations by the study teams before data entry. The incidence rate of reported AEFI was estimated per study group. The effect of interventions was compared between study groups by estimating the incidence rate (RR) and the attributable risk. The significance of the difference was estimated using the Z test, confidence intervals and *p* value. The Poisson regression model was used to estimate the effect of interventions on reported AEFI on incidence rates, after adjusting for potential confounders, namely the cumulative number of AEFI reported from week 1 to 4, the health region, the type of health facility and position of the health professionals acting as the AEFI focal points. Data were entered in epi info version 3.5.3 and analyzed using Stata version 10 (Texas, 2009) and IBM SPSS 19. The level of confidence of our estimates was 95%.

3. Results

3.1. Recruitment, participants' flow and baseline data

During the first half of December 2012, a total of 451 out of 468 registered health facilities (96.4%) in the two health regions were visited and asked to participate in the study. One hundred and three (22.8%) were excluded, including 39 (37.9%) in the Adamaoua and 64 (62.1%) in the North West health regions. Reasons for exclusion included absence of a cell phone networks (77 (74.8%)), the health facility was non-functional (21 (20.4%)) and other reasons (5(4.9%)). A total of 348 (77.2%) health facilities were included, and 116 were assigned to each of three groups. Three health facilities, including two in the SMS group and one in the supervision group, withdrew before the interventions started because the health

**Fig. 2.** Flow diagram of the study.

professionals selected to receive intervention were not available and could not be replaced. Fig. 2 shows the enrolment and assignment processes of health facilities in the flow in the study. Table 1 shows the characteristics of health facilities and health professionals by study groups.

3.2. Outcomes and risks estimation

Fig. 3 presents the evolution of the number of AEFI reported before intervention (weeks 1–4) and during intervention period (weeks 5–8) in the different groups. During the intervention period,

339 AEFI were reported from participating health facilities, including 91 from the SMS group, 185 from the supervision group, and 63 from the control group. The number of health facility – weeks observed was 456 in the SMS group, 460 in the supervision group and 464 in the control group. The incidence rates of reported AEFI were 20.0 (15.8–24.1) AEFI per 100 health facilities per week in the SMS arm, 40.2 (34.4–46.0) in the supervision arm and 13.6 (10.1–16.9) in the control arm.

The crude incidence rate of AEFI reporting rates of the interventions groups compared to the control groups is shown in Table 2. The incidence rates of reported AEFI in SMS and supervision groups

Table 1
Characteristics of health facilities and Health professionals included in the study, by intervention group.

Characteristics	Total		SMS group		Supervision group		Control group		<i>p</i> value	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%		
Health facilities										
<i>By region</i>										
North West region	263	76.2	87	33.1	87	33.1	89	33.8	0.980	
Adamaoua region	82	23.8	27	32.9	28	34.2	27	32.9	0.980	
<i>By type of health facility</i>										
Integrated health centers	231	66.9	79	34.2	74	32.0	78	33.8	0.870	
Other health facilities	114	33.1	35	30.7	41	36.0	38	33.3	0.700	
Health personnel										
<i>By position within the facility</i>										
Head of integrated health centers	216	62.6	79	36.6	72	33.3	65	30.1	0.360	
Other position in the health facility	129	37.4	35	27.2	43	33.3	51	39.5	0.110	
<i>By types of health professional</i>										
Nurses	325	94.2	107	33.0	110	33.8	108	33.2	0.970	
Other	20	5.8	7	35.0	5	25.0	8	40.0	0.590	

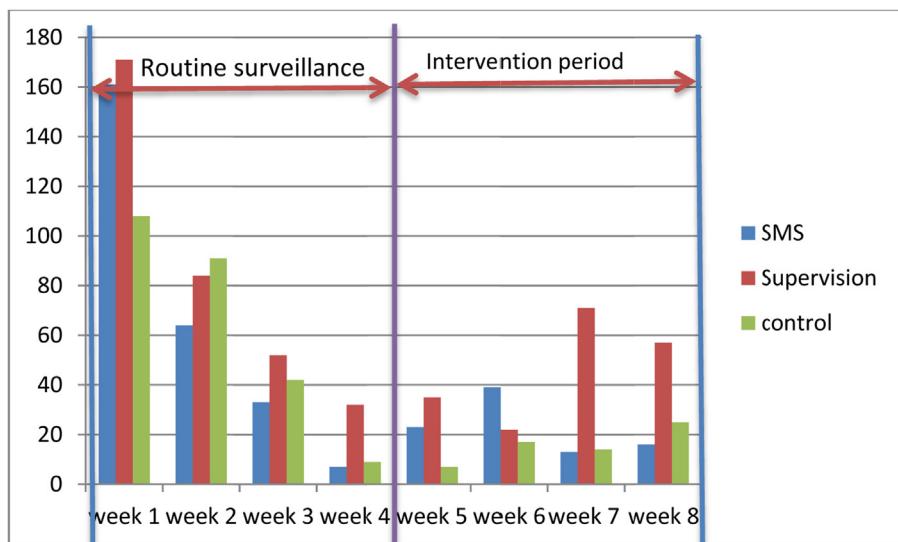


Fig. 3. Number of AEFI reported before the interventions (weeks 1–4) and during the intervention period (weeks 5–8) in the different intervention groups.

Table 2

Crude incidence (RR) rate comparing AEFI reporting rates of the interventions groups to that of the control group using simple Poisson regression.

Group	RR	95% IC RR	p value
SMS	1.5	(1.1–2.0)	0.022
Supervision	2.9	(2.2–3.9)	<0.001
Control	1		

were superior to that of the control group. The AEFI reporting rate in the supervision group was also superior to that in the SMS group. The attributable risk of AEFI reporting per 100 health facilities per week in the SMS and supervision groups compared to the control group were 6.38 (0.1–12.8) and 26.6 (9.9–33.3) respectively. This rate in the supervision group compared to the SMS group was 20.3 (13.3–27.3).

Table 3

Adjusted rate ratios comparing outcomes in interventions groups to that of the control group using multiple Poisson regression.

Group allocation	RR	95% IC RR	p value
<i>Groups</i>			
SMS	1.4	(1.0–1.9)	0.051
Supervision	2.8	(2.1–3.7)	<0.001
Control	1		
<i>Regions</i>			
Adamawa	0.3	(0.2–0.4)	<0.001
North west	1		
<i>Type of health facility</i>			
Integrated health centers	1.6	(1.2–2.2)	<0.001
District and other hospitals	3.1	(2.0–4.9)	<0.001
Private health center	1		
<i>Type of health professional receiving the intervention</i>			
Nurses	3.7	(1.0–9.8)	0.024
Lab technician	4.9	(1.3–18.0)	0.017
Other health professionals	1		
<i>Health professionals' position</i>			
Head of health facility	2.0	(1.5–2.7)	<0.001
Not heading the health facility	1		
Cumulative number of AEFI reported prior to the interventions (weeks 1–4 following immunization)	1.04	(1.04–1.06)	<0.001

AEFI: adverse events following immunization.

Table 3 presents the incidence rates of the interventions groups compared to the control group after adjustment for the cumulative number of AEFI reported during the four weeks prior to the intervention, the health region, type of health facility, and type and position of the health professionals serving as AEFI focal points. The incidence rate of reported AEFI in SMS group was superior but not statistically different to that of the control group [RR = 1.4 (0.8–1.6); p = 0.070], while the incidence rate of reported AEFI in supervision group remained significantly superior to that of the SMS [adjusted RR = 2.1 (1.6–2.7); p < 0.001] and control group [RR = 2.8 (2.1–3.7); p < 0.001].

A total of 17 serious AEFI were reported during the intervention period including 7 from the SMS, 9 from the supervision and 1 from the control groups. This resulted in incidence rate of 1.53 serious AEFI per 100 health facility per week in the SMS group, 1.95 in the supervision group and 0.22 in the control group.

4. Discussion

Results of this study show that weekly supervision of health professionals in charge of AEFI surveillance in health facilities significantly improved the reporting rate compared to sending standardized SMS to these health professionals or to the standard practices. Sending SMS to remind health professionals about AEFI surveillance improved AEFI reporting rates compared to the control group but not significantly. This study is unique in that it is the first measure the effects of supervision and SMS on AEFI reporting rate.

A benefit of supervision in increasing AEFI reporting rate, timeliness and completeness of AEFI reporting have already been observed during previous AEFI surveillance conducted following immunization campaigns in Cameroon [10]. These results are also in line with other studies of different health activities that showed benefits of supervision in improving job satisfaction, knowledge, skills and performances of health workers [13,27,28]. Unlike recommended in some guidelines, weekly supervision was done by nurses who were not superior to those they were supervising in terms of rank or qualifications (i.e., peers), but who were well trained and had time and resources to do their job properly. The supervision was interactive, and included responses to knowledge gaps. Thus, it was expected to not only remind supervisees about AEFI reporting, but also to improve their ability to detect and report AEFI. This approach has been shown from previous studies to be

more efficient and less costly, as well as to have a broader reach than routine supervision typically conducted on a less frequent basis by higher level health personnel who are not necessarily trained to supervise the tasks in question [27,29,30].

The fact that the effect of weekly SMS on AEFI reporting rates was not statistically different to that of control group does not mean that SMS has no effect on AEFI reporting. Our study, in fact, showed that the rates of reporting serious AEFI were quite similar in the supervision and SMS groups and both much higher than in the control group. A beneficial effect of SMS on AEFI reporting has been shown in Cambodia, but the study lacked a control group [31]. Studies conducted in various settings of the efficacy of SMS in improving health care delivery have had varying results [16,32,33]. Optimal circumstances and strategies for the use of SMS to remind health workers about AEFI reporting are still to be clearly defined [34,35]. The SMS in this study were designed to remind the targeted health workers about the AEFI case definition, the surveillance period, and the reporting process, with the expectation that all suspected AEFI cases would be reported and all serious cases investigated. The fact that there was no interaction between the sender and receivers of the SMS could have contributed to reduce the effectiveness of SMS compared to face-to-face supervision. Receiving, reading and understanding a SMS may not necessarily lead to the expected response, especially if the person receiving it is not constrained or motivated to do so. Previous studies have reported high response rate among health professionals after having incentives added to the SMS reminder although this option raises the question of sustainability when implemented in a routine program [36,37].

Supervision is already recognized as a useful intervention when successfully integrated into health activities and programs [27,39–42]. However, its effects are often below expectations because of the limitations of the health system to conduct it properly [41]. The concern is not only to determine how to set up supervision to make it more efficient, but also to identify the most efficient interventions that can replace or be associated with it in order to improve the monitoring of health interventions. One of the interesting findings of the present study is that it has shown that nurses can supervise other nurses on AEFI reporting at the district level. Further studies could be designed to evaluate the effectiveness and efficiency of different supervision strategies on AEFI reporting at all levels of the health system. It could also be useful to compare the efficiency of using nurses as peer supervisors to that of more typical supervision strategies using supervisors of higher level professionals and to determine the circumstances in which SMS can help to improve AEFI monitoring. Other interventions and modes of delivery could be tested such as sending letters, using incentives, sensitizing vaccinated populations using mobile phones or the internet, and training that have been shown to improve health program performance [43–47].

Though health facilities participating in this study were sampled from only two of the ten health regions of Cameroon, the characteristics and distribution of these health facilities and the health professionals working in them were similar to those in Cameroon as a whole [31,38]. This suggests that our findings are applicable to the country as a whole and to other health systems with similar characteristics [39].

This study has some limitations. Data on some important variables that could have been included in the regression model to adjust for confounding were not collected. These included number of new patient visits made during the intervention period per health facility and the immunization coverage rate of the population served by the health facility. The number of patient visits was not collected because patient registration forms and procedures are not standardized in the participating health facilities. The immunization coverage rate was not collected since immunization activities were conducted both in health facilities and communities

and reported per health area, but not per health facility. In addition, the completion rate of AEFI reporting forms was very low and some important variables such as, the date of consultation, were missing on the forms. These weaknesses did not allow us to estimate some important parameters of AEFI surveillance such as promptness and identification of all serious AEFI.

5. Conclusion

The results of this study show that weekly supervision of health professionals in charge of AEFI surveillance in health facilities significantly improved the AEFI reporting rate compared to sending standardized SMS to these health professionals or to routine AEFI-related activities. Sending weekly standardized SMS to remind health professionals on AEFI surveillance improved only slightly overall AEFI reporting rate. This study also demonstrates that it is feasible to effectively supervise health staff at the district level using nurses. If this approach can be confirmed to be sustainable over time, it should be scaled up to improve the monitoring health programs and activities in Cameroon and in other countries with similar health system.

We recommend that when planning AEFI surveillance during vaccination campaigns, supervision should be included as an intrinsic part of the program. Strategies need to be identified to improve the effectiveness of supervision to maximize its benefits. More work needs to be done to determine whether regular SMS can contribute to improvements in the rate of AEFI reporting, and if so, how and in which circumstances the impact can best be achieved. Other interventions such as alternating SMS and supervision or sending SMS to the vaccinated persons or their parents should also be tested.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.vaccine.2014.08.012>.

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