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CAUSES OF VACCINE WASTAGE IN THE EXPANDED PROGRAMME ON IMMUNISATION (EPI) IN THREE REGIONS OF CAMEROON: CENTRE, SOUTH AND LITTORAL

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ABSTRACT

Background: poor storage of vaccines can lead to a deterioration in their biological activity, and consequently lower immunization rates in populations vaccinated against a specific disease. As a result, the cold chain essential to vaccine storage must function optimally to guarantee vaccine quality at the time of injection. The aim of this study was to determine the causes of vaccine wastage in the Expanded Programme on Immunisation in the Centre, Littoral and South regions of Cameroon. **Methods:** We conducted a descriptive cross-sectional study in these three regions from January to June 2024. The causes of vaccine wastage were investigated in terms of suitability, cold chain reliability and the policy of using opened vials as recommended by the World Health Organization. The data were analysed using R software. Fisher's exact test and Pearson's Chi-square test of independence were used for comparisons (95%CI; $P < 0.05$). **Results:** Regarding the adequacy of the cold chain, 14% of hospitals did not have an alternative cold chain, 46% of cold chain managers did not know how to estimate the volume of vaccine storage required, 34% of health institutions did not have a contingency plan, and 44% of vaccinators did not master vaccine transport procedures. in terms of the reliability of the cold chain, the temperature was not regularly monitored in 22% of hospitals, 79% of health facilities did not have an alternative energy source, and 37% did not have an emergency plan in place. 38% of health establishments did not have a regular maintenance plan for cold chain equipment. For these three parameters, no difference was found between the three regions ($p<0.9$). The policy of using opened blanks was respected in all three regions. **Conclusion**: the adequacy and reliability of the cold chain are significantly implicated in vaccine wastage in our three study regions.

KEYWORDS: Vaccine, cold chain, opened vial, low immunization.

INTRODUCTION

Vaccines are altered pathogenic substances which, when inoculated in an individual, confer specific immunity against an antigen.[1] Ever since the discovery of effective vaccination in 1796[2], vaccines have played a major role in preventing and even eradicating infectious diseases. It helps prevent 2 to 3 million deaths every year and contributes to achieving the fourth Millennium Development Goal.[3,4] To ensure the health of their populations, governments have opted for prevention from an early age, in line with the recommendations of the World Health Organization (WHO). Every year, the expanded immunization programs (EPI) of countries around the world, particularly those in Africa, plan and set ambitious targets to vaccinate thousands of children, with the aim of eradicating poliomyelitis worldwide, eliminating maternal and neonatal tetanus and reducing measles mortality, among other things. However, the conditions under which vaccines are stored for later use do not always guarantee the transfer of the desired immunity.[5] Bearing in mind that vaccinating is not the same thing as immunizing, the storage of vaccines in cold chains (CDFs) requires rigorous quality control to define the optimum conditions for preserving the biological activity of vaccines. In Cameroon, the methods used to define the quality of CDFs do not always guarantee that they operate optimally, leading to a deterioration in vaccine quality and a probable loss of

national reserves. Cameroon is a Central African country with an estimated population of 30 million.[6] To ensure immunization coverage for its population, the Ministry of Public Health, through its Expanded Program on Immunization, includes among its objectives the assurance of annual immunization coverage for children under one year of age, with immunization coverage of at least 90% nationally and at least 80% in each health district.[7] Meeting these targets is directly linked to preserving the biological activity of the vaccines during distribution and storage in the health districts' CDFs to ensure their quality at the time of vaccination. Certain factors, such as the conformity of the FDC equipment, the optimal operation of the FDCs, the training and socio-economic conditions of the personnel carrying out the immunization, the lack of Estimation of needs, storage, FDC control, administrative management and administration of vaccines, poor storage of vaccines in the refrigerator, the absence of an emergency plan, refrigerators with temperatures outside the recommended ranges, and the absence of temperature monitoring sheets can all contribute to the deterioration of vaccine quality and probable wastage. The aim of this study was to determine the ultimate causes of vaccine wastage in the EPI in the Central, Southern and Littoral regions of Cameroon.

MATERIALS AND METHODS

Study site

The study was carried out in the Centre, South and Littoral regions of Cameroon **(Fig.1)**, more specifically in the regional public health delegations, the regional co-ordinations of the Expanded Programme on Immunisation, and in the health districts of these three regions, in particular for their best EPI performance indicators and according to their socio-economic, socio-demographic and socio-cultural determinants compared with the other regions.

Figure 1: Study Site.

Study population

The study population consisted of EPI managers, health districts and vaccinators in the Centre, South and Littoral regions.

The study included EPI managers from the three selected regions who were present at the time of the survey and had given their informed consent, and managers from health districts, EPI focal points and health facilities responsible for immunisation.

Study design

To achieve our objective, we conducted a descriptive cross-sectional study between January and June 2024. We assessed the adequacy of the cold chain, the reliability of the cold chain, and the policy for the use of

opened vials by vaccinators, in line with the recommendations of the World Health Organization.[8]

Assessment of the adequacy of the cold chain

The adequacy of the cold chain was evaluated by assessing the compliance of cold chain equipment with WHO standards[9], the availability of sufficient storage volume within the cold chain equipment, the existence of an alternative cold chain, the ability of managers to estimate the necessary storage volume and the availability of a contingency plan in the health facilities or health districts where the vaccines are stored, storage of vaccines and control of vaccine transport procedures.[10]

Assessing the reliability of the cold chain

The reliability of the cold chain was assessed by regular temperature control[11], sufficient freezing capacity, sufficient preservation capacity, accessibility to back-up power, the existence of an emergency plan[12] in the event of a break in the cold chain and the maintenance of cold chain equipment.[13]

Evaluation of the policy of using opened vials in accordance with WHO recommendations

In line with WHO recommendations[14], Cameroon has adopted a policy of using opened multi-dose vials. It stipulates that all lyophilised vaccines after reconstitution must be discarded at the end of the vaccination session, or no more than six hours after reconstitution. Opened vials of liquid vaccines (DTP-HepB-Hib, PCV-13, Td, IPV and OPV) must be kept for 4 weeks (from the date of opening, which must be shown on the label). To this end, we assess whether the vaccines have expired, whether they have been stored at the temperatures recommended by the WHO or the manufacturer, whether the control tablets are visible and valid, whether the vaccines have not been damaged by frost, whether they have not been contaminated by bacteria (asepsis rules observed when the doses are taken) and whether the labels are present on the vaccines.

Ethical considerations

The research authorisations issued by the regional public health delegations for the Littoral, the South and the Centre, in particular authorisation n°0173/AR/ MINSANTE/DRSPL/BCASS from the regional health delegation for the Littoral, n°441/AR/ MINSANTE/SG/DRSPS/BFP from the regional health delegation for the South, and n°460/AR/ MINSANTE/SG/DRSPC/BFP from the regional health delegation for the Centre, were obtained before the start of data collection. The free and informed consent of the study participants and the confidentiality of the study data were preserved by the strict application of the measures required to ensure compliance.

Statistical analysis

Data were entered into an Excel spreadsheet (Microsoft Office, USA) and subsequently analysed using R version 4.3.3 for Windows 11 professional. Data were presented in the form of frequencies (N, n) and percentages in tables. Fisher's exact test and Pearson's Chi-square test of independence were used for comparisons (95%CI; $P < 0.05$).

RESULTS

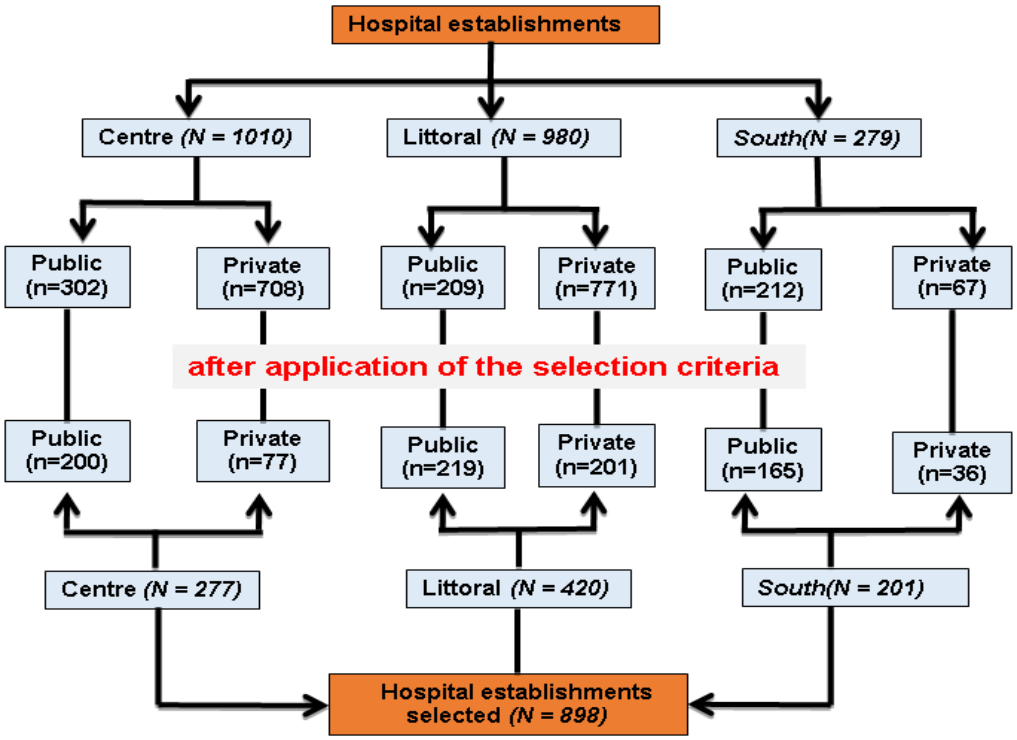

Figure 2: Selection chart for health establishments in the three regions studied.

Figure 2 below describes the procedure for selecting health establishments with a cold chain and involved in the extended vaccination programme in Cameroon, by region. using this procedure, we selected 898 health establishments in these three regions (fig.2).

Table I: Characteristics of the study population.

	Overall (N = 898)		Centre (N =277)		Littoral (N = 420)		South (N = 201)		
Characteristics	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**P-Value**
Health Promotion									**<0.001**
Public	576	64	184	66	208	49.3	184	92	
Private	319	35.7	93	34	209	50	17	8.5	
Religious	3	0.3	0	0	3	0.7	0	0	
Grade									**na**
Nurses	400	45	122	44	192	46	86	43	
Doctor	196	22	65	23	86	20	45	22	
Nurses' aides	141	16	40	14	67	16	34	17	
Point focal	108	12	32	12	52	12	24	12	
Midwife	35	3.9	13	4.7	14	3.3	8	4	
PEV logistician	18	2	5	1.8	9	2.1	4	2	
PEV responsibilities									**>0.9**
PEV data manager	718	80	215	78	342	81	161	80	
Head of private health facilities	106	12	38	14	44	10	24	12	
Head of integrated centre	34	3.8	11	4	15	3.6	8	4	
Head of district	20	2.2	8	2.9	8	1.9	4	2	
Director of first and third level hospitals	20	2.2	5	1.8	11	2.6	4	2	
PEV training over last three months									**>0.9**
Yes	646	72	199	72	302	72	145	72	
No	252	28	78	28	118	28	56	28	
Training modules									**na**
Cold chain manager	532	59	168	61	245	58	119	59	
equipment maintenance	162	18	47	17	81	19	34	17	
injection safety	90	19	29	10	41	9.8	20	10	
Vaccine logistics	54	6	17	6.1	25	6	12	6	
Data management	22	2.4	5	1.8	9	2.1	8	4	
EPI retraining	20	2.4	5	1.8	11	2.6	4	2	
Stock management	18	2	6	2.2	8	1.9	4	2	

***PEV**: Vaccine Expansion Programme; data are presented as frequency (N, n) and % (%), P-value: Fisher's exact test; Pearson's Chi-squared test. 95%IC statistically significant at P<0.05.*

Table I above describes the characteristics of the people recruited in our study and involved in cold chain management in these three regions (Table I). The majority of health institutions were public (64%), followed by private (35.7%) and then religious (0.3%) in all three regions. The health professionals most involved in managing the vaccination were nurses (45%), followed by doctors (22%) and nurses' aids (16%). Other groups were also present (17%) (Table I). The responsibilities of these healthcare professionals in the EPI were respectively PEV data manager (80%), Head of private health facilities (12%), Head of integrated centre (3.8%), Head of district (2.2%), Director of first and third level hospitals (2.2%). 28% of these people had not received any training in the previous three months. Most of the training received concerned cold chain management.

Table II: Assessment of the adequacy of the cold chain.

	Overall (N = 898)		Centre (N =277)		Littoral (N = 420)		South (N = 201)		
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**P-Value**
Conformity of equipment to WHO standards									**>0.9**
Yes	880	98	272	98	411	98	197	98	
No	18	2	5	2	9	2	4	2	
Availability of sufficient storage capacity									**0.8**
Yes	755	84	236	85	350	83	169	84	

No	143	16	41	15	70	17	32	16	
The existence of an alternative cold chain									**>0.9**
Yes	772	86	238	86	361	86	173	86	
No	126	14	39	14	59	14	28	14	
The ability of managers to estimate the volume of storage required									**0.6**
Yes	484	54	143	52	233	55	108	54	
No	414	46	134	48	187	45	93	46	
Existence of a contingency plan in the event of a break in the cold chain									**0.8**
Yes	593	66	179	65	281	67	133	66	
No	305	34	98	35	139	33	68	34	
Control of vaccine storage stages in cold chain equipment									
Yes	898	100	277	100	420	100	201	100	
Control of vaccine transport procedures									**0.8**
Yes	502	56	150	54	239	57	113	56	
No	396	44	127	46	181	43	88	44	

World Health Organization (WHO), data are presented as frequency (N, n) and % (%), P-value: Fisher's exact test; Pearson's Chi-squared test. 95%IC statistically significant at P<0.05.

Table II describes the parameters of cold chain adequacy in the three regions studied. 98% of cold chain equipment complied with WHO standards, and only 2% did not. There was no difference in these percentages between the three regions (p>0.9). 84% of cold chains had sufficient vaccine storage volume, 16% did not have sufficient storage volume and there was no difference in these percentages between these regions (p<0.8). 86% of health establishments had an alternative cold chain and 14% had no alternative cold chain. 46% of cold chain managers did not know how much vaccine to store in the cold chain and 34% of health establishments did not have a contingency plan in case of cold chain breakdown. 44% of vaccinators were not familiar with vaccine transport procedures (Table II).

Table III: reliability of the cold chain.

	Overall (N = 898)			**Centre (N =277)**			**Littoral (N = 420)**			**South (N = 201)**		
	n	**%**		**n**	**%**		**n**	**%**		**n**	**%**	**P-Value**
Regular temperature control												**>0.9**
Yes	701	78		216	78		329	78		156	78	
No	197	22		61	22		91	22		45	22	
Sufficient freezing capacity												**>0.9**
Yes	863	96		266	96		404	96		193	96	
No	35	4		11	4		16	4		8	4	
Sufficient capacity for storage												**>0.9**
Yes	863	96		266	96		404	96		193	96	
No	35	4		11	4		16	4		8	4	
Accessibility to emergency power												**0.6**
No	712	79		216	78		339	81		157	78	
Yes	186	21		61	22		81	19		44	22	
Existence of an emergency plan in the event of a break in the cold chain												**0.8**
Yes	567	63		174	63		269	64		124	62	
No	331	37		103	37		151	36		77	38	
Equipment maintenance												**>0.9**
Yes	557	62		172	62		261	62		124	62	
No	341	38		105	38		159	38		77	38	

Data are presented as frequency (N, n) and % (%), P-value: Fisher's exact test; Pearson's Chi-squared test. 95%IC statistically significant at P<0.05.

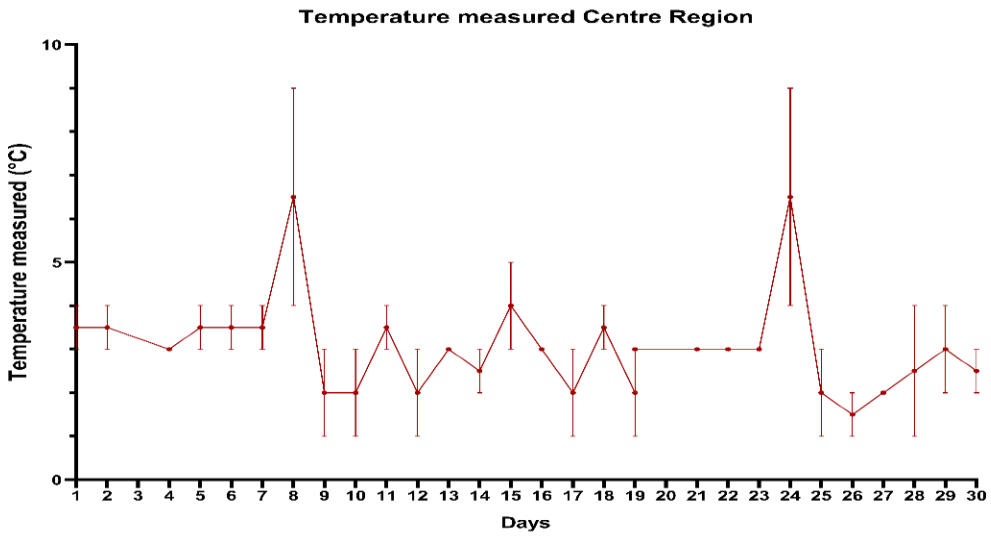

Figure 3a: Variation curve for average temperatures in the Centre Region.

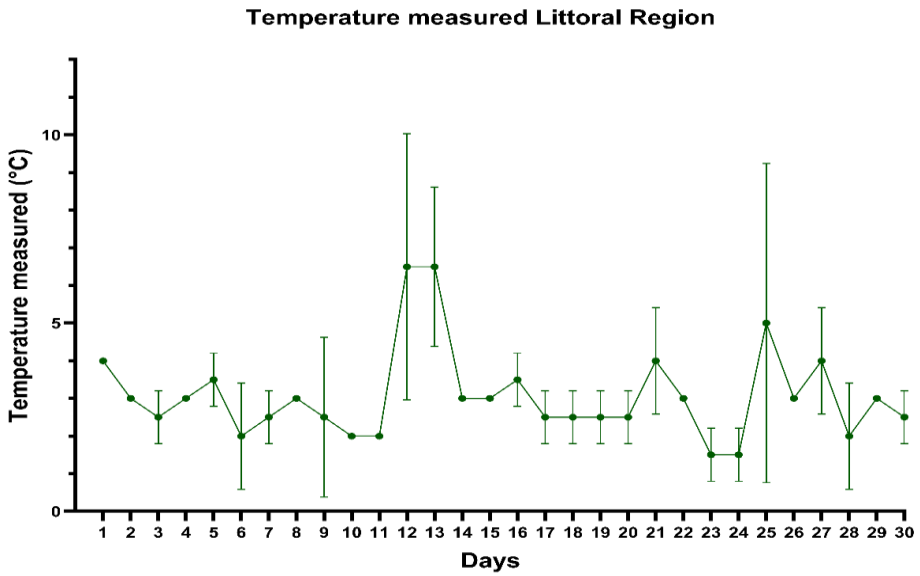

Figure 3b: Variation curve for average temperatures in the Littoral Region.

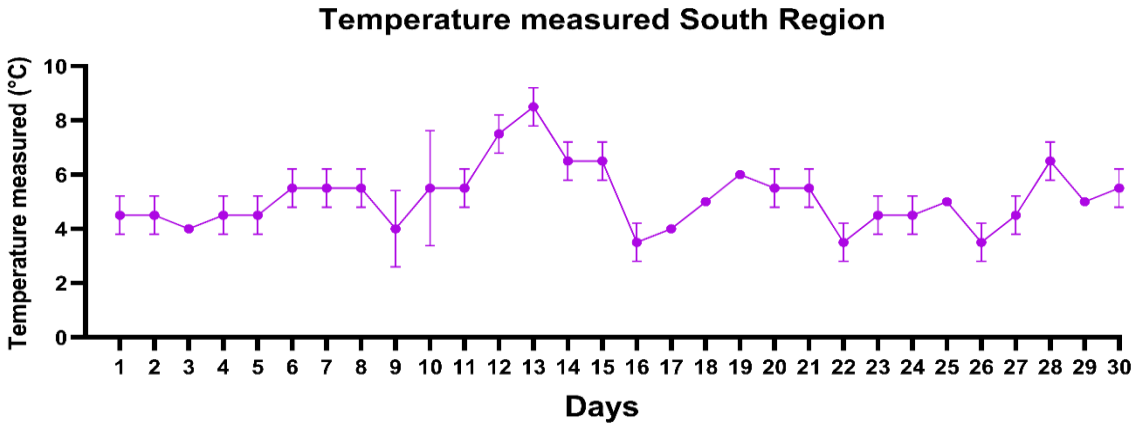

Figure 3c: Variation curve for average temperatures in the South Region.

Table III above is an analysis of the reliability of the cold chain. It shows that the temperature of the cold equipment was not regularly checked in 22% of the health facilities, 79% of the health facilities did not have

access to an alternative energy source (solar panels, generators), 37% of the health institutions did not have an emergency plan in the event of a break in the cold chain, and 38% of them did not have a maintenance plan for the cold chain equipment (Table III).

Figures 3a, 3b and 3c show the analysis of temperature variation over 30 days in the refrigeration units of the health establishments in the three regions included in our study. This analysis shows that in the Centre region temperatures remained within the normal range according to WHO recommendations, but some deviations were observed on the eighth and twenty-fifth days (Fig. 3a). In the Littoral region, temperature variations were noted between the ninth and mildest days and between the twenty-fifth and twenty-eighth days (fig.3b). In the South region, temperatures remained normal (fig.3c).

Table IV is an analysis of the policy for using opened bottles. This analysis shows that the policy for using opened bottles is respected in the three regions of our study (TableIV).

Table IV: Analysis of the policy for using opened bottles.

	Overall (N = 898)			**Centre (N =277)**			**Littoral (N = 420)**			**South (N = 201)**		
	n	**%**		**n**	**%**		**n**	**%**		**n**	**%**	**P-Value**
Vaccines expire												**na**
No	898	100		277	100		420	100		201	100	
Storage at temperatures recommended by the WHO or the manufacturer												**na**
Yes	898	100		277	100		420	100		201	100	
Visibility and validity of control stickers												**na**
Yes	898	100		277	100		420	100		201	100	
No bacterial contamination												**na**
No	898	100		277	100		420	100		201	100	
The presence of labels on vaccines												**na**
Yes	898	100		277	100		420	100		201	100	

WHO : World Health Organization; na : not applicable; data are presented as frequency (N, n) and % (%), P-value:

DISCUSSION

Our study is particularly interested in evaluating the factors responsible for the loss of vaccine quality in Cameroon, and in particular in the central, Littoral and southern regions. Cameroon's energy instabilities and low production rates mean that it is not always possible to guarantee optimal operation of the cold storage equipment where vaccines are kept, and therefore to guarantee better vaccine quality at the time of injection. This work therefore makes a scientific contribution by determining the elements in the cold chain that affect vaccine quality and therefore alter the biological activity of the vaccines, thereby preventing functional immunisation of the vaccinated population.

The assessment of the adequacy of the cold chain revealed that 46% of cold chain managers did not know how to estimate the storage volumes required in cold units for vaccines as recommended. This can be explained by the fact that 28% of EPI managers had not received refresher training three months before the period of our study and by the fact that there is no national strategy for evaluating vaccine storage volumes. Hirsh Bar Gai et al in 2018 defined a strategy for optimising storage volumes, which may be necessary for these regions.[15] 34% of hospital establishments did not have a contingency plan in place in the event of a break in the cold chain. The inaccessibility of some hospital establishments makes it difficult for control officers to carry out their duties. 44% of vaccinators did not comply with vaccine transport procedures. In the rural areas of our study regions, the lack of traceability of the means of transport encourages uncontrolled transport of the vaccines by the transport agents. Transport by means such as walking or motorbikes does not guarantee optimal vaccine storage temperatures and yet optimizing the means of transport will improve the quality and effectiveness of vaccines.[16]

An assessment of the reliability of the cold chain showed that 22% of the hospitals included in our study did not regularly check the temperatures of the refrigeration units. For the majority of them that did monitor these temperatures (78%), they sometimes exceeded the recommended limits.[17] Martin Dinaki Yakum et al in 2015 in North West Cameroon found that abnormal temperatures were recorded in 10 (20%) health facilities at the time of data collection and 12 (24%) in the 2 months prior to data collection. The factor significantly associated with abnormal temperature recording was the absence of an alternative energy source[18] as we found in the cold chain adequacy results (table II). The consequences of temperature variations during vaccine storage have already been demonstrated.[19] They can be responsible for a change in the biological activity of vaccines and a loss of their immunizing capacity. Failure to check the temperature regularly in the healthcare establishments concerned could lead to a loss of vaccine

quality. We also found that 79% of health facilities did not have an alternative energy source and that this percentage did not vary according to the regions studied ($p>0.1$). This is justified by the fact that health facilities do not have the necessary means to purchase alternative energy sources, which could lead to a significant loss of vaccine quality. Only certain private establishments and first-class hospitals have alternative energy sources, which are either generators or solar panels. This lack of alternative energy sources could be an obstacle to maintaining vaccine quality.[20] in the event of a breakdown in the energy available, leading to major losses of vaccines. We also found that 38% of health establishments did not have a system for maintaining cold chain equipment. This proportion remains high, and the reasons mentioned above explain these results.

Limitations

Our study covered only three of the country's 10 regions. In the coming days, we intend to explore these aspects in the other regions of the country.

CONCLUSION

The causes of the deterioration in the quality of vaccines in the cold chain of the health establishments in our regions studied are respectively the inadequacy of the cold chain in terms of availability of sufficient storage volume, the existence of an alternative cold chain, the ability of managers to estimate the storage volume, and the lack of mastery of vaccine transport procedures; the reliability of the cold chain in terms of regular temperature checks on cold equipment, the availability of an alternative energy source in the event of a power cut, the lack of an emergency plan in some health facilities in the event of a break in the cold chain, and the lack of a regular maintenance system for cold chain equipment in some health districts. Compliance with the policy of using opened vials is an advantage that we must maintain, and we must improve the other aspects of the cold chain to guarantee good quality vaccines.

Data availability

The data used to support the results of this study are available from the corresponding author on reasonable request.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

TTRS, ELG, and ANJC conceived the idea and the study. TTRS, BFAA, NTJC, AARA, NNVEC and NMws collected and enered the data in the field. ELG and ANJC supervised data collection in the regions. Author TTRS coordinated data entry, NMWS created figures, performed statistical analyses and interpreted the results with the help of TTRS. TTRS drafted the first version of the manuscript with the help of WSNM. Authors ELG, ANJC, TTRS and NMWS reviewed the paper for important intellectual content. Authors ELG and ANJC supervised the work at all stages. All authors read and approved the final document before submission.

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we declare that we have received no funding for this work.

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