

Original Research Article

Ineffective vaccination coverage linked to inadequate cold chain management practices in routine childhood immunization program in Narok County, Kenya

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ABSTRACT

Background: Poor cold chain management contributes to ineffective vaccinations. Ineffective vaccinations pose a risk of occurrence of vaccine preventable diseases. The study assessed the effective vaccination coverage of measles, tetani toxoid and hepatitis B in relation to the status of cold chain management practices

Methods: This was a cross sectional serosurveillance study of 378 vaccinated children using indirect Elisa IgG antibody testing of measles, tetani toxoid and hepatitis B vaccine. It also assessed the status of cold chain management practices in all the 91 public immunizing health facilities in Narok County, Kenya.

Results: The measles effective vaccination coverage was 62.2% (235/378). The tetani toxoid effective vaccination coverage was 70.6% (267/378). The effective vaccination coverage of hepatitis B was 79.1% (299/378). The proportion of Children who were effectively vaccinated against measles was 70.5% (31/44) in level 2 health facilities, 72.2% (104/144%) in level 3 health facilities, 85% (85/100) in level 4 facilities and 75% (9/12) in level 5 health facilities. The observed condition of the cold chain system was inadequate in 25 (48%) level 2, 6 (18.2%) level 3 and 20% of level 4 facilities. Up to date operational plan was available in 30 (57.7%) level 2, 25 (75.8%) in level 3, 4 (80%) in level 4 facilities. Vaccine supply and quality were inadequate in 43 (47.3%) health facilities. Immunization service delivery charter was partially implemented in 53 (58.2%) health facilities.

Conclusions: Inadequacies in cold chain management practices has contributed towards ineffective vaccination of children aged 12-23 months in Narok County, Kenya.

Keywords: Effective vaccination coverage, Cold chain management, Immunity, Serosurveillance

INTRODUCTION

Serological surveillance estimates the population-level immunity against vaccine preventable diseases and can be used in assessing vaccine effectiveness of vaccination programs.^{1,2} Plotkin computed various correlation tests and antibody protective titer level of various vaccines including measles (Microneutralization test/indirect Eliza; Protective level=120 mIU/ml), tetanus (toxin

neutralization test/indirect Eliza; protective level=0.1 IU/ml), and hepatitis B (indirect Eliza test; protective level=10 mIU/ml).² Vaccine viability is the significant determinant of vaccine effectiveness and is guaranteed by proper functioning cold chain system during collection, transportation, distribution and storage of vaccines.³⁻⁹ Cold storage and transportation of vaccine at recommended temperature affects vaccine viability.^{5,7} In addition, monitoring and maintenance of cold chain has

indirect impact on viability of vaccines.^{6,8,9} WHO set out vaccinology practice guidelines for management of vaccines and include the following sub domains; vaccine supply and forecasting; vaccine quality management and logistics; Immunization service delivery; and Immunization program management and financing.¹⁰⁻¹²

This is a serosurveillance study of measles, tetani toxoid and hepatitis B and an assessment of the status of cold chain management practices at all the public health facilities offering immunization services in Narok County, Kenya.

METHODS

Study setting

The study was carried out in Narok County, Kenya among children aged 12-23 months in sampled administrative wards and in all 91 health facilities offering immunization services in the County. Narok County is situated in south of the Rift Valley bordering Tanzania to the south, Bomet to the north, Kisii to the west and Nakuru to the east. It has 91 public health facilities offering immunization services (KNPHC, 2019).

Study design

This was a two-part cross-sectional study that involved; A) the serosurveillance of measles, tetanus and hepatitis B vaccines coverage among 378 vaccinated children and B) an assessment of cold chain management system in 91 public immunizing health facilities using validated WHO expanded program on immunization's (EPI) District standard guideline.

Sampling technique

The administrative wards in every Sub-County were sampled using proportionate stratified sampling. Then in every stratum (administrative ward), children meeting the study inclusion criteria in various households were physically identified and sampled using simple random sampling until desired sample size was attained in each stratum. This was done over the period 2020-2021.

Sample size determination

The prevalence of fully vaccinated children in Narok County was 58.5% (KDHS, 2014). In order to report the vaccination coverage with 95% confidence, the required sample size was calculated using the following Fisher et al formula;

$$n = \left(\frac{z_{1-\alpha/2}^2}{d} \right)^2 \times P \times (1 - P)$$

$$n = \left(\frac{1.96}{0.05} \right)^2 \times 0.585 \times (1 - 0.585) \quad n = 373 \text{ Children}$$

n= is the representative sample size

Z=1.96 is the coefficient of the significance level at 95% confidence interval;

P=58.5% is the proportion of vaccinated children in Narok County as per KDHS 2014;

d=0.05 is the margin of error under the 95% confidence interval.

Selected health facilities within the sampled administrative units were assessed and evaluated using WHO extended program on immunization standard guideline.

Eligibility criteria

Children aged 12-23 months with documentary evidence of immunization such as immunization card or mother and child health booklet, children should have no history of blood transfusion or malignancy and use of immunomodulators and intravenous immunoglobulins were excluded from the study.

Data collection and sample processing

Interviewer administered questionnaires were used to attain socio demographic and immunization characteristics. The collection, processing and transportation of blood was carried out under standard good laboratory practices. Approximately 2.5 ml of blood was collected through venipuncture by research assistants- all qualified phlebotomists from 25th March 2022 to 17th May, 2022. The good clinical and laboratory practices were followed from preparation of site for injection to analysis of blood serum. Briefly, the withdrawn 2.5 ml blood in the syringe was transferred to appropriate laboratory equipment/specimen tube or a vacutainer with a red top with or without calcium citrate and stored in a portable cold chain in -20°C. It was taken to the nearest health facility with centrifugation and refrigeration facilities to separate the serum using serum separation tubes with unique participant identifier and for cold storage.

The blood serum was then stored at -20° C, transported in dry ice by the principal investigator until it reached Metropolis pathology laboratory Eldoret for serological analysis. It was then stored at -70°C at the laboratory until it is analyzed. Indirect Elisa protocol was used to detect human IgG antibodies against the vaccine antigens (measles virus, tetanus and hepatitis B virus antigens). Ready to use specific IgG antibody level for measles, tetani and hepatitis B were studied using commercially available enzyme-linked immunoassay (Eliza) kit sourced from Abcam plc (Cambridge, UK). For serological analysis the detection, quantification and classification of antibodies were carried out as per the manufacturers' instructions.

The status of cold chain system and vaccine programming was evaluated using WHO EPI district guideline tool based on the availability and condition of the cold chain equipment and monitoring mechanism mounted at the facility. For availability and condition, the following aspects were assessed: availability of cold chain equipment at the facility; status of cold rooms and its accessories at the time of inspection; regularity of check cold chain equipment by technician; validity of the status of monthly chart; neatness of packaging of vaccines in the cold-room as well as completeness and availability of temperature daily read chart; safety of the room; type of refrigerator available in use; and order of vaccines in terms of time span. The monitoring of the cold chain System was done by physical direct observation and this included an assessment of: daily temperature record charts at the evening and at the morning; the presence or absence of cold chain monitor cards activator; availability of freeze watch; routine availability of power; transport of vaccine from central stores and adequacy of record keeping of vaccines.

Vaccine programming focused on three domain areas such as vaccine programming and financing, vaccine supply and quality logistics, and immunization service delivery. Each domain of vaccine programming was assessed using a checklist detailing its implementation and adherence.

Data analysis

Data analysis was carried out using STATA version 17. Descriptive Statistics such as means and frequencies were presented using tables and charts to summarize demographic, vaccination coverage, immunization characteristics and cold chain management practices.

Ethical considerations

The study was approved by Moi University and Moi Teaching and Referral Hospital Institutional Ethics Committee. The parent/guardian's permission were sought before any child was enrolled into the study. Confidentiality and privacy were assured by consenting in private spaces, deidentifying coded data and use of lock and key cabinets to store questionnaires and coded sample specimens.

RESULTS

Demographics and immunization characteristics

The study sampled 378 children aged 12-23 months from various households in 15 sampled administrative wards in all 6 Sub-Counties of Narok County. The mean age of children was 15.3 (SD=3.7) months. Out of 378 children, 255 (67.5%) were aged <17 months while 123 (32.5%) were aged ≥17 months. Up to 195 (51.6%) children were female while 183 (48.4%) were male. The mean age of the mothers was 28.9 (SD=7.3) years.

Out of 378 mothers, 102 (26.9%) reported that their children failed to receive vaccination services despite presenting themselves at a health facility due to many reasons mainly vaccine stock out (40%), late presentation of child at a health facility (15%), absence of immunizing medical staff/nurse (30%) and presence of very low number of children to vaccinate (15%). Among these 102 cases, 45 (44.1%) mothers had their children vaccinated at a later date and 57 (55.9%) children had a missed opportunity and failed to return to the health facility for vaccination services. However, a total of 276 (73.1%) mothers had never experienced any failure to vaccinate given physical presence at appropriate time at the immunizing health facility near them, though 70 (25.4%) of them had had their children missing at least one vaccine dose. Up to 347 (91.8%) children were vaccinated at a health facility while the rest 31 (8.2%) were vaccinated at an outreach center (Table 1).

Effective vaccination coverage

The effective vaccination coverage of measles, tetani and hepatitis B was calculated as the proportion of children who respectively expressed sufficient antibody titer threshold level that confers immunity against infection among 378 vaccinated children sampled. The measles effective vaccination coverage was 62.2% (235/378), with children aged <17 months 62.1% (146/235) and children aged ≥17 months were 37.9% (89/235). The effective vaccination coverage for tetani toxoid was 70.6% (267/378), comprising of 171 (64%) children aged <17 months and 96 (36%) children aged ≥ 17 months. The effective vaccination coverage for hepatitis B was 79.1% (299/378), with children aged <17 months comprising 67.6% (202/299) and children aged ≥17 months were 32.4% (97/299) (Table 2).

The effective vaccination coverage for children who received measles virus containing vaccine dose one was assessed based on the level of immunizing facility where they received the vaccine. The effective vaccination coverages were higher among children vaccinated at level 4 (85%) and 5 (75%) health facilities than those who received measles dose one at level two (70.4%) and level three (72.2%) immunizing health facilities. The effective vaccination coverage was 6.5% (2/31) among children who received measles virus containing vaccine dose one at an outreach center. The odds of a child being effectively vaccinated against any of the three tested antigens were 0.31 (69%) at level five immunizing health facility compared to OR=0.48 (52%) at level 2 immunizing health facility (Table 3).

Cold chain management practices

Observed conditional status of the cold chain system

The conditional status of the cold chain in all the 91 public immunizing health facilities was observed. All the 91 (100%) health facilities had cold chain facilities

mainly refrigerators and/or the portable cold boxes. There was constant vaccine supply in 9 (17.3%) level two health facilities, 15 (45.5%) level three health facilities and in all the 5 (100%) level four health facilities and a level five Narok County Referral Hospital.

The on-spot thermometer temperature reading in cold chain was in the required standard per the Division for Vaccines and Immunizations (DVI) temperature range (0°C to +8°C) in 50 (96.2%) level two health facilities, 33 (100%) level three health facilities, 5 (100%) level four health facilities and 1 (100%) level five health facility. The on-spot thermometer reading of cold chain was in abnormal range (below 0°C/above 8°C) in 2 (3.8%) level two health facilities. Moreover, 21 (40.4%) level 2 health facilities, 22 (66.7%) level three facilities and all level 4 and 5 health facilities displayed complete and updated daily temperature charts showing daily morning and evening temperatures as required and stipulated by DVI.

The vaccine vial monitor and card activator was functional in 28 (53.8%) level two health facilities, 25 (75.6%) level three health facilities, and all level four and five health facilities. The freeze watch was functional in 29 (55.8%) level two health facilities, 27 (81.8%) in level three health facilities, 4 (80%) in level four health facilities and was functional in level five health facility. The shake test routine procedures as routinely carried out and documented in 25 (48.1%) level two health facilities, 20 (60.6%) level three health facilities and all level four and five health facilities. There was documented evidence that cold chain biomedical technician made a must regular monthly cold chain engineering maintenance or cold chain functional assessment checks in 30 (57.7%) level two health facilities, 25 (75.8%) in level three health facilities, 3 (60%) in level four health facilities and was carried out in level five health facility.

Vaccine storage was proper in 30 (57.7%) level two, 21 (63.6%) level three, 4 (80%) level four and in level five health facilities. The vaccine storage was not proper in various immunizing health facilities due to inadequate air circulation (11%), presence of food and drinks in the refrigerator (15.4%), vaccine not kept in proper compartment (27.5%) and presence of water bottles (9.9%). The vaccines were neatly packaged in 35 (67.3%) level two health facilities, 26 (78.8%) level three health facilities, 4 (80%) level four health facilities and was neatly packaged in level five health facility.

The safety of the cold room was assured and adequate in 25 (48.1%) level two health facilities, 24 (72.7%) level three health facilities, 4 (80%) level four and 1 (100%) level five health facility.

Proper and up to date vaccine records were kept in 31 (59.6%) level two health facilities, 27 (81.8%) in level three health facilities and in all level four and five health facilities. Vaccine waste and rate of vaccine waste was recorded and documented in 41 (78.8%) level two health

facilities, 25 (75.8%) in level three health facilities, 2 (40%) in level four health facilities and was recorded properly in 1 (100%) level 5 health facility.

Other observations related to vaccines in cold stores that are non-compliant with DVI regulations were noted. Out of 91 health facilities assessed, 1 (1.1%) health facility was found to have combined negative incidences of non-functional refrigerator, expired vaccines, date not written in vaccine vials and temperatures were out of range. Another 10 (11%) health facilities had expiration dates not written/indicated on vaccines, 5 (5.5%) health facilities had fridges tag showing alarm, 7 (7.7%) health facilities had freeze tag showing alarm. Non-vaccines commodities were found in vaccine refrigerator in 23 (25.3%) health facilities (Table 4).

Immunization programming

In reference to immunization program management and financing, an up-to-date operational guideline that include up-to-date immunization schedule and policies were available in 30 (57.7%) level two, 25 (75.8%) level three and in all (100%) level four and five health facilities.

An up-to date immunization schedule and up-to-date annual operational plan/work plan was available in 47 (90.4%) level two, 30 (90.9%) level three and all level four and five health facilities. A well outlined and sufficient health facility budget for cold chain management was available in 17 (32.7%) level two, 6 (18.2%) level three, 3 (60%) level four and in the level five health facilities. In the past twelve months, critical immunization program activities were cancelled or substantially delayed by at least six months because of lack of funds were experienced in 12 (23.1%) level two, 10 (30.3%) level three and in 1 (100%) level five hospitals. County government of Narok, non-government organizations and other partners had a combined financial and service delivery role in immunization in more than half of all health facilities sampled, irrespective of the level of facility (Table 5).

In reference to vaccine supply, quality and logistics, there was at least 1 adequately trained person responsible for vaccine supply and commodity management in 14 (26.9%) level 2 facilities, 11 (33.3%) level 3 facilities, 3 (60%) in level 4 health facilities and was present in level 5 health facility. The health facility stores had sufficient cold chain equipment space and function in 11 (21.2%) level 2 facilities, 12 (36.4%) level 3 facilities, 4 (80%) in level 4 facilities and in level five health facility (Table 6).

In terms of vaccine forecasting and monitoring of vaccine, 23 (44.2%) level two facilities, 17 (51.5%) level three facilities and all level four and five immunizing health facilities have sufficient documented guidelines on how to forecast and monitor vaccine usage, including estimating and accounting for vaccine waste rate and estimating the target population as well as having

sufficient system for ordering vaccine from regional stores. However, the study found out that in the past 12 months, stock out of any vaccine had been experienced in 32 (61.5%) level two, 18 (54.5%) level three, 1 (20%) level four and in a level five health facility and the reasons given was stock out at the regional store in 23 (25.3%) health facilities, inaccurate forecasting in 18 (19.8%) health facilities, an experience of more wastage than expected in 8 (8.8%) health facilities and more demand than expected were experienced in 3 (3.3%) health facilities in the County. Specifically, BCG vaccine

was out of stock for more than two months in 4 (7.7%) level two facilities, 2 (6.1%) level three facilities and none in at least level four health facilities. Similarly, measles virus containing vaccine were out of stock for more than two months in 3 (5.8%) level two facilities and 3 (9.1%) level three health facilities. The DPT vaccines and OPV vaccines had similar trend. There was evidence of documented guidelines on proper waste management for vaccines and supplies in 42 (80.7%) level two health facilities, 31 (94%) level three health facilities, and all level four and five health facilities in County (Table 6).

Table 1: Demographics and immunization characteristics.

Variables	Category	N	Percentage (%)
Child's sex	Female	195	51.6
	Male	183	48.4
Age of children (in months)	<17	255	67.5
	≥17	123	32.5
Education level of mothers	College	76	20.1
	No formal education	53	14.0
	Primary	103	27.3
	Secondary and tertiary	146	38.6
Occupation of mothers	Employed	56	14.8
	Self employed	181	47.9
	Unemployed	141	37.3
Distance to health facility	<5 kilometers	172	45.5
	≥5 kilometers	206	54.5
Facility failure to vaccinate	Yes	102	26.98
	No	276	73.02
Vaccine schedule confusing	Yes	32	8.47
	No	346	91.53
Place of vaccination	Outreach	31	8.2
	Health facility	347	91.8
Had good adherence to vaccination schedule	Yes	301	79.63
	No	77	20.37

Table 2: Effective vaccination coverage per age.

Vaccine antigen	Age (in months)	N (%)
Measles	<17	146 (62.1)
	≥17	89 (37.8)
	Total	235 (62.2)
Tetani toxoid	<17	171 (67.1)
	≥17	96 (78.0)
	Total	267 (70.6)
Hepatitis B	<17	202 (79.2)
	≥17	97 (78.9)
	Total	299 (79.1)

In reference to immunization service delivery, there was evidence of documented guidelines on frequency of providing fixed immunizations sessions in 19 (36.5%) level 2 health facilities, 17 (51.5%) level three health facilities, and all level four and five health facilities in the County. Up to 14 (26.9%) level two health facilities, 9 (27.3%) level 3 health facilities, 3 (60%) level four and

level 5 health facilities in County have documented guidelines on conducting high quality fixed site EPI sessions such as guidance that covers clients flow waiting times, preparations and sequencing of health interventions, recordings and immunization massaging/communication. Main barriers to provision of high-quality fixed immunization services include long

waiting times (n=74; 81.3%), inadequate staff (n=77; 84.6%), difficulty in data recording (n=4; 4.4%), frequent stock out of supplies (n=17; 5.4%), lack of community volunteers (n=21; 23.1%) and inconvenient schedule of care givers (n=6: 6.6%) (Table 7).

There was evidence of documented guidelines on criteria and frequency of conducting outreach vaccinations, based on distance or accessibility in 30 (57.7%) level two health facilities, 25 (75.8%) level three health facilities, 4

(80%) level four and in level five health facilities in the County, with 6 (11.5%) of level two health facilities having no guidelines. The main health facility barriers to provision of high-quality outreach/mobile immunizations include insufficient transport (n=40; 44%), inadequate staff (n=64; 70.3%), insufficient reimbursements for staff (n=25; 27.5%), poor planning in terms of timing and choice of location (n=29;31.9%) and frequent stock out of vaccines and other supplies (n=5; 5.5%) (Table 7).

Table 3: Measles’ effective vaccination coverage per level of immunizing health facility.

Level of immunizing facility	Effective coverage		Odd ratio
	N	%	
Level 2	31/44	70.4	0.48
Level 3	104/144	72.2	ref
Level 4	85/100	85	0.38
Level 5	9/12	75	0.31
Outreach center	2/31	6.5	-

Table 4: Observed conditional status of the cold chain in 91 public health facilities.

Category of the variable	Number/% of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Constant availability of vaccine				
Regular	9 (17.3%)	15 (45.5%)	5 (100%)	1 (100%)
Irregular	43 (82.7%)	18 (54.5%)	0	0
On spot temperature reading at cold room				
0°C to 8°C	50 (96.2%)	33 (100%)	5(100%)	1(100%)
0°C< X>8°C	2 (3.8%)	0	0	0
Complete and updated daily temperature charts (morning and evening)				
Yes	21 (40.4%)	22 (66.7%)	5 (%)	1(100%)
No	31 (59.6%)	11 (33.3%)	0	0
Functional vial monitor and card activator				
Yes	28 (53.8%)	25 (75.6%)	5 (100%)	1 (100%)
No	24 (46.2%)	8 (24.4%)	0	0
Thermometer’s shake test routinely done				
Yes	25 (48.1%)	20 (60.6%)	5 (100%)	1 (100%)
No	27 (51.9%)	13 (40%)	0	0
Vaccine storage in the refrigerator				
Proper	30 (57.7%)	21 (63.6%)	4 (80%)	1 (100%)
Not proper	22 (42.3%)	8 (36.4%)	1 (20%)	0
Freeze watch working conditions				
Functional	29 (55.8%)	27 (81.8%)	4 (80%)	1(100%)
Not functional	23 (44.2%)	6 (18.2%)	1 (20%)	0
Evidence of regular monthly cold chain maintenance by biomedical technician				
Yes	30 (57.7%)	25 (75.8%)	3 (60%)	1 (100%)
No	22 (42.3%)	8 (14.2%)	2 (40%)	0
Neatness of vaccine packaging				
Neatly packaged	35 (67.3%)	26 (78.8%)	4 (80%)	1 (100%)
Somehow packaged	14 (26.9%)	7 (21.2%)	1 (20%)	0
Poorly packaged	3 (5.8%)	0	0	0
Safety of the cold chain room				
Adequate	25 (48.1%)	24 (72.7%)	4 (80%)	1 (100%)
Not adequate	27 (51.9%)	9 (27.3%)	1 (20%)	0
Documentation of vaccine records				
Complete and updated	31 (59.6%)	27 (81.8%)	5 (100%)	1 (100%)
Incomplete records	21 (40.4%)	6 (18.2%)	0	0

Continued.

Category of the variable	Number/% of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Documentation of vaccine waste and rates				
Complete and updated	41 (78.8%)	25 (75.8%)	2 (40%)	1 (100%)
Incomplete records	11 (21.2%)	8 (14.2%)	3 (60%)	0

Table 5: Immunization program management and financing.

Category of the variable	Frequency of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Up to date operation plan, guideline				
Up to date (good guide)	30 (57.7%)	25 (75.8%)	4 (80%)	1 (100%)
Partial (need updating)	20 (38.5%)	7 (21.2%)	1 (20%)	0
Not updated/schedule	2 (3.8)	1 (3.0%)	0	0
Up to date operational schedule and work plan				
Updated	47 (90.4%)	30 (90.9%)	5 (100%)	1 (100%)
Partially updated	5 (9.6%)	3 (9.1%)	0	0
Health facility have a budget itemizing all critical activities				
Yes-All covered	48 (92.3%)	29 (87.9%)	5 (100%)	1 (100%)
Partially covered	3 (5.8%)	4 (12.1%)	0	0
No	1 (1.9%)	0	0	0
Funds received sufficient to cover DVI functions including to reach hard-to-reach population				
Sufficient	17 (32.7%)	6 (18.2%)	3 (60%)	1 (100%)
Partially sufficient	35 (67.3%)	27 (81.8%)	2 (40%)	0
Critical immunization activities cancelled/substantially delayed for >6 months due to insufficient funds				
Yes	12 (23.1%)	10 (30.3%)	0	1 (100%)
No	40 (76.9%)	23 (69.7%)	5 (100%)	0
County government's role in financial and service delivery of vaccines at the facility				
Financial roles only	14 (26.9%)	3 (9.1%)	1 (20%)	0
Financial/service delivery	26 (50%)	23 (69.6%)	3 (60%)	1 (100%)
Service delivery only	12 (23.1%)	5 (15.2%)	1 (20%)	0
Other roles	0	2 (6.1%)	0	0
Non-governmental organizations and partners' role in financial and service delivery of vaccines at facility				
Financial roles only	31 (59.6%)	22 (66.7%)	1 (20%)	1 (100%)
Financial/service delivery	6 (11.5%)	0	2 (40%)	0
Service delivery only	10 (19.2%)	8 (24.2%)	2 (40%)	0
No role	5 (9.6%)	1 (3%)	0	0

Table 6: Vaccine supply, quality and logistics.

Category of the variable/Indicator	Frequency of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Presence of adequately trained and qualified person responsible for vaccine supply and management				
Yes-in place and adequately trained	14 (26.9%)	11 (33.3%)	3 (60%)	1 (100%)
Partial-in place but not adequately trained	37 (71.2%)	20 (60.6%)	2 (40%)	0
No	1 (1.9%)	2 (6.1%)	0	0
Facility's cold store have sufficient space and functional equipment				
Yes-sufficient space and functional	11 (21.2%)	12 (36.4%)	4 (80%)	1 (100%)
Partial-functional but need improvements	36 (69.2%)	20 (60.6%)	1 (20%)	0
No	5 (9.6%)	1 (3%)	0	0
Health facility have sufficient documented guidance on how to forecast and monitor vaccine usage				
Sufficient	42 (80.8%)	28 (84.9%)	5 (100%)	1 (100%)
Partially sufficient	8 (15.4%)	4 (12.1%)	0	0
Insufficient	2 (3.8%)	1 (3.0%)	0	0
Sufficient system for ordering vaccines from higher level				
Sufficient	24 (46.2%)	17 (51.5%)	5 (100%)	1 (100%)
Partially sufficient	28 (53.8%)	16 (48.5%)	0	0

Continued.

Category of the variable/Indicator	Frequency of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Sufficient transport mechanism for vaccines to reach service delivery points				
Sufficient	8 (15.4%)	8 (24.2%)	2 (40%)	1 (100%)
Partially sufficient	26 (50%)	22 (66.7%)	3 (60%)	0
Insufficient	18 (34.6%)	3 (9.1%)	0	0
Any vaccine stock out in the past 12 months				
Yes	32 (61.5%)	18 (54.5%)	1 (20%)	1 (100%)
No	20 (38.5%)	15 (45.5%)	4 (80%)	0
Main reasons for stock out vaccines				
Higher level stock out at regional store	11 (34.4%)	10 (55.6%)	1 (100%)	1 (100%)
Inaccurate forecasting	13 (40.6%)	5 (27.8%)		
More wastage than expected	6 (18.8%)	2 (11.0%)		
More demand than expected	2 (6.2%)	1(5.6%)		
DPT vaccine stock out for more than >2 months				
	1 (1.9%)	0	0	0
Measles vaccines stock out for more than >2 months				
	4 (7.7%)	2 (6.1%)	0	0
Measles vaccine stock out for less than <2 months				
	34 (65.4%)	6 (18.2%)	2 (40%)	1 (100%)
Tetani toxoid vaccine stock out for less than 2 months				
	14 (26.9%)	5 (15.2%)	2 (40%)	0
Health facility has guidelines on proper waste management for vaccines and supplies				
	42 (80.7%)	31 (94%)	5 (100%)	1 (100%)

Table 7: Immunization service delivery.

Category of the variable/indicator	Frequency of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Health facility have guidelines on frequency of providing fixed immunization sessions				
Yes-documented	19 (36.5%)	17 (51.5%)	5 (100%)	1 (100%)
Partial-could be improved	29 (55.8%)	14 (42.4%)	0	0
No	4 (7.7%)	2 (6.1%)	0	0
Health facility have guidelines on conducting a high-quality fixed site EPI session				
Yes-Documented	14 (26.9%)	9 (27.3%)	3 (60%)	0
Partial-could be improved	31 (59.6%)	20 (60.6%)	2 (40%)	1
No	6 (11.5%)	4 (12.1%)	0	0
Health facility's barriers to having high quality fixed immunization services				
No barriers-fixed session high quality	0	0	0	0
Long waiting time	42 (80.8%)	27 (81.8%)	4 (80%)	1 (100%)
Inconvenient schedule for caregivers	3 (5.8%)	3 (9.1)	0	0
Inadequate staff	45 (86.5%)	29 (87.9%)	3 (60%)	0
Difficulties in data recording	4 (7.7%)	0	0	0
Frequent stock out of supplies	11 (21.2%)	6 (11.5%)	0	0
Lack of community volunteers	9 (17.3%)	10 (30.3%)	2 (40%)	0
Health facility have guidelines on the criteria and frequency of conducting outreach vaccinations				
Yes-Documented	30 (57.7%)	25 (75.8%)	4 (80%)	1 (100%)
Partial-could be improved	13 (25%)	8 (24.2%)	1 (20%)	
No	6 (11.5%)			
Health facility barriers to providing high quality outreach/mobile immunization services				
No barriers-outreach is high quality	0	0	0	0
Insufficient transport	22 (42.3%)	15 (45.5%)	2 (40%)	1 (100%)
Not enough staff	39 (75%)	24 (72.7%)	1 (20%)	0
Insufficient reimbursements for staff	14 (26.9%)	9 (27.3%)	1 (20%)	1 (100%)
Poor planning (on timing or location)	19 (36.5%)	7 (21.2%)	3 (60%)	0
Frequent stock out of supplies	3 (5.8%)	2 (6.1%)	0	0
Health facility have guidelines on vaccinating children who are missing doses (late vaccinations/'catch up' vaccinations)				
Yes-adequate	7 (13.5%)	9 (27.3%)	3 (60%)	1 (100%)
Partial-could be improved	40 (76.9%)	21 (63.6%)	2 (40%)	0
No	5 (9.6%)	3 (9.1%)	0	0

Continued.

Category of the variable/indicator	Frequency of health facilities per level			
	Level 2, (n=52)	Level 3, (n=33)	Level 4, (n=5)	Level 5, (n=1)
Health facility has guidelines on how to conduct defaulter tracing				
Yes-adequate	8 (15.4%)	11 (33.3%)	3 (60%)	1 (100%)
Yes-but not adequate	40 (76.9%)	19 (57.6%)	2 (40%)	0
No	6 (11.5%)	3 (9.1%)	0	0
Do private providers deliver government-funded vaccines in this health facility				
Yes-all vaccines	0	0	0	0
Yes-some vaccines	0	0	0	0
No	52 (100%)	33 (100%)	5 (100%)	1 (100%)

DISCUSSION

The study revealed low effective vaccination coverage was linked to inadequate cold chain management practices. The measles effective vaccination coverages were higher among children vaccinated at higher level (level 4 and 5) health facilities than those vaccinated at lower-level immunizing health facilities (level 2 and 3 and outreach). Though the study found insignificant differences in effective vaccination coverage per level of health facility, there were low effective vaccination coverage and low compliance to standard cold chain management practices mostly in lower level immunizing health facilities. These findings therefore contradicted studies that documented that the level of immunizing health facility determines the effectiveness of vaccination.^{3,5-7,9} Poor cold chain management practices are partly attributed to primary vaccine failure that may lead to inadequate seroconversion of vaccines and subsequent low vaccine effectiveness.^{5,13,14} However, this insignificance in the present study could be attributed to inaccurate immunization data records keeping and the pastoralism/ migratory nature of the study population that may have experience 'cross over' of children to different levels of immunizing health facilities in the County, based on their location at time of seeking vaccination services.

Cold chain management is the main challenge in developing countries, where up to half of all lower-level primary health facilities (44%) do not adhere to twice daily registration of temperature records, non-functional vaccine vial monitors, card activators, non-functional refrigerators and poor vaccine storage, among other non-compliances.^{15,16} Poor vaccine cold chain management practices are attributed to cold chain handlers' inability to recognize that the potency of the vaccines is compromised leading to incidental administration of sub-potent vaccines, which increases the risks of occurrence of vaccine preventable disease.¹⁷

The present study showed that the observed conditional status of the cold chain at mostly lower-level immunizing health facilities were far below the standard for maintaining vaccine viability and effectiveness that is guaranteed by proper functioning cold chain system.^{3,5,18,19} Systemic errors in cold chain storage and transportation cost fortunes in wasted vaccines,

revaccinations and specialized transportation.^{19,20} WHO had earlier estimated that more than 50% of GAVI eligible countries reported a vaccine wastage rate exceeding the recommended range (2%-15%) and that up to 2.8 million vaccine doses were lost in 5 countries (Kenya not included) resulting from the cold chain failures.²¹

The on-spot thermometer reading was not within WHO and DVI's standards (0°C to +8°C) in some level two health facilities (3.8%). This has been observed by other studies in India and Thailand.^{6,7,22-24} WHO recommends using melting ice packs in cold boxes or vaccine carriers to protect vials from direct exposure with frozen ice packs, many health facilities in Narok county were using ice instead of ice packs. This substandard practice is common in many developing countries.^{15,22,26-28}

The present study showed that the vaccine vial monitor and card activator was not functional in some level two and three immunizing health facilities. This not only explain the higher effective vaccination coverage for measles among children vaccinated in at least level 4 health facilities compared to the lower-level ones but also highlight the cold chain management bottlenecks in lower-level health facilities. It has been demonstrated that changes in the vaccine vial monitor from stage I to 4 is associated with failure to maintain an adequate cold chain.²⁹ The present study finding is thus consistent with studies in Ethiopia India, Nigeria and North rift valley, Kenya that have found inadequacies in the functioning of a vaccine vial monitor in cold chain system.^{23,27,30-32}

The present study also showed similar trend in the functioning of the freeze watch as it was not functional across different facility levels. These contribute to poor potency of vaccines before expiry and against the adopted regulatory standards of the Kenya' Division for Vaccines and Immunization and WHO guidelines.³³ This also illustrate poor facility readiness to offer quality immunization services that can prevent the occurrence of vaccine preventable diseases.³⁴

The present study found that the cold chain biomedical technician has not made a must regular monthly cold chain engineering maintenance or cold chain functional assessment checks in lower-level health facilities. This finding indicates the inadequacies in human resource for

health contributes to poor viability of vaccines. This is similar to Ayaya et al findings that showed weakness in Division of Vaccines and Immunization, the then Kenya Extended Program on Immunization, KEPI program in Western Kenya which included poor maintenance of cold chain and inadequate number of staff.³⁵ It is also consistent with a study that reported that biomedical technician's role is vital in maintenance of vaccine potency and effectiveness.^{5,10,19}

The present study found improper vaccine storage in across different level of immunizing health facilities. This was generally indicated by inadequate air circulation, food and drinks in the refrigerator, vaccine nor kept in proper compartment and water bottles kept in health facilities cold chains systems. Neatness of vaccine arrangement was not consistent with vaccine arranged based on first to expire first-out (FEFO) principle in more than a quarter health facilities and safety of the cold room were not guaranteed as more than one person works in it simultaneously in a third of these health facilities. These compromises effectiveness of vaccinations. These findings have been observed in many developing countries including Ethiopia, Thailand and in the Bolivia.^{17,22-24,28}

The study revealed poor cold chain programming as reflected by gaps in immunization program management and financing, poor vaccine supply and logistics management as well as poor immunization services delivery at facility level. These findings are similar and well documented in many studies in various developing countries.^{13,15,22,26,27} This has resulted in stock out of vaccines, expiry of vaccines, poor vaccine forecasting and missed opportunities for vaccinations.

CONCLUSION

Ineffective vaccination coverage was linked to inadequacies in cold chain management practices and vaccine programming at public health facilities in Narok County, Kenya.

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