PHARMACY AND POISONS BOARD

REPUBLIC OF KENYA

Pharmacovigilance Summary Report: April 1st to June 30st 2024 (Q4)

The Pharmacy and Poisons Board is the National Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the manufacture and trade of drugs and poisons.

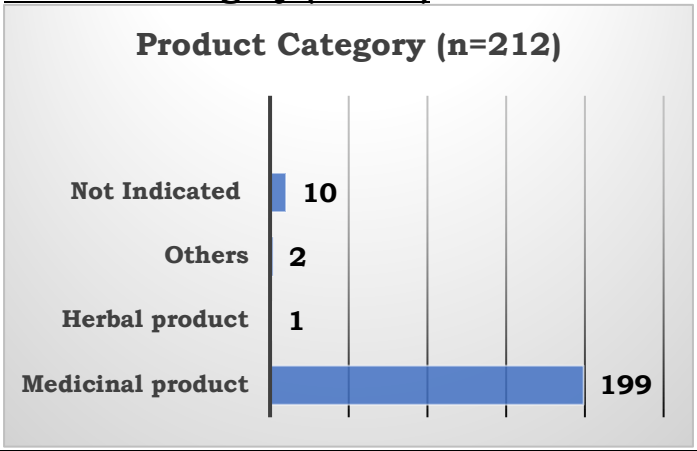
The PPB has 4 directorates of which the Department of Product Safety (PDS) under the Health Product and Technologies Directorate is responsible for Pharmacovigilance, Post-Marketing Surveillance, Clinical Trials & Medicines Information activities. PDS shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback mechanism and also encourage all stakeholders to report adverse events.

Since the introduction of PV in Kenya, a total of 19,754 individual case safety reports (ICSRs) have been submitted to the global database representing 2.7% of the total ICSRs submitted by African countries.

Suspected Adverse Drug Reactions (SADRs)

There were 223 suspected adverse drug reaction (SADR) reports submitted to the National Pharmacovigilance Centre within Quarter 4 (1st Apr -30th June 2024). Of the 223 reports, 212 (95.07%) reports were initial reports while 11 (4.93%) reports were follow-up reports. Of the 212 initial reports, 209 (98.58) were reports on suspected adverse drug reactions (SADR) while 3 reports (1.42%) were on therapeutic ineffectiveness.

Product Category (n=212)



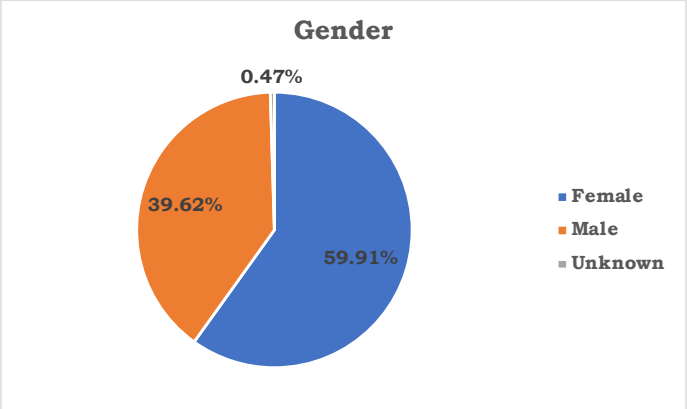
Most of the ADR cases reported were due to medicinal products (93.87%).
In one (0.47%) report, the product category was marked as herbal product reports while 2 reports (0.94%) had the product category marked as others.
In 10 reports (4.71%), the product category was not indicated by the reporter.

Age Group (n=212)

Age Group	Count	Proportion (%)
Adult	174	82.08%
Elderly	14	6.60%
Adolescent	8	3.77%
Child	8	3.77%
Neonate	5	2.36%
Infant	3	1.42%
Grand Total	**212**	**100.00%**

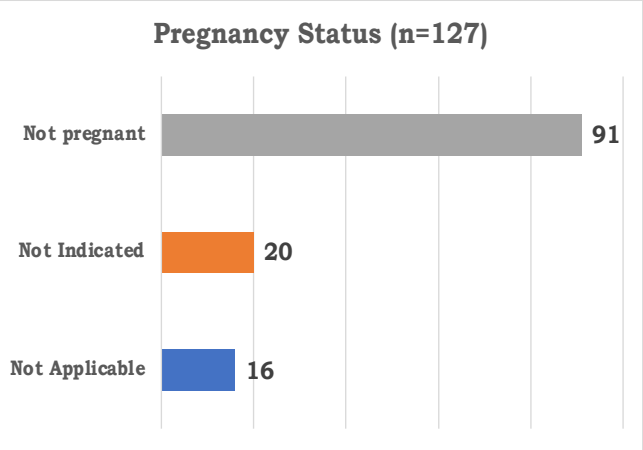
The prevalence of SADRs was highest (82.08%) amongst the adults (18-64) in comparison to the other age groups. This followed by the elderly age group (6.60%) and the children and adolescents (3.77%). The rest of the reports included the adolescent, infant and neonate age groups as shown above.

Gender (n=212)



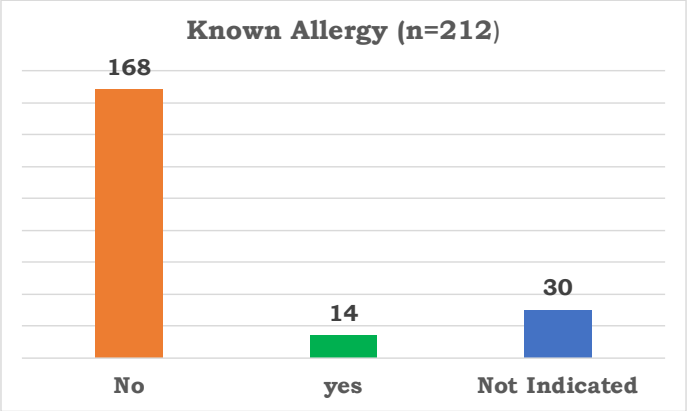
The frequency of reported SADRs was higher in female (59.91%, 127) as compared to male (39.62%, 84).
In one report (0.47%), the gender of the patient was not indicated.

Pregnancy Status (n=127)



Out of the 127 females with reported SADRs, 71.65% were not pregnant at the time of reporting. A total of 20 (15.75%) female cases reported did not indicate the pregnancy status while 16 (12.60%) reports indicated pregnancy status as not applicable

Known Allergy (n=212)



The frequency of reported SADRs was higher in patients with no history of known allergies (79.25%, 168) compared to those with known allergies (6.60%, 14).

A total of 30 reports (14.15%) did not indicate history of known allergy

Reported Allergen (n=6)

Reported Allergen	Count	Proportion (%)
Artemether/ Lumefantrine	1	16.67%
Aspirin	1	16.67%
Fluconazole	1	16.67%
Proteins	1	16.67%
Sulphur	2	33.33%
Grand Total	**6**	**100.00%**

Out of the 14 SADR reports with known allergies, 6 reports indicated the known allergens while 8 reports did not indicate the allergy type. Allergy to Sulphur was the most reported with 2 reports (33.33%).

The table above shows the known allergens documented in the SADR reports received in Q4.

Suspected medicines
(n=219)

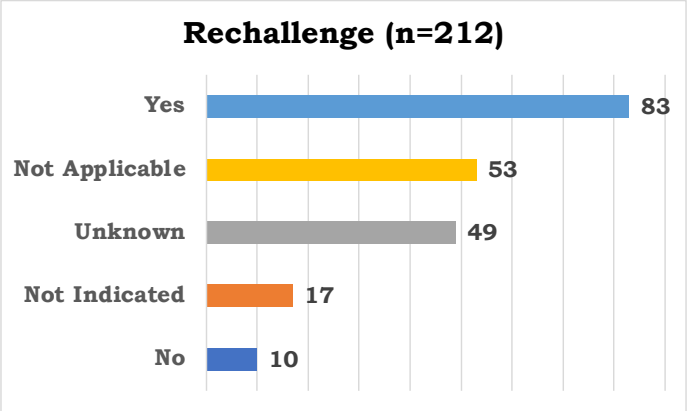
No	*Suspected Drug Name*	*Count*	*Proportions (%)*
1.	TDF/3TC/DTG (300mg/300mg/50mg)	39	17.81%
2.	RHZE (150mg/75mg/400mg/275mg)	23	10.50%
3.	Rifapentine/Isoniazid (300mg/300mg)	16	7.31%
4.	Cotrimoxazole BP 960mg	11	5.02%
5.	Tenofovir (300mg)	11	5.02%
6.	Levonogestrel	9	4.11%
7.	Isoniazid 300mg	9	4.11%
8.	Dolutegravir 50mg	7	3.20%
9.	Tenofovir/Lamivudine (300mg/300mg)	6	2.74%
10.	Ceftriaxone 1g	6	2.74%
11.	Atazanavir/Ritonavir (300mg/100mg)	5	2.28%
12.	Nifedipine	5	2.28%
13.	Cotrimoxazole BP 480mg	4	1.83%
14.	Metronidazole 400mg	3	1.37%
15.	Enalapril 5mg	3	1.37%
16.	Artemether/Lumefantrine	3	1.37%
17.	Tinidazole	3	1.37%

Key:
TLD*: Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg)*
RHZE*: Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (150mg/75mg/400mg/275mg)*

A total of 64 generic names/fixed dose combinations (FDC) were reported as suspected medicines in this quarter. Tenofovir/Lamivudine/Dolutegravir (300mg/300mg/50mg) FDC was the most frequently reported (17.81%).

The Rifampicin/Isoniazid/Pyrazinamide/Ethambutol (150mg/75mg/400mg/275mg) regimen was reported in 23 cases (10.50%), while Rifapentine/Isoniazid (300mg/300mg) fixed dose combination was reported in 16 reports (7.31%). The table above consists of a list of the most reported medicines in Quarter 4.

Rechallenge (n=212)



A rechallenge was conducted in 39.15% (83) of the 212 cases reported. In 4.72% (10) of the reported cases, rechallenge was not conducted.

The rechallenge status in 49 reports (23.11%) were marked as **unknown** and **not applicable** in 25% (53) of the reports. 8.02% (17) of the reports did not indicate if a re-challenge was done or not.

Reaction Reappear (n=83)

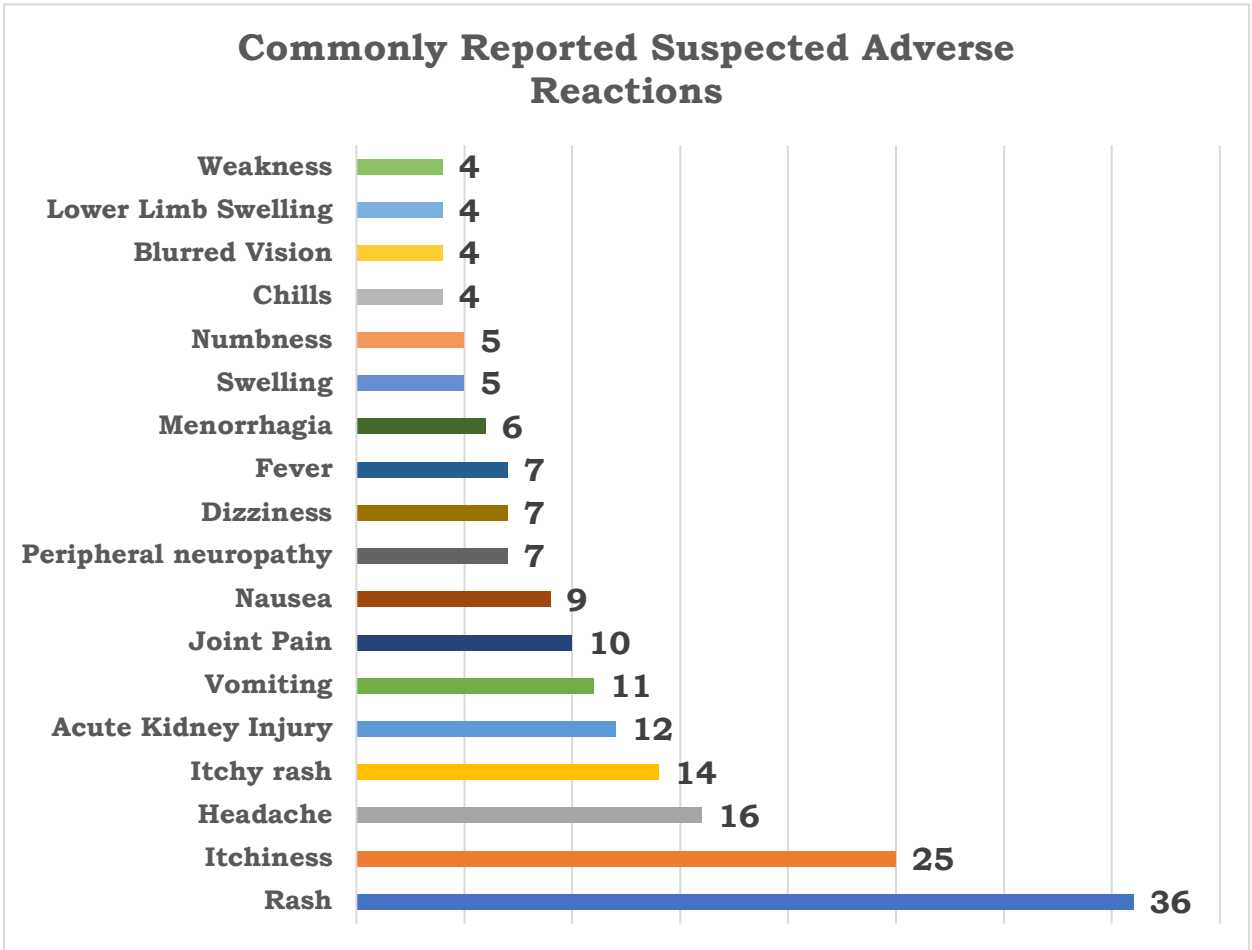
Reaction Reappear	Count	Proportions (%)
N/A	42	50.60%
Yes	13	15.66%
No	12	14.46%
Unknown	9	10.84%
Not indicated	7	8.43%
Grand Total	**83**	**100.00%**

The suspected ADR reappeared in only 15.66% of the cases where a rechallenge was done. However, in 14.46% of the cases (12), the suspected ADR did not reappear following a rechallenge.

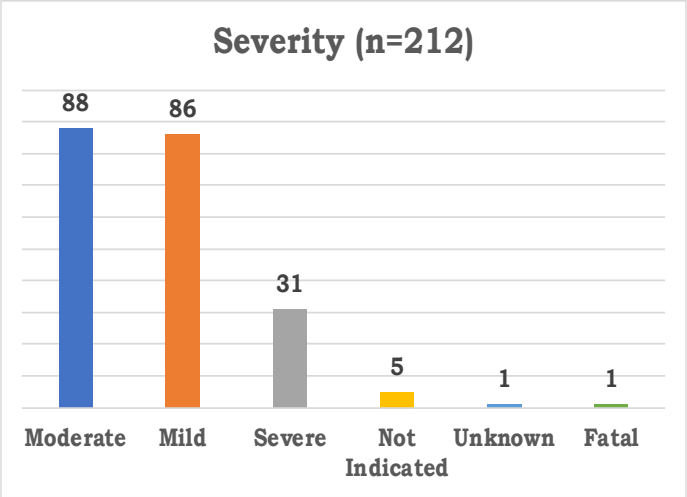
In most of the cases, the rechallenge outcome was marked as either **unknown**, **not indicated** or **not applicable** as shown in the table above.

Commonly reported adverse reactions

The following adverse drug reactions were commonly reported in Quarter 4: Rash (11.36%), Itchiness (7.89); and Headache (5.05%). The figure below shows adverse drug reactions reported in at least 4 reports.

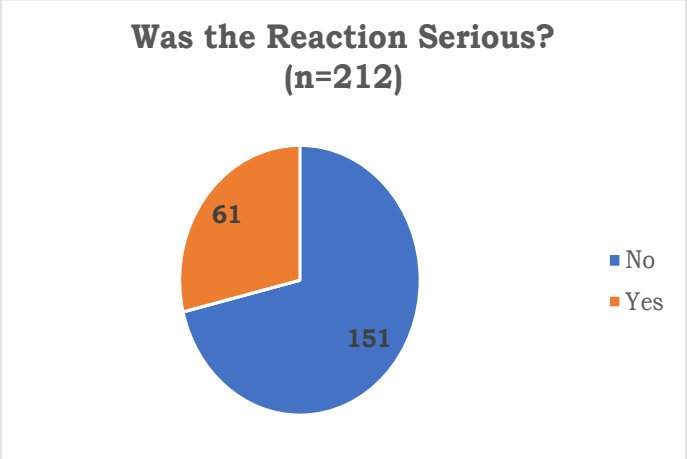


Severity (n=212)



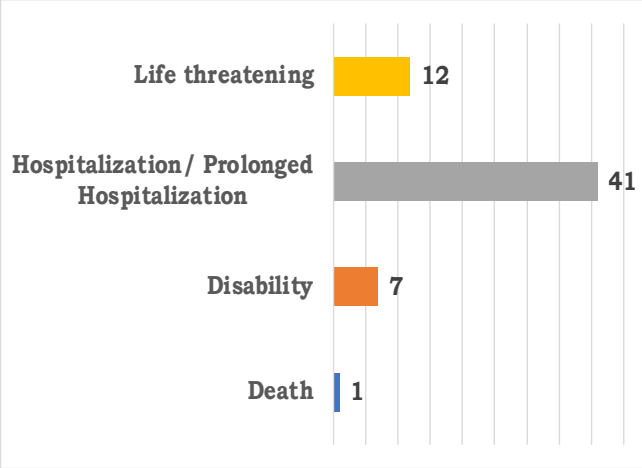
Of the 212 suspected adverse drug reaction reports received in Quarter 4, 14.62% (31) were classified as severe, 0.47% (1) was classified as fatal while 2.36% (5) of the reports did not indicate severity.
Most of the reports (41.51%, 88) were graded as being of moderate severity whereas 40.57% (86) of the reports were graded as mild.

Was the reaction serious? (n=212)



Of the 212 SADR reports received in Q4, 28.77% (61) were classified as serious while most of the received reports (71.23%, 151) were classified as not serious.

Reason for seriousness (n=61)

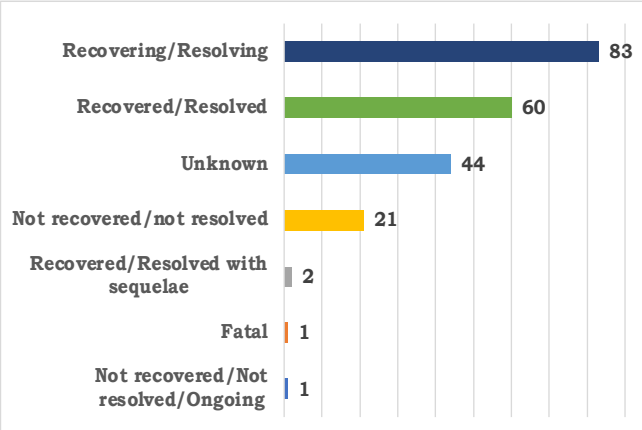


Out of the 61 serious SADR reports received, hospitalization/ prolonged hospitalization was the major reason for seriousness (67.21%, 41) followed by life threatening with 12 reports (19.67%). Only one (1.64%) was fatal. The other reason for seriousness marked by the reporters was disability as shown in the figure above.

Actions taken (n=212)

Action Taken	Count	Proportion (%)
Drug withdrawn	124	58.49%
Dose not changed	69	32.55%
Not applicable	7	3.30%
Unknown	5	2.36%
Dose reduced	4	1.89%
Dose increased	3	1.42%
Grand Total	**212**	**100.00%**

Outcome (n=212)



Among the actions taken by the health care workers following the occurrence of the adverse drug reaction included withdrawal of the offending drug in 58.49% (124) cases, dose reduction (1.89%, 4) and dose increased (1.42%, 3). A total of 69 reports (32.55%) indicated that the dose of the suspect medicine was not changed.

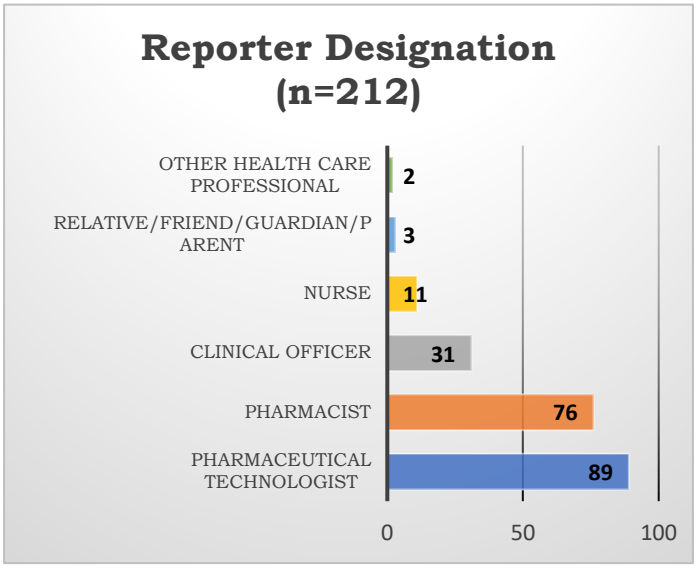
Out of the 212 SADR reports received in Q4, one case was fatal. A total of 39.15% of the cases were reported to be recovering/resolving at the time of reporting while 28.30% (60) of the cases were already recovered or resolved at the time of reporting.
The outcome was unknown in 20.75% (44) of the cases reported.

Diagnosis (n=253)

No	*Diagnosis*	*Count*	*(%)*
1.	HIV/AIDS	86	33.86%
2.	Tuberculosis	38	14.96%
3.	TPT	13	5.12%
4.	Not Indicated	12	4.72%
5.	URTI	10	3.94%
6.	FPS	10	3.94%
7.	Malaria	7	2.76%
8.	Hypertension	6	2.36%
9.	Pneumonia	5	1.97%
10.	PreP	3	1.18%
11.	Taeniasis	3	1.18%
12.	Diarrhea	3	1.18%
13.	Gastroenteritis	3	1.18%
14.	Body pain	2	0.79%
15.	Snake bite	2	0.79%
16.	Rash	2	0.79%
17.	Ca Breast	2	0.79%
18.	Fever	2	0.79%
19.	PEP	2	0.79%
20.	Amoebiasis	2	0.79%
21.	UTI	2	0.79%
22.	Lumbago	2	0.79%
23.	Meningitis	2	0.79%

The prevalence of SADRs in the period between 1st April 2024 and 30th June 2024 was highest among patients with HIV/AIDS (33.86%), followed by patients with Tuberculosis (14.96%), patients on Tuberculosis Preventive Therapy (5.12%) and patients with upper respiratory tract infections (3.94%). Overall, SADRs in this period were reported among patients with 57 different diagnoses.
A total of 12 reports (5.68%) lacked a diagnosis
A list of diagnoses with at least 2 and above SADR reports is shown on the left.

Key:
Ca Breast: *Cancer of the Breast*
FPS: *Family Planning Services*
HIV/AIDS: *Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome*
PreP: *Pre-Exposure Prophylaxis*
PeP: *Post Exposure Prophylaxis*
URTI*: Upper Respiratory Tract Infections*
UTI: *Urinary Tract Infection*
TB*: Tuberculosis*
TPT*: Tuberculosis Preventive Therapy*



Reporter designation

Majority of the SADR reports received by the national pharmacovigilance center in Quarter 4 were submitted by pharmaceutical technologists (41.98%, 89).

Pharmacists submitted 35.85% of the reports (76) followed by Clinical officers who submitted 14.62% (31) of the total reports

Institution

In this Quarter, only 104 facilities out of the 9,000 facilities listed in the Kenya Master facility reported SADRs. 25 facilities reported at least 3 reports and above. The top leading facilities were Tudor District Hospital (Mombasa) with 11 reports (5.19%) followed by Oresi hospital with 10 reports (4.72%). Nyamaraga Dispensary and Coast General Teaching and Referral Hospital were the third most reporting facilities in this quarter with 8 reports (3.77%) each. Below is a list of top 25 facilities with at least 3 reports and above.

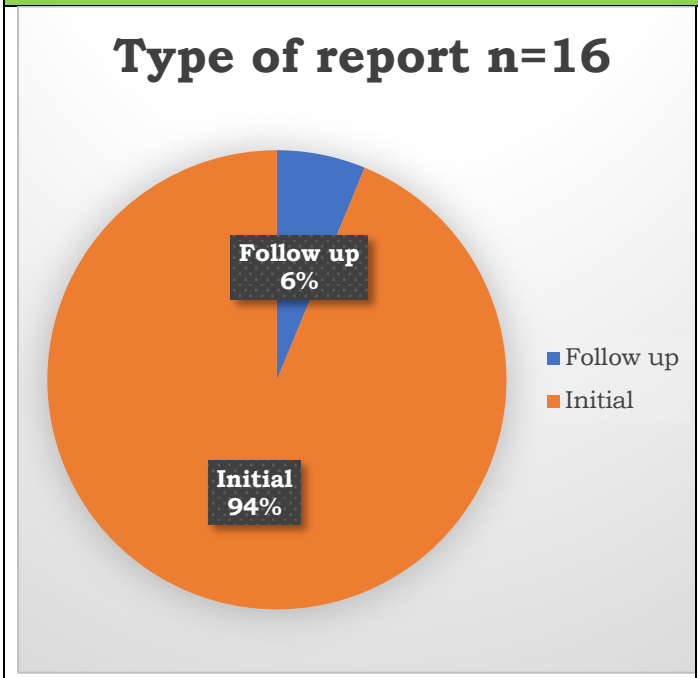
No	***Institution***	***Count***	***%***	***No***	***Institution***	***Count***	***%***
1	Tudor District Hospital (Mombasa)	11	5.19%	***14***	Dafra Pharma GmbH	3	1.42%
2	Oresi hospital	10	4.72%	***15***	Kianyaga Sub-County Hospital	3	1.42%
3	Nyamaraga Dispensary	8	3.77%	***16***	Chulaimbo County Hospital	3	1.42%
4	Coast General Teaching and Referral Hospital	8	3.77%	***17***	Kikoko Mission Hospital	3	1.42%
5	Nanyuki Teaching & Referral Hospital	7	3.30%	***18***	Consolata Mission Hospital (Mathari)	3	1.42%
6	Moi Teaching Refferal Hospital	5	2.36%	***19***	Gatundu District Hospital	3	1.42%
7	Butere Sub County Hospital	5	2.36%	***20***	Kanjinji Dispensary	3	1.42%
8	Gathigiriri Health Centre	4	1.89%	***21***	Independent Physician	3	1.42%
9	Webuye Hospital	4	1.89%	***22***	Maralal District Hospital	3	1.42%
10	Kangu Dispensary	4	1.89%	***23***	Ruiru Sub-County Hospital	3	1.42%
11	Kimilili Subcounty Hospital	4	1.89%	***24***	Kathiani Sub County Hospital	3	1.42%
12	Mwea Mission (Our Lady of Lourdes) Hospital	3	1.42%	***25***	Kikuyu (PCEA) Hospital	3	1.42%
13	P.C.E.A CHOGORIA HOSPITAL	3	1.42%				

County

SADR reports were received from 26 of the 47 counties. Kirinyaga county submitted the highest number of SADR reports (33, 15.57%) followed by Mombasa (26, 12.26%) and Nairobi (21, 9.91%) Counties. Below is a table of the counties that submitted SADR reports in quarter 4.

No	***County***	***Count***	***%***	***No***	***County***	***Count***	***%***
1	Kirinyaga	33	15.57%	***14***	Nyeri	6	2.83%
2	Mombasa	26	12.26%	***15***	Uasin Gishu	5	2.36%
3	Nairobi County	21	9.91%	***16***	Kitui	3	1.42%
4	Kiambu	15	7.08%	***17***	Samburu	3	1.42%
5	Kisii	14	6.60%	***18***	Kilifi	3	1.42%
6	Siaya	13	6.13%	***19***	Tharaka Nithi	3	1.42%
7	Makueni	9	4.25%	***20***	Embu	3	1.42%
8	Bungoma	8	3.77%	***21***	Homa Bay	2	0.94%
9	Laikipia	8	3.77%	***22***	Meru	2	0.94%
10	Migori	8	3.77%	***23***	Turkana	2	0.94%
11	Kisumu	8	3.77%	***24***	Murang'a	1	0.47%
12	Kakamega	8	3.77%	***25***	Elgeyo/Marakwet	1	0.47%
13	Machakos	6	2.83%	***26***	Narok	1	0.47%

Adverse Events Following Immunization (AEFI)

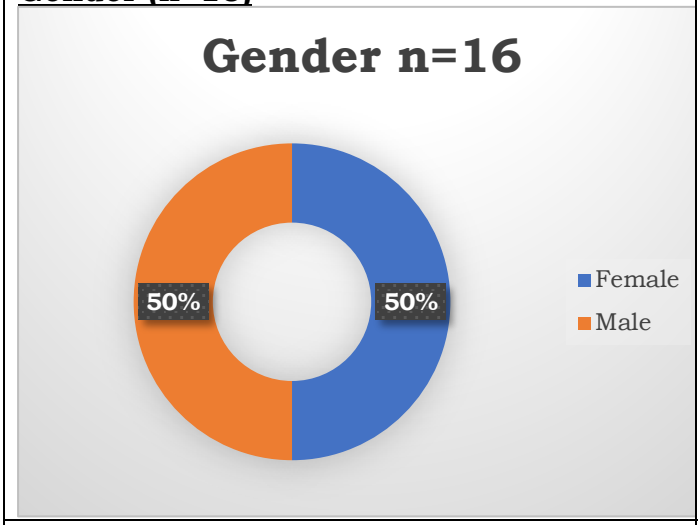


Vaccine type	*Count*	*%*
Pneumococcal conjugate vaccine	6	22.22%
Pentavalent Vaccine (DTP-HepB-Hib)	6	22.22%
Malaria (RTSS)Vaccine	5	18.52%
Rota virus vaccine	2	7.41%
Inactivated polio vaccine	2	7.41%
Rota virus vaccine	1	3.70%
Bivalent oral Polio vaccine	1	3.70%
Novel oral polio vaccine type 2 (nOPV2)	1	3.70%
Opv	1	3.70%
Covid-19 Vaccine - (Johnson & Johnsons) Janssen	1	3.70%
Human Papilloma virus vaccine	1	3.70%

The National Pharmacovigilance Centre received a total of 16 AEFI reports in the period between 1st April 2024 and 30th June 2025. 94% (15) of the reports received in this quarter were initial reports with only 6% (1) of the total being a follow-up report.

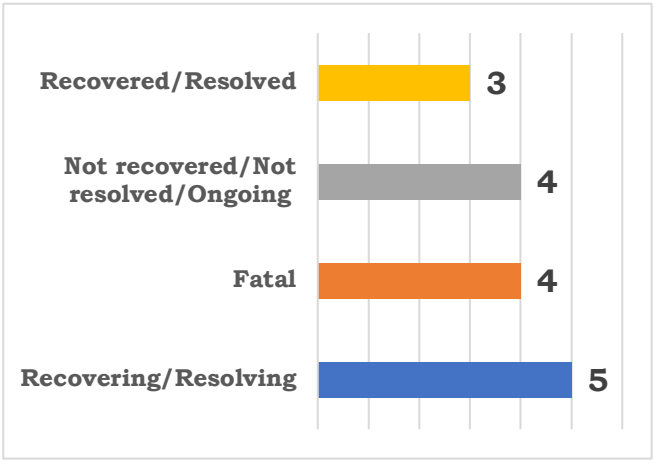
Of the total AEFI reports received, most events were caused by the Pneumococcal conjugate vaccine and Pentavalent Vaccine (DTP-HepB-Hib) (22.22%) each. Malaria (RTSS)Vaccine at 18.52% while Rota virus vaccine and Inactivated polio vaccine followed at 7.41% each.
The other reports received with other vaccines are as in the table above.

Gender (n=16)

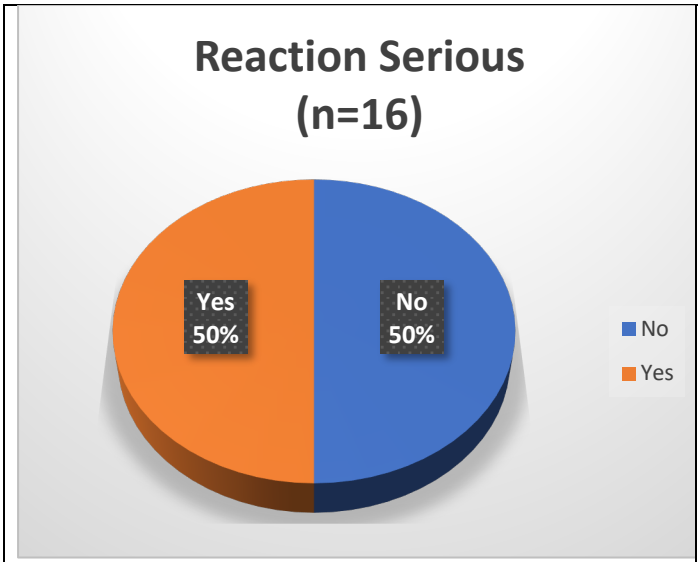


Of the AEFI reports received in this quarter, it was noted that both males and females were affected equally at 50% (8) each.

Outcome (n=16)



Of the 16 AEFI reports (initial and follow-up) received, 5 indicated the outcome as either recovering/resolving. 3 cases recovered while 4 cases had not recovered at the time of reporting. 4 cases were fatal.



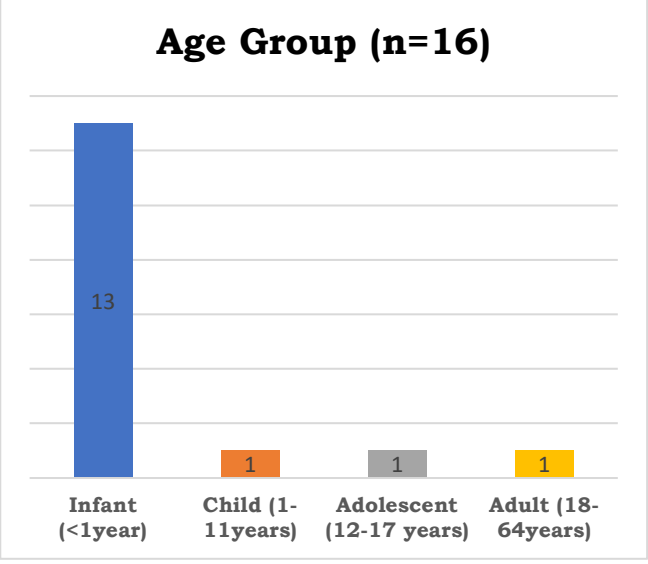
Reason for seriousness	*Count*	*Proportion*
Death	4	50.00%
Hospitalization or prolongation of existing hospitalization	2	25.00%
Other important medical event	1	12.50%
Life threatening	1	12.50%

Half of the AEFI reports 50% (8) received in this quarter were reported as not serious, with the other half reported as serious.

Of the AEFI reports noted to be serious 33% (4) were due to other medical important event, 25% (3) were due to hospitalization or prolonged hospitalization, 17% (2) were due to death, and 17% (2) were categorized as life threatening. 8% (1) of the cases were marked as serious due to persistent or significant disability.

Reporter Designation (n=16)

Reporter Designation	**Count**	**%**
Pharmacist	5	31.25%
Nurse	4	25.00%
Clinical officer	2	12.50%
Pharmaceutical technologist	2	12.50%
Nutritionist	1	6.25%
Research assistant	1	6.25%
Physician	1	6.25%



Majority of the AEFIs were reported by Pharmacists (31.25%). Nurses submitted 25.00% of the reports while pharmaceutical technologist and clinical officers submitted (12.50%) each. It was noted that the least reporting cadres were nutritionists, research assistants and physician each with one (1) report.

Majority of the AEFIs reported in this quarter affected the infant age group (<1 year) (13). The least affected age group in this quarter were the child (1-11 years), adolescents (12-17 years) and adult (18-65 years) with only (1) report.

Reporting institutions

No	Reporting Institution	Count	%	No	Reporting Institution	Count	%
1	Tudor District Hospital	2	12.50%	8	Got Winyo Dispensary	1	6.25%
2	Usenge Dispensary	2	12.50%	9	Simenya Health Centre	1	6.25%
3	Babadogo Health Centre	1	6.25%	10	Kangu Dispensary	1	6.25%
4	Oyani (SDA) Dispensary	1	6.25%	11	Ukwala Sub County Hospital	1	6.25%
5	Matercare Maternity Hospital	1	6.25%	12	Makadara Health Center	1	6.25%
6	Giaki Sub-District Hospital	1	6.25%	13	Asat Beach Dispensary	1	6.25%
7	Muhoroni County Hospital	1	6.25%	14	Mashambani Health Centre	1	6.25%

In this Quarter, only 14 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. The top leading facilities were Tudor District Hospital and Usenge Dispensary with 2 reports each. The remaining 12 facilities had one (1) report each.

Reporting Counties

No	County	Count	Proportion
1	Siaya	5	31.25%
2	Kisumu	3	18.75%
3	Mombasa	2	12.50%
4	Nairobi	2	12.50%
5	Migori	1	6.25%
6	Kirinyaga	1	6.25%
7	Isiolo	1	6.25%
8	Meru	1	6.25%

Additionally, AEFI reports were received from 10 of the 47 counties. Siaya county submitted the highest number of AEFIs reports (5) followed by Kisumu County (3). Mombasa and Nairobi counties submitted 2 reports each whereas four counties submitted one report as detailed in the above table.

Commonly reported AEFIs

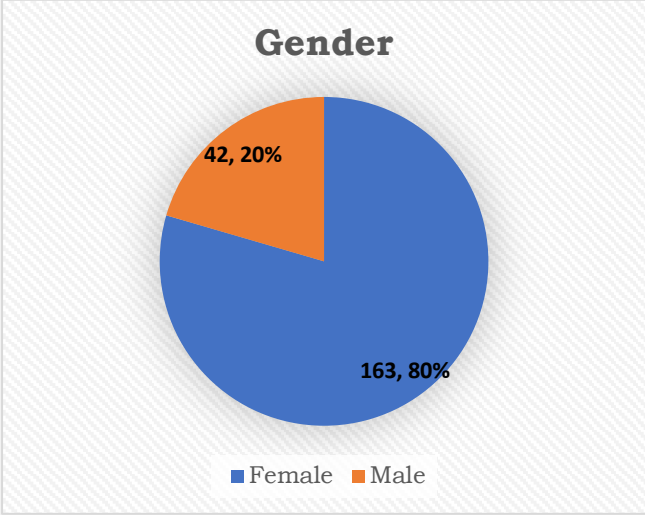
No	Event	Count	Proportion
1	High fever	8	42.11%
2	Injection site abscess	5	26.32%
3	Bleeding from upper palate	1	5.26%
4	Headache	1	5.26%
5	Irritability	1	5.26%
6	Convulsion	1	5.26%
7	Abscess at the armpit	1	5.26%
8	Generalized urticaria	1	5.26%

Of the AEFIs reported in this quarter, high fever was the most reported (42.11%) followed by injection site abscess (26.32%). The other reported AEFIs include; bleeding from upper palate, headache, irritability, convulsion, generalized urticaria and abscess at the armpit.

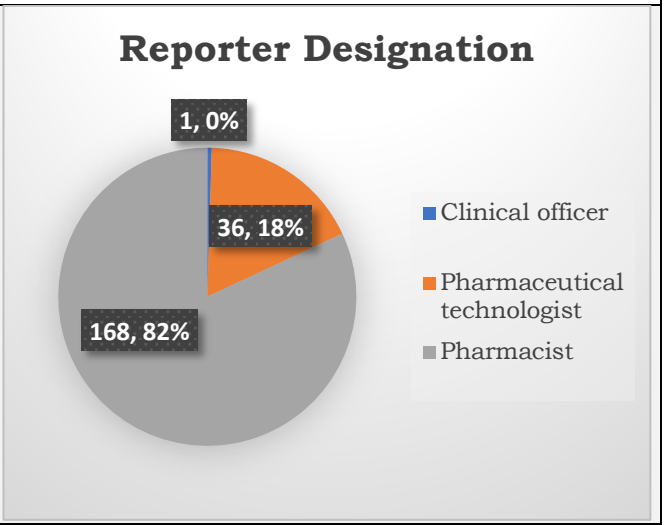
Medication Errors (MEs)

No	Institution	Count	%	No	Institution	Count	%
1	Tudor District Hospital (Mombasa)	115	56.10	9	Mutithi Health Centre	1	0.49
2	Kenyatta National Hospital	48	23.41	10	Kenyatta National Hospital	1	0.49
3	Nanyuki Teaching & Referral Hospital	15	7.32	11	Etago sub county hospital	1	0.49
4	Coast Province General Hospital	14	6.83	12	Wangige Sub County Hospital	1	0.49
5	Njegas Health Centre	2	0.98	13	Thika Level 5 Hospital	1	0.49
6	Lorugum sub-county Hospital	1	0.49	14	Kijabe (AIC) Hospital	1	0.49
7	Kerugoya County Referral Hospital	1	0.49	15	AIC Kijabe hospital	1	0.49
8	Mlaleo Health Centre (MOH)	1	0.49	16	Kirinyaga county	1	0.49

A total of 205 reports were received. Tudor District Hospital (Mombasa) submitted the highest number of reports 115 (56.10%), followed by Kenyatta National Hospital 48 (23.41%). Medication errors from other facilities were as shown in the table.



In Q4, the were more reports of medication errors among female patients 163% (79) than male patients 42% (50).



In all the cadres,the highest number of reports were submitted by pharmacists 168 (82%) and pharmaceutical technologists 36 (18%).

Hospital Ward

Hospital Ward/Department	Number of Errors	Percentage
Not Indicated	146	71.22
Outpatient	41	20
POSTNATAL Spontaneous Vaginal Delivery (SVD)	7	3.41
POSTNATAL (Caesarian Section)	7	3.41
Medical	2	0.98
New Born Unir	1	0.49
Pediatric Ward	1	0.49

Most reporters 146 (71.22%) did not indicate the ward/department where the error occurred. The Outpatient department had 41 (20%) of the reported errors, followed by Postnatal SVD 7 and Postnatal CS both with 7 (3.41%) reports.

Medication Errors and Age

Age	*Number of Errors*	*Percentage*
Adult	169	82.44
Child	11	5.37
Adolescent	9	4.39
Elderly	8	3.90
Neonate	4	1.95
Not Indicated	3	1.46
infant	1	0.49
Grand Total	***205***	***100***

The number of medication errors was highest among the Adults 169 (82.44%), followed by children 11 (5.37%). The distribution among other age groups is as shown in the table.

Process where Error Occur

Process	*Number of Errors*	*Percentage*
Prescribing	189	92.20
Administration	9	4.39
Dispensing (includes filling)	3	1.46
Transcribing	2	0.98
Others	2	0.98
Grand Total	***205***	*100*

In Quarter 4(Q4), most of the medication errors occurred during the prescribing process 189 (92.20%), followed by Administration 9 (4.39%). Other errors occurred during dispensing and transcribing.

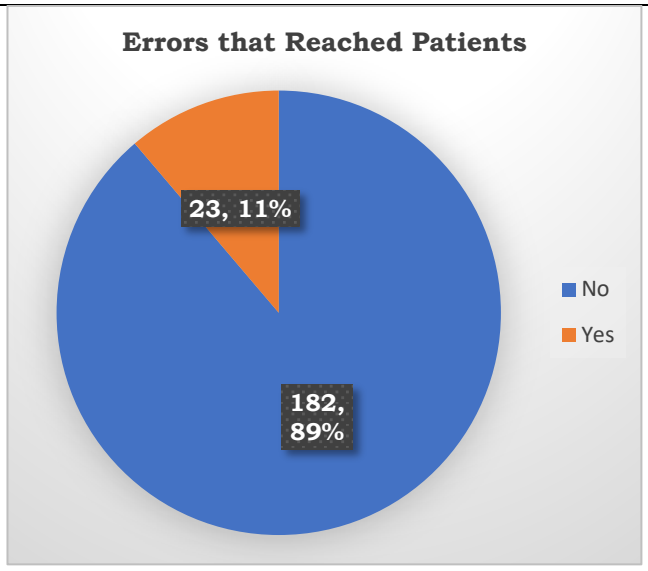
Medication Error Outcome

Outcome Come	**Number of Errors**	**Percentage**
Actual error-did not reach patient	171	83.41
Actual error-caused no harm	10	4.88
Not Indicated	8	3.90
Additional monitoring required-caused no harm	7	3.41
Potential error, circumstances/events have potential to cause incident	5	2.44
Treatment /intervention required-caused temporary harm	4	1.95
Grand Total	**205**	**100.00**

Most of the medication errors 171 (83.41%) did not reach the patient and for medication errors that actually reached the patient 10 (4.88%),they did not cause harm to the patient while 4 (1.95%) causes temporary harm.

County

County	**Count**	**%**
Mombasa	130	63.41
Nairobi	49	23.90
Laikipia	15	7.32
Kirinyaga	5	2.44
Kiambu	4	1.95
Turkana	1	0.49
Kisii	1	0.49
Grand Total	**205**	**100.00**



Most of the reports submitted were from Mombasa County 130 (63.41%), followed by Nairobi County at 40 (23.9%). Other counties reported as shown in the table.	In Quarter 4, 182 (89%) errors did not reach patients while 23 (11%) reached patients.

Clinic where Error Occurred

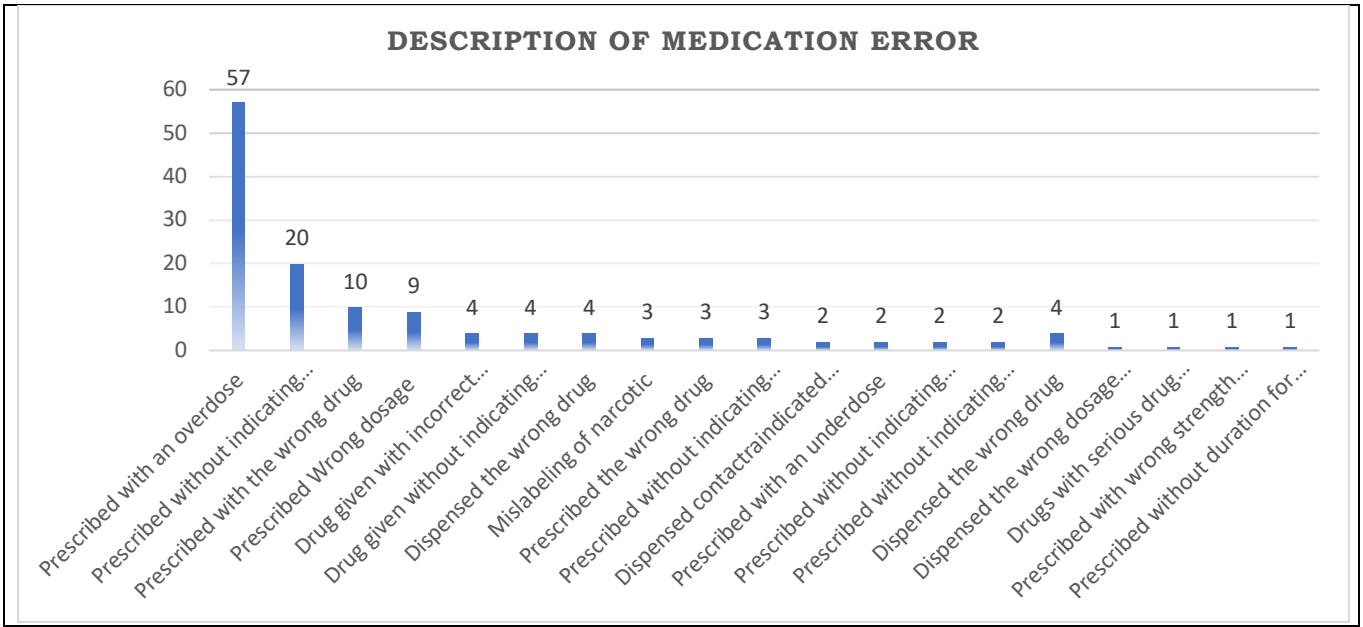
Clinic	*Number of Errors*	*Percentage*
MATERNITY	64	31.22
OUTPATIENT	59	28.78
Not Indicated	51	24.88
Diabetic Outpatient clinic	13	6.34
Cancer treatment Centre	13	6.34
Comprehensive Care Center (CCC)	2	0.98
In- patient pharmacy	1	0.49
Specialist	1	0.49
Progressive Pulmonary Care Unit (PPCU)	1	0.49
Grand Total	**205**	**100.00**

Most medication errors were reported from the maternity clinic 64 (31.22%), followed by the Outpatient Clinic 59 (28.78%). Other errors that occurred in the various clinics are as shown in the table above.

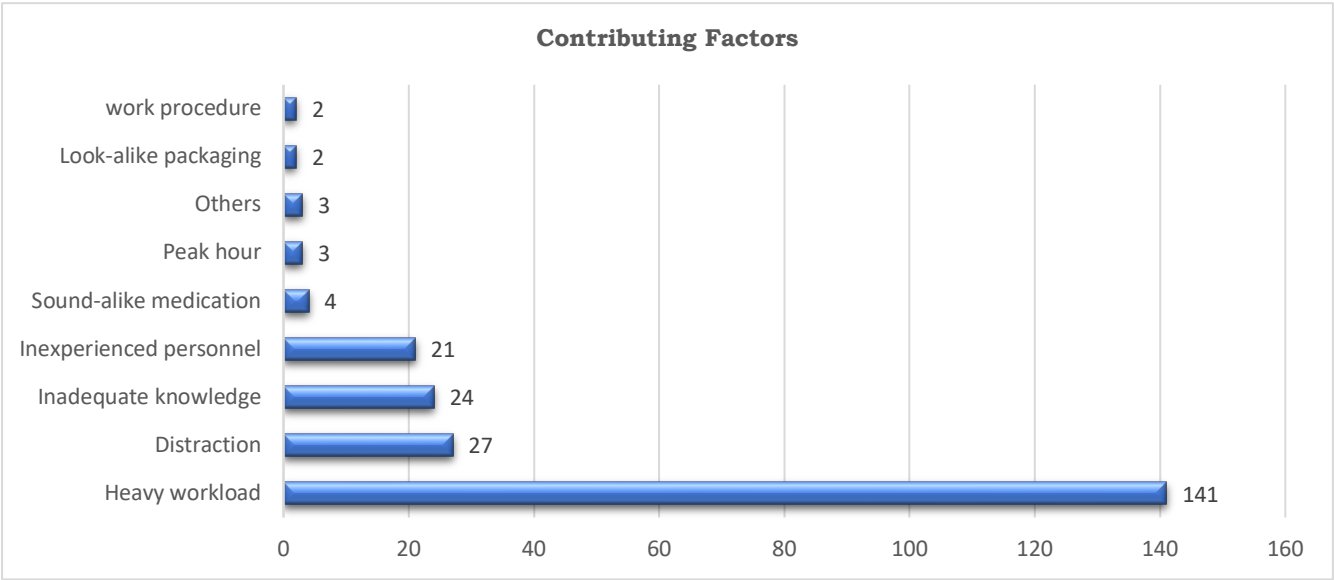
Drugs with Medication Errors

Medication	**No. of Reported Errors**	**Type of Error**
Aceclofenac/Serratiopeptidase	36	Prescription Error
Aceclofenac/Paracetamol/Chlorzoxazone	23	Prescription Error
Haematinic syrup	22	Prescription Error
Lactulose syrup	9	Prescription Error
Nitrofurantoin	8	Prescription Error
Surgical spirit plus chlorhexidine gluconate gel	7	Prescription Error
METRONIDAZOLE	6	Prescription Error
Paracetamol	5	Prescription Error
BUDESONIDE INHALER	4	Prescription Error

In Q4, the drugs with the highest incidence of medication errors are as shown in the table.

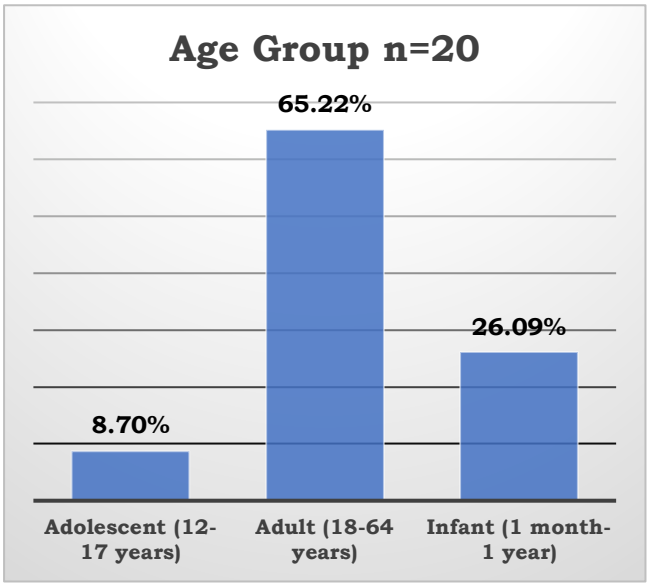


Of the reports received, the most frequent errors were prescription errors with overdose (58) reports, followed by Prescriptions that did not indicate frequency and duration of treatment which had 36 reports. Other descriptions are as shown in the table.

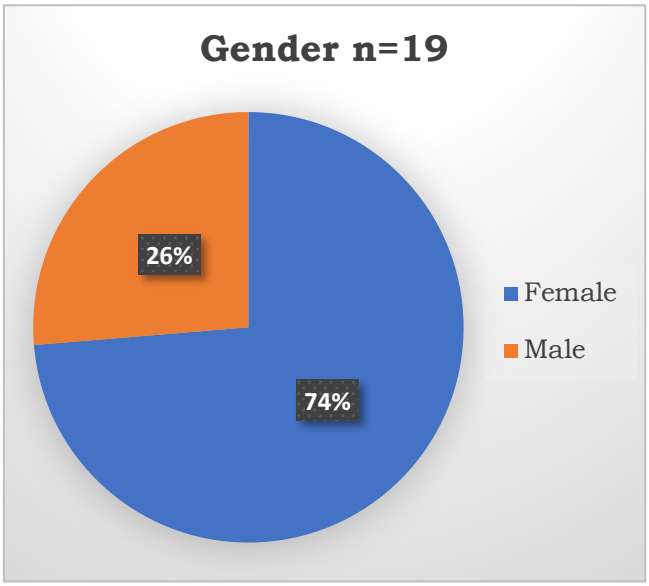


In quarter 4(Q4), heavy workload (141) ,distractions (27), inadequate knowledge (24), inexperienced personnel (21) were reported to be amongst the highest contributors to medication errors.

PUBLIC ADVERSE DRUG REPORTING (PADRS)



The incidence of PADRs was highest amongst adults 65.22% (14) followed by infants 26.09% (4) and infants 8.7% (2).



The incidences of PADRs were highest amongst females 74% (14). Male reporters constituted 26.32% (5) of all the PADRs. One report did not have the gender indicated.

Suspect medicine

The most commonly reported suspected medicine causing adverse drug reactions were Tenofovir/Lamivudine/Dolutegravir (4 reports), Dolutegravir 50MG (2) and Inactivated poliovirus/pneumococcal conjugate vaccine (2).

The rest of the suspected drugs were reported as shown in the table below.

No	***Drug***	***Count***	***Proportion***	***No***	***Drug***	***Count***	***Proportion***
1	Tenofovir/Lamivudine/Dolutegravir	4	22.22%	***8***	Chlorhexidine 5%	1	2.27%
2	Dolutegravir 50MG	2	11.11%	***9***	Metformin	1	2.27%
3	Inactivated poliovirus/pneumococcal conjugate vaccine	2	11.11%	***10***	Chlorpheniramine	1	2.27%
4	Cefuroxime	1	5.56%	***11***	MZ-Cal Plus	1	2.27%
5	Chloramphenicol syrup	1	5.56%	***12***	Chlorzoxazone	1	2.27%
6	Cotrimoxazole	1	5.56%	***13***	Bonjela soothing teething gel	1	2.27%
7	LIX- Sodium Hypochlorite solution 4.0 - 6.0% wv	1	5.56%				

Reaction

No	Reaction	Count	%	No	Reaction	Count	%
1	Abnormal changes with urination	8	19.05	12	Involuntary muscle movements	1	2.38
2	Bilateral oedema and rash classical of SJS	3	7.14	13	Joints and muscle pain	1	2.38
3	Blood clot	3	7.14	14	Memory Loss	1	2.38
4	Brain Fog	3	7.14	15	Numbness of the face and mucosal cavity immediately after taking the pills	1	2.38
5	Convulsions	3	7.14	16	Pain in the stomach	1	2.38
6	Dizziness or drowsiness	3	7.14	17	Pain or bleeding in the mouth	1	2.38
7	Drooling tongue	2	4.76	18	Rash	1	2.38
8	FEVER	2	4.76	19	Red/ painful eyes	1	2.38
9	Generalized body stiffness	2	4.76	20	Slurred speech	1	2.38
10	Headache	1	2.38	21	Vomiting or diarrhea	1	2.38
11	Heart Palpitations	1	2.38	22	Weight gain	1	2.38

The most commonly reported PADRs were abnormal changes with urination. Other reported PADRS were bilateral oedema and rash classical of SJS, blood clot ,brain fog, convulsions and drowsiness.

County

PADRs were received from 10 of the 47 counties. Nairobi County submitted the highest number of PADRs (9, 45%) followed by Kwale County and Nakuru County with 2 (10%) reports respectively. The rest of the counties submitted 1 report as shown in the table below.

No	County	Count	Proportion	No	County	Count	Proportion
1	Nairobi	9	45.00%	6	Kiambu	1	5.00%
2	Kwale	2	10.00%	7	Kisumu	1	5.00%
3	Nakuru	2	10.00%	8	Machakos	1	5.00%
4	Busia	1	5.00%	9	Siaya	1	5.00%
5	Homa Bay	1	5.00%	10	Turkana	1	5.00%

Blood Transfusion Reactions

There was one report of blood transfusion reactions received in quarter 4(Q4). The report was submitted by a pharmacist.

The incidence of Blood transfusion reaction was in a male adult (18-64 year) patient. The patient had received a blood transfusion due to severe blood loss due to severe microcytic anemia secondary to lower GI bleed. The patient had previously received a blood transfusion but had no previous reaction. The reported blood transfusion reaction reported was urticaria, hypotension, rigors and chills.

Medical Device Incidence Reports
There was one report of a medical device incident (MDI) reported in the quarter. The report was received from Nairobi County. The medical device incidents occurred to a male infant patient involving a poorly calibrated 5 cc syringe which was not used. The reported medical device incident involved a Revital 5cc Syringe manufactured by Revital Healthcare EPZ Limited which was poorly calibrated. The report was made by a nurse who classified the event as moderate and indicated the outcome of the patient as recovered.

For any queries, please contact the PV department at pv@ppb.go.ke or call ***0795743049.***

Please visit the PvERS web link at https://pv.pharmacyboardkenya.org/for more information on the reports received at the National Pharmacovigilance Center.

This document is produced by the National Pharmacovigilance Center

Data sources: PPB PV Center

WHO VigiLyze Database (*NB: the information does not represent the opinion of the World Health Organization*)