REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: October 1st to December 31st 2022 (Q2)

The Pharmacy and Poisons Board is the Drug 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.

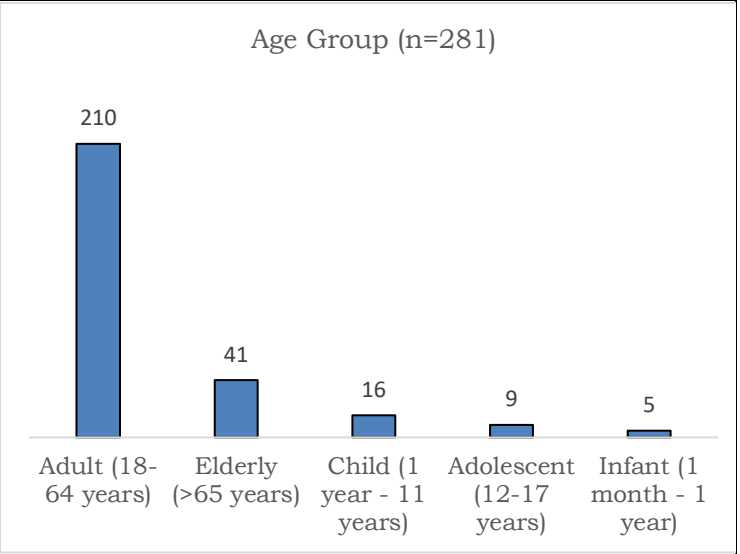
PPB has 4 directorates and one of them is the directorate of Health Products and Technologies (HPT). Pharmacovigilance & Post Marketing Surveillance are divisions in the department of product safety that falls under HPT. Other divisions Clinical Trials & Medicines Information. Product safety shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback mechanism and also encourage all stakeholders to report.

In this quarter 1 period, a total of 515 adverse events reports were submitted to PPB. 281 of the total reports were of suspected adverse drug reactions (sADRs), 16 adverse events following immunizations (AEFI), 100 from members of the public (PADRs) and 113 were medication error reports, 1 report of incident following use of a medical device and 1 blood transfusion reaction.

*Since the introduction of PV in Kenya, a total of **16,051** individual case safety reports has been submitted to the global data reports **32,760,345** (0.05%).*

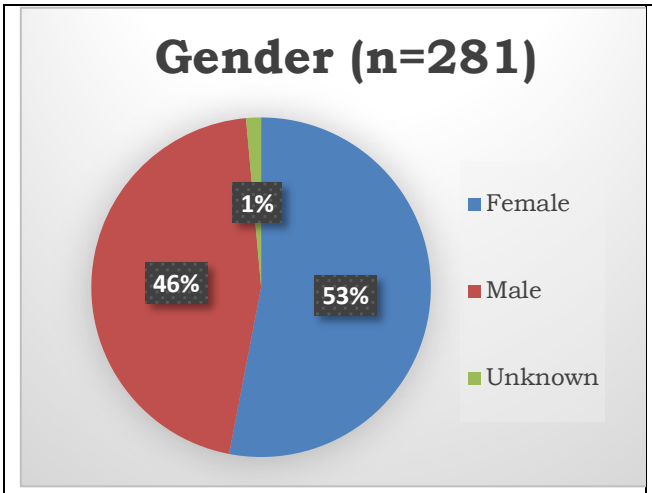
SADRs (Suspected Adverse Drug Reactions)

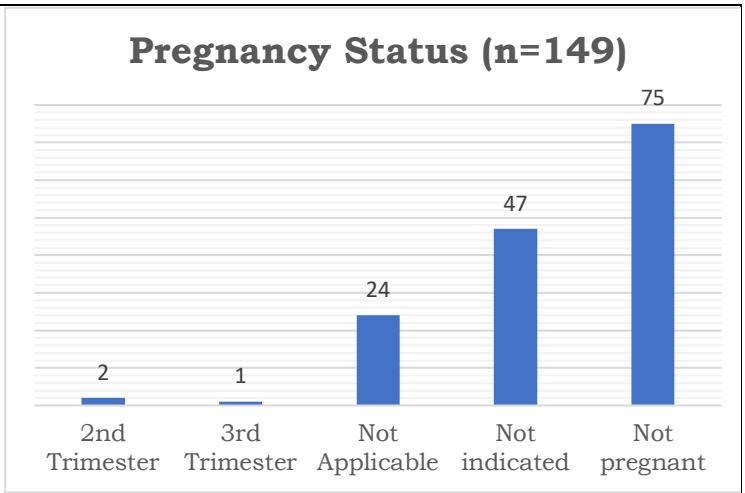
Product	Count	Percentage
Therapeutic Ineffectiveness	6	2.1%
Medicinal product	277	96.2%
Blood products	0	0.0%
Herbal product	3	1.0%
Cosmeceuticals	0	0.0%
Others	2	0.7%



Most of the reports on suspected ADRs in the 2nd quarter were caused by medicinal products (96.2%). All the 6 reports on therapeutic effectiveness were for medicinal products. Three SADRs (1.0%) were reported as caused by cosmeceuticals herbal products

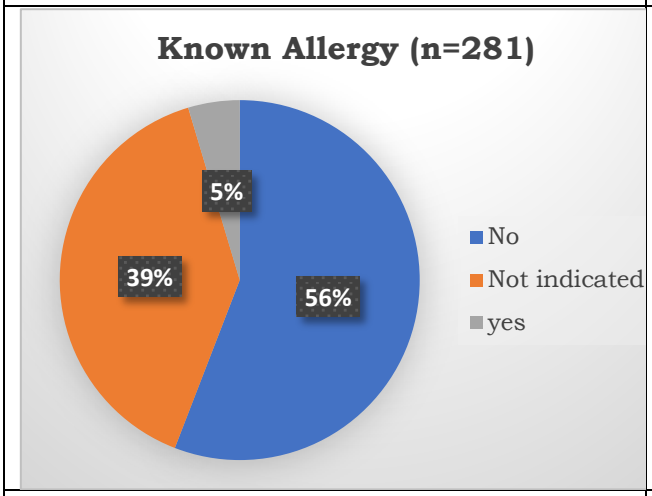
The incidence of SADRs was highest (74.7%) amongst the adult age group (18-64) in comparison to the others. The elderly age group made up 14.6% of the reported SADRs in this quarter while 5.7% of the SADRs were reported among children aged between 1 and 11 years





The frequency of reported SADRs was higher in female (53%, 149) compared to male (46%, 128). 4 reports did not have gender indicated on them

Out of the 149 Females with reported SADRs, 2 SADRs were reported among female patients who were in the 2nd trimester of pregnancy while 1 was reported in a female patient who was in the 3rd trimester. Majority of the affected females (50.3%) were not pregnant. A total of 47 (31.5%) SADR reports in female patients did not indicate the pregnancy status



Allergy Type (n=13)	Count of Allergy	Proportion
Not indicated	9	69.2%
Proteins	1	7.7%
Penicillin	1	7.7%
Cold	1	7.7%
Penicillin/Albendazole	1	7.7%
Total	**13**	**100.00%**

The frequency of reported SADRs was higher in patients with no history of known allergies (56%, 157) compared to those with known allergies (5%, 13). 111 reports (39%) did not indicate history of known allergy

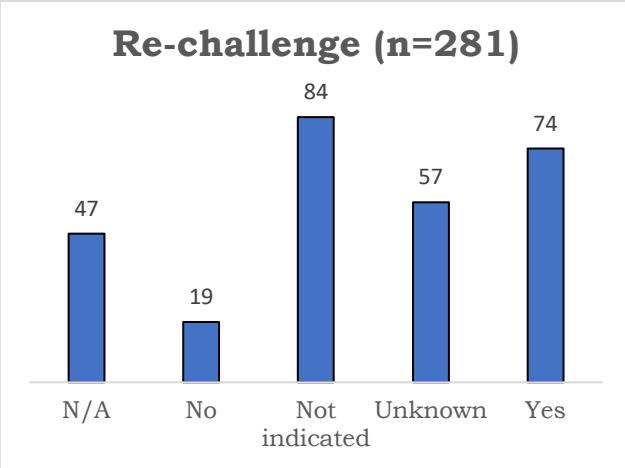
Out of the 13 SADR reports with known allergies, 9 (69.2%) did not indicate the allergy type. Proteins, Penicillin and Penicillin/Albendazole were each reported as the allergy type in one report

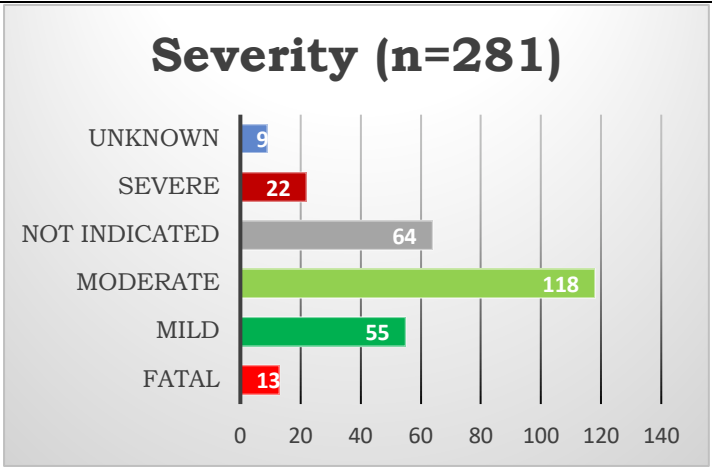
Generic name (n=281)

No	Generic Name	No of Reports	Proportion	No	Generic Name	No of Reports	Proportion
1	Tenofovir/Lamivudine/Dolutegravir	34	12.1%	12	Efavirenz/Lamivudine/Tenofovir	5	1.8%
2	Imatinib Mesylate	27	9.6%	13	Isoniazid Bp	4	1.4%
3	Sacubitril/Valsartan	24	8.5%	14	Amoxicillin Trihydrate/Potassium Clavulanate	4	1.4%
4	Sulphamethoxazole/Trimethoprim	19	6.8%	15	Glibenclamide	4	1.4%
5	Dolutegravir Sodium	16	5.7%	16	Levofloxacin	3	1.1%

6	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol	14	5.0%	17	Tenofovir/Lamivudine	3	1.1%
7	Rifapentin/Isoniazid	14	5.0%	18	Amlodipine Besilate	3	1.1%
8	Ranibizumab	12	4.3%	19	Paracetamol	3	1.1%
9	Nevirapine	9	3.2%	20	Isoniazid/Rifapentine	3	1.1%
10	Tenofovir Disoproxil Fumarate	7	2.5%				
11	Voxelotor	5	1.8%				

A total of 20 Generic names were reported as suspected medicines in a atleast 3 SADR reports and above in these quarter. Tenofovir/Lamivudine/Dolutegravir was the most reported suspected generic name among SADRs in this quarter with 34 reports (12.1%). Other most reported generic names were Imatinib Mesylate with 27 reports (9.6%), Sacubitril/Valsartan with 24 reports (8.5%), Sulphamethoxazole/Trimethoprim with 19 reports (6.8%) and Dolutegravir Sodium with 16 reports (5.7%). Above is a list of 20 most reported generic names. 4 reports did not indicate the generic name.





Of the total reports received in Q2, 26.3% (74) reported that a re-challenge was done while 6.8% (19) reported that a re-challenge was not done. 29.9% (84) of the reports did not indicate if a re-challenge was done or not.

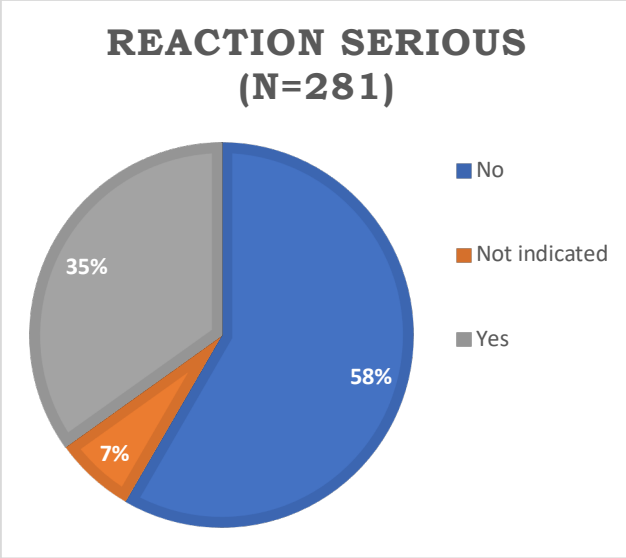
Of the total reports received in Q2, 7.8% (22) were classified as severe while 4.6% (13) were classified as fatal. 22.8% (64) of the reports did not indicate severity. Most of the reports (42%, 118) were graded as being of moderate severity

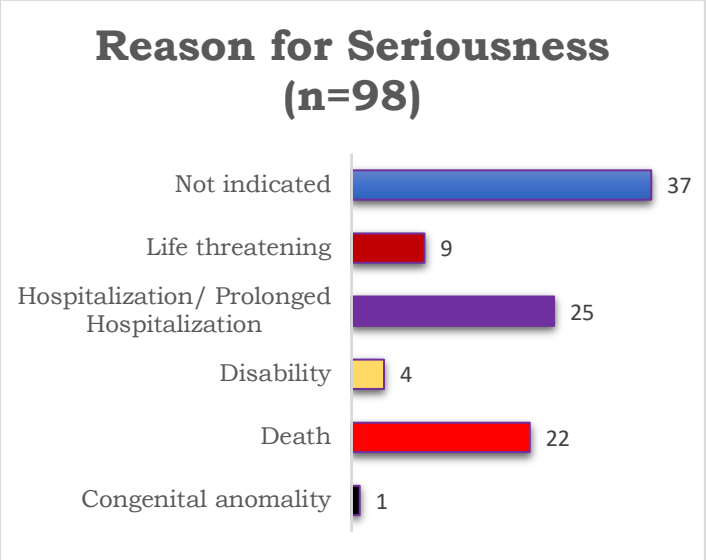
Reactions

Of the SADR reactions reported in this quarter, body itchiness was the most reported with 34 reports (6.9%). Other most reported reactions Headache with 28 reports (5.7%), Body rash with 19 reports (3.9%), Body weakness with 17 reports (3.5%), Skin rash and Joint pains with 15 reports (3.0%) each. The top 25 reported SADR reactions are listed below

No	Reaction	No of Reports	Proportion (%)	No	Reaction	No of Reports	Proportion (%)
1	Body itchiness	34	6.9%	14	Palpitations	7	1.4%
2	Headache	28	5.7%	15	Ocular hypertension	6	1.2%
3	Body rash	19	3.9%	16	Diarrhoea	6	1.2%
4	Body weakness	17	3.5%	17	Dizziness	6	1.2%

5	Skin rash	15	3.0%	18	Eye pain	6	1.2%
6	Joint pains	15	3.0%	19	Fever	6	1.2%
7	Nausea	14	2.8%	20	Oedema	5	1.0%
8	Fatigue	11	2.2%	21	Sweating	5	1.0%
9	Vomiting	10	2.0%	22	Insomnia	4	0.8%
10	Eye redness	9	1.8%	23	Photophobia	4	0.8%
11	Body swelling	8	1.6%	24	Lip swelling	4	0.8%
12	Skin itchness	8	1.6%	25	Weight gain	4	0.8%
13	Cough	7	1.4%	26	Hyperbilirubinemia	4	0.8%



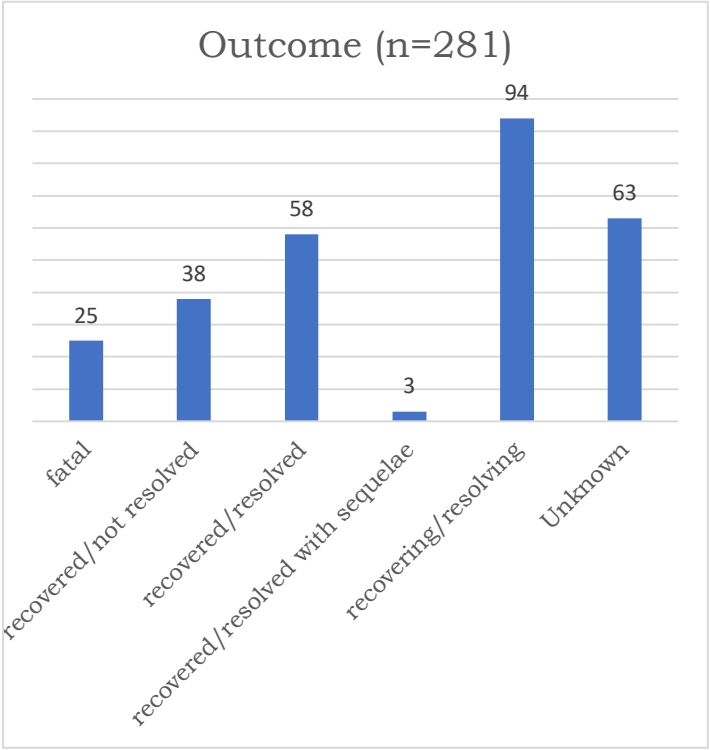


Of the 281 reports received in Q1, 35% (98) were classified as serious while 7% of the reports (19) did not indicate if the reaction was serious or not.

Out of the serious reactions reported, hospitalization/ prolonged hospitalization 25.5% (25) was the major reason for seriousness. 37 (37.8%) out of the 98 serious reactions reported did not indicate the reason for seriousness. A total of 22 reports (22.4% of 98 serious reactions) intimated death as the reason for seriousness

Actions taken

S/No	Row Labels	Count	Proportion (%)
1	Drug withdrawn	148	52.67%
2	Dose not changed	76	27.05%
3	Not applicable	30	10.68%
4	Unknown	21	7.47%
5	Dose reduced	4	1.42%
6	Dose increased	2	0.71%
	Grand Total	**281**	



Actions taken by the health care workers included; withdrawal of the offending drug 52.67% (148), dose reduction 4 (1.42%) and dose increase 2 (0.71%). A total of 76 reports (27.05%) indicated that the dose of the suspect medicine was not changed.

Out of the SADRs reported in Q1, 8.9% (25) were fatal and 20.1% (58) had recovered without complications whereas 3 patients (1.1% recovered with sequelae. 22.4% (63) of the reports indicated the outcome as unknown.

No	Diagnosis	Count	Proportion (%)
1	HIV/AIDS	69	24.56%
2	Cardiac Failure	23	8.19%
3	CML	17	6.05%
4	Tuberculosis	15	5.34%
5	TB Prophylaxis	13	4.63%
6	Hypertension	11	3.91%
7	URTI	8	2.85%
8	Sickle Cell Disease	7	2.49%
9	HIV/Tuberculosis	6	2.14%
10	GIST	5	1.78%
11	MDR Tuberculosis	3	1.07%
12	Type 2 DM	3	1.07%
13	Pneumonia	3	1.07%

Diagnosis

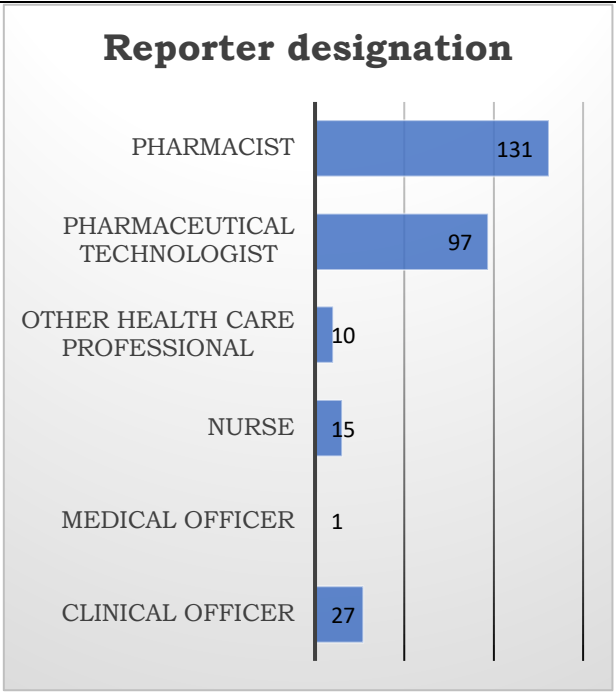
The incidence of SADRs in this quarter was highest among patients with HIV/AIDS with 69 reports (24.6%), followed by cardiac failure 23(8.19%), chronic myeloid leukaemia 17(6.1%) and TB 15(5.3%), TB Prophylaxis 13(4.63%), Hypertension 11(3.91%). A total of 35 reports (12.5%) did not indicate the diagnosis. A list of top top 13 diagnoses with atleast 3 and above reports is shown above

Reporter designation

Institution

In this 2nd Quarter, only 89 facilities out of the 9,000 facilities listed in the Kenya Master facility reported SADRs. 16 facilities reported at least 5 reports and above. The top leading facilities were Novartis Kenya with 70 reports (24.9%) followed by The Mater Hospital Mukuru with 16 reports (5.7%) and Bokole CDF Dispensary with 10 reports (3.6%). Below is a list of top 16 facilities

No	Institution	Count	Proportion
1	Novartis Kenya	70	24.9%



Majority of the reports 46.6% (131) and 34.5% (97) were submitted by pharmacists and pharmaceutical technologists respectively while other Healthcare Professionals submitted 3.6% (10) reports. Clinical officers submitted 9.6% (27) of the total reports

2	The Mater Hospital Mukuru	16	5.7%
3	Bokole CDF Dispensary	10	3.6%
4	Kiambu District Hospital	9	3.2%
5	Ministry of Health	7	2.5%
6	IQVIA	7	2.5%
7	Kenyatta National Hospital	7	2.5%
8	Gatundu District Hospital	6	2.1%
9	Oresi Health Centre	6	2.1%
10	Sigomere Health Centre	6	2.1%
11	Thika Level 5 Hospital	6	2.1%
12	Dreams Center Dispensary (Lang'ata)	5	1.8%
13	Makadara Health Centre	5	1.8%
14	Magongo (MCM) Dispensary	5	1.8%
15	Nyanza Provincial General Hospital (PGH)	5	1.8%
16	Kisumu District Hospital	5	1.8%

County

SADRs reports were received from 29 of the 47 counties. Nairobi county submitted the highest number of SADR reports (114, 40.6%) followed by Kiambu (29, 10.3%), Mombasa (25, 8.9%), Kisumu (16, 5.7%) and Kirinyaga (14, 5.0%). 9 counties submitted one SADR report in these quarter. Below is a table of the counties that submitted SADR reports in quarter 2.

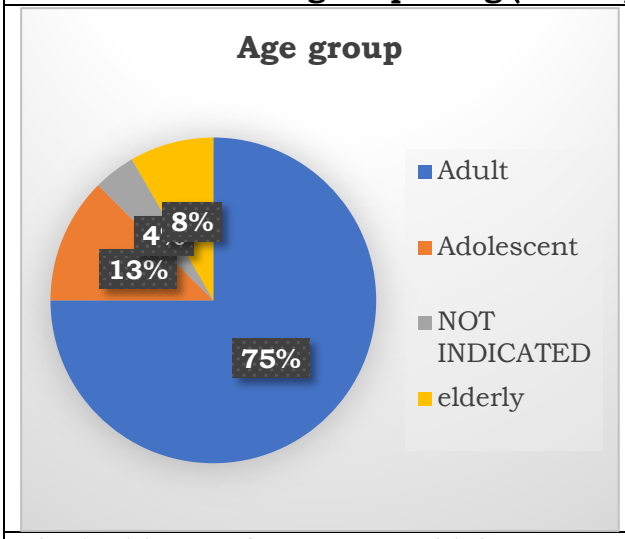
No	County	Count	Proportion	No	County	Count	Proportion
1	Nairobi	114	40.6%	16	Vihiga	2	0.7%
2	Kiambu	29	10.3%	17	Kajiado	2	0.7%
3	Mombasa	25	8.9%	18	Tharaka Nithi	2	0.7%
4	Kisumu	16	5.7%	19	Migori	2	0.7%
5	Kirinyaga	14	5.0%	20	Nakuru	2	0.7%
6	Siaya	12	4.3%	21	Trans Nzoia	1	0.4%
7	Kakamega	10	3.6%	22	Baringo	1	0.4%
8	Kisii	9	3.2%	23	Kilifi	1	0.4%
9	Embu	8	2.8%	24	Marsabit	1	0.4%
10	Machakos	7	2.5%	25	Kericho	1	0.4%
11	Makueni	6	2.1%	26	Nandi	1	0.4%
12	Busia	3	1.1%	27	Meru	1	0.4%
13	Nyandarua	3	1.1%	28	Nyamira	1	0.4%
14	Bung'oma	3	1.1%	29	Mandera	1	0.4%
15	Murang'a	3	1.1%				

Medical Device Incidences

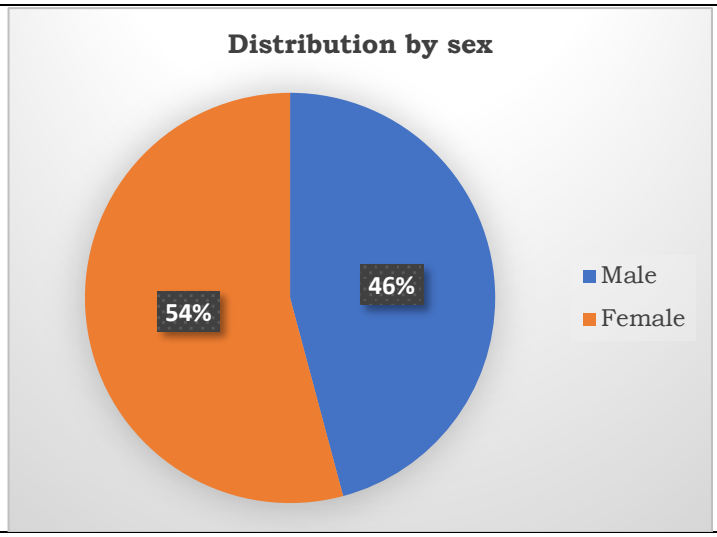
A total of 4 medical device incidences were reported in the 2nd Quarter. Two (2) of these reports were submitted in Nairobi County while Kisumu and Kitui County each submitted one medical device incidence report. Of the 4 incidences, 3 occurred in males and 3 reports indicated that the problem had been noted prior.

In all the 4 incidences, the devices were handled by healthcare professionals and were reported by Pharmaceutical Technologists (2 incidences), a pharmacist (1 incidence) and a Nurse (1 incidence). Two reports indicated event classification as unknown while the other 2 reports indicated fatal and mild, respectively, as the event classification. None of the reports indicated the reason for seriousness. Two reports indicated outcome as recovered and recovering respectively while 2 others indicated unknown as the outcome.
Cellulitis and abscess formation were reported with the implant while inability to define the dosage, inability to draw, and easy breakability were reported with one of the medical devices.

Public Adverse Drugs Reporting (PADRs)



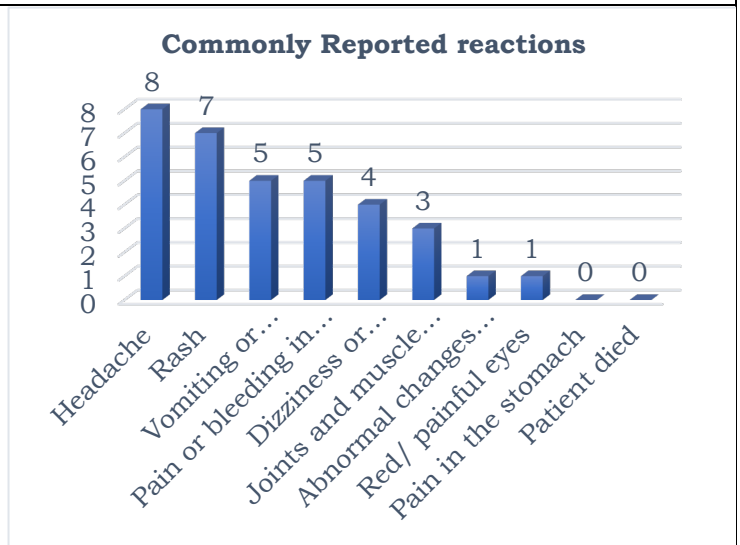
The incidence of PADRs was highest amongst the adult age group 75% (18) in comparison to the others. 4% (1) of the total reports did not have age indicated



The frequency of reported PADRs was higher in female 54% (13) compared to male 46%(11).

Medicines	Number reported	%
Not Iindicated	14	58.33%
Unknown	1	4.17%
TLD	3	12.50%
DTG 50MG	1	4.17%
Cycloserine	1	4.17%
Sabtracin Inj	1	4.17%
Dolutegravir	1	4.17%
RHZE	1	4.17%
Levofloxacin	1	4.17%
TOTAL	**24**	**100%**

The most commonly reported suspected medicine causing adverse reactions was



Most commonly reported PADR reactions were Headache, Rash, Vomiting or Diarrhea , Pain or

TLD(Tenofovir;Lamivudine;Dolutegravir) 12.5% (3) It is also important to note that 58.33% (14) of the reports did not have suspected medicine indicated, making these reports invalid.

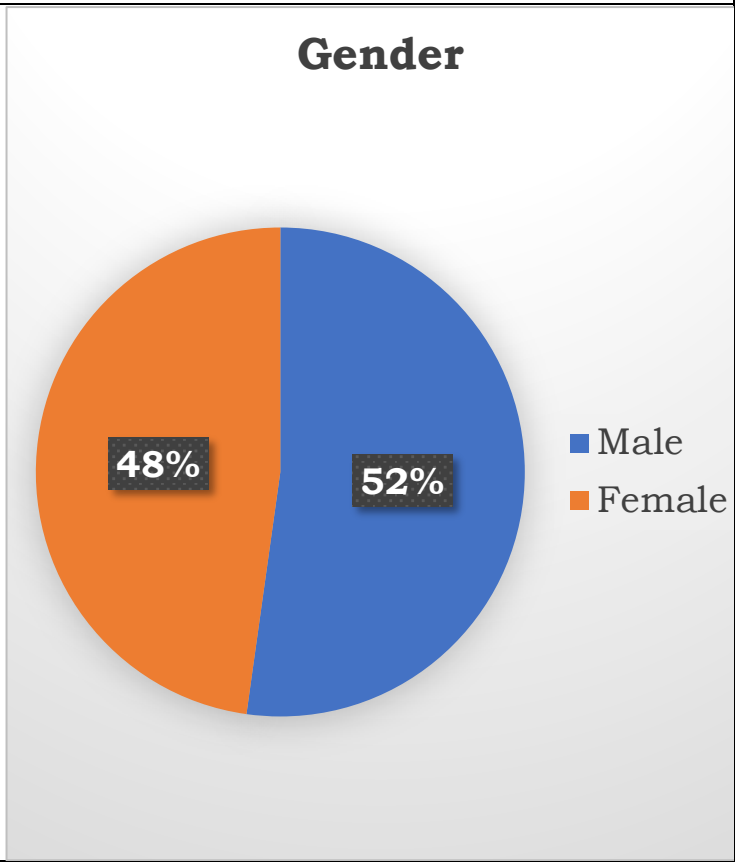
bleeding in the mouth ,Dizziness or Drowsiness and Joint and muscle Pain.
There were no incidences of patient death reported

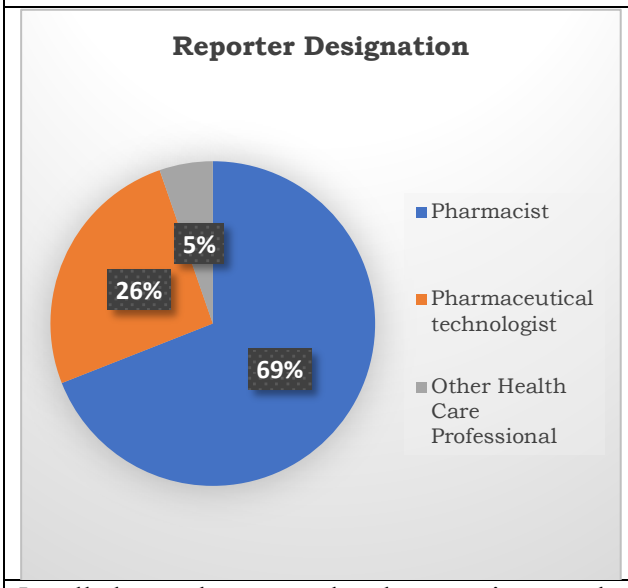
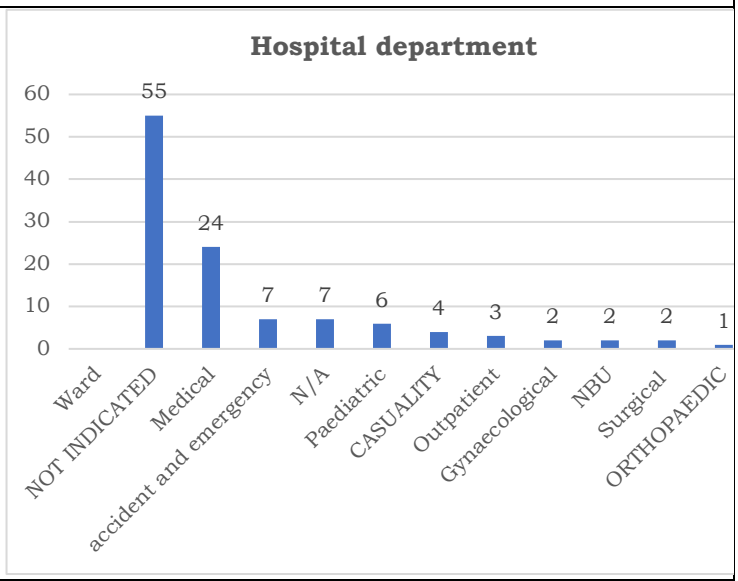
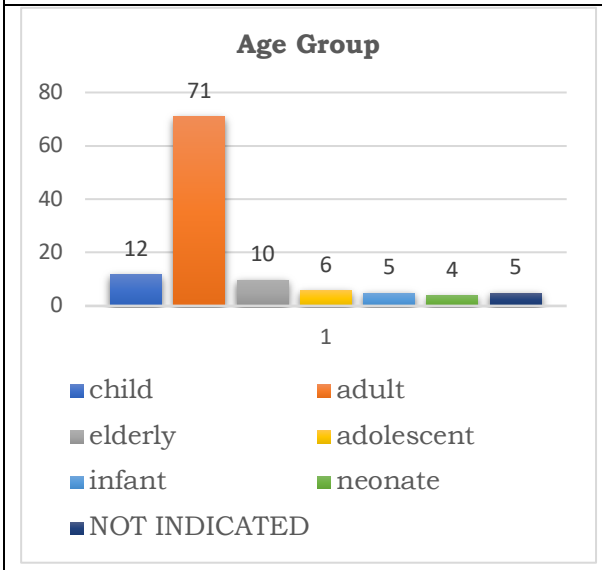
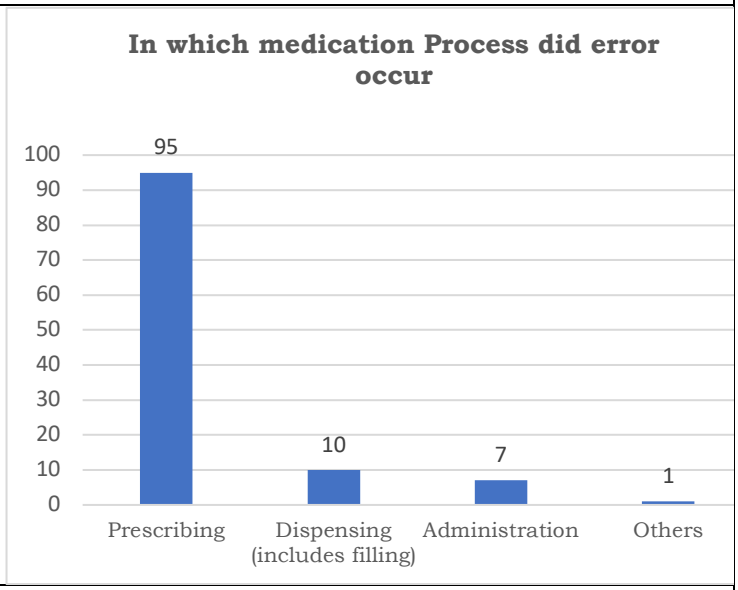
County	Number of reports
Meru	3
Mombasa	3
Kiambu	2
Nairobi County	2
Laikipia	2
Nyeri	2
Bomet	1
Kakamega	1
Bung'oma	1
Vihiga	1
Siaya	1
Kisumu	1
Garissa	1
Kitui	1
Makueni	1
Turkana	1
TOTAL	**24**

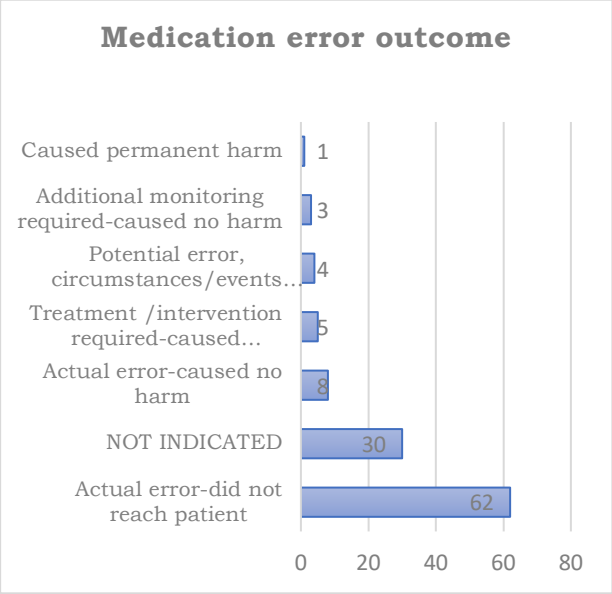
Additionally, PADR reports were received from 24 of the 47 counties. Meru and Mombasa County submitted the highest number of PADR reports (3) followed by Kiambu, Nairobi County, Laikipia and Nyeri County each having two reports.
The other reporting counties had only 1 report and they include; Bomet , Kakamega , Bung'oma , Vihiga , Siaya , Kisumu , Garissa , Kitui , Makueni and Turkana .

Medication Errors (MEs)

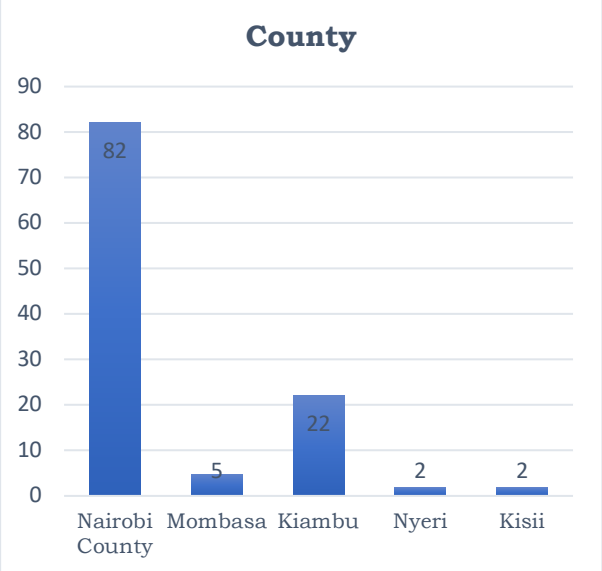
Institution	No.of Reports
Kenyatta National Hospital	80
Kiambu District Hospital	14
Thika Level 5 Hospital	5
Miritini CDF Dispensary	2
Nyeri Provincial General Hospital (PGH)	2
Port Reitz District Hospital	2
Kisii teaching & referral hospital	2
Tudor District Hospital (Mombasa)	1
Tigoni District Hospital	1
Special Treatment Clinic	1
Penda Health	1
Kiambu level 5 hospital	1
Karuri Health Centre	1
TOTAL	**113**



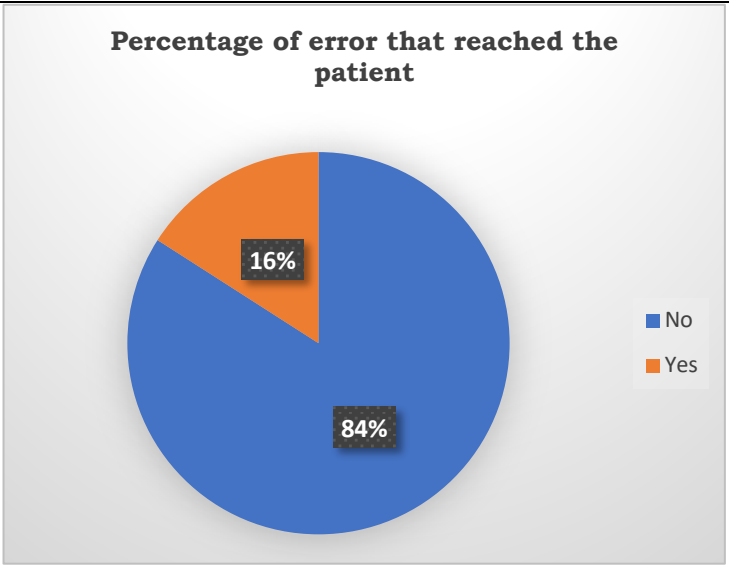
Of the 113 Medication error reports received, Kenyatta national hospital submitted the highest number of reports (80), followed by Kiambu District Hospital with 14 reports	In this quarter ,male patients 52% (59) were more affected in comparison to female patients 48% (54).
	
In all the cadres,mostly pharmacists and pharmaceutical technologists submitted reports. With most of the reports being received from pharmacists at 69%(78)	Most of the medication errors reported in the hospital ward occurred in the medical ward with 24 reports, followed by Accident and Emergency ward (7) ,then Pediatric ward (6) . 55 reports did not have location of event indicated.
	
The incidences of medication errors was highest amongst the adult age group at 62.8% (71) and Children 10.62% (12) in comparison to the others.	Most of the medication errors occurred during the prescribing process (95). The least of the errors occurred during administration(7).



Most of the medication errors did not reach the patient (62) and for medication errors that actually reached the patient ,they did not cause actual harm to the patient (8) .30 reports did not indicate the outcome of the medication error .



Most of the reports submitted were from Nairobi County 72.57% (82), followed by Kiambu County at 19.47% (22) and the least received was from Kisii and Nyeri whose contribution was 1.77% (2) respectively.



84% (95) of the reports indicated that the medication errors committed did not reach the patient. These are termed as near misses.

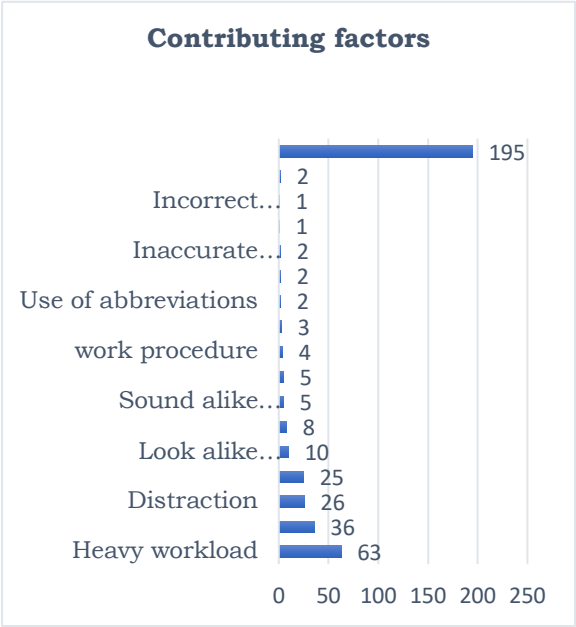
Clinic	Number of reports
Not indicated	52
Outpatient	30
Paediatric	5
Casuality outpatient	4
EMTCT clinic	3
Inpatient	3
staff clinic	2
SOPC	2
COC	2
Comprehensive care centre	2
Cardiology	1
MOPC	1

Additionally most of the medication errors occurred in the outpatient clinic, which reported 30 occurences, followed by Paediatric clinic with 5 occurences .52 reports did not indicate where the medication error occurred.

NCD	1
Diabetic	1
Orthopaedics	1

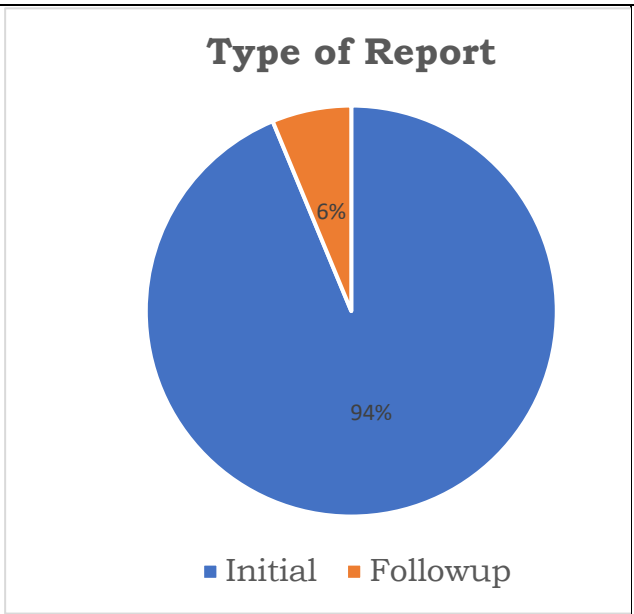
Description of error	**Number of reports**
Prescribed overdose	36
Prescribed wrong drug	13
Dispensed wrong drug	7
Prescribed wrong dose	8
Prescribed contraindicated drug	7
Error Not clearly explained	4
Prescribed with no dosage information	4
Prescribed underdose	3
Prescribed with wrong frequency of administration	5
Prescribed without duration of use	6
Dispensed overdose	3
Prescribed with wrong duration	2
Prescribed wrong route of administration	2
Prescribed with no duration of use	2
Administered underdose	1
Administered wrong drug	1
Dispensed drug without dosage and frequency	1
Dispensed Underdose	1
Dispensed wrong drug	1
Prescribed with no dosage and route information	1
Prescribed with no route	1
Prescribed without biodata information	1
Prescribed without dosage and frequency	1
Prescribed wrong route	1
Prescribed wrong strength	1
Prescribed without strength	1

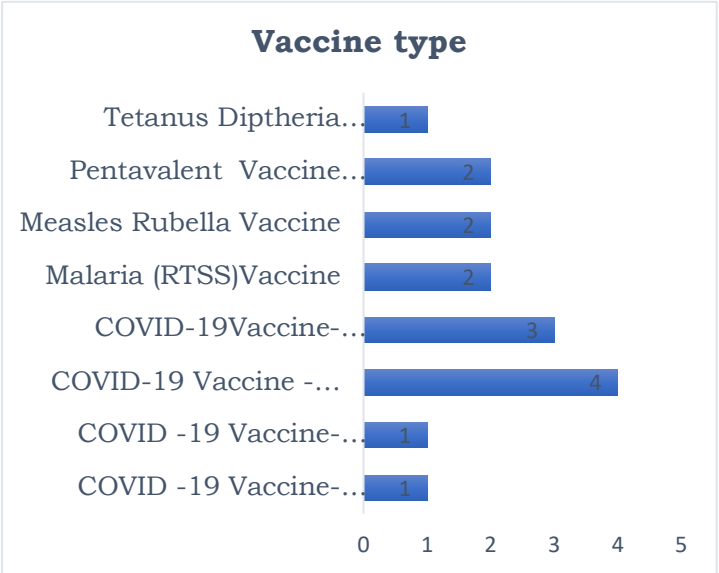
Of the reports received, the most frequent errors were prescription errors of overdosing that had 36 reports, followed by Prescriptions that had the wrong drug which constituted 13 reports.4 medication errors were not clearly explained by the reporter.



In this quarter ,heavy workload (63) , Peak hours (36) distractions (26), inadequate knowledge (25), and Look alike medications (11) were reported to be amongst the highest contributors to medication errors

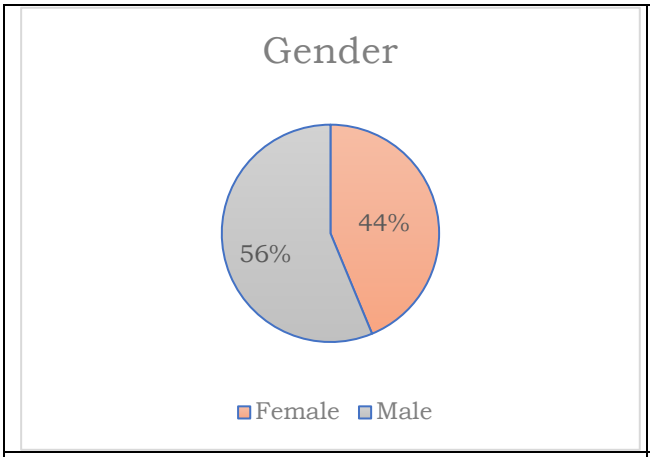
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIs)



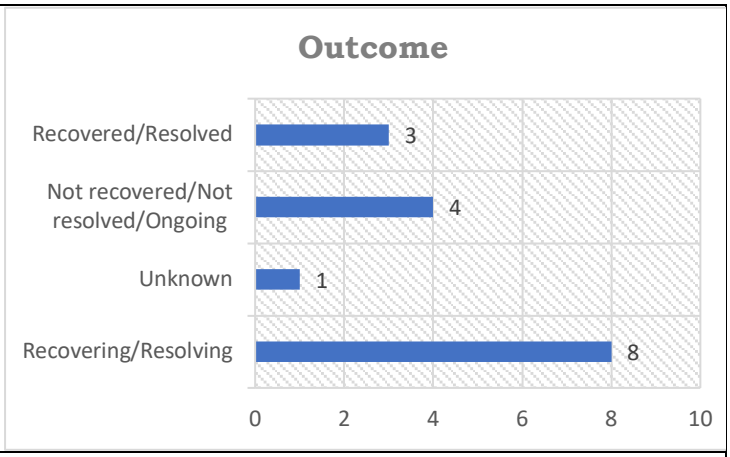


94% (16) of the reports received in this quarter were initial reports with only 6% (1) of the total being follow-up reports.

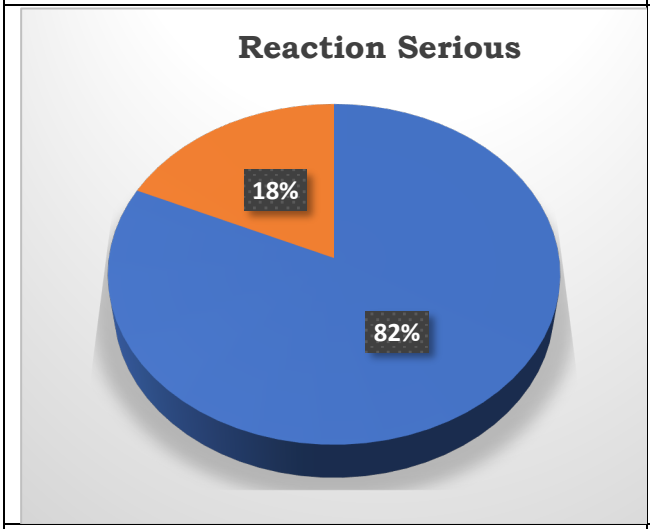
Of the AEFI reports received most events were caused by Covid-19 vaccines (9). The highest number of reports suspected the vaccine from Johnson and Johnson at 25% (4) followed by Covishield at 18.75% (3) with the least reports received from the Moderna, Pfizer and the tetanus vaccine at 6.25% (1).



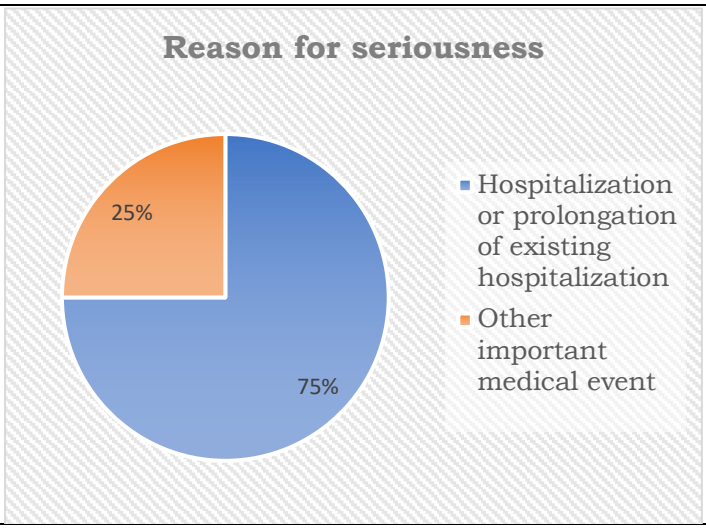
Of the total AEFI reports received in this quarter, it was noted that males were affected 56% (9) more than females 44% (7).



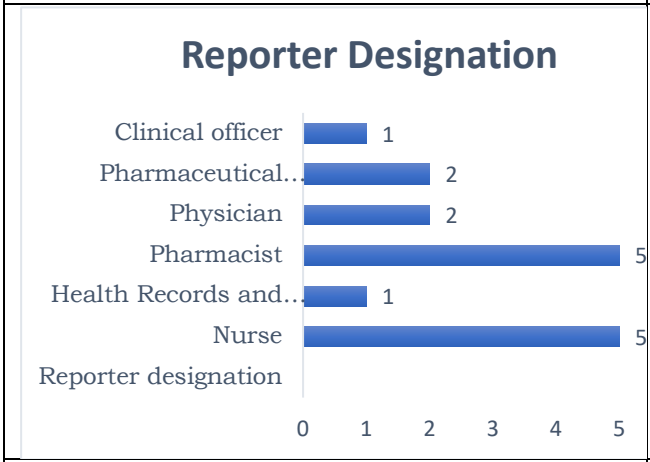
50% of the AEFI outcome cases were either recovering/resolving with (8) reports. 25% of the reported cases (4) were noted to not have not recovered with 18.75% (3) of the outcomes reported as recovered and resolved. Only 1 report was received whose outcome was unknown.



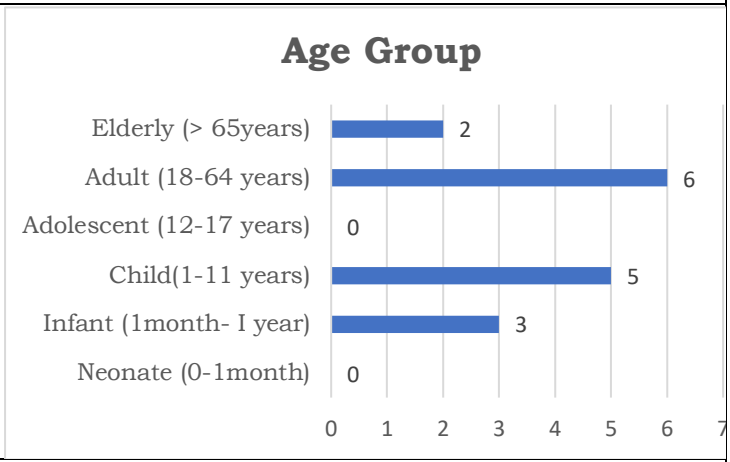
Majority of the AEFI reports 82% (12) received in this quarter were reported as not serious, with only 18% (4) reported as serious.



Of the AEFI reports noted to be serious 75% (3) were due to hospitalization or prolongation of existing hospitalization, and the remaining 25% (1) was because of a reported other important medical event.



Reporting of AEFIs remains of interest to pharmacists as 58.2 % (32) of the reports were submitted by that cadre. Pharmaceutical technologists submitted

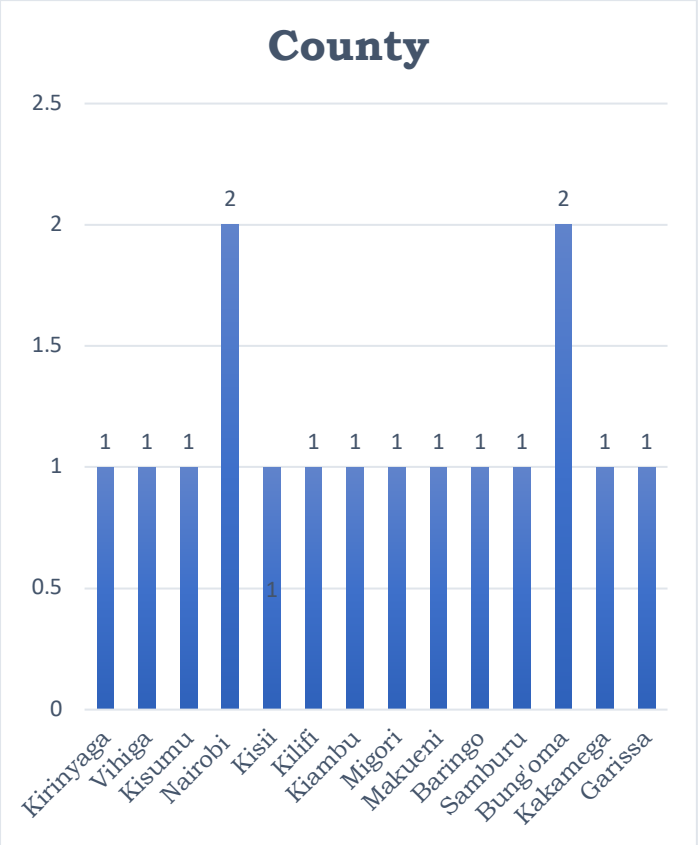


Majority of the AEFIs reported in this quarter affected the adult age group (6) and the child age group (5). The least affected age group in this quarter were the elderly with only (2) reports. No

7.27% (4) of the reports, while other health care professional contributed 34.5% (19) of the reports received. Majority of the reports (58.2%) were submitted by pharmacists.

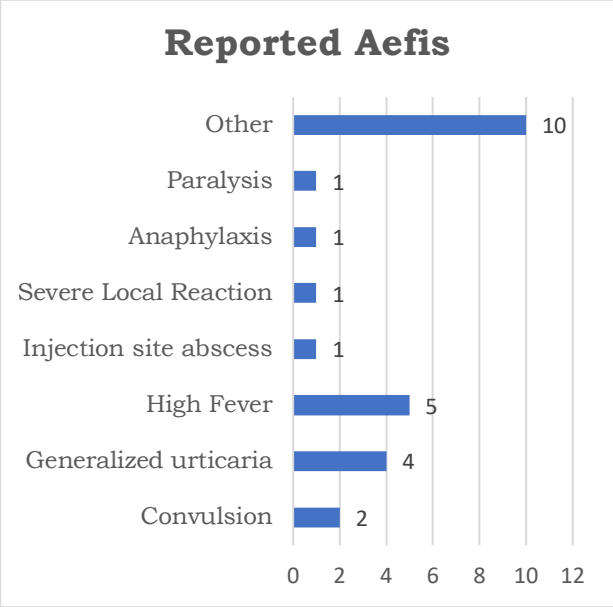
reports were received on the adolescent and neonate age group bracket.

Institution	Reports
Mwea Mission (Our Lady Of Lourdes) Hospital	
Vihiga Health Centre	
Kisumu central sub county	
Dandora II Health Centre	
KISII TEACHING & REFERRAL HOSPITAL	
Mtwapa Health Centre	
Jacaranda maternity	
St Camillus Mission Hospital	
Mwaani Dispensary	
Hulugho district baringo	
archers post subcounty hospital	
Webuye Hospital	
Kabula Dispensary	1
Lumakanda District Hospital	1
Garissa Provincial General Hospital (PGH)	1
Total	**16**



In this Quarter, only 15 facilities out of the 9,000 facilities listed in the Kenya Master facility reported AEFIs. The top leading facility was Dandora II Health center with 2 reports. The remaining facilities made 1 report each.

Additionally, AEFI reports were received from 14 of the 47 counties. Bungoma and Nairobi county submitted the highest number of AEFIs reports (2). The other reporting counties submitted 1 report including Kirinyaga, Vihiga, Kisumu, Kisii, Kiambu, Kilifi, Migori, Makueni, Baringo, Samburu, Kakamega and Garissa.



Specify	Reports
Buldging fontannel	1
Vomiting	2
Migrating Swollen & Painful Lymph Nodes	1
joint pain, dizziness	1
Severe bleeding	1
Severe LAP	1
Left Blocked ear, pain in left eye now blind and dizziness. Heavy heart, headache that is associated with pain pain on the neck, cough at night.andNumbness on the left leg	1
Cough,General Body Aches,Chills,Low Libido	1

Most of the events were captured as others 40% (10), followed by high fever at 20% (5) and Generalized urticaria 16% (4), there was no reported event of toxic shock syndrome.

The 40% of AEFIs reported as others was specified as indicated in the above table.

Blood Transfusion Reactions

This quarter received 1 blood transfusion reaction report.

Abbreviations: PPB = Pharmacy & Poisons Board; PV = Pharmacovigilance; sADR = suspected Adverse Drug Reaction; PQMP = Poor Quality Medicinal Product; PVERS = PV Electronic Reporting System, SOC = System Organ Classification

For any queries, please contact PV department on pv@pharmacyboardkenya.org or call ***0795743049.***

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*)