REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Pharmacovigilance Summary Report: 1st April to 30th June 2021/2022 (Q4)

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 510 adverse events reports were submitted to PPB. 210 of the total reports were of suspected adverse drug reactions (sADRs), 47 adverse events following immunizations (AEFI), 86 from members of the public (PADRs) and 165 were medication error reports, 1 on blood transfusion reaction and 1 report of incident following use of a medical device.

*Since the introduction of PV in Kenya, a total of **15,283** individual case safety reports has been submitted to the global data reports **32,760,345** (0.05%).*

Suspected Adverse Drug Reactions (SADRs)

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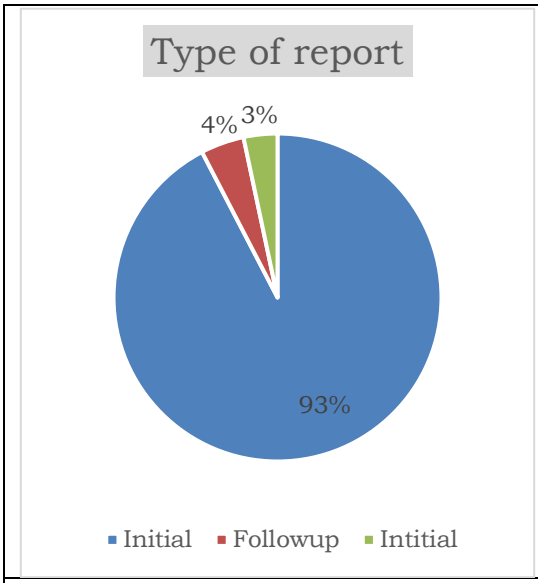
<td> 
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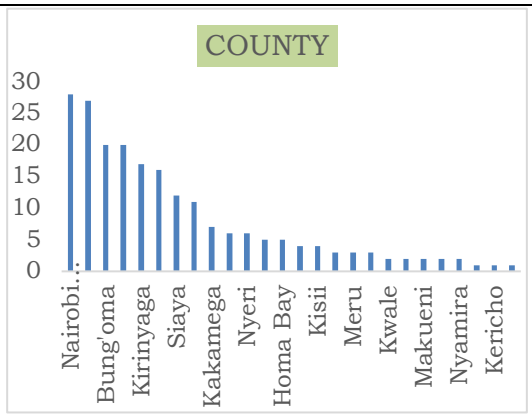
<td> 
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<td>Majority of the SADR reports in Q4 were initial (93%) while 3% of the reports were initial.</td>
<td>SADR reports were received from 26 of the 47 counties. Nairobi county submitted the highest number of SADR reports (28) followed by Kiambu (27), Bungoma and Migori (20) and Kirinyaga (17). Kericho, Kitui and Taita Taveta had one report</td>
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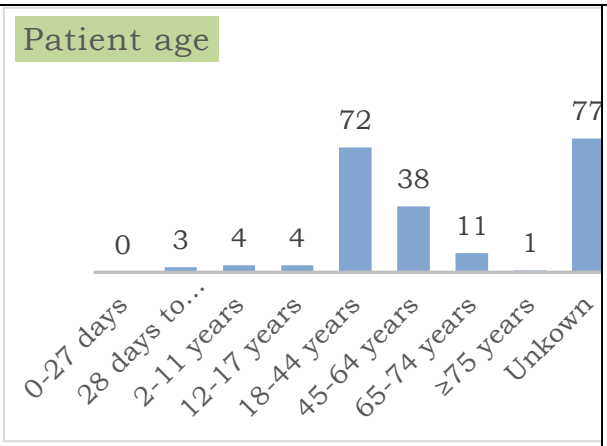
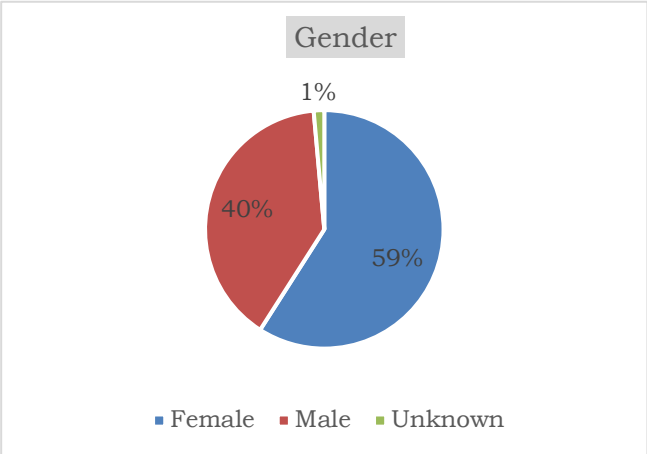
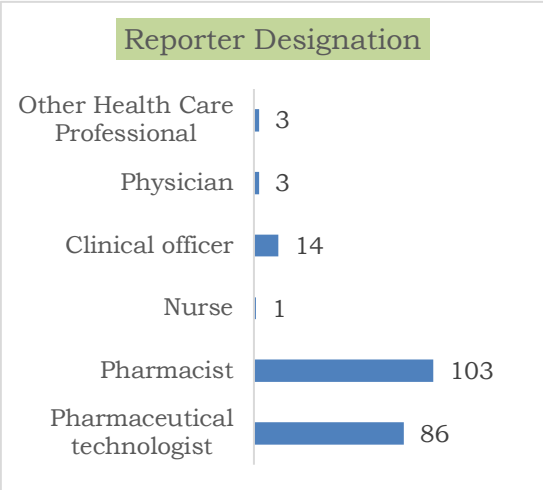


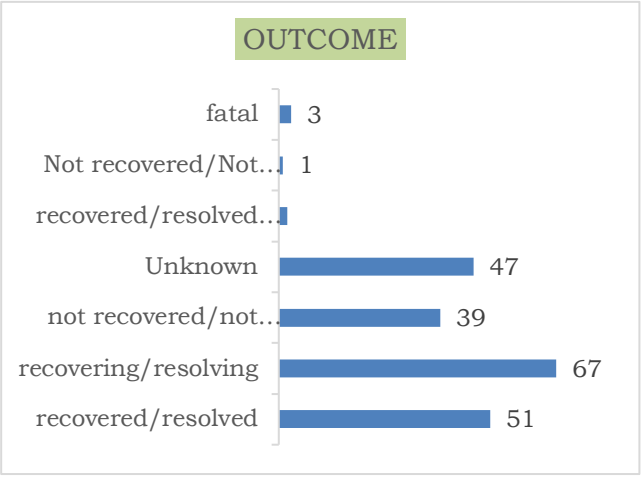
The highest incidence of SADRs was highest among the adult age group (18-44 and 45-64). 36.7% of the reports did not have age indicated.



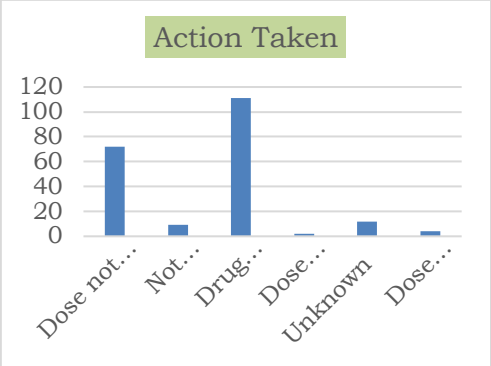
Most of the SADR events were reported among females (59%) while 40% were reported in Females (40%).



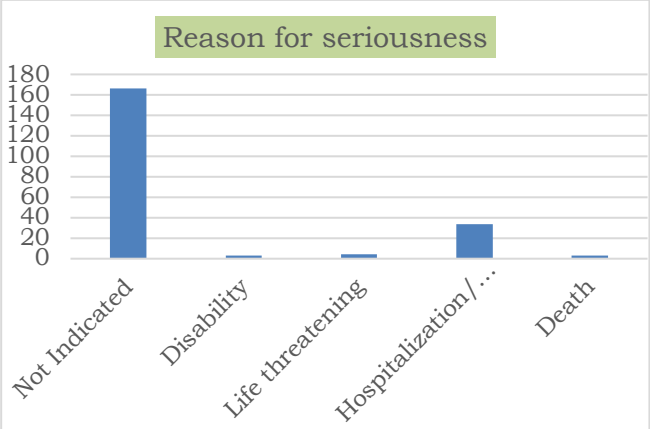
Majority of the reports were submitted by pharmacist and pharmaceutical technologists and only one report submitted by a nurse in this quarter



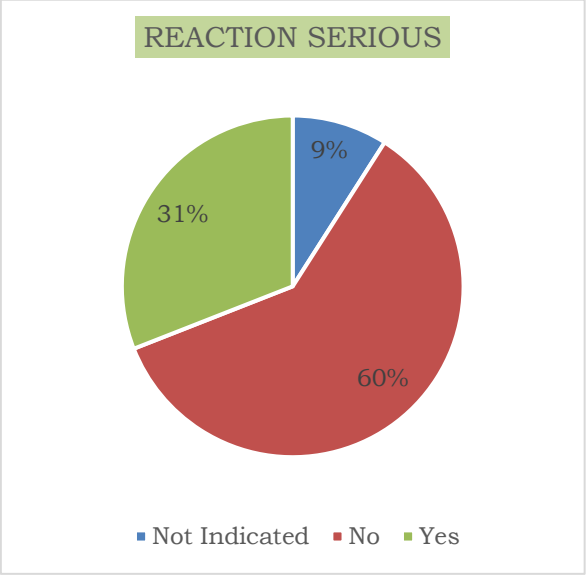
Majority of the events had either recovered/resolved or were recovering/resolving at the time of reporting.

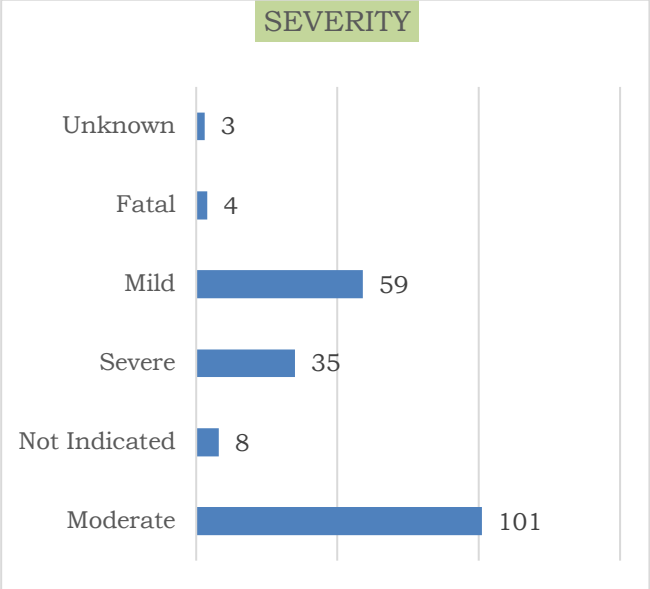


Action taken include withdrawal of the offending agent (52.86%), Dose reduction (1.9%). 34.29% did not change the dose.5.71% of the reporters did not indicate any action taken.



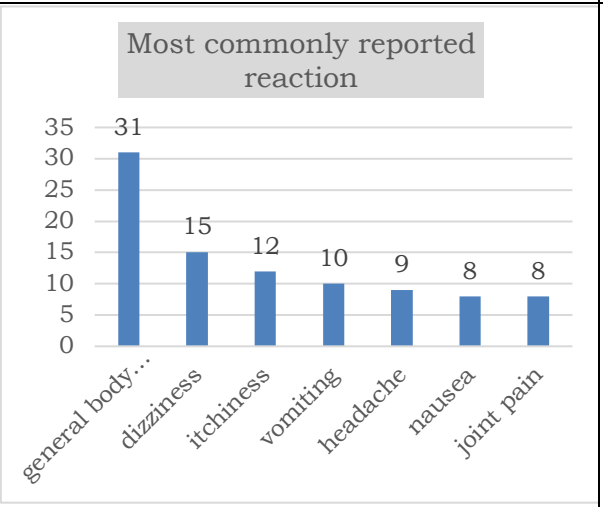
Out of the serious reactions reported, Hospitalization/Prolonged hospitalization was the major reason for seriousness. 79.05% of the reports did not indicate the reason for seriousness





31% of the reported reactions were serious while 60% of the applications were not serious.

On the incidence of severity, majority of the reports were moderate (48.10%) while 6.67% were severe



Institution	Frequency (n=210)	Proportion
Webuye Hospital	15	7.1
Kirinyaga county	11	5.2
St Camillus Mission Hospital	11	5.2
Machakos Level 5 Hospital	10	4.8
Aga Khan Hospital	10	4.8
Yala Sub-District Hospital	9	4.3
Kiambu District Hospital	8	3.8
Lodwar District Hospital	5	2.4
Gatundu District Hospital	5	2.4
Lumakanda District Hospital	5	2.4
Mikindani (MCM) Dispensary	5	2.4
SURGIPHARM LIMITED	5	2.4
Thika Level 5 Hospital	5	2.4
Nyeri Provincial General Hospital (PGH)	5	2.4

Most commonly reported SADRs were general body itching, dizziness, itchiness, vomiting, headache, nausea and joint pain

In this 4th Quarter, only 83 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs. 14 facilities reported at least 5 reports and above. The top leading facilities were Webuye Hospital with 15 reports (7.1%), followed by Kirinyaga County Hospital and St Camillus Mission Hospital at 11 reports each (5.2%). On the right is a list of top 14 facilities.

Medication Errors (MEs)

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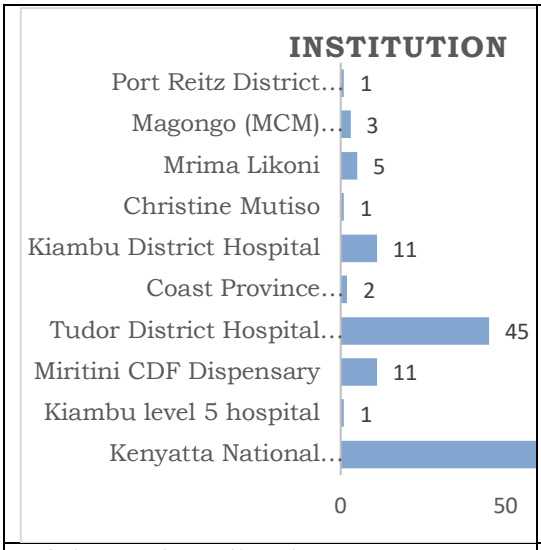
<td> 
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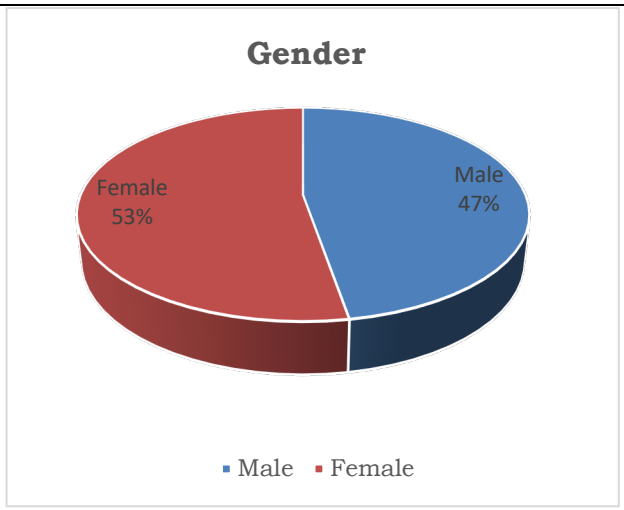
<td> 
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<td>Of the 165 Medication error reports received, Kenyatta national hospital submitted the highest number of reports (85), followed by Tudor District hospital (Mombasa) with 45.</td>
<td>In quarter 4, female patients (53%) were the more affected in comparison to male patients(47%).</td>
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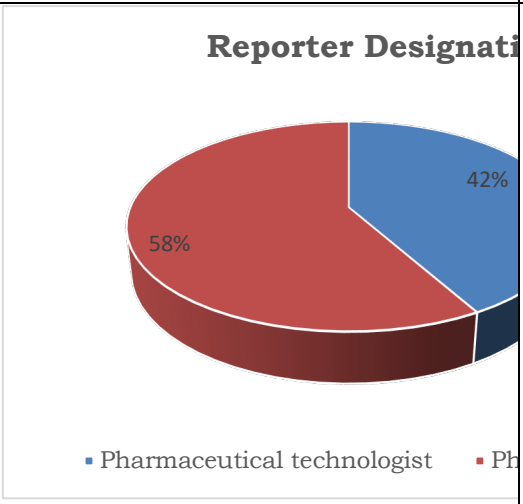
<td> 
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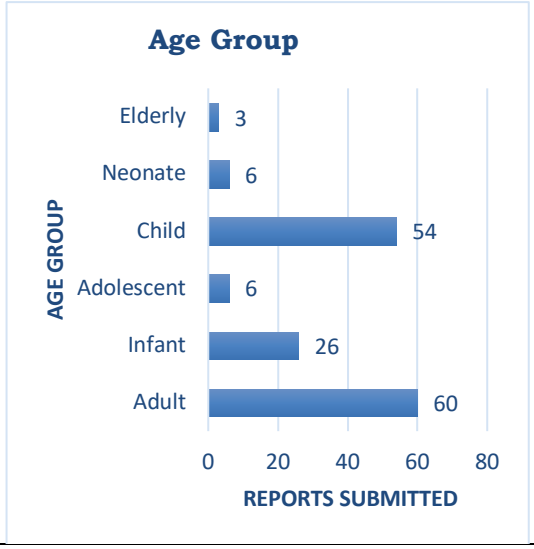
<td> 
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<td>From all the cadres only pharmacists and pharmaceutical technologists submitted reports. With most of the reports received from pharmacists at 58%.</td>
<td>The incidences of medication errors was highest amongst the adult age group at 39.31% and pediatric(34.83%) in comparison to the others.</td>
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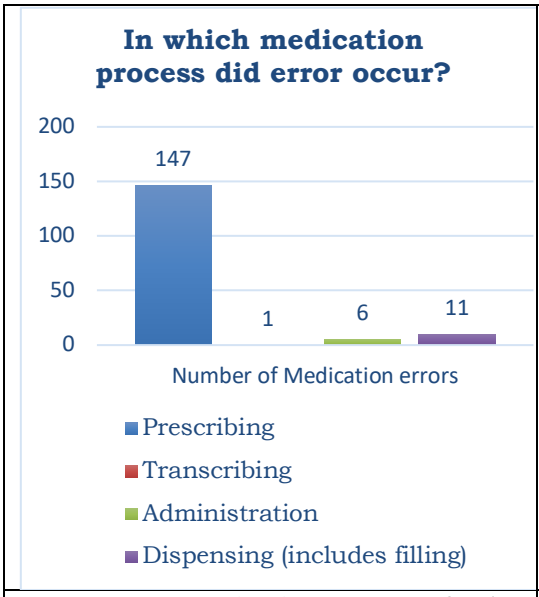
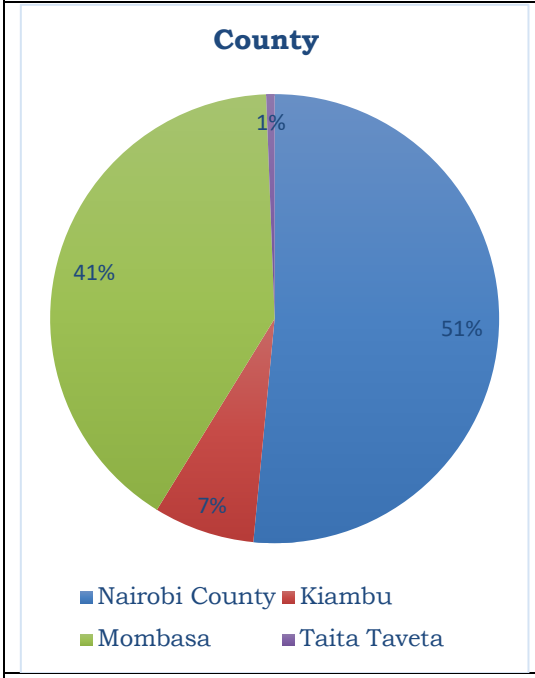
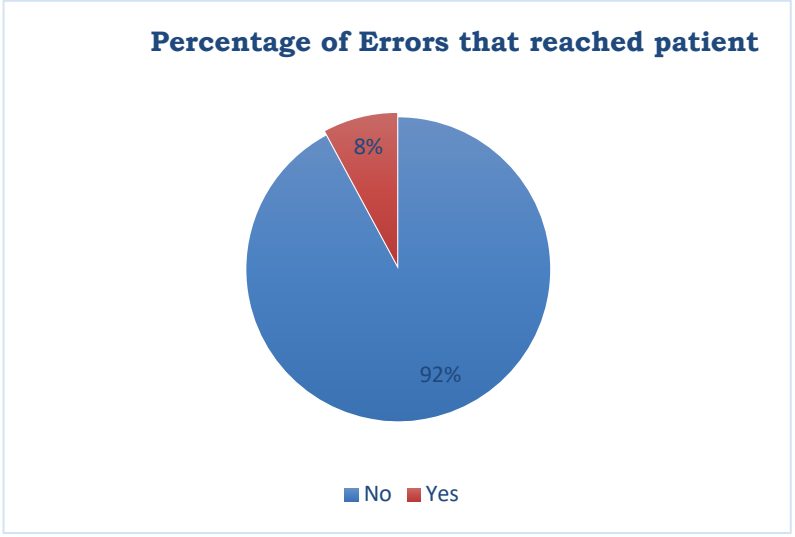


Medication Error Outcome	
Actual error-did not reach patient	1 3 4
Actual error-caused no harm	8
Initial/prolonged hospitalization-caused temporary harm	3
Potential error, circumstances/events have potential to cause incident	5
Treatment /intervention required-caused temporary harm	3

In Quarter 4(Q4), most of the medication errors occurred during the prescribing process, which had 147 reports indicating the same. The least of the errors occurred during transcribing

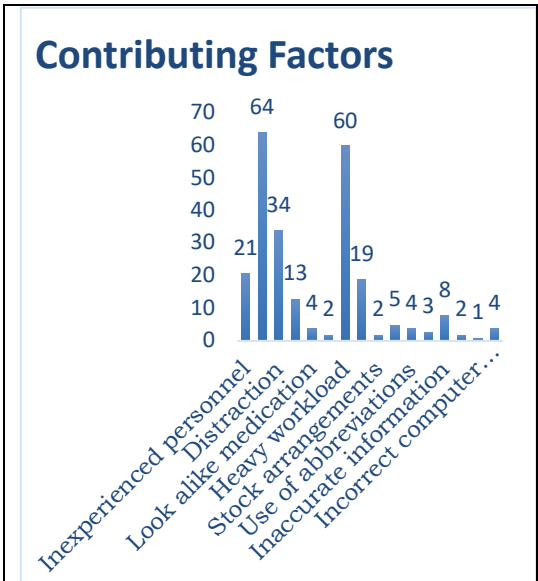
Of the medication errors that occurred,87.6% did not reach the patient and the 1.96% that reached the patient and caused temporary harm.



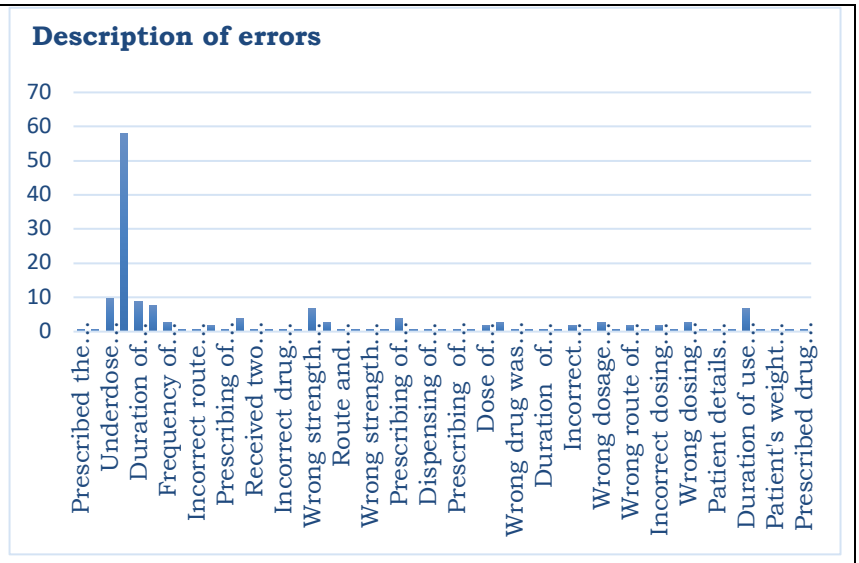


Most of the reports submitted were received from Nairobi County, which submitted the highest percentage (51%) followed by Mombasa County at 41% and the least received was From Taita Taveta whose contribution was 1%.

92% of the reports indicated that the medication errors committed did not reach the patient.

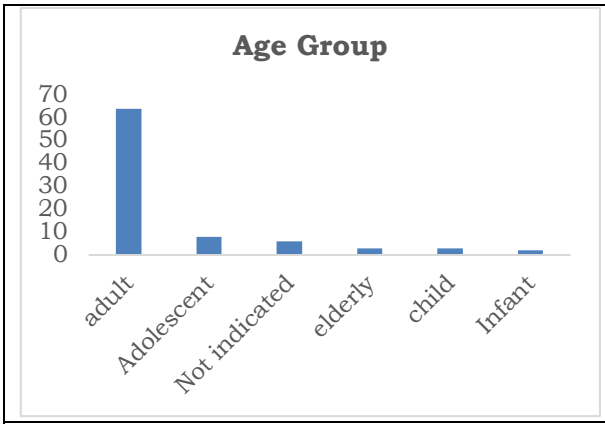


In quarter 4(Q4),inadequate knowledge, heavy workload and distaractions were reported to be amongst the highest contributors to medication errors.

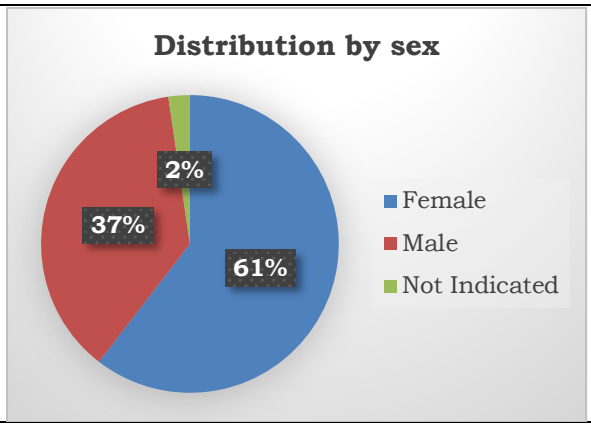


Of the reports received, the most frequently described errors were prescription errors that had incorrect duration of treatments indicated with 57 reports, followed by prescribing errors of overdosing with 42 reports.

Public Adverse Drug Reporting (PADRs)



The incidence of PADRs was highest amongst the adult age group (74.4%) in comparison to the others. 7% of the total reports did not have age indicated.



The frequency of reported PADRs was higher in female (61%) compared to male.

Suspected Medicines	Frequency (n=86)	Percentage(%)
Not indicated	39	45.3
Rifapentine& Iisoniazid 300/300 MG	19	22.1

Commonly Reported reactions	Frequency(n=86)	Percentage
Dizziness or drowsiness	28	18.2
Vomiting or diarrhea	27	17.5

Tenofovir Lamivudine Dolutegravir	4	4.7
Dynapar AQ INJ	3	3.5
CombiganbmoC	2	2.3
Astrazeneca	2	2.3
Zidovudine 300MG	2	2.3
Co-trimoxazole 960MG	1	1.2
Panadol; Haraka	1	1.2
Enalapril E	1	1.2
Cotrimoxazole	1	1.2
vaccine COVID	1	1.2
Megyl-400	1	1.2
Abacavir 120MG; dolutegravir 20MG	1	1.2
dolutegravir	1	1.2
ZolocanZ;	1	1.2
Saferon	1	1.2
dropsD3 Vitsol	1	1.2
lumefantrine Artemether	1	1.2
Cipladon	1	1.2
Nasal drops	1	1.2
AstraZeneca Booster	1	1.2
TOTAL REPORTS	86	100%

Headache	27	17.5
Pain in the stomach	21	13.6
Abnormal changes with urination	18	11.7
Rash	15	9.7
Joints and muscle pain	10	6.5
Pain or bleeding in the mouth	6	3.9
Red/ painful eyes	2	1.3
Patient died	0	0.0
TOTAL REPORTS	154	100%

The most commonly reported suspected medicines causing adverse reactions was Rifapentine and Isoniazid (22.1 %) and TLD (4.7%)

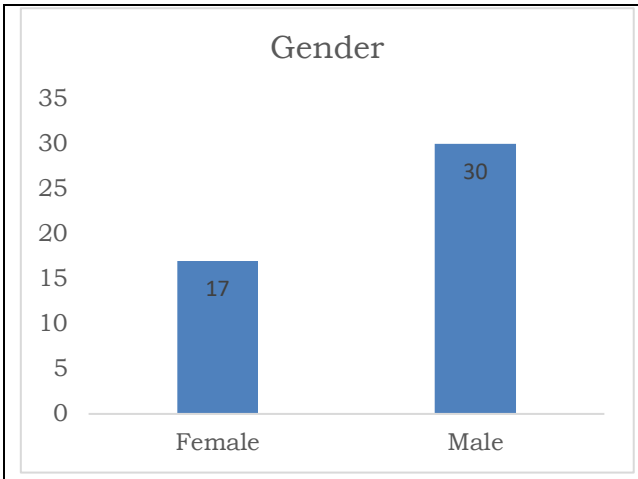
Most commonly reported PADR reactions were dizziness or drowsiness, Vomiting or diarrhea, Headache, Pain in the stomach, Abnormal changes with urination and rashes. There were no incidences of deaths due to adverse reactions reported

County	**count**	**Percentage**
Makueni	19	22.1
Nairobi County	17	19.8
Kiambu	5	5.8
Kajiado	4	4.7
Kisumu	4	4.7
Nakuru	4	4.7
Mombasa	3	3.5
Busia	3	3.5
Machakos	3	3.5
Bomet	2	2.3
Kilifi	2	2.3
Kakamega	2	2.3
Narok	2	2.3
Nyamira	2	2.3
Nandi	2	2.3
Kisii	2	2.3
Homa Bay	2	2.3

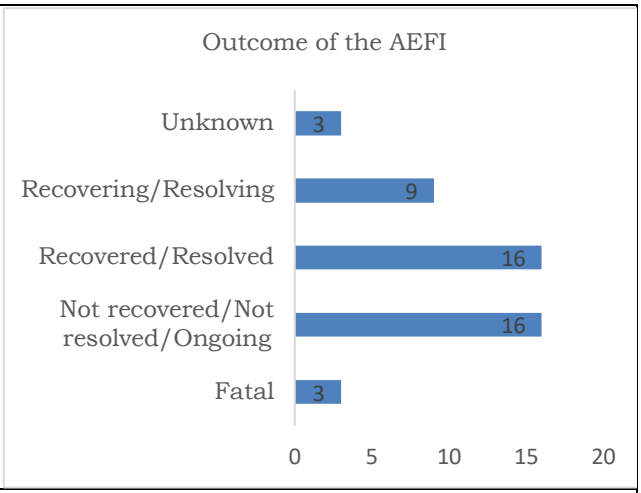
Additionally, PADR reports were received from 25 of the 47 counties. Makueni county submitted the highest number of PADR reports (19) followed by Nairobi (17), Kiambu (5), Kajiado and Machakos (4) reports each. The other reporting counties with less than 3 reports were Bomet, Kilifi, Kakamega, Narok, Nyamira, Nandi, Kisii, Homabay, Murang'a, Bungoma, Kitui,

Murang'a	1	1.2		
Bung'oma	1	1.2		
Baringo	1	1.2		
Vihiga	1	1.2		
Kitui	1	1.2		
Meru	1	1.2		
Siaya	1	1.2		
Embu	1	1.2		
TOTAL REPORTS	86	100%		

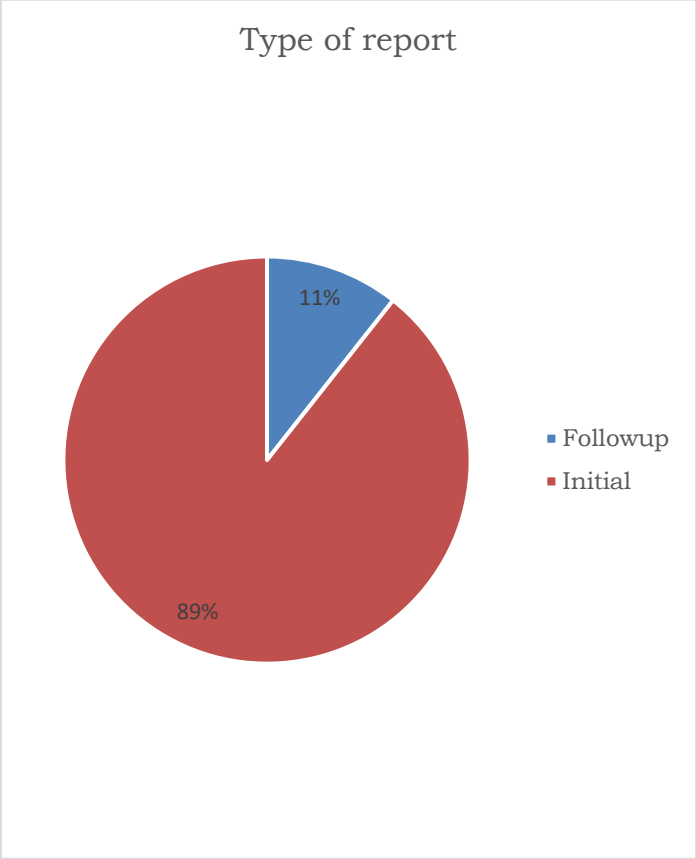
Adverse Events Following Immunizations (AEFIs)



Male was mostly affected by the AEFIs (63.8%) and females at (36.2%)



Half of the patients who suffered an event following immunization recovered or were recovering at the time of reporting (53.2%). In this quarter 4, there were 3 reported fatal cases.

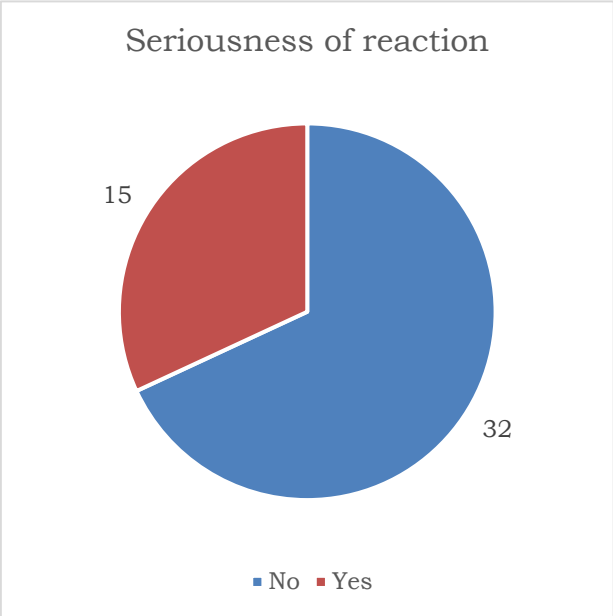


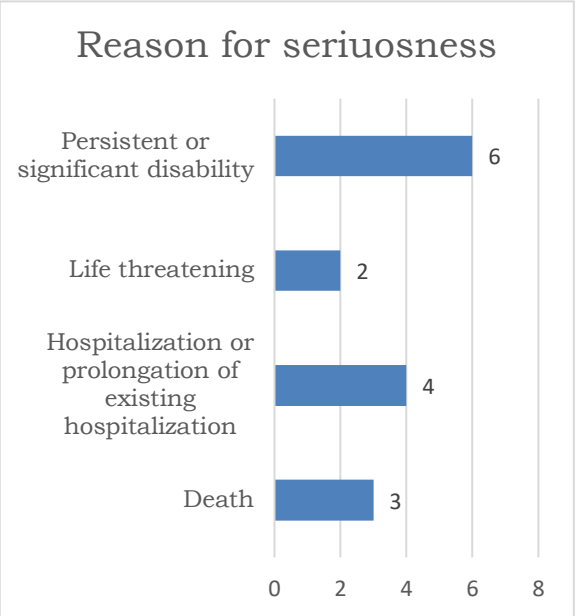
Vaccines types

BCG	1
Bivalent oral Polio vaccine; Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine	1
Covid -19 vaccine- AstraZeneca	7
Covid -19 vaccine- Moderna	4
Covid-19 vaccine - (Johnson & Johnsons) Janssen	11
COVID-19 Vaccine - PFIZER/BioNTech	13
Covid-19vaccine-covishield	2
Human Papilloma virus vaccine	2
Inactivated polio vaccine; Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Bivalent oral Polio vaccine	1
Malaria (RTSS)Vaccine	1
Measles Rubella Vaccine	1
Pentavalent Vaccine (DTP-HepB-Hib); Pneumococcal conjugate vaccine; Bivalent oral Polio vaccine	1
Not indicated	2
Total vaccines	**47**

89% of the reports received in Q4 were initial while 11% were follow-up reports

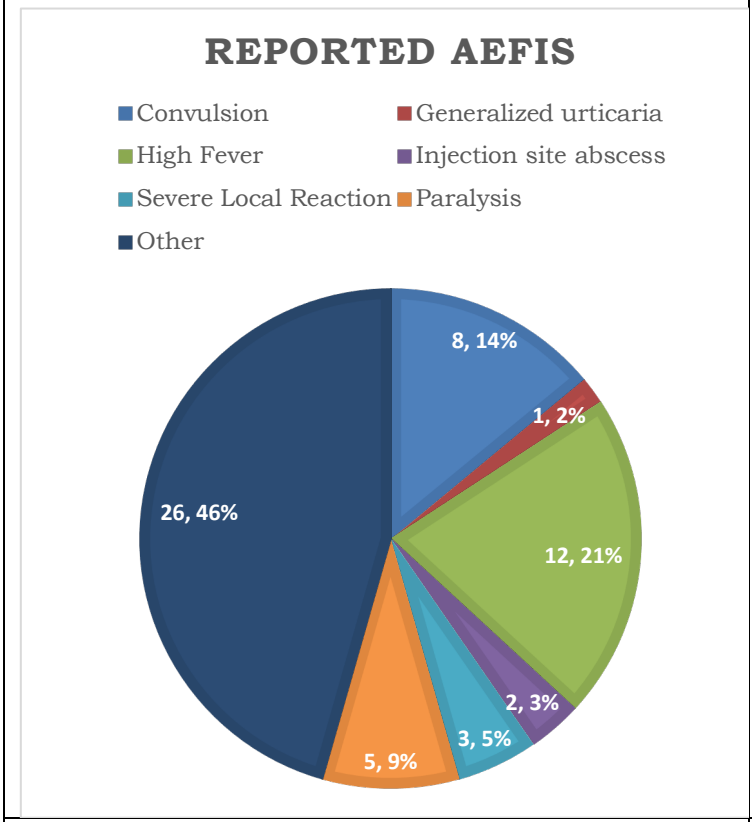
Most of the AEFIs reported were caused by Covid 19 vaccines. The highest reports were suspected to be caused by Pfizer (27.6%) followed by J & J vaccines at (23.4%) then AstraZeneca (14.9%) and Moderna (8.5%) respectively.





Majority of the reported events were not serious (68.1%).

Those that reported to be serious, 40% was due to persistent or significant disability, 26.7% caused hospitalization or prolonged hospitalization and 20% was due to death.



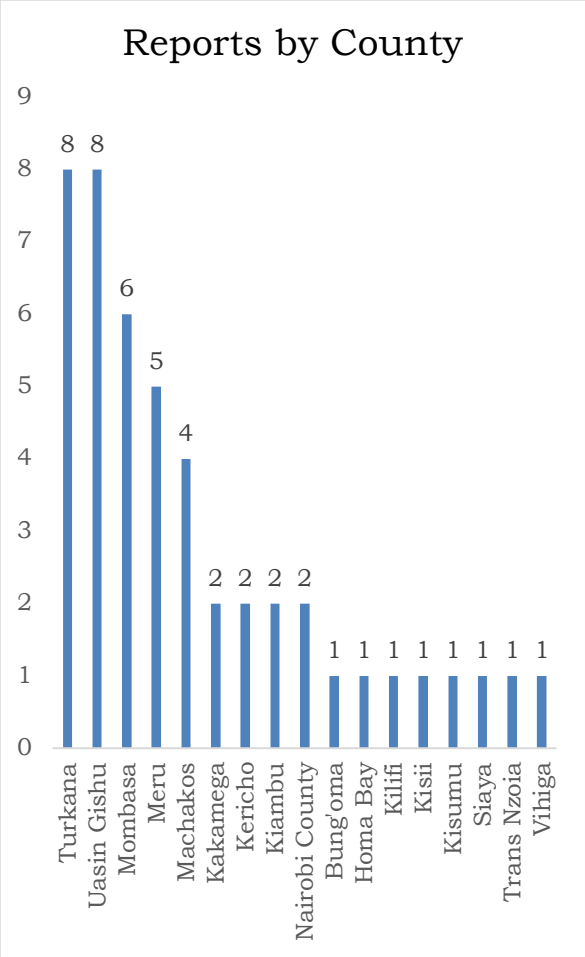
Most of the events were captured as others (46%), followed by high fever (21%), severe local reaction (14%) and the least was 2% due to injection site abscess and generalized urticaria

Specify	
Blurred vision	1
Death	1
Diarrhea and vomiting	1
Headache	2
Headache, General body malaise, Pain at injection site	1
indurations under the skin	1
Pain	1
Vomiting	1
Pain at Injection site and Body fatigue	1
Pain on the left arm and injection site after one week	1
Severe headache, abdominal pains general body malaise and loss of appetite	1
Not indicate/specified	14
Total	**26**

The other 46% of reported AEFIs was specified as indicated in the above table. 53.8% did not specify what other event they suffered.

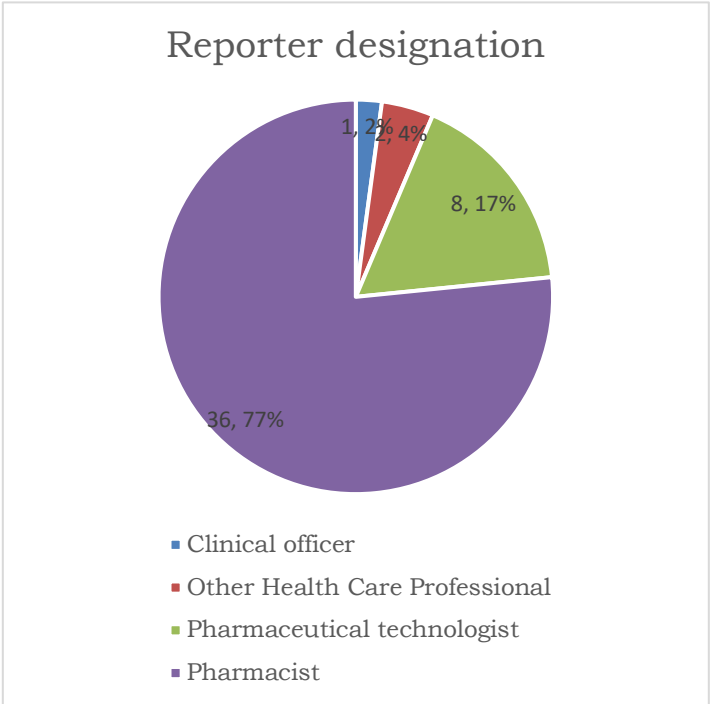
Institution	
Uasin Gishu District Hospital	8
Lodwar District Hospital	6
Meru District Hospital	5
Port Reitz District Hospital	4
Coast Province General Hospital	2
Kakamega Provincial General Hospital (PGH)	2
Kericho District Hospital	2
Lotubae dispensary	2
Machakos Level 5 Hospital	2
Athi River Health Centre	1
Bondo District Hospital	1
Cherangany Nursing Home	1
Chulaimbo Sub District Hospital	1
Gesusu Sub-District Hospital	1
Kianda 42 hospital	1
Kilifi District Hospital	1
Makadara Health Centre	1

Nyagoro Health centre	1
Ruiru sub county hospital	1
St. Veronica catholic church, syokimau	1
Tigoni District Hospital	1
Vihiga District Hosptial	1
Webuye Hospital	1
Total	**47**



Only 47 health care facilities reported AEFI events in Q4 with Uasin Gishu, Lodwar district hospital, Meru District hospital and Pory Reitz District hospitals sending most of the reports

Turkana, Uasin Gishu, Mombasa, Meru and Machakos counties contributed to the highest AEFI reports submitted in Q4



Reporting of AEFIs remains interest of pharmacists as 77% of the reports were submitted by that cadre. Pharmaceutical technologists submitted 17% of the reports in Q4 while other health care professional contributed 4% of the reports received.

Medical devices	Transfusion reactions
One report was received on defective 10cc syringe	One reaction was reported that affected a female patient. The reported event was flashing and other skin rash

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*)