



Ministry of Health

PPB Pharmacovigilance Centre

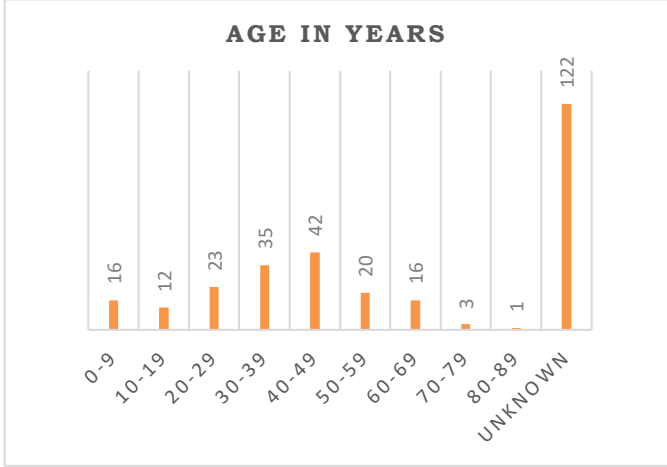
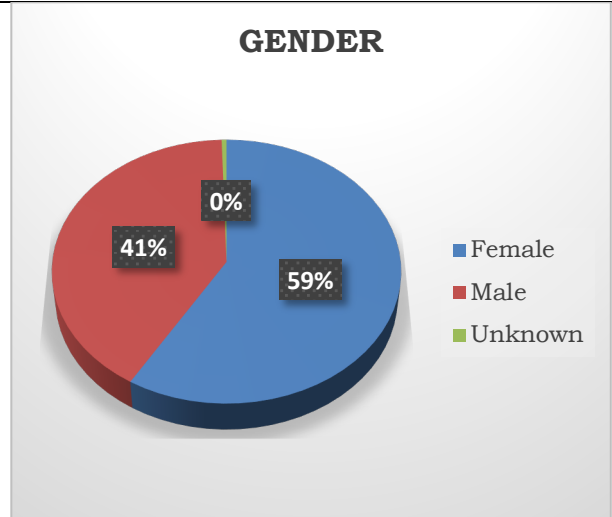
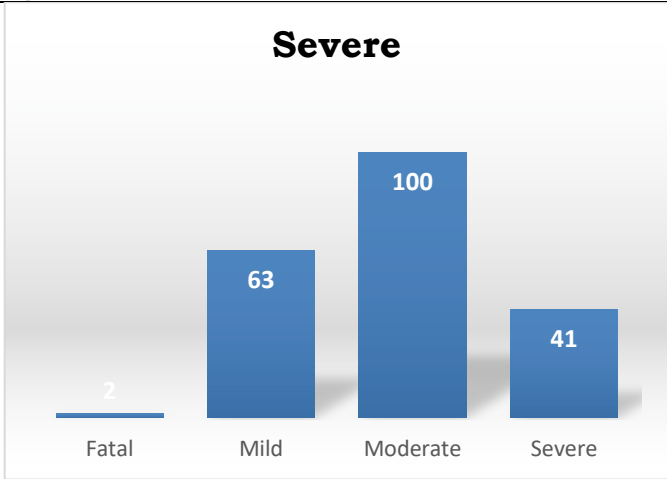
Pharmacovigilance Summary Report: **January-March 2022 (Q3)**

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 in drugs and poisons.

PPB has 4 directorates of which the Directorate of Medicines Information and Pharmacovigilance (MIPV) is responsible for Pharmacovigilance, Post-Market Surveillance, Clinical Trials & Medicines Information activities. MIPV shares quarterly pharmacovigilance reports with stakeholders to serve as a feedback mechanism and also encourage all stakeholders to report.

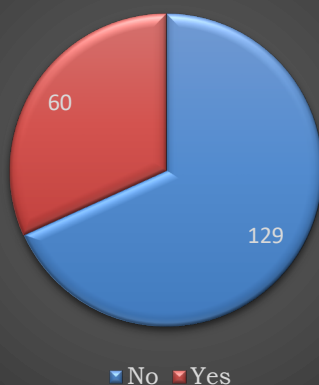
Since the introduction of PV in Kenya, a total of **16,050** individual case safety reports has been submitted to the global data reports **31,369,700** (0.06%).

SADRs

Therapeutic Ineffectiveness	3		
Medicinal product	208		
Blood products	0		
Herbal product	0		
Cosmeceuticals	0		
Others	0		
208 reports submitted were on suspected adverse drug reactions and 3 on suspected therapeutic ineffectiveness			
The incidence of ADRs was highest amongst the adult age group (40-49 and 30-39) in comparison to the others. 19.2% of the total reports did not have age indicated.			
			
The frequency of reported ADRs was higher in female (59%) compared to male.		79% of the reactions were not severe as reported.	

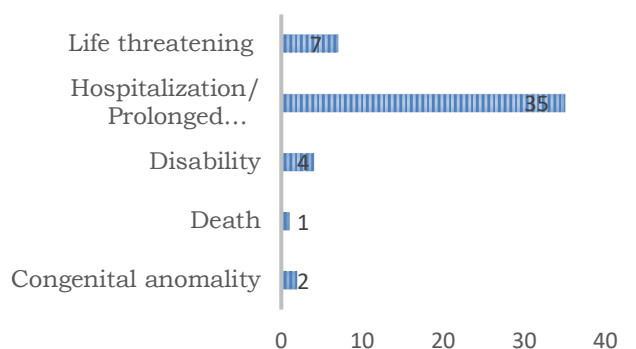


Seriousness



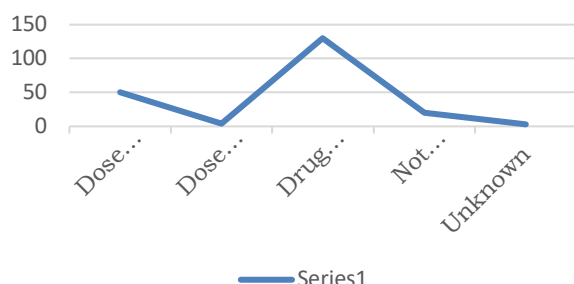
Of the total reports received in Q3, 29% were classified as serious.

Reason for seriousness



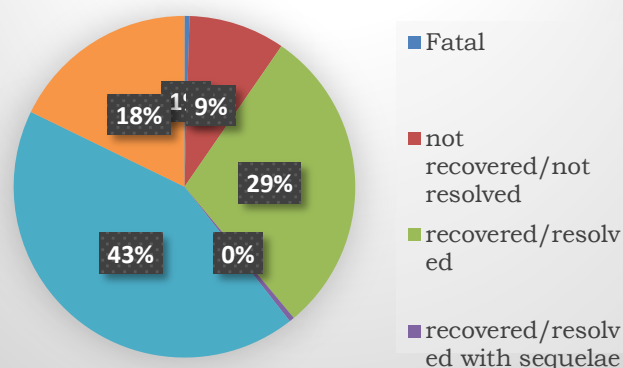
Out of the serious reactions reported, hospitalization (71.4%) was the major reason for seriousness.

ACTION TAKEN



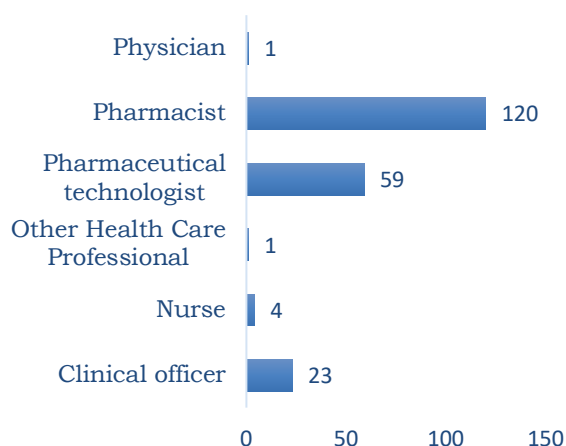
Actions taken by the health care workers included; withdrawal of the offending drug (63%). 27% reported that no change in dosage was made while, 1% did not indicate the action taken.

Outcome



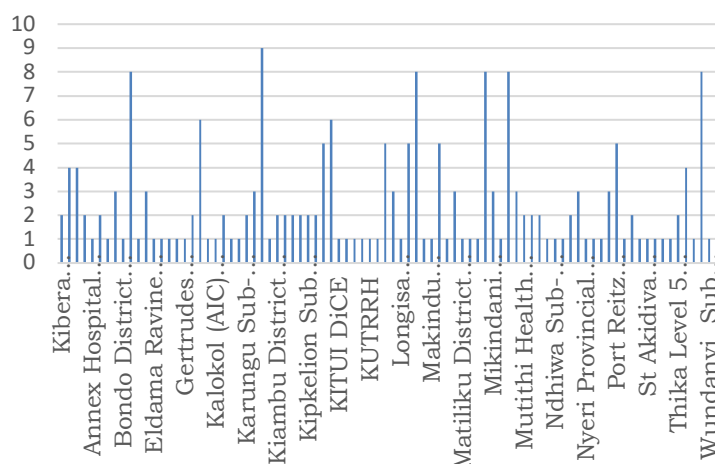
72% of the reported events had either recovered or resolved at the time of reporting.

Reporter designation



Majority of the reports (57.7%) of the reports were submitted by pharmacists while non- health professionals submitted 0.5% reports.

Facility

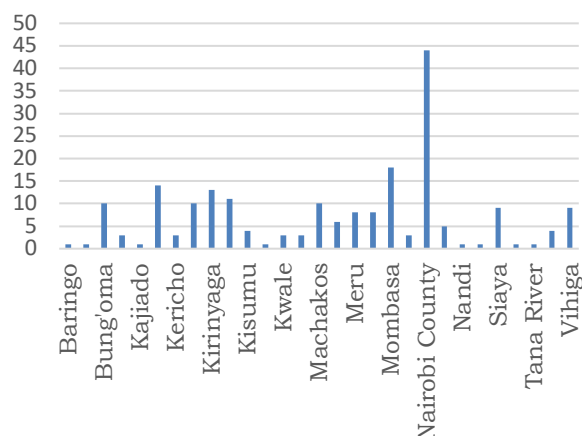


In this 3rd Quarter, only 86 facilities out of the 9,000 facilities listed in the Kenya Master facility reported ADRs. 14 facilities reported at least 5 reports and above. The top leading facilities were Kenyatta University Teaching Referral and Research Hospital

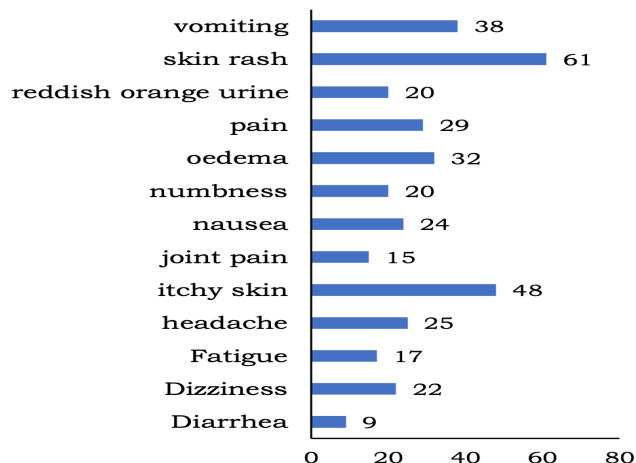


with 9 reports (4.3%), followed by Bungoma County Hospital, Machakos level 5 hospital, Meru County Hospital, Mumias Sub-County hospital and Vihiga County Hospital at 8 reports each (3.8%). Below is a list of top 14 facilities.

COUNTY



Commonly reported ADRs



Additionally, ADR reports were received from 29 of the 47 counties. Nairobi county submitted the highest number of ADR reports (44) followed by Mombasa (18), Kakamega (14), Kirinyaga (13) and Kisii (11). The other reporting counties with less than 3 reports were Baringo, Bomet, Kajiado, Kitui, Nandi, Nyeri, Taita Taveta and Tana River.

Most commonly reported ADR reaction were skin rash, itchy skin, vomiting, pain, headache and dizziness.

Suspected medicine	Frequency (n=1007)	Proportion (%)
Lamivudine	108	10.7
Tenofovir	108	10.7
Dolutegravir	103	10.2
Isoniazid	68	6.8
Cotrimoxazole	51	5.1
Pyridoxine	37	3.7
Rifampicin	37	3.7
Pyrazinamide	36	3.6
Ethambutol	33	3.3
Paracetamol	28	2.8
Rifapentin	28	2.8

The most commonly reported suspected medicine causing adverse reactions was Lamivudine (10.7%), Tenofovir (10.7%) followed by Dolutegravir (10.2%), Isoniazid (6.8%) and Cotrimoxazole (5.1%).

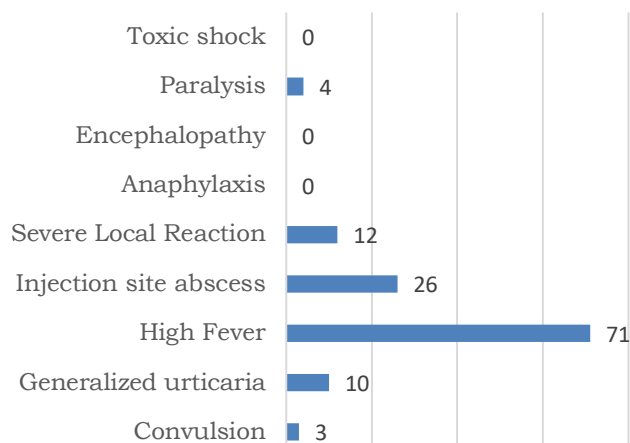


Adverse Events Following Immunizations (AEFIs)

<p>Age</p> <table border="1"> <thead> <tr> <th>Age Group</th> <th>Number of patients</th> </tr> </thead> <tbody> <tr><td>0-10</td><td>7</td></tr> <tr><td>10-20</td><td>45</td></tr> <tr><td>20-30</td><td>325</td></tr> <tr><td>30-40</td><td>225</td></tr> <tr><td>40-50</td><td>180</td></tr> <tr><td>50-60</td><td>98</td></tr> <tr><td>60-70</td><td>47</td></tr> <tr><td>70-80</td><td>21</td></tr> <tr><td>80-90</td><td>2</td></tr> <tr><td>110-120</td><td>1</td></tr> </tbody> </table>	Age Group	Number of patients	0-10	7	10-20	45	20-30	325	30-40	225	40-50	180	50-60	98	60-70	47	70-80	21	80-90	2	110-120	1	<p>Gender</p> <table border="1"> <thead> <tr> <th>Gender</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>Male</td><td>45%</td></tr> <tr><td>Female</td><td>55%</td></tr> <tr><td>Unknown</td><td>0%</td></tr> </tbody> </table>	Gender	Percentage	Male	45%	Female	55%	Unknown	0%
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<p>The incidence of AEFIs was highest amongst the adult age group (20-60) with 20-30 being the highest in comparison to the others.</p>	<p>The frequency of reported ADRs was higher in female (55%) compared to male.</p>																														
<p>SERIOUSNESS</p> <table border="1"> <thead> <tr> <th>Seriousness</th> <th>Number of patients</th> </tr> </thead> <tbody> <tr><td>Yes</td><td>22</td></tr> <tr><td>NO</td><td>944</td></tr> </tbody> </table>	Seriousness	Number of patients	Yes	22	NO	944	<p>REASON FOR SERIOUSNESS</p> <ul style="list-style-type: none"> Persistent or significant disability Hospitalization or prolongation of existing hospitalization Other important medical event <table border="1"> <thead> <tr> <th>Reason for Seriousness</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>Persistent or significant disability</td><td>54%</td></tr> <tr><td>Hospitalization or prolongation of existing hospitalization</td><td>23%</td></tr> <tr><td>Other important medical event</td><td>23%</td></tr> </tbody> </table>	Reason for Seriousness	Percentage	Persistent or significant disability	54%	Hospitalization or prolongation of existing hospitalization	23%	Other important medical event	23%																
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<p>Most of the reported AEFIs were not serious (98%)</p>																															

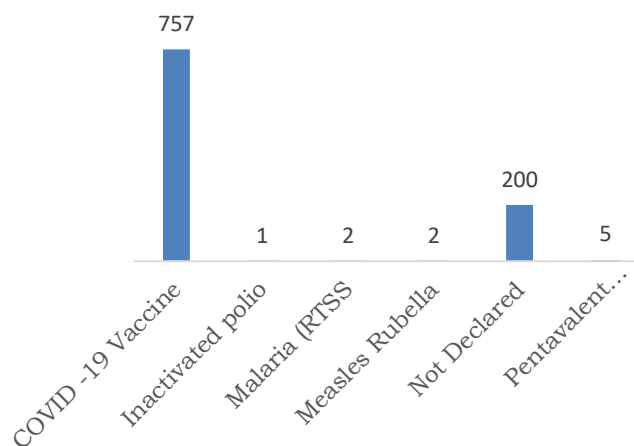


AEFI type



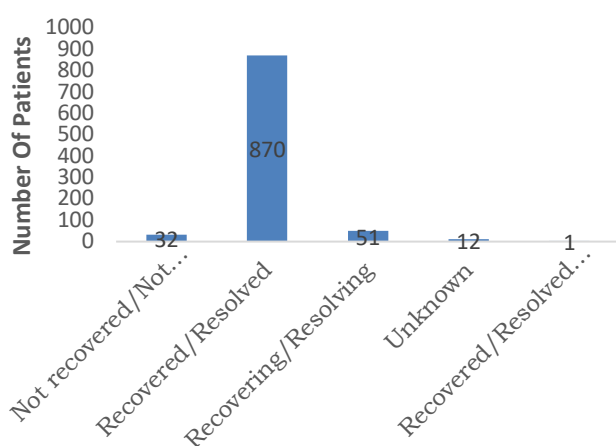
Most commonly reported AEFI was high fever, then injection site abscess and severe local reaction

Vaccine type



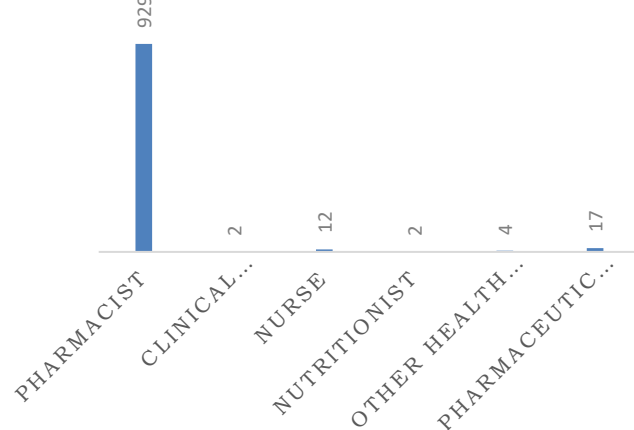
Most reports were related to covid-19 vaccines administration

Outcome



95% of the reported events had either recovered or were recovering at the time of reporting.

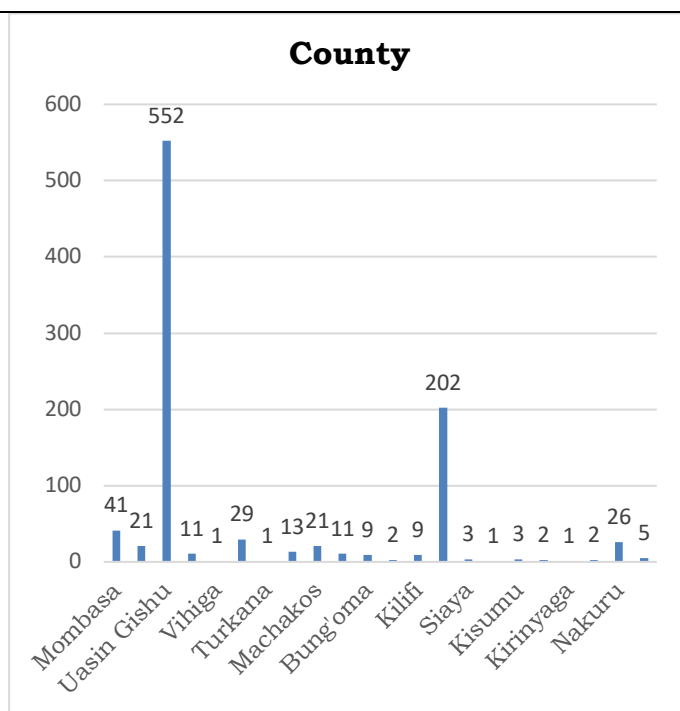
Reporter designation



Majority of the reports were submitted by pharmacists (95%)



Moi Teaching Referral Hospital	535
Nyeri Provincial General Hospital (PGH)	197
Nakuru Provincial General Hospital (PGH)	26
Coast Province General Hospital	24
Meru District Hospital	21
Tigoni District Hospital	18
Kajiado District Hospital	13
Uasin Gishu District Hospital	11
Machakos Level 5 Hospital	9
Mtwapa Health Centre	7
Port Reitz District Hospital	7
Mbagathi District Hospital	7
Webuye Hospital	6
Mikindani (MCM) Dispensary	5
Mukurweini Sub-District Hospital	5
Kiambu District Hospital	5
Busia District Hospital	5
Athi River Health Centre	4
Tudor District Hospital (Mombasa)	4
Lumakanda District Hospital	4
Kakamega Provincial General Hospital (PGH)	3
Bumula Health Centre	3
Ziwa Sub-District Hospital	3
Nguluni Health Centre	2
Huruma District Hospital	2
Kilifi District Hospital	2
Bondo District Hospital	2
Igegania Sub-District hospital	2
Garissa Provincial General Hospital (PGH)	2
Kiunyu Dispensary	2
Mumias Sub-District Hospital (Matungu)	2
Vihiga District Hospital	1
Lodwar District Hospital	1
Mathare North Health Centre	1
Huruma District Hospital07	1
Wangige Health Centre	1
GACHORORO HEALTH CENTRE	1





Mumias Level IV County Hospital	1	
Kangundo District Hospital	1	
Mutomo Mission Hospital	1	
Ikutha Health Centre	1	
Limuru cottage Hospital	1	
Ikombe Disp	1	
Wamunyu Health Centre	1	
Kisii Hospital (Level 5)	1	
Pharmacy and Poisons Board	1	
Lari Health Centre	1	
Star Hospital	1	
Kisumu District Hospital	1	
Coast General Teaching & Referral Hospital	1	
Kimbimbi Sub-District Hospital	1	
Hamptons Hospital	1	
Masinga Health Centre	1	
Nairobi South Medical Center	1	
Kombewa District Hospital	1	
Mwala District Hospital	1	
Hawinga Health Centre	1	
Oioibon Medical Centre	1	
Gertrudes Hospital	1	
Two facilities (Moi Teaching and Referral Hospital and Nyeri PGH) contributed to 76% of the reports submitted in Q3.		Highest reported events were from Uasin gishu and Nyeri counties

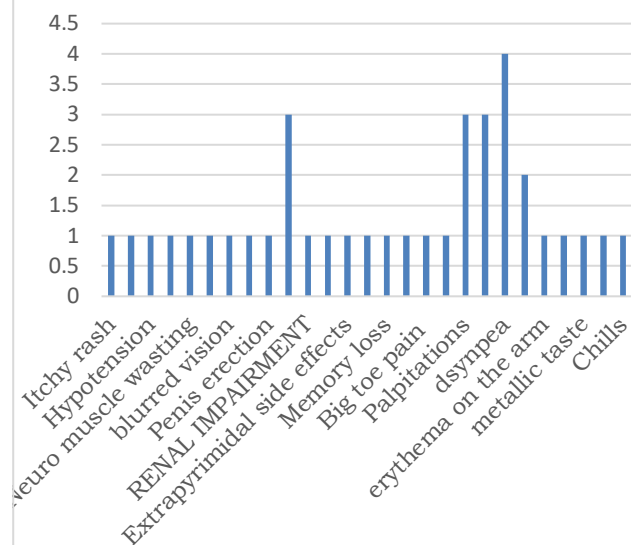
Public Adverse Drug Reactions (PADRs)

<p>Age group</p> <p>■ adult ■ elderly ■ infant ■ neonate ■ adolescent</p>	<p>Gender</p> <p>■ Female ■ Male ■ Not declared</p>
The incidence of events was highest amongst the adult age group followed by the elderly in comparison to the others. 0.2% of the total reports did not have age indicated.	The frequency of reported events was higher in female (59%) compared to male.



Vomiting or diarrhoea	6
Dizziness or drowsiness	5
Headache	7
Joints and muscle pain	7
Rash	10
Pain or bleeding in the mouth	2
Pain in the stomach	4
Abnormal changes with urination	3
Red/ painful eyes	3
Patient died	2
The label looks wrong	2
Has unusual material in it	2
The color is changing	3
The smell is unusual	2
The medicine/device is not working	2
The packet or bottle does not seem to be usual	3

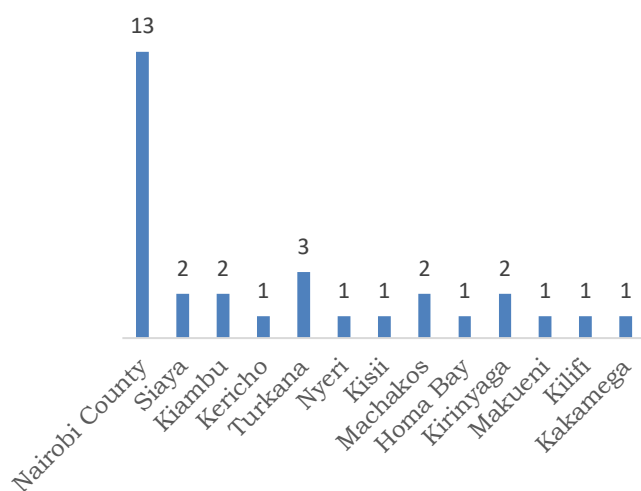
Other side effects



Most commonly reported events by the members of the public were rash, headache, joint & muscle pains, vomiting or diarrhea and pain in the stomach respectively

Commonly reported other side effects were fever, dyspnea, chills and palpitations

PADRs by county

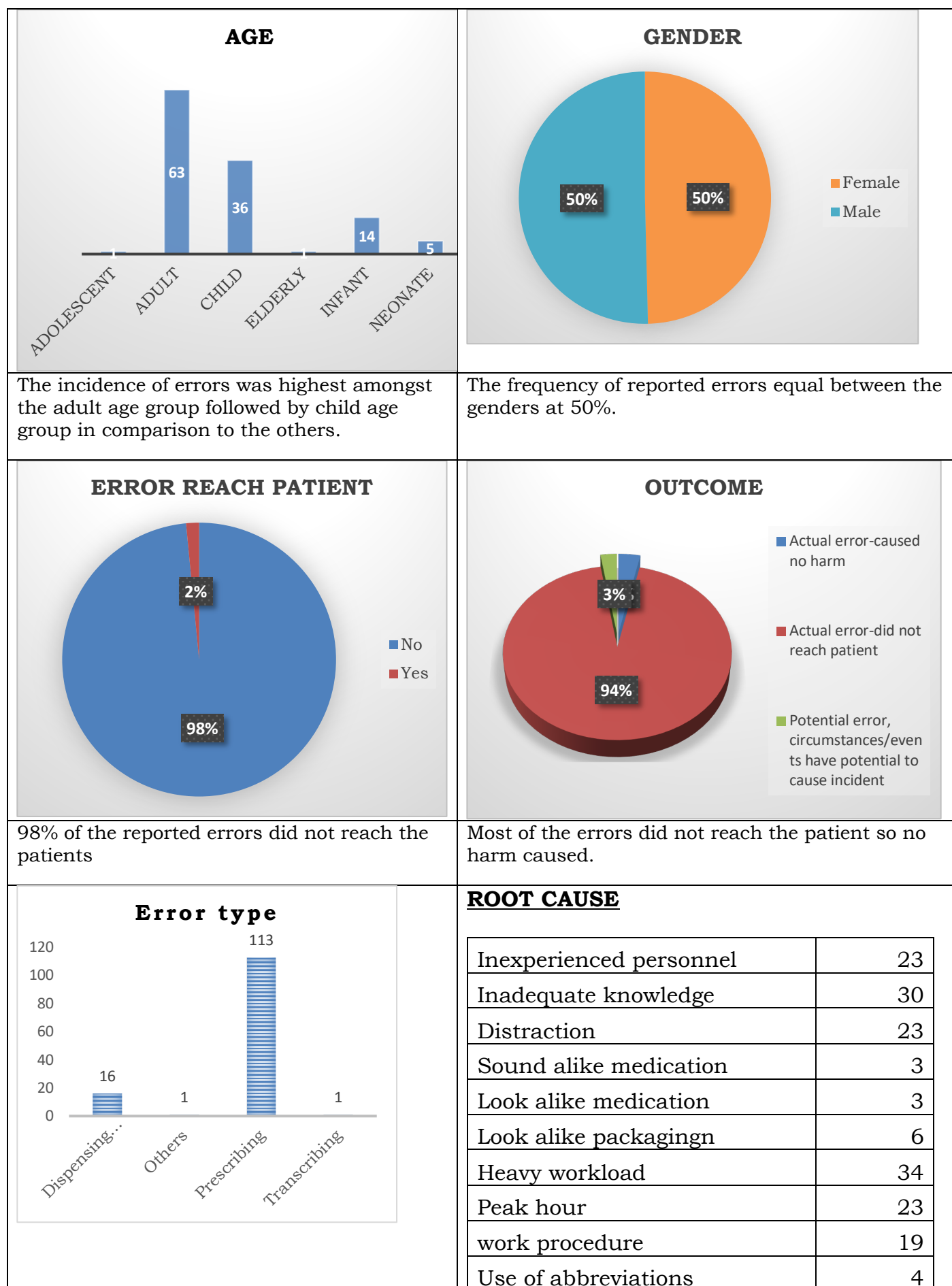


Manufacturer	Frequency
mylan	2
Oxford University's Jenner Institute and Vaccitech	1
Pfizer	1
labsLaurus	1
laurus lab limited	1
MACLEODS PHARMACEUTICALS LTD	1
AUROBINDO	3
Promed Pharmaceutical LTD	1
Delpharm Hunningue, France	1
Strides pharma science limited	1
ast Dong	1
Pfizer	1
Cosmos	1
PMC	1
Intas Pharmaceuticals	2
Therdose Pharma Private limited	2
getwell pharmaceuticals	1
human biologicals institute	1

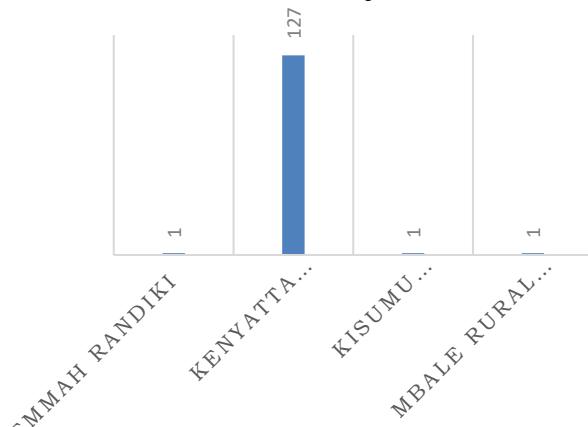
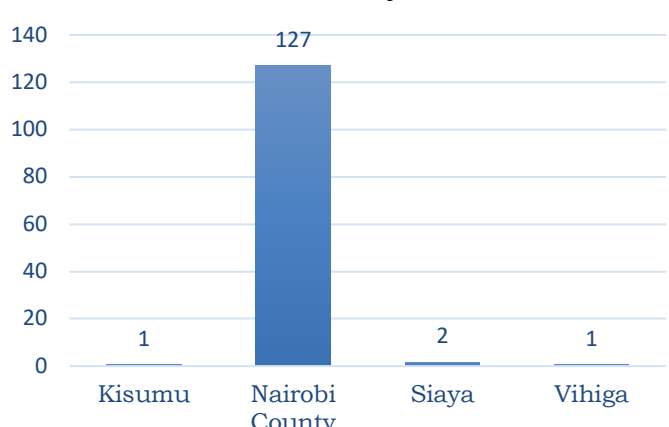
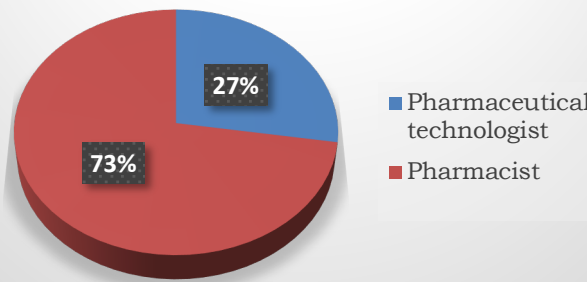
Most reports from patients/consumers came from Nairobi county followed by Turkana.



Medication Errors





	<table><tr><td>Illegible prescriptions</td><td>2</td></tr><tr><td>Inaccurate information</td><td>2</td></tr><tr><td>Wrong labelling</td><td>9</td></tr><tr><td>Incorrect computer entry</td><td>3</td></tr><tr><td>Others</td><td>6</td></tr></table>	Illegible prescriptions	2	Inaccurate information	2	Wrong labelling	9	Incorrect computer entry	3	Others	6										
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Most of the errors occurred at prescribing level followed by dispensing level (98%).	Heavy workload, inadequate knowledge, inexperienced personnel, distraction and peak hours were cited as the most common cause of the reported errors.																				
<div><p>Facility</p><table><thead><tr><th>Facility</th><th>Number of Reports</th></tr></thead><tbody><tr><td>EMMAH RANDIKI</td><td>1</td></tr><tr><td>KENYATTA NATIONAL HOSPITAL</td><td>127</td></tr><tr><td>KISUMU ...</td><td>1</td></tr><tr><td>MBALE RURAL ...</td><td>1</td></tr></tbody></table></div>	Facility	Number of Reports	EMMAH RANDIKI	1	KENYATTA NATIONAL HOSPITAL	127	KISUMU ...	1	MBALE RURAL ...	1	<div><p>County</p><table><thead><tr><th>County</th><th>Number of Reports</th></tr></thead><tbody><tr><td>Kisumu</td><td>1</td></tr><tr><td>Nairobi County</td><td>127</td></tr><tr><td>Siaya</td><td>2</td></tr><tr><td>Vihiga</td><td>1</td></tr></tbody></table></div>	County	Number of Reports	Kisumu	1	Nairobi County	127	Siaya	2	Vihiga	1
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Majority of the reports were submitted from 1 facility (Kenyatta National Hospital)	Nairobi county submitted most of the medication error reports.																				
<div><p>REPORTER DESIGNATION</p><table><thead><tr><th>Reporter Designation</th><th>Percentage</th></tr></thead><tbody><tr><td>Pharmacist</td><td>73%</td></tr><tr><td>Pharmaceutical technologist</td><td>27%</td></tr></tbody></table></div>	Reporter Designation	Percentage	Pharmacist	73%	Pharmaceutical technologist	27%	All the reports were submitted by pharmacy cadre, 73% pharmacists and 27% pharmaceutical technologists.														
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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).