دائـــــرة الـــصـــحـــة
DEPARTMENT OF HEALTH

ANALYSIS OF ADVERSE REACTION (AR) REPORTS 2016-2017

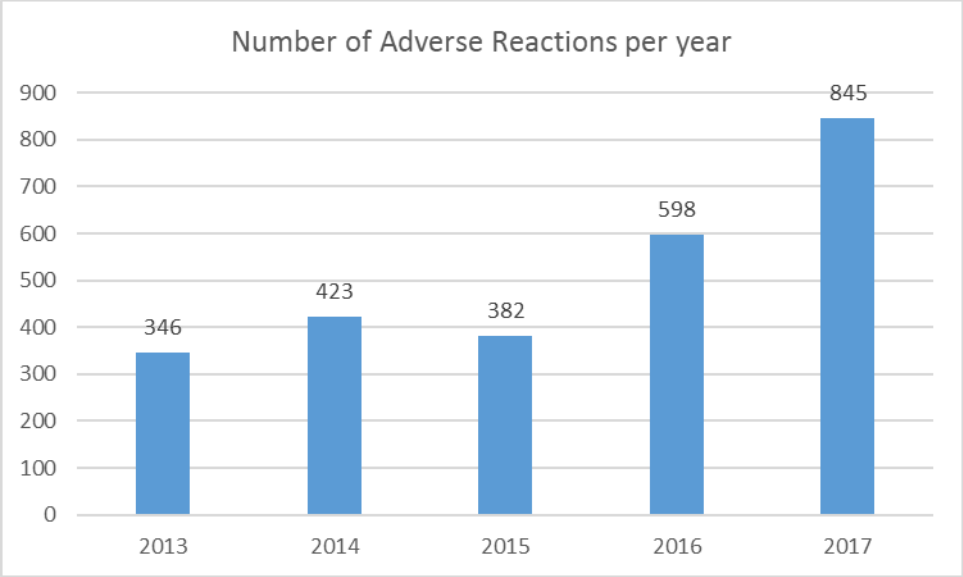
PHARMACOVIGILANCE PROGRAM

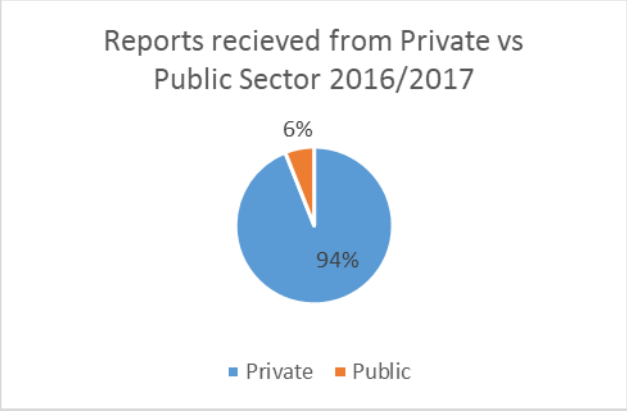
Introduction

DOH pharmacovigilance program was established in the emirate of Abu Dhabi since 2008. DOH pharmacovigilance program receives adverse drug reactions and medication errors from healthcare providers and professionals in Abu Dhabi. This report shows data and statistics for adverse drug reaction (AR) reports received during the period of 2016-2017. It follows the previous report of AR data analysis for the years 2013-2015 which is published on DOH website. Adverse reactions following immunizations reports are not included in this analysis.

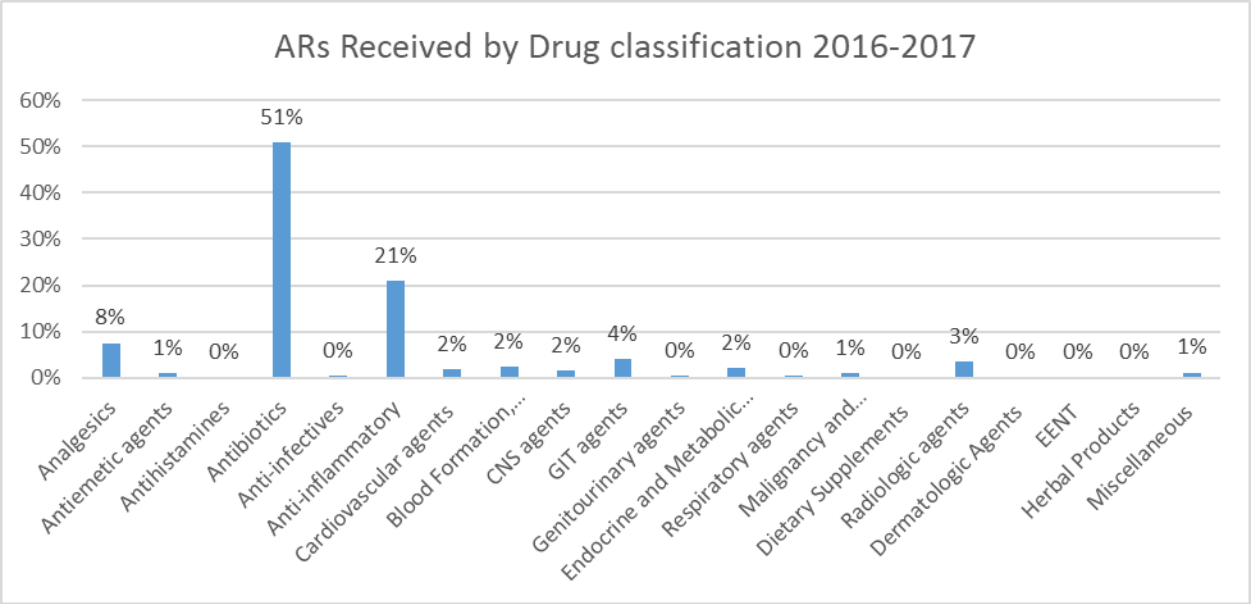
Number of Reports and Mode of reporting

A total of 1443 adverse reaction reports were submitted to the pharmacovigilance program during the period of January 2016 to December 2017 and were included in this analyses. Most of the reports were received through the online e-notification tool (93%). The remaining 7% were mainly received through email.





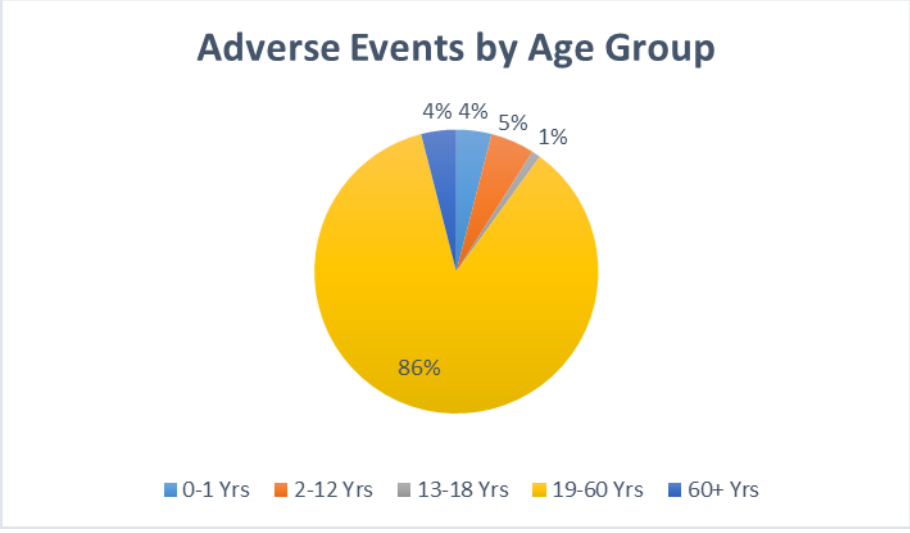
Adverse Reactions received by drug classification



The total number of suspected drugs reported was 1579. Some AR reports had more than one suspected drug reported, which explains why the number of drugs is more than the number of reports (1579 vs 1443). However, the total number of drug molecules by active ingredient reported was only 194.

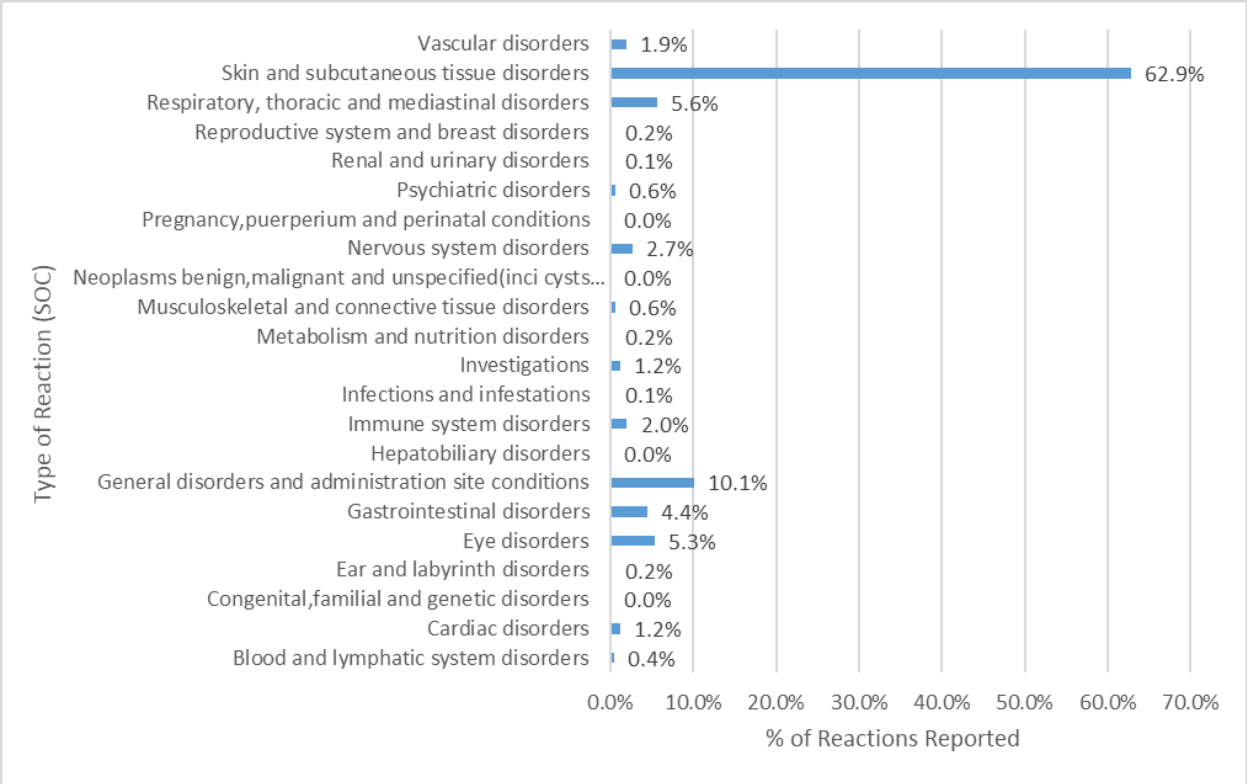
Antibiotics represent the highest therapeutic category associated with AR incidences, same findings as reported earlier (2013-2015 data). It is followed by anti-inflammatory and then analgesic drugs. Anti-inflammatory drugs are mainly non-steroidal anti-inflammatory drugs (NSAIDS) and analgesic drugs are paracetamol and opioids. The number of AR reports with radiologic agents and GIT agents are also notable.

Adverse Reactions received by Age Group



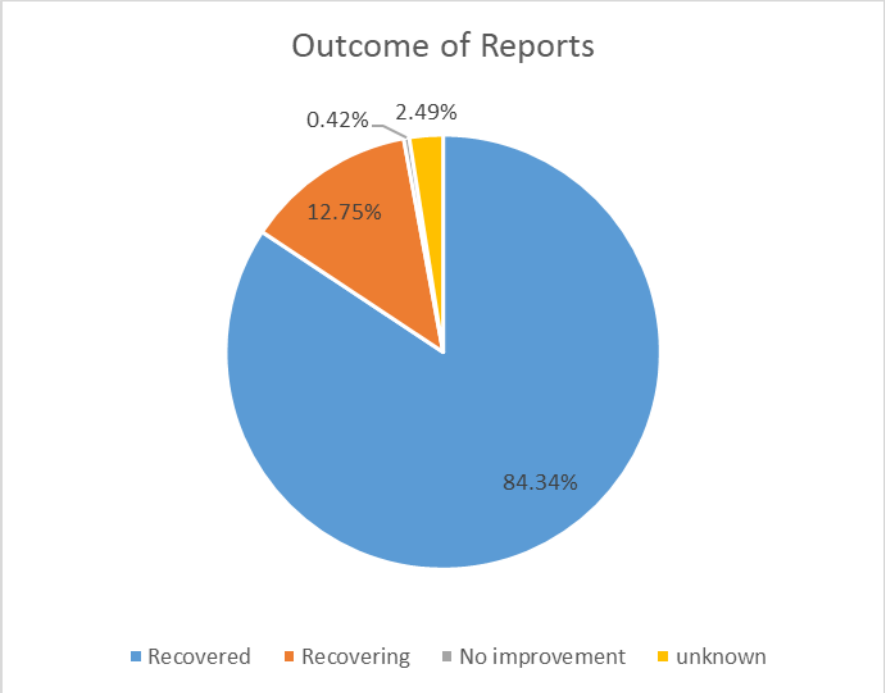
The data was also classified by age group. The above figure shows the estimated percentage of reports in each age group. Cases of young adults represent more than 80% of the AR reports.

Types of Adverse Reactions Reported

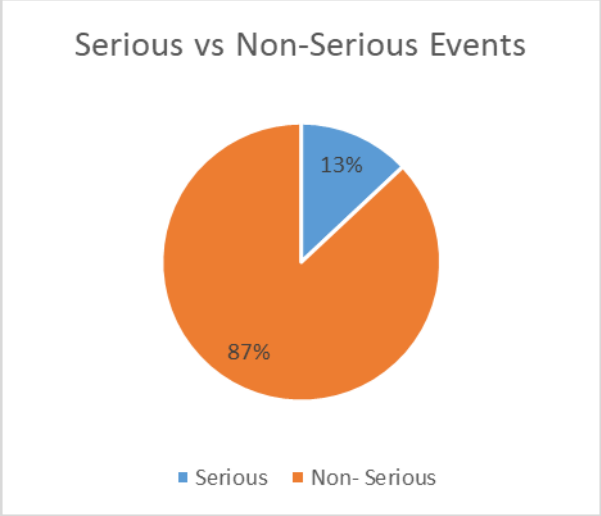


Adverse drug reaction terms reported were coded with the relevant “Preferred Term” and the associated “System Organ Class” (SOC) from the Medical Dictionary for Regulatory Activities (MeDdra) version 20.
Some reports had more than one reaction term to be associated with one or more drugs. A total of 2462 adverse reaction terms were reported in the 1443 reports analyzed.
More than 60% of the reactions reported were classified as “Skin and Subcutaneous Tissue Disorders”. “General Disorders and Administration Site Conditions”, “Respiratory Disorders”, “Gastrointestinal Disorders” and “Eye Disorders” each was involved in about 4% or greater of the reported reactions.
These findings are similar to that of the previous AR analysis for (2013-2015) data.

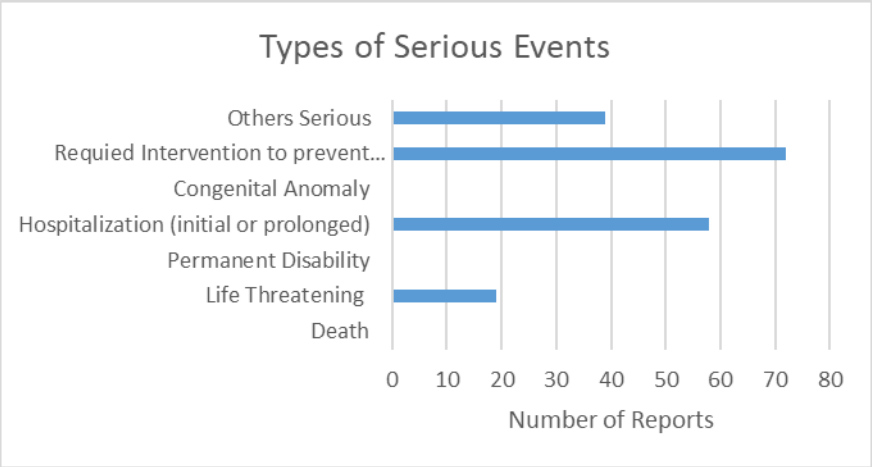
Outcome and Seriousness of the Adverse Events



In 84% of the submitted cases, patients had recovered from the adverse reaction. One hundred and eighty four cases (13%) were still recovering at the time of report submission. Only six cases showed no improvement while 36 cases had an unknown outcome.



Most of the submitted reports were non-serious. Healthcare professionals and providers are required to report all ARs whether serious or non-serious as per DoH standard aiming to capture all adverse reactions known and unknown.



A total of 188 serious reports where included in the analyses. Serious reports are those which fall under the categories mentioned in the above graph. Those which "required intervention to prevent permanent impairment/damage" were the most reported among serious reports. This was followed by cases, which required "hospitalizations". Only 19 cases experienced a "life threatening" situation.

Suspected Drugs in AR Reports

	Drug molecule/ Active Ingredient	Number of times Reported (2016/2017)
1	Ceftriaxone	280
2	Diclofenac	206
3	Ciprofloxacin	94
4	Levofloxacin	81
5	Paracetamol	70
6	Amoxicillin + Clavulanic Acid	59
7	Moxifloxacin	36
8	Cefazolin	35
9	Cefuroxime	34
10	PETHIDINE	33
11	Ioversol	32
12	Dexketoprofen (as trometamol)	28
13	Ibuprofen	22
14	Vancomycin	21
15	Metoclopramide	18
16	Metronidazole	18
17	Ranitidine	17
18	Cefepime	16
19	Ferric Carboxymaltose	16
20	Pantoprazole	15

Ceftriaxone was the most commonly reported drug suspected to be associated with an adverse reaction. Diclofenac comes next, followed by ciprofloxacin, then levofloxacin. These results confirmed that "antibiotics", followed by "anti-inflammatory drugs" are considered the highest therapeutic categories of drugs associated with AR incidences.

Examples of serious ARs

Description	MeDdra Preferred Term	Suspected active ingredient(s)
Immune system disorders	Anaphylactic reaction	Cefazolin (1), Gemifloxacin (1), Aceclofenac (1)
	Anaphylactic shock	Co-trimoxazole (1), Metronidazole (1), Diclofenac (2), Metoclopramide (1), Cefuroxime (1)
Neoplasms benign,malignant and unspecified(inci cysts and polyps)	Breast cancer	Liraglutide (1)
Cardiac Disorders	Cardiac arrest	Co-amoxiclav (1)
Nervous system disorders	Cerebrovascular accident	Ethinyloestradiol, Drospirenone/Yasmin (1)
	Guillain-Barre syndrome	Infliximab (1)
Eye disorders	Chorioretinopathy	Prednisolone (1), Mometasone furoate (2)
Metabolism and nutrition disorders	Euglycaemic diabetic ketoacidosis	Empagliflozin (1)
Blood and lymphatic system disorders	Haemolytic anaemia	Human Normal Immunoglobulin(1)
	Thrombocytosis	Hydrocortisone (1) Fludrocortisone(1)
	Thrombocytopenia	Heparin (1)
	Leukopenia	Clindamycin (1) Diclofenac (1)
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome, Toxic epidermal necrolysis	Carbamazepine(1), Etoricoxib (1), Paracetamol(1), Carisoprodol (1)Levetiracetam(1)
	Angioedema	Tolperisone (1), Ibuprofen (1), Paracetamol (1), Gemifloxacin (1), Aceclofenac (1)
Respiratory,thoracic and mediastinal disorders	Respiratory arrest	Ketorolac (1)
Vascular disorders	Circulatory collapse	Diclofenac (1)

Limitations

This analysis was done using data collected from spontaneous reports received from healthcare professionals. Data validity, reliability and accuracy are subjective. Reliable rates cannot be calculated and consequently risk cannot be measured.

Underreporting and poor quality reporting are also major challenges facing the pharmacovigilance program. These limit the usefulness of the data and reduce the chances to detect safety signals.

Recommendations and Future Steps:

To continue expanding DOH pharmacovigilance network.

To encourage healthcare professionals to continuously identify and report adverse drug reactions.

To increase awareness on importance of reporting adverse drug reactions to monitor the safety of medications, especially those newly introduced to the market.