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**ADVERSE DRUG REACTION REPORTING SYSTEM AT DIFFERENT HOSPITALS  
OF LAHORE - AN EVALUATION AND PATIENT OUT-COME ANALYSIS**

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**ABSTRACT**

Adverse drugs reactions (ADRs) are known to be a major cause of morbidity and mortality. However, only a very little proportion is reported. ADRs contribute to the incidence of adverse events, resulting in increased health care costs. An increase in the number and quality of reports by improving ADR reporting system in hospitals, highlight the importance of ADR including general awareness could improve patient outcome and save healthcare costs. Ministry of Health (MOH) has done some work but still major requirements are needed to run a proper ADR program.

The first part of this project was to review the ADR reporting system in Pakistani hospitals, to determine the factors contributing to the ADR reporting rate and benchmark with developed countries. Data was collected by self-administered questionnaire. The response rate was 83.3%. 24 (80%) hospitals have no proper ADR system; five (16.7%) hospitals are targeting few of the drugs for ADR reporting while only one (3.3%) hospital has a proper ADR policy including online reporting system as well. Only seven (23.3%) hospitals have a policy of ADR reporting which is running under Pharmacy Department.

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The next part of the project was a survey of 84 doctors and 52 Pharmacists selected from Lahore city, Pakistan to evaluate their involvement, understanding and reasons for reporting ADRs. A self-administered questionnaire was used to collect the data.

Response rate obtained for the doctors was (39.3% n=33) and (67.3% n=35) for hospital pharmacists. Thirty three (39.3%) doctors and thirty four (65.4%) pharmacists knew how to report ADR within the hospital while 9 (10.7%) doctors and 13 (25%) Pharmacists knew about the ADR reporting to Ministry of Health. Factors that would encourage respondents to report ADRs included seriousness of reaction (75.8%), unusual reaction (63.6%), reaction to a new product (66.6%) and confidence in the diagnosis of ADR (31.5%). Similarly, the discouraging factors are uncertain association (65.7%), awareness (57.6%), and concern about legal liability (51.4%).

It is observed that awareness of ADRs program need special attention with some concrete steps should be taken for the improvement of ADRs system in Pakistan. Continuing medical education, training and integration of ADR reporting into the clinical activities would definitely improve the patient outcome.

**Keywords: Adverse Drugs Reactions, Self-Administered Questionnaire, Hospital Pharmacists, Patient Outcome.**

## INTRODUCTION

Adverse drug reactions (ADRs) are negative results of drug therapy [1]. They are one of the major reasons of morbidity and mortality. It has been determined that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of patients which are hospitalized, experience an ADRs during their hospitalization [2].

Hospitals and health care providers struggle to deliver the safest care possible. However, adverse drug events are common [3-6], often preventable [7-11] and costly [12-17].

The reason of preventable adverse drug events is medication errors, which include errors in the process of ordering or delivering a medication and omission errors (e.g., failing to administer a drug according to prescription). It was estimated [18, 19], that approximately 1 % of medication errors result in adverse drug events. Minimizing or eliminating errors of medication is important to improve patient safety and the quality of hospital care. Medication error reporting is a necessary component of achieving these goals.

Although the debate regarding the need for voluntary or mandatory reporting systems continues, [20-22, 23-27] voluntary reporting systems are more appealing to institutions and are potentially valuable sources of information that hospitals could use for system wide improvements [28].

The objective of the study was to evaluate the current ADRs Reporting System in Pakistan Health care setting and compare it with ADRs System in developed countries and to identify the ADRs reporting trends in Lahore, Pakistan.

## **MATERIAL AND METHODS**

### **Research Methodology**

Prospective observational study was conducted to investigate the current ADRs Reporting System at Different hospitals of Lahore and compare it with the ADRs system in the developed countries.

Information relevant to the study was accessed by circulating Questionnaire to the respondents after obtaining ethical clearance from the Hospital.

### **Study Design**

Prospective study design was used to collect the information.

### **Study Type**

Survey method involving Doctors, Pharmacists of different hospitals of Lahore was carried out

### **Sample Size**

A total of 84 Doctors and 52 Pharmacists from 30 different hospitals in Lahore participated in the study.

### **Sampling Technique**

A Random Sampling technique was applied to collect the sample.

### **Sampling Procedure**

The relevant data or the related information was collected from all the health care professionals through one-to-one interview.

### **Study Tool**

The initial draft of the Questionnaires was made by utilizing different ADRs systems of developed countries, Literature evaluation, published research articles. In addition, this draft circulated to different health care professionals of different hospitals of Lahore and then finalized after necessary changes keeping in view the objectives of the study.

Different questionnaires were designed to collect the required information. One of the questionnaires was developed to gather the general hospital information including ADRs systems. Other two questionnaires were specific for Doctors and Pharmacists.

### **Statistical Analysis**

Statistical Analysis was conducted by using the statistical package – SPSS (statistical package for social sciences), Version

11.5. This analysis was carried out in two steps:

- 1) Descriptive Analysis
- 2) Inferential Analysis

Arithmetic Mean (Average) was calculated for quantitative variables, while for qualitative variables, frequencies and percentages were measured. Histogram was obtained for quantitative variables, while Pie chart and Bar chart were used to express the graphical picture of qualitative variables.

Pearson's Chi-Square test was used to measure the associations between different Variables in this study. For 2x2 contingency tables, where observed frequency less than 5, Fisher's Exact test were used to measure the associations between different variables.

## RESULTS AND DISCUSSION

### Descriptive Statistics of Categorical Variables

**Figure 1** shows that out of total 33 Doctors, 25 (75.7%) agreed regarding "Seriousness of the reaction". About "Unusual Reaction", 21 (63.6%) are Agreed Regarding "Reaction to a new product" 20 (60.6%) are Agreed. Similarly, About "Confidence in the diagnosis of the ADRs" 17 (51.5%) are Agreed.

**Figure 2** shows that out of total 35 Pharmacists, 30 (85.7%) agreed, regarding "Seriousness of the reaction". About "Unusual Reaction" 26 (74.3%) are Agreed,

Regarding "Reaction to a new product" 25 (71.4%) agreed. About "Confidence in the diagnosis of the ADRs" 17 (48.6%) agreed.

Data in **Figure 3** show that out of total 33 Doctors, 20 (60.6%) agreed regarding "Uncertain association". About the factors "Workload / Shortage of staff", "Report form not readily available" and "Not communicated / Awareness" 19 (57.6%) Doctors are agreed.

**Figure 4** show that out of total 35 Pharmacists, 23 (65.7) agreed regarding "Uncertain association". About "Not communicated / Awareness" 20 (57.1%) agreed. Considering the factors "Level of drug knowledge not adequate" and "Concern about legal liability" 18 (51.4%) Pharmacists agreed.

**Figure 5** shows that out of total 30 Hospitals, 20 (66.7 %) are Teaching Hospitals, 7 (23.3 %) are Non-Teaching Hospitals, 1 (3.3 %) is Private Hospital and 2 (6.7 %) are Other Hospitals.

Data in **Figure 6** shows that out of total 30 Hospitals, 22 (73.3 %) are Acute Care / General Hospitals, 3 (10.0 %) are Obs / Gyn Hospitals, 3 (10.0%) are Other Hospitals, 1 (3.3 %) is Children Hospital and 1 (3.3%) is Psychiatric Hospital.

Data in **Figure 7** indicate that out of total 30 Hospitals, In 4 (13.3 %) hospitals there are

<100 No. of Beds, 3 (10.0 %) hospitals have between 100-199 No. of Beds, 3 (10.0 %) hospitals have between 200-299 No. of Beds, 4 (13.3 %) hospitals have between 300-399 No. of Beds, 1 (3.3 %) hospital has between 400-499 No. of Beds and 15 (50.0 %) hospitals have More than or Equal to 500 No. of Beds.

**Figure 8** shows that out of total 30 Hospitals, 11 (36.7 %) Hospitals have between 1000-15000 No. of Admissions, 6 (20.0 %) Hospitals have between 15000-30000 No. of Admissions, 3 (10.0 %) hospitals have between 30000-45000 No. of Admissions, 6 (20.0 %) Hospitals have between 45000-60000 No. of Admissions, 3 (10.0 %) hospitals have between 60000-75000 No. of Admissions and 1 (3.3 %) hospital has between 90000-105000 No. of Admissions.

**Figure 9 and Table 1** shows that out of total 30 Hospitals, in 15 (50.0 %) Hospitals, there are 0-150 No. of Doctors, 11 (36.7 %) hospitals have 150-300 No. of Doctors, 3 (10.0 %) hospitals have 300-450 No. of Doctors and 1 (3.3 %) hospital has 750-900 No. of Doctors.

**Figure 10** shows that 6 (18.2%) out of 33 Doctors and 3 (8.6%) out of 35 Pharmacists suggested that documentation of ADRs should be carried out by “Doctors”. Similarly, 7 (21.2%) Doctors and 10 (28.6%)

Pharmacists suggested that documentation of ADRs should be done by “Pharmacists”.

It can be seen from **Figure 11** that out of total 30 Hospitals, 1 (3.3 %) Hospital responds 1-5 ADRs per Year, 1 (3.3 %) Hospital responds “Don’t Know”, 5 (16.7 %) Hospitals respond No ADRs and 23 (76.7 %) Hospitals show “No response” regarding Number of ADRs sent to MOH or any other body like FDA (USA)... etc.

**Figure 12** shows that out of total 30 Hospitals, 11 (36.7 %) Hospitals respond “No” and 19 (63.3 %) Hospitals show “No response” regarding any reward / fee for reporting ADRs in the Hospital.

**Figure 13** shows that out of total 84 Doctors, 62 (73.8 %) Doctors are Males and 22 (26.2 %) Doctors are Females.

**Figure 14** shows that out of total 52 Pharmacists, 22 (42.3 %) Pharmacists are Males and 30 (57.7 %) Doctors are Females

**Figure 15** shows that out of total 84 Doctors, 64 (76.2 %) have registration duration Under 7 Years, while out of total 52 Pharmacists, 35 (67.3 %) have registration duration Under 7 Years. On the other hand, 17 (20.2 %) Doctors have registration period Above 10 Years, while 7 (13.5%) Pharmacists have registration duration Above 10 Years.

**Figure 16** shows that out of total 84 Doctors 74 (88.1 %) have Working Experience Under

7 Years, while out of total 52 Pharmacists, 48 (92.3%) have Working Experience Under 7 Years.

**Figure 17** shows that out of total 33 Doctors 20 (60.6%) Doctors respond “NO” while out of 35 Pharmacists, 21(60.0%) Pharmacists respond “NO” about the adequacy of ADRs reporting in the hospital and submitting to MOH.

**Figure 18** shows awareness regarding “Thrombocytopenia with Heparin” and “Duodenal ulcer with Diclofenac”. On the other hand, pharmacists show more awareness regarding “Thrombocytopenia with Heparin” and “Neutropenia with ACE inhibitor”. The average awareness in Doctors (32.5%) is little more than Pharmacists (30.4%).

**Figure 19** shows the comparison of Unawareness about ADRs among respondents. Doctors have shown more Unawareness regarding “Headache with Venlafaxine” and “Weight loss with Venlafaxine”. While; Pharmacists reveal more Unawareness in case of “Headache with Venlafaxine” and “Constipation with Montelukast”. The average Unawareness in Doctors (67.5%) is less than Pharmacists (69.6%).

**Figures 20-22**, show the comparison of awareness and unawareness among respondents. The level of “Awareness” is high

among Doctors, but considering “Unawareness”, Pharmacists show high response.

**Figure 23** shows the comparison of ADRs awareness among respondents. This shows doctors have more awareness regarding “Duodenal ulcer with Diclofenac”, “DVT after oral Contraceptives” and “Neutropenia with ACE inhibitor”. On the other hand, pharmacists show more awareness regarding “Duodenal ulcer with Diclofenac” and “Jaundice with Frusemide”. The average awareness in Doctors (32.8%) is little more than Pharmacists (28.1%)

**Figures 24, 25** shows the comparison of Unawareness about ADRs among respondents. Doctors have shown more Unawareness regarding “Headache with Venlafaxine” and “Weight loss with Venlafaxine”. While; Pharmacists reveal more Unawareness in case of “Headache with Venlafaxine”, “Constipation with Montelukast” and “Weight loss with Venlafaxine”. The average Unawareness in Doctors (67.2%) is less than Pharmacists (71.9%). It is observed that the level of “Awareness” among Doctors is more than Pharmacists. On the other hand, Pharmacists show more “Unawareness” than Doctors.

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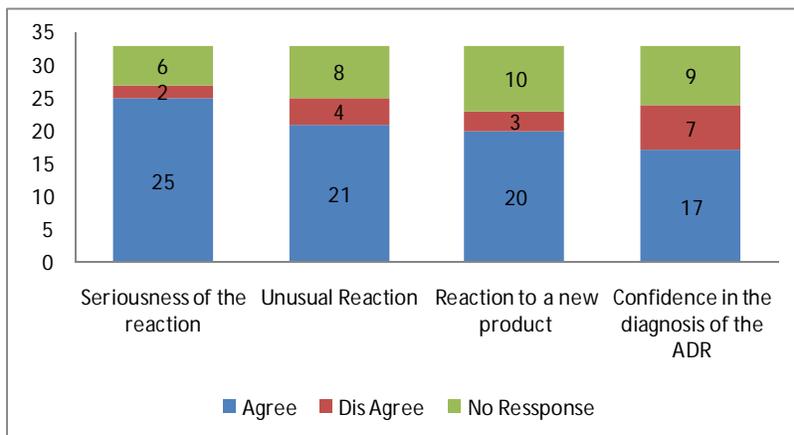


Figure 1: Factors Which Encourage Doctors to Report ADRs

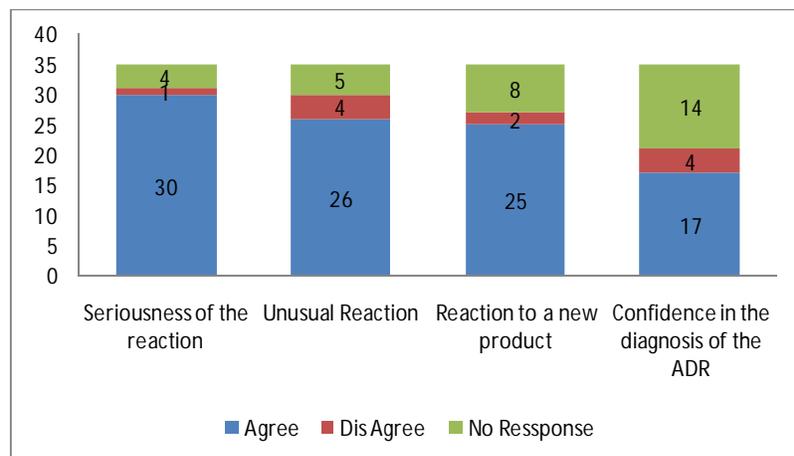


Figure 2: Factors Which Encourage Pharmacists to Report ADRs

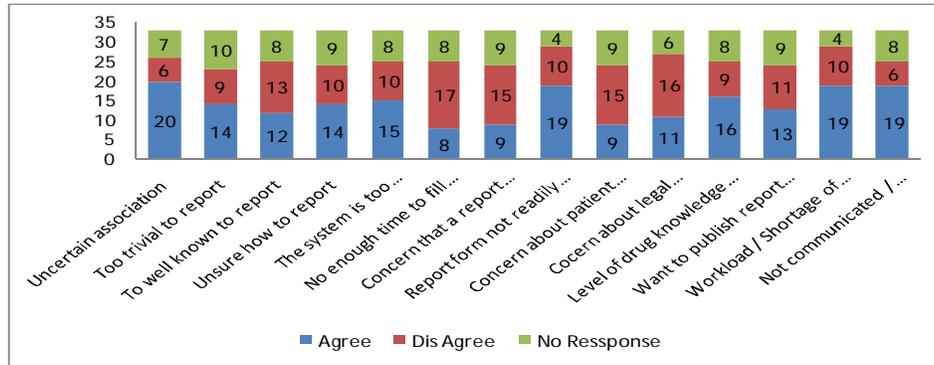


Figure 3: Factors Which Deter Doctors From Reporting ADRs

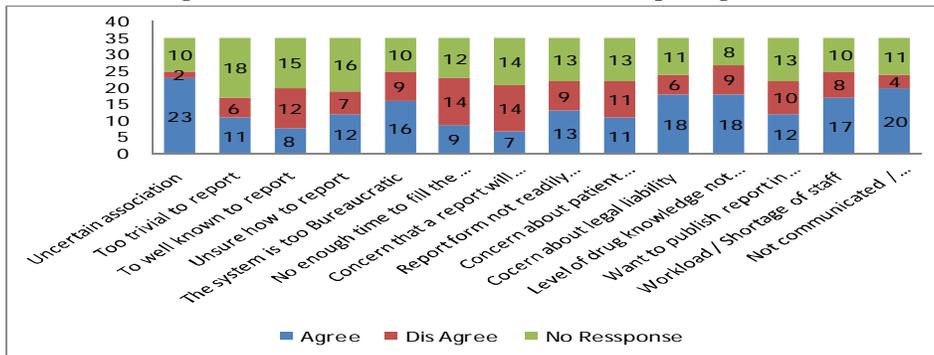


Figure 4: Factors Which Deter Pharmacists From Reporting ADRs

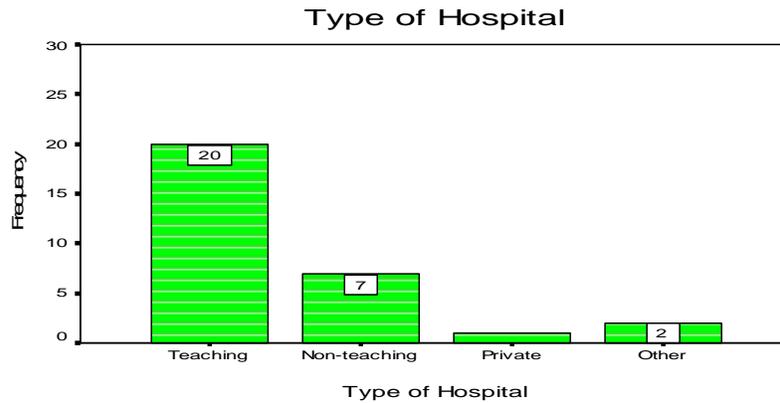


Figure 5: Frequency Distribution According to the Type of Hospital

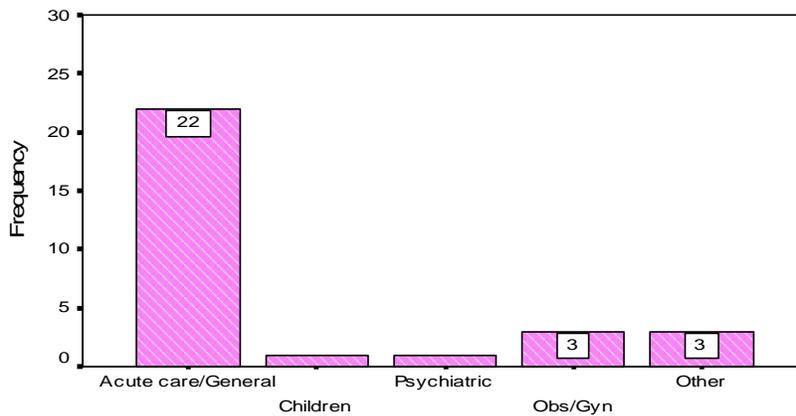
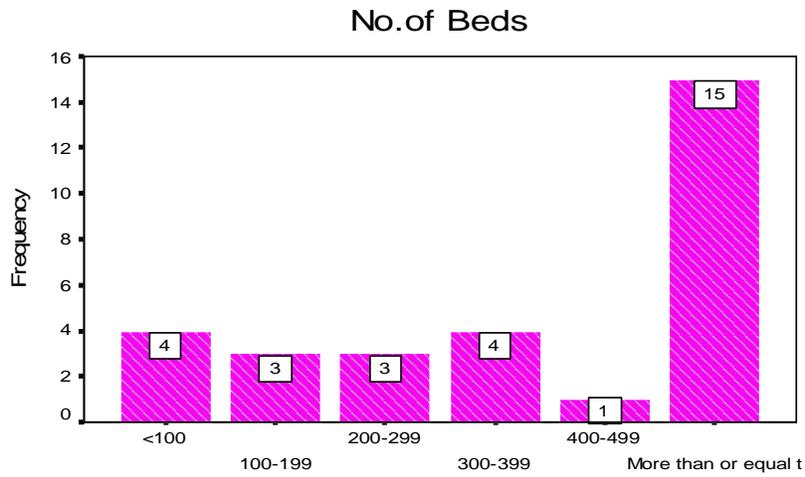
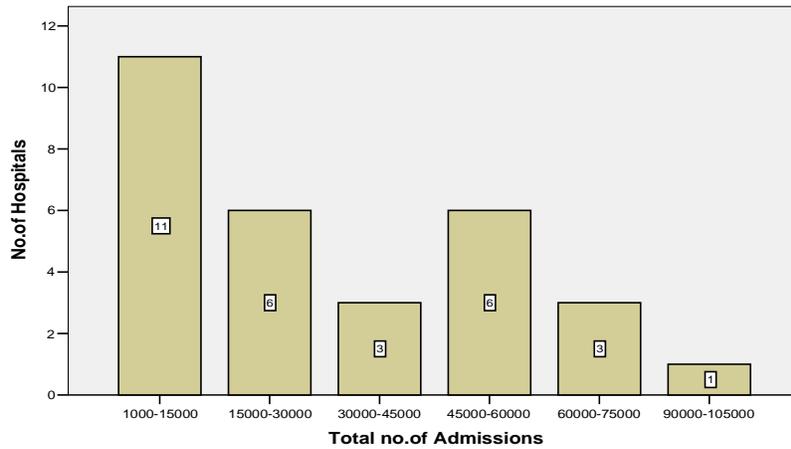


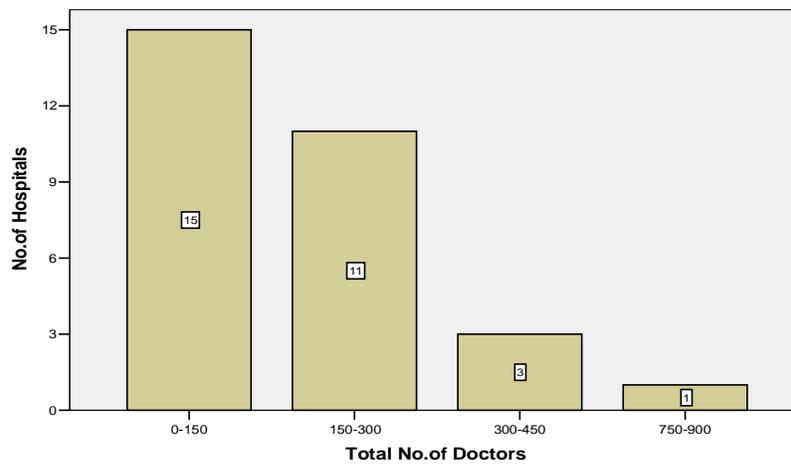
Figure 6: Frequency Distribution According to the Description of Hospital



**Figure 7: Frequency Distribution According to the No. of Beds**  
Total no. of Admissions



**Figure 8: Frequency Distribution According to the No. of Admissions**  
Total No. of Doctors



**Figure 9: Frequency Distribution According to the No. of Doctors in Each Hospital**

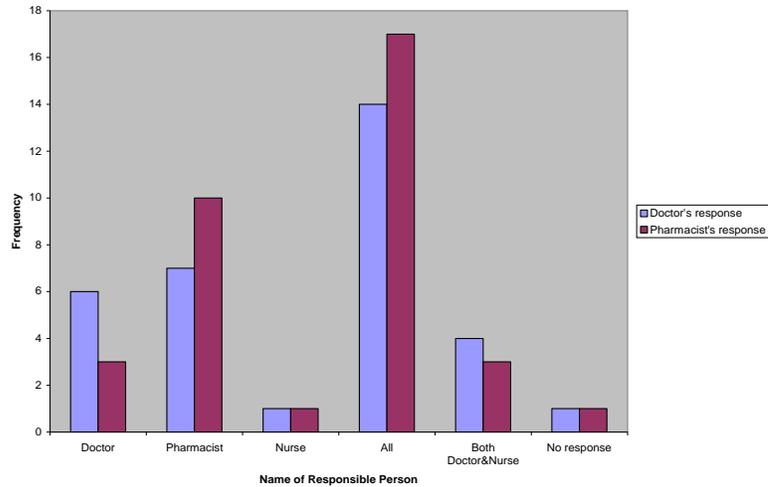


Figure 10: Comparison of Opinions of Doctors and Pharmacists About Documenting ADRs Reports

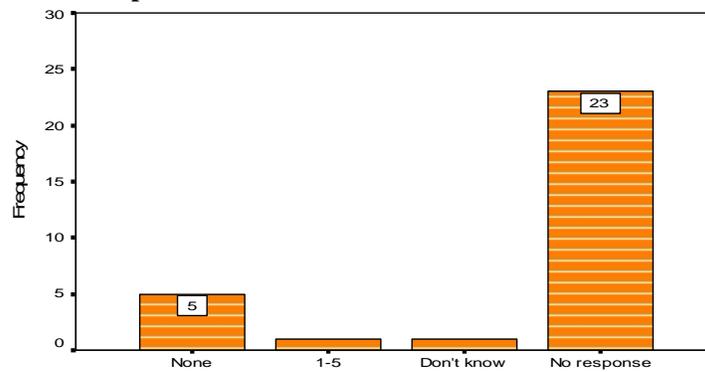


Figure 11: Number of ADRs Reports Submitted to Ministry of Health / Any Other Body/Year

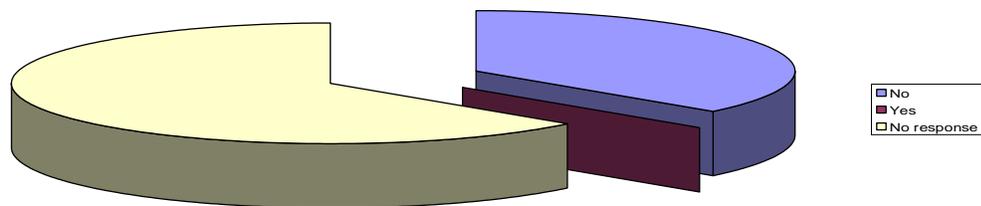


Figure 12: Summary of Feedback and Rewards for Reporting ADRs in Hospital

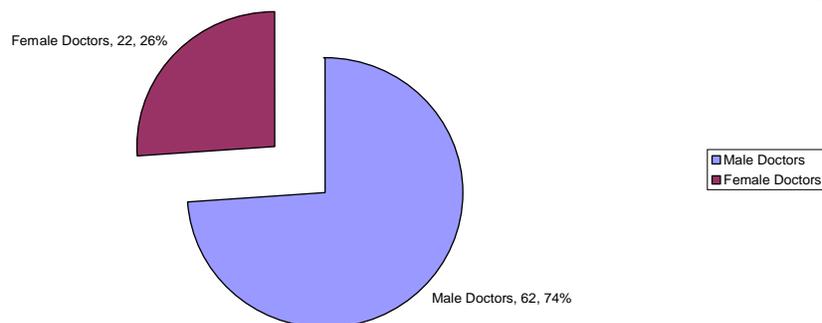


Figure 13: Gender of Doctor Respondents

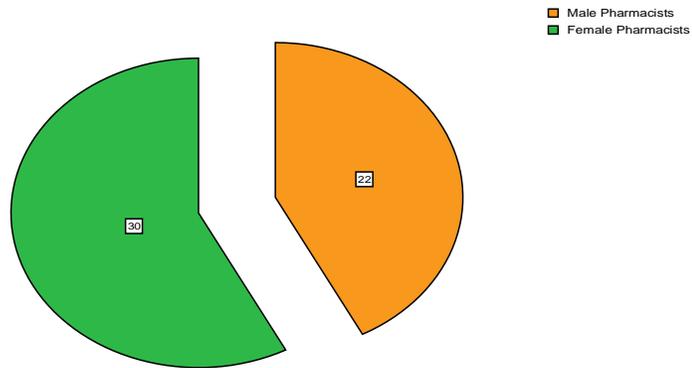


Figure 14: Gender of Pharmacist Respondents

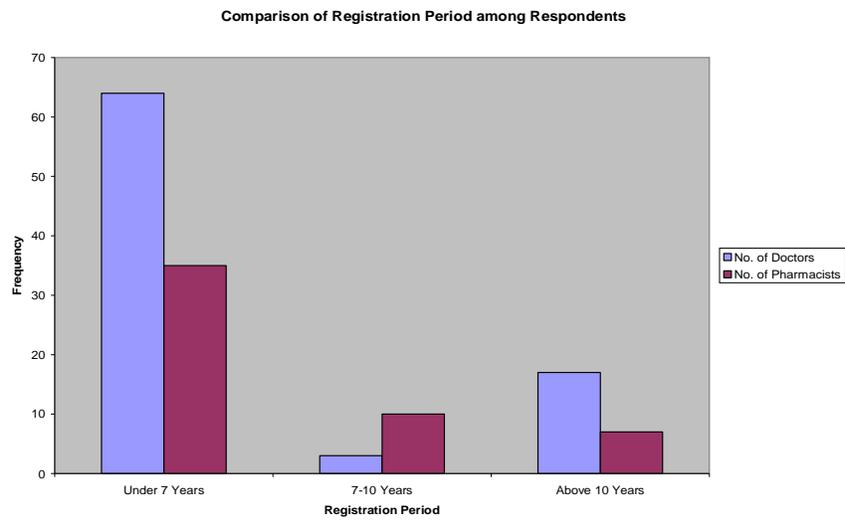


Figure 15: Comparison of Registration Period Among Respondents\

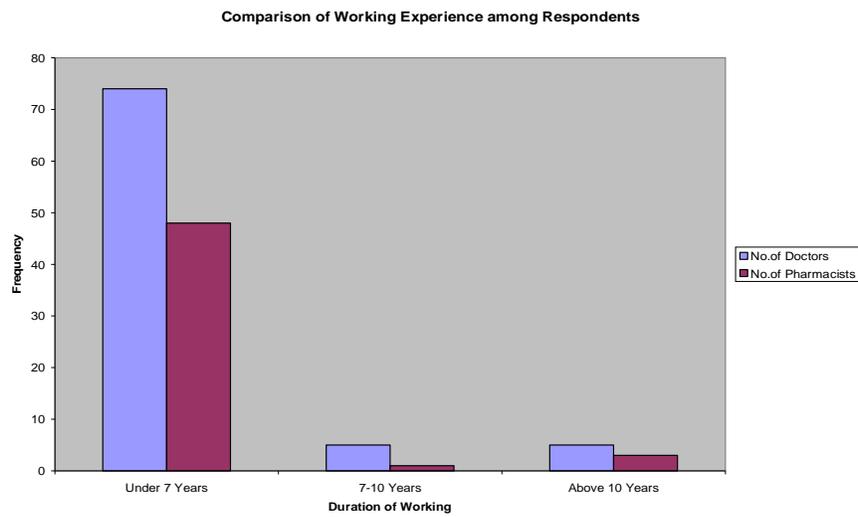


Figure 16: Comparison of Working Experience among Respondents

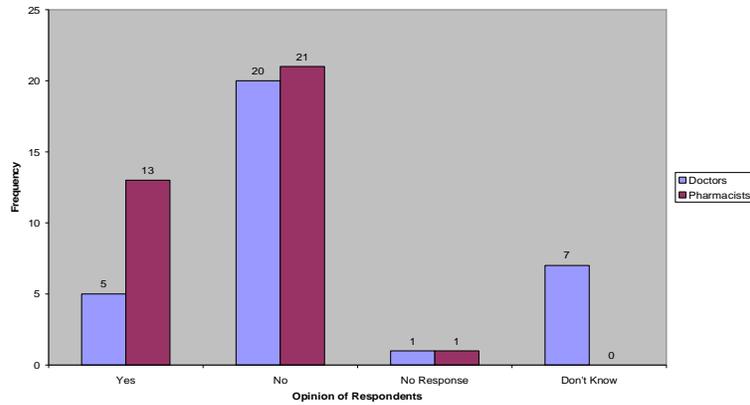


Figure 17: Comparison of Opinion of Respondents About the Adequacy of ADRs Reporting in the Hospital and Submitting to Ministry of Health

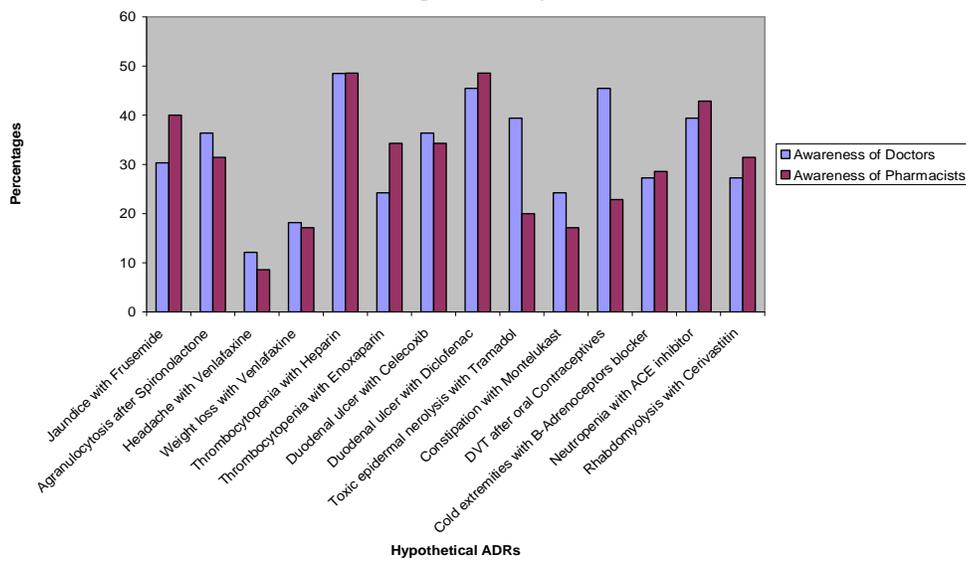


Figure 18: Comparison of ADRs Awareness among respondents

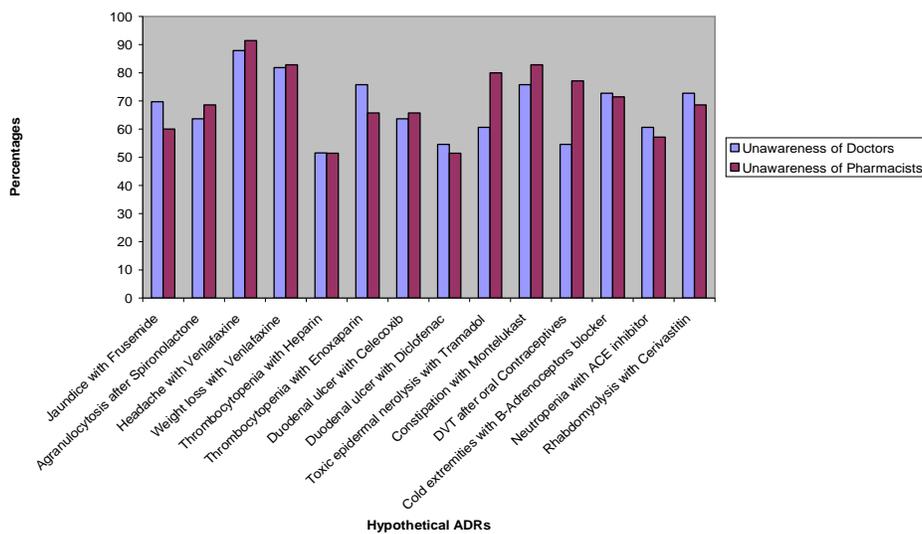


Figure 19: Comparison of ADRs Unawareness Among Respondents

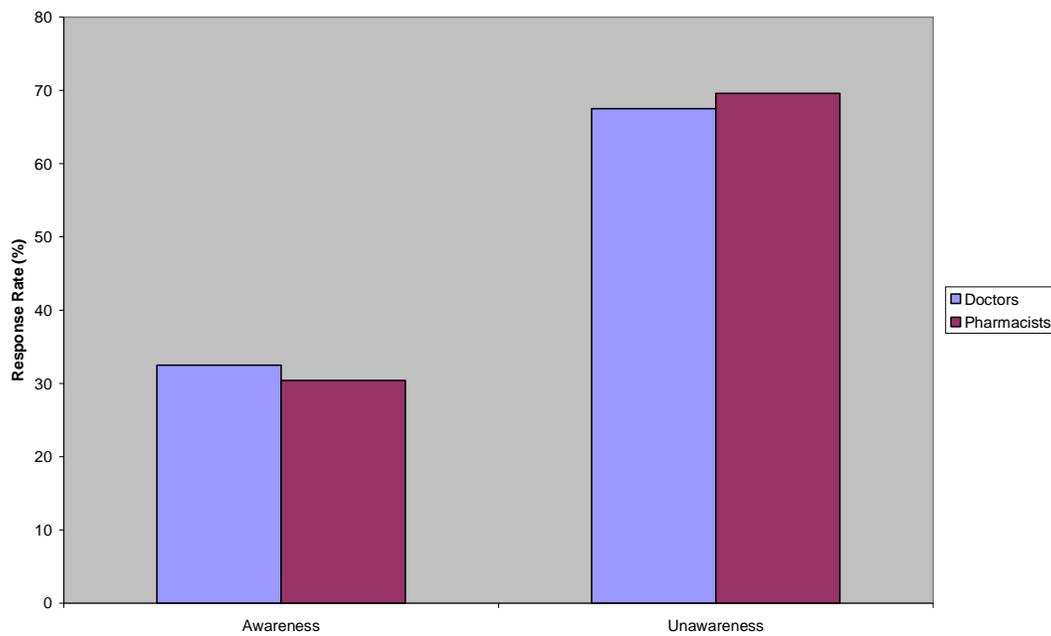


Figure 20: Comparison of ADRs Awareness & Unawareness Among Respondents

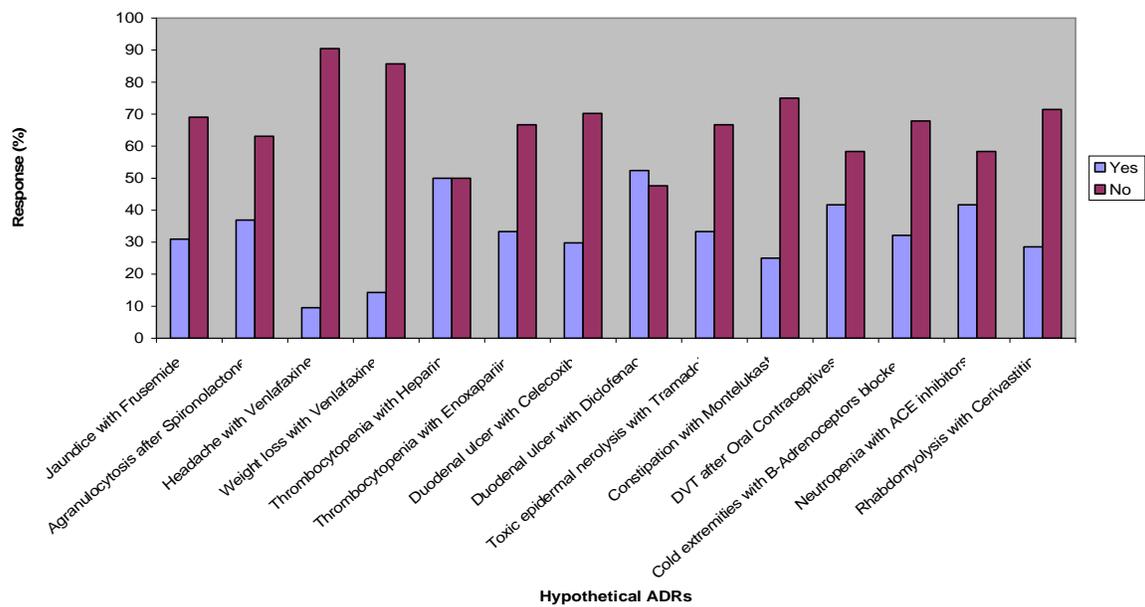


Figure 21: Doctor's Response About Hypothetical ADRs

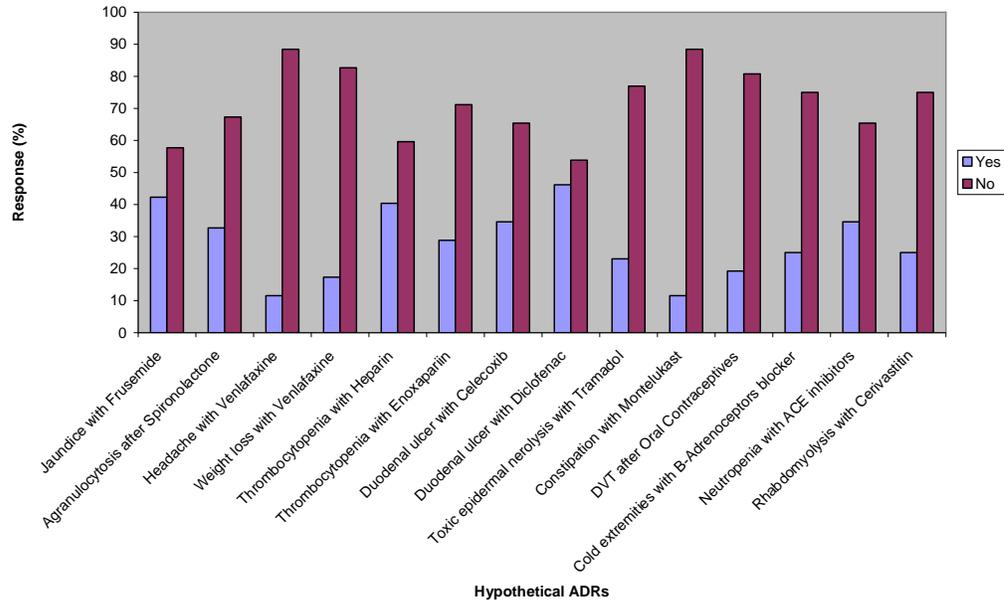


Figure 22: Pharmacist's Response About Hypothetical ADRs

Comparison of ADR awareness among Respondents

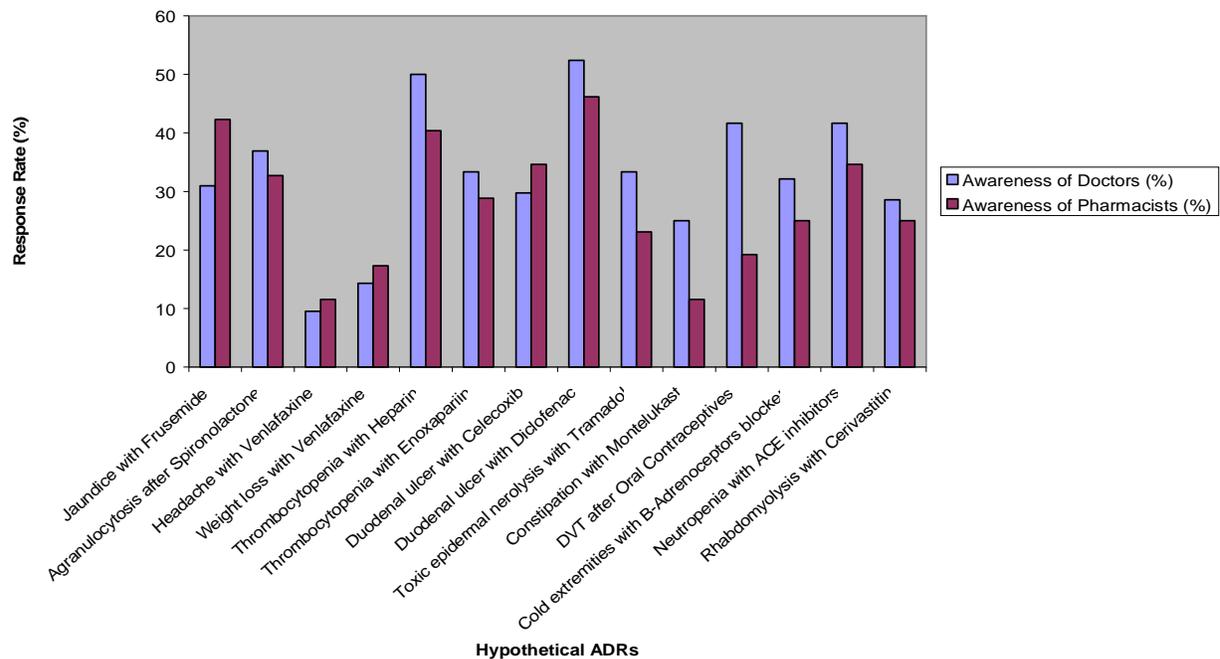


Figure 23: Overall Comparison of ADRs Awareness Among Respondents

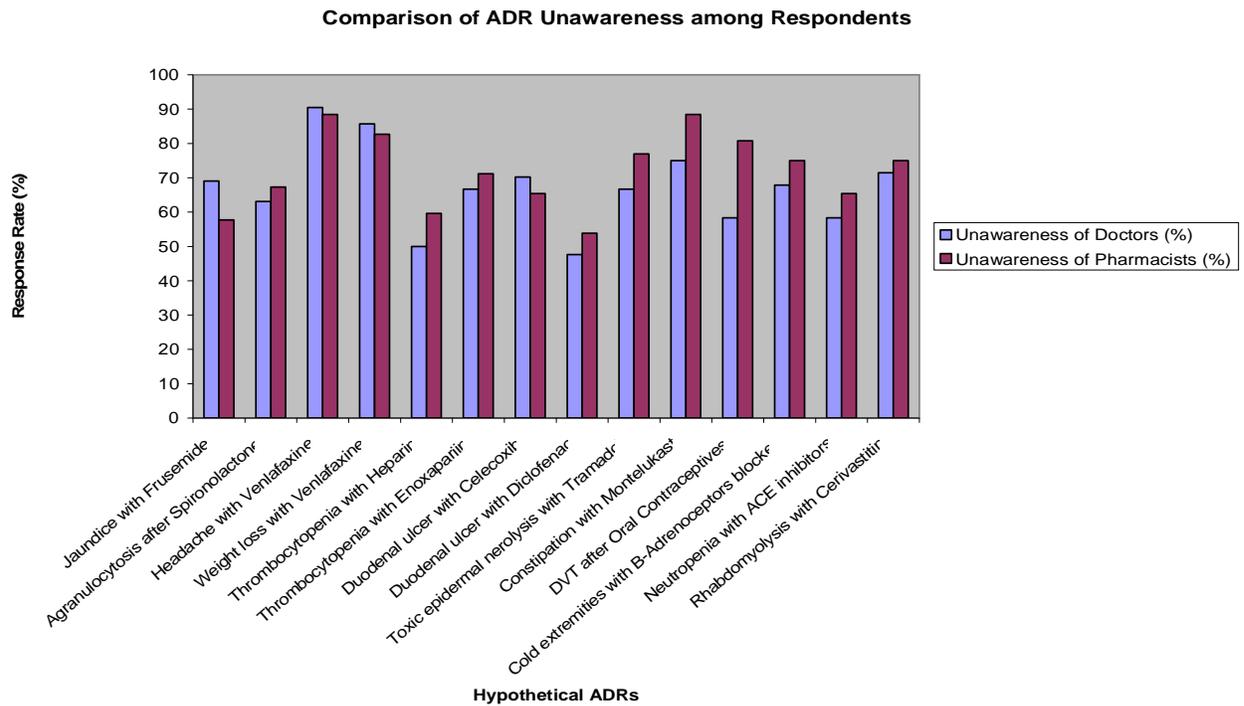


Figure 24: Overall Comparison of ADRS Unawareness Among Respondents

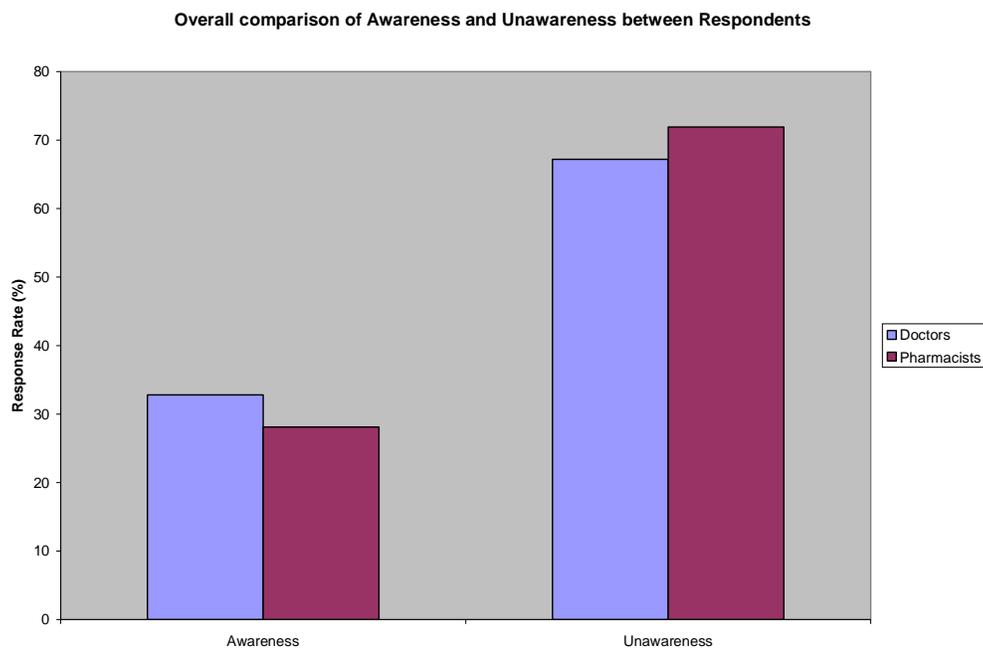


Figure 25: Overall Comparison of ADRS Awareness & Unawareness Among Respondents

Table 1: Frequency Distribution of Respondents

Name of Hospital	Total Pharmacists	Clinical Pharmacists	Total Doctors	Total Beds	No. of beds per Pharmacist
Mayo	43	30	847	1798	42
Services	7	0	430	1196	171
Sheikh Zayed	4	0	215	713	178
Jinnah	26	18	263	1250	48
Ganga Ram	3	0	400	768	256
L.G.H	9	0	250	706	78
Children	18	8	230	684	38
P.I.C	3	0	380	300	100
P.L.M.H	2	0	70	1400	700
Lady Aitchison	1	0	70	200	200
Lady Willingdon	1	0	150	350	350
Social Security	0	0	200	610	Nil
MianMunshi	2	1	45	130	65
Data Darbar	0	0	30	90	Nil
Railway Cairns	0	0	28	200	Nil
Wapda Hospital	2	0	55	250	125
ShaukatKhanum	13	4	130	96	7
Fatima Memorial	4	0	225	500	125
Shalimar	0	0	200	350	Nil
Fauji Foundation	1	0	50	200	200
HameedLatif	1	0	93	205	205
National Hospital	0	0	150	150	Nil
Ittefaq	1	0	210	312	312
Ghurki	0	0	150	450	Nil
Doctor's Hospital	2	0	72	180	90
Surgimed	0	0	95	114	Nil
Janki Devi	0	0	12	25	Nil
Ortho medical Complex	0	0	25	40	Nil
Ammar Medical Complex	0	0	32	30	Nil
Masood Hospital	1	0	10	40	40