STUDY OF DOCTORS FOR THEIR KNOWLEDGE, ATTITUDE AND PRACTICE FOR ADVERSE DRUG REACTION REPORTING IN GROUP HOSPITALS

Dissertation
at
IIHMR University, Jaipur

By
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Under the Guidance of
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MBA Pharmaceutical Management
2013-2015

Institute of Health Management Research,
Jaipur
2015

INSTITUTE OF HEALTH MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

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TO WHOM IT MAY CONCERN

This is to certify that the Ms. Samridhi Shri Gaur student of MBA Pharmaceutical Management 2nd year Batch (2013-15), IIHMR University, Jaipur is been working as field investigator for the project title "A study of key stakeholders for their knowledge, attitude & practice for Adverse Drug Reaction reporting in tertiary care hospitals in Jaipur District" from a period of 10th February 2015 to 12th May 2015. She is been involved in the preparation of tools, approval of hospitals and data collection in two major tertiary care hospitals in Jaipur district.

She has successfully carried out her part of work during this period. I wish him success for his future.

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This is to certify that SAMRIDHI SHRIGAUR student of MBA Hospital and Health Management from IIHMR University, Jaipur has undergone internship training at IIHMR University from 2014to2015.

The Candidate has successfully carried out the study designated to her during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

Col.(Dr)Ashok Kaushik

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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation title A study of doctors for their Knowledge,Attitude& Practice for ADR Reporting in group hospitals in Jaipur. and submitted by Samridhi Shrigaur. Enrollment No. 202 under the supervision of Dr.Sandeep Narula for award of MBA Pharmaceutical Management of the university carried out during the period from February 2015 to May 2015 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Signature 18/5/15

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Literature Review

It is known that the primary goal of medicines prescribed by the doctor is, individual benefit of the patient with minimum risk leading to overall improvement in the public health. But it is also true that no drug can be considered safe unless it is also proven effective in its intended use .

An adverse drug reaction can be defined as"an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment ,or alteration of the dosage regimen ,or withdrawal of the product .Such reaction are currently reported by use of the WHO's Adverse Reaction Terminology, which will eventually become a subset of the International Classification of Disease. Adverse drug reaction are classified into six types(with mnemonics):dose-releated(Augmented),non-dose-releated(Bizarre),dose- releated and time releated (Delayed), withdrawl (End of use), and failure of therapy (Edwards IR,2000). ADRs contribute to a significant number of morbidity and motality all over the world. ADR can be seen in clinical practice with both new as well as marketed medicines(WHO,2006)

The ADR reporting can be either voluntary or obligatory as per WHO (ICH) guidelines, but such process is not followed properly in practice keeping in view the low number of reporting in developing and underdeveloped nations(WHO,2006).Spontenous reporting of ADR is commonly practiced method for monitoring of ADR. Healthcare practitioners have an important role in Pharmacovigilance and Adverse drug reaction (ADR)reporting.

Many studies have been conducted to understand the knowledge ,attitude and practice of ADR reporting among doctors in india .(Manoj Goyal, August 2013) in the current scenario,the adverse consequences of the drug are detected in the early stage of drug development.
Recent published data suggest the less number of ADR cases reported by various PV center in major cities compared to rest of the world which indicate low awareness, knowledge, inadequate practice of ADR reporting is the region.

The current prevailing incidence of serious ADRs is 6.7% in india (Desai CK,2011).Adverse drug reaction constitute a significant health problem with consequence for the patient as well as for society. Supposed ADRs have been reported to occur in about 2-4% of hospitals patients.

Objectives

- To study knowledge, attitude and practices of doctors for ADR reporting of marketed drugs
- To suggest possible solutions, if required.

STUDY DESIGN

Regarding the study a doctor survey is designed which will be moreover a descriptive study for adverse effect reporting of marketed drugs in the hospitals. This study will further help for developing a system within hospital to report an ADR and provide ADR information sheets in Hospital . Study Design

Methodology

This study was a descriptive study with non-probability convenience sampling .80 doctors were taken as study sample in Jaipur hospital structured questionnaire containing questions regarding ADR reporting It was a quantitative study and analysis was carries around using SPSS.

Timeline

The study has been done in four stages first stage was the preparation tools for doctor survey which was expected to be complete in fifteen working days. Second stage (twenty) days for approval of hospitals. Third stage (forty five days) for pretesting of tools in the hospital and on the basis of pretesting make the changes in tools, finally updated tools was use to collect the primary data from doctors. fourth stage (ten days) for research proposal writing & presentation making.

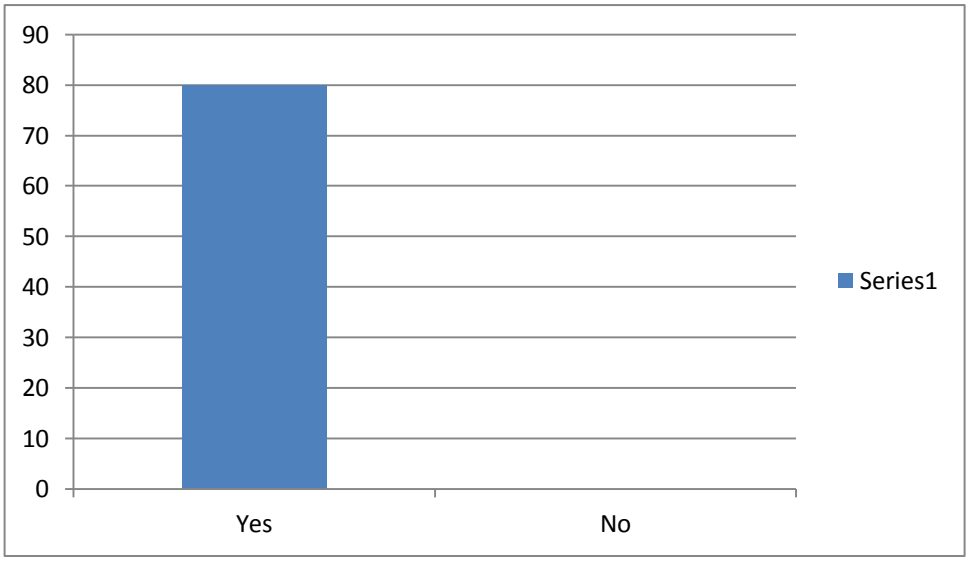
Doctor Survey

Result and Findings

(1)Have you heard the term Adverse Drug Reaction (ADR)?

Table no 1.1

Total respondents	Yes	No
80	80	0



Graph no 1.1

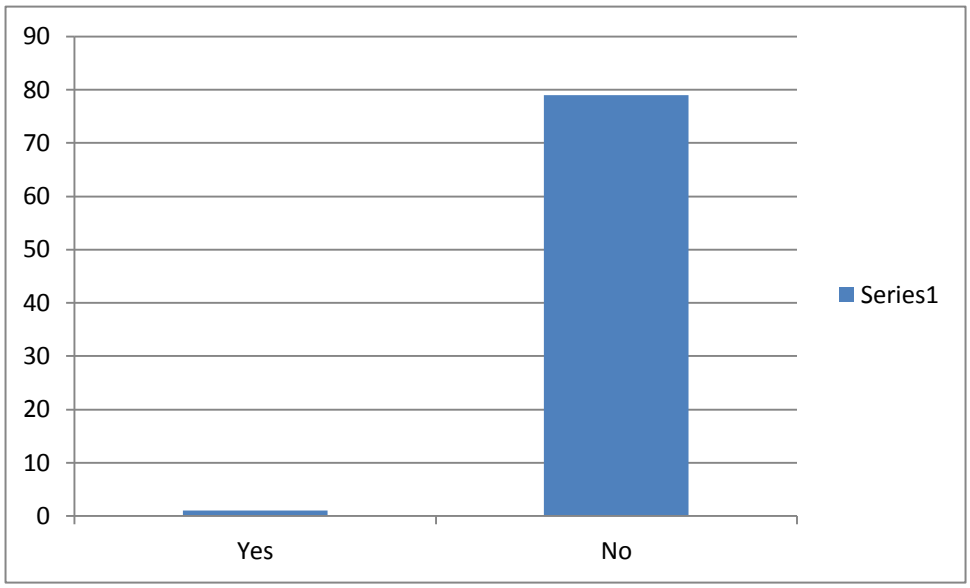
Findings:

As per the analysis of above graph no 1.1 eighty doctor heard the term Adverse drug reaction).

(2)Is adverse drug reaction is same as side effect?

Table no 1.2

Total respondents	Yes	No
80	1	79



Graph no 2.1

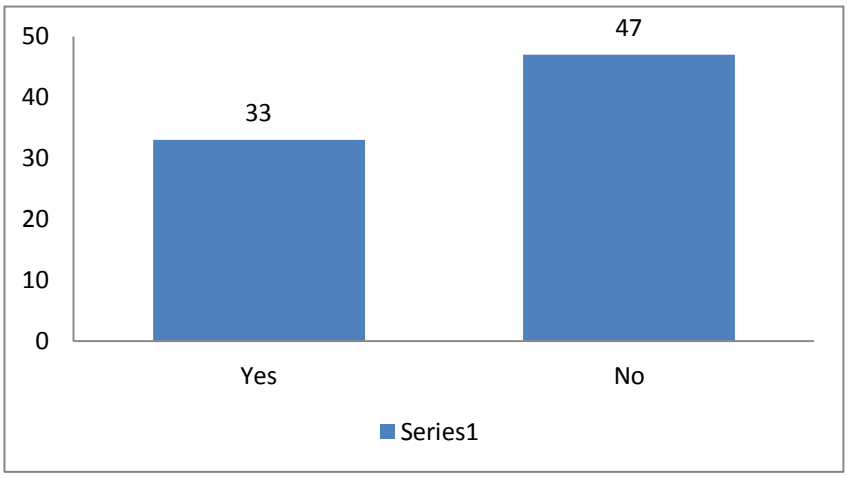
Findings:

As per the analysis of above graph no 2.1 seventy nine doctor not agreed on adverse drug reaction is same as side effect but one doctor agreed on adverse drug reaction is same as side effect.

(3)Have you heard about ADR reporting system in India?

Table no 1.3

Total respondents	Yes	No
80	33	47



Graph no 3.1

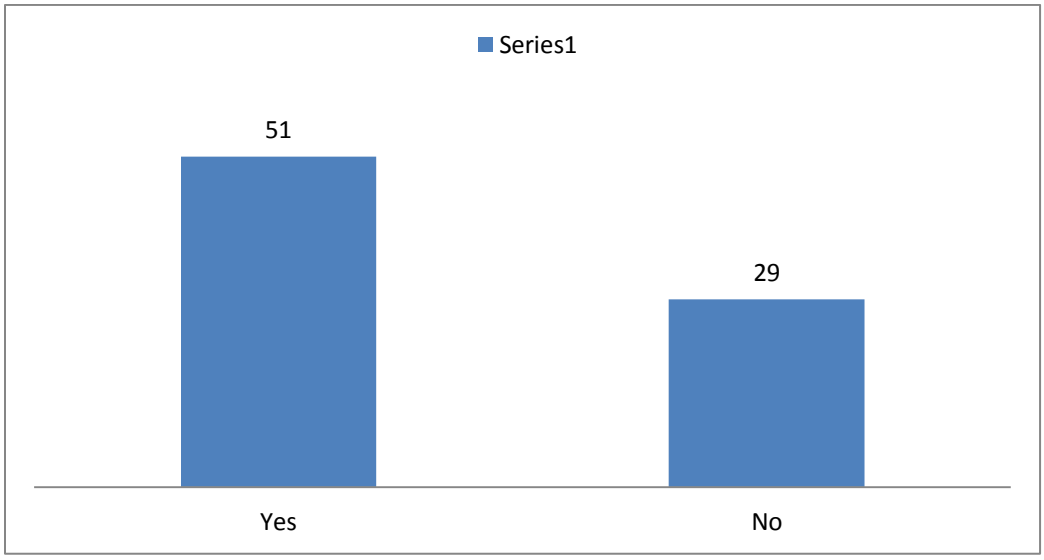
Findings:

As per the analysis of above graph no 3.1 thirty three doctor heard about ADR reporting system in India but fourty seven doctor had not heard ADR reporting system in india.

(4)Have you ever encountered patient with ADR in your clinical practice, in the last 12 months?

Table no 1.4

Total respondents	Yes	No
80	51	29



Graph no 4.1

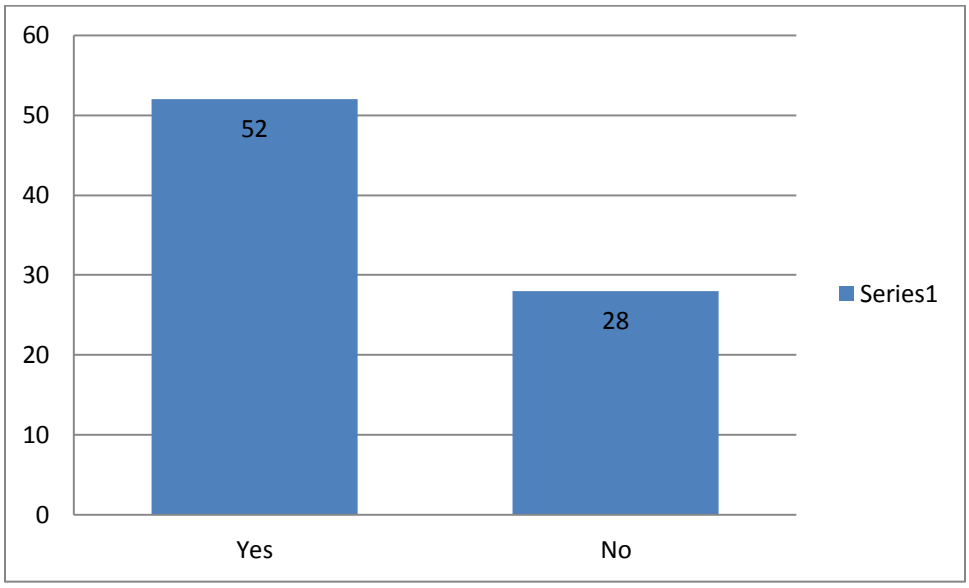
Findings:

As per the analysis of above graph no 4.1 fifty one doctor was encountered patient with ADR in their clinical practice and twenty nine doctor did notencountered patient with ADR in their clinical practice.

(5)Do you record the ADRs encountered in your practice?

Table no 1.5

Total respondents	Yes	No
80	52	28



Graph no 5.1

Findings:

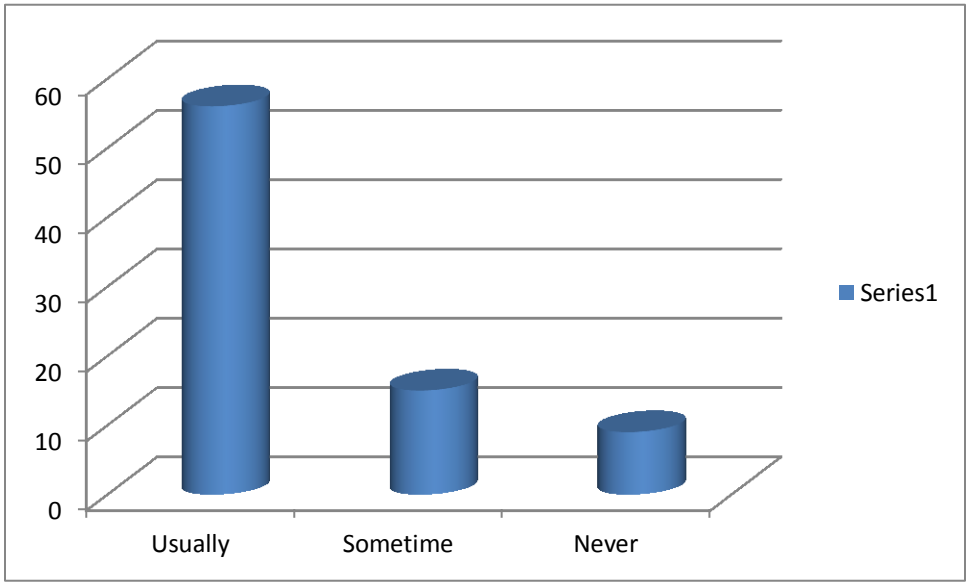
As per the analysis of above graph no 5.1 fifty two doctor record the ADRs encountered in their practice but twenty eight doctor did not record ADR in their practice .

(6)How often you report any ADRs?

Table no 1.6

G

Total respondents		Usually	Sometime	Never
80	56	15	9	



Graph no 6.1

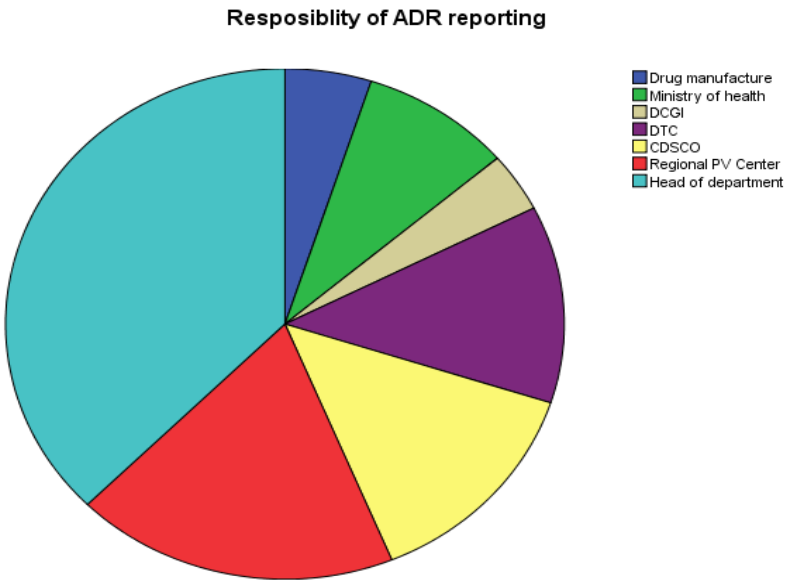
Findings:

As per the analysis of above graph no 6.1 fifty six doctor usually report ADR and fifteen doctor sometime report ADR ,only nine doctor never report ADR.

(7)To whom ADRs should be reported?

Table no 1.7

Total respondents	Drug manufacture	Ministry of health	DCGI	DTC	CDSCO	Regional PV center	Head of department
80	4	7	3	10	11	15	30



Graph no 7.1

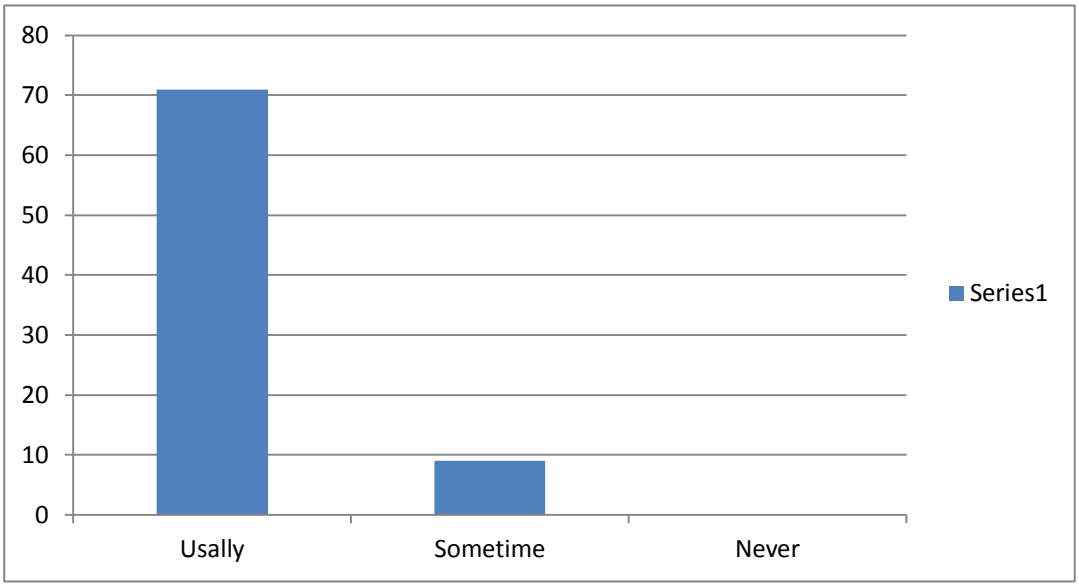
Findings:

As per the analysis of above graph no 7.1 thirty doctor given the preference Head of department,fifteen doctor given the preference Regional PV center and remaining doctors given the preference CDSCO, DTC, DCGI, Ministry of health, Drug manufacture.

(8)How often do you give advice to your patients on possible drug- drug or drug-food interactions?

Table no 1.8

Total respondents	Usually	Sometime	Never
80	71	9	0



Graph no 8.1

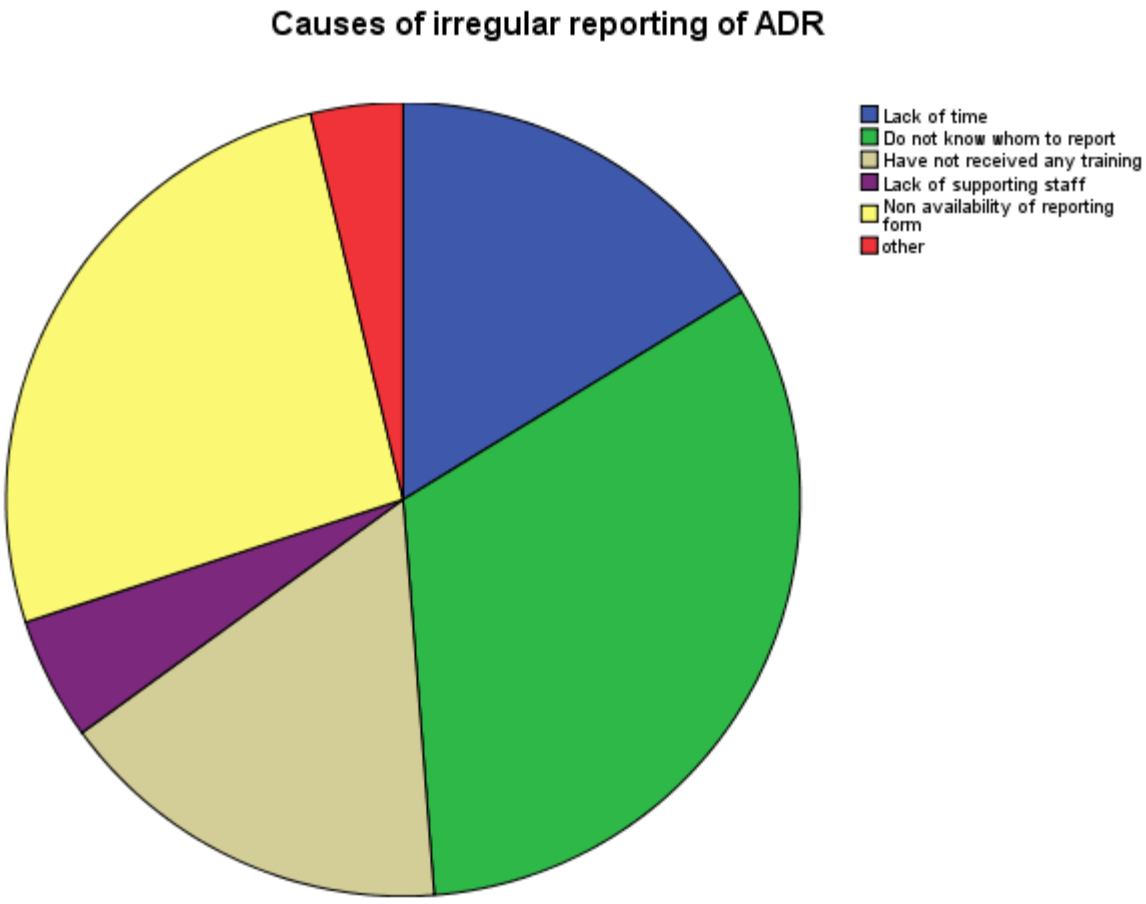
Findings:

As per the analysis of above graph no 8.1 seventy one doctor usually give advice to patients on possible drug- drug or drug- food interactions and nine doctor sometime give advice patients on possible drug- drug or drug- food.

(9)According to you, what are the main causes of irregular reporting of ADRs?

Table no 1.9

Total respondents	Lack of time	Do not know whom to report	Have not received any training	Lack of supporting staff	Non availability of reporting form	Other
80	13	26	13	4	21	3



Graph no 9.1

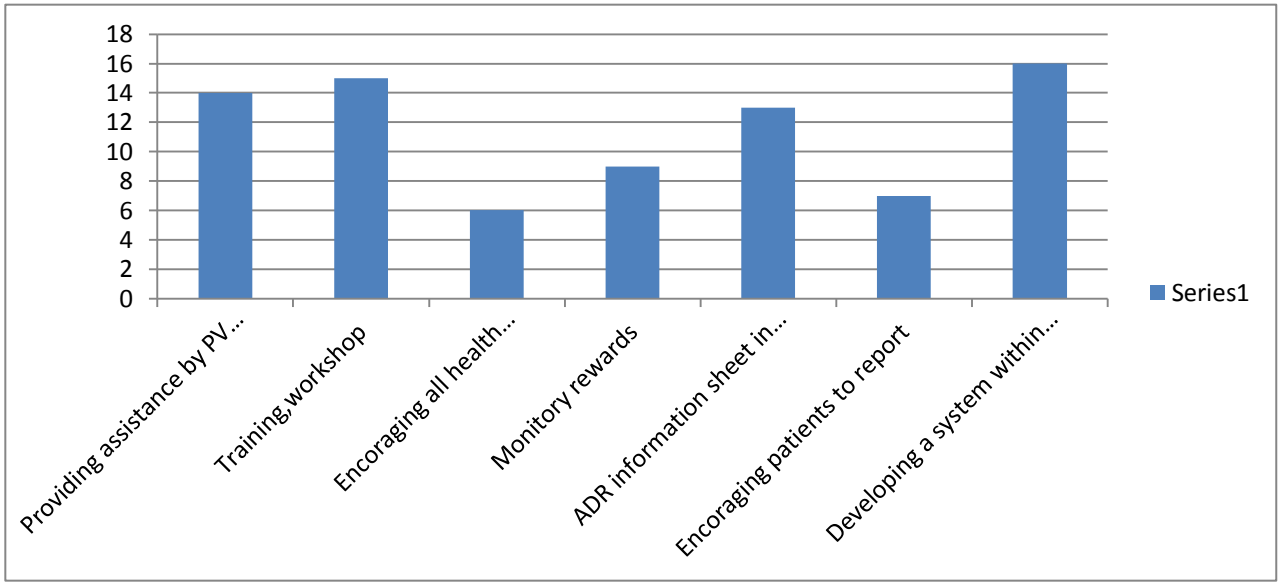
Findings:

As per the analysis of above graph no 9.1 twenty six doctor was agreed on Do not know whom to report and twenty one doctor agreed on Non availability of reporting form, thirteen doctor agreed on Lack of time, Have not received any training and four doctor agreed on Lack of supporting staff, three doctor given the other reason of irregular reporting.

(10)According to you, what are the possible ways to promote ADR reporting in India?

Table no 2.1

Total Respondent	Providing assistance by PV center	Training,workshop	Encoraging all health professional to report	Monitory rewards	ADR information sheet in hospital	Encoraging patients to report	Developing a system within hospital to report an ADR
80	14	15	6	9	13	7	16

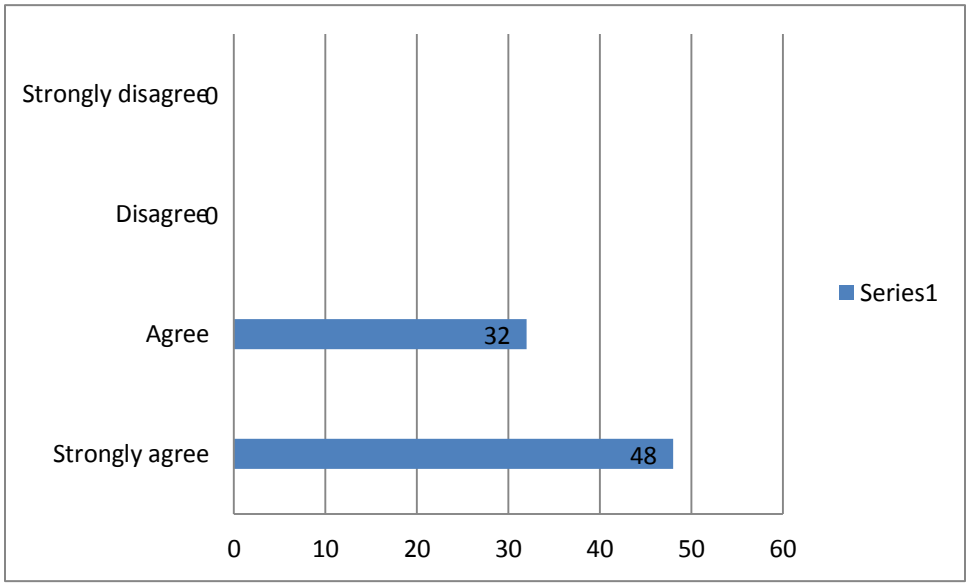


Graph no 10.1

Findings:

As per the analysis of above graph no 10.1 sixteen doctor was give preference to developing a system within hospital to report an ADR, fifteen doctor was give preference to Training, workshop and fourteen doctor was give preference to providing assistance by PV center, thirteen doctor was give preference to ADR information sheet in hospital, nine doctor was give preference to monitory rewards,seven was give preference to encouraging patient to report, ,six was give preference to encouraging all health professional to report.

(11)ADR reporting to be practiced regularly?

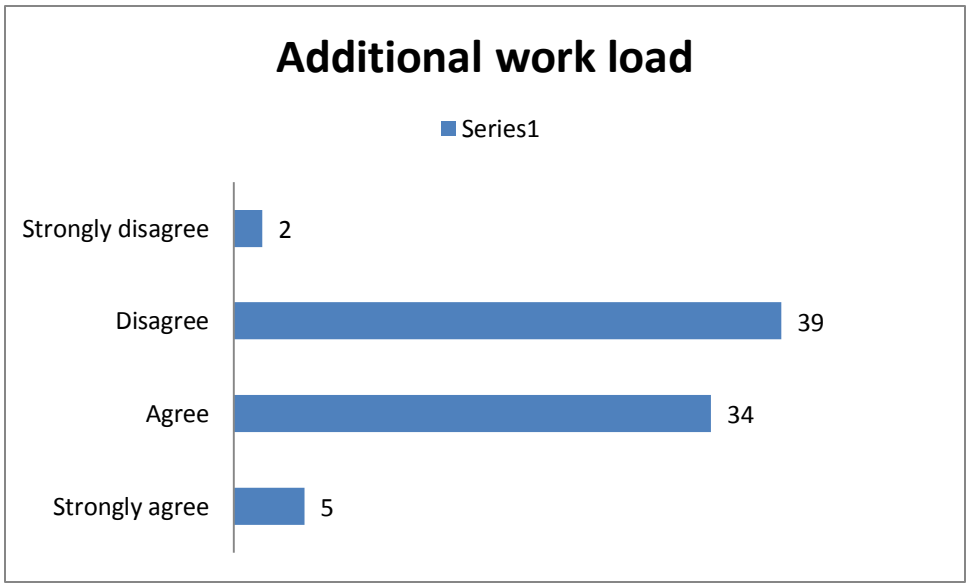


Graph no 11.1

Findings:

As per the analysis of above graph no 11.1 fourty eight doctor was strongly agree and thirty two doctor was agree on ADR reporting to be practiced regularly

(12)Reporting creates additional work load?

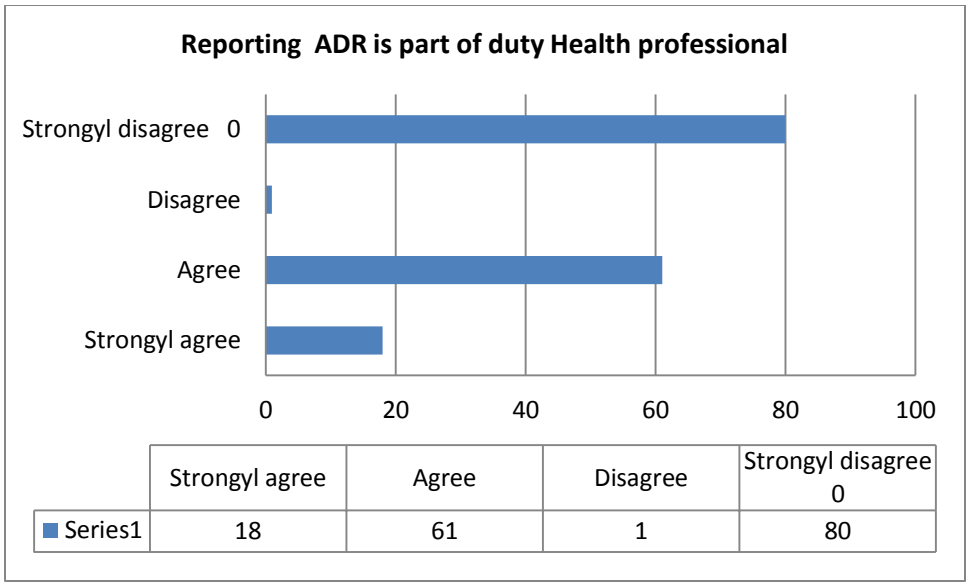


Graph no 12.1

Findings:

As per the analysis of above graph no 12.1 thirty nine doctor was disagree and thirty four doctor was agree,five doctor strongly agree and two doctor doctor was strongly disagree on reporting create additional work load.

(13)Reporting ADR is part of duty of Health professionals?

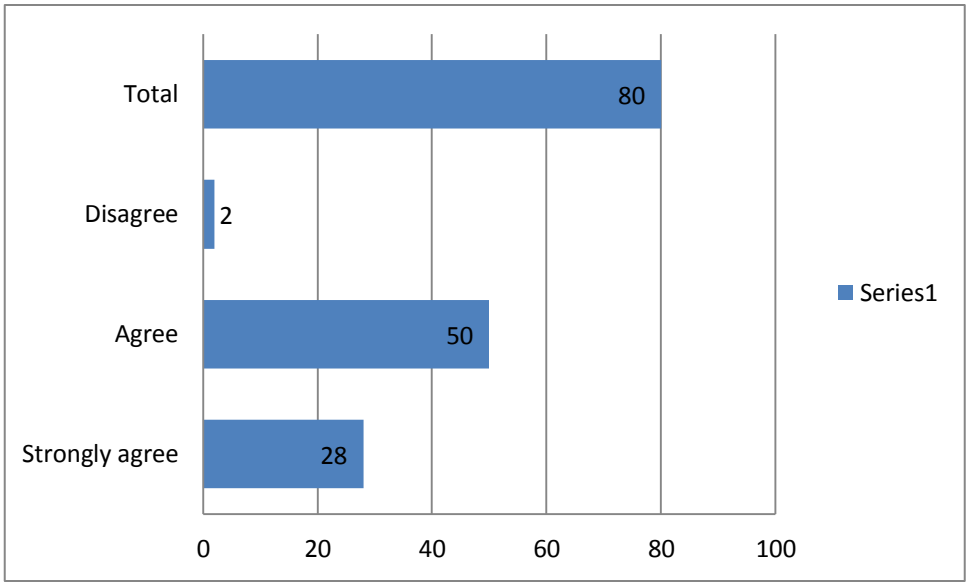


Graph no 13.1

Findings:

As per the analysis of above graph no 13.1 sixty one doctor was agree and eighteen doctor strongly agree, only one doctor was disagree on Reporting ADR is part of duty of Health professionals.

(14)Reporting about 'drug safety' is important?

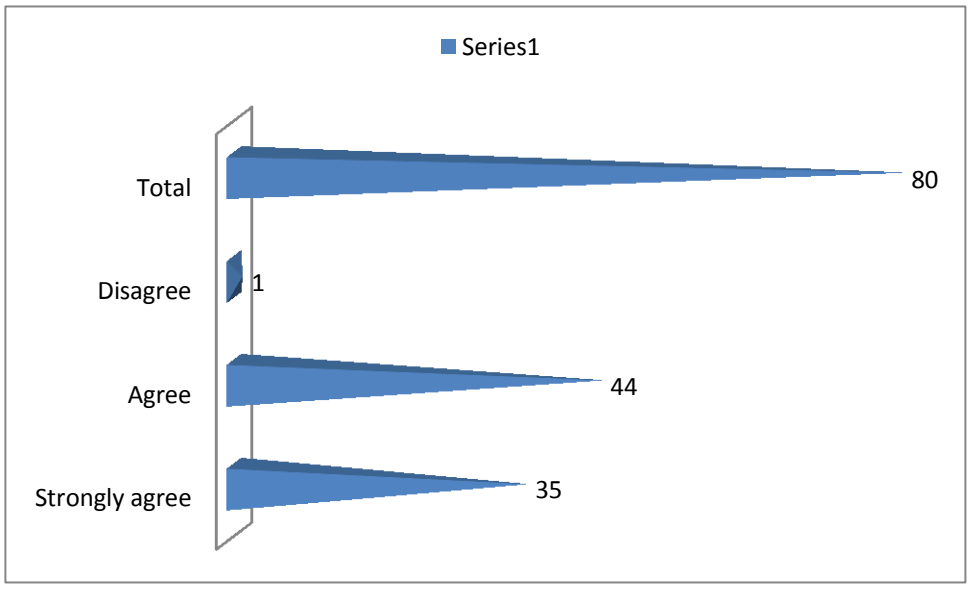


Graph no 14.1

Findings:

As per the analysis of above graph no 14.1 fifty doctor was agree ,twenty eight doctor strongly agree and two doctor was disagree on Reporting about 'drug safety' is important

(15)Reporting is beneficial to the patient?

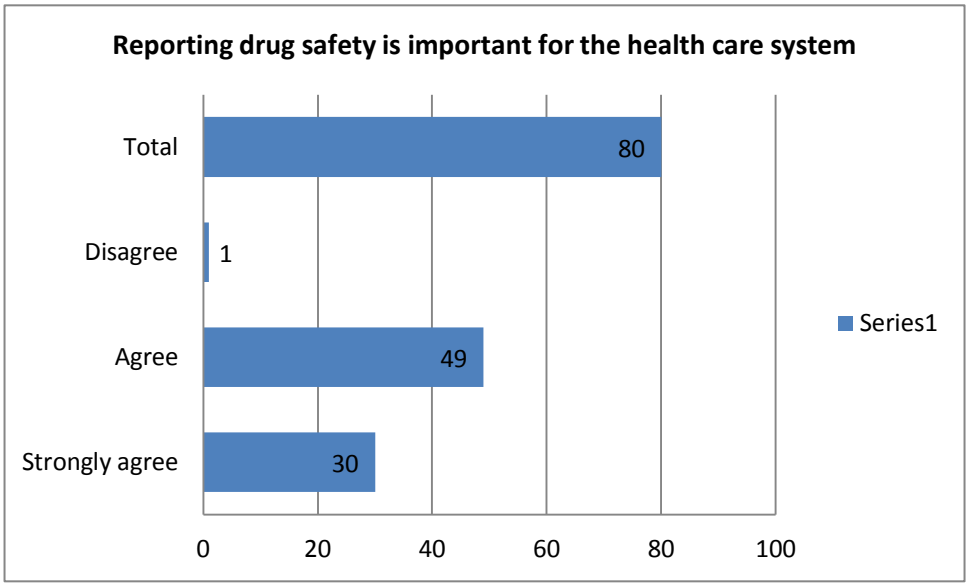


Graph no 15.1

Findings:

As per the analysis of above graph no 15.1 fourty four doctor was agree and thirty five was strongly agree and one doctor was disagree on reporting is beneficial to the patient.

(16)Reporting drug safety is important for the health care system?

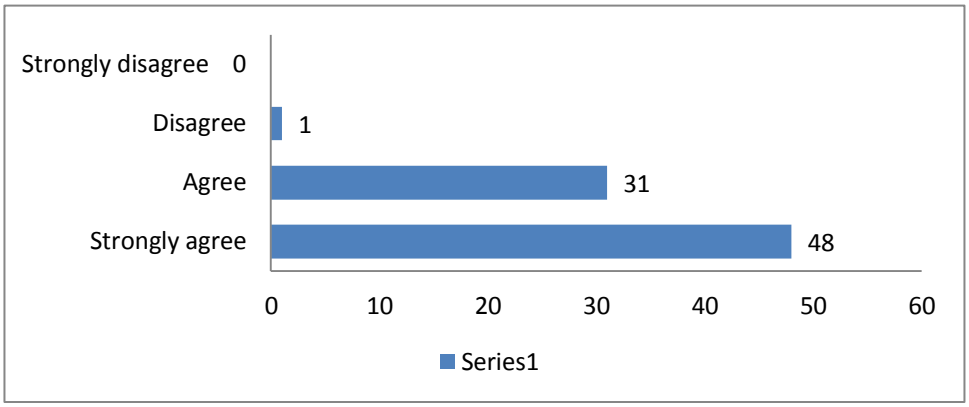


Graph no 16.1

Findings:

As per the analysis of above graph no 16.1 fourty nine doctor was agree and thirty doctor was strongly agree only one doctor was disagree on Reporting drug safety is important for the health care system

(17)There is a need to be sure, that specific ADR is related to a drug, before reporting?

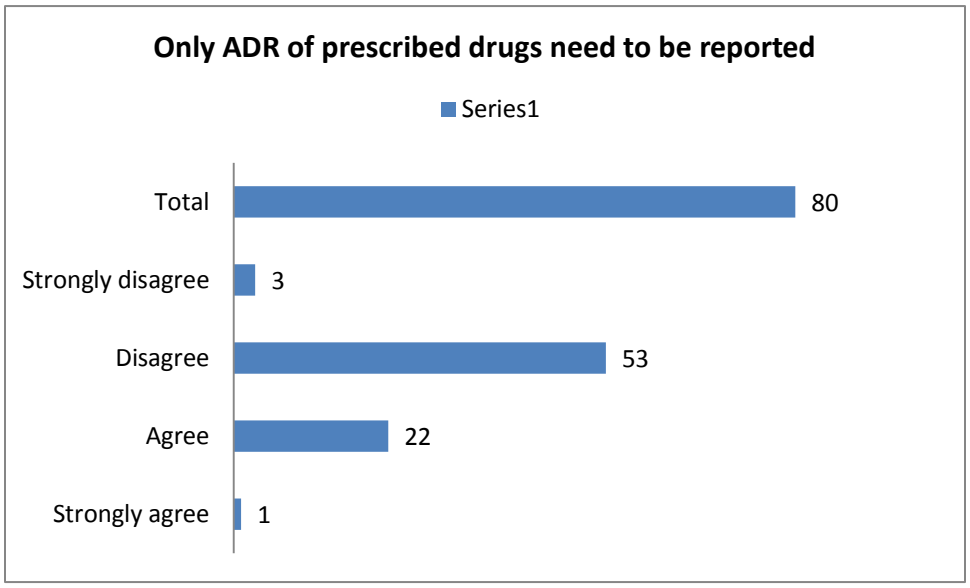


Graph no 17.1

Findings:

As per the analysis of above graph no 17.1 fourty eight doctor was strongly agree and thirty one doctor was agree on there is a need to be sure, that specific ADR is related to a drug, before reporting.

(18)Only ADR of prescribed drugs need to be reported?

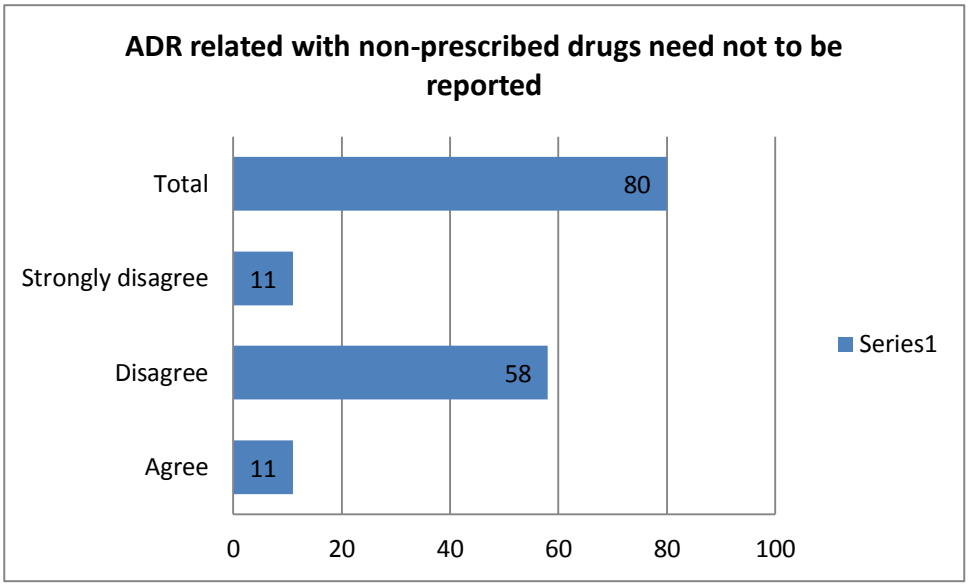


Graph no 18.1

Findings:

Out of eighty doctor fifty three was disagree and three was strongly disagree ,twenty two was agree only one doctor was strongly agree on Only ADR of prescribed drugs need to be reported.

(19)ADR related with non-prescribed drugs need not to be reported?

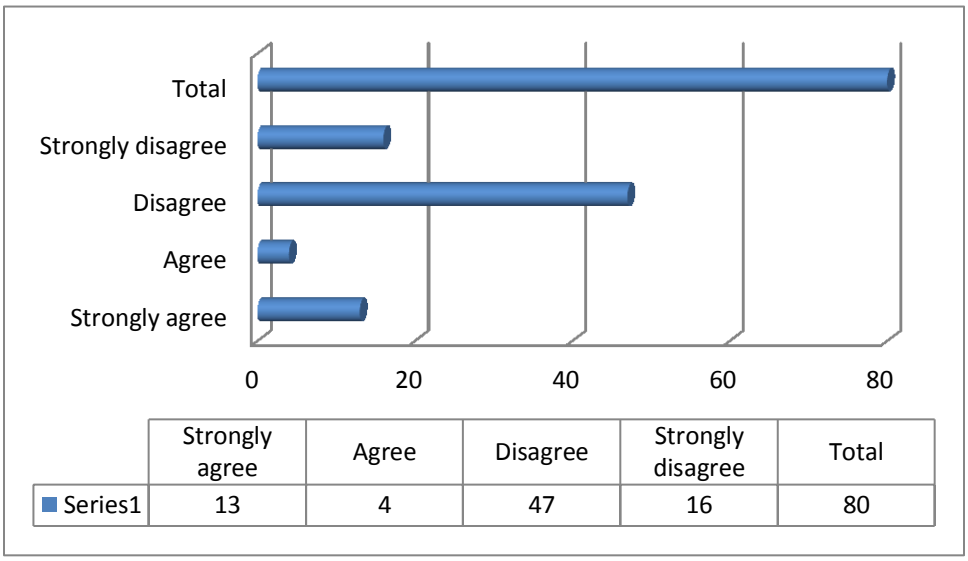


Graph no 19.1

Findings:

Out of eighty doctor fifty eight was disagree and eleven was strongly disagree and agree on ADR related with non-prescribed drugs need not to be reported

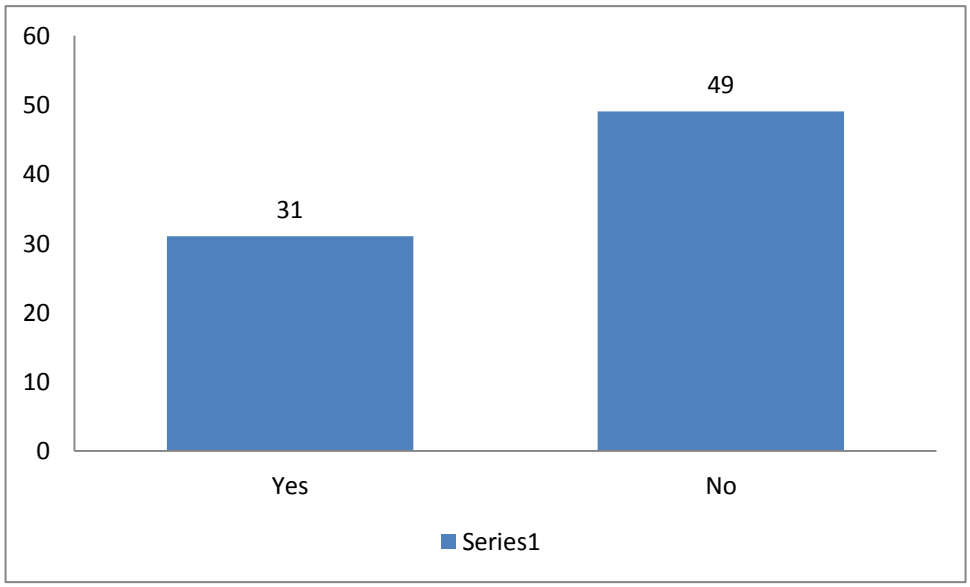
(20)Only ADR that cause persistent disability should be reported?



Findings: : Out of eighty doctors fourty seven was disagree ,sixteen was agree but thirteen was strongly agree and four was agree on ADR that cause persistent disability should be reported

(21)Is the ADR reporting form available in your organization? Graph no 20.1 Table no 2.2

Total respondents	Yes	No
80	31	49



Graph no 21.1

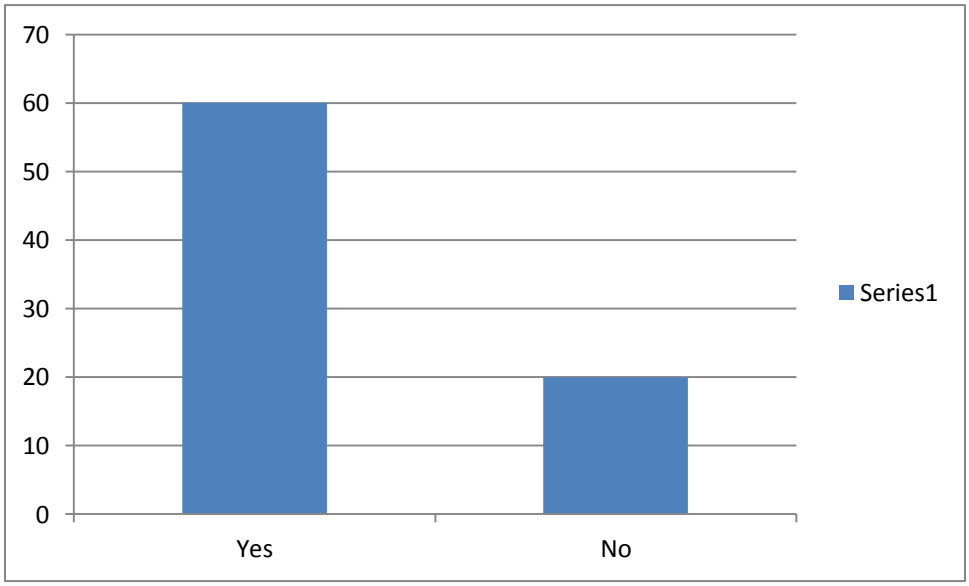
Findings:

Out of eighty doctor thirty one was know but fourty nine was not know the ADR reporting form available in their organization.

(22) Is ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'?

Table no 2.2

Total respondents	Yes	No
80	60	20



Graph no 22.1

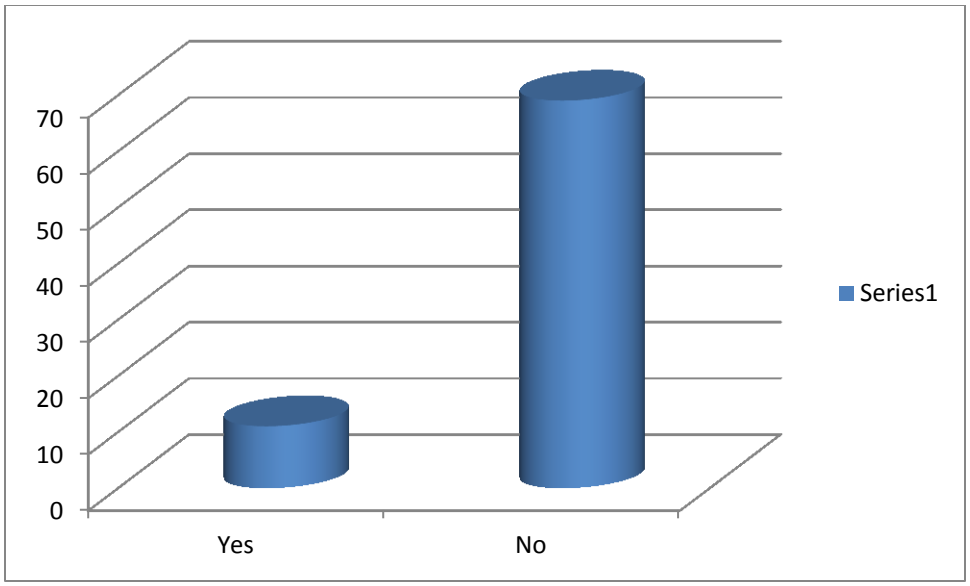
Findings:-

As per the analysis of above graph no 22.1 sixty doctor was give the positive response but twenty doctor was give the negative response on ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'.

(23)Have you had undergone any workshop/training specifically related to ADR reporting?

Table no 2.3

Total respondents	Yes	No
80	11	69



Graph no 23.1

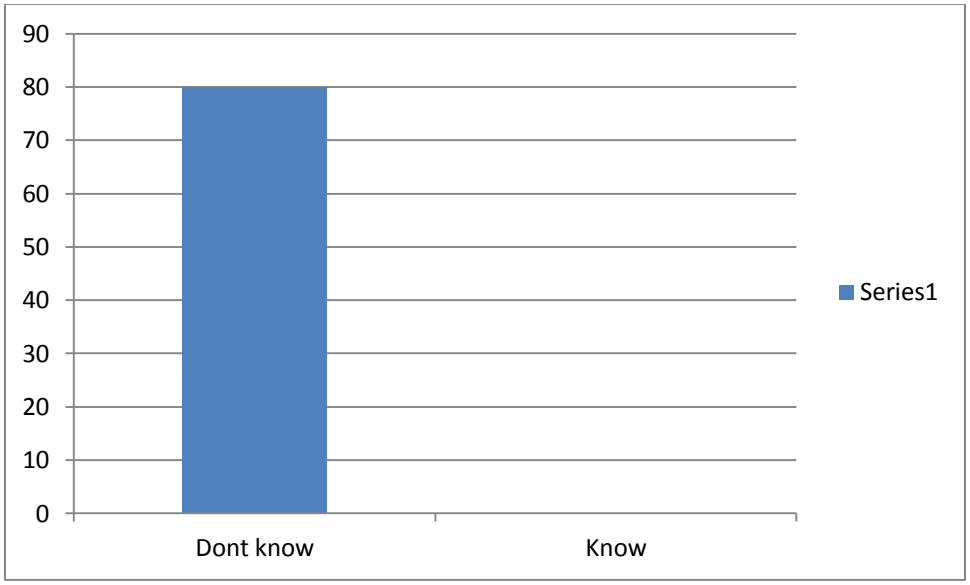
Findings:-

As per the analysis of above graph no 23.1 eleven doctor had undergone any workshop/training specifically related to ADR reporting but sixty nine doctor was not undergone any workshop/training specifically related to ADR reporting

(24)Where Regional office for reporting ADR is located?

Table no 2.4

Total respondents	Don't know	know
80	80	0



Graph no 24.1

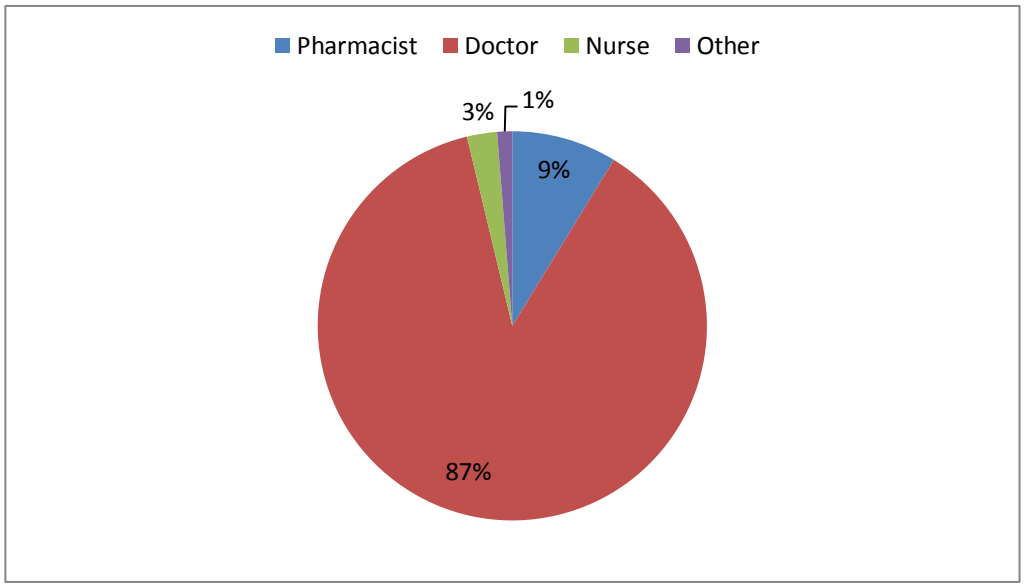
Findings:-

As per the analysis of above graph no 23.1 no one doctor was not know about the regional office for reporting ADR is located.

(25)Who is primarily responsible for explaining patient about side effects of drugs they are given?

Table no 2.5

Total respondents	Pharmacists	Doctor	Nurse	Other
80	7	70	2	1



Graph no 25.1

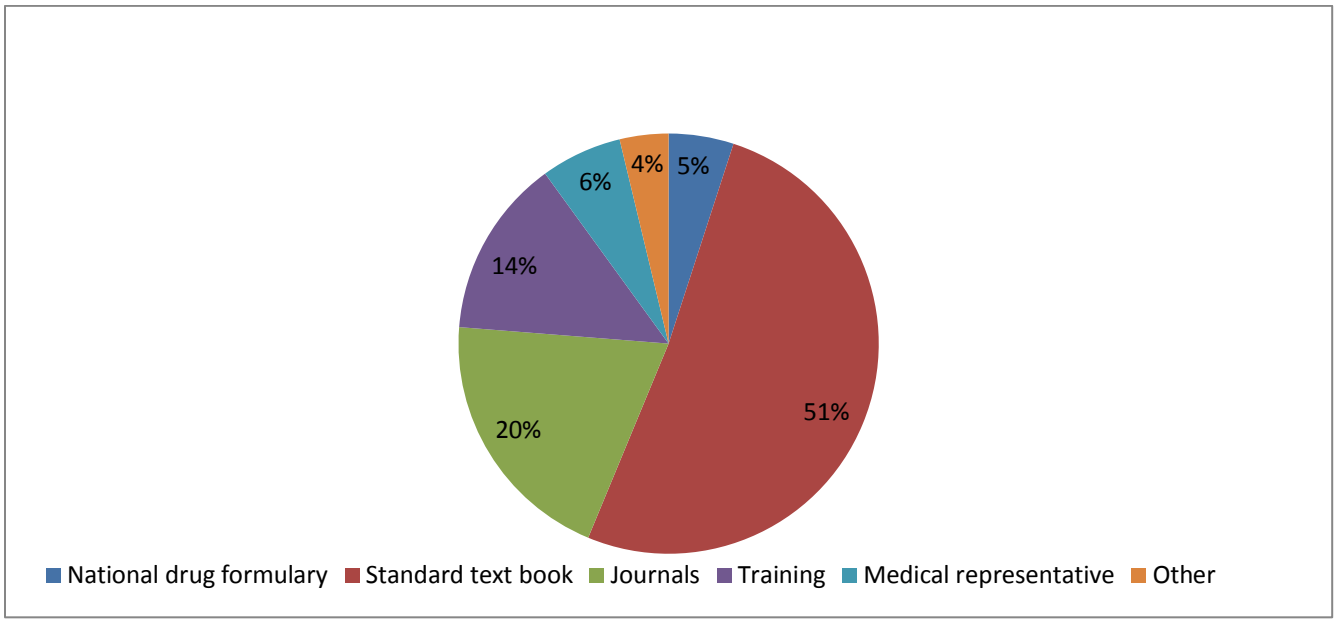
Findings:-

As per the analysis of above graph no 24.1 eighty seven percent doctor was give the preference physician and nine pecent doctor was give the preference to pharmacist,three percent doctor was give the preference nurse only one percent was give the preference to other on primarily responsible for explaining patient about side effects of drugs they are given.

(26)What is your source of information about ADR?

Table no 2.6

Total respondents	National drug formulary	Standard text book	Journals	Training	Medical Representative	Other
80	4	41	16	11	5	3



Graph no 26.1

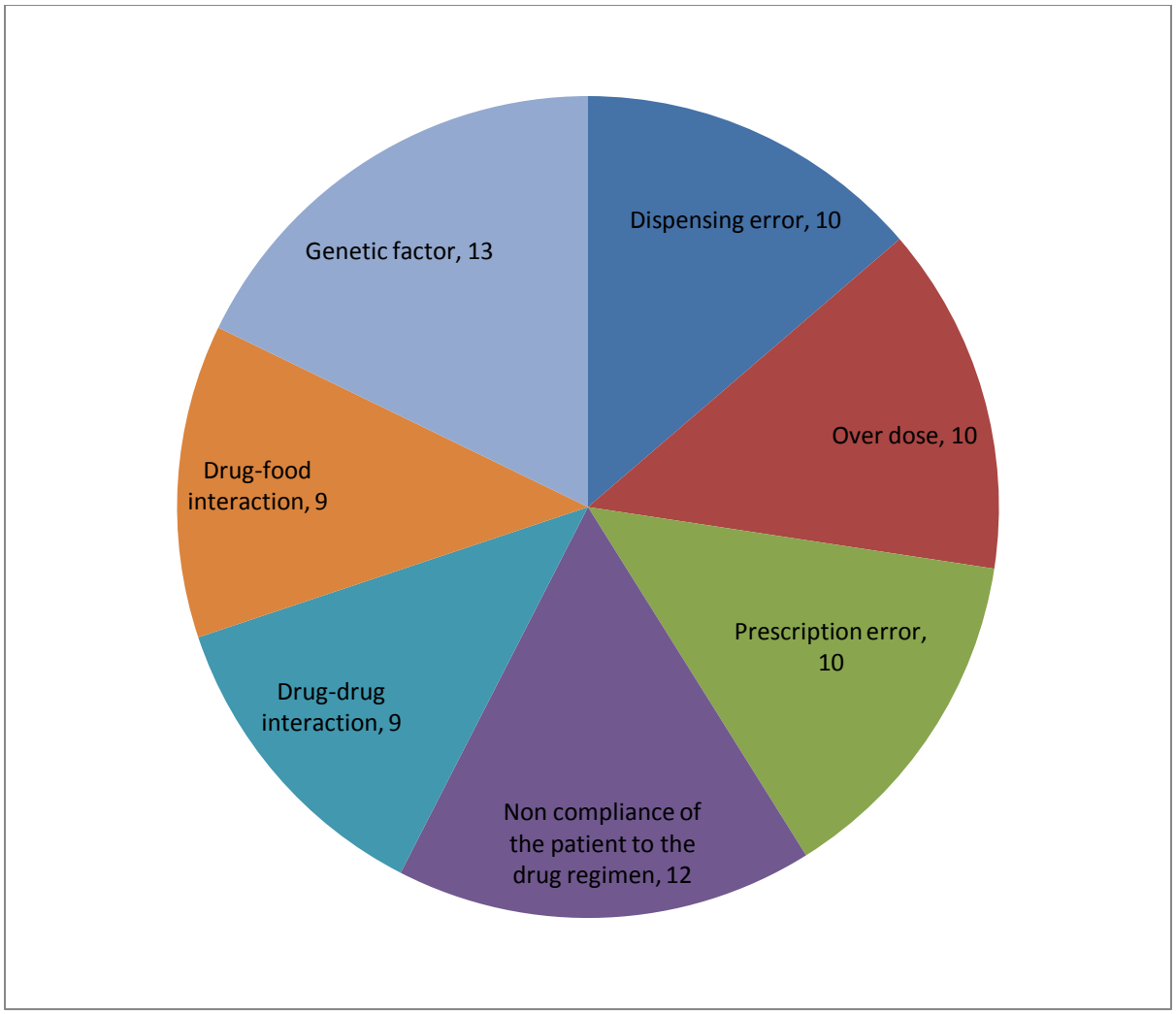
Findings:-

As per the analysis of above graph no 25.1 fifty percent doctor was give the preference standard text book ,twenty percent doctor was give the preference journals fourteen percent doctor was give the preference training,six percent doctor was give the preference medical representative and five percent was give the preference National drug formulary,four percent was give the percent others on source of information about ADR.

(27)What possible factor (s) predispose(s) a patient to ADR?

Table no 2.7

Total respondents	Dispensing error	Over dose	Prescription error	Non compliance of the patient to the drug regimen	Drug-drug interaction	Drug-food interaction	Genetic factor	Un-known factor	Other
80	10	10	10	12	9	9	13	7	0



Graph no 27.1

Findings:-

As per the analysis of above graph no 26.1 out of eighty thirteen doctor was give the preference Genetic factor,twelve doctor was give the preference Non compliance of the patient to the drug regimen,ten doctor was give the preference Dispensing error, Over dose, Prescription error and nine doctor was give the preference Drug-drug interaction, Drug-food interaction ,seven doctor was give the preference Un-known factor and no one doctor was give the preference others on possible factor (s) predispose(s) a patient to ADR.

Table No 2.8

Practice	Yes	%	No	%
Term ADR	80	**100**	0	**0**
ADR is same as side effect	1	**98.9**	79	**1.2**
ADR reporting system	33	**41.2**	47	**58.8**
Encountered patient in 12 month practice	51	**63.8**	29	**36.2**
Record the ADR in practice	52	**65**	28	**35**
Number of time report ADR	56(Usually),15(sometime)	**70,19**	9	**11**
Doctor advice to patient about the druug-drug & drug-food interaction	71(Usually),9(sometime)	**88.8,11.2**	0	**0**

Practice	**Yes**	**No**
Total 560	**368**	**192**
%	**65.71%**	**34.28%**

Table No 2.9

Attitude	Strongly agree(f)	%	Agree(f)	%	Disagree (f)	%	Strongly disagree (f)	%
ADR reporting to be practiced regularly	48	**60**	32	**40**	0	**0**	0	**0**
Reporting creates additional work load	5	**6.25**	34	**42.5**	39	**48.75**	2	**2.5**
Reporting ADR is part of duty of Health professionals	18	**22.5**	61	**76.25**	1	**1.25**	0	**0**
Reporting about 'drug safety' is important	28	**35**	50	**62.5**	2	**2.5**	0	**0**
Reporting is beneficial to the patient	35	**43.75**	44	**55**	1	**1.25**	0	**0**
Reporting drug safety is important for the health care system	30	**37.5**	44	**62.5**	5	**2.5**	1	**0**
specific ADR is related to a drug, before reporting	48	**60**	31	**38.8**	1	**1.2**	0	**0**
Only ADR of prescribed drugs need to be reported	1	**1.25**	22	**27.5**	53	**66.25**	4	**5**
ADR related with non-prescribed drugs need not to be reported	11	**13.8**	58	**72.5**	11	**13.8**	0	**0**
Only ADR that cause persistent disability should be reported	13	**16.2**	4	**5**	47	**58.8**	16	**20**

Attitude	**Strongly agree**	**Agree**	**Disagree**	**Strongly disagree**
Total 800	**237**	**380**	**160**	**22**
%	**29.62%**	**47.5%**	**20%**	**2.75%**

Table no 3.1

Knowledge	**Yes(f)**	**%**	**No(f)**	**%**
ADR reporting form available in your organization	31	**38.8**	49	**61.2**
ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'	60	**75**	20	**25**
workshop/training specifically related to ADR reporting	11	**13.8**	69	**86.2**
the duration of the training	0	**0**	80	**100**
Training place	0	**0**	80	**100**
know about mandatory time period in case of serious ADR reporting	21	**26.2**	59	**73.8**
Regional office for reporting ADR is located	0	**0**	80	**100**

knowledge	**Yes**	**No**
Total 560	**123**	**437**
%	**21.96%**	**54.62%**

CONCLUSION

On the basis of above analysis of practice, attitude, knowledge of doctors about the ADRs reporting :

Practice:

All the doctor was known about the term ADR(Adverse drug reaction) ,99% doctor was known adverse drug reaction is same as side effect only 1% doctor was not known about it. Only 41.2% doctor had heard about ADR reporting system in India and 63.8% doctor was encountered patient with ADR in their clinical practice.65% doctor was record ADR in their practice According to doctor(38%) ADR should be reported by the head of department.88.8% OF doctor usually give advice to patient on possible drug- drug or drug- food interactions. the main causes of irregular reporting of ADRs are that non availability of Reporting form, Do not know whom to report. Training ,workshops, seminars & regarding ADR identification and reporting and developing a system within hospital to report an ADR is possible ways to promote ADR reporting in India.

Attitude

Strongly agree 29.88 %doctor, agree 47.90% doctor ,disagree 19.67% doctor, strongly disagre25.22% doctor on ADR reporting to be practiced regularly, Reporting creates additional work load, Reporting ADR is part of duty of Health professionals, Reporting about 'drug safety' is important, Reporting is beneficial to the patient, Reporting drug safety is important for the health care system, specific ADR is related to a drug, before reporting, Only ADR of prescribed drugs need to be reported, ADR related with non-prescribed drugs need not to be reported, Only ADR that cause persistent disability should be reported.

Knowledge

21.96 % doctors give the answer in "Yes" and 54.26% % doctors give the answer in "No"on knowledge parameters ADR reporting form available in your organization, ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet', workshop/training specifically related to ADR reporting, duration of the training, Place of training, mandatory time period in case of serious ADR reporting, Regional office for reporting ADR is located.

At last on the basis of above mention information on of practice, attitude, knowledge of doctors about the ADRs reporting we can say that regular training ,increase awareness , developing a system within hospital to report an ADR . Doctors will surely improve the ADR reporting system

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