IMPACT OF EDUCATIONAL INTERVENTION ON PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG THE PRESCRIBERS AND NURSES IN A TERTIARY CARE TEACHING HOSPITAL OF NORTHERN INDIA

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Introduction

- ADR & UDAP of Pharmacovigilance
- ADRs account for 0.2%-24% of hospital admissions and 3.7% of the patients have fatal ADRs.[1]
- It is estimated that ADRs cause 197,000 deaths per year in the European Union with a cost of 79 billion EUR.[2]
- Spontaneous ADR Reporting- median underreporting rate of 94%.[3]

Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Natl Med J India, 200
http://www.haiweb.org/19072009/19July2009FactsheetTheEuropeanCommission'sProposalforaPharmacovigilanceDirective.pdf
Hazell L, et al. Under-reporting of adverse drug reactions: a systematic review. Drug Saf.2006; 29:385-396.

Why we did this study?

per the expansion of PvPI, to make the institute a peripheral ADR monitoring center; awareness about PV was checked and further work up needed to be done with the prescribing doctors working in the institute.

merous studies to asses Knowledge Attitude & Practices (KAP) surveys of pharmacovigilance (PV) have been ducted in various parts of India but no such study was conducted in our region.

revious study done by Muraraiah et al suggested that educational interventions and the improvement of the lities would help in enhancing the reporting rate.

vious studies have shown the lack of evaluation of the effects of intervention through questionnaire was one of itations in the study done by Tabali et al

Aim

- To improve the participation of healthcare workers at Era's Lucknow Medical College & Hospital in Pharmacovigilance program of India.

Objectives :-

- To asses the baseline KAP of PV amongst practitioners and nurses via survey questionnaire
- To plan strategies based upon baseline assessment of KAP of PV amongst practitioners and nurses.
- To evaluate the role of educational interventions in bringing an improvement in KAP of PV amongst practitioners and nurses via survey questionnaire

Methodology

dy settings

Era's Lucknow Medical College & Hospital (A tertiary care center in northern India)

get Respondents

Residents Faculty Members Nurses

dy Design : The study was conducted in 3 parts

cross-sectional, observational and questionnaire based KAP survey.

Implementation of strategies based upon the first part of the study for a period of two months.

Assessing the impact of interventions by conducting a post KAP questionnaire survey and assessment of the results to devise future work plan.

Questionnaire

Pre KAP

- A questionnaire containing 26 questions
  - 13 questions were of knowledge
  - 5 of attitude
  - 8 of practice.

Post KAP

- A similar modified questionnaire containing 22 questions
  - 10 questions were of knowledge
  - 5 of attitude
  - 7 of practice.

A response sheet including information like name (optional), however respondents were mandatorily asked to mention department, designation, Email address and telephone numbers.

Interventions

ACADEMIC

- Guest Lectures and Workshops
- Mailing educational material over E-Mails
- Special lectures for fresh first year residents
- A topic of pharmacovigilance during departmental seminar presentations.
- Communication

NON ACADEMIC / REGULATORY

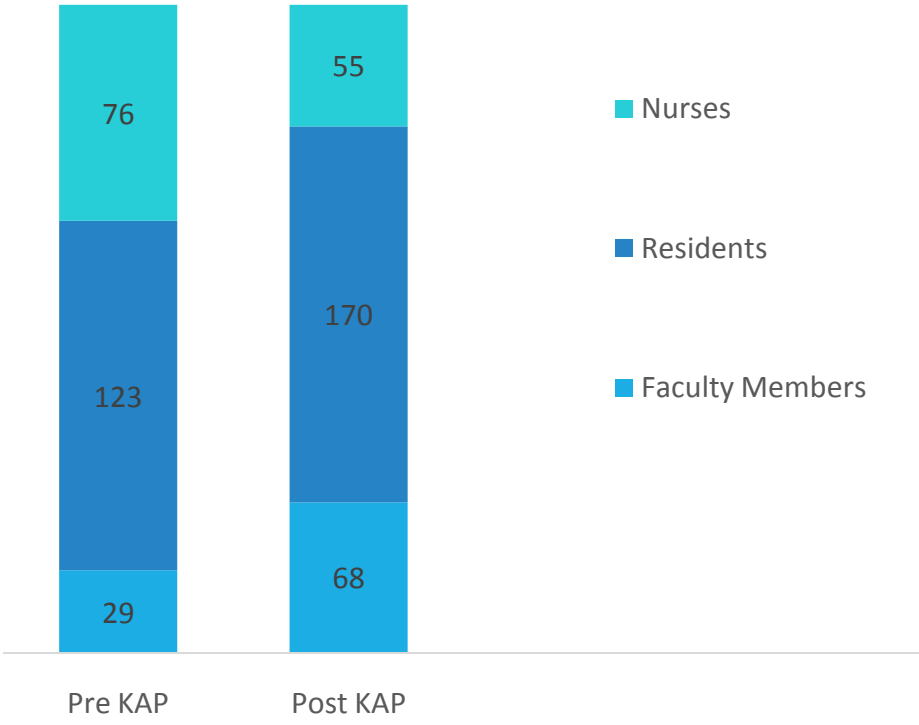
- Regular departmental rounds
- Posters pasted at various sites in the hospital
- Availability of ADR reporting forms
  - At OPD Block
  - In the IPD admission file
- Institutional Pharmacovigilance Committee meeti
- Regular formal notification reminders

Data Collection & Analysis

- Institutional pharmacovigilance committee meeting
- Institutional ethics committee clearance
- Consent signature on the response sheets
- Conducting survey
- Immediate collection of response sheets
- Recording the response using MS-Excel
- Generating graphical presentations of the results and the comparisons

Results

	Distributed	Retrieved	Analyzed	Response Rate
e P	356	252	228	64.04%
st P	321	310	293	91.28%



AT IS PHARMACOVIGILANCE?

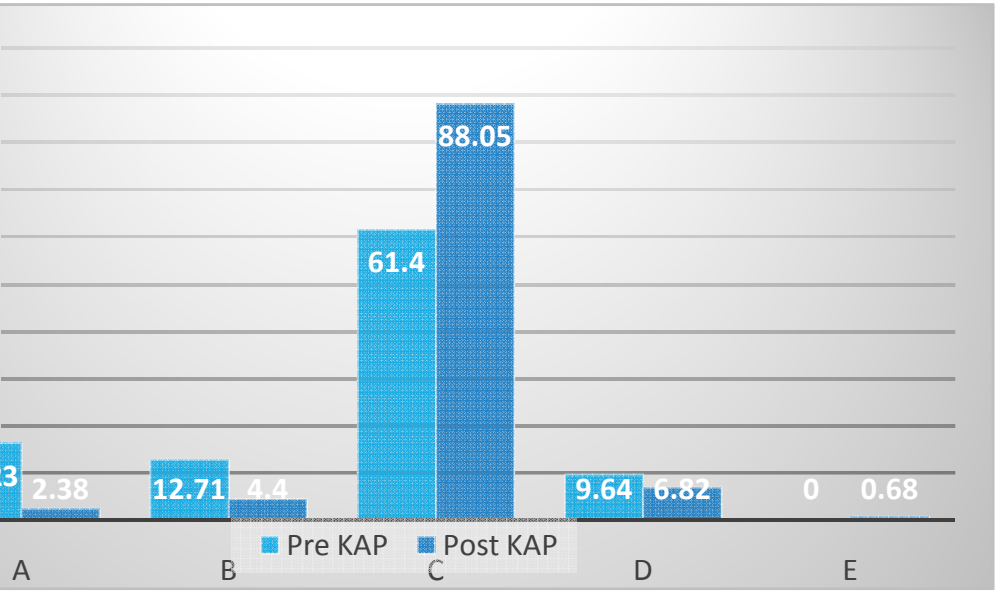
SCIENCE OF MONITORING ADR'S HAPPENING IN A AL.

PROCESS OF IMPROVING THE SAFETY OF DRUGS.

DETECTION, ASSESSMENT, UNDERSTANDING & TION OF ADVERSE EFFECTS.

SCIENCE DETECTING THE TYPE & INCIDENCE OF TER DRUG IS MARKETED.

OT KNOW



Q2. PURPOSE OF PHARMACOVIGILANCE ?

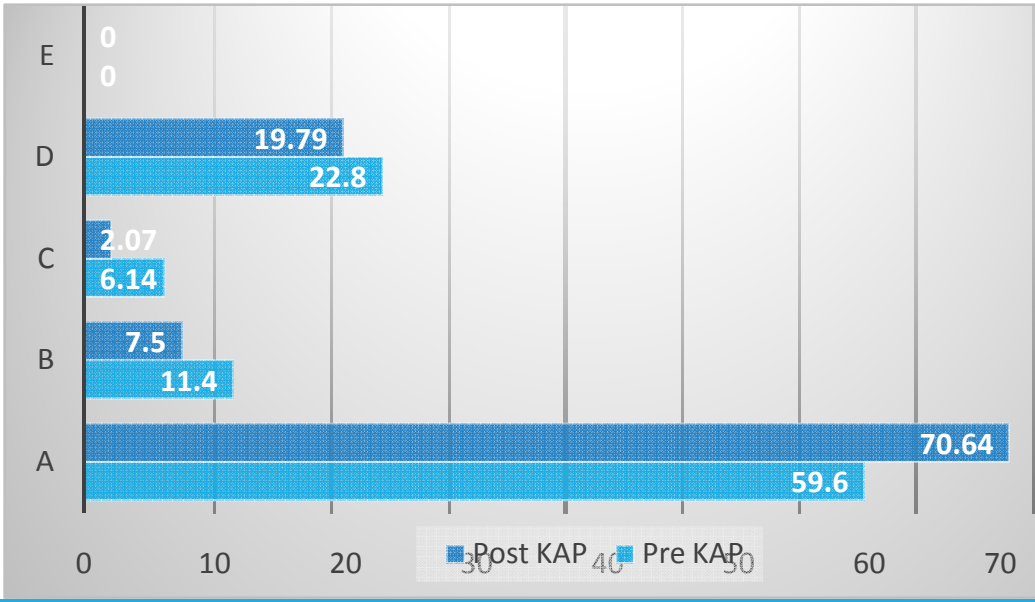
A) TO IDENTIFY SAFETY OF DRUGS .

B) TO CALCULATE INCIDENCE OF ADR'S.

C) TO IDENTIFY PREDISPOSING FACTORS TO ADR'S

D) TO IDENTIFY UNRECOGNIZED ADR'S

E) DO NOT KNOW



India, monitoring of ADR's is the responsibility of

tral Drugs Standard Control Organization (CDSCO).

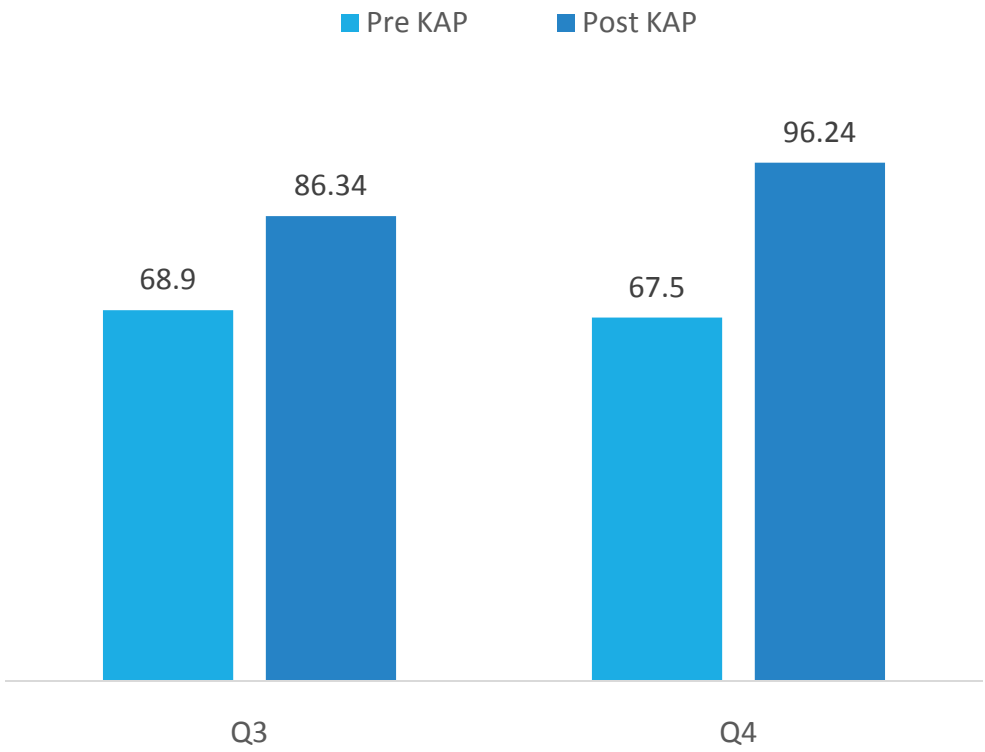
ian Institute of sciences.

rmacy Council of India .

dical Council of India (MCI).

not know

ware about ADR Reporting has a specific format?



Where is the National Pharmacovigilance Centre of located?

MS, New Delhi b) IPC, Ghaziabad

ie d) Kolkata

not know

ocation of International Pharmacovigilance center?

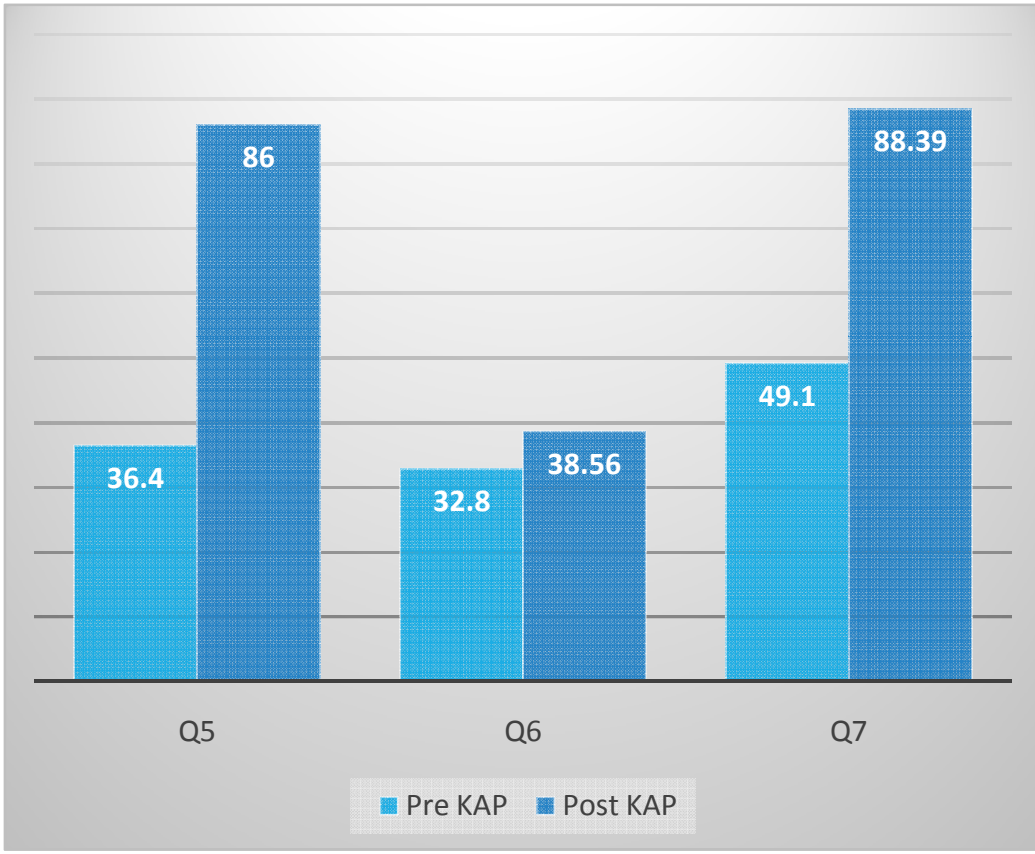
A b) UK

nce d) Australia

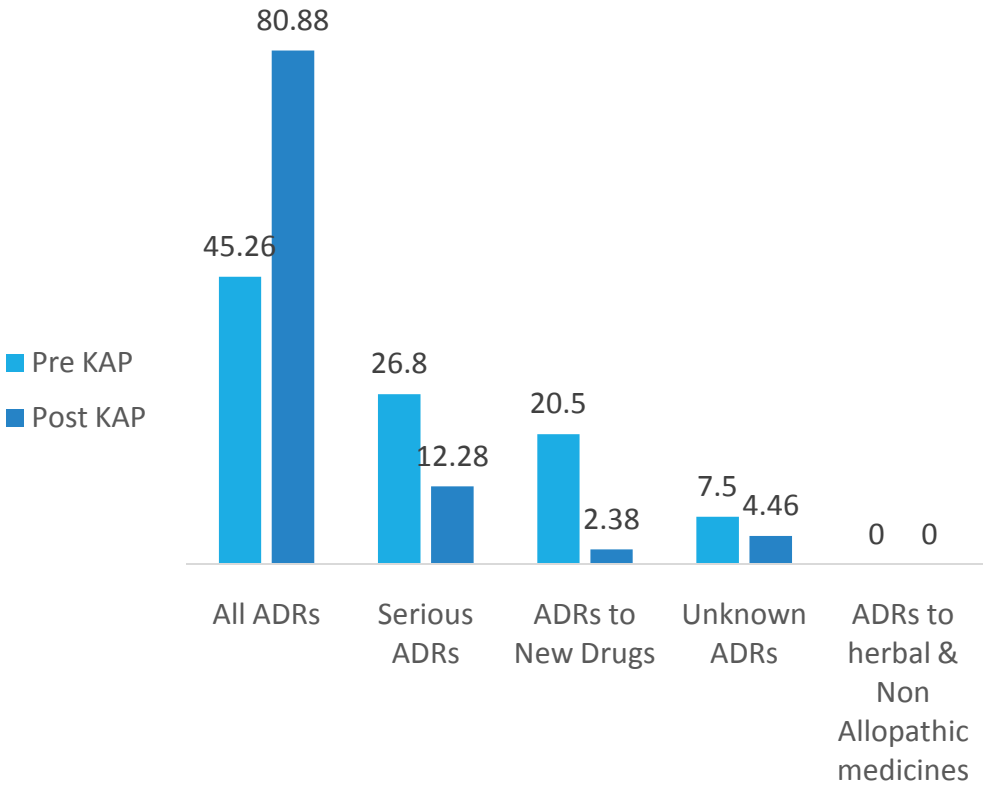
eden f) Do not know

wareness about peripheral pharmacovigilance r in U.P ?

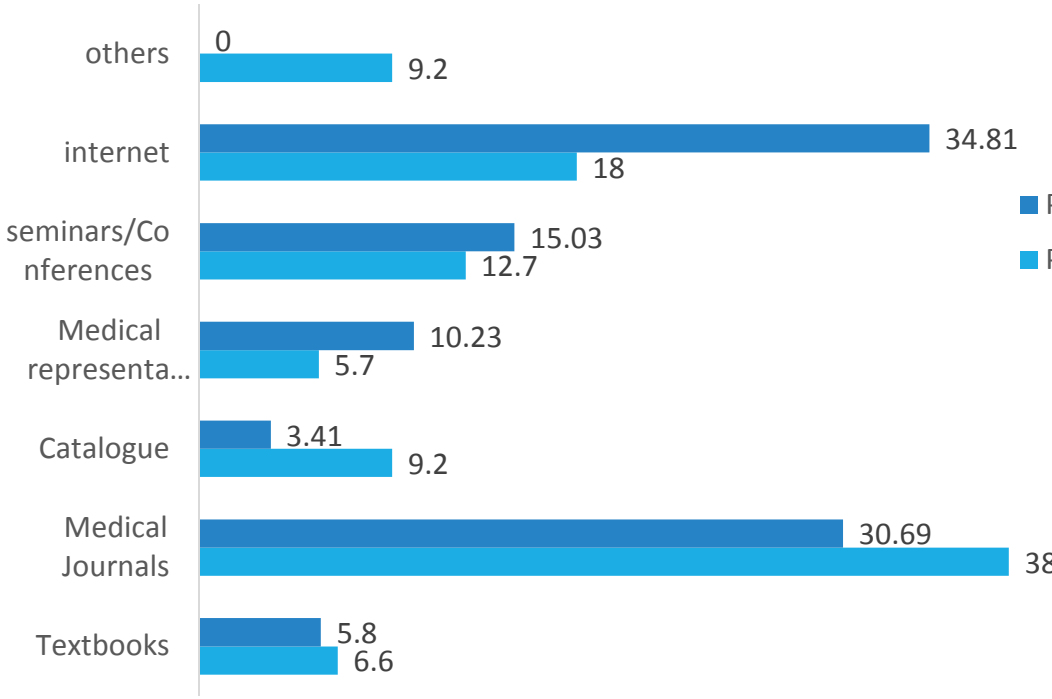
b) No



Q8. AWARENESS ABOUT WHICH ADR'S SHOULD BE REPORTED



Q9. SOURCE FROM WHICH THEY GOT INFORMATION REGARDING THE ADR'S OF NEW DRUGS

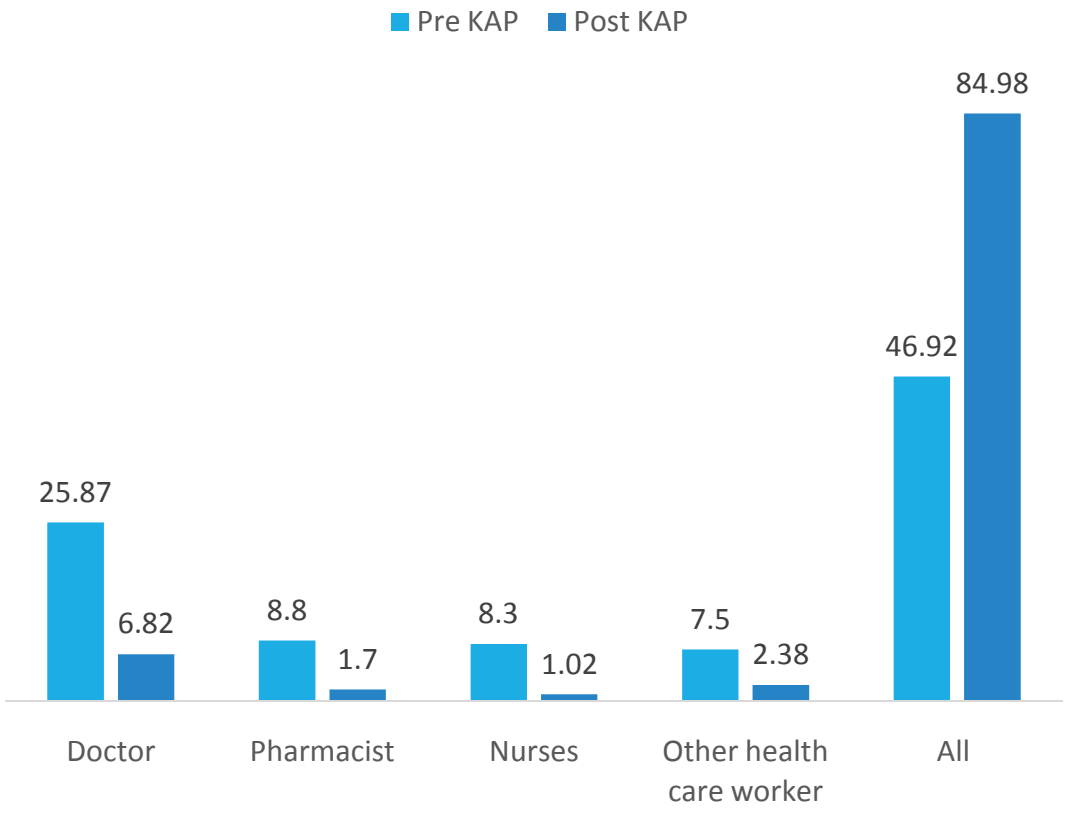


Q10. Knowledge about which healthcare professionals are responsible for reporting ADR's in a Hospital

a) Doctor b) Pharmacist

c) Nurses d) Health Workers

e) All of the above



Whether ADR reporting is necessary or not ?

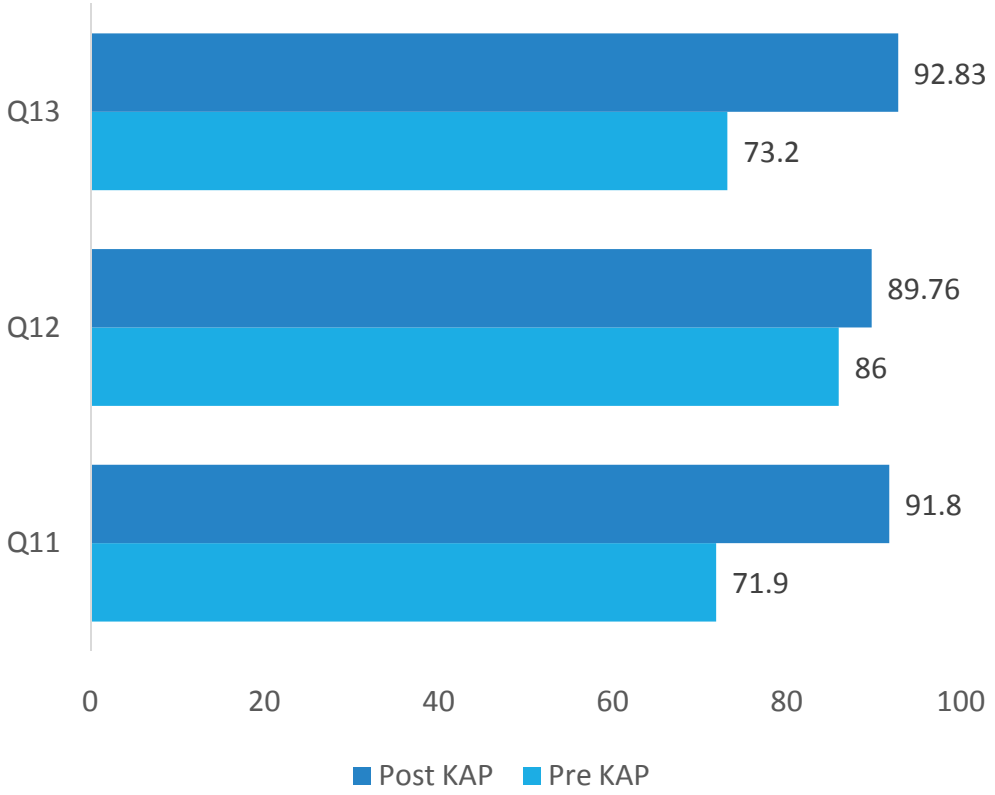
b) No c) Do not know

Should pharmacovigilance program be included in Under ate curriculum to create awareness amongst budding s ?

b) No c) Do not know

Should pharmacovigilance be taught in detail to care professionals ?

b) No c) Do not know

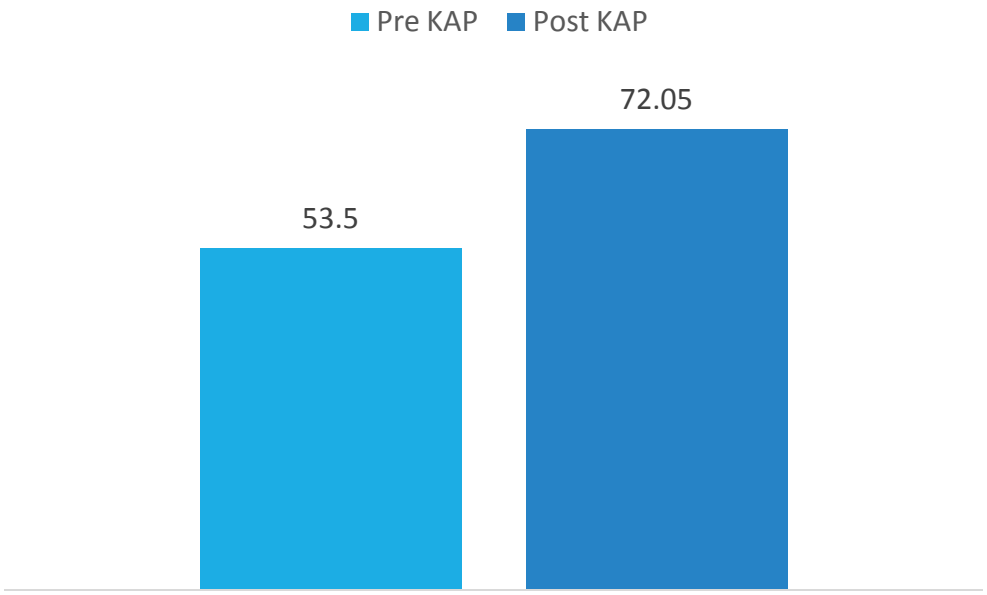


Q14. Whether reporting is a professional obligation or not

A) Yes

B) No

C) Do not know



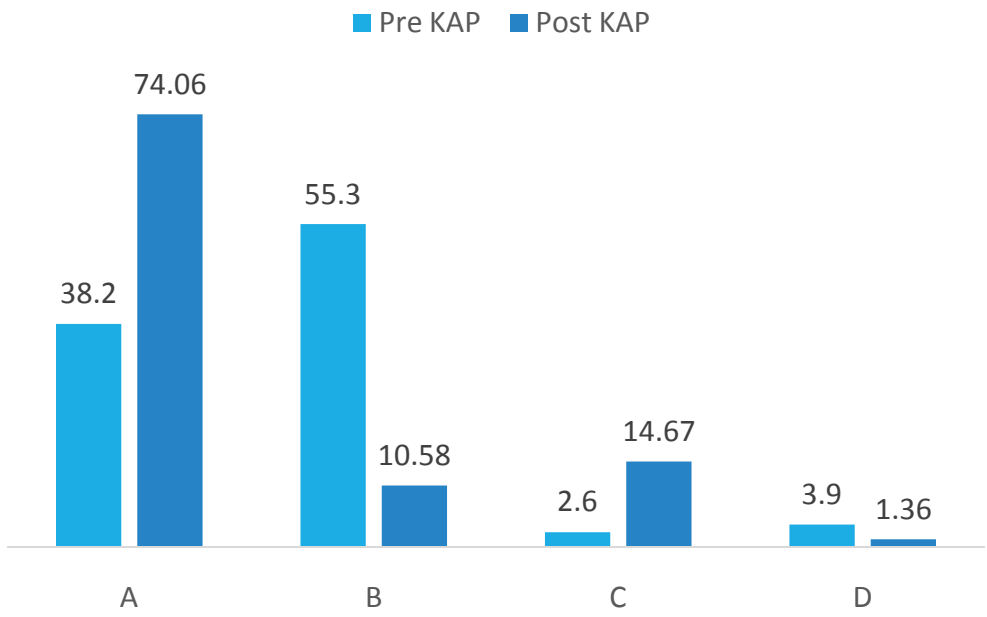
Q15. What was their opinion regarding establishment of ADR monitoring centre in every hospital

A) Should be in every hospital

B) Not Necessary

C) One center in a city is sufficient

D) Depends on number of beds in a hospital



Whether they provided ADR information of ribed drug

b) No

not know/Not aware

Whether they had free access to ADR Forms

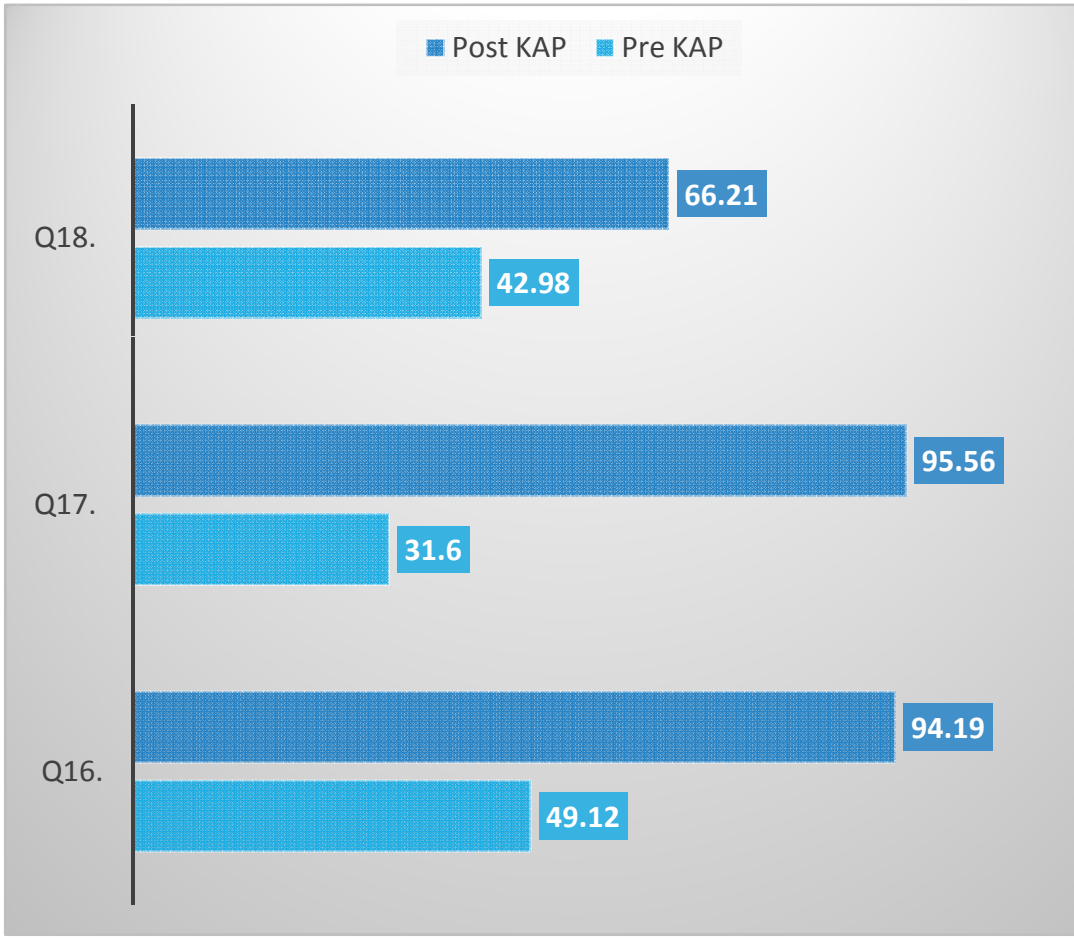
b) No

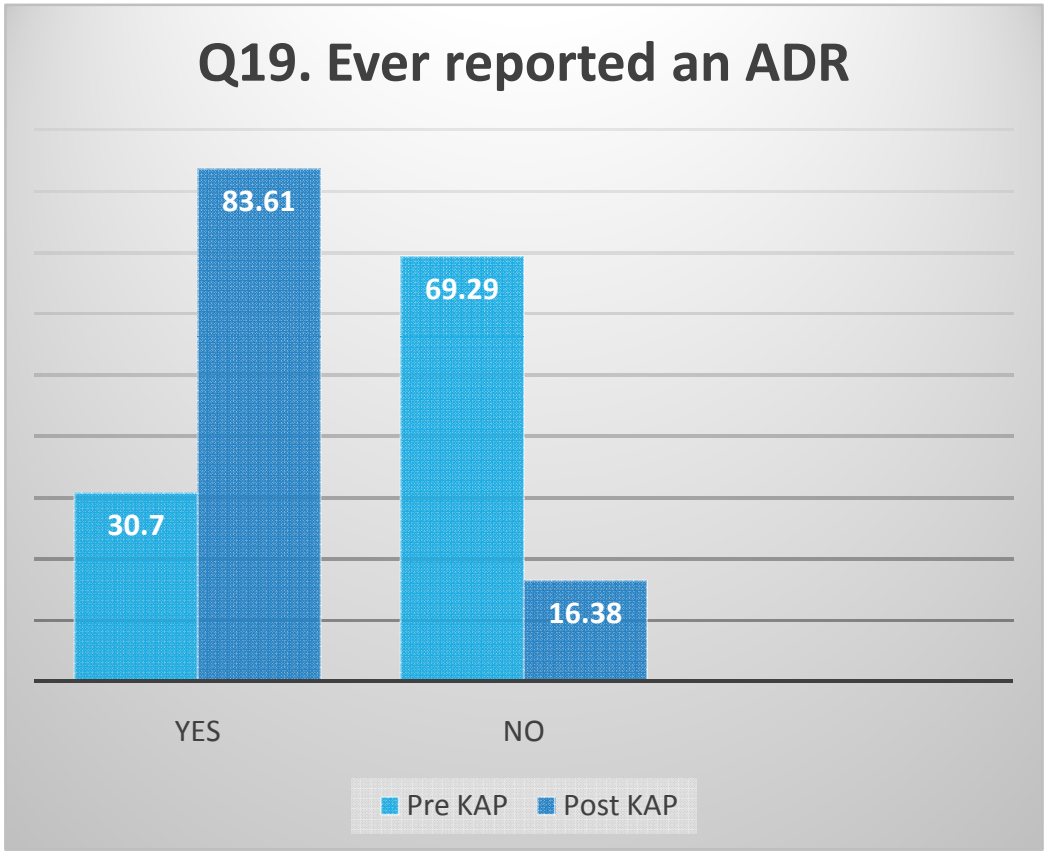
aware of ADR forms/Other means

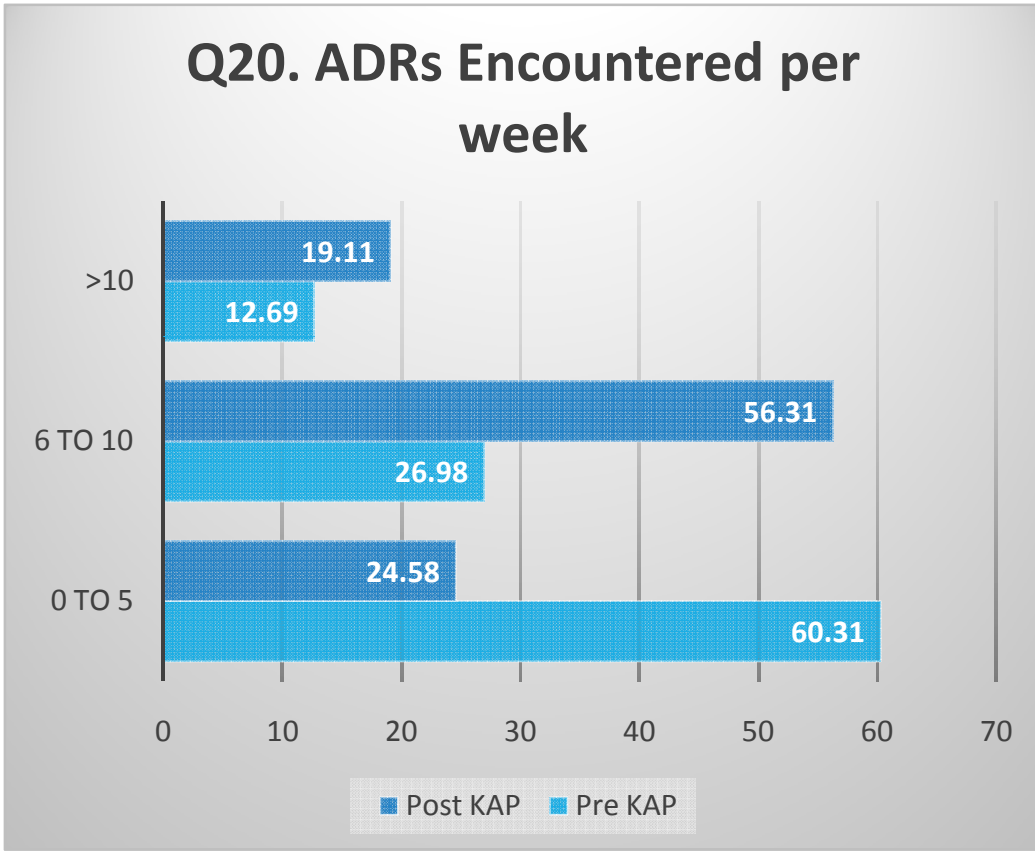
Whether they had ever been trained on how to t an ADR

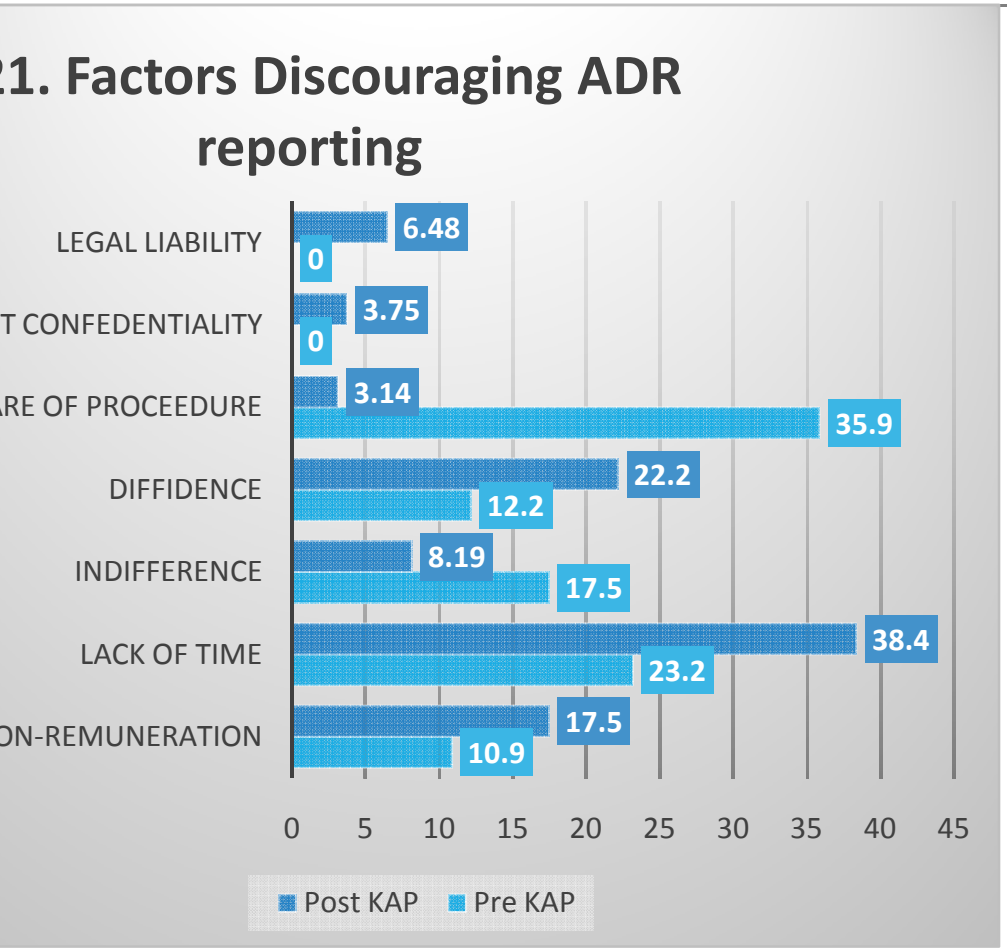
b) No

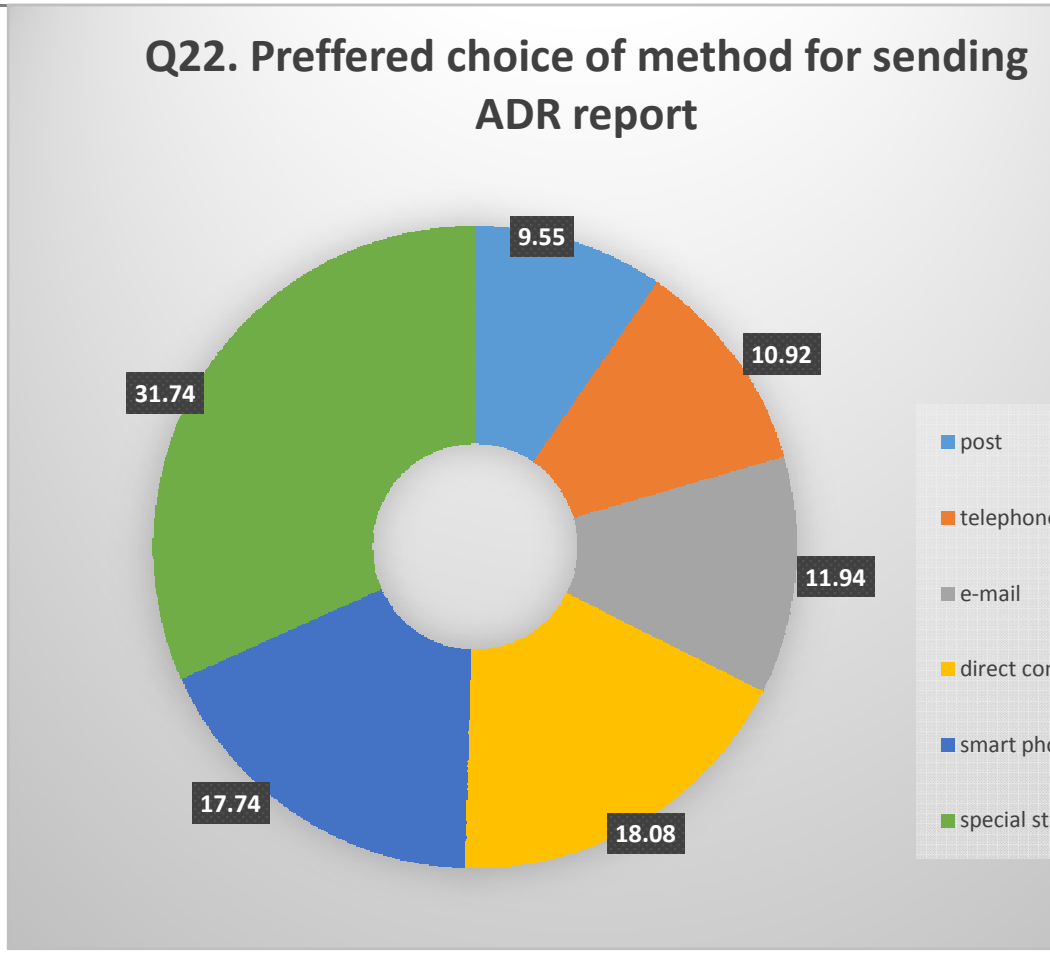
not know/remember




Q19. Ever reported an ADR
83.61
69.29
30.7
16.38
YES
NO
Pre KAP
Post KAP


Q20. ADRs Encountered per week
>10
6 TO 10
0 TO 5
19.11
12.69
56.31
26.98
24.58
60.31
0
10
20
30
40
50
60
70
Post KAP
Pre KAP


21. Factors Discouraging ADR reporting
LEGAL LIABILITY
T CONFEDENTIALITY
ARE OF PROCEEDURE
DIFFIDENCE
INDIFFERENCE
LACK OF TIME
ON-REMUNERATION
6.48
0
3.75
0
3.14
35.9
22.2
12.2
8.19
17.5
38.4
23.2
17.5
10.9
0
5
10
15
20
25
30
35
40
45
Post KAP
Pre KAP


Q22. Preffered choice of method for sending ADR report
9.55
10.92
11.94
18.08
17.74
31.74
post
telephon
e-mail
direct co
smart ph
special st

Discussion

- The overall results of the post- KAP questionnaire in our study were encouraging among doctors and nurses
- This figures are suggestive that continuing educational intervention is an important tool for increasing doctor's and nurse's awareness towards pharmacovigilance.
- This increase in awareness was reflected upon their practices of Pharmacovigilance, by an increase in detection and reporting of ADRS and also by the fact that clinicians had started to give ADR information to the patients.
- A positive change in attitude was also an encouraging and possible factor for an increase in practices of pharmacovigilance.
- In a similar educational interventional program in pharmacovigilance, study of Li Q, Zhang et al showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare professionals towards practice of pharmacovigilance.

The pre intervention KAP survey showed

- 61.4% and 59.6% respondents knew the definition and purpose of pharmacovigilance, respectively and 67.5% of the respondents were aware of the specific format of reporting.
- 46.26% and 46.92% of the respondents were aware that all ADRs are supposed to be reported and ADRs can be reported by all the healthcare professionals respectively.
- Even though, higher percentage of respondents were in favor of learning about phramacovigilance and necessity of ADR reporting, but only 53.5% & and 55.3% of the respondents were of the opinion that ADR reporting should be a professional obligation and setting up an ADR monitoring center was not necessary in every hospital.
- However, 49.12% of the respondents had prior been trained to report an ADR but only 30.12% had reported an ADR previously and 64% of the respondents did not even had an access to ADR form.
- These results were in accordance to Ramesh M et al, who also reported high level of awareness and a positive attitude amongst practitioners but a very limited practices of pharmacovigilance

Post intervention assessment highlighted the facts that:-

There was an increase in the level of awareness of respondents regarding pharmacovigilance and PvPI structur

92.83% (vs. 73.2%) of the respondents were now of the belief that ADR reporting is necessary and 80.88% (23 of the respondents were now aware that all ADR are supposed to be reported.

72.05%(vs. 53.5%) were now of the opinion that ADR reporting must be made compulsory and 74.06% respondents thought that every hospital must have an ADR monitoring center.

Our study was in accordance to the previous studies done by Figueiras et al , Brachi et al and Tabali et al, in displaying that increased awareness post interventions leads to increased practices of pharmacovigilance. This was demonstrated by the following data:-

- Now 94.19% of the respondents agreed that they had been trained in reporting ADR, and 83.61% of respondents told that they had reported ADRs.

Not aware of the procedure to report (35.9%) , lack of time (23.2%) and indifference were amongst the major factors discouraging practitioners in not reporting ADRs. These results were in accordance to the study conducted by Bisht M et al.

This fact was highlighted by 60.31% of the respondents who stated that they had only encountered 0-5 ADRs.

But however post interventions, as per data, only 3.14% of the respondents were not aware of the procedure, and there was also a reduction seen in respondent's attitude of indifference in discouraging them of reporting an A

But even after the interventions, lack of time was cited as the most common factor discouraging respondents.

Perhaps this was the reason that 31.74% respondents felt that a special staff was required to report an ADR and simplifying the procedure of reporting by methods such as smartphone apps were necessary.

Future Considerations

udies done by Figueiras et al , Brachi et al and Tabali et al showed the fading up of the effectiveness of intervention, e rate of ADR reporting had decreased. Our study was too short to ascertain this fact, but had to be considered .

osentino et al recommended to include pharmacovigilance as a topic in continuing education programs, we had also f e need of such and our data is also suggestive that Pharmacovigilance must be a regular part of under graduate syllab

nnovations to increase the reporting rates.

enefits of publications and dedicated journals.

edicated staff recruitment.

harmacovigilance OPDs for ADRs of OPD patients.

ncouragement letters & Communication

Conclusions

- Our study demonstrated that even though the practitioners had a decent level of awareness of pharmacovigilance and a positive attitude towards learning, but their practices were lacking.
- However feasible intensive educational interventions were strategized based upon the pre-intervention assessment of KAP survey.
- The result was not only the uplifted the level of awareness amongst practitioners but also brought a positive change towards application of pharmacovigilance.
- These interventions also led to increased and better practices of pharmacovigilance amongst practitioners.at our institute, making them a regular contributor of ADR information reports from our region.


hank You !!!