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A Survey on Knowledge, Attitude and Practice of Pharmacovigilance among the Healthcare Professionals

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ABSTRACT

This study shows that little awareness about the ADR reporting system among the healthcare professionals. The healthcare professionals are not knowing about where and how the ADRs had to be reported, the time limits for the reporting, etc. Therefore, it seems necessary to hold awareness programmes to improve the ADR reporting. The paramedical staff should also be encouraged for the ADRs reporting, since they are in closer contact with the patients for a longer duration and as they can play an important role in making the pharmacovigilance programs more efficacious. A majority of the healthcare professionals (94.9%) are felt that the ADR reporting should be compulsory. Very few healthcare professionals want to report an event if it was an already well recognized adverse reaction. In the clinical practice, the factors that discourage the healthcare professionals from a spontaneous reporting are a lack of knowledge about the reporting procedure and other practical issues such as the patient management and the patient confidentiality issues. To improve the spontaneity in the reporting rates, the healthcare professionals suggested the organization of training programmes and an uncomplicated reporting system with quick feedback regarding their

specific reports. This had to be reinforced by holding regular seminars/workshops, etc. In order to generalize our findings, it is imperative that similar studies be done in other teaching work place of the country. In conclusion, our study strongly suggested that there was a great need to create awareness among the healthcare professionals to improve the reporting of ADRs. The training sessions must clarify the roles of the various healthcare professionals in pharmacovigilance. There should be closer relationship between the healthcare professionals and the pharmacovigilance centres. The ADR reporting should be made an integral part of the clinical activities in order to improve the patient care.

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INTRODUCTION The World Health Organization (WHO) defines adverse drug reaction (ADR) as 'a response to a drug, which is noxious, unintended and that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease or for modification of physiological function'. Pharmacovigilance is the science and activities relating to the detection, understanding and prevention of adverse effects or any other medicine related problem.

Many relatively rare and important ADRs, drug interactions and specific toxicities are not captured during the clinical trial. Hence, it is essential to have a surveillance system for monitoring and reporting of ADRs consistently throughout the duration of use of a medicine in a population. This will help in detecting ADRs early, predicting their frequency and ensuring safe and efficacious use of medicines. Under the Pharmacovigilance Programme of India (PVPI), ADR monitoring centres (AMCs) have been established to coordinate ADR monitoring throughout India.

Underreporting of suspected ADRs by healthcare professionals is a widespread problem in India, and the contribution of ADR reporting is very low. Though ADR is a significant problem in children, pediatricians seem to neglect this aspect. A lot of studies and a few meta-analyses show that the knowledge, attitude and practice (KAP) of pharmacovigilance among health professionals in India, in general, is inadequate. KAP studies related to pharmacovigilance among pediatricians are lacking in literature.

Pharmacovigilance is an important element of any medical intervention which aims at enhancing patient

safety by assessing the risk-benefit profile of medicines. It is defined by WHO as "The science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems".

They are an essential part of the health care system by their contribution in reducing morbidity, emergency room visits, and hospitalizations. Considering the number of patients seen daily by primary care physicians it is essential to determine if there are gaps in the knowledge, attitudes, and practices in order to develop strategies that will address such gaps. Findings from various studies have revealed that ADR reporting by healthcare providers is linked to their knowledge, attitude and practice about pharmacovigilance.

Modern drug therapy has improved the way of managing and controlling diseases and is based on two essential factors: safety and effectiveness. Adverse drug reaction (ADR) continues to be a public health problem and its incidence is increasing worldwide, with high rates of morbidity and mortality, especially among more vulnerable groups, such as children and elderly. Besides that, it can severely affect the costs of healthcare systems.

Spontaneous reporting of suspected ADR is one of the main pharmacovigilance tools, especially after the marketing authorization for a new drug. It is vital for the rapid detection of serious and rare ADR, guiding hypotheses of causality, investigation priorities and regulatory measures. However, it depends on the adequate knowledge, attitudes and practices of the health professionals towards the ADR notification.

Some local studies indicate deficiencies regarding drug safety monitoring, knowledge about ADR and ADR notification forms. In this context, this study aims to assess the KAP among health professionals regarding pharmacovigilance and reporting ADR. Nassoro Lukeye), who screened the studies based on the set eligibility criteria, while the third reviewer facilitated consensus on any disagreements. The last search was conducted on February 1, 2024. The focus was on articles published in English that describe the application of molecular markers in the genetic purity assessment of crop varieties, specifically highlighting the position of African countries in the utilization of molecular markers, without restricting the publication date. Abstracts, review papers, articles in languages other than English, books, articles describing the molecular diversity of crops, and duplicate articles were excluded.

MATERIALS AND METHODS

Search strategy

- Subject selection

- Study location
- Data collection method for health care professionals
- Questionnaire form

Subject selection:

The Doctors and nurses were select from the hospitals, PHC, CHC and clinics. The pharmacist was also selected from the drug store and the hospital pharmacies.

Study location:

This cross-sectional study conducted at Hospitals, Drug stores, Laboratories, PHC centre and clinics.

Data collection method for health care professionals:

A survey questionnaire was focused to assess the knowledge, attitude and practice of pharmacovigilance. Healthcare professionals were approached and explain in brief about the study. A questionnaire was administered after a verbal consent. They were requested to reply to the questionnaire within sufficient time at single contact. Access to any information source was restricted while questionnaire being answered.

Questionnaire form: https://docs.google.com/forms/d/e/1FAIpQLScXfwQ8a6_MTA5Unu4CzMm9GjMg7VD0EiBRx7OQER2u7Gtuog/viewform?vc=0&c=0&w=1&flr=0

Figure 1: QR code for survey form

Inclusion and exclusion criteria

Inclusion criteria

1. Healthcare professionals (doctors, nurses, pharmacists) working in hospitals, clinics, or community health centers.

2. Professionals with at least 6 months of experience in their current role.

3. Willingness to participate in the survey and provide informed consent.

4. Ability to understand and respond to the survey questions.

Data extraction and analysis

exclusion criteria

1. Healthcare professionals who are not directly involved in patient care (e.g., administrators, researchers).

2. Healthcare professionals who are not familiar with pharmacovigilance concepts and practices.

RESULTS AND DISCUSSION

There are 23 questions in the questionnaire to assess the knowledge on ADR, attitude towards pharmacovigilance and their practice on ADR reporting. Of the 23 questions, 9 questions were knowledge based, 6 questions were attitude based and 8 questions were practice based. The response for this part of questionnaire was provided in the form of 'YES' and 'NO'. Result obtained from the survey are shown in the table below. The result observed is Knowledge Based 71.54% YES and 28.45% NO. Attitude Based 88.98% YES and 11.02% NO. Practice Based 56.54% YES and 43.46% NO.

1. Knowledge Based Questions.

1) Do you believe all the drugs available in market are safe? (YES/NO)

2) Are you aware of suspected Adverse Drug Reaction (ADR) reporting system in India? (YES/NO)

3) Are you aware of any drug that has been banned recently due to ADR? (YES/NO)

4) Do you believe herbal products have no ADR? (YES/NO)

5) Do you think reporting ADR is important as a health care professional? (YES/NO)

6) What is your expectation from the pharmacovigilance program?

7) Which regulatory body is responsible for monitoring of ADR in India?

- ❑ Central Drugs Standard Control Organization
- ❑ Indian Institute of Science
- ❑ Pharmacy Council of India
- ❑ Medical Council of India

8) Do you think pharmacovigilance awareness program/website should be freely accessible to everyone? (YES/NO)

9) Do you known the nearest adverse drug reaction monitoring centre (AMC) located from your working place? (YES/NO)

2. Attitude Based Questions.

1. Which are the health care professional responsible for reporting ADR?

- ❑ Doctor
- ❑ Pharmacist
- ❑ Nurses
- ❑ All of above

2. Do you think about to initiate ADR monitoring center in every work place? (YES/NO)
3. Do you think about reporting of adverse drug reaction is necessary? (YES/NO)
4. Do you think about pharmacovigilance should be included in academic curriculum of health care professionals (YES/NO)
5. Have you anytime read any article on prevention and management of ADR? (YES/NO)
6. Are you willing to report ADR? (YES/NO)

3. Practice Based Questions.

1. Have you ever experienced adverse drug reaction in your patient during your professional practice? (YES/NO)
2. Have you ever been trained on how to report ADR? (YES/NO)
3. Have you ever seen the ADR reporting form? (YES/NO)
4. Have you ever reported ADR to the AMC? (YES/NO)

5. Do you keep records of ADR? (YES/NO)

6. Do you know how the causality assessment of ADR is done? (YES/NO)

7. Are you part of the pharmacovigilance committee? (YES/NO)

8. Is there presence of designated officer for pharmacovigilance services in your work place? (YES/NO)

RESULT

There are 23 questions in the questionnaire to assess the knowledge on ADR, attitude towards pharmacovigilance and their practice on ADR reporting. Of the 23 questions, 9 questions were knowledge based, 6 questions were attitude based and 8 questions were practice based. The response for this part of questionnaire was provided in the form of 'YES' and 'NO'. Result obtained from the survey are shown in the table below. The result observed is

Knowledge Based 71.54% YES and 28.45% NO. Attitude Based 88.98% YES and 11.02% NO. Practice Based 56.54% YES and 43.46% NO.

1. Knowledge Based Questions.

Table 1: Knowledge based questions

QUESTIONS	YES(%)	NO(%)
1. Do you believe all the drugs available in market are safe?	57.4	42.6
2. Are you aware of suspected Adverse Drug Reaction (ADR) reporting system in India?	85.1	14.9
3. Are you aware of any drug that has been banned recently due to ADR?	67.3	32.7
4. Do you believe herbal products have no ADR?	45.5	54.5
5. Do you think reporting ADR is important as a health care professional?	94.1	6.99

6. Do you think pharmacovigilance awareness program/website should be freely accessible to everyone?	92.1	7.9
7. Do you known the nearest adverse drug reaction monitoring center (AMC) located from your working place?	65.3	34.7

2. Attitude Based Questions.

Table 2: Attitude based questions

QUESTIONS	YES(%)	NO(%)
1. Do you think about to initiate ADR monitoring center in every work place?	89.7	10.3
2. Do you think about reporting of adverse drug reaction is necessary?	96.6	3.4
3. Do you think about pharmacovigilance should be included in academic curriculum of health care professionals.	94.0	6.0
4. Have you anytime read any article on prevention and management of ADR?	76.9	23.1
5. Are you willing to report ADR?	88.0	12.0

3. Practice Based Questions.

Table 3 Practice based questions

QUESTIONS	YES(%)	NO(%)
1. Have you ever experienced adverse drug reaction in your patient during your professional practice?	65.8	34.2
2. Have you ever been trained on how to report ADR?	57.3	42.7
3. Have you ever seen the ADR reporting form?	53.8	46.2

4. Have you ever reported ADR to the AMC?	37.6	62.4
5. Do you keep records of ADR?	69.2	30.8
6. Do you know how the causality assessment of ADR is done?	64.1	35.9
7. Are you part of the pharmacovigilance committee?	30.8	69.2
8. Is there presence of designated officer for pharmacovigilance services in your work place?	55.6	44.4

4. Knowledge Based Questions.

10) Do you believe all the drugs available in market are safe? (YES/NO)

11) Are you aware of suspected Adverse Drug Reaction (ADR) reporting system in India? (YES/NO)

12) Are you aware of any drug that has been banned recently due to ADR? (YES/NO)

13) Do you believe herbal products have no ADR? (YES/NO)

14) Do you think reporting ADR is important as a health care professional? (YES/NO)

15) What is your expectation from the pharmacovigilance program?

16) Which regulatory body is responsible for monitoring of ADR in India?

- ❑ Central Drugs Standard Control Organization
- ❑ Indian Institute of Science
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17) Do you think pharmacovigilance awareness program/website should be freely accessible to everyone? (YES/NO)

18) Do you known the nearest adverse drug reaction monitoring centre (AMC) located from your working place? (YES/NO)

5. Attitude Based Questions.

7. Which are the health care professional responsible for reporting ADR?

- ❑ Doctor
- ❑ Pharmacist
- ❑ Nurses
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8. Do you think about to initiate ADR monitoring center in every work place? (YES/NO)
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8. Is there presence of designated officer for pharmacovigilance services in your work place?	55.6	44.4

CONCLUSION AND RECOMMENDATIONS

Conclusion

The survey highlights the need for improvement in knowledge, attitude, and practice of pharmacovigilance among healthcare professionals. Despite their crucial role in ensuring patient safety, the results indicate a significant gap in their understanding and implementation of pharmacovigilance principles. The findings emphasize the importance of education, training, and awareness programs to enhance healthcare professionals' knowledge and attitude towards pharmacovigilance.

Recommendations

1. Education and Training: Regular workshops, seminars, and training programs should be conducted to educate healthcare professionals on pharmacovigilance principles, adverse drug reaction reporting, and risk management strategies.

2. Awareness Programs: Awareness programs should be implemented to emphasize the importance of pharmacovigilance and adverse drug reaction reporting among healthcare professionals.

3. Development of Guidelines: Standardized guidelines and protocols for pharmacovigilance and adverse drug reaction reporting should be developed and disseminated among healthcare professionals.

4. Encouraging Reporting: Healthcare professionals should be encouraged to report adverse drug reactions, and a user-friendly reporting system should be established to facilitate reporting.

5. Continuous Monitoring: Continuous monitoring and evaluation of pharmacovigilance practices among healthcare professionals should be conducted to identify areas for improvement.

6. Interdisciplinary Collaboration: Interdisciplinary collaboration between healthcare professionals, pharmacologists, and other stakeholders should be fostered to promote pharmacovigilance and ensure patient safety.

CONFLICT OF INTERESTS

The author has not declared any conflict of interests.

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