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’.[1] Pharmacovigilance is the science and activities relating to the detection, understanding and prevention of adverse effects or any other medicine related problem.[2]

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

ABSTRACT

Background: Children are very much vulnerable to adverse drug reactions (ADRs) and also tend to have more severe form of adverse effects compared to adults. Though ADR is a significant problem in children, paediatricians seem to neglect this aspect. Knowledge, attitude and practice (KAP) studies related to pharmacovigilance among paediatricians are lacking in literature. Hence, this study was planned to know the gaps in KAP among paediatricians of Odisha and factors related to underreporting of ADR. Materials and Methods: Google Form containing the questions was shared to paediatricians of Odisha state working in both private and government organisations. The questionnaire was prepared based on previous studies and some new questions relevant to our scenario were added. The questionnaire contained six questions based on knowledge, four on attitude and three on practice of ADR. Apart from that, it contained questions to know their response regarding the factors that discourage paediatricians to report ADRs. There were 60 responses. Results: Among the paediatricians, 70%-80% were aware of the pharmacovigilance programme running in India. Also, 80%-90% agreed that ADR reporting is crucial in paediatric health care, while most of them were trained regarding ADR reporting. But only 50% of them had reported an ADR in their clinical practice, which clearly indicates towards underreporting. Conclusion: The motivation for voluntary reporting of ADRs among paediatricians for preventing the morbidity and mortality in this vulnerable population could be of immense importance, and hence, various workshops and CMEs should be conducted to improve the KAP of these doctors, so that the problem of underreporting could be minimised.

Keywords: Adverse Drug Reactions (ADRs), knowledge, attitude and practice (KAP), paediatricians, pharmacovigilance

Knowledge, attitude and practice (KAP) of pharmacovigilance among paediatricians of Odisha and factors related to poor reporting of adverse drug reactions

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Received: 29-11-2021 Revised: 10-02-2022 Accepted: 15-02-2022 Published: 22-07-2022

Access this article online

Quick Response Code: Website: www.jfmpc.com

DOI: 10.4103/jfmpc.jfmpc_2323_21

How to cite this article: Behera MR, Tripathy R, Srivastava V, Das MC. Knowledge, attitude and practice (KAP) of pharmacovigilance among paediatricians of Odisha and factors related to poor reporting of adverse drug reactions. J Family Med Prim Care 2022;11:3524-7.
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.

Children are very much vulnerable to ADRs and also tend to have more severe form of adverse effects, compared to adults. Frequent medication errors related to dosage, unidentified ADRs during the clinical trial which are mostly done in adult participants, different pharmacokinetics and pharmacodynamics of the drug compared to adults, frequent off-level prescriptions are few of the contributing factors related to increased incidence of ADRs in children. It is the need of the hour that adequate systems and practices for reporting of ADRs should be in place to ensure patient safety.

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, paediatricians 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 paediatricians are lacking in literature.

Primary care physicians are often the first contact point for the children seeking medical and preventive care. Studies show they may have positive attitude towards ADR reporting but have suboptimal knowledge and poor practices. Hence, they must be aware of the mechanism, benefit and implications of ADR reporting. This study is planned to know the gaps in KAP among paediatricians of Odisha and factors related to underreporting of ADRs, which may be useful for primary care physicians also.

**Materials and Methods**

**Study Design and Setting**

This was a questionnaire-based observational study conducted in the Department of Paediatrics in collaboration with the Department of Pharmacology, Kalinga Institute of Medical Sciences (KIMS). The Department of Pharmacology, KIMS has been functioning as one of the AMCs under the PVPI since 2015. All the clinical disciplines are involved in reporting of ADRs to this centre. But underreporting is an issue. So, we conducted this study to know the KAP among paediatricians on ADRs.

**Ethical Approval and Sample Size**

This study was approved by the institutional ethics committee (Ref. no. KIIT/KIMS/IEC/571/2021). Taking relative precision as 5% and desired confidence level as 95%, the sample size was calculated to be 50.

**Questionnaire**

This was a questionnaire-based study and done in Google Form. The questionnaire was prepared based on previous studies, and some new questions were added as relevant to our scenario. The questionnaire contained six questions based on knowledge, four based on attitude and three based on the practice of ADR. Apart from that, it contains questions to know the participants’ response regarding the factors that discourage reporting ADRs.

**Data Collection**

Google Form containing the questions was shared to paediatricians of Odisha state working in both private and government organisations. They filled up the form with their responses in each part of the questionnaire. The process of response collection went on for a period of 1 month. There were totally 60 responses.

**Statistical Analysis**

Results of the study are presented with percentages. Chi-square test was used to find the association between two attributes at \( P < 0.05 \) significance.

**Results**

Out of all paediatricians, 60% belonged to KIMS hospital, Bhubaneswar and the remaining 40% were from other hospitals. Regarding clinical experience, 50% had 1–5 years’ experience and 16.7% had more than 20 years of experience. Majority of the paediatricians (58.3%) were in the age group 25–35 years, followed by 25% in 36–50 years age group. Most of the paediatricians (90%) involved in this study were working in private medical colleges/hospitals and 10% were from government hospitals.

Also, 43.3% clinicians agreed that ADRs are more severe in children. Out of all responses, 66.7% supported to make ADR reporting mandatory and 70% opined that ADR reporting is a professional responsibility. Also, 50% clinicians were of the opinion that children under 10 years of age were more affected with ADRs. Regarding the causes of underreporting of ADRs, most of the clinicians (50%) reported lack of training as the cause and 30% were unaware of the reporting process.

**Discussion**

KIMS is a tertiary health care centre in Odisha located in the east zone of India. There is an AMC functioning in the Department of Pharmacology, where adverse events from all the clinical disciplines are being reported, including the Department of Paediatrics. There are many studies to find factors responsible for underreporting of ADRs among healthcare professionals. It is estimated that between 5% and 10% of ADRs are reported. There is lack of study among paediatricians regarding KAP on ADRs as well as causes of underreporting from paediatricians.

A study by Tandon et al in India concluded that the lack of knowledge and awareness about PVPI, lethargy, indifference, insecurity, complacency, workload and lack of training were the
common factors responsible for underreporting. A study on pharmacists in Delhi had also shown lack of proper knowledge of pharmacovigilance as a common cause of underreporting of ADRs.[14] In our study, the commonest cause of underreporting as mentioned by paediatricians was lack of training (50%) followed by lack of knowledge of reporting system (30%) [Figure 1]. Other causes were lack of time in clinical practice and failure to suspect occurrence of an ADR. A study on pharmacists of Spanish region also concluded that the common causes of under-reporting are to be realizing that ADR is not serious, thinking that the ADR is already known, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and a lack of time.[17] In a study from Kuwait, pharmacists are shown to have a better knowledge of pharmacovigilance and ADR reporting, compared to primary care physicians.[6] A similar study from a South African district showed the frequency of reporting to be only 16% among primary healthcare professionals and pharmacists.[14]

To increase the reporting of ADRs, there should be regular training programme for clinicians, paramedical health staffs and post graduate students on detection and reporting system of adverse events. Particularly, the healthcare professionals should be trained on how to fill up the ADR reporting form with available information about the reaction, patient and drug. Additionally, healthcare professionals should be encouraged to report any suspected adverse events they come across in their clinical practice, irrespective of proof of evidence or absolute certainty on whether it is related to the particular drug.

We used Google Form to assess the KAP among paediatricians of our state. Regarding knowledge, 73.3% of participants understood what pharmacovigilance is and 83.3% responded that they knew the availability of an ADR reporting form [Table 1]. This finding is similar to that of another study by Adisha et al.,[17] which showed 72.5% awareness of pharmacovigilance. Another study by Nisa et al.[18] showed good knowledge (83.1%) about pharmacovigilance among healthcare professionals. In our study, 91.7% clinicians were aware of existence of an ADR monitoring and reporting system in India. It is very encouraging to find that 91.7% paediatricians showed a positive attitude towards reporting of ADR [Table 2]. In contrast, Adisha et al.[17] concluded that 46.2% showed positive attitude, but Nisa et al.[18] showed the same result as our study regarding positive attitude (78.2%) of healthcare professionals for ADR reporting. In our study, 95% participants experienced ADR in their practice, but only 50% agreed that they have reported them. Also, 50% were trained on ADR reporting [Table 3]. A study done on government doctors of Ethiopia has shown that only 27.4% ever reported an ADR.[19] Before conducting any training programme for healthcare professionals to increase ADR reporting, it is very pertinent to know the important focus areas for sensitisation at a priority basis. For this purpose, many studies on KAP on ADR have been carried out, but our study is unique in the sense that we included only paediatricians as participants, who are treating a vulnerable group of patients. Further, we have mentioned the

![Figure 1: Various responses of paediatricians as causes of underreporting of ADRs. 1 – Lack of training, 2 – unaware of reporting process, 3 – apprehension of ADR diagnosis being wrong, 4 – no reward or remuneration, 5 – negative effect on doctor–patient relationship, 6 – lack of time, 7 – hamper private practice, 8 – one report will not affect the programme. ADR = adverse drug reaction](image)

**Table 1:** Results obtained from knowledge domain among paediatricians of Odisha

| Question                                                                 | Correct (%) | Incorrect (%) | Don’t Know (%) |
|--------------------------------------------------------------------------|-------------|---------------|----------------|
| Which of the followings best defines pharmacovigilance?                  | 73.3        | 26.7          | Nil            |
| In India, which is the regulatory body responsible for monitoring ADRs?  | 13.3        | 86.7          | Nil            |
| Are you aware of existence of ADR reporting and monitoring system in India? | 91.7        | 8.3           | Nil            |
| Is there a standard form available for reporting ADRs?                   | 83.3        | Nil           | 16.7           |
| Do you know where to report ADRs?                                       | 70          | 30            | Nil            |
| Is there any pharmacovigilance committee in your institute?              | 66.7        | 13.3          | 20             |

ADR = adverse drug reaction. A Kruskal-Wallis H test was performed to examine the knowledge domain and the variables were significant, H statistic 8.0614 (2, n=66), P (0.01776), that is, <0.05, indicating that the paediatricians are having adequate knowledge regarding ADR reporting and pharmacovigilance programme.

**Table 2:** Results obtained from attitude domain among paediatricians of Odisha

| Questions                                                                 | Disagree (%) | Neutral (%) | Agree (%) |
|--------------------------------------------------------------------------|--------------|-------------|-----------|
| Reporting of ADRs is necessary in paediatric practice                    | 8.3          | 3.3         | 88.4      |
| Do you think ADRs reporting and monitoring would benefit the patient care? | 1.6          | 5           | 93.4      |
| Paediatricians should be sensitised regarding pharmacovigilance by regular training | 5            | 1.6         | 93.4      |

ADR = adverse drug reaction. A Kruskal-Wallis H test was performed to examine the attitude domain and the variables were significant, H statistic 18.665 (2, n=66), P (0.00357), that is, <0.05, indicating that the paediatricians are having appropriate attitude regarding ADR reporting and pharmacovigilance programme.
risk factors for poor reporting of ADRs among them for the first time [Figure 1].

**Conclusion**

The process of ADR detection, evaluation and monitoring should be improved, especially for the paediatric population because they do not directly communicate and we have to depend on parents’ description. To improve spontaneous reporting of ADRs by paediatricians, emphasis should be given on regular educational workshop on pharmacovigilance. Also, awareness should be increased in the general population to notify if they experience any difficulty after medication intake. The motivation for voluntary reporting of ADRs among paediatricians for preventing the morbidity and mortality in this vulnerable population could be of immense importance, and hence, various workshops and continuing medical education (CMEs) should be conducted to improve the KAP of these doctors, so that the problem of underreporting could be minimised.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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