Original Research Article

Knowledge, Attitude, and Practice (KAP) of Pharmacovigilance among the different categories of frontline Covid-19 healthcare workers in a tertiary care hospital in West Bengal, India

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Received: 07-11-2021 / Revised: 24-12-2021 / Accepted: 14-01-2022

Abstract

Background: In these difficult times of Covid19 pandemic, there are rampant increase in uses of new/ old drugs which are approved or waiting to be approved or repurposed with a different dose and schedule to treat and prevent the disease. Information regarding ADRs are lacking for those drugs. Hence the need for ADR reporting by frontline Health Care Workers (HCW) are reemphasized to generate data regarding ADRs of these drugs. That's why this study was required to evaluate the status of Knowledge, attitude & practice (KAP) of HCWs regarding ADR reporting and to plan steps to improve if found not sufficient. **Materials & Methods:** A hospital-based cross sectional pretested close ended questionnaire-based observational study was carried out in-inpatient departments (IPD), outpatient department (OPD) & Pharmacy Department of RG Kar Medical College & Hospital, Kolkata aimed at evaluating KAP regarding ADR reporting in different categories of frontline Covid-19 HCWs. **Results**: About 138 HCWs participated in the study after properly filling up informed consent form. Data collected and analyzed to find out that there was inadequate knowledge in about half of the participants (47.1%) & poor practice regarding ADR reporting. Only 22.5% HCWs encountered & reported ADRs. But there was no lack of favorable attitude regarding ADR reporting (84.78%). **Conclusion**: These findings indicate that proper encouragement and appropriate steps by administration can reverse the status of knowledge practice regarding ADR reporting.

Keywords: Adverse drug reactions, Covid 19, Cross sectional study, knowledge, questionnaire, health care workers

Introduction

Medicines or drugs play a very important role in patient care not only in treatment but also in other aspects of management like diagnosis, prevention of diseases. According to the World Health Organization (WHO, 1966) "Drug is any substance or product that is used or is intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient"[1]. There are thousands of medicines available in the market globally. Large number of new medicines are also added every year to our medicinal armamentarium for management of disease. However, the safety of medicines remains to be a major concern.

One of the major reasons of morbidity and mortality all over the world is adverse drug reactions (ADRs)[2]. According to WHO, an adverse drug reaction (ADR) is any deleterious, inadvertent, and unwanted reaction to drugs when used for prevention, diagnosis, or treatment purposes at therapeutic doses or for modification of physiological malfunction which precludes accidental or deliberate overdosage or drug maladministration[3]. Every drug has got ability to cause ADRs. Whenever a drug is given to a patient, we are exposing that patient to the risk of ADRs. The consequences of an ADR may include damage to the proper functioning of a patient's body internally and/or externally, prolonged hospitalization, increase in health-care expenses, significant disability/ incapacity, life-threatening injuries, congenital anomaly, and even death[4].A study in France, suggested that up to 123,000 patients per year present to their general practitioner with ADRs[5]. ADRs account for upto 30% of hospital admissions in USA and Canada, upto 10.6% of admissions in Europe[6]. Some studies focusing on vulnerable populations such as paediatric & geriatric patient groups revealed up to 39% of ADRs in paediatric patients can be life-threatening or fatal[7]. A national study from the USA estimated that upto 35.5% of emergency department visits in older adults are due to drug-related causes[8]. Studies from Europe revealed similar results[9,10]. Not only ADRs have a major impact on public health but also reduce patients' quality of life and

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impose a significant financial cost in the health care delivery system[11,12]. ADR reporting and monitoring is the utmost necessity to prevent and treat ADRs. The history of ADR monitoring has dated back about 60 years since thalidomide disaster that caused phocomelia in children in many countries[11,13]. ADR monitoring done by pharmacovigilance which is the science and activity related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems[14]. In India, origin of Pharmacovigilance goes back to the year 1986, when officially an ADR monitoring system consisting of 12 regional centres was proposed with each centre covering a population of 50 million. However, there was no progress made till 1997 when India joined the WHO Adverse Drug Reaction Monitoring[15]. Major obstacles globally in the success of Pharmacovigilance programme to achieve its goal is under reporting of ADRs [16]. All ADRs ranging from minor to severe reactions should be reported specially ADRs to new medicines, serious adverse drug reactions, unexpected reactions, and potentially serious or clinically significant drug interactions. In addition, uncertainty about causal relationship should not be a reason for nonreporting[3,17].Various studies have reported under reporting of ADRs. Multiple factors may be responsible for that[18]. It is important for healthcare professionals (HCP) to know how to report and where to report an ADR. ADR reporting further assumes greater importance in this time of worldwide pandemic of COVID-19. A number of drugs approved or waiting to be approved to treat and prevent the disease under expedited clinical trial mode under Emergency Use Authorization by FDA, DCGI & other drug regulatory agencies of various country[19]. They are also used in a dose, duration and frequency not used for other indications which are approved previously. Hence ADR reporting may be only way to get information regarding adverse reactions for those drugs. Rampant Over the counter (OTC) uses of medicines in this pandemic era further increases the risk of ADRs[20,21]. Proper knowledge, attitudes and practices regarding ADR in all levels of health care workers absolute necessary for promoting ADR reporting. Otherwise, ADR reporting cannot achieve its goal. In this study we wanted to assess knowledge, attitude and practice (KAP) of Pharmacovigilance among healthcare professionals to identify factors attributable for under reporting of ADRs & device policy to address deficiency.

Materials and Methods

Study Settings, Study Design and Study Population

This study is a hospital-based cross sectional pretested close ended questionnaire-based observational study design which was carried out in- inpatient departments (IPD), outpatient department (OPD) & pharmacy department of RG Kar Medical College & Hospital, Kolkata. Data analysis was made in the department of pharmacology, RG Kar Medical College & Hospital, Kolkata. Study population included doctors, pharmacy professionals and nurses who were working in this hospital as frontline Health Care Worker (HCW) in the management of COVID 19 patients during the study.

Study duration, Sampling strategy, and Sample size

The study was conducted between 10th to 30th, November, 2021. Convenience sampling technique was used to select HCWs who played frontline roles in management of COVID 19 in this hospital. A total of 138 HCWs including doctors, pharmacists and nurses participated in this study during the study duration.

Operational definition

I. **Adverse drug reaction**

II. Any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment, or decrease in dose or indicates caution in the future use of the same drug[22].

III. **Pharmacovigilance**

IV. Science and activities relating to the detection, assessment, understanding and prevention of adverse effect or any other drug related problems[23].

Study variables

Independent variables

Age, sex, occupation.

Dependent variables

Overall knowledge of HCPs about ADR reporting, Overall attitude of HCPs towards ADR reporting, Overall Practice of HCPs about ADR reporting

Data collection tools

A pretested close ended self-administered questionnaire developed by modifying the tools from other similar studies and pilot testing done at the beginning of the study[17, 24-27]. This questionnaire aimed at collecting data regarding knowledge, attitude and practice of Pharmacovigilance from the respondents.

Ethical approval, Study Methods

Study commenced after getting approval from Institutional Ethics Committee of RG Kar Medical College & Hospital. General information and objectives of the study carefully explained to participants in writing and properly signed consents were taken from them prior distributing the questionnaire for the study. Appropriately filled questionnaires from the participants were collected and analyzed. At all stages confidentiality of the participants were maintained. Data analysis was done in Department of Pharmacology, RG Kar Medical College & Hospital, Kolkata.

Data Management & Analysis

Data were entered into Epi info version 3.5.3 cleaned, and then exported to Statistical Package for the Social Sciences (SPSS) version 20 for analysis. In this study, knowledge of frontline HCWs about ADR reporting was assessed with thirteen questions. Each correct response had a score of 1 and incorrect response had a score of 0. Thus, total knowledge score varies from 0 to 13. The level of knowledge among participants was categorized by using mean knowledge score.

Knowledge Category	Criteria
Adequate Knowledge	Individual with knowledge score≥ mean knowledge score
Inadequate Knowledge	Individual with knowledge score< mean knowledge score

All participants' attitude towards ADR was evaluated by using twelve questions rated on a three point Likert scale. A response of "agree" was given a score of 3, "neutral" a score of 2, and "disagree" a score of 1. So, the total attitude score for individuals varies from 12-36 The level of attitude among participants was categorized as follows

Attitude Category	Criteria
Favourable attitude	Individual with attitude score≥ 75% of max total attitude score
Unfavourable attitude	Individual with attitude score< 75% of max total attitude score

HCWs' practice was assessed by identifying whether they documented and reported ADRs or not. Good practice was considered for those individual participants who documented and reported the encountered ADRs.

Results

Demographic Characteristics

The study was conducted in RGKMCH among 138 HCWs to assess Knowledge, Attitude & Practice towards ADR reporting. From 138 self-administered questionnaires distributed, all questionnaires were adequately filled and returned. Among 138 participants, 31 (22%) and 107 (78%) were males and females, respectively. The mean age of participants was 32.28 (±7.68), and majority of them were in the age group of 25–34 years (78, 57%). Majority of participants were nurses (82, 59.42%) followed by doctors (50, 36.23%) & pharmacist professionals (6, 4.35%). (Fig. 1, 2, 3).

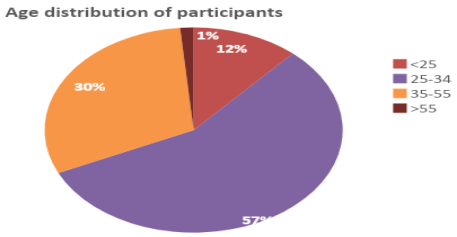

Fig 1: Distribution of Age of participants. (n = 138)

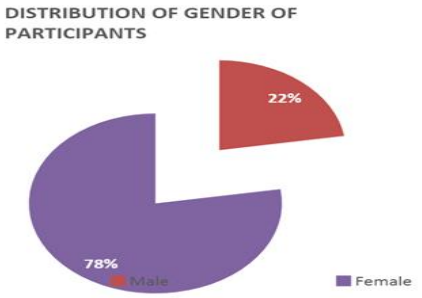

Figure 2: Distribution of Gender of participants. (n = 138)

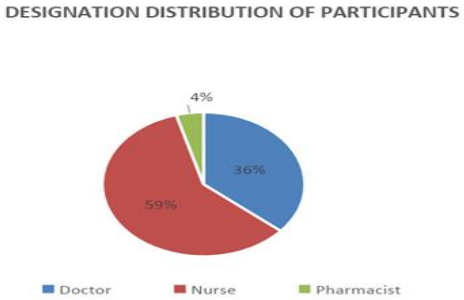

Figure 3: Distribution of Designation of the participants. (n = 138)

Knowledge of HCWs on ADR Reporting

Thirteen different questions were used to assess knowledge of frontline HCWs on ADR reporting. 120 (86.96%) participants knew the term pharmacovigilance. Likewise, 92 (66.67%) and 87 (63.04%) participants knew the existence of national ADR reporting system and ADR reporting forms in India, respectively. 81 (58.7%) participants knew the process of ADR reporting. 88 (63.77%) participants appropriately knew where to report if encounter a case of possible ADR. However less than half of participants (50 (36.23%)) knew that ADR reporting can be done simply by a Mobile App. 92 (66.67%) participants knew that the possibility of an ADR should be the first differential diagnosis at all times in patients taking medicines. When overall knowledge of participants was assessed, the study revealed that 73(52.9%) of participants had adequate knowledge of ADR reporting. Large number of participants (65(47.1%)) did not have adequate knowledge of ADR reporting. Distribution of Overall knowledge of ADR reporting given in Table 1 & Figure 4.

Table 1: Distribution of Knowledge in different categories of HCWs. (n=138)

HCW Category	Participants with Adequate knowledge (Percentage %)	Participants with Inadequate knowledge (Percentage %)
Nurse	**51(62.2)**	**31(37.8)**
Doctor	**21(42)**	**29 (58)**
Pharmacist	**1(16.7)**	**5(83.3)**

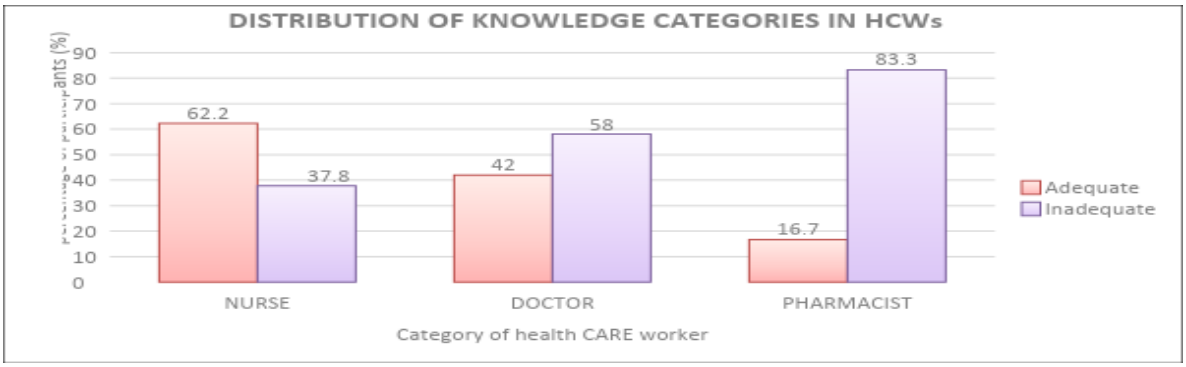

Fig 4: Distribution of Knowledge categories in different categories of HCWs.(n=138)

Attitude of HCWs towards ADR Reporting

Attitude of HCWs towards ADR Reporting assessed by 12 different questions. 125 (90.58%) participants agreed that ADR reporting should be part of their duty and 99 (71.74%) agreed that one report of ADR can make a difference. Besides, 137 (99.28%) and 134 (97.1%) agreed that reporting ADR is important for the public health and improves quality of patient care, respectively. 114 (82.61%) participants agreed that ADRs should be reported spontaneously regularly. However, approximately half of participants (72 (52.17%)) worried about legal problems while ADR reporting & 49 (35.51%) participants feared that ADR reporting will produce additional workload on them. Overall attitude towards ADR reporting assessment in this study revealed largely Favorable attitude among HCWs (117(84.78%)). Distribution of Overall attitude for ADR reporting in different categories of HCWs given in Table 2 & Figure 5.

Table 2: Distribution of Attitude in different categories of HCWs. (n=138)

HCW Category	Favorable attitude (%)	Unfavorable attitude (%)
Nurse	65(79.3)	17 (20.7)
Doctor	47(94)	3(6)
Pharmacist	5(83.3)	1(16.7)

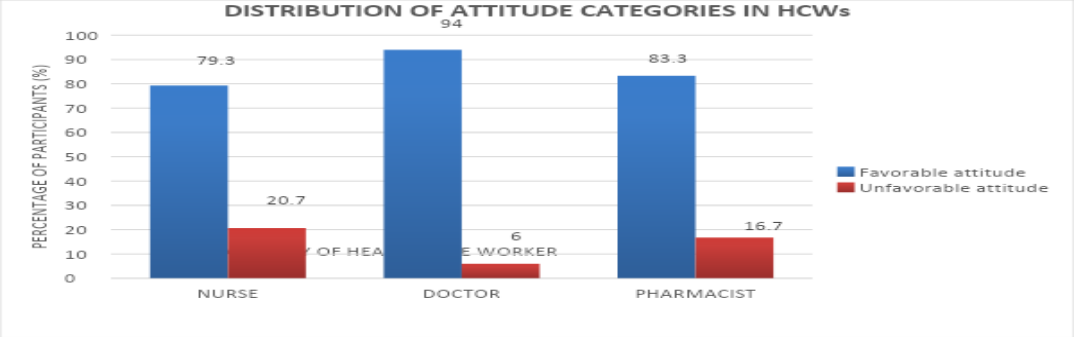

Fig 5: Distribution of Attitude categories in different categories of HCWs. (n=138)

Practice of HCWs regarding ADR identification, reporting & advice

Present study has found that only a small number of participants (31 (22.5%)) encountered & reported at least one patient with ADR in the past 12 months. 12 (8.7%) of HCWs failed to report ADR even after detection of ADR at the same period of time. However, a large number of HCWs (95 (68.8%)) failed to detect & report even one ADR in last 12 months (Figure 6). ADR detection and reporting was done only by 10 nurses (12.2% among study participant nurses) whereas among doctors 21 doctors (42% among study participant doctors) have done ADR detection and reporting. But there was no pharmacist who have detected and reported ADR in the previous 12 months period (Figure 7). However, practice of advising their patients on possible adverse effects of drugs by HCWs were frequent. Only 8(6%) HCWs have never given advice on possible adverse effects of drugs they prescribed, dispensed, or administered (Figure 8).

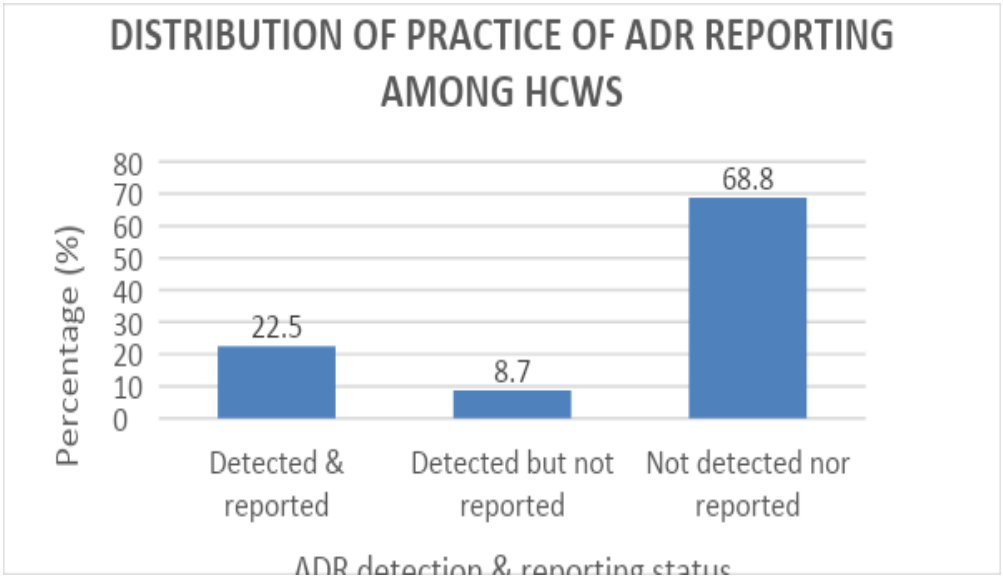

Fig 6: Distribution of Practice of ADR reporting among HCWS in last 12 months. (n=138)

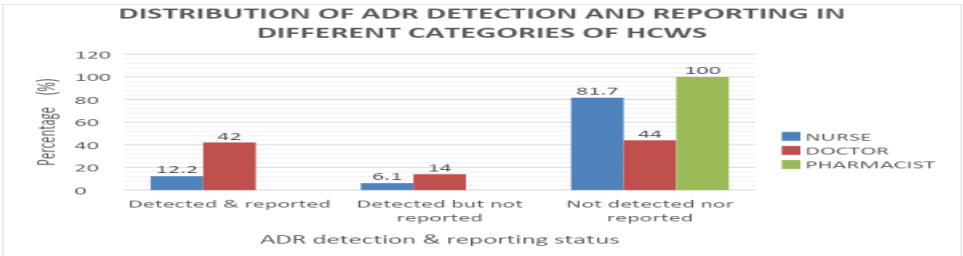

Fig 7: Distribution of ADR detection and reporting in different categories of HCWS in last 12 months. (n=138)

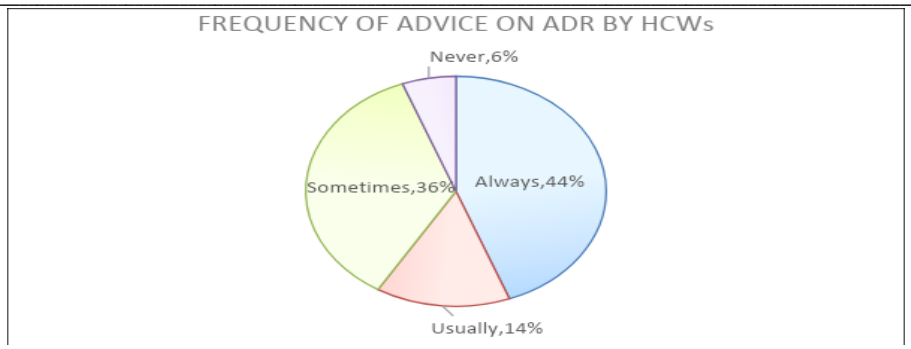

Fig 8: Frequency distribution of advice on ADRs by HCWs. n= 138

Discussion

The present study was a questionnaire-based cross-sectional study. A total of 138 HCWs of three categories – nurses (60%), doctors (36%) & pharmacists (4%) participated in this study. The mean age of participants was 32.28 (±7.68) years with majority of them were in the age group of 25–34 years (78, 57%).

Study revealed that 52.9% of participant HCWs had adequate knowledge of ADR reporting which is better than 16.9% in Pakistan in 2018[28], 39.4% in Nepal in 2011[29] & 39.6% in Saudi Arabia[30]. But lower than 77% in Philippines[31]. 86.96% of the participants knew the term pharmacovigilance and its activities which are greater than 62.4% of a study conducted in India in 2015[32]. Moreover, the present study indicated that majority of participants knew national ADR reporting system (66.67%) which was greater than 22.81% of Ethiopian study conducted in 2019[33] but lesser than 75.2% of a similar study conducted in southern India[32]. 58.7% of HCWs knew the process of ADR reporting in our study which was better than 20.18% of Ethiopian study[33]. In our study, among the different categories of HCWs, more nurses (62%) had adequate knowledge followed by doctors (42%) corroborative to the finding of a similar study in Philippines[31]. But the finding was different from the result obtained from the study conducted in a tertiary center of Ethiopia[34] where more pharmacy professionals knew about ADR reporting. Probable explanations behind this finding may be ADR reporting system of this institution lacked active participation of pharmacist due to greater workload for them.

Despite significant number (47.1%) of inadequate knowledge among HCWs, majority (84.78%) had favorable attitude towards ADR reporting which is in the similar lines of other studies conducted in South India[32]. But this finding is higher than other studies in (26.9%) Malaysia[35] & (66.3%) Nepal[29]. 90.58% HCWs opined that ADR reporting should be part of their duty which is similar to other findings[33,34]. But 35.51% & 52.17% feared of additional workload & legal problems respectively which we believe substantially affecting their motivation of ADR reporting. Among different HCWs, doctors (94%) had the most favorable attitude towards ADR reporting. Greater understandings of the significance of ADR reporting in patient care and participation in periodical reinforcement program on this topic of the doctors might explain this finding.22.5% of HCWs had encountered and reported ADRs in the present study. A similar kind of finding seen in study conducted in South India (22.8%)[32]. 68.8% failed to detect & report atleast one ADR. So, the practice of reporting ADR in this hospital is poor.

One explanation may be our first line HCWs are inexperienced in hands on training of ADR reporting as understood from their age group distribution. So, in spite of having adequate theoretical knowledge of ADR and positive attitude ADR reporting practice lacking. We are also stressing on another fact that being a tertiary hospital catering to a large area of one of the world's densely populated region, they have a huge workload which may be discouraging such practice.

Conduction of this study had a few limitations. One of the limitations of the study was that all frontline HCWs working in this hospital was not included in the study and only those who were having shifts at the time of data collection included in the study. The sample size was small and also not equal for different categories because of convenient sampling. So statistical testing of the KAP parameters between different categories of HCWs was not possible. As this study used questionnaire for data collection, recall bias might have affected the data obtained. So, we opined that similar kind of study can be conducted in future stressing more on the factors responsible for non-reporting of ADR. Use of online mode to send questionnaire to all the HCWs may be undertaken. Possibly a multicentric study will also enable to get a complete picture of KAP regarding ADR reporting in this region.

We recommend a provision of regular hands-on training on ADR reporting by competent bodies involving not only doctors but also nurses and pharmacists. Curriculum of undergraduate and postgraduate students of medicine, nursing and pharmacy should include not only theory but also due emphasize on practical training on ADR reporting. Number of ADR reported yearly should be included in assessment of students as well as in appraisal of doctors, nurses, and pharmacy personnel for promotion. Incentivizing in terms of credit or recognition of concerned HCWs may encourage them to report ADRs spontaneously. Simplification of the ADR reporting form and providing proper support for ADR form fill up may simplify and make the reporting less time consuming.

Conclusion

ADRs though ignored but pose significant problems in drug therapy and cause major impact on public health. ADRs cause reduction of patients' quality of life and produce a considerable financial burden on the patient as well as society. Thus, ADR reporting is very essential in generating data that will prevent ADRs by improving HCWs knowledge of drugs and its interaction with particular patient characteristics. The present study identified that only half of HCWs working in this tertiary hospital had adequate knowledge on ADR reporting, though there was no dearth of positive attitude for ADR reporting, overall practice was poor. This positive attitude can be channelized to gather appropriate knowledge and practice for ADR reporting. Collaborative works required between different departments and hospital administration required to achieve that goal. Change in hospital policy regarding ADR reporting and arranging appropriate activities may be undertaken to promote ADR reporting practice.

Acknowledgement

The Authors of this paper heart fully acknowledge, NCC-PvPI and AMC, R G Kar Medical College (Kolkata) for supporting our study.

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Conflict of Interest: Nil Source of support: Nil