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EVALUATION OF ADVERSE DRUG REACTIONS USING DROP BOX AT TERTIARY CARE CENTRE: A STEP TOWARDS PHARMACOVIGILANCE

Pharmacology

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ABSTRACT

Background: India rates below 1% in terms of ADR reporting against the world rate of 5%. The reporting of ADRs has become a crucial component of the monitoring and evaluation activities which are performed in most of the hospitals. The Ministry of Health & Family Welfare has initiated the National Pharmacovigilance Program which is coordinated by the Central Drugs Standard Control Organization in New Delhi. Under this program peripheral, regional and zonal Pharmacovigilance Centers are asked to work cohesively to improve ADR reporting in India.

Materials & Methods: The present study was carried out at RUHS College of Medical Sciences attached hospital RDBP Jaipuria hospital, Jaipur (Rajasthan) during the period of six months from February 2019 to July 2019. Clearance from institutional ethical committee was taken prior to the study. In the present study safely locked 'ADR notification drop boxes' (with the key purpose printed on them) were installed systematically in all the wards of our tertiary care hospital.

Results: In the present study we found that that 3 adverse drug reactions notified in the first month, which was followed by 4 adverse drug reactions notified in third month, followed by 5 adverse drug reactions notification in fourth month. 7 adverse drug reactions were notified in fifth month and 12 adverse drug reactions notified July month.

Conclusions: We concluded from present study that drop box can be one of the easy methods to report adverse drug reactions. Drop box also provides a quick method to health care professional and patients to report adverse drug reactions. Reporting of ADRs is compulsory and it should be made an integral part of the patient care.

KEYWORDS

Adverse Drug Reactions, Drop Box, Pharmacovigilance.

INTRODUCTION

World Health Organization (WHO) describes that adverse drug reactions (ADRs) are unwanted and noxious effects of the prescribed drug, when it is applied for the treatment of disease or given for diagnosis (1). It is widely known fact that no drug is completely free from side effects. India holds a large number of drug consuming population. For the safety profile of the drug its clinical trials and safety databases are validated for its execution in the market (2). There is a plethora of counterfeit and substandard drugs or drugs belonging to alternative systems of medicine like Ayurveda, Unani, Siddha, Homeopathy and drugs which have been banned/withdrawn in other countries (3).

India rates below 1% in terms of ADR reporting against the world rate of 5%. This means that India is lagging behind in terms of reporting ADR as compared to world scenario. The reporting of ADRs has become a crucial component of the monitoring and evaluation activities which are performed in most of the hospitals (4). To overcome this rate, the Ministry of Health & Family Welfare has initiated the National Pharmacovigilance Programme (NPP) which is coordinated by the Central Drugs Standard Control Organization (CDSCO) in New Delhi. Under this programme 24 peripheral, five regional and two zonal Pharmacovigilance Centers are asked to work cohesively to improve ADR reporting in India (5)

When a novel drug's safety is under process, it is being constantly supervised by pharmacovigilance centers for the identification of adverse effects of the drug. Moreover, they also take important steps to control the adverse effect of drugs by understanding and assessing the risk associated with the drug (6). To get sustained result in ADR reporting, there should be strong collaboration of Department of pharmacology and other clinical departments. Assistance should be provided by the CDSCO to sponsor ADR boxes, notification forms and ADR alert cards under the National Pharmacovigilance Programme (NPP) (7).

The current study was carried out for ease and successful reporting of adverse reaction amongst healthcare professionals. The main objective of this study is to assess adverse drug reaction reporting using Adverse Drug Reaction (ADR) notification drop box.

MATERIALS & METHODS

The present study was carried out at RUHS College of Medical Sciences attached hospital RDBP Jaipuria hospital, Jaipur (Rajasthan). Duration of the study was 6 months (from February 2019 to July 2019). Clearance from institutional ethical committee was taken prior to the study.

Procedure of study: In the present study safely locked 'ADR notification drop boxes' (with the key purpose printed on them) were installed systematically in all the wards of our tertiary care hospital. For convenience of notifier we also kept 'ADR notification forms' along with drop boxes. ADR notification forms were designed in a simple way which included only necessary information's such as name of patient, age of patient, drug name, description of drug reactions and details of reporter as shown in Figure 1. Other information's required to fill red colored CDSCO reporting form given by pharmacovigilance centre were collected from the hospital supply. To maintain the patient's safety, each patient with an adverse drug reaction was provided an 'adverse drug reactions alert card' at the time of discharge from the hospital along with medical records and advise the patient to kept it with them at the time of hospital visit or consulting with other health care providers in the future.

Analysis of Data: All the data from all drop boxes of different places of hospitals were collected at monthly interval and data was gathered and organized for further analysis. The data were analyzed using MS Excel 2010 spread sheet, Epi Info v7.2 and SPSS v22.

RESULTS

In the present study we used a drop boxes to evaluate adverse drug reactions. Before installation of drop boxes an education programme was carried out for all health care professionals. In the programme, health care professionals were educated about use of drop boxes, adverse drug reaction reporting.

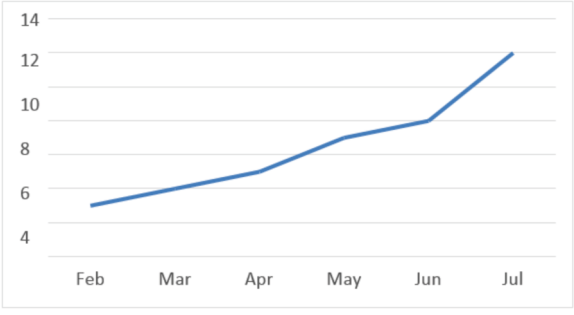
In month of February we collected only 3 adverse drug reaction forms from drop boxes. In March no significant increase in adverse drug reaction forms was noticed (only 4 ADRs). In April and May we collected total 12 adverse reaction forms (5 in April and 7 in May). A better improvement in ADR collection was reported in month of June and July. We collected total 20 ADR forms collectively from month of June and July as shown in Table 1 and Figure 2. ADR reporting increased from 8 to 12 in last two months (50% increases in ADR reporting).

Table 1: N umber of ADRs reported in the 6 months after installing the ADR notification drop boxes

Month	Number of adverse drug reactions reported
February	3
March	4
April	5
May	7
June	8
July	12

Figure 1: Adverse Drug Reaction (ADR) Notification Drop Box with ADR Notification form

Figure 2: ADR reporting from February to July using drop- box



DISCUSSION

Most difficult task is to encourage clinicians and other related governing persons who are frequently in contact with patients. Many factors like lack of awareness, training and time contributes in low level of ADR reporting. Lack of essentiality in reporting ADR by government can also be an additional factor for low count of ADR reporting (8). The only way to impart the habitude amongst health professional besides the educational programme is to provide them with an easy and quick method of reporting. Safely locked 'ADR notification drop boxes' (with the key purpose printed on them) were installed systematically in all the wards and selected outpatient departments (OPDs) in the hospital can be the ultimately solution for this. Along with these boxes ADR notification forms also putdown in a way that notifier (doctor, intern, medical student or nurse) find it easy to report an ADR (9).

When doctor, intern, medical student or nurse suspects an adverse drug reaction, they filled the notification form and dropped in the 'ADR notification drop box'. All the notification form data was collected and analyzed at monthly intervals. The drug manufacturer's salt name and batch number details were provided by the 'notifier' and same was tracked down with the help from the hospital drug store (10). After completing all the required details, the red coloured reporting form the Central Drugs Standard Control Organization, provided by the pharmacovigilance centre, was completed. All the health care providers were educated about the adverse drug reactions notification drop boxes and notification forms at regular monthly intervals. Since a major proportion of India's population prefers government hospitals when they seek health care facilities, a good ADR database can be generated from these hospitals (11).

ADR reporting increased from 3 to 12 in present study. Dang A et al at the tertiary care hospital of Goa medical college conducted a study for 3 months using drop box for ADR collection and found 14 adverse drug reactions notified in the first month, which was followed by 23 adverse drug reactions reported in the second month and this was followed by 32 adverse drug reactions notified in third month (12).

CONCLUSION

Drop boxes may play an important role in pharmacovigilance because it is an easy and quick method to report adverse drug reactions. Drop boxes can be installed in all the hospitals to collect more ADRs and it should be an integral part of hospitals. An 'adverse drug reactions alert card' should issue to the patients at the time of discharge from the hospital along with medical records and advise the patient to kept it with them at the time of next hospital visit or consulting with other health care providers in the future.

REFERENCES:

1. Jill E Maddison SWP. Adverse Drug Reaction - an overview. ScienceDirect [Internet]. 2008;2(1). Available from: https://www.sciencedirect.com/topics/medicine-and-dentistry/adverse-drug-reaction
2. Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med J R Coll Physicians London. 2016 Oct 1;16(5):481–5.
3. Dang A, Bhandare PN. The profile of voluntary reported adverse drug reactions at a tertiary care hospital: A fifteen month prospective study. J Clin Diagnostic Res. 2012 Nov 15;6(9):504–1509.
4. Sahu RK, Yadav R, Prasad P, Roy A, Chandrakar S. Adverse drug reactions monitoring: prospects and impending challenges for pharmacovigilance. Vol. 3, SpringerPlus. SpringerOpen; 2014.
5. Bavdekar SB, Karande S. National pharmacovigilance program. Indian Pediatr [Internet]. 2006 Jan;43(1):27–32. Available from: http:// www. ncbi. nlm.nih. gov/ pubmed/16465003
6. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance Programme of India: Recent developments and future perspectives. Vol. 48, Indian Journal of Pharmacology. Med know Publications; 2016. p. 624–8.
7. Biswas P. Pharmacovigilance in Asia. J Pharmacol Pharmacother [Internet]. 2013;4(5):7. Available from: http://www.jpharmacol.com/text.asp?2013/4/5/7/120941
8. Khopkar U. Reporting of drug eruptions: The national pharmacovigilance program. Indian J Dermatol Venereol Leprol [Internet]. 2005;71(1):1. Available from: http://www.ijdvl.com/text.asp?2005/71/1/1/13776
9. Singh J, Singh H, Rohilla R, Kumar R, Gautam CS. Lack of Awareness of Pharmacovigilance among Young Health-care Professionals in India: An Issue Requiring Urgent Intervention. Int J Appl basic Med Res [Internet].;8(3):158–63. Available from: http://www.ncbi.nlm.nih.gov/pubmed/30123745
10. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK "Yellow card scheme": Literature review, descriptive and qualitative analyses, and questionnaire surveys. Vol. 15, Health Technology Assessment. 2011. p. 1–234.
11. Dorji C, Tragulpiankit P, Riewpaiboon A, Tobgay T. Knowledge of Adverse Drug Reaction Reporting Among Healthcare Professionals in Bhutan: A Cross-Sectional Survey. Drug Saf. 2016 Dec 1;39(12):1239–50.
12. Amit D, Rataboli P V. Adverse drug reaction (ADR) notification drop box: An easy way to report ADRs. Br J Clin Pharmacol. 2008;66(5):723–4.