Research Article
AMERICAN JOURNAL OF PHARMACY AND HEALTH RESEARCH
www.ajphr.com
2015, Volume 3, Issue 2
ISSN: 2321–3647(online)

Users' Profile of the Adverse Drug Reaction Reporting System in Brazil: A Pilot Study

Carolina Baraldi A. Restini[1*], Cleber Massato Toda [2], Jessica Natalia Andre[2]
1. Full professor and Researcher at the Master Program in Health and Education. Full professor, tutor and researcher at the Medical School. University of Ribeirao Preto UNAERP, Brazil.
2. Master Students Master Program in Health and Education. University of Ribeirao Preto UNAERP, Brazil.

ABSTRACT

To investigate the profile of potential users of the Brazilian Adverse Drug Reaction Reporting System that take care of the pharmaceutical product information, concerning to the their knowledge of its regulatory authorities safety and effective use of drugs. This was an observational cross-sectional study with descriptive and analytical characteristics. Four hundred and fourteen people were surveyed in 2013 from May to August, and after gathering the data. A high percentage of lack of knowledge about the Brazilian Drugs Reporting System was observed regarding consumers with 95.37% (n = 309) (95% CI: 93.08- 97.66) and professionals who deal with medications and drugs with 68.89% (n = 62) (95% CI: 59.32- 78.45). Considering the population who knows about the System, only a few number of notifications were observed, consumers with 0.93 % (n = 3) (95% CI: 0.12 - 1.97) and health professionals with 8.89 % (n = 8) (95% CI: 3.01-14.77). Three Adverse Drugs Reactions cases were observed: Steven Johnson disease (due to phenobarbital use), drug-induced diabetes (betamethasone), and partial loss of voice (chloramphenicol). None of them were reported to the System. The results obtained indicate an elevated percentage of lack of knowledge and underutilization of the Brazilian Adverse Drug Reaction Reporting System. Therefore, it is necessary for educational interventions to be adopted in order to increase notifications.

Keywords: Rational Use of Medicines (RUM), Adverse Drug Reaction Reporting System (ADRRS / NOTIVISA), Adverse Drugs Reactions (ADR), Unified Health System (UHS / SUS), National Healthy Surveillance System (NHSS / ANVISA), Pharmacovigilance.

*Corresponding Author Email: carolbaraldi@hotmail.com
Received 19 January 2015, Accepted 31 January 2015

Please cite this article as: Restini CBA *et al*., Users' Profile of the Adverse Drug Reaction Reporting System in Brazil: A Pilot Study. American Journal of Pharmacy & Health Research 2015.

INTRODUCTION

Rational Use of Medicines (RUM) should be stimulated as a method of guarantying expected efficacy and safety. Even with all the warning and the RUM, it can be denoted the eminent occurrence of Adverse Events (AE), defined as unwanted effects, organic damage, or unpleasant symptomatology after the use a particular medication[1]. In agreement with the Brazilian pharmaceutical joint resolution (resolution RDC nº 4/2009), AE are classified as: (1) suspicion of Adverse Drugs Reactions (ADR), (2) AE because of quality shifts in medications, (3) AE due to unapproved use of medication, (4) drug interactions, (5) total or partial absence in therapeutic effectiveness, (6) medication-related intoxications, (7) abusive use of medications, (8) potential and real prescription errors[2]. Out of the AE belonging to Pharmacovigilance's interest, ADR stands out for being the focus of devastating tragedies related to medication use and for the fact that half the drugs promote adverse reactions detected mostly in the post-commercialization phase[3]. A classic example of ADR is thalidomide, which caused terrible consequences in relation to fetal malformation. Kava-Kava (*Piper methysticum L*), an herb abundantly prescribed to relieve anxiety and insomnia, is another example since it was responsible for 25% of hepatotoxicity in Switzerland and Germany[4]. ADR is responsible for about 3 – 6% of hospital admissions; approximately four percent of new drugs are withdrawn for circulation due to issues triggered by these reactions[5]. ARM is associated with ten main causes of death in the United States and it produces a yearly expenditure ranging from 1.5 to 4 billion US dollars[6]. In 2009 in Brazil, according to a report from Brazilian National Poisoning Information System – BNPIS (in Brazilian Portuguese it is called *SINITOX: Sistema Nacional Informações Tóxico-farmacológicas*), there were 71 registered deaths related to medications and 26,753 cases of intoxications caused by medication. In 2011 medication was the main cause of intoxication occupying the number one rank with 29, 105 cases[7]. Brazil holds the fifth position in the world rank of medication consumption, and the first position in Latin America[8]. The yearly expense of medication by the Unified Health System (UHS), a Brazilian Public Health System, is about R$ 2 billions[9]. Since its creation in Brazil in 1999, the National Healthy Surveillance System – NHSS (in Brazilian portuguese it is called *ANVISA: Agencia nacional de vigilância sanitaria*) has developed a series of initiatives to promote patient safety in relation to medication use like the establishment of the National Center for Care and Monitoring of drugs used in hospitals ("*Hospital and Drugstores Sentinel Surveillances*"). In 2009 the Brazilian Adverse Drug Reaction Reporting System – ADRRS (in Brazilian portuguese it is called *NOTIVISA: Sistema*

de notificação em vigilância sanitaria) was established as a tool to receive notification of AE and technical complains related to products supervised by NHSS, like medication, vaccines and medical equipment[10]. In this sense, the main goals of NHSS aim to avoid and/or ease such problems. Although there are no data on the use of ADRRS, due to broad disclosure of high problems related to medications the underuse of this tool is recognized. This underuse most likely reaches both the patients who use the medications and the professionals that therapeutically deal with them. Therefore, the development of works that outline data search on the use of ADRRS should be encouraged. In consequence, this work's objective aims to analyze the use of the Brazilian ADRRS through a focus on the population who use drugs and medications and a focus on health professionals who deal with medications as therapeutic tools.

MATERIALS AND METHOD

The study was observational and cross-sectional, and descriptive and analytical in character. Data collection was done through inquiries about the level of lack of knowledge or underutilization of ADRRS regarding voluntary ADR notifications and Technical Complaints (TC) that concerned a sample of the Brazilian population who is consumer of drugs and medications and also samples of health professionals who deal with medications as therapeutic tools. The survey included 414 people amid collaborators who worked in a hospital and internal and external clients of two drug stores in the city of Dourados in the state of Mato Gorsso Grosso do Sul (MS), Brazil. Chronological analysis was done every time it was possible as a way to provide contextual descriptive and comparative analysis. Considering the population's profile and where the data collection was done (n is small and finite), this project's sampling technique used a simple, random sample done by convenience. Therefore, it was necessary to consider sample reposition procedures (in case of abandonment/ losses), and necessary to work with the chance of not needing sample reposition. Professionals properly trained done the data collection from May to August of 2013. The researchers were oriented about the work's nature and objective, and were included and cleared to begin answering the questionnaire only after having had demonstrated comprehension and having had voluntarily signed an Informed Consent Form (ICF). It should be emphasized that the researched had been oriented about the importance of answering the questions attentively and responsibly. As the questionnaires came to an end, researchers received orientation and information on the relevance of making notifications and on who is authorized to do this procedure. For data analysis, this work adopted the computer program named Prism in its 5.0 version. The variables were organized in graphs and tables with

absolute and percentage values. The results were analyzed in order to calculate confidence intervals with a 95% confidence interval (CI_{95}). The project had approval from the ethics in human research committee from the University of Ribeirao Preto (UNAERP) under the number 191.053, as well as a record numbered 07371312.5.0000.5498 in the governmental platform from the Brazilian Ministry of Health. All data collected were kept confidential considering the research as their main goal.

RESULTS AND DISCUSSION

The Figure 1 is aimed to show data concerned to the knowledge of ADRRS. According to the results a high percentage of lack of knowledge about ADRRS was observed regarding consumers (group A) with 95.37% (n = 309) (95% CI: 93.08- 97.66) and professionals who deal with medications (group B) with 68.89% (n = 62) (95% CI: 59.32- 78.45). Health professionals are unaware of the concept of ADR, because the majority did not have contact with this subject during academic years[11]. In addition, a professional who is unaware of pharmacovigilance has neither the capacity nor the arguments to adequately guide the population, which, consequently, becomes susceptible to AE, and lacks appropriate information on how to act given medication-induced problems[6]. Along data from literature, the obtained results indicate that under-notification and/or lack of notification could be due to the academic foundation. The Figure 2 presents data concerned to the correct use if the ADRRS. Considering the population who know of ADRRS and of its appropriate use, Figure 2 shows low usage percentage in Group A with 0.93% (n=3) (95%CI: -0.12 – 1.97) as well as in Group B with 8.89% (n=8) (95%CI: 3.01 – 14.77). Since many professionals lack knowledge about ADRRS, they will not know how to use it. In real life, the population usually does not notify the system, and when it seeks health professionals to report problems, many of the experts are unaware of what of the system or don't know how to deal with the situation[12]. There is evidence proving that most professionals would rather study and orient patients about pathologies than use ADRRS. Furthermore, evidence affirms that the unpreparedness of these professionals harm notification delivery making it inexistent in some regions[6]. Pharmacist has always been the class of health professionals with more notifications, followed by doctors and nurses. Since ADRRS was founded, there has been noted an increased notification percentage done by pharmacy technicians, nurse technicians, dental hygienists, in addition to other categories of professionals in the health department. In this manner, ADRRS contributes to the development of pharmacovigilance mainly due to an easy access that encourages notification as well as learning from given products' data[13]. Results from

the study of the ADRRS notification are showing the Figure 3, demonstrating that most subjects who were surveyed had never notified. In Group A only one person filled out the notification form and handed it to ANVISA 0,31% (n=1) (95%CI: -0,30 – 0,91) while the great majority 99,69% (n=323) (95%CI: 99,09 – 100) did not notify. In Group B four professionals notified (one filled out the form and handed it to NHSS and the other three filled out the form and emailed them) 4,44% (n=4) (95%CI: 0,19 – 8,70) while the remainder did nothing 95,56% (n=86) (95%CI: 91,30 – 99,81). A greater lack of knowledge about ADRRS is expected from professionals who do not deal with health; consequently, the use of this platform by these professionals is less. On the other hand, the opposite is expected from health professionals. Nevertheless, the data demonstrates that only 4.44% notified the system. Health professionals are only responsible for 31% of the notifications[13]. According to ADRRS's report in 2012, only 4.1% of a total of 16,547 notifications were reported by self-employed professionals[14]. A study done in Portugal from 2007 to 2008 during a total of 20 months aimed to evaluate the results of intervention on an increase in quantity and in relevance of ADR notifications. It involved 1103 pharmacists who had goals of educational intervention through workshops and phone calls; their work attained a 300% increase in notification number. The outcome, therefore, clarifies how important it is for health professionals to know and be able to correctly pass on information about the sense of notifying[15]. Through the results, it becomes evident that participation from professionals who deal directly with medication is important in ADR notification[16]. Educational intervention performed with health professionals is relevant, because it increases the number of spontaneous ADR notifications[15].

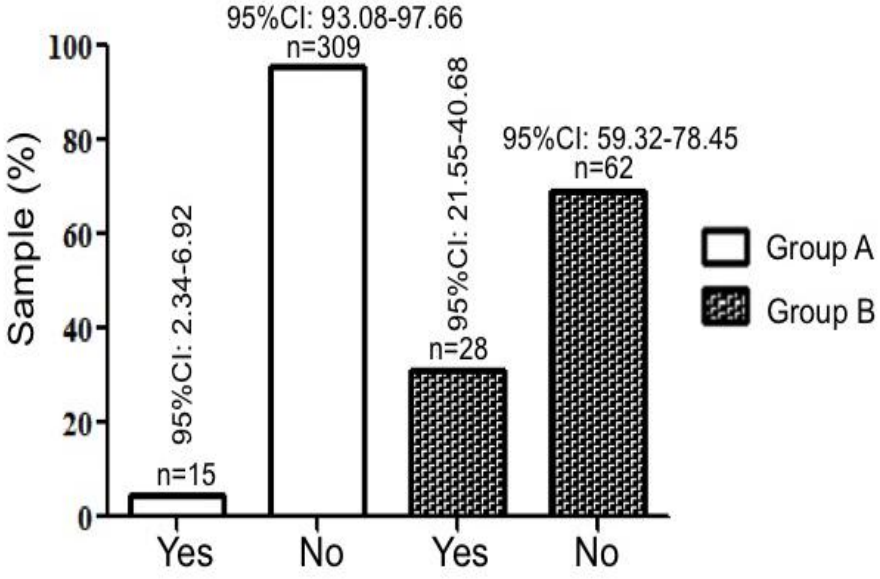

Figure 1: Knowledge of ADRRS

The sample comes from the Heart Hospital and Drugstores from the city of Dourados, MS - Brazil. Group A (n=324) is composed of surveyed volunteers (consumers) who were not related with the health professional actuation, and Group B (n=90) is composed of health professionals and is divided in function of knowledge of ADRRS, Dourados-MS, Brazil, 2014.

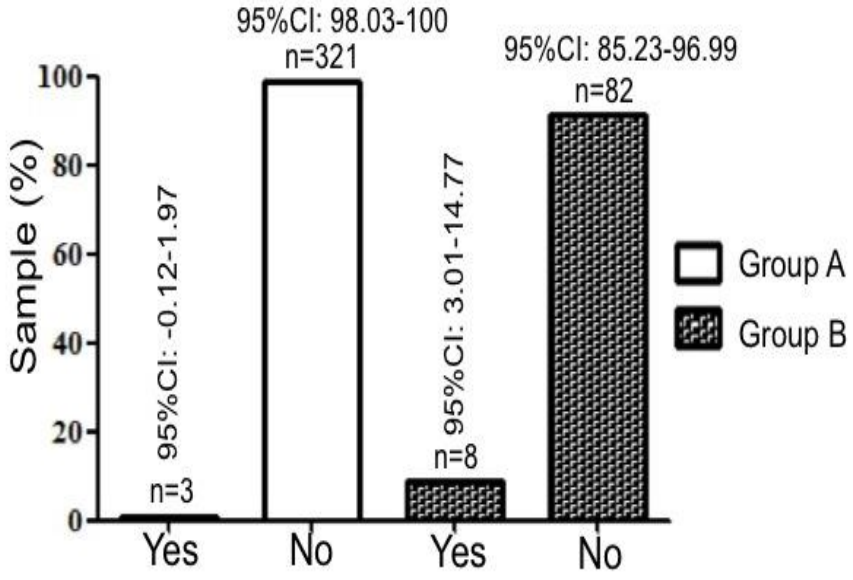

Figure 2: Use of ADRRS.

The sample comes from the Heart Hospital and Drugstores from the city of Dourados in the state of MS in Brazil. Group A (n=324) is composed of surveyed volunteers (consumers) who were not related with the health professional actuation, and Group B (n=90) is composed of health professionals and is divided in function of use of ADRRS, Dourados-MS, Brazil, 2014.

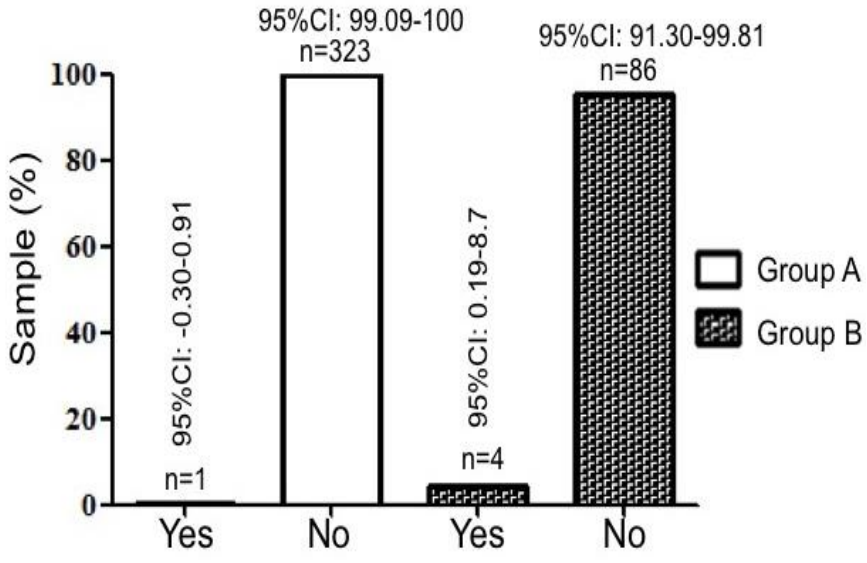

Figure 3: Notification of ADRRS.

The sample comes from the Heart Hospital and Drugstores from the city of Dourados, MS in Brazil. Group A (n=324) is composed of surveyed volunteers (consumers) who were not related with the health professional actuation, and Group B (n=90) is composed of health professionals and is divided in order to figure out how many people notified ADRRS, Dourados-MS, Brazil, 2014.

CONCLUSION

The results obtained from the population included in this research indicate an elevated percentage of lack of knowledge and underutilization of ADRRS. These facts consequently caused a low number of AE and TC notifications; therefore, it is of extreme importance for capable health departments, and mainly for health professionals, who deal with medication, to adopt an attitude of educational intervention. With this attitude, it is expected for notifications to increase in the Brazilian state of Mato Grosso do Sul, Brazil. In addition, it can contribute to NHSS's decision making, for example in demanding pharmaceutical industries to improve product quality in order to reduce ADR and promote Rational Use of Medicine (RUM).

REFERENCES

1. Pinheiro HCG, Pepe VLE. Reações adversas a medicamentos: conhecimento e atitudes dos profissionais de saúde em um hospital-sentinela de ensino do Ceará-Brasil, 2008. Epidemiol. Serv. Saúde 2011;20:127-9.
2. Government of Brazil. Brazilian Health Surveillance Agency. Resolução RDC n. 4 de 10 de fevereiro de 2009. Dispõe sobre as normas de Farmacovigilância para detentores de registro de medicamentos para uso humano. Diário Oficial da União, Poder Executivo, Brasília, DF, 11 de fevereiro de 2009.
3. Dias TA, Velloso JQ, Santos CCC. A importância e perspectivas do sistema de farmacovigilância. Revista de Trabalhos Acadêmicos 2010;23:231-3.
4. Dally A. Thalidomide: was the tragedy preventable? The Lancet 1998;351:1197-99.
5. Alfaro MR, Fernandez CG, Gross SC, Socorro YA. Farmacovigilância em pacientes con el vírus de inmunodeficiência humana/sida en un hospital de Zimbabwe. Medisan 2012;16:326.
6. Abjaude SAR, Zanetti ACB, Marques LAM, Rascado RR. Omissão em Notificações: resultado do desconhecimento em Farmacovigilância. Revista da Universidade Vale do Rio Verde. Três Corações 2013;11:267-76.
7. Government of Brazil. Ministry of Health. Sistema Nacional de Informações Tóxico-farmacológicas. Instituto de Comunicação e Informação Científica e Tecnológica em Saúde,

2014.

8. Souza HWO, Silva JL, Neto MS. A importância do profissional farmacêutico no combate a automedicação no Brasil. Rev Elet. de Farm 2008;5:67-72.
9. Melo DO, Ribeiro E, Storpirtis S. A importância e a história dos estudos de utilização de medicamentos. Rev Bras. Ciências Farm 2006 Oct-Dec;42:475-85.
10. Cassiani S. H. B. A segurança do paciente e o paradoxo no uso de medicamentos. Revista Brasileira de Enfermagem 2005;58:95-9.
11. Salviano LHMS, Luiza VL, Ponciano AMS. Percepção e condutas de profissionais da Estratégia de Saúde em Família acerca das reações adversas a medicamentos. Epidemol. Serv. Saúde 2011 Jan/Mar;20:47-56.
12. Baldoni AO, Pereira LRL. O impacto do envelhecimento populacional brasileiro para o sistema de saúde sob a óptica da farmacoepidemiologia: uma revisão narrativa. Rev. Ciênc. Farm. Básica e Apl 2011; 32:313-21.
13. Mendes MCP, Pinheiro RO, Avelar KES, Teirxeira JL, Silva GMS. História da Farmacovigilância no Brasil. Revista Brasileira de Farmácia 2008; 89(3):246-51.
14. Government of Brazil. Ministry of Health. ANVISA. Relatório do NOTIVISA. NOTIVISA, 2014.
15. Vaz IR, Herdeiro MT, Polonia J, Figueiras A. Estratégias para aumentar a sensibilidade da farmacovigilância em Portugal. Revista Saúde Pública 2011;45:129-35.
16. Pereira ST, Batista PN, Gomes KKLB, Freitas RM, Nunes LCC. Avaliação das notificações de EA a medicamentos de um hospital de Picos- Piaiu. Rev Bras Farm Hosp Serv Saude 2012 Jul/Sep;3:18-23.

AJPHR is
Peer-reviewed
monthly
Rapid publication
Submit your next manuscript at
editor@ajphr.com / editor.ajphr@gmail.com