

## Research Paper:

## Investigating the Reasons for Failing to Report Adverse Drug Reactions (ADR) by Nurses of Neonatal Intensive Care Unit in the Year 2015



Mahtab Mahboubi<sup>1</sup>, Leili Borimnejad<sup>2\*</sup>, Hamid Haghani<sup>3</sup>, Parvin Tatarpour<sup>4</sup>

1. Department of Pediatric Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.

2. Nursing Care Research Center, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.

3. Department of Biostatistic, School of Health, Iran University of Medical Sciences, Tehran, Iran.

4. Department of Medical Surgical Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.



**Citation:** Mahboubi, M. et al., 2017. Investigating the Reasons for Failing to Report Adverse Drug Reactions (ADR) by Nurses of Neonatal Intensive Care Unit in the Year 2015. *Journal of Client-Centered Nursing Care*, 3(2), pp. 133-138. <https://doi.org/10.32598/jccnc.3.2.133>

**doi:** <https://doi.org/10.32598/jccnc.3.2.133>

Article info:

Received: 04 Dec. 2016

Accepted: 22 Mar. 2017

## ABSTRACT

**Background:** Due to their inherent characteristics, neonates hospitalized in the neonatal intensive care units are more often exposed to medication errors and its adverse effects. The aim of this study is to determine the reasons for failure to report Adverse Drug Reaction (ADR) experienced by nurses employed at these units in educational and treatment centers affiliated to the Iran University of Medical Sciences in the city of Tehran in the year 2015.

**Methods:** This cross-sectional study was conducted by using Gupta and colleagues' Questionnaire with its validity and reliability verified by the research team in Iran. Data were collected by using the available sampling method in the educational and treatment centers affiliated to Iran University of Medical Sciences, from November 2015 to March 2016. The collected data were analyzed by using SPSS software version 16.

**Results:** Of 96 nurses taking part in this study, 68 (70.8%) had experienced incidences of adverse drug reactions. However, only 43 of them (44.8%) have reported them. Regarding the reasons for not reporting ADRs, 51 nurses (53.1%) stated difficulty in detecting the incidence of error, 19 (19.8%) stated not having the right to receive remuneration for doing so, 16 (16.7%) stated the shortage of time, and 10 (10.4%) reported lack of effectiveness had they reported it.

**Conclusion:** Since many complications can be prevented in neonates by timely reporting of these ADRs, it is recommended that removing the impediments in the path of reporting errors should come under consideration as a management and care priority by directors and officials of medical centers.

### Keywords:

Adverse Drug Reaction,  
Patient safety, Nurses,  
Neonatal Intensive Care  
Units (NICU)

\* Corresponding Author:

Leili Borimnejad, PhD

Address: Nursing Care Research Center, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.

Tel: +98 (912) 5029548

E-mail: l.borimnejad@gmail.com

## 1. Background

**A**dverse Drug Reaction (ADR) is a major cause of mortality worldwide and is the third cause of mortality next to cancer and heart disease in the United States (Aspinal et al. 2003). It is associated with a huge economic load regarding healthcare costs such as hospitalization and is considered a major public health problem (Brvar 2009). It has been estimated that costs associated with problems related to drugs in outpatient cares are more than 177 billion USD annually in the United States. This estimation is considerable compared to costs associated with other major ailments in the United States such as diabetes (174 billion USD in 2011), obesity (147 billion USD in 2009), and cardiovascular diseases (503 billion USD in 2009) (Ernst & Grizzle 2001). Neonates constitute a vulnerable group; hence, their drug treatment procedure is complicated and requires several stages. Even a minor error in drug treatment procedure will have considerable adverse effects in neonates. Drug errors comprise 47% of medical errors reported in the voluntary Vermont-Oxford reporting system. With a 14.3 birth rate in every 1000 people in the United States and entry rate of 6.6% to Neonatal Intensive Care Units (NICU), the consequences of drug errors in NICU can be considerable (Antonucci 2014).

Advancement in the care of neonates has resulted in the increase of survival rate for prematurely born and sick neonates who often need intravenous treatment. The unavailability of solutions in different concentrations leads to required computations in prescribing medications and dilution of medications that would expose the neonates to higher risks of drug errors and side effects (Costa et al. 2013). Neonates are prone to more serious complications due to ADR because of their small size, physiological prematurity, limited reparative abilities, rapid changes in body weight and surface, impediments in communication with the caregiver, reduction in body metabolism, and excretion of the drug due to immature kidney and liver. It is known that the intensive care unit is an environment recognized as having a high risk for the incidence of drug error (Taheri et al 2013). About 50% of iatrogenic complications have been found in neonatal intensive care units (Kanter, Turenne & Slonim 2004; Jain, Basu & Parmar 2009; Sekar 2010).

ADRs can range from minimal damage to damages leading to infant mortality. Some researchers believe that the incidence of some of these complications may be due to simultaneous administration of several

drugs or the defensive reaction of the infant's body to a specific drug. Thus, due to direct communication with the infants, nurses have a vital role in the detection and timely reporting of these incidents. However, the rate of reporting by nurses is lower compared with the real statistics (John et al. 2012). Studies conducted in several communities have mentioned numerous reasons for failure to report ADR. In an investigation conducted in Turkey, the most important reason why nurses did not report ADRs was the fear of legal consequences (Gok & Sari 2017).

In an extensive study conducted on 554 nurses, the most important reasons for not reporting ADRs were the perception of nurses toward the reporting process as being bureaucratic and their lack of belief in the importance of their role in ADR (De Anjelia et al. 2015). Despite the importance of this issue in the NICUs, no research has yet been conducted in this field in Iran. Therefore, the present study aimed to determine the reasons for not reporting drug errors committed by nurses employed at NICUs in the educational and treatment units affiliated to the Iran University of Medical Sciences in Tehran in the year 2015.

## 2. Materials & Methods

### Type of study and the participants

The present study was a cross-sectional and descriptive study. All the nurses employed at the NICUs of the treatment and educational centers affiliated to Iran University of Medical Sciences and had at least 6 months of work background in those wards took part in this study.

### Collection of data

The knowledge survey questionnaire, attitude and the performance of experts of healthcare with regard to ADRs were tools considered by Gupta et al. (2015). Since this questionnaire was being implemented for the first time in Iran, the content validity method was used to determine the validity of the data collection tools. After the tools are translated into Persian by a team of translators and then reverse translated, they were evaluated by 8 members of the scientific faculty of the School of Nursing and Midwifery of the Iran University of Medical Sciences.

These questionnaire tools included 20 questions: seven questions (questions 1 to 7) related to the knowledge assessment, four questions (questions 8 to 11) related to

attitude assessment, and eight questions (questions 12 to 19) related to performance evaluation. Scoring was awarded from 0 to 4 to these questions. One question (question 20) was related to the reasons for not reporting. The necessary corrections were made after collecting different opinions. For determining the scientific trust of the tools' retest, the Cronbach's alpha method was determined to be 0.738. Data were analyzed using SPSS software version 19 and employing descriptive statistics. The percentage of responses to each option was announced in the results.

### Ethical considerations

The researcher obtained approval (code: IR.IUMS.REC.1394.9313387004) from the ethics committee of Iran University of Medical Sciences for conducting this study. Then, written consent was obtained from the nurses who were inclined to participate in the study. For the purpose of preventing any potential misunderstanding, the aim of the study was explained to them, and the questionnaire was placed at their disposal. Fifteen minutes of time were provided to them to fill out the questionnaire, and sampling was conducted from November 2015 to March 2016.

### 3. Results

All the 96 participants in this study were women. From among them, 28.4% were single and 71.6% were married. Regarding educational qualification, 95.7% held Bachelor's Degree and 4.3% held Master's Degree. Regarding work experience, 28.3% had worked for 1 to 4 years, 43.5% had a work experience between 5 and 9 years, 21.7% between 10 to 14 years, and 6.5% had a work record of 15 years and more. A total of 68 (70.8%) nurses had experienced ADR in their patients during their professional work while 43 (44.8%) of them had

reported the ADR to the drug care center. The reasons for not reporting ADRs are mentioned in Table 1.

### 4. Discussion

This study showed that there is a gap between the frequency of ADRs that have been experienced and those reported by nurses employed at neonatal care units in Iran. Studies conducted in different countries have reported different results regarding the gap between the level of ADRs and the number of reported cases. A study conducted in Sweden showed that despite the nurses being aware of their role in reporting ADRs, more than half of them did not report these cases (Ekman et al. 2012). In a study conducted in Turkey, it was found that only 1.2% of drug side effects had been reported by nurses under the study (Alan et al. 2013). Nearly 9% of nurses under the study had previously experienced ADR and about 91% of them had not reported the ADR (Hanafi et al. 2012). In the present study, the four main reasons for failure to report were as follows: difficulty in detecting the incidence of error, not having remuneration for doing so, shortage of time, and ineffectuality of reporting.

In a study, 24.75% of Master's Degree students announced that they do not have sufficient time to report ADR while 44.55% did not know how and to whom they should report the ADR. The same study also revealed that the insufficiency of motivation and training for reporting ADR and pharmacovigilance discouraged them from reporting. Another study found that the lack of awareness of the existence of an ADR monitoring center in the medical institute they are working in (81.0% participants), lack of awareness of the drug care program (72.4%), lack of training to detect ADR (65.5%), fear factor (63.7%), weakness (58.6%), lack of understanding the ADR risk (39.6%), inadequate perception of the risk of non-allopathic and herbal medicines (31%), indifference (27.5%), and the

**Table 1.** Distribution of the frequency of reasons on failure to report ADR in nurses employed at NICUs

Causes	Frequency	%	Valid Percentage
Lack of remuneration	19	19.8	19.8
Time deficit for reporting ADR	16	16.7	16.7
Ineffectiveness of an unreported case of ADR	10	10.4	10.4
Difficult decision making on whether ADR has actually occurred	51	53.1	53.1
Total	96	100	100

concern that their report may be wrong (27.5%) were among the reasons for not reporting such complications (Khan, Goyal & Tonpay 2015).

In his study in Nigeria, Adedeji et al. (2013) reported that 87.5% of the participants did not consider reporting as a useful tool in the prevention of ailments related to drugs and mortality. The lack of awareness of the existence of the yellow color form for reporting (68.6%) and weak knowledge for reporting (48.6%) were among the other reasons for failure to reporting ADR (Adedeji et al. 2013). Another reason for not reporting the suspected drug response and its side effects was that the physician-in-charge did not consider it necessary to report drug reaction (Ekman et al. 2012).

Not knowing the location for reporting ADR (70%), lack of awareness on how to report (68%), and lack of access to the yellow color card (49.2%) were the main reasons stated by the participants in the Desai (2011)'s study. Another study found that the reasons for not reporting ADRs include uncertainty of the drug's involvement in causing the complication and the lack of awareness of the existence of ADR National Center (Salehifar, Ala & Gholami 2007). In the study by Ghasemian, the lack of awareness of the existence of the national system for reporting ADR, and to a certain extent, the lack of willingness to report due to the lack of sufficient time or lack of confidence in the performance of the national reporting system were stated by the participants as the reasons for not reporting ADR (Ghasemian, Mahmoudi & Khalilian 2006).

The comparison of the results of this study with the studies conducted in various countries showed that this issue is a global challenge. Thus, it is important to consider that timely reporting of drug error can prevent many complications in neonates who are a sensitive group exposed to risk. Removing the obstacles on the path of reporting drug error should also be considered as a management and healthcare priority.

Considering the importance of the active and pivotal role of nurses in hospitals, especially the correct implementation of drug therapy programs and implementation of specific care during therapy, their knowledge and awareness about drug complications and its reporting method should be improved (Bigi & Bocci 2017). Steps should be taken in this area, such as the publication of a guide for drug complications and the method for reporting these complications and the comparative face to face training. It is recommended that a committee should be formed for the training of the person-

nel who promote their personal development. Efforts should be made for training related to the personnel's occupation so that their capabilities are enhanced. It should also be noted that a qualitative study should be conducted for explaining the obstacles to reporting so as to achieve more precise results.

## Acknowledgments

This article is a part of Master thesis of first author entitled *The knowledge, attitude and the performance of neonatal nurses with regard to ADRs* and was approved by the International Department of the Iran University of Medical Sciences. We hereby express our gratitude toward all of the personnel and officials who assisted us in conducting this study. Distribution of the frequency of reasons on failure to report ADRs in nurses employed at neonatal intensive care wards at educational and treatment centers affiliated to Iran University of Medical Sciences in the year 2015.

## Conflict of Interest

The authors declared no conflicts of interest.

## References

- Adedeji, W. A., Ibraheem, W. A. & Fehintola, F. A., 2013. Attitude and practice of doctors toward adverse drug reactions (ADRs) reporting in a Nigerian tertiary health facility. *Annals of Ibadan Postgraduate Medicine*, 11(2), pp. 77-80. PMID: PMC4111063
- Ahmad, A., et al., 2013. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspectives in Clinical Research*, 4(4), pp. 204-10. doi: 10.4103/2229-3485.120168
- Alan, S., et al., 2013. An evaluation of knowledge of pharmacovigilance among nurses and midwives in Turkey. *Indian Journal of Pharmacology*, 45(6), pp. 616-8. doi: 10.4103/0253-7613.121375
- Antonucci, R., 2014. Preventing medication errors in neonatology: Is it a dream. *World Journal of Clinical Pediatrics*, 3(3), pp. 37-44. doi: 10.5409/wjcp.v3.i3.37
- Arici, M. A., et al., 2015. Short and long-term impact of pharmacovigilance training on the pharmacovigilance knowledge of medical students. *Indian Journal of Pharmacology*, 47(4), pp. 436-9. doi: 10.4103/0253-7613.161272
- Aspinall, M. B., et al., 2002. Improving adverse-drug-reaction reporting in ambulatory care clinics at a Veterans Affairs hospital. *American Journal of Health-System Pharmacy*, 59(9), pp. 841-5. PMID: 12004462

- Bhagavathula, A. S., et al., 2016. Health professionals' knowledge, attitudes and practices about pharmacovigilance in India: A systematic review and meta-analysis. *PLoS One*, 11(3), p. e0152221.
- Bigi, C. & Bocci, G., 2017. The key role of clinical and community health nurses in pharmacovigilance. *European Journal of Clinical Pharmacology*, 73(11), pp. 1379-87. doi: 10.1007/s00228-017-2309-0
- Brvar, M., et al., 2009. The frequency of adverse drug reaction related admissions according to method of detection, admission urgency and medical department specialty. *BMC Clinical Pharmacology*, 9(1). doi: 10.1186/1472-6904-9-8
- Costa, P. et al., 2013. Incidence of nonelective removal of percutaneously inserted central catheters according to tip position in neonates. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 42(3), pp. 348-56. doi: 10.1111/1552-6909.12030
- De Angelis, A., et al., 2015. Nurses' reporting of suspect adverse drug reactions: a mixed-methods study. *Annali dell'Istituto superiore di sanita*, 51(4), pp. 277-83. doi: 10.4415/ANN\_15\_04\_06
- Desai, C. et al., 2011. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspectives in Clinical Research*, 2(4), p. 129. doi: 10.4103/2229-3485.86883
- Ekman, E. et al., 2012. Awareness among nurses about reporting of adverse drug reactions in Sweden. *Drug, Healthcare and Patient Safety*, 4, pp. 61-6. doi: 10.2147/dhps.s31103
- Ernst, F. R. & Grizzle, A. J., 2001. Drug-related morbidity and mortality: Updating the cost-of-illness model. *Journal of the American Pharmaceutical Association* (1996), 41(2), pp. 192-9. doi: 10.1016/s1086-5802(16)31229-3
- Ghasemian, R., Mahmoudi, M. & Khalilian, A. R., 2006. Physicians' knowledge, attitude and performance regarding adverse drug reaction and its reporting in Sari-2004. *Journal of Mazandaran University of Medical Sciences*, 15(50), pp. 97-104.
- Gök, D. & Sarı, H. Y., 2017. Reporting of medication errors by pediatric nurses. *Journal of Nursing Education and Practice*, 7(9), p. 25. doi: 10.5430/jnep.v7n9p25
- Grissinger, M. C. & Kelly, K., 2005. Reducing the risk of medication errors in women. *Journal of Women's Health*, 14(1), pp. 61-7. doi: 10.1089/jwh.2005.14.61
- Gupta, S. et al., 2015. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *Perspectives in Clinical Research*, 6(1), p. 45. doi: 10.4103/2229-3485.148816
- Hanafi, S., et al., 2012. Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting. *Iranian Journal of Nursing and Midwifery Research*, 17(1), pp. 21-5.
- Jain, S., Basu, S. & Parmar, V., 2009. Medication errors in neonates admitted in intensive care unit and emergency department. *Indian Journal of Medical Sciences*, 63(4), p. 145. doi: 10.4103/0019-5359.50763
- John, L. et al., 2012. Reporting of adverse drug reactions: An exploratory study among nurses in a teaching hospital, Ajman, United Arab Emirates. *DARU Journal of Pharmaceutical Sciences*, 20(1), p. 44. doi: 10.1186/2008-2231-20-44
- Kanter, D. E., Turenne, W. & Slonim, A. D., 2004. Hospital-reported medical errors in premature neonates. *Pediatric Critical Care Medicine*, 5(2), pp. 119-23. doi: 10.1097/01.pcc.0000112370.55948.8e
- Khan, S., Goyal, C. & Tonpay, S., 2015. A study of knowledge, attitudes, and practice of dental doctors about adverse drug reaction reporting in a teaching hospital in India. *Perspectives in Clinical Research*, 6(3), p. 144. doi: 10.4103/2229-3485.159938
- Salehifar, E., Ala, S. H. & Gholami, K. H., 2007. Knowledge, attitude and performance of pharmacists and nurses in Mazandaran province, Iran regarding adverse drug reaction and its reporting, 2005. *Journal of Mazandaran University of Medical Sciences*, 16(56), pp. 115-25.
- Sekar, K. C., 2010. Iatrogenic complications in the neonatal intensive care unit. *Journal of Perinatology*, 30, pp. S51-6. doi: 10.1038/jp.2010.102
- Taheri, E., et al., 2013. The study of type and amount of medication errors in neonatal intensive care units and neonatal units. *Iranian Journal of Critical Care Nursing*, 6(1), pp. 21-8.
- Vora, M. et al., 2015. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. *Journal of Advanced Pharmaceutical Technology & Research*, 6(1), p. 29. doi: 10.4103/2231-4040.150369

