



## A QUESTIONNAIRE BASED STUDY ON THE KNOWLEDGE, ATTITUDE AND PRACTICE OF HEMOVIGILANCE AMONG POST GRADUATE RESIDENTS AND NURSES AT A TERTIARY CARE TEACHING HOSPITAL.

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### ABSTRACT

**BACKGROUND:** Blood and blood product transfusion is a life-saving intervention, therefore hemovigilance is an urgent need to identify and prevent occurrence of transfusion related reactions so as to improve the patient safety and quality of blood delivered. Nowadays throughout the globe hemovigilance setups have been enforced in most developed countries, to monitor the adverse reactions and episodes associated with blood donations and transfusions.

**METHODS:** This is a cross-sectional, questionnaire-based study conducted among postgraduate residents and nurses (n=100) of tertiary care teaching hospital. A structured validated questionnaire of 20 multiple choice questions was administered in postgraduate residents and nurses to obtain information about knowledge, attitude, and practices of hemovigilance. This study also helps to identify the factors responsible for underreporting of transfusion reactions and the possible ways to improve it.

**RESULTS:** Total 100 responses were recorded. It has been observed that 59.5% postgraduates and 36% nurses have knowledge about Hemovigilance. 58% postgraduates & 50% nurses have documented adverse transfusion reactions (ATR). Only 38% postgraduates and 18% nurses were trained to report ATR. According to respondents, launching of a toll-free helpline number, development of mobile application and training of healthcare professionals are possible ways to improve reporting of transfusion reactions whereas lack of knowledge, time constraints are some of the hindlers.

**CONCLUSION:** It can be concluded from the present study that respondents have a very superficial understanding about hemovigilance, therefore special efforts to sensitize the health care professionals and to strengthen the hemovigilance programme is very important.

**KEYWORDS :** Adverse transfusion reactions(ATR), Hemovigilance, Transfusion reactions reporting.

### INTRODUCTION:-

Quality and safety of transfusion therapy plays a key role in improving health so blood and blood product transfusion is a life-saving intervention.<sup>1</sup> A transfusion reaction can be defined as any transfusion, having certain risks and any unfavourable event occurring in the patient during or after transfusion, for which no other reason can be found.<sup>2</sup> Blood is categorized as a drug, as per the Drug and Cosmetic Act.<sup>3</sup> At the end of the 1980s, the transmission of infections by blood prompted the need for a greater awareness on the safety of blood and pioneer work on hemovigilance started in France.

The word "Hemovigilance" was coined in France in 1991 in analogy to the already existing term Pharmacovigilance. In transfusion medicine pharmacovigilance deals with plasma derivatives: clotting factor concentrates immunoglobulins, albumin, and other fractionated products. Hemovigilance, as the name suggests, is responsible for blood components: whole blood, erythrocytes concentrates, thrombocytes concentrates, and fresh frozen plasma.<sup>4</sup> Hemovigilance is derived from the Greek word "haema" means blood and the Latin word "Vigilance" means watchful. Hemovigilance is one piece of blood safety jigsaw and it is important to recognize its limitations when evaluating transfusion risks. Hemovigilance has become a crucial part of the blood safety concept. It is enforced all over the globe in most developed countries, to monitor the adverse events and episodes related to blood donations and transfusions.

Based on the reports of World health organization (WHO), International Society of Blood Transfusion (ISBT) and International Hemovigilance Network (IHN), the hemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components up to the follow-up of its recipients intended to collect and assess information on adverse effects resulting from the use of blood products and to prevent their occurrence or recurrence.<sup>5,6</sup> WHO has taken some initiatives in

order to support and consolidate the hemovigilance program in resource poor countries. Fundamental aim of these initiatives is to strengthen and expand national systems for data collection and management, risk assessment, surveillance and vigilance for policy decisions and programme planning for safe blood transfusion. In 2007, WHO organized a 'Global Consultation on Universal Access to Safe Blood Transfusion'. The international experts and participants of this consultation gave recommendations to WHO on developing quality systems throughout the blood transfusion chain<sup>7</sup>. WHO has also established a mechanism of collecting and reporting data of blood transfusion services from 194 WHO Member States (annually) based on 20 key quantitative blood safety indicators and using a comprehensive data collection tool.

Hemovigilance programme of India (HvPI) was launched on 10th December 2012. It is a centralized, well-structured programme for monitoring of adverse transfusion reactions and administration of blood products. It was launched by Indian Pharmacopoeia Commission (IPC), in collaboration with National Institute of Biologicals (NIB), Noida, Ministry of Health & Family Welfare, Government of India.<sup>8,9</sup> Goal of this program is to trail adverse reactions and episodes related to blood transfusion and blood product. A software "Haemo-Vigil" has been developed to collect and analyse the data related to hemovigilance all over the country. For HvPI to collect and analyse data related to biologicals and hemovigilance, National Institute of Biologicals is acting as the coordinating centre, the ultimate goal of this HvPI is to be a part of the IHN which presently has 28 countries as its member.

Hemovigilance system is dependent on traceability of blood and blood products from donors to recipients and vice versa, and on the monitoring, reporting, investigation and analysis of adverse events. The information thus generated through this system is a key to introduce required amendments in blood policies and guidelines that lead to increase safety and

quality of the entire transfusion process.<sup>10</sup> The incidence of adverse transfusion reactions in India varies with studies which show incidences ranging from as low as 0.27% to as high as 1.05%.

Indian reports on adverse transfusion reaction monitoring have been very low. This may be because monitoring is still evolving. Unfortunately, in India reporting of transfusion related adverse events are not mandatory. In addition, studies had reported underreporting by the medical staff and thus most of the minor adverse events do not come in attention; therefore, the exact incidences of various types of transfusion reactions are not known. It is known that the medical practitioners like doctors, can report, but the awareness that a nurse and pharmacist can also do so is very low. This is one of the main reasons for the underreporting of transfusion reactions<sup>11</sup>.

Active involvement of paramedical staff (nurses) in spontaneous reporting of adverse transfusion reactions will help in improving the reporting rates, since they are in closer contact with more patients for a longer duration than doctors. Among the Asian countries, a well-established hemovigilance system is lacking and there is paucity of data on hemovigilance except for Japan, which has published a report on adverse reactions<sup>12</sup>. Without hemovigilance, it is impossible to definitively weigh the risk associated with transfusion and consequently difficult for healthcare professionals to assess the benefit/ risk ratio and counsel pre-transfusion patients accordingly. Considering the deep concern over the underreporting prevailing among the doctors & in order to improve the reporting rate, it is important to improve the knowledge, attitude and practice of the healthcare professionals with regard to the adverse transfusion reaction reporting and the hemovigilance. This study will not only benefit the participants, but their knowledge and practice will safeguard the wellbeing and healthcare of society.

**MATERIALS AND METHODS:-**

- **Study Design:** It was a prospective, cross-sectional, observational questionnaire based study.
- **The Study Duration:** This study was carried out from November 2019 to January 2020.
- **Study Population:** Postgraduate residents and nurses of a tertiary care teaching hospital in Maharashtra.
- Approval from Institutional Ethics Committee was taken before initiation of the study.
- Strict confidentiality of participants was maintained during the study.

**Selection Criteria:-**

**Inclusion criteria:**

- a. Participants (postgraduate residents and nurses) who were willing to participate in the study.

**Exclusion criteria:**

- a. Participants (post graduate residents and nurses) not willing to participate in study.
- b. Incomplete questionnaires.

**Sample size:**

A total of 100 participants (50 post graduate residents and 50 nurses) was given the self-designed prevalidated questionnaire with 20 multiple choice questions and their response was analysed.

All participants were informed about the objectives and procedure of study before its initiation and those willing to participate were given the questionnaire. Any doubt regarding questionnaires was clarified by investigators. Written informed consent was obtained from each

respondent. The collected data was checked, reviewed and organized for its completeness. Only completely filled questionnaire were selected for final data analysis.

**This questionnaire consisted of:**

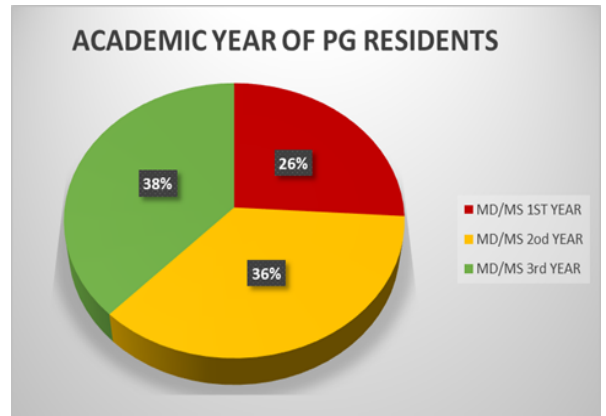
- Demographic data of postgraduate students about the branch (clinical/nonclinical/Para-clinical) and the year of MD/MS.
- Total 20 questions: 8 questions regarding knowledge, 6 attitude based regarding reporting, 4 for practice, 1 reasons for underreporting and 1 for possible ways to improve reporting of transfusion reaction.

**Statistical Analysis:-**

The returned questionnaires were checked for completeness of the data and the descriptive data will be expressed in percentages using Microsoft Excel sheet.

**RESULTS:-**

A total of 100 participants responded to the questionnaire. Out of these, 50 were postgraduate students of MD/MS: clinical (21), nonclinical (13) and pharmacology (32) and 50 were nurses.



**Figure 1: Academic year of postgraduate residents**

Figure 1 shows academic year of postgraduate residents: 26% were first year ,36% were second year ,38% were third year. This study includes more % of second and third year students as they are more exposed to patients than first year students.

**Table 1: Response to the knowledge based questions**

Sr. no	Questions	PG Residents (n= 50)	Nurses (n=50)
1	What is the definition of Hemovigilance	72%	28%
2	Hemovigilance started in which country and in which year?	32%	22%
3	Which type of transfusion reaction should be reported?	76%	52%
4	Is national hemovigilance program an integral part of the PvPI? (pharmacovigilance program of India)	96%	78%

Table 1 shows that 72% of postgraduates and 28% of nurses know the correct definition of Hemovigilance. About 32% of postgraduates and 22% nurses are aware about where and when hemovigilance started. Likewise, about 76% of postgraduates and 52% of nurses were aware of which types of transfusion reaction should be reported. 96% postgraduates ,78% of nurses knew that national hemovigilance program is an integral part of PvPI (Pharmacovigilance program of India).

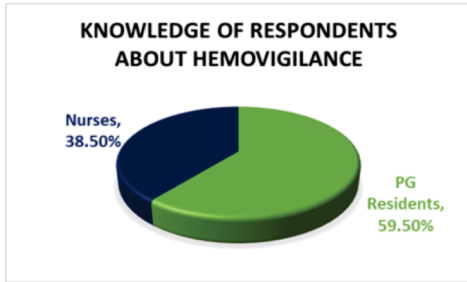


Figure 2: Percentage of respondents having knowledge about hemovigilance

Figure 2 summarizes that nurses have poor knowledge about hemovigilance as compared to postgraduate residents.

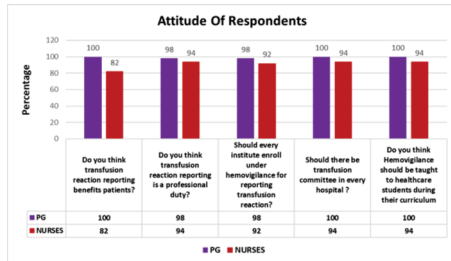


Figure 3: Attitude of respondents towards reporting transfusion reactions

Figure 3 summarizes that all the respondents have positive attitude towards reporting of transfusion reactions. According to them hemovigilance should be taught to healthcare students during their curriculum.

Table 2: Practice of transfusion reaction reporting among respondents

Questions	PG Residents		Nurses	
	Yes	No	Yes	No
Have you attended any CME /workshops/seminars on hemovigilance?	34%	66%	16%	84%
Had you ever found any transfusion reaction during your professional practice?	78%	22%	72%	28%
Have you documented any transfusion reaction?	58%	42%	50%	50%
Have you ever been trained on how to report transfusion reactions?	38%	62%	18%	82%

Table 2 shows that only 34% of postgraduate residents and 16% of nurses have attended workshop on hemovigilance. Though 78% postgraduate residents and 72% of nurses had found transfusion reaction during their professional practice, only 58% postgraduate residents and 50% of nurses have documented transfusion reaction. Among the respondents only 38% of postgraduate residents and 18% of nurses have been trained on how to report transfusion reactions.

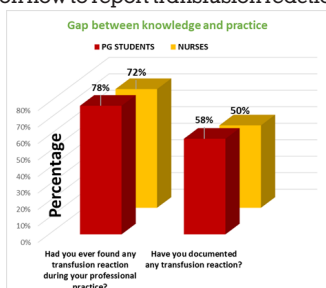


Figure 4: Gap between the ATR experienced in professional practice and ATR reported by postgraduate students and nurses.

Figure 4 reveals that there is considerable gap of 20% and 22% between adverse transfusion reactions experienced in professional practice and adverse transfusion reactions reported by postgraduate students and nurses respectively. This gap could be because of lack of knowledge and training.

Table 3: Factors discouraging from reporting of transfusion reactions

Factors discouraging from reporting of transfusion reactions	% of responses
a) Lack of knowledge on how and where to report?	77%
b) Legal liability issue	8%
c) Lack of time to report	10%
d) Reporting of known reaction is not required	1%
e) Busy to look actively for transfusion reaction	4%

Table 3 shows the factors that discourage respondents from reporting transfusion reactions. Maximum respondents were of opinion that lack of knowledge on how and where to report, is the main hindering factor for reporting of transfusion reactions.

Table 4: Possible ways to improve reporting of transfusion reactions

Possible ways to improve reporting of transfusion reactions	% of responses
a) Launching of a toll-free helpline number.	51%
b) Development of mobile application.	23%
c) Remuneration of transfusion reaction reporting.	4%
d) Healthcare professionals should be trained in reporting.	15%
e) Reporting of transfusion reactions be made more easy.	7%

Table 4 shows the possible ways in improving transfusion reaction reporting. It has been suggested by 51% of respondents that the launching of a toll-free helpline number and development of mobile application might increase the reporting. Other encouraging factors like training to report transfusion reactions and reporting process should be made easy. Only 4% have suggested remuneration for transfusion reaction reporting as the possible ways to improve reporting of transfusion reactions.

**DISCUSSION: -**

Hemovigilance is ultimate quality indicator for transfusion reactions reporting. The primary objective of present study was to evaluate the KAP of postgraduate residents and nurses about hemovigilance. The secondary objective was to find out the reasons for underreporting of transfusion reactions and also to find out the possible ways of improving reporting. For the present study, postgraduate students and nurses were recruited. The response rate of study participants was found to be much higher (100%) as compared to the similar studies conducted in other places like in Nagpur by Amit Date et al (75%), in South India by Narmada Sireesha et al (59%).<sup>13</sup> This indicates the curiosity towards a fairly new concept of hemovigilance. The finding of the study revealed many facts about the inadequate knowledge regarding hemovigilance and also showed the factors that may cause hurdles in reporting of transfusion reactions. The comparison with the results of the published studies from India demonstrated that knowledge and attitude towards hemovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ATR reporting is still deficient among them.

Active involvement of nurses in spontaneous reporting of adverse transfusion reactions will help in improving the reporting rates, since they are in closer contact with patients

for a longer duration than doctors. Results from this study showed that the knowledge level about hemovigilance was found to be poor in nurses (38.5%) as compared to postgraduate students (59.5%) this indicates that awareness about hemovigilance program and transfusion reaction reporting is necessary. Adequate knowledge will improve the perception towards reporting and will ultimately result in the increased practice of hemovigilance reporting. Only 72% of the respondents were aware of the transfusion reaction reporting system in India. 32% of the participants knew about the regional transfusion reaction reporting center. This indicates that since hemovigilance programme has just been launched a lot of doctors and nurses are not aware of it.

About 97% of respondents are of a view of having transfusion reaction committee in every hospital. Hospital transfusion committee plays major role in dealing with hemovigilance and risk management, providing supervision and advocacy for transfusion practice and controlling multi-disciplinary teams with quality and risk management tools. On a simplistic level, the hospital transfusion committee (HTC) sets appropriate policies and procedures, reviews and revise them and monitors practice against them<sup>14</sup>.

In the present study, 97% of respondents were of the opinion that hemovigilance should be taught to medical and nursing students during their curriculum. Though 96% of respondents think that transfusion reaction reporting is a professional duty only 58% of postgraduates and 50% of nurses have actually reported ATR in their professional practice because of lack of training (only 28% of respondents were trained to report ATR). This indicates that there is a considerable gap between the ATRs experienced in professional practice and ATRs reported by postgraduates and nurses (figure 4). In this study, 66% postgraduate students and 84% nurses had not attended any CME on transfusion reaction reporting.

The determinants of underreporting, from this study include lack of knowledge on how and where to report (77%), lack of time for reporting (10%), legal liability issue (8%), busy to look actively for transfusion reaction (4%) and possible ways to improve reporting could be launching of a toll-free helpline number, development of mobile application, remuneration of transfusion reaction reporting, reporting of transfusion reactions be made more easy. It has become unconditionally essential for WHO, national hemovigilance centers to provide the necessary materials for ATR reporting and to make the reporting procedure easy across the tertiary, secondary and primary health care centers worldwide. It can be apparent from this study that the appropriate clinical use of blood requires National policy and guidelines for blood transfusion, standard operating procedures for blood transfusion, hospital transfusion committee and training of all staff involved in blood transfusion, also hemovigilance system for monitoring, reporting and investigating adverse events associated with transfusion<sup>15</sup>. This will not only help in safe administration of blood and blood products but also prevent avoidable transfusion reactions.

#### CONCLUSION:-

Our study included not only doctors but nurses also because among the healthcare providers, nurses are in a unique position to monitor and report ATRs. The study concludes that postgraduate students and nurses have inadequate knowledge about transfusion reporting system, which is responsible for poor practice of transfusion reaction reporting. Therefore, our study emphasized the fact that there is an urgent need to create the awareness regarding hemovigilance programme of India through CMEs, workshops and seminars at regular intervals and train the doctors and paramedical staff on how to report a transfusion reaction. Apart from that other possible ways to improve

transfusion reaction reporting are launching of a toll-free helpline number and mobile application. This will help to enhance spontaneous reporting rate and safety of the patients to a large extent.

#### Acknowledgement:

We would like to thank the postgraduate students and nurses who participated in the study.

#### Conflict of Interest:

There is no conflict of interest.

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