

## ASSESSMENT OF KNOWLEDGE, ATTITUDE, AND PRACTICE OF HAEMOVIGILANCE AMONG POST-GRADUATES AT A TERTIARY CARE TEACHING HOSPITAL IN HYDERABAD–A CROSS-SECTIONAL STUDY

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### ABSTRACT

**Objective:** Transfusion of blood and blood products is a life-saving intervention but has the potential to cause adverse events. Haemovigilance is an organized system that includes monitoring, identification, reporting, investigating, and analyzing adverse events related to transfusion and the manufacture of blood products. However, reporting of adverse reactions is markedly less in our country. This study is intended to assess knowledge, attitude, and practice of Haemovigilance among post-graduates (PGs) and to scrutinize various causes of Underreporting.

**Methods:** A cross-sectional pre-validated questionnaire-based study was carried out in Osmania medical college and hospital, Hyderabad over 4 months among 150 PGs.

**Results:** Only 120 PGs out of 150, provided their responses. Only 20% of the PGs knew about the Haemovigilance program. 41.6% knew how to report and who can report. 2% knew about Hemo-vigil and Donor vigil software. 100% of PGs show a positive attitude towards transfusion reaction reporting and agreed that Haemovigilance activities should include in the undergraduate curriculum. Medicolegal liability issues, lack of knowledge, and lack of time were the main factors that forbade them from reporting.

**Conclusion:** A positive attitude towards Haemovigilance exists among PGs but knowledge regarding the Haemovigilance program was poor and the practice of transfusion reactions reporting was significantly reduced. Hence, our study suggests the inclusion of the procedure of transfusion reactions reporting in the Undergraduate curriculum and augmentation of CMEs/workshops/seminars to PGs.

**Keywords:** Haemovigilance, Knowledge, Attitude, Practice, Haemovigilance program of India, KAP study.

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### INTRODUCTION

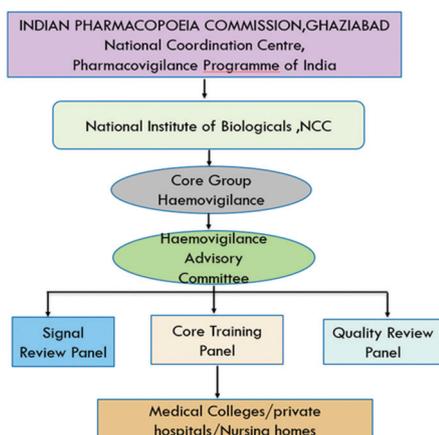
The term "Haemovigilance" is an analogy to the already existing term "pharmacovigilance," derived from the Greek word "Haema" means blood, and Latin word "vigilance" means watchful/special attention [1]. Haemovigilance is an organized scheme of monitoring, identifying, reporting, investigating, analyzing adverse events and reactions, primarily focusing on safety. Blood is categorized as a drug as per the Drugs and Cosmetics Act [2]. It was initially developed by French Blood Agency in 1994 [3]. Nowadays Haemovigilance systems have been enforced all over the globe. According to the WHO, every year around 118.5 million blood donations are accomplished globally and about 13,300 blood centers in 169 countries report collecting a total of 106 million donations [4]. Most of the developed countries such as Canada, Netherlands, Denmark, and UK are linked to International Haemovigilance Network [5]. Among the Asian countries, a well-developed Haemovigilance system is lacking. After Japan, the Haemovigilance program of India (HvPI) is a member of INH in Asian countries. In India, there is a lack of a standardized and efficient Haemovigilance system as the reporting of adverse transfusion events is not mandatory [1,6].

Indian Pharmacopoeia Commission (IPC) in association with the National Institute of Biologicals (NIB) Noida, Uttar Pradesh has launched the HvPI on December 10, 2012, across the country under Pharmacovigilance Programme of India (PvPI), Ministry of Health and Family Welfare, Government of India. The main objective of this program is to trace adverse reactions associated with blood transfusions and blood donations [7]. The program has been administered under the broad ambit of PvPI with a

dedicated budgetary provision of Rs. 29.36 crore during the 12<sup>th</sup> 5-year plan (2012-2017) [8]. According to the latest report, a total of 8162 transfusion reactions were reported to HvPI [9]. The Coordination Centre is the NIB, where the data will be collected, analyzed, and formulate guidance documents for reporting serious blood transfusion adverse effects including Transfusion Reaction Reporting Form [10,11]. An organogram regarding functions of the Haemovigilance program has been outlined by the joint recommendation of IPC-NIB which includes the Core group and the Haemovigilance advisory committee. The signal review panel, Core training panel, and Quality review panel constitute part of the organogram provide information to the technical associate in the institution such as medical colleges, hospitals, nursing homes, etc. Unnecessary transfusions should be avoided [12,13]. There has been a concern and debate in the medical literature regarding the use of blood and blood products. Hemovigilance reports are kept confidential, which means no patient, clinician, staff member or healthcare facility is identifiable from data contained within the report.

Reporting of adverse transfusion reactions is done online via Hemo-Vigil software and reporting of adverse blood donor reactions is done via Donor-Vigil software available on NIB website [www.nib.gov.in](http://www.nib.gov.in), Tollfree number 1800-180-2588 or report to Adverse Drug Reaction Monitoring Centres (AMCs) [14]. The involvement of postgraduates (PGs) in Haemovigilance programs is considered to be vital in ensuring blood transfusion for better patient health outcome benefits. Therefore, this study aims to evaluate and explore the awareness among PGs towards Haemovigilance program.

**Haemovigilance organogram**



**METHODOLOGY**

**Site of study**

This study was conducted at Osmania medical college and its hospitals, Telangana from April 2021 to July 2021. The approval to conduct this study was obtained from the Institutional Ethics Committee of Osmania Medical College, (IEC/OMC/2021/M.No.02/Acad-111) before the study.

**Study design**

This is a Cross-sectional Pre-validated questionnaire-based study. The study was designed to assess the details such as knowledge, attitude, and practice (KAP) of PGs toward Haemovigilance, possible causes of under-reporting, and the ways to improve reporting of transfusion reactions.

**Study duration**

4 months.

**Sample size**

150 PGs (both male and female).

**Selection method**

The study population was drawn from all clinical and non-clinical PGs of Osmania medical college and hospital and were given a total of 21 questionnaires on KAP related to Haemovigilance and asked to list out reasons for not reporting and underreporting.

**Inclusion and exclusion criteria**

All PGs who gave consent to participate in the study were included. The PGs who were not willing to participate in the study and those who were on leave were excluded.

**Statistical analysis**

Information from the returned questionnaire was entered and analyzed by Statistical Package for Social Sciences version 23 software (SPSS). Data are tabulated and percentages are calculated.

**RESULTS**

The demographic details of participants involved in the study were categorized based on gender distribution, pre, and para-clinical departments, and year of post-graduation in Table 1.

Most of the PGs knew transfusion reactions analogous to other studies [15]. While assessing the knowledge of Haemovigilance among PGs, from Table 2 it was found that 100% of PGs were aware of transfusion reactions, but only 41.6% of PGs knew how to report and who can report. Graphical presentation of knowledge related to Haemovigilance is shown in Graph 1.

From Table 3, the study showed that attitude towards transfusion reaction reporting is improving, 90% of PGs had a positive attitude toward transfusion reaction reporting and 100% thought that reporting benefits patients which helps in improving healthcare outcomes.

**Table 1: Sociodemographic variables/characteristics of the study participants**

Demographic variables- post-graduates	No of participants
Pre-clinical	26
Para-clinical	30
Clinical	64
Male	70
Female	50
1 <sup>st</sup> year	65
2 <sup>nd</sup> year	34
3 <sup>rd</sup> year	21

**Table 2 : Knowledge of Haemovigilance among post-graduates**

S. No.	Knowledge related questions	Yes (%)	No (%)
1.	Do you know about transfusion reactions?	100	0
2.	Do you know that transfusion reactions can be prevented?	80	20
3.	Do you know that blood transfusion reactions can be reported?	80	20
4.	Any idea where to report transfusion reactions?	50	50
5.	Do you know how and who can report transfusion reaction?	41.6	58.4
6.	Do you know about the Haemovigilance program?	20	80
7.	Existence of a Toll-free number reporting transfusion reactions?	10	90
8.	Full form of TRRF	7.5	92.5
9.	Constituents of Haemovigilance advisory committee	2.5	97.5
10.	3 phases explaining targets of HvPI	2.5	97.5
11.	Knowledge about Haemo-vigil and Donor-vigil software	2	98

TRPF: Transfusion Reaction Reporting Form, HvPI: Haemovigilance program of India

**Table 3: Attitude toward haemovigilance among post-graduates**

S.no	Attitude related questionnaire	Agree (%)	Disagree (%)
1.	Every institute should enroll under Haemovigilance	50	50
2.	One Haemovigilance Centre is enough for a city	80	20
3.	Reporting of each transfusion reaction is essential	90	10
4.	Haemovigilance should include in the undergraduate curriculum	100	0
5.	Do you think reporting benefits patients?	100	0

**Table 4: Practice related questionnaire among post-graduates**

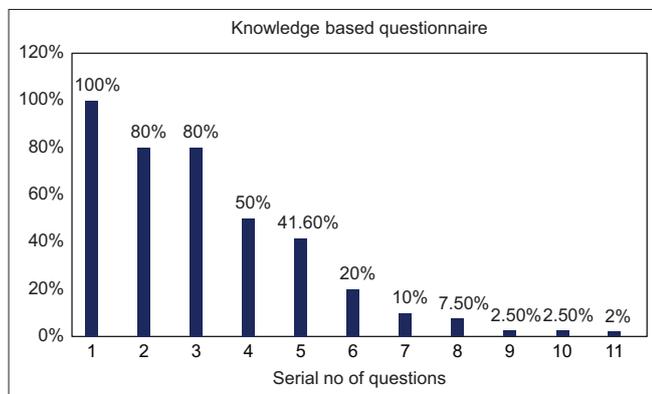
S.no	Practice related questions	Yes	No
1.	Have you reported any transfusion reactions to the Haemovigilance center?	0	100
2.	Have you ever found any transfusion reactions during your professional practice?	5	95
3.	Have you attended any CMEs/Workshops/seminars on Haemovigilance?	20	80
4.	Have you documented any transfusion reactions?	80	20
5.	Are you willing for reporting?	100	0

From Table 4 it is clear that PGs had a positive opinion towards improving practices. From Table 5 the factors discouraging from

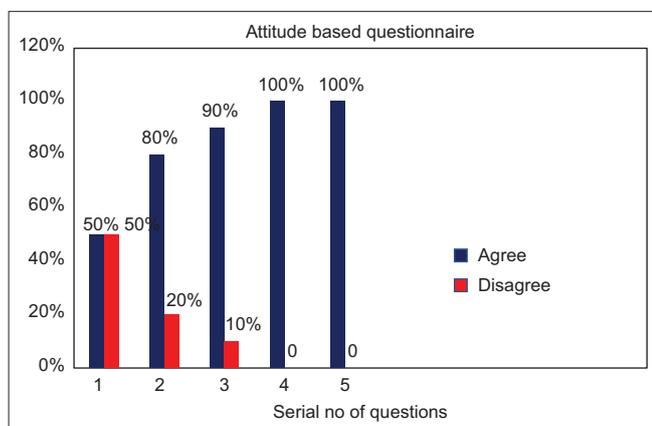
**Table 5: Factors discouraging reporting of transfusion reactions**

S. No	Factors discouraging reporting of transfusion reactions	No of PGs (%)
1	Lack of knowledge, where and how to report	60 (72)
2	Legal liability issue	10 (8.3)
3	Lack of time	40 (33.3)
4	Fear of negative effect of the report	8 (6.66)
5	No remuneration/incentives for reporting	2 (1.66)

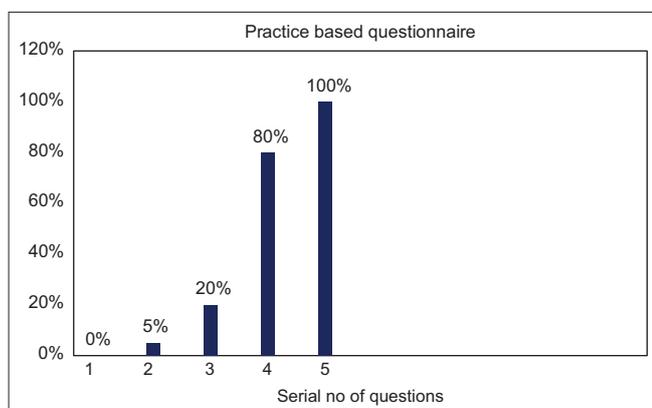
PGs: Post-graduates



**Graph 1: That there is a relative decline in knowledge of Haemovigilance among post graduates**



**Graph 2: An improving positive attitude of post graduates**



**Graph 3: Progress in practices of post graduates that reduce the under-reporting of adverse drug reactions**

reporting among PGs include lack of knowledge (72%), followed by lack of time (33.3%), Legal liability issues (8.3%), Fear of negative effect of

the report (6.66%), and 2% reported due to lack of remuneration or incentives.

The results are such as several KAP studies conducted on KAP regarding haemovigilance [16,17]. Vigilance in hospital transfusion practice is of paramount importance to improve patient safety. As the way to improve Haemovigilance reporting, maximum felt that more training should be conducted, reporting forms to be made easier, Toll-free helpline reporting to be made mandatory, organizing CME/workshops and availability of the mobile application [6]. Seminars/CMEs/Workshops can be useful in spreading knowledge regarding Haemovigilance to various doctors and other health care professionals which can help in creating awareness [18].

**DISCUSSION**

Haemovigilance plays a fundamental role in tracing and reducing the adverse events related to blood transfusions and blood products by seeking the active involvement of PGs. KAP of Haemovigilance among PGs were seen in this study. The main objectives of Haemovigilance are to monitor transfusion reactions, create awareness, and generate evidence-based recommendations. To the best of our knowledge, this was the first study in Telangana designed to assess the awareness among PGs.

In our current study, all the PGs were aware of transfusion reactions, but only 41.6% of PGs knew how to report and who can report. The results are similar to the KAP study by HimaBindu *et al.* 2020 [19]. Only 20% had an idea about the Haemovigilance program. As we go to the depth of knowledge from the questions (7-13) about the Haemovigilance program, there was a drought in knowledge which is the main reason for under-reporting. Graph 2 indicates that shows 90% of PGs had a positive attitude towards transfusion reaction reporting and although having a positive attitude, the reporting rate of transfusion reactions was none. Graph-3 explains that fortunately most PGs agreed that reporting of transfusion reactions is necessary and awareness that Haemovigilance should be taught in detail to PGs emphasize that they have started to understand the importance of Haemovigilance. This also seems to be an encouraging step toward the establishment of a successful Haemovigilance system.

The present study highlights underreporting factors as the main problem in the Haemovigilance system, nature of transfusion reaction, fear of consequences, lack of training, absence of well-defined hemovigilance structure and protocol, lack of computerization, and use of software [20]. The hospital transfusion committee should have the authority to determine transfusion policy and elucidate its problems [21].

Although high awareness and positive attitude of PGs are strengthening points, Lack of time, Legal liability issues, Fear of negative effects of the report, and lack of remuneration or incentives are the limiting factors in our study.

**CONCLUSION**

Haemovigilance is an unceasing process of analysis of transfusion reactions and data collection to explore their causes and outcomes and prevent their incidence. It is an imperative tool to improve the quality of the blood transfusion chain, primarily focusing on safety and a significant part of the quality system for blood transfusion.

Our study concludes that most of the PGs have a positive attitude towards transfusion reaction reporting. Knowledge regarding the Haemovigilance program was poor and the score on practice was significantly less. Vigilance programs and their committee work should be included mandatorily in the undergraduate curriculum. Proper education and active participation can be a better choice for minimizing transfusion-related events. It also suggests the need for the execution of relevant policies and educational interventions to enable them to

incorporate the knowledge into their clinical practice. It is expected that current Haemovigilance systems in hospitals and medical colleges will contribute to the regulation of optimal blood use shortly.

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#### AUTHOR CONTRIBUTIONS

Dr. Swarupa Rani Kasukurthi has planned, designed the concept of the manuscript, and drafted the manuscript, Dr. Aitha Swetha Rani has supported in drafting the manuscript, Dr. Chakradhar T and Dr. Bhuvaneshwari E reviewed the manuscript, Ms. Sravani Marpaka collected the reference articles.

#### CONFLICTS OF INTEREST

None declared.

#### FUNDING SOURCE

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