

## RESEARCH ARTICLE

# Knowledge, attitude, and practice of reporting transfusion reactions in hemovigilance among health-care professionals in a tertiary care teaching hospital of northern India

Rukhsana Chowdhary, Vijay Khajuria, Vineeta Sawhney

Department of Pharmacology, Government Medical College, Kathua, Jammu and Kashmir, India

Correspondence to: Rukhsana Chowdhary, E-mail: rukhsanachowdhary77@gmail.com

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### ABSTRACT

**Background:** Blood transfusion is a lifesaving procedure but has potential to cause adverse events. Hemovigilance is a program that ensures safety of transfusion reactions by monitoring every step of transfusion process from donor to recipient. However, reporting of adverse reactions is far less in our country. **Aim and Objective:** The aim of the study was to assess the knowledge, attitude, and practice (KAP) of health-care professionals and examine various causes of underreporting in our tertiary care hospital. **Material and Methods:** This observational cross-sectional questionnaire-based study was conducted in Department of Pharmacology Government Medical College (GMC) Kathua in associated hospital for the period of 1 month after obtaining approval from Institutional Ethics Committee of the college under no-IEC/GMCK/18/Pharma/dated-18/2/2020. Fifty randomly selected health-care professionals including doctors, nurses, and pharmacists were the volunteers. They were provided with a sheet containing 37 pre-validated questions and the time period of 30 min was provided to respond to the questions. The questionnaire contained 37 questions composed of nine questions of knowledge, six questions for attitude, four for practice, 11 for underreporting, and eight for possible ways to improve reporting of reactions. **Results:** The sheets of responses were analyzed and results revealed that awareness of hemovigilance was 84%, while knowledge to report adverse events was 76%, whereas 88% volunteers were aware that reporting is essential and can benefit patient care. Among these, 24% of volunteers had attended coronal mass ejection (CME's). As per attitude meaning agreed that reporting of reactions is essential and hemovigilance should be taught to health-care professionals, practices that revealed that a few had attended CME's and only 20% of these volunteers had ever reported adverse reactions related to blood transfusion. As for as underreporting is concerned majority felt where to report reaction (72%) and lack of time (56%) followed by legal liability issues (52%) were main causes of underreporting. **Conclusion:** Although the health-care professional volunteers had good knowledge and attitude but the practice score was far less. Therefore, to report adverse reactions of blood transfusion and lack of time was major perceived causes of underreporting. Such results underscore the importance of incorporating the education of hemovigilance in their duty curriculum to address their problems.

**KEY WORDS:** Hemovigilance; Adverse Drug Reactions; Blood Transfusion; Knowledge; Attitude; Transfusion Reactions

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### INTRODUCTION

Blood transfusion is a lifesaving procedure but the risk of adverse reaction to transfusion is an untoward effect which varies from being relatively mild to lethal.<sup>[1]</sup> These reactions are mostly acute that occurs within 24 h of transfusion and delayed occurring within days or months of transfusion.

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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 to collect and assess information on adverse effects resulting from the use of blood products and to prevent their occurrence or recurrence.<sup>[2,3]</sup> The word haem means blood and vigilance means special attention.<sup>[4]</sup> Hemovigilance was initiated in France in 1994 following infective and non-infective complications related to transfusion of blood and its components.<sup>[5]</sup>

National surveillance scheme serious hazards of transfusion (SHOT), a voluntary reporting scheme by U.K was launched in 1996 to improve standards of hospital transfusion practice, educate users on transfusion hazards and their prevention, aid production of clinical guidelines in blood transfusion, and inform national policy on transfusion safety.<sup>[6]</sup> Based on the aims of SHOT scheme, hemovigilance was launched in many countries.<sup>[7,8]</sup>

Hemovigilance program of India (HvPI) was launched jointly Indian Pharmacopoeia Commission and National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, and Government of India on 10 December of 2012<sup>[9]</sup> with the purpose to identify, collect, combine, and examine the adverse reactions/events associated with transfusion of blood or its components with the aim of identifying the trends suggesting suitable practices and interventions needed to improve the patient care, safety, and providing suggestions to the authorities to make the changes in policy for improving transfusion safety.<sup>[10]</sup> HvPI is being implemented as integral part of Pharmacovigilance Programme of India across the country. HvPI has developed a software hemovigil to aid reporting of hemovigilance reports.

The adverse transfusion reactions vary from minor to life threatening. Incidence in India of these reactions is variable ranging from as low as 0.27% to as high as 1.05% as reported by few studies<sup>[11]</sup> whereas a study from J and K India<sup>[1]</sup> reported overall 3% incidence of reactions. However, the true scenario may be different as reporting of transfusion reactions are less in India. This stems out of fact because our health-care professionals are still not versant with reporting of these adverse effects. Moreover, the reporting of hemovigilance reports is still not still mandatory and may contribute the under-reporting.<sup>[11-15]</sup>

Hence, the present study was undertaken with the primary objective of evaluating the knowledge, attitude, and practice (KAP) and causes of under reporting of hemovigilance among health-care professionals as they play very important role in reporting adverse reactions related to blood transfusion. As such no such study has been conducted in this institution till date this is the first kind of its study which will be helpful in improving KAP of health-care professionals about blood transfusion.

## MATERIALS AND METHODS

This observational cross-sectional questionnaire-based study was conducted in Department of Pharmacology of Government Medical College (GMC) Kathua and associated hospital a tertiary care teaching hospital.

The approval for conducting this study was obtained from Institutional Ethics Committee of the college under no-IEC/GMCK/18/Pharma/dated-18/2/2020. Total duration of this study was 1 month w.e.f March 1, 2020. Health-care professionals (i.e., doctors, nurses, and pharmacists) were included in the study. Informed consent was taken from the participants. Study was a questionnaire based, self-structured, validated, and designed to assess the details such as demographic data, knowledge, and attitude of health-care professionals toward hemovigilance and practice of transfusion reaction reporting, possible causes of under reporting and the ways to improve reporting of transfusion reactions. The questionnaire was divided into six subsections. First section pertained to demographic profile, while sections assessing knowledge had nine questions, attitude (six questions), and practice (four questions). While section evaluating possible factors of underreporting had ten questions and possible ways to improve reporting had eight questions. The volunteers were required to respond to these questions.

Sheet of paper containing a total of 37 questionnaires was distributed among 50 randomly selected health-care professionals and a time period of 30 min was allotted for answering these questions. Participants were not allowed to consult each other nor they were permitted to consult network sites. They were asked not to write their names but the designation of participants was recorded. Information from the returned questionnaire form were analyzed and coded and entered into excel sheet and analyzed by statistically and expressed as numbers and percentage.

## RESULTS

Our study showed 100% response rate of 50 eligible health-care professionals involved in study, as all returned their completely filled questionnaire form within 30 min. As shown in Table 1 among these respondents 52% were doctors, 24% nurses, and 24% were pharmacists. About two-third (36%) of participants were male and 64% were female which makes male:female ratio of 1:2. The average age of the participants was between 20 and 30 years.

While assessing the knowledge of the health-care professionals, it was found that 42 (84%) were aware of hemovigilance program and transfusion reactions reporting 38 (76%), as given in Table 2. Whereas 44 (88%) agreed that reporting of transfusion reaction is essential and can benefit the patients.

Overall 40 (80%) participants agreed that hemovigilance should be taught to health-care professionals during their curriculum, 44 (88%) believed that transfusion reaction reporting is a professional duty, 12 (24%) have attended coronal mass ejection (CME) on hemovigilance, 28 (56%) have come across adverse transfusion reaction while discharging duties, and only 22 (44%) have reported it to the hemovigilance center.

The attitude of health-care professionals in this study was highly positive regarding hemovigilance program as per the mean/response of majority of the participants where they strongly agreed upon the given statements remained 17.34, agree 23.34, strongly disagreed 1.67, disagree 2, and 6 were undecided, as shown in Table 3.

In response to practice based questionnaire, very less, that is, only 14% of health-care professionals were found to

**Table 1: Sociodemographic variables/characteristics of the study participants (n=50)**

Demographic variables	n (%)
Age	
<20 years	4 (8)
20–30 years	22 (44)
>30 years	24 (48)
Sex	
Male	18 (36)
Female	32 (64)
Occupation	
Doctors	26 (52)
Nurses	12 (24)
Pharmacists	12 (24)
Educational qualification	
12 <sup>th</sup> pass	12 (24)
Graduation	18 (36)
Post-graduation	20 (40)

**Table 2: Knowledge of hemovigilance among study participants (n=50)**

Variables	n (%)
Awareness of hemovigilance program	42 (84)
Awareness of reporting of transfusion reaction reporting	38 (76)
Reporting of transfusion reaction is essential	44 (88)
Transfusion reaction reporting can benefit patients	44 (88)
Hemovigilance be taught to health-care professionals during their curriculum	40 (80)
Transfusion reaction reporting is a professional duty	44 (88)
Attended CME on hemovigilance	12 (24)
Have come across adverse transfusion reaction while discharging professional duties	28 (56)
Have reported it to the hemovigilance center	22 (44)

CME: Coronal mass ejection

have active participation in reporting of transfusion-related reactions as perhaps majority of the participants, that is, 46 out of 50 have never attended any CME/seminar/workshop on hemovigilance as per Table 4.

However, health-care professionals agreeing with the factors discouraging transfusion reaction reporting Table 5 was 36 (72%) for how and where to report, lack of time to report 28 (56%), legal liability issues 26 (52%), difficult to decide whether the transfusion reaction has occurred or not 22 (44%), only blood bank can report 14 (28%), fear of consequences 24 (48%), concern that report may be wrong 20 (40%), reporting of known reaction is not required 18 (36%), single unreported case may not affect the database 24 (48%), and no remuneration for reporting remained 28 (56%).

In this study, about two-third, that is, 44% of the participants agreed with the variables mentioned in Table 6. Mentioning the possible ways to improve reporting of transfusion reactions.

## DISCUSSION

Hemovigilance plays an important role in tracking and reducing the adverse events related to blood transfusions and blood products by seeking the active involvement of health-care professionals. Main objectives of hemovigilance are to monitor transfusion reactions, create awareness among health-care professionals, generate evidence-based recommendations, advice CDSCO for safety related regulatory decisions, communicate findings to all key stakeholders, and to create national and international linkages.<sup>[10]</sup>

There are reports elucidating that in spite of the thrust on reporting blood and its related products adverse reactions still the scenario in India is much below desired. Therefore, the present study was conducted with prime focus to examine KAP and evaluating reasons of under reporting and possible ways to improve reporting of transfusion reactions in our tertiary care teaching institution.

Health-care professionals are backbone of bridge between patients and health-care system which if encouraged can certainly reduce morbidity and mortality related to transfusion reactions of blood and its products.<sup>[16]</sup>

According to the current study, health-care professionals had good knowledge about concept of hemovigilance program (84%) irrespective of their qualification which shows that in addition to doctors paramedical staff such as nurses and pharmacists can play a very important role in reporting acute transfusion reactions. Similar to our results, previous trial by Shivgunde *et al.* 2018<sup>[17]</sup> suggest awareness of nurses and pharmacists up to 71%.

In the current trial, the awareness of reporting of transfusion reactions was 76% which is quite high than reported by

**Table 3: Attitude of the participants toward reporting transfusion reactions (n=50)**

Variables	Response of the participants				
	Strongly agree	Agree	Strongly disagree	Disagree	Undecided
Reporting of transfusion reaction is essential	30	16	2	0	2
Transfusion reaction reporting benefit patients	20	22	0	4	4
Hemovigilance should be taught to health-care students during their curriculum	14	24	0	2	10
Every institute should enroll under hemovigilance for reporting transfusion reactions	18	26	0	2	6
Only one hemovigilance center in every city will be sufficient for reporting reaction	10	22	6	2	10
Transfusion reaction reporting is a professional duty	12	30	2	2	4
Total	104	140	10	12	36
Mean	17.34	23.34	1.67	2	6

**Table 4: Practice of transfusion reactions reporting (n=50)**

Variables	Response	
	Yes	No
Have you attended any CME's/workshop/seminars on hemovigilance	4 (8)	46 (92)
Had you ever found any transfusion reaction during your professional practice	20 (40)	30 (60)
Have you documented any transfusion reaction	22 (44)	28 (56)
Have you reported any transfusion reaction to the hemovigilance center	10 (20)	40 (80)
Total	56 (14)	144 (36)

CME: Coronal mass ejection

**Table 5: Factors discouraging transfusion reaction reporting/under-reporting (n=50)**

Variables	Yes (%)	No (%)
How and where to report the reaction	36 (72)	14 (28)
Lack of time to report	28 (56)	22 (44)
Legal liability issues	26 (52)	24 (48)
Difficult to decide transfusion reaction has occurred or not	22 (44)	28 (56)
Only blood bank can report	14 (28)	36 (72)
Fear of consequences	24 (48)	26 (52)
Concern that report may be wrong	20 (40)	30 (60)
Reporting of known reactions is not required	18 (36)	32 (64)
Single unreported case may not affect the database	24 (48)	26 (52)
No remuneration for reporting	28 (56)	22 (44)
Total	240 (24)	260 (26)

Date *et al.* 2016<sup>[18]</sup> who documented 38.88%. However, the number of participants in their trial was quite high (120) as compared to the current trial.

In the current study, the results revealed that 24% of HCP's had attended any CME on hemovigilance. These findings are in concurrence with earlier report by Date *et al.* 2017<sup>[19]</sup> showing that 20% of HCP in their study had attended CME.

**Table 6: Possible ways to improve reporting of transfusion reactions**

Variables	Yes	No
Health-care professionals should be trained in reporting	48 (96)	2 (4)
CME's/workshop/seminars	42 (84)	8 (16)
Making reporting compulsory	42 (84)	8 (16)
Keep the availability of transfusion reporting forms in the wards	44 (88)	6 (12)
Make transfusion reaction reporting easier	46 (92)	4 (8)
Launching of a toll-free helpline no.	46 (92)	4 (8)
Development of mobile application	42 (84)	8 (16)
Remuneration of transfusion reaction reporting	42 (84)	8 (16)
Total	352 (44)	48 (6)

CME: Coronal mass ejection

However, later report by Shivgunde *et al.* 2018 (17) has documented only 9% attended CMEs. This discrepancy could be due to large sample size of 220 of HCP compared to 50 in the current trial. Such result underscores importance of encouraging CMEs, teaching hemovigilance during their curriculum. Such measures shall improve smooth functioning of hemovigilance program.

The present study shows 20% of health-care professionals reported the transfusion reaction to the hemovigilance center. According to global trends of reporting adverse events, a survey national blood collection and utilization survey on 2018 by the United States scheme suggested that 2.6 adverse events were reported per thousand units transfused in comparison to 3–7 events in other national schemes AABB, 2009 (American association of blood banks). Even within countries with relatively well developed hemovigilance system such as Europe and Canada, there are variable reporting rates from 0.2 to 0.7 per thousand units transfused and ranges from none to 6.8 from other participating hospitals in the UK.<sup>[20]</sup> Also as per records, overall reports submitted to SHOT per annum is now 3500 of which some were withdrawn because of incomplete event information.

However, the present study highlights underreporting factors as the main problem in hemovigilance system which are lack of awareness how and where to report a reaction, the nature of transfusion reaction, fear of consequences, lack of training, absence of well-defined hemovigilance structure and protocol, no development of evidence based guidelines, lack of computerization, and use of hemovigil software<sup>[21]</sup> and also mentioned that because of the different nature (mild, non-specific) of some reactions it becomes difficult to decide whether the transfusion reaction has occurred or not especially if it occurs after a long time of transfusion which further contributes to under reporting and the similar problem had been acknowledged by 44% participants in our present study.

Looking into suggested possible ways of improving reporting transfusion reactions in the current study, the majority of the health-care professionals had stressed upon making reporting easier by development of a mobile application for online submission of reporting forms, impart training (CME/seminars/workshop). Thus, an increase in reporting can be made and this is in agreement with a study conducted to report ADR as pre-KAP and post-KAP survey.<sup>[22,23]</sup>

In connection to online submission of reporting forms, it can make a way feasible for health-care professionals in reporting transfusion reactions. A special report on hemovigilance program<sup>[24]</sup> enlists guidelines for reporting transfusion reactions, transfusion reaction reporting form, standardized definitions of transfusion reactions (immunological hemolysis due to ABO incompatibility or other alloantibodies and non-immunological hemolysis), and hemovigil software for online reporting of transfusion reactions.

Hemovigil programming was uplinked to NIB site under the guidance of advisory committee for hemovigilance<sup>[4]</sup> to further improve reporting and smooth functioning of hemovigilance system. A national blood policy was established which strongly suggested the need of transfusion committee at hospital level (HTC) and was taken into consideration in 2002 according to which the HTC should have authority within hospital for determining hospital transfusion policy and resolving problems related to it.<sup>[25,26]</sup>

Besides above, response of majority (84%) of the participants in our study indicates to make reporting compulsory and remuneration of reporting. This also seems to be encouraging steps toward establishment of hemovigilance system. It also suggests the need of implementation of appropriate policies and educational interventions to enable them to incorporate the knowledge into their clinical practice.

Although high awareness and positive attitude of health-care professionals are strengthening points of the study but not sufficient to overcome underreporting in the absence of appropriate policies to make reporting reactions compulsory,

remuneration for reporting, and legal liabilities issues which remains the limiting factors in our study.

## CONCLUSION

Blood transfusion is a lifesaving procedure but carry inherent risk of adverse reaction. The reporting of these events is primarily carried out by the health-care professionals. However, still there is underreporting of these events. Therefore, in the present study, the KAP and causes of under reporting of hemovigilance were studied among 50 health-care professionals comprised doctors (52%), nurses and pharmacists (24% each). Maximum number of the participants (84%) had awareness of hemovigilance program and also showed fairly positive attitude. However, in spite good knowledge and attitude the practice was found lacking as only 8% admitted to had attended CME/seminar and 80% never reported the adverse event to hemovigilance center. For underreporting maximum participants felt how and where report was prime cause (72%) followed by lack of time, remuneration (56% each), and legal liability (52%). As for ways to improve hemovigilance reporting maximum felt that more training should be imparted (96%), reporting forms to made easier, toll free helpline (92% each) reporting to be made mandatory and organizing CME/workshops and availability of mobile application (84% each).

Outcome of the study suggests that though the knowledge and attitude regarding hemovigilance was fairly high but still the score on practice was low. To improve, the reporting more thrust should be on more training, reporting form to be made simple, availability of mobile application, toll free helpline, and more CMEs or workshops.

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