IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)
e-ISSN: 2278-3008, p-ISSN:2319-7676. Volume 10, Issue 5 Ver. IV (Sep - Oct. 2015), PP 13-17
www.iosrjournals.org

Assessment of Healthcare Professional Awareness towards Haemovigilance (HvPI) Programme of India in South India

Narmada Sireesha. V[1], Pavan Kumar Reddy. G.V[1], Jollireddy Sravani[2], Dr. Shoba Rani. R. H[3], Dr. Mohanraj Rathinavelu[4]

[1](Resident – Intern, Doctor of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research – RIPER, Anantapuramu, Andhra Pradesh, India - 515721)
[2](V Year Student, Doctor of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research – RIPER, Anantapuramu, Andhra Pradesh, India - 515721)
[3](Professor & Principal, Al - Ameen College of Pharmacy, Hosur Road, Bangalore, Karnataka, India - 560027)
[4](Assistant Professor & Academic In-charge, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research – RIPER, Anantapuramu, Andhra Pradesh, India - 515721)

Abstract: *Haemovigilance concerns the follow-up of whole blood and labile blood components for transfusion: red cell concentrates, platelets and plasma (fresh frozen plasma, FFP). The major requirement of any transfusion medicine is 'zero risk' to the recipient, as the aftermaths of any error during transfusion is huge. The proposed prospective observational study of six month duration was performed in a tertiary care teaching hospital of Andhra Pradesh aimed in evaluation and to explore the awareness among healthcare professionals towards Haemovigilance Programme of India (HvPI), which included 83 healthcare professionals, provided with an validated questionnaire designed with an extensive literature survey and expertise suggestion. Among the total 200 healthcare professionals working in the hospital only 59% (n=118) provided their responses. Of these responses 70.3% (n= 83) were analyzed and the rest 29.7% (n=35) were not included in the analysis because of incomplete information. The response to the HvPI questionnaire was not more satisfactorial as expected, the doctors were more aware about HvPI in comparison to the nurses, pharmacist and biochemists. A majority of the healthcare professionals opined that the HvPI significance as to be well promoted by the Government of India, by making a web page and to improve the Knowledge, attitude and perception / practice about HvPI doctors suggested the organization of training programmes (regular seminars / workshops) in all healthcare setup. In conclusion, haemovigilance is an imperative tool to improve the quality of the blood transfusion chain, primarily focusing on safety and an important part of the quality system for blood transfusion which promotes health outcomes in which healthcare professionals contribution is significant.*

Keywords: *Blood transfusion, Haemovigilance, Haemovigilance Programme of India (HvPI), Healthcare professionals, KAP study*

I. Introduction

Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety. Haemovigilance systems have shown that blood transfusion is relatively safe compared with the use of medicinal drugs and that at least in Europe blood components have reached a high safety standard [1]. Blood is categorized as a dug as per the Drugs and Cosmetics Act, Ministry of Health & Family Welfare, Government of India and Blood Banking services are regulated by the rules therein. Haemovigilance Programme of India (HvPI) was launched by Dr. Surinder Singh on 10th Dec 2012 in already enrolled 90 Medical Colleges under PvPI as an integral part of Pharmacovigilance Programme of India (PvPI). Haemovigilance is an important part of the quality system for blood transfusion. It implies methods for identifying errors, adverse events and reactions including alert systems, investigation of complaints, traceability systems, notification systems and audits of practice. Haemovigilance focuses on complications in donors and adverse reactions patients and includes failures in the production line, complications in donors related to blood donation, 'near-miss' events, retrospective registration of unwanted events and prospective action with early warning in a rapid alert system of threats. Haemovigilance concerns the follow-up of whole blood and labile blood components for transfusion: red cell concentrates, platelets and plasma (fresh frozen plasma, FFP). The first blood transfusions in the 17th century were attempts to transfuse humans with blood of animals (innocent lambs were favourite) for all kinds of illnesses. In the 18th century, however, the French King Louis XIV forbade the transfusion of animal blood to people by law because it was considered too dangerous [2]. In the 19th century, Henri Leacock and James Blundell pioneered inter-human transfusion as a live saving therapy for severe blood loss. Blundell warned however to apply this therapy only as ultimum refugium because it was also dangerous [3]. Due to matching and anti-coagulation blood transfusion became less dangerous in the 20th century and an accepted therapy also for less vital indications. Although it was realized that transfusion was certainly not without risk, data were lacking

about the actual risk of blood transfusion. At the end of the 1980s, the transmission of infections by blood created the need for a greater awareness on the safety of blood and pioneer work on haemovigilance started in France in 1991 with the set up of monitoring systems by Blood Transfusion Committees, resulting in a national haemovigilance network in 1994 [4, 5]. Haemovigilance is a set of surveillance rules which envelops the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), purporting to collect and assess information on emergent or inexpedient effects resulting from the therapeutic use of labile blood products, and to avoid their occurrence or recurrence [6]. The major requirement of any transfusion medicine is 'zero risk' to the recipient, as the aftermaths of any error during transfusion is huge. The potential risks associated with blood transfusion are HIV, hepatitis, sepsis from bacterial contamination and trauma [7].

Hence there is a need for a haemovigilance system which can assure patient safety and promote public health. The ultimate purpose of haemovigilance is to prevent the repetition of adverse events and reactions [8]. Blood transfusion is not without risk. Although the risks of HIV and hepatitis transmission have diminished, haemovigilance programs highlight that other significant transfusion hazards remain. Sepsis from bacterial contamination is the most common residual infectious hazard in developed countries, and events due to clerical error are problematic. Unnecessary transfusions should be avoided [9]. The involvement of healthcare professionals in haemovigilance programs is considered to be vital in ensuring the safe blood transfusion for better patient health outcome benefits.

Therefore, the aim and objective of this study was to evaluate to evaluate and explore the awareness among healthcare professionals towards Haemovigilance Programme of India (HvPI).

II. Methodology

2. 1Site of Study

The study entitled "Assessment of Healthcare professionals awareness towards Haemovigilance Programme of India (HvPI) in South India" was carried out in a 1200 bedded tertiary care hospital located at Anantapur, Andhrapradesh.

2.2 Study Design

A Prospective Observational study was carried out to evaluate the awareness among (Healthcare Professionals) doctors, nurses and pharmacists towards HvPI.

2.3 Study Duration 06 Months

2.4 Study Population & Sampling

During the study period of 06 months, there were total of 83 participants as Healthcare professionals (36 doctors, 22 nurses, pharmacists 16, Biochemists 09) working in the hospital, participated in the study.

2.5 Inclusion and exclusion criteria

All the healthcare professionals (doctors, nurses and pharmacists, biochemists) working in the hospital during the study period were included. The healthcare professionals who were not willing to participate in the study and the ones who were on leave were excluded.

2.6 Design of Questionnaire

The questionnaire was a 15 item inventory Questionnaire, the items were generated from the literature and adaptation from previous studies and a two step validation process was followed for its accuracy and uniqueness. Initially, the questionnaire comprised of 20 inventories, modified to 15 in final by 02 step validation process.

In step 01, Questionnaire Validation Three faculties with expertise knowledge and practice in drug use research and PvPI were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire (limitations on questionnaire was a feedback which was rectified by eliminating 05 questions which was felt more complex for the participants). The observations and comments of the lecturers were taken in to the account.

In step 02, Questionnaire validation to test the validity and reliability of the questionnaire, the survey form was pilot tested by administering it to sample of 15 Healthcare professionals who did not participate in the study. The overall Cronbach's alpha value calculated was 0.72, which required no further modifications in questionnaire.

III. Results

Among the total 200 healthcare professionals working in the hospital only 59% (n=118) provided their responses. Of these responses 70.3% (n= 83) were analyzed and the rest 29.7% (n=35) were not included in the analysis because of incomplete information. Demographic details of the participants involved in the study was

categorized based on gender distribution, age distribution, professional status and educational qualification the results of which were thoroughly analyzed and reported in Table. 1.

Table 1. Demographic details of the Healthcare professionals (n = 83)

S. no	Demographic details	No. of Participants		
01	Gender Distribution			
	Male	54		
	Female	29		
02	Age Distribution (Years)		Male	Female
	21 – 30	18	12	06
	31 – 40	22	15	07
	41 – 50	27	16	11
	51 – 60	16	11	05
03	Professional Status		Male	Female
	Doctors	36	22	14
	Nurses	22	05	17
	Pharmacists	16	10	06
	Biochemists	09	06	03
04	Educational Qualification		Male	Female
	MBBS	19	10	08
	MBBS with specialty	17	12	06
	BSc in Nursing	14	05	09
	Diploma in Nursing	08	-	08
	B. Pharmacy	06	04	02
	D. Pharmacy	10	06	04
	Biochemists	09	06	03

The positive response to the questionnaire prepared for the HvPI study, the results of which were thoroughly analyzed and reported in Table. 2.

Table 2. Responses for HvPI Questionnaire

Questions	Doctors	Nurses	Pharmacists	Biochemists
When did the centralized, structured HvPI programme was launched in India?	24 (66.67%)	08 (36.36%)	07 (43.75%)	05 (55.55%)
HvPI in India was established and governed by?	24 (66.67%)	08 (36.36%)	07 (43.75%)	05 (55.55%)
Total number of Centres under HvPI in India?	18 (50%)	05 (22.73%)	06 (37.5%)	04 (44.44%)
Constitution of HvPI?	14 (38.89%)	04 (18.18%)	05 (31.25%)	01 (11.11%)
The person who launched Haemovigilance Programme of India (HvPI)	20 (55.55%)	05 (22.73%)	04 (25%)	04 (44.44%)
TRRF abbreviation	24 (66.67%)	04 (18.18%)	02 (12.5%)	06 (66.67%)
Haemovigilance Programme of India (HvPI) enrolled centres in Andhra Pradesh	10 (27.78%)	03 (13.64%)	03 (18.75%)	06 (66.67%)
Haemovigilance Programme of India (HvPI) software	16 (44.44%)	02 (9.09%)	03 (18.75%)	05 (55.55%)
When and where the terminology / word 'haemovigilance" was coined?	20 (55.55%)	02 (9.09%)	05 (31.25%)	03 (33.33%)
The average annual Blood collection in India according to HvPI?	14 (38.89%)	03 (13.64%)	03 (18.75%)	07 (77.78%)
Dedicated budgetary provision during 12th Five year plan for HvPI?	09 (25%)	02 (9.09%)	02 (12.5%)	02 (22.22%)
Licensed blood banks in India?	08 (22.22%)	02 (9.09%)	02 (12.5%)	03 (33.33%)
What are all the Three Phases explaining the Targets of HvPI?	08 (22.22%)	02 (9.09%)	03 (18.75%)	02 (22.22%)
Haemovigilance reporting system in HvPI is mandatory or voluntary?	08 (22.22%)	02 (9.09%)	03 (18.75%)	04 (44.44%)
How many Transfusion Reaction Reports (TRR) are submitted via Haemo-Vigil Software by how many centres under HvPI?	04 (11.11%)	01 (4.5%)	03 (18.75%)	01 (11.11%)

IV. Discussion

To the best of our knowledge, this was the first study in south India design to assess the awareness among healthcare professionals towards the HvPI (Haemovigilance Programme of India) in a tertiary care teaching hospital of India. Overall, the responses of the healthcare professionals were low as the participation was lower and ignorance was one of the factors among HCP's. Among the total 200 healthcare professionals working in the hospital only 59% (n=118) provided their responses. Of these responses 70.3% (n= 83) were analyzed and the rest 29.7% (n=35) were not included in the analysis because of incomplete information. Demographic detail reported that participants were maximum male in comparison to female and also the ratio of healthcare professional was doctors (36) in the study. The study showed that the positive responses to HvPI Questionnaire was satisfactorial in Doctors in comparison to other healthcare professionals, Doctors delivered responses related to the HvPI basics but not on the constitution of HvPI, HvPI enrolled centres in Andhra Pradesh, Software of HvPI, budgetary provision, Phases of HvPI targets, annual average of blood collection. The responses found in Nurses and Pharmacists was deprived in comparison to that of Biochemists (Laboratory professionals). A majority of the healthcare professionals opined that the HvPI significance as to be well promoted by the Government of India, by making a web page and to improve the Knowledge, attitude and perception / practice about HvPI doctors suggested the organization of training programmes (regular seminars / workshops) in all healthcare setup and an educational intervention could increase the HCP's awareness on HvPI were physicians would be able to incorporate the knowledge that they gained from their training into their everyday clinical practice.

V. Conclusion

Haemovigilance "a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence". It is an imperative tool to improve the quality of the blood transfusion chain, primarily focusing on safety and an important part of the quality system for blood transfusion. In conclusion, in our study the awareness of healthcare professionals towards HvPI was not to the satisfactorial level. Learning, promotion and practice of HvPI is of more significance value for the betterment of Health outcome and safety of the public which has to be established in all healthcare setup.

Acknowledgements

The authors would like to thank all faculties of Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research (RIPER) and Dr. Yiragamreddy Padmanabha Reddy Professor and Principal – RIPER, for their valuable guidance and constant support.

References

[1] R. R. P. de Vries, J.-C. Faber, P. F. W. Strengers, Muhammad Amir, Haemovigilance: an effective tool for improving transfusion practice; Vox Sanguinis 2010 International Society of Blood Transfusion, Vox Sanguinis (2011) 100, 60–67.
[2]. Bernard J: La legende du Sang. Paris, Ed. Flammarion, 1992.
[3]. Schmidt PJ, Leacock AG: Forgotten transfusion history: John Leacock of Barbados. BMJ 2002; 325(7378): 1485–1487.
[4]. Noel L, Debeir J, Cosson A: The French haemovigilance system. Vox Sang 1998; 74(Suppl 2):441–445.
[5]. Andreu G, Morel P, Forestier F, et al.: Hemovigilance network in France: organization and analysis of immediate transfusion incident reports from 1994 to 1998. Transfusion 2002.
[6]. ihm-org.com [about/definition-of-haemovigilance] International Haemovigilance Network. [Cited: 5/2/2014]. Available from: http://www.ihn-org.com/about/definition-ofhaemovigilance/42(10):1356–1364.
[7]. Engel Brecht S, Wood EM, Cole-Sinclair MF, 'Clinical transfusion practice update: haemovigilance, complications, patient blood management and national standards.' PMID: 24033212 [PubMed - indexed for MEDLINE].
[8]. Adele Giampaolo, Vanessa Piccinini, Liviana Catalano, Francesca Abbonizio, and Hamisa Jane Hassan, PMCID: PMC2535888, doi: 10.2450/2007.0001-07.
[9]. Sunelle Engelbrecht, Erica M Wood, Merrole F Cole-Sinclair, Clinical transfusion practice update: haemovigilance, complications, patient blood management and national standards, MJA 199 (6) • 16 September 2013.

Annexure 1 Questionnaire to assess the awareness among Healthcare Professionals towards HvPI with answers

S. no	Questions	Answers
01	When did the centralized, structured HvPI programme was launched in India?	10 December 2012
02	HvPI in India was established and governed by?	Indian Pharmacopeia Commission (IPC), Ministry of Health & Family Welfare, Government of India.
03	Total number of Centres under HvPI in India?	134
04	Constitution of HvPI?	15 Members
05	The person who launched Haemovigilance Programme of India (HvPI)	Dr. Surinder Singh
06	TRRF abbreviation	Transfusion Reaction Reporting Form
07	Haemovigilance Programme of India (HvPI) enrolled centres in Andhra Pradesh	14
08	Haemovigilance Programme of India (HvPI) software	Haemo-Vigil Software – IPC – NIB: IT Team
09	When and where the terminology / word 'haemovigilance" was coined?	1991, in France
10	The average annual Blood collection in India according to HvPI?	7 – 8 Million units
11	Dedicated budgetary provision during 12^{th} Five year plan for HvPI?	Rs 29.36 Crore
12	Licensed blood banks in India?	2545
13	What are all the Three Phases explaining the Targets of HvPI?	Initiation Phase Expansion & Consolidation Phase Expansion & Maintenance Phase
14	Haemovigilance reporting system in HvPI is mandatory or voluntary?	Voluntary
15	How many Transfusion Reaction Reports (TRR) are submitted via Haemo-Vigil Software by how many centres under HvPI?	143 reports, by 09 centres