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# HAEMOVIGILANCE: IT'S IMPLICATION - A CROSS SECTIONAL STUDY IN A TERTIARY CARE AND SOME URBAN HOSPITALS, PERAMBALUR

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## ABSTRACT

**Introduction:** According to the sound knowledge of the nature, adverse effects of blood transfusion is essential in order to detect known and previously unknown adverse effects of current or new blood components can be monitored by means of central registration of transfusion reactions in a timely manner. **Objectives:** To evaluate the awareness and implication of the existing haemovigilance programme of India, in a Tertiary care Hospital and of some urban hospitals blood banks of Perambalur district. **Study Type:** It was a questionnaire based, cross sectional study, incorporated knowledge, practices and attitude based questionnaire from the area of Haemovigilance. **Study Subjects:** Total 100 Healthcare professional (HCPs), like, Pathologist, General Medicine Physician, Pediatrician, Surgeon, Orthopedician, Anesthesia, Obstetrician, Casualty Medical Officer, Blood bank in-charge, Junior and senior residents who were involved to provide emergencies medical services, i.e., whose services depends on routine blood or blood product transfusion, attempted the questionnaire. **Results:** The enrolled 100% healthcare professional were concerned with the routine blood or blood transfusion activities, 38% HCPs were familiar about the terminology "Haemovigilance", 30% HCPs knew partially about some blood or blood product included in the definition of haemovigilance. The out of 100 HCPs, 67% doctors, 10% nurses, 5% hematologist, 7% anesthetist, 3% surgeon; pediatrician; obstetrician; physician, and 8% medical and Paramedical staffs responded that, these HCPs can report transfusion associated adverse reactions. The only 19% HCPs responded that Registered blood bank under HvPI can report transfusion associated adverse reactions. The only 14% HCPs responded that Haemo-vigil software used to report transfusion associated adverse reactions. The only 8% HCPs were aware about the eighteen parameters are included in the TRRF. All the HCPs were not reported blood transfusion associated adverse reaction within last 3 years of their practice to the National Coordinating Centre of HvPI. Only 3% HCPs were attended WORKSHOP/CME/SEMINAR/CONFERENCE on the area of the transfusion related adverse reactions reporting. Only 1% HCPs knew that the transfusion associated reactions should be reported to the district authority according to the NACO (National AIDS Control Organization) system. Only 11% HCPs were aware about the NACO has already prescribed standard form for the reporting transfusion associated reactions. Within last three years only 4% HCPs were reported the transfusion associated reactions which were out of 30 transfusions and this reporting was according to the NACO guidelines. **Conclusion:** According to the obtained results; it is noticed that the haemovigilance programme of India is in infancy state, only, 19% healthcare professionals were familiar about the terminology "Haemovigilance" and even no one aware about how and where transfusion related adverse reactions should be reported. Thus, much more awareness programme haemovigilance should be conducted among the healthcare professionals.

**KEYWORDS:** Haemovigilance, Haemo-vigil, Transfusion Related Reporting Form, HvPI, NACO (National AIDS Control Organization).

## INTRODUCTION

Human blood and blood product's transfusion is always possess some level of risk. The introduction of the Serious Hazards of Transfusion was initiated in 1996 and has been a heightened awareness that blood transfusion can cause harm.[1]

Haemovigilance is a risk monitoring system integral to the practice of transfusion medicine whose ultimate purpose is to improve the quality and safety of transfusion therapy.[2]

The haemovigilance programme of India launched by the Haemovigilance Advisory Committee of India during its

first meeting on 29th November, 2012 held at National Institute of Biologicals (NIB), Noida.[3]

So, on the above background, we decided to evaluate present status regarding haemovigilance in a Tertiary care Hospital and of some urban hospitals blood banks of Perambalur district.

**OBJECTIVES**

1. To evaluate the awareness regarding the existing haemovigilance programme of India, in a Tertiary care Hospital and of some urban hospitals blood banks of Perambalur district.
2. To evaluate implication of the haemovigilance programme in the blood bank of a Tertiary care Hospital and of some urban hospitals blood banks of Perambalur district.

**MATERIALS AND METHODS**

**Ethical Approval:** The study was initiated after getting ethical approval from the Institutional Ethics Committee (Human studies).

**Study location:** A tertiary care Hospital, i.e., Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur, some urban hospitals blood banks of Perambalur district.

**Study Type:** A Questionnaire based, cross sectional study, incorporated questionnaire was knowledge, practices and attitude based from the area of Haemovigilance.

**Study participants:** All the healthcare professionals who were involved for routine blood transfusion to the needy patients assigned for the study.

**Consent of the study participants:** Questionnaire was distributed to each participant by direct contact and before attempting the questions, his/her written consent were obtained.

**Study questionnaire:** The questions no. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 16 and 17 were knowledge based, while questions no. 12, 13, 15 and 18 were practice based and question no. 1 and 14 were attitude based question.

**Prescribed Questionnaire:** The below written questionnaire distributed to the study participants directly and after their consent asked them to attempt in 15 minutes, at the end of the time re-collected the questionnaire.

**Q.1** My medical professional degree related to blood /blood product transfusion associated routine activity is:
CONCERNED NOT CONCERN

**Q.2** Are you familiar with **the word "HAEMOVIGILANCE" elsewhere before attempting this question?**
YES NO

**Q.3 Where 'BLOOD BANK' should be registered to follow the Guidelines of Haemovigilance Programme of India (HvPI)?**
KNOW DON'T KNOW

If, you know, write Name and address of the Authorized Centre:
……
……
……
……

**Q.4 Which component of blood or blood products are included in the definition of "HAEMOVIGILANCE"?**
KNOW DON'T KNOW

If, you know, write the name of blood components:

| | | |
|---|---|---|
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
| …… | ……..... | …… |
| …… | **.....** | ……..… |

**Q.5** Who (healthcare professionals) can report transfusion associated adverse reactions?
(1)……, (2)……, (3)……
(4)……

**Q.6** Which BLOOD BANK can report transfusion associated adverse reactions? (Tick appropriate answer with □)
(a) Any blood bank, (b) Registered blood bank under specified Centre of HvPI, (c) Both (a) and (b) option can report, (d) Both option (a) and (b) cannot report.

**Q.7** Who can enroll under umbrella of HvPI?
(1)……., (2)……,
(3)…….. , (4) …… of India.

**Q. 8 When HvPI** (Haemovigilance Programme of India) **launched** and **initially** how many number of **Medical Colleges enrolled**?
:
……

……

**Q.9** What is name of the software by which transfusion associated adverse reactions to be reported?

**(a) Vigiflow, (b) vigibase, (c) haemo-vigil, (d) vigibind, (e) Don't know, (f) Not sure.**

**Q.10 How many NUMBERS of transfusion associated adverse reactions parameters** are included in the TRRF (Transfusion Reaction Reporting Form)?

(a) NINE, (b) EIGHTEEN, (c) TWENTY SEVEN (d) Options a, b, c are wrong, (e) Don't know, (f) Not sure.

**Q.11** Name **transfusion associated adverse reactions parameters** which are included in the TRRF (Transfusion Reaction Reporting Form):

……
……
……
……..
……
……..

**Q.12** How many **approximate number** of **blood transfusion associated adverse reactions** have reported by you within last three years to the NCC (National Coordinating Centre) of HvPI? (If not reported, tick with □)

……..... , Not reported because I was unaware about the HvPI.

**Q.13** How did you report the blood transfusion associated adverse reactions?

(a) Manually filled TRRF and posted through postal dept. (b) Filled online TRRF and submitted through the specified software system of the HvPI. (c) Did not report because I was unaware about the HvPI.

**Q.14** Did you PARTICIPATE any workshop, CME, Seminar, Conference related to the Haemovigilance WITHIN LAST THREE YEARS?

YES NO

**Q.15** How did /do you manage, if any blood / blood product transfusion associated adverse reactions happened with your concern patient?

……
……

**Q.16** As per the NACO (National AIDS Control Organization) where transfusion associated reaction should be reported?

……
……..……

**Q.17** Any standard form of transfusion associated reaction has been prescribed by NACO?

YES No
Don't know Not sure

**Q.18** How many transfusion associated reactions have been reported within last three years by you as per the guideline of NACO to the higher authority?

**Study Subjects**

Total 100 Healthcare professional (HCPs), like, Pathologist, General Medicine Physician, Pediatrician, Surgeon, Orthopedician, Anesthesia, Obstetrician, Casualty Medical Officer, Blood bank in-charge, Junior and senior residents who were involved to provide emergencies medical services, i.e., whose services depends on routine blood or blood product transfusion, attempted the questionnaire. After collecting the answers-sheets from the participants, we distributed the Answers – key, which are mentioned below, to provide awareness regarding the Haemovigilance.

**Key to the Questionnaire**

After, re-collections of the distributed questionnaire, printed answers key provided to give awareness regarding the haemovigilance system.

Ans.2: National Institute of Biologicals
National Coordinating Centre-Haemovigilance Programme of India Ministry of Health & Family Welfare, Government of India

A-32, Sector-62, NOIDA, Uttar Pradesh NIB website: http://nib.gov.in/
Email: haemovigilance@nib.gov.in

Ans.3:

| | | |
|---|---|---|
| Whole Blood Red Blood Cells Platelets Apheresis Platelets Pooled/ RDP Solvent detergent (SD) Plasma FFP Cryoprecipitate | Any other blood products: | Plasma Products (Please Specify) |

Ans.4: Any healthcare professional: Doctors, nurses, Dentists, and Pharmacists.

Ans.5: Only the Centres registered with the HvPI report the Transfusion Reactions to the NCC-HvPI, NIB, NOIDA by entering the data into the Transfusion Reaction Reporting Form (TRRF) in the HaemoVigil Software.

Ans.6: Medical Colleges, Research Institutes, Hospitals, Blood Banks of India

Ans.7: Haemovigilance Programme was launched on **10th Dec 2012** in already **enrolled 90 Medical Colleges under PvPI** as an integral part of Pharmacovigilance

Programme of India.
Ans.8: Haem-vigil
Ans.9: EIGHTEEN

Ans.10:
1. Immunological haemolysis d/t ABO incompatibility
2. Immunological haemolysis d/t the All-antibody
3. Non-Immunological haemolysis
4. Transfusion –transmitted bacterial infection
5. Anaphylaxis/hypersensitivity
6. Transfusion related acute lung injury (TRALI)
7. Transfusion transmitted viral infection (HBV)
8. Transfusion transmitted viral infection (HCV)
9. Transfusion transmitted viral infection (HIV-1/2)
10. Transfusion transmitted viral infection- others
11. Transfusion transmitted parasitical infection (malaria)
12. Transfusion transmitted parasitical infection-others
13. Post transfusion purpura
14. Transfusion associated graft versus host disease (TAGvHD)
15. Febrile Non-haemolytic Transfusion Reactions (FNHTR)
16. Transfusion associated dyspnoea (TAD)
17. Transfusion associated circulatory overload (TACO)
18. Other Reactions.

**Statistical Analysis**

Response of the each questions analyzed by using Microsoft Excel 10 and calculated percent, then plotted on the bar chats.

**RESULTS**

The enrolled 100% healthcare professional were concerned with the routine blood or blood transfusion activities (See the Fig. 1).

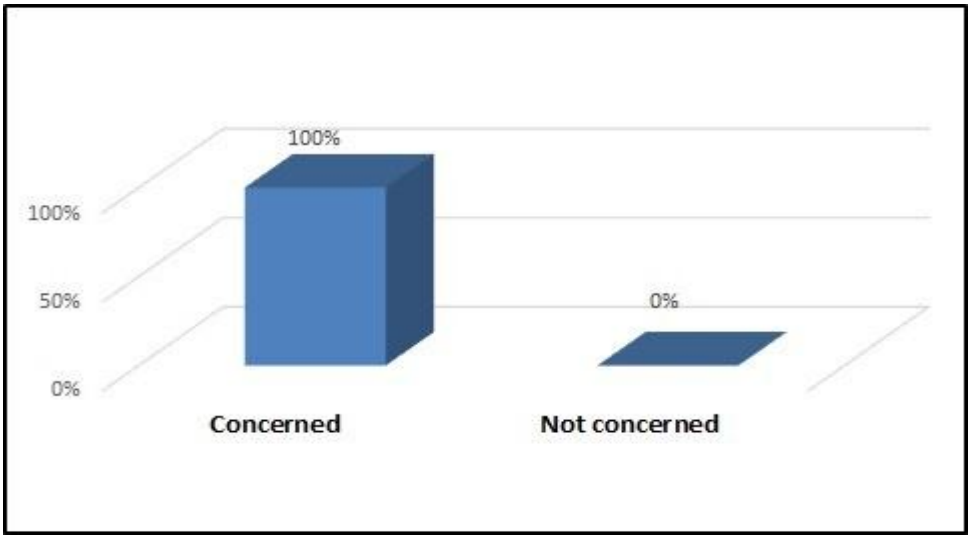



**Figure 1: Medical Professional Degree Concerned with Blood Transfusion associated activities Routine Practice.**

There were no any healthcare professionals aware about the address regarding registration of blood bank as per the norms of the HvPI (Haemovigilance Programme of India), only 38% HCPs were familiar about the terminology "Haemovigilance", and 30% HCPs were knowing partially about some blood or blood product included in the definition of haemovigilance (See the Fig. 2).

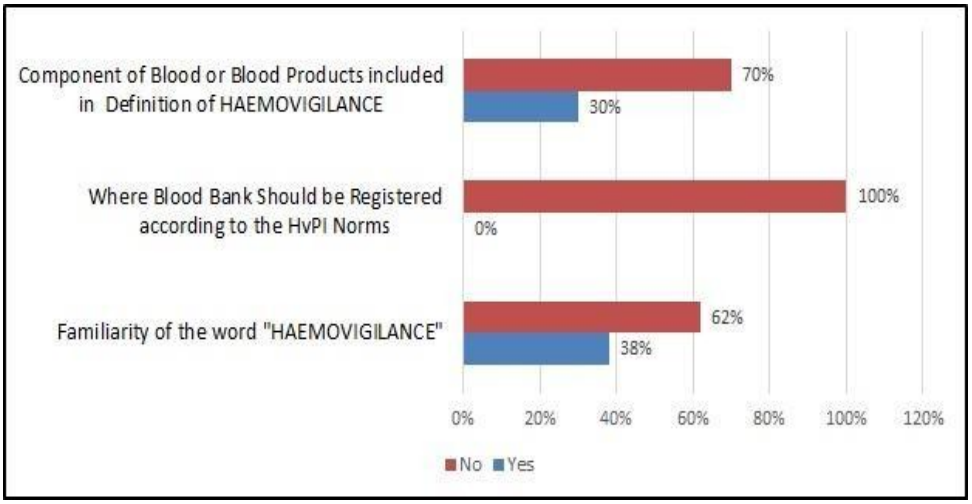



**Figure 2: Knowledge of Haemovigilance.**

The out of 100 HCPs, 67% doctors, 10% nurses, 5% hematologist, 7% anesthetist, 3% surgeon; pediatrician; obstetrician; physician and 8% medical and Paramedical staffs responded that, these HCPs can report transfusion associated adverse reactions (See the Fig. 3).

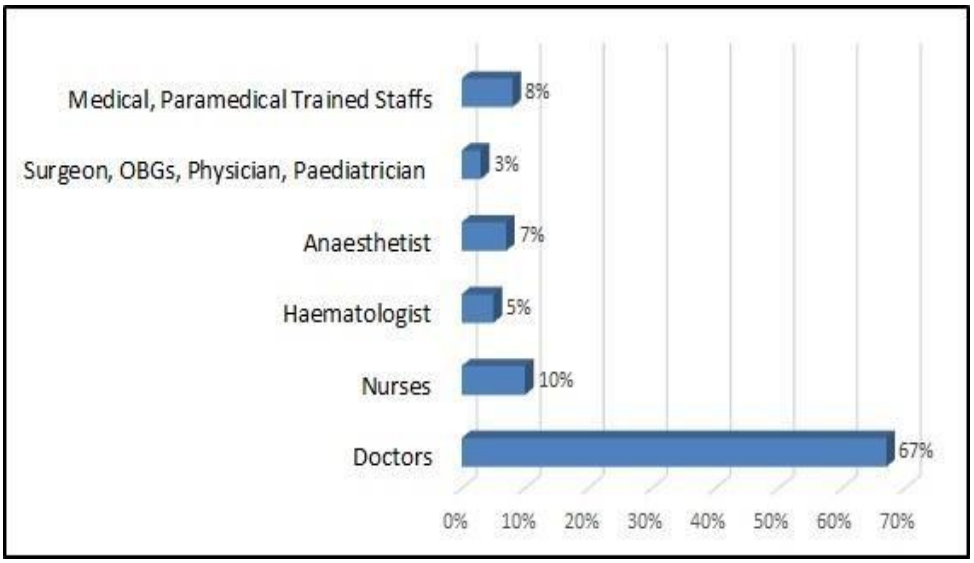



**Figure 3: Which Healthcare Professionals can report Transfusion Associated.**

**Adverse Reactions?**

The only 19% HCPs responded that Registered blood bank under HvPI can report transfusion associated adverse reactions (see the Fig. 4).

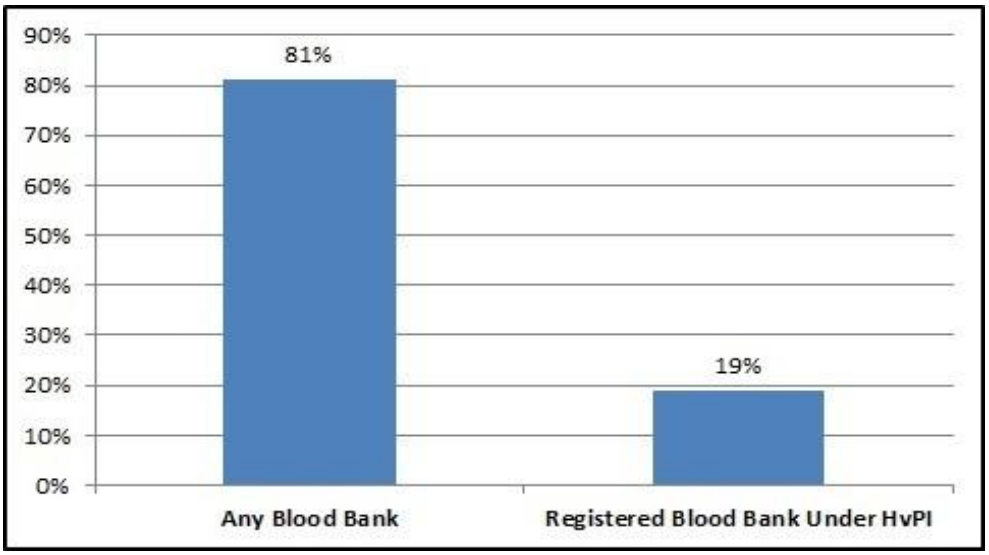
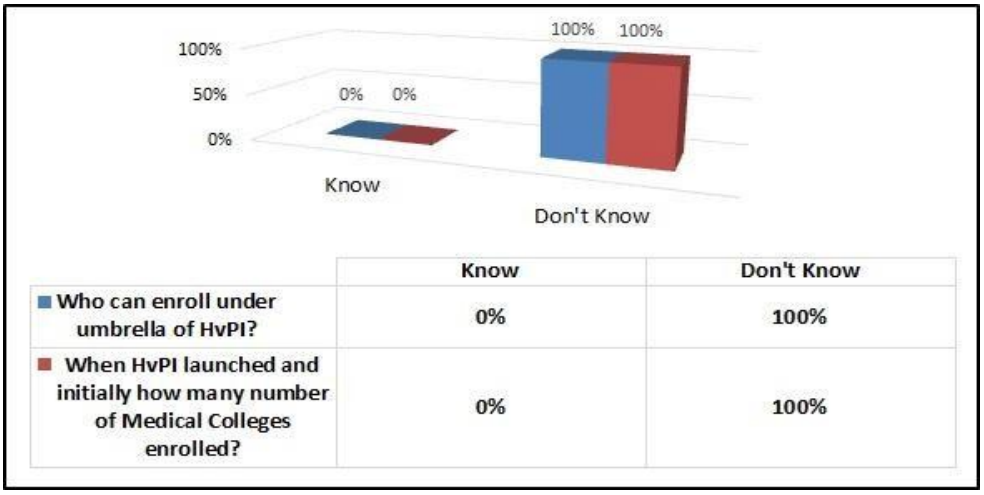



**Figure 4: Which Blood Bank can report transfusion associated adverse reactions?.**

The 100% HCPs were unaware about enrolling under umbrella of HvPI", and no one aware regarding the "when HvPI launched and initially how many number of medical colleges enrolled under the HvPI" (see the Fig. 5).




| | Know | Don't Know |
|---|---|---|
| Who can enroll under umbrella of HvPI? | 0% | 100% |
| When HvPI launched and initially how many number of Medical Colleges enrolled? | 0% | 100% |

**Figure 5: Which Healthcare Professionals) can enroll under umbrella of HvPI?. When HvPI launched and initially how many number of Medical Collegesenrolled?.**

The only 14% HCPs responded that Haemo-vigil software used to report transfusion associated adverse reactions (see the Fig. 6).

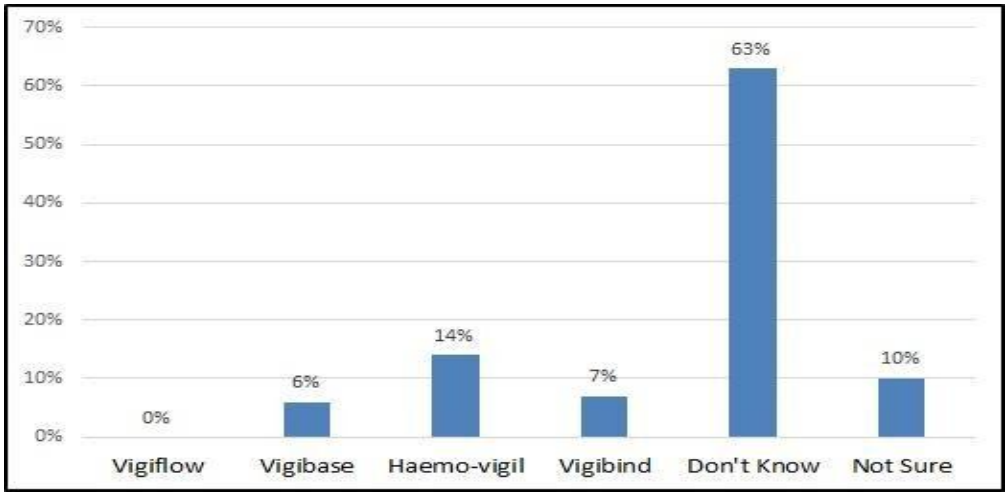



**Figure 6: Which Software used to Report Transfusion Associated Adverse Reactions?.**

The only 8% HCPs were aware about the eighteen parameters are included in the TRRF and 60% HCPs were not knowing and 22% HCPs were unaware about the TRRF (see the Fig. 7).

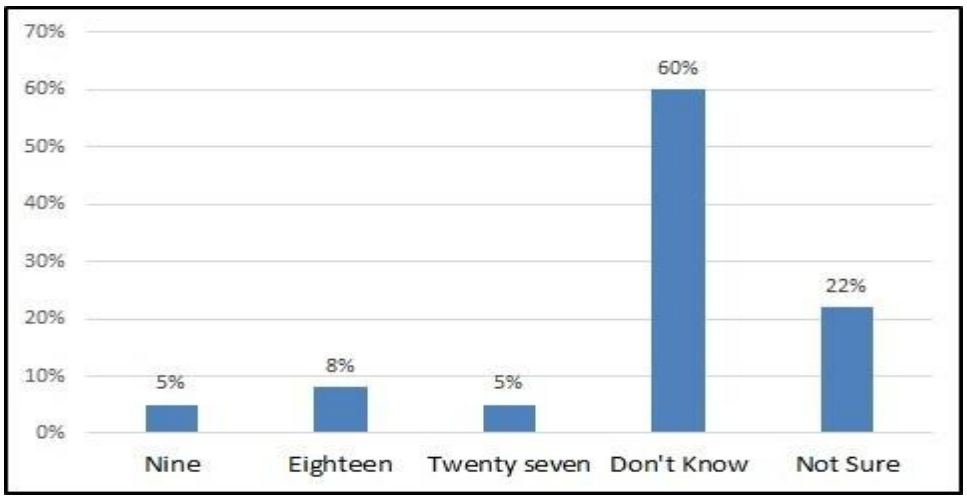



**Figure 7: How many numbers of transfusion associated adverse reactions parameters are included in the TRRF (Transfusion Reaction Reporting Form)?.**

All the HCPs were not reported blood transfusion associated adverse reaction within last 3 years of their practice to the National Coordinating Centre of HvPI (see the Fig. 8).

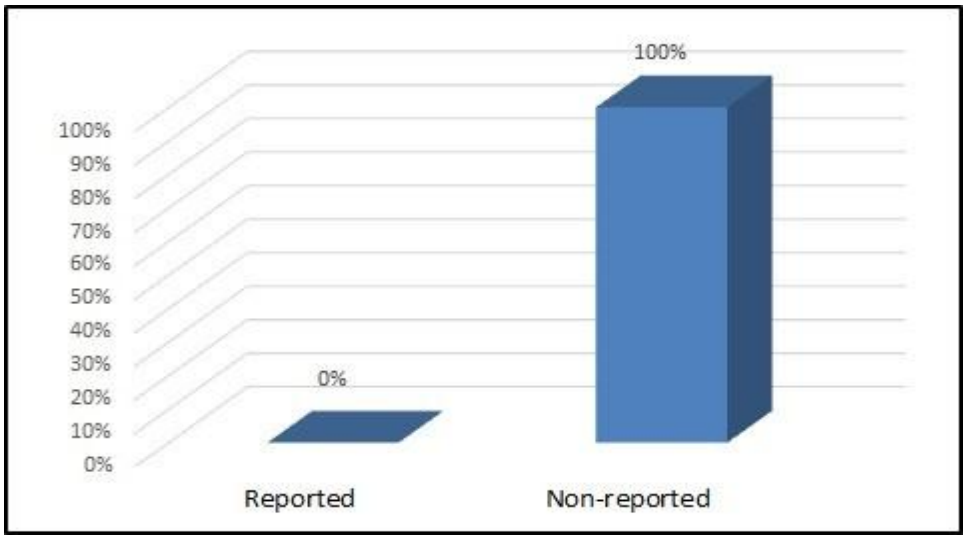



**Figure 8: Approximate Number of Blood Transfusion Associated Adverse Reactions Reported within last three years to the NCC (National Coordinating Centre) of HvPI?.**

Only 3% HCPs were attended WORKSHOP/CME/SEMINAR/CONFERENCE on the area of the transfusion related adverse reactions reporting.

Only 1% HCPs were knowing that the transfusion associated reactions should be reported to the district authority according to the NACO (National AIDS Control Organization) system.

Only 11% HCPs were aware about the NACO has already prescribed standard form for the reporting transfusion associated reactions.

Within last three years only 4% HCPs were reported the transfusion associated reactions which were out of 30 transfusions and this reporting was according to the NACO guidelines.

**DISCUSSION**

Haemovigilance is the systematic surveillance of transfusion-related adverse events (AE) and reactions (AR), encompassing the entire transfusion chain and aimed at improving the safety of the transfusion process. A haemovigilance system is an integral part of quality management in a blood system and is essential for the continual improvement of the quality and safety of blood products and to increase the safety, efficacy and efficiency of blood transfusion.[4]

The Govt. of India launched haemovigilance programme of India on 29th November, 2012.[3] Initial Phase-1, ninety medical colleges were included to implement the HvPI programme, and later, all medical colleges of India advised to implement the HvPI in phase-2 by 2016.[4]

In the present study out of 100 HCPs, 67% doctors, 10% nurses, 5% hematologist, 7% anesthetist, 3% surgeon; pediatrician; obstetrician; physician and 8% medical and Paramedical staffs responded that, these HCPs can report transfusion related adverse reactions. But, according to the HvPI any HCPs can report transfusion related adverse reactions.

In the present study, only 19% HCPs responded that registered blood bank under HvPI can report transfusion associated adverse reactions.

Since, the Haemo-vigil software system launched in 2014, 2nd April[5] and in the present study only 14% HCPs had aware about the Haemo-vigil software used to report transfusion associated adverse reactions.

According to the present study, only 8% HCPs were aware about the Transfusion Reaction Reporting Form. The only 8% HCPs were aware about the EIGHTEEN parameters are included in the TRRF. And, even no one reported transfusion associated adverse reactions within last three years of their clinical practice to the affiliated centre.

No one was aware about the blood or blood related adverse reactions reporting system. Only 3% HCPs were attended.

WORKSHOP/CME/SEMINAR/CONFERENCE on the area of the transfusion related adverse reactions reporting.

Only 1% HCPs were knowing that the transfusion associated reactions should be reported to the district authority according to the NACO (National AIDS Control Organization) system.

Only 11% HCPs were aware about the NACO has already prescribed standard form for the reporting transfusion associated reactions.

Within last three years only 4% HCPs were reported the transfusion associated reactions which was out of 30 transfusions and this reporting was according to the NACO guidelines.

## CONCLUSION

According to the obtained results; it is noticed that the haemovigilance programme of India is in infancy state, only, 19% healthcare professionals were familiar about the terminology "Haemovigilance" and even no one aware about how and where transfusion related adverse reactions should be reported. Thus, much more awareness programme haemovigilance should be conducted among the healthcare professionals.

## LIMITATIONS

The present study data is giving only information about the knowledge, attitude and practices of the assigned healthcare professionals regarding the Haemovigilance programme of India and all the obtained response was based on asked questions of the given questionnaire.

## CONFLICT OF INTEREST

There was no any conflict of interest.

## ACKNOWLWDGEMENT

We acknowledged all the assigned healthcare professionals who participated for the study.

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