

## HEMOVIGILANCE AND POST-TRANSFUSION REACTIONS TO BLOOD COMPONENTS IN PATIENTS WITH SOLID TUMORS

MIROSLAV BANOVIĆ, MARIJA LOVRIĆ, IRENA VELIKI DALIĆ and MIRO BANOVIĆ\*

University Hospital for Tumors, Zagreb, Croatia

\*Cand. Med., School of Medicine University of Rijeka, Croatia

---

### Summary

Hemovigilance is a system of surveillance and alarm in transfusion activities from blood donor selection to the follow-up of the blood component recipients, gathering and analyzing all untoward effects of blood transfusion in order to correct their cause and prevent recurrence. A 5-year surveillance (2005-2009) showed the overall consumption of 6790 unit doses (1358/year): erythroconcentrate (EC)  $973.4 \pm 71$ , platelet concentrate (PC)  $216 \pm 66.93$ , fresh frozen plasma (FFP)  $122.4 \pm 59.05$  and cryoprecipitate (CP)  $46.2 \pm 26.63$ . During the five years, there were 38 adverse events (22 non-hemolytic febrile transfusion reactions (NHFTR), 16 allergic reactions (AR), or an average annual rate of 7.6 reactions (4.4 NHFTR, 3.2 AR). Neither serious adverse events nor death was reported. EC caused 0.043% of NHFTR (risk 1:2,326) and 0.015% of AR (risk 1:3,125), while FFP lead to 0.18% of NHFTR (risk 1:556) and 1.18% of AR (risk 1:85). No reaction to PC and CP was reported. The annual rate for 10,119 blood components (EC,PC, FFP,CP) was 0.043% of NHFTR (risk 1:2,326), and 0.032% of AR (risk 1:3,125). Our results are within the range of worldwide standards.

KEYWORDS: *hemovigilance, red blood cells, post-transfusion reaction*

### HEMOVIGILANCIJA I POSLIJETRANSFUZIJSKE REAKCIJE NA KRVNE SASTOJKE U BOLESNIKA SA SOLIDNIM TUMORIMA

#### Sažetak

Hemovigilancija je sustav nadzora i alarma u transfuzijskoj medicini. Prati tijek krvi i krvnih pripravaka davatelja do krajnjeg potrošača. Prikuplja i analizira neželjene događaje kako bi ih bilo manje u budućnosti. Potrošnja doza praćena je 5 godina (2005-2009) i bila je 6790 (1358/god): eritrokoncentrata (EK)  $973,4 \pm 71$ , trombokoncentrata (TK)  $216 \pm 66,93$ , svježe smrznute plazme (SSP)  $122,4 \pm 59,05$  i krioprecipitata (KP)  $46,2 \pm 26,63$ . Tijekom 5 godina bilo je 38 neželjenih reakcija (22 nehemolitičnih febrilnih transfuzijskih reakcija NHFTR, 16 alergijskih reakcija AR). Prosječno godišnje 7,6 reakcija (4,4 NHFTR, 3,2 AR). Nije bilo težih reakcija i smrti. EK su izazvali 0,043% NHFTR (rizik 1:2326) i 0,015% AR (rizik 1:3125), a SSP 0,18% NHFTR (rizik 1:556) i 1,18% AR (rizik 1:85). Reakcija na TK i KP nije bilo. Na 10119 pripravaka (EK,TK,SSP,KP) godišnje bilo je 0,043% NHFTR (rizik 1:2326), te 0,032% AR (rizik 1:3125). Naši rezultati su u rangu svjetskih standarda.

KLJUČNE RIJEČI: *hemovigilancija, eritrociti, poslijetransfuzijska reakcija*

---

### INTRODUCTION

The hemovigilance system was first set up in France in 1991 as tools of utmost importance for the safety and quality of blood transfusion (1). Almost all countries in the world have organized a

system corresponding to hemovigilance (2). In England, they use the term SHOT (serious hazards of transfusion) for hemovigilance (3). Europe is connected through the European hemovigilance network (EHN)(4).

## MATERIAL AND METHODS

A retrospective study was carried out via reports of a 5-year surveillance (2005-2009) of consumption of erythroconcentrate (EC), platelet concentrate (PC), fresh frozen plasma (FFP) and cryoprecipitate (CP) including adverse reactions to these components. In the observed period, 6790 unit doses (1358/year) were transfused. The graphic representation includes the results for EC, FFP, and the values for all blood components (EC, PC, FFP, CP) are expressed by a mean, standard deviation and percentage, and relative to risk.

## RESULTS

During the 5-year surveillance there were 6790 units of blood and blood products transfused and 38 adverse reactions (22 FNHTR, 16 AR) report-

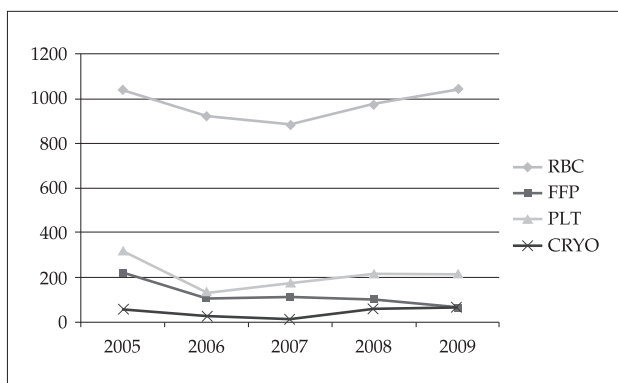


Figure 1. Five-year consumption of blood and blood products. RBC = red blood cells, FFP = fresh frozen plasma, PLT = platelets, CRYO = cryoprecipitate.

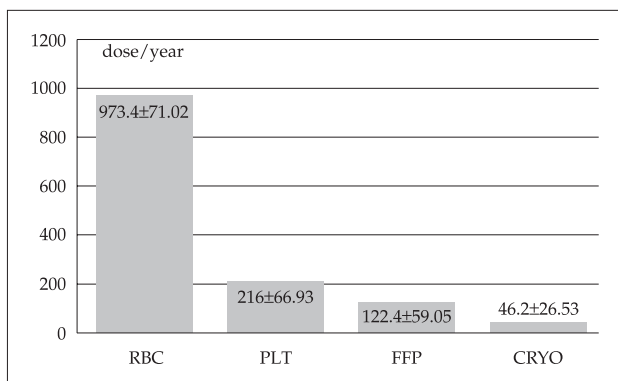


Figure 2. Consumption of red blood cells (RBC), platelets (PLT), fresh frozen plasma (FFP) and cryoprecipitate (CRYO).

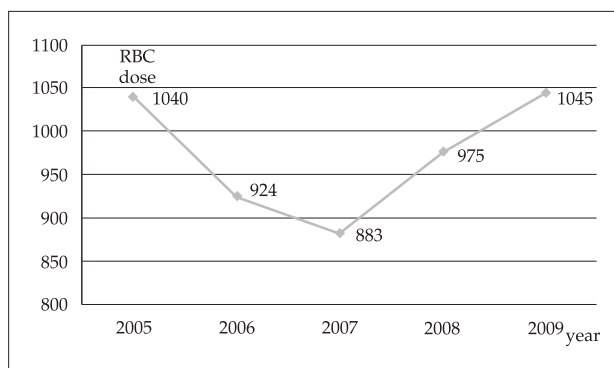


Figure 3. Five-year consumption of red blood cells (RBC).

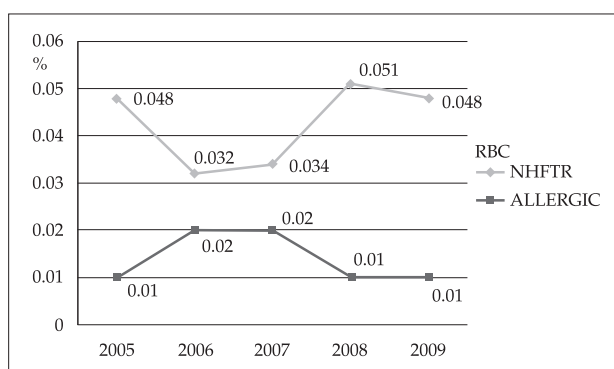


Figure 4. Five-year surveillance of RBC allergic and febrile non-hemolytic transfusion reactions (FNHTR).

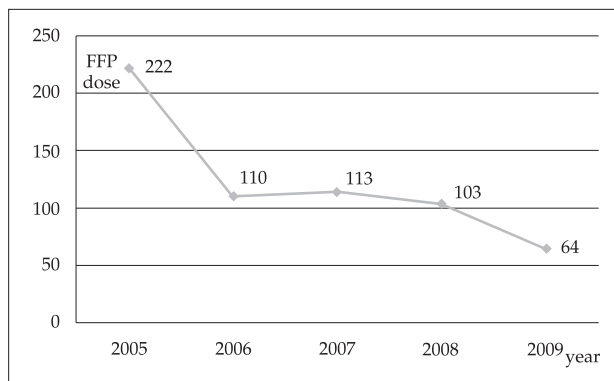


Figure 5. Five-year consumption of fresh frozen plasma (FFP).

ed, or 1358 units transfused and 7.6 adverse reactions (4.4 FNHTR, 3.2 AR) reported per year on the average.

## DISCUSSION

After the analysis of our own results and an attempt to compare them with those worldwide, a

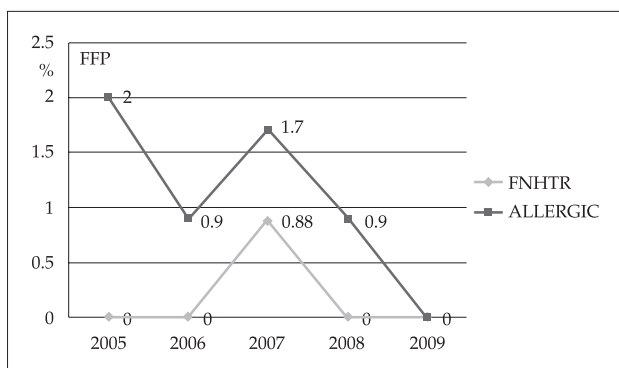


Figure 6. Five-year surveillance of fresh frozen plasma (FFP) allergic and febrile non-hemolytic transfusion reactions (FNHTR).

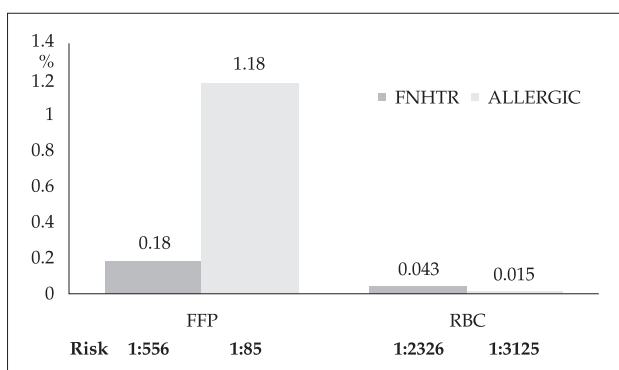


Figure 7. Current risk of RBC and FFP post-transfusion reactions in the University Hospital for Tumors, Zagreb, Croatia. Fresh frozen plasma (FFP) and red blood cells (RBC) post-transfusion allergic and febrile non-hemolytic transfusion reactions (FNHTR).

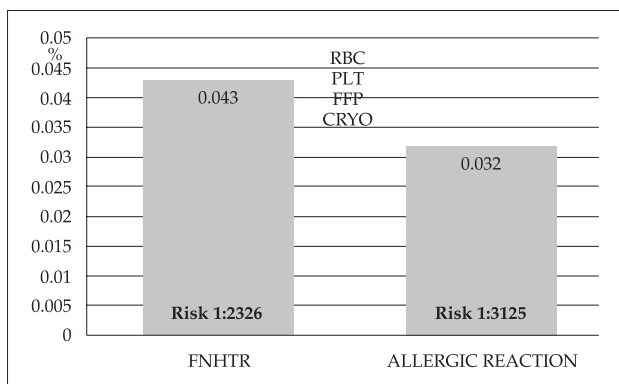


Figure 8. Current risks of all blood transfusion products in the University Hospital for Tumors, Zagreb, Croatia. Post-transfusion allergic and febrile non-hemolytic transfusion reactions (FNHTR) after 10119 transfusion.

question arises as to how and what items to compare. Discrepancies between statistical tests make

a meaningful comparison rather difficult. We are interested in assessing the risk for any adverse event, and want both to trace the cause and to reduce its occurrence. If our results showing 38 adverse reactions (22 FNHTR and 16 AR) were expressed as a percentage, i.e. FNHTR = 58%, AR = 42%, it would turn out that almost every other transfusion triggers a reaction. Since the results obtained in other studies are shown in this manner, the comparisons shown in Table 1 should be calculated using data available from these studies. The calculation requires knowledge of not only the number of adverse reactions but of the overall number of transfused units. Only then a comprehensive insight into the function of hemovigilance can be provided. Comparison with literature data shows less transfusion risk in Croatia than in other countries in the world. Our results for FNHTR are better than those reported in Switzerland (5), Malta (6), New Zealand (7) and Norway (9). As regards AR, our results are superior to that obtained in Switzerland, New Zealand and Norway (Table 1). This suggests that our hemovigilance program is systematically implemented and meets by a large percentage the world standards for collection, processing and administration of blood and blood products.

Table 1.

WORLDWIDE RESULTS FOR HEMOVIGILANCE VERSUS OURS. IN COMPARISON TO OUR RESULTS, FRANCE REPORTS LOWER RISK FOR FNHTR AND AR, AND MALTA FOR AR.

Febrile non-hemolytic transfusion reaction		Allergic reaction		References
%	Risk	%	Risk	
0.06	1:1,667	0.04	1:2,500	Switzerland (5)
0.05	1:2,000	0.02	1:5,000	Malta (6)
0.13	1:769	0.10	1:1,000	New Zealand (7)
0.028	1:3,571	0.025	1:4,000	France (8)
0.081	1:1,235	0.038	1:2,632	Norway (9)
0.043	1:2,326	0.032	1:3,125	University Hospital for Tumors, Zagreb, Croatia

## CONCLUSION

The 5-year surveillance of adverse reactions to blood products provide data showing the quality of the hemovigilance system in the University

Hospital for Tumors, Zagreb, Croatia. In spite of our technical limitations, our results are comparable with the results elsewhere in the world. It is necessary always to insist upon the latest computer technology and continuous improvement of quality control to further reduce the risk of transfusion therapy. The adjustment of criteria at the global level should also be thought of to improve both comparison of results and experience exchange.

#### REFERENCES

1. Salmi R. Les supports épidémiologiques de l'hémovigilance. *Transf Clin Biol* 1994;6:421-4.
2. Faber JC. Haemovigilance around the world. *Vox Sang* 2002;83:71-6.
3. SHOT Steering group. SHOT Annual Report 1997-1998. 1999.
4. Faber JC. Haemovigilance in Europe: the European haemovigilance network. *Transf Clin Biol* 2001;8: 285-90.
5. Ruesch M, Jutz M. Haemovigilance annual report, Swissmedic 2008:4-14.
6. Vella M. Haemovigilance annual report Department of Health Care Malta 2008:29-31.
7. Badami K, Dagger J, Dinesh D, Gosh S, Flanagan P. Annual report NZ Blood, New Zealand 2008:7-9.
8. Agence française de sécurité sanitaire des produits de santé, Annual Haemovigilance Report 2008:15-22.
9. Overvåking av blod i Norge TROLL. Blodtransfusjonstjenesten i Norge 2007:7.

*Author's address: Miroslav Banović, M.D., Ph.D., University Hospital for Tumors, Department of Transfusion Medicine, Ilica 197, 10000 Zagreb, Croatia*