

Payment for whole blood donations in Lithuania: the risk for infectious disease markers

V. Kalibatas

National Blood Center, Vilnius, Lithuania

Vox Sanguinis

Background and Objectives In Lithuania, remuneration for whole blood donations still prevails, with the government covering payment for the donors. The payment per donation in cash is equal to 40 litas (€11.6); it is offered to all blood donors and accepted by the majority of them. Donors who gave blood and received the payment are treated as remunerated donors; those who gave blood and did not take the payment are treated as non-remunerated ones. The purpose of this study was to assess the risk of payment for whole blood donations and to analyse the prevalence of infectious diseases markers per 100 remunerated and non-remunerated, first-time and regular whole blood donations, and to compare the risk ratios of infectious disease markers of remunerated and non-remunerated whole blood donations in 2005 and 2006 at the National Blood Center in Lithuania.

Materials and Methods Whole blood donors were categorized as follows: (i) first-time donor, remunerated; (ii) first-time donor, non-remunerated; (iii) regular donor, remunerated; and (iv) regular donor, non-remunerated. The blood donations were analysed for the presence or absence of the following infectious disease markers: anti-hepatitis C virus (anti-HCV), hepatitis B surface antigen (HBsAg), anti-human immunodeficiency virus (anti-HIV $1/2$) and syphilis. Only confirmed infectious disease markers were classified. To assess the risk of payment for whole blood donations, the prevalence of infectious disease markers per 100 donations in the different donor groups and the risk ratios between the remunerated and non-remunerated donations were determined.

Results The prevalence per 100 first-time remunerated donations was: for anti-HCV 1.84 (2005) and 2.98 (2006); for HBsAg 1.73 (2005) and 2.03 (2006); for syphilis 0.67 (2005) and 1.03 (2006). The prevalence per 100 first-time non-remunerated donations was: for anti-HCV 0.93 (2005) and 0.98 (2006); for HBsAg 1.57 (2005) and 1.33 (2006); for syphilis 0.29 (2005) and 0.47 (2006). The first-time donors who were remunerated for whole blood donations had a significantly higher prevalence of infectious disease markers per 100 donations and a higher risk ratio for at least three infectious disease markers (HBsAg, anti-HCV and syphilis) as compared to first-time donors who were non-remunerated. The regular donors who were non-remunerated for whole blood donations had the lowest prevalence of all infectious disease markers: anti-HCV 0.03 (2005) and 0.04 (2005); syphilis 0.06 (2005) and 0.02 (2006); and any positive cases of HBsAg and anti-HIV $1/2$ were found both in 2005 and 2006. No statistically significant differences in incidence and risk ratio existed when comparing the regular donations who were remunerated and non-remunerated.

Conclusion The payment for whole blood donors provides a higher risk for infectious disease markers of first-time donations at the National Blood Center in Lithuania.

Key words: blood safety, infectious disease markers, non-remunerated blood donations, remunerated blood donations.

Received: 6 August 2007,
revised 26 October 2007,
accepted 26 October 2007,
published online 7 December 2007

Correspondence: Vytenis Kalibatas, National Blood Center, Zolyno str. 34, Vilnius 10210, Lithuania.
E-mail: vyteka@takas.lt

Introduction

Blood transfusion is an essential part of modern health care, and the safety of blood and blood products remains a continuing cause of concern worldwide [1,2]. It is recognized that the safest donors are regular, voluntary, non-remunerated blood donors from low-risk population groups who donate blood for humanitarian reasons [3–5]. Almost all studies have shown that unpaid donors are safer than paid donors [6] due to the failure to mention illnesses or lifestyles involving a risk occurring more frequently among remunerated donors [7]. Most studies, including recent ones, report that paid donors have higher rates of infectious disease markers than unpaid donors [8].

Principles of self-sufficiency from voluntary and non-remunerated donations have been recommended and promoted by the Council of Europe [9], and they also have been adopted by the Council of the European Communities in Directive 2002/98 EC [10]. Lithuania, a member state of European Union (EU) since the year 2004, seeks to change the current blood collection system from remunerated donors to non-remunerated ones. Lithuania has quite a lengthy history of remunerated donation. During the Soviet occupation period (1941–1991), the benefits given for non-remunerated blood donors did not fall under the definition of modern voluntary non-remunerated donations. After the independence in 1991 till the year 2003, non-remunerated donations have not been mentioned in Lithuanian legal acts whatsoever. Lithuania had used the compensation system for non-remunerated blood donations, and linked the amount of remuneration to the donor's pay and provided them the possibility to generate income from blood donations [11–13]. Only in year 2003, for the first time, the right to non-remunerated donation of blood or blood components, has been approved. In 2004, the Lithuanian government ratified a new regulation, which stated that upon a donor's request, the latter was to be paid 40 litas (€11.6) in cash from the national budget funds [11]. Such payment is considered as compensation for travel and supplementary nourishment expenses; in addition, it does not fall under the definition of a modern, voluntary, non-remunerated donation. The remuneration is offered to all blood donors, and it is accepted by majority of them. Therefore, all donors who gave blood and received compensation in cash are treated as remunerated donors. All the rest of the donors, who are not accepting compensation in the form of cash, are treated as voluntary and non-remunerated donors, and their donations fully meet the definition of modern, voluntary, non-remunerated donation. Such payment is still in effect at this writing.

The current Lithuanian blood collection system is represented by two blood establishments: one public institution National Blood Center and one private entity; and two hospital-based blood banking facilities, which prepare blood components

only for their own purposes. The majority of blood donations are taken in blood establishments (98.55% in 2006); the rest – in hospital-based blood banks (1.45% in 2006).

Objectives

The purpose of the study was to assess the risk of payment for whole blood donations. The objectives of the study were to analyse the prevalence of infectious disease markers per 100 remunerated and non-remunerated donors, and first-time and regular whole blood donations, and to estimate the risk ratios of infectious disease markers of remunerated whole blood donations in comparison with non-remunerated whole blood donations at the National Blood Center in Lithuania in 2005 and 2006.

Materials and methods

All whole blood donations at the National Blood Center between 2005 and 2006 have been analysed. The data are based on donations at only one blood establishment, although this establishment does collect a large proportion of blood donations of Lithuania's supply. Each donation was designated to one of the following donation groups: (i) first-time remunerated whole blood donation, (ii) first-time non-remunerated whole blood donation, (iii) regular remunerated whole blood donation, and (iv) regular non-remunerated whole blood donation. The first-time donation is considered the blood donation from the person who has never donated blood or components, the regular one – from the person who has donated blood repeatedly or routinely. Also, each donation was classified into one of the following infectious disease groups: (i) seronegative for all of four infectious disease markers; (ii) seropositive for anti-hepatitis C virus (anti-HCV); (iii) seropositive for hepatitis B surface antigen (HBsAg); (iv) seropositive for anti-human immunodeficiency virus (anti-HIV 1/2); and (v) seropositive for syphilis. It is important to note that there have not been any donations positive for more than one infectious disease marker. Only seropositive donations have been analysed and confirmed by confirmatory tests. The donor screening and the selection process of the donors did remain the same from 2005 through 2006. Table 1 gives a description of the serological and confirmatory tests used.

Statistical analysis

The prevalence of infectious disease markers was calculated per 100 donations; the number of confirmed positive serological donations was treated as the nominator and the denominator was calculated as the sum of all serological negative donations and all seropositive donations for a particular infectious disease marker.

Table 1 Serological and confirmatory tests

No.	Marker	Test	Confirmatory tests	Institution in which confirmatory test is performed
1	HBsAg	HBsAg V2 MEJA immunoassay, Abbott AxSym	HBsAg neutralization; HBV-PCR	AIDS Center of Lithuania
2	Anti-HCV	Anti-HCV V3-0 MEJA immunoassay, Abbott AxSym	IFA, IB; HCV-PCR	AIDS Center of Lithuania
3	Anti-HIV 1/2	Anti-HIV g0 MEJA immunoassay, Abbott AxSym	Western blot, HIV1-p24 antigen neutralization; HIV2-ELISA	AIDS Center of Lithuania
4	Syphilis	Passive haemagglutination test for detection of antibodies against <i>T.pallidum</i> Inno-TPHA, Innogenetics	TPHA, ID-Pagia and Dia-Medical	National Blood Center

The risk ratio was estimated in order to compare the risk for infectious disease markers for remunerated and non-remunerated whole blood donations. The *ad/bc* cross-tabulation was used for estimating the risk ratio. Statistical significance was considered when the *P* value was < 0.05 [17]. The analysis of the data was performed using Statistica, version 5.5.

Results

Figure 1 shows the number of remunerated and non-remunerated blood donations in Lithuania between 2001 and 2006. In recent years, the number of non-remunerated blood

donations has increased, as well as the proportion of non-remunerated blood donations. In 2006, the proportion of non-remunerated donations had reached 21.62% of all donations.

On an annual basis, the National Blood Center acquires approximately 60% of all blood donations in Lithuania. As in Lithuania, the remunerated donations are prevalent at the National Blood Center, but the proportion of non-remunerated donations is slightly higher as compared to Lithuania during the last 2 years. Figure 2 shows the proportion of non-remunerated blood donations, both in Lithuania and the National Blood Center, between 2001 and 2006. Due to an active internal policy to encourage non-remunerated blood

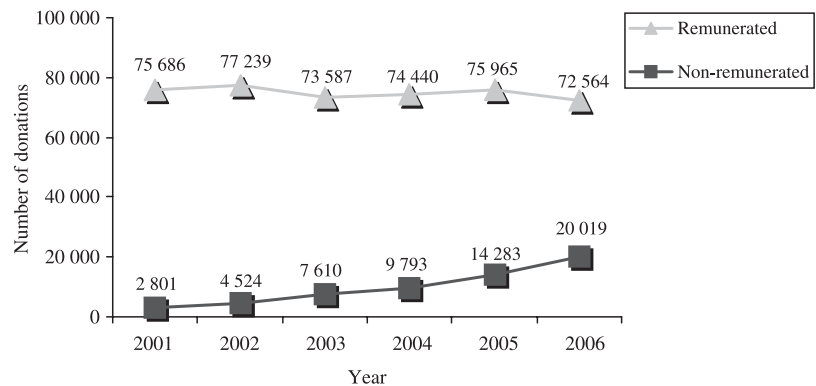


Fig. 1 Remunerated and non-remunerated blood donations in Lithuania (2001–2006).

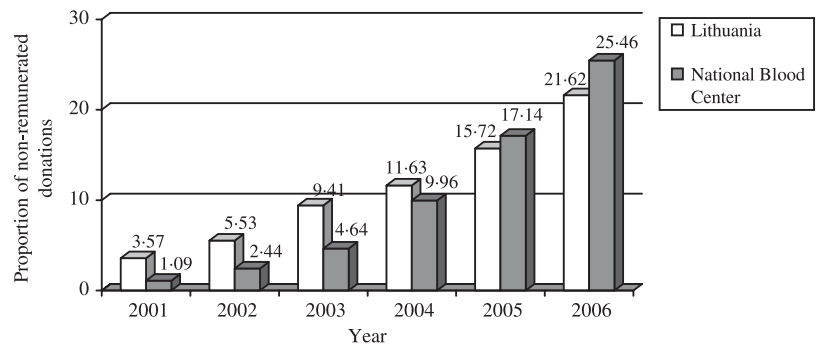


Fig. 2 Proportion of non-remunerated blood donations in Lithuania and the National Blood Center (2001–2006).

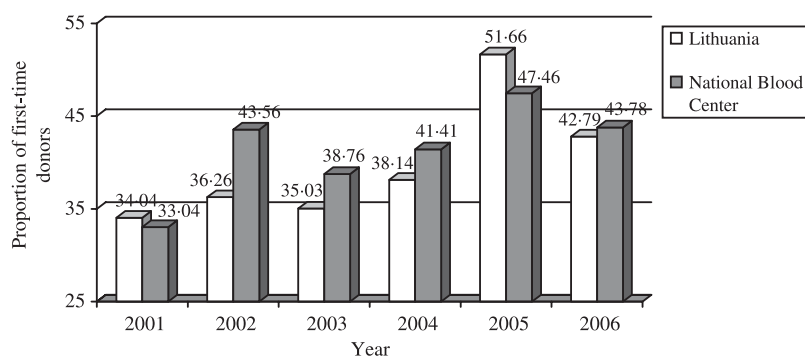


Fig. 3 Proportion of first-time donors in Lithuania and the National Blood Center (2001–2006).

Table 2 Whole blood donations with confirmed infectious disease markers at the National Blood Center (2005 and 2006)

Donation type	Remuneration	Numbers	HBsAg		Anti-HCV		Anti-HIV 1/2		Syphilis	
			2005	2006	2005	2006	2005	2006	2005	2006
First time	Remunerated	Marker positive	141	120	150	178	1	1	54	60
		All donations	8 146	5 906	8 155	5 964	8 006	5 787	8 059	5 846
	Non-remunerated	Marker positive	77	79	45	58	0	0	14	28
		All donations	4 877	5 951	4 845	5 930	4 800	5 872	4 814	5 900
Regular	Remunerated	Marker positive	4	3	45	36	2	1	29	12
		All donations	31 933	30 340	31 974	30 373	31 931	30 338	31 958	30 349
	Non-remunerated	Marker positive	0	0	1	2	0	0	2	1
		All donations	3 409	5 244	3 410	5 246	3 409	5 244	3 411	5 245

donations during the past few years [14–16], a massive advertisement effort took place in Lithuania, resulting in a high proportion of first-time donors. Figure 3 shows the proportion of first-time donors in Lithuania and the National Blood Center between 2001 and 2006.

In 2005, there were 48 708 whole blood donations at the National Blood Center; 40 360 of the donations were remunerated and 8348 of the donations were non-remunerated. Of the 40 360 remunerated donations, 8351 were from first-time donors and 32 009 donations were from regular donors. Of the 8348 non-remunerated whole blood donations, there were 4936 donations from first-time donors and 3412 donations from regular donors. In 2006, there were 47 818 whole blood donations at the National Blood Center; 36 534 of the donations were remunerated and 11 284 were non-remunerated donations. Of the 36 534 remunerated donations, there were 6145 donations from first-time donors and 30 389 donations were from regular donors. Of the 11 284 non-remunerated whole blood donations, there were 6037 donations from first-time donors and 5247 donations were from regular donors.

The summary of confirmed positive serological markers among the remunerated and non-remunerated, as well as the first-time and regular whole blood donations, in 2005 and 2006 is presented in Table 2. It should be noted that the

presented denominator summarizes all serological negative donations and all confirmed seropositive donations for a particular infectious disease marker.

Both in 2005 and 2006, first-time remunerated donors had a higher prevalence per 100 donations for all four infectious disease markers as compared to non-remunerated donors. Statistical significant differences were estimated for anti-HCV and syphilis markers in 2005; and for HBsAg, anti-HCV and syphilis in 2006, respectively. There were no significant differences between the regular remunerated and non-remunerated donations with respect to all infectious disease markers. The prevalence of confirmed infectious disease markers per 100 donations in 2005 and 2006 is presented in Table 3. The prevalence of anti-HCV per 100 donations was the highest in remunerated first-time donations (1.84 in 2005; 2.98 in 2006), and the difference was statistically significant compared to non-remunerated first-time donations (0.93 in 2005; 0.98 in 2006), remunerated regular donations (0.14 in 2005; 0.11 in 2006) and non-remunerated regular donations (0.03 in 2005; 0.04 in 2006). The prevalence of HBsAg per 100 donations was the highest in remunerated first-time donations (1.73 in 2005; 2.03 in 2006) as well, and statistically significant differences existed compared with non-remunerated first-time donations (1.33 in 2006) and remunerated regular donations (0.012 in 2005; 0.01 in 2006).

Table 3 The prevalence of confirmed infectious markers per 100 donations at the National Blood Center (2005 and 2006)

Marker	2005				2006			
	First-time donations		Regular donations		First-time donations		Regular donations	
	Remunerated	Non-remunerated	Remunerated	Non-remunerated	Remunerated	Non-remunerated	Remunerated	Non-remunerated
HBsAg	1.73 ^a	1.57	0.012	0	2.03 ^c	1.33	0.01	0
Anti-HCV	1.84 ^b	0.93	0.14	0.03	2.98 ^b	0.98	0.11	0.04
Anti-HIV 1/2	0.012	0	0.006	0	0.017	0	0.003	0
Syphilis	0.67 ^b	0.29	0.09	0.06	1.03 ^b	0.47	0.04	0.02
All	4.14 ^b	2.75	0.25	0.088	5.84 ^b	2.73	0.17	0.06

^a*P* < 0.05, comparing to remunerated regular donations per the same year.

^b*P* < 0.05, comparing to non-remunerated first-time, remunerated regular and non-remunerated regular donations per the same year.

^c*P* < 0.05, comparing to non-remunerated first-time and remunerated repeat donations per the same year.

The prevalence of syphilis per 100 donations also was highest in remunerated first-time donations (0.67 in 2005; 1.03 in 2006) and the difference was statistically significant compared to non-remunerated first-time donations (0.29 in 2005; 0.47 in 2006), remunerated regular donations (0.09 in 2005; 0.04 in 2006), and non-remunerated regular donations (0.06 in 2005; 0.02 in 2006). The prevalence of anti-HIV 1/2 was very low in remunerated both first-time and regular donations (from 0.003 till 0.017), and any cases were found in non-remunerated donors. Comparing the prevalence of infectious disease markers in year 2005 and in year 2006, the prevalence of anti-HCV per 100 donations in remunerated first-time donations in 2006 was higher compared to the prevalence of anti-HCV per 100 donations in remunerated first-time donations in 2005. Remunerated first-time donors had the 1.14% increased likelihood of being anti-HCV positive in 2006, comparing to 2005. The prevalence of syphilis per 100 donations in remunerated first-time donations in 2006 compared with the prevalence of anti-HCV per 100 donations in remunerated first-time donations in 2005. Remunerated first-time donors had the 0.36% increased likelihood of being syphilis positive in 2006, comparing to 2005. The prevalence of all infectious disease markers per 100 donations in remunerated first-time donations was higher in 2006 (5.84) comparing to the same donor group in 2005 (4.14). There were no statistically significant differences between 2005 and 2006 in comparing all other donor groups.

Both in 2005 and 2006, a higher risk was estimated for remunerated whole blood donations for HBsAg, anti-HCV and syphilis markers. A statistically significant higher risk of remunerated whole blood donations compared to non-remunerated whole blood donations was estimated for anti-HCV and syphilis markers for first-time donors in 2005, and for HBsAg, anti-HCV and syphilis markers in 2006, respectively. A statistically significant higher risk of

remunerated whole blood donations compared to non-remunerated whole blood donations was estimated also for all infections for first-time donors. There was no statistically significant risk for regular donations compared to remunerated and non-remunerated whole blood donations. Table 4 summarizes the risk ratio for infectious disease markers comparing remunerated and non-remunerated whole blood donations at the National Blood Center in 2005 and 2006.

Discussion

It is important to note that the blood collection system that exists in Lithuania affords the unique possibility to compare the risks among remunerated and non-remunerated donations, because it is a possibility to compare the same – whole blood donor population. Also, the payment for whole blood donors is organized and covered by the government of Lithuania (not by blood establishments), providing universal payment throughout Lithuania. During this analysis, whole blood donations have been analysed from one blood establishment that acquires more than 60% of all whole blood donations in Lithuania per year, therefore the same procedures have been applied for serological and confirmatory testing for each donation. And, finally, there were high proportions of first-time donations; therefore, the results of the analysis were not influenced by small numbers of donations.

The possible limitations of this analysis include two main issues. The first one concerns the issue of prevalence, as well as risk analyses, which are related to donations, not to donors. It was possible to determine only first-time whole blood donors. Due to limitations of the database system, it was difficult to determine regular whole blood donors, therefore the whole blood donations have been analysed. The second issue concerns that the post-transfusion infections among

Table 4 The risk ratio for infectious disease markers for remunerated and non-remunerated whole blood donations at the National Blood Center (2005 and 2006)

Marker	Donation type	2005			2006		
		Risk ratio ^a	χ^2 value	P-value	Risk ratio ^b	χ^2 value	P-value
HBsAg	First-time	1.09	0.43	> 0.05	1.54	8.91	< 0.05
	Regular	-	-	-	-	-	-
Anti-HCV	First-time	1.99	17.06	< 0.001	3.11	61.55	< 0.001
	Regular	4.80	2.95	> 0.05	3.11	2.71	> 0.05
Anti-HIV 1/2	First-time	-	-	-	-	-	-
	Regular	-	-	-	-	-	-
Syphilis	First-time	2.31	8.25	< 0.05	2.17	12.02	< 0.001
	Regular	1.55	0.36	> 0.05	2.07	0.51	> 0.05
All	First-time	1.52	17.09	< 0.001	2.2	71.51	< 0.001
	Regular	2.85	3.46	> 0.05	2.99	3.77	> 0.05

^aRisk ratio value, estimating risk of infectious disease between remunerated and non-remunerated donations, year 2005.

^bRisk ratio value, estimating risk of infectious disease between remunerated and non-remunerated donations, year 2006.

recipients of blood components have not been analysed, as such cases have not been reported from the hospitals.

Analysis of the prevalence of infectious disease markers per 100 donations at the National Blood Center showed that the highest prevalence, both in first-time and regular donations, were observed for anti-HCV, followed by HBsAg and syphilis. The prevalence of anti-HCV, HBsAg and syphilis per 100 donations was the highest in remunerated first-time whole blood donations, and the statistically significant differences have been estimated in comparison with first-time non-remunerated, regular remunerated and regular non-remunerated donations. The estimated risk ratio for anti-HCV, HBsAg and syphilis was higher as well in remunerated first-time whole blood donations compared to non-remunerated first-time whole blood donations. A unit of whole blood, which has been estimated to be positive for an infectious disease marker, is discarded and therefore no longer represents a risk at the particular moment. The risk arises from the consequence that remunerated donors are more likely to contain undetectable incident cases, as stated Van der Poel *et al.* 'paid donors are more likely to donate blood during the "window period", when blood borne viruses may not be detectable in screening tests ... Paid donations therefore result in a higher risk that ... blood components ... are infectious' [8].

Kretschmer *et al.* [18] emphasized that in populations in which the frequency of transfusion-transmitted infection markers is low and donors donate blood repeatedly, blood units transfused to patients from remunerated donors have lower seroconversion rates than those from non-remunerated donors. Unfortunately, this is not the case in Lithuania, where the prevalence of hepatitis B, hepatitis C and syphilis is high [19]. The results of the analysis of the data from the National Blood Center in Lithuania fully support the meaning that paying for blood donations provides a higher risk of trans-

fusion-transmitted infections. The results of this analysis confirm that remunerated donations have higher rates of infectious disease markers than non-remunerated donations. Regular non-remunerated whole blood donors are the safest donor group in Lithuania. Overall, the results of the analysis of infectious disease markers in whole blood donations at the National Blood Center showed that voluntary, non-remunerated blood donors are less likely to carry transmissible diseases than remunerated donors; the same finding applies to regular donors when compared with first-time donors.

Conclusion

First-time remunerated whole blood donations have a statistically significant higher prevalence per 100 donations and risk ratio for at least three infectious disease markers (HBsAg, anti-HCV and syphilis) compared to first-time non-remunerated donations. No statistically significant differences in prevalence and risk ratio were found when comparing regular remunerated and non-remunerated whole blood donations. Therefore, the payment for whole blood donors provides a higher risk for infectious disease markers of first-time donations at the National Blood Center in Lithuania.

References

- 1 WHO: *Global Database on Blood Safety: Report 2001–2002*, 2004. Available at http://www.who.int/bloodsafety/GDBS_Report_2001-2002.pdf
- 2 Muller-Breitkreutz K: Results of viral marker screening of unpaid blood donations and probability of window period donations in 1997. EPFA Working Group on Quality Assurance. *Vox Sang* 2000; **78**:149–157

- 3 WHO: *Aide-Memoire for National Blood Programmes. Quality Systems for Blood Safety*. WHO/BCT/02.02. WHO, 2002
- 4 WHO: *Aide-Memoire for National Health Authorities. Safe Blood Components*. WHO/EHT/05.01. WHO, 2005
- 5 International Federation of Red Cross and Red Crescent Societies: *Making a Difference: Recruiting Voluntary, Non-Remunerated Blood Donors*. International Federation of Red Cross and Red Crescent Societies, Geneva, Switzerland, 2002
- 6 Molison PL, Engelfriet CP, Contreras M: *Blood Transfusion in Clinical Medicine*, 9th edn. Oxford, Blackwell Scientific Publications, 1993
- 7 Boltho Massarelli V: Ethics of transfusion: the Council of Europe's view. in Van Aken W, Genetet B (coordinators). *Transfusion Medicine. A European Course on Blood Transfusion*. France, Centre National d'Enseignement à Distance, 1994:11–39
- 8 Van der Poel CL, Seifried E, Schaasberg WP: Paying for blood donations: still a risk? *Vox Sang* 2002; 83:285–293
- 9 Recommendation no. R(15) 15: *Guide to The Preparation, Use and Quality Assurance of Blood Components*. 13th edn. Strasbourg, Council of Europe Publishing, 2007
- 10 The European Parliament and the Council of the European Union: Directive 2002/98/EC of the European Parliament and of the Council of January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. *Official Journal of the European Union* 2003, L33/30–39
- 11 Buciniene I, Stoniene L, Blazeviciene A, Kazlauskaitė R, Skudienė V: Blood donors' motivation to non-remunerated blood donation in Lithuania. *BMC Public Health* 2006; 6:166
- 12 Seimas of the Republic of Lithuania: *Law on Social Insurance of the Republic of Lithuania*, No I-1337 (in Lithuanian). Available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=1327
- 13 Seimas of the Republic of Lithuania: *Law on Blood Donation of the Republic of Lithuania*, No I-1611 (in Lithuanian). Available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=32919
- 14 Ministry of Health of the Republic of Lithuania: *Order of Minister of Health on 12-11-2004*, adopting the program of promoting voluntary blood donorship for year 2004 (in Lithuanian)
- 15 Ministry of Health of the Republic of Lithuania: *Order of Minister of Health on 17-10-2005*, adopting the program of promoting voluntary blood donorship for year 2005 (in Lithuanian) Available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_e?p_id=264612&tp_query=&tp_tr2=
- 16 Ministry of Health of the Republic of Lithuania: *Order of Minister of Health on 28-11-2006*, adopting the program of promoting voluntary blood donorship for year 2006–2015 (in Lithuanian) Available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_e?p_id=288481&tp_query=&tp_tr2=
- 17 Last JM (ed.): *A Dictionary of Epidemiology*, 3rd edn. Oxford, Oxford University Press, 1995
- 18 Kretschmer V, Weippert-Kretschmer M, Slonka J, Karger R, Zeiler T: Perspectives of paid whole and plasma donation. *Dev Biol (Basel)* 2005; 120:101–111
- 19 Lithuanian Health Information Center: available at <http://www.lsic.lt/html/en/lhic.htm-Health Statistics/Selected Notifiable Infectious Diseases in 2000–2006>