

isolates from pigs or liver of pigs.<sup>24</sup> It should be noted that among 12 HEV RNA-positive donors from Hokkaido, 10 isolates (83%) showed high nucleotide homology (>95%) of 412-nucleotide sequences with the isolates from pigs or pig livers from Hokkaido. The results are consistent with the possibility that at least some of the HEV RNA-positive donors were infected through the zoonotic food-borne route. Similarly, Feagins and colleagues<sup>21</sup> recently reported that of the 127 packages of commercial pig livers purchased from local grocery stores in the United States, 14 (11.0%) tested positive for the presence of HEV RNA. The widespread distribution of HEV is being clarified in developed countries other than Japan.<sup>22,23</sup>

In this study, IgM anti-HEV-positive as well as HEV RNA-positive samples were also frequently found in eastern Japan. IgM anti-HEV is known as a marker of the early seroconversion period. ALT elevation is observed in the early/middle stage of the infection; that is, ALT elevation follows viremia and accompanies/precedes seroconversion.<sup>24</sup> Most (12/15) of the HEV RNA-positive donor samples were positive for the presence of IgM anti-HEV. Of the 15 IgM anti-HEV-positive samples, 14 showed elevated ALT levels higher than 200 IU per L.

Although there were no HEV RNA-positive samples and only one IgM anti-HEV-positive sample detected in donors with elevated ALT levels of 61 to 199 IU per L, 2.7 percent of them were positive for the presence of IgG anti-HEV, which was comparable to the positive rate (3.2%) of IgG anti-HEV-positive donors with elevated ALT levels higher than 200 IU per L. In contrast to IgM anti-HEV-positive donors, IgG anti-HEV-positive donors were not associated with positive HEV RNA. There are several reports from Japan that IgG anti-HEV-positive samples are not rare (1.9%-14.1%) in blood donors with normal ALT levels who are mostly HEV RNA-negative.<sup>13,25,26</sup> In the present report we observed that the number of IgG anti-HEV-positive samples increased with advancing age in both groups, that is, one with an ALT level higher than 200 IU per L and the other with ALT levels of 61 to 199 IU per L. The IgG anti-HEV appears to be present for a prolonged period after infection. Ijaz and his colleagues<sup>27</sup> reported HEV-infected patients with non-travel-associated disease were more likely to be older and tended to be male in England. They estimated that male sex is a risk factor for acquiring the non-travel-associated disease. Most (14/15) of our HEV RNA-positive donors were also male. Because high-ALT-level donors were male-dominant, it will be necessary to investigate whether HEV RNA-positive donors were also male-dominant in ALT-normal donors. We also observed in this report that the number of IgG anti-HEV-positive donors increased with advancing age. This suggests that high prevalence of IgG anti-HEV in older Japanese persons is the consequence of their increased exposure to HEV with time. Among donors with ALT levels of higher than 200 IU per L, positive rates

of IgG anti-HEV and HEV RNA were dissociated in Fukuoka (IgG anti-HEV vs. HEV RNA, 3.9% vs. 0.6%) and Tokyo (5.7% vs. 1.2%), in contrast to those (6.9% vs. 4.6%) in Hokkaido. These observations suggest that HEV infection was once prevalent in Fukuoka and Tokyo, while it is now prevalent in Hokkaido. It will be essential to investigate HEV prevalence among blood donors with normal ALT levels in each area of Japan to clarify these points.

As to the donors with ALT levels higher than 500 IU per L, our preliminary study indicated that, besides HEV, other viruses (hepatitis A virus [HAV], Epstein-Barr virus [EBV], cytomegalovirus [CMV], and human parvovirus B19 [B19]) were detectable in some of the 41 donors (data not shown). Among hepatitis-associated viruses, screening tests including nucleic acid testing (NAT) for HCV and HBV have been implemented in Japan. Although ALT testing may not be very effective in the early stage of infection or as a surrogate test for HBV or HCV infection, it may be an effective method for eliminating the other hepatitis viruses in transfusion blood, especially HEV, HAV, EBV, CMV, and B19, which could be eliminated from blood for transfusion by ALT testing. Although the distinct populations collected during different periods, HEV RNA was detected in 8 of 41 (19.5%), 1 of 124 (0.8%), and 0 of 364 (0.0%) among donors with high ALT levels of 500 or greater, 200 to 499, and 61 to 199 IU per L in Hokkaido, respectively. Therefore, it is assumed that HEV RNA-positive rate may be lower among the ALT-normal donors (ALT < 61 IU/L) and that elimination of blood with high ALT levels may be effective in reducing the risk of infection caused by HEV. HEV NAT screening has been implemented as a trial in Hokkaido, the highest HEV-prevalent area in Japan.

Further, elimination of blood donors with ALT levels of 500 IU per L or greater would be an effective tool to reduce the infection risks of not only HEV but also HAV, EBV, CMV, and B19. Although ALT testing appears effective in decreasing the risk for infection of HEV, there are some problems. First, ALT testing resulted in the loss of much of the donor blood, which might have been appropriate for transfusion. Approximately 2 percent of donated blood is disqualified owing to an elevated ALT level of greater than 60 IU per L in Japan. Ninety-eight percent of these donors had an ALT level of less than 200 IU per L. Furthermore, studies in the United States and Europe have confirmed that values of ALT in normal males are considerably higher than those in normal females so that a single cutoff value for ALT rejects a higher proportion of men than women.<sup>28,29</sup> Second, hepatitis viruses including HEV RNA were detected in ALT-normal donors. It has been reported that HEV RNA-positive samples were detected in volunteer donors with ALT levels of 61 IU per L.<sup>13</sup> In the near future, it is necessary to compare the virus-positive rates both in normal and in high-ALT donors and to reevaluate

a cutoff value of ALT after considering the balance of the benefits and costs.

Besides ALT testing, IgM anti-HEV screening may be effective to eliminate asymptomatic HEV RNA-positive donors in the middle stage of infection. Most of the HEV-positive samples with high ALT levels were also positive for the presence of IgM anti-HEV, although neither ALT test nor IgM anti-HEV will be effective to eliminate HEV-positive donors in the window period. Since the zoonotic food-borne route appears to be a major cause of HEV infection in Japan,<sup>1-8</sup> it is most important to halt the potential spread of HEV by disseminating information on the risk of eating viscera or vaccination of animals as reservoirs.

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医薬品 研究報告 調査報告書

識別番号・報告回数		報告日	第一報入手日 2008. 11. 20	新医薬品等の区分 該当なし	総合機構処理欄
一般的名称	人血清アルブミン	研究報告の公表状況	Qu L, Triulzi D. TRANSFUSION 2008-Vol. 48 Supplement	公表国	
販売名(企業名)	赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社)			米国	
研究報告の概要	<p>○米国の供血者におけるヘルペスウイルス8(HHV 8)ゲノム 背景:カポジ肉腫の原因となるヘルペスウイルス8(HHV 8)について、これまで供血者のウイルスゲノム陽性率は系統的に調査されたことがなかった。 方法:ランダムに選択された米国供血者から分離したCD19+Bのリンパ球DNA抽出物からHHV8ゲノムを検出するため、高感度定量RT-PCR法を用いた。血液採取から24時間以内にCD19+Bリンパ球を選択し、HHV8のPCR反応のDNAインプットを決定するため、GAPDH遺伝子の細胞標的を用いて、DNAの細胞相当量を定量した。 結果:950名の供血者から検体入手し、684名から<math>1 \times 10^6</math> B細胞相当以上の精製DNAが得られた。RT-PCRにてGAPDH細胞標的を増幅させ、それぞれの供血者の細胞DNA量を測定した。HHV8 RT-PCR反応には、<math>3 \times 10^5</math> B細胞(全血1 mL中のB細胞の総量に当たる)に相当する細胞DNAを加えた。検出限界8コピーのRT-PCRで、<math>3 \sim 6 \times 10^5</math> CD 19+ Bリンパ球相当のDNAからHHV8ゲノムは検出されなかった(95% CI: 0~3/684)。 結論:PCR反応の検出限界が8コピーであるRT-PCRにおいてHHV8ゲノムが検出されなかったことから、健康な供血者中のHHV8ゲノム陽性率は極めて低い。</p>				使用上の注意記載状況・ その他参考事項等
	報告企業の意見	今後の対応	<p>赤十字アルブミン20 赤十字アルブミン25</p> <p>血液を原料とすることに由来する感染症伝播等</p>		
<p>米国の供血者のヘルペスウイルス8(HHV 8)ゲノム陽性率について、高感度定量RT-PCR法によりDNAの細胞相当量を定量した結果、684名の供血者からはHHV8ゲノムは検出されなかったとの報告である。 HHV-8は脂質膜を持つ大型DNAウイルスである。これまで、本剤によるHHV-8感染の報告はない。本剤の製造工程には、平成11年8月30日付医薬発第1047号に沿ったウイルス・プロセスバリデーションによって検証された2つの異なるウイルス除去・不活化工程が含まれていることから、本剤の安全性は確保されていると考える。</p>		<p>本剤の安全性は確保されていると考えるが、今後も情報収集に努める。</p>			



Groups for Comparison	Crude Prev (% Positive)	Adjusted Odds Ratio* (95% CI)
Southeast vs. Northeast US	49.0 vs. 28.2	2.25 (2.2, 2.3)
Age group $\geq 70$ years vs. <20-29 years	60.6 vs. 27.9	5.20 (5.0, 5.4)
Female vs. male	35.9 vs. 28.9	1.52 (1.5, 1.5)
US vs. Non-US born	31.0 vs. 62.7	0.40 (0.4, 0.4)
Asian vs. white	65.3 vs. 30.0	3.20 (3.0, 3.4)
Black vs. white	60.0 vs. 30.0	2.99 (2.9, 3.1)
Hispanic vs. white	50.3 vs. 30.0	2.27 (2.2, 2.4)
Transfused vs. non-transfused	40.3 vs. 31.7	1.13 (1.1, 1.2)
Body mass index (BMI, kg/M <sup>2</sup> ) <18.5 vs. $\geq 35$	27.5 vs. 34.7	0.8 (0.8, 0.9)

\* Adjusted for region, gender, age, race/ethnicity, country of birth, body mass index (BMI), transfusion, collection procedure, and first-time vs. repeat status.

#### Disclosure of Conflict of Interest

Ram Kakaiya, Darrell Trulzi, John D. Roback, Junyong Faing, Yongling Tu, Steven Kleinman, Michael P. Busch, Jorge A. Rios, Christopher Hillier, Simone Glynn, George Schreiber, for the Retrovirus Epidemiology Donor Study-II: Nothing to Disclose  
Jerome L. Gottschall: Not Specified

#### SP197

**Control Charts for Monitoring Viral Incidence Rates: An Illustration**  
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**Background:** Monitoring of new and repeat donor incidence rates is a means to ensure control of transfusion related infectious disease transmission risks. In the Netherlands systematic evaluation of annual incidence rates is performed since the 1980s. Analysis of infection data allows identification of trends in incidence rates and of years with excessively deviating incidence rates. Analysis results can potentially pinpoint to areas for improvement of blood supply safety. **Methods:** HIV infection data from the years 1995 through 2006 were analyzed using a Shewhart Control Chart which is commonly applied in industrial statistics. The likelihood of the observed number of incidents in a particular year is calculated on basis of the mean incidence rate over the whole observation period and the population size in that particular year. The observed number of incidents is presumed to follow a Poisson distribution. **Results:** The results show that in the year 2002 there was an unusual increase in the HIV incidence rate. The likelihood of the observed 8 infections (or more) in that year on basis of the average HIV incidence rate (0.0000057) is less than 0.7% (1 in 138). **Conclusion:** Given the low-exceedance probability it is unlikely that the observed 8 infections in 2002 were a chance finding. This conclusion holds even if the result is corrected for multiple testing (as there are 12 years of observation). Therefore other causes for the incidence rate increase in this particular year should be considered. Control Charts can be easily applied to monitor and control viral incidence rates. The graphical presentation of the Control Chart (not give here) provides an intuitive and easily interpretable result.

#### Disclosure of Conflict of Interest

Mart P. Janssen, Cees L. van der Poel: Nothing to Disclose

#### SP198

**Cost-Utility of a Publicly Funded Hepatitis B Vaccination Program for Blood Donors in British Columbia, Canada**  
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**Background:** The current strategy for preventing transfusion-transmitted hepatitis B virus (TT-HBV) infection in Canada and the United States relies on donor behavioral risk and laboratory screening. The objective of this study, undertaken in British Columbia (BC) Canada in 2007, was to assess the cost-utility and benefits to transfusion safety, of offering a publicly funded HB vaccination program for previously unvaccinated blood donors. **Methods:** A "health care payer" perspective, using deterministic estimates, was taken. Fixed costs (e.g. space) and savings from prevented infections were not included. Direct and indirect program costs associated with vaccinating eligible donors through the existing regional, mixed, public health/physician vaccine delivery model in BC, were included in the analysis, along with relevant blood donor and recipient data, obtained from Canadian Blood Services (CBS) and the BC Ministry of Health. Ninety percent of donors

under 25 years were estimated to have had prior HB vaccination. Sensitivity analyses were conducted around estimates for prevalence of prior HB vaccination among donors >25 years (10-30%) and HB vaccine uptake (80-100%). **Results:** As of May 2007 there were 52,758 active donors in BC and CBS attracts approximately 8000 new donors per year in the province. Assuming 100% vaccine uptake among eligible donors, total program cost over the first program year ranged between \$CDN 2.55 M and \$CDN 3.04 M. Program cost would drop to \$CDN 0.38 M in the following year. Up to 2.46 TT-HBV infections might be averted in the first 2 program years, with a corresponding range of cost-utility based on scenarios of 30% and 10% prevalence of prior HB vaccination among donors >25 years, of \$CDN 6.92-\$8.09 M per Quality Adjusted Life-Year (QALY) gained. An estimated one TT-HBV related death would be averted over 40-80 years. **Conclusions:** Although costing about \$2.90 M in the first year (assuming 100% uptake), program cost would drop by 87% to about \$0.38 M in the following year and likely continue to decrease in ensuing years, as the proportion of new donors previously HB vaccinated increases, as a result of existing public health HB immunization programs. The estimated cost-utility of the program in its first 2 years, approximately \$7.77 M per QALY, would also improve over the longer term. Although not within the usual cost-utility range of many healthcare interventions, it is comparable to that of other safety measures implemented by many blood suppliers over the past decade, such as donor nucleic acid testing for HIV and hepatitis C virus. Conceptually, this program could expand the current means of enhancing blood safety, which focus on donor risk behavior screening and testing, to include donor primary disease prevention, that better integrates blood safety into a comprehensive public health disease-prevention strategy.

#### Disclosure of Conflict of Interest

Mark Bigham, Jane Buxton, Shannon Waters: Nothing to Disclose

#### SP199

**Detection of Hepatitis C Virus in Brazilian Blood Donors - Age Group Study**  
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**Background:** Hepatitis C virus (HCV) is a public health problem worldwide; it is estimated that about 170 millions people are infected and 2.4 millions only in Brazil. Blood transfusion is one way of HCV transmission that fortunately has relative decreased after introduction of ELISA and genomic tests. The 3rd generation ELISA test (ELISA1) targeted to antibodies against HCV capsid and 4th generation ELISA test (ELISA2) directed to antibodies against the capsid and the core proteins allied to HCV genomic test provide most powerful instruments of safe HCV detection. **Methods:** One year screening of 98,581 blood bank samples of healthy donors at COLSAN/UNIFESP using immunological and molecular HCV tests. It was studied 584 (0.59%) positive ELISA1 donors samples (ELISA Hepanostika HCV ultra - BioMerieux); all these samples were submitted to ELISA2 (ELISA Ortho HCV - Ortho) and to genomic HCV amplification by Reverse Transcriptase Nested-Polymerase-Chain-Reaction (RT-NPCR). The blood donors were distributed in five age groups; to study the rate for HCV detection tests. **Results:** It was detected 333 samples (0.34%) positive to both ELISA tests and the presence of HCV genome in 208 samples (0.21%). The age groups rates were: 18-29 years - 0.41%/ELISA1 and 0.13%/RT-NPCR; 30-39 years - 0.62%/ELISA1 and 0.19%/RT-NPCR; 40-49 years - 0.75%/ELISA1 and 0.32%/RT-NPCR; 50-59 years - 0.96%/ELISA1 and 0.42%/RT-NPCR; 60-65 years - 1%/ELISA1 and 0.27%/RT-NPCR. **Conclusions:** Immunological and molecular tests comparison demonstrated that 65% HCV positive ELISA1 test do not correspond to positive viral genome detection in Brazilian blood donors at COLSAN/UNIFESP. Despite been characterized as healthy donors 0.2% of the blood donors in our Institution have positive genomic HCV test, remarkably groups 40-49 and 50-59 years.

#### Disclosure of Conflict of Interest

Fabricio Carvalho, Jose Augusto Barreto, Madalena Pares, Itafiana Rodart, Cleidenice Silva, Mittermeyer Reis: Nothing to Disclose

#### SP200

**Herpesvirus 8 (HHV 8) Genomes in US Blood Donors**  
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**Background:** HHV-8 is a gamma-herpesvirus that causes Kaposi's sarcoma. The prevalence of viral genomes in blood donors has not been systematically studied. **Methods:** We employed a sensitive and quantitative real-time PCR