easy to use, FDA approved test to confirm repeat reactives or to resolve discrepant results is lacking.
Aims: To develop a supplemental test for confirming the presence of antibodies to *T. cruzi* in repeatedly reactive blood or plasma units identified by a screening assay.
Methods: The immunoblot assay is based on four different recombinant antigens (rAgs) FP3, FP6, FP10, and TcF, for the detection of antibodies to *T. cruzi*. Each rAg was constructed with multiple antigenic domains of *T. cruzi* including repetitive sequences and non-repetitive sequences. The rAgs are fitted as discrete lines onto the strip. Antibody responses were visually assessed against two internal calibrators (low and high) also applied to the immunostrip as discrete lines. The immunoblot assay sensitivity was evaluated with 688 RIPA confirmed chagasic specimens. The specificity was evaluated with 821 unscreened specimens from random U.S. blood donors and 531 specimens of 30 different unrelated medical conditions, including leishmaniasis, malaria, and autoimmune diseases, or potentially interfering substances. The interpretation of results was as follows: (a) no bands or a single test band = NEGATIVE; (b) two or more test bands with a least on band having intensity of 1+ or higher = POSITIVE; and (c) multiple faint test bands (±) = INDETERMINATE. All samples were initially tested in the PRISM Chagas screening assay; and reactive samples were also tested in two different ELISA and in a radio-immunoprecipitation assay (RIPA).
Results: All 688 chagasic samples showed two to four rAg test bands and were interpreted as positive in the immunoblot assay; sensitivity of 100% (688/688). Among 821 unscreened specimens of random donors, 819 showed none or a single test band, and one gave two faint test bands. One specimen was repeatedly reactive in PRISM Chagas assay, two reference ELISAs, and confirmed in RIPA as positive; while another specimen was non-reactive in these reference tests. Of the 531 specimens with disease states or potentially interfering substances, 525 tested negative, two confirmed positive, 1 false-positive, and three indeterminate.
Conclusions: The sensitivity of the immunoblot assay in the geographically-diverse group of chagasic specimens was 100% (688/688). The resolved specificity of random donor specimens was also 99.88% (819/820). The recombinant antigen based immunoblot assay, in multiple lots and run by multiple technicians, has demonstrated great potential as a supplemental test to confirm the presence of antibodies to *T. cruzi* in blood specimens. Design verification and validation of this assay are ongoing.

P-615

HEPATITIS B VIRUS DETECTION AMONG VOLUNTARY BLOOD DONORS IN THE MUNICIPALITY OF STRUMICA

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In spite of the progress in the development of diagnostic, therapeutic and prophylactic methods, virus hepatitis still present a serious global health problem. The possibility of transmission of these infections through transfusion of blood and blood derivates implies obligatory control of the donated blood.
Aim: To show the prevalence of Hepatitis B (HBsAg) in volunteer blood donors for the period from 2001 till 2006.
Materials: The presence of virus markers was analyzed in the serum of 9166 blood donors who donated blood at the Department of transfuziology, General Hospital-Strumica, in the period from 2001 till 2006.
Methods: The samples were tested for the presence of viral markers (HBsAg), using tests for HBsAg (Abbott Auxyme Monoclonal EIA).
Results: The presence of markers for Hepatitis B (HBsAg) were found in 89 (0.97%) blood donors. In 2001 the presence of HBsAg was found in 12 blood donors, 2002 – in 20 blood donors, 2003 in 14 blood donors, 2004 in 17 blood donors, 2005 in 14 blood donors, 2006 in 12 blood donors. With A blood group were 42 (47.2%) blood donors, with O blood group were 28 (31.4%) blood donors, with B blood group were 10 (11.2%) blood donors and with AB blood group were nine (10.2%) blood donors.
Conclusion: The obligatory testing of the donors blood is of exceptional importance to prevent the transmission of diseases. Moreover, a significant ring in the chain for ensuring safe blood is the selection of a qualitative donor, that is a donor who donates blood volontarily, freely, anonymously and periodically.

P-616

OCCULT HEPATITIS B VIRUS INFECTION IN BLOOD DONORS FROM CENTRAL PORTUGAL

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Background: The detection of HBV DNA in serum without HBsAg and with/without the presence of antibodies (anti-HBc/anti-HBs), defines the state of the occult hepatitis B virus infection. The prevalence in endemic areas varies from 7% to 19%, while in the west countries varies from 0% to 9%, being greater in people with anti-HBc and/or anti-HBs. Low serum HBV DNA titers, in the range of 100–1000 copies/mL, are typical in occult HBV infection. A high prevalence of occult HBV has been reported in hepatocellular carcinoma (HCC).
Aims: The appearance of the nucleic acid testing (NAT) with great sensibility allows us to identify a population with HBsAg negative but with low levels of HBV DNA in serum. In our Centre all donors are screened for HBV DNA, HIV RNA and HCV RNA.
Methods: In the screening of the hepatitis B serologic markers we have used ELISA and quimioluminiscence tests. In the screening of the HBV DNA we have used the Transcription Mediated Amplification (TMA) technology, in single testing, with predicted HBV detection rate of 50% and 95% of 3.1 and 7.4 IU/mL, respectively.In the screening of HBV viral load we have used PCR technology, with detection limit of 60 IU/mL.
Results: The Regional Blood Centre (Coimbra) started the screening of the HBV DNA to all donors in October 2006. Until November 2007, we have studied 20.881 donors. We found three cases of occult hepatitis B virus infection.
Conclusions: Some aspects need to be investigated, especially the relationship between the occult hepatitis B virus infection and the infectivity of the different blood components. The sensibility of the NAT is very important in the precocious detection of the HBV DNA in blood donors.

P-617

PREVALENCE OF HEPATITIS E VIRUS INFECTION IN BLOOD DONORS IN DIFFERENT CITIES OF CHINA

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Background: Hepatitis E virus (HEV) is a single strand and non-enveloped RNA virus. HEV infection is normally transmitted via the faeco-oral route. However HEV recently emerged as a transfusion-transmitted pathogen. Several transfusion-transmitted HEV infections have been reported in

HEV-hyperendemic or nonhyperendemic countries. In China, neither HEV antibodies nor HEV RNA are systematically tested in blood donors. Alanine aminotransferase (ALT) in serum/plasma has been tested in all blood donors since 1960s in China, before hepatitis B surface antigen screening. With the introduction of specific anti-HCV and viral nucleic acid testing (NAT), ALT test is no longer used in routine donor screening in many countries. However, ALT measurement is still retained as a screening tool for blood donors in China, in consideration that viral hepatitis is endemic in China, although ALT has low specificity for detecting individuals with transfusion-transmitted virus infection risk and its value is controversial.

Aims: To evaluate the prevalence of HEV infection among blood donors in four cities of China and to evaluate the value of ALT measurement for eliminating HEV infectious blood in blood donors.

Methods: Donor samples with negative results in routine screening (anti-HCV, anti-HIV1/2, HBsAg, syphilis and ALT) and samples with ALT elevated alone were collected from four blood centers in four Chinese cities, Beijing (North), Urumchi (Northwest), Kunming (Southwest), and Guangzhou (South) in 2005 and were frozen at -40?. A total of 6665 blood donor samples were tested for anti-HEV IgG, anti-HEV IgM and HEV Antigen (Ag) by enzyme-linked immunoassays (WANTAI Biological Enterprise Co. Ltd. Beijing, China) in 2007. Repeated positive results defined as a positive result. The Person Chi-Squared test or Fisher's exact test were used for the statistical analysis.

Results: Of the 6665 blood donors tested, the prevalence of anti-HEV IgG, anti-HEV IgM and HEV Ag were 24.23% (1615/6665), 1.08% (72/6665) and 0.03% (2/6665) respectively. The prevalence of anti-HEV IgG, anti-HEV IgM and HEV Ag were all higher in 487 donors with elevated ALT alone (30.80%, 2.05% and 0.21%, respectively) than in 6178 donors with negative results in routine screening (23.71%, 1.00% and 0.02%)

Table HEV Seroprevalence in blood donors

Samples	Cities	Numbers Tested	Anti-HEV IgG (%)	Anti-HEV IgM (%)	HEV Ag (%)
Samples with negative results in routine screening	Beijing	2378	458 (19.26%)	30 (1.26%)	0 (0.00%)
	Urumchi	1910	341 (17.85%)	14 (0.73%)	1 (0.05%)
	Kunming	1170	431 (36.84%)	11 (0.94%)	0 (0.00%)
	Guangzhou	720	235 (32.64%)	7 (0.97%)	0 (0.00%)
	Total	6178	1465 (23.71%)	62 (1.00%)	1 (0.02%)
Samples with elevated ALT alone	Beijing	72	16 (22.22%)	2 (2.78%)	0 (0.00%)
	Urumchi	247	45 (18.22%)	1 (0.40%)	0 (0.00%)
	Kunming	152	84 (55.26%)	6 (3.95%)	0 (0.00%)
	Guangzhou	16	5 (31.25%)	1 (6.25%)	1 (6.25%)
	Total	487	150 (30.80%)	10 (2.05%)	1 (0.21%)
Total		6665	1615 (24.23%)	72 (1.08%)	2 (0.03%)

Data were shown as "numbers of positive samples (positive rate)"

($P < 0.05$). Of the two HEV Ag positive donors, one had negative results in routine screening and had average HEV Ag ELISA S/CO ratio of 3.4, anti-HEV IgG (-), anti-IgM (-); the other had elevated ALT alone and had average HEV Ag ELISA S/CO ratio of 18.0, anti-HEV IgG (+) with average S/CO ratio of 10.8, anti-HEV IgM (-). The following table shows the more detailed results.

Conclusions: Hepatitis E virus is endemic in China. Among blood donors with negative results in routine screening in China, about 1% are anti-HEV IgM (+) or HEV Ag (+) and may be HEV infectious. ALT screening may have some role in eliminating HEV infectious blood in China.

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P-618

Abstract withdrawn.

P-619

POLYMORPHISM OF HLA-DRB1 OF THE UYGHURS IN CHRONIC HEPATISIS B IN KHOTAN AREA XINJIANG CHINA

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This abstract is read by title only.

P-620

IMPACT OF PHOTOCHEMICAL TREATMENT OF PLATELET COMPONENTS (INTERCEPT™) ON PLATELET AND RBC COMPONENT USE BY HEMATOLOGY PATIENTS DURING 3 YEARS OF ROUTINE PRACTICE

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Background: In 2003 the Blood Transfusion Center (BTC), Cliniques Universitaires Mont Godinne (CUMG) initiated universal use of pathogen inactivated INTERCEPT Platelets (I-P, Cerus Europe BV, Amersfoort, Netherlands) for transfusion (txn) support of thrombocytopenia. Hematology patients require intensive txn support.

Aims: To examine the impact of I-P adoption on platelet (PLT) and red blood cell concentrate (RBC) use by hematology patients, the duration of support, the number of PLT txn per patient, total PLT dose per patient, and total RBC units per patient were compared for 3 years before I-P adoption, when only conventional PLT (C-P) were used, and for 3 years after adoption of I-P. RBC use served as a surrogate for hemostasis efficacy of PLT txn and was evaluated during periods of PLT support and periods without PLT txn support.

Methods: In both periods, PLT were collected by apheresis in reduced plasma concentration with process leukocyte reduction. For C-P, T-Sol (Fenwal, La Chatre, France) with a ratio to plasma of 70:30% was used. For I-P, Intersol (Cerus) with a ratio to plasma of 65:35% was used. I-P components (2.5–6.0-E11 PLT) were treated with amotosalen (150 μmol/L) plus UVA (3 J/cm sq) to inactivate pathogens and leukocytes. I-P replaced gamma irradiation, bacteria detection, and CMV serology. I-P and C-P were available for issue the day after collection. Days of txn support were calculated from the first PLT txn until 5 days after the last PLT txn. An

Effect of I-P Adoption on Platelet and RBC Use

Parameter	CP	IP	P
Platelet Use (mean/median)			
Patients supported	272	276	
Days of PLT support	31.6/15	33.1/15	0.70
PLT txn/pt	20.8/10	24.2/11	0.17
Total PLT dose (10^{11})/pt	87.3/41	100.8/43	0.19
RBC Use During Platelet Support (mean/median)			
Patients transfused	222	244	
Total RBC units/pt	16.4/8.0	17.6/7.0	0.64
RBC Use Outside of Platelet Support (mean/median)			
Patients transfused	237	235	
Total RBC units/pt	12.7/8.0	12.7/8.0	0.99

別紙様式第2-1

No. 30

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研究報告の概要

○米国医師会がゲイ男性の供血5年延期を「容認できる」との考え

米国医師会(AMA)は、男性同性愛行為を行った供血者の供血延期期間を生涯から5年間に変更するとした連邦の方針を支持するという声明を採択した。この声明は2008年のAMA年次総会で採択され、「AMAは、現在の科学的エビデンスとリスク分析モデルに基づき、MSMに対する5年間の供血延期は容認できる(supportable)と認める」と述べている。AMAによると、「容認できる」という言葉は、基本的に、FDAに対して新しい方針を通知し「実施に協力する」ことを意味している。また、AMAは今回の変更に対して反対を主張しない。

FDAは1977年以降、採血事業者に対し、MSMの供血を生涯延期とすることを求めてきた。AMAの声明は、血液事業者団体が主張する1年間の供血延期により近いものとなっている。血液事業者は、供血延期は金銭や薬物と引き替えのセックスなどハイリスク行為に対して実施すべきであると主張してきた。また、最近ではゲイ・グループによる反対運動、政府機関や大学での議論も行われ、一部の大学では構内での移動採血を中止しようとする動きが出ていた。

報告企業の意見	今後の対応
米国医師会は、男性同性愛行為を行った供血者の供血延期期間を生涯から5年間に変更するとした連邦の方針を支持するという声明を採択したとの報告である。MSMのHIV等ウイルス感染率は高く、日本においても1年間の献血延期の他、検査目的の献血禁止などの対策を引き続き行っていく必要がある。	日本赤十字社は、輸血感染症対策として、男性と性的接触を持った男性は1年間献血不適としている。今後も引き続き情報の収集に努める。

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AMA Deems Five-Year Blood Donor Deferral for Gay Men "Supportable"

The American Medical Association (AMA) has adopted a statement indicating it may support changing the federal policy imposing a lifetime deferral for potential blood donors who have had sex with men to a five-year deferral.

The statement, adopted by the AMA House of Delegates at the 2008 AMA Annual Meeting June 14-18 in Chicago, reads: "*The AMA recognizes that based on existing scientific evidence and risk assessment models, a shift to a five-year deferral policy for blood donation from men who have sex with men (MSM) is supportable.*"

According to the AMA, the word "supportable" basically means the organization will notify the Food and Drug Administration of its new policy and "will be open to work with groups to advance the policy." In addition, the AMA will not speak up against efforts to examine changing the federal deferral requirement.

The FDA requires blood collectors to permanently defer men who have had sex with men (MSM) since 1977 from blood donation. The AMA statement, recommended by its Council on Science and Public Health, hews closer to the one-year deferral for MSM called for in a joint recommendation by America's Blood Centers, AABB, and the American Red Cross. The organizations said such a policy is more consistent with deferrals for other high-risk activities, such as receiving money or drugs for sex. They have argued that public education and the development of sensitive nucleic acid amplification tests have significantly reduced the residual risk of sexually transmitted diseases entering the blood supply.

In recent years, the controversial federal policy has sparked a number of protests by gay groups, who say it was inspired by and promotes unfair stereotypes, and arguments among government officials and academics, who say it is violates non-discrimination policies. This year alone, California's San Jose State University decided to ban blood drives on its 30,000-student campus over discrimination concerns. At Sonoma State University in Santa Rosa, a professor suggested ending blood drives there because the lifetime deferral violates the university's non-discrimination policy, though after a protracted debate involving faculty and students the university decided to allow blood collection to continue. The Santa Clara County Board of Supervisors in February voted unanimously to oppose the federal policy and encourage federal lobbyists to work to overturn the ban.

(continued on page 2)

AMA Statement (continued from page 1)

The AMA statement is expected help in those efforts because it underlines the problems of the mathematical models being used to assess risk.

"Any policy decision on blood donation deferral of the MSM population must be governed by the best available scientific evidence, but there are inherent weaknesses in mathematical models used in the risk assessments on this issue that continue to generate some uncertainty. With respect to the MSM population, it appears that a policy change from a permanent lifetime deferral to a five-year deferral following the last MSM contact may be supportable, but societal and ethical consequences must be analyzed should this decision be advanced," according to the statement.

The AMA considers current risk models weak because they rely on an insufficient number of studies and study groups that aren't large enough to provide predictive results, the organization said. AMA also found that, depending on the inputs, modeling studies reflect different risk assessments, creating uncertainty in the data.

The residual risk that an HIV-infected unit of blood will enter the blood supply is estimated at about 1 infected donation for every 2.1 million donations. Given that there are about 14.5 million blood donations annually, the residual risk is about 7 infected units every year. However, the AMA said, it is clear that 7 HIV-infected units do not enter the US blood supply annually undetected. Since the implementation of NAT in 1999, there have been four incidences where HIV has been transmitted via a blood transfusion, the last in 2002. In all four cases, the donors denied engaging in risky behavior at screening. So, out of more than 112 million whole blood units transfused, only 4 resulted in HIV transmission – far lower than predicted by the risk models.

In suggesting that a five-year deferral might be warranted, the AMA pointed to a study that found, compared to blood donors who did not report MSM contact, blood donors who reported the behavior within five years had five times the number of reactive test results. However, those who had not practiced male-to-male sex in at least five years had no significant difference in reactive tests than those who did not report MSM contact at all. The organization reasoned then that data suggest men who practice five-year abstinence from homosexual sex "essentially present no greater risk than the general population."

(continued on page 3)

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