Dr. Neil Cashman, Chief Science Officer of Amorfix.

In the most recent panel, NIBSC provided Amorfix with 500 frozen blinded human plasma samples which included some samples spiked with vCJD brain prions. The EP-vCJD(TM) test successfully detected all (100% sensitivity) of the spiked samples down to a 1 in 100,000 dilution of 10% brain homogenate (1/1,000,000 dilution of vCJD brain). The test scored one sample initially positive (initial reactivity of 99.8%) but upon repeat testing correctly identified the sample as negative (specificity of 100%). In the first blinded panel, Amorfix tested 1,000 fresh UK plasma samples with identical perfect results.

http://www.amorfix.com

別紙様式第2-1

No. 5

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	新医薬品等の区分	総合機構処理欄
				2008. 11. 20	該当なし	

一般的名称	人血清アルブミン	研究報告の公表状況	Dorsey K, Zou S, Schonberger L, Fang C, Dodd R. TRANSFUSION 2008-Vol. 48 Supplement	公表国 米国
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)			

研究報告の概要

○古典的CJDの輸血伝播リスクは、仮にあるとしてもvCJDよりも有意に低い一USルックバック試験
背景:1995年に米国赤十字(ARC)と疾病管理予防センター(CDC)は、古典的クロイツフェルト・ヤコブ病(CJD)についてのルックバック調査による評価を開始した。これまで、ヒトにおける古典的CJDの輸血伝播の報告はない一方、変異型CJD(vCJD)の輸血伝播は英国で報告されている。
方法:供血後にCJDと診断された供血者(CJD供血者)に由来する血液成分の受血者を登録した。生存受血者については登録以降毎年バイタルサインをモニターした。受血者が死亡した場合は死因を調査し、2005年末までの死亡を網羅した。
結果:古典的CJDを発症した供血者計35名(2名を除き孤発性CJD)および受血者430名を本試験に登録した。2005年までに生存受血者88名(1,135人年)、死亡受血者326名(813.5人年)、後に追跡不能となった受血者16名(64.5人年)の合計2,013人年の輸血後追跡調査が行われた。受血者のうち、144名は5年以上生存(長期生存者)し、CJDによる死亡は確認されなかった。長期生存者については、さらに関係する製剤輸血日と供血者のCJD診断日の間隔を調査し、英国におけるvCJDの観察と比較した。CJDの輸血伝播リスクは、vCJDと比べて有意に低かった($p = 0.0117$, Fisher の直接確率検定)。
結論:今回のルックバック検査の結果は、孤発性CJDの受血者への輸血伝播の証拠がないことを示しており、CJDの輸血伝播のリスクは(仮にあったとしても)vCJDと比較して有意に低いことを示すものである。

報告企業の意見	今後の対応
古典的CJDを発症した供血者計35名に由来する血液成分の受血者430名のルックバック調査の結果、孤発性CJDが輸血で伝播する証拠はなく、リスクはvCJDと比較して有意に低いとの報告である。	これまでの疫学研究等では、血液製剤を介して古典的CJD(弧発性、遺伝性および医原性CJD)が伝播するという証拠はない。またCJDの病原因子とされる異常プリオンがアルブミン製剤の製造工程で効果的に除去されるとの報告もあるが、輸血あるいは第Ⅷ因子製剤によりvCJDに感染する可能性が示唆されたことから、今後も引き続き情報の収集に努める。なお、日本赤十字社は、CJD、vCJDの血液を介する感染防止の目的から、献血時に過去の海外渡航歴(旅行及び居住)、CJDの既往歴(本人、血縁者)、hGH製剤投与の有無を確認し、該当するドナーを無期限に献血延期としている。

使用上の注意記載状況・その他参考事項等

赤十字アルブミン20
赤十字アルブミン25

血液を原料とすることに由来する感染症伝播等

Disclosure of Conflict of Interest

Shadaba Asad, Leonard Mermel, Joseph Sweeney: Nothing to Disclose

S86-030K

Direct Assessment of CMV Transfusion Transmitted Risks Post Universal Leukoreduction

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Background: CMV transmission through transfusion remains a clinical concern. Two effective strategies to reduce the risks of CMV TTD have been the provision of CMV seronegative blood and leukoreduction. Even though it is still under debate, these two methods have been considered operationally equivalent in many institutional policies. For many hospitals, universal leukoreduction has become the main strategy for the prevention of CMV TTD. Direct assessment of CMV TTD risk is lacking in the era of universal leukoreduction. In this study, through prospective clinical follow-up and testing of transfusion recipients (TR) for CMV Ab and nucleic acids and CMV Ab testing of their linked donors, the risk for CMV TTD was studied. **Methods:** As part of a prospective study of multiple donor exposure TRs, CMV TTD risk was assessed. Transfused units were all leukoreduced and not prospectively screened to be CMV seronegative. CMV total Ab and Nucleic Acid testing (NAT) were performed on all TRs baseline samples. For TR with negative baseline CMV testing, all follow-up TR samples were tested for CMV total Ab and NAT, and retained linked donor samples were tested for CMV total Ab. In cases when CMV TTD was suspected based on seroconversion, with or without supportive clinical evidence, donors were also tested for CMV NAT when possible. Evaluable transfusion was defined as a transfusion with TR sample(s) collected 14 to 180 days post transfusion in TR with a negative baseline CMV testing. **Results:** 46 evaluable TRs were negative for CMV at baseline. There were 1319 evaluable cellular blood component transfusions. Out of these, there were 655 RBCs for 43 TRs and 664 platelets for 31 TRs. Out of 1319 retained linked donor samples, 485 were positive for CMV total Ab. There were 19 case investigations due to changes in CMV testing results. Three appeared to be true infections or seroconversion. These may be related to transfusion; however, there was no definitive proof from donor follow-up that they were transfusion associated. Two were determined to be true infections but not transfusion related. Six were attributed to passive Ab transfer. Eight could not be determined due to inadequate information. **Conclusion:** Based on the No. of infections or seroconversions over the No. of TRs who were seronegative at baseline, the calculated CMV potential TTD rate was as high as 6.5% (3/46). Based on the No. of infection or seroconversions over the No. of transfused donor units, the calculated CMV potential TTD risks was: for leukoreduced but non-CMV screened cellular products, as high as 0.23% (3/1319); for leukoreduced and CMV sero-positive (tested after transfusion) cellular products, as high as 0.62% (3/485). In summary, post-universal leukoreduction, CMV-transfusion-transmission, while uncommon, may still occur.

Disclosure of Conflict of Interest

Richard Cable, Shimian Zou, Kerri Dorsey, Yanlin Tang, Cheryl Hapip, Russell Melmed, Jonathan Trouern-Trend, Chyang Fang, Melanie Champion, Roger Dodd: Nothing to Disclose
YanYun Wu: ARC – Grants or Research Support

S87-030K

A Linked Donor and Recipient Study of B19 Viral Transmission by Blood Component Transfusion

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Background: B19 virus (B19V) transmission by pooled plasma products has occurred from Factor VIII when DNA concentration (conc) exceeded 10^4 IU/mL and from SD plasma at a DNA conc of $>10^7$ IU/mL; this has led to *"in process" screening of recovered and source plasma units for high* B19V DNA concs (~10^6 IU/mL). Although several cases of B19V infection have occurred from component (cmpt) transfusion (tx), B19 screening is generally not performed for transfusable components as there has been no systematic study of this transmission rate or its association with B19 DNA conc. **Methods:** DNA positive (pos) donations (dntns) were identified by screening frozen repository plasma specimens using a previously validated sensitive kinetic PCR assay. Tx transmission was evaluated using various B19V assays to test pre- and 6-12 months post-tx specimens from adult surgical patients who received B19 DNA pos and negative (neg) control components; controls were selected in a 2:1 ratio and matched for factors influencing B19 transmission by non-tx routes. B19 transmission was inferred if either DNA, IgG, or IgM seroconversion occurred post-tx as demonstrated by replicate testing. Rates were determined in susceptible (susc) (i.e. pre-tx IgG antibody (Ab) neg) recipients and controls. **Results:** 105 of 12,529 donor specimens (0.83%) were B19 DNA pos; see the Table for plasma DNA concs. 110 components (mostly rbcs) from 103 pos donations with DNA <10^6 IU/mL (all of which were IgG Ab pos) were transfused to 105 recipients. There was no evidence of B19 infection in 21 susc case recipients (rate = 0.0%; 95% CI: 0.0-13.3) *or in 43 susc control recipients (rate = 0.0%;* 95% CI: 0.0-6.7). The estimated tx-transmission rate was thus 0.0% (95% CI: 0.0-13.3). Two components with >10^6 IU/mL were transfused to pre-tx B19 IgG Ab pos recipients, precluding assessment of tx transmission. **Conclusions:** Although we documented a high frequency of low conc (especially <10^3 IU/mL) B19 DNA and IgG Ab pos donations, the lack of tx transmission by these components indicates that such transmission does not occur, or if it occurs, is relatively uncommon (≤13%). These data do not support the need for real time screening of blood components with a sensitive B19 NAT assay.

TABLE. Linkage of B19 DNA pos components to recipients

B19 DNA conc (IU/mL)	# pos dntns	# DNA pos cmpts txd to susc recipients	# DNA pos cmpts txd to non-susc recipients	Total # DNA pos. cmpts txd to recipients
<20	56	15	45	60
20-<100	19	2	18	20
10^2-<10^3	23	3	22	25
10^3-<10^4	4	1	3	4
10^4-<10^5	0	0	0	0
10^5-<10^6	1	0	1	1
Subtotal	103	21	89*	110*
≥10^6	2	0	2	2
Total	105	21	91*	112*

* More than one component was txd for some pos donations; some recipients received more than 1 pos component.

Disclosure of Conflict of Interest

Steven Kleinman, Simone Glynn, Tzong-Hae Lee, Leslie Tobler, Karen Schlumpf, Deborah Todd, for the NHLBI Retrovirus Epid Donor Study-II, Michael P. Busch: Nothing to Disclose

S88-030K

The Risk of Transfusion Transmission of Classic CJD Is Lower Than vCJD, If not Zero – Results from US Look-Back Study

K Dorsey[1] (Dodd@usa.redcross.org), S Zou[1], L Schonberger[2], C Fang[1], R Dodd[3]. *[1]American Red Cross, Rockville, MD;[2]Atlanta, GA;[3]American Red Cross Blood Services, Rockville, MD.*

Background: In 1995, the American Red Cross (ARC) and the Centers for Disease Control and Prevention (CDC) initiated a look-back investigation to assess the risk of transfusion transmission of classic forms of Creutzfeldt – Jakob disease (CJD), sporadic, familial and iatrogenic CJD. The presence of the infectious agent of classic CJD in blood has been documented in experimental animals, but no transfusion transmission of classic CJD in humans has been reported. In contract, transfusion transmission of variant CJD (vCJD) has been documented in the United Kingdom. **Methods:** Blood donors who were subsequently diagnosed as having CJD (CJD donors) were identified by reports primarily from collaborating blood centers, the Food and Drug Administration (FDA), and family members. Following verification that the CJD diagnosis was made by a neurologist or confirmed by a pathologist, blood centers identified the donations made by the CJD donor and located the hospitals that received any of the blood components. The recipients of these components that were identified by hospitals were enrolled into the study. Their vital status, and cause of death, if deceased, was monitored by searching CDC's National Death Index (NDI) database at enrollment and every year thereafter for surviving recipients. The last NDI search covered deaths through the end of 2005. **Results:** A total of 35 blood donors with classic (non-variant) CJD and 430 recipients were enrolled in the study. All but 2 donors had sporadic CJD. Through 2005, recipients contributed a total of 2,013 person-years (py) of follow-up time since receipt of their blood transfusion, 1,135 py from 88 surviving recipients, 813.5 py

from 326 deceased recipients and 64.5 py from 16 recipients who were subsequently lost to follow up. Among the recipients, 144 survived 5 years or more (long-term survivors). No deaths from CJD were identified among the recipients. The most common causes of death among the recipients were cancers followed by cardiovascular diseases. The long-term survivors were further analyzed by the interval between the date of transfusion of the implicated unit and the date of diagnosis of CJD in the donor. A comparison of observations of vCJD in the UK (TMER study) using recipients who lived 5 or more years post-transfusion and had received the unit of blood from a donor whose symptoms occurred 60 months prior to onset of symptoms. The transfusion transmission risk of CJD was statistically significantly lower than that of vCJD ($p = 0.0117$, Fishers exact test). **Conclusions:** The results from this look-back study continue to show no evidence of transfusion transmission of sporadic CJD to recipients. The results indicate that the risk, if any, of transfusion transmission of CJD is significantly lower that than that of vCJD.

Disclosure of Conflict of Interest

Kerri Dorsey, Shimian Zou, Lawrence Schonberger, Chyang Fang, Roger Dodd: Nothing to Disclose

S89-030K

Current Value of Serologic Test for Syphilis as a Surrogate Marker for Bloodborne Viral Infections among US Blood Donors

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Background: Routine serologic screening for syphilis has been conducted for two reasons: 1) preventing transfusion transmission of syphilis although its value has been shown to be limited; 2) serving as a surrogate marker for infections caused by other pathogens such as HIV. This study assessed the current value of the test in safeguarding the blood supply against other presently tested viral infections. **Methods:** Testing results for voluntary and directed, whole blood, repeat donors in 2005-2006 with a large US blood supplier were analyzed. All donations were tested according to standard procedures for anti-HIV, HIV RNA, anti-HCV, HCV RNA, HBsAg, antibodies against human T-lymphotropic virus (anti-HTLV), syphilis and other markers. Incidence rate was defined as the number of confirmed seroconverters or viral RNA converters over total number of person-years observed. Sensitivity referred to the number of confirmed syphilis seroconverters among all confirmed converters for another infection, such as HIV, whereas positive predictive value (PPV) was the number of confirmed HIV converters among all confirmed syphilis seroconverters. Applying the sensitivity of syphilis testing in identifying new infections of another agent to the estimated number of donors during the window-period of the other infection gave the estimated number of window-period (w-p) units removed by syphilis testing. **Results:** There were significantly higher frequencies of HIV, HCV, HBsAg and HTLV positive donations among those with positive syphilis tests although such samples would not be expected to escape detection because of the use of multiple tests for most markers. Among 3,068,320 repeat donors with confirmed testing for both syphilis and anti-HIV, 168 seroconverted for syphilis but not for anti-HIV, 57 seroconverted for anti-HIV but not for syphilis, with only 1 seroconverted for both, resulting in an incidence ratio of 331 (95% CI: 46, 2390) between syphilis seroconverters vs. non-seroconverters, a sensitivity of 1.7% and a PPV of 0.6%. There were 4 additional HIV RNA converters who did not seroconvert for syphilis, resulting in an incidence ratio of 309 (43, 2231), a sensitivity of 1.6% and a PPV of 0.6%. No syphilis seroconverters converted for HCV, HBsAg or anti-HTLV. The result for HIV represented an estimated removal by syphilis testing of 0.11 w-p units out of a total of 9.5 million repeat donations during the two-year period if only anti-HIV is tested and of 0.07 w-p units if HIV RNA is also tested. **Conclusion:** Our data show that syphilis testing has a very low sensitivity and PPV for detecting other viral infections. It presents no surrogate value for HCV, HBV and HTLV infections and could only remove approximately one HIV window-period unit out of every 95 million donations from repeat donors.

Disclosure of Conflict of Interest

Shimian Zou, Edward Notari, Chyang Fang, Susan L. Stramer, Roger Dodd: Nothing to Disclose

Transfusion Practice/Clinical Case Studies

S90-030L

Accumulation of Thrombospondin-1 (TSP-1) in Packed Red Blood Cells Is Reduced by Whole Blood Leukoreduction Filters

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Background: Independent of other factors related to shock, blood transfusion is a risk factor for multiorgan failure (MOF) in trauma. The risk of organ failure, sepsis, and death correlates with increasing transfusion amount. Pathological specimens of organs of patients with MOF and disseminated intravascular coagulation (DIC) show widespread microvascular thrombosis. Multiple hemostatic changes occur in MOF leading to DIC. Degranulation of platelet granule glycoproteins correlates with the severity of MOF. TSP-1(thrombin sensitive protein) is one of the most abundant proteins in the platelet α-granule comprising 25%, and is part of a class of extracellular proteins which modulate cell-matrix interactions. TSP-1 is produced by platelets, megakaryocytes, endothelial cells, fibroblasts, monocytes, macrophages, and osteoblasts. TSP-1 binds to extracellular molecules including heparin, collagen, fibrinogen, fibronectin, plasminogen, plasminogen activator, and osteonectin. TSP-1 also binds to cells via CD36, CD47, and integrins. TSP-1 plays a role in platelet adhesion with other cells and with extracellular proteins. The accumulation of TSP-1 in PRBC was evaluated during PRBC storage as a possible contributor to MOF due to transfusion. **Methods:** Ten units of whole blood were separated into equal aliquots, one filtered with whole blood leukoreduction filters (Leukotrap-SC RC, Pall) and one unfiltered. Half units of PRBC were prepared and stored at 4°C in CPD-AS3. Aliquots from each unit were removed weekly, and plasma was separated from the cellular component and frozen at −80°C for simultaneous testing of PRBC supernatant for TSP-1 by ELISA (Pierce Searchlight). **Results:** During storage TSP-1 levels in PRBC supernatant increased to 24 times that seen on the day of collection. Filtration at collection results in maintenance of day 0 levels throughout storage. **Conclusions:** RBCs adhere to endothelium as they age. In trauma, with massive transfusion of old RBCs, the RE system is overwhelmed by rapid infusion of PS expressing cells which can occlude small vessels. The presence of molecules in PRBC supernatant which can lead to adhesion of platelets and leukocytes with further occlusion may contribute to development of MOF. This is especially important in the face of ongoing endothelial injury. The use of leukoreduction filters at collection prevents accumulation of TSP-1 during PRBC storage keeping levels similar to those in fresh PRBC units.

	TSP-1 pg/mL			
Day	Filtered	SD	Unfiltered	SD
0	102,433	70,504	732,522	431,231
7	215,464	166,957	2,078,779	1,880,785
14	458,247	394,759	8,208,680	5,229,551
21	508,753	425,944	17,884,850	6,446,864
28	646,694	647,201	11,887,478	7,368,030
35	837,582	641,212	11,719,325	3,082,931
42	773,083	663,248	11,791,379	6,323,265

Disclosure of Conflict of Interest

Lisa Cardo, Donna Wilder: Nothing to Disclose

S91-030L

Does Leukoreduction of Blood Products Influence Outcomes? An Analysis of 842,738 Hospital Inpatients

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Background: Allogeneic leukocytes have been implicated as a cause of transfusion-related immunomodulation (TRIM) and have been associated with post-operative infection (POI) and systemic inflammatory response syndrome (SIRS) in transfused patients. Universal leukoreduction (LR) of red blood cell (RBC) units has been proposed as a means of eliminating TRIM and improving outcomes but the success of this strategy remains uncertain. We performed a retrospective analysis of 842,738 hospitalized patients from 20 hospitals treated between 2002 and 2007 included in our database (COMPARE™, Infonalé/Haemonetics®, Braintree, MA) to determine the influence of LR on the incidence of POI and SIRS in hospitalized patients. **Methods:** Primary diagnosis, age, gender, race, emergency admission, any surgery, co-morbidities, severity of illness, any RBC, only LR RBCs (LR), any NON LR RBCs (NON LR), and NON LR RBCs plus

別紙様式第2

別紙(2)-3

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 2009年3月30日	新医薬品等の区分 該当なし	厚生労働省処理欄
一般的名称	乾燥 pH4 処理人免疫グロブリン		研究報告の公表状況	A recipient of immunoglobulin from a donor who developed vCJD Vox Sanguinis April 1, 2009, 96/3 (270)	公表国 英国	
販売名（企業名）	①サングロボール ②サングロボール点滴静注用 2.5g （CSL ベーリング株式会社）					

研究報告の概要 1690

問題点（vCJD に感染した供血者のプリオン伝播のリスク）

10 年間再発性の呼吸器感染に罹患していた 61 歳女性が分類不能型免疫不全症（CVID）と診断された。抗体欠乏の診断が遅延することは、残念ながら稀なことではない。患者は 1995 年から静注用人免疫グロブリン（商品名 Vigam 、BPL 社、英国）で週 3 回の治療を受けていた。1997 年 1 月から 1998 年 2 月の期間に当該患者は、後に vCJD を発症した供血者の血漿を含有した静注用人免疫グロブリンを投与された。患者は 5g 製剤 8V（バッチナンバーVGD049）、2.5g 製剤 4V（バッチナンバーVGD050）を投与された。これらのバッチの推定 ID50/g は、それぞれ 0.0000112 と 0.0000688 であった。患者は 72 歳で内臓の腺癌の再発のため死亡した。

国立クロイツフェルト・ヤコブ病サーベイランスユニットで検死が実施された。死亡後に防腐処置を施された。この過程が体組織中のプリオン物質の検出に影響するかは不明である。脾臓とリンパ節中のプリオン蛋白をウエスタン・ブロット法で検査したが陰性であった。

組織学的、免疫化学的またはウエスタン・ブロット法による解析で、脳内にプリオン蛋白が存在するエビデンスは見出せなかった。

関与しているバッチによる治療と関連性の無い死亡との間隔が 9 年であったが、赤血球成分による vCJD 伝播症例の間隔（5-8.5 年）より長かった。そのため、もし異常プリオンが伝播していたならば、エビデンスが発見されるのは当然である。

vCJD を発症した供血者の血漿を含有した静注用人免疫グロブリンを投与されたが、当該患者は臨床的に vCJD を発症せず、組織病理学的及び分子技術によりプリオン蛋白が沈着しているエビデンスを発見できなかった。

現在まで赤血球成分によるプリオン伝播は 4 症例報告されているが、静注用人免疫グロブリンによるプリオン伝播の症例報告は無い。

静注用人免疫グロブリンなどのプール血漿の製品の安全性は、伝播する可能性を減少する製造方法での多数の工程により高まっている。

現在の静注用人免疫グロブリンの製造方法は $5\log_{10}$ までプリオン分子を削減できるので、たとえ供血にプリオン蛋白が含有されていても静注用人免疫グロブリンによる vCJD 伝播のリスクは低い。

静注用人免疫グロブリンによる vCJD 伝播の報告は無いが、伝播の可能性を避けるため予防的措置として 1997 年から英国の血漿は、血漿分画製剤の製造に使用されていない。

静注用人免疫グロブリンは多くの適応症があり、世界の需要は供給を上回っている。

現在、英国では静注用人免疫グロブリンの使用できる適応症が厳重に制限されている。世界の市場から英国の供給を賄うことが次第に困難になってきているため、血漿分画製剤の製造への英国血漿使用の禁止を継続すべきかどうか再調査するのが適切かもしれない。

このことから、現在の論争を巡る多くの問題点が浮かび上がってくると考える。

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
これまで本剤によるvCJDが伝播した報告はない。製造工程において異常プリオンを低減し得るとの報告があるものの、理論的なvCJD等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与することを添付文書に記載し、注意喚起している。	今後とも新しい感染症に関する情報収集に努める所存である。