Other coagulation factors (FII, FV, FVII, F IX, FX, FXI, FXIII) were less affected by PCT. The mean factor activities in PCT-FFP were within the reference ranges. Retention of activity after PCT ranged from 81 to 97 percent. Of specific importance were the levels of FVII, which is the factor with the shortest half-life and thus the most critical for transfusion support of acquired complex coagulopathy. In addition, levels of the anticoagulant PC and PS and AT were relatively unaffected by PCT and α2-AP was well conserved.

There was slight prolongation in PT and aPTT. PCT-FFP, however, retained PT and aPTT within the reference range. The slight changes in PT and aPTT after PCT were not associated with any adverse clinical observations in controlled clinical trial settings, and treatment of congenital coagulation defects has demonstrated consistent correction of both the PT and aPTT after transfusion with PCT-FFP.[3-5,12]

The results of this study demonstrate that there is good retention of relevant coagulation factor activities and antithrombotic protein function in PCT-FFP from either apheresis or whole blood and that these products meet the requirements for therapeutic plasma. In a separate study, the effect of storage on FI, FII, FV, FVII, FVIII, F IX, FX, and FXI has been evaluated.[13] The results show that therapeutic levels of these factors were conserved in PCT-FFP after 12 months of storage at −18°C and after 18 months of storage at −25°C. Similar results were obtained in storage studies conducted at one of the three centers (Site S, data not shown) with PCT-FFP prepared from apheresis plasma frozen up to 1 year. In addition, clinical trials with PCT-FFP have shown that this product is sufficient for therapeutic support of patients with each of the major clinical indications for plasma transfusion.

The effect of PCT on plasminogen and von Willebrand factor (VWF) has also been evaluated.[14,15] After treatment, plasminogen was within normal ranges and retained 94 percent. The von Willebrand antigen, VWF:ristocetin cofactor, components of the von Willebrand complex, including multimers and VWF:CP activity, remained within normal ranges and demonstrated greater than 98 percent retention. Because of the stability of these factors after treatment, they were not included in the current validation study.

When the results were compared between sites or between types of plasma, significant differences were observed, although the differences were small, not likely of clinical relevance, and did not appear to follow a specific pattern. The observed differences could simply be due to the geographic variation in the plasma characteristics and the slight variation in the processing techniques. Of particular interest is that the FVIII activities as well as the retention for apheresis PCT-FFP in Site B were significantly higher than the values obtained in the other two sites. This difference could not be completely explained by the different apheresis collection platforms. Site S used the Haemonetics platform, but the same Baxter platform was used in both Site B and Site L. The observed difference between Site B and Site L was most likely due to the variation in donor population and processing techniques. Different anticoagulants may introduce variability but were poorly defined and not well evaluated. Overall, PCT-FFP manufactured in the three different geographic locations were of comparable quality. All met the respective national and European standards for transfusable FFP.

Previous studies with cryoprecipitate prepared from photochemically treated plasma yielded approximately 95 and 88 percent retention of fibrinogen and FVIII, respectively, compared to cryoprecipitate prepared from untreated plasma.[16] Cryosupernatant prepared from photochemically treated plasma retained adequate levels of critical plasma proteins for plasma exchange therapy in acute thrombocytopenic purpura. These data indicate good preservation of hemostasis control proteins such as PS, α2-AP, and VWF-cleaving protease activity.[17]

In summary, the results of process validation studies from three European centers demonstrated the consistency of the PCT process for FFP. From a blood center perspective, scaleup manufacturing of PCT-FFP in routine is feasible by the ability to treat individual large-volume units of fresh apheresis plasma and small pools of whole blood–derived plasma. The mixture of whole blood plasma from two or three matched donations is similar to the procedure for whole blood–derived PLT components. Since adult patients will require 4 to 6 FFP units (200 mL each) for a therapeutic episode, donor exposures are consistent with current practice in which whole blood plasma units are processed individually. A similar PCT system utilizing amotosalen and UVA light for PLT components has been in routine use in some blood centers in European countries.[18] Both PLT and plasma components are treated with the same UVA illumination device thus simplifying the logistics of implementation of two pathogen inactivation systems in one blood center.

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医薬品 研究報告 調査報告書

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				2008. 5. 26	該当なし	

一般的名称	(製造承認書に記載なし)	研究報告の公表状況	Blue DE, Cruz J, Limiac A, Spinola S, Davis TE, Waxman D, McCarthy L, Smith D. American Society for Microbiology 108th General Meeting; 2008 Jun 1-5; Boston.	公表国 米国
販売名(企業名)	合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社)			

研究報告の概要

○輸血による*Babesia microti*死亡例

輸血によって*Babesia microti*に感染し死亡する例は赤血球を含む輸血100万単位あたり1件未満と見積もられている。疾患は通常無症候性だが、無脾症、高齢、免疫抑制状態の患者では感染によって死に至ることがある。

症例:腎臓疾患で透析を必要としていた61歳の女性患者。入院45日前に赤血球2単位を輸血され、その後更に2単位追加輸血された。入院前日、吐き気と発熱を訴えたため、血液培養をオーダーし、抗生物質が投与された。リハビリ施設に戻る際に、体温は39.4℃を示し、低血圧で、昇圧剤を必要とし、敗血症の症状を呈した。血液塗抹標本では、赤血球の5~15%にトロフォゾイト(栄養体)があり、*Plasmodium falciparum*か*B. microti*と考えられた。静注キニジン及びクリンダマイシン投与が開始された。赤血球交換により寄生虫血症は1%まで低下した。投薬は適切だったが、播種性血管内凝固症候群(DIC)を発症し6日後に死亡した。外出や旅行はしていなかったため、唯一のリスクファクターは輸血と考えられた。

結果:*Babesia*はCDCで形態学的に確認された。患者の入院時の検体では6%の寄生虫血症と*B. microti* PCR陽性が認められた。輸血された製剤の供血者4名のうち1名がIFAで*B. microti*陽性となった。供血者はダニに噛まれた記憶はなく、流行地域に旅行したこともなかった。

結論:上の臨床症状と転帰は*Babesia*の輸血伝播による死亡例の中では珍しいものではないが、中西部で発生したという点が他と異なっている。ベクターIxodes scapularisが寄生する中西部のオジロジカの頭数増加に伴い、供血者における*Babesia microti*抗体陽性率を解明する為の研究を行うべきである。

報告企業の意見	今後の対応
輸血によると考えられる*Babesia microti*に感染し死亡した症例の報告である。	今後も引き続き、新興・再興感染症の発生状況等に関する情報の収集に努める。

使用上の注意記載状況・その他参考事項等

合成血「日赤」
照射合成血「日赤」

血液を介するウイルス、細菌、原虫等の感染
vCJD等の伝播のリスク

Abstract Title: Fatal Transfusion-Transmitted *Babesia microti*

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Keywords: Babesia,transfusion-transmitted

Background: Fatal transfusion-transmitted *B. microti* has an estimated incidence of <1:1,000,000 per unit of transfused red cell containing blood products. The disease is usually asymptomatic; however, fatal infections occur in asplenic, elderly or immunosuppressed individuals. **Case Report:** The 61-year-old female patient had renal disease requiring dialysis. Forty-five days prior to admission she received two units of packed red cells and then two more. One day prior to admission, the patient complained of nausea and fever. Blood cultures were ordered and antibiotics administered. Upon returning to the rehabilitation facility, she spiked temperatures to 103°F and was admitted to the hospital. She was hypotensive, requiring vasopressor support, and appeared to be septic. The blood smear revealed trophozoites in 5 to 15% of red cells, probable species: *Plasmodium falciparum* vs. *B. microti*. Treatment with intravenous quinidine and clindamycin was begun. A red cell exchange reduced parasitemia to 1%. Despite appropriate medication, the patient developed disseminated intravascular coagulation and expired 6 days later. Since she was confined indoors and did not travel, the only risk factor was transfusion. **Results:** *Babesia* was confirmed morphologically by CDC with 6% parasitemia and PCR positivity for *B. microti* from the patient's specimen at admission. The three donors available for testing were negative for *B. microti* and all samples were negative for *P. falciparum* by PCR. One blood donor and the patient were positive for *B. microti* by immunofluorescent antibody (IFA). The seropositive donor had no recollection of a tick bite and did not travel to endemic areas. **Conclusion:** The above clinical presentation and course is not atypical for rare fatal cases of transfusion-transmitted *Babesia*. This is an unusual case as it arose in the Midwest. With the expanding Midwest white-tailed deer populations harboring the vector, *Ixodes scapularis*, studies to determine the regional incidence of *Babesia microti* seropositive blood donors may be warranted.

医薬品 研究報告 調査報告書

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一般的名称	人赤血球濃厚液	研究報告の公表状況	飯岡大, 前追善智, 中村文彦, 林孝昌, 津田勝代. 第56回日本輸血・細胞治療学会総会; 2008 Apr 25-27; 福岡.	公表国
販売名(企業名)	赤血球濃厚液-LR「日赤」(日本赤十字社) 照射赤血球濃厚液-LR「日赤」(日本赤十字社)			日本

研究報告の概要

○血小板濃厚液の輸血後に、急性呼吸不全と*Bacillus cereus* (*B. cereus*)による髄膜炎を併発した症例

【緒言】輸血後細菌感染症は、診断・治療に難渋し、時に致命的な状態になることもある。我々は、*B. cereus*の輸血後感染症で急性呼吸不全および重症髄膜炎を併発した症例を経験し、その治療および診断経過が今後の対策につき有用と考えられここに報告する。

【症例】76歳女性。64歳に再生不良性貧血と診断、免疫抑制療法に不応で、71歳よりは赤血球および血小板輸血が定期的に必要となった。平成19年4月、血小板輸血を施行中、発熱・悪寒、その後急速な呼吸不全を認め、胸部X線・心エコー検査より、輸血関連肺障害(TRALI)と判断した。メチルプレドニゾロン500mg投与で呼吸状態は改善し発熱も消退した。しかし発症12時間後、嘔気・頭痛の出現と共に再び発熱を認めた。感染症を考え直ちに抗生剤を開始したが悪化し、発症16時間後には右方への眼球偏位と意識障害(昏睡)が出現した。髄液検査にて細胞数・蛋白の増加を認め、脳波でも異常波を認めたことから、細菌性髄膜炎および症候性てんかんと診断した。その後、抗生剤および抗てんかん薬が奏効し、発症第13日には意識清明となり、発症第25日には後遺障害なく退院できた。輸血関連感染の診断目的に当院で各種培養検査を施行したところ、血小板残液の鏡検・培養検査で*B. cereus*が検出された。髄液では、初回抗生剤投与後に採取した影響もあり鏡検・培養検査は陰性であったが、遺伝子検査PCR法にて、血小板製剤と同一菌株の*B. cereus*が検出され、今症例が輸血後感染症から髄膜炎に進展したと考えられた。一方で、凍結処理された供血者保存血漿では、培養検査・遺伝子検査共に陰性であった。

【考察】TRALI様の急性呼吸不全を呈した際は、輸血後感染症も視野に入れた対応が必要である。髄膜炎併発例の報告はこれまでに無いが、輸血後感染症治療では髄液移行性も考慮した抗生剤選択が求められる。培養検査だけでなく、遺伝子検査まで施行することが、診断及び同一菌株の証明に重要である。

使用上の注意記載状況・その他参考事項等

赤血球濃厚液-LR「日赤」
照射赤血球濃厚液-LR「日赤」

血液を介するウイルス、
細菌、原虫等の感染
vCJD等の伝播のリスク

自発報告:2007年5月28日付1-07000033

報告企業の意見	今後の対応
血小板濃厚液の輸血後に、TRALI様の急性呼吸不全と髄膜炎を併発し、血小板残液から*Bacillus cereus*が検出された症例の報告である。 本症例について、日本赤十字社では抗白血球抗体、抗顆粒球抗体検査を実施し、臨床経過及び診断基準よりTRALIであると評価した。患者の血液培養が陰性で、当該血小板製剤と同一採血時の凍結血漿では無菌試験陰性であったことから、輸血による細菌感染があったかどうかは不明である。	日本赤十字社では、輸血による細菌感染予防対策として平成18年10月より血小板製剤について、また、平成19年3月より全血採血由来製剤について、初流血除去を導入した。また、全ての輸血用血液製剤について、平成19年1月より保存前白血球除去を実施している。さらに、輸血情報リーフレット等により細菌感染やウイルス感染について医療機関へ情報提供し注意喚起しているほか、細菌感染が疑われる場合の対応を周知している。今後も細菌やウイルスの検出や不活化する方策について情報の収集に努める。

(19)

WS-3-3 血小板濃厚液の輸血後に，急性呼吸不全と Bacillus cereus (B.cereus) による髄膜炎を併発した症例

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【緒言】輸血後細菌感染症は，診断・治療に難渋し，時に致命的な状態になることもある．我々は，*B.cereus* の輸血後感染症で急性呼吸不全および重症髄膜炎を併発した症例を経験し，その治療および診断経過が今後の対策につき有用と考えられここに報告する．【症例】76 歳女性．64 歳に再生不良性貧血と診断，免疫抑制療法に不応で，71 歳よりは赤血球および血小板輸血が定期的に必要となった．平成 19 年 4 月，血小板輸血を施行中，発熱・悪寒，その後急速な呼吸不全を認め，胸部 X 線・心エコー検査より，輸血関連肺障害（TRALI）と判断した．メチルプレドニゾロン 500mg 投与で呼吸状態は改善し発熱も消退した．しかし発症 12 時間後，嘔気・頭痛の出現と共に再び発熱を認めた．感染症を考え直ちに抗生剤（ビアペネム）を開始したが悪化し，発症 16 時間後には右方への眼球偏位と意識障害（昏睡）が出現した．髄液検査にて細胞数・蛋白の増加を認め，脳波でも異常波を認めたことから，細菌性髄膜炎および症候性てんかんと診断した．その後，抗生剤（バンコマイシンも併用）および抗てんかん薬が奏効し，発症第 13 日には意識清明となり，発症第 25 日には後遺障害なく退院できた．輸血関連感染の診断目的に当院で各種培養検査を施行したところ，血小板残液の鏡検・培養検査で *B.cereus* が検出された．髄液では，初回抗生剤投与後に採取した影響もあり鏡検・培養検査は陰性であったが，遺伝子検査 PCR 法にて，血小板製剤と同一菌株の *B.cereus* が検出され，今症例が輸血後感染症から髄膜炎に進展したと考えられた．一方で，凍結処理された供血者保存血漿では，培養検査・遺伝子検査共に陰性であった．【考察】TRALI 様の急性呼吸不全を呈した際は，輸血後感染症も視野に入れた対応が必要である．髄膜炎併発例の報告はこれまでに無いが，輸血後感染症治療では髄液移行性も考慮した抗生剤選択が求められる．培養検査だけでなく，遺伝子検査まで施行することが，診断及び同一菌株の証明に重要である．

別紙様式第2-1

No. 9

医薬品 研究報告 調査報告書

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一般的名称	人赤血球濃厚液	研究報告の公表状況		公表国
販売名(企業名)	赤血球濃厚液-LR「日赤」(日本赤十字社) 照射赤血球濃厚液-LR「日赤」(日本赤十字社)		SignOnSanDiego.com. 2008 Mar 26.	米国

研究報告の概要

○カリフォルニア州サンディエゴ郡の梅毒症例急激に増加

カリフォルニア州サンディエゴ郡の年間梅毒症例数は、最低となった2000年の28例から昨年(2007年)は340例まで急増した。州の他の大都市の郡と比べて非常に急激な増加である。増加率は州全体の2倍以上、全国の3倍以上になる。州から派遣された5名の専門家チームは、梅毒と診断された人々と連絡をとって、性的パートナーを探し、検査を受けるよう勧めている。

全国的に、梅毒感染者の大部分は他のHIV陽性の男性と無防備な性交渉を行うHIV陽性の男性であり、サンディエゴ郡でも同様の傾向が見られる。昨年、当郡で梅毒と診断された人の84パーセントは男性と性交渉がある男性(MSM)であり、大半はHIV陽性だった。米国疾病対策予防センター(CDC)は、医師に対し、MSMの患者が年に1度梅毒のルーチンの検査を受けるよう奨励することを求めている。

連邦当局は、梅毒と他の性感染症(STD)の蔓延に対しても懸念を抱いている。先週、CDCは全国の梅毒症例数が7年連続で増加したと発表した。CDCは連邦の予算配分を変更してSTD教育と予防の取り組みに力を入れるよう要求している。AIDSや癌、心臓病と比較すると、米国のSTDの症例数は多くはない。しかし、連邦、州および地域の当局は、STD症例の増加が重要な公衆衛生問題であると認識している。

使用上の注意記載状況・その他参考事項等

赤血球濃厚液-LR「日赤」
照射赤血球濃厚液-LR「日赤」

血液を介するウイルス、
細菌、原虫等の感染
vCJD等の伝播のリスク

報告企業の意見	今後の対応
カリフォルニア州サンディエゴ郡の梅毒症例数が、2000年以降急増しているとの報告である。	日本赤十字社では、輸血感染症対策として問診時に梅毒を含む性感染症の既往歴を確認し、梅毒の既往歴、治療歴のある人は献血不適としている。また、献血血液に対して梅毒血清学的検査を実施し、陽性血液を排除している。今後も引き続き、新興・再興感染症の発生状況等に関する情報の収集に努める。

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More Health news

Syphilis cases up sharply in county

STD prevention, education efforts to be heightened

By Cheryl Clark
UNION-TRIBUNE STAFF WRITER

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Alarmed by San Diego County's more than 1,100 percent rise in syphilis cases between 2000 and last year, state health officials are using five investigators to help the region stem the spread.

"San Diego's increase is a cause for concern because we're just not understanding why it's being transmitted in the frequency that we're seeing," said Dr. Douglas Hatch, chief of California's division of communicable disease control.

The search for causes and solutions includes debate about whether safe-sex education needs to be explicit and targeted at men who have sex with men. That group accounts for most of the syphilis infections in the county and nationwide.

San Diego County's annual syphilis caseload skyrocketed from 28 in 2000 – when the infection total hit a low – to 340 last year. It is a much sharper rise than in the state's other large urban counties, including San Francisco, Los Angeles, Orange and Alameda. It's also more than double the statewide percentage of increase and triple that of the nation.

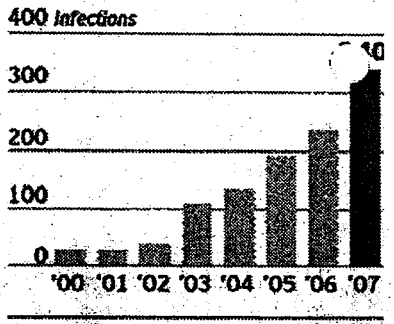
The team that the state dispatched to San Diego County consists of three investigators who recently started aiding county officials and two who were already working with them but have increased their level of assistance. They are contacting people who were diagnosed with syphilis, finding their sexual partners and urging those people to get tested so they can receive treatment and not transmit the bacteria.

Federal officials are also concerned by the spread of syphilis and other sexually transmitted diseases. Last week, the U.S. Centers for Disease Control and Prevention said the national syphilis case count had increased for the seventh consecutive year.

The agency wants to change federal funding formulas so states and counties can obtain more money for STD education and prevention efforts.

The United States' STD numbers aren't huge when compared to those for AIDS, cancer or heart disease.

REPORTED SYPHILIS INFECTIONS COUNTYWIDE



SOURCE: California Dept. of Public Health
MATT PERRY / Union-Tribune

REPORTED SYPHILIS INFECTIONS BY COUNTY

Sampling of counties with large populations

County	2000	2007	Change
San Diego	28	340	1,1 %
Los Angeles	152	827	444%
Orange	28	141	404%
San Francisco	54	202	274%
Alameda	14	39	179%
Statewide	330	2,002	507%

SOURCE: California Dept. of Public Health
MATT PERRY / Union-Tribune

But officials at the federal, state and local levels all have identified the growth of STDs as an important public health issue Public agencies and nonprofit groups spend hundreds of millions of dollars each year on STD prevention and testing.

Nationwide, an increasingly large portion of people infected with syphilis are HIV-positive men who have unprotected se with other HIV-positive men.

The trend is reflected in San Diego County. Last year, 84 percent of the people diagnosed with syphilis in San Diego County were men who had sex with men, and a big segment of them were HIV-positive, state health officials said.

Medical experts said the region's proximity to the border and its substantial tourist trade also could be contributing to

unsafe sex, which leads to higher numbers of syphilis cases and other STDs.

Syphilis likely has spread in San Diego County because at-risk men aren't telling health care providers about their sexual behavior and don't get tested, said Terry Cunningham, chief of the county's HIV, STD and Hepatitis branch.

He also blames health care providers who don't consistently address the issue with their patients.

The CDC is asking physicians to be more diligent in encouraging male patients who have sex with men to undergo routine screenings for syphilis, perhaps once a year.

Public health officials and various nonprofits diverge on a major point – how best to emphasize STD prevention. They ask:

▪How explicit must the anti-STD message be to draw enough attention?

▪Will public-service ads that are candid about sexual practices turn off or offend some people?

▪Should awareness campaigns aggressively focus on men who have sex with men, perhaps by using images of male couples?

San Diego County's approach is to address all individuals who face exposure to sexually transmitted diseases, said Holly Crawford, a spokeswoman for the county's Health and Human Services Agency.

"Targeting only specific populations . . . could lead to a false sense of security among the general population," she said. "STDs do not recognize gender, age, sexual orientation or location."

Greg Cox, chairman of the county Board of Supervisors, said the county is "addressing the issue of sexually transmitted diseases among all at-risk populations through bilingual education campaigns, alerts to doctors and STD education and testing at county clinics.

"I'm concerned about any disease or illness that affects the people of our region . . . but I am optimistic that our efforts wil succeed in bringing down the disturbing case numbers."

The county has allocated more than $1.5 million in state funds for this fiscal year to five nonprofit groups that work on STD prevention. They are the Family Health Centers of San Diego; San Diego Lesbian, Gay, Bisexual Transgender Community Center; San Diego Youth and Community Center; San Ysidro Health Center; and Vista Community Clinic.

The Vista clinic does outreach in neighborhoods where people who engage in high-risk sexual activities congregate, said director Barbara Mannino. The four other groups declined to discuss how they're using their grants.

The county also tries to reach high-risk populations in central San Diego by placing safe-sex ads in bus shelters and gay-themed publications.

Despite those efforts, some who work on STD prevention said more must be done to connect with specific risk groups.

"San Diego County's message is, 'We're all at risk.' That's true, but some people are much more at risk than others. What are they doing to target gay men and their sexual practices in bathhouses, for example?" said Oscar de la O, a founding member and president of Bienestar.

The nonprofit group tries to educate high-risk individuals in Southern California about syphilis and other STDs.

Bienestar outreach worker Abigail Madariaga is atransgendered woman, which means she was born a man but identifies and lives as a woman. On a recent evening, she and fellow STD educator Antonio Munoz talked to people watching a drag queen performance at Urban Mo's bar and nightclub in Hillcrest.

Madariaga said her orientation allows her to spread the safe-sex message more effectively to many of the estimated 1,500 other transgendered people in the region, as well as to gays, lesbians and bisexuals watching the drag show.

In San Francisco, public health workers spend time in Internet chat rooms, where gay men often make their connections. They began doing so after discovering how syphilis was spreading in many cases, said Dr. Jeffrey Klausner, director of STD prevention for the San Francisco Department of Public Health.

San Francisco has established medical clinics friendly to the gay community. Its health officials also conduct public awareness campaigns that show sex "as a positive, normal and healthy activity, rather than use fear and avoidance as a motivator," Klausner said.

One of those initiatives was the "Healthy Penis" program, which featured outreach workers dressed in costumes resembling penises and syphilis sores. That got people's attention, Klausner recalled.

The city has seen a drop in syphilis cases – from 348 cases in 2004 to 202 last year.

Klausner blamed the spread of syphilis elsewhere on reduced funding for anti-STD efforts and said health leaders in each community need to target their messages to those most at risk. "Increasing rates of STDs are what you can expect when there are no resources," he said.

San Diego County's share of state money for STD education and prevention this fiscal year is down $280,000 from last year.

Beyond money, many safe-sex campaigns are thwarted by politicians' fear of candor, said Michael Weinstein, president of the AIDS Healthcare Foundation in Los Angeles.

"They must make it obvious they are talking about sex," he said. "The sooner we stop treating this as a dirty little secret, the better off we'll be."

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感染症定期報告の報告状況(2008/6/1～2008/8/31)

血対ID	受理日	報告者名	一般名	生物由来成分名	原材料名	原産国	含有区分	文献	症例	適正使用措置
80101	2008/06/06	ベネシス	ポリエチレングリコール処理抗破傷風人免疫グロブリン 乾燥抗破傷風人免疫グロブリン	破傷風抗毒素	人血液	米国	有効成分	有	無	無
80102	2008/06/10	バイエル薬品	pH4 処理酸性人免疫グロブリン	人免疫グロブリンG	ヒト血液	米国	有効成分	有	無	無
80103	2008/06/17	日本赤十字社	人赤血球濃厚液	人赤血球濃厚液	人血液	日本	有効成分	有	有	無
80104	2008/06/17	日本赤十字社	人全血液	人全血液	人血液	日本	有効成分	有	無	無
80105	2008/06/17	日本赤十字社	抗HBs人免疫グロブリン	抗HBs人免疫グロブリン	人血液	日本	有効成分	有	無	無
80106	2008/06/17	日本赤十字社	洗浄人赤血球浮遊液	洗浄人赤血球浮遊液	人血液	日本	有効成分	有	有	無
80107	2008/06/24	化学及血清療法研究所	乾燥スルホ化人免疫グロブリン	スルホ化人免疫グロブリンG	ヒト血液	①米国、②日本	有効成分	有	無	無
80108	2008/06/27	バクスター	乾燥イオン交換樹脂処理人免疫グロブリン	人免疫グロブリンG	人血漿	米国	有効成分	無	無	無
80109	2008/06/27	バクスター	乾燥イオン交換樹脂処理人免疫グロブリン	人血清アルブミン	人血漿	米国	添加物	無	無	無
80110	2008/07/03	ベネシス	人ハプトグロビン	人ハプトグロビン	人血液	日本	有効成分	有	無	無
80111	2008/07/15	化学及血清療法研究所	乾燥濃縮人血液凝固第Ⅷ因子	血液凝固第Ⅷ因子	ヒト血液	日本	有効成分	有	無	無
80112	2008/07/16	富士フィルムRIファーマ	テクネチウム大凝集人血清アルブミン(99mTc)	テクネチウム大凝集人血清アルブミン(99mTc)	ヒト血液	米国	有効成分	有	無	無
80113	2008/07/24	CSLベーリング	乾燥濃縮人アンチトロンビンⅢ	乾燥濃縮人アンチトロンビンⅢ	ヒト血液	米国、ドイツ、オーストリア	有効成分	有	有	無
80114	2008/07/25	ノボノルディスクファーマ	エプタコグ アルファ(活性型)(遺伝子組換え)	ウシ新生仔血清	ウシ血液	ニュージーランド	製造工程	無	無	無
80115	2008/07/25	ノボノルディスクファーマ	エプタコグ アルファ(活性型)(遺伝子組換え)	ウシ胎仔血清	ウシ血液	ニュージーランド、オーストラリア、米国及びカナダ	製造工程	無	無	無
80116	2008/07/25	ノボノルディスクファーマ	エプタコグ アルファ(活性型)(遺伝子組換え)	ブタ膵臓由来トリプシン	ブタ膵臓(抽出物)	不明	製造工程	無	無	無
80117	2008/07/25	ノボノルディスクファーマ	エプタコグ アルファ(活性型)(遺伝子組換え)	エプタコグ アルファ(活性型)(遺伝子組換え)	エプタコグ アルファ(活性型)(遺伝子組換え)	該当しない	有効成分	無	無	無
80118	2008/07/28	日本製薬	乾燥人血液凝固第Ⅸ因子複合体	血液凝固第Ⅸ因子複合体	人血液	日本	有効成分	有	無	無
80119	2008/07/29	日本メジフィジックス	放射性医薬品基準ガラクトシル人血清アルブミンジエチレントリアミン五酢酸テクネチウム(99mTc)注射液	ガラクトシル人血清アルブミンジエチレントリアミン五酢酸テクネチウム(99mTc)	生物学的製剤基準人血清アルブミン	日本	有効成分	無	無	無
80120	2008/07/29	日本赤十字社		合成血	人血液	日本	有効成分	有	無	無
80121	2008/07/31	バクスター	ルリオクトコグ アルファ(遺伝子組換え)	培養補助剤(抗第Ⅷ因子モノクローナル抗体製造用-1)	ウシ血液	米国	製造工程	無	有	無
80122	2008/07/31	バクスター	ルリオクトコグ アルファ(遺伝子組換え)	ウシ血清アルブミン	ウシ血液	米国	製造工程	無	有	無