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
				2009. 4. 15	該当なし	
一般的名称	人赤血球濃厚液		研究報告の公表状況	CDC. Available from: http://www.cdc.gov/ncidod/dvbid/westnile/surv&controlCaseCount08_detailed.htm.	公表国 米国	
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)					

研究報告の概要

○2008年米国におけるウエストナイルウイルスの流行状況
米国疾病対策センターが発表した2008年の米国におけるウエストナイルウイルスの流行状況である。症例数は、2008年1月1日から12月31日までに発生し、2009年4月10日までに州や地方の保健当局からArboNETを通じて米国疾病対策センターに報告された軽症例及び重症例の合計である。46の州から1356例の感染例が報告され、うち687例(51%)で脳炎や髄膜炎を発症、624例(46%)で発熱、45例(3%)が他の症状/詳細不明だった。死亡に至ったのは44例だった。
神経侵襲性疾患が多く報告されているのは、軽症例より重症例の方が報告されやすいというサーベイランスの報告バイアスによるものである。また、サーベイランスシステムは無症候感染を検出するようには設計されていない。人口調査データからは、ウエストナイルウイルスに感染した人(無症候感染を含む)のうち、神経侵襲性疾患を発症するのは1%未満であることが示唆されている。

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
2008年、米国におけるウエストナイルウイルス感染症例は46州から1356例が報告され、うち687例で脳炎や髄膜炎を発症、死亡に至ったのは44例だったとの報告である。	日本赤十字社では、輸血感染症対策として問診時に海外渡航歴の有無を確認し、帰国(入国)後4週間は献血不適としている。また、ウエストナイルウイルス感染の国内発生に備え、平成17年10月25日付血液対策課発事務連絡に基づき緊急対応の準備を進めているほか、厚生労働科学研究「献血血の安全性確保と安定供給のための新興感染症等に対する検査スクリーニング法等の開発と献血制限に関する研究」班と共同して対応について検討している。今後も引き続き情報の収集に努める。

⑧

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Division of Vector-Borne Infectious Diseases
West Nile Virus

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Statistics, Surveillance, and Control

Maps and Data | Surveillance Program | Guidelines | Case Definition | See Also

Final 2008 West Nile Virus Activity in the United States

State	Encephalitis/ Meningitis	Fever	Other Clinical/Unspecified	Total	Fatali
Alabama	11	7	0	18	0
Arizona	62	43	9	114	7
Arkansas	7	2	0	9	0
California	292	149	4	445	15
Colorado	17	54	0	71	1
Connecticut	5	2	1	8	0
Delaware	0	0	1	1	0
District of Columbia	4	1	3	8	0
Florida	3	0	0	3	0
Georgia	4	3	1	8	0
Idaho	2	31	6	39	1
Illinois	12	4	4	20	1
Indiana	3	0	1	4	0
Iowa	3	0	3	6	1
Kansas	14	17	0	31	0
Kentucky	3	0	0	3	0
Louisiana	18	31	0	49	1
Maryland	6	7	1	14	0
Massachusetts	1	0	0	1	0
Michigan	11	4	2	17	0
Minnesota	2	8	0	10	0
Mississippi	22	43	0	65	2
Missouri	12	3	0	15	1
Montana	0	3	2	5	0
Nebraska	7	40	0	47	1
Nevada	9	5	2	16	0
New Jersey	6	4	0	10	2
New Mexico	5	3	0	8	0
New York	32	14	0	46	6
North Carolina	2	0	1	3	0
North Dakota	2	35	0	37	0

Ohio	14	1	0	15	1
Oklahoma	4	5	0	9	0
Oregon	3	13	0	16	0
Pennsylvania	12	2	0	14	1
Rhode Island	1	0	0	1	0
South Carolina	0	1	0	1	0
South Dakota	11	28	0	39	0
Tennessee	12	7	0	19	1
Texas	40	24	0	64	1
Utah	6	18	2	26	0
Virginia	0	0	1	1	0
Washington	2	1	0	3	0
West Virginia	1	0	0	1	0
Wisconsin	4	3	1	8	1
Wyoming	0	8	0	8	0
Totals	**687**	**624**	**45**	**1356**	

West Nile encephalitis and West Nile meningitis are forms of severe disease that affect a person's nervous system. Encephalitis refers to an inflammation of the brain, meningitis is an inflammation of the membrane around the brain and the spinal cord.
Click here for further explanation of WN meningitis and/or encephalitis.

West Nile fever refers to typically less severe cases that show no evidence of neuroinvasion. WN fever is considered a notifiable disease, however the number of cases reported (as with all diseases) may be limited by whether persons affected seek care, whether laboratory diagnosis is ordered and the extent to which cases are reported to health authorities by the diagnosing physician.

Other Clinical includes persons with clinical manifestations other than WN fever, WN encephal or WN meningitis, such as acute flaccid paralysis. **Clinical/Unspecified** cases are those for wh sufficient clinical information was not provided.

See the **case definition** (2004) for Neuroinvasive and Non-Neuroinvasive Domestic Arbovira Diseases. From the CDC Epidemiology Program Office.

Total Human Cases Reported to CDC: These numbers reflect both mild and severe humar disease cases occurring between January 1, 2008 to December 31, 2008 as reported through A 10, 2009 to ArboNET by state and local health departments. ArboNET is the national, electron surveillance system established by CDC to assist states in tracking West Nile virus and other mosquito-borne viruses. Information regarding 2008 virus/disease activity is posted when suc cases are reported to CDC.

Of the 1356 cases, 687 (51%) were reported as West Nile meningitis or encephalitis (neuroinvasive disease), 624 (46%) were reported as West Nile fever (milder disease), and 4 (3%) were clinically unspecified at this time. Please refer to state health department web sites further details regarding state case totals.

Note: The high proportion of neuroinvasive disease cases among reported cases of West Nile v disease reflects surveillance reporting bias. Serious cases are more likely to be reported than n cases. Also, the surveillance system is not designed to detect asymptomatic infections. Data fr population-based surveys indicate that among all people who become infected with West Nile v (including people with asymptomatic infections) less than 1% will develop severe neuroinvasi disease. See: Mostashari F, Bunning ML, Kitsutani PT, et al. Epidemic West Nile Encephalitis, N York, 1999: Results of a household-based seroepidemiological survey. Lancet 2001;358:261-2

For Case Information:
1999|2000|2001|2002|2003|2004|2005|2006|2007|2008

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National Center for Zoonotic, Vector-Borne, and Enteric Diseases

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別紙様式第2-1

No. 8

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
				2009. 3. 15	該当なし	
一般的名称	解凍人赤血球濃厚液		研究報告の公表状況	New York City Department of Health and Mental Hygiene, 2009 Feb 23. Available from: http://www.nyc.gov/html/doh/downloads/pdf/cd/2009/09md05.pdf	公表国 米国	
販売名(企業名)	解凍赤血球濃厚液「日赤」(日本赤十字社) 照射解凍赤血球濃厚液「日赤」(日本赤十字社) 解凍赤血球-LR「日赤」(日本赤十字社) 照射解凍赤血球-LR「日赤」(日本赤十字社)					

研究報告の概要

○ニューヨーク市における輸血関連バベシア症の増加

2008年9月以降6ヵ月間でニューヨーク市民の輸血関連バベシア症7例が確認され、これまでの年平均1～2症例と比べて急増した。輸血を受ける患者は免疫抑制状態など基礎疾患を有する場合が多く、医療従事者はバベシア症を疑わない可能性がある。

バベシア症は、赤血球に寄生する原虫*Babesia microti*を原因とする、重症あるいは死亡に至るダニ媒介疾患である。健常宿主では無症候または軽症の場合が多く、未治療では1年以上感染が持続することがある。自然感染は、ニューヨーク市近隣に生息する*Ixodes scapularis*(クロアシダニ)によって起こる。若虫の数が多い春と夏の間、伝播リスクは最大となる。

ニューヨーク市民のバベシア症症例数は、1989年以降徐々に増加しており、近隣地域でも同様の傾向が認められた。これは、輸血関連症例の増加によることが考えられる。2002年には16例、2008年の暫定データでは39例が報告されている。

輸血関連バベシア症は、赤血球(新鮮、凍結)と血小板による症例のみが報告されている。FDAによると、1979年以降80例以上が報告されており、ほとんどは最近10年間の症例であった。現在、供血血液のバベシア感染スクリーニング検査はない。発熱やバベシア感染の既往歴のある供血者は供血延期となるが、低レベルの寄生虫血症を生じた無症候性感染者の供血は回避できない。

ニューヨーク市の臨床医は、過去3ヵ月以内に輸血歴または臓器移植歴がある原因不明の発熱および(または)溶血性貧血の患者には、輸血関連バベシア症を考慮するべきである。潜伏期間は、ダニ媒介性バベシア症で1～4週間、輸血関連バベシア症で2～9週間と考えられる。疑わしい症例に対してはバベシア症検査を実施し、陽性の場合はニューヨーク市衛生局ならびにニューヨーク州保健局(NYSDOH)に報告しなければならない。

報告企業の意見	今後の対応
2008年9月以降の6ヵ月間、ニューヨーク市において輸血関連バベシア症の報告が急増し、ニューヨーク市衛生局は、医療従事者に対し、3ヵ月以内に輸血または臓器移植の既往歴があり、発熱および(または)溶血性貧血を有する患者の鑑別診断にバベシア症を考慮するよう勧告したとの報告である。	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

解凍赤血球濃厚液「日赤」
照射解凍赤血球濃厚液「日赤」
解凍赤血球-LR「日赤」
照射解凍赤血球-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

(9)

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Thomas R. Frieden, MD, MPH
Commissioner

Health

Health Advisory #5:
Increase in Transfusion-associated Babesiosis in NYC

- **Seven cases of transfusion-associated babesiosis have been identified among New York City (NYC) residents since September 2008; this is a notable increase over baseline as previously an average of one to two transfusion-associated cases were reported annually;**
- **The NYC Health Department is asking providers to consider babesiosis in the differential diagnosis of patients with fever and/or hemolytic anemia who have a history of transfusion or organ transplant within the preceding 3 months;**
- **Suspected cases should be tested for babesiosis (see below for details), and laboratory positive cases should be reported to the NYC Health Department as well as the New York State Department of Health (NYSDOH) Blood and Tissue Resources Program (see contact information below).**

Please distribute to staff in the Departments of Internal Medicine, Pediatrics, Family Medicine, Infection Control, Infectious Disease, Emergency Medicine, Critical Care, Hematology/Oncology, Pharmacy, Blood Bank and Laboratory Medicine.

February 23, 2009

Dear Colleagues,

Reported cases of transfusion-associated babesiosis among New Yorkers have increased during the previous 6 months. In the past, an average of 1-2 reports of transfusion-associated babesiosis was received by the Department annually; since September 2008, 7 cases have been identified. Patients receiving transfusions often have underlying illnesses, including immunosuppressive conditions, and providers may not suspect babesiosis, especially during winter months when travel to endemic areas is less common. This alert reminds providers to consider babesiosis in the differential diagnosis for patients with febrile illnesses and/or hemolytic anemia who have received blood components or transplanted organs in the preceding 3 months.

Babesiosis is a rare, sometimes severe or fatal tick-borne disease caused by *Babesia microti*, a parasite that infects red blood cells. Symptoms occur most frequently in elderly, asplenic or immunocompromised individuals and may include fever, hemolytic anemia, thrombocytopenia, diarrhea, acute renal failure, DIC and ARDS. In healthy hosts, infection is often asymptomatic, or causes mild illness with fever, headache, myalgia and malaise. Untreated infections can persist for up to a year or longer.

Naturally acquired *Babesia* is transmitted by infected *Ixodes scapularis*, or blacklegged ticks, which are also known to transmit *Borrelia burgdorferi* (Lyme disease) and *Anaplasma phagocytophilum* (anaplasmosis). The blacklegged tick is only rarely found in NYC; however it is present in nearly all areas surrounding the City. Highly endemic areas for *Babesia microti* near NYC include Long Island (especially Fire and Shelter Islands), Connecticut, New Jersey and Massachusetts. Transmission risk is greatest during spring and summer, when nymphal ticks are abundant.

The number of cases of babesiosis reported among NYC residents has gradually risen since 1989 when 2 cases were reported. This trend has been seen in the surrounding region as well. This may in part explain the increased number of transfusion-associated cases. In 2002, 16 cases were reported, and provisional data for 2008 has 39 cases reported to date, see Table 1).

Table 1. Reported Cases of Babesiosis in NYC 2002-2008

2002	2003	2004	2005	2006	2007	2008
16	25	16	18	38	25	39

Transmission through blood transfusion can occur when blood components collected from a parasitemic donor are transfused to a susceptible recipient. To date, transmission has been reported only with red blood cells (both fresh and frozen) and platelets. According to the FDA, since 1979 over 80 cases of transfusion-associated babesiosis have been reported in the US, the majority of which occurred during the past decade[1]. Currently, there is no laboratory screening of the blood supply for evidence of infection with *Babesia*. Donors are deferred if they have a fever at the time of donation or report a history of *Babesia* infection, but this practice alone is unable to prevent asymptomatic individuals with low levels of parasitemia from serving as donors.

Clinicians in NYC should consider transfusion-associated babesiosis in any patient presenting with unexplained febrile illness and/or hemolytic anemia who received blood components or organ transplantation in the preceding three months. The incubation period for tick-associated babesiosis can range from 1 to 4 weeks; for transfusion-associated babesiosis, 2 to 9 weeks.

Diagnosis can be made by identifying ring forms (which closely resemble *Plasmodium falciparum*) and tetrad forms within red blood cells on a Giemsa or Wright stained blood smear. *Babesia* polymerase chain reaction (PCR) and serologic tests are available commercially to assist with the diagnosis. Confirmatory testing, including review of blood smears and submission to NYS for PCR, if deemed necessary, is available through the NYC Public Health Laboratory. A request form must be completed for specimen submissions. For more information, call the Parasitology Laboratory at (212) 447-2972 during business hours. Forms can be found online at http://www.nyc.gov/html/doh/html/labs/labs_forms.shtml .

Treatment is generally not recommended for asymptomatic or mild self-limiting infections. For patients in whom illness is more severe, combination drug therapy has been successful. While the combination of clindamycin and quinine for 7 days was used historically, side effects including tinnitus and gastroenteritis can be problematic. More recently, the combination of atovaquone and azithromycin has been favored as this regimen is equally effective and results in fewer side effects[2]. In rare instances, an exchange transfusion may be indicated. For additional information on treatment options, refer to the Medical Letter, Drugs for Parasitic Infections. See http://www.dpd.cdc.gov/dpdx/HTML/PDF_Files/MedLetter/Babesiosis.pdf.

Additional information is available on the DOHMH website at: http://www.nyc.gov/html/doh/html/cd/cdbab.shtml or the CDC website at: http://www.cdc.gov/ncidod/dpd/parasites/babesia/default.htm

Please call the Bureau of Communicable Disease at 212-788-9830 with any questions regarding testing, diagnosis, reporting or management of suspected cases of babesiosis. Cases of transfusion-associated babesiosis must also be reported to the NYSDOH Blood and Tissue Resources Program at 518-485-5341. A report must also be made to your hospitals' transfusion service so they can notify the blood center that supplied the blood components.

Cases can be reported to the DOHMH by telephone (212-788-9830) or facsimile transmission (212-788-4268) using the paper or electronic Universal Reporting form (URF). **The URF and instructions can be obtained from your hospital's Infection Control Practitioner or downloaded from the DOHMH website at http://home2.nyc.gov/html/doh/html/hcp/hcp-urf.shtml. Visit http://home2.nyc.gov/html/doh/html/hcp/hcp.shtml to join NYC-MED in order to submit a URF online.**

As always, we greatly appreciate your cooperation and collaboration in our efforts to detect, investigate and prevent infectious diseases in New York City.
Sincerely,

Sally Slavinski, DVM, MPH, ACVPM — *Annie Fine, MD*

Sally Slavinski, DVM, MPH, ACVPM, Assistant Director
Zoonotic, Influenza and Vectorborne Disease Unit (ZIVDU)
Bureau of Communicable Disease

Annie Fine, MD, Medical Director
ZIVDU
Bureau of Communicable Disease

[1] Gubernot D et al. Babesia Infection through Blood Transfusions: Reports Received by the US Food and Drug Administration, 1997-2007. CID 2009;48 (1 January):pps 25-30.
[2] Krause PJ et al. Atovaquone and azithromycin for the treatment of babesiosis. NEJM 2000 Nov 16;343(20):1454-8.

別紙様式第２
番号８

医薬品
医薬部外品　　研究報告　調査報告書
化粧品

識別番号・報告回数			報告日	第一報入手日 2009年5月14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	人ハプトグロビン					
販売名（企業名）	ハプトグロビン静注2000単位「ベネシス」（ベネシス）	研究報告の公表状況	感染症学雑誌/；第83回日本感染症学会総会・学術講演会（2009.4.23.24） 2009；83(3)：214		公表国 日本	

研究報告の概要

平成20年8月、仙台市においてリケッチア症を疑う患者が発生した。発熱、全身倦怠感を主訴とし、受診時に発疹と刺し口が確認された。急性期の全血ならびに刺し口の生検材料、回復期の血清がリケッチア症の実験室診断に供され、Rickettsia japonicaに対する抗体価の有意な上昇を確認した。生検材料を用いたPCRにより、17KDa外膜蛋白遺伝子上のリケッチア属共通のプライマー（Rr17/Rr20）、R. japonica 極東アジアのロシアや中国の患者から報告されているR. heilongiangensisに一致したことから、9月に感染推定地域の現地調査を実施した。野鼠の捕獲とともにマダニ類の採集を行い、抗体測定、分離、17KDa のPCR とともにgltA、ompAを標的としたPCR を実施し、患者材料から得られたリケッチア遺伝子情報と比較検討した。3頭のドブネズミがR. heilongiangensisに対して高い抗体価を示し、3個体の Haemaphysalis concinaより17KDa、gltA、ompAの遺伝子領域において患者材料から得られた遺伝子配列と一致するものが検出されるとともに、同じ遺伝子配列を有するリケッチア（R. heilongiangensis）が分離された。以上のことから、国内にR. japonicaによる日本紅斑熱とは異なる紅斑熱リケッチア症が存在することが示され、H. concinaが生息する地域において同様の患者が発生している可能性が示唆された。今後、H. concinaの分布をより明確にするとともに、R. heilongiangensisなど保有するリケッチアの情報の蓄積と国内のリケッチア症に関する疫学をよりいっそう進めることが求められる。

報告企業の意見	今後の対応
国内にR. japonicaによる日本紅斑熱とは異なるR.heilongiangensisによる紅斑熱リケッチア症が存在することについての報告である。 リケッチア属のグラム陰性菌は0.3～0.5×0.8～2.0μmの大きさであり、万一Rickettsia Heilongiangensisが本剤の原料血漿に混入したとしても、除菌ろ過等の製造工程において除去されると考えている。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。

使用上の注意記載状況・その他参考事項等

2. 重要な基本的注意
(1) 本剤の原材料となる献血者の血液については、HBs抗原、抗HCV抗体、抗HIV-1抗体、抗HIV-2抗体、抗HTLV-I抗体陰性で、かつALT(GPT)値でスクリーニングを実施している。更に、プールした試験血漿については、HIV-1、HBV及びHCVについて核酸増幅検査(NAT)を実施し、適合した血漿を本剤の製造に使用しているが、当該NATの検出限界以下のウイルスが混入している可能性が常に存在する。本剤は、以上の検査に適合した血漿を原料として、Cohnの低温エタノール分画で得た画分から人ハプトグロビンを濃縮・精製した製剤であり、ウイルス不活化・除去を目的として、製造工程において60℃、10時間の液状加熱処理及びウイルス除去膜によるろ過処理を施しているが、投与に際しては、次の点に十分注意すること。

(10)

G0904327

O-151 上天草地域に連続発生した日本紅斑熱の臨床的検討

上天草市立上天草総合病院
○廣岡亜矢，津郡孝則，原喜由香，和田正文，
糸永浩太郎，脇田喜雄，樋口定信

日本紅斑熱は1984年に馬原によって最初に報告された，発熱，全身の紅斑，肝機能障害を特徴とするダニ媒介性のリケッチア症で，感染症法の4類感染症に分類されている．重症例では播種性血管内凝固症候群に陥り，死亡例の報告もある．患者は西日本の太平洋側に多く，年間100名ほどが報告されている．熊本県では平成14年に八代市で80歳の男性の発生例が報告されてから平成17年までの報告例はなかった．我々の施設のある上天草市は八代市と有明海に囲まれた比較的温暖な環境である．天草地域における日本紅斑熱は平成18年に1例発症以後，平成19年には11例，平成20年10月現在までに6例が報告されている．熊本県下発症例すべてが天草地域に限局している．また鑑別疾患としてのツツガムシ病の報告は皆無である．今回我々は上天草地域に発生した症例について疫学調査を行った．患者の平均年齢は72.5歳（57～100歳）で，男女比はおおよそ2:3であった．初発症状は頭痛，発熱，倦怠感が多く，ダニ暴露から発症までは平均3日であった．身体所見上，全身に疼痛や掻痒を伴わない辺縁不整の紅斑と刺し口が見られ，検査所見上，CRPの上昇，血小板減少，低アルブミン血症が多くに認められた．全例，ミノサイクリンの投与で速やかに解熱し治癒した．日本紅斑熱には β-ラクタム剤が無効であるので，発疹を伴う発熱性疾患の鑑別疾患として重要であると考えられる．

X0980005

O-152 仙台市で確認された新しい紅斑熱リケッチア症

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矢野泰弘[4]，高野　愛[5,6]，川端寛樹[5,6]，花岡　希[1]，
斉藤若奈[2]，岸本寿男[1]

平成20年8月，仙台市においてリケッチア症を疑う患者が発生した．発熱，全身倦怠感を主訴とし，受診時に発疹と刺し口が確認された．急性期の全血ならびに刺し口の生検材料，回復期の血清がリケッチア症の実験室診断に供され，*Rickettsia japonica*に対する抗体価の有意上昇を確認した．生検材料を用いたPCRにより，17KDa外膜蛋白遺伝子上のリケッチア属共通のプライマー（R1/R2），*R.japonica*を標的としたプライマー（R35/R10）で陽性であった．しかしながら，シークエンス解析により，*R.japonica*に極めて近縁であるが，極東アジアのロシアや中国の患者から報告されている*R.heilongjiangensis*に一致した．ことから，9月に感染推定地域の現地調査を実施した．野鼠の捕獲とともにマダニ類の採取を行い，抗体測定，分離，17KDaのPCRとともに*gltA*，*ompA*を標的としたPCRも実施し，患者材料から得られたリケッチア遺伝子情報と比較検討した．3頭のドブネズミが*R.heilongjiangensis*に対して高い抗体価を示し，3個体の*Haemaphysalis concinna*より17KDa，*gltA*，*ompA*の遺伝子領域において患者材料から得られた遺伝子配列と一致するものが検出されるとともに，同じ遺伝子配列を有するリケッチア（*R.heilongjiangensis*）が分離された．以上のことから，国内に*R.japonica*による日本紅斑熱とは異なる紅斑熱リケッチア症が存在することが示され，*H.concinna*が生息する地域において同様の患者が発生している可能性が示唆された．今後，*H.concinna*の分布をより明確にするとともに，*R.heilongjiangensis*など保有するリケッチアの情報の蓄積と国内のリケッチア症に関する啓発をよりいっそう進めることが求められる．

番号2

別紙3

研究報告調査報告書

識別番号・報告回数			第一報入手日 ：平成21年7月8日	新医薬品等の区分 ：該当なし	総合機構処理欄
一般的名称	－	研究報告の公表状況	－	公表国： 日本	
販売名（企業名）	－				使用上の注意記載状況等・その他参考事項等

研究報告の概要

50代後半の男性が，右母趾のウオの目をカッターで自己切除したところ黒く変色し，その範囲は徐々に拡大．後に右下肢の腫脹が出現し自力で動けず緊急搬送された．到着時体温38.8度，WBC 28,200/μl，CRP 24.1mg/dL，肝機能不全，血液凝固異常が認められた．右母趾に悪臭と壊疽を伴う重度の蜂巣炎がみられ，右下肢が発赤腫脹，X線所見で右大腿部までガス像が認められた．直ちに壊疽部切開後排膿を認め，下腿中央までの切開で膿が腓腹筋に沿って大量に存在していた．
入院直後に採取した右母趾由来膿よりC群レンサ球菌が検出され，Streptococcus dysgalactiae subsp. dysgalactiae による初めての人感染症例と考えられた．

報告企業の意見	今後の対応
本報告は，当該生物由来製品による感染症情報ではない． 本報告を“新規感染症”と考え，報告する．	今後も感染症情報の収集に努め，当該生物由来製品に係る情報を入手した場合には速やかに調査・報告を行い安全性の確保に努める．

MedDRA/J Ver. 12.0J

NMP2009-0003

Streptococcus dysgalactiae subsp. *dysgalactiae* による初めてのヒト侵襲性感染症例

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長野則之[1]，○外山雅美[1]，長野由紀子[2]，荒川宜親[2]

【序文】*Streptococcus dysgalactiae* subsp. *dysgalactiae* に起因する STSS を伴う壊死性筋膜炎症例について報告する．【症例】50 代後半の男性で半年前に右母趾のウオの目をカッターで自己切除．3 ヶ月前より右母趾が黒く変色しているのに気付きその範囲は徐々に拡大．1 週間前頃より右下肢の腫脹が出現し自力で動けず救急搬送される．到着時体温 38.8℃で WBC 28,200/μL，CRP 24.21 mg/dL，肝機能不全，血液凝固異常が認められた．また Glucose 226 mg/dL で糖尿病が判明．右母趾に悪臭と壊疽を伴う重度の蜂巣炎がみられ，右下肢が発赤腫脹，X 線所見で右大腿部までガス像が認められた．直ちに壊疽部切開後排膿を認め，下腿中央までの切開で膿が腓腹筋に沿って大量に存在しデブリードメント施行．翌日全身状態悪化の為右大腿遠位 1/3 以下の切断術が施行された．CMZ 次いで ABPC＋CLDM が投与され術後経過良好にて第 48 病日に転院．入院直後採取の右母趾由来膿よりラクトース非分解性，β 溶血性の C 群レンサ球菌及び同等数の *Proteus mirabilis* が検出され，腓腹筋由来膿からは優位な菌数をもって C 群レンサ球菌が検出された．本菌はストレプトキナーゼ陰性と 16S rDNA 解析から 99.2% の相同性で *S. dys. spp. dysgalactiae* と同定された．また，スーパー抗原遺伝子 *speG* 及び壊死性軟組織感染症発症の要因と考えられている病原遺伝子 *sagA* の保有が確認され，*emm* 遺伝子型 *stL1929.0* であった．【考察】*S. dysgalactiae* subsp. *equisimilis* による STSS 等のヒト侵襲性感染症の報告が増加しつつあるのに対し，*S. dys.* subsp. *dysgalactiae* は元来ヒト以外の動物由来株に接続されている亜種名で，ウシ STSS やイヌ菌血症などが報告されている．本報は *S. dys.* subsp. *dysgalactiae* による初めてのヒト感染症例と考えられるが，本菌のように新たな病原遺伝子を獲得することでヒトへの感染性を高めていく可能性を含め，本亜種についての研究の必要性が促される．

別紙様式第2-1

No. 6

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
				2009. 3. 15	該当なし	
一般的名称	解凍人赤血球濃厚液		研究報告の公表状況	FDA, CBER. Available from: http://www.fda.gov/Cber/blood/fatal08.pdf.	公表国 米国	
販売名（企業名）	解凍赤血球濃厚液「日赤」（日本赤十字社） 照射解凍赤血球濃厚液「日赤」（日本赤十字社） 解凍赤血球-LR「日赤」（日本赤十字社） 照射解凍赤血球-LR「日赤」（日本赤十字社）					

研究報告の概要

○FDAに報告された供血後及び輸血後の死亡例 2008年度概要

2005年度から2008年度にかけて米国食品医薬品局（FDA）に報告された供血後及び輸血後の死亡例の概要である。

2008年度に、FDAは受血者72件、供血者10件の死亡報告を受領した。受血者死亡例の内訳は、46件が輸血に関連したもの、8件が死亡原因として輸血を排除できないもの、18件が輸血と関連しないものであった。輸血に関係した（または可能性のある）死亡報告は、2006年度の73件、2007年度の63件と比べて54件に減少した。

2005年度から2008年度の統合データ223件において、輸血関連急性肺障害（TRALI）による死亡報告がもっとも多く（51%）、次いで溶血性反応（25%）、微生物感染（13%）の順であった。TRALIは、過去4年間の死亡報告の半数以上を占めているが、2008年度は35%と大幅に少なくなった。

2008年度の微生物感染は7件で、このうちバベシア症が5件、*Staphylococcus aureus* 及び *Staphylococcus epidermidis* がそれぞれ1件であった。2005年度から2008年度の合計では、微生物感染28件のうち10件（36%）をバベシア症が占めている。

使用上の注意記載状況・その他参考事項等

解凍赤血球濃厚液「日赤」
照射解凍赤血球濃厚液「日赤」
解凍赤血球-LR「日赤」
照射解凍赤血球-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
2005年度から2008年度にかけて米国食品医薬品局（FDA）に報告された供血後及び輸血後の死亡例の概要である。	日本赤十字社では、薬事法及び関連法令に従い輸血副作用・感染症情報を収集し、医薬品医療機器総合機構を通じて国に報告している。今後も引き続き輸血副作用・感染症に関する情報の収集に努める。

(12)

Fatalities Reported to FDA Following Blood Collection and Transfusion

Annual Summary for Fiscal Year 2008

I. Background

As previously mentioned in the annual summary of fatalities reported to the FDA in Fiscal Years (FY) 2005, FY2006, and FY2007, the blood supply is safer today than at any time in history. Due to advances in donor screening, improved viral marker tests, automated data systems, and changes in transfusion medicine practices, the risks associated with blood transfusion continue to decrease. Overall, the number of transfusion related fatalities reported to the FDA remains small in comparison to the total number of transfusions. In 2006 there were approximately 30 million components transfused.[1] During the proximate period of FY2006, there were 73 reported transfusion related and potentially transfusion related fatalities, with subsequent decreases to 63 in FY2007 and 54 in FY2008.

CBER is distributing this summary of transfusion fatality reports received by the FDA to make public the data received in FY2008, to provide the combined data received over the last four fiscal years, and to compare the FY2008 reports to the fatality reports received in FY2007, FY2006, and FY2005. We also include information on the infrequent reports of post-donation fatalities. Throughout this report we note changes over time, but the reader should interpret these changes cautiously, given the small numbers of reports and inherent variations in reporting accuracy. The significance of shifts in numbers derived from small populations may appear to be greater than they really are.

Refer to Sections 606.170(b) and 640.73 of Title 21, Code of Federal Regulations (21 CFR 606.170(b) and 21 CFR 640.73), for fatality reporting requirements. For information regarding the notification process, see our web page, Notification Process for Transfusion Related Fatalities and Donation Related Deaths, http://www.fda.gov/cber/transfusion.htm. For further information, see our *Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion*, September 2003.[2]

A team of CBER medical officers reviews the documentation submitted by the reporting facilities and obtained by the FDA investigators, to assess the relationship, if any, between the blood donation or transfusion and the reported fatality.

1 Whitaker BI, Green J, et al. The 2007 Nationwide Blood Collection and Utilization Survey Report. Washington (DC): Department of Health and Human Services; 2008.
2 Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion, September, 2003. http://www.fda.gov/cber/gdlns/bldfatal.htm.

If you have questions concerning this summary, you may contact us using any of the three following options.

1. Email us at fatalities2@fda.hhs.gov,
2. Call us at 301-827-6220, or
3. Write us at:
   FDA/Center for Biologics Evaluation and Research
   Office of Compliance and Biologics Quality
   Division of Inspections and Surveillance (HFM-650)
   1401 Rockville Pike, Suite 200 North
   Rockville, Maryland 20852-1448

II. Results

During FY2008 (October 1, 2007, through September 30, 2008), we received a total of 82 fatality reports. Of these reports, 72 were transfusion recipient fatalities and 10 were post-donation fatalities.

Of the 72 transfusion recipient fatality reports, we concluded:
a) 46 of the fatalities were transfusion-related,
b) in 8 cases we were unable to rule out transfusion as the cause of the fatality,
c) 18 of the fatalities were unrelated to the transfusion.

We summarize the results of our review in the following sections. Sections A through D of this document present the transfusion-related fatalities. Sections E and F and Table 4 present the fatality reports which were unrelated to the transfusion, or in which we could not rule out the transfusion as the cause of death. Section G presents the post-donation fatality reports.

A. Overall Comparison of Transfusion-Related Fatalities Reported from FY2005 through FY2008

In combined FY2005, FY2006, FY2007, and FY2008, Transfusion Related Acute Lung Injury (TRALI) caused the highest number of reported fatalities (51%), followed by hemolytic transfusion reactions (25%) due to non-ABO (15%) and ABO (10%) incompatibilities. Complications of microbial infection, Transfusion Associated Circulatory Overload (TACO),

and anaphylactic reactions each accounted for a smaller number of reported fatalities (Table 1 and Figure 1).

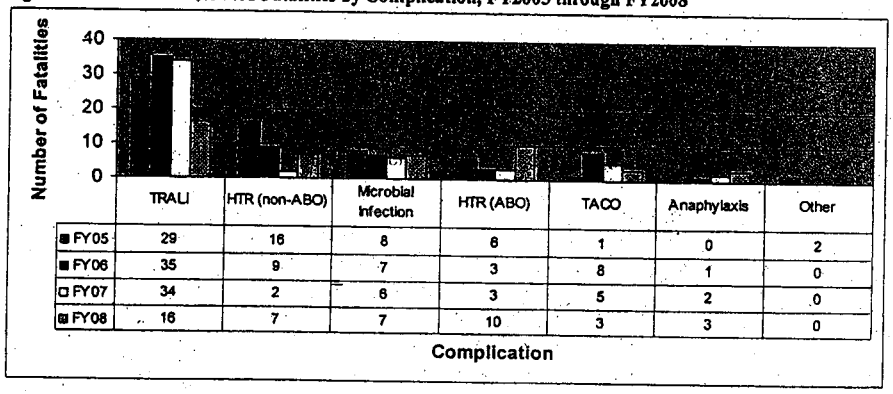
Table 1: Transfusion-Related Fatalities by Complication, FY2005 through FY2008

Complication	FY05	FY05	FY06	FY06	FY07	FY07	FY08	FY08	Total	Total
	No.	%	No.	%	No.	%	No.	%	No.	%
TRALI	29	47%	35	56%	34*	65%	16*	35%	114	51%
HTR (non-ABO)	16	26%	9	14%	2	4%	7	15%	34	15%
Microbial Infection	8	13%	7	11%	6	12%	7	15%	28	13%
HTR (ABO)	6	10%	3	5%	3	6%	10	22%	22	10%
TACO	1	2%	8	13%	5	10%	3	7%	17	8%
Anaphylaxis	0	0%	1	2%	2	4%	3	7%	6	3%
Other	2**	3%	0	0%	0	0%	0	0	2	1%
Totals	62	100%	63	100%	52	100%	46	100%	223	100%

*In FY2007, our review committee began using the Canadian Consensus Conference criteria[3,4] for evaluating TRALI cases – these numbers includes both "TRALI" and "possible TRALI" cases

**Other: Includes one case of Graft vs. Host Disease (GVHD) and one therapeutic plasma exchange (TPE) error (use of a treatment column contraindicated due to patient's medical history)

Figure 1: Transfusion-Related Fatalities by Complication, FY2005 through FY2008



B. Transfusion Related Acute Lung Injury (TRALI)

[3] Goldman M, Webert KE, Arnold DM. et al. Proceedings of a consensus conference: towards an understanding of TRALI. Transfus Med Rev 2005;19:2-31.

[4] Kleinman S, Caulfield T, Chan P, et al. Toward an understanding of transfusion-related acute lung injury: statement of a consensus panel. Transfusion 2004;44:1774-1789.

While TRALI represented 51% of confirmed transfusion related fatalities reported to CBER over the last four fiscal years, in FY2008 fatalities due to TRALI decreased to 35% of confirmed transfusion related fatalities, compared to 65% in FY2007, 56% in FY2006, and 47% in FY2005. The number of TRALI fatalities associated with receipt of Fresh Frozen Plasma (FFP) decreased from 22 (63% of TRALI cases) in FY2006 to 12 (35% of TRALI cases) in FY2007 to 4 (25% of TRALI cases) in FY2008 (Figure 2). TRALI fatalities associated with receipt of Apheresis Platelets increased from 1 (3% of TRALI cases) in FY2007 to 5 (31% of TRALI cases) in FY2008. The percentage of FY2008 TRALI fatalities associated with receipt of Red Blood Cells (31% of TRALI cases) was comparable to that reported in FY2007 (35% of TRALI cases).

In Calendar Year 2006, transfused plasma products accounted for approximately 13% of all transfused components, apheresis platelets (using platelet concentrate equivalent units) – approximately 30%, and red blood cell-containing products – approximately 49%.[5] In comparison, for the combined fiscal years 2005-2008, FFP and other plasma accounted for 48% (55/114) of reported TRALI fatalities, apheresis platelets accounted for 10% (12/114), and RBC's accounted for 24% (27/114).

In FY2008, the 16 TRALI cases were temporally associated with products from 20 donors. Of these donors, 17 (85%) were tested for white blood cell (WBC) antibodies (Table 2). Antibody tests were negative in 18% of those tested. Of those tested, Human Leukocyte Antibodies (HLA) were present in 58% of donors. Human Neutrophil Antibodies (HNA) were present in 12% of donors, but these reactions were weak and non-specific. Some of the donors had multiple antibodies. Reporters who included patient testing data were able to match donor antibodies with recipient cognate antigens in 4 of the 16 cases, implicating 4 female donors. In two cases, reporters were able to identify **recipient** antibodies that matched or were a probable match to **donor** cognate antigens. In another case, both donor and recipient antibodies were identified which matched cognate antigens in the corresponding recipient and donor.

Of the 20 implicated donors, reports identified 13 females (65%) and 7 males (35%).

Although the transfusion community has taken voluntary measures to reduce the risk of TRALI, this complication of transfusion continues to be one of the leading causes of transfusion-related fatalities reported to the FDA. Data show that the largest percentage of fatal TRALI cases are associated with female donors with white blood cell antibodies, and recent literature describes efforts to selectively use plasma from male donors for transfusion.[6,7,8] In November, 2006, the American Association of Blood Banks (AABB) issued an Association Bulletin (#06-07), which included a recommendation that blood collection and transfusion facilities begin implementation of TRALI risk reduction measures for all high plasma-volume components. The measures include interventions to minimize the preparation of these components from donors known to

[5] Whittaker BI, op.cit. Tables 4-1 and 4-2.

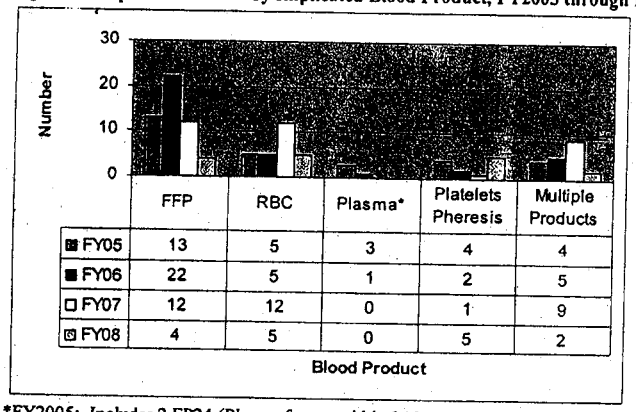
[6] Curtis, BR, Mcfarland JG. Mechanisms of transfusion-related acute lung injury (TRALI): anti-leukocyte antibodies. Crit Care Med 2006;34(5 Suppl):S118-S123.

[7] Eder AF, Herron R, Strupp A, et al. Transfusion-related lung injury surveillance (2003-2005) and the potential impact of the selective use of plasma from male donors in the American Red Cross. Transfusion 2007;47:599-607.

[8] Chapman CE, Williamson LM, Cohen H, et al. The impact of using male donor plasma on hemovigilance reports of transfusion-related acute lung injury (TRALI) in the UK (abstract). Vox Sang 2006;91(Suppl 3):227.

have white blood cell antibodies or who are at increased risk for developing these antibodies.[9] Some of the more current literature further describes efforts to reduce the use of plasma for transfusion prepared from female donors.[10,11]

Figure 2: Reports of TRALI by Implicated Blood Product, FY2005 through FY2008



*FY2005: Includes 2 FP24 (Plasma frozen within 24 hours after collection) and 1 Liquid Plasma
FY2006: Includes 1 FP24

Table 2: Donor Antibodies Identified in Association with TRALI, FY2007 and FY2008

Donor Leukocyte Antibodies	FY07 No.	FY07%	FY08 No.	FY08%
HLA Class I	18	17%	3	18%
HLA Class II	6	6%	2	12%
HLA Class I and II	15	14%	6	35%
HNA	17	16%	2	12%
HLA and HNA	6	6%	2	12%
Negative	42	41%	2	12%
Total Donors Tested	104	100%	17	100%

This table does not include the 59 donors that were not tested for WBC antibodies in FY07 and the 3 donors that were not tested in FY08.

[9] Transfusion-related acute lung injury. AABB Association Bulletin (#06-07). Bethesda: American Association of Blood Banks;2006 Nov 3.
[10] Wright S, Athey S, Leaver A, et al. The effect of male-donor-only fresh frozen plasma on the incidence of acute lung injury following ruptured abdominal aortic aneurysm repair. Crit Care 2007;11:374.
[11] Chapman CE, Stainsby D, Jones H, et al. Ten years of hemovigilance reports of transfusion-related acute lung injury in the United Kingdom and the impact of preferential use of male donor plasma. Transfusion ;doi:10.1111/j.1537-2995.2008.01948.x

C. Hemolytic Transfusion Reactions

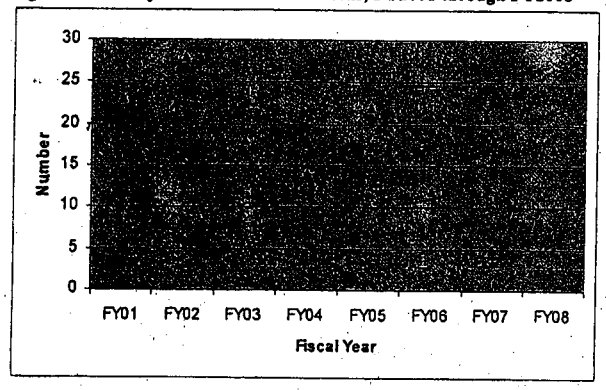
In FY2008, hemolytic transfusion reactions were the leading cause of transfusion related fatalities reported to CBER, representing 37% of confirmed transfusion related fatalities. The number of reported fatal hemolytic transfusion reactions increased to 17 in FY2008, as compared to 5 in FY2007, and 12 in FY2006. The recent increase is due to an increase in reports of ABO hemolytic reactions, with reports of 10 in FY2008, as compared to 3 in both FY2007 and FY2006. Reports of non-ABO hemolytic transfusion reactions also increased from 2 in FY2007 to 7 in FY2008 (Figure 1 and Table 3). Despite the FY2008 increase in the number of reported fatalities due to hemolytic transfusion reactions, we have seen an overall decrease in this number since FY2001 (Figure 3).

Table 3: Hemolytic Transfusion Reactions by Implicated Antibody, FY2005 through FY2008

Antibody	FY05 No.	FY05 %	FY06 No.	FY06 %	FY07 No.	FY07 %	FY08 No.	FY08 %	Total No.	Total %
ABO	6	27%	3	25%	3	60%	10	59%	22	39%
Multiple Antibodies*	6	27%	4	33%	1	20%	1	6%	12	21%
Jk^b	3	14%	0	0%	0	0%	2	12%	5	9%
Other**	3	14%	0	0%	0	0%	0	0%	3	5%
Kell	1	5%	1	8%	0	0%	2	12%	4	7%
Jk^a	1	5%	1	8%	1	20%	0	0%	3	5%
Fy^a	0	0%	1	8%	0	0%	2	12%	3	5%
Fy^b	0	0%	1	8%	0	0%	0	0%	1	2%
E	1	5%	0	0%	0	0%	0	0%	1	2%
I	1	5%	0	0%	0	0%	0	0%	1	2%
Js^a	0	0%	1	8%	0	0%	0	0%	1	2%
Totals	22	100%	12	100%	5	100%	17	100%	56	100%

*FY2005 antibody combinations included E+c, Fy^a+K, Fy^a+Jk^b, E+I+A_1, possible C+E+K; Wr^a+warm autoantibody.
*FY2006 antibody combinations included E+c, S+K, Jk^b+cold agglutinin, unidentified auto- and alloantibodies.
*FY2007: anti-M+C
*FY2008: anti-C+K+Fy^b+S+N+V+Js^a+Go^a+warm autoantibody.
**FY2005: Includes one report of non-immune hemolysis, one report of an unidentified antibody to a low incidence antigen, and one report of Cold Agglutinin Syndrome due to *Mycoplasma pneumonia* or Lymphoma.

Figure 3: Hemolytic Transfusion Reactions, FY2001 through FY2008



In FY2008, there were ten reports of fatal hemolytic transfusion reactions due to ABO-incompatible blood transfusions:

- 5 cases: recipient identification error at the time of transfusion
- 1 case: blood bank clerical error (incorrect sample used for testing)
- 3 cases: sample collected from incorrect patient[12]
- 1 case: transfusion of high-titer anti-B in group O Apheresis Platelets following group B bone marrow transplant

[12] MacIvor D, Triulzi DJ. Enhanced detection of blood bank sample collection errors with a centralized patient database. Transfusion 2009;49:40-43.

D. Microbial Infection

In FY2008, there were 7 reported fatalities attributed to microbial infection compared with reports of 6 in FY2007, 7 in FY2006, and 8 in FY2005. Two different bacteria were implicated in two fatalities, and five other fatalities resulted from Babesia transmission following Red Blood Cell transfusions from donors who subsequently tested positive for Babesia. The babesiosis cases accounted for 71% (5/7) of the microbial infections associated with transfusion fatalities in FY2008, as compared to 50% (3/6) in FY2007, 29% (2/7) in FY2006, and none reported in FY2005. Babesia accounted for 36% (10/28) of reported cases over the last four fiscal years, followed by *Staphylococcus aureus*, which accounted for 18% (5/28) (Table 4).

After seven years with no reported deaths due to transfusion-transmitted Babesiosis, CBER received reports of 10 transfusion-transmitted Babesiosis deaths during the four-year reporting period. For additional information, see the CBER article published in January 2009 describing fatal Babesiosis cases received by CBER from 1997-2007.[13]

There was one strict anaerobe, *Eubacterium limosum,* implicated in a fatal bacterial infection during the 4-year reporting period; this fatality occurred in FY2005. The remaining bacteria are facultative anaerobes.

Since FY2006, the number of reports of fatal microbial infections associated with apheresis platelets has remained unchanged (Figure 4). This finding is consistent with an overall decrease in the number of bacterial infections associated with apheresis platelets since FY2001 (Figure 5).

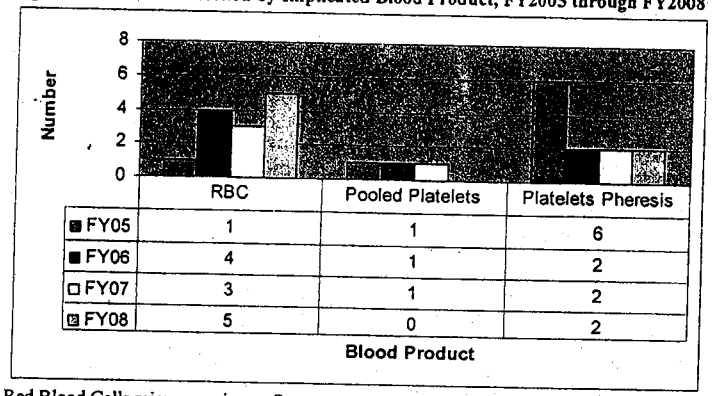
Table 4: Microbial Infection by Implicated Organism, FY2005 through FY2008

Organism	FY05	FY05	FY06	FY06	FY07	FY07	FY08	FY08	Total	Total
	No.	%	No.	%	No.	%	No.	%	No.	%
*Babesia**	0	0%	2	29%	3	50%	5*	63%	10	36%
Staphylococcus aureus	3	37%	0	0%	1	17%	1	13%	5	18%
Escherichia coli	0	0%	3	43%	0	0%	0	0%	3	11%
Serratia marcescens	2	24%	0	0%	0	0%	0	0%	2	7%
Staphylococcus epidermidis	1	13%	0	0%	0	0%	1	13%	2	7%
Staphylococcus lugdunensis	1	13%	0	0%	0	0%	0	0%	1	4%
Eubacterium limosum	1	13%	0	0%	0	0%	0	0%	1	4%
Morganella morganii	0	0%	1	14%	0	0%	0	0%	1	4%
Yersinia enterocolitica	0	0%	1	14%	0	0%	0	0%	1	4%
Group C Streptococcus	0	0%	0	0%	1	17%	0	0%	1	4%
Klebsiella oxytoca	0	0%	0	0%	1	17%	0	0%	1	4%
Total	8	100%	7	100%	6	100%	7	100%	28	100%

*Four *Babesia microti* and one probable *Babesia MO-1* species

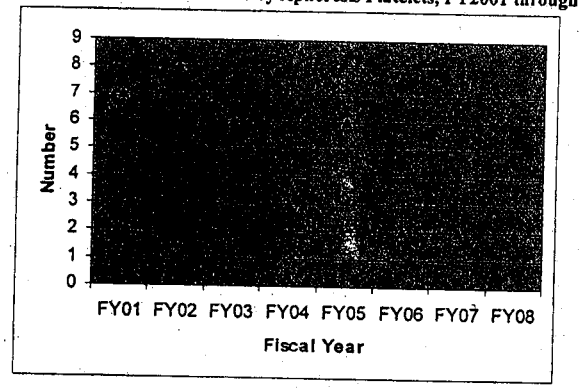
[13] Gubernot DM, Lucey CT, Lee KC et al. *Babesia* Infection through Blood Transfusions: Reports Received by the US Food and Drug Administration, 1997-2007. Clin Infect Dis 2009;48:000-000, electronically published, 26 November 2008.

Figure 4: Microbial Infection by Implicated Blood Product, FY2005 through FY2008



Red Blood Cells microorganisms: *S. marcescens (1), E. coli (1), Y. enterocolitica (1), B. microti (9), B. MO1(1)*
Pooled Platelets microorganisms: *S. aureus (1), E. coli (1), Streptococcus dysgalactiae (1)*
Platelets Pheresis microorganisms: *S. aureus (4), S. marcescens (1), S. lugdunensis (1), S. epidermidis (2), E. limosum (1), E. coli (1), M. morganii (1), K. oxytoca (1)*

Figure 5: Bacterial Infection by Apheresis Platelets, FY2001 through FY2008



E. Transfusion Not Ruled Out as Cause of Fatality

In these reported fatalities, the reporting facilities were unable to identify a specific complication of transfusion as the cause of death. Often, these patients had multiple co-morbidities, and after review of the investigation documentation, our medical reviewers could neither confirm nor rule out the transfusion as the cause of the fatality (Table 5). We did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

Combining the transfusion related fatalities with those that our medical officers could not rule out, there was a decrease in total reported fatalities from 63 in FY2007 to 55 in FY2008.

F. Not Transfusion Related

After reviewing the initial fatality reports and the investigation documentation, we categorized a number of reported fatalities as "Not Transfusion Related." Our medical reviewers concluded that, while there was a temporal relationship between transfusion and subsequent death of the recipient, there was no evidence to support a causal relationship (Table 5). Thus, we did not include these reported fatalities in the analysis in Sections II.A through II.D (transfusion-related fatalities), above.

Table 5: Fatalities Not Related to Transfusion or Transfusion Not Ruled Out, FY2005 through FY2008

	FY05	FY06	FY07	FY08
Not Transfusion Related	21	8	13	18
Not Ruled Out	14	10	11	8
Totals	35	18	24	26

G. Post-Donation Fatalities

There was a small decrease in FY2008 in the number of reported fatalities following Source Plasma donation, and one fatality following donation of Apheresis Red Blood Cells (Table 6). In all of these cases, our medical reviewers concluded that, while there was a temporal link between the donations and the fatalities, there was no evidence to support a causal relationship between the donations and subsequent death of the donors.

In FY2008, we received reports of two fatalities following Whole Blood donation collected by manual methods. In both cases, our medical reviewers found no evidence to support a causal relationship between the donation and subsequent death of the donor.

Table 6: Post-Donation Fatality Reports by Donated Product, FY2005 through FY2008

Donated Product	FY05	FY06	FY07	FY08
Source Plasma	2	10	13	7
Whole Blood	6	4*	2**	2
Apheresis Platelets	0	0	2	0
Apheresis Red Blood Cells	0	0	0	1
Total	8	14	17	10

*Includes 2 autologous donations
**Autologous donations