別紙様式第２－１

医薬品　研究報告　調査報告書

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<tr><td>識別番号・報告回数</td><td colspan="2"></td><td>報告日</td><td>第一報入手日
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該当なし</td><td>機構処理欄</td></tr>
<tr><td>一般的名称</td><td colspan="2">ﾃｸﾈﾁｳﾑ大凝集人血清ｱﾙﾌﾞﾐﾝ（99mTc）</td><td rowspan="2">研究報告の公表状況</td><td rowspan="2">Reuters News 26 Feb 2005</td><td>公表国

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<tr><td>販売名（企業名）</td><td colspan="2">テクネMAAキット（第一RI）</td></tr>
<tr><td>研究報告の概要</td><td colspan="6">これまで人間では感染が確認されていなかった2種類のヒトTリンパ球向性ウィルスが日常的にサルを狩猟している人々から分離された。これらのウィルスは既知のHTLV-1、HTLV-2ウィルスと近縁のウィルスであり、これらのウィルスは白血病や炎症、神経疾患をきたす。HIVの起源は人類以外の霊長類ウィルスが種を超えて感染したと考えられており、またこれらウィルスの潜伏期間は数十年にわたるため、感染拡大につながるおそれもあるとの報告。</td><td>使用上の注意記載状況・その他参考事項等

特になし</td></tr>
<tr><td colspan="4">報告企業の意見</td><td colspan="3">今後の対応</td><td></td></tr>
<tr><td colspan="4">サルウィルスがヒトに感染した場合、ヒトからヒトへ血液、性行為、母子感染等で伝播し、感染拡大につながる可能性があり、また、HTLVウィルス類は潜伏期間が長いことからもすでに広範囲に感染している可能性もあるとの報告であり、重大な新規の感染症に関する報告と判断する。</td><td colspan="3">本報告は、人において新規のウィルスが確認されたとの報告であり、感染の結果、人においてどのような症状を呈するかについては、未だ明らかになっておらず、現時点で、当該生物由来製品に関し、措置を行う必要はないと判断致します。今後も関連情報の収集に努める所存です。</td><td></td></tr>
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New virus may have come from monkeys, experts say

26 Feb 2005 00:45:10 GMT
Source: Reuters

By Maggie Fox, Health and Science Correspondent

WASHINGTON, Feb 25 (Reuters) - Two new retroviruses never before seen in humans have turned up among people who regularly hunt monkeys in Cameroon, researchers reported on Friday.

Like the AIDS virus, these viruses insert their genetic material directly into cells and perhaps even into a person's or animal's chromosomes. Closely related versions of the viruses cause leukemia, inflammatory and neurological diseases.

The two new viruses are called human T-lymphotropic virus types 3 and 4 or HTLV-3 and HTLV-4. They are closely related to two known viruses called HTLV-1 and HTLV-2, which experts believe were transmitted to people, like HIV, from monkeys and apes.

"Because HIV originated as a cross-species infection from a non-human primate virus, the question was how much cross-species retrovirus infections are occurring and what are the consequences of these infections," said Walid Heneine of the U.S. Centers for Disease Control and Prevention, who led the study.

They examined blood samples from 930 Cameroonians who had handled or eaten bush meat -- monkeys or apes hunted for food.

They used antibody screening and genetic analysis to find at least six different simian retroviruses had infected 13 of the people.

"Two hunters were infected with two previously unknown HTLV viruses. One person was infected with HTLV-3, which is genetically similar to a simian virus, STLV-3, and represents the first documented human infection with this virus," the researchers told the 12th Annual Retrovirus Conference being held in Boston.

"The second hunter was infected with HTLV-4, a virus distinct from all previously known human or simian T-lymphotropic viruses."

"It's totally new so we don't know any other simian virus that is related to it," Heneine said in a telephone interview.

Now the team, which includes researchers at Johns Hopkins University in Baltimore, plans to look more extensively in Central Africa for the virus, Heneine said. "They could be more widespread than we think they are," he said.

Heneine said up to 25 million people globally are infected with HTLV-1 and 2.

Currently, specialized tests are needed to find the viruses, he said.

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"It's a new virus. You pause, you say, where is this virus coming from. I don't think you should be taking it lightly," Hemeine said.

After infecting one person, simian viruses often spread from person to person through sex, mother-to-child transmission, and other exchanges of blood and body fluids.

Like HIV, the incubation period for HTLV viruses to cause disease can last decades, the CDC said.

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医薬品　研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
一般的名称	－		研究報告の公表状況	Transfusion 2004;44:1695-9.	公表国 米国	
販売名（企業名）	－					

研究報告の概要	使用上の注意記載状況・その他参考事項等
米国では血液の WNV スクリーニング法として、2 タイプの核酸増幅法 (NAT) で、6 人又は 16 人のミニプール (MP) 検査を実施し、陽性であった場合は個別テスト (IDT) を行う。IDT 対象となった献血者は少なくとも 4 週間は献血を中止し、当該血液の他、検査前 28 日以内の血液成分製剤は廃棄処分としている。 本稿では、6 人 MP-NAT 陰性血液の輸血により WNV 脳炎を発症した 80 歳男性について報告する。 手術時に 26 人に由来する 26 ユニット (赤血球 8、新鮮凍結血漿 6、血小板 12) の血液成分製剤を受血し、その 15 日後に精神錯乱をきたし、2 日間発熱を認め WNV 脳炎が疑われたため、血清および脳脊髄液を採取し検査したところ、WNV 特異抗体 (IgM) を検出した。 この 26 人の血液からは 41 ユニットの血液成分製剤が製造され、その内、検査可能な容量が保存されていた 13 検体について 2 種類の PCR 法を行った結果、1 検体で陽性反応が見られ、12 検体は陰性であった。 筆者らは、この 26 例中 24 例から follow-up 検体を入手し、WNV 特異抗体 (IgM) を検査した結果、NAT 陽性であった 1 例と他の 2 例が陽性であった。問題となった献血者は、WNV 感染症の症状はまったく認められず、WNV RNA 濃度は MP-NAT 検出限界以下にあったと考えられる。 今回の調査で MP-NAT 陰性血液の輸血による WNV 伝播が示唆されたが、手術前の血液検体がなく、蚊の刺咬も除外できなかった。無徴候性の WNV 感染症にある献血者が多数認められることから、より高感度の WNV-NAT 検査法を採用し、WNV 感染症の罹患率が高い地区では IDT 検査を採用するといった対策が必要と思われる。 献血血液スクリーニングを目的とした WNV NAT によって輸血感染リスクは低減化されてきたが、MP-NAT では低ウイルス価の献血者が検出されない可能性が残されている。	

報告企業の意見	今後の対応
MP-NAT 陰性血液の輸血による WNV 伝播に関する報告である。血漿分画製剤での感染伝播の報告はなく、製造工程中にウイルスの不活化除去を目的とした工程を設けているが、今後とも関連情報に注意していく。	今後とも WNV に関連する情報の収集に努めていく。

TRANSFUSION COMPLICATIONS

West Nile virus blood transfusion-related infection despite nucleic acid testing

Alexandre Macedo de Oliveira, Brady D. Beecham, Susan P. Montgomery, Robert S. Lanciotti, Jeffrey M. Linnen, Cristina Giachetti, Larry A. Pietrelli, Susan L. Stramer, and Thomas J. Safranek

BACKGROUND: A case of West Nile virus (WNV) encephalitis associated with transfusion of blood that did not react when tested for WNV by minipool (MP) nucleic acid testing (NAT) is described. A Nebraska man developed clinical encephalitis 13 days after surgery and transfusion of 26 blood components. Antibody testing confirmed WNV infection. An investigation was initiated to determine the source of this infection.

STUDY DESIGN AND METHODS: The patient's family members were interviewed to identify risk factors for WNV infection. Residual samples were retested for WNV RNA using transcription-mediated amplification (TMA) assay and two polymerase chain reaction (PCR) assays. Blood donors' follow-up serum samples were collected. All samples were tested for WNV-specific immunoglobulin M antibodies.

RESULTS: The patient's family denied recent mosquito exposure. The 20 blood components collected after July 2003 did not react when tested for WNV in a six-member MP-NAT at the time of donation. Retrospective individual testing identified one sample as WNV-reactive by the TMA assay and one of the PCR assays. Seroconversion was demonstrated in the donor associated with this sample.

CONCLUSION: WNV RNA detection by individual donation NAT demonstrates viremic blood escaping MP-NAT and supports transfusion-related WNV transmission. MP-NAT may not detect all WNV-infected blood donors, allowing WNV transmission to continue at low levels. WNV NAT assays might vary in sensitivity and pooling donations could further impact test performance. Understanding MP NAT limitations can improve strategies to maintain safety of the blood supply in the United States.

West Nile virus (WNV), a mosquito-borne flavivirus, was initially seen in the US in 1999 and first reported among Nebraska residents in 2002.[1,2] Humans serve as incidental hosts, and most infections are asymptomatic; approximately 30 percent of infections result in a non-neuroinvasive disease known as West Nile fever, and less than 1 percent of infected individuals develop severe diseases such as meningitis and/or encephalitis.[3-5] In the US, a total of 9862 human cases of WNV disease were reported in 45 states and the District of Columbia in 2003. Nebraska reported more than 1900 human WNV cases in 2003, ranking second only to Colorado.[6] Blood transfusion-related transmission of WNV infection during the 2002 US epidemic prompted rapid development of two investigational nucleic acid testing (NAT) assays to screen donated blood for WNV viremia: the TaqScreen WNV test (Roche

ABBREVIATIONS: IDT = individual donation testing; IND = investigational new drug; MP(s) = minipool(s); PRNT = plaque reduction neutralization test; SLE = St Louis encephalitis; WNV = West Nile virus.

From the Epidemic Intelligence Service, Division of Applied Public Health Training, Epidemiology Program Office, Centers for Disease Control and Prevention, Atlanta, Georgia; the Office of Epidemiology, Nebraska Health and Human Services System, Lincoln, Nebraska; the Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Fort Collins, Colorado; Gen-Probe Inc., San Diego, California; Roche Molecular Systems Inc., Pleasanton, California; and the American Red Cross, Gaithersburg, Maryland.

Address reprint requests to: Thomas J. Safranek, Nebraska Health and Human Services, 301 Centennial Mall South, PO Box 95007, Lincoln, NE 68509-5007; e-mail: tom.safranek@hhss.state.ne.us.

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TRANSFUSION 2004;44:1695-1699.

Molecular Systems Inc., Pleasanton, CA) and the Procleix WNV assay (Gen-Probe Inc., San Diego, CA).[7,8] (Use of trade names is for identification purposes only and does not constitute endorsement by the US Public Health Service or the Centers for Disease Control and Prevention [CDC].) The tests were implemented between June and August 2003.[9,10] Because of automation constraints, the tests are performed with minipools (MPs) of either six (TaqScreen assay) or 16 (Procleix assay) donations. A limited number of blood centers have the capacity to routinely screen by individual donation testing (IDT); in addition, some programs converted to IDT for limited periods during the 2003 epidemic. Donated blood from reactive pools is individually retested to identify the WNV-reactive donation. Donors associated with WNV-reactive individual tests are deferred from donation for at least 4 weeks. The WNV-reactive donation and any of that donor's unexpired blood components obtained in the 28 days before the reactive tests are discarded. In this report, we describe the investigation of a patient who developed WNV encephalitis after receiving blood that had did not react with NAT for WNV in a six-member MP.

CASE REPORT

On August 4, 2003, an 80-year-old Nebraska man underwent open-heart surgery. During surgery, the patient received 26 blood components because of massive bleeding: 8 units of red blood cells, 6 units of fresh frozen plasma (FFP), 2 units of single-donor platelets (PLTs), and 10 units of random-donor PLTs. The patient recovered and was discharged to home 10 days later.

On August 19, 2003, 15 days after transfusion, the patient was rehospitalized after experiencing mental confusion and fever for 2 days. The patient's condition worsened, and he was placed on ventilatory support for 3 weeks. His condition gradually improved, and he was subsequently transferred to a rehabilitation facility.

WNV encephalitis was suspected, and serum and cerebrospinal fluid were collected during the second hospitalization. These tested positive for the presence of WNV-specific immunoglobulin M (IgM) antibodies at the Nebraska Public Health Laboratory (Table 1).

On September 10, 2003, 37 days after transfusion, a convalescent serum sample was collected from the patient. This sample tested positive for the presence of WNV by WNV-specific IgM enzyme-linked immunosorbent assay (ELISA) and WNV plaque reduction neutralization test (PRNT) and negative for the presence of St Louis encephalitis (SLE) by PRNT at the CDC (Table 1).

Upon receipt of the first positive WNV IgM test, the hospital infection-control practitioners notified the Office of Epidemiology at the Nebraska Health and Human Services System and an investigation was launched to determine the source of this infection.

MATERIALS AND METHODS

Family members of the infected patient were interviewed in August 2003 to evaluate the potential for mosquito exposure after surgery. In addition, all transfused blood components were identified and traced to their donors. Residual samples from the donation testing tubes and unused co-components were located and stored frozen (-20°C). Implicated donors were interviewed about symptoms consistent with WNV infection, and a follow-up blood sample was collected in September 2003.

Quarantined residual samples were tested individually for the presence of WNV RNA with three different laboratory tests: the two investigational assays used for WNV blood donor screening and an in-house assay. The tests were a transcription-mediated amplification assay (Procleix WNV assay, Gen-Probe Inc.) and two different dynamic quantitative polymerase chain reaction (PCR) assays: TaqScreen WNV test (Roche Molecular Systems Inc.) and an in-house PCR (CDC, Fort Collins, CO).[11-13] Reactive specimens were further tested with the commercial assays: 10 replicates with undiluted samples and 10

TABLE 1. Laboratory tests performed on the index patient at time of readmission and convalescence, Nebraska, 2003

Laboratory study	Collection date	Result	Normal values
Hemoglobin (g/100 mL)	8/20/2003	11	13.5-17.0
WBC count (x10^3 cells/mm^3)	8/20/2003	9	4-10
Differential (%)			
Neutrophils		57	40-80
Lymphocytes		39	20-45
Monocytes		3	0-10
Eosinophils		1	0-7
Basophils		0	0-2
Serum			
Glucose (mg/dL)	8/20/2003	103	65-120
Protein (g/dL)	8/20/2003	6.1	6.0-8.3
CSF*			
Glucose (mg/dL)	8/20/2003	58	<105
Protein (mg/dL)	8/20/2003	98.4	<42
WBC count (cells/mm^3)	8/20/2003	155	<3
Mononuclear (%)		39	
Segmented neutrophils (%)		61	
Arbovirus studies			
WNV IgM (serum)	8/20/2003	Positive	Negative
WNV IgM (CSF)	8/20/2003	Positive	Negative
WNV IgM (serum)	9/10/2003	Positive	Negative
WNV PRNT	9/10/2003	Positive	Negative
SLE PRNT	9/10/2003	Negative	Negative

* CSF = cerebrospinal fluid.

with MP-dilution levels (1:6 for the TaqScreen assay and 1:16 for the Procleix assay). Viral load of reactive specimens was determined by quantitative PCR (SuperQuant for WNV, National Genetics Institute, Los Angeles, CA) and through dilutional studies at CDC and Gen-Probe Inc.

Residual samples from donations and follow-up samples were tested with WNV IgM antibody-capture ELISA. WNV infection was confirmed with PRNT for WNV and SLE.[14]

RESULTS

Exposure assessment

Family members denied recent mosquito exposure, reporting that the patient was hospitalized or bedridden at home during the 2 weeks before symptom onset. The infected patient received 26 blood components from 26 different donors. These donations generated 41 additional blood components: 18 were transfused to other patients, 17 were quarantined, and 6 were discarded before our investigation began.

Six of the 26 donations took place in February 2003 and had no residual samples available at the time of investigation. The remaining 20 donations were made in July and August 2003. Thirteen of these had approximately 200 mL of quarantined FFP available for testing; the other 7 had approximately 2 mL of serum remaining.

Results from donations

The CDC PCR, the investigational TaqScreen assay, and the investigational Procleix assay were all carried out on the 13 high-volume specimens by the developers of each test. One specimen reacted by the Procleix assay, equivocal by the CDC PCR, and did not react by the TaqScreen assay. A subsequent CDC PCR assay with an increased RNA extraction volume reacted. The viral load in this sample was estimated to be 560 copies per mL by the SuperQuant assay and 40 and 30 copies per mL by CDC and Gen-Probe Inc., respectively. Replicate results with the Procleix assay showed reactivity in all 10 replicates with undiluted samples and in 3 of 10 at 1:16 dilution. The TaqScreen assay exhibited reactivity in 5 of 10 and 2 of 10 replicates at undiluted and 1:6-diluted samples, respectively. This donation generated 1 unit of PLTs, which was transfused to the index patient. The other 12 high-volume samples did not react in all NAT assays.

The seven 2-mL specimens were aliquotted and sent to CDC and the other test developers' laboratories. They all did not react by the CDC PCR and the Procleix assay. Volume was insufficient for the TaqScreen assay.

WNV-specific IgM was negative for all 20 donations that had residual samples available for testing. Test results are shown in Table 2.

Donor follow-up

We obtained follow-up samples from 24 of the 26 donors in mid-September 2003 and tested these for WNV-specific IgM antibodies. The median interval between donation and follow-up sample collection was 44 days (range, 38-219 days). The donor associated with the NAT-positive sample (Donor A) and two other donors tested positive for IgM antibodies (Table 2). Confirmatory PRNT tests were positive for the presence of WNV and negative for the presence of SLE on these three samples. These three donors denied WNV symptoms during the 30 days before and after donation.

Blood co-components from WNV-specific IgM-positive donors

The two additional blood components derived from Donor A's donation were not transfused. Units from the other two IgM-positive donors were transfused to two other patients. Both recipients were asymptomatic for WNV. One tested negative for the presence of WNV IgM, and the other declined testing.

TABLE 2. Test results obtained on donated blood and follow-up samples for the 26 donors, Nebraska, 2003

	Original donation				Follow-up sample		
Donor	WNV IgM	CDC PCR	Procleix assay	TaqScreen assay	WNV IgM	WNV PRNT	SLE PRNT
A	Negative	Reactive*	Reactive	Did not react	Positive	Positive	Negative
B	Negative	Did not react	Did not react	Did not react	Positive	Positive	Negative
C	Negative	Did not react	Did not react	NA†	Positive	Positive	Negative
D-M	Negative	Did not react	Did not react	Did not react	Negative	NA	NA
N	Negative	Did not react	Did not react	Did not react	NA	NA	NA
O-T	Negative	Did not react	Did not react	NA	Negative	NA	NA
U-Y‡	NA	NA	NA	NA	Negative	NA	NA
Z‡	NA	NA	NA	NA	NA	NA	NA

* Test performed using high extraction volume.
† NA = not available.
‡ Donations from February 2003.

DISCUSSION

This investigation describes a patient with WNV encephalitis acquired through transfusion of WNV viremic blood that went undetected by MP-NAT screening but reacted for WNV by IDT. Our conclusion is supported by the detection of WNV RNA in one of the donations, followed by seroconversion in the corresponding donor. The implicated donor never developed symptomatic WNV infection. WNV RNA likely was present at levels below the detection limit of the MP format.

Although this investigation suggests WNV blood transfusion-related infection, it has three main limitations. First, the infected patient could have contracted WNV before surgery. Because no presurgical samples from the infected patient were available for testing, excluding existing infection was impossible. Second, it was not possible to rule out mosquito exposure as the mode of transmission. The patient denied symptoms before surgery, however, and his convalescent condition kept him hospitalized or indoors at home, making this other source of infection unlikely. Finally, because two other seroconversions were documented among these donors, we cannot exclude the possibility of an alternate-source donor. Recipients of co-components, however, from donated blood from the seroconverters did not experience WNV symptoms, nor was WNV RNA identified in residual samples from their donations. The high incidence of WNV infection in Nebraska during summer 2003 makes it possible that these persons were infected after donating blood.

Although the six donations from February 2003 were not available for NAT, these donations occurred before WNV was circulating in Nebraska. In addition, follow-up samples from five of these donors were negative for the presence of WNV-specific IgM antibodies, making them an unlikely source of infection.

WNV blood transfusion-related infections were first described during the 2002 epidemic.[7,8] To minimize this risk, the Food and Drug Administration (FDA) recommended deferring donors reporting fever with headache in the week before donation.[15] In addition to the clinical screening, beginning June 2003, NAT was introduced as a blood-screening tool with protocols conducted under FDA's investigational new drug (IND) mechanisms.[9,10] Recognizing technology and resource constraints, the IND protocols allowed for blood donation screening in MPs of 6 (TaqScreen assay) or 16 (Procleix assay) members. Pooling donations may reduce assay sensitivity and increase the possibility of missing donors with low-level viremia.

In this report, the six-member MP TaqScreen assay performed on the donations did not react, and the blood products were released for use in accordance with the IND protocol. A patient developed WNV encephalitis 13 days after transfusion with these products, a time frame compatible with WNV's incubation period. Residual samples from these donations were subsequently retested at three laboratories. For one donation, samples tested with replicate tests inconsistently reacted by the TaqScreen assay but reacted by the Procleix assay. Viral quantitation of that sample detected low levels of WNV RNA, although variability among quantitative results was observed. Dilutional testing showed that the MP format compromised test performance compared with IDT. The replicate testing also indicated that differences in sensitivity might exist between the investigational NAT assays. Further evaluation is necessary to confirm these conclusions.

The timely development of WNV NAT and its implementation under the IND mechanism are the result of an extraordinary effort by commercial laboratories, CDC, FDA, and the blood-collection community to enhance the safety of the blood supply in the US. In 2003, a total of 818 US blood donations were identified as "presumed viremic," which is defined as repeat reactivity on the same or on a different NAT assay.[16] The high number of viremic donors with asymptomatic WNV infection highlights the need for highly sensitive WNV-specific NAT to ensure blood supply safety. In addition, strategies such as the implementation of IDT in regions with high WNV infection rates should be considered.

NAT for human immunodeficiency virus-1 and hepatitis C virus has improved the identification of infected donors and is universally performed by the US blood industry, although it has been demonstrated to be cost-ineffective by traditional expenditure versus benefit estimates for medical interventions.[17-19] NAT could be cost-effective for WNV screening of the blood supply, because seasonal incidence is high in certain geographic areas, infection is asymptomatic in more than 80 percent of cases, and long periods of viremia can occur.[20,21]

WNV can be effectively transmitted through blood transfusions. The burden of WNV blood transfusion-related disease is probably underestimated owing to the low rate of symptomatic disease among recipients and the difficulty in establishing blood transfusion as the source of WNV infection.[8] The presence of infectious WNV in donated blood necessitates the application of viral detection testing such as NAT. Additional studies are needed to define the sensitivity of current NAT assays, their ability to detect low-level viremic donations, and their cost-effectiveness. This would allow optimization of testing protocols.

Emerging infectious diseases pose risks to blood safety.[22] Health-care workers and public-health authorities should maintain surveillance for the possibility of WNV and other arboviral transmission through blood transfusions. The development and implementation of WNV NAT for blood screening has contributed to a decreased risk of blood-borne transmission in the US. Nevertheless, low-viremic donors may go undetected by MP-NAT.

ACKNOWLEDGMENTS

We are indebted to Michael P. Busch, MD, PhD, Blood Systems Research Institute, San Francisco, California, for his assistance in facilitating laboratory testing. We thank Amy Broulik and Stephanie Miller, both from Gen-Probe Inc., and Lawrence Cheng, from Roche Molecular Systems Inc., for their excellent technical assistance.

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