別紙様式第 2-1

番号 32

# 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 | 厚生労働省処理欄 |
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| 一般的名称 | インターフェロンα-2b<br>(遺伝子組換え) | 研究報告の公表状況 | ProMED 情報<br>記事番号:20040409-0050<br>Apr. 7, 2004 | 公表国<br>米国 | |
| 販売名(企業名) | イントロン A(シェリング・プラウ(株)) | | | | |

| 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 |
|---|---|
| 献血および輸血スクリーニング検査、2003 年ー米国:<br>献血血液での西ナイルウイルスサーベイランスと輸血に関係した感染伝播について記載されている。(米国、2003 年)<br><br>番号 31 と同一情報 | なし |

| 報告企業の意見 | 今後の対応 |
|---|---|
| 本報告は、輸血が原因と考える感染報告であるが、本製品への汚染を示す報告ではなかった。 | 今後とも継続的な情報収集および評価検討を行う。 |

# ProMED情報(詳細)

| | |
|---|---|
| 記事番号 | 20040409-0050 |
| 重要度 | C |
| タイトル | PROWest Nile virus update 2004 - USA (03) |
| 感染症名 | |
| 主症状 | |
| 日付 | 0004/04/07 |
| 流行国 | 米国 |
| 和訳概要 | ウエストナイルウイルス、最新状況2004年-米国(03)#<br>目次:<br>[1]鳥類-カリフォルニア州。<br>[2]サーベイランスデータ-フロリダ州。<br>[3]献血および輸血スクリーニング検査、2003年-米国:MMWR。<br>[1]鳥類-カリフォルニア州、情報源:The Sacramento Bee、4月3日。<br>州南部でウエストナイルウイルス陽性のカラスが確認された。<br>カリフォルニア州南部にて、死亡した野鳥3羽でウエストナイルウイルスが検出されたと、州保健局が発表した。ウエストナイルウイルスは、4月1日にSan Gabriel Valleyで採取された死亡したカラス1羽と、3月31日にOrange郡で採取されたフィンチ(ヒワ・アトリ類)2羽で確認された。<br>州保健局責任者は、「この州のサーベイランスシステムは、州内のウエストナイルウイルス活動性を厳密にモニターしている」と述べた。<br>今年はまだヒト患者からウエストナイルウイルスは検出されていない。<br>[2]サーベイランスデータ-フロリダ州、投稿者:Walter J Tabachnick, PhD。<br>フロリダ州での状況とデータ解釈についてのコメント。<br>ProMED-mail記事を疫学的な解釈に使用する際には細心の注意が必要である。<br>すべての受動的データ採集システムでそうであるように、ProMED-mailに送付されるデータは不完全である。<br>ウエストナイルウイルス陽性野鳥と感染検知用ニワトリは、2001年7月3日に州内で初のウエストナイルウイルス感染野鳥が確認されて以来、毎月採集されている。フロリダ州全域から州保健局が集めたサーベイランス情報はウェブサイトで確認できる。<br>http://www.doh.state.fl.us/Environment/hsee/arbo/surv_info.htm。<br>[3]献血および輸血スクリーニング検査、2003年-米国:MMWR、2004年; 53(13): 281-4、4月9日。<br>献血血液でのウエストナイルウイルスサーベイランスと輸血に関係した感染伝播-米国、2003年。<br>2002年に輸血を介したウエストナイルウイルス感染伝播(TAT、輸血に関係した感染伝播)が、米国内の血液供給に新たな脅威となった。ウエストナイルウイルス感染伝播においては、媒介蚊による感染伝播が主要な感染経路ではあるが、TATが確認されたことから、献血された血液でのウエストナイルウイルススクリーニングの必要性が強調された。2003年6月に各血液銀行(BCAs)は、全献血血液をスクリーニングし、隔離・回収すべき潜在的に感染性を帯びた献血血液を特定するため、調査ウエストナイルウイルス核酸増幅検査(NATs)を実施した。この際のスクリーニングでは、2003年6月～12月の間に、血液約600万単位に関して実施され、少なくとも818件のウイルス血症のある献血血液を除去するという結果となった。この報告では、2003年に実施された献血血液スクリーニング結果を要約し、血液の輸血された分画に現行の検査では検出できない少量のウイルスが含まれていたため発生したウエストナイルウイルスTAT事例6件を記述する。こうしたデータからは、ウエストナイルウイルスに対するスクリーニングが血液製剤の安全性を高めたことが示された。しかし、輸血に関係したウエストナイルウイルス感染伝播のわずかな危険性は残る。この危険性に取り組むため、2004年にはスクリーニング戦略の変更が計画されている。<br>以下、項目表題のみ訳す。<br>血液銀行(BCAs)検査活動内容。<br>サーベイランス活動内容。<br>輸血に関係したウエストナイルウイルス感染伝播調査。<br>MMWR編集部注釈: |

情報詳細【和文】

ウエストナイルウイルス、最新状況2004年-米国(03)#
目次:
[1]鳥類-カリフォルニア州。

[2]サーベイランスデータ-フロリダ州。
[3]献血および輸血スクリーニング検査、2003年-米国:MMWR。
[1]鳥類-カリフォルニア州、情報源:The Sacramento Bee、4月3日。
州南部でウエストナイルウイルス陽性のカラスが確認された。
カリフォルニア州南部にて、死亡した野鳥3羽でウエストナイルウイルスが検出されたと、州保健局が発表した。ウエストナイルウイルスは、4月1日にSan Gabriel Valleyで採取された死亡したカラス1羽と、3月31日にOrange郡で採取されたフィンチ(ヒワ・アトリ類)2羽で確認された。
州保健局責任者は、「この州のサーベイランスシステムは、州内のウエストナイルウイルス活動性を厳密にモニターしている」と述べた。
今年はまだヒト患者からウエストナイルウイルスは検出されていない。
[2]サーベイランスデータ-フロリダ州、投稿者:Walter J Tabachnick, PhD。
フロリダ州での状況とデータ解釈についてのコメント。
ProMED-mail記事を疫学的な解釈に使用する際には細心の注意が必要である。
すべての受動的データ採集システムでそうであるように、ProMED-mailに送付されるデータは不完全である。ウエストナイルウイルス陽性野鳥と感染検知用ニワトリは、2001年7月3日に州内で初のウエストナイルウイルス感染野鳥が確認されて以来、毎月採集されている。フロリダ州全域から州保健局が集めたサーベイランス情報はウェブサイトで確認できる。
http://www.doh.state.fl.us/Environment/hsee/arbo/surv_info.htm。
[3]献血および輸血スクリーニング検査、2003年-米国:MMWR、2004年; 53(13): 281-4、4月9日。
献血血液でのウエストナイルウイルスサーベイランスと輸血に関係した感染伝播-米国、2003年。
2002年に輸血を介したウエストナイルウイルス感染伝播(TAT、輸血に関係した感染伝播)が、米国内の血液供給に新たな脅威となった。ウエストナイルウイルス感染伝播においては、媒介蚊による感染伝播が主要な感染経路ではあるが、TATが確認されたことから、献血された血液でのウエストナイルウイルススクリーニングの必要性が強調された。2003年6月に各血液銀行(BC[illegible]は、全献血血液をスクリーニングし、隔離・回収すべき潜在的に感染性を帯びた献血血液を特定するため、調査ウエストナイルウイルス核酸増幅検査(NATs)を実施した。この際のスクリーニングでは、2003年6月～12月の間に、血液約600万単位に関して実施され、少なくとも818件のウイルス血症のある献血血液を除去するという結果となった。この報告では、2003年に実施された献血血液スクリーニング結果を要約し、血液の輸血された分画に現行の検査では検出できない少量のウイルスが含まれていたため発生したウエストナイルウイルスTAT事例6件を記述する。こうしたデータからは、ウエストナイルウイルスに対するスクリーニングが血液製剤の安全性を高めたことが示された。しかし、輸血に関係したウエストナイルウイルス感染伝播のわずかな危険性は残る。この危険性に取り組むため、2004年にはスクリーニング戦略の変更が計画されている。
以下、項目表題のみ訳す。
血液銀行(BCAs)検査活動内容。
サーベイランス活動内容。
輸血に関係したウエストナイルウイルス感染伝播調査。
MMWR編集部注釈:

情報詳細【英文】

Return-Path: <mlist@promed.isid.harvard.edu>
Received: from qvg1.forth.go.jp (promed.isid.harvard.edu [134.174.190.40])
by qmail1.forth.go.jp (Post.Office MTA v3.6.2 release 110
ID# 1002-391U1000L100S0V36J) with ESMTP id jp;
Fri, 9 Apr 2004 08:31:02 +0900
Received: from promed.isid.harvard.edu(134.174.190.40) by qvg1.forth.go.jp via csmap
id 76bcc254_8a01_11d8_8f7a_00304827aeac_6239;
Fri, 09 Apr 2004 08:39:52 +0000 (UTC)
Received: from localhost (daemon@localhost)
by promed.harvard.edu (8.9.3+Sun/8.9.3) with SMTP id TAA03402;
Thu, 8 Apr 2004 19:31:59 -0400 (EDT)
Received: by promed.harvard.edu (pmm_mailer v1.12); Thu, 8 Apr 2004 19:07:27 -0400
Received: (from majordom@localhost)
by promed.harvard.edu (8.9.3+Sun/8.9.3) id TAA12274;
Thu, 8 Apr 2004 19:07:23 -0400 (EDT)
Date: Thu, 8 Apr 2004 19:07:23 -0400 (EDT)
Message-Id: <200404082307.TAA12274@promed.harvard.edu>
To: promed-ahead-edr@promedmail.org
From: ProMED-mail <promed@promed.isid.harvard.edu>
Subject: PRO/AH/EDR> West Nile virus update 2004 - USA (03)
X-ProMED-Id: 20040408.0958
Sender: owner-promed-ahead-edr@promed.isid.harvard.edu
Precedence: bulk
WEST NILE VIRUS UPDATE 2004 - USA (03)
**********
A ProMED-mail post

<http://www.promedmail.org>
ProMED-mail is a program of the
International Society for Infectious Diseases
<http://www.isid.org>
In this update:
[1] Birds - (California)
[2] Surveillance data - (Florida)
[3] Blood donation and transfusion screening 2003 - USA : MMWR update
******
[1] Birds - (California)
Date: 3 Apr 2004
From: ProMED-mail <promed@promedmail.org>
Source: The Sacramento Bee, Sat 3 Apr 2004 [edited]
<http://www.sacbee.com/content/news/story/8732331p-9659844c.html>
California: West Nile virus positive crow found in south of state

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West Nile virus has been detected in 3 dead birds in Southern California, the state Department of Health Services has announced. The virus was found in a dead crow in the San Gabriel Valley on Thu 1 Apr 2004 and in 2 local house finches in Orange County on Wed 31 Apr 2004 [already reported in previous ProMED-mail posts].
"West Nile virus has been detected earlier than expected in 2004, probably due to unseasonably warm weather," state health director Sandra Shewry said in a prepared statement. "The state's surveillance system is closely monitoring for any evidence of the virus across the state."
The virus has not yet been detected in humans in 2004. During 2003, 3 people, all from Southern California, tested positive for the virus.
California is one of the last states to be affected; in 2003 the virus was linked to 9389 illnesses and 246 deaths in 46 states.
[byline: Dorsey Griffith]
******
[2] Surveillance data - (Florida)
Date: Sun 4 Apr 2004
From: Walter J Tabachnick, PhD <WJT@mail.ifas.ufl.edu>
Situation in Florida and a comment on data interpretation

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"In a preceding update [see: West Nile virus update 2004 - USA (01) 20040401.0885] the moderator commented that: "It may be indicative of the characteristics of the impending outbreak in 2004 that the first reports have originated from the south (Texas) and the west coast (California)". These may indeed be the 1st reports sent to ProMED-mail. However, clearly ProMED-mail reports should be used to interpreting (sic) epidemiology with great caution. Like any passive data collecting system, the information sent voluntarily to ProMED-mail is likely incomplete. West Nile virus-positive wild birds and sentinel chickens have continually been detected in Florida every month since the 1st West Nile virus-infected bird was detected in Florida on 3 Jul 2001. Florida surveillance information collected by the Florida Department of Health from throughout the state can be viewed at <http://www.doh.state.fl.us/Environment/hsee/arbo/surv_info.htm>. The "1st" reports of positive birds may not provide any useful information about the characteristics of a presumed 2004 impending outbreak in humans, if indeed such an outbreak does occur. Florida has continuing evidence of year-long West Nile virus transmission with relatively few human cases to date. Of course this could change and is of great concern. Florida continues to monitor West Nile virus transmission using a sentinel surveillance system."
—
Walter J Tabachnick, PhD
Director, Florida Medical Entomology Laboratory
Professor of Entomology and Nematology
University of Florida - IFAS
200 9th St, SE
Vero Beach, FL 32962
<WJT@mail.ifas.ufl.edu>
[We are very aware of the dangers of over-interpreting reports received by

ProMED-mail — hence my comment was prefaced by the phrase "....may be indicative....". It is only recently, however, that ArboNET and Health Canada have compiled and released comprehensive surveillance data for North America. Even so, trends are difficult to analyse with certainty, because surveillance data are recorded at state or provincial level, and practice and commitment are variable. For example some states/provinces ceased to report data after the first appearance of West Nile virus at county level (whereas others did not), which makes direct comparison of numerical data problematic. During 2003, West Nile virus infection appeared to spread westwards, leaving a much diminished epidemic toward the east. (To what extent reporting fatigue in the east and the novelty of the situation in the west contributed to this situation is difficult to access.) - Mod.CP]
******
[3] Blood donation and transfusion screening 2003 - USA : MMWR update
Date: Thu 8 Apr 2004
From: ProMED-mail <promed@promedmail.org>
Source: Morb Mortal Wkly Rep 2004; 53(13): 281-4, Fri 9 Apr [edited]
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5313a1.htm>
Update: West Nile virus screening of blood donations and transfusion-associated transmission — United States, 2003

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In 2002, transfusion-associated transmission (TAT) of West Nile virus (WNV) infection acquired through blood transfusion marked the emergence of a new threat to the US blood supply (1). Although mosquitoborne transmission remains the predominant mode of WNV transmission (2), identification of TAT underscored the need for WNV screening of donated blood. In June 2003, blood-collection agencies.(BCAs) implemented investigational WNV nucleic acid-amplification tests (NATs) to screen all blood donations and identify potentially infectious donations for quarantine and retrieval. This screening was performed on about 6 million units during June to December 2003, resulting in the removal of at least 818 viremic blood donations from the blood supply. This report summarizes the results of blood-donation screening tests conducted during 2003 and describes 6 cases of WNV TAT that occurred because of transfusion of components containing low levels of virus not detected by the testing algorithm. These data indicate that blood screening for WNV has improved blood safety. However, a small risk of WNV transfusion-associated transmission remains. To address this risk, changes to screening strategies are planned for 2004.
BCA testing activities

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In June 2003, under the Food and Drug Administration's (FDA) investigational new drug (IND) mechanism, BCAs began screening donations by using NATs from 2 test-kit manufacturers. Initial screening protocols included NAT performed on mini-pools (MP NAT) of samples from 6 or 16 donations, depending on the test-kit manufacturer. Donation samples that were part of reactive mini-pools were tested individually. Any reactive samples were re-tested by individual donation testing (IDT NAT). In certain cases, an alternate sample from the same donation or an alternate NAT might have been used for re-testing. In addition, selected blood banks serving areas with epidemic activity stopped using this MP NAT screening algorithm and implemented IDT NAT screening during limited periods of the epidemic season. Donors of IDT NAT-reactive samples identified by either screening method were asked to participate in a BCA-directed follow-up study to confirm WNV infection and evaluate for the persistence of WNV RNA in blood samples collected subsequently. Both follow-up samples and the index-donation samples were tested for WNV-specific IgM antibody. Donations that were IDT NAT-reactive were not released for transfusion; these donors were deferred from donating blood again until >28 days after the date of collection for the last NAT-reactive sample and the documented development of WNV-specific antibody.
To determine the sensitivity of the MP NAT-screening algorithm, certain BCAs performed retrospective testing studies in selected areas that experienced high rates of viremic donations. In these studies, individual components of archived MP NAT-negative donation samples were re-tested by IDT NAT.

Surveillance activities

For surveillance purposes, a donation that was repeatedly reactive on IDT NAT was considered to be from a presumptive viremic donor (PVD). Cooperating local blood centers provided reports of PVDs (including donor age, sex, postal code, and date of donation) to state health departments, which provided reports to ArboNET, the national arbovirus surveillance system. As of 31 Mar 2004, state and local health departments had reported 818 PVDs to ArboNET; dates of collection ranged from 25 Jun to 2 Dec 2003 [data presented as a figure in the original text]. Complete information was available for 811 (99 per cent) of these PVDs; 6 (1 per cent) had West Nile viral encephalitis or meningitis subsequent to donation (median age: 45 years, range: 28 to 76), 137 (17 per cent) had West Nile fever (median age: 46 years, range: 17 to 76), and 654 (81 per cent) remained asymptomatic. Of the PVDs reported to ArboNET, 691 (85 per cent) were residents of 9 states (Colorado, Kansas, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming). These states experienced WNV epidemics in 2003 and accounted for 60 per cent of reported cases of West Nile viral encephalitis or meningitis.

WNV transfusion-associated transmission investigations

Since 2002, public health authorities have been encouraged to investigate reports of WNV illness among patients who had received blood transfusions <4 weeks before illness onset and to report these suspected TAT cases to CDC. A probable TAT was defined as transfusion to a recipient who 1) had a confirmed WNV infection (3) and 2) had received a blood product from a NAT-reactive index donation associated with a donor with WNV-specific IgM antibody in the index donation or a follow-up collection. A confirmed TAT case was defined as meeting the criteria for a probable case and having any one of the following criteria: 1) Unlikely mosquito exposure during the 14 days before recipient illness onset; 2) testing of remaining diagnostic samples from the hospitalized transfusion recipient indicating that WNV infection occurred at the time of transfusion; or 3) transfusion of a co-component of the infectious donation into another recipient who then had a confirmed WNV infection. A case was classified as a non-case if WNV infection could not be confirmed in the recipient <4 weeks after the implicated transfusions, if WNV RNA was not identified in any implicated donation, or if all implicated donors were seronegative for WNV. If samples were not available to satisfy the criteria for probable, confirmed, or non-case classification, the case was considered inconclusive.

During 2003, a total of 23 suspected cases of WNV TAT were reported to CDC. Public health authorities reported 15 suspected cases of WNV TAT among patients who had WNV illness after receiving transfusions. Another 8 suspected cases were in recipients of components derived from low-level viremic donations that were identified during special retrospective studies of MP-negative blood retested with IDT NAT by 2 BCAs. Follow-up of these 8 cases was performed to determine whether WNV infection had resulted from the implicated transfusions. As a result of these 23 investigations, 6 cases were classified as confirmed or probable WNV TAT, 11 as non-cases, and 3 as inconclusive. As of 27 Mar 2004, 3 cases remained under investigation. In each of these 6 confirmed or probable cases, the recipient received components from multiple donations; however, only one infectious blood component was found in each case. All 6 of these infectious donations had been collected during the period 29 Jul to 18 Sep 2003, and were not identified in MP screening. The median age of the 6 recipients was 63 years (range: 13 to 82); 4 had WNV encephalitis, one had West Nile fever, and one critically ill patient did not have discernible WNV-compatible illness despite confirmed WNV infection. A sufficient index-donation sample was available to estimate the titer of the implicated donor's viremia in 4 of 6 cases: the median estimated viremia was 0.11 plaque-forming units per milliliter (pfu/mL) (range: 0.06 to 0.5 pfu/mL). 2 of these 6 cases were reported previously (4); a description of a 3rd case follows.

On 31 Aug 2003, a boy aged 13 years was admitted to a hospital with multiple injuries. On 1 Sep 2003, he received 3 units of packed red blood cells. On 9 Sep 2003, after hospital discharge, he had a maculopapular

rash. On 12 Sep 2003, he was readmitted to the hospital with fever, headache, vomiting, and diarrhea, consistent with West Nile fever; blood drawn on that day was positive for WNV-specific IgM antibody.
The 3 transfused blood units had been collected during the 2nd week of August 2003. No donors of this blood reported symptoms of WNV illness before or after donation. Samples from these donations were non-reactive for WNV RNA by MP NAT performed on 6-specimen mini-pools. All other components derived from these 3 donations were quarantined immediately; there were no co-component recipients. Recalled plasma samples from the 3 index donations were WNV IgM-negative. One donor seroconverted evidenced by development of WNV-specific IgM antibody in serum collected 50 days after donation. Recalled plasma from this donor was reactive when tested by IDT NAT. CDC confirmed results by using polymerase chain reaction; the estimated viral load was 0.09 pfu/mL. The recipient recovered without sequelae.
(Reported by: S Kleinman, MD, American Assoc of Blood Banks, Victoria, British Columbia, Canada. M Busch, MD, Blood Systems Research Institute, San Francisco, California. S Caglioti, Blood Systems Laboratories, Tempe, Arizona. SL Stramer, PhD, R Dodd, PhD, American Red Cross, Gaithersburg, Maryland. DM Strong, PhD, Puget Sound Blood Center, Seattle, Washington. W Dickey, MD, Belle Bonfils Memorial Blood Center, Denver, Colorado. B Salvidar, MS, M Gilchrist, PhD, Univ of Iowa Hygienic Laboratory, Iowa City; S Brend, MPH, Iowa Dept of Public Health. H Nakhasi, PhD, J Epstein, MD, J Goodman, MD, Center for Biologics Evaluation and Research, Food and Drug Administration. M Chamberland, MD, M Kuehnert, MD, Div of Viral and Rickettsial Diseases. L Petersen, MD, N Crall, A Marfin, MD, Div of Vector-Borne Infectious Diseases, National Center for Infectious Diseases; T Boo, MD, S.Montgomery, DVM, EIS officers, CDC.)
MMWR editorial note

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Previous studies have documented that an estimated 80 per cent of WNV-infected people remain asymptomatic but are believed to have viremia lasting a median of 6.5 days (5,6). Asymptomatic WNV-infected people with viremia probably represent the largest risk group of blood donors. Because symptom screening at the time of blood donation will not identify most viremic donors, screening by NAT was implemented rapidly to identify potentially infectious blood donations by detecting WNV RNA. Use of blood-donor screening for WNV by NAT under the IND mechanism has enhanced the safety of the blood supply. Despite this enhanced safety, documentation of the 6 WNV TAT cases in 2003 indicates that blood components containing low levels of virus might escape detection and that at least some of these might be infectious. Virus loads in infectious donations were considerably lower in 2003 than in 2002 (1). In 2002, the estimated viremia levels in implicated donations were 0.8 to 75 pfu/mL, compared with 0.06 to 0.5 pfu/mL for TAT cases during 2003. The reasons for this lower range are unclear, and the lower limit of donor viremia that can lead to transfusion-associated infection is unknown.
Data collected during 2003 will be considered by the blood supply community in collaboration with public health authorities when developing screening strategies for 2004, when widespread seasonal transmission of WNV is expected to continue. MP screening will continue to identify most persons who donate during the short viremic period, but prospective IDT might be implemented in regions with high WNV-infection rates (that is, high MP-screening--test yields). However, the capacity of laboratory equipment and personnel for performing IDT and the availability of reagents are limited, and the higher false-positive rate of IDT (compared with MP screening) could have a negative short-term impact on the availability of blood in these regions.
About 4.5 million people receive blood or blood products annually. Although people who need blood transfusions should be aware of the limited risk for WNV infection, the benefits of receiving needed transfusions outweigh the potential risk for WNV infection. In addition, blood donation poses no risk to the donor for acquiring WNV, and the US Public Health Service encourages blood donation. FDA, CDC, and the blood-collection community will continue to evaluate WNV-screening strategies to ensure blood safety.
References

(1) Pealer LN, Marfin AA, Petersen LR, et al. Transmission of West Nile virus through blood transfusion — United States, 2002. N Engl J Med 2003; 349: 1236-45.
(2) CDC. West Nile virus activity — United States, November 20-25, 2003. MMWR 2003; 52: 1160.
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別紙様式第２－１



# 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 | 厚生労働省処理欄 |
|---|---|---|---|---|---|---|
| 一般的名称 | 輸血用血液 | | 研究報告の公表状況 | MMWR 2004:53(13)281-284. | 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 |
|---|---|
| 2003年6月25日～12月2日の間に約600万ユニットに対し、ウエストナイルウイルス(WNV)の核酸増幅検査(NAT)スクリーニングが実施され、少なくとも818ユニットが除外された。<br>WNVを保有している可能性のある供血者818例のうち完全な情報が得られたのは811例で、そのうちの6例は供血後にウエストナイル脳炎又は髄膜炎を発症し、137例はウエストナイル熱を認めたが、654例は無症候であった。<br>2003年に、CDCに報告された輸血によるWNV感染が疑われた症例は23例で、供血後にWNV関連疾患を認めた患者からの輸血を受けた症例が15例、ミニプールNAT陰性で個別NATで低陽性血の受血者が8例であった。<br>この23例の追跡調査では、WNV輸血感染確定例又は疑い例が6例、非輸血感染例が11例、不明が3例で、3例が評価を継続中である。輸血感染確定又は疑い例の6例は、いずれも複数回受血していたが、WNV陽性血液は各々1回のみであった。このWNV陽性血液はいずれも、2003年7月29日～9月18日間に採血されたものであり、ミニプールNATでは確認されなかった。<br>この受血者6例のうち、4例はウエストナイル脳炎、1例はウエストナイル熱が認められたが、残る1例ではWNV感染が確定されたものの、WNVの症状は認められなかった。<br>今までの研究によれば、WNV感染者の約80％は無症候であり、その血中ウイルスは約6.5日持続するとされているので、これらの無症候感染者は最大リスクを伴う供血者群である。NATスクリーニングを適用することによって安全性が高められたが、輸血による感染例が6例報告されたことから低濃度の場合はすり抜ける可能性があり、それは感染性があることが示唆されたが、輸血感染を引き起こす血中ウイルス価の最低レベルは判明していない。<br>ミニプールNATは継続され、感染の多い地域では個別NATが適用される可能性があるが、偽陽性によって供給に影響が出る可能性もある。今後もスクリーニング法について継続的に評価する予定である。 | |

| 報告企業の意見 | 今後の対応 |
|---|---|
| 当社血漿分画製剤の製造工程には、複数のウイルス不活化又は除去工程を導入し、西ナイルウイルスと類似したウシ下痢症ウイルス(ＢＶＤＶ)を用いた不活化・除去効果を確認しているので、特段の対応は必要ないと考える。 | 今後もウイルス不活化等の安全対策に関する情報収集に努めていく。 |

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MMWR

*Weekly*

April 9, 2004 / 53(13);281-284

# Update: West Nile Virus Screening of Blood Donations and Transfusion-Associated Transmission — United States, 2003

In 2002, transfusion-associated transmission (TAT) of West Nile virus (WNV) infection acquired through blood transfusion marked the emergence of a new threat to the U.S. blood supply (*1*). Although mosquito-borne transmission remains the predominant mode of WNV transmission (*2*), identification of TAT underscored the need for WNV screening of donated blood. In June 2003, blood-collection agencies (BCAs) implemented investigational WNV nucleic acid–amplification tests (NATs) to screen all blood donations and identify potentially infectious donations for quarantine and retrieval. This screening was performed on approximately 6 million units during June–December 2003, resulting in the removal of at least 818 viremic blood donations from the blood supply. This report summarizes the results of blood-donation screening tests conducted during 2003 and describes six cases of WNV TAT that occurred because of transfusion of components containing low levels of virus not detected by the testing algorithm. These data indicate that blood screening for WNV has improved blood safety. However, a small risk of WNV transfusion-associated transmission remains. To address this risk, changes to screening strategies are planned for 2004.

### BCA Testing Activities

In June 2003, under the Food and Drug Administration's (FDA) investigational new drug (IND) mechanism, BCAs began screening donations by using NATs from two test-kit manufacturers. Initial screening protocols included NAT performed on mini-pools (MP NAT) of samples from six or 16 donations, depending on the test-kit manufacturer. Donation samples that were part of reactive mini-pools were tested individually. Any reactive samples were retested by individual donation testing (IDT NAT). In certain cases, an alternate sample from the same donation or an alternate NAT might have been used for retesting. In addition, selected blood banks serving areas with epidemic activity stopped using this MP NAT screening algorithm and implemented IDT NAT screening during limited periods of the epidemic season. Donors of IDT NAT–reactive samples identified by either screening method were asked to participate in a BCA-directed follow-up study to confirm WNV infection and evaluate for the persistence of WNV RNA in blood samples collected subsequently. Both follow-up samples and the index-donation samples were tested for WNV-specific IgM antibody. Donations that were IDT NAT–reactive were not released for transfusion; these donors were deferred from donating blood again until ≥28 days after the date of collection for the last NAT-reactive sample and the documented development of WNV-specific antibody.

To determine the sensitivity of the MP NAT–screening algorithm, certain BCAs performed retrospective testing studies in selected areas that experienced high rates of viremic donations. In these studies, individual components of archived MP NAT–negative donation samples were retested by IDT NAT.

### Surveillance Activities

For surveillance purposes, a donation that was repeatedly reactive on IDT NAT was considered to be from a presumptive viremic donor (PVD). Cooperating local blood centers provided reports of PVDs (including donor age, sex, postal code, and date of donation) to state health departments, which provided reports to ArboNET, the national arbovirus surveillance system.

As of March 31, 2004, state and local health departments had reported 818 PVDs to ArboNET; dates of collection ranged from June 25 to December 2, 2003 (Figure). Complete information was available for 811 (99%) of these PVDs; six (1%) had West Nile viral encephalitis or meningitis subsequent to donation (median age: 45 years, range: 28–76 years), 137 (17%) had West Nile fever (median age: 46 years, range: 17–78 years), and 654 (81%) remained asymptomatic. Of the PVDs reported to ArboNET, 691 (85%) were residents of nine states (Colorado, Kansas, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming). These states experienced WNV epidemics in 2003 and accounted for 60% of reported cases of West Nile viral encephalitis or meningitis.

### WNV Transfusion-Associated Transmission Investigations

Since 2002, public health authorities have been encouraged to investigate reports of WNV illness among patients who had received blood transfusions <4 weeks before illness onset and to report these suspected TAT cases to CDC. A probable TAT was defined as transfusion to a recipient who 1) had a confirmed WNV infection (*3*) and 2) had received a blood product from a NAT-reactive index donation associated with a donor with WNV-specific IgM antibody in the index donation or a follow-up collection. A confirmed TAT case was defined as meeting the criteria for a probable case and having any one of the following criteria: 1) unlikely mosquito exposure during the 14 days before recipient illness onset; 2) testing of remaining diagnostic samples from the hospitalized transfusion recipient indicating that WNV infection occurred at the time of transfusion; or 3) transfusion of a co-component of the infectious donation into another recipient who then had a confirmed WNV infection. A case was classified as a noncase if WNV infection could not be confirmed in the recipient <4 weeks after the implicated transfusions, if WNV RNA was not identified in any implicated donation, or if all implicated donors were seronegative for WNV. If samples were not available to satisfy the criteria for probable, confirmed, or noncase classification, the case was considered inconclusive.

During 2003, a total of 23 suspected cases of WNV TAT were reported to CDC. Public health authorities reported 15 suspected cases of WNV TAT among patients who had WNV illness after receiving transfusions. Another eight suspected cases were in recipients of components derived from low-level viremic donations that were identified during special retrospective studies of MP-negative blood retested with IDT NAT by two BCAs. Follow-up of these eight cases was performed to determine if WNV infection had resulted from the implicated transfusions. As a result of these 23 investigations, six cases were classified as confirmed or probable WNV TAT, 11 as noncases, and three as inconclusive. As of March 27, 2004, three cases remained under investigation.

In each of these six confirmed or probable cases, the recipient received components from multiple donations; however, only one infectious blood component was found in each case. All six of these infectious donations had been collected during July 29–September 18, 2003, and were not identified in MP screening. The median age of the six recipients was 63 years (range: 13–82 years); four had WNV encephalitis, one had West Nile fever, and one critically ill patient did not have discernible WNV-compatible illness despite confirmed WNV infection. A sufficient index-donation sample was available to estimate the titer of the implicated donor's viremia in four of six cases: the median estimated viremia was 0.11 plaque-forming units per milliliter (pfu/mL) (range: 0.06–0.5 pfu/mL). Two of these six cases were reported previously (*4*); a description of a third case follows.

On August 31, 2003, a male aged 13 years was admitted to a hospital with multiple injuries. On September 1, he received three units of packed red blood cells. On September 9, after hospital discharge, he had a maculopapular rash. On September 12, he was readmitted to the hospital with fever, headache, vomiting, and diarrhea, consistent with West Nile fever; blood drawn on that day was positive for WNV-specific IgM antibody.

The three transfused blood units had been collected during the second week of August 2003. No donors of this blood reported symptoms of WNV illness before or after donation. Samples from these donations were nonreactive for WNV RNA by MP NAT performed on six-specimen mini-pools. All other components derived from these three donations were quarantined immediately; there were no co-component recipients. Recalled plasma samples from the three index donations were WNV IgM negative. One donor seroconverted evidenced by development of WNV-specific IgM antibody in serum collected 50 days after donation. Recalled plasma from this donor was reactive when tested by IDT NAT. CDC confirmed results by using polymerase chain reaction; the estimated viral load was 0.09 pfu/mL. The recipient recovered without sequelae.

**Reported by:** *S Kleinman, MD, American Assoc of Blood Banks, Victoria, British Columbia, Canada. M Busch, MD, Blood Systems Research Institute, San Francisco, California. S Caglioti, Blood Systems Laboratories, Tempe, Arizona. SL Stramer, PhD, R Dodd, PhD, American Red Cross, Gaithersburg, Maryland. DM Strong, PhD, Puget Sound Blood Center, Seattle, Washington. W Dickey, MD, Belle Bonfils Memorial Blood Center, Denver, Colorado. B Salvidar, MS, M Gilchrist, PhD, Univ of Iowa Hygienic Laboratory, Iowa City; S Brend, MPH, Iowa Dept of Public Health. H Nakhasi, PhD, J Epstein, MD, J Goodman, MD, Center for Biologics Evaluation and Research, Food and Drug Administration. M Chamberland, MD, M Kuehnert, MD, Div of Viral and Rickettsial Diseases. L Petersen, MD, N Crall, A Martin, MD, Div of Vector-Borne Infectious Diseases, National Center for Infectious Diseases; T Boo, MD, S Montgomery, DVM, EIS officers, CDC.*

## Editorial Note:

Previous studies have documented that an estimated 80% of WNV-infected persons remain asymptomatic but are believed to have viremia lasting a median of 6.5 days (*5,6*). Asymptomatic WNV-infected persons with viremia likely represent the largest risk group of blood donors. Because symptom screening at the time of blood donation will not identify most viremic donors, screening by NAT was implemented rapidly to identify potentially infectious blood donations by detecting WNV RNA.

Use of blood-donor screening for WNV by NAT under the IND mechanism has enhanced the safety of the blood supply. Despite this enhanced safety, documentation of the six WNV TAT cases in 2003 indicates that blood components containing low levels of virus might escape detection and that at least some of these might be infectious. Virus loads in infectious donations were considerably lower in 2003 than in 2002 (*1*). In 2002, the estimated viremia levels in implicated donations were 0.8–75 pfu/mL, compared with 0.06–0.5 pfu/mL for TAT cases during 2003. The reasons for this lower range are unclear, and the lower limit of donor viremia that can lead to transfusion-associated infection is unknown.

Data collected during 2003 will be considered by the blood supply community in collaboration with public health authorities when developing screening strategies for 2004, when widespread seasonal transmission of WNV is expected to continue. MP screening will continue to identify most persons who donate during the short viremic period, but prospective IDT might be implemented in regions with high WNV-infection rates (i.e., high MP-screening–test yields). However, the capacity of laboratory equipment and personnel for performing IDT and the availability of reagents are limited, and the higher false-positive rate of IDT (compared with MP screening) could have a negative short-term impact on the availability of blood in these regions.

Approximately 4.5 million persons receive blood or blood products annually. Although persons needing blood transfusions should be aware of the limited risk for WNV infection, the benefits of receiving needed transfusions outweigh the potential risk for WNV infection. In addition, blood donation poses no risk to the donor for acquiring WNV, and the U.S. Public Health Service encourages blood donation. FDA, CDC, and the blood-collection community will continue to evaluate WNV-screening strategies to ensure blood safety.

**Acknowledgments**

This report is based in part on contributions by L Pietrelli, Roche Molecular Systems, Alameda, California. T Gahan, L DesJardin PhD, Univ of Iowa Hygienic Laboratory, Iowa City, Iowa. RS Lanciotti, PhD, A Lambert, A Noga, R Hochbein, Div of Vector-Borne Infectious Diseases, CDC.

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4. CDC. Update: Detection of West Nile virus in blood donations—United States, 2003. MMWR 2003;52:916–9.
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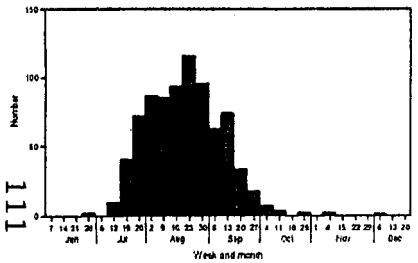
## Figure

**FIGURE. Number* of presumed West Nile–viremic blood donors, by week of donation — United States, 2003**




* N = 818.

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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 | 厚生労働省処理欄 |
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| 一般的名称 | － | | 研究報告の公表状況 | AABB Weekly Report 2004：10(26)12. | 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 |
|---|---|
| 英国のナショナルブラッドサービスは献血血液の西ナイルウイルス（WNV）に対する検査を開始した。このことにより、米国又はカナダへの旅行したドナーの保留をしていない。 以前は6月1日～11月30日の間にカナダまたは米国へ渡航していた供血者は英国に戻った後28日間保留されていたが、この制限は撤廃された。 | |

| 報告企業の意見 | 今後の対応 |
|---|---|
| 日本においては、薬食血発第0713001号(平成16年7月13日付)にて、海外からの帰国者は4週間の採血禁止期間を設ける旨が通知されている。<br>本報告による対応の必要はないと考える。 | 今後もWNVに関する規制情報等について、情報収集に努めていく。 |

stem cells, which form neurons and glial cells, in the same culture dishes with human endothelial cells, which form the lining of blood vessels. Over time, about 6 percent of the mouse neural stem cells began to show signs that they had developed into cells similar to endothelial cells. The new cells expressed CD146, Flk-1 and VE Cadherin, protein markers that are associated with endothelial cells. They also retained a single nucleus and had only mouse chromosomes, suggesting they had converted into a different type of cell rather than merged with an existing human endothelial cell. Similar results were seen when these same neural stem cells were transplanted into the brains of mice early in development. **Reference:** *Nature* 2004; 430:350 – 356, doi:10.1038/nature02604

## Health Care

**The number of new HIV infections among men who have sex with men (MSM) at public HIV-testing sites in San Francisco and Los Angeles did not increase during 1999–2002, a period when syphilis cases among MSM increased substantially in both cities,** according to the Center for Disease Control and Prevention (CDC). The stability of HIV infection rates may be due to the number of new syphilis cases being small compared with the numbers of MSM at risk for HIV infection, according to CDC's *Morbidity and Mortality Weekly Report.* The report also suggested that cases may not be increasing because MSM with primary or secondary syphilis had longstanding HIV infection before they acquired syphilis. "However, if the outbreaks of syphilis continue unabated, HIV incidence among MSM at public HIV-testing sites and in the larger MSM community might increase," CDC reported. "Recommendations include behavioral risk assessment, frequent sexually transmitted disease screening, and prompt treatment of syphilis in HIV-infected persons and their partners to control syphilis outbreaks and prevent a potential increase in HIV infections.

## International

**The United Kingdom's National Blood Service has begun testing donated blood for West Nile virus (WNV).** As a result, the service will no longer defer donors for travel to the United States or Canada. Previously, blood donors who had visited any part of Canada or the United States between June 1 and Nov. 30 were deferred from donating for 28 days after returning to the UK. These restrictions have been lifted.

## Industry

**Immucor, Inc. announced that Galileo has been cleared in Canada and Japan.** Galileo is Immucor's second generation, bidirectional, fully automated walk-away instrument for the hospital blood bank transfusion laboratory, donor centers and reference laboratories. It is already cleared for use in the United States.

**Philadelphia-based CorCell, Inc. and German based VITA 34, both cord blood banks, merged to form VITA 34 INTERNATIONAL AG, a new holding company headquartered in Leipzig, Germany.** CorCell and VITA 34 will continue to operate under their established brand names in their respective markets. Both companies are wholly owned subsidiaries of VITA 34 INTERNATIONAL AG. American operations will continue to be directed from the Philadelphia headquarters of CorCell.

## People

President George Bush has nominated General Services Administration's inspector general, **Daniel Levinson**, as the new HHS inspector general, the White House announced. Levinson previously served as chairman of the Merit Systems Protection Board, an agency that protects federal employees from partisan political practices and management abuses, and as general counsel to the Consumer Product Safety Commission and deputy counsel to the Office of Personnel Management. A certified fraud examiner, he also served as chief of staff for former **Rep. Bob Barr** (R-Ga). If confirmed by the Senate, Levinson will replace **Dara Corrigan**, who has served as acting chief deputy inspector general since the resignation of her predecessor, **Janet Rehnquist**, just over a year ago.


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別紙様式第 2-1

番号 15

# 医薬品　研究報告　調査報告書

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| 一般的名称 | インターフェロンα-2b<br>(遺伝子組換え) | 研究報告の公表状況 | CDC/MMWR<br>53(05); 103-105<br>Feb. 13, 2004 | 公表国<br>米国 | |
| 販売名(企業名) | イントロン A(シェリング・プラウ(株)) | | | | |

| 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 |
|---|---|
| 米軍人における天然痘ワクチンによる二次および三次感染ー米国内および世界、2002ー2004:<br>2002 年 1 月～2004 年までに 578,286 人の軍人が予防接種を受け、407,923 例が初接種であった。接種を受けた 30 例においてその配偶者(12 例)、性的接触者(8 例)、友人(8 例)、子供(2 例)が家庭内での接触感染が疑われた。このうち 18 例が PCR によりウイルスが確認され、この 18 例のうちの 16 例が単純皮膚感染、2 例が眼感染であった。18 例のうち 12 例が配偶者または成人の性的接触者であった。 | なし |

| 報告企業の意見 | 今後の対応 |
|---|---|
| 本報告は、二次および三次感染の報告であり、原材料血液による人への感染や本製品への汚染を示す報告ではなかった。 | 今後とも継続的な情報収集および評価検討を行う。 |

MMWR

*Weekly*

February 13, 2004 / 53(05);103-105

# Secondary and Tertiary Transfer of Vaccinia Virus Among U.S. Military Personnel --- United States and Worldwide, 2002--2004

In December 2002, the Department of Defense (DoD) began vaccinating military personnel as part of the pre-event vaccination program (*1*). Because vaccinia virus is present on the skin at the site of vaccination, it can spread to other parts of the body (i.e., autoinoculation) or to contacts of vaccinees (i.e., contact transfer). To prevent autoinoculation and contact transfer, DoD gave vaccinees printed information that focused on hand washing, covering the vaccination site, and limiting contact with infants (*1*,*2*). This report describes cases of contact transfer of vaccinia virus among vaccinated military personnel since December 2002; findings indicate that contact transfer of vaccinia virus is rare. Continued efforts are needed to educate vaccinees about the importance of proper vaccination-site care in preventing contact transmission, especially in household settings.

DoD conducts surveillance for vaccine-associated adverse events by using automated immunization registries, military communication channels, and the Vaccine Adverse Events Reporting System (VAERS). Contact transfer cases are defined as those in which vaccinia virus is confirmed by viral culture or polymerase chain reaction (PCR) assays. Other cases are classified as suspected on the basis of lesion description and reported linkage to a vaccinated person 3--9 days before lesion development.

During December 2002--January 2004, a total of 578,286 military personnel were vaccinated; 508,546 (88%) were male, and 407,923 (71%) were primary vaccinees (i.e., received smallpox vaccination for the first time). The median age of vaccinees was 29 years (range: 17--76 years). Among vaccinees, cases of suspected contact transfer of vaccinia were identified among 30 persons: 12 spouses, eight adult intimate contacts, eight adult friends, and two children in the same household. These cases were reported from Colorado (four), North Carolina (four), Texas (four), Alaska (two), California (two), Connecticut (one), Kansas (one), New Jersey (one), Ohio (one), South Carolina (one), Washington state (one), West Virginia (one), and overseas (seven). The sources of suspected contact transfer were all male service members who were primary vaccinees. Except for six male sports partners, all infected contacts were female.

Vaccinia virus was confirmed in 18 (60%) of the 30 cases by viral culture or PCR. Sixteen (89%) of the 18 confirmed cases involved uncomplicated infections of the skin; two (11%) involved the eye (*3*). None resulted in eczema vaccinatum or progressive vaccinia. Twelve (67%) of the 18 confirmed cases were among spouses or adult intimate contacts. The observed rate of contact transfer was 5.2 per 100,000 vaccinees overall or 7.4 per 100,000 primary vaccinees. Among 27,700 smallpox-vaccinated DoD health-care workers, no transmission of vaccinia from a vaccinated health-care worker to an unvaccinated patient or from a vaccinated patient to an unvaccinated health-care worker has been identified.

Two (11%) of the 18 confirmed cases of transfer of vaccinia virus resulted from tertiary transfer. One involved a service member, his wife, and their breastfed infant; the other involved serial transmission among male sports partners.

## Case Reports

**Case 1.** In early May 2003, a service member received his primary smallpox vaccination. Approximately 6--8 days after vaccination, he experienced a major reaction (i.e., an event that indicates a successful take; is characterized by a papule, vesicle, ulcer, or crusted lesion, surrounded by an area of induration; and usually results in a scar) (*4*). The vaccinee reported no substantial pruritus. He slept in the same bed as his wife and kept the vaccination site covered with bandages. After bathing, he reportedly dried the vaccination site with tissue, which he discarded into a trash receptacle. He also used separate towels to dry himself, rolled them so the area that dried his arm was inside, and placed them in a laundry container. His wife handled bed linen, soiled clothing, and towels; she reported that she did not see any obvious drainage on clothing or linen and had no direct contact with the vaccination site.

In mid-May, the wife had vesicular skin lesions on each breast near the areola but continued to breastfeed. Approximately 2 weeks later, she was examined at a local hospital, treated for mastitis, and continued to breastfeed. The same day, the infant had a vesicular lesion on the upper lip, followed by another lesion on the left cheek (*5*). Three days later, the infant was examined by a pediatrician, when another lesion was noted on her tongue. Because of possible early atopic dermatitis lesions on the infant's cheeks, contact vaccinia infection with increased risk for eczema vaccinatum was considered. The infant was transferred to a military referral medical center for further evaluation. On examination, the infant had seborrheic dermatitis and no ocular involvement. Skin lesion specimens from the mother and

infant tested positive for vaccinia by viral culture and PCR at the Alaska Health Department Laboratory and at Madigan Army Medical Center. Because both patients were stable clinically and the lesions were healing without risk for more serious complications, vaccinia immune globulin was not administered. Neither patient had systemic complications from the infection.

**Case 2.** In July 2003, a service member who had been vaccinated was wrestling with an unvaccinated service member at a military recreational function when the bandages covering the vaccination site fell off. The unvaccinated service member subsequently wrestled with another unvaccinated service member. Six days later, both unvaccinated service members had lesions on their forearms, neck, and face. Skin lesion specimens from both men tested positive for vaccinia virus by PCR and viral culture at Tripler Army Medical Center's microbiology laboratory.

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## Editorial Note:

The findings in this report indicate that the primary risk for secondary transfer of vaccinia was among persons who shared a bed; 12 of the 18 confirmed cases were spouses or adult intimate contacts. However, the majority of vaccinated DoD personnel who shared a be did not transfer vaccinia virus to their contacts. The frequency of contact transfer in the military vaccination program is comparable t rates observed during the 1960s, although persons are less likely to be immune to vaccinia today and thus are more susceptible to contact transfer (*1*).

The first case of tertiary transfer described in this report underscores the need for breastfeeding mothers with household contact with vaccinees to take precautions to prevent inadvertent transmission of vaccinia to their infants. Direct contact is presumed to be the major mode of transmission, but clothing and bed linen might act as vectors for secondary transmission. Tertiary transmission, although rare, is facilitated when the secondary infection is not recognized.

Programs that educate health-care workers, vaccinees, and contacts should note that new vesicles or pustules that appear <15 days after the vaccinia scab falls off from the vaccination site might be vaccinia infections. Although an infant living in the home is not a contraindication to vaccination of a family member in a nonoutbreak setting, measures to prevent transmission include having vaccinees launder their own linens and towels and change their bandages away from other household members.

During the 1960s, the rate of unintentional infection with vaccinia in secondary contacts was two to six cases per 100,000 primary vaccinees (*4,6,7*). During that period, two thirds of reported contact infections occurred among children, typically siblings. Such spread could manifest as an inadvertent infection or, in more severe fashion, as eczema vaccinatum or progressive vaccinia. Infections of the skin predominated, with rarer ocular involvement posing a risk for scarring or keratitis. In the current DoD smallpox vaccination program, no cases of eczema vaccinatum have occurred, although the population of atopic dermatitis patients might have increased substantially since the 1960s (*8*). During the 1960s, eczema vaccinatum resulted in deaths, and two thirds of such cases were related t contact transfer of vaccinia virus (*6*). In the current DoD smallpox vaccination program, careful screening of DoD vaccinees and their household contacts for skin diseases along with targeted education likely contributed to both screening out vaccine candidates with personal or close-contact contraindications and educating vaccinees about proper infection-control measures.

Health-care workers and the public should report suspected cases of contact transfer of vaccinia virus to their state or local health departments and to VAERS at http://www.vaers.org, or by telephone 800-822-7967. Viral culture or PCR assays, important for confirming vaccinia virus, are available from the majority of state public health laboratories.

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| 29-65 | 米AABB | Weekly News | HPを閲覧するには個別に会員登録をする必要があります。 | vCJD(ヒト), 血液 | AABB Weekly Report 2004年2月13日<br>研究者による輸血によるvCJD伝播の可能性の評価:<br>2月7日号のLancetに発表された2つの研究によると, 変異型クロイツフェルト・ヤコブ病(vCJD)は血液伝播の可能性がある。英国研究者による研究では英国患者が輸血によりvCJDに感染した可能性を示唆している。フランス研究者による研究ではサル(マカーク)でvCJDの静脈感染の試験を行ない, この経路による感染リスクが現在過小評価されている可能性が示された。両研究によってvCJD感染源の可能性としての輸血の公衆衛生との密接な関わりが強調され | | | |