HOME
Newsdesk
NGO Latest
EMERGENCIES
Africa
Americas
Asia
Europe
Middle East
COUNTRY PROFILES
Select a country
TOPICS
Select a topic
IMAGES
Reuters Pictures
NGO Photos
Satellite Images
Interactive Map
RESOURCES
NGO Directory
Jobs
Training
NGO SERVICES
Alerting
NGOs join here
Why join AlertNet?

AlertNet Challenge
Latest quiz...
GO

LOW GRAPHICS
GET WEEKLY EMAIL
ALERTING

WEEKLY APPEAL

Oxfam responds to the critical situation in locust-affected West Africa

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.

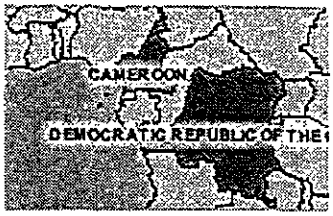
Currently, specialized tests are needed to find the viruses, he said.

Topics
- Health
- Technology
- HIV/AIDS

MC

Emergencies
- HIV/AIDS in Africa
- Central African conflicts
- Congo conflict

MC

Countries


RESET FULL-SIZE M
- Cameroon profile
  · View map
- Democratic Republic of Cor profile
  · View map

MC

NGO latest
- RWANDA/GACACA - GACA(HEARINGS TO START WITH "ACTION", SAYS OFFICIAL
  FH - Switzerland
- Hundreds feared dead in Afghanistan's harshest win for years
  Christian Aid - UK
- Ten years of humanity in Belarus
  IFRC - Switzerland
- Alarming health situation i DRC's Ituri camps as MSF resumes their relief activiti
  MSF International
- Vietnamese Boy Loses Leg: and Arm to War Era Bomb
  Clear Path International USA

MC

Latest news
- Japan food panel to meet Friday on mad cow disease
  Source: Reuters
- U.S. House panel backs $2

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

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。

使用上の注意記載状況・その他参考事項等

報告企業の意見	今後の対応
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。

5

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.

Received for publication April 9, 2004; revision received June 14, 2004, and accepted June 30, 2004.

TRANSFUSION 2004;44:1695-1699.

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.

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.

REFERENCES

1. Nash D, Mostashari F, Fine A, et al. The outbreak of West Nile virus infection in the New York City area in 1999. N Engl J Med 2001;344:1807-14.
2. West Nile virus activity—United States, August 21-28, 2002, and Illinois, January 1-August 27, 2002. MMWR Morb Mortal Wkly Rep 2002;51:764-6.
3. Petersen LR, Marfin AA. West Nile virus: a primer for the clinician. Ann Intern Med 2002;137:173-9.
4. Weiss D, Carr D, Kellachan J, et al. Clinical findings of West Nile virus infection in hospitalized patients, New York and New Jersey, 2000. Emerg Infect Dis 2001;7:654-8.
5. Chowers MY, Lang R, Nassar F, et al. Clinical characteristics of the West Nile virus fever outbreak, Israel, 2000. Emerg Infect Dis 2001;7:675-8.
6. 2003 West Nile virus activity in the United States (Internet). Atlanta: Centers for Disease Control and Prevention; 2004 [accessed 2004 Jun 2]. Available from: http://www.cdc.gov/ncidod/dvbid/westnile/surv&controlCaseCount03_detailed.htm
7. Harrington T, Kuehnert MJ, Kamel H, et al. West Nile virus infection transmitted by blood transfusion. Transfusion 2003;43:1018-22.
8. Pealer LN, Marfin AA, Petersen LR, et al. Transmission of West Nile virus through blood transfusion in the United States in 2002. N Engl J Med 2003;349:1236-45.
9. Detection of West Nile virus in blood donation—United States, 2003. MMWR Morb Mortal Wkly Rep 2003;52:769-72.
10. Blood centers begin implementing WNV donor screening tests. ABC Newslett 2003:1-3.
11. Linnen JM, Lewis M, Broulik A, et al. Procleix® WNV assay: a transcription-mediated amplification based assay for screening blood donations for West Nile virus RNA. Transfusion 2003;43S:129A.
12. Gallarda JL, Cheng L, Pai A, et al. Non-clinical performance of the Roche TaqScreen™ West Nile virus system. Transfusion 2003;43S:129A.
13. Lanciotti RS, Kerst AJ, Nasci RS, et al. Rapid detection of West Nile virus from human clinical specimens, field-collected mosquitoes, and avian samples by a TaqMan reverse transcriptase-PCR assay. J Clin Microbiol 2000;38:4066-71.
14. Martin DA, Muth DA, Brown T, et al. Standardization of immunoglobulin M capture enzyme-linked immunosorbent assays for routine diagnosis of arboviral infections. J Clin Microbiol 2000;38:1823-6.
15. Guidance for industry: revised recommendations for the assessment of donor suitability and blood and blood product safety in cases of known or suspected West Nile virus infection (Internet). Rockville (MD): Center for Biologics Evaluation and Research; 2003 [accessed 2003 Nov 1]. Available from: http://www.fda.gov/cber/gdlns/wnvguid.htm
16. Update: West Nile virus screening of blood donations and transfusion-associated transmission—United States, 2003. MMWR Morb Mortal Wkly Rep 2004;53:281-4.
17. Schreiber GB, Busch MP, Kleiman SH, et al. The risk of transfusion-transmitted viral infections. N Engl J Med 1996;334:1685-90.
18. Stramer SL. US NAT yield: where are we after 2 years? Transfus Med 2002;12:243-53.
19. Jackson BR, Busch MP, Stramer SL, Aubuchon JP. The cost-effectiveness of NAT for HIV, HCV, and HBV in whole-blood donations. Transfusion 2003;43:721-9.
20. Mostashari F, Bunning ML, Kitsutani PT, et al. Epidemic West Nile encephalitis, New York, 1999: results of a household-based seroepidemiological survey. Lancet 2001;358:261-4.
21. Biggerstaff BJ, Petersen LR. Estimated risk of West Nile virus transmission through blood transfusion during an epidemic in Queens, New York City. Transfusion 2002;42:1019-26.
22. Chamberland ME. Emerging infectious agents: do they pose a risk to the safety of transfused blood and blood products? Clin Infect Dis 2002;34:797-805.

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 2005 年 4 月 15 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	①ポリエチレングリコール処理抗破傷風人免疫グロブリン ②乾燥抗破傷風人免疫グロブリン	研究報告の公表状況	FDA/CBER, 20050414	公表国 アメリカ		
販売名 （企業名）	①テタノブリンーIH（ベネシス） ②テタノブリン（ベネシス）					

研究報告の概要

本ガイダンス案は 2003 年 5 月発行の最終ガイダンスの改訂版であり、輸血用血液製剤（全血、血液成分）および注射用又は非注射用製剤の製造に用いられる血液成分（回収血漿、原料白血球、並びに原料血漿を含む）に適用されるが、組織の採取業者又は人の血液以外の細胞及び組織には適用されない。

・主な変更点は次のとおり。

①供血禁止及び再登録

・供血前 1 週間以内に「発熱を伴った頭痛」がする血液ドナーを供血禁止とはしない（この項目は次回問診表から削除される）。

・WNV 感染又は WNV 感染の疑いがあると医学的に診断された血液ドナーは、診断時点又は発症時点のどちらか遅い方から 120 日間は供血禁止される。

・NAT により供血禁止された血液ドナーは、陽性のドネーションの 120 日以降、120 日の供血停止期間の間又は後に採取された追跡サンプルについて個別 NAT による再検査が陰性であれば再登録できる。

・追跡サンプルが個別 NAT 陽性であった血液ドナーは、その採血日から更に 120 日間は供血禁止される。2 回目の供血禁止された血液ドナーの再登録は、再登録前に個別 NAT が陰性でなければならない。

・追跡検査を行わない場合は、WNV NAT 陽性に基づいて供血停止されたドナーは無期限に供血禁止とし、将来の科学的データにより供血禁止期間が明白となるまでは保留とする。

・WNV シーズン中に供血後に他には説明できない WNV 感染を示唆する発熱を報告した血液ドナーは症状発生から 120 日間は供血禁止される。血液ドナーは、供血後 2 週間以内に起こった原因不明の WNV 感染を示唆する頭痛を伴う発熱又は他の症状を積極的に報告することが推奨される。

・当該供血日から 120 日後に個別 NAT 陰性に基づいて再登録されることを条件として、輸血後 WNV 伝播と潜在的関係がある血液ドナーは供血禁止される。

②有効期限内血液成分の回収及び隔離

・もし血液ドナーの WNV 感染の医療診断が後に報告されたなら、関係する供血からの有効期限内血液成分は速やかに回収及び隔離しなければならない。
関係する供血とは、WNV 発症の 14 日前から、WNV 診断時点又は発症時点のどちらか遅い方から 120 日間までの間の供血と定義される。

・もしレシピエントが発症前 120 日以内に血液ドナーからの血液製剤を受け、WNV 感染と診断されたなら、その血液ドナーは WNV 伝播に潜在的に関与していると考えられる。この供血からの関係する血液成分はすべて疑い有りとみなされる。疑い有りとされたドネーションの 120 日前と 120 後（120 日を含む）までの間に疑いドナーから収集された有効期限内血液成分は速やかに回収及び隔離しなければならない。

③輸血レシピエントへの通知

・もし血液ドナーの WNV 感染の医学的診断が後に報告されたなら、レシピエントへの通知を目的に採血所は、血液ドナーの発症 14 日前から発症後 120 日の全てのユニットについて記録の遡及調査を行わなければならない。

・特定の血液ドナーがレシピエントへの WNV 伝播源と考えられる場合には、輸血サービス、レシピエント、治療担当医師への通知のために採血所は、WNV 伝播が示唆されたドネーションの供血日前後 120 日間のすべてのユニットについての記録の遡及調査を行わなければならない。

使用上の注意記載状況・その他参考事項等

代表としてテタノブリンーIH の記載を示す。

2. 重要な基本的注意

(1) 本剤の原材料となる血液については、HBs 抗原、抗 HCV 抗体、抗 HIV-1 抗体、抗 HIV-2 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高力価の破傷風抗毒素を含有する血漿を原料として、Cohn の低温エタノール分画で得た画分からポリエチレングリコール 4000 処理、DEAE セファデックス処理等により抗破傷風人免疫グロブリンを濃縮・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濾過膜処理（ナノフィルトレーション）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。

医薬品
医薬部外品　　研究報告　調査報告書
化粧品

報告企業の意見	今後の対応	
米国でのWNV感染した血液ドナーにおけるFDAのガイダンスの改訂版である。 今回のガイダンス案では前回のガイダンスにおいて供血禁止とされた「発熱を伴った頭痛」を有するドナーは供血禁止とはされず、また一度供血禁止されたドナーの再登録には個別NAT陰性が確認されなければならないなどが変更されている。 FDAは、2003年5月の業界向けガイダンス改訂版において、「FDAは全ての血漿分画製剤について現在行われているウイルス低減工程を再調査した。現在行われている方法は、WNVと分類上関連しているフラビウイルスを不活化することがバリデートされている。」と評価し、CPMPもまたポジションステートメントにおいて、血漿分画製剤の製造工程でWNVは不活化・除去されると評価している。 弊社への米国の原料血漿供給元では、2003年6月よりWNVの問診を開始している。万一、原料血漿にWNVが混入したとしても、BVDをモデルウイルスとしたウイルスバリデーション試験成績から、本剤の製造工程において十分に不活化・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。	

Guidance for Industry

Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Additional copies of this draft guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance, contact Division of Blood Applications, Office of Blood Research and Review at 301-827-3524.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
April 2005

Contains Nonbinding Recommendations

Draft – Not for Implementation

Table of Contents

Contains Nonbinding Recommendations

Draft – Not for Implementation

Guidance for Industry

Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This draft guidance document provides revisions to our previously published final guidance entitled, "Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection," dated May 2003. Our current thinking is that these revised recommendations should be applied prospectively, i.e. that actions taken under previous guidance do not need to be reconsidered subject to the additional provisions of this guidance. This draft guidance revises the final West Nile Virus (WNV) guidance to add a recommendation to defer donors suspected of having WNV infection or diagnosed with WNV infection for 120 days after diagnosis or onset of illness, whichever is later. The guidance further recommends that donors be deferred on the basis of a reactive investigational screening test for WNV. At their discretion, blood establishments may reenter such donors after 120 days from the date of their reactive donation, provided that they are retested and found negative by individual donation testing (IDT NAT) for WNV on a follow-up sample obtained during or after the 120 day deferral period. If the follow-up sample is reactive for WNV, we, FDA, recommend that the donor be deferred for an additional 120 days from the date the sample was collected, and that the donor be retested and found negative by IDT NAT for WNV before reentry after the second deferral period. We recognize that follow-up testing by IDT NAT of donors deferred based on reactive NAT for WNV may not be feasible or practical at all blood centers. In cases where follow-up testing is not performed, we recommend that donors deferred on the basis of positive NAT for WNV remain deferred indefinitely, pending future scientific data to clarify the necessary period of deferral in the absence of further testing.

This draft guidance applies to Whole Blood and blood components intended for transfusion and blood components intended for use in further manufacturing into injectable products or non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma. Within this document, "donors" refers to donors of all such products and "you" refers to blood establishments. We use the term "WNV season" to mean either (a) May 1 to November 30, or