Europe [5,15]. Pregnant women, families with young children, older people, and those with significant comorbidity should be advised to consult their physician before travelling to the Indian subcontinent, and travellers should be informed about the magnitude of the risk of contracting the disease and decide according to their own judgment. There are no specific preventive medications or vaccines for chikungunya fever, but there are steps travellers can take to reduce risk of being bitten by infected mosquitoes [15]. Despite infecting millions of people worldwide, chikungunya infection has been neglected since its discovery. Worldwide, there are a number of other infections with mosquito-transmitted viruses (arboviruses) with similar symptoms which may be confused with chikungunya, such as Sindbis, Ross River and dengue, and these, together with a detailed travel history, should be considered in the differential diagnosis in returning travellers.

Considering high number of cases, and lack of specific antiviral therapy, it is imperative that specific antiviral agents and vaccine be developed. Although the disease is self-limiting, sustained and intensified control measures (such as regular fogging with pesticides, awareness of the disease and vector, detection and elimination of vector breeding sources, proper facilities for health care and community awareness about the prophylactic measures) are required to control the further spread of the disease. The government of India has taken up necessary steps, in accordance with the NVBDCP guidelines on reducing mosquito breeding sources, use of temephos larvicide in recommended doses, the release of larva-eating fish (*Gambusia*) into the wells and the water bodies to control the mosquito menace and deployment of mobile teams (three teams per district in the affected districts, consisting of epidemiologists, public health specialists, microbiologists and entomologists for assessment of the situation and providing technical assistance and guidelines) and mobilisation of health workers and volunteers [16,17]. Finally, measures to improve clinical management, especially early detection, nutritional support to the affected patients, and other preventive measures may largely mitigate the disease. The wider issues of ecology, current agricultural practices, water management systems, and human behaviour patterns will need to be reviewed. This requires a combination of strategies and we need to proceed with a sense of urgency in this matter.

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back to top

別紙様式第2-1

No. 13

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	機構処理欄
				2007. 1. 26	該当なし	

一般的名称	(製造承認書に記載なし)	研究報告の公表状況	毎日新聞. 2007 Jan 24.	公表国
販売名(企業名)	合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)			日本

研究報告の概要

○チクングニヤ熱:日本人女性が感染 国内で初確認

1月24日、厚生労働省はスリランカから帰国した30歳代の女性が、チクングニヤ熱に感染していたと発表した。国内で日本人の感染が確認されたのは初めてである。女性は2006年11月中旬、スリランカで発熱し、現地でチクングニヤ熱かデング熱と診断された。女性はすでに症状は回復し、在住するスリランカに戻っている。

厚労省によると、チクングニヤ熱は発熱や関節炎、発疹などが特徴で、死亡率は極めて低い。蚊を介して感染し、人から人への感染はない。

報告企業の意見	今後の対応
日本国内でスリランカから帰国した日本人のチクングニヤ感染が初めて確認されたとの報告である。	日本赤十字社では、輸血感染症対策として問診時に海外渡航歴の有無を確認し、帰国後4週間は献血不適としている。国内でチクングニヤ感染が確認されたため、渡航歴確認の徹底を図っている。また、チクングニヤ熱の既往歴がある場合、治癒後6ヵ月間は献血不適としている。今後も引き続き、新興・再興感染症の発生状況等に関する情報の収集に努める。

使用上の注意記載状況・その他参考事項等

合成血「日赤」
照射合成血「日赤」
合成血-LR「日赤」
照射合成血-LR「日赤」

血液を介するウイルス、細菌、原虫等の感染
vCJD等の伝播のリスク

3

チクングニヤ熱：日本人女性が感染 国内で初確認

厚生労働省は24日、スリランカから帰国した30歳代の女性が、チクングニヤ熱に感染していたと発表した。国内で日本人の感染が確認されたのは初めて。女性は昨年11月中旬、スリランカで発熱し、現地でチクングニヤ熱かデング熱と診断された。女性はすでに症状は回復し、在住するスリランカに戻っている。

厚労省によると、チクングニヤ熱は発熱や関節炎、発疹（はっしん）などが特徴で、死亡率は極めて低い。蚊を介して感染し、人から人への感染はない。【玉木達也】

毎日新聞 2007年1月24日 東京夕刊

別紙様式第2-1

No. 11

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	機構処理欄
				2007. 1. 24	該当なし	

一般的名称	(製造承認書に記載なし)	研究報告の公表状況	AABB Weekly Report. 2006 Dec 15; 1.	公表国
販売名(企業名)	合成血「日赤」(日本赤十字社) 照射合成血「日赤」(日本赤十字社) 合成血-LR「日赤」(日本赤十字社) 照射合成血-LR「日赤」(日本赤十字社)			米国

研究報告の概要

○FDAは最初のシャーガス病スクリーニング検査を認可;AABBは実施のためのガイダンスを整備

2006年12月13日、米国食品医薬品局(FDA)は、シャーガス病の病因であり、致死性感染を引き起こすおそれのある住血原虫Trypanosoma cruziを検出する新しい供血者スクリーニング検査試薬を認可したと発表した。認可されたOrtho T. cruzi ELISA Test Systemは、患者血清あるいは血漿中のT. cruzi抗体を検出する検査試薬で、この種の検査法としては初めてFDAから認可を受けた。供血者の他、臓器や細胞、組織提供者のスクリーニングに使用することも予定されている。

米国血液銀行協会(AABB)は、採血施設が検査導入とその期間を決定し、供血者と受血者のフォローアップのためのガイダンスを提供するのに役立つよう、協会公報#06-08を12月14日に発表した。具体的な勧告内容は、出荷停止、遡及調査、自己血輸血で繰り返し検査陽性となった場合の成分製剤出荷の認可、供血延期措置、通知、確認試験、供血者の医学的評価のための供血延期などの事項が盛り込まれている。

FDAによると、原虫感染が多い地域からの移民の増加によって、米国における輸血や臓器移植によるシャーガス病伝播の危険性は高まっている。AABBは協会公報中で、採血施設は検査導入の是非を決定する際に、採血地域内のメキシコや中南米から移住してきた人の割合を考慮すべきであると勧告している。

使用上の注意記載状況・その他参考事項等

合成血「日赤」
照射合成血「日赤」
合成血-LR「日赤」
照射合成血-LR「日赤」

血液を介するウイルス、細菌、原虫等の感染
vCJD等の伝播のリスク

報告企業の意見	今後の対応
FDAがシャーガス病の供血者スクリーニング検査試薬を初めて認可し、AABBが実施に備えガイダンスを発行したとの報告である。	日本赤十字社は、輸血感染症対策として献血時に海外渡航歴の有無を確認し、帰国後4週間は献血不適としている。また、シャーガス病の既往がある場合には献血不適としている。今後も引き続き情報の収集に努める。

Volume 12, Number 43
December 15, 2006

FDA Licenses First Chagas' Screening Test; AABB Offers Guidance for Potential Implementation

The Food and Drug Administration (FDA) announced Dec. 13 that it has granted a license for a new test to screen blood donors for the protozoan parasite *Trypanosoma cruzi*, a blood-borne parasite that causes Chagas' disease, a serious and potentially fatal infection. The screening test, Ortho *T. cruzi* ELISA Test System, detects the *T. cruzi* antibody in a sample of the donor's serum or plasma and is the first such test approved by FDA. In addition to screening people who donate blood, this test is intended for use in screening plasma and serum samples from organ, cell and tissue donors. According to the agency, the Ortho-Clinical Diagnostics test identifies infected donors and can help reduce the risk of disease transmission through blood transfusion or organ transplantation.

"The availability of this test offers an important new safety measure to protect recipients of blood, organs and tissues against a potentially very serious, though uncommon infection," said Jay Epstein, MD, director of the Office of Blood Research and Review in FDA's Center for Biologics Evaluation and Research (CBER).

AABB issued Association Bulletin #06-08 on Dec. 14 to help facilities determine whether to implement a licensed test and the time frame for implementation, as well as to provide guidance for donor and recipient follow-up. The specific recommendations address topics such as quarantine, lookback, and approval for release of components from autologous donors that test repeat reactive; donor deferral, notification, and confirmatory testing; as well as referral of donor for medical evaluation. The recommendations included in this bulletin were developed by the Chagas' Working Group, a subgroup of the AABB Transfusion-Transmitted Diseases Committee.

According to FDA, "concerns about the potential for transfusion and organ-transmitted Chagas' disease in the U.S. have heightened concern due to the increase in the number of U.S. residents who previously lived in countries where infection is common." The association bulletin

Inside *Weekly* ...

notes that the *T. cruzi* parasite is only found in the continental Americas, usually Latin America. The presence of the parasite in the U.S. and Canada is increasing, however, due to higher rates of immigration of individuals from endemic areas. As a result, AABB recommends in the association bulletin that facilities consider the percentage of people in their collection area who have immigrated from Mexico and Central and South America in determining whether to implement a licensed test.

Chagas' disease is typically a mild but chronic infection, usually without symptoms. As noted in the association bulletin, the lifetime risk of severe heart or intestinal problems in infected individuals averages about 30 percent and may occur many years after the initial infection. In some cases, however, infection may lead to organ damage, particularly of the heart and esophagus. Infection in immunocompromised individuals, such as those undergoing cancer therapy or receiving an organ transplant, can cause acute and life-threatening symptoms. Natural infections of Chagas' disease are transmitted mainly when the feces of an infected bug are rubbed into a bug bite, other wound, or directly into the eyes or mucous membranes. Other primary forms of transmission include congenital transmission, organ transplantation, blood transfusion and by ingestion of contaminated foods, although this is rare.

To view Association Bulletin #06-08 in its entirety, visit the AABB Web site at www.aabb.org under "Members Area > Association Bulletins."

AABB Urges FDA Panel to Say No to National Drug Codes for HCT/Ps

An FDA panel listened this week to concerns raised by professional associations, drug manufacturers, drug distributors, pharmacies and others about one portion of a proposed rule that seeks to make major changes to the National Drug Code (NDC) system, described in 21 CFR Part 207. The proposed rule, published Aug. 29, 2006, in the *Federal Register,* also expands the scope of products subject to NDC system requirements, adding licensed human cells, tissues, and cellular and tissue-based products (HCT/Ps) to the list of covered products.

For decades, FDA has required that each drug product listed with the agency have an NDC number — a unique 10-digit, three-segment number — that identifies the drug's labeler, the specific product and the package size. The drug's labeler, identified by the first number segment, is any firm that manufactures or distributes a drug. The second set of numbers, known as the product code, identifies a specific strength, dosage form and formulation for a particular firm. The third number segment, the package code, identifies package sizes and types. Currently, FDA assigns labeler codes, but labelers assign both the product and package codes.

If the proposed rule becomes final as written, however, FDA would assign *all* segments of the NDC. The agency believes that by taking control of assigning each of these numbers, it would be able to trace back every product to its manufacturer. Also, as the agency prepares to implement electronic listing of drugs, it hopes to avoid having duplicate NDC numbers, which could potentially be a problem once all of the numbers reside in one system.

In comments before the panel, critics of the NDC portion of the proposed rule indicated that waiting for FDA to assign NDC codes could create delays in providing consumers with access to new drugs. In addition, the new process, which also requires NDC numbers to be printed on product labels and to have different product codes when manufacturers change or when information changes, could create inefficiencies and add costs to manufacturers' processes. Heidi Horn, associate director of regulatory

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 2006年12月25日	新医薬品等の区分	厚生労働省処理欄
一般的名称	①②③人血清アルブミン ④乾燥濃縮人血液凝固第Ⅷ因子 ⑤乾燥濃縮人血液凝固第Ⅸ因子	研究報告の公表状況	FDA News/20061213	公表国 アメリカ		
販売名 （企業名）	①献血アルブミン-Wf（ベネシス） ②献血アルブミン(5%)-Wf（ベネシス） ③アルブミン-Wf（ベネシス） ④コンコエイトーHT（ベネシス） ⑤クリスマシンーM（ベネシス）					

研究報告の概要

米国FDAは本日（2006年12月13日）、重篤且つ致死性の寄生虫感染症のシャーガス病を引き起こす血液由来寄生虫を血液ドナーからスクリーニングする新しい試験を承認した。この試験はORTHO T. cruzi ELISAと呼ばれ、trypanosoma cruzi抗体を検出するもので、FDAによって承認された初めての試験である。
FDAによって検討された試験は99%以上の精度を有し、感染していると考えられるヒトの199の血液検体中198を陽性と検出した。70,000を超えるドナー検体について行われた実地試験では、陽性と誤って確認された検体の数は極めて少なく、100,000件の試験当り僅か2-3件であった。
この試験は、全血の供血者のスクリーニングに加えて、臓器、細胞及び組織ドナーからの血漿及び血清をスクリーニングするのに用いられるよう計画されている。この試験は現時点で、この病気の診断用には承認されていない。

使用上の注意記載状況・その他参考事項等

代表として献血アルブミン-Wf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献血者の血液については、HBs抗原、抗HCV抗体、抗HIV-1抗体、抗HIV-2抗体、抗HTLV-I抗体陰性で、かつALT（GPT）値でスクリーニングを実施している。更に、プールした試験血漿については、HIV-1、HBV及びHCVについて核酸増幅検査（NAT）を実施し、適合した血漿を本剤の製造に使用しているが、当該NATの検出限界以下のウイルスが混入している可能性が常に存在する。本剤は、以上の検査に適合した血漿を原料として、Cohnの低温エタノール分画で得た画分から人アルブミンを精製し、アルブミン濃度5w/v%に調整した製剤であり、ウイルス不活化を目的として、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。

報告企業の意見	今後の対応
FDAがシャーガス病を引き起こす血液由来寄生虫を血液ドナーからスクリーニングする新しい試験を承認したとの報告である。 血漿分画製剤からのトリパノソーマ原虫伝播の事例は報告されていない。また、万一原料血漿にTrypanosoma cruziが混入したとしても、除菌ろ過等の製造工程において十分に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。

FDA News

FOR IMMEDIATE RELEASE
P06-198
December 13, 2006

Media Inquiries:
Karen Riley, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Approves First Test to Screen Blood Donors for Chagas Disease

The U.S. Food and Drug Administration (FDA) today approved a new test to screen blood donors for a blood-borne parasite that causes Chagas disease, a serious and potentially fatal parasitic infection. The test, called the ORTHO T. cruzi ELISA Test System, detects antibodies to the *Trypanosoma cruzi (T. cruzi)* parasite and is the first such test approved by FDA.

"Our blood supply is now extremely safe from diseases once frequently transmitted by blood, such as HIV. However, we are constantly faced with new threats," said Jesse L. Goodman, MD, MPH, Director of CBER. "Evaluating this test involved a high degree of interaction between FDA scientists, the blood industry and test developers. It is part of an ongoing effort to, wherever possible, identify emerging threats and provide the tools needed to help keep blood safe."

It is estimated that as many as 11 million people are currently infected by T. cruzi, most commonly in parts of Mexico, Central and South America. Most have no symptoms or signs of the disease. The infection is usually acquired from the bite of an infected insect but also can be transmitted through blood transfusions or organ transplants. Early infection is usually mild and unrecognized, but persists lifelong and may lead to organ damage, particularly of the heart and esophagus, causing an estimated 50,000 deaths annually worldwide. Infection also can be severe in people whose immune systems are suppressed, such as organ transplant recipients. Concerns about the potential for transfusion and organ transmitted Chagas disease in the United States have heightened due to the increase in the number of U.S. residents who previously lived in countries where the infection is common. This new test identifies infected donors and therefore can reduce the risk of disease transmission through blood transfusion or organ transplantation.

"The availability of this test offers an important new safety measure to protect recipients of blood, organs and tissues against a potentially very serious, though uncommon infection," said Jay Epstein, MD, Director of the Office of Blood Research and Review in FDA's Center for Biologics Evaluation and Research (CBER).

In studies reviewed by FDA, the test was found to be accurate 99% or more of the time—detecting 198 out of 199 blood specimens from individuals believed to be infected. In field trials of over 70,000 donor samples, the number of individuals falsely identified as positive was extremely small, only 2-3 per 100,000 test results.

In addition to screening people who donate whole blood, this test is intended for use in screening plasma and serum samples from organ, cell and tissue donors. At this time, the test is not approved to diagnose the disease.

The ORTHO T. cruzi ELISA Test System is manufactured by Ortho-Clinical Diagnostics, Inc., Raritan, NJ

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