別紙様式第2-1

No. 15

医薬品 研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
				2009. 2. 18	該当なし	
一般的名称	乾燥濃縮人血液凝固第Ⅷ因子		研究報告の公表状況	ProMED 20090218.0669, 2009 Feb 18. 情報源:AllAfrica, This Day report, 2009 Feb 16.	公表国 ナイジェリア	
販売名(企業名)	クロスエイトM250(日本赤十字社) クロスエイトM500(日本赤十字社) クロスエイトM1000(日本赤十字社)					

研究報告の概要

○ナイジェリア:ラッサ熱ー専門家が拡大に対する懸念を表明
Irrua の専門病院院長は、最近のラッサ熱の広範囲の感染拡大を懸念しており、2008年1月から12月にかけて、229人の感染疑い患者が報告され、30人が死亡していることを明らかにした。
2009年2月14～15日のNational Lassa Fever Stakeholders Forum〈全国ラッサ熱関係者フォーラム〉において、2008年12月～2009年1月に感染の疑いのある患者および感染確定患者が、それぞれ60%、80%急増したことが報告された。
しかし、Irruaの専門病院は、ドイツ・ハンブルグのBehard-Notch熱帯疾患協会、米国ハーバード大学の協力を得て、ラッサ熱に対する対策が実施されていることも明らかにした。

使用上の注意記載状況・その他参考事項等

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血液を原料とすることに由来する感染症伝播等
vCJD等の伝播のリスク

報告企業の意見	今後の対応
ナイジェリアでは、2008年1月から12月にかけて、229人のラッサ熱感染疑い患者が報告され、30人が死亡している。また、2008年12月～2009年1月に感染の疑いのある患者および感染確定患者は、それぞれ60%、80%急増したとの報告である。 ラッサウイルスはアレナウイルス群に属する、脂質膜を持つ比較的大型のRNAウイルスである。これまで、本剤によるラッサウイルス感染の報告はない。本剤の製造工程には、平成11年8月30日付医薬発第1047号に沿ったウイルス・プロセスバリデーションによって検証された2つの異なるウイルス除去・不活化工程が含まれていることから、本剤の安全性は確保されていると考える。	本剤の安全性は確保されていると考えるが、念のため今後も情報収集に努める。なお、日本赤十字社では帰国(入国)後4週間は献血不適とし、輸入感染症の防止に努めている。

(12)

MedDRA/J Ver.11.0J

Nigeria: Lassa Fever - Specialist Expresses Concern Over Spread

Adibe Emenyonu

16 February 2

lin — The Chief Medical Director of Irrua Specialist Hospital, Prof George Akpede, has expressed concern over wide spread of Lassa fever in recent times, disclosing that out of 229 suspected cases reported between January a December 2008, 30 people died.

Prof Akpede, who spoke at National Lassa Fever Stakeholders Forum at Ekpoma, weekend noted that there had b a marked rise in the number of suspected and confirmed cases between December 2008 and January 2009 representing about 60 percent and 80 percent increases respectively.

, however, disclosed that some drastic measures were under way as the Irrua Specialist Teaching Hospital had entered into partnerships with Behard-Notch Institutue of Tropical Medicine, Hamburg, Germany and Harvard University, USA for collaboartion in lassa fever research and control efforts.

Part of the collaboration according to him had resulted in the donation of diagnostic facilities for the confirmation the disease in the hospital without samples being nedded to be sent out of the country any longer.

In his contribution, member representing Esan Central/Esan West/Igueben Federal Constituency in the House of Representatives, Mr. Patrick Ikhariale, also expressed concern over the spread of the lassa fever epidemic nation-w and called for urgent control measures at the national level.

Ikhariale assured that he would draw the attention of the National Assembly to the menace posed by the disease to millions of Nigerians.

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Archive Number 20090218.0669
Published Date 18-FEB-2009
Subject PRO/AH/EDR> Lassa fever - Nigeria

LASSA FEVER - NIGERIA
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Date: Mon 16 Feb 2009
Source: AllAfrica, This Day report [edited]
<http://allafrica.com/stories/200902160188.html>

Nigeria: Lassa fever -- specialist expresses concern over spread
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The chief medical director of Irrua Specialist Hospital, Prof George Akpede, has expressed concern over the wide spread of Lassa fever in recent times, disclosing that out of 229 suspected cases reported between January and December 2008, 30 people died.

Prof Akpede, who spoke at National Lassa Fever Stakeholders Forum at Ekpoma [at the] weekend [14-15 Feb 2009] noted that there had been a marked rise in the number of suspected and confirmed cases between December 2008 and January 2009 representing about 60 percent and 80 percent increases respectively. He, however, disclosed that some drastic measures were under way as the Irrua Specialist Teaching Hospital had entered into partnerships with Behard-Notch Institute of Tropical Medicine, Hamburg, Germany, and Harvard University, USA for collaboration in Lassa fever research and control efforts. Part of the collaboration, according to him, had resulted in the donation of diagnostic facilities for the confirmation of the disease in the hospital without samples having to be sent out of the country any longer.

In his contribution, [the] member representing Esan Central/Esan West/Igueben Federal Constituency in the House of Representatives, Mr. Patrick Ikhariale, also expressed concern over the spread of the Lassa fever epidemic nation-wide and called for urgent control measures at the national level. Ikhariale assured that he would draw the attention of the National Assembly to the menace posed by the disease to millions of Nigerians.

[Byline: Adibe Emenyonu]

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Communicated by:
ProMED-mail Rapporteur A-Lan Banks

[Lassa fever is a zoonotic disease, whereby humans become infected from contact with infected animals. The animal reservoirs of Lassa virus are rodents of the genus _Mastomys_, the "multimammate rat." Lassa virus-infected animals do not become ill, but they can shed the virus in their urine and faeces. (A photograph of a multimammate rat can be accessed at
<http://i127.photobucket.com/albums/p145/hawthornrats/other%20pets/multis/I

In humans Lassa viral haemorrhagic fever is an acute illness of 1-4 weeks duration that occurs in West Africa. The virus is a single-stranded RNA virus belonging to the virus family _Arenaviridae_. Lassa fever is known to be endemic in Guinea (Conakry), Liberia, Sierra Leone, and parts of Nigeria, but probably exists in other West African countries as well.

About 80 percent of human infections are asymptomatic; the remaining cases have severe multi-system disease, where the virus affects several organs in the body, such as the liver, spleen, and kidneys. The incubation period of Lassa fever ranges from 6-21 days. It has been estimated that about 300 000 to 500 000 cases of Lassa fever and 5000 deaths occur yearly across West Africa. The overall case-fatality rate is 1 percent, and up to 15 percent among hospitalized patients.

The disease is especially severe late in pregnancy, with maternal death and/or fetal loss occurring in greater than 80 percent of cases during the 3rd trimester.

Humans usually become infected with Lassa virus from exposure to excreta of infected _Mastomys_. Lassa virus may also be spread between humans through direct contact with the blood, urine, faeces, or other bodily secretions of a person with Lassa fever. There is no epidemiological evidence supporting airborne spread between humans. Person-to-person transmission occurs in both community and health care settings, where the virus may be spread by contaminated medical equipment, such as re-used needles.

The current increase in cases of Lassa fever in some parts of Nigeria may by a consequence of increased abundance of the vector or some other factor resulting in increased contact between humans and rodents promoting the spread of the disease in the human population. - Mo

The HealthMap/ProMED-mail interactive map of Nigeria is available at <http://healthmap.org/promed/en?v=9.6,6.1,6>. - CopyEd.MJ]

[see also:
Lassa fever - UK ex Nigeria (03): fatal 20090130.0414
Lassa fever - UK ex Nigeria (02) 20090124.0308
Lassa fever - UK ex Nigeria 20090123.0296
2008

Lassa fever - Nigeria (02) 20080611.1847
Lassa fever - Nigeria: (Ebonyi) 20080323.1100
2007

Lassa fever - Nigeria 20071205.3925
Lassa Fever - South Africa ex Nigeria 20070222.0657
2005

Lassa fever - Nigeria (Edo) 20050303.0654
2004

Lassa fever - Nigeria (Edo) 20040214.0487
Lassa fever - Nigeria: RFI 20040213.0482
2001

Lassa fever, suspected - Nigeria (Edo) (02) 20010319.0552
Lassa fever, suspected - Nigeria (Edo): RFI 20010315.0524
2000

Lassa fever - Germany ex Nigeria (03) 20000424.0609
Lassa fever - Germany ex Nigeria (02) 20000405.0497
Lassa fever - Germany ex Nigeria 20000404.0495]
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別紙様式第２－１

医薬品　研究報告　調査報告書

番号：3

識別番号・報告回数			報告日	第一報入手日 平成 21 年 4 月 6 日	新医薬品等の区分 該当なし	機構処理欄
一般的名称	ﾃｸﾈﾁｳﾑ人血清ｱﾙﾌﾞﾐﾝ (99mTc)		研究報告の公表状況	Promed 20090402.1272	公表国 ブラジル	
販売名（企業名）	テクネアルブミンキット （富士フイルムＲＩファーマ株式会社）					使用上の注意記載状況・その他参考事項等
研究報告の概要	要約：サンパウロでの黄熱の母子感染に関する初めての報告： サンパウロ奥地において、2009 年 2 月末より黄熱が流行しているが、その中で母子感染が確認された。黄熱における母子感染の報告は前例のないことである。息子への感染は血清学的検査で確認されている。 報告者は、「今後は我々は黄熱症例の妊婦により注意をはらう必要がある」と説明している。 住民の 90%以上への大量のワクチン接種により、黄熱のリスクは減少しており、現在の一番の懸念事項は、奥地で流行している黄熱が都市部へ移動し拡大することである。					特になし
報告企業の意見			今後の対応			
編集者によれば、黄熱が属するフラビウイルス属では、胎盤経由の感染伝播の可能性が元々言われていること、また、今回の流行で最も懸念されているのは、現在の奥地での発生が、都市部へ拡大することであって、この母子の垂直感染により、現地規制当局でも特に措置等を講じるということではないということである。また、子への感染は血清学的検査で確認されていることであるので、詳細は不明であるものの、重大な感染症の新規感染経路に関する報告と判断する。			ヒト血液を原料とする血漿分画製剤とは直接関連のない報告であり、現時点では特に措置等は必要ないと判断する。			

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Archive Number 20090402.1272
Published Date 02-APR-2009
Subject PRO/AH/EDR> Yellow fever - South America (20): Brazil (SP)

YELLOW FEVER - SOUTH AMERICA (20): BRAZIL (SAO PAULO)
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A ProMED-mail post
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Date: Tue 31 Mar 2009
Source: Terra [in Portuguese, trans & summ. Mod. TY, edited]
<http://noticias.terra.com.br/brasil/interna/0,,OI3672572-EI306,00.html>

Public health physicians of Universidade Estadual Paulista (UNESP) who are fighting the epidemic of yellow fever [YF] in the interior of Sao Paulo [state] were surprised on Tuesday [31 Mar 2009] to see the transmission of disease from a mother to her child. The discovery is unprecedented. "This type of transmission scared us because it has never been reported before in the medical literature," said Tania Ruiz, Coordinator of the Center for Epidemiological Surveillance of the Hospital of Unesp in Botucatu (Sao Paulo).

According to the Coordinator, the serological tests proved that a baby, son of a [YF] infected mother, was born with the disease. The serological tests are results of studies by researchers from UNESP and other institutions of the country According to Tania, the immediate importance of discovery is in the procedures adopted in epidemics the disease. "From now on, we need to take more care with pregnant [YF cases]," she explained.

The epidemic of yellow fever in Sao Paulo began on 27 February [2009]. This Tuesday [31 Mar 2009], 2 more cases were reported. The total documented confirmed deaths from the disease reached 8 in the cities of Piraju, Sarutaia and Itatinga in the southern part of the state. So far, 15 total reported [YF cases] were confirmed.

Mass vaccination is still being done in health posts and even supermarkets. According to Tania, over 90 percent of residents of these municipalities are immunized, which reduces the risks [of YF infection]. However, most health concern is to prevent the disease, currently considered to be a sylvan [jungle transmission cycle], that might move into an urban area.

So far, all cases are related to victims who were in rural areas. According to public health officials, the expansion of the disease into urban areas would be "a disaster."

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[This is not surprising, nor is it a reason for alarm. The yellow fever virus is a flavivirus; other flaviviruses, such as dengue virus, can have transplacental transmission.

The poor infant, now an orphan, is not a public health threat for urbanization of yellow fever, should it happen, it would certainly not be by means of a case (rare) of vertical transmission. - Mod.LJS]

[A map of Brazil showing the location of Sao Paulo state can be accessed at
<http://www.lib.utexas.edu/maps/americas/brazil.jpg>.
A HealthMap/ProMED-mail interactive map of Brazil can be accessed at
<http://healthmap.org/promed/en?q=3451133&v=-10.8,-53.1,4>.
- Mod.TY]

[see also:
Yellow fever - South America (19): Brazil (SP) 20090326.1180
Yellow fever - South America (18): Brazil (SP) 20090323.1140
Yellow fever - South America (17): Brazil (RS), monkey 20090223.0748
Yellow fever - South America (16): 20090219.0700
Yellow fever - South America (15): Brazil (RS) 20090211.0618
Yellow fever - South America (14): Brazil (MG ex RS) 20090201.0456
Yellow fever - South America (12): Brazil (RS) 20090128.0389
Yellow fever - South America (08): Brazil (RS) monkey, susp. 20090122.0279
Yellow fever - South America (07): Brazil (RS), susp. 20090120.0251
Yellow fever - South America (06): Brazil (RS), susp 20090118.0211
Yellow fever - South America (02): Brazil (RS), susp., corr. 20090109.0091
Yellow fever - South America (02): Brazil (RS), susp. 20090108.0079
2008

Yellow fever - South America (26): Brazil (SP), Peru 20080608.1823
Yellow fever - South America (19): Paraguay 20080326.1136
Yellow fever - South America (18): Brazil (PR) 20080319.1061]
.....jw/ty/ejp/mpp

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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 平成21年1月19日	新医薬品等の区分 該当なし	機構処理欄
一般的名称	ﾃｸﾈﾁｳﾑ人血清ｱﾙﾌﾞﾐﾝ（^{99m}Tc）	研究報告の公表状況	CDC/MMWR 58(01)4-7/2009.1.16	公表国 米国	
販売名（企業名）	テクネアルブミンキット（富士フイルムＲＩファーマ株式会社）				
研究報告の概要	要約：ラクロス(La Crosse)脳炎ウイルスの先天性感染の可能性―ウエストヴァージニア,2006-2007： 米国ウエストヴァージニアで、妊婦における初めてのラクロス脳炎ウイルス（LACV）感染症例に関する報告があり、その後分娩時の臍帯血清からLACV特異的IgM抗体が検出されたことから、子の先天性LACV感染の可能性が示唆された。子は出生時及び出生後６ヶ月間はとくに異常は認められておらず、LACVの兆候も示していない。さらに母親が子の血清等の検体の採取を拒絶していることから、血清中のLACV特異的IgM抗体の有無等は確認できていないため、子の先天性LACV感染は可能性であり、確定されたものではない。ウエストヴァージニアは、蚊媒介性のLACVが多発する地域であるため、それらの地域の妊婦は蚊を避けるようアドバイスすべきと提言している。				使用上の注意記載状況・その他参考事項等 特になし
報告企業の意見		今後の対応			
子のLACV先天性感染については、確定したものではなく可能性の報告ではあるが、重大な感染症の新規感染経路（可能性）に関する報告であるため、感染症定期報告の対象と判断する。		ヒト血液を原料とする血漿分画製剤とは直接関連のない報告であり、現時点では特に措置等は必要ないと判断する。			

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The findings in this report are subject to at least three limitations. First, identification of hospitalizations for pneumonia and nonpneumonia ARI was based on ICD-9-CM codes and might be subject to misclassification, despite internal quality control and validation for consistency within the Nationwide Inpatient Sample. Second, establishing the etiology of pneumonia is difficult. Nationwide Inpatient Sample data are deidentified before public release and chart reviews cannot be performed to confirm recorded diagnoses. Because most pneumococcal pneumonias are classified as pneumonias without further characterization, this report provides an estimate of the effect of PCV7 on all-cause pneumonia without regard to pneumococcal serotypes. Furthermore, serotyping is not part of routine diagnostic work-ups, and this information would not be recorded in medical charts. However, the decrease in nonpneumonia ARI hospitalizations among children aged <2 years suggests that the decreases in pneumonia hospitalizations were unlikely to result from a shift in coding of pneumonia to nonpneumonia ARI codes. Finally, factors other than shifts in coding could affect hospitalization rates. Reduced clinician concerns for severe pneumococcal disease among immunized children, for example, might lead to outpatient treatment rather than hospitalization. However, other data indicate that ambulatory-care visits for pneumonia among children aged <2 years also have decreased since introduction of PCV7 (5). In addition, the proportion of all hospitalizations that were attributable to pneumonia or nonpneumonia ARI decreased significantly, suggesting that the declines were unlikely to result from a secular reduction in overall hospitalization rate.

Despite the substantial morbidity associated with childhood pneumonia, no pneumonia-specific prospective population-based surveillance system exists for monitoring trends in the incidence of pneumonia hospitalizations or pneumonia-related ambulatory-care visits in the United States. Monitoring childhood pneumonia is important for the evaluation of effects of current and future pneumococcal immunization programs. Increases in pneumococcal disease caused by serotypes not included in PCV7 could result in some increase in pneumonia, even though observed increases in non-PCV7 serotype IPD have been modest thus far (9). In addition, extended-valency pneumococcal conjugate vaccines are expected to be licensed by late 2009 to early 2010 and might further reduce pneumonia rates. Finally, vaccination of children against influenza, as recommended by the Advisory Committee on Immunization Practices, is increasing and also might reduce pneumonia hospitalization rates (10).

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Possible Congenital Infection with La Crosse Encephalitis Virus — West Virginia, 2006–2007

La Crosse encephalitis virus (LACV) is a mosquitoborne bunyavirus of the California encephalitis serogroup (1). During 2003–2007, West Virginia had the greatest number of cases (95) and highest incidence of LACV disease (5.1 cases per 100,000 population) of any state.* The majority of persons infected with LACV either have no symptoms or a mild febrile illness; a limited number experience encephalitis (2). Although only 1%–4% of those infected with LACV develop any symptoms, children aged <16 years are at highest risk for severe neurologic disease and possible long-term sequelae (2,3). The effects of LACV infection during pregnancy and the potential for intrauterine transmission and adverse birth or developmental outcomes are unknown. This report describes the first known case of LACV infection in a pregnant woman, with evidence of possible congenital infection with LACV in her infant, based on the presence of immunoglobulin M (IgM)

*Confirmed and probable California serogroup viral (mainly La Crosse) encephalitis cases, human, United States, 1964–2007, by state. Available at http://www.cdc.gov/ncidod/dvbid/arbor/pdf/cal_lac.pdf.

antibodies in umbilical cord serum at delivery. The infant was born healthy with normal neurologic and cognitive functions and no LACV symptoms. Further investigation is needed to confirm the potential for intrauterine LACV transmission and to identify immediate and long-term health risks posed to infants. Because of the potential for congenital infection, pregnant women in areas where LACV is endemic should be advised to avoid mosquitoes; health-care providers should monitor for LACV infection and sequelae among infants born to women infected with LACV during pregnancy.

In August 2006, a previously healthy woman aged 43 years in week 21 of her pregnancy was admitted to a West Virginia hospital after experiencing severe headaches, photophobia, stiff neck, fever, weakness, confusion, and a red papular rash. The patient had reported a 3-month history of severe headaches, which were diagnosed initially as migraines and treated with morphine for pain. Two previous pregnancies had proceeded without complication, and each resulted in delivery of a healthy infant. The patient's medical history included anxiety, depression, and hypothyroidism, for which she received ongoing thyroid hormone replacement therapy.

After hospital admission, analysis of cerebrospinal fluid revealed an elevated white blood cell count (556 cells/mm^3 [94% lymphocytes, 5% monocytes, and 1% polymorphonuclear neutrophilic leukocytes]), elevated protein (66 mg/dL), and normal glucose (55 mg/dL). A diagnostic panel for viral encephalitis was performed, and the patient's serum was determined positive for the presence of LACV-specific IgM and immunoglobulin G (IgG) antibodies by immunofluorescence assay and for IgM by capture enzyme-linked immunosorbent assay (ELISA) (Table). The patient's serum was negative for IgM and IgG antibodies to the other three diseases in the diagnostic panel: eastern equine encephalitis, western equine encephalitis, and St. Louis encephalitis. A diagnosis of La Crosse encephalitis was made, and supportive therapy was initiated. During hospitalization, the patient experienced a low-grade fever and exhibited panleukocytosis (absolute neutrophil count: 12,800/μL), which persisted after discharge despite resolution of clinical signs.

After reporting the case to the West Virginia Department of Health and Human Resources, active follow-up of the patient and her fetus was initiated in collaboration with the patient's primary-care providers and CDC. With her consent, the patient's medical and prenatal histories were reviewed. Because guidelines for evaluating pregnant women infected with LACV do not exist, interim guidelines for West Nile virus were used to direct maternal and infant follow-up (*4*). Specifically, collection of blood and tissue products at time of delivery was arranged with the patient's obstetrician. Umbilical cord serum and maternal serum were tested for LACV-specific antibodies by ELISA and serum-dilution plaque-reduction neutralization test (PRNT). Sera also were tested for neutralizing antibodies to the closely related Jamestown Canyon virus by PRNT to rule out potential cross-reactivity. Umbilical cord and placental tissue were tested for LACV RNA by reverse transcription–polymerase chain reaction (RT-PCR). Data were collected regarding the infant's health at delivery and through routine well-child visits during the first 6 months of life.

The patient had a normal, spontaneous, vaginal delivery of a healthy girl at approximately 40 weeks gestation. The child had normal birth weight (2,970 g), length (52 cm), and head circumference (33 cm). Apgar scores at 1 minute and 5 minutes postpartum were within normal limits (8 and 9, respectively). LACV-specific IgM antibodies were detected in umbilical cord serum, although no evidence of LACV RNA was detected in umbilical cord tissue or placental tissue by RT-PCR (Table).

The mother declined collection of additional specimens of infant serum for confirmation of congenital LACV infection. Maternal serum collected at 11 weeks postpartum was positive for LACV IgG antibodies but negative for IgM. Except for intermittent nasal congestion associated with upper respiratory infections, the infant remained healthy and exhibited appropriate growth and development through the first 6 months of life. No neurologic abnormalities or decreased cognitive functions were observed.

Reported by: *A Hinckley, PhD, Div of Vector-Borne Infectious Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases; A Hall, DVM, EIS Officer, CDC.*

Editorial Note: This report summarizes the first case of symptomatic LACV infection identified during pregnancy. Congenital LACV infection of the fetus was suggested through identification of IgM antibodies in umbilical cord serum, although the newborn was asymptomatic and development was normal. Although unlikely to cross the placental barrier, LACV IgM antibodies detected in cord serum might have been attributable to transplacental leakage induced by uterine contractions that disrupt placental barriers during labor, which has been documented for anti-*Toxoplasma* IgM antibodies (*5*). Because specificity of standard laboratory techniques used to detect LACV IgM antibodies in cord serum or newborn serum is unknown, a follow-up evaluation of infant serum is necessary to confirm congenital infection. However, in this case, the mother declined collection of any additional specimens from her infant.

Certain infectious diseases have more severe clinical presentations in pregnant women (*6*). Symptomatic LACV infection is rare among adults; therefore, effects of pregnancy on the risk for or severity of illness are unknown. Because LACV-specific IgM can be present for as long as 9 months after infection (*1*), LACV might not have been responsible for the symptoms reported during this woman's pregnancy. However, the woman resided in an area where LACV is known to be endemic; during 2006, 16 (24%) of 67 LACV cases in the United States reported to CDC occurred in West Virginia, including three other cases from the same county as this patient.† Although antimicrobial treatment of pregnant women often is controversial because of limited information regarding efficacy and risk to the developing infant (*7*), certain in vitro evidence indicates that the antiviral agent ribavirin might be useful for treating LACV infection in nonpregnant patients (*2*). However, supportive treatment continues as the standard of care for managing all LACV patients (*2*).

Congenital infection with other arboviral diseases has been reviewed and documented previously (*8*). Although no human congenital infection with a bunyavirus of the California serogroup has been reported, congenital infection with other bunyaviruses of the Bunyamwera serogroup has been associated with macrocephaly. In addition, animal studies have determined that infection with LACV during pregnancy can cause teratogenic effects in domestic rabbits, Mongolian gerbils, and sheep (*9,10*).

Pregnant women in areas where LACV is endemic should take precautions to reduce risk for infection by avoiding mosquitoes, wearing protective clothing, and applying a mosquito repellent to skin and clothing. Additionally, health-care providers serving areas where LACV is endemic should consider LACV in the differential diagnosis of viral encephalitis. As a nationally notifiable disease, all probable and confirmed cases of LACV should be reported to the appropriate state and local public health authorities. When LACV infection is suspected in a pregnant woman or infant, appropriate serologic and virologic testing by a public health reference laboratory is recommended. Testing breast milk for the presence of LACV also might be reasonable to evaluate the potential for maternal-infant transmission and to determine the suitability for continued breastfeeding. Additional investigations are needed to confirm the potential for congenital infection with LACV and to identify immediate and long-term health risks LACV poses to infants.

TABLE. Summary of laboratory test results during investigation and follow-up of possible congenital infection with La Crosse encephalitis virus (LACV) — West Virginia, 2006–2007

Collection date	Specimen	Test	Result
August 20, 2006	Maternal serum	LACV IgM* capture ELISA†	Positive
	Maternal serum	LACV IgM IFA§	Positive
	Maternal serum	LACV IgG¶ IFA	Positive
	Maternal serum	LACV neutralizing antibodies PRNT**	Positive
	Maternal serum	JCV†† neutralizing antibodies PRNT	Negative
January 5, 2007	Placental tissue	LACV RNA RT-PCR§§	Negative
	Umbilical cord tissue	LACV RNA RT-PCR	Negative
	Umbilical cord serum	LACV IgM capture ELISA	Positive
	Umbilical cord serum	LACV IgG capture ELISA	Equivocal
	Umbilical cord serum	LACV neutralizing antibodies PRNT	Positive
	Umbilical cord serum	JCV neutralizing antibodies PRNT	Negative
March 23, 2007	Maternal serum	LACV IgM capture ELISA	Negative
	Maternal serum	LACV IgG capture ELISA	Positive

* Immunoglobulin M.
† Enzyme-linked immunosorbent assay.
§ Immunofluorescence assay.
¶ Immunoglobulin G.
** Plaque-reduction neutralization test.
†† Jamestown Canyon virus.
§§ Reverse transcription–polymerase chain reaction.

† La Crosse encephalitis, human: cumulative 2006 data. Available at http://diseasemaps.usgs.gov/2006/lac_us_human.html.

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Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis

Guidelines for the use of nucleic acid amplification (NAA) tests for the diagnosis of tuberculosis (TB) were published in 1996 (*1*) and updated in 2000 (*2*). Since then, NAA testing has become a routine procedure in many settings because NAA tests can reliably detect *Mycobacterium tuberculosis* bacteria in specimens 1 or more weeks earlier than culture (*3*). Earlier laboratory confirmation of TB can lead to earlier treatment initiation, improved patient outcomes, increased opportunities to interrupt transmission, and more effective public health interventions (*4,5*). Because of the increasing use of NAA tests and the potential impact on patient care and public health, in June 2008, CDC and the Association of Public Health Laboratories (APHL) convened a panel of clinicians, laboratorians, and TB control officials to assess existing guidelines (*1,2*) and make recommendations for using NAA tests for laboratory confirmation of TB. On the basis of the panel's report and consultations with the Advisory Council for the Elimination of TB (ACET),* CDC recommends that NAA testing be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities, such as contact investigations. These guidelines update the previously published guidelines (*1,2*).

Background

Conventional tests for laboratory confirmation of TB include acid-fast bacilli (AFB) smear microscopy, which can produce results in 24 hours, and culture, which requires 2–6 weeks to produce results (*5,6*). Although rapid and inexpensive, AFB smear microscopy is limited by its poor sensitivity (45%–80% with culture-confirmed pulmonary TB cases) and its poor positive predictive value (50%–80%) for TB in settings in which nontuberculous mycobacteria are commonly isolated (*3,6,7*).

NAA tests can provide results within 24–48 hours. The Amplified *Mycobacterium tuberculosis* Direct Test (MTD, Gen-Probe, San Diego, California) was approved by the Food and Drug Administration (FDA) in 1995 for use with AFB smear-positive respiratory specimens, and in a supplement application, an enhanced MTD test was approved in 1999 for use with AFB smear-negative respiratory specimens from patients suspected to have TB. In addition, the Amplicor *Mycobacterium tuberculosis* Test (Amplicor, Roche Diagnostics, Basel, Switzerland) was approved by FDA in 1996 for use with AFB smear-positive respiratory specimens from patients suspected to have TB. NAA tests for TB that have not been FDA-approved also have been used clinically (e.g., NAA tests based on analyte specific reagents, often called "home-brew" or "in-house" tests) (*8,9*).

Compared with AFB smear microscopy, the added value of NAA testing lies in its 1) greater positive predictive value (>95%) with AFB smear-positive specimens in settings in which nontuberculous mycobacteria are common and 2) ability to confirm rapidly the presence of *M. tuberculosis* in 50%–80% of AFB smear-negative, culture-positive specimens (*3,7–9*). Compared with culture, NAA tests can detect the presence of *M. tuberculosis* bacteria in a specimen weeks earlier than culture for 80%–90% of patients suspected to have pulmonary TB whose TB is ultimately confirmed by culture (*3,8,9*). These advantages can impact patient care and TB control efforts, such as by avoiding unnecessary contact investigations or respiratory isolation for patients whose AFB smear-positive specimens do not contain *M. tuberculosis*.

Despite being commercially available for more than a decade (*1*), NAA tests for TB have not been widely used in the United States largely because of 1) an uncertainty as to whether NAA test results influence case-management decisions or TB control activities; 2) a lack of information on the overall cost-effectiveness of NAA testing for TB; and 3) a lack of demand from clinicians and public health authorities. However, recent

* Additional information regarding ACET is available at http://www.cdc.gov/maso/facm/facmacet.htm.

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医薬品
医薬部外品　研究報告　調査報告書
化粧品

識別番号・報告回数		報告日	第一報入手日 2009年1月13日	新医薬品等の区分	厚生労働省処理欄
一般的名称	①献血アルブミン-WI ②献血アルブミン(5%)-WI ③ノイアート ④ノイアート静注用 1500 単位 ⑤ハプトグロビン注-ヨシトミ ⑥コンコエイト-HT	研究報告の公表状況	OIE/2008/12/23	公表国 フィリピン	
販売名(企業名)	①②人血清アルブミン ③④乾燥濃縮人アンチトロンビンIII ⑤人ハプトグロビン ⑥乾燥濃縮人血液凝固第Ⅷ因子				使用上の注意記載状況・その他参考事項等
研究報告の概要	ブタにおけるEbola-Reston ウイルスの初めての検出： フィリピンにおいて，ブタからEbola-Reston ウイルスが検出されたことを受けて，フィリピン政府が国連FAO，OIEおよびWHOに専門家の派遣を要請したことが発表された。 2007年および2008年にNueva EcijaおよびBulacanの農場においてブタの死亡が増加したことから調査が開始され，2008年5月，6月および9月に病気のブタのサンプルが研究所に送付され，10月に豚繁殖・呼吸器障害症候群（PRRS）およびEbola-Reston ウイルス感染が確認された。 ブタにおいてEbola-Reston ウイルスが検出されたのは世界的に初めてである。フィリピンのサルにおいては1989–1990年，1992年および1996年にアウトブレイクしたことが確認されている。 フィリピン保健当局は，感染したブタと接触したと思われる人における初期検査はEbola-Reston ウイルス感染陰性であったと報告した。 フィリピンの農務省動物産業局（BAI）は感染した家畜はすべて破棄され，埋められるか焼却され，施設は消毒されたこと，また，感染地域は厳しい検疫と管理体制の下にあることをOIEに報告した。				使用状の注意にヘパリン由来の感染症に関連する記載なし。
	報告企業の意見		今後の対応		
	フィロウイルス科エボラウイルス属には，エボラ・アイボリーコーストウイルス，エボラ・ザイールウイルス，エボラ・スーダンウイルス，エボラ・レストンウイルスの4種がある。エボラレストンウイルスは，長径 800～1,500nm，短径 80～100nm のエンベロープを有する RNA ウイルスであり，人にも感染するが重病や死に至る危険性はないと言われている。ヘパリンからのエボラウイルス感染に関する報告は，入手していない。 万一，ブタ原料にエボラ・レストンウイルス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，ヘパリンの製造工程中の過酸化水素処理，加熱処理工程で十分に不活化・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。		

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First detection of Ebola-Reston virus in pigs

FAO/OIE/WHO offer assistance to the Philippines

MANILA 23 December 2008 – Following the detection of the Ebola-Reston virus in pigs in the Philippines, the UN Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) announced today that the government of the Philippines has requested the three agencies send an expert mission to work with human and animal health experts in the Philippines to further investigate the situation.

An increase in pig mortality on swine farms in the provinces of Nueva Ecija and Bulacan in 2007 and 2008 prompted the Government of the Philippines to initiate laboratory investigations. Samples taken from ill pigs in May, June and September 2008 were sent to international reference laboratories which confirmed in late October that the pigs were infected with a highly virulent strain of Porcine reproductive and respiratory syndrome (PRRS) as well as the Ebola-Reston virus.

Although co-infection in pigs is not unusual, this is the first time globally that an Ebola-Reston virus has been isolated in swine. It is not, however, the first time that the Ebola-Reston virus has been found in the Philippines : it was found in monkeys from the Philippines in outbreak s that occurred in 1989-1990, 1992, and 1996.

The E bola virus belongs to the Filoviridae family (filovirus) and is comprised of five distinct species: Zaïre , Sudan , Côte d'Ivoire, Bundibugyo and Reston . Zaïre , Sudan and Bundibugyo species have been associated with large Ebola hemorrhagic fever (EHF) outbreak s in Africa with high case fatality ratio (25–90%) while Côte d'Ivoire and Reston have not. Reston species can infect humans but no serious illness or death in humans have been reported to date.

Since being informed of this event in late November, FAO, OIE and WHO have been making every effort to gain a better understanding of the situation and are working closely with the Philippines Government and local animal and human health experts.

The Department of Health of the Philippines has reported that initial laboratory tests on animal handlers and slaughterhouse workers who were thought to have come into contact with infected pigs were negative for Ebola Reston infection, and that additional testing is ongoing. The Bureau of Animal Industry (BAI) of the Philippines Department of Agriculture has notified the OIE that all infected animals were destroyed and buried or burned, the infected premises and establishments have been disinfected and the affected areas are under strict quarantine and movement control. Vaccination of swine against PRRS is ongoing in the Province of Bucalan. PRRS is not transmissible to humans.

The planned joint FAO/OIE/WHO team will work with country counterparts to address, through field and laboratory investigation, important questions as to the source of the virus, its transmission, its virulence and its natural habitat, in order to provide appropriate guidance for animal and human health protection.

Until these questions can be answered, the FAO and WHO stressed the importance of carrying out basic good hygiene practices and food handling measures.

Ebola viruses are normally transmitted via contact with the blood or other bodily fluids of an infected animal or person. In all situations, even in the absence of identified risks, meat handling and preparation should be done in a clean environment (table top, utensils, knives) and meat handlers should follow good personal hygiene practices (e.g. clean hands, clean protective clothing). In general, hands should be r egularly washed while handling raw meat.

Pork from healthy pigs is safe to eat as long as either the fresh meat is cooked properly (i.e. 70°C in all part of the food, so that there is no pink meat and the juices run clear), or, in the case of uncooked processed pork, national safety standards have been met during production, processing and distribution.

Meat from sick pigs or pigs found dead should not be eaten and should not enter the food chain or be given to other animals. Ill animals should be reported to the competent authorities and proper hygiene precautions and protection should be taken when destroying and disposing of sick or dead pigs. The Philippines Department of Agriculture has advised the Philippine public to buy its meat only from National Meat Inspection Services certified sources.

As a general rule, proper hygiene and precautionary measures (wearing gloves, goggles and protective clothing) should also be exercised when slaughtering or butchering pigs. This applies both to industrial and home-slaughtering of pigs. Children and those not involved in the process of slaughtering should be kept away.

December 2008

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Maria Zampaglione

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