symptoms, you should immediately seek professional medical care; inform your health-care provider that you have visited an area currently experiencing a malaria outbreak.

Visit the CDC's Travelers' Health website for <u>Health information for Travelers to Countries in the Caribbean.</u>

Additional information about malaria can be found at the CDC Malaria homepage.

Health-care providers needing assistance with diagnosis or management of suspected cases of malaria should call the CDC Malaria Hotline: 770-488-7788 (M-F, 8 am-4:30 pm, Eastern Time). For consultation after hours, call 770-488-7100 and ask to speak with a CDC Malaria Branch clinician.

Date: June 30, 2005

Content Source: National Center for Infectious Diseases, Division of Global Migration and Quarantine

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. 然為對於聯◆對關於1525至2000年的

Centers for Disease Control and Prevention, 1600 Clifton Rd, Allania, GA 30333, U.S.A Tel: (404) 638-3311 / Public Inquiries: (404) 639-3534 / (800) 311-3435



# 医薬品 研究報告 調査報告書

				報告日	第一報入手日	新医薬品	等の区分	機構処理欄
識別番号-報告回数				IN EI M	2006. 7. 3			IN ITTO LIM
一般的名称		(製造承認書に記載なし)			ProMED. 20060624-1758, 20		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)		研究報告の公表状況			キルギスタ ン・・	
研究報告の概要	じているにもかかれ Djuzenovから提供 された。このうちほ 貯水池である。Ak 散布も時々散布が キルギスタンにおり	都で79例のマラリアだっらず、流行は拡大された。マラリア撲滅とんどはBishkek地、 Bata村とKalis ordo	中である。以下の情 或のための予防活動 方のAk-Bata村とKa o村の819世帯で殺! 5。マラリア治療には 9年に一度撲滅され	60例はBishkek地方、19の 報はBishkekにある国立衛 がには数年必要である。キー lis ordo村の住民だった。 由剤を散布した。しかし、信 Primosinが有効で、人道が たものの、1986年以降は、	新生疫学監視センタ・ ルギスタンでは2005年 感染の中心は、Chu 主民に問題を理解され 幾関から十分な量の	ー副所長のA 年に125例の ysk地方のAl せるのは困難 薬が送られて	dilbek 症例が登録 a-Archinsk で、殺虫剤 いる。	合成血「日赤」 照射合成血「日赤」 血液を介するウイルス、
	報	と告企業の意見		今後の対応				
ł ·	デスタンの首都で79 中であるとの報告で	例のマラリア症例が ある。	登録され、流行が	日本赤十字社では、輸血有無を確認し、帰国後43 マラリア感染に関する新	週間は献血不適とし	ている。今後	も引き続き、	



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Archive Number 20060624,1758
Published Date 24-JUN-2006

Subject PRO/EDR> Malaria - Kyrgyzstan (Bishkek)

MALARIA - KYRGYZSTAN (BISHKEK)

A ProMED-mail post

<http://www.promedmail.org>

ProMED-mail is a program of the

International Society for Infectious Diseases

<http://www.isid.org>

Date: Sat, 24 Jun 2006

From: ProMED-mail Russian correspondent AP promed@promedmail.org>

Source: Kyrgyzstan Press [22 Jun 2006; trans. Mod.NR; edited]

<http://pr.kg/n/detail.php?id=3D8576>

In the capital of Kyrgyzstan 79 cases of malaria have been registered; 60 from Bishkek and 19 from the Chuysk region. Despite preventive measures, the outbreak is growing. This information was provided by the deputy chief of the state sanitary epidemiological surveillance (SES) center in Bishkek, Adilbek Djuzenov.

According to Adilbek Djuzenov, it requires several years of preventive work to destroy a malaria focus. Kyrgyzstan registered 125 malaria cases in 2005, of whom most were inhabitants of Ak-Bata and Kalis Ordo villages of Bishkek. The epicenter of the spread is the Ala-Archinsk reservoir in the Chuysk region.

According to Djuzenov, 819 households at Ak-Bata and Kalis ordo have been sprayed with insecticides. However, it is challenging for the population to understand the problem, and [only] sometimes do people allow the SES staff to spray their houses.

According to Adilbek Djuzenov, the disease can be treated with Primosin [ProMED does not know what drug is being referred to under this brand name], and enough drugs were delivered by humanitarian aid.

ProMED-mail 

promed@promedmail.org>

[ProMED reported 88 cases of malaria in Bishkek in 2005. We still do not have a species identification. Malaria was eradicated in Kyrgyzstan in 1959; however, from 1986 onwards, as a result of the importation of malaria by military personnel returning from Afghanistan, a few local cases have been registered annually. In 1986 and 1987, 14 and 10 autochthonous malaria cases were detected, respectively. In 1988, 21 cases due to local transmission were registered. In 2002; a total of 2267 autochthonous \_P. vivax\_ cases were reported in the southwestern regions of the country, including Batken, Osh and Jalal-Abad.

The explosive resumption of malaria transmission in Kyrgyzstan was the result of immigration of a number of infected people from Tajikistan into the Batken region. In 2004-2005, there was a significant decrease in the reported number of autochthonous malaria cases (42 in 2005). However, in 2004 the first autochthonous case of P. falciparum malaria was reported in the Aravan district of the southern part of Kyrgyzstan, in an area bordering Uzbekistan, and in 2005 the number of autochthonous cases of P. vivax malaria increased in the outskirts of Bishkek, the capital of the country (Source:

<a href="http://www.euro.who.int/malaria/ctryinfo/affected/20020712 17">http://www.euro.who.int/malaria/ctryinfo/affected/20020712 17</a>>). ProMED reported 88 cases of malaria from Kyrgyzstan in 2005 in

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contrast to the 42 the country reported theough WHO. This indicates
that there may be some underreporting of cases. - Mod.EP]
[Bishkek is the capital of Kyrgyzstan and its population is 768 000.
The Chuysk region borders Bishkek and has 765 700 people. - Mod.NR}
[A good map of Kyrgystan can be found at:
<http://www.lib.utexas.edu/maps/commonwealth/kyrgyzstan_pol96.jpg>. - Mod.MPP]
[see also:
2005
Malaria - Kyrgyzstan (02) 20050823.2489
Malaria - Kyrgyzstan 20050723.2124
2004
Malaria, falciparum - Kyrqyzstan (Osh) 20040815.2263
2002
Malaria, autochthonous - Russia (Moscow) 20020608.4439
2001
Malaria, autochthonous - NIS: 1992-2000 20010819.1962
2000
Malaria, autochthonous - Kazakhstan (02) 20000904.1507
Malaria, autochthonous - Russia (Krasnoyarsk) 20000816.1366
Malaria - Russia (Moscow) 20000525.0827
1999
Malaria, autochthonous - Russia (Ryazan) 19990909.1593
1998
Malaria - Turkmenistan (02) 19981218.2398
Malaria - Kyrgyzstan (02) 19980910.1825
Malaria - Azerbaijan & Newly Independent States 19980714.1332
Malaria, epidemic - Azerbaijan (02) 19980708.1278
Malaria, epidemic - Azerbaijan: RFI 19980706.1269]
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.....nr/mpp/ep/pg/mpp

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## 医薬品 研究報告 調査報告書

調	別番号·報告回数			報告日			<b>等の区分</b> なし	機構処理欄		
	一般的名称	(製造承認書に記載なし)			AABB Association Bulletin. 2006 Apr 26.		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)		研究報告の公表状況			米国			
	○AABBがムンプスウイルスの流行に対応して、AABBは感染者と感染者に接触した人を一時的に供血延期とすることを勧告した。 輸血によるムンプスの流行に対応して、AABBは感染者と感染者に接触した人を一時的に供血延期とすることを勧告した。 輸血によるムンプスウイルスの感染はこれまで確認されていないが、ウイルス血症が起こることは知られている。このため、輸血による感染の可能性を考慮して、AABBの感染症委員会とFDAはムンプス流行地域の採血施設が予防策をとることに合意した。 採血施設への勧告の内容は以下の通りである。 ・教育施設での移動採血を実施するかどうか、地元自治体や州の公衆衛生当局に照会すること。 ・供血海込まれる人に対して、疾患についての情報提供を行うこと。 ・最近ムンプスに罹患した人については、すべての症状が消えてから14日間供血延期とすること。感染者と接触した人については、覚えている最後の接触から28日間延期すること。 ・供血後にムンプスと診断された場合は、症状が消える前28日間および消えた後14日間の供血由来の製品は回収、隔離保管、廃棄を行うこと。供血後に感染者との接触が報告された場合は、覚えている最後の接触後28日間の供血由来の製品は回収、隔離保管、廃棄を行うこと。供血後に感染者との接触が報告された場合は、覚えている最後の接触後28日間の供血由来の製品は回収、隔離保管、廃棄を行うこと。 ・採血施設は、ムンプスが流行している施設あるいは地域での供血由来の新鮮凍結血漿については製造および使用を避け、他の製剤に転用してもよい。 受血者への通知については勧告していないが、輸血によるムンプスウイルス感染のリスクを推定するために行っても構わない。									
愿	<b>オ</b> 国中西部でのムンプン 染者に接触した人を の報告である。									



Advancing Transfusion and Cellular Therapies Worldwide

#### ASSOCIATION BULLETIN

#06-04

Date:

April 26, 2006

To:

**AABB Members** 

From:

Christopher D. Hillyer, MD - President

Karen Shoos Lipton, JD - Chief Executive Officer

Re:

Recommendations for Blood Collection Facilities in Response to Epidemic

Mumps in the Midwest

#### Background

The state of Iowa is experiencing a large outbreak of mumps that began in December 2005. As of April 20, 2006 more than 1,000 suspect, probable and confirmed cases have been reported to the Iowa Department of Public Health. The majority of infections are among persons 18-25 years of age. Cases initially predominated in postsecondary educational facilities (colleges, universities, trade schools, etc). However, in recent weeks many cases have been reported outside these venues. Additional cases of mumps, possibly linked to the Iowa outbreak, are also under investigation in eight neighboring states, including Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska and Wisconsin. The outbreak is expected to spread further, perhaps nationally.

The source of the current US outbreak is unknown. However, the mumps strain has been identified as serogroup G, the same as that circulating in the United Kingdom (UK). The outbreak in the UK has been ongoing from 2004 to 2006 and has involved more than 70,000 cases. The individuals had been fully immunized [with two doses of Measles-Mumps-Rubella (MMR) vaccine] in approximately 70% of the cases investigated to date.

Mumps is an acute viral infection characterized by a nonspecific prodrome including myalgia, anorexia, malaise, headache and fever, followed by acute onset of unilateral or bilateral tender swelling of parotid or other salivary glands. In unvaccinated populations, an estimated 30-70% of mumps infections are associated with typical acute parotitis. However, as many as 20% of infections are asymptomatic and nearly 50% are associated with nonspecific or primarily respiratory symptoms (cough, sore throat), with or without parotitis.

Complications of mumps infection can include deafness, orchitis, oophoritis, or mastitis (inflammation of the testicles, ovaries or breasts, respectively), pancreatitis,

meningitis/encephalitis and spontaneous abortion. With the exception of deafness, these complications are more common among adults than children.

Natural transmission of mumps virus occurs by direct contact with respiratory droplets (ie, coughing and sneezing), saliva or contact with contaminated fomites. The incubation period is generally 16-18 days (range 12-25 days) from exposure to onset of symptoms. Mumps can be spread from an infected person by droplets for about five days after onset of symptoms; however, virus has been found in the saliva of patients for as long as nine days after onset.

Members of the AABB Transfusion-Transmitted Diseases (TTD) Committee and representatives of the US Food and Drug Administration (FDA) have discussed the potential transfusion transmission of mumps to transfusion recipients from donors with unrecognized infection and asymptomatic viremia. Transfusion transmission of mumps virus has never been observed; however, viremia is known to occur, although the kinetics are poorly characterized. Information suggests that the viremia is in the form of both cell-associated and free virus. Whether transfusion-acquired disease would present with clinical signs that would allow recognition of mumps after transmission by this unnatural route is unknown.

### Recommendations

On the basis of the current state of knowledge about the possibility of transfusion-transmitted mumps, the TTD Committee and the FDA agree that a precautionary approach should be adopted by blood collection facilities in areas affected by epidemic mumps until more information is available.

- 1. Blood drives at postsecondary educational facilities or other similar facilities in areas experiencing epidemic mumps should be scheduled or canceled at the discretion of the collection facility's medical director in consultation with local and/or state public health authorities. In making the decision, medical directors should use information about mumps activity in the general area and at the specific institution where the blood drive is scheduled. Decisions should be consistent with efforts to minimize the risk of the theoretical transmission of mumps yet maintain local and regional blood supplies adequate for medical need.
- 2. Donor information: Prospective donors in areas experiencing epidemic mumps should be provided with information about the existence of mumps in the local area, the concern about its theoretical transmission by blood, and the donor deferral criteria specified below. This information can be in any of the following forms:
  - a. Information provided by recruiters before presentation to donate.
  - b. Written information provided at registration that allows self-deferral before screening and/or during administration of the donor history questionnaire.
  - c. New questions added to the donor history questionnaire to allow deferral at the time of screening.

These options are similar to those accepted by FDA at the time of the severe acute respiratory syndrome (SARS) epidemic. The decision to implement these measures in all

or part of a blood region should be made by the collection facility medical director in consultation with local and/or state public health authorities and using information about mumps activity in the area.

- 3. Donor eligibility: A donor is required to be well on the day of donation.
- 4. Temporary deferral criteria.
  - a. Donors with recent mumps infection should be deferred until 14 days after the resolution of all symptoms of infection.
  - b. Donors who have had contact with a person or persons with mumps should be deferred until 28 days after the last recognized contact. Contact is defined as any of the following situations:
    - i. Living in the same dwelling (eg, house, apartment, dormitory room) as a case patient with a diagnosis of mumps.
    - ii. Recognized direct contact with upper respiratory secretions (eg, kissing) or sharing utensils that might be contaminated with upper respiratory secretions (eg, eating utensils, cups, drinking glasses) with a case patient with a diagnosis of mumps.
    - iii. Recognized contact within three feet of a case patient with a diagnosis of mumps without the use of barrier precautions (mask and eye protection).
  - c. Per the AABB Standards for Blood Banks and Transfusion Services, 23rd Edition, receipt of MMR vaccination requires deferral for 28 days.
- 5. Post donation information: It is probable that if the epidemic is sustained, blood collection facilities will begin to receive post donation information about donors who have developed mumps or who have had recognized contact with mumps that had not been recognized and reported at the time of a prior donation. Because of the relatively long incubation period of mumps, there is a possibility that some of these donors may have been viremic at the time of their donation.
  - a. When a donor provides post donation information that he or she has been diagnosed with mumps, the donor should be deferred for 14 days after resolution of all symptoms of infection. Any products collected in the 28 days before or the 14 days after resolution of symptoms should be recalled, quarantined and destroyed unless used for research.
  - b. When a donor provides post donation information that he or she was the contact of a mumps case patient, as defined above, the donor should be deferred for 28 days after the last recognized contact. Any products collected from the first date of such contact until 28 days after the last recognized contact should be recalled, quarantined and destroyed, unless used for research.
- 6. Plasma for further manufacture (source and recovered) is not affected by these recommendations because virus inactivation procedures used to manufacture plasma derivatives should robustly inactivate this enveloped virus.

- 7. Collection facilities may want to consider refraining from the production and transfusion of fresh frozen plasma from collections from institutions or locales with epidemic mumps and diverting of such plasma for further manufacture. (Relabeling of previously manufactured fresh frozen plasma from such institutions or locales for further manufacture will require a variance from FDA as was required for West Nile virus in 2003.)
- 8. No recommendation is being made to perform consignee notification for the purpose of recipient notification at this time. However, some blood collection facilities, transfusion services and providers may wish to do so, to facilitate an estimate of the risk, if any, of transfusion transmission of the mumps virus. Appropriate samples for study might include plasma, serum and cells from the index donation for serology, viral culture and nucleic acid amplification, and the same on samples of recipients. Serial samples on the donor and recipients may be useful to study seroconversion and viral kinetics if infection is suspected.
- 9. Collection facilities that implement measures to prevent the theoretical transmission of mumps virus by transfusion should include notification to the FDA in their annual report.

America's Blood Centers (ABC) and American Red Cross (ARC) concur with these recommendations.

## 医薬品 研究報告 調査報告書

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識別番号·報告回数				報告日	第一報入手日	新医薬品		機構処理欄
-				·	2006. 6. 20	該当	なし	
	一般的名称	(製造承認書に記載なし)			Pischer SA, Graham MB, Kuehnert Srinivasan A, Marty FM, Comer JA, CD, DeMeo DL, Shieh WJ, Erickson DeMaria A Jr, Davis JP, Delmonico	Guarner J, Paddock n BR, Bandy U, El - Pavlin B, Likos	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)		研究報告の公表状況	A. Vincent MJ, Sealy TK, Goldsmit Rollin PE, Packard MM, Patel M, Re Nichol ST, Fishman JA, Ksiezek T, Transplant Recipients Investigation 2006 May 25;354(21):2235-49.	h CS, Jernigan DB, owland C, Helfand RF, Zaki SR; LCMV in	米国	
	背景:2003年12月		目形臓器の移植を受	O伝播 けた2つの患者群を調査 、ナーが判明したため、各			 そと症状が	使用上の注意記載状況。 その他参考事項等
研	方法: 2名のドナー 組織化学染色に	ー及び8名の被移植 にり調べ、原因を明ら	者から採取した試料 かにした。臨床的紹	を、ウイルス培養、電子顕色の特徴を調査し、疾患	質微鏡、血清学的検査	至、分子解析		合成血「日赤」 照射合成血「日赤」
究報告	団でも、LCMVはドナーから検出されなかった。2005年のドナーは、自宅で飼っていたペットのハムスターと接触しており、このハ							血液を介するウイルス、細菌、原虫等の感染
の概	の							vCJD等の伝播のリスク   
要	なかった。被移植者8名のうち7名が、移植後9から76日の間に死亡し、リバビリン投与及び減量した免疫抑制療法を受けていた 被移植者1名が生存した。 結論: 臓器移植によるLCMV感染の伝播が見られた2つの集団についてまとめた。							
	THE HOLD WASHINGTON							
	報告企業の意見			今後の対応				
		4月に固形臓器の移 パ性脈絡髄膜炎ウィ	•	今後も引き続き、新たな る情報の収集に努める。	ウイルス等による感染	症の発生状	況等に関す	
考え	考えられたとの報告である。						•	
						•		