

医薬品 研究報告 調査報告書

識別番号・報告回数		報告日	第一報入手日	新医薬品等の区分	厚生労働省処理欄
一般的名称	乾燥濃縮人アンチトロンビンⅢ		2009年5月7日	該当なし	
販売名(企業名)	アンスロビンP-ベーリング (CSL ベーリング株式会社)	研究報告の公表状況	Information about Newly Emerging 2009 H1N1 Influenza Virus and Blood Safety http://www.fda.gov/cber/flu/h1n1/bldsafety.htm	公表国 米国	
研究報告の概要 148	<p>問題点 (2009 年の新興の H1N1 型インフルエンザウイルス感染と血液の安全性)</p> <p>米国で 2009 年に新興の H1N1 型インフルエンザウイルス感染が発生していて、このウイルスが輸血により感染するか疑問視されている。米国や他の国において輸血による季節性インフルエンザが伝播した症例は報告がなく、現在まで輸血による H1N1 型インフルエンザウイルスの伝播の報告はない。FDA は継続して CDC と共同作業しており、またこのインフルエンザの発生と血液の安全性及び有用性に対するインパクトを監視するため、AABB のパンデミックインフルエンザ及び血液供給に関する組織間作業委員会と密接に連絡を取っている。今のところ、临床上必要な場合、輸血のベネフィットが血液や血液製剤による H1N1 型インフルエンザウイルス伝播の理論的な危険性を含むリスクを上回ることを忘れないのが重要である。FDA の規制 (FDA regulations at 21 CFR 640.3) において、健康でない人は献血には適していないし、血液事業者はこれらの潜在的な供血者の供血を保留しなければならない。</p> <p>現在、血液事業者が実施している供血者スクリーニングにより、H1N1 型インフルエンザウイルスの症状を有する患者を同定すべきである。H1N1 型インフルエンザウイルスの人での症状は、通常のヒトインフルエンザと似ていて発熱、咳や喉の痛み、体の痛み、頭痛、寒気や疲労である。H1N1 型インフルエンザウイルスに関連した下痢や嘔吐の報告もある。メキシコや米国において重症化や死亡例が報告されている。現在実施している供血者スクリーニングは、特にヒトに H1N1 型インフルエンザが発生している地域での H1N1 型インフルエンザ伝播のリスクを減少する上で重要な手段である。さらに、良い衛生状態を維持する際に血液事業者が実施している標準的な手法や感染制御の手法は、血液事業における H1N1 型インフルエンザの起こりうる拡大を最小限にするのに役立つであろう。</p> <p>2006 年 10 月の FDA ガイダンス "Biologic Product Deviation Reporting for Blood and Plasma Establishments" に従い、血液事業者は、供血者のインフルエンザ様疾患の供血後報告 (a post donation report) が、既に収集された製品の適切性またはその供血者の将来の供血の適格性を評価すべきかを示していないか検討すべきである。さらに H1N1 型インフルエンザが同定された症例の国及び現地当局への通常の報告に加えて、インフルエンザの輸血による伝播に関する懸念を引き起こす症例がある血液事業者は、州及び現地健康部門と同様に適切に "Therapeutics and Blood Safety Branch of the CBER Office of Biostatistics and Epidemiology" に電話する。</p> <p>新興の 2009 年の H1N1 型インフルエンザウイルスはエンベロープを有する大きなウイルスである。製造販売業者が実施したバリデーションテストでは、現在の血液製剤の製造工程により類似ウイルスが不活化・除去されることが示されている。</p>				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			
本剤によるインフルエンザウイルス伝播の報告はない。鳥インフルエンザウイルスが 60℃10 時間の液状加熱で不活化される報告があるため、本剤の製造工程でインフルエンザウイルスが不活化されると考えられる。	今後とも新しい感染症に関する情報収集に努める所存である。				

2009 H1N1 Flu Virus

Information about Newly Emerging 2009 H1N1 Influenza Virus and Blood Safety

I. Background

The ongoing outbreak of new emerging 2009 H1N1 Influenza Virus (H1N1 flu) infections in the United States has raised questions about whether this virus can be transmitted through blood transfusion. No case of transfusion transmitted seasonal influenza has ever been reported in the United States or elsewhere, and, to date, no cases of transfusion transmitted H1N1 flu have been reported. FDA is continuing to work with the Centers for Disease Control and Prevention (CDC) and is in close contact with the AABB Interorganizational Task Force on Pandemic Influenza and the Blood Supply to monitor this outbreak and its impact on blood safety and availability.

At this time, it is important to remember that, when clinically indicated, the benefits of a transfusion far outweigh the risks, including any theoretical risk of H1N1 flu transmission through blood or blood products.

II. Blood Safety Provisions

Donor Deferral

Under FDA regulations, individuals who are not in good health are not suitable to donate blood and blood establishments must defer these potential donors. (See FDA regulations at 21 CFR 640.3.) Blood donor screening procedures currently in place at blood establishments should identify persons with symptoms of H1N1 flu infection. The symptoms of H1N1 flu in people are similar to the symptoms of regular human influenza and include fever, cough, sore throat, body aches, headache, chills and fatigue. Some people have reported diarrhea and vomiting associated with H1N1 flu. Severe illness and deaths have been reported among infected individuals in Mexico and in the U.S.

The donor screening procedures in place today are important measures in reducing the theoretical risk of transfusion transmitted H1N1 flu, particularly in areas where human cases are occurring. In addition, the continued standard practice of blood establishments in maintaining good hygiene and infection control practices will help to minimize possible spread of H1N1 flu in blood establishments. Staff member hand washing between contacts with different donors is especially important.

Additional information on illness with H1N1 flu and general control strategies can be obtained at the Centers for Disease Control and Prevention (CDC) website at <http://www.cdc.gov/swineflu/index.htm>.

Potential Component Quarantine and Retrieval

Consistent with FDA's October 2006 Guidance on Biologic Product Deviation Reporting for Blood and Plasma Establishments (see <http://www.fda.gov/cber/gdlns/devbld.htm>) Medical Directors of blood establishments should consider whether a post donation report of a flu-like illness in a donor indicates that the previously collected products are unsuitable and that the donor's suitability for future donations should be assessed (e.g. deferral until well.) In addition to routine reporting of identified cases of H1N1 flu to state and local health departments, medical directors with any case

raising concerns regarding potential transfusion transmission of influenza, may contact us at the Therapeutics and Blood Safety Branch of the CDER Office of Biostatistics and Epidemiology at 301-827-3974, as well as the CDC via state and local health departments, as appropriate.


Safety of Plasma Derivatives

The newly emerging 2009 H1N1 Influenza Virus is a large lipid-enveloped virus. Validation studies performed by the product manufacturers have shown that viruses with similar characteristics to this agent are effectively inactivated and/or removed by the manufacturing processes in place for these products.

[Return to 2009 H1N1 Flu Virus Main Page](#)

Updated: April 30, 2009

医薬品 研究報告 調査報告書

識別番号・報告回数	非該当	非該当	報告日 非該当	第一報入手日 非該当	新医薬品等の区分 非該当	総合機構処理欄
一般的名称	エプタコグアルファ(活性型)(遺伝子組換え)		研究報告の公表状況	CIDRAP News, 2009年4月24日	公表国 米国	
販売名(企業名)	注射用ノボセブン 1.2mg 注射用ノボセブン 4.8mg					
研究報告の概要	<p>研究報告の題名: インフルエンザ A ウイルス(H1N1)-ブタ・ヒト 器官別大分類: 感染症および寄生虫症/基本語: インフルエンザ</p> <p>2009年4月24日、CDCは、メキシコでの致死的な呼吸器疾患発生例から得た検体は、米国の患者からのブタインフルエンザ株と一致したと発表した。</p>					<p>使用上の注意記載状況・その他参考事項等</p> <p>【使用上の注意の記載状況】 感染症発現については、記載なし。 感染症に対する安全対策については、冒頭に記載あり。</p> <p>【その他参考事項】 ブタ皮由来ゼラチンについては今回の調査期間後の一部変更承認によって、新たに感染症定期報告対象の成分となっており、次回より感染症定期報告を行なう。</p>
	報告企業の意見	今後の対応				
<p>本剤は製造工程においてブタ臓由来トリプシンおよびブタ皮由来ゼラチンを使用しているが、本剤の製造工程においてはウイルスの不活化及び除去を目的とした精製を施す等、感染症に対する安全対策を講じていることから、ブタ臓由来トリプシンおよびブタ皮由来ゼラチンを経由して本剤にインフルエンザウイルス(H1N1)が混入する可能性は極めて低いものとする。</p>			<p>今後とも感染症情報の収集に努めるとともに、必要に応じて本剤の安全対策に関する検討を行なう。</p>			

about the extent of the spread or the illness spectrum." WHO said today that Canada's national laboratory has confirmed swine flu A/H1N1 in 18 isolates from Mexican patients, 12 of which were genetically identical to the swine flu viruses from California.

WHO and CDC both said they were sending representatives to Mexico to assist local authorities, and WHO said it has alerted its Global Alert and Response Network. Besser said that WHO will likely convene an expert panel to discuss raising the pandemic alert level from 3 (human infection with new influenza subtype with only rare human-to-human spread) to 4 (small clusters with localized human-to-human transmission). He said the experts will consider 3 factors: the novelty of the virus, disease severity, and how easily transmission of the virus is sustained. Global health officials might consider a containment strategy such as dispatching antiviral medications to affected parts of Mexico in an attempt to stop the spread of the virus, but Besser said that such a measure might not work, because there are signs that the virus has already spread from human to human over long distances. "A focused, well defined area is not something we've seen here," he said. CDC officials have said the swine flu A/H1N1 virus is susceptible to the newer antivirals oseltamivir (Tamiflu) and zanamivir (Relenza), but not the older ones, amantadine and rimantadine. Jeff McLaughlin, a spokesman for GlaxoSmithKline, the maker of Relenza, told CIDRAP News that the company is watching the swine flu developments closely. Terry Hurley, a spokesman for Roche, which produces Tamiflu, said its "rapid response stockpile" is on 24-hour standby, as usual, for deployment to WHO, which has not yet requested it.

The threat from the swine flu virus serves as a reminder for individuals and businesses to think about their own level of preparedness, Besser said. "This is a time for people to be thinking about that teachable moment." So far, federal officials have not changed their travel recommendations to California, Texas, or Mexico, though they have issued an advisory about the increased health risk in certain parts of Mexico, urging travelers to take standard precautions such hand washing, staying home when sick, and using good coughing and sneezing hygiene.

[byline: Lisa Schnirring]

--
communicated by:
ProMED-mail
<promed@promedmail.org>

[The "swine" influenza A(H1N1) virus associated with current outbreaks of respiratory illness in the southern region of the USA and in Mexico appears to be a complex reassortant containing genome components from avian, human, and swine virus sources. Such a virus is unique and it is too early to conclude that this virus has originated in swine.

According to the CDC website (<<http://www.cdc.gov/swineflu/>>) swine influenza (swine flu) is a respiratory disease of pigs caused by type A influenza viruses that regularly cause outbreaks of influenza among pigs. Swine flu viruses do not normally infect humans; however, human infections with swine flu do occur, and cases of human-to-human spread of swine flu viruses has been documented. From December 2005 through February 2009, a total of 12 human infections with swine influenza were reported from 10 states in the United States. Since March 2009, a number of confirmed human cases of the new strain of swine influenza A (H1N1) virus infection in California, Texas, and Mexico have been identified.

Whatever the origin of the current outbreak virus it is likely that the designation swine influenza virus will stick. - Mod.CP]

[2] Strain identity
Date: Fri 24 Apr 2009
Source: CBC News [abbreviated and edited]
<<http://www.cbc.ca/health/story/2009/04/24/health-flu-mexico090424.html>>

Canadian lab confirms human swine flu cases in Mexico

 "Today we have received results which confirm that the virus is human swine influenza," Leona Aglukkaq told a press conference in Ottawa, Ontario, Canada. A handful of cases of flu-like illness in Canadian residents who recently returned from Mexico are being monitored; however, "there have been no confirmed cases of human swine influenza yet" here, said Dr David Butler-Jones, Canada's chief public health officer.

Mexico sent 51 specimens for testing to Canada's National Microbiology Laboratory on Wednesday [21 Apr 2009]. 16 positives of swine flu were found among the samples. Mexican health minister Jose Angel Cordova said on Friday that 20 people were killed in the outbreak and 1004 were infected throughout the country, prompting WHO to convene an emergency meeting on Saturday. Officials closed schools, museums and libraries in Mexico City on Friday to limit spread of the virus.

Dr Rich Besser, acting head of the US Centers for Disease Control (CDC), said early analysis of Mexican samples of the virus showed it is very similar to those responsible for 8 American cases, one confirmed on Friday. All the US victims have recovered. Canada is working with Mexican and US health officials to confirm that the virus in both countries is linked and is in fact a new strain of influenza A H1N1 human swine virus, he added.

"This is an interesting virus. It's a brand new virus, not only to humans but to the world," said Dr Frank Plummer, scientific director of the Winnipeg lab. "About 80 per cent of the virus is highly related to a North American body [?] of swine flu that's been around for a number of years, but about 20 per cent of it comes from an Eurasian variety of swine flu 1st seen in Thailand, so it's recombined [re-assorted ?] to create something totally new. How it did that, where it did it, when it did it, I don't think we know yet."

CDC said the current strain of swine flu includes genetic material from 4 sources: North American swine influenza viruses, North American avian influenza viruses, human influenza virus, and swine influenza viruses found in Asia and Europe -- a new combination that has not been recognized anywhere in the world before. There appears to be human-to-human spread in both the US and Mexico over a wide geographic area at this point, but investigators are still checking for direct contact with swine.

WHO spokesperson Gregory Hartl said the agency needs to determine whether the outbreaks constitute an international public health threat. Hartl also said 12 of 18 samples taken from victims in Mexico showed the virus had a genetic structure identical to that of the virus found in California earlier this week. But he said the agency needs more information before it changes its pandemic alert level, which currently stands at 3 on a scale of one to 6. The virus was 1st reported earlier this week as US health officials scrambled to deal with the diagnoses of 7 people with the never-before-seen strain in Texas and California. The states share a border with Mexico not far from a town where 2 deaths were reported.

Hartl said health officials are dealing with 3 separate events in Mexico, with most of the cases in and around the capital, Mexico City. Most of the cases have occurred in healthy young adults, he added. "Because these cases are not happening in the very old or the very young, which is normal with seasonal influenza, this is an unusual event and a cause for heightened concern," Hartl said in an interview from WHO headquarters in Geneva. It is also rare to see such high flu activity so late in the season, he said. "The end of April, especially in a place like Mexico, you would think that we would see quite a steep decline," said Hartl.

On Thursday [23 Apr 2009], Canadian health officials issued advice warning travellers who have recently returned from Mexico to be on alert for flu-like symptoms that could be connected to the illness.

--
 communicated by:
 Steven McAuley
 Medical student
 University of Otago
 Dunedin, New Zealand