

医薬品 研究報告 調査報告書

識別番号・報告回数			報告日 2009年7月22日	第一報入手日 2009年4月25日	新医薬品等の区分 該当なし	機構処理欄
一般的名称	ヘパリンナトリウム		研究報告の公表状況	http://www.who.int/csr/don/2009_04_24/en/index.html	公表国 米国	
販売名（企業名）	ヘパリンナトリウム注1万単位/10mL「味の素」 ヘパリンナトリウム注5万単位/50mL「味の素」 ヘパリンナトリウム注10万単位/100mL「味の素」 ヘパリンナトリウム注N5千単位/5mL「味の素」 ヘパリンナトリウム注N1万単位/10mL「味の素」			http://www.who.int/csr/don/2009_04_27/en/index.html		http://www.who.int/mediacentre/news/statements/2009/h1n1_20090427/en/index.html
141 研究報告の概要	特になし					
米国、メキシコにおけるインフルエンザ様疾患について（2009.4.24 WHO EPR サイト） 米国政府は米国内の7人の豚インフルエンザA/H1N1確定症例（5人がカリフォルニア、2人がテキサス）と9人の疑いがある症例を報告した。確定症例7人は、1例のみ短期入院を要したが、いずれも軽度のインフルエンザ様疾患であり、死亡例は報告されていない。 メキシコ政府は、3つの別々の事例を報告した。メキシコ連邦区における調査で、3月18日からインフルエンザ様疾患の症例が挙がり始めた。4月中に症例数は確実に増え、4月23日までに854人以上の肺炎が首都圏で発生している。うち、59人は死亡している。メキシコ中部のSan Luis Potosiでは24人のインフルエンザ様疾患が発生し、3人が死亡と報告されている。また、米国国境近くのMexicaliからは、4人のインフルエンザ様疾患（死亡例はなし）が報告されている。メキシコの症例では、18例がカナダの研究機関で豚インフルエンザA/H1N1であることが確認されており、そのうち12症例はカリフォルニアの豚インフルエンザA/H1N1ウイルスと遺伝学的に一致している。 これらの症例は主に若年健康人に発生している。インフルエンザは、通常幼児が高齢者が罹患するが、メキシコではこの年齢層に大きな影響が出ていない。人の症例が動物インフルエンザウイルスに関連していること、地理的に離れた多地域で発生していること、さらに通常見られない年齢層が罹患していることにより、これらの事例は非常に危惧される。 今回流行した豚インフルエンザA/H1N1ウイルスはこれまでに豚やヒトから検出されていない。このウイルスは少なくともオセルタミビルには感受性を示すが、アマンタジンとリマンタジンには耐性を示している。						
豚インフルエンザ update3（2009.4.27 WHO EPRサイト） 最近の豚インフルエンザA（H1N1）の発生状況は刻々と変化している。2009.4.27現在、米国政府は、40症例（死亡例なし）で人への豚インフルエンザ（H1N1）感染を確認したと報告した。メキシコは、7症例の死亡を含む同ウイルスへの感染を26症例で確認したと報告した。スペインが1症例（死亡例なし）、カナダは、6症例（死亡例なし）を報告した。						
豚インフルエンザ（2009.4.27 WHO Media centre サイト） 国際保健規則（2005年）にのっとり設立した緊急委員会が2009年4月27日、2回目となる会合を開催した。 委員会は米国、メキシコ、カナダで確認された豚インフルエンザA/H1N1型の発生について入手可能なデータを検討した。また、ほかの国への感染拡大可能性の報告についても検討された。 委員会の助言を基に、WHOの事務局長は次のように決定した。 インフルエンザの大流行についてのパンデミックアラートを現行のフェーズ3からフェーズ4に引き上げる。引き上げは大流行の危険性が高まったことを示すが、大流行は不可避ではない。さらなる情報によっては、WHOはパンデミックアラートをフェーズ3に戻すか、より高度な水準へ引き上げることを決定するかもしれない。引き上げの決定は、第一に疫学的データが人から人への感染を示すこと、また地域レベルでの感染を引き起こすウイルスである可能性があることに基づいてなされた。						



報告企業の意見	今後の対応	
<p>豚由来のインフルエンザA/H1N1が人に感染し、感染拡大を示唆する報告、人において死亡する恐れがある報告、及びインフルエンザA/H1N1が人から人に感染することが示されたとの報告。既知の感染症であるが、発生頻度の増加、感染症の重大性、新たに人から人へ感染することが示された点から研究報告に該当すると判断する。</p> <p>弊社ヘパリンナトリウム製剤は、ウイルス不活性能力が高いと考えられる工程を経て製造を行っている。</p> <p>現時点で特別な安全対策を講じる必要はないと考える。</p>	<p>今後も情報収集に努める。</p>	

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Influenza-like illness in the United States and Mexico

24 April 2009 -- The United States Government has reported seven confirmed human cases of Swine Influenza A/H1N1 in the USA (five in California and two in Texas) and nine suspect cases. All seven confirmed cases had mild Influenza-Like Illness (ILI), with only one requiring brief hospitalization. No deaths have been reported.

The Government of Mexico has reported three separate events. In the Federal District of Mexico, surveillance began picking up cases of ILI starting 18 March. The number of cases has risen steadily through April and as of 23 April there are now more than 854 cases of pneumonia from the capital. Of those, 59 have died. In San Luis Potosi, in central Mexico, 24 cases of ILI, with three deaths, have been reported. And from Mexicali, near the border with the United States, four cases of ILI, with no deaths, have been reported.

Of the Mexican cases, 18 have been laboratory confirmed in Canada as Swine Influenza A/H1N1, while 12 of those are genetically identical to the Swine Influenza A/H1N1 viruses from California.

The majority of these cases have occurred in otherwise healthy young adults. Influenza normally affects the very young and the very old, but these age groups have not been heavily affected in Mexico.

Because there are human cases associated with an animal influenza virus, and because of the geographical spread of multiple community outbreaks, plus the somewhat unusual age groups affected, these events are of high concern.

The Swine Influenza A/H1N1 viruses characterized in this outbreak have not been previously detected.

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Alert & Response Operations

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Diseases

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Because there are human cases associated with an animal influenza virus, and because of the geographical spread of multiple community outbreaks, plus the somewhat unusual age groups affected, these events are of high concern.

The Swine Influenza A/H1N1 viruses characterized in this outbreak have not been previously detected in pigs or humans. The viruses so far characterized have been sensitive to oseltamivir, but resistant to both amantadine and rimantadine.

The World Health Organization has been in constant contact with the health authorities in the United States, Mexico and Canada in order to better understand the risk which these ILI events pose. WHO (and PAHO) is sending missions of experts to Mexico to work with health authorities there. It is helping its Member States to increase field epidemiology activities, laboratory diagnosis and clinical management. Moreover, WHO's partners in the Global Alert and Response Network have been alerted and are ready to assist as requested by the Member States.

WHO acknowledges the United States and Mexico for their proactive reporting and their collaboration with WHO and will continue to work with Member States to further characterize the outbreak.

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27 April 2009

Swine influenza - update 3

27 April 2009 -- The current situation regarding the outbreak of swine influenza A(H1N1) is evolving rapidly. As of 27 April 2009, the United States Government has reported 40 laboratory confirmed human cases of swine influenza A(H1N1), with no deaths. Mexico has reported 26 confirmed human cases of infection with the same virus, including seven deaths. Canada has reported six cases, with no deaths, while Spain has reported one case, with no deaths.

Further information on the situation will be available on the WHO website on a regular basis.

WHO advises no restriction of regular travel or closure of borders. It is considered prudent for people who are ill to delay international travel and for people developing symptoms following international travel to seek medical attention, in line with guidance from national authorities.

There is also no risk of infection from this virus from consumption of well-cooked pork and pork products. Individuals are advised to wash hands thoroughly with soap and water on a regular basis and should seek medical attention if they develop any symptoms of influenza-like illness.

Related links

[Swine influenza web site](#)
Daily updates will be posted on this site.



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Health topics Statement by WHO Director-General, Dr Margaret Chan
27 April 2009

Publications

Data and statistics Swine influenza

Programmes and projects The Emergency Committee, established in compliance with the International Health Regulations (2005), held its second meeting on 27 April 2009.

Media centre

News The Committee considered available data on confirmed outbreaks of A/H1N1 swine influenza in the United States of America, Mexico, and Canada. The Committee also considered reports of possible spread to additional countries.

Events

Fact sheets

Multimedia On the advice of the Committee, the WHO Director-General decided on the following.

Contacts

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[Current WHO phase of pandemic alert](#)

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- The Director-General has raised the level of influenza pandemic alert from the current phase 3 to phase 4.

The change to a higher phase of pandemic alert indicates that the likelihood of a pandemic has increased, but not that a pandemic is inevitable.

As further information becomes available, WHO may decide to either revert to phase 3 or raise the level of alert to another phase.

This decision was based primarily on epidemiological data demonstrating human-to-human transmission and the ability of the virus to cause community-level outbreaks.

- Given the widespread presence of the virus, the Director-General considered that containment of the outbreak is not feasible. The current focus should be on mitigation measures.

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- Given the widespread presence of the virus, the Director-General considered that containment of the outbreak is not feasible. The current focus should be on mitigation measures.
- The Director-General recommended not to close borders and not to restrict international travel. It was considered prudent for people who are ill to delay international travel and for people developing symptoms following international travel to seek medical attention.
- The Director-General considered that production of seasonal influenza vaccine should continue at this time, subject to re-evaluation as the situation evolves. WHO will facilitate the process needed to develop a vaccine effective against A(H1N1) virus.
- The Director-General stressed that all measures should conform with the purpose and scope of the International Health Regulations.