neurologic signs, cerebrospinal fluid pleocytosis, an electroencephalogram indicative of encephalitis, or abnormal neuroimaging indicative of infection or inflammation.

- † Not done.
- § Aspartate transaminases (normal range: 10--45 U/L).
- ¶ Alanine aminotransferase (normal range: 10--50 U/L).
- \*\* Gamma glutamyltranspeptidase (normal range: 3--30 U/L).
- †† White blood cell count.
- §§ Red blood cell count.
- ¶ Enzyme immunoassay. All four patients had nasopharyngeal specimens obtained and tested for influenza A and B antigen by using Directigen EZ Flu A+B (EIA), QuickVue Influenza A+B test (EIA), or direct fluorescent assay using D3 Ultra.
- \*\*\* All four patients' nasopharyngeal specimens were confirmed positive for novel influenza A (H1N1) virus by Dallas County Department of Health and Human Services, using CDC-approved primers and probes.
- ††† Direct fluorescent assay.
- §§§ Real-time reverse--transcription polymerase chain reaction (performed at CDC).
- ¶¶ Human parainfluenza virus type 3.
- \*\*\*\* CSF viral PCR testing was performed by Viracor, using the Luminex multiplex respiratory viral panel (xTAG), which tests for 10 different viruses (influenza A and B; parainfluenza 1, 2, and 3; respiratory synctial virus A and B; adenovirus; human metapneumovirus; and rhinovirus).
- †††† Herpes simplex virus.

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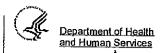
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# 医薬品

## 医薬部外品 研究報告 調査報告書

## 化粧品

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Canadian Food Inspection Agency Agence canadienne d'inspection des aliments . Canadä

Animals > Animal Diseases > Swine Influenza

# Swine Influenza - Advice for Veterinarians and Swine Producers

The Canadian Food Inspection Agency (CFIA) has been notified of cases of human swine influenza (swine flu) in the southern United States and Mexico. Information to date indicates that human-to-human transmission of the virus has occurred. The <u>Public Health Agency of Canada (PHAC)</u> is currently coordinating the <u>Canadian response to this situation</u>, and the CFIA is providing support and expertise as required. For more information, visit http://www.phac-aspc.gc.ca.

At this point, there are no signs of increased disease or death in Canadian swine. However, as a precaution, the CFIA is asking producers, veterinarians and labs to increase their vigilance in monitoring for and reporting swine disease. Suspected cases of illness in pigs should be reported to veterinarians, provincial authorities or the CFIA. Similarly, PHAC recommends that anyone who is experiencing severe flu-like symptoms contact their health care provider.

#### What is swine influenza?

Swine influenza is a contagious respiratory disease of pigs. The disease is commonly seen in North and South America, Asia and Europe. Illness is cause by type A Influenza viruses, which also affect a range of other animals, as well as humans.

#### Are humans affected by swine influenza?

Yes, but human cases of swine influenza are normally uncommon. Most often, cases involve people who have had close contact with pigs, such as farmers and veterinarians. Some cases of human-to-human transmission have been reported. Symptoms of human illness are similar to regular flu: cough, nausea, body aches, fatigue, runny nose and congestion.

Although the risk of human illness is low, anyone having contact with pigs or potentially contaminated equipment should thoroughly wash their hands and limit contact with possibly infected pigs.

Swine, avian and human influenza viruses can combine within pig cells to form new influenza viruses. Flu-like symptoms in swine or people that may have had contact with swine should be reported to animal or public health professionals. Doing so will allow health authorities to maintain a current understanding of the viruses circulating in the animal and human populations.

## What are the symptoms in pigs?

Signs of swine influenza include the following:

- fever
- loss of appetite
- weight loss
- coughing
- sneezing
- nasal discharge
- difficulty breathing

· reduced fertility or abortion

Swine influenza generally does not lead to death, and affected animals usually recover within five to seven days.

#### How do pigs become infected?

Normally, virus spreads when infected pigs cough or sneeze in close quarters with other pigs. Contaminated equipment or other objects may also play a role in transmitting virus. Influenza virus from birds and humans can also infect pigs.

#### How can pigs be protected?

The following actions can potentially prevent swine influenza:

- vaccinating animals
- · ensuring farm working maintain good hygiene
- following strict biosecurity practices
- providing adequate ventilation in barns
- · identifying and segregating sick animals as early as possible

#### What roles do veterinarians and producers play?

Veterinarians should work closely with clients to develop management strategies to limit the incidence and spread of swine influenza. As part of this approach, veterinarians suffering from the "flu" should limit contact with pigs, and farm workers should follow similar advice. Given the current situation, particular caution should be exercised with visitors to farms, especially those who may have recently returned from the southern United States or Mexico.

## Does swine influenza affect food safety?

No, swine influenza is not a food safety concern.

For additional information: www.inspection.gc.ca

Date modified: 2009-04-26

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# Rapid communications

# EPIDEMIOLOGY OF INFLUENZA A(H1N1) V VIRUS INFECTION IN JAPAN, MAY - JUNE 2009

T Shimada (tomoes@nih.go.jp)¹, Y Gu¹, H Kamiya¹, N Komiya¹, F Odaira¹, T Sunagawa¹, H Takahashi¹, T Toyokawa¹, Y Tsuchihashi¹, Y Yasui¹, Y Tada¹, N Okabe¹

1. Infectious Diseases Surveillance Center, National Institute of Infectious Diseases, Tokyo, Japan

Between 9 May and 4 June 2009, a total of 401 laboratory-confirmed cases of influenza A(H1N1)v virus were reported in Japan, from 16 of the 47 Japanese prefectures. The two areas most affected were Osaka prefecture and Kobe city where outbreaks in high schools occurred leading to school closures. To date all cases have had symptoms consistent with seasonal influenza and no severe or fatal cases have been reported.

Following the emergence of a new influenza A(H1N1) virus (henceforth: influenza A(H1N1) virus) and the relevant declarations by the World Health Organization (WHO) [1], the Ministry of Health, Labour and Welfare (MHLW) of Japan launched a case-based surveillance for influenza A(H1N1) virus infection in addition to the existing sentinel surveillance system for seasonal influenza and imposed entry screening on travelers from affected areas (Canada, Mexico and the United States) starting from 28 April 2009 [2].

The following case definitions of suspected and confirmed cases have been used:

A suspected case of influenza A(H1N1)v virus infection is defined as a person with high fever (>38°C) OR at least two acute respiratory symptoms (nasal obstruction/rhinorrhea, sore throat, cough, fever/feverishness) AND who meets at least one of the following criteria:

- a) within the last seven days returned from a country or region with an epidemic of influenza A(H1N1)v;
- b) was in close contact (within two meters) with a confirmed case within the past seven days;
- c) handled samples suspected of containing influenza A(H1N1)virus in a laboratory or other setting within the past seven days;

A confirmed case of influenza A(H1N1)v virus infection is defined as a person with high fever (>38°C) OR at least two acute respiratory symptoms (nasal obstruction/rhinorrhea, sore throat, cough, fever/feverishness) AND influenza A(H1N1)v virus infection that has been laboratory confirmed by real-time PCR and/or viral isolation.

For all travellers from the affected areas who are febrile at the entry, a quarantine officer performs a rapid diagnostic test for influenza. If the result of rapid test is positive for influenza A, a PCR test for influenza A(H1N1)v is done. The Quarantine Law and the Pandemic Influenza Preparedness Action Plan of the Japanese Government request confirmed cases and close contacts of confirmed cases to be hospitalised/isolated for seven days considered to be the infectious period [3,4].

The primers for conventional and real-time RT-PCR for the detection of A(H1N1)v virus were developed by the National Institute of Infectious Diseases and became available on 29 April. All 75 prefectural and municipal public health institutes and quarantine stations in Japan became ready to perform conventional and real-time RT-PCR test by 4 May. Since the first laboratory-confirmed cases were reported on 9 May, the number of cases of influenza A(H1N1)v increased continuously, resulting in a total of 401 laboratory-confirmed cases as of 4 June 2009. This report summarises the epidemiological characteristics of the confirmed cases reported in Japan from May to June.

The first four laboratory-confirmed cases of influenza A(H1N1)v were reported at the Narita International Airport quarantine station on 9 May 2009. The patients were travellers who returned from Canada on 9 May. Although all of them showed mild symptoms, they were hospitalised in an isolation ward of a designated hospital for seven days, in accordance with the Quarantine Law and the Pandemic Influenza Preparedness Action Plan of the Japanese Government [3,4].

The first laboratory-confirmed cases without travel history were detected on 16 May as follows:

A high school in Ibaraki city, in Osaka prefecture near the border with Hyogo prefecture, noticed an increase in the number of absentees due to influenza-like symptoms in the middle of May 2009. On 16 May the school was closed in conformity with the School Health Law [5]. According to this law (enacted in 1958), influenza-like illness/seasonal influenza is one the infectious diseases that can trigger school closure. The number of absentees that leads to school closure is decided by the school authorities. In many cases, 5 to 10 absentees in a class may lead to closing the class; 2-3 closed classes may lead to school closure.

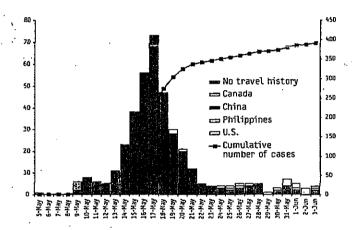
None of the sick high school pupils in Ibaraki had travel history to the countries affected by the new influenza. On 16 May, five teenagers were confirmed with influenza A(H1N1)v virus infection: one from the school in Ibaraki in Osaka prefecture, and four from Kobe City in the neighbouring Hyogo prefecture. Subsequently, outbreaks in three schools were reported during the next few days in these adjacent prefectures. The local governments of Kobe City and Osaka prefecture implemented extensive school closures, deciding to close not only schools with infected students but all schools in both districts, for one to two weeks from 16 May. As a result, over

4,200 schools with around 650,000 children/students were closed. By 19 May, the number of confirmed cases reported in the two districts reached 172. However, after school closures, the number of new confirmed cases decreased (Figure 1). By 4 June a total of 357 cases were reported from the two prefectures.

Outside these two prefectures only sporadic cases were reported, the majority of whom had a travel history abroad or an epidemiological link to a traveller from affected areas including

FIGURE 1

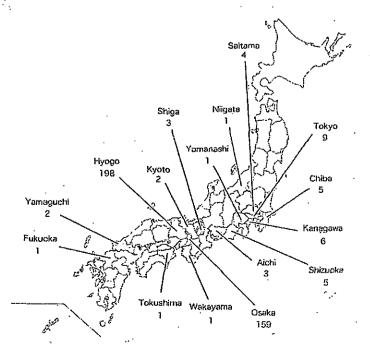
Confirmed cases of influenza A(H1N1)v virus infection in Japan, by date of onset and cumulative number as of 4 June 2009 (n=392\*)



\* Nine cases without the record of onset of illness were excluded

FIGURE 2

Geographical distribution of confirmed cases of influenza A(HINI)v virus infection in Japan as of 4 June 2009 (n=401)



Osaka (Figure 2). In all, confirmed cases were reported from 16 of the total of 47 Japanese prefectures.

Reflecting the outbreaks in high schools described above, confirmed cases in the age group of 15-19 years accounted for 64% (256) of all cases, followed by 10% (40) of cases in the age group of 10-14 years. Only four cases (1%) were over 60 years of age (Figure 3). Overall, the median age of cases was 16.0 (range 1-69 years). Male cases accounted for 63% (254) and female cases for 37% (147) of all cases. Large outbreaks observed in high schools may have contributed to the difference in gender (as more boys than girls attend the affected schools).

Information on clinical symptoms was available for 217 confirmed cases (Figure 4). The most frequent were fever (206, 95%), cough (128, 59%), and sore throat (85, 39%). Thirteen cases (6%) reported diarrhoea and five cases (2%) had nausea.

FIGURE 3

Age distribution of confirmed cases of influenza A(H1N1)v virus infection in Japan as of 4 June 2009 (n=401)

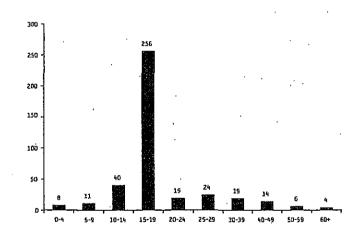
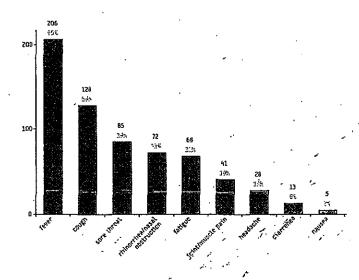


FIGURE 4

Clinical symptoms of confirmed cases of influenza A(H1N1)v virus infection in Japan as of 4 June 2009 (n=217)



Antiviral treatment of either oseltamivir or zanamivir was prescribed to about 90% of the 217 confirmed cases with known clinical symptoms.

No cases with pneumonia and/or respiratory failure, requiring ventilatory support, were reported. Other severe symptoms such as multiple organ failure were not reported either. Only three cases required hospitalisation due to underlying medical conditions, although a total of 135 cases were hospitalised for the purpose of isolation based on the Quarantine Law and the Pandemic Influenza Preparedness Action Plan of the Japanese Government [3,4].

Among the confirmed cases, six (including two cases aged over 60 years) had underlying diseases: asthma (3), asbestosis (1), epilepsia (1), myodystrophia (1), and one case was pregnant. As of 4 June 2009, no severe or fatal case had been reported.

The epidemiological characteristics of the patients with influenza A(H1N1)v virus infection have been reported by the investigation teams including members of IDSC/NIID and local government, who conclude that the severity of disease is similar to that of seasonal influenza [6,7].

The next steps include addressing the questions of how to improve the surveillance system to detect, monitor, and control the cases of influenza A (H1N1)v and how to prepare for the more severe cases as the epidemic is expected to expand in the winter season. We need to decide when the case-based surveillance for influenza A(H1N1)v should be ceased and integrated into the sentinel surveillance of seasonal influenza. To evaluate the pathogenicity, planned surveillance systems, such as severe pneumonia surveillance and ILI cluster surveillance, should be launched before the coming winter season. The Pandemic Influenza Preparedness Action Plan of the Japanese Government also needs to be amended so that medical resources would not be wasted by the patients with mild symptoms merely for the purpose of isolation.

#### Acknowledgement

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## 医薬品

# 医薬部外品 研究報告 調査報告書

## 化粧品

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識別番号・報告回数	:		<b>報告日</b> 年 月 日	第一報入手日 2009 年 7 月 6 日	新医薬品等の区分 該当なし	総合機構処理欄
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International Society for Infectious Diseases

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Date: Mon 29 Jun 2009
Source: BBC News [edited] 
<a href="http://news.bbc.co.uk/1/bi/health/8124987.stm">http://news.bbc.co.uk/1/bi/health/8124987.stm</a>

Experts have reported the 1st case of swine flu that is resistant to Tamiflu [oseltamivir], the main drug being used to fight the pandemic. Roche Holding AG confirmed a patient with HINI influenza in Denmark showed resistance to the antiviral drug. David Reddy, company executive, said it was not unexpected given that common seasonal flu could do the same.

The news comes as a 9 year old girl has become the 3rd to die in the UK with swine flu. It is understood from her doctors at Birmingham Children's Hospital that she had underlying health conditions. It is not yet known whether swine flu contributed to her death.

Meanwhile, the Department of Health has announced a big jump in the number of patients in England confirmed with swine flu, up 1604 since Friday [26 Jun 2009], taking the UK total so far to 5937. A Health Protection Agency spokeswoman stated that: "Routine sampling in the UK has shown that there is currently no resistance to oseltamivir or zanamivir." Experts have been using Tamiflu, also known as oseltamivir, in a bid to stop the HINI spreading in communities. If taken early, it ensures that symptoms are mild and reduces the chance of a victim giving the illness to someone else.

This 1st reported case of resistance developed in a swine flu patient taking Tamiflu. Mr Reddy stressed that there were no signs of a Tamiflu-resistant strain of HIN1 circulating in the community. This is in contrast to seasonal HIN1 flu, where a Tamiflu resistant strain emerged last year [2009] and is now widely circulating. Experts fear if this were to happen, it could render Tamiflu ineffective [in treatment of the swine flu HIN1 virus infection]:

Another antiviral drug, called zanamivir or Relenza, made by GlaxoSmithKline, is also effective against swine flu. The UK government has been stockpiling these antiviral drugs and currently has enough to treat half of the population, with a contract to bring that up to 80 per cent as soon as possible. Supplies of flu vaccine have also been ordered, and the 1st doses could be administered in the autumn [2009].

A spokeswoman for the Health Protection Agency said: "The Health Protection Agency continues to watch for antiviral resistance and will be carrying out regular sample testing throughout this outbreak. We have been monitoring antiviral drug resistance since the beginning of this outbreak. Routine sampling in the UK has shown that there is currently no resistance to oseltamivir or zanamivir." Virologist Professor John Oxford said: "I'm not

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                                                     Influenza A (HiM1) - worldwide (58); USA, Africa 20090607.2109
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                                       Influenza A (HIN1) - worldwide (64): case count, pandemic 20090616.2221
                                  Influenza A (HIMI) - worldwide (65); antivirajs in pregnancy 20090616.2224
                                         Influence A (HiWi) - worldwide (68); southern hemisphere 20090618.2333
                                     Influenza A (Hill) - worldwide (69): other viral infections 20090618.2254
                                                    Influenza A (HIM1) - worldwide (70): risk factors 20090619.2260
                                 Influenza A (HiMl) - worldwide (72): case count, epidemiology 20090619.2261
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                                             reofated in Denmark remains sensitive to the alternate neuraminidase
                                      independently elsewhere. It is presumed that the Tamifiu-resistant virus
       remains to be seen whether the Tamiflu-resistant virus will spread in Europe and beyond and
    indiscriminate use of the drug in the treatment of what is still a relatively mild disease. It
                 origin A Hill influenza virus is not unexpected in view of the widespread and somewhat
worldwide (83); antiviral resistance 20090705.2417] The emergence of Tamifiu-resistant 209 swine-
         resistance has been observed in seasonal A(HlN1) viruses. [ see posting Influence A (HlN1)
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            have been sensitive to oseltamivir and zanamivir but resistant to M2 inhibitors, although
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spread. We will soon know the answer."

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surprised about this finding. The question is whether it is going to

Influenza A (HIN1) "swine flu": worldwide ... / 20090428.1601

Influenza A (HIN1) "swine flu": worldwide (03) 20090428.1600

Influenza A (HIN1) "swine flu": Worldwide (02) 20090427.1586

Influenza A (HIN1) "swine flu": Worldwide (20) 20090427.1583

Influenza A (HIN1) virus, human: worldwide 20090426.1577

Influenza A (HIN1) virus, human - New Zealand, susp 20090426.1574

Influenza A (HIN1) virus, human - N America (04) 20090426.1566

Influenza A (HIN1) virus, human - N America (03) 20090426.1566

Influenza A (HIN1) virus, human - N America (02) 20090425.1557

Influenza A (HIN1) virus, human - N America 20090425.1557

Influenza A (HIN1) virus, human - N America 20090425.1556

Influenza A (HIN1) virus, swine, human - USA (02): (CA, TX) 20090424.1546

Influenza A (HIN1) virus, swine, human - USA: (CA) 20090422.1516

Influenza A (HIN1) virus, swine, human - USA: (CA) 20090422.1516

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## 医薬品

# 医薬部外品 研究報告 調査報告書

## 化粧品

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一般的名称		 研	究報告の公表状況	World now at the start of influenza pandemic http://www.who.int/mediacews/statements/2009/hln1_c_phase6_20090611/en/inde	centre/n _pandemi	公表国スイス	
で、インフルエ したと表明にた 染の第二波に備 少数確認されて 力を注ぐべきで さらに、WHO は	ンザパンデミックの基準を 。一方で、感染の広がりは えるよう強く要望を出すと いるにとどまっている国で あることを求めている。ま	が満たしたこと はフェーズ 6 で ともに、この では監視の継続 た、ヒトやも 造業者に対し	とが判明し、この事実ではあるが、重症度とのインフルエンザ感染である。既に感染ができなめ、既に感染がでの移動制限や国境閉鎖、季節性インフルエン	での知見や専門家等が評価した基づいて感染のフェーズをしては、中等度と位置づけて、の対応として、感染症例が拡大している国においては感は推奨しないと表明している。 世は推奨しないと表明している 関は推奨しないと表明している 関はでいる。	5から6に5 いる。各国に まだ確認され 染症患者へる 3。	引き上げる事と こ対しては, 感 れていない或は の適切な管理に	使用上の注意記載状況 その他参考事項等 BYL-2009-0391
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最大の流行を示すフ ンザは多くは重症化 の確保が要求される	た新型インフルエンザ(H1N ェーズ 6 と判定, 宣言され しない傾向があるが, 感染に る。 また, インフルエン mivir の確保にも努める必	た。 本インフ/ に備えたワクラ ザ治療薬でも	ルエ に注視し、情報 チン	インフルエンザ感染について の収集に努める。	,さりに健康	<b>東を智かす情報</b>	





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Contacts .

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Statement to the press by WHO Director-General Dr Margaret Chan 11 June 2009

World now at the start of 2009 influenza pandemic

Dr Margaret Chan

Director-General of the World Health Organization

Ladies and gentlemen,

In late April, WHO announced the emergence of a novel influenza A virus.

This particular H1N1 strain has not circulated previously in humans. The virus is entirely new.

The virus is contagious, spreading easily from one person to another, and from one country to another. As of today, nearly 30,000 confirmed cases have been reported in 74 countries.

This is only part of the picture. With few exceptions, countries with large numbers of cases are those with good surveillance and testing procedures in place.

Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable.

I have conferred with leading influenza experts, virologists, and public health officials. In line with procedures set out in the International Health Regulations, I have sought guidance and advice from an Emergency Committee established for this purpose.

On the basis of available evidence, and these expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met.

I have therefore decided to raise the level of influenza pandemic alert from phase 5 to phase 6.

The world is now at the start of the 2009 influenza pandemic.

We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch.

No previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning. The world can now reap the benefits of investments, over the last five years, in pandemic preparedness.

We have a head start. This places us in a strong position. But it also creates a demand for advice and reassurance in the midst of limited data and considerable scientific uncertainty.

Thanks to close monitoring, thorough investigations, and frank reporting from countries, we have some early snapshots depicting spread of the virus and the range of illness it can cause.

We know, too, that this early, patchy picture can change very quickly. The virus writes the rules and this one, like all influenza viruses, can change the rules, without rhyme or reason, at any time.

Globally, we have good reason to believe that this pandemic, at least in its early days, will be of moderate severity. As we know from experience, severity can vary, depending on many factors, from one country to another.

On present evidence, the overwhelming majority of patients experience mild symptoms and make a rapid and full recovery, often in the absence of any form of medical treatment.

Worldwide, the number of deaths is small. Each and every one of these deaths is tragic, and we have to brace ourselves to see more. However, we do not expect to see a sudden and dramatic jump in the number of severe or fatal infections.

We know that the novel H1N1 virus preferentially infects younger people. In nearly all areas with large and sustained outbreaks, the majority of cases have occurred in people under the age of 25 years.

In some of these countries, around 2% of cases have developed severe illness, often with very rapid progression to life-threatening pneumonia.

Most cases of severe and fatal infections have been in adults between the ages of 30 and 50 years,

This pattern is significantly different from that seen during epidemics of easonal influenza, when most deaths occur in frail elderly people.

Many, though not all, severe cases have occurred in people with underlying chronic conditions. Based or limited, preliminary data, conditions most frequently seen include respiratory diseases, notably asthma, cardiovascular disease, diabetes, autoimmune disorders, and obesity.

At the same time, it is important to note that around one third to half of the severe and fatal infections are occurring in previously healthy young and middle-aged people.

Without question, pregnant women are at increased risk of complications. This heightened risk takes on added importance for a virus, like this one, that preferentially infects younger age groups.

Finally, and perhaps of greatest concern, we do not know how this virus will behave under conditions typically found in the developing world. To date, the vast majority of cases have been detected and investigated in comparatively well-off countries.

Let me underscore two of many reasons for this concern. First, more than 99% of maternal deaths, which are a marker of poor quality care during pregnancy and childbirth, occurs in the developing world

Second, around 85% of the burden of chronic diseases is concentrated in low- and middle-income countries.

Although the pandemic appears to have moderate severity in comparatively well-off countries, it is prudent to anticipate a bleaker picture as the virus spreads to areas with limited resources, poor health care, and a high prevalence of underlying medical problems.

Ladies and gentlemen,

ુલેલ્વર જ્યારે છે. જેવર હોલેલ્ જર્મ કુંદે ન માર્લ્યું કહુંદે કે લોકો

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A characteristic feature of pandemics is their rapid spread to all parts of the world. In the previous century, this spread has typically taken around 6 to 9 months, even during times when most international travel was by ship or rail.

Countries should prepare to see cases, or the further spread of cases, in the near future. Countries where outbreaks appear to have peaked should prepare for a second wave of infection.

Guidance on specific protective and precautionary measures has been sent to ministries of health in all countries. Countries with no or only a few cases should remain vigilant.

Countries with widespread transmission should focus on the appropriate management of patients. The testing and investigation of patients should be limited, as such measures are resource intensive and car very quickly strain capacities.

WHO has been in close dialogue with influenza vaccine manufacturers. I understand that production of vaccines for seasonal influenza will be completed soon, and that full capacity will be available to ensure the largest possible supply of pandemic vaccine in the months to come.

Pending the availability of vaccines, several non-pharmaceutical interventions can confer some protection.

WHO continues to recommend no restrictions on travel and no border closures.

Influenza pandemics, whether moderate or severe, are remarkable events because of the almost universal susceptibility of the world's population to infection.

- We are all in this together, and we will all get through this together.

Thank you.

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#### 医薬品 研究報告 調査報告書

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# 一般的名

#### 販売名(企業名)

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①献血アルブミン 20 "化血研"、②献血アルブミン 25 "化血研"、③人血清アルブミン "化血研"\*、④ "化血研" ガンマーグロブリン、⑤ガ

インフルエンザウイルス粒子は 70~120nm の球形または多形性で、8 本の分節状マイナス一本鎖 RNA を核酸として有する。エンベロープの表面に赤血球凝集素(HA)とノイラミダーゼ(NA)のスパイクを持ち、その抗原性により 16 種類の HA 亜型および 9 種類の NA 亜型に分類される。

今回の新型インフルエンザの原因ウイルスは、1930 年代以降に発見された米国由来のブタインフルエンザウイルス、ヒトインフルエンザウイルス (H3N2)、鳥インフルエンザウイルスの 3 つのウイルスの遺伝子がブタインフルエンザとして再集合してできたウイルスに、さらにユーラシア大陸由来のブタインフルエンザウイルスの遺伝子の一部の分節が再集合して加わったものであると推察されている。新型インフルエンザは、これまでのところ限られた知見しか得られていないが、そのヒトからヒトへの感染伝播経路は従来の季節性インフルエンザに準ずると考えられている。すなわち、感染、発病者の咳やくしゃみとともに口から発せられる飛沫による飛沫感染が主な感染経路であり、患者との直接、間接の接触による接触感染も感染経路としての可能性がある。臨床症状であるが、これまでのところ、この新型インフルエンザのヒトへの病原性は、高病原性鳥インフルエンザウイルス A/H5N1 のヒト感染例とは異なって、ヒトに対する病原性はそれほど高くはないと考えられている。

#### 報告企業の意見

(http://idsc.nih.go.jp/idwr/douko/2009d/17douko.html)

弊所の血漿分画製剤の製造工程には、冷エタノール分画工程、ウイルス除去膜ろ過工程あるいは加熱工程等の原理の異なるウイルス除去及び不活化工程が存在しているので、ウイルスクリアランスが期待される。各製造工程のウイルス除去・不活化効果は、「血漿分画製剤のウイルスに対する安全性確保に関するガイドライン(医薬発第 1047 号、平成 11 年 8 月 30 日)」に従い、ウシウイルス性下痢ウイルス(BVDV)、仮性狂犬病ウイルス(PRV)、ブタパルボウイルス(PPV)、A型肝炎ウイルス(HAV)または脳心筋炎ウイルス(EMCV)をモデルウイルスとして、ウイルスプロセスバリデーションを実施し、評価を行っている。今回報告したインフルエンザウイルスは、エンベロープの有無、核酸の種類等からモデルウイルスとしては BVDV が該当すると考えられるが、上記バリデーションの結果から、弊所の血漿分画製剤の製造工程が BVDV の除去・不活化効果を有することを確認している。また、これまでに当該製剤によるインフルエンザの報告例は無い。以上の点から、当該製剤はインフルエンザウイルスに対する安全性を確保していると考える。

# 農林水産省

#### プレスリリース

平成21年10月21日 農林水産省

#### 大阪府における豚への新型インフルエンザの感染事例について

本日、大阪府の養豚農場の豚から分離されたウイルスは現在国内で流行している新型インフルエンザウイルスであることが確認されました。 当該農場に対して、臨床検査、遺伝子検査により異常がないことが確認されるまで、飼養豚の移動を自粛するよう要請しました。 なお、世界保健機関(WHO)等の国際機関によれば、適切に処理された豚肉を人が食べてインフルエンザに感染することはありません。

#### 1.経緯

大阪府の養豚農場で分離されたインフルエンザウイルスについて、(独)農研機構動物衛生研究所が、H亜型検査(遺伝子解析)及びN亜型検査(遺伝子解析)を実施した結果、本ウイルスは、H1N1亜型であり、現在国内で流行している新型インフルエンザウイルスと同一であることが本日確認されました。

#### 2.対応

大阪府において、当該農場に対して、臨床検査、遺伝子検査(PCR検査法)により異常がないことが確認されるまで、飼養豚の移動を自粛するよう要請しました。 なお、当該農場からと畜場へは、検査で陰性を確認した豚のみを出荷することとしています。

#### 麗 報道機関へのお願い

- 1、現場での取材は、本病の豚への感染を引き起こすおそれもあることから、厳に慎むようお願いします。
- 2. 今後とも、本病に関する情報提供に努めますので、生産者等の関係者や消費者が根拠のない噂などにより混乱することがないよう、ご協力をお願いします。

世界保健機関(WHO)等の国際機関によれば、適切に処理された豚肉を人が食べてインフルエンザに感染することはありません。

#### -- お問い合わせ先 --

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農林水産省

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## 医薬品 研究報告 調査報告書

一般的名称         人血清アルブミン           赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社) 赤十字アルブミン20%静注4g/20mL(日本赤十字社) 赤十字アルブミン20%静注10g/50mL(日本赤十字社) 赤十字アルブミン25%静注12.5g/50mL(日本赤十字社) 赤十字アルブミン25%静注12.5g/50mL(日本赤十字社) 十分         研究報告の公表状況         CDC. Available from: http://wwwn.cdc.gov/travel/cont ent/outbreak- notice/chikungunya-fever.aspx         米国	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 2009. 7. 21 該当なし		総合機構処理欄	
ホ十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社) <b>販売名(企業名)</b> 赤十字アルブミン20%静注4g/20mL(日本赤十字社) 赤十字アルブミン20%静注10g/50mL(日本赤十字社)	一般的名称	赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社) 赤十字アルブミン20%静注4g/20mL(日本赤十字社) 赤十字アルブミン20%静注10g/50mL(日本赤十字社)			http://wwwn.cdc.gov/travel/content/outbreak-			,
				研究報告の公表状況			ſ	

|現状:2009年1月以降、チクングニヤ熱症例数の増加がタイ、マレーシア、インドを含むアジアの一部地域で報告されている。チ クングニヤ熱は蚊の媒介でヒトに感染が広がるウイルス感染症である。症状には、急な発熱、関節痛(腫脹を伴うこともある)、悪 寒、頭痛、吐き気、嘔吐、腰痛、紅斑などがある。流行地域は主にアフリカとアジアだが、2007年にはイタリアでの限定的な伝播 が見られた。

タイでは、2009年7月22日時点で、プーケットなどの観光地を含むタイ南部で大規模なアウトブレイクが発生している。タイ保健省 によると50の県で34,200例が記録されたが、死亡例はなかった。マレーシアでは、7月18日時点で2,900例以上のチクングニヤ熱 症例が主に北部地域から報告された。インドでは、4月29日時点で2,700例以上の症例が主に南部地域から報告されたが、死亡 |例はなかった。報告数の増加に伴い、アジアの他の国々では監視を強化している。

|渡航者向け勧告:流行地への渡航者は蚊に刺されないよう、朝晩に戸外に出る場合は虫除けを使用すること。罹患した場合は 医師の診察を受けること。また、他人への感染拡大を防ぐため、蚊に刺されないよう注意すること。

「チクングニヤ熱の潜伏期間は通常3~7日である。症状は数日~2週間持続するが、数週間にわたって疲労感を感じる患者もい る。ほとんどの患者が関節痛や関節炎を報告しており、数週間~数ヶ月続くこともある。症状はデング熱によく似ているが、出血 やショック症状は通常見られず、ほとんどは入院を必要としない。患者は自然治癒し、死亡に至ることは滅多にない。チクングニ ヤ熱の治療薬はないため、治療は対症療法が中心となる。

#### 使用上の注意記載状況・ その他参考事項等

赤十字アルブミン20 赤十字アルブミン25 赤十字アルブミン20%静注 4g/20mL 赤十字アルブミン20%静注 10g/50mL 赤十字アルブミン25%静注 12.5g/50mL

血液を原料とすることに由来す る感染症伝播等

#### 報告企業の意見

## 今後の対応

ないよう注意喚起する情報を発表したとの報告である。 チクングニヤウイルスは脂質膜を持つRNAウイルスである。これ まで、本製剤によるチクングニヤウイルス感染の報告はない。本 製剤の製造工程には、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 製剤の安全性は確保されていると考える。

タイ、マレーシア、インドにおいてチクングニヤ熱のアウトブレイ 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 |クが発生し、米国疾病対策センターが渡航者向けに蚊に刺され|(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。



## Outbreak Notice Chikungunya Fever in Asia

This information is current as of today, August 17, 2009 at 00:28 EDT

Updated: July 29, 2009

#### Situation Information

Since January 2009, a growing number of cases of chikungunya fever has been reported in parts of Asia, including Thailand, Malaysia, and India. Chikungunya fever is a disease caused by a virus that is spread to people through the bite of infected mosquitoes. Symptoms can include sudden fever, joint pain with or without swelling, chills, headache, nausea, vomiting, lower back pain, and a rash. Chikungunya mainly occurs in areas of Africa and Asia. In 2007, limited transmission of Chikungunya virus occurred in <a href="Italy (Arravel/destinations/Italy.aspx">Italy (Arravel/destinations/Italy.aspx</a>).

#### Thailand

As of July 22, 2009, a large outbreak of chikungunya fever has affected the southern region of <a href="https://Thailand.aspx)">Thailand.aspx)</a> including some tourist destinations, such as Phuket. According to the Ministry of Public Health in Thailand, over 34,200 cases have been documented this year in 50 provinces, with no deaths reported. The most affected areas are the southern provinces of Songula, Narathiwat, Pattani, and Yala.

Recent reports show that Chikungunya virus has now from the southern provinces to all other regions of the country.

#### Malaysia

As of July 18, 2009, the Ministry of Health in Malaysia (/trave/destinations/Malaysia.aspx) has reported over 2,900 cases of chikungunya fever. The most affected areas are the northern provinces of Kedah, followed by Selangor, Kelantan, Perak and Sarawak.

#### India

As of April 29, 2009, the Directorate of National Vector Borne Disease Control Programme in <u>India (/travel/destinations /India.aspx)</u> has reported over 2,700 suspected cases of chikungunya fever, with no deaths reported. The most affected areas are the Karnataka, followed by Andhra, Goa, and Kerala states.

In response to the growing number of reports, other countries in Asia have increased surveillance for chikungunya fever.

#### Advice for Travelers

No medications or vaccines are available to prevent a person from getting sick with chikungunya fever. CDC recommends that people traveling to areas where chikungunya fever has been reported take the following steps to protect themselves from mosquito bites.

- The best way to avoid Chikungunya fever is to avoid mosquito bites. When outdoors during the day and at night, use insect repellent (http://www.cdc.gov/ncidod/dvbid/westnile/qa/insect\_repellent.htm#proper) on exposed skin.
  - Look for a repellent that contains one of the following active ingredients: DEET, picaridin (KBR 3023), Oil of Lemon Eucalyptus/PMD, or IR3535. Always follow the instructions on the label when you use the repellent.
  - In general, repellents protect longer against mosquito bites when they have a higher concentration (%) of any of these active ingredients. However, concentrations above 50% do not offer a distinct increase in protection time. Products with less than 10% of an active ingredient may offer only limited protection; often from 1-2 hours.
  - The <u>American Academy of Pediatrics (/travel florward.aspx?t=aHR0cDovL3d3dy5hYXAub3JnL3B1YmxpY2VkL0JSX1JlcGVsbGVudHMuaHRt-QBZllvSqqfw%3d)</u>
     approves the use of repellents with up to 30% DEET on children over 2 months of age.



If you get sick with a fever and think you may have chikungunya fever, you should seek medical care. Although there is no specific treatment for the disease, a doctor may be able to help treat your symptoms. Avoid getting any other mosquito bites, because you could transmit the disease to other people through mosquitoes.

For more travel health information, see the <u>destinations (/travel/destinations/list.aspx)</u> section and search for the country you are planning to visit.

#### More Information

The incubation period for chikungunya (time from infection to illness) can be 2-12 days, but is usually 3-7 days. Chikungunya fever typically lasts a few days to 2 weeks, but some patients feel fatigue lasting several weeks. Most patients have reported severe joint pain or arthritis, which may last for weeks or months. The symptoms are similar to those of dengue fever, but, unlike dengue, people who have chikungunya fever do not usually experience hemorrhage (bleeding) or go into shock. People with chikungunya fever generally get better on their own and rarely die from the disease.

There is no specific drug treatment for chikungunya fever, and medical care is usually focused on treating the symptoms of the disease. Bed rest, fluids, and mild pain medications such as ibuprofen, naproxen, or acetaminophen (paracetamol) may relieve symptoms of fever and aching, provided there are no medical contraindications for using these medications. Most people are not sick enough to need to stay in the hospital. All people who become sick with chikungunya fever should be protected against additional mosquito bites to reduce the risk of further transmission of the virus.

For more information, see-

- Chikungunya (http://www.cdc.goy/ncidod/dvbid/Chikungunya/CH\_FactSheet.html) (CDC Fact Sheet)
- Traveling with Children: Resources (http://wwwn.cdc.gov/travel/contentChildTravel.aspx) (CDC Travelers' Health website)

## Other Mosquito-Related Diseases.

In many of the areas where chikungunya is present, there are other diseases spread by mosquito bites, such as <u>dengue</u> (<a href="mailto:dravel/yellowbook/2010/chapter-5/dengue-fever-dengue-hemorrhagic-fever-aspx">dengue-fever-dengue-hemorrhagic-fever-aspx</a>), <a href="mailto:mail

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   National Center for Preparedness, Detection, and Control of Infectious Diseases



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