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別紙様式第２－１

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 2010年1月25日	新医薬品等の区分 該当なし	総合機構処理欄
一般的名称	別紙のとおり		研究報告の公表状況	2009-2010 Influenza Season Week 1 ending January 9, 2010 : 3	公表国 米国	
販売名（企業名）	別紙のとおり					

研究報告の概要	問題点：the Iowa Department of Public Health から、ヒトにおける初のブタインフルエンザA(H3N2)感染事例が報告された。 ヒトにおける新規インフルエンザAウイルスの感染事例1例が the Iowa Department of Public Health から報告された。患者は2009年9月に発症したが、入院の必要は無く、回復した。同ウイルスはブタインフルエンザA（H3N2）と同定され、2009年11月に精査された。ブタからの暴露は不明である一方、同ウイルスのヒトーヒト感染の証拠は認められていない。新規インフルエンザA感染事例の速やかな同定及び精査は流行の拡大規模及びヒトーヒト感染の可能性の評価に重要である。新規インフルエンザAウイルスのヒト感染における調査は通年で実施されている。

報告企業の意見	今後の対応
別紙のとおり	今後とも関連情報の収集に努め、本剤の安全性の確保を図っていきたい。

使用上の注意記載状況・その他参考事項等
記載なし。

MedDRA/J ver.12.0

別紙

一般的名称	①人血清アルブミン、②人血清アルブミン、③人血清アルブミン*、④人免役グロブリン、⑤人免役グロブリン、⑥人免役グロブリン、⑦乾燥ペプシン処理人免疫グロブリン、⑧乾燥ペプシン処理人免疫グロブリン、⑨乾燥スルホ化人免疫グロブリン、⑩乾燥スルホ化人免疫グロブリン、⑪乾燥スルホ化人免疫グロブリン、⑫乾燥スルホ化人免疫グロブリン、⑬乾燥スルホ化人免疫グロブリン、⑭乾燥スルホ化人免疫グロブリン*、⑮乾燥濃縮人活性化プロテインC、⑯乾燥濃縮人血液凝固第Ⅷ因子、⑰乾燥濃縮人血液凝固第Ⅷ因子、⑱乾燥濃縮人血液凝固第Ⅷ因子、⑲乾燥濃縮人血液凝固第Ⅷ因子、⑳乾燥濃縮人血液凝固第Ⅸ因子、㉑乾燥濃縮人血液凝固第Ⅸ因子、㉒乾燥濃縮人血液凝固第Ⅸ因子、㉓乾燥濃縮人血液凝固第Ⅸ因子、㉔乾燥抗破傷風人免疫グロブリン、㉕乾燥抗破傷風人免疫グロブリン、㉖抗HBs人免疫グロブリン、㉗抗HBs人免疫グロブリン、㉘トロンビン、㉙フィブリノゲン加第ⅩⅢ因子、㉚フィブリノゲン加第ⅩⅢ因子、㉛乾燥濃縮人アンチトロンビンⅢ、㉜乾燥濃縮人アンチトロンビンⅢ、㉝ヒスタミン加人免疫グロブリン製剤、㉞ヒスタミン加人免疫グロブリン製剤、㉟人血清アルブミン*、㊱人血清アルブミン*、㊲乾燥ペプシン処理人免役グロブリン*、㊳乾燥濃縮人アンチトロンビンⅢ
販売名(企業名)	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ガンマーグロブリン筋注450mg/3mL「化血研」、⑥ガンマーグロブリン筋注1500mg/10mL「化血研」、⑦献血静注グロブリン“化血研”、⑧献血グロブリン注射用2500mg「化血研」、⑨献血ベニロンーⅠ、⑩献血ベニロンーⅠ静注用500mg、⑪献血ベニロンーⅠ静注用1000mg、⑫献血ベニロンーⅠ静注用2500mg、⑬献血ベニロンーⅠ静注用5000mg、⑭ベニロン*、⑮注射用アナクトC2,500単位、⑯コンファクトF、⑰コンファクトF注射用250、⑱コンファクトF注射用500、⑲コンファクトF注射用1000、⑳ノバクトM、㉑ノバクトM注射用250、㉒ノバクトM注射用500、㉓ノバクトM注射用1000、㉔テタノセーラ、㉕テタノセーラ筋注用250単位、㉖ヘパトセーラ、㉗ヘパトセーラ筋注200単位/mL、㉘トロンビン“化血研”、㉙ボルヒール、㉚ボルヒール組織接着用、㉛アンスロビンP、㉜アンスロビンP500注射用、㉝ヒスタグロビン、㉞ヒスタグロビン皮下注用、㉟アルブミン20%化血研*、㊱アルブミン5%化血研*、㊲静注グロブリン*、㊳アンスロビンP1500注射用
報告企業の意見	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。 今回の報告はヒトにおける初めてのブタインフルエンザA（H3N2）感染事例報告であるが、感染経路は明らかになっていない。また、ヒトに対し高病原性であるような情報も示されていない。 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。

*現在製造を行っていない

2009-2010 Influenza Season
Week 1 ending January 9, 2010

All data are preliminary and may change as more reports are received.

Synopsis: During week 1 (January 3-9, 2010), influenza activity continued to decrease in the U.S.

- 139 (3.6%) specimens tested by U.S. World Health Organization (WHO) and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories and reported to CDC/Influenza Division were positive for influenza.
- All subtyped influenza A viruses reported to CDC were 2009 influenza A (H1N1) viruses.
- One human infection with a novel influenza A virus was reported.
- The proportion of deaths attributed to pneumonia and influenza (P&I) was below the epidemic threshold.
- Seven influenza-associated pediatric deaths were reported. Six deaths were associated with 2009 influenza A (H1N1) virus infection and one was associated with an influenza A virus for which the subtype was undetermined.
- The proportion of outpatient visits for influenza-like illness (ILI) was 1.9% which is below the national baseline of 2.3%. One of the 10 regions (region 9) reported ILI above their region-specific baseline.
- No states reported widespread influenza activity, nine states reported regional influenza activity, the District of Columbia, Puerto Rico, and 15 states reported local influenza activity, Guam and 24 states reported sporadic influenza activity, and the U.S. Virgin Islands and two states reported no influenza activity.

National and Regional Summary of Select Surveillance Components

HHS Surveillance Regions**	Outpatient ILI†	% positive for flu‡	Number of jurisdictions reporting regional or widespread activity§	A (H1)	A (H3)	2009 A (H1N1)	A (unable to subtype)¶	A (Subtyping not performed)	B	Pediatric Deaths
	Data for current week			Data cumulative since August 30, 2009 (Week 35)*						
Nation	Normal	3.6%	9 of 54	29	52	61,332	313	19,225	228	236
Region 1	Normal	3.0%	1 of 6	4	2	3,320	14	469	10	6
Region 2	Normal	4.9%	2 of 4	4	4	1,484	0	1,098	9	11
Region 3	Normal	2.8%	1 of 6	3	7	10,554	48	1,456	16	13
Region 4	Normal	6.5%	2 of 8	0	5	7,326	90	4,123	63	45
Region 5	Normal	3.1%	0 of 6	7	23	9,356	52	1,333	15	33
Region 6	Normal	2.2%	1 of 5	0	3	3,475	45	4,722	41	66
Region 7	Normal	3.0%	0 of 4	3	1	3,299	3	769	3	8
Region 8	Normal	3.0%	0 of 6	6	2	9,766	0	3,770	59	13
Region 9	Elevated	4.8%	2 of 5	0	4	8,175	47	1,167	10	31
Region 10	Normal	7.3%	0 of 4	2	1	4,567	14	318	2	10

*Influenza season officially begins each year at week 40. This season data from week 35 will be included to show the trend of influenza activity before the official start of the 2009-10 influenza season.
**HHS regions (Region 1: CT, ME, MA, NH, RI, VT; Region 2: NJ, NY, Puerto Rico, US Virgin Islands; Region 3: DE, DC, MD, PA, VA, WV; Region 4: AL, FL, GA, KY, MS, NC, SC, TN; Region 5: IL, IN, MI, MN, OH, WI; Region 6: AR, LA, NM, OK, TX; Region 7: IA, KS, MO, NE; Region 8: CO, MT, ND, SD, UT, WY; Region 9: AZ, CA, Guam, HI, NV; and Region 10: AK, ID, OR, WA). Use of the national baseline for regional data or regional baselines for state data is not appropriate.
†Elevated means the % of visits for ILI is at or above the national or region-specific baseline.
‡National data are for current week; regional data are for the most recent three weeks.
§Includes all 50 states, the District of Columbia, Guam, Puerto Rico, and U.S. Virgin Islands.
¶Subtyping results for the majority of specimens in this category were inconclusive because of low virus titers.

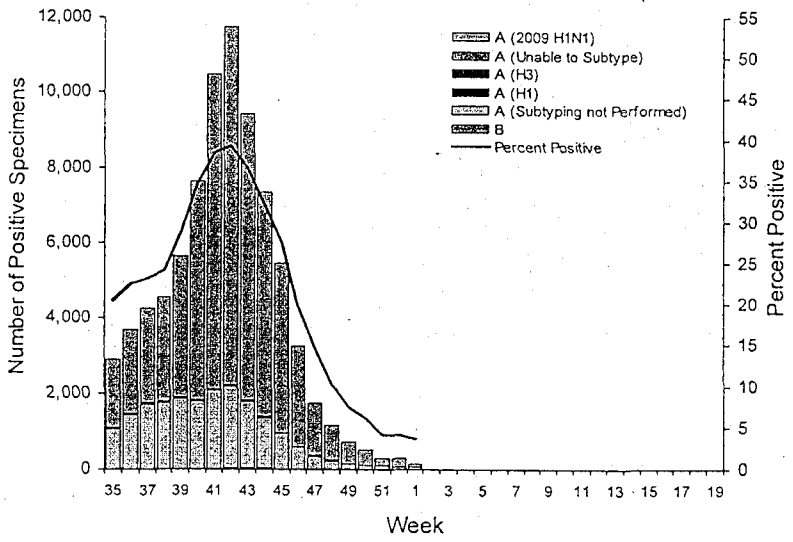
U.S. Virologic Surveillance: WHO and NREVSS collaborating laboratories located in all 50 states and Washington D.C., report to CDC the number of respiratory specimens tested for influenza and the number positive by influenza type and subtype. The results of tests performed during the current week are summarized in the table below.

	Week 1
No. of specimens tested	3,886
No. of positive specimens (%)	139 (3.6%)
Positive specimens by type/subtype	
Influenza A	137 (98.6%)
A (2009 H1N1)	78 (56.9%)
A (subtyping not performed)	58 (42.3%)
A (unable to subtype)*	1 (0.7%)
A (H3)	0 (0.0%)
A (H1)	0 (0.0%)
Influenza B	2 (1.4%)

*Subtyping results for the specimen in this category was inconclusive because of low levels of viral RNA.

During week 1, influenza B viruses co-circulated at low levels with 2009 influenza A (H1N1) viruses. All subtyped influenza A viruses reported to CDC this week were 2009 influenza A (H1N1) viruses.

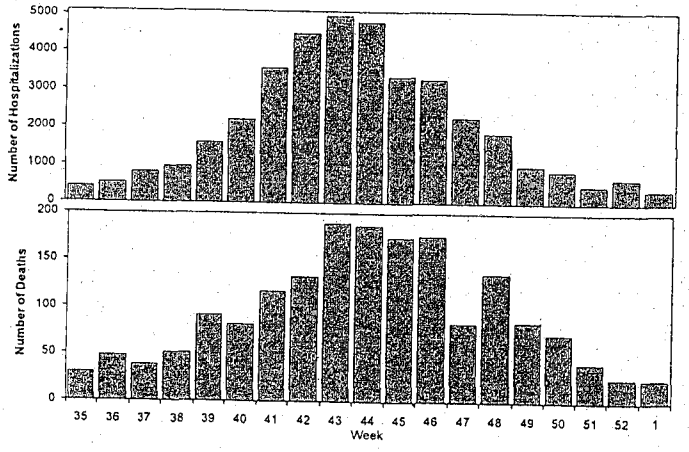
Influenza Positive Tests Reported to CDC by U.S. WHO/NREVSS Collaborating Laboratories, National Summary, August 30, 2009-January 9, 2010



Novel Influenza A Virus: One case of human infection with a novel influenza A virus was reported by the Iowa Department of Public Health. The case patient had onset of symptoms in September 2009, but did not require hospitalization and has fully recovered. The virus was identified as swine influenza A (H3N2) and investigated in November 2009. No clear exposure to swine was identified, but no evidence of sustained human-to-human transmission with this virus was found. Early identification and investigation of novel influenza A cases is critical to evaluate the extent of the outbreak and possible human-to-human transmission. Surveillance for human infections with novel influenza A viruses is conducted year-round.

Pneumonia and Influenza Hospitalization and Death Tracking: The Aggregate Hospitalization and Death Reporting Activity (AHDRA) system was implemented on August 30, 2009, and replaces the weekly report of laboratory confirmed 2009 H1N1-related hospitalizations and deaths that began in April 2009. Jurisdictions can now report to CDC counts of hospitalizations and deaths resulting from all types or subtypes of influenza, not just those from 2009 H1N1 influenza virus. To allow jurisdictions to implement the new case definition, counts were reset to zero on August 30, 2009. From August 30, 2009 – January 9, 2010, 38,454 laboratory-confirmed influenza-associated hospitalizations and 1,779 laboratory-confirmed influenza-associated deaths were reported to CDC. CDC will continue to use its traditional surveillance systems to track the progress of the 2009-10 influenza season.

Weekly Laboratory-Confirmed Influenza-Associated Hospitalizations and Deaths Reported to AHDRA, National Summary, August 30, 2009 – January 9, 2010



Antigenic Characterization: CDC has antigenically characterized one seasonal influenza A (H1N1), seven influenza A (H3N2), six influenza B, and 944 2009 influenza A (H1N1) viruses collected since September 1, 2009.

One seasonal influenza A (H1N1) virus was tested and is related to the influenza A (H1N1) component of the 2009-10 Northern Hemisphere influenza vaccine (A/Brisbane/59/2007).

The seven influenza A (H3N2) viruses tested showed reduced titers with antisera produced against A/Brisbane/10/2007, the 2009-2010 Northern Hemisphere influenza A (H3N2) vaccine component, and were antigenically related to A/Perth/16/2009, the WHO recommended influenza A (H3N2) component of the 2010 Southern Hemisphere vaccine formulation.

Influenza B viruses currently circulating globally can be divided into two distinct lineages represented by the B/Yamagata/16/88 and B/Victoria/02/87 viruses. The influenza B component of the 2009-10 vaccine belongs to the B/Victoria lineage. The six influenza B viruses tested belong to the B/Victoria lineage and are related to the influenza vaccine component for the 2009-10 Northern Hemisphere influenza vaccine (B/Brisbane/60/2008).

Nine hundred forty-two (99.8%) of 944 2009 influenza A (H1N1) viruses tested are related to the A/California/07/2009 (H1N1) reference virus selected by WHO as the 2009 H1N1 vaccine virus. Two viruses (0.3%) tested showed reduced titers with antiserum produced against A/California/07/2009.

Annual influenza vaccination is expected to provide the best protection against those virus strains that are related to the vaccine strains, but limited to no protection may be expected when the vaccine and circulating virus strains are so different as to be from different lineages. Antigenic characterization of 2009 influenza A (H1N1) viruses indicates that these viruses are only distantly related antigenically and genetically to seasonal influenza A (H1N1) viruses, suggesting that little to no protection would be expected from vaccination with seasonal influenza vaccine. It is too early in the influenza season to determine if seasonal influenza viruses will circulate widely or how well the seasonal vaccine and circulating strains will match.

Antiviral Resistance: Since September 1, 2009, one seasonal influenza A (H1N1), eight influenza A (H3N2), one influenza B, and 830 2009 influenza A (H1N1) virus isolates have been tested for resistance to the neuraminidase inhibitors (oseltamivir and zanamivir), and 2,096 2009 influenza A (H1N1) original clinical samples were tested for a single known mutation in the virus that confers oseltamivir resistance. In addition, one seasonal influenza A (H1N1), 11 influenza A (H3N2), and 837 2009 influenza A (H1N1) virus isolates have been tested for resistance to the adamantanes (amantadine and rimantadine). The results of antiviral resistance testing performed on these viruses are summarized in the table below. Additional laboratories perform antiviral testing and report their results to CDC and positive results from that testing are included in the footnote.

Antiviral Resistance Testing Results on Samples Collected Since September 1, 2009.

	Viruses tested (n)	Resistant Viruses, Number (%) Oseltamivir	Viruses tested (n)	Resistant Viruses, Number (%) Zanamivir	Isolates tested (n)	Resistant Viruses, Number (%) Adamantanes
Seasonal Influenza A (H1N1)	1	1 (100.0)	0	0 (0)	1	0 (0)
Influenza A (H3N2)	8	0 (0)	0	0 (0)	11	9 (81.8)
Influenza B	1	0 (0)	0	0 (0)	N/A*	N/A*
2009 Influenza A (H1N1)	2,926	39†‡ (1.3)	830	0 (0)	837	834 (99.6)

*The adamantanes (amantadine and rimantadine) are not effective against influenza B viruses.
†Two screening tools were used to determine oseltamivir resistance: sequence analysis of viral genes and a neuraminidase inhibition assay.
‡ Additional laboratories perform antiviral resistance testing and report their results to CDC. Three additional oseltamivir resistant 2009 influenza A (H1N1) virus has been identified by these laboratories since September 1, 2009, bringing the total number to 42.

All of the subtyped influenza A viruses reported during week 1 were 2009 influenza A (H1N1) viruses, and nearly all of 2009 H1N1 viruses tested since April 2009 have been resistant to the adamantanes (amantadine and rimantadine).

Antiviral treatment with oseltamivir or zanamivir is recommended for all patients with confirmed or suspected influenza virus infection who are hospitalized, are at higher risk for influenza complications, or who have lower respiratory tract or progressive disease. Additional information on antiviral recommendations for treatment and chemoprophylaxis of influenza virus infection is available at http://www.cdc.gov/H1N1flu/recommendations.htm.

2009 influenza A (H1N1) viruses were tested for oseltamivir resistance by a neuraminidase inhibition assay and/or detection of genetic sequence mutation, depending on the type of specimen tested. Original clinical samples were examined for a single known mutation in the virus that confers oseltamivir resistance in currently circulating seasonal influenza A (H1N1) viruses, while influenza virus isolates were tested using a neuraminidase inhibition assay that determines the presence or absence of neuraminidase inhibitor resistance, followed by neuraminidase gene sequence analysis of resistant viruses.

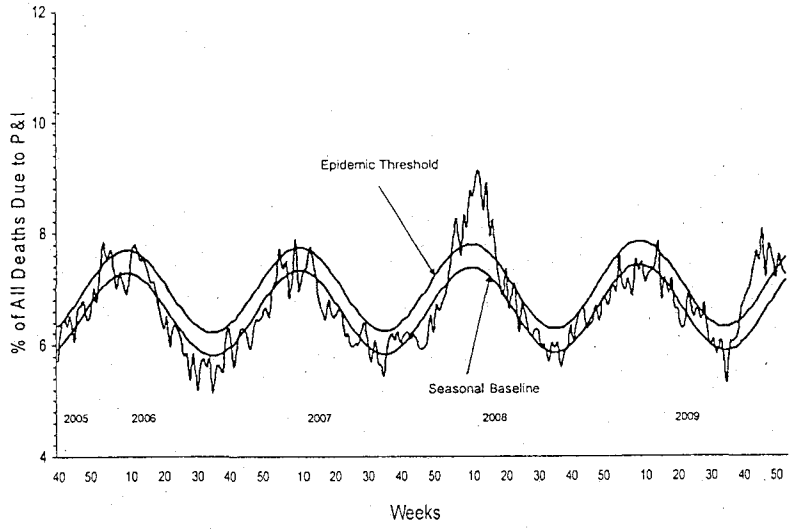
The majority of 2009 influenza A (H1N1) viruses are susceptible to the neuraminidase inhibitor antiviral medication oseltamivir; however, rare sporadic cases of oseltamivir resistant 2009 influenza A (H1N1) viruses have been detected worldwide. A total of 52 cases of oseltamivir resistant 2009 influenza A (H1N1) viruses have been identified in the United States since April 2009. While the total number of cases has not increased over the previous week, one previously reported case was reclassified and one new case was identified. Forty-two of these specimens

were collected after September 1, 2009. The proportion of oseltamivir-resistant 2009 H1N1 viruses does not represent the prevalence of oseltamivir-resistant 2009 H1N1 in the U.S. Most cases were tested because drug resistance was suspected. All tested viruses retain their sensitivity to the neuraminidase inhibitor zanamivir. Of the 52 total cases identified since April 2009, 40 patients had documented exposure to oseltamivir through either treatment or chemoprophylaxis, nine patients are under investigation to determine exposure to oseltamivir, and three patients had no documented oseltamivir exposure. Occasional development of oseltamivir resistance during treatment or prophylaxis is not unexpected. Enhanced surveillance, an increased availability of testing performed at CDC, and an increasing number of public health and other clinical laboratories performing antiviral resistance testing increase the number of cases of oseltamivir resistant 2009 influenza A (H1N1) viruses detected. All cases are investigated to assess the spread of resistant strains in the community.

To prevent the spread of antiviral resistant virus strains, CDC reminds clinicians and the public of the need to continue hand and cough hygiene measures for the duration of any symptoms of influenza, even while taking antiviral medications (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5832a3.htm).

Pneumonia and Influenza (P&I) Mortality Surveillance: During week 1, 7.3% of all deaths reported through the 122-Cities Mortality Reporting System were due to P&I. This percentage was below the epidemic threshold of 7.6% for week 1.

Pneumonia and Influenza Mortality for 122 U.S. Cities
Week ending 1/9/2010



Influenza-Associated Pediatric Mortality: Seven influenza-associated pediatric deaths were reported to CDC during week 1 (Illinois, Michigan, New York [2], Oregon, and Texas [2]). Six deaths were associated with 2009 influenza A (H1N1) virus infection and one was associated with an influenza A virus for which the subtype was undetermined.. The deaths reported during week 1 occurred between October 11 and December 19, 2009.

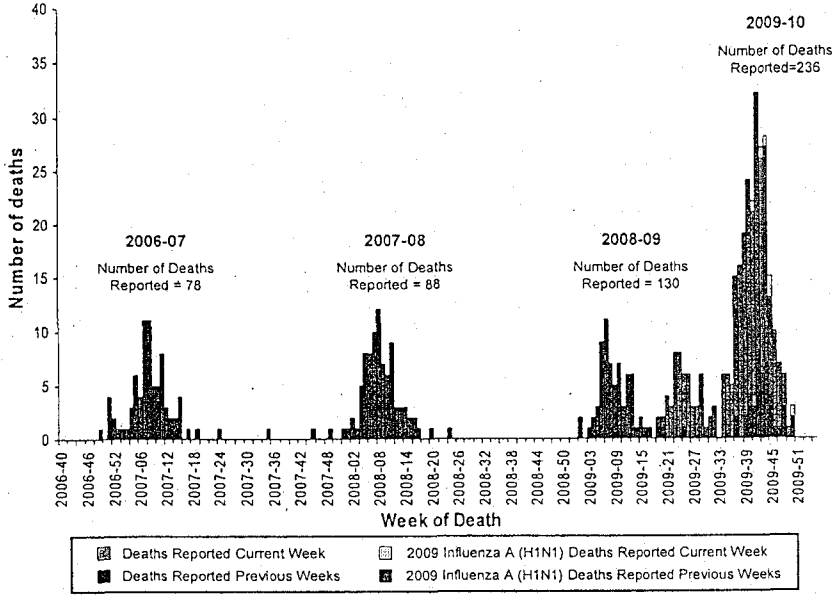
Since August 30, 2009, CDC has received 236 reports of influenza-associated pediatric deaths that occurred during the current influenza season (43 deaths in children less than 2 years old, 26 deaths in children 2-4 years old, 87 deaths in children 5-11 years old, and 80 deaths in children 12-17 years old). One hundred ninety-five (83%) of the 236 deaths were due to 2009 influenza A (H1N1) virus infections, 40 were associated with an influenza A virus for which the subtype is undetermined, and one was associated with an influenza B virus infection. A total of 255 deaths in children associated with 2009 influenza A (H1N1) virus infection have been reported to CDC.

Among the 236 deaths in children, 121 children had specimens collected for bacterial culture from normally sterile sites and 39 (32.2%) of the 121 were positive; *Streptococcus pneumoniae* was identified in 10 (25.6%) of the 39 children and *Staphylococcus aureus* was identified in 11 (28.2%) of the 39 children. Two *S. aureus* isolates were sensitive to methicillin, eight were methicillin resistant, and one did not have sensitivity testing performed. Twenty-six (66.7%) of the 39 children with bacterial coinfections were five years of age or older, and 14 (35.9%) of the 39 children were 12 years of age or older.

Laboratory-Confirmed Influenza-Associated Pediatric Deaths by Date and Type/Subtype of Influenza.

Date	2009 H1N1 Influenza	Influenza A-Subtype Unknown	Seasonal Influenza	Total
Number of Deaths REPORTED for Current Week – Week 1 (Week ending January 9, 2010)	6	1	0	7
Number of Deaths OCCURRED since August 30, 2009	195	40	1	236
Number of Deaths OCCURRED since April 26, 2009	255	43	2	300

Number of Influenza-Associated Pediatric Deaths by Week of Death: 2006-07 season to present

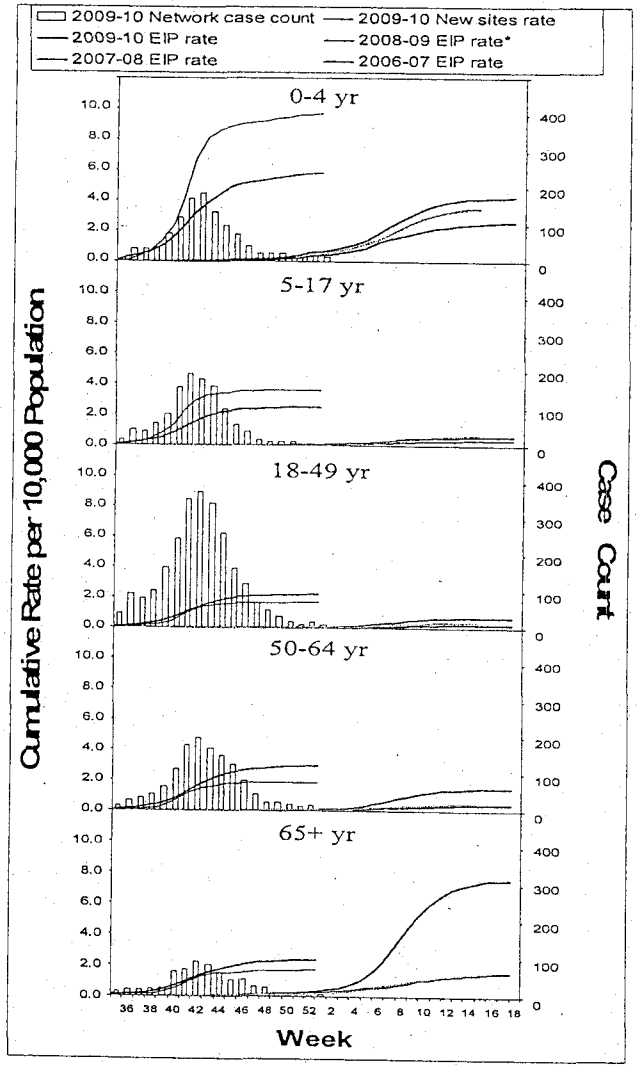


Influenza-Associated Hospitalizations: Laboratory-confirmed influenza-associated hospitalizations are monitored using a population-based surveillance network that includes the 10 Emerging Infections Program (EIP) sites (CA, CO, CT, GA, MD, MN, NM, NY, OR and TN) and 6 new sites (IA, ID, MI, ND, OK and SD).

During September 1, 2009 – January 9, 2010, the following preliminary laboratory-confirmed overall influenza associated hospitalization rates were reported by EIP and the new sites *(rates include influenza A, influenza B, and 2009 influenza A (H1N1))*:

Rates [EIP (new sites)] for children aged 0-4 years and 5-17 years were 5.9 (9.7) and 2.5 (3.6) per 10,000, respectively. Rates [EIP (new sites)] for adults aged 18-49 years, 50-64 years, and ≥ 65 years were 2.2 (1.7), 2.9 (1.8) and 2.4 (1.7) per 10,000, respectively.

EIP Influenza Laboratory-Confirmed Cumulative Hospitalization Rates, 2009-10 and Previous Three Seasons*

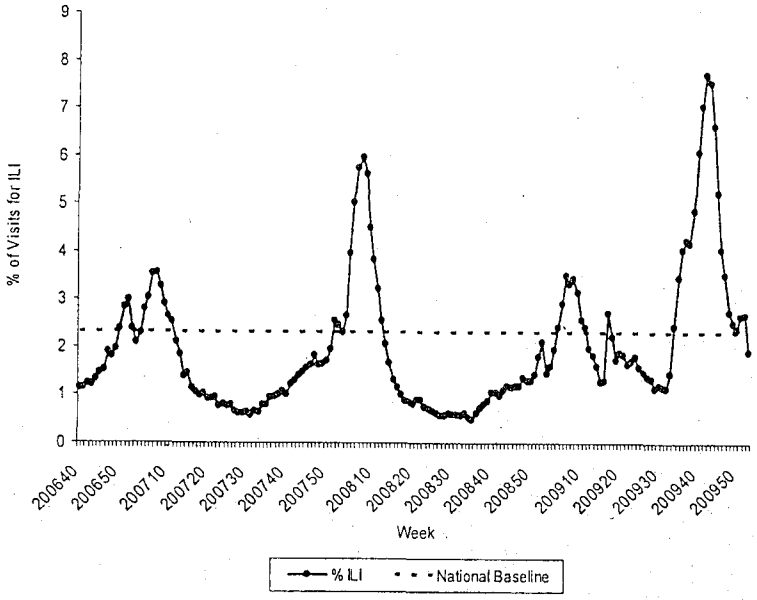


* The 2008-09 EIP rate ended as of April 14, 2009 due to the onset of the 2009 H1N1 season.

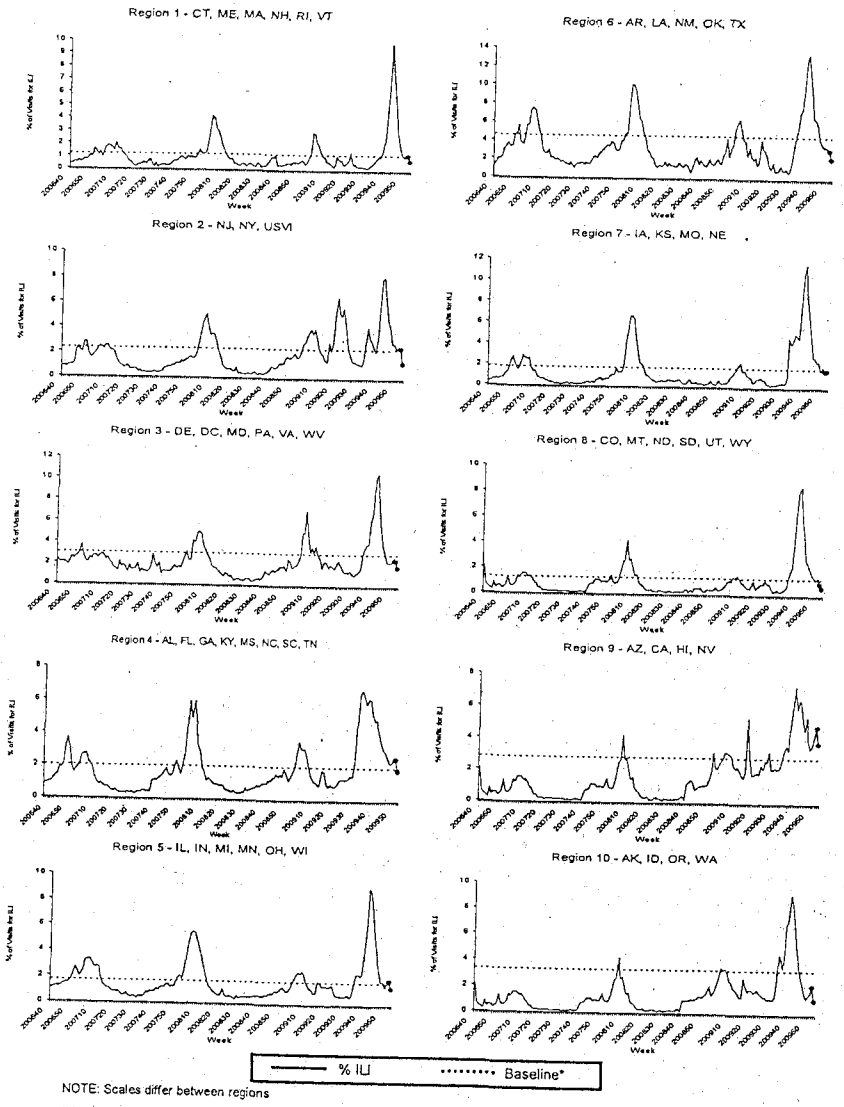
Outpatient Illness Surveillance: Nationwide during week 1, 1.9% of patient visits reported through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) were due to influenza-like illness (ILI). This percentage is below the national baseline of 2.3%.

The increase in the percentage of outpatient visits for ILI during weeks 51 and 52 is likely influenced by a reduction in routine health care visits during the holiday season, as has occurred during previous seasons.

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, October 1, 2006 – January 9, 2010



On a regional level, the percentage of outpatient visits for ILI ranged from 0.6% to 3.8% during week 1. One of the 10 regions (Region 9) reported a proportion of outpatient visits for ILI above its region-specific baseline levels. Regions 1, 2, 3, 4, 5, 6, 7, 8, and 10 reported ILI below their region-specific baselines. (Note: Use of the national baseline for regional ILI data or regional baselines for state-level data is not appropriate.)



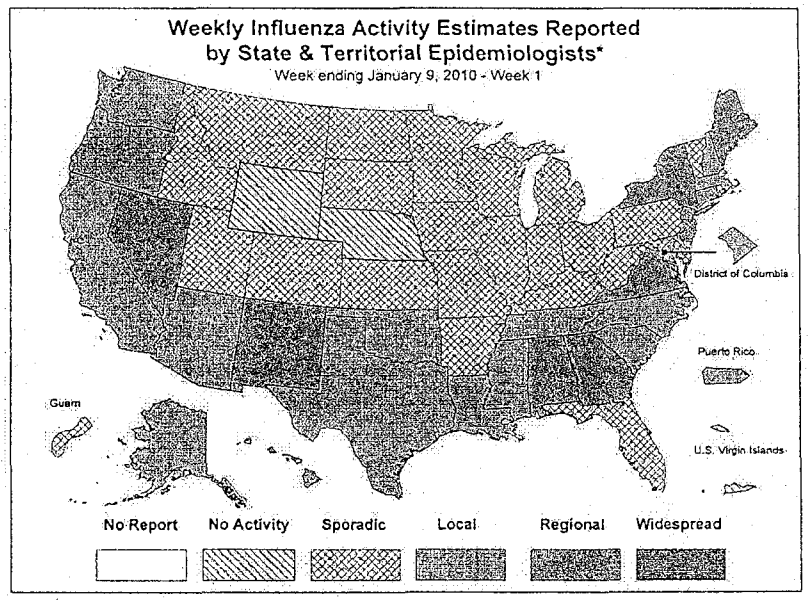
NOTE: Scales differ between regions

*Use of the regional baselines for state data is not appropriate.

Geographic Spread of Influenza as Assessed by State and Territorial Epidemiologists: The influenza activity reported by state and territorial epidemiologists indicates geographic spread of both seasonal influenza and 2009 influenza A (H1N1) viruses and does not measure the severity of influenza activity.

During week 1, the following influenza activity was reported:

- No states reported widespread influenza activity.
- Regional influenza activity was reported by nine states (Alabama, Georgia, Hawaii, Maine, Nevada, New Jersey, New Mexico, New York, and Virginia).
- Local influenza activity was reported by the District of Columbia, Puerto Rico, and 15 states (Alaska, Arizona, California, Connecticut, Louisiana, Massachusetts, Mississippi, New Hampshire, North Carolina, Oklahoma, Oregon, South Carolina, Tennessee, Texas, and Washington).
- Sporadic influenza activity was reported by Guam and 24 states (Arkansas, Colorado, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Missouri, Montana, North Dakota, Ohio, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, and Wisconsin).
- The U.S. Virgin Islands and two states (Nebraska and Wyoming) reported no influenza activity.



* This map indicates geographic spread & does not measure the severity of influenza activity

A description of surveillance methods is available at: http://www.cdc.gov/flu/weekly/fluactivity.htm
Report prepared: January 15, 2010.

別紙様式第2-1

No. 6

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. 11. 12	該当なし	
一般的名称	人血清アルブミン		研究報告の公表状況	ABC Newsletter #38. 2009 Oct 23; 13-14.	公表国	
販売名(企業名)	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)				ヨーロッパ	

研究報告の概要			使用上の注意記載状況・その他参考事項等
○EU規制当局はインフルエンザパンデミック時の献血条件緩和を検討 欧州連合の血液規制委員会(Blood Regulatory Committee)は、H1N1インフルエンザ・パンデミック時の供給確保のため2つの緩和策を検討していると報告した。ヨーロッパ各国の代表は、パンデミックが深刻化した場合、輸血用血液が10-15%不足するのではと懸念している。血液規制委員会は、ヨーロッパ血液連盟(EBA)や各国の監督官庁に9月末開催の会議への出席を依頼し、血液の安定供給のためにどの基準を緩和するかを検討した。 この結果、インフルエンザ様症状回復後の献血延期期間はEU指令では14日間だが、これを7日間に短縮することがドナー確保に大きな効果があると多くの国が評価した。また、ヘモグロビン値を女性12.5g/dL、男性13.5g/dLから女性12g/dL、男性13g/dLにすることについて合意した。	報告企業の意見	今後の対応	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
欧州連合の血液規制委員会は、H1N1インフルエンザ・パンデミック時の供給確保のため、インフルエンザ様症状回復後の献血延期期間の短縮とヘモグロビン値の基準の緩和を検討しているとの報告である。 インフルエンザは毎年流行をみる最もポピュラーな疾患であるが、本剤によるいかなるインフルエンザ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ため、本剤の安全性は確保されていると考える。		日本赤十字社では、問診で発熱などの体調不良者を献血不適としている。更に、平成21年5月18日付薬食血発第0518001号「新型インフルエンザの国内発生に係る血液製剤の安全性確保について」に基づき、新型インフルエンザの患者又は罹患の疑いのある患者と7日以内に濃厚な接触があった人の献血を制限するほか、献血後に新型インフルエンザと診断された場合には当該血漿の使用を禁止している。新型インフルエンザが流行した場合、献血者減少につながることも予想されることから、今後も引き続き情報の収集に努める。	

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