

TABLE 2. Cross-reactive microneutralization (MN) antibody response to novel influenza A (H1N1) virus* in adult recipients of seasonal influenza vaccines

Vaccine	Influenza season	Influenza virus	Age group (yrs)	No.	% with fourfold or greater increase in antibody titer†	% with MN titer of $\geq 160^{\ddagger}$		Geometric mean titer (GMT) [§]		Postvaccination to prevaccination ratio
						Prevaccination	Postvaccination	Prevaccination (95% CI)**	Postvaccination (95% CI)	
TIV††	2007-08	A/Solomon Is/3/2006	18-64	134	74	28	92	48 (40-59)	561 (462-682)	12
		A/California/04/2009			19	9	25	28 (23-34)	53 (43-66)	2
	2008-09	A/Brisbane/59/2007	18-40	83	78	20	88	29 (22-38)	546 (418-713)	19
		A/California/04/2009			12	6	7	11 (9-14)	21 (16-26)	2
	2007-08	A/Solomon Is/3/2006	>60	63	54	14	54	31 (22-42)	143 (105-194)	5
		A/California/04/2009			3	33	43	92 (71-121)	97 (74-127)	1

* A/California/04/2009.

† A fourfold or greater increase in antibody titer indicates seroconversion (a response to the vaccine).

‡ A linear regression model was used to predict the MN titer for seasonal H1N1 viruses that corresponded to a hemagglutination inhibition (HI) antibody titer of 40. (Serum HI antibody titers of 40 are associated with at least a 50% decrease in risk for influenza infection or disease [7]). In adult populations, an HI titer of 40 corresponds with an MN titer of ≥ 160 .

§ A titer of 1280 was used for all samples with a titer of ≥ 1280 . The dilution of sera in the first well is based on the combination of a 1:10 serum dilution with an equal volume of diluted virus for a final serum dilution referred to as 1:10. In the statistical models, study participants were treated as random effects sampled from a larger population of study participants, and duplicate samples were treated as random effects nested within each study participant.

** Confidence interval.

†† Trivalent, inactivated influenza vaccine.

to the novel influenza A (H1N1) virus than are contemporary seasonal H1N1 strains. Ongoing assessment of the cross-reactive antibody response among persons in different age groups might identify a particular age group that would allow further clarification of the cross-reactive serologic response. Development of a strain-specific vaccine against the novel influenza A (H1N1) virus is needed for optimal protection against the virus among persons of all ages.

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Federal and State Cigarette Excise Taxes — United States, 1995-2009

On April 1, 2009, the largest federal cigarette excise tax increase in history went into effect, bringing the combined federal and average state excise tax for cigarettes to \$2.21 per pack and achieving the *Healthy People 2010* (HP2010) objective (27-21a) to increase the combined federal and average state cigarette excise tax to at least \$2 per pack (1). This report summarizes changes in the federal excise tax, as well as state excise taxes for all 50 states and the District of Columbia (DC) from December 31, 1995 to April 1, 2009.* The findings indicate that the federal excise tax increased from 24 cents per pack in 1995 to \$1.01 per pack in 2009, and the average state excise tax increased from 32.7 cents per pack to \$1.20 per pack during the same period.† These increases represent a 321% increase in the federal excise tax and a 267% increase in the average state excise tax since 1995. Price increases should be combined with other evidence-based policy and clinical

* For this report, DC is included among results for states.

† The federal tax of \$50.33 for cigarettes is levied per 1,000 cigarettes. When calculated per pack of 20 cigarettes, this is \$1.0066 per pack. For this study, this fractional tax is referred to as \$1.01 per pack.

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 2009年4月22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	MMWR. 2009;58:1-3	公表国 米国	使用上の注意記載状況・ その他参考事項等
販売名(企業名)	別紙のとおり				
研究報告の概要	<p>問題点：南カリフォルニア周辺郡において、ヒトからヒトへ感染した可能性のある新しいブタインフルエンザ A 株 (H1N1) 感染事例が報告された。</p> <p>2009年4月17日、CDCは、南カリフォルニア周辺郡に住む小児の熱性呼吸器疾患症例2例がブタインフルエンザ A (H1N1) ウイルス感染によるものであったと判断した。2症例から検出されたウイルスは、遺伝子的に非常に近く、アマンタジン及びリマンタジンに耐性を示し、米国やそれ以外の国でも報告されたことがないブタ又はヒトインフルエンザウイルスの遺伝子片を併せ持っていた。いずれの小児もブタとは接触しておらず、感染源は不明である。感染源の確認と、類似するブタインフルエンザウイルスに感染した患者が他にいないかどうかの確認が行われている。</p> <p>このウイルスはヒトインフルエンザ A の新しいサブタイプではないが、このブタインフルエンザ A (H1N1) の新株はヒトインフルエンザ A (H1N1) ウイルスとは本質的に異なっており、感染しやすいヒトが多い可能性があり、季節性インフルエンザワクチン H1N1 株では予防できない可能性が懸念される。2症例にはブタへの暴露がないことから、この新しいインフルエンザウイルスがヒトからヒトへ感染した可能性が高い。</p>				記載なし
	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。			

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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人免疫グロブリン、⑤乾燥ペプシン処理人免疫グロブリン、⑥乾燥スルホ化人免疫グロブリン、⑦乾燥スルホ化人免疫グロブリン*、⑧乾燥濃縮人活性化プロテインC、⑨乾燥濃縮人血液凝固第Ⅷ因子、⑩乾燥濃縮人血液凝固第Ⅸ因子、⑪乾燥抗破傷風人免疫グロブリン、⑫抗 HBs 人免疫グロブリン、⑬トロンビン、⑭フィブリノゲン加第ⅩⅢ因子、⑮乾燥濃縮人アンチトロンビンⅢ、⑯ヒスタミン加人免疫グロブリン製剤、⑰人血清アルブミン*、⑱人血清アルブミン*、⑲乾燥ペプシン処理人免疫グロブリン*、⑳乾燥人血液凝固第Ⅸ因子複合体*、㉑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献血静注グロブリン “化血研”、⑥献血ベニロン-I、⑦ベニロン*、⑧注射用アナクト C 2,500 単位、⑨コンファクト F、⑩ノバクト M、⑪テタノセーラ筋注用 250 単位、⑫ヘパトセーラ、⑬トロンビン “化血研”、⑭ボルヒール、⑮アンスロビン P、⑯ヒスタグロビン、⑰アルブミン 20%化血研*、⑱アルブミン 5%化血研*、⑲静注グロブリン*、⑳ノバクト F*、㉑アンスロビン P 1500 注射用
報 告 企 業 の 意 見	<p>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。</p> <p>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。(http://idsc.nih.gov/idwr/douko/2009d/17douko.html)</p> <p>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性化工程が存在しているため、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・不活性化効果は、「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・不活性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ウイルス感染の報告例は無い。</p> <p>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られる。</p>

*現在製造を行っていない



MMWR

Dispatch

April 21, 2009 / 58 (Dispatch); 1-3

Swine Influenza A (H1N1) Infection in Two Children --- Southern California, March--April 2009

On April 17, 2009, CDC determined that two cases of febrile respiratory illness occurring in children who resided in adjacent counties in southern California were caused by infection with a swine influenza A (H1N1) virus. The viruses from the two cases are closely related genetically, resistant to amantadine and rimantadine, and contain a unique combination of gene segments that previously has not been reported among swine or human influenza viruses in the United States or elsewhere. Neither child had contact with pigs; the source of the infection is unknown. Investigations to identify the source of infection and to determine whether additional persons have been ill from infection with similar swine influenza viruses are ongoing. This report briefly describes the two cases and the investigations currently under way. Although this is not a new subtype of influenza A in humans, concern exists that this new strain of swine influenza A (H1N1) is substantially different from human influenza A (H1N1) viruses, that a large proportion of the population might be susceptible to infection, and that the seasonal influenza vaccine H1N1 strain might not provide protection. The lack of known exposure to pigs in the two cases increases the possibility that human-to-human transmission of this new influenza virus has occurred. Clinicians should consider animal as well as seasonal influenza virus infections in their differential diagnosis of patients who have febrile respiratory illness and who 1) live in San Diego and Imperial counties or 2) traveled to these counties or were in contact with ill persons from these counties in the 7 days preceding their illness onset, or 3) had recent exposure to pigs. Clinicians who suspect swine influenza virus infections in a patient should obtain a respiratory specimen and contact their state or local health department to facilitate testing at a state public health laboratory.

Case Reports

Patient A. On April 13, 2009, CDC was notified of a case of respiratory illness in a boy aged 10 years who lives in San Diego County, California. The patient had onset of fever, cough, and vomiting on March 30, 2009. He was taken to an outpatient clinic, and a nasopharyngeal swab was collected for testing as part of a clinical study. The boy received symptomatic treatment, and all his symptoms resolved uneventfully within approximately 1 week. The child had not received influenza vaccine during this influenza season. Initial testing at the clinic using an investigational diagnostic device identified an influenza A virus, but the test was negative for human influenza subtypes H1N1, H3N2, and H5N1. The San Diego County Health Department was notified, and per protocol, the specimen was sent for further confirmatory testing to reference laboratories, where the sample was verified to be an unsubtypable influenza A strain. On April 14, 2009, CDC received clinical specimens and determined that the virus was swine influenza A (H1N1). The boy and his family reported that the child had had no exposure to pigs. Investigation of potential animal exposures among the boy's contacts is continuing. The patient's mother had respiratory symptoms without fever in the first few days of April 2009, and a brother aged 8 years had a respiratory illness 2 weeks before illness onset in the patient and had a second illness with cough, fever, and rhinorrhea on April 11, 2009. However, no respiratory specimens were collected from either the mother or brother during their acute illnesses. Public health officials are conducting case and contact investigations to determine whether illness has occurred among other relatives and contacts in California, and during the family's travel to Texas on April 3, 2009.

Patient B. CDC received an influenza specimen on April 17, 2009, that had been forwarded as an unsubtypable influenza A virus from the Naval Health Research Center in San Diego, California. CDC identified this specimen as a swine influenza A (H1N1) virus on April 17, 2009, and notified the California Department of Public Health. The source of the specimen, patient B, is a girl aged 9 years who resides in Imperial County, California, adjacent to San Diego County. On March 28, 2009, she had onset of cough and fever (104.3°F [40.2°C]). She was taken to an outpatient facility that was participating in an influenza surveillance project, treated with amoxicillin/clavulanate potassium and an antihistamine, and has since recovered uneventfully. The child had not received influenza vaccine during this influenza season. The patient and her parents reported no exposure to pigs, although the girl did attend an agricultural fair where pigs were exhibited approximately 4 weeks before illness onset. She reported that she did not see pigs at the fair and went only to the amusement section of the fair. The Imperial County Public Health Department and the California Department of Public Health are now conducting an investigation to determine possible sources of infection and to identify any additional human cases. The patient's brother aged 13 years had influenza-like symptoms on April 1, 2009, and a male cousin aged 13 years living in the home had influenza-like symptoms on March 25, 2009, 3 days before onset of the patient's symptoms. The brother and cousin were not tested for influenza at the time of their illnesses.

Epidemiologic and Laboratory Investigations

As of April 21, 2009, no epidemiologic link between patients A and B had been identified, and no additional cases of infection with the identified strain of swine influenza A (H1N1) had been identified. Surveillance data from Imperial and San Diego

counties, and from California overall, showed declining influenza activity at the time of the two patients' illnesses. Case and contact investigations by the county and state departments of health in California and Texas are ongoing. Enhanced surveillance for possible additional cases is being implemented in the area.

Preliminary genetic characterization of the influenza viruses has identified them as swine influenza A (H1N1) viruses. The viruses are similar to each other, and the majority of their genes, including the hemagglutinin (HA) gene, are similar to those of swine influenza viruses that have circulated among U.S. pigs since approximately 1999; however, two genes coding for the neuraminidase (NA) and matrix (M) proteins are similar to corresponding genes of swine influenza viruses of the Eurasian lineage (1). This particular genetic combination of swine influenza virus segments has not been recognized previously among swine or human isolates in the United States, or elsewhere based on analyses of influenza genomic sequences available on GenBank.* Viruses with this combination of genes are not known to be circulating among swine in the United States; however, no formal national surveillance system exists to determine what viruses are prevalent in the U.S. swine population. Recent collaboration between the U.S. Department of Agriculture and CDC has led to development of a pilot swine influenza virus surveillance program to better understand the epidemiology and ecology of swine influenza virus infections in swine and humans.

The viruses in these two patients demonstrate antiviral resistance to amantadine and rimantadine, and testing to determine susceptibility to the neuraminidase inhibitor drugs oseltamivir and zanamivir is under way. Because these viruses carry a unique combination of genes, no information currently is available regarding the efficiency of transmission in swine or in humans. Investigations to understand transmission of this virus are ongoing.

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Editorial Note:

In the past, CDC has received reports of approximately one human swine influenza virus infection every 1–2 years in the United States (2,3). However, during December 2005–January 2009, 12 cases of human infection with swine influenza were reported; five of these 12 cases occurred in patients who had direct exposure to pigs, six in patients reported being near pigs, and the exposure in one case was unknown (1,4,5). In the United States, novel influenza A virus infections in humans, including swine influenza infections, have been nationally notifiable conditions since 2007. The recent increased reporting might be, in part, a result of increased influenza testing capabilities in public health laboratories, but genetic changes in swine influenza viruses and other factors also might be a factor (1,4,5). Although the vast majority of human infections with animal influenza viruses do not result in human-to-human transmission (2,3), each case should be fully investigated to be certain that such viruses are not spreading among humans and to limit further exposure of humans to infected animals, if infected animals are identified. Such investigations should include close collaboration between state and local public health officials with animal health officials.

The lack of known exposure to pigs in the two cases described in this report increases the possibility that human-to-human transmission of this new influenza virus has occurred. Clinicians should consider animal as well as seasonal influenza virus infections in the differential diagnosis of patients with febrile respiratory illness who live in San Diego and Imperial counties or have traveled to these areas or been in contact with ill persons from these areas in the 7 days before their illness onset. In addition, clinicians should consider animal influenza infections among persons with febrile respiratory illness who have been near pigs, such as attending fairs or other places where pigs might be displayed. Clinicians who suspect swine influenza virus infections in humans should obtain a nasopharyngeal swab from the patient, place the swab in a viral transport medium, and contact their state or local health department to facilitate transport and timely diagnosis at a state public health laboratory. CDC requests that state public health laboratories send all influenza A specimens that cannot be subtyped to the CDC, Influenza Division, Virus Surveillance and Diagnostics Branch Laboratory.

Interim guidance on infection control, treatment, and chemoprophylaxis for swine influenza is available at <http://www.cdc.gov/flu/swine/recommendations.htm>. Additional information about swine influenza is available at <http://www.cdc.gov/flu/swine/index.htm>.

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* Available at <http://www.ncbi.nlm.nih.gov/Genbank>.

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一般的名称	人ハプトグロビン			サイエンス(電子版) 2009; 10.1126/SCIENCE.1176062	公表国 メキシコ	
販売名 (企業名)	ハプトグロビン静注 2000 単位「ベネシス」 (ベネシス)					
研究報告の概要	<p>新型インフルエンザ A (H1N1) の致死率は 1957 年のアジア風邪並みの約 0.4% で、感染力も季節性のインフルエンザより高いとする分析結果を、英ロンドン大等からなる国際チームがまとめた。</p> <p>新型インフルエンザ A (H1N1) ウイルスは世界的に急速に広がっている。パンデミックになる可能性の判断は限られたデータでは難しいが、適切な保健対応を伝達するためには不可欠である。メキシコでの大流行、国際的な広がりやの早期情報およびウイルス遺伝的変異について分析することにより、感染力と重症度の早期の評価を実施した。4 月後半までにメキシコで 23,000 人(範囲: 6,000~32,000) が感染し、その時報告された死亡例から致死率 (CFR) は 0.4% (範囲: 0.3~1.5%) と我々は推測する。不確定ではあるが、臨床的重症度は 1918 年の世界的に流行したインフルエンザより低い、1957 年のインフルエンザと同等であると思われる。感染力を示す R_0 は遺伝的分析で中央値 1.2 人であったのに対して、3 つの異なる疫学的分析では、1.4~1.6 人であった。この推定値の範囲は 4 月後半にメキシコで起こったヒト-ヒト感染が 14 回~73 回繰り返されたことと一致する。感染力は、季節性インフルエンザより実際は高く、過去の世界的に流行したインフルエンザの低い方の R_0 値に匹敵する。</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	
<p>新型インフルエンザ A (H1N1) の致死率は 1957 年のアジア風邪並みの約 0.4% で、感染力も季節性のインフルエンザより高いとする報告である。</p> <p>インフルエンザ A (H1N1) はオルソミクソウイルス科に属し、ビリオンは球形で、直径 80~120nm の脂質エンベロープを有する比較的大きな RNA ウイルスである。万一、インフルエンザ A (H1N1) が原料血漿に混入したとしても BVD をモデルウイルスとしたウイルスバリデーション試験成績から、製造工程にて十分に不活化・除去されると考えている。</p>				<p>本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。</p>		<p>2. 重要な基本的注意</p> <p>(1) 本剤の原材料となる献血者の血液については、HBs 抗原、抗 HCV 抗体、抗 HIV-1 抗体、抗 HIV-2 抗体、抗 HTLV-I 抗体陰性で、かつ ALT (GPT) 値でスクリーニングを実施している。更に、プールした試験血漿については、HIV-1、HBV 及び HCV について核酸増幅検査 (NAT) を実施し、適合した血漿を本剤の製造に使用しているが、当該 NAT の検出限界以下のウイルスが混入している可能性が常に存在する。本剤は、以上の検査に適合した血漿を原料として、Cohn の低温エタノール分画で得た画分から人ハプトグロビンを濃縮・精製した製剤であり、ウイルス不活化・除去を目的として、製造工程において 60℃、10 時間の液状加熱処理及びウイルス除去膜によるろ過膜処理を施しているが、投与に際しては、次の点に十分注意すること。</p>