

**National Surveillance Plan  
for Swine Influenza Virus:  
Including Novel H1N1 2009 Virus**

**August 07, 2009**

**Version 2.0**

U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
Veterinary Services



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## Executive Summary

This document is a preliminary national surveillance plan for Swine Influenza Virus (SIV) in swine, including the Novel H1N1 2009 Virus, and is based on the information currently available on influenza virus strains in swine. The immediate goals of the surveillance program are to:

1. Determine if the Novel H1N1 2009 Virus, currently exists in U.S. swine;
2. Detect any new influenza virus strains in swine in a timely manner;
3. If present, determine the virus distribution of new influenza strains in swine, including the Novel H1N1 2009 Virus to inform further policy decisions; and
4. Determine genetic characteristics of new viruses necessary for vaccine and diagnostics development.

This surveillance plan will allow for the differentiation of new influenza virus strains from other circulating strains of SIV and monitor genetic changes of SIV isolates in pigs with influenza-like illness (ILI). Although participation in this surveillance program is voluntary at this time, participation is highly recommended by the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) branch due to the pandemic potential of new influenza virus infection in people and the subsequent economic impacts to the swine industry

Research results from the United States (ARS), the European Union, and other groups suggest that the Novel H1N1 2009 Virus is capable of infecting and causing disease in swine. Further, epidemiological information from Canada, Argentina, and Australia suggests that infected people and swine can transmit and cause infection within and between species. The surveillance plan will be appropriately revised as additional information becomes available.

The current surveillance components of SIV surveillance include:

- 1) Surveillance of swine populations epidemiologically linked to a human case of SIV.** This surveillance will cover swine populations known to be linked with a human infection of SIV (including the Novel H1N1 2009 Virus). Animal health officials, in cooperation with public health investigators, may collect samples from swine that are known to be linked with a human infection of SIV. The extent of swine sampling as a result of human exposure will be decided on a case-by-case basis and will be performed in cooperation with the licensed veterinarian having a valid client-patient relationship with the owner/operation.
- 2) Case-compatible swine accessions submitted to Veterinary Diagnostic Laboratories.** This surveillance will cover on-farm swine populations in which pigs are showing ILI. Producers, veterinarians, or other personnel who observe pigs on farms should collect and submit samples from pigs showing an ILI for SIV testing. Samples from this surveillance stream consist of nasal swabs from live sick pigs, or lung tissues from mortalities meeting the case definition criteria

for SIV (including the Novel H1N1 2009 Virus). This surveillance is aimed primarily at commercial populations; however, with education and outreach, the surveillance may also target small enterprises.

- 3) Surveillance of sick swine at first points of concentration or commingling events such as auctions, markets, fairs, or other swine exhibition events.** This surveillance targets primarily small farm and backyard herds. These are sites with an increased potential for disease spread and/or elevated human exposure. Animal health officials or licensed veterinarians that observe pigs with ILI at these events should be aware of influenza virus in pigs and the potential for certain strains in humans to infect pigs and vice versa. When off-loaded pigs or groups of swine exhibit ILI nasal swabs or lung tissue should be collected and submitted to a participating veterinary diagnostic lab.

Sampling of swine at slaughter or processing facilities is not a component of SIV surveillance. Swine with signs of ILI that arrive at federally inspected facilities should be handled according to standard protocols and procedures of the USDA Food Safety and Inspection Service.

Because respiratory disease and various strains of mild influenza are common in pigs, quarantining animals that are sampled is not recommended unless clear evidence is present to suggest human risk. Nonetheless, documentation of the location and ownership is strongly recommended to allow follow-up.

Objectives:

- Detect the presence and distribution of viruses that are, or may be of public health concern (including the Novel H1N1 2009 Virus) to protect public health and swine markets;
- Identify genomic sequences of viruses that may be relevant for vaccine or diagnostic reagent development;
- Collect geographical and temporal data related to SIV in the United States swine population.

Although one of this surveillance plan's intentions is timely detection of the presence and distribution of the Novel H1N1 2009 Virus in U.S. swine to protect public health and swine markets, many of the same principles are used to maintain a broader surveillance effort aimed at all swine influenza strains. The broader surveillance objectives are to:

- Detect changes in the swine influenza virus genome from isolates of sick pig case submissions received by NAHLN-associated diagnostic laboratories from producers and swine veterinarians. Isolates will be shared with CDC per Interagency agreement (IAA).
- Provide accessible geographical and temporal data related to genomic sequences of interest to animal and public health officials.

Immediate expected outcomes include:

- Knowledge of the presence and distribution of new influenza viruses (including Novel H1N1 2009 Virus) in U.S. swine populations that can be used to make timely, informed, and scientific decisions about disease control measures, diagnostic reagents, preventative measures, human health implications, and trade negotiations;
- Establish a baseline for emerging SIV genomics in U.S. swine;
- Aggregate and share SIV isolate information that will assist researchers and the animal health industry in developing targeted swine influenza diagnostic assays and effective vaccines; and
- Develop a standardized response plan administered through VS and State cooperative field structure for suspected SIV inter-species transmission events in humans, and swine, including fairs and swine events where human-swine cross-exposure is suspected.

Long-term outcomes may include:

- Build “One Health” protocols and system capacity for emerging zoonotic SIV viruses as well as other possible emerging pathogens;
- Aggregate and share SIV isolate information that will assist researchers and the animal health industry in developing targeted swine influenza diagnostic assays and effective vaccines;
- Facilitate further research and understanding of the ecology and epidemiology of SIV infection in swine; and
- Develop a better understanding of epidemiologic factors and procedures that either limit or enhance the mutation and spread of SIV in the swine population.

## **Introductory Information**

This document will be reviewed and modified as additional information is gained about the general epidemiology of SIV, emerging SIV strains, and specifically the Novel H1N1 2009 Virus in swine. As the current event evolves, immediate surveillance activities will progress to longer-term monitoring of emerging influenza viruses in pigs.

Endemic strains of swine influenza virus (particularly of the sub-type H1N1) have been circulating in U.S. swine populations for over 75 years. Recently, a novel influenza virus of swine origin, now labeled the Novel H1N1 2009 Virus, was identified as the cause of human cases of influenza in the United States. Subsequently this virus spread globally in human populations and was declared a human pandemic by the World Health Organization (WHO) in June 2009. This new virus is a reassortant with selected genes of swine origin that are unique due to their Euro-Asian descent. As of July 31, 2009, the virus has been identified in humans and in multiple swine herds in Canada (May-July 2009), Argentina (July 2009) and Australia (July 2009) Additional information is needed to determine the absence, presence, and extent (if present) of the Novel H1N1 2009 Virus in U.S. swine herds.

Although endemic SIV in swine is not listed as a notifiable disease to the World Organization for Animal Health (OIE), the Novel H1N1 2009 Virus is reportable as an emerging disease. Furthermore, human infection with any novel influenza A virus -- including swine influenza viruses -- is notifiable through public health channels based on the pandemic potential of these viruses. Based on the human pandemic and the knowledge that swine are susceptible to this virus, confirmed swine cases of the Novel H1N1 2009 Virus will be closely monitored.

Due to the economic impact of endemic SIV on swine producers, various SIV surveillance efforts have been ongoing for decades with the primary purpose of managing animal health. University, State, and private diagnostic laboratories maintain and update extensive databases of swine influenza viruses, including genomic sequences. However, these efforts have been limited in what they have been able to provide to the National picture of SIV and there are challenges associated with isolate sharing due to the proprietary restrictions.

Animal health and public health partners recognized the need for a more integrated and coordinated surveillance strategy. As a result of common concerns related to pandemic influenza, Veterinary Services, in collaboration with the Centers for Disease Control and Prevention (CDC) and other stakeholders, initiated the development of a pilot SIV surveillance program in July 2008. This collaborative SIV surveillance effort was in the early stages of implementation when the recent human events occurred. Subsequently the implementation of SIV surveillance activities was expedited.

### **1.1 Disease Description**

SIV is a respiratory disease of swine caused by a type A influenza virus. Historically, swine influenza is commonly found in swine herds of North and South America, Asia, and Europe. Endemic SIV of the H1N1 subtype has been circulating in United States swine populations for over 75 years. SIV has evolved from a seasonal disease caused by a single, relatively stable genotype to an endemic respiratory disease caused by multiple SIV genotypes causing illness in swine herds year-round. It is important to note that the commonly circulating endemic SIV subtype is not the Novel H1N1 2009 Virus.

There is currently limited information about how the Novel H1N1 2009 Virus affects swine. Outbreaks in Canadian swine describe morbidity/mortality caused by the Novel H1N1 2009 virus similar to the endemic strains of H1N1 influenza currently circulating in U.S. swine. Characterization of human isolates of virus in pigs has been performed by the U.S. Department of Agriculture's Agricultural Research Service (ARS) and at other international sites with similar results. Therefore, this surveillance plan is based on what is known about circulating SIV strains in pigs and the assumption that the Novel H1N1 2009 virus biologically behaves similarly to other swine flu viruses. Appendix 1 provides detailed background information on swine influenza viruses in swine.

## ***1.2 Rationale and Purpose for Surveillance***

### **Background information about the Novel H1N1 2009 Virus outbreak**

On April 17, 2009, cases of febrile respiratory illness in two children residing in adjacent counties in southern California were diagnosed with a novel influenza A (H1N1) virus infection by CDC. The viruses from the two cases are closely related genetically, were identified to be of swine origin, and contain a unique combination of gene segments that previously have not been reported among swine or human influenza viruses in the United States. However, neither of the children had contact with pigs, and the infection source is unknown. Investigations were initiated in California to identify the source of infection and to determine whether additional people were ill from infection with similar influenza viruses. Investigations rapidly expanded to Texas and across the United States as additional human cases were found. Since information about human cases of novel influenza in the United States was first released, human infection with this novel swine H1N1 virus has also been confirmed in several countries across North America and Europe. The virus has been designated as Novel H1N1 2009 Virus by USDA and CDC.

Although H1N1 is not new in humans or swine, this Novel H1N1 2009 Virus strain is substantially different from circulating human influenza viruses. This suggests that a large proportion of the human population might be susceptible to infection, and that the current seasonal influenza vaccine might not provide protection.

There is scant information about the presence, absence, or extent of the Novel H1N1 2009 Virus in U.S. swine herds; however infection of swine in Canada and abroad have elevated concern that it may enter the US swine population.

The H1N1 subtype of SIV has been endemic in the United States swine populations for decades. Although the Novel H1N1 2009 Virus is not known to exist in U.S. swine populations, the potential does exist. In response to this outbreak, U.S. pork producers have enhanced biosecurity measures to prevent the Novel H1N1 2009 Virus introduction into naïve herds.

Many trade partners have implemented at least partial bans on U.S. swine and pork product exports due to the human outbreak of Novel H1N1 2009 Virus in the United States. The export market affected by initial bans totaled nearly \$1 billion. As of July 28, 2009, eleven countries continue to maintain their bans even though these bans are not warranted as stated by the OIE.

### **Rationale for surveillance**

SIV in swine is not a reportable or regulated disease. However the disease has a major economic impact on the swine industry and in recent years, an escalating impact human health. New subtypes or strains of SIV that emerge as a result of genetic shift or drift of the virus can result in an increased threat to animal or human health. This is evidenced by the current pandemic outbreak of the Novel H1N1 2009 Virus.

By monitoring changes in circulating swine influenza virus strains, emerging variants that may be a health threat can be indentified, allowing animal and human health officials to update diagnostic tests, anticipate vaccine needs and develop response plans. Furthermore, novel SIV strains (e.g. Novel H1N1 2009 Virus) in swine may qualify as an emerging disease, as defined by OIE, and an official OIE notification of infection in swine or other species is warranted (OIE Code 1.1.3).

From the public health perspective, human infection with a novel influenza A virus is a human notifiable condition based on its pandemic potential. Novel influenza A viruses are defined as viruses that are found in humans but are not typically considered human subtypes (novel flu viruses originate from animals such as birds or pigs), or those that cannot be subtyped by standard methods. This includes all swine influenza viruses.

### **Purpose of surveillance**

The primary purposes of the surveillance for SIV (including the Novel H1N1 2009 Virus) in swine are to:

1. Determine if the Novel H1N1 2009 Virus currently exists in U.S. swine;
2. Detect any new influenza virus strains in swine in a timely manner;
3. If present, determine the virus distribution of new influenza strains in swine including the Novel H1N1 2009 Virus to inform further policy decisions; and
4. Determine genetic characteristics of new viruses necessary for vaccine and diagnostics development.

This surveillance plan describes the methods to collect, manage, and analyze standardized epidemiological and genomic data to achieve these purposes. Some information is currently available on SIV virus in swine, but this information is not centralized, cannot be easily aggregated for analysis that would benefit the current SIV situation, and contains significant gaps. This surveillance plan describes standardized approaches to collecting SIV information throughout the U.S. Information collected will be used to assess the SIV status in U.S. swine and take appropriate actions to protect livestock and human health.

### **1.3 Surveillance Objectives**

Objectives:

- Detect the presence and distribution of viruses that are, or may be of public health concern (including the Novel H1N1 2009 Virus) to protect public health and swine markets;
- Identify genomic sequences of viruses that may be relevant for vaccine or diagnostic reagent development;
- Collect geographical and temporal data related to SIV in the United States swine population.

The broader surveillance objectives are to:

- Detect changes in the SIV genome of isolates from sick pig cases submitted to NAHLN-associated diagnostic laboratories from producers and swine veterinarians. Isolates will be shared with CDC per IAA.
- Provide accessible geographical and temporal data related to genomic sequences of interest to animal and public health officials.

### **1.4 Expected Outcomes: Products, Decisions, and Actions**

Immediate expected outcomes include:

- Knowledge of the presence and distribution of new swine influenza viruses (including Novel H1N1 2009 Virus) in U.S. swine populations that can be used to make timely, informed, and scientific decisions about disease control measures, diagnostic reagents, preventative measures, human health implications, and trade negotiations;
- Establish a baseline for emerging swine influenza virus genomics in U.S. swine;
- Aggregate and share SIV isolate information that will assist researchers and the animal health industry in developing targeted swine influenza diagnostic assays and effective vaccines; and
- Develop a standardized SIV swine surveillance response plan administered through VS and State cooperative field structure for suspected SIV inter-

species transmission events in humans and swine, including fairs and swine events where human-swine cross-exposure is suspected.

Long-term outcomes may include:

- Build “One Health” protocols and system capacity for emerging zoonotic SIV viruses as well as other possible emerging pathogens;
- Aggregate and share SIV isolate information that will assist researchers and the animal health industry in developing targeted swine influenza diagnostic assays and effective vaccines;
- Facilitate further research and understanding of the ecology and epidemiology of SIV infection in swine; and
- Develop a better understanding of epidemiological factors and procedures that either limit or enhance the mutation and spread of SIV in the swine population.

### **1.5 Stakeholders and Responsible Parties**

Stakeholders in SIV surveillance include industry representatives and individuals responsible for designing, implementing, managing, and disseminating information. Specific parties with an interest in this surveillance plan include:

<b>Stakeholders</b>	<b>Interest</b>
National Pork Board (NPB)	Industry scientific issues
National Pork Producers Council (NPPC)	Industry policy issues
State pork associations	State-specific industry issues
State Veterinarians	State regulatory control programs
American Association of Swine Veterinarians (AASV)	State-based cooperative surveillance issues
Swine practitioners	Herd health, worker health, industry viability
Commercial companies	Manufacture and sales of SIV vaccines, commercial reagents and assays in the U.S.
Centers for Disease Control and Prevention (CDC)	Human health interface
USDA-APHIS-VS	Protecting animal health and potential trade implications

<b>Responsible Parties</b>	<b>Responsibility</b>
USDA APHIS Veterinary Services National Animal Health Policy and Programs <ul style="list-style-type: none"> <li>• National Center for Animal Health Programs (NCAHP)</li> <li>• National Center for Import and Export (NCIE)</li> </ul> Eastern and Western Region: Directors, swine epidemiologists, and area veterinarians-in-charge (AVICs) and field staffs	Cooperative data sharing <ul style="list-style-type: none"> <li>• Policy, budget and implementation</li> <li>• Import, export and international health status management</li> <li>• Field implementation and reporting</li> </ul>

Centers for Epidemiology and Animal Health <ul style="list-style-type: none"> <li>• National Surveillance Unit (NSU)</li> <li>• Center for Animal Health Information and Analysis(CAHIA)</li> </ul> Office of the Chief Information Officer (OCIO)	<ul style="list-style-type: none"> <li>• Development and evaluation of surveillance plans; data analysis</li> <li>• Risk-based analysis</li> <li>• Spatial analysis</li> <li>• IT systems for SIV surveillance information management</li> </ul>
National Veterinary Services Laboratories (NVSL)	<ul style="list-style-type: none"> <li>• Diagnostic laboratory support; reference laboratory services and budgeting</li> </ul>
National Animal Health Laboratory Network (NAHLN)	<ul style="list-style-type: none"> <li>• Sample testing and data reporting</li> </ul>
Center for Veterinary Biologics	<ul style="list-style-type: none"> <li>• SIV vaccine and commercial reagent licensing and testing</li> </ul>
National Animal Disease Center, Agriculture Research Service (NADC-ARS)	<ul style="list-style-type: none"> <li>• Genome sequencing; studies in pigs; data reporting</li> </ul>
Selected diagnostic labs	<ul style="list-style-type: none"> <li>• Case identification and sample submission</li> </ul>
State Veterinarians	<ul style="list-style-type: none"> <li>• Jointly responsible with AVIC for field implementation</li> </ul>
Centers for Disease Control and Prevention (CDC)	<ul style="list-style-type: none"> <li>• Human–swine interface case identification and funding</li> <li>• Cooperative data sharing</li> </ul>

## Population Description and Sampling Methods

### 1.6 Population Definitions

The surveillance program will target the following populations:

1. **Surveillance of swine populations epidemiologically linked to human cases of SIV.** In the event of a human case of SIV (including the Novel H1N1 2009 Virus) infection in which exposure to swine may have been involved, USDA will work closely with Federal and State public health officials, the SAHO, and the swine industry to determine the appropriate course of action. If it is determined that there is an epidemiological link between swine and an infected person, the health status of the swine should be assessed under direction of the SAHO and in cooperation with the licensed veterinarian having a valid veterinary client relationship with the operation. Animal health officials will work cooperatively with public health officials in public health investigations. For example, during a public health investigation of a confirmed human case of a swine influenza virus (including the Novel H1N1 2009 Virus), it is determined that there is both opportunity and likelihood of exposure of pigs. This would be a scenario for triggering an animal health determination about the appropriate course of action with the exposed swine. If the exposed swine are observed to have signs of ILI that meet the case definition, collection of samples from animals of cooperating

owners should be undertaken. If there are no clinical signs, the animal's caretaker should be requested to observe and report the first appearance of flu-like signs. Samples from this surveillance stream will include nasal swabs or lung tissue, and the extent of sampling in this population will be decided on a case-by-case basis.

2. **Case-compatible swine accessions submitted to Veterinary Diagnostic Laboratories.** This surveillance will cover on-farm swine populations. If swine on a farm are observed to have signs of ILI that meet the established case definition, nasal swab and/or tissue samples may be collected by or under the supervision of a licensed veterinarian and submitted to a participating veterinary diagnostic laboratory as part of the normal and routine disease monitoring and/or diagnostic process for the herd. This surveillance is aimed primarily at commercial populations; however, with education and outreach, the surveillance may also target small enterprises.
3. **Surveillance of sick swine at first points of concentration or commingling events such as auctions, markets, fairs, and other swine exhibition events.** This surveillance targets primarily small farm and backyard herds. These sites have an increased potential for disease spread and/or human exposure is elevated. Animal health officials or licensed veterinarians that observe pigs with ILI at these events should be aware of influenza virus in pigs and the potential for certain strains in humans to infect pigs and vice versa. When off-loaded pigs or groups of swine exhibit ILI, nasal swabs or lung tissue may be collected by or under the supervision of a licensed veterinarian and submitted to a participating veterinary diagnostic lab for SIV testing.

Sampling of swine at slaughter or processing facilities is not a component of SIV surveillance. Swine with signs of ILI that arrive at federally inspected facilities should be handled according to standard protocols and procedures of the USDA Food Safety and Inspection Service.

## **1.7 Case Definitions**

### **Test eligible case:**

- A pig or swine herd exhibiting clinical signs consistent with SIV; *OR*
- A pig or swine herd epidemiologically linked to positive human cases (without ILI in swine); *OR*
- A pig or swine herd epidemiologically linked to confirmed Novel H1N1 2009 Virus infected herds (without ILI in swine).

### **Presumptive positive case:**

- A pig or swine herd epidemiologically linked to positive human cases *AND* exhibits ILI in swine; *OR*
- A pig or swine herd epidemiologically linked to confirmed Novel H1N1 2009 Virus infected herds *AND* exhibits ILI in swine; *OR*

- A pig or swine herd that meets test eligible criteria *AND* tests positive using the Matrix PCR *AND* additional testing has not been completed.

**Additional specific criteria for Novel H1N1 2009 Virus:**

- A pig or swine herd that meets test eligible criteria *AND* tests positive using the Matrix PCR (confirmed influenza A, H1 etiology) *AND* 2009 N1 PCR, but has not been confirmed by NVSL.

**Confirmed positive case:**

- A presumptive positive case that has successfully undergone virus isolation with isolate confirmed as SIV.

**Additional specific criteria for Novel H1N1 2009 Virus:**

- A presumptive positive case that has successfully undergone virus isolation with isolate confirmed as SIV *AND* based on genomic sequencing confirms 2009 Novel H1N1 2009 Virus with repeat testing and sequencing performed at NVSL.

**1.8 Data Sources and 1.9 Sampling Methods for each surveillance stream**

Surveillance will target the categories of samples listed below.

**A. Surveillance of swine populations epidemiologically linked to a human case of SIV**

**Data Sources**

Animal health officials, in cooperation with public health investigations will determine swine that are epidemiologically linked to human infections on a case by case basis.

**Sampling Methods**

Animal health officials, in cooperation with a licensed veterinarian with a valid client patient relationship with the swine operation may collect nasal swabs and/or lung from swine that meet a test eligible case definition described under 1.7 of this document. Animals to be sampled should be in the acute phase of the disease, febrile with serous nasal discharge and cough. The initial recommendation is to collect samples from up to ten (10) case compatible animals. If the total number of case compatible animals in the group (i.e. epidemiologic unit) exceeds expected morbidity further investigation is warranted. In such a case, epidemiologic guidance should be sought from State or Federal officials.

Samples may be submitted to a participating veterinary diagnostic laboratory. Case data should be submitted with samples. Initial data elements important for SIV surveillance data analysis are: location information (premises ID or physical

address of collection site); collection date; collector (person) name, address, city, State; lab accession number; tissue type for the sample; results of testing.

## **B. Case-compatible swine accessions submitted to veterinary diagnostic laboratories**

### **Data Sources**

A licensed veterinarian or persons under the direct supervision of a licensed veterinarian may submit samples from SIV-suspect swine for SIV PCR and/or VI diagnostic testing to participating veterinary diagnostic labs.

### **Sampling Methods**

A licensed veterinarian or persons under the direct supervision of a licensed veterinarian may collect and submit for diagnosis, nasal swabs and/or lung from swine meeting a test eligible case definition described under 1.7 of this document. Animals to be sampled should be in the acute phase of the disease, febrile with serous nasal discharge and cough. The initial recommendation is to collect samples from up to ten (10) case compatible animals that come from each group (i.e. the epidemiologic unit).

Collected samples should be submitted to a participating veterinary diagnostic laboratory. Specific case data is requested with sample submission. Initial data elements to be collected for SIV surveillance data analysis are: location information (premises ID or physical address of collection site); collection date; collector (person) name, address, city, State; lab accession number; tissue type for the sample; results of testing.

## **C. Targeted surveillance of sick pigs at first points of concentration or comingling events**

### **Data Sources**

Veterinarians who observe pigs displaying ILI at swine events (e.g., fairs, expos, etc), zoos, markets, or auctions should submit samples from these animals for SIV PCR and/or VI diagnostic testing to participating veterinary diagnostic labs.

### **Sampling Methods**

A licensed Veterinarian or a person under the direct supervision of a licensed veterinarian may collect nasal swabs and/or lung tissue from groups of swine that are exhibiting ILI or meet a test eligible case definition (described under 1.7 of this document) after off-loading. Animals to be sampled should be in the acute phase of the disease, febrile, with serous nasal discharge and cough. The initial recommendation is to collect samples from up to ten (10) case compatible animals from the originating group (i.e. the epidemiologic unit). If the total number of case compatible animals at the exhibition exceeds expected morbidity, then

further investigation is warranted. In such a case, epidemiologic guidance should be sought from State or Federal officials.

Collected samples should be submitted to a participating veterinary diagnostic laboratory. Case data should be submitted with samples. Initial data elements requested to be collected for SIV surveillance data analysis are: location information (premises ID or physical address of premises where the animal originates from); collection site, collection date; collector (person) name, address, city, State; lab accession number; tissue type for the sample; results of testing.

### **Confidence in detection of novel SIV**

Emerging influenza viruses such as the Novel H1N1 2009 Virus, are believed to be new to the U.S. swine population, thus an introduction onto a premise will likely result in at least a 2-fold increase in morbidity.

Assuming 95 percent sensitivity and 100 percent specificity of the SIV PCR and/or VI diagnostic test, followed by necessary confirmatory testing, random testing of 10 sick animals (febrile with serious nasal discharge and cough) provides 95 percent confidence in detecting SIV in at least one of the targeted samples, if the virus is present in at least *30 percent of the sick animals* in that group (i.e. the epidemiologic unit).

### **Education and Outreach**

Appropriate education / communication will be provided to producers, swine veterinarians, selected industry representatives, diagnostic labs, and State and Federal veterinarians. Pertinent topics to be included in the education campaign are: the importance and purpose of SIV surveillance; case definitions; submission procedures for samples; and the requested epidemiologic information.

## **Analysis, Reporting and Presentation**

### ***1.10 Data Analysis, Reporting and Interpretation***

#### *Data Management*

All SIV surveillance data collected will eventually be managed by the Animal Health Surveillance Management (AHSM) IT system. These data will include observational data, laboratory test results data, and available epidemiologic data.

#### *Data Analysis and Interpretation*

VS' National Surveillance Unit (NSU) will be responsible for SIV surveillance data analysis, working in collaboration with all stakeholders to determine their needs as users of the data. Analysis will be provided to VS management, and VS units including NVSL, CVB, Program and Regional Staff, and National Center for Import Export (NCIE). Information will be shared with CDC (per IAA) and with industry and other stakeholders as appropriate. Data release will meet all Federal Privacy Law requirements and appropriate VS policy statements.

The VS National Surveillance Unit will complete the following analyses, based on the availability of submitted epidemiologic data:

- Analyses on the presence and distribution of the virus;
- Surveillance system sensitivity analysis;
- Economic benefit/cost analysis;
- Summary reports of number of samples collected in each data stream and accompanying descriptive statistics;
- Performance and evaluation of each data stream.

#### *Data Presentation and Reporting*

Due to the potentially sensitive nature of data, protocols for assuring data confidentiality and security will be established. Confirmed, stakeholder and management approved surveillance data may be posted on the National Animal Health Surveillance System Web site for sharing with the public. Reports containing national-level summary data should also be included in the annual U.S. Animal Health Report to demonstrate the surveillance efforts.

### **1.11 Data Presentation and Reporting**

During the early stages of SIV surveillance, monthly reports will be generated to keep stakeholders abreast of changes that may be occurring. Reporting will then move to quarterly reporting as appropriate to the national SIV situation. Annual summary reports will be generated during normal reporting cycles.

Reports from data will minimally include (as data are available):

- Number of samples collected from the surveillance stream versus the expected numbers contained in the surveillance plan;
- Analysis of problems or issues within the sampling stream;
- A summary of individual lab data;
- Summary of compiled epidemiological data; and
- Evaluation of the sample stream efficacy and identification of needed changes.

## **Implementation, Budget and Evaluation**

### **1.12 Surveillance System Implementation: Priorities, Timelines, and Internal Communications**

#### **Priorities**

- To determine if the Novel H1N1 2009 Virus isolated in humans in April 2009 currently exists in U.S. swine;
- To monitor genetic changes of SIV isolates from ILI in pigs; and

- To isolate viruses suitable for vaccine and/or diagnostic reagent development;
- To share isolates with CDC per IAA;
- To collect, analyze and disseminate accessible geographical and temporal epidemiological data related to SIV positive cases and the more virulent genomic sequences of interest to animal health officials.

## **Timelines**

This program will be ready for initial implementation by the middle of May 2009, as requested by the USDA Secretary of Agriculture.

## **Internal Communications**

An SIV Pilot Working Group comprised of staff from NVSL, NCAHP, NAHLN, NCAHEM and NSU has been in existence since August 2008. This group will be expanded to include VS Regional staff as part of an SIV leadership group. The SIV leadership group will focus on the priorities identified above in final development of the surveillance plan, implementation activities, and addressing stakeholder concerns. Surveillance plan updates may arise from these discussions to address concerns. All proposed changes to the surveillance plan will be reviewed by the SIV leadership group.

The details of communication and reporting pathways of surveillance analysis results will be determined in the implementation plan.

### ***1.13 Resources and Budget***

Detailed funding allocations will be developed as availability of funding is clarified. For immediate needs, APHIS will utilize available funds from the CDC-funded pilot SIV surveillance project per the IAA.

Blanket purchase or cooperative agreements with NAHLN labs and their associated diagnostic labs for submissions related to these criteria/case definitions will be used. IAA funding will be disbursed by VS to identify and characterize case-compatible sample isolates and submit the isolate data and associated histories to the SIV database. These agreements have been put in place.

### ***1.14 Surveillance Plan Performance Metrics***

Laboratory based surveillance relies on observation and reporting of clinical signs by an owner, producer, veterinarian, other animal health official (animal identification coordinator, wildlife biologist, game warden, etc) or a participant in the animal industry (livestock hauler, market and slaughter plant personnel, etc). Geographically, submission of sick pig samples should represent all swine production types in all areas of the United States.

The USDA NASS 2007 Agricultural Census estimates 66,000 swine operations. A total sampling pool of 79,200 groups (i.e. epidemiologic units) (120% of NASS estimate) is

estimated, given that some farms involve multiple production sites for sampling. An estimated 50 percent (or higher) incidence of respiratory illness (clinical signs) over a one year period is likely among these operations. At ten samples per group, approximately 198,000 sample submissions are expected for initial Matrix PCR screening from 19,800 sites. Protocol is to further characterize two samples from matrix positive sets of 10. Assuming that 75 percent of the groups tested are matrix positive (1 or more of 10 samples positive), approximately 29,700 samples are expected for further testing to determine specific virus isolate identification.

*[For budgeting purposes the above sampling volume analysis is assumed to include submissions from all sampling streams. Future evaluation of actual sample submission and results of Matrix PCR screening will allow for greater accuracy in predicting future sample testing volumes.]*

In the short-term, the targeted surveillance of sick pigs at livestock markets, swine exhibitions and fairs will be implemented in as many locales as possible with existing Federal and State personnel and livestock market and exhibition veterinarians. There are many APHIS-approved markets (more than 1700 total); therefore, it may be necessary to target markets, based on their volume and associated network (geographic catchment), if possible. As funding becomes available, it is recommended that the number and geographic catchment areas increase.

In the short term, the following metrics will be evaluated to assess the surveillance program and its ability to meet objectives stated in the plan. These evaluations will be conducted monthly initially; as the situation changes, reports will be provided on an appropriate timeline. Metrics include:

- Evaluation of the numbers of sample submissions to NVSL through NAHLN labs;
- Evaluation of the numbers of samples submitted associated with a cooperative investigation of a human–animal interface event;
- Evaluation of the isolates of interest being identified;
- Evaluation of isolates shared with CDC;
- Evaluation of isolate sequencing and / or study in pigs; and
- Evaluation of communications between NAHLN, NVSL, NADC, VS and CDC.

### **1.15 Surveillance System Evaluation**

In addition to the performance metrics identified above, the surveillance will be evaluated for overall effectiveness in meeting the plan's outlined objectives and goals. NSU personnel, along with the SIV Leadership Group, will assess implementation progress, actual obtained sample numbers, budgets, and applicability of performance metrics, and stakeholder needs. Modifications to the plan will be made as necessary.

## **Appendix 1: Background information on swine influenza viruses and current H1N1 Outbreak Virus**

SIV is the cause of an infectious respiratory disease of swine. Infection of pigs with SIV occurs throughout the world. It is commonly found in North and South America, Asia, and Europe, and it has been reported in Africa. In the United States, SIV was first recognized in 1918 as a swine disease in Western Illinois; however, the virus was not isolated from swine until 1930. Since its identification in 1930, SIV has evolved from a seasonal disease caused by a single, relatively stable genotype to a year round, endemic respiratory disease caused by multiple SIV genotypes (Gramer, 2005).

Although SIV is not a notifiable disease to the World Organization for Animal Health (OIE), it has a major economic impact on the swine industry in the United States as part of the swine respiratory disease complex. Furthermore, reassortant SIV is of increasing zoonotic concern due to its proclivity to exchange of genetic material with influenza viruses of other species, particularly human and avian hosts (genetic shift), and to rapidly mutate (genetic drift).

### **Etiology of swine influenza**

Swine influenza viruses are classified as members of the family *Orthomyxoviridae*, genera *Influenzavirus A* (Type A). They are enveloped and have single stranded negative sense RNA with a segmented genome that allows for reassortment and production of novel virus mutants. The type designation (A, B, or C) is based upon the antigenic character of the virus envelope and the nucleoprotein within the virus particle. Type A influenza viruses are further divided into subtypes based on two surface glycoprotein antigens: hemagglutinin (HA) and neuraminidase (NA). Sixteen HA (H1-H16) and nine NA (N1-N9) antigens have been identified. Type A subtypes are designated according to their unique HA and NA surface antigen combinations. The most common subtypes found in North America are H1N1, H1N2 and H3N2 (Choi et al 2002; Webby et al 2004). Recently subtypes H3N1 and H2N3 have been identified (Lekcharoensuk et al, 2006; Ma 2007).

Envelope viruses such as SIV are susceptible to heating, drying, and chemical disinfectants that contain lipid solvents. Avian influenza A viruses have been shown to be stable for up to four weeks in water at 4 degrees C, and up to 5 days in water at 20 degrees C.

### **Clinical Signs related to swine flu viruses**

In swine, the disease course, nature, and severity of SIV will vary with the strain and/or isolate of the virus, the age and immune status of the pig, the presence of concurrent viral infections, and whether the SIV infection is complicated by secondary infection. Morbidity can reach 100 percent, and mortality in confirmed cases can range from 1-3 percent in the absence of complications (AVMA 2007). Sporadic outbreaks with higher mortality have recently been reported anecdotally.

Clinical signs associated with the new Novel H1N1 2009 Virus strain are unknown. Classical SIV clinical infection of swine presents as an acute upper respiratory disease. The incubation period is 1-3 days. Breeding animals that have been infected with SIV acquire active immunity to the virus and remain largely unaffected by subsequent re-infection by sufficiently homologous strains.

Respiratory signs include coughing (barking), nasal and/or ocular discharge, sneezing, and dyspnea. Hyperthermia in excess of 105 degrees F may be observed with associated anorexia, weight loss, lethargy, prostration, huddling and piling. Most pigs recover within 5-7 days in the absence of complications. Complicated infections can extend recovery times and dramatically increase the mortality rate. Boars and sows may experience impaired reproductive performance following infection. Reduced fertility in boars is a result of decreased semen quality and output. Sows may exhibit delayed return to estrus, abortion, or decreased litter size and viability of piglets depending on the stage of gestation when infected. Aborting sows are usually anorexic for 2 to 3 days and may have a fever up to 105 degrees F. Lactating sows may have reduced milk production resulting in adverse affects in nursing piglets.

### **Epidemiology of swine flu viruses**

Endemic herds may be asymptomatic with sporadic outbreaks, usually during cooler months. Sows in herds with endemic SIV may have sporadic abortions and low conception rates. Epidemic SIV follows a seasonal rhythm, peaking during periods of the greatest environmental stress to the pigs. Disease onset is typically precipitated during periods of heat or cold stress. These phases can be related to the fall and winter months in the Midwest, and the late summer months in the South and Southeast. In the epidemic form, infection is apparent in all age groups. Disease onset is acute and dramatic. Normal animals can become very sick within hours. The virus is primarily excreted through nasal secretions during the acute febrile stage of the disease. Pigs can begin shedding the virus within 24 hours of infection and may continue to shed for up to 10 days. In naïve herds, abortion rates can be widespread and reach as high as 10 percent very quickly. Abortion storms are characterized by high fevers, sows off feed, abortions, coughing, and death. The SIV-induced abortion storms will pass in less than two weeks.

Management systems, husbandry procedures, and poor biosecurity practices can result in the introduction of SIV into a herd. Generally introduction occurs when new stock or infected animals are moved or mixed into a herd. In production herds, the virus may persist through the infection of susceptible young pigs, no longer protected through maternal antibodies. Influenza viruses are spread easily by people and contaminated equipment moving between infected and non-infected herds.

Exposure to wildlife, shore birds and waterfowl, especially ducks, presents additional opportunities for the introduction of an influenza virus into a swine herd. Infected birds shed the virus through feces, sometimes for extended periods of time. Fecal contamination of drinking water sources, or lagoons used for wash down procedures can

inadvertently result in exposure. Since 1998, reassortants of SIV have included avian genes. Avian origin viruses (subtypes H4N6, H3N3, and H1N1) have also been found in swine populations (Widjaja 2004; Olsen 2003; Suarez 2002; Castrucci 1992; Webster 1992; Karasin 2000 and 2004).

There is anecdotal evidence for area spread of SIV infections; however, definitive epidemiological studies are lacking. Influenza viruses can be spread through both direct and indirect routes. Direct nose-to-nose contact can result in primary disease transmission within the herd, or from exposure to feral animals if the management system allows. Indirect transmission may occur through the inhalation of infected droplets that can be propelled short distances through coughing, the inhalation of aerosolized virus (dried droplet nuclei) over longer distances, shared feed and water, or through inanimate objects or fomites such as people, contaminated equipment, or vehicles.

Once an influenza virus is established in a herd, it is able to replicate and undergo genetic drift and reassortment regardless of its origin. If genetic changes result in the generation of an antigenically different subtype, then the herd may be susceptible to the new subtype despite vaccination or immune status.

## **Ecology of animal influenza viruses**

Aquatic birds, primarily waterfowl, shore birds, and golden terns, are a natural reservoir for all influenza type A infections. However, these viruses can infect a variety of mammals and birds, with many species serving as amplification hosts, including swine and humans.

Type A viruses are constantly undergoing small antigenic modifications as the result of point mutations in their genetic makeup. The segmented genome gives the viruses the inherent ability to exchange genetic material with other viruses through reassortment. The resulting reassortant viruses can pose a threat to swine health if the acquired genetic modifications lead to an antigenic change in the virus such that the existing immunity of swine populations is ineffective (Gramer 2006). As a result, endemic SIV can continually infect susceptible pigs, resulting in acute respiratory disease, poor growth performance, and mortality, despite vaccination.

Swine are susceptible to, and support replication of, both avian and human influenza viruses. This unique characteristic has labeled swine as a re-assortment (“mixing”) vessel for avian, human, and swine influenza subtypes, and thus a potential origin of a novel reassortant virus that may trigger a pandemic human influenza outbreak.

Although virus transmission across species is rare, avian to pig and pig to avian transmissions of type A viruses have been documented. Serologic studies have shown that turkeys can carry antibodies to classical swine H1N1 (i.e., the predominant swine flu virus prior to 1998). Swine H1N1, H1N2, and more recently, H3N2, have been isolated from turkeys (Suarez 2002; Choi et al 2004). Genetic analysis of H1N1 viruses in turkeys and pigs shows a high degree of genetic exchange between the two species.

Swine influenza viruses are potentially zoonotic and can be directly transmitted between humans and pigs. There is a considerable amount of evidence establishing the bidirectional exchange of viruses between pigs and humans. In 1976, the zoonotic nature of swine H1N1 influenza viruses was confirmed when influenza viruses isolated from humans were found to be antigenically and genetically identical to an H1N1 SIV isolated from a recent swine influenza outbreak. Since that time, there have been multiple reports from North America of SIV subtypes being isolated from humans with influenza-like illness.

Five human cases of SIV in 2007 were in contact with swine displaying clinical signs of upper respiratory disease in public event settings with human-swine interactions. Both the people and the swine then displayed signs of influenza infection. The virus did not attain the ability to easily spread among people in any of these cases. Based on the short incubation times and variable symptoms that can be expressed in both humans and pigs, it is not clear whether virus transmission was from human to pig or pig to human or both.

Prior to 1998, influenza in pigs was caused by one predominant circulating virus known as the classical swine H1N1. In 1998, new reassortant H3N2 strains of SIV were identified in several swine populations across the United States. These new strains were either double reassortants with genetic material from swine and human influenza strains, or triple reassortants of avian, human, and swine influenza strains (Gramer 2005). Since 1998, novel viruses with combinations of genetic components of H1N1 and H3N2, now endemic in the United States, have rapidly emerged.

Swine have been identified as a major intermediate host where avian influenza strains have adapted for replication in humans (Webby 2006). Currently human-swine reassortant H1N2 and H1N1 influenza viruses are circulating in pigs throughout the United States (Gramer 2008). Recent findings have shown that new or novel reassortant influenza viruses have been transmitted between humans and pigs (Webby 2007, CDC 2007). In 2007, five human cases of swine influenza were confirmed in three different States. These individuals developed clinical signs following an interface with swine at a public event. Surface antigen testing identified swine influenza H1N1 virus in all cases. However, genetic sequencing revealed triple reassortant isolates with swine, human, and avian components, similar to the predominant SIV circulating in pigs in North America (CDC communication).

## **Methods for Control of endemic swine flu viruses**

Control of SIV related disease is handled through management practices, biosecurity measures, and vaccination programs. There are no cost-effective therapies, although antibiotics may be used for secondary infections. In non-infected herds, prevention is focused on maintaining a closed herd and incorporating good biosecurity procedures. On infected premises, an all-in, all-out production system can be used to keep age or weight-matched groups together throughout the production process, with cleaning and disinfection of facilities between groups. This method minimizes the potential for direct

SIV transmission between groups of animals, and indirect transmission from equipment and the environment.

Preventive vaccination programs for SIV are commonly incorporated into management practices to produce active immunity and either reduce the risk of SIV entering into the herd or protect against respiratory disease associated with endemic SIV. Vaccination does not provide complete protection; however, it reduces viral shedding, and lessens the severity of the infection. Vaccinated sows will confer some passive immunity protection to piglets.

Commercially licensed and autogenous vaccines are available in the United States. USDA-licensed vaccines are available as killed monovalent or polyvalent products. They have been proven to be effective against both H1N1 and H3N2 SIV infection of pigs and sows (Erickson 2001).

For vaccination programs to be most effective, the vaccine must include the likely SIV subtypes to cause disease due to variable levels cross protection between SIV subtypes. Vaccine manufacturers and producers are challenged by continued antigenic drift and shift in circulating SIV subtypes, rendering older influenza vaccine subtypes non-protective. The need for rapidly updated effective vaccines becomes more critical as new trivalent reassortants emerge and diverge. In response to this dilemma, the USDA's Animal and Plant Health Inspection Service, Centers for Veterinary Biologics (CVB) recently issued guidance to currently licensed SIV vaccine firms, allowing for expedited regulatory procedures for the update of SIV strains in current USDA licensed veterinary vaccines (USDA VS 2007).

## **Diagnosis of swine influenza**

Diagnosis can be based on a combination of clinical signs, typical gross and histopathologic lesions, and diagnostic tests that include serology, virus isolation and nucleic acid or antigen-based tests. A definitive diagnosis requires detection of virus or viral antigens in the tissues or secretions of a clinically infected animal.

Postmortem gross lesions in uncomplicated cases of SIV are those of viral pneumonia. Lesions are usually limited to the apical and cardiac lobes of the lungs. Altered lung tissue is consolidated and darkly colored. The airways are likely to be distended and filled with blood-tinged fibrinous exudates. Associated mediastinal and bronchial lymph nodes are usually enlarged. Severe cases may involve more than one half of the lung tissue.

Diagnostic tests can be run on ante mortem nasal or oropharyngeal swabs or on post mortem lung tissue from acutely infected animals. Maternal antibodies in piglets can complicate the diagnosis of disease by either inhibiting active piglet antibody production, or by suppressing virus production and odds of isolation.

Virus identification is best accomplished by collection of samples within 24-48 hours after development of clinical signs. Acute animals will be febrile and exhibiting a cough with serous nasal discharge.

Diagnostic methods for viral detection include virus isolation, antigen detection by immunoassay and molecular based assays such as reverse transcriptase polymerase chain reaction (RT-PCR) and partial or full genomic sequencing. Virus isolation with SIV is challenging and requires critical timing for sample collection since the virus is only shed for about 3-5 days following infection. RT-PCR assays show excellent specificity, good sensitivity and can differentiate subtypes. However, full genomic sequencing is necessary to detect more subtle changes in the SIV genome (Personal Communication Amy Vincent 2008).

Detection of serum antibodies is a common method used to diagnose infection. Currently Hemagglutination Inhibition (HI) testing is the most common method used to diagnose SIV. An advantage of the HI assay is that it can discriminate between different subtypes and antigenic variants within a subtype. However, it is restricted to a specific subtype, so its diagnostic value diminishes with the emergence of novel reassortant subtypes (Long et al 2004; Wu 2006; Janke 2000). Two commercial ELISA tests have been licensed for both H1N1 and H3N2 subtypes, but their ability to differentiate antibodies against different isolates has not been well documented. Newer ELISA antibody tests have been developed that can differentiate between virus exposure and vaccination (Wu 2006) but are not commercially available. There can be some cross reactivity with H1N1 and H3N2 SIV in some tests, such as ELISA or indirect immunofluorescence assay (IFA), because Type A influenza viruses share a common matrix protein and nucleoprotein. Serum neutralization (SN) assays measure the level of antibodies that are capable of neutralizing the virus however this test is labor intensive, virus specific, and is not generally used for routine diagnostic screening.

#### ***Diagnostic testing for the H1N1 flu outbreak strain***

Testing animals to identify the Novel H1N1 2009 Virus strain will require agent specific diagnostic tests that are not yet available, but currently under development. Initially a Matrix PCR will be used as a screening test to identify cases of swine influenza from case compatible submissions, followed by Virus Isolation (VI) then genetic sequencing of the H, N, and M genes for differentiation and confirmation. Virus-specific probes can be developed and validated, but will require time to accomplish.

#### ***Possible zoonotic relevance***

The United States has encountered several recent SIV events of possible zoonotic relevance. These include:

- (1) The current events surrounding the novel Novel H1N1 2009 Virus causing human clinical illness globally (described above). This unique reassortant virus is of swine origin, contains genes of swine, avian and human lineage, and components originate from multiple continents (North America and Euro-Asia);

- (2) Triple reassortant (containing genes of avian, porcine, and human flu virus origin) swine influenza A (H1N1) infections and disease in humans (2007-2009) in Iowa, Illinois, Ohio, Texas, and South Dakota. Concurrent swine and human infections with an identical triple reassortant SIV genome were reported in Ohio in 2007; and
- (3) The first isolation and identification of an avian and swine virus reassortant H2N3 influenza A virus causing infection and disease in swine in the U.S. in 2006. This isolate was a cause for public health concern because the swine H2N3 virus was infectious and highly transmissible in swine and ferrets under experimental conditions.

It is important to note that the increased detection of SIV infections in humans may reflect a real increase in human infections, or it could be the result of enhanced diagnostic capabilities at state public health laboratories. In June 2007, the Council for State and Territorial Epidemiologists (CSTE) reporting requirements were amended to make human infection with novel influenza A viruses, including SIV, a nationally notifiable condition.

Dr. Amy Vincent states the following in a 2008 American Association of Swine Veterinarians (AASV) paper: “Reassortant viruses arising from the mixing of genes from swine, human, and avian influenza viruses in the swine host have epidemic potential in the pig population and may have pandemic potential in the human population. This underscores the importance of limiting the introduction of new influenza viruses to the swine population and *monitoring for newly emerging viruses* (emphasis added)” (Vincent, 2008).

Dr. Marie Gramer states in her 2008 AASV paper: “It is important to note that most influenza viruses isolated from US swine are triple reassortant viruses, containing genes of avian, human and swine influenza virus origin. These triple reassortant influenza viruses of swine are postulated to have an increased affinity for reassortment. Furthermore, the presence of multiple lineages of influenza viruses circulating concurrently sets the stage for virus variation and the appearance of new strains, *reinforcing the need for regular subtyping, serotyping and genetic sequencing* (Gramer 2008).

Currently, veterinarians send samples from swine with clinical signs that are consistent with SIV to USDA-ARS, CDC, universities (including National Institute of Health Centers of Excellence) and NVSL. However, because of intellectual property issues and lack of coordination among these entities, there is inconsistent communication among these entities that results in:

- Limited sharing of knowledge of these SIV detection events in swine;
- Unknown incidence of SIV infections in swine in the United States;
- Unknown animal or public health relevance of isolates; and
- Little context for evaluating the significance of genomic changes in SIV.

Further, the U.S. pork industry supports an estimated 550,200 domestic jobs, generates more than \$97.4 billion annually in total U.S. economic activity, and contributes \$34.5 billion to the U.S. gross national product. In 2006, the United States exported 1,262,499 metric tons of pork valued at \$2.864 billion. Pork exports depend directly on open and transparent disclosure of the commercial segment's disease status to all trading partners.

Possible mutating zoonotic reassortant swine influenza virus is a potential risk to this vital industry for several reasons:

- Potential for pandemic human illness;
- Infections in the pig population can cause severe illness and death loss;
- Farm workers and their families may be at risk for influenza infection from or to the pigs for which they care. Caretaker attendance and animal care compliance could fall precipitously in the wake of the threat of an influenza pandemic;
- Neighboring communities may be put at risk for pandemic influenza infection by proximity to sick pigs and / or infected swine workers;
- Demand for pork domestically may drop significantly in the wake of public loss of confidence in its safety in the wake of a zoonotic swine influenza outbreak; and
- With 15 percent to as much as 25 percent of the current pork supply merchandised in export markets, the U.S. swine industry risks huge financial losses should when trading partners impose bans or additional restrictions.

These findings have increased interest by VS, ARS, and CDC in establishing a formal surveillance process for selected influenza events and shared virus analysis in a timely and structured manner. This process will monitor occurrences and encourage viral genetic analysis, assisting in understanding the swine (animal) and human health epidemiology and relevance of selected SIV events.

VS-NVSL has been collaborating with CDC on these recent swine and human SIV detection events, but a more coordinated awareness and information sharing process with veterinary diagnostic labs is needed to better detect and monitor changes in SIV in U.S. swine populations.

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