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To: Healthcare Providers, Hospitals, Laboratories, Local Health Departments
From: NYSDOH Bureau of Communicable Disease Control and Wadsworth Laboratory

HEALTH ADVISORY: UPDATE #4
SWINE-ORIGIN INFLUENZA A (H1N1) VIRUS (S-OIV) INFECTION
Please distribute immediately to all staff in the Departments of Laboratory Medicine, Critical Care, Emergency Medicine, Family Practice, Internal Medicine, Infectious Disease, Infection Control, Pediatrics, Pulmonary Medicine, and all inpatient and outpatient units.

Introduction
The New York State Department of Health (NYSDOH) is providing this advisory regarding the ongoing investigation of swine-origin influenza A (H1N1) virus (S-OIV) infections being conducted by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).

*****Update #4 contains significantly new information/recommendations and should replace all previously released S-OIV Health Advisories*****

The guidance in this advisory is intended for providers seeing patients outside of New York City. For guidance related to providers seeing patients in New York City, see the New York City Department of Health and Mental Hygiene (NYCDOHMH) Advisories at: www.nyc.gov/health/nycmed.

This interim information is based on currently available information and will likely change as additional information becomes available. This update is current as of 5:00 PM on 5/7/09.

1. Background

CDC is working with the World Health Organization (WHO), state and local officials in all affected states and cities to conduct an ongoing investigation of a nationwide outbreak of human cases of S-OIV infection to determine the source and extent of the infection both in the US and internationally. Cases were first identified when specimens were determined to be positive for influenza A but could not be subtyped with standard methods. Subsequent subtyping at CDC determined that patients were infected with S-OIV. Total numbers of nationwide confirmed cases for this investigation are updated daily on the CDC web site at: http://www.cdc.gov/flu/swine/investigation.htm. Total numbers of international confirmed cases for this investigation are updated daily on the WHO website at: http://www.who.int/en/.

2. Clinical guidance for assessment, testing, and treatment

Current assumptions made for these clinical guidance recommendations:

- There are adequate stores of antiviral medications to treat all seriously ill patients.
- Limitations in the prophylactic antiviral medication supply are a likely inevitability that will require a focused approach to postexposure prophylaxis for both health care workers (HCW) and high-risk individuals.
- Most influenza illness, including S-OIV infection, will be mild to moderate and self-limiting.
- As a vaccine against S-OIV is developed, antiviral recommendations are likely to change.
- There are insufficient laboratory testing resources to perform S-OIV confirmatory testing on all patients with symptoms of influenza.

Clinical Assessment

These guidelines are intended to provide a general approach. Clinicians are urged to continue their normal practice to every extent possible and apply sound clinical judgment to the approach of each individual patient. It is important to remember that the clinical symptoms and presentation of S-OIV infection may be similar to other respiratory illnesses and should be considered in the context of a complete differential diagnosis. At the same time, it is equally important to recognize that, as with seasonal influenza, infants, elderly adults, and persons with compromised immune systems may have atypical presentations, such as presenting without a fever (due to inability to mount a fever response), hypothermia, or sepsis-like syndrome.

Clinicians should consider S-OIV in the differential diagnosis of any person presenting with acute febrile respiratory illness, which is defined as a measured temperature of ≥37.8°C (100°F) and recent onset of at least one of the following:

1. rhinorrhea or nasal congestion
2. sore throat
3. cough

Patients with uncomplicated S-OIV disease have experienced fever, chills, headache, cough, sore throat, rhinorrhea, shortness of breath, myalgias, arthralgias, fatigue, vomiting, or diarrhea. The estimated incubation period is unknown and could range from 1-7 days, and more likely 1-4 days.

A person considered at high-risk for complications of S-OIV infection is the same as for seasonal influenza at this time. As more epidemiologic and clinical data become available, these risk groups might be revised. High-risk populations include:

- Children <5 years old (the risk for severe complications from seasonal influenza is highest among children <2)
- Adults ≥65 years.
- Persons with the following conditions:
    - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus)
    - Immunosuppression, including that caused by medications or by HIV
- Pregnant women
- Persons <19 years who are receiving long-term aspirin therapy
- Residents of nursing homes and other chronic-care facilities

Testing Recommendations
The following patients should be tested locally for influenza A:

- Patients hospitalized for acute febrile respiratory illness, and
- Non-hospitalized patients who have acute febrile respiratory illness and who are at high-risk for severe disease

  If the patient meets the reporting criteria (see Section 3), the LHD will work closely with hospitals and providers to determine which specimens should be submitted to the Wadsworth Center, according to epidemiologic criteria defined by the NYSDOH.

Patients who report mild illness AND who have no underlying medical conditions that place them at higher risk of complications from influenza need not be seen in the office. These patients can be screened by phone, given symptomatic treatment recommendations, and instructed to contact their physician for any signs of worsening severity of illness. Those patients with mild illness should be provided with educational information about preventing influenza transmission and advised to stay home for 7 days after symptom onset or until they are symptom-free for 24 hours. For typical clinical management purposes, **patients with mild illness who have no underlying medical conditions should NOT be tested for influenza because screening tests will not influence treatment decisions.**

Exposure (to a confirmed or probable S-OIV case or to a geographic area where S-OIV has been identified) alone is not an indication for hospital or emergency room referral. Patients who report serious illness should be further evaluated; the most appropriate setting for the evaluation of a severely ill patient may be the hospital emergency room. Do **NOT** send patients to an emergency department unless you believe hospital admission may be warranted.

Antiviral Treatment
Refer to Section 7 for current case definitions for confirmed, probable and suspected cases of S-OIV.

Antiviral treatment is ***recommended*** for the following individuals:

1. Confirmed, probable, or suspected cases of S-OIV infection in hospitalized patients.
2. Confirmed, probable, or suspected cases of S-OIV infection in patients at high-risk for influenza complications.

Clinical judgment is an important factor in treatment decisions. Persons with suspected S-OIV infection who present with an uncomplicated febrile illness typically do not require treatment unless they are at higher risk for influenza complications. Many patients who have had S-OIV infection, but who are not in a high-risk group, have had a self-limited respiratory illness similar to typical seasonal influenza. For most of these patients, the benefits of using antivirals may be modest. Therefore testing, treatment, and chemoprophylaxis efforts should be directed primarily at persons who are hospitalized or at higher risk for influenza complications.

Antiviral treatment with zanamivir or oseltamivir should be initiated as soon as possible (ideally within 48 hours) after the onset of symptoms. Recommended duration of treatment is 5 days. The S-OIV is sensitive (not resistant) to the neuraminidase inhibitors, oseltamivir and zanamivir, and resistant (not sensitive) to the adamantanes, amantadine and rimantadine.

Table 1: Summary of testing and treatment recommendations for patients with suspect, probable, or confirmed S-OIV infection

	Mild Illness		**Severe Illness**	
High-risk medical conditions that increase complications of influenza	**TEST?**	**TREAT?**	**TEST?**	**TREAT?**
	YES	Recommended	YES	Recommended
NO high-risk medical conditions that increase complications of influenza	**TEST?**	**TREAT?**	**TEST?**	**TREAT?**
	NO	Clinical judgment	YES	Recommended

Antiviral Chemoprophylaxis
When chemoprophylaxis is indicated, either oseltamivir or zanamivir should be initiated as soon as possible following the exposure and should continue for **10 days** following the last known exposure to S-OIV infection.

Postexposure antiviral chemoprophylaxis is ***recommended*** for the following individuals:

1. Household close contacts who are at high-risk for complications of influenza of a confirmed, probable, or suspected case
2. Health care workers or public health workers who were not using appropriate personal protective equipment (PPE) during close contact with an ill confirmed, probable, or suspected case of S-OIV infection during the case's infectious period.
3. Children attending school or daycare who are at high-risk for complications of influenza and who had close contact (face-to-face) with a confirmed, probable, or suspected case.

Pre-exposure antiviral chemoprophylaxis should only be used in limited circumstances. Certain persons at ongoing occupational risk for exposure who are also at higher risk for complications of influenza (e.g., health care personnel, public health workers, or first responders who are working in communities with S-OIV outbreaks) should carefully follow guidelines for appropriate PPE or consider temporary reassignment.

Table 2: S-OIV antiviral medication dosing recommendations (table extracted from Infectious Disease Society of America guidelines for seasonal influenza)

Agent, group		**Treatment (5 days)**	**Chemoprophylaxis (10 days)**
Oseltamivir			
Adults		75 mg capsule twice per day for 5 days	75 mg capsule once per day
Children (age 12 months or older*) by weight	≤15 kg	60 mg per day divided into 2 doses	30 mg once per day
	15-23 kg	90 mg per day divided into 2 doses	45 mg once per day
	24-40 kg	120 mg per day divided into 2 doses	60 mg once per day
	>40 kg	150 mg per day divided into 2 doses	75 mg once per day
Zanamivir			
Adults		Two 5-mg inhalations (10 mg total) twice per day	Two 5-mg inhalations (10 mg total) once per day
Children		Two 5-mg inhalations (10 mg total) twice per day(age, 7 years or older)	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older)

Table 3: S-OIV antiviral medication dosing recommendations for children <12 months*

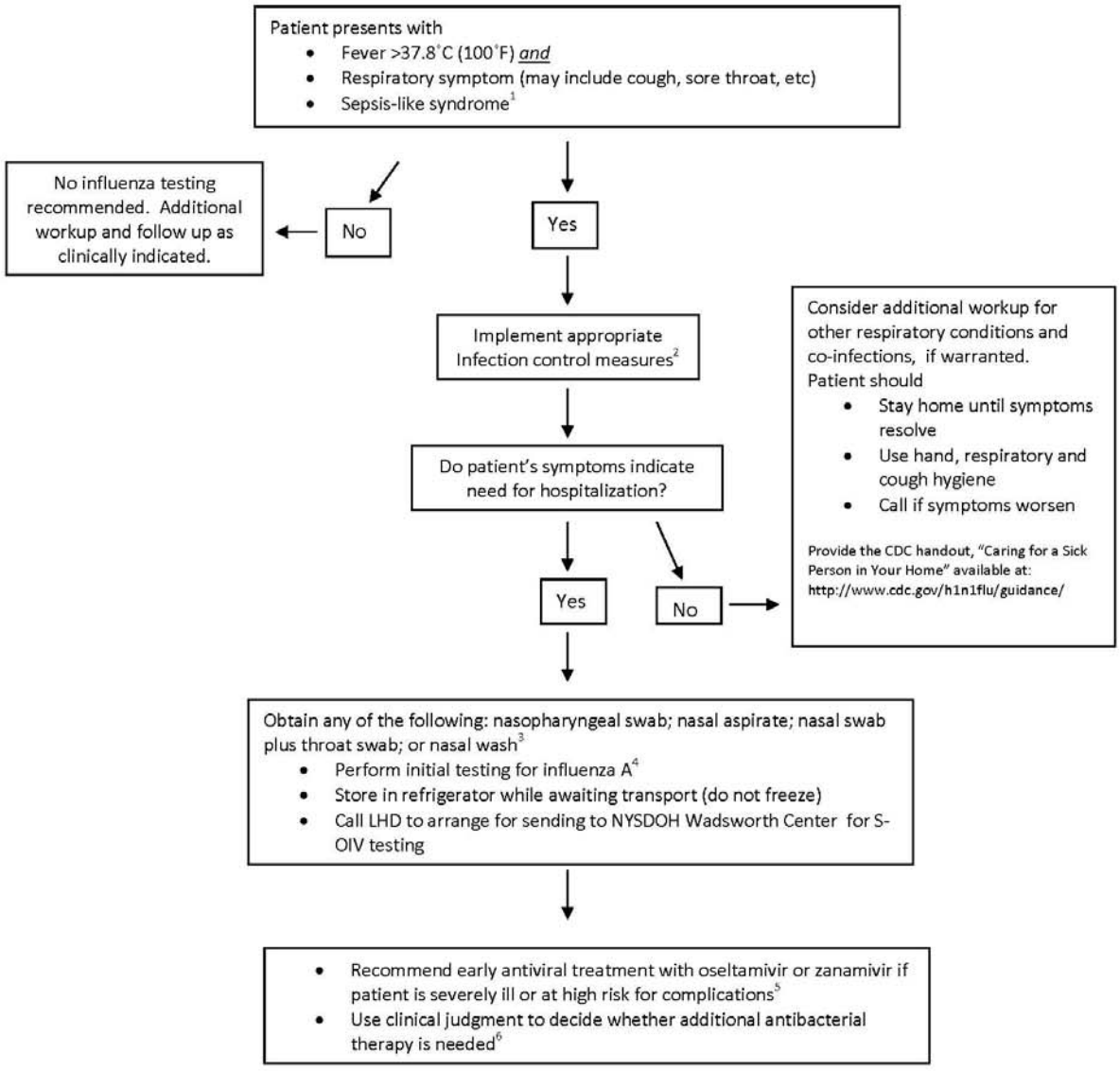
Agent, group		**Treatment (5 days)**	**Chemoprophylaxis (10days)**
Oseltamivir			
Children (age <12 months)	<3 months	12 mg twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
	3-5 months	20 mg twice daily	20 mg once daily
	6-11 months	25 mg twice daily	25 mg once daily

* Oseltamivir use for children < 12 months old was recently approved by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) and dosing for these children is age-based. Healthcare providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed swine-origin H1N1 influenza or who has been exposed to a confirmed swine H1N1 case, and carefully monitor infants for adverse events when oseltamivir is used.

Adverse reactions to antiviral therapy

Health care professionals and consumers may report serious adverse events (side effects) with the use of these products or product quality problems to the FDA's MedWatch Adverse Event Reporting program by calling 1-800-FDA-1088 or online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm or by submitting a MedWatch Form 3500 (available at: http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) via mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

Testing and Treatment Algorithm for Swine-origin Influenza A (H1N1) Virus (S-OIV) in New York State



1. As with seasonal influenza, infants, adult ≥65 years-old, and persons with compromised immune systems may have atypical presentations.
2. Information on infection control can be found at: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.
3. Nasal washes require appropriate personal protective equipment. See: http://www.cdc.gov/swineflu/guidelines_infection_control.htm.
4. Real-time reverse transcriptase polymerase chain reaction (RT-PCR) is the preferred laboratory test for identifying S-OIV. Rapid antigen tests and immunofluorescence tests have unknown sensitivity and specificity to detect S-OIV H1N1. For more information, please see: http://www.cdc.gov/swineflu/specimencollection.htm.
5. Information on use of antiviral agents can be found at: http://www.cdc.gov/swineflu/recommendations.htm.
6. Interim guidance for clinicians is available at: http://www.cdc.gov/swineflu/identifyingpatients.htm.

3. Reporting criteria for suspected cases of S-OIV infection
Physicians should report any unusual clusters of febrile respiratory illness to the local health department (LHD) immediately. Local public health authorities may request testing of patients associated with a suspect outbreak, even if the patient's illness is mild.

Until further notice, reporting of suspected cases of S-OIV to public health will be based on both the geographic distribution of the virus and the severity of illness in suspected cases. Medical providers should stay updated regarding the geographic spread of S-OIV by checking the distribution map on the NYSDOH website at: http://www.nyhealth.gov/diseases/communicable/influenza/h1n1/.

In addition, providers are requested to report all suspected cases of S-OIV to public health based on the following criteria:

1. Reporting of suspect cases with severe illness (hospitalized)

- Physicians should order influenza A testing on all patients admitted to the hospital for acute febrile respiratory illness.
- Report ALL patients hospitalized for acute febrile respiratory illness who test positive for influenza A or who test positive for influenza but typing is not available.
- Report any hospitalized patients with acute febrile respiratory illness who test influenza negative or are not tested but are highly suspicious for S-OIV.

2. Reporting of suspect cases with mild illness (non-hospitalized)

- Physicians seeing patients in counties where S-OIV has not been previously confirmed should report to the LHD mild (non-hospitalized) cases of acute febrile respiratory illness who meet either of the following criteria:
  - onset within 7 days of close contact with a person who is a confirmed case of S-OIV infection, or
  - onset within 7 days of travel to a geographic region (affected states, NYC, and affected NYS counties) where there are one or more confirmed S-OIV cases.

How to report

- Physicians should report any patient meeting the above reporting criteria immediately by telephone to the LHD.
- If there are difficulties reaching the LHD, the provider should contact the NYSDOH. During business hours, call 518-473-4439; after hours, call 1-866-881-2809.

All hospitals and providers desiring to submit S-OIV specimens to Wadsworth Center MUST coordinate submission through their LHD.

- The LHD will be the primary consultant and will work closely with hospitals and providers to determine which specimens should be submitted to the Wadsworth Center, according to epidemiologic criteria defined by the NYSDOH (see Section 8).
- Once the LHD has given approval to the clinician for the patient specimen to be submitted to Wadsworth Center for testing, the clinician should complete the NYSDOH Virus

Detection History Form, DOH-1795
(http://www.wadsworth.org/divisions/infdis/virology/forms/VRSLPatientHistoryFormDOH-1795.pdf)
noting testing is for a suspect case of S-OIV infection. Also note relevant patient clinical and travel history on this form and results of any influenza laboratory testing that has already been performed.

- Specimens should be shipped refrigerated (not frozen) overnight to Wadsworth Center Griffin Laboratory. Specific instructions and contact information for providers are available at: http://www.wadsworth.org/divisions/infdis/virology/collectsubmit.htm.

4. Infection control recommendations

Due to accumulating evidence that S-OIV is comparable to seasonal influenza in its spectrum of illness and transmission pattern and does not appear to be causing unusual mortality compared to seasonal influenza, NYSDOH is now recommending that infection control measures for S-OIV be similar to those taken for seasonal influenza. These measures are consistent with recommendations developed and distributed by NYCDOHMH on 5/6/09.

Since S-OIV is a novel virus, its clinical and epidemiologic features are only now being elucidated, and these recommendations are therefore subject to change. There is no effective vaccine and it is assumed that much if not all of the population is susceptible to the virus. It is also possible that this virus may become more virulent in the future, in which case these recommendations would be revised.

Efforts to maximize adherence to recommendations for seasonal influenza, including meticulous respiratory hygiene and cough etiquette, should be practiced in all medical facilities. This includes the placement of a surgical facemask on all patients with febrile respiratory illness in all patient settings, in order to reduce the spread of the virus to health care workers and patients. These infection control recommendations apply to ALL patients with influenza, including confirmed or probable S-OIV, or with febrile respiratory illness.

Inpatient settings and hospital emergency departments

- Continue to advise patients with fever and acute respiratory symptoms, such as cough or sore throat, to notify the triage nurse immediately. Patients with these complaints should be placed in a single room with closed door if possible, or asked to wait at least 3-6 feet away from other people. The patient should be asked to wear a surgical mask as tolerated and to perform hand hygiene.
- Use STANDARD and DROPLET precautions for routine medical care of patients with confirmed or probable S-OIV, or febrile respiratory illness. Negative pressure airborne infection isolation rooms (AIIRs) and N95 respirators are no longer recommended for routine patient care for patients with S-OIV or febrile respiratory illness.
- Aerosol-generating procedures (e.g., bronchoscopy, intubation and extubation, and deep open tracheal suctioning) should be performed, when feasible, in a negative pressure (AIIR). Fit-tested N95 respirators and eye protection (goggles or face shield) should be worn by health care personnel performing these procedures.
- Any patient with febrile respiratory illness should be placed in a private room for medical care whenever possible.
- Patients should wear a surgical facemask when outside their room or when being transferred.
- Health care workers examining; caring for; or obtaining nasal, nasopharyngeal or pharyngeal specimens from patients with probable or confirmed S-OIV or febrile respiratory illness should wear a surgical facemask.
- If tuberculosis is being considered, the patient should be placed in an AIIR and staff entering the room should wear a fit-tested N95 respirator.
- **Hand hygiene is absolutely essential** and should be performed before and after patient care, and before donning and after removal of a surgical facemask. Fit-tested

N95 masks and eye protection (goggles or face shields) are *not* necessary except for aerosol-generating procedures as described above.

- Nebulized treatments for patients with febrile respiratory illness should be provided in a private room with closed door if at all possible or 6 feet apart at a minimum if a private room is not available. If private rooms are limited, reserve the private rooms for patients with febrile respiratory disease. If no private room is available, use a curtain or other barrier between patients who are in the same room when performing nebulized treatments.
- Visitors should be asked to perform hand hygiene before entering and after exiting the patient's room and advised to wear a surgical facemask while in the room with the patient.

Clinics, medical offices or other ambulatory care settings

- Patients with febrile respiratory illness in outpatient settings should be asked to wear a surgical facemask, as tolerated, upon entry, while waiting, and while being examined and cared for.
- Staff who have close contact, including examining or providing direct medical care for the patient with febrile respiratory illness, should wear a surgical facemask and gloves, and should put the facemask on ideally before entering the room.
- Staff should be instructed to perform hand hygiene and put facemask on first followed by gloves. When patient care is complete, remove gloves first then facemask, and perform hand hygiene.
- If a nasopharyngeal swab or other respiratory specimen is being collected, the patient should be instructed to remove the facemask briefly for specimen collection, then replace the mask as soon as the specimen is obtained.
- Meticulous hand hygiene should be performed before and after removal of PPE and before and after patient care.

All staff working in hospital or medical office settings should be instructed NOT to work if they are ill. If they become ill while working, they should be instructed to cease patient care and go home immediately and follow their facility's employee health policies. While waiting to go home, they should be asked to wear a surgical facemask and to sit away from other staff and patients.

Transmission-based precautions definitions

Adapted from Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007, available at: *http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf.*

Standard Precautions: A group of infection prevention practices that apply to all patients, including: respiratory and cough etiquette; hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices.

- Based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents.
- The application of Standard Precautions during patient care is determined by the nature of the HCW-patient interaction and the extent of anticipated blood, body fluid,

or pathogen exposure. For some interactions (e.g., performing venipuncture), only gloves may be needed; during other interactions (e.g., intubation), use of gloves, gown, and face shield or mask and goggles is necessary.

Droplet Precautions: A group of infection prevention practices intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions, including wearing a mask for close contact with an infectious patient

- Use Droplet Precautions as recommended in HICPAC/CDC Isolation Guideline found on the CDC website at: http://www.cdc.gov/ncidod/dhqp/gl_isolation.html for patients known or suspected to be infected with pathogens transmitted by respiratory droplets (i.e., large-particle droplets >5μm in size) that are generated by a patient who is coughing, sneezing, or talking.
- A single patient room is preferred for patients who require Droplet Precautions.
- Patients on Droplet Precautions who must be transported outside of the room should wear a mask if tolerated and follow Respiratory Hygiene/Cough Etiquette.

5. Continuing guidance

The NYSDOH will provide updated guidance as additional information and CDC recommendations become available. Updated information is frequently posted on the CDC website at: http://www.cdc.gov/flu/swine/investigation.htm.

Several additional CDC guidance documents can be found at: http://www.cdc.gov/swineflu/guidance/. Some currently posted guidance documents include:

- Interim Guidance-HIV-Infected Adults and Adolescents: Considerations for Clinicians Regarding Swine-Origin Influenza A (H1N1) Virus, 5/3/09
- H1N1 Flu and Patients With Cardiovascular Disease (Heart Disease and Stroke), 5/2/09
- Fact Sheet on Key Mental/Behavioral Health Issues Related to Social Distancing, 5/5/09
- Interim Guidance for Emergency Medical Services (EMS) Systems and 9-1-1 Public Safety Answering Points (PSAPs) for Management of Patients with Confirmed or Suspected Infection, 4/29/09
- Emergency Use Authorization (EUA) of Medical Products and Devices, 5/2/09
- Interim Guidance: Taking Care of a Sick Person in Your Home, 5/1/09
- Interim Guidance for Airlines Regarding Flight Crews Arriving from Domestic and International Areas Affected by Swine Influenza, 4/30/09
- Interim Guidance to Assist Flight Deck and Cabin Crew in Identifying Passengers Who May Have Novel H1N1 Flu, 4/30/09
- Interim Novel Influenza A (H1N1) Guidance for Cruise Ships, 5/4/09
- Pregnant Women and Swine Influenza Considerations for Clinicians, 5/1/09

6. Laboratory reporting

In the near future clinical laboratories will be conducting their own S-OIV assays and reporting the results to the ordering providers. The following reporting requirements are in effect until further notice for all clinical laboratories that establish S-OIV testing capabilities:

- ALL S-OIV test results (all positives, negatives, and indeterminant results) must be reported via the Electronic Clinical Laboratory Reporting System within 24 hours.
    - For patients residing in New York City, reports must be submitted to the Bureau of Communicable Disease, Box 22A, NYCDOHMH, 125 Worth Street, New York, NY 10013 by the US Postal Service, by fax at (212) 788-4268 or electronically through ECLRS.
- For patients residing outside of New York City, laboratories must also report immediately via telephone notification all positive results for S-OIV by contacting the LHD.

7. Surveillance case and outbreak definitions for infection with S-OIV
The CDC case definitions for the purpose of investigation of suspected, probable, and confirmed cases of S-OIV infection are as follows:

A ***confirmed case*** of S-OIV infection is defined as a person with an acute febrile respiratory illness with laboratory confirmed S-OIV infection by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

A ***probable case*** of S-OIV infection is defined as a person with an acute febrile respiratory illness who is positive for influenza A, but negative for H1 and H3 by influenza RT-PCR

A ***suspected case*** of S-OIV infection is defined as a person with acute febrile respiratory illness

- with onset within 7 days of close contact with a person who is a confirmed case of S-OIV infection, or
- with onset within 7 days of travel to a community either within the United States or internationally where there are one or more confirmed S-OIV cases, or
- that resides in a community where there are one or more confirmed S-OIV cases.

Definition of an outbreak, by location type
A health care facility (HCF) outbreak is defined as follows:

- For long term care facilities only
    - Two or more cases of acute febrile respiratory illness or a single laboratory confirmed/probable case of S-OIV in a resident
- For all other health care settings
    - Acute febrile respiratory illness in a patient or healthcare worker after known HCF-setting exposure to a confirmed, probable, or suspect case of S-OIV and no other exposures (eg., community exposures) that would place them in the suspect case category.
    - Laboratory confirmed/probable test result in a HCF patient whose onset of acute febrile respiratory illness is seven or more days AFTER admission to the hospital.

A ***community outbreak*** is generally defined as a cluster of illness in ≥2 non-co-habitating people who are epidemiologically linked.

8. Epidemiologic criteria for submission of specimens to NYSDOH Wadsworth Center
The following outlines the criteria that LHDs should use for approving submission of specimens for swine-origin influenza A (H1N1) virus (S-OIV) testing. All requests for submission of S-OIV specimens to Wadsworth Center MUST be coordinated through LHDs.

For counties with confirmed or probable S-OIV cases:

- At this time, NO specimens from suspect cases with mild illness should be sent to Wadsworth Center
- Submit ALL specimens from persons with acute febrile respiratory illness who:
    1. Are admitted to the hospital and test either:
        a. positive for Influenza A
        b. positive for Influenza, typing not available

    OR

    2. Are associated with acute febrile respiratory illness outbreaks (community-associated or health care facility-associated)

For counties with NO confirmed or probable S-OIV cases:

- At this time, a maximum of 2-3 specimens per county per day from **cases with mild illness** who meet the suspect case definition should be sent to Wadsworth Center. The highest priority specimens are from patients with non-subtypeable Influenza A.
- Submit ALL specimens from persons with acute febrile respiratory illness who:
    1. Are admitted to the hospital and test either:
        a. positive for Influenza A
        b. positive for Influenza, typing not available

    OR

    2. Are associated with acute febrile respiratory illness outbreaks (community-associated or health care facility-associated)
- As S-OIV disease is confirmed in other geographic regions of the state, those affected counties will then follow the guidance detailed above for counties with confirmed or probable S-OIV.

9. S-OIV biosafety guidelines for laboratory workers

This guidance is for laboratory workers who may be processing or performing diagnostic testing, including virus isolation, on specimens from patients with suspected S-OIV infection.

Diagnostic laboratory work on clinical samples from patients who are suspected cases of S-OIV infection should be conducted in a BSL2 laboratory. All sample manipulations should be done inside a biosafety cabinet (BSC).

Viral isolation on clinical specimens from patients who are suspected cases of S-OIV infection should be performed in a BSL2 laboratory with BSL3 practices (enhanced BSL2 conditions) as described below.

Additional precautions for viral isolation procedures include:

* Recommended Personal Protective Equipment (based on site specific risk assessment)
* Respiratory protection – fit-tested N95 respirator or higher level of protection.
* Shoe covers
* Closed-front gown
* Double gloves
* Eye protection (goggles or face shields)

Waste

* All waste disposal procedures should be followed as outlined in your facility standard laboratory operating procedures.

Appropriate disinfectants

* 70% Ethanol
* 5% Lysol
* 10% Bleach

All personnel should self monitor for fever and any symptoms of S-OIV infection, which include cough, sore throat, vomiting, diarrhea, headache, runny nose, and muscle aches. Any illness should be reported to your supervisor immediately.

For personnel who had unprotected exposure or a known breach in personal protective equipment to clinical material or live virus from a confirmed case of S-OIV, antiviral chemoprophylaxis with zanamivir or oseltamivir for 10 days after exposure can be considered.

10. Diagnostic laboratory testing for suspected S-OIV infection

- The preferred specimen is a nasopharyngeal swab in viral transport medium. ONLY ONE specimen per patient needs to be submitted to Wadsworth Center for testing.
- **Use Dacron or rayon swabs with a fine-tip flexible metal shaft, or NP-flocked swab with flexible plastic shaft, for nasopharyngeal swab. Do not use calcium alginate or wooden-shafted swabs**. **Immediately after collecting specimen, place swab in sterile vial containing 2 ml (at a minimum 0.5 ml) of viral transport medium. Keep sample cold (4ºC) after collection.**

  Collection Guidelines:

  - **Nasopharyngeal swab:** Use a swab with a fine, flexible metal shaft and Dacron or rayon tip, or a flocked swab with long, flexible, plastic shaft, specific for nasopharyngeal swab sample collection. Insert swab into posterior nasopharynx. Rub swab against mucosal surface and leave in place for 5 seconds to absorb secretions. Collection of specimens from both nostrils increases amount of material available for analysis. Place swab in a vial of viral transport medium. Use scissors to cut metal shaft, or snap plastic shaft of flocked swab, so that top of vial can be screwed on tightly.

  - **Nasopharyngeal aspirate**: Requires source of suction (syringe, vacuum pump, or wall suction), specimen trap with two outlets, and catheter (no. 6 to 14 depending on size of patient). Without applying suction, insert catheter through nose into posterior nasopharynx (approximately the distance from tip of the nose to the external opening of the ear when measured in a straight line). Apply gentle suction, leaving catheter in place for a few seconds, then withdraw slowly. Suction contents of a vial of viral transport medium or non-bacteriostatic saline through catheter tubing to assist in moving material from tubing into trap and to add viral transport media to specimen. Transfer specimen to a screw cap tube for transport to laboratory.

  - **Nasopharyngeal wash**: Use rubber bulb (1-2 oz for infants) or syringe to instill 3-5 ml of non-bacteriostatic saline into one nostril while occluding the other. If patient is able to co-operate, instruct them to close glottis by making a humming sound with mouth open. If a rubber bulb is used, release pressure on bulb to allow saline and mucus to enter bulb. Remove from nose and squeeze into vial of transport media. If syringe is used, apply suction to syringe to recover saline and nasal secretions. Alternately, hold sterile container such as urine cup under patient's nose and ask patient to expel material into it. In either case, add recovered saline-nasal secretions to a vial of viral transport media.

- Results of testing of initial cases suggest that rapid EIA influenza tests may be insensitive for the detection of S-OIV and these assays should not be relied on as screening tests for this agent. However, a rapid influenza antigen detection test may be performed on the nasopharyngeal sample using standard BSL2 work practices in a Class II biological safety cabinet. Regardless of the result, specimens should still be referred to the Wadsworth Center for further testing in coordination with the local health department (LHD).

- At this time the recommended front-line assay is a real-time RT-PCR assay that detects influenza A. If sub-typing assays for H1 and H3 are available, they should also be performed. If the sample is influenza A positive but H1 and H3 negative and therefore not sub-typeable, the sample should be considered as a "probable" case of S-OIV. **Samples producing non-subtypeable results on these assays should be reported to the LHD and shipped immediately to the Wadsworth Center for S-OIV testing.** When shipping, include test results from all assays.

- Submit a completed Virus Reference and Surveillance Laboratory patient history form (http://www.wadsworth.org/divisions/infdis/virology/forms/VRSLPatientHistoryFormDOH-1795.pdf) with the specimens.

- Viral culture may be performed on respiratory specimens from patients suspected of having S-OIV infection, who meet the surveillance criteria as described in the advisory update. All specimen manipulations and viral culture procedures should be performed under BSL2 containment with enhancements as described in the laboratory safety guidelines.

- It is essential that specimens be sent to the Viral Reference and Surveillance Laboratory at the Wadsworth Center Griffin Laboratory as soon as possible after collection. If shipped within two days of collection, store at 4ºC post-collection and ship with cold packs to maintain temperature at 4ºC. Do not use wet ice. If shipment is delayed >2 days, then the specimens should be stored frozen at -70ºC and shipped on dry ice.

- It is the shipper's responsibility to ensure that appropriate shipping materials are used. Please contact your carrier for shipping and packaging information. Patient specimens must be shipped as "Diagnostic Specimens." All specimens must be shipped "Priority Overnight" and received within 24 hours via chosen carrier.

  Address for courier shipping:
  Wadsworth Center, NYSDOH
  Griffin Laboratory
  Virus Reference and Surveillance Laboratory
  5668 State Farm Road (Rt. 155)
  Slingerlands, NY 12159