

Technical Section E: Clinical Issues



Executive Summary

Clinicians play an important role in early detection of initial pandemic influenza cases in a community. Early identification and isolation of cases and quarantine of contacts may slow the disease spread within a community. Early diagnosis and treatment with antivirals may hasten recovery (this occurs in seasonal influenza). Because the signs and symptoms of a novel influenza virus infection are consistent with many other infections, early detection, diagnosis, treatment and control are difficult.

This technical section will work in conjunction with **Technical Sections C and D**. In addition, further planning and implementation will be coordinated with three other areas of the plan: **Technical Sections B, F, and H**.

An expert advisory group has been formed by the MDH, comprised of physician-experts on influenza, Minnesota infectious disease physician leaders, and an infection control practitioner (ICP). This group will advise the IDEPC Medical Director about clinical issues related to novel strains of influenza and pandemic influenza including issues related to clinical evaluation, treatment, containment, and infection control.

The MDH Clinical Infection Control Team (C-ICT) will carry out the activities indicated in this section. This team's primary work will be to respond to any occurrences of suspect or probable cases of novel influenza occurring in the state. These staff will:

1. Provide consultation to clinicians on individual suspect cases of novel influenza;
2. Advise clinicians on infection control issues that will arise when these patients are evaluated and treated; and
3. Assist clinicians in accessing MDH laboratory services for novel influenza diagnosis.

The C-ICT will also develop materials for dissemination to clinicians across the state on the recommended diagnostic and laboratory testing for suspect cases of novel influenza. The approach of the recommended clinical diagnostic process will vary depending on the stage of the pandemic. Case identification during the pandemic alert period will hinge upon a combination of clinical and epidemiologic features. During the pandemic period, diagnosis will be based more on clinical symptoms and less on diagnostic testing.

The C-ICT will also rely on information technology (IT) support to help develop and maintain a tracking system (Novel Influenza Case Tracking Database) for suspect, probable, and confirmed novel influenza cases. In the pandemic alert phases and early in the pandemic period it will be likely that the specific case status of each suspect case of novel influenza (ruled-out, ruled-in, or still suspect) will influence other actions to be taken by the MDH. Examples include the need for disseminating public risk communication messages and responding to trigger points for activities described elsewhere in this section.

The case-tracking database will be closely modeled after a similar system used at MDH during the outbreak of Severe Acute Respiratory Syndrome (SARS). In these pandemic alert phases and early in the pandemic period, in addition to other ongoing surveillance methods, data from the Novel Influenza Case Tracking Database will be summarized and disseminated by ITIH staff responsible for influenza surveillance (see **Technical Section B**). Later in the pandemic, case-based surveillance will no longer be possible and other surveillance methods will be relied upon (see **Technical Section B**). The Novel Influenza Case Tracking Database will also interface with the Isolation and Quarantine Monitoring Database (see **Technical Section C**).

Health and Human Services (HHS) Recommendations

Overview

The HHS Pandemic Influenza Plan describes clinical roles and responsibilities in Supplement 5. Principal roles for state and LPH agencies in the pandemic-alert period are outlined. They include:

- Educating providers about novel/pandemic influenza,
- Facilitating testing, and
- Investigating suspect cases.

In the pandemic period, state and LPH agencies should update providers regularly and work to investigate and report special pandemic situations.

In the pandemic alert phases, evaluation of patients with suspect novel influenza illness will be based on meeting both clinical and epidemiologic criteria.

Clinical criteria

These include hospitalized patients with severe influenza-like illness (ILI) including pneumonia, or non-hospitalized patients with ILI and strong epidemiological suspicion of novel influenza exposure. HHS also provides guidance on special circumstances, such as high-risk groups or individuals with high-risk exposures that have atypical symptoms.

Epidemiologic criteria

The criteria important for determining whether a patient has possibly contracted H5N1 influenza include:

1. Travel to an area affected by this virus, plus
 - Direct contact either with poultry, or
 - Close contact with a person known or suspected to have contracted H5N1 influenza, during their period of illness, or
2. Occupational risks—any of the following groups
 - Workers handling birds known or suspected to be infected by H5N1 viruses, or
 - Workers in laboratories that contain H5N1 viruses, or
 - Healthcare workers in contact with patients known or suspected to have H5N1 influenza.

The HHS Plan recommends that during the pandemic phase, patients suspected to have an illness due to a novel influenza virus should be placed on droplet (infection control) precautions. The state of Minnesota differs from the HHS plan in recommending use of full-barrier (infection control) precautions, including standard, contact, and airborne, plus eye protection (see **Technical Section D**).

Therefore, in contrast to droplet precautions (HHS recommendation) in which surgical masks are recommended for most patient care, MDH recommends that healthcare workers in contact with suspect cases use respirators, such as N95 masks or positive air purifying respirators (PAPRs) (see **Technical Section D**).

Other initial patient management advice from HHS is focused on specific laboratory and other diagnostic testing, hospitalization vs. outpatient treatment, initiation of antiviral treatment,

evaluation of potentially exposed contacts, and interpretation of positive and negative tests for seasonal and novel influenza viruses.

HHS guidelines anticipate that during the pandemic period the need to conduct extensive testing for the novel virus will be reduced, as will the need for other diagnostic tests (i.e., to try to establish an alternate diagnosis) because:

- There will be fewer medical and diagnostic resources, and
- When the virus is already circulating within a community, information, on the epidemiologic criteria used to identify suspect cases will be less useful.

In the pandemic period several other clinical management recommendations will change, including that only those patients who have severe complications will be hospitalized (care at home will be more likely); and an important focus of clinical care will be prevention of secondary complications such as post-influenza community-acquired pneumonia.

Boxes, figures, tables, and appendixes 1-3 included at the end of the Clinical Guidelines supplement of the HHS Plan give detailed clinical information addressing the evaluation, management and treatment of cases of novel influenza and post-influenza pneumonia. These are readily adaptable for use by clinicians across the state.

Planning Activities

Rationale

Clinicians play a critical role in the identification of cases of novel influenza. The MDH will provide guidelines on the clinical approach to patients with novel influenza based upon a review of epidemiological and clinical data, federal guidelines, WHO guidelines, a review of the scientific evidence, medical literature, and consultation from technical experts.

Triggers

Interpandemic/pandemic alert period

During the interpandemic/pandemic alert period (phases 1-5), the following events or developments may serve as clinical triggers:

- Evidence of animal-to-human transmission.
- Evidence of limited human-to-human transmission.
- Evidence of increased human-to-human transmission.
- Evidence of significant human-to-human transmission.

Pandemic period

In addition to the clinical trigger points noted for the interpandemic/pandemic alert period, the following trigger points may come into play during the pandemic period (phase 6):

- Efficient and sustained human-to-human transmission.

Actions

Pandemic alert period

The following clinical actions are planned, anticipated, or already underway for the pandemic alert period (phases 3-5).

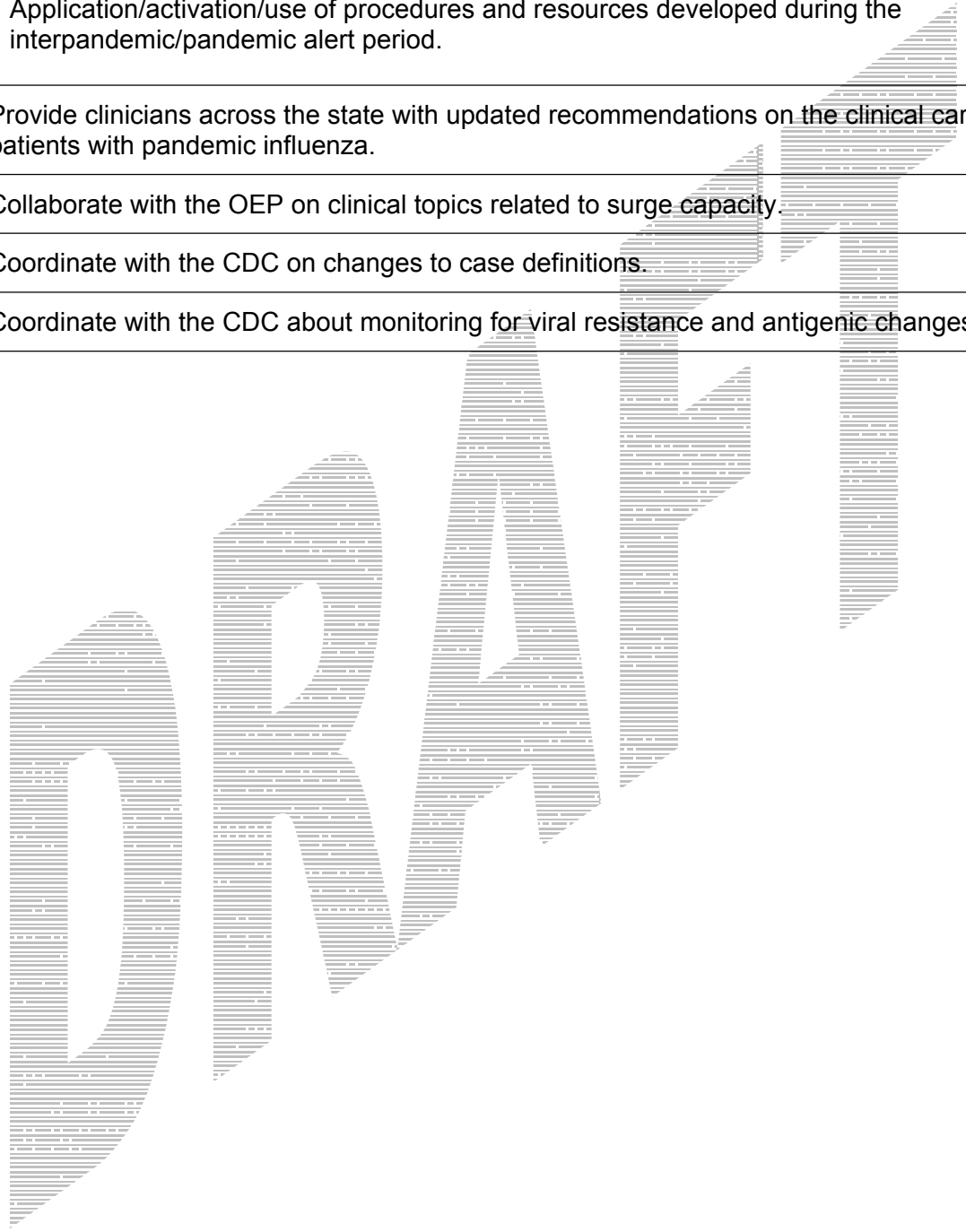
Phase 3 - 5
1. Notify clinicians across the state, LPH, ICPs, and hospitals about clinical and epidemiologic criteria for suspect cases of H5N1/other novel influenza strains (see Attachment O).
2. Update clinicians across the state, LPH, ICPs, and hospitals about changing clinical and epidemiologic criteria for suspect cases of H5N1/other novel influenza strains.
3. Coordinate protocols with the MDH-PHL to: <ul style="list-style-type: none"> ▪ Facilitate quick delivery of appropriately collected specimens to MDH-PHL, ▪ Communicate about the relative urgency of testing for different patients based on the strength of epidemiologic and clinical data, and isolation and quarantine issues related to the case (gatekeeper role), ▪ Track the capacity/burden of MDH-PHL testing, and ▪ Efficiently communicate results from MDH-PHL to the C-ICT staff responsible for the case, to influenza surveillance staff in ITIH, and to the patient's provider.
4. Contract with infectious disease physician(s) to consult with clinicians in the state on complex cases/issues related to pandemic influenza and to advise the C-ICT on specific clinical cases, taking call, etc.
5. Assess the need for and establish an MDH stockpile of oseltamivir for treatment and prophylaxis in coordination with Strategic National Stockpile (SNS).
6. Develop funding mechanisms for stockpiling antivirals and/or personal protective equipment, i.e., reimbursement or cost sharing by hospitals/ health plans, state funding, or other means of funding.
7. Identify additional personnel (surge capacity) for staffing warmlines for clinicians during the pandemic period.
8. Determine a system for monitoring viral strains for antigenic changes, and antiviral resistance during later pandemic alert phases and the pandemic period.
9. Work with IQ and legal teams to implement IQ.
10. Work with IQ team to address clinical questions of individuals or groups in IQ.
11. Work with CDC Quarantine officers at the MSP Quarantine Station to identify suspect cases of AI in individuals or groups on airplanes.
12. Facilitate the evaluation and assist with clinical questions about individuals or groups in IQ.

Pandemic period

Many of the anticipated clinical activities for the pandemic period (phase 6) will involve:

- Continuation of activities initiated during the interpandemic/pandemic alert period; or
- Application/activation/use of procedures and resources developed during the interpandemic/pandemic alert period.

1. Provide clinicians across the state with updated recommendations on the clinical care of patients with pandemic influenza.
2. Collaborate with the OEP on clinical topics related to surge capacity.
3. Coordinate with the CDC on changes to case definitions.
4. Coordinate with the CDC about monitoring for viral resistance and antigenic changes.



Roles and Responsibilities

State and local roles and responsibilities are identified below. Regional roles are also identified when applicable. This is not an exhaustive list. Furthermore, although roles and responsibilities are listed, the MDH recognizes that the infrastructure to support these planning efforts is evolving and may not yet be in place.

State			
	Roles and responsibilities	Coordinating entity	Explanation
Clinical Advisory Group	Establish a clinical advisory working group of expert infectious disease clinicians to advise Medical Director about clinical issues related to novel strains of influenza/pandemic influenza.	Primary: MDH IDEPC Medical Director Contributor MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH ITIH other MDH ADIC Staff	The group's purpose is principally to assist with planning in the Pandemic Alert Period but they may be able to be convened during the Pandemic Period as well.
Information Sharing	Inform clinicians (also ICPs, other health care providers, local public health agencies) about current clinical criteria for suspect cases of novel/pandemic influenza, recommended clinical and laboratory evaluation of those cases, and clinical guidelines for treating common post-influenza complications.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator Contributor: MDH ITIH, MDH IDEPC Webmaster MDH OEP Health Alert Network Multi-Agency Coordination Centers	Initial information is needed for use during the Pandemic Alert Period.

State			
	Roles and responsibilities	Coordinating entity	Explanation
Information Sharing	Update clinicians on changes in federal guidance and relevance to clinical management in Minnesota as any of the following change: pandemic alert phase, spread of the pandemic, changes in federal guidance on clinical issues, etc.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator Contributor: MDH ITIH, MDH IDEPC Webmaster MDH OEP Health Alert Network Multi-Agency Coordination Centers	Updates will be provided during later Pandemic Alert Phases and during the Pandemic Period.
Training	Organize and train members for C-ICT from among epidemiologists and nurse specialists.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator EIS Officer MDH Infectious Disease Medical Consultant Contributor: MDH ITIH MDH IDEPC LPH	

State			
	Roles and responsibilities	Coordinating entity	Explanation
Case Management	Serve as case managers to: 1) advise treating clinicians about immediate infection control measures; 2) advise/direct the clinician to information on recommended diagnostics (for influenza or alternate diagnoses); 3) advise and coordinate specimen collection for tests to be run at the MDH laboratory; 4) answer questions about prophylaxis of contacts, 5) trace close contacts of suspect cases and 6) serve as a single point of contact for suspect cases and their family members.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT Contributor: MDH ITIH MDH IDEPC	The C-ICT will direct more difficult clinical questions to the medical director, or as back up, the EIS officer (if a physician), or an infectious disease physician contracted for this purpose.
Surveillance Data	Maintain necessary surveillance data;	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT Contributor: MDH ITIH MDH IDEPC	

State			
	Roles and responsibilities	Coordinating entity	Explanation
Warmline	Staff and supervise “warm” lines for clinicians.	Primary: MDH C-ICT Contributor: MDH ITIH MDH IDEPC MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator	We would expect a high volume of calls from clinicians as the pandemic worsens concerning: 1) infection control, 2) general diagnostic/treatment recommendations 3) rapidly changing epidemiologic criteria (especially if web fails or operates only intermittently), and 4) clinical advice for more difficult clinical cases. With very high case volume, individual case management would no longer be feasible for all cases.
Information Sharing	Inform clinicians of when and how to report suspect cases of novel/pandemic influenza disease, and about the urgency of such reports.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT Contributor: MDH-PHL MDH ITIH MDH IDEPC Webmaster	

State			
	Roles and responsibilities	Coordinating entity	Explanation
Communication	Communicate with clinicians about discontinuation of case based surveillance, new hospital based surveillance and/or changing consultation and laboratory testing resources at MDH.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT Contributor: MDH-PHL MDH ITIH MDH IDEPC Webmaster	
Database Development	Develop a novel influenza case-tracking database.	Primary: MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT MDH IDEPC Webmaster Contributor: MDH-PHL MDH ITIH	
Communication	Communicate regularly with the CDC clinical pandemic influenza team, with clinical teams in other states, jurisdictions and territories, and the CDC quarantine officers assigned to the Minneapolis-St. Paul International Airport.	Primary: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT Contributor: MDH-PHL MDH ITIH	

State			
	Roles and responsibilities	Coordinating entity	Explanation
Training	Assist with plans and materials to be used to train/educate local public health staff about novel/pandemic influenza, specifically those focused on clinical and infection control issues.	Primary: PHPC PHNC MDH EFS MDH OEP Contributor: MDH IDEPC Medical Director MDH IDEPC Clinical Coordinator MDH IDEPC Infection Control Coordinator MDH C-ICT MDH ITIH	
Local			
	Roles and responsibilities	Coordinating entity	Explanation
Content Experts	Assure that some staff will be responsible (and remain updated) as local experts in the content.	Primary: LPH Hospitals ICPs Contributor: PHPC PHNC MDH EFS MDH OEP Multi-Agency Coordination Centers MDH IDEPC Infection Control Coordinator MDH C-ICT	

Local			
	Roles and responsibilities	Coordinating entity	Explanation
Content Experts	Answer basic clinical and infection control questions, and be able to refer clinicians to MDH as necessary.	Primary: LPH Hospitals ICPs Contributor: PHPC PHNC MDH EFS MDH OEP Multi-Agency Coordination Centers MDH IDEPC Infection Control Coordinator MDH C-ICT	This would be particularly important in the Pandemic Period, when changes in clinical and epidemiologic suspect case criteria, and in recommended diagnostic testing are anticipated.
Messaging	Monitor that messages about clinical and epidemiologic suspect case criteria and diagnostic testing are consistent with those being disseminated by local ICPs and hospitals.	Primary: LPH Hospitals ICPs Contributor: PHPC PHNC MDH EFS MDH OEP Multi-Agency Coordination Centers MDH IDEPC Infection Control Coordinator MDH C-ICT	This will be especially important that there is consistent with current MDH and CDC guidelines. Notify the MDH with any inconsistencies or questions.

Local			
	Roles and responsibilities	Coordinating entity	Explanation
Information Sharing	Provide feedback to MDH concerning needs that local ICPs, hospitals and clinicians feel are not being met in the area of clinical management information.	Primary: LPH Hospitals ICPs Contributor: PHPC PHNC MDH EFS MDH OEP Multi-Agency Coordination Centers MDH IDEPC Infection Control Coordinator MDH C-ICT	

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