

08-04

STATEMENT OF POLICY

Pandemic Influenza Antivirals

Policy

The National Association of County and City Health Officials (NACCHO) is concerned with (1) the availability of oral influenza antivirals such as Oseltamivir for treatment and prophylaxis of first responders and critical infrastructure workers; (2) the engagement of private sector partners who stockpile antivirals; (3) the improvement of systems to distribute antivirals during a pandemic; (4) the improvement of timely access to antiviral treatment; and (5) the health risks of home stockpiling. The recommendations in this policy statement are framed around the Centers for Disease Control and Prevention (CDC) models for a severe pandemic influenza outbreak, which estimate 80 million individuals becoming ill and potentially needing treatment with antivirals nationwide.¹

In 2014, the federal policy on stockpiling shifted from a joint federal and state stockpiling model to a federal only model due to unsustainable maintenance costs and other logistical challenges associated with state stockpiling.² In a severe pandemic, the CDC is unlikely to permit the use of federally stockpiled oral antiviral medications for flu prevention, primarily due to constraints on the availability of such medications.³ Although both Tamiflu and Relenza are approved by the Food and Drug Administration (FDA) for use as prophylaxis, and CDC clinical guidance documents address the use of antivirals for prophylaxis, clinical guidance differs from usage policy.^{3,4} Clinical antiviral guidance (which supports use of federally stockpiled antivirals for prophylaxis) focuses on considerations for the individual patient, while drug usage policy (which highly restricts the use of federally stockpiled antivirals for prophylaxis) considers community-based circumstances and takes into account issues related to drug supply and other factors.⁴

Prophylaxis for influenza consumes very large quantities of antivirals per person as compared to their use in treatment; even though antivirals may be available during a pandemic through both government-purchased stockpiles and moment-of-need purchasing capability from private suppliers, there will only be a finite supply. Thus decisions will need to be made about the use and allocation of such supplies. The opportunities and challenges associated with antiviral distribution and dispensing will vary depending on the severity of a pandemic.^{5,6} Antiviral prophylaxis does have a place in mild to moderate pandemic scenarios and for seasonal influenza; however, the following policy recommendations are focused on severe influenza pandemics for which federally stockpiled antivirals are projected to be available for treatment only.³

NACCHO recommends the following with regard to stockpiling and distribution of oral antivirals for pandemics:



- NACCHO supports the federal government’s continued role as the primary stockpiler of antivirals for treatment purposes via the Strategic National Stockpile, and supports the CDC’s efforts to acquire a sufficient quantity of medications to treat all individuals projected to become ill during a severe pandemic.² NACCHO does not support state antiviral stockpiling for treatment of ill individuals as the Strategic National Stockpile should have sufficient supply for treatment during a severe pandemic.
- Since federal stockpiles of antivirals will not be available for prophylaxis in a severe pandemic scenario, state and local agencies that wish to make medications available for prophylaxis of first responders and critical infrastructure should procure, maintain, and properly manage their own stockpiles for this purpose in accordance with manufacturer instructions. To assist with implementation of this directive, all state and local governmental public health departments and other public sector agencies should have access to the best pricing available for influenza antivirals, including prices negotiated by the federal government or public purchasing collectives. Federal policies such as the permissibility of using Public Health Emergency Preparedness (PHEP) funds to purchase antivirals should be continued. In addition, using CDC Emergency Use Instructions authority to communicate any applicable FDA extensions of antiviral expiration dating beyond a manufacturer’s labeled expiration dating (e.g., under FDA’s expiration dating extension authority) may be helpful in facilitating state and local stockpiling efforts.^{2,5,7,8} State and local governmental agencies currently holding stockpiles of oral antivirals should maintain such caches to the extent possible by replacing expiring medications with those with longer shelf lives. However, expired medications should be disposed of since there are currently no Emergency Use Authorizations in effect for oral antivirals.⁹
- Private-sector companies with the financial and occupational health capacity should stockpile influenza antivirals for essential employees who provide continuity of operations during an emergency and for those whose duties create a high risk of exposure to pandemic influenza.¹⁰ Private-sector stockpiling for prophylaxis would increase the availability of antivirals within a community during a pandemic; reduce the financial and logistical burdens on local health departments to stockpile and dispense large quantities of antivirals for the general public; and contribute to efforts to sustain first response services and critical infrastructure and maintain continuity of essential community services during a pandemic. It would also allow greater opportunity for local health departments to focus on distribution to vulnerable populations that do not have access to antivirals through their employers. Local health departments should seek information regarding medication types and quantities stockpiled by private-sector entities in their communities and provide technical assistance to these partners on distribution, tracking, and health education.
- NACCHO supports increasing the speed at which CDC’s Division of Strategic National Stockpile (DSNS) can deploy oral antivirals to state and local partners.⁶ NACCHO also supports state and local agencies developing the capability to effectively store and redistribute antivirals within their jurisdictions.⁶ Further reductions in the time required to deploy antivirals from federal stockpiles to the point of dispensing should expedite getting drugs into the hands of healthcare facilities and improve healthcare providers’ ability to initiate treatment of ill individuals within the optimum timeframe.⁵ Pharmacies will also require access to these supplemental supplies of antivirals.^{6,11} Quantities and timeframes for delivery of resources shipped by CDC should be coordinated in the moment between CDC, pharmaceutical manufacturers and distributors, and receiving health departments.

- NACCHO does not support state and local public health policies that encourage individual home stockpiling of antivirals due to concerns about safety, proper storage, and increased drug resistance.

Justification

Certain antivirals are efficacious in countering influenza virus and could be the sole initial medical countermeasure against a pandemic strain—albeit with variable impact depending on the strain—until an effective vaccine is available.^{3,4} (Other interventions including infection control practices could also limit the spread of such a pathogen.) Antiviral stockpiling is a helpful preparedness tool for mitigation and response to pandemic influenza.

The federal government has set a goal of stockpiling sufficient quantities of antivirals to treat 25% of the nation's population (the percentage projected to become ill) during a severe pandemic.^{5,6} The CDC is currently updating guidance for state and local governmental agencies, as well as guidance for private-sector partners, on antiviral stockpiling and use during a pandemic. Despite advances in medical countermeasure distribution and dispensing planning, health departments still face significant challenges in rapid distribution of oral antivirals to pharmacies and healthcare facilities, where they can be pre-positioned to treat ill individuals.^{5,6}

Antiviral stockpiling is one of many mitigation and response strategies for reducing morbidity and mortality during an influenza pandemic; however, NACCHO recognizes that there are limitations to the effectiveness of antiviral stockpiling and use during a pandemic. Current antivirals may not necessarily be effective against the strain of influenza causing the pandemic.¹ Also, antivirals are costly to procure and store and have a finite shelf-life. Local health departments must assess the cost-effectiveness of maintaining local antiviral stockpiles based upon their jurisdiction's current and future needs.

Forthcoming federal guidance on state, local, and private-sector antiviral stockpiling and use should include a realistic assessment of logistical challenges to distributing and dispensing antivirals during an influenza pandemic. Such challenges could include reductions in the available workforce as individuals become ill or stay home to care for family members; balancing demands for antivirals for treatment and prophylaxis; space and appropriate conditions to properly store the medications for an extended period; the potential need for social distancing; limited access to sufficiently trained and experienced logistical staff for a surge response; and record-keeping requirements.^{5,6} However, these challenges are balanced by positive planning factors such as the likelihood of advanced warning of a pandemic and the potential to leverage state and local public health medication distribution and dispensing capabilities developed for anthrax and seasonal flu.

Private-sector stockpiling of antivirals may reduce some of the currently projected inadequacy in access to antivirals for prophylaxis during an influenza pandemic within many states and localities.¹⁰ Encouraging private-sector entities, particularly critical infrastructure providers, to stockpile antivirals for administering prophylaxis to their employees and family members helps to ensure that government-owned stockpiles will be more readily available for prophylaxis and/or treatment of vulnerable and impacted populations and sends a strong message that

pandemic preparedness is a community-wide responsibility. Therefore, it is important to increase the amount of antivirals available in communities for the prevention of pandemic influenza.

References

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Record of Action

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