NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

08-04

STATEMENT OF POLICY

Pandemic and Severe Seasonal Respiratory Virus Therapeutics

Policy

The National Association of County and City Health Officials (NACCHO) supports (1) the availability of therapeutics (e.g., antivirals, monoclonal antibodies) for the treatment of respiratory virus (e.g., influenza, COVID-19, Respiratory syncytial virus (RSV)) cases and prophylaxis of at-risk and/or high-risk contacts of cases; (2) the improvement of systems to assure therapeutics are available during severe seasonal respiratory virus outbreaks and accessible by the public during pandemics; (3) the improvement of timely access to therapeutics; and recognizes the health risks of home stockpiling of antivirals. 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 between 64 to 96 million individuals becoming ill and potentially needing access to antivirals nationwide, and the COVID-19 pandemic morbidity, which was estimated to be 104 million COVID-19 cases over its course.[1,2] These estimates, with consideration for co-occurrence with other viral outbreaks, illustrate the stress that can occur on the US therapeutic supply.

Therapeutics are now prescribed regularly by physicians and are often readily available in commercial pharmacies. In addition, they are often covered by insurance company drug formularies, and some are available in generic form to reduce out-of-pocket costs.[3] To meet the needs of these scenarios, local and state stockpiling of therapeutics is ongoing. However, due to the increasing costs required to procure and maintain local and state stockpiles, federal guidance and further funding support is needed.

In a severe pandemic, there may be restrictions on the broad use of federally stockpiled therapeutics.[4,5] These barriers raise equity concerns and may impact groups who are uninsured, underinsured, or unable to afford the cost of these medications. The therapeutics may be set aside for first responders, first receivers, or critical infrastructure personnel to assure continuity of essential services or may be recommended to protect those at higher risk of infection or severe disease (e.g., pregnant women, children, or those with chronic disease).[4,5] Yet another strategy may be to attempt to slow community spread of disease by providing prophylaxis to case contacts during early outbreaks or nodes of transmission (school age children, travelers).

Although several drugs (e.g. Tamiflu, Relenza, and Beyfortus) are approved by the Food and Drug Administration (FDA) for use as prophylaxis, and CDC clinical guidance documents address the use of therapeutics s for prophylaxis, in therapeutic prioritization scenarios, clinical guidance may be modified to consider community-based circumstances, national therapeutics supply, and other factors.[4,5,6] For example, prophylaxis for respiratory viral diseases requires

greater quantities of antivirals per person than treatment, potentially making this a less desirable use in the case of a shortage. However, use as prophylaxis has occurred during past respiratory virus outbreaks and may still be justified in certain instances.

While therapeutics may be available during a pandemic through both government-purchased stockpiles and commercial pharmacies, there may be spot shortages as witnessed in the 2018 H3N2 severe flu season, the COVID-19 pandemic, and the 2022-2023 respiratory virus season.[7,8] During those years, the nation saw high levels of outpatient clinic and emergency department visits for influenza- or COVID-like illness, high respiratory virus-related hospitalization rates and deaths, and elevated and geographically widespread respiratory virus activity for an extended period. As most pharmacies rely on just-in-time inventory methods designed to cut costs and decrease waste by receiving goods only as they are needed, this can result in widespread shortages. Under these conditions, federal guidance may be extremely useful in informing the use and equitable allocation of scarce resources.[7,9] The opportunities and challenges associated with therapeutic access will vary depending on the severity of the illness and may require the cooperation of the therapeutics manufacturers, pharmaceutical distributors, large pharmacy chains, or intervention by the federal government. The following policy recommendations are focused on severe respiratory virus seasons or pandemics for which federally stockpiled therapeutics are projected to be limited.[4,5]

NACCHO recommends the following regarding stockpiling and distribution of therapeutics for respiratory virus pandemics or severe seasonal outbreaks:

- NACCHO supports the U.S. Department of Health and Human Service Administration for Strategic Preparedness and Response's (ASPR) maintenance of sufficient quantities of a range of FDA-approved or authorized therapeutics in the Strategic National Stockpile for use during a pandemic or severe seasonal outbreak.[10]
- Since federal stockpiles of therapeutics may not be available for prophylaxis in a severe seasonal outbreak or pandemic scenario, state and local agencies that wish to make therapeutics available for prophylaxis of first responders and critical infrastructure personnel should procure, maintain, and properly manage their own stockpiles for this purpose in accordance with manufacturer instructions. To assist with implementation of this directive, state and local governmental public health agencies wishing to procure respiratory virus therapeutic caches using alternative sources of funding should have access to the best pricing available negotiated by the federal government or public purchasing collectives with the therapeutic manufacturers.
- Federal policies such as the permissibility of using Public Health Emergency Preparedness (PHEP) funds to purchase antivirals should be continued. In addition, federal authority to communicate any applicable FDA extensions of therapeutic expiration dating beyond a manufacturer's labeled expiration dating (e.g., under FDA's shelf life extension authority) is helpful in facilitating state and local stockpiling efforts. [10,11,12] State and local governmental agencies currently holding therapeutics stockpiles should maintain such caches to the extent possible by replacing expiring medications with those with longer shelf lives and follow FDA/CDC/ASPR SNS guidance on MCM expiration dating extensions by holding on to expired therapeutics until additional testing is conducted or further data evaluations are made by FDA.

- NACCHO supports increasing accessibility of therapeutics to state and local partners. NACCHO also supports state and local agencies further refining their capability to store and redistribute therapeutics within their jurisdictions to eligible partners (e.g., healthcare facilities or pharmacies) due to shortages that may occur in their traditional supply-chains. Further reductions in the time required to distribute therapeutics from federal stockpiles to the dispensing nodes should improve accessibility and community health outcomes. Quantities and timeframes for delivery of resources shipped by ASPR should be coordinated between CDC, ASPR SNS, pharmaceutical manufacturers and distributors, and receiving health departments on an as-needed basis
- NACCHO does not encourage individual home stockpiling of therapeutics due to concerns about safety, proper storage, and increased drug resistance.
- NACCHO believes in the equitable distribution of and access to therapeutics.

Justification

The use of therapeutics is efficacious in countering severe respiratory virus outbreaks and pandemics. The timely administration of therapeutics will be a critical factor in mitigating the health consequences and impacts of a severe seasonal outbreak or pandemic.[13,14] Consequently, therapeutic stockpiling is a helpful preparedness tool for mitigation and response to severe respiratory virus outbreaks and pandemics. However, NACCHO recognizes that therapeutic caches can be costly and that there is no guarantee that currently available medications will be effective against future pandemic or seasonal strains.[1] Also, therapeutics have a finite shelf-life. State and local health departments must assess the cost-effectiveness of maintaining therapeutic stockpiles based upon their jurisdiction's current and future needs.

The federal government has set a goal of stockpiling sufficient quantities of therapeutics to treat 25% of the nation's population (the percentage projected to become ill) during a severe pandemic.[15,16] The CDC and ASPR SNS are regularly updating guidance for state and local governmental agencies on therapeutic stockpiling and use during a pandemic or severe seasonal outbreak. Despite advances in medical countermeasure distribution and dispensing planning, health departments still face significant challenges in rapid distribution of therapeutics to frontline providers.

Federal guidance on state and local therapeutic stockpiling and use should include a realistic assessment of logistical challenges of storing and using therapeutics during a severe respiratory virus outbreak or pandemic. Such challenges could include: (A) Reductions in the available workforce as individuals become ill or stay home to care for family members; (B) Balancing demands for therapeutics for treatment and prophylaxis; (C) Space and appropriate processes to cycle, maintain product integrity, and properly store the medications for an extended period; (D) Logistics of storing medications for a long period of time, ensuring stock is rotated, and medications are kept within expiration status; (E) Limited access to sufficiently trained and experienced logistical staff for a surge response; and (F) Record-keeping requirements.[17] However, these challenges are balanced by the likelihood of advanced warning of a pandemic or severe outbreak and the potential to leverage highly developed state and local public health medical countermeasure capabilities for other public health threats.

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Record of Action

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