REPORT BRIEF • APRIL 2008

ANTIVIRALS FOR PANDEMIC INFLUENZA: GUIDANCE ON DEVELOPING A DISTRIBUTION AND DISPENSING PROGRAM

At the request of the Department of Health and Human Services (DHHS), the Institute of Medicine (IOM) Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic considered best practices and policies for providing antiviral treatment and prophylaxis during a pandemic event.

A well-matched vaccine against the pandemic strain of influenza virus would be an ideal pandemic response but will require several months to develop and produce. Thus, antiviral medications will be used to contain the outbreak and to mitigate hospitalization and mortality rates. Currently, federal and state governments stockpile two drugs—oseltamivir and zanamivir—that are approved by the Food and Drug Administration (FDA).

Any planning for an influenza pandemic must consider two basic assumptions: uncertainty and scarcity. As a starting point, the committee acknowledged that the process of planning is complicated by many unknowns such as the origin of the pandemic; the characteristics of the pandemic strain of influenza virus, including its susceptibility to antivirals; the likelihood and speed of emerging antiviral resistance; and the implications of antiviral shelf-life issues. Changes in what is known may require frequently revisiting planning assumptions and adapting policies and plans. Furthermore, the amount of antivirals in government stockpiles is not sufficient for all potential uses, and it is unclear whether larger stockpiles are desirable or feasible given the cost, opportunity costs (allocating funds to this rather than to other public health strategies), and uncertainties associated with antiviral medications.

Although the committee notes that final determinations about which priority groups should receive scarce antivirals cannot be made in advance of a pandemic . . . it recommends a first level of prioritization.

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RECOMMENDATIONS

ANTIVIRAL STOCKPILES

- The federal government should clarify the nation’s goals for antiviral use in an influenza pandemic. If these goals include treatment of all anticipated cases and a level of prophylaxis, fiscal appropriations will be needed to expand the national stockpile to meet these goals.

- Unlike federal stockpiles, state- and private-sector stockpiles are not covered under the Shelf-Life Extension Program.1 This means antivirals purchased by non-federal entities may expire before they are used. Therefore, the federal government’s Shelf-Life Extension Program should be expanded to include other public and private sector entities that are stockpiling antivirals for use in an influenza pandemic.

- DHHS needs to develop a process to use the knowledge acquired by the FDA in the operation of the Shelf-Life Extension Program to facilitate the use of properly stored, recently expired medications that exist in supplies outside the Shelf-Life Extension Program in the event that these medications are needed because of a shortage.

- To promote mutual trust, collaboration, and coordination, memorandums of understanding or similar agreements should be developed between public health agencies and private-sector entities in their jurisdictions.

SUPPORTING DECISION MAKING

- The federal government—in collaboration with state and local governments—should support the development of a national ethical framework to guide the allocation of antivirals during a severe influenza pandemic. Developing the framework should incorporate processes to obtain input from the public and a wide array of stakeholders.

- A federal advisory body needs to be formed as soon as possible to advise the federal government and its partners on the planning and implementation of the public health and medical responses to an influenza pandemic, including antiviral use. Options for establishing an advisory body include creating a subcommittee under the National Biodefense Science Board or creating a new federal advisory committee to DHHS.

- Communication is a critical dimension of preparing for antiviral distribution and dispensing. As a result, state and local public health officials preparing for an influenza pandemic should develop partnerships with (1) the media, including ethnic media; (2) leaders of local communities of faith; (3) community-based clinics; and (4) other trusted organizations and community leaders to convey vital public health information clearly, simply, and in a manner that respects and reflects cultural and linguistic differences.

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1 The program tests batches of drug for viability beyond the date on the label.
In the pre-pandemic period, DHHS should undertake an effort similar to that for influenza vaccine priorities—national in scope, inclusive of diverse populations and viewpoints, and in keeping with a shared ethical framework—to discuss and develop a prioritization scheme for antiviral treatment and prophylaxis that is capable of adjustments in real-time in response to the influenza pandemic.

**EFFICIENT USE OF ANTIVIRALS**

- Federal and state pandemic influenza planners need to make available outbreak prophylaxis for health care and emergency personnel, who are in short supply and will have repeated and difficult-to-control exposure, a first priority for prophylactic antiviral use. Post-exposure prophylaxis for other health care personnel and emergency responders should be a second priority. Post-exposure prophylaxis of household contacts of infected individuals should be a third priority if stockpiled antivirals are insufficient to meet all prophylaxis objectives.

- In order to use antivirals sparingly and strategically based on available epidemiologic data and local circumstances, efforts should be made to minimize the need for outbreak prophylaxis among health care and emergency responders and efficiently allocate scarce resources. Necessary measures include proper and consistent use of personal protective equipment and grouping of workers in subsets to stagger their exposure to infected patients, thus reducing the number who need prophylaxis at any given time and shortening the duration of needed prophylaxis.

**INFORMATION SYSTEMS FOR AN ANTIVIRAL PROGRAM**

- Despite the many barriers, systems for tracking who receives antivirals will be needed, especially in the context of a severe pandemic and limited supplies. Therefore, DHHS needs to support and fund public health agencies to develop or expand information systems for tracking dispensed antivirals. The development or expansion of these systems should make use of existing information resources or systems, consider information technology needs for other dimensions of pandemic influenza response, comply with Centers for Disease Control and Prevention standards, and be interoperable and robust.

- DHHS should also consider options in addition to the FDA Adverse Event Reporting System to capture adverse events resulting from use of antiviral drugs to ensure active and timely reporting. One option is a network of sentinel sites that can collect data that are representative of antiviral use nationally.

**CONCLUSION**

Implementation of an antiviral program for pandemic influenza, whether it occurs in the near or distant future, will need to take into account many constantly evolving factors. Notwithstanding the final characteristics of the pandemic, it is clear that many of these issues need to be addressed in advance in order to form a solid foundation for later decision making. Several activities require special attention: developing an ethical framework for making difficult decisions, ensuring supply commensurate with antiviral program goals, and maintaining flexibility to react to changes in the course of the pandemic and address the diverse needs of localities.
FOR MORE INFORMATION . . .

Copies of Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, www.nap.edu. The full text of this report is available at www.nap.edu.

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COMMITTEE ON IMPLEMENTATION OF ANTIVIRAL MEDICATION STRATEGIES FOR AN INFLUENZA PANDEMIC

JUNE E. OSBORN, M.D. (Chair), President Emerita, Josiah Macy, Jr. Foundation
KAREN G. GERV AIS, Ph.D., Director, Minnesota Center for Health Care Ethics, Minneapolis, MN
SANDRA R. HERNANDEZ, M.D., Director and Chief Executive Officer, San Francisco Foundation, CA
JAMES G. HODGE, Jr., J.D., LL.M., Associate Professor, Executive Director, Center for Law and the Public’s Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD
NICOLE LURIE, M.D., M.S.P.H., Director, RAND Center for Population Health and Health Disparities, Co-Director, RAND Center for Domestic and International Health Security, Arlington, VA
ANDREW T. PAVIA, M.D., Professor, Division of Infectious Diseases, University of Utah School of Medicine, Salt Lake City
M. PATRICIA QUINLISK, M.D., M.P.H., Medical Director, State Epidemiologist, Iowa Department of Public, Health, Des Moines

STUDY STAFF

ALINA BACIU, M.P.H., Study Director
AMY GELLER, M.P.H., Senior Health Policy Associate
TIA CARTER, Senior Project Assistant (through January 2008)
LOUISE JORDAN, Senior Project Assistant (from February 2008)
ROSE MARIE MARTINEZ, Sc.D., Director, Board on Population Health and Public Health Practice