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How should a limited supply of flu vaccine be rationed during a flu pandemic?

Background

In a typical October to March flu season,[1] 36,000 deaths occur, mostly in a high-risk population.[2] Frequent mutation of the influenza virus necessitates annual development of a new vaccine. Unfortunately, this process inadequately prepares for the emergence of a new flu strain via antigenic shift and a flu pandemic could result, as in 1918, 1957, and 1968 when avian flu viruses integrated human viral elements.[3] Recent avian flu outbreaks in Asia and the Netherlands suggest another pandemic may occur if the virus spreads efficiently among persons,[4] killing up to 207,000 in the U.S. alone.[5]

The current HHS pandemic flu preparedness plan allocates resources to expand vaccine production year-round,[6] and the CDC has ordered 2 million doses of avian flu vaccine to aid in rapid vaccine development,[7] but a vaccine shortage is inevitable, due to the 6 – 8 month time lag between outbreak detection and vaccine production.[8]

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[1] Medicine Net, "Flu Season Starts Slow, More Vaccine Available," http://www.medicinenet.com/script/main/art.asp?articlekey=40937
[2] Boston Public Health Commission, "2003 11-28: BPHC Urges Resident to Get Flu Shots," http://www.bphc.org/news/press_release_content.asp?id=250
[3] Arnold S. Monto, "The Threat of an Avian Influenza Pandemic," *The New England Journal of Medicine 352,* no. 4 (27 January 2005), 323-5.
[4] *Ibid.*
[5] Health and Human Services, "Pandemic Influenza Preparedness and Response Plan: Core Document," http://www.dhhs.gov/nvpo/pandemicplan/finalpandemiccore.pdf
[6] Health and Human Services, "Core Document."
[7] Paul Recer, "CDC Chief: Mutated Bird Flu Could Cause Global Pandemic," Associated Press, *The Examiner*, February 22, 2005, p.12.
[8] Health and Human Services, "Annex 5: Vaccine Development and Production," http://www.dhhs.gov/nvpo/pandemicplan/annex5.pdf

During this year's (and the 2000) shortage, the government relied on "voluntary rationing," requesting that vaccine be administered only to those at "high-risk."[9] However, reports of price gouging surfaced as vaccine was stolen and sold for up to $100 per dose.[10] Still, appeals for rationing and voluntary abstention from vaccination have left a 5 million-dose surplus with the cost falling on government and private providers. Clearly, efficient use of available resources to limit a pandemic flu outbreak is essential.

Landscape

The Bush administration officially supported voluntary rationing on October 13, 2004,[11] when the President urged others to save flu vaccine for those at highest risk. While the Department of Homeland Security has overall authority in an emergency,[12] several HHS agencies have roles during a pandemic flu.

The CDC is the lead agency in working with the state health departments, surveillance efforts, and development of the pandemic flu reference strains used to manufacture mass quantities of vaccine.[13] The Food and Drug Administration, which regulates and licenses all vaccines, and the Health Research and Services Administration, which oversees the National Vaccine Injury Compensation Program, must work together to address the liability issues likely to stem from accelerated vaccine production.[14]

The U.S. Constitution "give(s) administrative agencies [handling] the public health and safety broad powers to act in emergencies…[including] the power to order the

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[9] "Voluntary Flu Vaccine Rationing Urged in U.S.," Associated Press, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20041006/US_fluvaccine_20041006/
[10] "Over 60 Boxes of Flu Vaccine Stolen From Medical Office," http://www.thekcrachannel.com/health/3820684/detail.html
[11] U.S. Representatives Rosa DeLauro and John B. Larson in a letter to HHS Secretary Tommy G. Thompson, October 21, 2004., http://www.house.gov/larson/pr_041022.htm
[12] Health and Human Services, "Core Document."
[13] *Ibid.*
[14] *Ibid.*

seizure…of property without a prior hearing, and the right to issue emergency rules with the same effect as statutes without having to go through the usual notice and comment rule making process."[15] However, Congress must authorize spending for all programs and pass legislation to create any new HHS programs or limit manufacturer and provider liability. The 2004 budget authorized $50 million for "modernizing flu vaccine production," but HHS requested $100 million.[16] Some Democrats oppose vaccine rationing, and will need to be convinced of its necessity.[17]

State and local health departments represent potential outlets for dispensing vaccine, and may be concerned about expanding their role in vaccine delivery, if it means increased costs, a strain on their workforce, and detraction from other programs.

Private healthcare providers administer 85% of the doses,[18] and may view a government takeover as a threat to their income and autonomy, which they and their lobbies are likely to oppose. Vaccine administrators will also seek medical liability limits.

Vaccine producers stand to gain financially from increased demand, but will face time constraints in producing a pandemic vaccine, and are likely to seek rapid approval, liability limitations, and a guarantee of purchase prior to producing a new vaccine.

Options

The following options are assessed by examining targeting of coverage, costs, and feasibility, based on ease of implementation, existing precedents, and strength of support.

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[15] Edward Richards, "Emergency Measures to Manage Flu Vaccine Shortage," LSU Law Center, http://biotech.law.lsu.edu/cases/vaccines/oregon_flu.htm

[16] Associated Press, "Voluntary Rationing of Flu Vaccine Urged," NewsMax, http://www.newsmax.com/archives/articles/2004/10/6/141422.shtml

[17] U.S. Reps. DeLauro and Larson.

[18] WebMD, "U.S. Health Officials Release National Flu Pandemic Plan," *Nation's Health 34*, http://www.medscape.com/viewarticle/490354

Option 1. "Federal Purchase and State Administration" – Under this option, the federal government purchases all available vaccine, and sells doses to the state health departments at a fixed rate, who then administer all doses according to HHS risk-guidelines. This option increases the likelihood of effective targeting of coverage by centralizing vaccine supply, allowing tracking of all doses from purchase through administration, and regulating prices. Local public health departments are better able to assess local needs than the federal government. However, this option has limited feasibility, as the existing precedent is voluntary rationing, and strong private sector opposition and limited public sector opposition to this option is likely, making implementation of this option a challenge.

Option 2. "Federal Purchase and Private Administration" – Under this option, the federal government purchases all available vaccine, and sells doses to private providers at a fixed rate, who then administer all doses according to HHS risk-guidelines. This option provides some effective targeting of coverage by centralizing the supply, but after distribution, it lacks the ability to track doses of vaccine. As for price regulation, the government selling doses to private providers at a fixed rate does not guarantee that providers sell doses to the public at a fixed rate. Private providers may however be in the best position to assess local needs. This option is moderately feasible, as the current majority of vaccine is privately administered, making implementation of this option relatively easy, given major private sector support and limited public sector opposition.

Option 3. "Voluntary Rationing" – Under this option, the federal government allows the private sector to purchase the vaccine and asks them to give doses to the at-risk first. This option targets coverage and controls costs least effectively. Vaccine supply

is not well tracked, and voluntary compliance is not enforceable. Market forces dominate in the absence of a policy intervention with the potential for price gouging. Also, without clear federal guidelines, states may act alone. "Eight states and the District of Columbia [have] issued emergency orders directing providers to not vaccinate anyone not identified by the CDC as high risk, [with] failure to comply with those orders… [leading to] fines of up to $1,000 or to six months imprisonment."[19] Yet, this option, as the existing model, is the most feasible, requiring no Congressional action to maintain the status quo.

Recommendation

Federal purchase and state administration is the best option during a flu pandemic. While it may be difficult to change the mindset of patients from physician vaccination to public administration of shots, targeted coverage is essential to effectively stem the spread of flu, and no other system exists to track, regulate, and deliver the vaccine, necessitating federal intervention. While the cost to the government of purchasing all vaccine might be high, it allows one centralized body to enter into guaranteed-purchase agreements with vaccine manufacturers, which will hasten the production process, and greatly reduce the likelihood of price gouging. Also, as states will purchase the vaccine from the federal government, a large portion of the costs are spread over a wider base. The limited feasibility of this option is significant. Congressional approval must be sought to limit vaccine producers' and administrators' liability, and authorize spending for the purchase of vaccine, but the dire threat posed by a flu pandemic should lessen legislative resistance, allowing this plan to go forward rather quickly.

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[19] Janet Colwell, "Strategies for Coping with the Flu Vaccine Shortage," American College of Physicians, http://www.acponline.org/journals/news/nov04/flu_shortage.htm