Citizen Voices on Pandemic Flu Choices

A Report of the Public Engagement Pilot Project on Pandemic Influenza

Participating Organizations

Atlanta Journal Constitution
Institute of Medicine
Georgia Department of Human Resources, Division of Public Health
Massachusetts Health and Human Services
National Immunization Program at the Centers for Disease Control and Prevention
National Vaccine Program Office in the Department of Health and Human Services
Nebraska Health and Human Services
Oregon Department of Human Services
Practicum Limited
Richard Lounsbery Foundation
Study Circles Resource Center
The Keystone Center
University of Georgia
University of Nebraska Public Policy Center

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Preface

The Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) described in this report was based on three premises: (1) that the formulation of vaccine policies which involve a consideration of values as well as science requires policy-makers to understand the range of society's values on the issues; (2) that the process which will best reflect society's values is a public engagement process which involves both stakeholders, including experts, and citizens with diverse backgrounds and perspectives; and, (3) that an inclusive public process which provides an opportunity for frank, open dialogue and careful deliberation will produce sounder, more supportable decisions in the short term and result in greater public trust over the longer term.

The level of public engagement or degree of interaction required to achieve meaningful dialogue and deliberation goes well beyond the focus groups, consultations, and listening sessions that are routine today. A consortium of organizations which recognized the necessity for this enhanced public input into the value laden vaccine policy decisions sponsored this project. We want to acknowledge here our gratitude to them for enabling us to carry out a project to test the feasibility and utility of enhanced public engagement on a complex health policy decision.

In the spring of 2005, gaps existed in the first Health and Human Services (HHS) Influenza Pandemic Plan and more guidance was considered desirable on how best to allocate the relatively meager supplies of vaccine likely to be available in the first months of a pandemic. To whom should it be given? To achieve what objectives?

This report describes the convening of a representative group of stakeholders and citizens-at-large, the structure and process of stakeholder and citizen dialogues and deliberations, and the decisions made and recommendations that were developed.

At the outset of the project, some in the vaccine community feared the process could be disruptive by providing a platform for extreme viewpoints espoused by a small minority; that citizens could not be enticed to participate; that citizens would not be able to gain sufficient understanding of the technical issues surrounding pandemic influenza to offer useful advice; that the project would be a wild card added into the game of policy making around vaccines. No one who observed any of the multiple meetings of this project has described them as disruptive. Quite the contrary, most observers were surprised by the general public's interest in participating, their rapid grasp of the central issues, and their willingness to deliberate and make hard choices.

We were genuinely moved by seeing our democracy in action−seeing very diverse groups in Washington, D.C., Georgia, Massachusetts, Nebraska, and Oregon gather in table groups and engage in respectful, often passionate dialogue, knowledgeably shoulder the burden of weighing alternatives, find common ground, answer the vaccine question of interest to policy-makers, and provide their own ideas about how to best prepare for pandemic influenza.

We believe that this project has provided a much needed and timely demonstration for the vaccine community−that enhanced public engagement to address value laden issues in vaccine policy is feasible in real time and can yield useful recommendations.

To all the volunteer participants, including stakeholders, citizens, and experts who served as resource persons who gave up time with family, traveled for multi-day meetings, and bravely articulated deeply held values in a room full of strangers, we wish to express our heartfelt thanks. Your work described in this report demonstrates in concrete terms the value of our democratic ideals and beliefs, helps light the way to conduct further work on other policy challenges we face, and begins to restore the trust in government and the societal consensus needed to take full advantage of the potential of vaccines to improve public health.

Roger H. Bernier, PhD, MPH
Edgar K. Marcuse, MD, MPH
Co-Chairs, PEPPPI

Executive Summary

Background

This Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) was initiated in July 2005 to discuss and rank goals for a pandemic influenza vaccination program and to pilot test a new model for engaging citizens on vaccine related policy decisions (The Vaccine Policy Analysis CollaborativE, VPACE). The Pilot Project was sponsored by a network of interested organizations listed on the cover of this report. To conduct this public consultation, the sponsors engaged stakeholders from various organizations with an interest in pandemic influenza (the National Stakeholder Group), and individual citizens-at-large from the four principal regions of the United States. The anticipated major benefits from this public consultation were the development of an improved plan to combat pandemic influenza and one more likely to gain public support, and a demonstration that citizens can be productively engaged in informing vaccine related policy decisions.

Approaches Used

PEPPPI was carried out in five phases−two day-and-a-half dialogue and deliberation meetings with approximately 50 national stakeholders and consultants, a day-long consultation with over 100 citizens-at-large in Atlanta which took place in between the two stakeholder meetings, and three half-day sessions conducted with approximately 150 citizens-at-large in Massachusetts, Nebraska, and Oregon where citizens were shown the results of the earlier deliberations and asked for their feedback. Altogether, approximately 300 participants with diverse backgrounds and points of view came together to learn the basic facts needed to have an informed discussion about pandemic influenza, to engage in give and take discussions about potential goals for the use of limited supplies of vaccine, to weigh the tradeoffs between competing goals, and to select the goals considered most important to achieve with scarce vaccine.

Findings

Both citizens-at-large and the National Stakeholder Group decided–with a very high level of agreement–that ***assuring the functioning of society*** should be the first immunization goal followed in importance by ***reducing the individual deaths and hospitalizations due to influenza*** (i.e. protecting those who are most vulnerable and at risk). Because of the still high importance of the second goal, the groups added that the first goal should be achieved using the minimum number of vaccine doses required to assure that function. This would allow the remaining doses to be used as soon as possible for those at highest risk of death or hospitalization. There was little support for other suggested goals to vaccinate young people first, or to use a lottery system or a first come first served approach as top priorities.

The groups also defined the federal government's role as providing broad guidance with responsibility for more specific interpretation and implementation remaining with state and local health authorities. Both the public participants in this Pilot Project and the expert advisory bodies which deliberated separately, the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee, chose protecting society's caretakers and persons at high risk among their top priorities. However, the weight attached by the citizens-at-large and the National Stakeholder Group to "Assuring the Functioning of Society" appeared to be greater than the weight placed on this goal by the expert advisory bodies. Their joint subcommittee placed higher priority on protecting high risk persons and lower priority on most of the categories of persons responsible for assuring the functioning of society.

In addition, the PEPPPI groups developed and deemed important several recommendations related to pandemic planning. They stated the government needs to: (1) build and maintain the public's trust by decision-making that is transparent and characterized by seeking the public's input and coupled with enhanced communication and education; (2) allow the flexibility in the plan to address the unique circumstances dependent on the epidemiology of the event; (3) take action in addition to market forces to increase vaccine production capacity; (4) support the development of other public health measures to protect the public from the influenza illness; and, (5) provide resources to other regions of the world. The groups also felt it was important that the more specific decisions regarding the categories of persons to receive limited supplies of vaccine be made by health experts and not by elected or appointed representatives without public health qualifications.

Conclusions

This Pilot Project provides "proof of principle" to the vaccine community that a diverse group of stakeholders and citizens-at-large can be recruited to learn about a technical subject, interact respectfully, and reach a productive outcome on an important policy question. Preliminary results from the independent evaluation of all the sessions conducted by the University of Nebraska reaffirmed this conclusion. Furthermore, the corroboration of the results of the deliberations from the four sessions involving the general public in disparate regions of the country, as well as with the National Stakeholder Group meeting in Washington D.C., gives additional weight to the recommendations. Recognition of the importance and utility of these findings was made evident in the HHS Pandemic Influenza Plan released in early November 2005 which described the agency's consideration of the priorities that emerged from the PEPPPI project. More public discussion of a similar type was called for in the HHS plan.

Chapter One
Background and Introduction

In June 2003, the Wingspread Group, a diverse team of key stakeholders in immunization named after the site of its first meeting place, presented to the National Vaccine Advisory Committee (NVAC), a proposal entitled the Vaccine Policy Analysis CollaborativE (VPACE), outlining an enhanced framework for effective stakeholder and citizen engagement in vaccine policy analysis. The Wingspread Group urged the immunization community to move beyond traditional forms of public engagement such as public education and soliciting input at formal public hearings to create the capacity for collaborative problem solving on certain vaccination questions or decisions where different values must be weighed in addition to technical considerations.

The Wingspread Group recommendations are captured in the Final Summary Report and Proposal for the Vaccine Policy Analysis CollaborativE (VPACE) available at http://www.keystone.org/html/pandemic_flu.html.

In order to fully demonstrate to the Centers for Disease Control and Prevention (CDC) and its broader constituency the value of conducting such collaborative group processes, members of the Wingspread Group sought an opportunity to test their new model using an important issue of immediate concern. A $75,000 grant from the Richard Lounsbery Foundation to The Keystone Center provided the opportunity to leverage other resources and recruit partners to pilot test the VPACE approach with a current issue in immunization, namely who should be vaccinated first in the event of an influenza pandemic when supplies of vaccine are limited. Subsequent sponsors included those participating organizations listed on the cover of this report.

Purpose and Outcomes

The Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) began in July 2005 with plans to forward a final report to the Secretary of Health and Human Services and other decision-makers by November 2005. It engaged citizens, local/state and federal governmental officials, academics, non-governmental organizations, health care providers, and industry representatives in deliberations about which groups in the population require the earliest protection against influenza in the event of a pandemic when supplies of vaccine are still limited. Making these difficult choices would fill a notable gap in the first U.S. Pandemic Influenza Preparedness and Response Plan released in the summer of 2004.

This Pilot Project had a dual purpose: (1) to evaluate a new mechanism for engaging the public on vaccine policy decisions; and, (2) to better inform a pending government decision by providing a ranked list of immunization goals to guide prioritization of vaccine use during a pandemic event.

Overall Project Design

The project was designed to include both stakeholder representatives from a broad spectrum of organized and pertinent interest groups (herein called the National Stakeholder Group), as well as individual citizens-at-large not representing any organization or interest group. Both types of participants were deemed important to include to secure a broad spectrum of ideas, experiences, perspectives and values and to allow for different types of dialogue and deliberation on the issues.

The key features of the VPACE model are:

1) A focus on undecided science policy choices which involve both technical and values considerations;
2) Opportunities for independent fact-finding and balanced learning about the topic at hand from credible sources on all sides of the issue;
3) Inclusion as participants of both stakeholders with acknowledged interests and citizens without agendas;
4) Neutral facilitation;
5) Opportunities for both frank dialogue and genuine deliberation to take place; and
6) Linkage to the government decision-making process and decision-makers.

Thus, the inclusion of ordinary citizens permitted a large number of individuals with no particular agendas from a broad cross-section of the population to have input that reflects what well informed Americans think about the issues. The National Stakeholder Group allowed for the full spectrum of active interest groups to bring their detailed knowledge to the table, to engage constructively in on-going dialogue, to build understanding regarding their respective interests, and to jointly problem-solve to create proposals that work to address as many interests as possible. The National Stakeholder Group also served as the body through which the input of citizens-at-large is considered and weighed before formulating any final conclusions or recommendations. Citizen Feedback Sessions in different parts of the country after the preparation of a draft report permitted a larger and more varied number of citizens to evaluate the conclusions and to provide suggestions for changes prior to final release of the report.

The Public Engagement Pilot Project on Pandemic Influenza was carried out in five phases between the five month period of July to November 2005.

Phase I	July 2005	First meeting of the National Stakeholder Group to frame the issue and define the project.
Phase II	August 2005	Deliberation day for citizens-at-large to select their highest priority goals for an influenza vaccination program.
Phase III	September 2005	Second deliberation meeting of the National Stakeholder Group to consider the input from citizens-at-large and to select the highest priority goals integrating all public perspectives.
Phase IV	September & October 2005	Feedback Sessions with citizens-at-large in Massachusetts, Nebraska, and Oregon to obtain citizen reactions to the highest priority goals and suggestions for changes to the draft report.
Phase V	October & November 2005	Preparation of the final report from the National Stakeholder Group on the public's perspective on the highest priority goals for a national pandemic influenza vaccination program.

At the project's inception, a Steering Committee (members are noted on Attachment A) was convened comprising a representative cross-section of stakeholder interests related to the issue. Their role was to provide on-going guidance on process and substantive issues related to the Pilot Project.

The National Stakeholder Group sessions were chaired by Edgar Marcuse MD, MPH, Associate Medical Director, Seattle Children's Hospital, Professor of Pediatrics at the University of Washington, and a member of the Advisory Committee on Immunization Practices (ACIP) and Roger Bernier, PhD, MPH, Senior Advisor for Scientific Strategy and Innovation at the National Immunization Program, CDC.

The Institute of Medicine (IOM) under the leadership of Kathleen Stratton, PhD, hosted the National Stakeholder Group sessions and, in consultation with the stakeholders, coordinated the subject matter experts and consultants who provided balanced, independent information.

The Keystone Center and key staff members led by Mary Davis Hamlin provided neutral facilitation and overall process support to the project. In consultation with stakeholders, The Keystone Center assisted with the convening, agenda development, facilitation, logistical support and coordination of and drafting of the meeting summaries and final report.

The Local Citizen Dialogue and Feedback Sessions in Atlanta and Massachusetts, Nebraska, and Oregon were led by Jon Abercrombie and Matthew Leighninger of the Study Circles Resource Center with additional neutral facilitation by Whitney Shipley, a contractor affiliated with the Center for Biopreparedness Education at the Nebraska Medical Center.

In addition, the project secured the services of an evaluation team from the University of Nebraska Public Policy Center led by Mark DeKraai and an evaluation advisor, Miriam Wyman, a consultant with Practicum Limited, a Toronto-based consulting firm.

Chapter Two
Phase I–Framing The Issues and Defining the Project

National Stakeholder Meeting–July 13 & 14, 2005

A complete set of meeting materials (agenda, handouts, presentations, participant list, meeting summary, etc.) can be found at http://www.keystone.org/html/pandemic_flu.html. Selected materials–noted in the below text–are also attached to this report.

Approach

Approximately 50 persons including some 35 stakeholders (Attachment A) from multiple different groups with a special interest in pandemic influenza (such as health care providers, ethnic minority organizations, federal agencies, citizen advocacy organizations, and vaccine manufacturers), met twice–in July and September–to develop goals to guide immunization priorities in the event of a pandemic event. The first meeting served to better define the purposes of the project, secure essential background information, build mutual understanding regarding the values and interests important to the participants, and frame the issues for subsequent deliberation.

Harvey Fineburg, President of the Institute of Medicine, and Bruce Gellin, Director of the National Vaccine Program Office, provided keynote opening statements and introduced the Co-Chairs, Roger Bernier, and Ed Marcuse. The group's operating protocols were also reviewed, refined and ratified (Attachment B).

Background Information/Presentations

The Steering Committee identified a preliminary set of background information materials to provide to the Stakeholder Group to ensure informed deliberations. The presentations and speakers included:

- Basic Information About Influenza (Flu 101)–David Shay, Medical Officer, National Center for Infectious Diseases, CDC
- Standard Vaccination Policy/Assumptions during the Regular Flu Season–Bill Atkinson, Medical Epidemiologist, National Immunization Program, CDC
- Past/future Pandemics–Bill Atkinson, Medical Epidemiologist, National Immunization Program, CDC
- Vaccines in a Pandemic Influenzas Event–Alan Hinman, Senior Public Health Scientist, Public Health Informatics Institute, Task Force for Child Survival and Development, and National Vaccine Advisory Committee
- Ethical Considerations–Daniel Wikler, Mary B. Saltonstall Professor of Population Ethics, Harvard University

- Legal Considerations–Peter Jacobson, Professor of Health Law and Policy, University of Michigan, School of Public Health
- International Perspectives–Arlene King, Public Health Agency of Canada

The ethics exercise presented by Daniel Wikler was particularly compelling to the group. It helped participants grasp the nature of values dilemmas and the challenges incumbent in policy decisions involving competing values and no obvious right choice.

Small Group Facilitated Discussions

After the initial background presentations and exercises, mixed-interest groups with neutral facilitators were asked to jointly explore the range of values and interests that they as individuals and their constituencies deem important to guide immunization priorities. They were provided a handout with illustrative values, goals, and population subgroups to support their discussion (Attachment C). In addition, they wrestled with the questions below:

- How comfortable are you considering prioritization decisions not based on "protect the most vulnerable?"
- What is important to you about any ranking?
- Why is this task particularly troubling in light of your personal beliefs and things you and your constituency cherish?
- What would you need to hear (if anything) before you changed your mind?
- What are your deepest concerns about determining vaccination priorities?

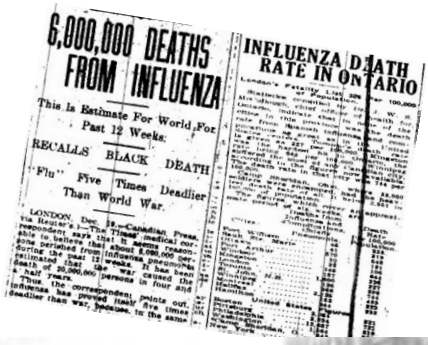
The outcomes from these small group discussions were shared in the plenary and built the foundation for framing the deliberations of subsequent sessions.

Below are three dilemmas posed to the participants:

Example 1:
You are chief of a ward with 100 patients. 50 of these patients need 2 pills to survive. One pill does not help them. 50 of these patients need 1 pill to survive. You have 50 pills. You can't get more. Who should get the pills? On what basis should they be chosen?

Example 2:
Five children are playing on a trolley track as the trolley approaches. If the trolley is diverted to a spur, their lives will be saved; but one child is playing on the spur. The driver has a heart attack. You would be able to divert the trolley. Should you do so?

Example 3:
You are a surgeon with five patients who need 5 organs. You could harvest one healthy patient and save all 5. Should you?


6,000,000 DEATHS FROM INFLUENZA

This Is Estimate For World For Past 12 Weeks.

RECALLS BLACK DEATH

"Flu" Five Times Deadlier Than World War.

INFLUENZA DEATH RATE IN ONTARIO

Chapter Three
Phase II–Getting Citizen Input

Atlanta Citizen Dialogue Session–August 27, 2005

A complete set of meeting materials (agenda, handouts, presentations, participant list, can be found on the website at http://www.keystone.org/html/pandemic_flu.html. Selected materials–noted in the below text–are also attached to this report.

Background Information

On Saturday August 27, 2005, 101 citizens participated in an all-day public engagement event at the Loudermilk Center for the Regional Community in downtown Atlanta. The participants were a diverse representation of gender, age (adults from 18 to 78) and ethnicity. Fourteen tables of participants were supported by volunteer facilitators as well as technical experts from multiple private and public organizations, including cadres from the University of Georgia and CDC.

The Study Circles Resource Center provided lead process design and facilitation services for the event, including drafting a discussion guide which structured the deliberations of the day.

KIDazzle Child Care & Learning Center in downtown Atlanta donated day care services. Free, convenient parking, and onsite meals encouraged maximum attendance and eased the cost and logistical burdens of participating.

Welcome and Charge To The Citizens

The participants were welcomed by Dr. Steve Cochi, Acting Director of the National Immunization Program (NIP); Dr. Roger Bernier, Senior Advisor in NIP and Co-Chair of this Public Engagement Pilot Project on Pandemic Influenza; Mr. Chris Hinton, Honorary Citizen Participant, an Atlanta area businessman, and former Atlanta Falcons football player; and Ms. Sarah Landry, Associate Director for Policy in the National Vaccine Program Office at the Department of Health & Human Services (HHS).

Dr. Bernier gave the group its charge: Rank in priority order a list of potential goals for a national pandemic influenza vaccination program. **These potential goals were:**
(1) Save those most at risk
(2) Put children and young people first
(3) Limit the larger effects on society
(4) Use a lottery system
(5) Use the principle of "first come, first served"

Presentations and Exercises

Dr. William Atkinson, Medical Epidemiologist, National Immunization Program, CDC, provided background information to the citizens and fielded questions from the group on influenza disease/ vaccine and on past/future pandemics. Citizens were also given a handout pre-reviewed by experts containing all the essential facts about influenza entitled "20 Answers You Need To Know."

Participants carried out an ethics dilemma exercise constructed by Harvard ethicist Daniel Wikler and modified by Emory University ethicist Kathy Kinlaw. The exercise surfaced the underlying values which could serve as the drivers for the choices to be made later in the day about vaccination goals.

Dialogue and Deliberation

Participants engaged in collaborative discussions in the early afternoon to identify and weigh the tradeoffs among the different goals for a national pandemic influenza vaccination program. At the end of the deliberations, each of fourteen table groups selected their highest ranked goal by placing three dots next to the most favored goals on the list of five. Participants were free to place all of their dots on their first choice or could distribute their dots across two or three goals.

Ten of the fourteen tables selected the goal "limit the larger effects on society" as the most important. Four tables selected "save those at highest risk" as the most important goal. Overall, the ranking was as follows:

133	"dots"	Limit the larger effects on society
104	"dots"	Save those most at risk
29	"dots'	Put children and young people first
18	"dots"	Use a lottery system
4	"dots"	Use the principle of "first come, first served"

In the final plenary session, the lead facilitator asked the citizens group as a whole if they would vaccinate all of society's caretakers first, or allocate some proportion of the limited vaccine supply to save those at high risk. The majority of persons who raised their hands were in favor of splitting the available vaccine.

During the plenary discussion, some citizens stated they were uncertain that they could trust government to pay attention to the results of their deliberations. This uncertainty was initially expressed in some of the smaller table group discussions. The newspaper article published after the meeting described the concern citizens had and stated that "some of them left the meeting skeptical that their efforts would make much difference."

The final afternoon session involved participant brainstorming on actions needed to prepare for an influenza pandemic. Participants stressed the need for a proactive, comprehensive U.S. pandemic

influenza plan, which should include an immediate education and communication campaign. Participants reported that this campaign should provide the public with timely information on pandemic influenza issues, as well as information on general hygiene and ways to prevent influenza transmission.

Citizens also suggested that the number of influenza manufacturers should be increased to produce a more adequate supply of vaccine in the U.S.

Among the innovative ideas suggested was the creation of a TV reality show depicting "real-time" government and citizens preparations for the pandemic. Another idea was to reinstitute the Red Cross Home Nursing course to alleviate some of the burden on hospitals that may result from an influenza pandemic. It was also suggested that pandemic influenza public health messages be included in electric and water bills, bank statements and grocery bags.

The persons from these organizations were observers:

CDC Office of Health Communications
CDC Office of Public Health Partnerships
CDC Office of Strategy and Innovation
CDC Office of Surveillance
Middle Tennessee State University
Massachusetts Department of Health
Oak Ridge Institute for Science and Education
The Human Resources and Services Administration
The National Vaccine Information Center
The Public Health Agency of Canada
The Swedish Institute for Infectious Disease Control
Wisconsin Women's Network

Final Sessions

The final session of the day gave the participants an opportunity to indicate their own personal degree of agreement with the group's goal ranking as previously noted. Using a scale of 1-10 with the higher numbers indicating a stronger degree of agreement, at least 87% of the participants (N=72) rated the strength of their agreement with the outcome at 8 or above on this scale.

Participants also recorded their individual ranking of the goals. The results of this survey showed that the goal to "limit the effects on the larger society" received 65 first priority rankings, 12 second place, and very few below that level. The goal to "save those most at risk" received 11 first priority rankings, 59 second place, 8 third place, and very few below that level.

Media Coverage

Media coverage for the event included articles about the meeting in the Atlanta Journal-Constitution (AJC) on the day before and the day after the meeting (Attachment D). Factual errors were made in reporting the goal rankings which were reflected in a misleading headline and in the total number of attendees. On August 31, 2005, the reporter and the public editor for the newspaper acknowledged the factual errors and published corrections. As Co-Chair of the Pilot Project, Dr. Bernier also wrote a letter to the editor of the AJC to make clear that the results of the citizen deliberations were recorded correctly by the organizers and would be accurately transmitted to decision-makers.

Chapter Four
Phase III–Getting Stakeholder and Citizen Input Combined

National Stakeholders Meeting II–September 7 & 8, 2005

A complete set of meeting materials (agenda, handouts, presentations, participant list, etc.) can be found on the website at http://www.keystone.org/html/pandemic_flu.html. Selected materials–noted in the below text–are also attached to this report.

Background Information

In September, the National Stakeholder Group received additional informational handouts and presentations in response to the group's earlier requests for supplementary data. Two citizen participants from the Atlanta Dialogue Session also provided an overview of the outcomes from their meeting as well as personal insights about participating in that event. The other presentations included:

- FEMA/Homeland Security Critical Services Designations Update–Marion Warwick, U.S. Department of Homeland Security
- How Might a Lottery Work?–Logistical/Feasibility Considerations, Jeff McMahan, Department of Philosophy, Rutgers University
- County Perspective from Last Year's Flu Vaccine Rationing–Carol Jordan, Senior Health Care Administrator, Montgomery County Maryland Government
- Public Behaviors in a Crisis–Monica Schock-Spana, Center for Biosecurity, University of Pittsburgh
- Additional Considerations Regarding Pandemic Influenza–Michael Osterholm, University of Minnesota, School of Public Health
- ACIP's Proposal Regarding Vaccination Priorities–Dr. Steve Cochi, National Immunization Program, CDC (Attachment E)

Monica Schock-Spana's presentation of evidence which debunked commonly held myths about disasters provided rich information for subsequent discussions by the group. Her full presentation is included as Attachment F. A summary of the myths is also listed below.

- MYTH #1: Disasters are equal opportunity events; they happen in random and in quirky, but essentially democratic ways.[1] Hurricanes, outbreaks, heat waves, earthquakes, and chemical spills kill indiscriminately. They do not care "who" the victim is.
- MYTH #2: Whether people comply with evacuation plans, isolation and quarantine, or other public health and safety orders, is strictly a matter of "personal choice."
- MYTH #3: When life and limb are threatened on a mass scale, people panic. They revert to their savage nature, and social norms readily break down.
- MYTH #4: Command-and-control is the most effective management approach to an "emergency." Centralized, insular decision-making and authority structures among trained professionals guarantee the least harm to people and property. Ordinary civilians and everyday institutions are inadequate to deal with crises.
- MYTH #5: Acts of God and Nature are pre-ordained. There is no real way to thwart their ultimate outcome. The same goes for Bureaucratic Red-Tape, another so-called immutable force.

[1]Walter Peacock. *Consequences of Disaster Myths*, 30th Annual Hazards Research and Applications Workshop, Boulder, CO, July 12, 2005.

Small/Large Group Facilitated Discussion

The stakeholders were organized into several mixed interest groups to weigh the advantages and disadvantages of an initial list of possible goals for a national pandemic influenza vaccination program. (Attachment G). The small groups considered:

- What are the underlying values for each goal?
- What are the potential value tradeoffs for each goal?
- What are the implications of a goal's implementation (such as who would be vaccinated or not be vaccinated) and other consequences or concerns?

Below is the illustrative list of goals used to initiate the small and large group discussions. Refer to Attachment H for a summary of the group's discussion of each goal.

POTENTIAL GOALS USED TO INITIATE DISCUSSION

#1. Give everyone an equal chance to be protected.

A. Lottery

B. First come, first served policy

#2. Protect persons with the most life ahead of them.

#3. Seek to protect those of any age or health condition most or more likely to die from a new influenza strain.

#4. Assure public safety.

#5. Maintain emergency and/or life saving services.

#6. Protect society's key government leaders and decision-makers.

#7. Protect those providing the most critical services which keep society running.

#8. Provide some vaccine to other countries even if it is at the expense of vaccinating some persons in the United States.

#9. Protect those who provide homeland security and those who defend us against military threats abroad.

#10. Assure vaccine production.

After an in-depth discussion of the potential goals, the group, using a ranking exercise coupled with additional large group negotiations, developed the following framing and ranking of goals to guide vaccination policy during a pandemic influenza event.

Statement Of Citizens and Stakeholders On Priorities For The Use Of Pandemic Influenza Vaccine

Hierarchy of Goals

#1 Assure Functioning of Society.

#2 Reduce Individual Deaths and Hospitalizations Due to Influenza.

Process:

The group recognizes that the federal government will provide only broad guidelines and that specific decisions about who to vaccinate will be made at the local level (state and local health departments, specific facilities).

#1. Assure Functioning of Society:

- Assure production, distribution and administration of vaccines (includes manufacturing, workers associated with vaccine clinics, etc.).
- Maintain emergency response and life saving services.
- Assure provision of other critical services. This might include but is not limited to: public safety and maintaining law and order; protecting society's key government leaders and decision-makers; maintaining homeland security, utilities, food distribution, and communications.

#2. Reduce Individual Deaths and Hospitalizations Due to Influenza:

A. Protect those most or more likely to die from a new influenza strain, as defined by ACIP/NVAC recommendations, unless the emerging epidemiology of pandemic influenza defines new risk groups.

B. Healthy persons 2 to 64 years old not in other groups.

Assumptions: The preceding statement was developed within the context of the assumptions below.

(1) There will be a limited supply of vaccines in the early days of the pandemic, therefore prioritizing who receives the limited supply is important.

(2) The government will buy all the vaccine supply and distribute it at the same time to all states across the country based on population size (while remaining flexible enough to address considerations such as seasonal population fluctuations etc.).

(3) The group based their recommendations not on a mild or worst case scenario but on a moderately severe pandemic as described in Trust for America's Health Report, "A Killer Flu?," which anticipates half a million deaths and two million hospitalizations.

(4) All age groups will be attacked equally by the virus; however, death and hospitalization rates most likely will be highest in infants under 1 and persons 65 and older as occurs with annual influenza epidemics.

(5) Based on mathematical modeling work done by Martin Meltzer, CDC, probably no more than 10-15% of the workforce will be out sick or taking care of a sick relative on any one day during the peak of the pandemic.

(6) The goal of the vaccine is to protect the persons to whom it is given or their close contacts and not to decrease transmission in the general population−there will not be enough vaccines available to adopt a strategy to effectively reduce transmission.

(7) Vaccine is used only in persons for whom it works well and priorities will not be based on anticipated life expectancy.

Additional Recommendations

Allocation

The three statements under the first goal, "Assure the Functioning of Society," should be viewed as an articulation of the key societal functions that need to be maintained, not categories within which all service providers would be vaccinated. Further, the Stakeholder Group considered the functions in the first goal as equally important, therefore, crucial individuals related to each function would be vaccinated simultaneously–not sequentially. The amount of doses allocated to the first goal will depend on the severity of the pandemic but regardless should be based on the minimum number doses required. If "Assuring the Functioning of Society" does not require a large allocation of doses, then the second goal, "Reducing Individual Deaths and Hospitalizations Due to Influenza" will receive an allocation of vaccine doses sooner.

Flexibility

Any plan intending to address a pandemic event needs to remain flexible in order to respond to implications of the epidemiology and severity of the event. Effective planning will also require a greater understanding of the public health infrastructure at the state and local levels to inform what will really be needed to keep society functioning. The group noted the need to develop trigger points, or key metrics, to guide the proportional allocation between the two primary goals. The group also recommended the need to create a model and plan around the most severe potential scenario such as the 1918 event.

Federal Government Role
The Stakeholder Group noted that it is the federal government's role to provide broad guidance but that state and local authorities should be responsible for interpreting them at a more detailed level. The group urged the CDC to work with the National Governors Association to assess individual states' assets relative to their ability to respond to a pandemic event. A multi-sector approach (state and local governmental agencies, non-governmental organizations, business, special needs and disadvantaged populations) must be taken in planning and education efforts.

Building Production Capacity
Although the group recognized the inevitable shortage of vaccines early in a pandemic event, they stressed the imperative of enhancing production capacity. The group noted that enhancing production capacity will require government intervention and investment as opposed to relying on the market system alone.

Building and Maintaining Trust: Transparency/Communication/Education
Building and maintaining trust with the public is crucial. The government's actions in preparation for and during the pandemic event must be transparent and responsive to citizens' needs, concerns and input. The Stakeholder Group urged that decisions need to be made by appropriate experts and not within the political arena. Early and clear education about the characteristics and implications of a pandemic event is important–particularly focused on how it will differ from a regular flu season. The public will also need to understand the inevitable limits to vaccine supply in the early days of the pandemic. The group urged the government to apply lessons learned from the recent small pox experience. For example, a national credible spokesperson should be named to support the educational effort. It is also essential to carefully explain why children as a group are not specifically named as a priority vaccination goal–e.g. the group believed that the best way to safeguard the well-being of children in such an event is to ensure societal functioning. Finally, the group felt that it will be important to obtain commitments from vaccinated individuals stating that they will conduct the work for which they received the immunization.

International
The group believed that any national pandemic plan should include providing resources to other regions of the world, particularly to support early detection, containment, and participating in global alliances to increase global production capacity. The group specifically noted that the United States needs to assist the World Health Organization in its global efforts.

Multi-pronged Approach
A full range of tools and strategies in addition to vaccination should be planned for and employed by the government during a pandemic event.

Chapter Five
Phase IV–Citizens' Reactions To Vaccine Priorities

Feedback Sessions in Massachusetts, Nebraska, and Oregon on September 17, 24, and October 1, respectively.

Approximately 40 citizens-at-large from Massachusetts, 85 citizens from Nebraska, and approximately 40 citizens from Oregon met on successive Saturdays in mid-September and early October 2005. After hearing a presentation from a local epidemiologist and/or an infectious diseases expert and asking questions to learn the essential facts about influenza, participants were informed about the highest priority goals selected and the conclusions reached by the National Stakeholder Group which deliberated in Washington in July and September 2005. The citizens were organized into table groups which then brainstormed around these goals to identify their reactions. Following a presentation and a group discussion of the goals, the groups were asked if they concurred with the goals as stated or whether they wished to see changes in the goals statement. The facilitator then determined the degree of support for any proposed changes.

In Massachusetts, the citizens concurred with "Assure the Functioning of Society" as the first and "Reduce Individual Deaths and Hospitalizations" as the second priority goal. This concurrence was obtained after it was explained to the citizens that assuring the functioning of society would be accomplished by using only the minimum number of doses necessary, and thereby allowing the remaining vaccine to be used to target the second priority goal (specifically, to protect high risk individuals) as soon as possible.

Citizens also stated that the number of different types of services considered critical to achieve the first priority goal could be reduced from the list presented, and that not all persons employed in the critical services categories would need to be vaccinated to assure the functioning of society. In this context, assuring the functioning of society is assumed to mean assuring the functions most essential to saving or protecting lives directly at the front lines of service, and not to mean all societal functions needed to keep society functioning optimally or even normally.

Examples of other potentially useful ideas which emerged from the session with Massachusetts citizens were that consideration would have to be given to protecting the family members of persons judged to be critical service providers, and that transparency and open communication with the public about all aspects of the pandemic planning would be important to assure the fairness and trust essential to the plan's success.

See Attachment I for more details.

In Nebraska, approximately one half of the citizens present concurred with the statement of goals as written and this agreement appeared to be because the citizens trusted state and local government decision-makers and appreciated the flexibility which the statement would afford them. The remaining half of the citizens identified five potential changes in the statement–the proposed change which received the most support was the proposal to modify the wording of the statement to make it more clear that the high risk groups would be identified based on the emerging epidemiology of influenza at the time of the pandemic and not based on the traditional high risk groups as identified by the ACIP and the NVAC.

The other proposed changes had only limited support. Examples of these other ideas were: (1) a proposal to rework the priority groups to include students and teachers and to set aside a small percentage of the vaccine for a lottery so that those persons without any claim to the vaccine initially might nevertheless retain some hope of being vaccinated; (2) a proposal to create guidelines for adjusting the implementation of the vaccination program if there is public panic or other social disorder; and, (3) a proposal to further define who is expected to be in the group of those most likely to die.

Agreeing with Massachusetts, citizens proposed the need to give clear advice on how to protect against influenza to persons who are not likely to get vaccinated because they are not on the list of priority groups.


NIGHT EXTRA
The Seattle Daily Times
CHURCHES, SCHOOLS, SHOWS CLOSED
EPIDEMIC PUTS BAN ON ALL PUBLIC ASSEMBLIES
SEATTLE TO MAKE FIGHT ON DISEASE
AMERICANS AND FRENCH SMASH FOE
U.S. TROOPS SMASH HUNS IN ARGONNE

See Attachment J for more details.

In Oregon, almost all of the citizens who participated in the feedback session concurred with the priority goals described in the statement but wanted to see some changes made. They agreed with citizens in Nebraska and Massachusetts in calling for better definition of who would be eligible for vaccination in the first priority category and they were strong in their desires to have the decisions about vaccination priorities made by public health experts rather than by political appointees. Also, Oregonians were interested in exploring strategies which could protect people by limiting people's exposure to influenza by means other than vaccination.

An example of another important warning to emerge from the Oregon citizen session−that was also expressed in other states−was the need to have a lot of education and training for the public if vaccine priorities are to be made public. The anticipation is that people will not respond well to being left out of the vaccination program without advanced education and training.

See Attachment K for more details.

Proposed Changes to the Findings and Recommendations of the Citizens and Stakeholders

All three Feedback Sessions agreed with the Atlanta citizens-at-large and with the National Stakeholder Group's goal rankings for vaccine allocation during a pandemic event. The Feedback Sessions were not provided with the Stakeholder Group's "Additional Recommendations." Therefore it is even more compelling that the Feedback Sessions also wanted to forward additional recommendations to decision-makers and to note how similar their recommendations are to those from the National Stakeholder Group. The Stakeholder Group reviewed and discussed the key themes from the Feedback Sessions and adopted them as part of their final recommendations with certain caveats.

All of these proposed changes (with the exception of bullet 1) have been incorporated into the findings and recommendations of this report:

1. Reduce the number of different types of services considered critical to "Assure the Functioning of Society" in goal one by identifying those categories most essential to saving or protecting lives at the front lines of service. *The Stakeholder Group agreed in principle with the above statement but noted that the specific task is outside of their scope of work.*

2. Clarify that not 100% of all person in each critical category in goal one needs to be vaccinated to "Assure the Functions of Society."

3. Clarify that the high risk groups to be vaccinated during a pandemic should be based on the epidemiology of the pandemic event.

4. Request that the decisions about which population groups are priority groups should be made by appropriate experts and not within the political arena.

Chapter Six
Evaluation Results

The PEPPPI project contracted separately for an independent evaluation with the University of Nebraska Public Policy Center and with a public engagement expert from Practicum Limited, a Toronto-based consulting group. The results of the preliminary evaluation were available in December 2005 at the time this report was completed and a more comprehensive evaluation will be reported at a later date. Below are the key findings from the preliminary evaluation for each of the main goals of the PEPPPI project. Overall, the evaluators found that the PEPPPI was largely successful in meeting its multiple process-related goals (see below). A more detailed presentation of the methods and results of the process evaluation, including many illuminating comments from the participants in the multiple sessions, are included in Attachment L of this report.

Overview

Participation and Representation

Goal 1a: Attract citizens to participate in the process in four locations: Georgia, Massachusetts, Nebraska, and Oregon.

Preliminary results and observations indicate the process was successful in attracting citizens to participate in the process with good attendance at the meetings: 101 in Atlanta, Georgia; approximately 40 in Massachusetts; 85 in Omaha, Nebraska; and 35 in Portland, Oregon. Many citizens indicated they were motivated to participate primarily through civic duty or an interest in the topic.

Goal 1b: Recruit participants who reflect a diversity of perspectives, and with varying demographic characteristics such as age, gender, race/ethnicity, and education.

The demographic information of Atlanta, Boston, Omaha, and Portland participants indicates the groups were diverse based on age, gender, race/ethnicity, and education, although they may not have reflected the general population. Participants included a larger number of persons who were in the 55 – 64 age category, more females than males, and had higher education levels than the general population. Observers and citizens perceived that there was good diversity in perspectives and political views, although some noted that persons who were poor were not well represented.

Knowledge of Participants and the Dialogue and Deliberation Process

Goal 2a: Provide information to participants so they have sufficient knowledge about pandemic influenza to adequately consider and discuss the issue of the prioritization of pandemic influenza vaccination and potential goals for a vaccination program.

The process designed by the project organizers was successful at increasing citizens' knowledge levels. Results indicate citizens participating at all four locations significantly increased their knowledge after receiving information about pandemic influenza and participating in the deliberations. Survey results

indicate the D.C. Stakeholders had a relatively high level of knowledge about pandemic influenza before engaging in the deliberative process or receiving information at the meeting. Further, stakeholders and citizens believed they had enough information to have well-informed opinions about vaccine allocation.

Goal 2b: Design and implement a process that promotes a balanced, honest, and reasoned discussion of the issues while respecting diversity of views.

The preliminary results indicate stakeholders and citizens generally believed the process was of high quality. Results indicate that participants at all six meetings felt comfortable talking, felt that others felt comfortable talking, and thought the discussion was fair to all participants. Respondents at all locations tended to believe that the process produced credible, relevant and independent information. Participants indicated that the discussion was balanced and that no one person or group dominated the process. There was less agreement about whether important points were left out of the discussion; participants in the shorter Boston, Omaha and Portland meetings felt important points were left out. Observers generally perceived that the high quality facilitation resulted in the balanced deliberation.

Goal 2c: Provide a forum for citizens to deliberate and consider multiple points of view. The evaluation tests the assumption that deliberation affects the opinions and judgments of participants related to prioritization of pandemic influenza vaccination.

Citizens at all four locations tended to believe that the process helped them understand trade-offs. Pre and post-survey results indicate that citizens and stakeholders changed their opinions about social values, goals and priority populations as a result of the process.

Value of Citizen Participation and Overall Value of the Consultation

Goal 3a: Citizens contribute useful information for the stakeholder deliberations, and stakeholders consider and integrate citizen input into their recommendations.

Responses from stakeholders regarding how they considered citizen input were mixed. Most stakeholders who were interviewed indicated they considered the citizen input very seriously. Others, however, indicated that the citizen impact did not have a great deal of influence.

Goal 3b: Citizen and stakeholder input receives serious consideration by decision-makers and adds value to the input already being received from expert groups. A key aspect of the evaluation is to understand how citizen and stakeholder input is used by decision-makers in establishing pandemic influenza vaccination priorities.

This goal was not formally assessed in the first phase of the study by the evaluation team but will be reported later.

A preliminary assessment of the utility of the consultation can be gleaned from the statements made in the HHS Pandemic Influenza Plan in November 2005 about the PEPPPI initiative. They indicate

HHS interest in the goal accorded the highest priority by the citizens-at-large and the National Stakeholder Group, but ranked lower by the HHS expert advisory bodies, namely "Assuring the Functioning of Society".

According to the HHS Plan, "Advisory Committee recommendations are presented in this report to provide guidance for planning purposes and to form the basis for further discussion of how to equitably allocate medical countermeasures that will be in short supply early in an influenza pandemic.
Two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC), provided recommendations to the Department of Health and Human Services on the use of vaccines and antiviral drugs in an influenza pandemic.

Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. The primary goal of a pandemic response considered was to decrease health impacts including severe morbidity and death; secondary pandemic response goals included minimizing societal and economic impacts. However, as other sectors are increasingly engaged in pandemic planning, additional considerations may arise. The advisory committee reports explicitly acknowledge the importance of this−for example highlighting the priority for protecting critical components of the military. ***Finally, HHS has recently initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs. Though findings of the outreach are preliminary, a theme that has emerged is the importance of limiting the effects of a pandemic on society by preserving essential societal functions…"*** [Emphasis added]

<u>Citizen and Stakeholder Satisfaction</u>

Goal 4a: Citizens are satisfied with the process and believe their input will be considered by decision-makers.

There was agreement by stakeholders and citizens that the process produced a positive outcome. Stakeholders and citizens at all sites also generally agreed that decision-makers would consider their input−although this belief was not strong. Stakeholder and citizens believed that the process would increase the public's support of the decision ultimately made.

Goal 4b: As a result of the process, the relationships among participating stakeholders improve.

Most stakeholders thought that the process had changed their relationship with other stakeholders. These changes included strengthening the relationships, creating a better understanding of each other's thoughts and priorities, bringing stakeholders closer together, and creating relationships that did not exist prior to the process.

Chapter 7
Summary and Conclusions

The Public Engagement Pilot Project on Pandemic Influenza (PEPPPI), a public consultation, successfully conducted multiple dialogue and deliberation sessions involving approximately 300 citizens and stakeholders in different parts of the United States. Participants with diverse backgrounds and points of view came together to learn the basic facts needed to have an informed discussion about pandemic influenza, to engage in give and take discussions about potential goals for the use of limited supplies of vaccine, to weigh the tradeoffs between competing goals, and to select the goals considered most important to achieve with scarce vaccine. In all parts of the Pilot Project, participants decided with a very high level of agreement that "Assuring the Functioning of Society" should be the first goal and "Reducing Individual Deaths and Hospitalizations Due to Influenza" should be the second priority goal. The first goal is to be implemented using the minimum vaccine necessary to assure the functioning of society and, once assured, using the maximum number of doses possible to reduce individual deaths and hospitalizations due to influenza. There was little support for other goals to vaccinate young people first, or to use a lottery system or a first come first served approach as top priorities.

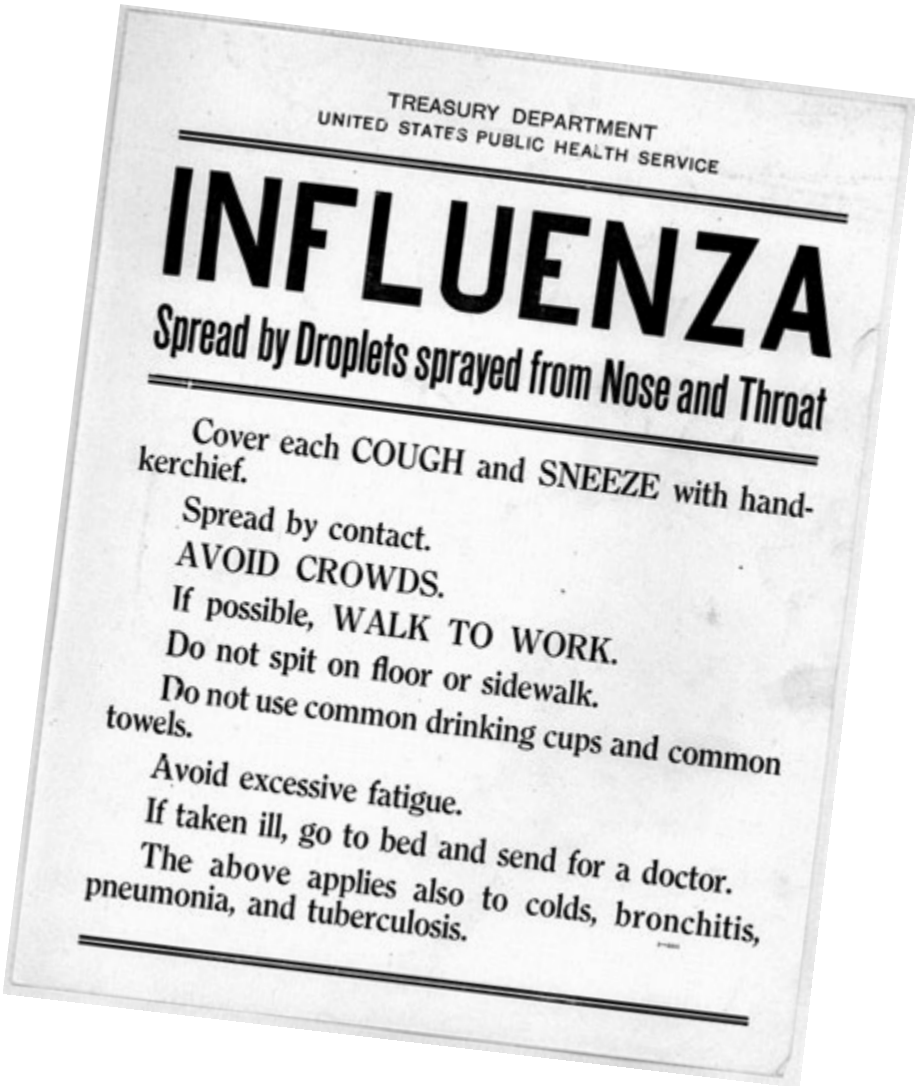
The consistency of the results of the deliberations in four separate populations of diverse citizens from the four principal regions of the United States and the consistency of the results between citizens at large and the group of stakeholders representing the major organizations or sectors with a strong interest in influenza give considerable weight to the findings even though the number of participants was still relatively small. According to Daniel Yankelovich, a public engagement expert, a principal outcome from public engagement is determination of "the boundaries of political permission." It seems clear from the Pilot Project what these boundaries are for decision-makers and technical experts.

Both the public participants in this Pilot Project and the expert advisory bodies, the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee, chose protecting society's caretakers and persons at high risk among their top priorities. However, the weight attached by the public to "Assuring the Functioning of Society" appeared to be greater than the weight placed on this goal by the two advisory bodies which placed higher priority on protecting high risk persons ahead of most of society's caretakers.

The soundest policy may require further elaboration on how both of these goals can be pursued together. Perhaps the public's concept of "Assuring the Functioning of Society" but using the minimum number of doses necessary to do so at the discretion of state and local public health officials has the potential of including the most categories of persons deemed critical to the functioning of society while at the same time being able to conserve as many doses as possible for high risk persons.

This Pilot Project has provided "proof of principle" that a diverse group of stakeholders and citizens-at-large could be recruited without financial incentives to learn about a technical subject, interact respectfully in give and take discussions, and reach a productive outcome by ranking goals related to the use of pandemic influenza vaccine as charged by the organizers. The degree of public engagement that was achieved was at a higher level of interactivity than what is normally achieved in vaccine related decision-making in the United States and showed that this higher level of public or citizen engagement is possible. Other pending vaccine policy questions which involve considerations of both facts and values, such as strategies for the use of the new human papilloma virus vaccine, may be good candidates for enhanced public engagement to help inform future decision-making.

A fuller assessment of the potential benefits from this Pilot Project is still underway and potentially important findings will be reported at a later date.



TREASURY DEPARTMENT
UNITED STATES PUBLIC HEALTH SERVICE

INFLUENZA

Spread by Droplets sprayed from Nose and Throat

Cover each COUGH and SNEEZE with handkerchief.

Spread by contact.

AVOID CROWDS.

If possible, WALK TO WORK.

Do not spit on floor or sidewalk.

Do not use common drinking cups and common towels.

Avoid excessive fatigue.

If taken ill, go to bed and send for a doctor.

The above applies also to colds, bronchitis, pneumonia, and tuberculosis.