

H1N1 Vaccination Program: Public Engagement Meetings
Draft Summary
New York, New York – August 22, 2009

Introduction

On August 22, 2009, 85 members of the public met in New York to learn about the H1N1 virus and hear a presentation about the decisions already made about vaccination. At the request of the Centers for Disease Control and Prevention, they discussed a set of decisions that will have to be made in the very near future about the vaccination program. These decisions were encapsulated in three scenarios representing three different levels of effort by public agencies, clinics and service providers in making vaccine available.

Option 1 – Go Slow

- A few additional sites added to seasonal flu sites
- Goal to meet an expected low public demand for vaccine
- No rush to vaccinate early on
- Slight increase in communication
- Slight increase in volunteer involvement
- Slight increase in partnerships
- Slight increase in safety, disease, and coverage monitoring

Option 2 – Moderate Effort

- Goal to promote vaccination to eligible groups, set up extra vaccination sites beyond those used for a regular flu year, and vaccinate a large number of the eligible groups relatively quickly
- Aim to raise the expected low public demand for vaccine
- Enhanced communication
- Enhanced volunteer involvement
- Enhanced partnerships
- Enhanced safety, disease, and coverage monitoring

Option 3 – Full Throttle

- Significant additional federal, state, and local funds invested in creating numerous extra vaccination sites in both the public and private sectors
- Aim to create and respond fully and speedily to significant public demand for vaccination even if the severity of the illness is initially perceived to be low
- Extensive communication activities to stimulate public demand
- Extensive networks of volunteers and partners are identified and ready to spring into action
- Aggressive monitoring of safety, disease, and coverage to collect timely data and take any corrective actions needed to improve the program or protect public safety

Public Viewpoints – What matters most to you in connection with a vaccination program?

Time

- Having sufficient time to test and to manufacture the vaccine
- Allowing more time for testing larger numbers of people with the novel H1N1 vaccine
- Allowing more time for educating the population and raising awareness about H1N1 Virus
- Having sufficient time to collect information

Information

- Need for sufficient, objective information
- Starting with a full-throttle effort at prevention and information distribution
- Educating people about the efficacy of colloidal silver
- Need for accurate, complete information
- Addressing misinformation through the media
- Need for informed consent
- Disseminating information without hysteria and fear
- Giving people facts
- Transparency
- Preventing panic
- Getting enough information to the people who need it most, including those with language barriers
- Need for a public education campaign about the symptoms and who is at risk, so hospitals are not overwhelmed
- Public education campaign on hygiene for prevention including natural immune boosters
- Avoiding unduly alarming the population
- Accurate, transparent information to make truly informed decisions
- Need for honest, measured, trends as the flu season progresses
- Lack of information to base a decision on
- Government should be prepared; preparation should be based on viable, correct information
- Important to explain to public the risk/benefit so that consent is truly informed
- Transparency and full disclosure of facts/data
- Specifics of Vaccine – who makes it; how effective is it; side effects
- Information provided to the public must be credible
- Concern that a lack of established knowledge about H1N1 will hinder efforts to intervene
- Need for full, honest disclosure concerning adverse effects
- Need for full, honest disclosure concerning efficacy
- Concern that ambiguity lends to complacency
- Need to raise public awareness through CDC, media
- No sense of urgency about the pandemic; there is fear among participants that the US will not be ready for an outbreak

Research/Testing

- Need for more research before producing vaccine
- Demonstrating safety before vaccinating the general public
- Effective vaccine testing
- Safety of vaccine
- Effectiveness of vaccine

- Getting results of trials out quickly, including details – numbers in the trial, numbers who are in high-risk groups; side effects
- Sense that scientific/medical efforts should be directed to prevention (finding root cause) of virus, instead of reacting with vaccine program
- Concern that current trials/testing not sufficient to learn about risks/complications of vaccine

Trust

- Avoiding unduly alarming the population
- Motives of government and pharmaceutical industry
- Trust in government
- Concern that the voluntary program will become a mandatory one
- Staying with a voluntary approach
- Liability protection for vaccine manufacturers
- Drug companies' profit motive
- Lack of trust – CDC and pharmaceutical companies
- Concern that experts are not unbiased
- Government's failure to address the needs of low-income and minority people
- Concern about being coerced to take vaccines even if the program is voluntary
- Greater trust of doctors and scientists than of politicians

Resources

- Balancing resources slated for this vaccine programs with other needs or the next crisis
- Concern over lack of infrastructure to support disseminating resources that are allocated to H1N1; resources will not be appropriately allocated or utilized efficiently.

Safety

- Long-term health impacts from vaccination
- The potential dangers of thimerosal and squalene
- Avoiding as many vaccine side effects as possible
- Demonstrating safety before vaccinating the general public
- Balancing the risks and benefits of vaccination
- Personal and family safety
- Need for people injured by vaccine to be treated at expense of government or vaccine manufacturer

Access

- The possibility that there is more demand than supply
- Protecting those who are traditionally underserved
- Having sufficient vaccine for the rest of the world
- Concern over selected priority groups – Who, who decided, what criteria they used
- Need for all groups to have access to vaccine, regardless of class, color, citizenship
- Giving everyone an equal chance of being vaccinated regardless of age or risk status

Effective Vaccination Program

- Need for an effective program including having sufficient resources, enough vaccination sites, a system for vaccine recall, communication, volunteers
- Prevent widespread illness for people who work in the health care industry

- Prevent illness in pregnant women
- Vaccine may be unnecessary
- Coordination between CDC and other government agencies so that the effort is streamlined
- Need for a plan B if vaccination doesn't work
- Stopping the spread of flu and loss of life, labor, and being able to do what you want
- Making vaccination available to those most at risk
- Protecting the maximum number of persons from getting sick from H1N1
- Concern that the vaccine will actually spread viral infection
- Consider mandating health care providers because they can infect patients
- Need for a holistic approach that includes non-pharmaceutical approaches
- Preventing the maximum number of deaths and hospitalizations caused by the novel H1N1 virus
- Being as prepared as possible in advance of the epidemic

Flexibility

- Allowing some flexibility in response to changing characteristics of the epidemic

H1N1 Severity

- Credibility of information about the severity and spread of the virus

Preferences

The New York participants favored the go-easy approach by a plurality, with 44.74 percent of the participants selecting go easy. A moderate effort received the support of more than a third (36.84%) of the participants. The full-throttle approach was supported by 18.42 percent of the participants.

| | | |
|-------------------------------------|----|--------|
| I Prefer Option 1 – Go Easy | 34 | 44.74% |
| I Prefer Option 2 – Moderate Effort | 28 | 36.84% |
| I Prefer Option 3 – Full Throttle | 14 | 18.42% |
| Totals | 76 | 100% |

Should the H1N1 outbreak prove to be less severe than anticipated, the go-easy approach is supported by a majority. The moderate level was supported by just over one quarter of the participants, assuming a less severe outbreak. However, the full-throttle approach received support from the same fourteen participants, or 19% of those responding.

| | | |
|-------------------------------------|----|--------|
| I Prefer Option 1 – Go Easy | 39 | 53.42% |
| I Prefer Option 2 – Moderate Effort | 20 | 27.40% |
| I Prefer Option 3 – Full Throttle | 14 | 19.18% |
| Totals | 73 | 100% |

Under the assumption of a more severe outbreak, 23 participants, or roughly a third of the group, continue to favor a go-easy approach. Roughly a quarter of the participants support a moderate level-of-effort under a more-severe assumption. Support for a full-throttle approach grows to 41.43% of the group should there be a more severe outbreak.

| | | |
|-------------------------------------|----|--------|
| I Prefer Option 1 – Go Easy | 23 | 32.86% |
| I Prefer Option 2 – Moderate Effort | 18 | 25.71% |
| I Prefer Option 3 – Full Throttle | 29 | 41.43% |
| Totals | 70 | 100% |

In the first round of the polling exercise aimed at uncovering some of the primary reasons for preferring one level of effort over another, the New York meeting participants placed a lack of trust in government-sponsored programs and preventing the maximum number of deaths and hospitalizations as their top choices with 19% of the votes for each of these two choices. Wanting to avoid vaccine side effects and allowing for flexibility both received 15% of the votes. No other reason received double-digit support from the poll takers in the first round.

In the second round, the same two items were at the top of the poll. The lack of trust in government-sponsored programs topped the list with 23% of the votes. Preventing the maximum number of deaths and hospitalizations received 14.86% of the votes. Advanced preparation, avoiding side effects,

allowing for flexibility, going easy on some items while going full-throttle on others and allowing time for testing followed closely with 8-11% of the votes for each of these five items.

In the third round, the percentage range narrows with a high of 17.81% and a low of 4.11%. Lack of trust continued to top the poll. Advanced preparation moved up in this round with 15% with preventing deaths and hospitalizations moving down to the third preference, equal to avoiding side effects, at 12.33%. Avoiding alarm moved up to nearly 10% in this round, followed by allowing time for testing and allowing flexibility.

Spending government resources on other more pressing public needs and avoiding the costs associated with the loss of life and hospitalizations were at or near the bottom of the poll in all three rounds.

2009 Vaccination Program Preference

| | Responses | | | | | |
|--|-----------|--------|--------|--------|-------|--------|
| | First | | Second | | Third | |
| I want to avoid as many vaccine side effects as possible. | 11 | 15.07% | 7 | 9.46% | 9 | 12.33% |
| I want to allow more time for testing larger numbers of people with the novel H1N1 vaccine | 1 | 1.37% | 6 | 8.11% | 6 | 8.22% |
| I want to spend government resources for other more pressing public needs. | 3 | 4.11% | 4 | 5.41% | 5 | 6.85% |
| I want to avoid unduly alarming the population. | 5 | 6.85% | 3 | 4.05% | 7 | 9.59% |
| I lack trust in government sponsored programs | 14 | 19.18% | 17 | 22.97% | 13 | 17.81% |
| I prefer an approach that includes some of the advantages of two approaches (full-throttle on some things, go-slow on others). | 8 | 10.96% | 7 | 9.46% | 3 | 4.11% |
| I prefer an approach that allows some flexibility in response to changing characteristics of the epidemic. | 11 | 15.07% | 7 | 9.46% | 6 | 8.22% |
| I want to prevent the maximum number of deaths and hospitalizations caused by the novel H1N1 virus. | 14 | 19.18% | 11 | 14.86% | 9 | 12.33% |
| I prefer to be as prepared as possible in advance of the epidemic. | 5 | 6.85% | 8 | 10.81% | 11 | 15.07% |
| I want to avoid the costs associated with loss of life and with hospitalizations. | 1 | 1.37% | 4 | 5.41% | 4 | 5.48% |
| Totals | 73 | 100% | 74 | 100% | 73 | 100% |

Working from a list of eight additional goals, participants registered preferences for a first, second and third choice. In the section of the poll that focused on other goals (including those elements that may not vary as level-of-effort varies) a steadfast 17 participants selected “none” as a way of registering that they do not support vaccination. In the first of three rounds of polling, 27% of participants identified “protecting the maximum number from getting sick...” as the most important goal. This item received no less than a quarter of the votes in each of the next two rounds and was the most frequently selected item in all three rounds. Allowing time for education also received 27% in the first round; support for this item decreased in each successive round. The only other items to receive double-digit-percentage support in any round are equal access to vaccines, protecting subgroups that are traditionally underserved and conserving vaccine for donation to other countries. The table below lists the preferences in all three rounds.

2009 Vaccination Program Preference – other goals

| | Responses | | | | | |
|--|-----------|--------|--------|--------|-------|--------|
| | First | | Second | | Third | |
| I want to protect the maximum number of persons from just getting sick from H1N1 in the first place. | 20 | 27.03% | 18 | 24.66% | 18 | 28.12% |
| I want a vaccination program that gives everyone an equal chance of being vaccinated regardless of age or risk status. | 5 | 6.76% | 11 | 15.07% | 5 | 7.81% |
| I want a vaccination program on a first come first served basis while supply is limited. | 1 | 1.35% | 2 | 2.74% | 2 | 3.12% |
| I want to make sure to protect the subgroups in the population who have been traditionally underserved. | 4 | 5.41% | 9 | 12.33% | 9 | 14.06% |
| I want to protect our citizens but also conserve vaccine for donation to other poor countries which need vaccine. | 5 | 6.76% | 1 | 1.37% | 8 | 12.50% |
| I want to accelerate vaccine availability before all testing is completed. | 2 | 2.70% | 2 | 2.74% | 0 | 0% |
| I want to allow more time for educating the population and raising awareness about H1N1 virus. | 20 | 27.03% | 13 | 17.81% | 5 | 7.81% |
| None of these (If you are opposed to the vaccination program, you can select this one each time.) | 17 | 22.97% | 17 | 23.29% | 17 | 26.56% |
| Totals | 74 | 100% | 73 | 100% | 64 | 100% |

To examine the polling differently, one might give weight to a first-choice selection, a smaller weight to a second-choice selection and no weight to a third-choice selection. If one multiplies the number of first-choice responses by three, the number of second-choice responses by two and applies no weight to the third-choice responses, the results are as follows:

| 2009 Vaccination Program Preference – Weighted | Weighted First | Weighted Second | Weighted Third | Total | Rank |
|--|-----------------------|------------------------|-----------------------|--------------|-------------|
| I lack trust in government sponsored programs | 42 | 34 | 13 | 89 | 1 |
| I want to prevent the maximum number of deaths and hospitalizations caused by the novel H1N1 virus. | 42 | 22 | 9 | 73 | 2 |
| I want to avoid as many vaccine side effects as possible. | 33 | 14 | 9 | 56 | 3 |
| I prefer an approach that allows some flexibility in response to changing characteristics of the epidemic. | 33 | 14 | 6 | 53 | 4 |
| I prefer to be as prepared as possible in advance of the epidemic. | 15 | 16 | 11 | 42 | 5 |
| I prefer an approach that includes some of the advantages of two approaches (full-throttle on some things, go-slow on others). | 24 | 14 | 3 | 41 | 6 |
| I want to avoid unduly alarming the population. | 15 | 6 | 7 | 28 | 7 |
| I want to spend government resources for other more pressing public needs. | 9 | 8 | 5 | 22 | 8 |
| I want to allow more time for testing larger numbers of people with the novel H1N1 vaccine | 3 | 12 | 6 | 21 | 9 |
| I want to avoid the costs associated with loss of life and with hospitalizations. | 3 | 4 | 4 | 12 | 10 |

Given these weights, ‘lack of trust in government-sponsored programs’ ranks first, followed by ‘preventing the maximum number of deaths and hospitalizations’. ‘Avoiding vaccine side effects’ and ‘maintaining flexibility in the approach’ follow in third and fourth.

| 2009 Vaccination Program – Other – Weighted | Weighted First | Weighted Second | Weighted Third | Total | Rank |
|--|----------------|-----------------|----------------|-------|------|
| I want to protect the maximum number of persons from just getting sick from H1N1 in the first place. | 60 | 36 | 18 | 114 | 1 |
| None of these (If you are opposed to the vaccination program, you can select this one each time.) | 51 | 34 | 17 | 102 | 2 |
| I want to allow more time for educating the population and raising awareness about H1N1 virus. | 60 | 26 | 5 | 91 | 3 |
| I want a vaccination program that gives everyone an equal chance of being vaccinated regardless of age or risk status. | 15 | 22 | 5 | 42 | 4 |
| I want to make sure to protect the subgroups in the population who have been traditionally underserved. | 12 | 18 | 9 | 39 | 5 |
| I want to protect our citizens but also conserve vaccine for donation to other poor countries which need vaccine. | 15 | 2 | 8 | 25 | 6 |
| I want to accelerate vaccine availability before all testing is completed. | 6 | 4 | 0 | 10 | 7 |
| I want a vaccination program on a first come first served basis while supply is limited. | 3 | 4 | 2 | 9 | 8 |

‘Protecting the maximum number from getting sick’ ranks first. Opposition to the vaccination program ranks second. ‘Time for education’ and ‘equal access’ follow in third and fourth.

Pros and Cons – Three Approaches

The participants discussed the three levels of effort, exploring the advantages and disadvantages of each. While some took issue with the assumptions and with the absence of a no-vaccination choice, the small groups did work through the discussion of pros and cons. Their reactions to the three approaches are as follows:

Go Slow

Pros

- Allows the focus to be on educating the public
- Allows knowledge of alternative approaches to come to the front of the public discussion
- Allows for time to see if vaccine side effects emerge before widening the vaccination program
- Is sufficient for disseminating the necessary information for those at greatest risk
- Provides an adequate level of communication about the disease and the effectiveness of vaccination

- Is fiscally sound
- Matches best the need for freedom of choice
- Allows for health officials to see how severe the flu will be
- Puts resources in the right place
- Will reduce unnecessary hysteria
- Enables other public health concerns to be addressed
- Allows for vaccine availability for those especially at risk
- Provides the ability to inform the public of risks and benefits
- Will allow for information to be based on current information
- Gives more time to inform and educate the public on the results of vaccine trials
- Matches the level of uncertainty and the absence of information
- Matches the level of need
- Prevents fear
- Prevents mobilization of volunteers until the need is demonstrated
- Allows the U.S. to conserve our resources for nations with fewer resources
- Allows a history to be gathered
- Gives people time to digest information as it becomes available
- Will prevent people from rushing to emergency rooms
- Allows for fewer resources and taxpayer money to be used
- Allows time to obtain information, evaluate negative effects of vaccine and assess virus spread
- Promotes informed consent
- Allows more time to collect information
- Allows information about safety from trials to be used in the vaccination program
- Gives manufacturers time to alter vaccine in reaction to southern hemisphere experience

Cons

- Risks more people getting sick
- May lead to panic if more people get sick
- Would be irresponsible if the pandemic is severe
- Prevents enough information from getting to people who need it most
- Is insufficient to overcome language barriers
- Prevents citizens who need to get the vaccine from getting the vaccine due to lack of information
- Prevents information from reaching the public
- Prevents a coherent presentation of the necessary information
- May forestall a necessary ramp up if pandemic becomes severe
- Prevents government from preparing properly for a serious epidemic
- Leads to only those who are well connected having access to the small amount of vaccine that is available
- Risks a more serious outbreak/epidemic
- Risks the economy and infrastructure
- Could result in a higher number of flu cases
- Will stress emergency rooms as people who are not vaccinated go there to be treated
- Wastes government resources

Intermediate

Pro

- Best of both slow and full throttle approaches
- Balanced approach in the face of so many unknown factors
- There is no way to know, for sure, how widespread or how severe the disease will be or exactly how effective or safe the vaccine is
- Balances interests – time to educate/inform; vaccine readily available; see vaccine safety trials
- Realistic to execute
- Politically expedient
- More monitoring of results
- Without clear expectations, we need to be ready to act
- More likely to reach vulnerable populations
- Allows time for CDC to fine tune their approach by analyzing data.
- Gives more time to think about side effects
- Preserves ability to spring into action
- Allows easy increase or decrease in response to public demand
- Avoids scaring people
- Provides an opportunity for cost/benefit analysis

Con

- Doesn't allow time to see the effects
- Wishy-washy
- Risks that health care providers will not be vaccinated and will infect patients
- Not enough to prevent pandemic expected based upon historical data
- Is unnecessary/overkill
- Risks side effects
- May not allow for quick ramp-up if pandemic becomes severe
- Too much uncertainty/not enough data to justify this choice

Full Throttle

Pros

- Allows for early communication efforts
- Will result in less panic/alarm
- Protects our nation's infrastructure and economy, which are fragile.
- Allows for life-saving level of effort
- Is the safest approach
- Addresses the high risk circumstances
- Allows for quick information dissemination
- Allows for full readiness to prevent a catastrophe
- Would save the maximum number of lives
- Would prevent severe illness
- Allows for more brains and a larger community effort to fight the problem and therefore would be more effective
- Would influence other countries to follow suit
- Allows CDC and the media to provide full communication and education to the public

- Since vaccination is voluntary, all effort can be made to increase the # of sites, improve vaccination recall, increase safety monitoring and improve disease surveillance
- Allows for focus on self quarantine, school closings, social distance, hand sanitizer
- Improves outlook for adult immunization programs, generally
- Allows for learning more about the disease and the vaccine
- Allows for awareness among risk populations of vaccination and of side effects
- Can improve residual immunity to future viruses
- Provides effective education as data becomes available, especially for high risk groups
- Informs members of high risk groups and make experts available to them
- Would decrease hospital stays, loss of time away from work and school and death

Cons

- May not be the best use of limited financial resources
- Will still allow people to fall through the cracks
- Would reduce our ability to help other nations
- Could be more coercive than voluntary
- Fails to allow for sufficient time to gather information regarding side effects of vaccine
- Could scare people and cause panic
- Would limit funding and resources for other purposes
- Risks credibility if the outbreak is less severe
- Fuels distrust in government
- Is an intrusion by government
- May use resources without increasing vaccination rates
- Ignores past history
- Is costly
- Would not allow time to discover possible negative effects of vaccination
- May move too quickly to fully understand appropriate dosing
- Risks side effects from multiple vaccinations
- Moves ahead before data about efficacy and side effects are available
- Reduces trust
- Risks oversaturation of the message, leading to public resistance or complacency
- Risks public confusion
- Is a mismatch between the resources required and the reality of the threat posed by the virus