

**H1N1 Vaccination Program: Public Engagement Meetings
Facilitator Worksheets for Small Group Discussion
Denver August 8, 2009**

Introduction

On August 8, 2009, eighty-five members of the public met in Denver 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.

[insert definition – go slow, full throttle, intermediate]

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

The participants were presented with values statements aimed as summarizing different points of view and belief systems about vaccination. Three perspectives dominated this aspect of the discussion:

1. For many of the participants in the small-group discussions, what mattered most was protecting the maximum number of citizens/people from getting H1N1. For many of these, a full-throttle approach is acceptable.
2. The freedom to make ones own healthcare decisions is a dominant value for many of the participants. For those who are concerned that a full-throttle approach is a small step from mandatory vaccination, or that a full-throttle approach represents a kind of government arm twisting, this freedom comes into play. For many of these participants, the importance of freedom to make one's own healthcare decisions aligns best with a government go-slow approach. By going slow, the government leaves members of the public free to exercise their own choices about vaccination. A lack of trust in the motives behind a government-sponsored, full-throttle approach compound the concerns and move participants further toward preferring a go-slow approach. This aligned with limiting the role of government in healthcare decision making.
3. A third, dominant perspective was protecting the maximum number from vaccine side effects. Many of the participants expressed concerns with the limited testing of the H1N1 vaccines, the very brief time between vaccine production and vaccine distribution and the inability to test the vaccine thoroughly in the time before the vaccination program begins.

The tension between 1 and 3 was a part of every small group conversation and in many groups, dominated the deliberation. To balance among these three, many focused on the principles of a truly informed consent – a deep level of education from very credible sources; restraint from the government as a way of demonstrating that there is no bias in favor of vaccine companies or of

forced choice; and a forthright, unambiguous declaration of vaccine testing results and side-effects information.

The Denver discussion circled around the idea of a full-throttle informational campaign and availability for those who want to be vaccinated with a go-slow vaccine promotion effort. An assertive promotion campaign by government is inversely associated with public trust in the intervention the government seeks to promote. The discussions focused on improving communication and doing so with a specific emphasis on the elements related to both trust and informed consent in a voluntary vaccination program:

- Clear information about the uncertainties related to the upcoming flu season and the likelihood of a return of the H1N1 flu
- Clear and unbiased information about vaccine testing and safety
- Forthright acknowledgment of the risk-benefit balance in vaccination
- Continued, unambiguous reiteration of the voluntary nature of the vaccination program
- A full-throttle education effort with real restraint in promotion/advocacy
- Non-government, unbiased expertise along side government experts

In addition, speakers focused on providing the larger context around vaccination including ways to prevent infection other than vaccination. Some focused on a learn-as-you-go approach, others on the need for long-term study of vaccination safety and possible vaccine-related health effects. Trust was a major theme and those who spoke to it focused on the relationship between government and vaccine manufacturers and the mistrust that stems from the liability protections government has given to vaccine manufacturers.

Electronic Poll

Participants registered their opinions in an anonymous, electronic poll focused on both the three levels of effort and the underlying values. The moderate level received the most support; this remained unchanged if the outbreak is less severe than expected. The go-slow approach received the lowest level of support in the primary poll. A majority prefer a full-throttle approach if the outbreak is more severe than estimated.

I Prefer Option 1 – Go Slow	22	27.85%
I Prefer Option 2 – Moderate Effort	32	40.50%
I Prefer Option 3 – Full Throttle	25	31.65%
Totals	79	100%

If less severe

I Prefer Option 1 – Go Slow	29	36.25%
I Prefer Option 2 – Moderate Effort	38	47.50%
I Prefer Option 3 – Full Throttle	13	16.25%
Totals	80	100%

If more severe

I Prefer Option 1 – Go Slow	18	22.78%
I Prefer Option 2 – Moderate Effort	22	27.85%
I Prefer Option 3 – Full Throttle	39	49.37%
Totals	79	100%

In the poll of values statements, the results were these:

Protect maximum number from the risk of getting the flu caused by the H1N1 virus	39	48.15%
Freedom to make my own health care decisions	13	16.05%
Protect maximum number from possible vaccine side effects (lack of trust in vaccine safety)	12	14.81%
Limit expenditure of government resources	2	2.47%
Flu caused by the novel H1N1 virus won't be as severe as predicted	2	2.47%
Even if flu caused by the novel H1N1 virus is as severe as predicted, i won't get sick	0	0%
Limit government role in health care decision (lack of trust in government in this arena)	13	16.05%
Totals	81	100%

However, when paired with protect max, the gap between “Freedom” and “Protect max” shrinks significantly.

Freedom to make my own health care decisions	33	41.77%
Protect maximum number from the risk of getting the flu caused by the H1N1 virus	46	58.23%

The only other pairing to produce a large change in preferences and narrow the gap is:

Protect maximum number from possible vaccine side effects (lack of trust in vaccine safety)	29	37.18%
Protect maximum number from the risk of getting the flu caused by the H1N1 virus	49	62.82%

The polling results are consistent with conclusions of the small-group discussions. An expanded statement from the small-group discussions follows:

Small-group discussion – what are your main concerns related to an H1N1 vaccination program?

- Information
 - Managing public fears/concerns
 - Ability to get clear, accurate information to people
 - Helping people make informed choices based on risks, needs, options and unknowns
 - Proliferation of inaccurate information
 - Transparency
 - Diverse ways to bring information to reach different parts of the public and reach all audiences
 - Fairness and accuracy are essential
 - Complexity of information stemming from the combination of H1N1 vaccine with the seasonal vaccine
 - Applying the lessons learned from Mexico, the UK and other countries
 - Public access to truthful, correct information that would help an individual make an informed decision
 - Adequacy, accuracy of information about possible side-effects of vaccination
 - Absence of information about side-effects at the start of the vaccination program
 - Need information about vaccination rules, method, process (where, when and how vaccine will be available)
 - Need outreach to different communities (inclusion)
 - Need diverse methods of communicating
 - Need education about ways (other than vaccination) to preventive the flu
 - Need effective methods for presenting information so that everyday people can comprehend it
 - Responding to misinformation
 - Providing enough information to the public
 - Sources, accuracy, and availability of the information (as much as possible)
 - Need for comprehensive communication that speaks to vaccination and other methods of prevention simultaneously (including alternative remedies and healthy lifestyles)
 - Need to encourage personal responsibility—staying home from work when sick, not sending children to school, personal hygiene and other preventative measures
 - Educate about risks and benefits
- Infrastructure/logistics
 - Adaptability and readiness of any program, but especially a full-throttle approach
 - Getting vaccine out in a timely manner
 - Distribution to end users
 - Distribution chain efficiency – timelines
 - Sufficient supply: ability to meet maximum demand

- Providing vaccination in schools without interrupting education
- Qualifications and supply of vaccinators
- Have a plan in place so that we are ready for what happens
- Make the plan flexible and adaptable to adjust to public demand and public concerns and changes in the virus
- Government/Governance
 - What are the circumstances or process for making voluntary/mandatory decisions (who makes these) transparent
 - Concern that any program is voluntary
 - Trust in government and pharmaceutical companies
 - Concern that profit is driving vaccination decisions
 - Lack of government and corporate accountability for liabilities/risks
 - Transparency leads to trust
 - Concern that vaccination would be made mandatory
 - Concern that companies could require vaccination for employees
 - Without a mandatory program, school children are at risk
 - Concern that the government is over-reacting, over-stating flu risk
 - Concern that a full-throttle approach, with a mild flu season will damage trust in future government recommendations/vaccination programs
 - Ability of the government to adjust if the strain changes in the midst of the vaccination program
 - Concern that government is not motivated by public health; by politics instead
 - Concern that information is being withheld
 - Concern that the government is using fear to fuel vaccination to support vaccine company profits
 - Who/how are quarantine/closing decisions made; what is the process/system for making those decisions
 - Need full reporting of clinical trials as results are known, particularly those that raise safety concerns
- Biological
 - Ability to adapt vaccine to strain
 - Virulence of strain: does it warrant extraordinary efforts?
 - Geographic migration of virus
 - Virus mutation in the midst of the vaccination plan (or between the two vaccinations)
- Effectiveness
 - Risk that people won't get the second dose for H1N1
 - Concern that culture doesn't allow for people to miss work when sick and not suffer economically
- Health and Safety
 - Need adequate vaccine testing
 - Concern that the vaccine will make people sick

- Risk of simultaneous vaccinations – H1N1 and others
- Need a definitive study of the long-term health effects of vaccination on human health
- Need to study the safety of this H1N1 vaccination program
- Fetal health impacts from vaccination
- Impacts on individuals with existing health conditions
- Tracking side-effects
- Individual rights and liberties
 - Concern that the program could be made mandatory program
 - Concern that individuals would not be permitted to exercise informed consent
- Protection from H1N1
 - Ability to protect family members within the highest risk category
 - Coverage for high-risk populations
 - Protecting children and service providers
 - Risk that a too-slow approach is not protective enough
- Equity
 - Access to vaccine for underserved populations
 - Equal access based on race, geography, income
- International Leadership
 - Impact of our vaccination program on other countries
 - Willingness to share extra vaccine with other countries
- Economic Effects
 - Go-slow approach, if many get sick, could disrupt economic activity
 - Economic impact of wide-spread illness

Pros and Cons of a Go-Slow Approach

Pros

- Doing it right – slow and steady
- This approach avoids vaccination risks
- This aligns with safety concerns from long-term effects
- Aligns with safety concerns and the desire for more testing of the vaccine and its side effects
- Going slow on vaccination while going full throttle on education is the best approach
- Going slow allows time for education and prevention
- Distrust of government leads to a preference for go slow
- Going slow allows for providing feedback on safety and success as you proceed
- Buys time to study risks of vaccine
- More time to distribute information to public
- Time to consider other and additional ways to protect public when pandemic hits
- With go slow, there is opportunity to test the safety of vaccines

Cons

- Cost of health care could be high as those with the flu access care
- Disruption if this level of preparation is inadequate to the flu outbreak
- This approach is problematic because go slow means less information reaches the public
- This is a reactive rather than proactive strategy
- Doesn't prepare us if impact is worse than expected and then we can't catch up
- People who would be interested may be left out, even w/in priority groups
- Slower approach could take more time to ramp up and the if the illness spreads quickly, there is concern for people not being able to work
- The downside is that "going easy" may mean we are less prepared if the pandemic is severe
- People may not think that vaccination is important if a go easy approach is used
- People may not be serious enough about to take the vaccination, particularly people at risk like younger people

Pros and Cons of a Full-Throttle Approach

Pros

- More individual choice – full-throttle makes it possible to exercise individual choice to be vaccinated or not to be vaccinated
- Prevention saves money
- Being preparedness reduced potential disruption in sectors like the economy, education, healthcare and social systems
- If this approach educates the public of prevention/treatment options, it helps them plan, prepare, protect themselves, understand the options available to handle the situation
- Safety – cover all bases; be prepared
- Action is needed
- It is easier to scale down an approach after the fact than to ramp it up
- It is best to be prepared given the possible health risks
- Peace of mind to know that we came prepared
- Thinking beyond our borders, the extra attention/resources could also help other countries affected by H1N1
- Fast = safe, protects the most people, prevents irreversible outcomes
- In full-throttle approach, media will distribute information and can clarify the relationship between government and corporations
- Highly transmittable, conduct of others affects me, my children are at risk
- There is a solution, use it
- Protect public service providers, school teachers
- Don't let the few jeopardize the safety of the many – the commonwealth of air
- Use triage to distribute vaccine to those most at risk, most exposed
- You may regret you went slow because death is not reversible
- High likelihood of equal access
- The health care arena has to be prepared, has to have the infrastructure in place/available to respond immediately to whatever the outcome

- The reality of our government is that we will shoot for a full throttle approach but end up more in the middle because of resource limitation
- Different arenas will need a different level of approach (i.e. health care and schools need full throttle but maybe more moderate for private agencies)
- There is comfort in knowing that if a full throttle approach is used, we will be best prepared at this level.
- If there is an overproduction of vaccine using this approach, what remains could possibly be shared with other nations which would help us serve a global leadership position
- Full throttle approach would be best because it means we are best prepared

Cons

- Concerns that infrastructure wouldn't be in place to get vaccine administered even though they are available
- There is not enough data to go full force; more information should be required before adopting a full-throttle approach
- This strategy could waste money
- Not enough people will be affected to need this possibility
- Resources would be overburdened at all levels
- Use of fear may compromise effective decision-making
- Make/create undue risk or tolerance by giving to those who don't need it
- This feels like one step away from mandatory vaccines
- The vaccine needs to be readily and easily available to those who are at risk and decide to get it
- The government should not pressure people; should not scare people into getting vaccinated
- This approach would take a lot of resources spent on an unknown (the degree of severity of the pandemic) that could possibly detract from other needs that we know exist
- This approach provides us with the least opportunity to evaluate the safety of the vaccine

Pros and Cons of an Intermediate Approach

Pros

- Planning how to handle spread of virus in case it becomes an issue which does not seem to be urgent at this point
- Respond to fears with enough information about what would be the best course of action
- This is an adequate response
- Manages limited resources
- Manages for uncertainty
- It would allow for more flexibility.
- Could be acceptable if the virus ended up being more virulent
- Extremes aren't good
- This met the needs for safety and efficient use of our resources
- It balances the pros and cons
- Leaves money for what we know people are needing
- Would reduce government propaganda and allow for more personal choice
- Important to be our brothers' keeper

- The economic disruption and other health concerns posed by the virus mean that people should be protected
- It is also important to protect more vulnerable populations such as the poor, immigrants, and those with chronic illness
- Health departments and schools are good resources to use to connect with at-risk populations and monitor vaccination
- The cost of vaccination is so much less than the cost of an extended hospital stay; this could be an effective use of government resources
- Balances history/known with the unknowns
- Allows for flexibility if impact is less or worse than expected
- Provides motivation for people to take action, but not heavy-handed
- There is still an opportunity to test safety of the vaccines
- There is more protection if the pandemic is severe
- Middle of the road would be best because it balances resources, safety, preparation

Some expressed interest in a wider range of choices, including no vaccination program with a focus instead on alternative measures of prevention and education.

Preliminary Draft