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## What Did the 2009 Swine Flu Pandemic Response Accomplish?

**Biot Report #679:** January 13, 2010

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As the 2009 swine flu consternation slowly fades into history, barring a third wave, some alert observers from a variety of countries and cultures are beginning to ask questions, such as what did pandemic preparedness and response accomplish? Who benefited from the efforts? Who did not? How much did the efforts cost? Were the preparedness and response activities a good value? How good? Why? For whom?

What trends characterize the health management of anthrax bioterrorism, SARS, avian flu, and novel swine flu outbreaks in the decade 2001-2010? In these four outbreaks, were preparedness and response activities based on reliable and valid data and information? Is anyone studying preparedness and response processes and outcomes for these four outbreaks as a group?

Do infectious disease preparedness and response activities have different relevance and impacts on particular health systems and societies? Was broad, multisectoral cooperation and coordination in response to the H1N1 pandemic health crisis in evidence, or did preparation and response devolve to the health sector alone, by intention or not?

Why did public health managers use emergency and disaster management language, i.e., terms such as preparedness and response? Are these terms useful in the management of health crises? Why? Why not? Are other terms native to the health sector more useful in health crisis management?

Were operational plans for health crisis preparedness and response tested before implementation? If yes, by whom? With whom? Were they tested in cooperation with the key components of health, such as health care providers (hospitals, physicians, nurses)? Were they tested with the other critical infrastructure sectors besides public health, i.e., agriculture and food, water, emergency services, government, defense industrial base, information and telecommunication, energy (electrical, oil, gas), transportation (aviation, rail, highways, trucking, busing, pipelines, maritime, mass transit), banking and finance, chemical industry and hazardous materials, manufacturing, and postal and shipping?

Was development and testing of operational plans limited to a group of health officials or health management academics, or consultants working for the previous two groups? What is the contribution of antivirals such as Tamiflu to pandemic preparedness and response processes and outcomes? What is the contribution of just-in-time vaccines to pandemic preparedness and response outcomes? What is the contribution of coughing or sneezing into one's elbow crook? What is the contribution of hand washing education and monitoring?

Is one pandemic response measure (antiviral, vaccine, cough/sneeze etiquette) more reliably obtained than the other? Is one more efficacious than the other? Does one cost more than the other? Is one easier to distribute than the other? Which one is a better value? For whom? Is one more hazardous than the other? Are any of these measures of performance undergoing quantification? Who is doing the quantification? Where? When? Will the public receive the results of performance assessment relative to pandemic preparedness and response? Where? When?

Below are some perspectives on these issues:

### I. Pan American Health Organization's Perspective: Pandemics Create Complex Social Circumstances



Dr. Ciro Ugarte, PAHO. Source: <http://web.archive.org/web/2011011030232/http://w...;> accessed January 13, 2010.

Dr. Ciro Ugarte made the following observations in Disasters Preparedness and Mitigation in the Americas (October 2009, Issue 112, published by the Pan American Health Organization) (PAHO):

1. Throughout history, many outbreaks of disease have resulted in high numbers of deaths, with very different impacts on particular health systems and societies.
2. During a disease outbreak, the number of cases may be less relevant than the presence of the disease itself. For example, the entire world mobilized to respond to 6 deaths resulting from the anthrax bioterrorism in the United States (2001) and 44 deaths from SARS in Canada (2003). Both events had enormous social and economic consequences beyond the health sector.
3. Health preparedness planning is often known only to a limited group of health officials.
4. In very few cases are operational plans developed and tested with all key components of the health sector and other sectors.
5. Seldom are sufficient personnel trained in tasks envisaged in the plan.
6. Seldom are supplies and resources provided that will be needed to respond to a health crisis.
7. Response to a health crisis is direct proportion to the level of preparedness.
8. Prioritizing the health and lives of the population above other considerations is not without major social and economic impacts, such as tourism, trade, and transport, on which countries, such as Mexico, may depend for continued existence.
9. Too often decisions are based on fear, rumors, and conspiracy theories; the intrusion of political and economic factors; and insufficient official information. These problems are multiplied by the press and electronic media, which are sometimes much more difficult to control than the disease itself.
10. Counting confirmed cases becomes the highest priority. Suspected cases are not as important, even when they are serious or cause more deaths than a new pathogen.
11. Other national priorities and more pressing public health needs are put aside, and sometimes a health outbreak, such as

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- the novel H1N1 pandemic, is used for purposes that have nothing to do with control of the disease. In such a context, the public expects and often demands authorities to carry out visible and urgent actions to demonstrate their concern for protecting the health of citizens. Among the most common are closing airports and using extreme measures to control foreign borders. Such actions require a major investment of resources and personnel, and have proven time and again to have little value in preventing a disease from entering a country.
12. During the 2009 H1N1 pandemic, the health sector took the lead in responding to the outbreak in almost all countries, but in many cases, they also took charge of actions that should have been dealt with by other sectors and actors, were unrelated to surveillance and diagnosis of disease, and were only marginally relevant to the response, if at all.
  13. A major weakness in the response to the 2009 H1N1 pandemic was the lack of more active involvement from the health services network (i.e., hospitals, physicians, nurses), precisely those who were treating the sick.
  14. All actors who are involved in the preparedness phase do not take action during the response phase. This is wrong.
  15. The health sector needs to be open, strengthen coordination with other sectors, and share responsibility. Institutions and countries as a whole must recognize and make better use of their national potential.
  16. It is necessary to maintain a balance between responding to a pandemic and other public health priorities. (1)

### II. Australian Government's Perspectives: Federal Government Overreacted and Vaccine Manufacturers Profited



**Mr. Dutton. Source:**  
<http://web.archive.org/web/20111011030232/http://w...;>  
 accessed January 13, 2010.

**Nicola Roxon. Source:**  
<http://web.archive.org/web/20111011030232/http://w...;>  
 accessed January 13, 2010.

The opposition in the Australian Parliament in Canberra is "the party or parties with the second largest number of seats in the House of Representatives." Its responsibilities include "highlighting mistakes and proposing alternatives." (2) The opposition on January 7, 2010,

called for a review of the federal government's handling of the swine flu vaccination program after it emerged taxpayers may have to foot the bill for the vaccine, despite only a quarter of it so far being shipped to doctors. Opposition health and ageing spokesman Peter Dutton described the pre-purchase of 21 million doses of the vaccine -- at an estimated cost of \$120 million -- as another "blunder" in the health portfolio.

"Clearly, serious mistakes have been made and there are more questions than answers," Mr. Dutton told The Australian. "The opposition believes the Rudd government's handling of this issue needs further independent investigation and review. Millions of dollars of taxpayers' money has been spent and confidential agreements have been entered into with major drug companies, and so independent analysis is warranted."

The Australian reported yesterday that the federal government was contractually obliged to buy 21 million doses of the H1N1 vaccine from pharmaceutical company CSL, even though only about 5.1 million doses have so far been shipped to vaccination providers. Health Minister Nicola Roxon this week urged Australians, particularly children and pregnant women, to be vaccinated, a call backed up by the Australian Medical Association. But medical experts are divided on the need for population-wide vaccination.

Ms Roxon yesterday defended the government's decision to buy the 21 million doses. "I think that we made the right decision and a cautious one," she said. "We simply don't have a crystal ball that can tell us when the disease will commence in Australia in large numbers." Ms Roxon would not comment on whether taxpayers would have to pay the CSL bill but pointed to remarks she made last month indicating the government signed the contract on the initial assumption it would need two doses per person.

The government has refused to outline the exact cost of the 21 million vaccines it purchased. "We're in the fortunate position, given the data from CSL, that there is only one dose required for adults, which means we will be able to vaccinate anyone in the community who wants to be vaccinated," Ms Roxon said this week. Mr Dutton said the vaccination program was "unravelling as Nicola Roxon's latest stuff up. To cover her tracks the minister is now conducting a clearance sale of last year's stock," Mr Dutton said. "Get it out the door, regardless of whether the vaccines are well-targeted or not." If she worked for Myer or David Jones, the minister would be sacked for poor ordering, poor marketing and dismal sales."

Almost 5000 people were admitted to hospital last year suffering from swine flu, and almost 200 died from the disease. The AMA has particularly urged people in high-risk groups, such as indigenous people and pregnant women, to be vaccinated. (3)

### III. National Institutes of Health, USA, Perspectives: Tamiflu Saves Lives!



**Dr. David Morens. Source:**  
<http://web.archive.org/web/20111011030232/http://n...;>  
 accessed January 13, 2010.

**Dr. Anthony Fauci. Source:**  
<http://web.archive.org/web/20111011030232/http://c...;>  
 accessed January 13, 2010.

David Morens, M.D. and Anthony Fauci, M.D., both of the National Institutes of Health, ponder the 2009 H1N1 pandemic. Dr. Morens said the following in a December 28, 2009, article in USA Today:

- This one [2009 H1N1 pandemic] is really different, so different that it's forcing us to confront everything we thought we knew about flu, even a year ago. (Dr. Morens)
- We always thought pandemics were severe. Now we have a pandemic that has proven no more severe than other pandemics [this part of the statement does not make sense to this writer] and in fact, many epidemics of seasonal influenza. (Dr. Morens)
- Tamiflu and other medications have been unsung saviors in the pandemic. Antivirals (Tamiflu) have saved lives. (Dr. Fauci)

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**IV. University of Pennsylvania, USA, Perspective: Make all the Health Care Workers Get the Vaccine and Don't Let Them Have Tamiflu**

**Dr. Ebbing Lautenbach.** Source: <http://web.archive.org/web/2011011030232/http://w...;> accessed January 13, 2010.

Ebbing Lautenbach, M.D., et al. in their article "Initial response of health care institutions to emergency of influenza" (Clinical Infection Diseases, 2010, Volume 50 [4]), declared the following:

- Future efforts to optimize response to H1N1 should include curtailing personal stockpiling of antivirals (Tamiflu).
- Future efforts to optimize response to H1N1 should include mandatory vaccination of health care workers.

**V. European Nations' Perspective: Turn Off the Vaccine Spigot!**

On January 12, 2010, European nations pounced on pandemic vaccine excess because of limited demand (Reuters):

- Governments in rich countries are cutting orders for H1N1 swine flu vaccines because of limited uptake and the fact one dose is enough to protect adults against the virus, rather than two as originally anticipated.
- The reductions mean sales of H1N1 vaccines by companies such as GlaxoSmithKline, Novartis and Sanofi-Aventis may be lower than initially forecast. The cutbacks so far include:
  - GERMANY: GlaxoSmithKline has agreed with the German government to slash the amount of swine flu vaccine it will supply to approximately 70 percent of the original order. This reduces the contract to 34 million doses from 50 million initially ordered.
  - UNITED STATES: The United States says it has halved its order for H1N1 flu vaccine from Australia's CSL, but is not certain how far orders from other suppliers will be trimmed. CSL said the U.S. order was cut partly because the company had diverted some of its early output to the Australian government. Sanofi-Aventis, the largest supplier of flu vaccine to the U.S. market, said it was meeting all its U.S. contracts.
  - FRANCE: France has cancelled 7 million doses of swine flu vaccine from Novartis, just under half the amount ordered, and a further 9 million doses from Sanofi-Aventis. The French government has said it aims to cancel 50 million of the total 94 million doses originally ordered from Sanofi, Novartis and Glaxo.
  - BRITAIN: Britain says it is in talks with its main H1N1 vaccine supplier GlaxoSmithKline about reducing further supplies and might exercise a break clause in its contract with Baxter International.
  - SPAIN: Spain said last month it was negotiating with its main suppliers Novartis and Glaxo about returning excess stocks of H1N1 vaccine.
  - NETHERLANDS: The Dutch government was the first to flag up the vaccine surplus problem, announcing plans in November to sell on up to 19 million of the 34 million doses that it had ordered.
  - BELGIUM: Glaxo said it was negotiating with Belgium about reducing its supply of vaccines.
  - SWITZERLAND: Switzerland plans to donate or sell some 4.5 million excess vaccine doses.

**VI. U.S. Federal Government Perspective: We Can't Be Too Cautious; Keep the Vaccine Coming"**

**Kathleen Sebelius, U.S. Department of Health and Human Services.**  
<http://web.archive.org/web/2011011030232/http://p...;> accessed January 13, 2010.

U.S. Secretary of Health and Human Services Kathleen Sebelius said the following in a January 11, 2010 AP story by Lauran Neergaard titled "Too much flu vaccine? Shot push this week to tell" (6):

U.S. officials say they're deliberately delaying [the decision to unload leftover pandemic H1N1 vaccine] "The danger is in turning off the spigot before we really know what the winter flu season looks like, what the demand is," Health and Human Services Secretary Kathleen Sebelius told the AP. "As long as there is demand, the good news is we will have a supply." More than 60 million people are thought to have been vaccinated so far, and the U.S. is flush enough that Sebelius said the long-promised donation of 25 million doses to developing countries is ready to ship.

Flu vaccine is a balancing act. Every year the nation throws away millions of leftover shots. They actually last well beyond their June 30 expiration dates. But because each year's flu vaccine is a mix of three different strains, with at least one change to the recipe almost every year, leftovers are destroyed to avoid confusion.

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This year is different. The government ordered 250 million doses of swine flu vaccine to be made in bulk, but just over half of it to be put into vials ready to go into people's arms or up their noses. That was a strategic move, because vaccine stored in bulk lasts far longer — meaning leftover bulk antigen could be stored and used as an ingredient in next fall's flu vaccine if it looks like it will be needed again.

In fact, nasal-spray vaccine maker MedImmune already has frozen bulk supplies in anticipation of doing just that. (6)

### VII. Vaccine Maker Perspective: We'll Use the Extra Vaccine in the Next Seasonal Flu Shot

"Because the virus hasn't mutated yet, specialists expect this H1N1 strain to be designated part of next fall's all-in-one vaccine [seasonal flu shot] when regulators meet in February to set the recipe." (6)

### VIII. Council of Europe Perspective: "A Mild Flu and a False Pandemic?"

A January 11, 2010, article titled "Drug companies face European inquiry over swine flu vaccine stockpiles," by James Sturcke and Owen Bowcott reads:

European health chiefs are to hold emergency talks about whether pharmaceutical giants have unduly influenced governments into squandering public money on vast stockpiles of unnecessary [vaccine]. The Council of Europe will debate a resolution that accuses drug companies of leaning on public health officials to alarm governments about the risks of H1N1 flu. The talks, due to be held later this month, come as British ministers decide what to do with a surplus of as many as 20m doses of vaccine ordered at the height of the swine flu outbreak. "The governments have sealed contracts with vaccine producers where they secure orders in advance and take upon themselves almost all the responsibility."



Wolfgang Wodarg. Source: <http://web.archive.org/web/2011011030232/http://w...;> accessed January 13, 2010.

"In this way, the producers of vaccines are sure of enormous gains without having any financial risks. So they just wait, until WHO [World Health Organization] says 'pandemic' and activate the contracts," Wolfgang Wodarg, head of health at the Council of Europe, told the Daily Mail. Wodarg, who proposed the resolution, added that H1N1 virus was "a mild flu and a false pandemic." (7)

### IX. World Health Organization: "Criticism is Part of the Cycle"

A Reuters article by Jonathan Lynn titled, "WHO to review handling of pandemic" (January 12, 2010) says:

The World Health Organisation is to examine its handling of the H1N1 pandemic, the group said on Tuesday, after accusations by some politicians that it exaggerated the dangers of the virus under pressure from drug companies. The United Nations health agency will review the way it dealt with the outbreak of swine flu once the pandemic has subsided, WHO spokeswoman Fadela Chaib told a news briefing. "Criticism is part of an outbreak cycle. We expect and indeed welcome criticism and the chance to discuss it," she said, adding the WHO's review would involve independent outside experts and its results would be made public.



Dr. Margaret Chan, WHO. Source: <http://web.archive.org/web/2011011030232/http://u...;> accessed January 13, 2010.

Fadela Chaib, WHO. Source: <http://web.archive.org/web/2011011030232/http://w...;> accessed January 13, 2010.

But she said it was too soon to say when the examination would take place or which experts would be involved.

In the latest complaint about the way authorities have dealt with the pandemic, the Council of Europe, a political forum of most European countries, is to determine whether drug companies influenced public health officials to spend money unnecessarily on stockpiles of H1N1 vaccines. Chaib said the WHO took its work of providing independent advice to its 193 member states seriously, and guarded against the influence of vested interests.

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Several countries are cutting back orders for H1N1 vaccines as it becomes clear that the outbreak, declared a global pandemic by the WHO in June, is not as severe as at first feared. Governments will have an opportunity to question the WHO about H1N1 at a meeting of its 34-member board next week. The WHO's top flu expert, Keiji Fukuda, will brief the board on Jan. 18 about the latest developments in the first influenza pandemic in more than 40 years.

Developing countries still lack adequate access to both antivirals and vaccines despite donations from industrialised countries and drug makers, the WHO said. Some 200 million doses of H1N1 vaccine and funding of some \$12 million have been pledged to date, it said in a document prepared for the board. "Significant progress in international solidarity has been achieved, through donations by developed countries and manufacturers, but overall access to antiviral medicines and vaccines in developing countries remains limited," it said.

GlaxoSmithKline, Novartis and Sanofi-Aventis are among H1N1 vaccine producers. The WHO last week delivered donated H1N1 vaccine to Mongolia and Azerbaijan, the first of 95 developing and middle-income countries targeted to receive supplies. It aims to provide these countries with enough vaccine to cover 10 percent of their populations, with health care workers a top priority. The WHO said last week that southern hemisphere countries struck by H1N1 last year are now broadly protected against new infections, and sickness levels are declining in much of the northern hemisphere, including North America where it first emerged last April. According to lab-confirmed cases, swine flu has killed at least 12,799 people, but the real toll is much higher and will take several years to establish, the WHO says.

### Notes:

1. The website of PAHO is at <http://web.archive.org/web/2011011030232/http://n...>; accessed January 12, 2010. The country membership of the PAHO is available there.
2. Australian "Federal Parliament." Available at <http://web.archive.org/web/2011011030232/http://a...>; accessed January 13, 2010.
3. Jodie Minus: "Inquiry call for swine flu vaccine rollout." The Australian. January 7, 2010. Available at <http://web.archive.org/web/2011011030232/http://w...>; accessed January 13, 2010.
4. Clinical Infectious Diseases article is available at <http://web.archive.org/web/2011011030232/http://w...>; accessed January 13, 2010.
5. Reuters article is available at <http://web.archive.org/web/2011011030232/http://w...>.
6. AP article is available at <http://web.archive.org/web/2011011030232/http://a...>; accessed January 12, 2010.
7. Council of Europe article is available at <http://web.archive.org/web/2011011030232/http://w...>; accessed January 12, 2010.



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