

UNIVERSITY OF MASSACHUSETTS BOSTON

**QUESTIONING THE LEGITIMACY OF THE WORLD HEALTH
ORGANIZATION DECLARATION OF THE H1N1 INFLUENZA
PANDEMIC OF 2009**

**MASTER'S DEGREE CAPSTONE PAPER
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIRMENTS
FOR THE DEGREE OF MASTER OF SCIENCE IN PUBLIC AFFAIRS – INTERNATIONAL RELATIONS**

**DEPARTMENT OF CONFLICT RESOLUTION, HUMAN SECURITY, AND GLOBAL GOVERNANCE
McCORMACK GRADUATE SCHOOL OF POLICY AND GLOBAL STUDIES**

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CONVOCATION JUNE 2011

ABSTRACT:

This paper is an assessment of the 2009 declaration of the H1N1 pandemic by WHO. It argues that it is possible that WHO did not make a legitimate decision in declaring the pandemic. The facts are that WHO did not follow its operating protocol created in 2003. WHO was not transparent in managing conflict of interest among members of its Emergency Committee. WHO took advice from experts of the Emergency Committee in regard to the pandemic while the member's identity was kept secret. WHO did not disclose the conflict of interest of committee members. There were "sleeping contracts" between large pharmaceutical companies and countries government. On these grounds, WHO failed the world in declaring the 2009 H1N1 influenza pandemic.

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To Ben and Berette, my parents

And ye shall know the truth, and the truth shall make you free.

John 8:32 KJV

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INTRODUCTION:

At the end of the 2009 H1N1 influenza pandemic, the world was left with many questions regarding the cause and effect of the pandemic, and whether it truly was a pandemic. In this paper, I will address one of the many questions surrounding that pandemic. Was it legitimate for the World Health Organization (WHO) to declare the H1N1 influenza flu virus a pandemic? I chose to ask this question because global media predicted that the lives of two billion people around the globe would be affected negatively by this pandemic.¹ Prior to this declaration, the world had experienced the 1918 influenza pandemic called ‘The Spanish Flu’. It resulted in some 40 - 50 million deaths, mostly among young people.² More recently, the milder Hong Kong flu pandemic of 1968 resulted in a million deaths worldwide.³ In contrast, the 2009 H1N1 pandemic was neither remotely catastrophic nor severe. On August 10, 2010, at the official end of the pandemic,⁴ it was reported that only 18,449 people died of the H1N1 influenza pandemic worldwide.⁵ With such a huge gap in mortality between the new pandemic and those of the past,

¹Niko Kyriakou, "Swine Flu Didn't Fly," *Huffpost World*. TheHuffingtonPost.com, Inc. January 27, 2010. http://www.huffingtonpost.com/nikod-kyriakou/swine-flu-didnt-fly_b_438783.html (accessed April 16, 2011).

² Marc P. Girard *et al.* eds., "The 2009 A (H1N1) influenza virus pandemic: A review," *Vaccine (Elsevier)* 28 (2010): 4895-4902, quoting Niall P. A. S. Johnson and Juergen Mueller, "Updating the Accounts: Global Mortality of the 1918-1920 "Spanish" Influenza Pandemic." *Bulletin of the History of Medicine* (The Johns Hopkins University Press) 76, no. 1 (2002): 105-115.

³ Global Security.org, "Homeland Security: 1968 Hong Kong Flu," n.d. http://www.globalsecurity.org/security/ops/hsc-scen-3_pandemic-1968.htm (accessed April 18, 2011).

⁴ World Health Organization, "Media centre:H1N1 in post-pandemic period," August 10, 2010. http://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/index.html (accessed May 10, 2011).

⁵ World Health Organization, "Global Alert and Response (GAR): Pandemic (H1N1) 2009 - update 112," August 6, 2010. http://www.who.int/csr/don/2010_08_06/en/index.html (accessed April 17, 2011).

one is left to wonder about the differences among these pandemics. A pandemic is defined as a worldwide epidemic of a disease and it occurs when a new influenza virus appears against which the human population has no immunity.⁶ This paper will investigate the evidence that led WHO to declare the 2009 influenza pandemic. I will argue that given the circumstances surrounding that decision, it was not legitimate for WHO to declare the 2009 H1N1 influenza virus outbreak a pandemic.

In analyzing the facts on the ground before the June 2009 declaration, it is difficult to believe that these facts resulted in the calling for a worldwide pandemic. Some of the main issues that have raised these concerns follow. First, WHO failed to follow its own policies and guidelines in making recommendations about the pandemic.⁷ In 2003, WHO instituted new guidelines for making recommendations regarding worldwide health threats. These guidelines emphasized using systematic reviews and evidence-based research in making recommendations about national and global health interventions.⁸ This was necessary for the regulation of the role of outside experts in developing recommendations⁹ and the legitimacy of its recommendations.¹⁰ Yet, the guidelines were not followed in the events leading to the announcement of the pandemic. Second, the pandemic was declared without transparency in the decision making

⁶ World Health Organization, "Global Alert and Response (GAR): Pandemic preparedness," May 8, 2011. <http://www.who.int/csr/disease/influenza/pandemic/en/> (accessed May 8, 2011).

⁷ World Health Organization, *Guidelines For WHO Guidelines*, Geneva, 2003, 16.

⁸ Andrew D. Oxman, John N. Lavis, and Atle Fretheim, "Use of Evidence in WHO recommendations," *The Lancet* 369 (2007): 1883- 1889.

⁹ *Ibid.*, 1883.

¹⁰ World Health Organization, *Guidelines For WHO*, 16.

process.¹¹ In a critical report, *The handling of the H1N1 pandemic: more transparency needed*, a British Member of Parliament, for the Parliamentary Assembly of the Council of Europe (PACE), Paul Flynn stated that WHO failed to provide clear and transparent standards in their selection of experts to advise them about the pandemic. This lack of transparency generated concern regarding conflict of interest among the members.

Third, a month before the announcement, WHO redefined the meaning of ‘pandemic’.¹² Under the new meaning, a pandemic does not need to cause large numbers of deaths, illnesses, and hospitalizations. Also, with this new definition, a pandemic would only require worldwide distribution and mild severity.¹³ From April 2009, when the virus was first discovered in Mexico, to June 2009, before the declaration of the pandemic, there were only 144 deaths from the H1N1 virus.¹⁴ In comparison, the mildest 20th Century pandemic, named the Hong Kong H3N2 outbreak, killed millions of people worldwide.¹⁵

The new definition of an influenza pandemic created confusion when compared to seasonal influenza.¹⁶ It caused serious disagreement in the science community as to what

¹¹ Paul Flynn, Social, Health and Family Affairs Committee. Parliamentary Assembly of the Council of Europe. *The handling of the H1N1 pandemic: more transparency needed*, (2010), 1-18. http://assembly.coe.int/CommitteeDocs/2010/20100329_MemorandumPandemie_E.pdf.

¹² Flynn, *Handling of the H1N1 pandemic*, 5.

¹³ World Health Organization, *Global Alert and Response (GAR): Pandemic preparedness*, n.d. <http://www.who.int/csr/disease/influenza/pandemic/en/> (accessed April 18, 2011).

¹⁴ Kyriakou, *Swine Flu*.

¹⁵ Global Security, *Hong Kong Flu*.

¹⁶ Peter Doshi, "How should we plan for pandemics? *BMJ* 339 (2009): 603-605.

constitute a pandemic.¹⁷ Fourth, WHO primarily relied on a guideline which was written by a pharmaceutical consultant in making recommendations for the use of vaccine to fight the pandemic.¹⁸ Finally, there were “sleeping contracts” between the pharmaceutical companies and countries governments prior to WHO’s declaration. These contracts would become active upon declaration of a pandemic. As a result of these contracts, the pharmaceutical companies were interested that an outbreak be declared a pandemic.¹⁹

BACKGROUND AND BROADER CONTEXT

It had been the policy of the World Health Organization from 1951 and until recently to solicit expert opinions in the development of their health policy recommendations.²⁰ This method has been the general practice of how WHO sets its health recommendations to assist target populations, healthcare professionals, managers of health facilities (e.g. hospitals) or regions, and public policy makers in member states with their healthcare needs.²¹ These recommendations addressed a wide range of clinical, public health, and health policy topics related to achieving health goals. However, this practice by WHO in setting recommendations for the past 50 years has shown to have limitations. Research has demonstrated that expert opinions can be very

¹⁷ Flynn, *Handling of the H1N1 pandemic*, 1.

¹⁸ Deborah Cohen and Philip Carter, "WHO and the pandemic flu “conspiracies”." *BMJ* 340 (2010): 1274 -1279.

¹⁹ Flynn, *Handling of the H1N1 pandemic*, 13

²⁰ Oxman, *Evidence in WHO recommendations*, 1883.

²¹ *Ibid.*

limited.²² Experts have been known to not use systematic methods in reviewing studies before they make recommendations.²³ As a result, their recommendations frequently fail to reflect the overall summary of the best available evidence of research.²⁴ They also have shown to disagree among themselves about the results of particular research.²⁵

Since 2005, much attention and discussion from the international community have been placed on how to harness health research evidence more effectively in order to achieve the United Nations' millennium development goals as well as national health goals, particularly in low- and middle income countries.²⁶ One important focus in this discussion has been the call to develop mechanisms to support the use of research evidence in developing clinical practice guidelines, health technology assessments, and health policy.²⁷

At a conference at the World Health Assembly in Geneva in May 2005, these discussions and debates culminated in the passage of a two-part resolution that established specific accountabilities for developing mechanisms to support the use of research evidence in

²² Ibid.

²³ Ibid.

²⁴ Ibid.

²⁵ Andrew D. Oxman and Gordon H. Guyatt, "The Science of Reviewing Research." *Annals New York Academy of Sciences* 703 (1993): 123-131.

²⁶ John N Lavis, Andrew D Oxman, Ray Moynihan, and Elizabeth J Paulsen. "Evidence-informed health policy I— Synthesis of findings from a multi-method study of organizations that support the use of research evidence." *Implementation Science*, (2008) 3:53.

²⁷ Ibid.

developing health policy.²⁸ The first part of the resolution called on WHO member states to, “establish or strengthen mechanisms to transfer knowledge in support of evidence-based public health and health-care delivery systems, and evidence-based health-related policies.”²⁹ The second part of the resolution called on WHO's Director-General to “assist in the development of more effective mechanisms to bridge the divide between ways in which knowledge is generated and ways in which it is used, including the transformation of health-research findings into policy and practice.”³⁰

The role of the World Health Organization

According to its Constitution³¹, Article 1, states: “The objective of the World Health Organization... shall be the attainment by all peoples of the highest possible level of health.” (World Health Organization, 1946, 2) WHO is responsible to coordinate and direct international health work and provide technical assistance and aid in emergencies.³² WHO is responsible to inform the public on health matters as it seeks to eradicate epidemic, endemic and other diseases. Indeed, WHO is the international authority on public health recommendations for the 193 affiliated member states.³³ In the light of its overwhelming success regarding the eradication of

²⁸ World Health Assembly, *Resolution 58.34 on the Ministerial Summit on Health Research*, Geneva, World Health Organization, 2005, 141-143.

²⁹ *Ibid.*

³⁰ *Ibid.*

³¹ World Health Organization. *Constitution of the World Health Organization*. New York: World Health Organization, 1946, 1-18.

³² Flynn, *Handling of the H1N1 pandemic*, 7.

³³ *Ibid.*

major human diseases (such as smallpox) and the control of others, WHO has earned the trust from its member states. Furthermore, it is that trust that ensure WHO's recommendations are followed as prescribe to member states.

In terms of pandemic matters, WHO has a governing structure that allows it to efficiently collaborate with its affiliate member states. Its principal governing body is the World Health Assembly which is the supreme decision-making body of WHO.³⁴ It meets in Geneva and is attended by delegations from all member states. Its primary function is to determine the health policies of WHO. The Health Assembly appoints the Director-General and supervises financial policies of WHO.³⁵ It is responsible for approving reports from WHO Executive Board. The WHO Executive Board is composed of 34 members qualified in the field of healthcare and are elected for three-year terms.³⁶

Second, WHO is governed by the Strategic Advisory Group of Experts (SAGE) which serves as the main advisory body for developing policy related to vaccine and immunization for the pandemic.³⁷ SAGE is comprised of 15 members who are appointed for an initial term of three years. SAGE's terms of reference and members are made available through the WHO website. Before their appointments, all members have to sign a declaration of interest with the purpose of excluding conflicts of interest between any of their professional activities and their advisory

³⁴ Ibid

³⁵ Ibid.

³⁶ Ibid

³⁷ Ibid.

function within WHO.³⁸ If members have conflict of interest, they are not allowed to take part in SAGE's meeting or work which would affect that interest.³⁹

Finally, under the provisions of the International Health Regulations (IHR) of 2005,⁴⁰ Article 48, WHO Director-General is allowed to appoint an Emergency Committee for special advice on matters related to acute public health events and emergencies of international concern. In response to cases of swine influenza A (H1N1), reported in Mexico and the United States of America, the Director-General convened a first Emergency Committee meeting on 25 April 2009 to assess the situation and advise her on appropriate responses. Unfortunately, the membership of this Committee was not made public which is against WHO's policy.⁴¹ It was on the advice from this Committee that WHO's Director-General, Dr. Margaret Chan, declared the H1N1 influenza pandemic on 11 June 2009.⁴²

In reporting about the pandemic, WHO described the H1N1 virus as an influenza virus that had never been identified in people before the pandemic.⁴³ Genetic studies and analyses of the virus have shown that it originated from animal influenza viruses.⁴⁴ This explains its

³⁸ Ibid.

³⁹ World Health Organization, *Guidelines For WHO*, 16.

⁴⁰ World Health Organization. *International Health Regulation (2005): Second Edition*. Switzerland: World Health Organization, 2008, 1-74.

⁴¹ World Health Organization. *Preview Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009*. World Health Organization, 2011, 1-33.

⁴² Flynn, *Handling of the H1N1 pandemic*, 8.

⁴³ Flynn, *Handling of the H1N1 pandemic*, 5.

⁴⁴ Ibid.

common denomination as “swine flu”. It is unrelated to the human seasonal H1N1 viruses that have been in general circulation since 1977.⁴⁵ Flynn in his report stated, “This declaration at a very early stage of the event and shortly after the detection of first infections in Mexico in April 2009 was,...only possible because the description of pandemic alert phases was modified by WHO in May 2009, and notably the criteria relating to the severity of the disease removed as a pre-condition ...”⁴⁶

From 2003 to 2009, WHO defined pandemic as “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous numbers of deaths and illness.”⁴⁷ However, in May 2009, WHO defined the pandemic as “ An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity.” The difference here is that the older definition of pandemic emphasized the virus causing an enormous amount of deaths and is highly severe worldwide. In contrast, the new definition only requires a mild severity of the virus worldwide.

This change in definition of the pandemic was problematic because it went against WHO’s 2003 decision making policy to use systematic reviews instead of just using isolated expert opinions. In 2003, WHO adopted a new set of guidelines entitled Guidelines For WHO

⁴⁵ Ibid.

⁴⁶ Ibid.

⁴⁷ Peter Doshi. "How should we plan for pandemics?" BMJ 339 (2009): 603-605, in quoting World Health Organization. Pandemic preparedness, <http://classic-web.archive.org/web/20050207101237/http://www.who.int/csr/disease/influenza/pandemic/en/>.

Guidelines.⁴⁸ It stated, “It is recommended that WHO should follow . . . method of systematic reviews to the extent possible.”⁴⁹ These new guidelines were adopted because of a growing demand for rigorous processes which require decision-making to be based on research evidence.⁵⁰ These new processes are systematic reviews which demand systematic and transparent approaches to access, synthesize, and interpret research evidence. They integrate research based evidence with other information, values, and judgments in order to support policy makers to formulate recommendations or make decisions.⁵¹ In contrast, the traditional approach relies heavily on the opinions of experts and use isolated single study to make decision. This approach can be bias for the fact that it is based on limited research evidence.⁵² I will later explain why this actually did become a problem in the case of H1N1 pandemic and could lead to further problems in the future if this precedent of skipping systematic reviews is not curtailed.

Broader Context and Ramifications of not Holding Protocol

The broader context here is that globally influential organizations such as WHO, International Monetary Fund (IMF) and The World Bank (WB) must preserve trust in their operations throughout the world. These organizations’ very existence is based on their interactive service with member governments and individuals everywhere. When an organization fails to deliver on its promises or gives a false alarm, this leads to a lack of trust. This organization

⁴⁸ World Health Organization, *Guidelines For WHO*, 1-23.

⁴⁹ *Ibid.*

⁵⁰ Lavis, *Use of research evidence*, 3:53.

⁵¹ *Ibid.*

⁵² Oxman, *Evidence in WHO recommendations*, 1883.

becomes less credible in the eyes of the general public who depend on it. In the case of the WHO, it should preserve trust in the process of declaring emergency health warnings to member countries. For example, when the system works properly, emergency health warnings cause member states to respond quickly and appropriately to serious threats. However, when trust is compromised in an organization, this leads to lack of cooperation among the organization and its clients. Thus, it is crucial that WHO determine beforehand whether its decisions are evidence-based thereby following proper protocol and maintaining trust.

When large organizations make decisions outside of their operating protocol, these decisions can be premature with costly consequences. In the case of the pandemic, WHO affiliated member states responded by buying large supply of vaccines to fight off the pandemic. According to estimations by the international investment bank JP Morgan, the sales of H1N1 vaccines in 2009 were expected to result in overall profits of between 7 and 10 billion dollars to pharmaceutical laboratories producing vaccines.⁵³ The issue here is that states bought the supply of vaccines upon the recommendations of WHO, but their population were not as nearly affected by deaths and infectious cases of the pandemic as predicted by WHO. Dr. Wolfgang Wodarg, a medical expert specializing in epidemiology and former Chair of the PACE Sub-committee on Health, at a public hearing on "The handling of the H1N1 pandemic: more transparency needed", in Strasbourg on 26 January 2010, stated "We were told this was a 'flu which would threaten humanity, and millions would fall ill. This is why millions of dollars of medications were bought. The WHO basically held the trigger for the pandemic preparedness plans; they had a key

⁵³ Flynn, *Handling of the H1N1 pandemic*,14.

role to play in deciding on the pandemic. Around 18 billion dollars was spent on this pandemic worldwide.”⁵⁴

At that hearing, many doubts were raised about WHO’s handling of the pandemic. WHO’s public reputation and trust were tarnished. Some like Paul Flynn have questioned WHO and stated, “The world has been frightened by a series of health scares – SARS, Avian ‘Flu and now Swine ‘Flu. We now know, in hindsight, that the fears that were aroused do not appear to be justified. So we want to know how decisions on pandemics are taken – are they taken on the best scientific, epidemiological evidence, or are they influenced by other interests? That is the basis of this complaint. With H1N1, did the WHO, once again, frighten the world without any substantial evidence?”⁵⁵ Others, Dr. Ulrich Keil, Director of the WHO Collaborating Centre for Epidemiology at the University of Munster, stated, “We are witnessing a gigantic misallocation of resources in terms of public health. Governments and public health services are wasting huge amounts of money in investing in pandemic diseases whose evidence base is weak.”⁵⁶

Given this taint to its reputation, it is critical to determine whether the declaration of the pandemic itself was legitimate. In that, whether systematic reviews were applied and followed for evidence leading to the declaration. I will go on to explain why it is so vital for WHO to use this rigorous process to authenticate its recommendations and in that they will regain the trust that they once had.

⁵⁴ Parliamentary Assembly Council of Europe. Extracts of statements made by the leading participants at the public hearing on "The handling of the H1N1 pandemic: more transparency needed?", January 26, 2010. <http://assembly.coe.int/ASP/APFeaturesManager/defaultArtSiteView.asp?ID=900> (accessed May 14, 2011).

⁵⁵ Ibid

⁵⁶ Ibid

THEORETICAL /CONCEPTUAL PERSPECTIVES: REVIEW OF THE LITERATURE

Given what I have stated earlier regarding the limitations of experts opinions and single isolated studies, WHO decided in 2003 to change and create new guidelines entitled *Guidelines For WHO Guidelines*. These guidelines recommended WHO to be more thorough and systematic in its decision making process.⁵⁷ The guideline stated, “Evidence should be gathered in a systematic process to avoid or minimize bias. It is recommended that WHO should follow the Cochrane method of systematic reviews to the extent possible.”⁵⁸

This recommendation was necessary in order for WHO to alleviate bias in its decision making process. In WHO’s guidelines, evidence means empirical data derived from formal research or systematic investigation, using any type of science or social science methods.⁵⁹ The concept of systematic reviews is critical in scientific determination and public policy setting. According to Cynthia D. Mulrow, Associate Professor at the University of Texas Health Science Center, Divisions of General Medicine and Geriatrics, in San Antonio, Texas, systematic reviews, “Establish whether scientific findings are consistent and can be generalized across populations, settings, and treatment variations, or whether findings vary significantly by

⁵⁷ World Health Organization, *Guidelines For WHO*. 1-23

⁵⁸ World Health Organization, *Guidelines For WHO*, 6.

⁵⁹ Lucie Rychetnik, Michael Frommer, Penelope Hawe, and Alan Shiell. "Criteria for evaluating evidence on public health interventions." *Journal of Epidemiology and Community Health* 56 (2002): 119–127.

particular subsets.”⁶⁰ Mulrow makes this point to emphasize the reliability and accuracy of using systematic reviews as an efficient tool to make recommendations rather than using a single study.⁶¹ That is, using a single study, a policy maker or expert would be less accurate at making recommendation. Starting in 2003 WHO sought in its protocol to use systematic reviews as a method to ensure the credibility of its recommendations to its clients, policy makers, and government officials.

Mulrow explains that systematic reviews are well established in the scientific community.⁶² Given that health care providers, researchers, and policy makers are overwhelmed with new information in their respected field, they need systematic reviews to efficiently help them to integrate existing information with the new information. They need these reviews for rational decision making.⁶³ Mulrow states that systematic reviews are based on eight premises. First, systematic reviews allow large quantities of information to reduce into palatable pieces for digestion. An estimated of two millions articles are published annually in the biomedical literature in over 20,000 journals.⁶⁴ Through critical examination, evaluation, and synthesis, systematic reviews separate the insignificant, unsound, or redundant literature from the salient and critical studies that are worthy of reflection.⁶⁵ Secondly, decision and policy makers have great need to integrate the critical pieces of biomedical information to estimate the variables and

⁶⁰ Cynthia D. Mulrow, “Rationale For Systematic Reviews.” *British Medical Journal* 309 (1994): 597-599.

⁶¹ *Ibid*, 597.

⁶² *Ibid*.

⁶³ *Ibid*.

⁶⁴ *Ibid*.

⁶⁵ *Ibid*

outcomes in their studies. These reviews help them to identify, justify, and refine hypotheses. The reviews help researchers and policy makers to recognize and avoid pitfalls of previous work. They help researchers to estimate sample sizes. These reviews help health policy makers to formulate guidelines and legislation concerning the use of diagnostic tests and treatment strategies.⁶⁶

Thirdly, systematic reviews are an efficient scientific technique. Although sometimes arduous and time consuming, a review is usually quicker and less costly than embarking on a new study. Fourth, generalization of scientific findings can be established in systematic reviews. The diversity of multiple reviewed studies provides an interpretive context not available in any one study. Fifth, systematic reviews assess the consistency of relationships. That is, it assess whether research evidences are in the same directions and of the same general magnitudes. More specifically, systematic reviews can determine consistency among studies of the same intervention or even among studies of different interventions.⁶⁷

Sixth, systematic reviews are able to explain data inconsistencies and conflicts in data. Whether a treatment strategy is effective in one setting and not in another or among certain subjects can be assessed. Seventh, an often cited advantage of quantitative systematic reviews in particular is increased power. Quantitative reviews or meta-analysis have been likened to "a tower of statistical power" that allow researchers to rise above the body of evidence, survey the landscape, and map out future directions. Finally, Mulrow's eighth premise is that quantitative

⁶⁶ Ibid.

⁶⁷ Ibid, 598.

systematic reviews allow increased precision in estimating the risk or effect of size. In all, Mulrow finds it important that systematic reviews are critical to public policy recommendation due to the fact that systematic reviews limit bias and improve the reliability and accuracy of recommendations.⁶⁸

The Cochrane Method

Early in WHO's Practice Guidelines⁶⁹ establishing their future protocol in 2003, WHO leaders recognized the need for much stricter guidelines:

“The demand for guidelines has contributed to the development of improved methodologies for basing guidelines on the most rigorous science available...key steps, which have been identified, are: selection of the topic, synthesis of evidence, formulation of recommendations, consultation and peer review, dissemination and implementation, review and updating.”⁷⁰

WHO chose the Cochrane method of systematic reviews in order to assure that evidence for its recommendations was more accurate and reduced the possibility of bias.⁷¹ The Cochrane reviews are rigorous in prescribing policy makers accurate information. They were created in

⁶⁸ Ibid, 599.

⁶⁹ World Health Organization, *Guidelines For WHO*, 2.

⁷⁰ Ibid.

⁷¹ Ibid,6.

1993 by the Cochrane Collaboration, in Oxford, England.⁷² The Collaboration has more than 10,000 people from more than 80 countries contributing to its work.⁷³ Its mission is, "to help people make well-informed decisions about health care by preparing, maintaining and promoting the accessibility of systemic reviews of the effects of healthcare interventions."⁷⁴

The Cochrane Collaboration published the *Cochrane reviewers' handbook glossary* (date??) in which it defines systematic reviews as follows:

A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made (Antman 1992, Oxman 1993). The key characteristics of a systematic review are:

- a clearly stated set of objectives with pre-defined eligibility criteria for studies;
- an explicit, reproducible methodology;
- a systematic search that attempts to identify all studies that would meet the eligibility criteria;
- an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and

⁷² Jimmy Volmink, Nandi Siegfried, Katharine Robertson, and A. Metin Gülmezoglu, "Research synthesis and dissemination as a bridge to knowledge management: The Cochrane Collaboration." *Bulletin of the World Health Organization* 82 (2004): 778-783.

⁷³ *Ibid.*, 778.

⁷⁴ *Ibid.*

- a systematic presentation, and synthesis, of the characteristics and findings of the included studies.

Many systematic reviews contain meta-analyses. Meta-analysis is the use of statistical methods to summarize the results of independent studies (Glass 1976). By combining information from all relevant studies, meta-analyses can provide more precise estimates of the effects of health care than those derived from the individual studies included within a review (see Chapter 9, Section [9.1.3](#)). They also facilitate investigations of the consistency of evidence across studies and the exploration of differences across studies.⁷⁵

The steps involved in preparing a systematic review are as follows: (Fig 1)⁷⁶

Box 1. Steps involved in preparing a systematic review

1. State the objectives of the review
2. Define the eligibility criteria for including studies
3. Identify all potentially eligible studies
4. Apply the pre-specified eligibility criteria
5. Assess the quality of included studies
6. Assemble the most complete dataset feasible
7. Analyse this dataset using statistical synthesis (meta-analysis) and sensitivity analysis, if appropriate and possible
8. Prepare a structured report of the research

⁷⁵ Julian PT Higgins and Sally Green, "Cochrane Handbook for Systematic Reviews of Interventions," Version 5.1.0, The Cochrane Collaboration, 2011. March 2011. <http://www.cochrane-handbook.org/> accessed May 15, 2011).

⁷⁶ Volmink, *The Cochrane Collaboration*, 779.

The Cochrane Collaboration has provided a distinct global infrastructure for preparing and maintaining systematic reviews.⁷⁷ Cochrane systematic reviews focus on the benefits and risks of health-care interventions. In an article in the *Journal of Epidemiology and Community Health*, Lucie Rychetnik, from the School of Population Health and Health Services Research, University of Sydney, and others, defined intervention as, “a set of actions with a coherent objective to bring about change or produce identifiable outcomes.”⁷⁸ Thus systematic reviews prescribe to policy makers what action they should take in deciding on intervention for a particular outbreak.

Systematic reviews follow a set format. They undergo extensive peer review. They are published electronically in the Cochrane library and are updated periodically.⁷⁹ In the myriad of health information available in print and electronic media, much of which is of poor quality, Cochrane reviews represent an excellent source of reliable evidence for health policy recommendations. Such resource provides a secure foundation for informing the decision made by health-care providers, policy makers, researchers, and consumers than do traditional reviews or consensus statements by experts.⁸⁰

⁷⁷ Ibid.

⁷⁸ Lucie Rychetnik, Michael Frommer, Penelope Hawe, and Alan Shiell. "Criteria for evaluating evidence on public health interventions." *Journal of Epidemiology and Community Health* 56 (2002): 119–127.

⁷⁹ Ibid

⁸⁰ Volmink, *The Cochrane Collaboration*, 779, quoting Les M. Irwig, Merrick Zwarenstein, Anthony B. Zwi, and Iain Chalmers. "A flow diagram to facilitate selection of interventions and research for health care." *Bulletin of the World Health Organization* 76 (1998): 17-24.

According to John Lavis and Francisco B. Posada, and others writing in the *Lancet* journal,⁸¹ the importance of systematic reviews is also to improve health and reduce health inequalities of people around the world.⁸² The task of public policy makers is to find the best solutions to health problems and fit these solutions into complex and overstretched health systems.⁸³ In the article, Lavis and others argue that policy makers need to bring changes in these complex health systems. The way they can make these changes is to provide research-based answers to questions. Policy makers are encouraged to seek systematic reviews on important issues and commissioning reviews when none exists. Finally, the salient point of this article was that policy makers need to place more value on such work in their deliberations and in their interactions with stakeholders rather than relying on a single study of an expert.⁸⁴

Lavis and others make the point that systematic reviews support public policy makers in two major ways.⁸⁵ First, systematic reviews reduce bias in the estimation of the effectiveness of an intervention. Systematic reviews help to identify all reported and unreported studies that address the research question. They help select studies that meet explicit criteria, by appraising the quality of the studies using explicit criteria, and by synthesizing the study results with a

⁸¹ John N Lavis, Francisco Becerra Posada, Andy Haines and Eric Osei, "Use of research to inform public policymaking," *The Lancet*, 2004: 1615-1621.

⁸² *Ibid*, 1615.

⁸³ *Ibid*.

⁸⁴ *Ibid*.

⁸⁵ *Ibid*.

transparent process.⁸⁶ The likelihood that public policymakers will be misled by research is lower with systematic reviews than with individual studies.⁸⁷

Second, systematic reviews reduce the role that chance has in estimating the effectiveness of recommendations. This happens by the fact that systematic reviews increase the number of units for study, and thereby provide more precise estimates of effect.⁸⁸ This sometimes results in even better estimation of effectiveness of an intervention in specific subgroups. In this Lancet article by Lavis and others, I concur with the conclusion that the public and policymakers are to be more confident about the outcome of a health intervention when systematic reviews are used and applied.⁸⁹

In another article in the *Journal of Health Services Research & Policy*, John Lavis and Huw Davies and others explain the advantages of systematic reviews to prospective clients.⁹⁰ First, systematic reviews answer questions about ‘what works.’⁹¹ The possibility of being misled by research evidence is lower with a systematic review than with an individual study.⁹² Second, confidence in what can be expected from an intervention is higher with a systematic review than

⁸⁶ Ibid.

⁸⁷ Ibid, 1615.

⁸⁸ Ibid, 1616.

⁸⁹ Ibid, 1620,1621.

⁹⁰ John Lavis, Huw Davies, Andy Oxman, Jean-Louis Denis, Karen Golden-Biddle and Ewan Ferlie. "Towards systematic reviews that inform healthcare management and policy-making." *Journal of Health Services Research & Policy* 10 (2005): 35–48.

⁹¹ Ibid, 35.

⁹² Matthias Egger, George Davey Smith, and Douglas G. Altman. *Systematic reviews in health care. Meta-analysis in context*. London: BMJ Books, 2001.

with an individual study.⁹³ Third, making recommendations from an existing systematic review is more efficient than individual research of literature. In researching the literature, one struggles with appraising the quality of the research. This process is more effective and transparent using systematic reviews.⁹⁴ Fourth, a systematic review can be more constructively contested than an individual study. The transparency in each phase of a systematic review enables disputes to be focused on the decisions made in each phase of a review as well as on the applicability of the review in different contexts.⁹⁵

Criteria for Evaluating Evidence

Rychetnik and peers argued that public health interventions are complex, programmatic and context dependent.⁹⁶ The evidence for their effectiveness must be comprehensive to encompass that complexity. They stated that public health interventions need to be adequately appraised by established criteria in order to judge the effectiveness of evidence in clinical setting. The evaluation of evidence through the use of systematic reviews must enable the detection of the success or failure of an intervention.⁹⁷

⁹³ Ibid.

⁹⁴ Lavis, *Towards systematic reviews*, 36.

⁹⁵ Ibid.

⁹⁶ Lucie Rychetnik, Michael Frommer, Penelope Hawe, and Alan Shiell. "Criteria for evaluating evidence on public health interventions." *Journal of Epidemiology and Community Health* 56 (2002): 119–127.

⁹⁷ Lucie Rychetnik, Michael Frommer, Penelope Hawe, and Alan Shiell. "Criteria for evaluating evidence on public health interventions." *Journal of Epidemiology and Community Health* 56 (2002): 119–127.

Elizabeth Waters Professor E Waters, from the School of Health and Social Development, Faculty of Health and Behavioral Sciences, Deakin University, Australia wrote that public health decision makers, funders, practitioners, and the public are interested in the evidence that underpins public health decision making. Decisions in public health cover a vast range of activities. With the ever increasing global volume of primary research, quality systematic reviews of all the available research that is relevant to a particular practice or policy decision are an efficient way to synthesize and utilize research efforts. Waters makes the point that the Cochrane method of systematic reviews aims to increase and support the quality and quantity of public health recommendations.⁹⁸ Furthermore, she stated that the methods used to provide evidence of effectiveness must be sufficiently comprehensive to encompass the complexity of public health interventions.⁹⁹

CRITICAL ANALYSIS OF WHO'S PANDEMIC DECLARATION

In the case of H1N1 pandemic of 2009, the events that led to its declaration are as followed. In the spring of 2009, a new type of influenza virus, never before linked to human disease, emerged and rapidly spread throughout the world. The novel strain of influenza virus A (H1N1) causing the pandemic was identified on 23 April, 2009, after outbreaks of the deadly

⁹⁸ Elizabeth Waters, Jodie Doyle, Nicki Jackson, Faline Howes, Ginny Brunton, and Ann Oakley. "Evaluating the effectiveness of public health interventions: the role and activities of the Cochrane Collaboration." *Journal of Epidemiol Community Health* 60 (2006): 285–289.

⁹⁹ *Ibid.*

“swine flu” were reported in Mexico.¹⁰⁰ Additional cases of the illness began appearing in the U.S., and individuals were soon confirmed to be infected by the same viral strain as the patients in Mexico. The new virus was infecting large numbers of people and was highly transmissible between humans.¹⁰¹ During the initial phases of the H1N1 influenza, infections were reported in 9 countries on 29 April 2009. Later, more cases were confirmed in 74 countries and territories around the world. It was this global spread which led WHO to declare increasing phases of pandemic emergency from level 4 which means “Evidence of Increased Human-to-Human Transmission” and to Phase 5 which means “Evidence of Significant Human-to-Human Transmission,”¹⁰² and inform the world that a pandemic was in progress. On 11 June 2009, WHO thus officially declared the situation as pandemic influenza phase 6.¹⁰³

1. Lack of evidence for the pandemic

In assessing the evidence prior to the declaration, it is important to note that WHO’s policy set in 2003 recommended that its evidence has to be gathered in a systematic fashion to minimize the possibility of bias and that WHO should follow the Cochrane method.¹⁰⁴ That is, evidence cannot be based on a single study or experts opinions. They need to fit pre-specified eligibility

¹⁰⁰ Mary Chang, Catherine Southard, and Maura Sullivan. Learning from the 2009 H1N1 Influenza Pandemic. *RMS*, 2010, 1-23.

¹⁰¹ *Ibid*,4.

¹⁰² *Ibid* ,5.

¹⁰³ World Health Organization. Media centre: World now at the start of 2009 influenza pandemic. June 11, 2009. http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html (accessed May 11, 2011).

¹⁰⁴ World Health Organization, *Guidelines For WHO*, 6.

criteria which improve the basis for making decisions on generalization over a population.¹⁰⁵

Rychetnik makes the point that evidence is an empirical data derived from formal research or systematic investigation, using any type of science or social science methods. According to the Cochrane method recommended by WHO, it defines evidence as empirical data that fits pre-specified criteria in order to answer a specific research question.

It follows then, was there evidence for WHO to raise the H1N1 influenza outbreak to a full scale global pandemic on June 11, 2009? Given that the outbreak was first reported in Mexico on 23 April 2009, one week after on 29 April 2009 WHO declared a phase 5 pandemic alert. WHO stated, “Based on assessment of all available information, and following several expert consultations, I have decided to raise the current level of influenza pandemic alert from phase 4 to phase 5... All countries should immediately activate their pandemic preparedness plans. Countries should remain on high alert for unusual outbreaks of influenza-like illness and severe pneumonia... This change to a higher phase of alert is a signal to governments, to ministries of health and other ministries, to the pharmaceutical industry and the business community that certain actions should now be undertaken with increased urgency, and at an accelerated pace.”¹⁰⁶

It is important to note that level 5 means the highest threat level short of global pandemic.¹⁰⁷ Epidemiological information at that time was mixed, suggesting a severe disease in Mexico but

¹⁰⁵ *Ibid*, 6.

¹⁰⁶ World Health Organization. Media Center: Influenza A(H1N1). April 29, 2009. http://www.who.int/mediacentre/news/statements/2009/h1n1_20090429/en/index.html (accessed May 15, 2011).

¹⁰⁷ Doshi, *Plan for pandemics*, 603

mild everywhere else.¹⁰⁸ Given these facts, the issue is whether WHO had followed its protocol of using evidence gathered in a systematic fashion to minimize bias? Second, whether the evidence they had can be generalized over a population. The answers to these questions are best answered using systematic reviews. It was reported on March 18, 2011 that Nick Royle, Chief Executive Officer of the Cochrane Collaboration, stated that the experts who advised Dr. Chan had no experience with conducting systematic reviews.¹⁰⁹ In that, given the lack of data suggesting a severe spread of the disease worldwide, and the lack of use of systematic reviews by the experts for the pandemic, it is likely that the experts were bias and ill-advised in not following WHO's protocol. As such, Dr. Chan might have erred in declaring the pandemic alert to a phase 5 within a week of its initial appearance.

On June 11, 2009 when WHO made the announcement of the outbreak from level 5 to level 6, which means a full scale global pandemic, there was insufficient evidence that the cases and amount of death were sufficient to warrant the pandemic.¹¹⁰ Evidence that the virus could cause high mortality was nominal, as the pattern of morbidity and mortality that emerged was akin to a seasonal flu strain of mild to moderate virulence.¹¹¹ In the US, the Center for Disease Control and Prevention (CDC) reported an estimated between about 8,720 and 18,050 2009 H1N1-

¹⁰⁸ Ibid.

¹⁰⁹ Royle, Nick. "The Cochrane Collaboration." Influencing World Health Organization policy. March 18, 2011. <http://www.cochrane.org/about-us/relations-world-health-organization/influencing-world-health-organization-policy> (accessed May 11, 2011).

¹¹⁰ Chang, *2009 H1N1 Influenza Pandemic*, 5.

¹¹¹ Ibid.

related deaths occurred between April 2009 and March 13, 2010. The mid-level in this range is about 12,270 2009 H1N1-related deaths.¹¹² Please see figure 2 for the breakdown by category CDC Estimates of 2009 H1N1 Cases and Related Hospitalizations and Deaths from April 2009 through March 13, 2010, by age group.¹¹³ In Europe, figures from the Stockholm based European Centre for Disease Prevention and Control (ECDC), showed the H1N1 flu caused about 3000 deaths in Europe in 2009.¹¹⁴

¹¹² Centers for Disease Control and Prevention. Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009 – April 10, 2010. May 14, 2010. http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm (accessed May 16, 2011).

¹¹³ Ibid.

¹¹⁴ European Centre for Disease Prevention and Control. Mortality from influenza: Mortality from influenza: Comparing deaths from seasonal and pandemic influenza. n.d. http://ecdc.europa.eu/en/healthtopics/H1N1/basic_facts/Pages/mortality_from_influenza.aspx (accessed May 16, 2011).

Table 1

CDC Estimates of 2009 H1N1 Cases and Related Hospitalizations and Deaths from April 2009 through March 13, 2010, By Age Group

2009 H1N1	Mid-Level Range*	Estimated Range*
Cases		
0-17 years	~19 million	~14 million to ~28 million
18-64 years	~35 million	~25 million to ~51 million
65 years and older	~6 million	~4 million to ~9 million
Cases Total	~60 million	~43 million to ~88 million
Hospitalizations		
0-17 years	~86,000	~61,000 to ~127,000
18-64 years	~158,000	~112,000 to ~232,000
65 years and older	~26,000	~19,000 to ~39,000
Hospitalizations Total	~270,000	~192,000 to ~398,000
Deaths		
0-17 years	~1,270	~900 to ~1,870
18-64 years	~9,420	~6,700 to ~13,860
65 years and older	~1,580	~1,120 to ~2,320
Deaths Total	~12,270	~8,720 to ~18,050

* Deaths have been rounded to the nearest ten. Hospitalizations have been rounded to the nearest thousand and cases have been rounded to the nearest million. Exact numbers also are available on the CDC website.

In contrast from the numbers from Table 1, in the US, the CDC estimates that seasonal flu deaths from the 1976-1977 to 2006-2007 flu season ranged from a low of about 3,000 to a high of about 49,000 people.¹¹⁵ Furthermore, in Europe, it is estimated that seasonal flu kills about 40, 000 people in a moderate year and 220,000 in a particularly severe season.

Given that fewer people have died from the 2009 influenza pandemic than from ordinary seasonal influenza,¹¹⁶ this has led members of the scientific community to become concerned

¹¹⁵ Centers for Disease Control and Prevention. Seasonal Influenza (Flu):Questions & Answers:Estimating Seasonal Influenza-Associated Deaths in the United States: CDC Study Confirms Variability of Flu . February 8, 2011. http://www.cdc.gov/flu/about/disease/us_flu-related_deaths.htm (accessed May 16, 2011).

¹¹⁶ European Centre for Disease Prevention and Control, *Mortality from influenza*.

when WHO rapidly moved towards pandemic level 6 at a time when the influenza presented relatively mild symptoms.¹¹⁷ This combined with the change in the definition of pandemic levels in May 2009, just only a month before the declaration of the H1N1 pandemic, heightened concerns. Dr. Wolfgang Wodarg, at the public hearing in Strasbourg on 26 January 2010, stated the declaration of the current pandemic was only made possible by changing the definition of a pandemic and by lowering the threshold for its declaration.¹¹⁸

2. Lack of transparency

According to the IHR of 2005,¹¹⁹ Article 48, Dr. Chan can appoint an Emergency Committee for special advice on matters related to acute public health events and emergencies of international concern. However, the membership of this Committee was to be public. According to the IHR review of the pandemic, it stated:

WHO should clarify its standards and adopt more transparent procedures for the appointment of members of expert committees, such as the Emergency Committee, with respect to potential conflicts of interest. The identity and relevant background, experience

¹¹⁷ Flynn, *Handling of the H1N1 pandemic*, 9.

¹¹⁸ Flynn, *Handling of the H1N1 pandemic*, 9.

¹¹⁹ World Health Organization. *International Health Regulation (2005): Second Edition*. Switzerland: World Health Organization, 2008, 1-74.

and relationships of Emergency Committee members should be publicly disclosed at the time of their proposed appointment, with an opportunity for public comment.¹²⁰

In the event leading to the 2009 pandemic, WHO did not revealed the identity of the members of the Emergency Committee whose role were to guide WHO on its policy regarding the beginning and end of the pandemic in 2009.¹²¹ This committee became secret to the public.¹²² This was against WHO's policy. As result of this, grave deficiencies have been identified regarding the transparency of decision-making processes relating to the pandemic. They have generated concerns about the possible influence of the pharmaceutical industry on some of the major decisions relating to the pandemic.¹²³ This lack of transparency if it continues, it will result in a low level of trust in the advice given by major public health institutions. This may prove to be a dangerous scenario in the case of the next disease of pandemic proportion and which may turn out to be much more deadly than the H1N1 pandemic.¹²⁴

In reviewing the pandemic, IHR noted that WHO failed to make public the conflict of interest of the members of the Emergency Committee. IHR noted this shortcoming as follow:

Lack of a sufficiently robust, systematic and open set of procedures for disclosing, recognizing and managing conflicts of interest among expert advisers. In particular,

¹²⁰ Ibid, 20.

¹²¹ Flynn, *Handling of the H1N1 pandemic*,8.

¹²² Cohen, *WHO and the pandemic flu*, 1278.

¹²³ Flynn, *Handling of the H1N1 pandemic*,8.

¹²⁴ Ibid,1.

potential conflicts of interest among Emergency Committee members were not managed in a timely fashion by WHO. Five members of the Emergency Committee and an Adviser to the Emergency Committee declared potential conflicts of interest. None of these were determined sufficiently important to merit the members' exclusion from the Emergency Committee. The relationships in question were published, along with the names of the members of the Emergency Committee, when the pandemic was declared over on 10 August 2010. Before this information was published, however, assumptions about potential ties between Emergency Committee members and industry led some to suspect wrongdoing. The Review Committee recognizes that WHO is taking steps to improve its management of conflicts of interest, even as this review has proceeded.¹²⁵

This affirmation of WHO's wrongdoing by IHR strengthens the case that WHO did not follow protocol. It undermines WHO's decision making process and generates undue possibility of influence of the pharmaceutical industry. It follows that, the affirmation of WHO's wrongdoing and the secrecy of the committee, gave life to conspiracy theories, particularly around the activation of dormant pandemic vaccine contracts.¹²⁶ A key question will be whether the pharmaceutical companies, which had invested around \$4bn in developing a vaccine, had supporters inside the emergency committee, who then put pressure on WHO to declare a

¹²⁵ World Health Organization, *Preview Report of the International Health Regulations*, 16.

¹²⁶ Cohen, *WHO and the pandemic flu*, 1279.

pandemic.¹²⁷ After all, it was the declaration of the pandemic that triggered the activation of vaccine contracts.

In his report to the Parliamentary Assembly of the Council of Europe, Paul Flynn named in the report as rapporteur describes the issue of sleeping contracts as followed:

Another factor which nurtured suspicions about undue influence was that the pharmaceutical companies had a strong vested interest in the declaration of a pandemic and subsequent vaccination campaigns. This interest arose partly from early contractual arrangements regarding any new influenza pandemic (some were concluded between member states and pharmaceutical groups in the period 2006/2007 just after the avian flu scare). Various European countries signed so-called “sleeping contracts” with large pharmaceutical groups which were supposed to take effect on the declaration of a pandemic by WHO. Whilst this anticipation of a major public health event by governments and pharmaceutical groups could be generally welcomed, ...there is evidence of doubtful commercial practices followed by some industrial groups. The rapporteur refers in particular to pressure exerted on national governments to activate “sleeping contracts” after very short delays of reflection (using the argument of “first come – first served”) and the attempt to transfer the main responsibility for side-effects of vaccines to the governments themselves.¹²⁸

¹²⁷ Ibid.

¹²⁸ Flynn, *Handling of the H1N1 pandemic*,5.

3. Protocol not followed

In my final assessment of the evidence that led to the declaration of the pandemic, I will argue that WHO did not follow its operating protocol which recommended the use of systematic reviews in developing its health policy recommendation. On 11 June 2009, Dr. Margaret Chan, the Director General of WHO, announced to the world's media:

I have conferred with leading influenza experts, virologists, and public health officials. In line with procedures set out in the International Health Regulations, I have sought guidance and advice from an Emergency Committee established for this purpose. On the basis of available evidence, and these expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met. I have therefore decided to raise the level of influenza pandemic alert from phase 5 to phase 6. The world is now at the start of the 2009 influenza pandemic.¹²⁹

From this announcement, the pandemic started; however, it did not mention systematic reviews as a source of authentication for this major international health policy recommendation. In 2003, WHO had specifically chosen the Cochrane method to assure that evidence for its recommendations were accurate and limited of any bias.¹³⁰ The Cochrane reviews are rigorous and sound in answering specific question for policy makers. The maker of these reviews is the Cochrane Collaboration. The Collaboration is an international organization that produces

¹²⁹ World Health Organization. *Start of 2009 influenza pandemic*.

¹³⁰ *Guidelines For WHO*, 6.

systematic reviews and meta-analyses of health care interventions.¹³¹ The Collaboration is well placed to contribute in evaluating and summarizing existing evidence about vaccines and antivirals.¹³² The Collaboration works with WHO in identifying, appraising and evaluating the best available evidence for decision making.¹³³

In early March 2011, Nick Royle, CEO of the Collaboration, was invited to comment on a report by WHO entitled *Preview Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009*.¹³⁴ The report summarized the conclusions and recommendations of the IHR Review Committee, who were commissioned to review WHO's response to the H1N1 pandemic.¹³⁵ This report will later be presented to the World Health Assembly, in May 2011.

Mr. Royle stated that WHO failed to appoint members of the Emergency Committee with experience with systematic reviews.¹³⁶ That is, the members of the Emergency Committee did not have the experience to conduct the necessary systematic reviews of the evidence of the pandemic. These experts relied on their expertise to advise Dr. Chan regarding the H1N1

¹³¹ Nick Royle, "The Cochrane Collaboration: Influencing World Health Organization policy." March 18, 2011. <http://www.cochrane.org/about-us/relations-world-health-organization/influencing-world-health-organization-policy> (accessed May 11, 2011). The Collaboration's full response to the Preview Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009.

¹³² Ibid

¹³³ Ibid

¹³⁴ World Health Organization, "Preview Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009," World Health Organization, 2011.

¹³⁵ Royle, *Influencing World Health Organization policy*.

¹³⁶ Ibid.

outbreak. This method in the past has proven to be ineffective and limited in developing policy recommendations.¹³⁷ Given that these opinions were not within systematic reviews, they were likely to be limited in advising Dr. Chan about the right decision to make in regard to the H1N1 flu outbreak.

In 2003, WHO established a new set of protocols for developing health policy recommendations.¹³⁸ The protocol was supposed to emphasize the need to conduct systematic reviews in assisting providers, recipients and other stakeholders to make informed decisions about appropriate health interventions.¹³⁹ The systematic reviews were to consist of using evidence that fits pre-specified eligibility criteria which improve the basis for making decisions on generalizability over a population.¹⁴⁰

According to WHO, evidence should be within its protocol to inform decision makers about appropriate health intervention.¹⁴¹ This means that evidence should be gathered from a systematic process in order to avoid or minimize bias.¹⁴² The strength of policy recommendations is directly linked to the evidence.¹⁴³ WHO had set 3 phases to determine its evidence. First, the data is analyzed in order to determine an accurate estimate of a treatment in

¹³⁷ Oxman, *Evidence in WHO recommendations*, 1883.

¹³⁸ World Health Organization, *Guidelines For WHO*, 1-23.

¹³⁹ *Ibid*, 2.

¹⁴⁰ *Ibid*, 6.

¹⁴¹ *Ibid*, 2.

¹⁴² *Ibid*.

¹⁴³ *Ibid*, 5.

different settings and populations.¹⁴⁴ This analysis helps to answer the question of what is the best evidence on efficacy and effectiveness. If there are cases of insufficient evidence, WHO should opt to issue consensus statements and acknowledge that these recommendations are based on expert opinions. WHO's protocol makes the point that these consensus statements are to be issued with a limited lifespan during which time WHO will invest in resources to ensure that the necessary research is being done to provide evidence needed the next time around.¹⁴⁵ That is, the recommended systematic process to ascertain evidence will take place.

The second phase of developing evidence is to determine the tradeoffs between the costs of applying possible recommendations on a population versus the population health impacts.¹⁴⁶ That is, the evidence would answer the question whether the intervention would do more good than harm to a population. This would consist of studying a number of scenarios. As a result of this evidence, decision makers would be able to ascertain whether to make recommendations in the context of local and national conditions.¹⁴⁷ After this step, the decision maker can move to the next phase of evidence which is the localization process.

During the third phase of evidence or the localization process, WHO seek to provide any technical assistance necessary to member countries to help them make their own recommendations.¹⁴⁸ This means WHO is to provide local or regional cost-effectiveness data of

¹⁴⁴ Ibid,6.

¹⁴⁵ Ibid.

¹⁴⁶ Ibid,7

¹⁴⁷ Ibid.

¹⁴⁸ Ibid.

the intervention. This also includes providing data on other interventions which might be of comparable or better cost-effectiveness for that particular country. Finally, WHO would provide data on the resources required to carry out the interventions which include financial start-up and capital costs.¹⁴⁹

In examining WHO's protocol since it was instituted in 2003, various studies have shown that WHO had failed short in following its protocol. In a study published by the *Lancet* in 2007, Andrew D. Oxman, John N. Lavis, and Atle Fretheim found that the directors of the 16 departments that developed recommendations reported that expert committees rarely commissioned systematic reviews to do their work.¹⁵⁰ When asked specifically about using evidence of effects that is evidence with supporting data only a small number of directors reported using systematic reviews of such evidence.¹⁵¹ None of the directors reported using concise summaries of findings for the most important outcomes (i.e. benefits, harms, and costs) of each option being considered. Many directors instead reported using background documents. For example, some background documents were prepared by experts according to their own conventions. Other directors reported leaving the use of evidence up to the experts, feeling that evidence of effects was not relevant for some recommendations, and feeling that randomized trials were not appropriate for some types of interventions. Only one director reported grading the quality of the evidence.¹⁵²

¹⁴⁹ *Ibid*

¹⁵⁰ Oxman, *Evidence in WHO recommendations*, 1885.

¹⁵¹ *Ibid.*

¹⁵² *Ibid.*

The directors highlighted several other weaknesses with the processes used to develop recommendations. They mentioned weaknesses such as the failure to involve key organizations, the failure to use evidence from other sectors, the creation of high expectations, and the conflict that exist over data. These weaknesses spring from the fact that the directors do not follow the guidelines instituted by WHO to develop recommendations.¹⁵³ In some cases, some of the directors stated, “I would have liked to have had more evidence to base recommendations on. We should have conducted a literature search.”¹⁵⁴ Others stated, “We never had the evidence base well documented. We should have reviewed evidence at a very early stage.”¹⁵⁵

Giving this culture within WHO which favors experts’ opinions, it was logical for Dr. Chan to rely on them for advice on the influenza outbreak. Furthermore, this process of decision making within WHO has been around for a long time. Since 1956, WHO’s recommendations have been derived from the advice of experts rather than the systematic reviews approach.¹⁵⁶ Even when the pandemic officially ended in August 10, 2010, Dr. Chan credited only the advice of the experts of the Emergency Committee. She stated,

The world is no longer in phase 6 of influenza pandemic alert. We are now moving into the post-pandemic period. The new H1N1 virus has largely run its course. These are the views of members of the Emergency Committee, which was convened earlier today by teleconference. The Committee based its assessment on the global

¹⁵³ *Ibid*, 1887.

¹⁵⁴ *Ibid*, 1886.

¹⁵⁵ *Ibid*.

¹⁵⁶ *Ibid*, 1883.

situation, as well as reports from several countries that are now experiencing influenza. I fully agree with the Committee's advice.¹⁵⁷

In this statement, it is clear that Chan fully relied and agreed with the advice of the experts opinions of the pandemic. This was the case even when the committee members had no experience with systematic reviews.¹⁵⁸ As such, it was also problematic, that they did not use WHO's evidence in their decisions and recommendations about the outbreak. It was reported that WHO's made recommendations to countries governments about vaccine such as oseltamivir (Tamiflu) and zanamivir (Relenza) to use against the outbreak.¹⁵⁹ However, these vaccines did not go through any systematic reviews.¹⁶⁰

In a report by WHO written in 2010 which sought to explain the use of Tamiflu to treat influenza flu pandemic, it stated, "There are no systematic reviews or randomized controlled trials assessing the efficacy and safety of antivirals for pandemic influenza A (H1N1) 2009 infection."¹⁶¹ In the same report, WHO also reported for Zanamivir (Relenza) and stated, " There

¹⁵⁷ World Health Organization. Media centre:H1N1 in post-pandemic period . August 10, 2010. http://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/index.html (accessed May 10, 2011).

¹⁵⁸ Royle, *Influencing World Health Organization policy*.

¹⁵⁹ Cohen, *WHO and the pandemic flu*, 1274.

¹⁶⁰ World Health Organization. WHO Guidelines for Pharmacological Management of Pandemic Influenza A(H1N1) 2009 and other Influenza Viruses : Part II Review of Evidence. World Health Organization, 2010.

¹⁶¹ *Ibid.*

are no systematic reviews or randomized controlled trials assessing the efficacy of zanamivir for pandemic (H1N1) 2009 infection.”¹⁶²

In these WHO’s reports and statements by Dr. Chan, it is clear that WHO’s 2003 protocol and guidelines were not followed in terms of conducting systematic reviews. Furthermore, since the experts did not use evidence within WHO’s protocol to inform Dr. Chan about appropriate vaccine, their recommendations were likely to be tainted. Their recommendations for the pandemic were also probable to be unsound given that they were not based on evidence that can substantiate the efficacy and effectiveness of the antiviral vaccine to intervene against the outbreak.

In assessing the 2009 declaration of the H1N1 pandemic by WHO, it is possible that WHO did not make a legitimate decision. The facts are that WHO did not follow its operating protocol. WHO was not transparent in managing conflict of interest among members of the Emergency Committee. WHO took advice from experts of the Emergency Committee in regard to the pandemic while the member’s identity was kept secret. WHO did not disclose the conflict of interest of committee members. There were “sleeping contracts” between large pharmaceutical companies and countries government. On these grounds, WHO failed the world in declaring the 2009 H1N1 influenza pandemic.

¹⁶² *ibid.*

4. Counter Argument

Giving the fact, that my research of WHO's decision making process of the pandemic did not have all the data about the pandemic, it is arguable that some data may in fact show that WHO was legitimate in declaring the pandemic of 2009. Some data can show that despite WHO's lacking in transparency and not following its protocol, and data to substantiate the pandemic, WHO made the right decision. However, it would still remain that WHO's failing to follow its protocol during the pandemic had curtailed its trust among its clients.

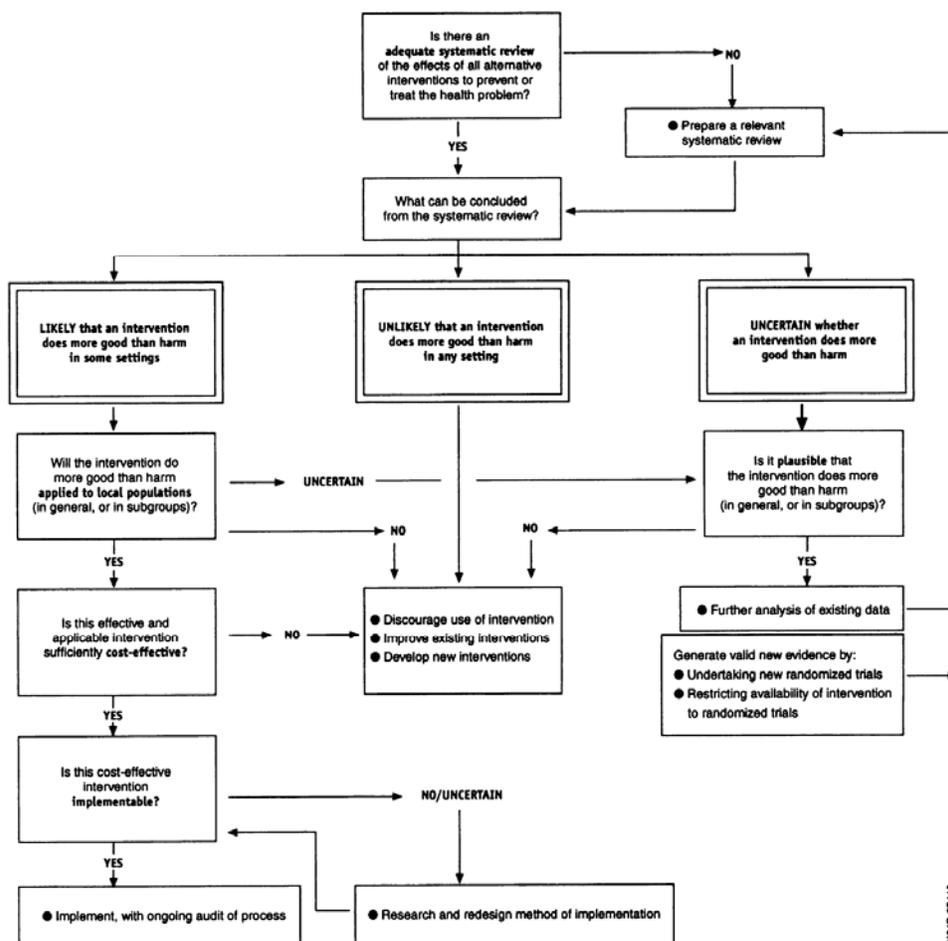
POLICY IMPLICATIONS

In moving forward, WHO would need to consider instilling greater trust within the agencies and country governments that it advises and to which it makes health recommendations. With the trust among its clients, WHO would be able to respond more efficiently if a pandemic would ever manifest itself. This trust can be achieved in the following manner. WHO should use and apply systematic reviews as recommended in its protocol in making future health recommendation. That is, WHO should make use of a decision flow diagram, as discussed in the article by Les Irwig and others, in the journal Bulletin of the World Health Organization, in selecting health care interventions. Please see the flow diagram¹⁶³

¹⁶³ Les M. Irwig, Merrick Zwarenstein, Anthony B. Zwi, and Iain Chalmers. "A flow diagram to facilitate selection of interventions and research for health care." Bulletin of the World Health Organization 76, no. 1 (1998): 17-24.

A flow diagram for health care decisions

Fig. 1. Flow diagram for selecting health care interventions and identifying research needs.



This diagram should aid WHO in system-wide planning, in assessing interventions for a single group of health problems, in evaluating a single intervention, and in prioritizing research on health care interventions.

CONCLUSION

In this paper, I argued that WHO failed to follow its protocol of using research based evidence and systematic reviews. WHO's evidence for the declaration of the pandemic was not transparent nor substantiated. WHO failed to manage conflict of interest of the members of the Emergency Committee. As a result of these arguments, I believe WHO's declaration of 2009 influenza pandemic was not legitimate. The implication of this decision is that member countries of the European Union have come to have less trust and more suspicion of WHO. If and when a new and real pandemic would arise, WHO would be less effective in enrolling these countries to follow its recommendation.

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