H1N1 Returns, Again: The Globalization, Re-Conceptualization and Vaccination of "Swine Flu"

James Ricci

With the emergence of H1N1 in April 2009 and the subsequent declaration of a pandemic by the World Health Organization, infectious diseases have once again taken a prime position on the international health agenda. This, though, is not the first time that an influenza pandemic has been anticipated months prior to the start of flu season. In March 1976, the United States began preparations for a H1N1 pandemic that was suspected to be of the same type as the 1918 Spanish Flu. Accordingly, the on-going H1N1 preparations and policies invite a historical comparison with the events of three decades past. Specifically, this article will explore whether on the international level a qualitative shift in how infectious diseases, in particular the production and distribution of vaccines, are conceptualized and engaged has materialized as generated by globalization, and suggests that the state still drives the international, as opposed to global response to influenza.

INTRODUCTION

In April 2009, Mexico announced that an outbreak of H1N1 (swine flu) had spread across the country.[1] International health actors such as the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) similarly confirmed the presence of the virus and suggested that immediate preventative measures be taken. Within short order, national influenza plans were activated, states shared epidemiological information, and the global race for a vaccine began in earnest. Much like political effect of the SARS outbreak in 2003, the possibility of a 1918 Spanish Flu pandemic, which killed approximately 50 million people, moved to the forefront in planning discussions and provided much of the drive behind the rush to a common policy. Over the following months, the virus spread globally and by June the WHO declared, for the first time in the twenty-first century, a pandemic. However, this did not mark the first time that an influenza pandemic was predicted months prior to the start of the flu season.

In February 1976, the death of a United States Army recruit triggered one of the largest influenza programs in history. In just over a month, the United States set into motion a program that attempted to vaccinate every American citizen (200 million) against a strain of H1N1 (swine flu) that was thought to be similar to the 1918 Spanish Flu. Similar to 2009, the 1918 event provided authorities in 1976 strong motivation, and was perhaps the strongest factor in the rush to develop a comprehensive policy. After the enactment of the National "Swine Flu" Influenza Immunization Program in April, national vaccinations began in October. However, the program immediately ran into problems when the vaccine was linked to the deaths and disability of a small portion of those who

had received the vaccines. The program was suspended in December 1976, effectively ending the national vaccination drive. Even as concerns about the vaccine provided a large factor for suspending the program, the fact that a 1918 type of event never emerged ultimately killed the program.

As of this writing (March 2010), a H1N1 pandemic on the scale of 1918 has similarly not emerged. Accordingly, this provides an opportunity to explore these related events, and this article seeks to explore the globalization claims of Global Health Governance (GHG) through the H1N1 lens. In particular, GHG suggests that the rapid political, economic, and social developments, among others, of the late twentieth century have driven states, international institutions, transnational actors, and non-governmental organizations to interact in a qualitatively new manner. The fact that the United States acted alone, for the most part, in 1976 suggests that infectious diseases are currently conceptualized differently. However, the seemingly more interconnected policies of 2009-10 may in fact reflect individual state policies that overlap. Whether globalization, as a cause and effect, represents the driving factor behind this alternative approach to preventative policy remains a critical question which is still unfolding.

This article is skeptical about the GHG approach to globalization, and suggests that its role in a significant shift in the formation and dissemination of international health policy is overstated. This, though, does not suggest that the increased interaction between the increasing number of global actors has had no impact. In fact, this is a reality. Despite a shift in how infectious diseases are conceptualized, as well as which actors participate in policy, the state, especially Western states, remains the determinative actor in the engagement of these microscopic agents. Accordingly, this article will proceed via four sections. Sections one and two will provide background on the 1976 and 2009 H1N1 policies, respectively. The third section will explore the globalization claims of GHG through these policies, particularly in respect to the production and distribution of vaccines, and analyze the extent to which the three decade gap between events has experienced any significant changes in how international actors conceptualize the world, other actors, and infectious diseases. Finally, section four suggests that a return to nationally-based vaccine production facilities demonstrates the ability of states to resist the forces of globalization.

H1N1, 1976

As the 1975-76 flu season in the United States drew to a close, nothing in particular suggested trouble on the horizon. In an average American influenza season, roughly 30,000 deaths are attributed to influenza related complications, with similar proportions found throughout the world. The virus primarily strikes the very young and old due to the weaker immune systems of these demographics. However, in 1918-19, the great “Spanish Flu,” which killed approximately 50 million people, disproportionately struck the normally healthy 25-50 year old age range. Despite nearly 90 years of effort, the cause of that pandemic still confuses public health authorities, and continues to drive many to actively pursue solutions in the prevention of its return. Annual meetings of influenza specialists

focus on the complexity of this particular pathogen and seek to design vaccines that would eliminate the virus.[2] Despite the eradication of smallpox by the late 1970s, influenza remains a stubborn foe.

For some public health officials, the events of early February on one United States Army base dramatically highlighted the nightmare scenario envisioned by many. In the eastern state of New Jersey, a nineteen-year old Army recruit at Fort Dix fell ill with influenza-like symptoms and subsequently died on a training march. Other recruits displayed similar symptoms and Army doctors soon contacted local civil authorities to warn of a potential outbreak.[3] This started a process through which a relatively small, local cluster of cases eventually made its way to CDC facilities in Atlanta. Importantly, once federal authorities characterized the outbreak as swine flu this local issue quickly grabbed national attention. The assumed relationship, by some, between swine flu and the 1918-19 pandemic removed the events of New Jersey from the realm of seasonal and placed it into the special.[4]

This, though, does not suggest any sense of consensus among public health officials. Some remained quite skeptical about the sudden association between a statistically insignificant sample size and claims of the imminent return of pandemic influenza. As Neustadt and Fineburg argued, once in the machinery of bureaucracy, the biological became political and took on a life of its own.[5] In fact, the whole swine flu event highlights the inherently political nature of public health and demonstrates that medical experts, regardless of Hippocratic oaths and guiding ideals, are political actors with agendas. Within a month, federal officials started to construct plans for an immunization program that would attempt to vaccinate over 95 percent of the American population, which was about 200 million people. Even as proponents of the program noted that the probability of a pandemic remained low and openly acknowledged that many important questions remained unanswered, the speed at which the Democratically-controlled Congress and Republican President approved $US135 million program demonstrated how relatively little resistance emerged.[6] By mid-April, less than two months after the confirmed swine flu results, the vaccination program became law.

Unlike the pandemics of 1918, 1957, and 1968 in which countries around the world recognized a common threat, in 1976 only the United States pushed forward in such dramatic fashion. The WHO initially supported the general idea of mass vaccination, especially as the success of the smallpox program demonstrated the viability of such an approach.[7] However, WHO support was based on additional research and keeping alert, as opposed to moving forward with a full vaccination program. Further, support from the WHO as well as other countries disappeared by late spring as surveillance information indicated that the likelihood of the development of swine flu into pandemic flu remained very low. Reception for the US program from the international community remained cool.[8] With the exception of Canada, which purchased vaccines, no other country participated in the program or implemented a similar one.

Much like the 2009 strain of H1N1, the production of a vaccine emerged as the central policy tool. After the federal government signed a liability law which

shielded the pharmaceutical industry and accepted financial responsibility for any deaths or related injury, vaccine production began. However, due to political debates as well as technical problems, most of the doses were not available until November, even though influenza season started in October. Further compounding the political considerations was the fact that the program received more criticism over the summer as additional evidence suggested that the likelihood of a pandemic remained low. Federal authorities, though, continued to recommend that all citizens get a shot, the epitome of the government's encouragement came when President Ford was publicly injected in front of the camera. The pharmaceutical industry produced 40 million doses by the start of the flu season with their distribution and administration shortly there afterwards. However, problems quickly emerged.

Even though side effects are expected with any mass immunization program, within weeks the emergence of Guillain-Barre Syndrome (GBS) surprised many. As GBS can cause paralysis and death, public health officials attempted to assuage a concerned public and continued to recommend the flu vaccine to the country. After the suspension of the program in several parts of the country, the national program continued with some of those regional programs rejoining. By late November, though, surveillance data indicated that the probable emergence of a H1N1 pandemic remained low, if not highly improbable. Accordingly, the government suspended the program in mid-December. This was also associated with questions about the relationship between the vaccine and GBS, and the program eventually was cancelled in early 1977.[9] At the time of suspension, less than quarter of the country received the vaccine and more deaths were attributed to GBS than swine flu. In fact, only a handful of recorded cases of swine flu emerged in the 1976-77 season.

Neustadt and Fineberg argued that despite genuine attempts by officials to protect the public and isolate party politics from the debate, the decision to frame the program as "go or no-go" on limited information set a course in which reasonable objectives and concerns never emerged into the national debate.[10] Silverstein, though, took a more pessimistic view in that while it is inherently difficult to understand infectious diseases and offer predictions, officials at the time used the available information poorly and injected *too much politics* ("what will the voters think if we get it wrong?").[11] Wecht drew similar conclusions.[12] These medical-political debates and questions still persist. One element that played an important role in the failure to predict the pandemic was the lack of international participation and what input was received was generally discarded.[13] Despite the 1918 Spanish Flu being global in nature, the United States concluded, almost alone, that a similar event may unfold and dramatic action was needed. More than thirty years later, though, the United States along with the WHO and numerous states participated in a much more coordinated response.

H1N1, 2009

While various international health agencies officially acknowledged the presence of H1N1 in late April 2009, the virus appears to have emerged in Mexico as early as mid-March 2009.[14] Around that time, Mexican health authorities noticed an increased in the number of influenza-like illnesses which is a common feature experienced towards the end of the flu season. In fact, previous influenza samples sent to the CDC for testing were found to be negative for swine flu. Starting in mid-April, though, a case of atypical pneumonia in southern Mexico caused public health authorities to request that local and regional hospitals collect laboratory specimens and report all severe respiratory infections. Similarly in Mexico City and Southern California (United States), more cases of influenza-like illnesses emerged. Then on April 17, CDC confirmed that swine influenza A (H1N1) was the cause of two cases in Southern California.

Some criticism was leveled at Mexico for being too slow to report suspected cases to international health agencies.[15] However, the few reported cases, as well as the time needed to confirm each case (usually sent to Canadian and American laboratories), more likely reflected the fact that Mexico was following international standards. What became particularly clear to officials in Mexico and the United States, though, was that this strain of influenza required special attention. Within short order, the WHO assembled a team of experts to evaluate the available epidemiological information. In accordance with the International Health Regulations 2005 (IHR), which came into force in 2007, and following the advice of the "Emergency Committee," WHO Director Margaret Chan declared the H1N1 outbreak "a public health emergency of international concern."[16] While this differed from labeling the outbreak a pandemic, it did indicate the level of concern given to these confirmed cases. Unlike in 1976, the United States and the WHO shared a similar conception of the virus as well as the need to proceed through a common framework.

Despite widespread public health consensus that border closures would provide little, if any, protection against the spread of H1N1, some countries in Asia, Europe, and South America implemented travel and trade restrictions with the United States and, particularly, Mexico.[17] The European Union Health Minister publically called for travel restrictions to these North American countries; though those comments were later softened to the immediately affected areas.[18] The sale of pork became an issue of concern, and China, Russia, and South Korea taking some of the most aggressive measures and banned the import of Mexican and American products.[19] In fact, countries in the Asia-Pacific, where the memory of the 2003 SARS outbreak remained fresh, took some of the earliest preventive steps. In particular, China appeared especially concerned to avoid a repeat of the political and public health disaster that visited the country during that outbreak. The speed at which diseases (i.e. air-travel) could and did spread suggested that without an immediate, even if draconian, response, H1N1 would materialize.

However, despite the many attempts to contain H1N1 though border-related measures, even if it was only from a public relations perspective, the virus quickly appeared in Asia, Europe, and South America and continued to spread throughout North America. Unlike the SARS outbreak which, for the most part,

remained geographically contained, H1N1 cases emerged throughout the world and across a multitude of countries and geography. Even as the number of deaths remained extremely low, especially in comparison to SARS at similar time intervals, the number of cases continued to rise at an exceptionally quick rate. This acceleration played a key role in the WHO decision to raise the pandemic alert level from 4 to 5, and later to 6 – with level 6 being a pandemic – with the political dimensions of this decision immediately questioned.[20] Importantly, as the WHO later received criticism about its use of these alert levels, it must be noted that this system was designed to denote the presence of a particular disease (geography and morbidity) as opposed to how lethal it is (mortality). Of even greater concern to public health officials, though, was whether this was the initial phase of outbreak that could turn into an even larger killer.

In the decades since the 1976 swine flu episode, influenza has continued to pose serious challenges to researchers and policy makers. The ability of the virus to mutate and move between hosts makes predicting and reacting to an outbreak difficult, even in the age of increasingly sophisticated and technical modern medicine. The high level and ongoing H5N1 (avian influenza) preparations demonstrated the degree to which officials prioritize these types of events. Further, though the number of people who personally remember the 1918 Spanish Flu (which was a type of the H1N1 strain) has diminished greatly since 1976, it still played large on the minds and actions of policy makers in 2009. Undoubtedly, modern antibiotics and ventilation technologies would reduce the mortality levels.[21] However, many experts still view influenza as a threat, due in large part to modern transportation that can easily move individuals and groups around the globe in days. As such, the impact of a potential 1918 type event – with a vivid oral, written, and visual history – cannot be underemphasized.

Accordingly, as H1N1 raced around the world, a pandemic in the context of 1918 remained at the forefront. While the decision to raise the WHO pandemic alert level to 6 in June represented a technical process which did not inherently mean that deaths of millions of people was likely, it did push national and international authorities to expand existing plans and develop new procedures that took into consideration elements particular to this strain of H1N1. Even as authorities continued to share surveillance information, one particular element of these plans, vaccine production, moved to the forefront. Expert committees at the WHO, as well as at the national level, began to examine the type of vaccine to be produced and methods of distribution. Vaccine production, which will be developed in greater detail in the following section, is a relatively slow process that takes months. Thus, if a pandemic was emerging or – as experienced in 1918 – a second and third wave of the virus developed later in the year, planning and production needed to start immediately.

By July 24 the CDC discontinued mortality and morbidity estimates due to difficulty in confirming each case as well as the fact that many cases were being not being reported for a host of factors.[22] Into the fall, which signifies the start of flu season in the Northern Hemisphere, H1N1 remained a priority for national health authorities as the concern about a second wave remained present. However, through December and into 2010, the number of deaths from H1N1

remained marginally higher (some estimates even suggested lower) than deaths associated with seasonal flu. Initial concerns about a case-fatality as experienced in 1918 (or during SARS) were assuaged as H1N1 was proved to be much less deadly for most demographics than initially expected.[23] By the start of March 2010, nearly a year had eclipsed since H1N1 emerged as a potential threat. In fact, the greatest concern for many national authorities, especially those in Western Europe and North America, was how to unload the millions of vaccines that were not used.[24]

GLOBALIZATION AND VACCINATION

Globalization, GHG, and the State: Defined and Challenged

GHG scholars argue that in the late twentieth century, a qualitative shift in both how actors *engage* each other and *conceptualize* the world in which they participate has emerged. In particular, the concept of globalization is used to define these significant changes. While globalization is complex, with competing and overlapping definitions, several themes exist within globalization, which are generally recognized as the process of people, businesses, and nations becoming increasingly interconnected and interdependent through the vehicles of trade, communication, cultural, and trade, among others.[25] GHG scholars recognize the longer historical narrative in which actors as far back as the Roman Empire and Han China have traded goods through intermediaries; with some tracing globalization back even further.[26] Rather, the interactions in the early twenty-first century represent a critically new development in an age-old process.[27] In the context of infectious diseases, the changes experienced between the 1976 and 2009 H1N1 episodes represented nothing more than simply turning the calendar.

Among other elements within this globalization framework, which includes the increased interaction between actors as well as shifts in perception of time and distance,[28] is the claim that the state no longer remains the lone central actor within an international system of states. In particular, the argument is that globalization constricts the ability of the state to handle many emerging health issues such as infectious diseases simply because there are too many variables to address.[29] While the state will not disappear in the short to medium run, and even as states are resisting some globalizing forces, [30] globalization has successfully challenged state control of health policy.[31] Further, as the state no longer defines economic, political, and social interactions, among others, a new thinking and approach is needed in the response to the determinants of health.[32] Strange strikes a particularly pessimistic tone and argues that the state can no longer determine domestic and international policy outcomes.[33]

For GHG scholars like Fidler, the SARS outbreak represented a significant qualitative shift in political authority in which the forces of globalization ushered in a new post-Westphalian era.[34] Infectious diseases as well as larger public health issues were simply too large and interconnected to be handled solely by the state. Cortell and Peterson similarly suggest that actors such as the WHO have emerged in the post-SARS political landscape with the authority and power

to shape *global* health. Even as the post-Westphalian model has been modified in the intervening years in attempt to present a more nuanced understanding of SARS and larger health issues, Kirton and Cooper claim that the mounting evidence demonstrates that the world is in fact moving away from the Westphalian model with the state as the dominant pillar toward a more complex global framework.[35] Though not dismissing the state and recognizing its continued relevance, Stevenson and Cooper suggest that even countries like China are losing the capacity to protect its citizens from the health threats of a globalized world.[36]

To a certain extent, the globalization framework presented by GHG scholars is correct. There has been a significant shift in how actors conceptualize the world. As Bashford notes, new methods of transportation, for example, have undoubtedly both aided in the spread of diseases and, importantly, challenged the manner in which the state confronts these pathogens.[37] Clark similarly argues that globalization and the state are historically developed transnational forces in which the political dynamic between the two shift across time.[38] Even Navarro, who questions the extent and novelty of globalization, acknowledges that there has been a change in how the state interacts with other actors, especially in context of health.[39] This, though, is more than simply a change of language (Neustadt and Fineberg explored how air-travel and "Jet-spread" were discussed in 1976.)[40] Globalization has introduced a new set of challenges which forces the state to interact at increasing speeds, and with increasing complexity. The spread of H1N1 from Mexico in March to dozens of countries by May demonstrates these new elements within international interactions. However, critically, this alone does not yet equate to a shift away from the state and the corresponding international framework.

It is here, in the engagement of infectious diseases like H1N1, that this article challenges the GHG claims about the state. Even in the globalized era of the instant global communication and rapid mass transit, Mann warns that scholars must be cautious of the enthusiastic claims of globalization as it tends to exaggerate both the former strengths of the state as well as its current decline.[41] Hurrell and Woods similarly describe how globalization is not necessarily "inevitable" and that states, especially strong states can open or close markets.[42] This idea of strong states (Western industrial) becomes particularly important in the context of vaccine production and distribution as explored in the following section. Though the state may not be in fashion and even though "many may find [the state] morally unpalatable, politically bankrupt, or just plain behind the times," Kolodziej argues the state is the only organizing principle that currently exists that can provide for the defense of the individual.[43] Particularly in the context of health, Szlezák et al. note that national health systems as the generators of global health solutions are often underemphasized or overlooked in "enthusiastic discussions of new approaches to the architecture of global health."[44] This is especially true in respect to H1N1.

Change in Vaccine Production

Following Jenner's successful demonstration of a vaccination against smallpox in 1796, vaccines have remained a cornerstone of public health. In fact, second to surveillance, central to current national and international influenza preparedness plans is the implementation of vaccination programs.[45] Since the late 1940s, the production cycle for influenza vaccines, which includes a very precise timetable as well as carefully planned manufacturing and delivery mechanisms, has remained the same and takes about six months to bring to market. While this process has successfully produced tens of millions of doses, problems have emerged, such as in 2004 when United Kingdom-based Chiron Corporation destroyed 50 million doses because of suspected contamination.[46] However, changes in technology, such as reverse genetics or cell-based cultures, will add complexity in both the production and standardization of vaccines in the twenty-first century.[47]

While these technological changes offer the potential to revolutionize the vaccine production process, the vaccine industry itself has already undergone a major transformation. Mahoney, Pablos-Mendez, and Ramachandran suggest that even as far back as the mid-1950s with polio, the methods through which vaccines were created and distributed started to change.[48] Due to a decrease in the number of diseases, particularly in developed Western countries, coupled with the increased regulation and cost associated with vaccine production, the private sector assumed many of the essential roles formally held by national authorities. Further, the relationship between public and private sector public health interests in the context of infectious disease vaccines grew increasingly complicated as the 1976 Swine Flu Incident demonstrated.[49] The vaccine industry was rapidly changing.

This change was strikingly reflected in the number of producers of vaccines through the world. By 2000, over 85 percent of the world's supply of influenza vaccine was produced by nine companies located in nine Western Industrial countries.[50] These numbers also highlight the division between developing and developed countries in that almost all of the influenza vaccines for Africa and Latin America come from these nine countries. It is this skewed production capacity that generates political tensions between states. Additionally, fewer companies are producing vaccines and in the Unites States, for example, the number of total producers of all vaccines has been reduced from 26 in 1967 to 12 in 2002, with 5 of those specializing in common childhood diseases and only one for influenza.[51] Poorer countries are forced to compete for access to vaccines. Even if these developing nations could afford vaccines, in many cases the pharmaceutical industry currently produces a fraction of the total 7 billion (or more) dosages needed to match the global population. Vaccine production is also effected by mergers and acquisitions as well as the relatively low market value of vaccines versus other products.[52]

In the decades since the 1976 H1N1 "outbreak" in the United States, vaccine production has become globalized and shifted away from direct state control. This, though, is not to suggest that the state has gotten out of the vaccine business. In fact, Archibugi and Bizzarri suggest that 70 percent of "all drugs with therapeutic gains have been the direct result of the public sector's involvement."[53]

In particular, much of the initial research for diseases like influenza comes from government funded universities and research institutes, for example, the number of patents issued to academic institutions in the United States more than doubled between 1993 and 1999.[54] However, the end result of the research process, safe vaccines, is still primarily controlled by the pharmaceutical industry. With the probability of a pre-clinical vaccine (prior to random, human testing) reaching the market estimated at 0.22 (5:1 odds against), the industry is particularly aware of getting a high rate of return on those vaccines and drugs that actually make it to market.[55]

The increased participation of the pharmaceutical industry in global public health is undeniable. Multinational corporations (MNCs) have become synonymous with the shifts in how vaccines are developed and marketed. In terms of profitability, the industry ranks second only to mining and crude oil production.[56] This actual change in the means of production, though, does not reflect a withering of state power and control. As developed in the following section, claims of a WHO-pharmaceutical conspiracy in the development and purchase of H1N1 drugs reflects the thoughts, within some corners, that power has truly shifted to these multinational entities with no loyalty expect to the bottom line.[57] More closely associated with GHG and globalization claims is that the pharmaceutical industry *along with* non-state actors such as the Bill and Melinda Gates Foundation and public-private sector alliances like the GAVI Alliance (GAVI) have emerged to fill development and research gaps as well as challenge the traditional state-based approaches to vaccine awareness, production, and distribution. It is here that the GHG argument about a shift in governance runs into trouble.

Non-state actors, transnational institutions, public-private partnerships, and the state

The idea that solutions to infectious diseases require a coordinated, multi-sector approach is not contested. Nor is the fact the states, particularly Western industrial, have failed to live up to development pledges. In a complicated process (or perhaps sets of processes) that involves more than simply producing vaccines, states *should* be doing more to address a range of public health issues. However, regardless of shortcomings, especially in the area of vaccine production, states still control the vaccine market. This, though, does not suggest on the international level that states – as well as the pharmaceuticals – remain the only actors. In fact, since the 1990s a range of non-state actors, transnational institutions, and public-private partnerships have emerged to engage the issues that surround infectious diseases. As highlighted by the race to find a HIV vaccine, global research and collaboration is both essential and has generated important advancements in the science of virus knowledge.[58]

The emergence of the Gates Foundation in the 1990s represented a change in contributions from non-state actors to the fight against infectious diseases. These actors have assets measured in billions of dollars and, according to some, have the ability to "rearrange the public health universe."[59] Initiatives such as the

AIDS Vaccine Integrated Project (AVIP) have had success in developing networks that explore HIV/AIDS vaccine research.[60] Similarly, the International AIDS Vaccine Initiative has been important in coordinating public-private relationships by bringing together market-based solutions and traditional government funded research.[61] On the ground, GAVI has had success in providing diphtheria, tetanus, and pertussis vaccines to some of the poorest regions of the world.[62] After a lull in financial commitment to vaccination programs for developing countries experienced in the early 1990s, these actors have introduced critical vaccines into areas devoid or lacking in international assistance.

However, and despite these important achievements, large gaps remain. As one review of the AVIP notes, success has been limited.[63] In particular, these multi-billion dollar foundations and MNCs do not have the resources (assuming they have the desire), to meet the infectious disease vaccine demands of developing countries. MNCs, for example, need "push mechanisms" to pursue vaccines that would otherwise be unprofitable and hence would not get research funding.[64] These funds and mechanisms can only, at this point in time, come from the state. No other organizational structure can marshal such resources. For example, the Global Fund to Fight AIDS, Tuberculosis, and Malaria has received US$14.2 billion to date from states as compared to US$0.8 billion from non-state actors, of which approximately 70 percent comes from the Gates Foundation.[65]

This should not be mistaken as a statement that the Gates Foundation and NGOs themselves are arguing that they are a substitute for the state. In fact, many of these organizations conceptualize state cooperation and participation as essential in achieving larger public health goals. Rather, the GHG *claim* of a significant shift in authority to these actors is decidedly overstated. The state is still the key, central actor in the vaccine debates. Despite the physical production process of H1N1 vaccines being controlled by MNCs, the state dictates the production and allocation of vaccines; especially influenza.

1976 = 2009

The rapid spread of H1N1 from Mexico and the western United States to most of the world within a matter of months reflected the interconnected nature of infectious diseases in the twenty-first century. While the troop-carrying ships of World War I provided effective mechanisms for the "Spanish Flu," the airplane proved much more effective in spreading the microscopic virus to the farthest reaches of the globe. In fact, by June 2009, countries on all continents had H1N1 cases and fatalities.[66] The "globalized" nature of the virus rendered traditional methods of public health prevention (i.e. border closings) ineffective, which explains why WHO strongly encouraged states not to resort to these methods in an attempt to contain influenza.[67] However and as noted earlier, some states resorted to these twentieth-century techniques, with travel warning and trade restrictions some of the earliest responses. In this context, some of the policy tools wielded by states reflected outmoded methods at tackling a unique

challenge. As Dodgson, Lee, and Drager argue, infectious diseases policy requires a global perspective and response.[68]

This, though, does not mean that the realities of a "jet-set" global society have triggered a significant political shift in which emerging actors have replaced established ones. To be sure, states recognize altered dynamics in which technical and biological problems that happen "over there" have ramifications at home. For example, the United States notes in respect to influenza pandemics, no country is immune from the threat of disease regardless of socio-economic development.[69] To address this, the WHO became the default policy reference point in which states filtered national responses through this "global lens."[70] Particularly in the post-SARS environment, states recognized that "Westphalian" responses to "post-Westphalian" problems were no longer effective, and a political change was required. International threats were becoming, if not already, global. However, and critically, this shift in the technical and biological landscape does not, in and of itself, represent a fundamental change in the political environment. As seen in the production and distribution of vaccines, states continued to pursue an approach based on national interest.

Despite the improvements in the production of influenza vaccine in the wake of H5N1 (avian flu) planning, major short-falls persisted. Even with WHO claims of increased production capacity by 2010, the actual vaccine capacity in 2007 was only 900 million, with higher levels dependent on best-case scenarios.[71] Thus, traditional self-interest (at both the state and non-state levels) played a significant role in how vaccines were distributed during the H1N1 pandemic. The emergence of a general trend of vaccine cooperation and engagement, particularly since the mid-2000s, suggests that collaboration amongst the various international public health authorities may have created an environment in which a greater proportion of the vaccines are allotted to poorer countries. A 2009 commitment from the United States, in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, and the United Kingdom, to donate ten percent of its H1N1 vaccines to the WHO suggests that a more equitable system of distribution is emerging.[72] However, and as highlighted by the fact that "only" a record 143 to 146 million doses, for a country of 300 million citizens, were available to Americans in 2008, states, particularly Western industrial, were the driving force behind the H1N1 vaccines purchases.[73]

This skewed allocation of resources generated a critical response from many commentators.[74] Those, particularly in the developing world, would be unable to get access to potentially life-saving medicine. By fall 2009, many influenza producers stopped taking vaccine orders simply because they did not have the capacity to meet global demand with many public health officials concerned about the shortage.[75] This led some to suggest that the WHO and the pharmaceutical industry were engaged in a questionable relationship which forced the purchase of unnecessary products.[76] The discussions of this issue within Europe demonstrates its saliency regardless of (as of this writing) convincing evidence. In fact, the ability of non-state actors to actively influence and play a major role in global policy processes, though not necessarily through fraudulent deception, forms a central part of the claims of the GHG framework.

As noted in the previous section, though, this should not be interpreted as shift in political authority and power away from the state.

In many critical ways, the 2009 H1N1 event followed a similar pattern to that of 1976. Centrally, a "point of no return" approach persists in which states continue to pursue worst-case scenario policies.[77] Rather than sinister claims of global conspiracy, states appeared locked into a programmed policy response as demonstrated by the fact that even as information increasingly demonstrated that a H1N1 pandemic on the scale of 1918, or even 1957, was no longer imminent, states and WHO continued to vaccinate and push the vaccine.[78] Whether this was the correct policy or even if, in the larger context, existing public health structures need significant changes, GHG scholars are correct in noting the inadequate nature of current infectious disease policy. However, the response to the 2009 H1N1 pandemic was primarily driven through the state. While surveillance information and to a certain extent, the public relations response to the pandemic was filtered through a globalized, WHO lens, the vaccine response was still state (i.e. international) based. Not only are states the only actors with the means to purchases and distribute vaccine, they are also the current organizational framework to which individuals and social units look to for a defense against these microscopic threats.

CONCLUSION

With the 2009-10 flu season not as dire as predicted by some in April 2009, attention quickly returned to the assumption that led to the activation of national and international influenza plans. While the science behind public health is constantly developing and few, if any, officials claim that particular pandemics are guaranteed, some of the more dire claims made at the start of the H1N1 pandemic are understandably coming into question. The state-based response to this event not only followed patterns similar to those experienced in 1976, but also reflected policy that is grounded in outdated techniques. However, the commitment to the WHO by states does represent an important shift away from narrow national perspectives to a broader engagement of global issues that transcend traditional approaches to infectious diseases. The globalized nature of issues and the interconnectedness of actors are challenging the *international* model of organization. However, as the current methods of vaccine production and distribution demonstrate, the international has not yet become the global.

The H1N1 pandemic, though, is acutely highlighting the sometimes desperate responses of states to the increasingly complex challenges of diseases and larger issues of public health. While international public health is not "obsolete" in the sense of explaining the current methods of issue engagement and response, Lapaige is correct in noting that new actors and new relationship are driving a crisis in public health.[79] This crisis arises in large part to the inadequate nature of state-based solutions to issues of health. The skepticism and apathy towards H1N1 policies as expressed by the populations of Europe and the United States does represent an important signal of how the state no longer retains an unquestioned legitimacy and source of authority in the eyes of

individuals.[80] If the state is no longer able to convince its population on the relatively simple issue of influenza, then engagement of more complex health issues such as obesity are seemingly destined to failure if similar policy paths are pursued. Increasingly, health is no longer governed by the state, with globalized actors playing a larger role in how individuals conceptualize and engage health. Much of the initial claims about H1N1 and subsequent failure of them to materialize does suggest that individuals may be turning to other mechanisms of health organization.

The shift to a global health framework, though, is not likely in the short to medium term. The H1N1 pandemic does highlight the more immediate issue of vaccine production and distribution in a globalized world and the significant political changes that are being generated. The division between developing and developed countries is problematic and, in the context of this article, provides a critical window into globalized health research. Namely, how states and other actors deal with dwindling vaccine producers in the face of increased numbers of infectious diseases as well as population is a very real challenge. Ironically, one of the current responses to this globalized problem of infectious diseases is the creation and reemergence of national vaccine production facilities in developing countries. In Brazil and India, for example, generic versions of influenza and HIV drugs are being produced (or actively financed) by national authorities with some success.[81] Unlike developed states, which are pursuing market based solutions, developing states are using national methods to get access to vaccines.

Whether this duel response to essentially the same problem is sustainable remains to be seen. It does, though, represent an important shift in thinking – at least on the global scale. To be sure, market based-solutions have brought efficiency, both in terms of cost, as well as delivery time, for certain types of drugs. However, without vast state investment in the field of research and development, many of the current multinational pharmaceuticals companies would be unable to turn profits, let alone survive. Despite the rhetoric and overall commitment to the free-market by many key actors, particularly in the West, the reality of the state in the field of health is undeniable and will remain so for the foreseeable future. Still, much like the biological evolution of viruses that constantly adapt to the environment, a political fusion of state and market-based policy solutions in the arena of vaccine development, production, and distribution will be necessary in order address this and other public health challenges.

James Ricci *is an Associate Lecturer in Politics at Cardiff University.*

[1] The name "swine flu" is inaccurate as H1N1 (2009) consisted of avian, human, and swine strains of the influenza virus. This article will refer to the various strains by the scientific nomenclature (H1N1) as adopted by the WHO and CDC, among other international health authorities.

[2] Philip Selby ed., *Influenza: Virus, Vaccines, and Strategy – Proceedings or a Working Group on Pandemic Influenza, Rougemont, 26 – 28, January 1976* (Rougemont: Academic Press, 1976).

[3] Philip Boffey, "Swine Flu Vaccination Campaign," *Science* 193, no. 4253 (1976), 559-563.
[4] Sharon L. Begley, "The Failure of the 1976 Swine Influenza Immunization Program," *Yale Journal of Biology and Medicine* 50 (1977): 45-656.
[5] Richard E. Neustadt and Harvey V. Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease* (Washington DC: U.S. Government Printing Office, 1978).
[6] Walter R. Dowdle, "The 1976 Experience," *Journal of Infectious Diseases* 176, supp. 1 (1997): 69-70.
[7] "Flu Shots Back by World Agency," *Los Angeles Times*, 27 March 1976, A20.
[8] Neustadt and Fineberg, *The Swine Flu Affair*, 35.
[9] Thomas E. Baynes Jr., "Liability for Vaccine Related Injuries: Public Health Considerations and Some reflections on the Swine Flu Experience," *Saint Louis University Law Journal* 44 (1977-1978): 44-88.
[10] Neustadt and Fineberg, *The Swine Flu Affair*, 12.
[11] Arthur M. Silverstein, *Pure Politics and Impure Science* (Baltimore: The Johns Hopkins University Press, 1981).
[12] Cyril H. Wecht, "The Swine Flu Immunization Program: Scientific Venture or Political Folly", *American Journal of Law and Medicine* 3, no. 4 (1977-78).
[13] Neustadt and Fineberg suggested that since WHO, Britain, and Canada lacked research and surveillance funds, all were willing to follow the lead of the United States. See Neustadt and Fineberg, *The Swine Flu Affair*, 35.
[14] This article recognizes that a definitive H1N1 (2009-10) timeline has not yet emerged. Repeated attempts have been made to construct these events as accurately as possible.
[15] Laura Vargas-Parada, "H1N1: A Mexican Perspective," *Cell* 139, no. 7 (2009): 1203-1205.
[16] Margaret Chan, "Swine influenza," *World Health Organization*, 25 April 2009. Available at: http://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/index.html <15 February 2010>.
[17] Lawrence O. Gostin, "Influenza A(H1N1) and Pandemic Preparedness Under the Rule of International Law," *Journal of the American Medical Association* 301, no. 22 (2009): 2376-2378.
[18] Priya Shetty, "Preparation for a pandemic: influenza A H1N1," *Lancet* 9, no. 6 (2009): 339-340.
[19] William a. Kerr, "Political Precaution, Pandemics and Protectionism," *Estey Centre Journal of International Law and Trade Policy* 10, no. 2 (2009): 1-14.
[20] David P. Fidler, "H1N1 after action review: learning from the unexpected, the success and the fear," *Future Microbiology* 4, no. 7 (2009): 767-769.
[21] David M. Morens, Jeffery K. Taubenberger, and Anthony S. Fauci, "The Persistent Legacy of the 1918 Virus," *New England Journal of Medicine* 3, no. 361 (2009): 225-229.
[22] "2009 H1N1 Early Outbreak and Disease Characteristics," *Centers for Disease Control and Prevention*. Available at: http://www.cdc.gov/H1N1FLU/surveillanceqa.htm <15 February 2010>.
[23] Maggie Fox, "Study confirms low mortality for swine flu," *Reuters*. Available at: http://www.reuters.com/article/idUSTRE5B64DL20091207 <15 February 2010>.
[24] Andrew Jack, "Move to recover cost of flu vaccine," *FT.com*. Available at: http://www.ft.com/cms/s/0/182021e8-fe52-11de-9340-00144feab49a.html?nclick_check=1 <15 February 2010>.
[25] Ronald Labonte and Renee Torgerson, "Interrogating globalization, health and development: Towards a comprehensive framework for research, policy and political action," *Critical Public Health* 15, no. 2 (2005): 157-179.
[26] Kelley Lee, "Globalisation: what is it and how does it affect health," *Medical Journal of Australia* 180 (2004): 157.
[27] David P. Fidler, "Globalization, International Law, and Emerging Diseases," *Emerging Infectious Diseases* 2, no.1 (1996): 77-84.
[28] Julio Frenk and Octavio Gómez-Dantés, "Globalization and the Challenges to Health Systems," *Health Affairs* 21, no. 1 (2002): 160-165.
[29] Roger S. Magnusson, "Non-communicable diseases and global health governance: enhancing global processes to improve health development," *Globalization and Health* 3, no. 2 (2007). Available at: http://www.globalizationandhealth.com/content/3/1/2.

[30] Richard Dodgson, Kelley Lee, and Nick Drager, *Global Health Governance: A Conceptual Review* (Geneva: World Health Organization and London School of Hygiene and Tropical Medicine, 2002), 19; David P. Fidler, "Architecture amidst Anarchy: Global Health's Quest for Governance," *Global Health Governance Journal* 1, no. 1 (2007): 1-17.
[31] Gill Walt, "Globalisation of international health," *Lancet* 351 (1998): 434.
[32] Douglas Bettcher and Kelley Lee, "Globalisation and public health," *Journal of Epidemiology and Community Health*, 56 (2002): 14.
[33] Susan Strange, "Political Economy and International Relations," In *International Relations Theory Today*, eds. Ken Booth and Steve Smith (Oxford: Polity, 1995), 161-162.
[34] David P. Fidler, *SARS, Governance and the Globalization of Disease* (London: Palgrave, 2004).
[35] Andrew F. Cooper and John J. Kirton, "Innovation in Global Health Governance," in *Innovation in Global Health Governance*, ed. Andrew F. Cooper and John J. Kirton (Aldershot: Ashgate, 2009), 305-327.
[36] Michael A. Stevenson and Andrew F. Cooper, "Overcoming Constraints of State Sovereignty: global health governance in Asia," *Third World* Quarterly 30, no. 7 (2009): 1380.
[37] Alison Bashford, "'The age of universal contagion': history, disease and globalization," in Alison Bashford ed., *Medicine at the Border: Disease, Globalization and Security, 1850 to present* (Basingstoke: Palgrave, 2006), 11.
[38] Ian Clark, *Globalization and International Relations Theory* (Oxford: Oxford University Press, 1999), 52.
[39] Vicente Navarro, "Health and Equity in the World in the Era of 'Globalization'," *International Journal of Health Services* 29, no. 2 (1999): 222.
[40] Neustadt and Fineberg, *The Swine Flu Affair*, 11.
[41] Michael Mann, "Has globalization ended the rise of the nation-state?," In *International Order and the Future of World* Politics, eds. T.V. Paul and John A. Hall (Cambridge: Cambridge University Press, 1999), 259.
[42] Andrew Hurrell and Ngaire Woods, "Globalisation and Inequality," *Millennium: Journal of International Studies* 24, no. 3 (1995): 447.
[43] Edward A. Kolodziej, "Security Studies for the Next Millennium: Quo Vadis?," In *Critical Reflections on Security and Change*, eds. Stuart Croft and Terry Terriff (London: Frank Cass, 2000), 29.
44 Nicole A. Szlezák, Barry R. Bloom, Dean T. Jamison, Gerald T. Keusch, Catherine M. Michaud, Suerie Moon, William C. Clark, "The Global Health System: Actors, Norms, and Expectations in Transition," *PLoS* 7, no. 1 (2010), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2796301/pdf/pmed.1000183.pdf <27 March 2010>.
[45] Peter A. Patriarca and Nancy J. Cox, "Influenza Pandemic Preparedness Plan for the United States," *Journal of Infectious Diseases* 176, (Suppl 1) (1997): S4-S7.
[46] John Treanor, "Weathering the Influenza Vaccine Crisis," *New England Journal of Medicine* 351, no. 20 (2004): 2037-2040.
[47] Catherine Gerdil, "The annual production cycle for influenza vaccine," *Vaccine* 21 (2003): 1776-1779.
[48] Richard T. Mahoney, Ariel Pablos-Mendez, and S. Ramachandran, "The introduction of new vaccines into developing countries III. The role of intellectual property," *Vaccine* 22 (2004): 786-792.
[49] Michelle M. Mello and Troyen A. Brennan, "Legal Concerns and the Influenza Shortage," *American Medical Association* 294, no. 14 (2005): 1817-1820.
[50] David S. Fedson, "Pandemic Influenza and the Global Vaccine Supply," *Clinical Infectious Disease* 36 (2003): 1552-1561.
[51] Patricia M. Danzon, Sousa Pereira Nuno, and S Tejwani Sapna, "Vaccine Supply: A Cross-National Perspective," *Health Affairs* 24, no.3 (2005): 706-717.
[52] Julie Milstien and Scott Lambert, "Emergency response vaccines—a challenge for the public sector and the vaccine industry," *Vaccine* 21 (2002): 146-154.

[53] As referenced from Daniele Archibugi and Kim Bizzarri, "The Global Governance of Communicable Disease: The Case for Vaccine R&D," *Law and Policy* 27, no. 1 (2005): 38.
[54] Mahoney, Pablos-Mendez, and Ramachandran, "The introduction of new vaccines into developing countries," 789.
[55] Irina Serdobova and Marie-Paule Kieny, "Assembling a Global Vaccine Development Pipeline for Infectious Diseases in the Developing World," *Health Policy and Ethics* 96, no. 9 (2006), 1558.
[56] "Top industries: Most profitable," *Fortune*, 20 July 2009, http://money.cnn.com/magazines/fortune/global500/2009/performers/industries/profits/ <2 February 2010>
[57] Mark Honigsbaum, "Was swine flu ever a real threat?" *Telegraph*, 2 February 2010. Available at http://www.telegraph.co.uk/health/swine-flu/7130303/Was-swine-flu-ever-a-real-threat.html <10 February 2010>.
[58] Richard D. Klausner et al., "The Need for a Global HIV Vaccine Enterprise," *Science* 300 (2003): 2036-2039.
[59] Jon Cohen, "Gates Foundation Rearranges the Public Health Universe," *Science* 295, no. 5562 (2002): 2000.
[60] Flavia Ferrantelli et al., "Building collaborative networks for HIV/AIDS vaccine development: the AVIP experience," *Springer Seminars in Immunopathology* 28 (2006): 289-301.
[61] Joanna Chataway et al., "The International AIDS Vaccine Initiative (IAVI) in a Changing Landscape of Vaccine Development: A Public/Private Partnership as Knowledge Broker and Integrator," *European Journal of Development Research* 19, no. 1 (2007): 100-117.
[62] Chunling Lu, "Effect of the Global Alliance for Vaccines and Immunisation on diphtheria, tetanus, and pertussis vaccine coverage: an independent assessment," *Lancet* 368 (2006): 1088-95.
[63] Flavia Ferrantelli et al., "Building collaborative networks for HIV/AIDS vaccine development.".
[64] John Clemens and Luis Jodar, "Introducing new vaccines into developing countries: obstacles, opportunities and complexities," *Nature Medicine* 11, no. 4 (Suppl) (2005): 12-15.
[65] "Pledges & Contributions," *Global Fund to Fight AIDS, Tuberculosis and Malaria*. Available at: http://www.theglobalfund.org/en/pledges/
[66] "Pandemic (H1N1) 2009 – Update 60," *World Health Organization*. Available at: http://www.who.int/csr/don/2009_08_04/en/index.html <15 February 2010>.
[67] Tom Randall, "Swine Flu Border Closures are Political, WHO Says," *Bloomberg*, 27 April 2009. Available at: http://www.bloomberg.com/apps/news?pid=20601087&sid=aGUBidP8t38A&refer=worldwide <15 February 2010>.
[68] Richard Dodgson, Kelley Lee and Nick Drager, *Global Health Governance: A Conceptual Review* (London: World Health Organization and London School of Hygiene and Tropical Medicine, 2002).
[69] "HHS Pandemic Influenza Plan," *Department of Health and Human Services*. Available at: http://www.hhs.gov/pandemicflu/plan/appendixc.html <15 February 2010>.
[70] Julie L. Gerberding, "Testimony," *United States Senate Committee on Health, Education, Labor, and Pensions*, 29 April 2003, http://www.hhs.gov/asl/testify/t030429_a.html <15 February 2010>.
[71] Gregory A. Poland, Robert M. Jacobson, and Paul V. Targonski, "Avian and pandemic influenza: An overview," *Vaccine* 25 no. 16 (2007): 3057-3061.
[72] Office of the Press Secretary, "President Announces Plan to Expand Fight Against Global H1N1 Pandemic," *The White House*, 17 September 2009. Available at: http://www.whitehouse.gov/the_press_office/President-Announces-Plan-to-Expand-Fight-Against-Global-H1N1-Pandemic/ <15 February 2010>.
[73] Centers for Disease Control and Prevention, "Immunization Update," *Centers for Disease Control and Prevention*. Available at http://www.cdc.gov/vaccines/news/newsltrs/imwrks/2008/200805.htm <10 February 2010>.
[74] Lawrence O. Gostin, "Redressing the Unconscionable Health Gap: A Proposal for a Global Plan for Justice," Presented at the *International Conference on Realising the Rights to Health and*

Development for All, 28 October 2009, Ha Noi, Viet Nam. Available at http://www.healthandrights.com/images/File/Prof%20Gostin%20English.pdf <15 February 2010>.

[75] Michael D. Shear and Rob Stein, "Why such a shortage of swine flu vaccine," *Washington Post*, 27 October 2009. Available at: http://www.washingtonpost.com/wp-dyn/content/article/2009/10/26/AR2009102603487.html <15 February 2010>.

[76] Ulrich Keil, "Hearing on 'The handling of the H1N1 pandemic: more transparency needed?': Introductory statement by Prof. Dr. Ulrich Keil," *Social, Health and Family Affairs Committee of the Parliamentary Assembly of the Council of Europe*. Available at http://www.assembly.coe.int/CommitteeDocs/2010/20100126_ContributionKeil.pdf <10 February 2010>.

[77] Peter Doshi, "How should we plan for pandemics?," *British Medical Journal* 339 (2009): 603-605.

[78] Richard Schabas and Neil Rau, "How the WHO overshot on H1N1," *The Global and Mail*, 27 January 2010. Available at: http://www.theglobeandmail.com/news/opinions/how-the-who-overshot-on-h1n1/article1436739/ <15 February 2010>.

[79] Véronique Lapaige, "'Globalized Public Health': A Non-linear and Transdisciplinary Interactive Model for Analyzing Contemporary Globalization's Impacts and Influences on Public Health," *Risk Management and Healthcare Policy* 2 (2009): 73-89.

[80] Cathy Gulli, "Swine Flu Fiasco," *Maclean's* 122, no. 41 (2009): 50.

[81] Amy S. Nunn1, Elize M. Fonseca, Francisco I. Bastos, Sofia Gruskin, Joshua A. Salomon, "Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment," *PLoS Medicine* 4, no. 11 (2007). Available at: http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0040305 <15 February 2010>.