Research Report

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Title of Research: Social and Political Dimensions of Public Health Policy: The Case of Influenza
Purpose of Research:

Public health policies do not sit idly in vacuums. They both perform and are performed upon. Amplified by the power of mass communications, public health policy holds the capacity to move populations both physically and psychologically, promote states of alarm and to lay anxieties to rest. The logic of many public health policies is utilitarian, its object the population ahead of the individual. But most approaches to public health are in practice still squarely concerned with the individual. How public health policy is formed in allegedly democratic nations such as the United States and Japan is the subject of my research. Asking how public health policy is formed allows us to begin a conversation about decision making regarding our health—who is to make these decisions? On what basis? How shall public health funds be used? What kind of evidence is sufficient to claim a decision is “evidence-based”? Who should have access to that evidence? Will it be vulnerable to critical appraisals from independent researchers? Why are certain histories remembered and other not? Why are certain people empowered to make decisions—and others not? Why are certain viruses focused on while others not? These questions allow us to glimpse at the contemporary science and politics of public health.

Content/Methodology of Research:

My research employs the tools of a variety of disciplines: history, anthropology, political science, and epidemiology. For the past four years, this cross-disciplinary approach has allowed me to focus on the topic of influenza from a multiple angles—considering both social, political, and technical aspects of influenza (the disease) and influenza vaccination (the public policy). This approach has proved very successful, and resulted in seven publications since 2005. I hope to extend this methodology as I pursue the wider topic of public health policy.

To carry out my doctoral dissertation research on Japanese public health policy, I made arrangements to live in Japan for around one year beginning in October, 2008. For the first half year of my research in Japan, I interned within the Japanese Ministry of Health, Labour, and Welfare, half of the time in the International Affairs section, and the remainder in the Division of Tuberculosis and Infectious Diseases. By contract, I am not permitted to discuss information learned while at the Ministry without prior review and approval, so here I will only discuss the content and nature of my work. I primary utilized two approaches: participant observation and case study considering the topic of pandemic influenza. I requested and received ethical approval for interviews from the Massachusetts Institute of Technology (MIT) Committee on the Use of
Humans as Experimental Subjects before leaving for Japan. At the Ministry, I worked alongside employees and attended their meetings. Most ministry documents bound for public release or those drafted in response to Diet inquiry go through multiple stages of drafting and review before they leave the Ministry. Being an intern allowed me to witness—and at times participate in—this process of crafting official answers. I also attended several international health conferences which allowed me to interact with public health officials from countries across the world (including the United States) which was important for my research.

Following my internship at the Ministry, I arranged for a research student position at the National Institute of Infectious Diseases (NIID). The NIID is a government institution responsible for technical assessment and on the ground outbreak investigations of infectious diseases. As chance would have it, my time at the NIID coincided with the NIID’s early outbreak investigations of novel influenza virus H1N1 in May, 2009. This allowed me to witness, on a daily basis, the evolving understanding and reaction to this outbreak deemed a pandemic by the World Health Organization. This was a great opportunity as I had witnessed the creation of pandemic preparedness policy while serving as an intern at the Ministry of Health, Labour and Welfare. The month I was in the NIID allowed for study into the interaction of policy and practice.

Following these two positions within the public health bureaucracy of Japan, I began another project as a member of a Cochrane review of neuraminidase inhibitors for influenza, one of the two primary pharmacological approaches governments around the world planned to fight a future pandemic of influenza. We gathered material for review through a variety of databases searches and literature reviews as well as through a Freedom of Information Act (FOIA) request to the United States Food and Drug Administration. These papers were primarily concerned with the effectiveness and safety of the drug. Our group also attempted to obtain raw data from authors of several clinical trials. Working with the Cochrane team allowed me both the opportunity to study the effects of a drug as well as to study the human dynamics of what is known as EBM (evidence based medicine).

Conclusion/Observation

My detailed case study of an influenza drug expected to be used in great quantities and for entire populations at a time, with the background of my experience in the public health sector in Japan led me to conclude that many difficulties remain for a sound basis to public health decision making. At its core, evidence based medicine requires the evidence base underlying public health policy to be of high quality. Confidence based on a tested and publicly accessible evidence base will better inform policy making than a closed evidence base not open to independent scrutiny. In our study (Jefferson et al. 2009a) of the globally stockpiled oseltamivir (Tamiflu), we concluded that we could not say with any confidence whether the drug provides a therapeutic advantage (a better balance of harms and benefits) than cheap, over the counter medicines such as paracetemol (Doshi 2009b). For prevention of influenza, we do not know whether oseltamivir offers an advantage over handwashing and other barrier interventions, and the frequency and type of possible harms of oseltamivir are poorly understood (Jefferson et al. 2009b).

How the benefits of a globally stockpiled drug could become so widely recognized yet simultaneously open to question likely has no simple explanation, but it may be in part due to the
extensive role of trust throughout the system of drug regulation. New drug applications are often thousands of pages long, too complex to be fully and critically evaluated on a deadline with limited manpower. Most regulators, unfortunately, find themselves in such a situation. Furthermore, the successful marketing of drugs by manufacturers may result in policy makers coming to believe a drug is more efficacious than drug regulators have certified. Differences in drug regulation standards between countries can have a similar effect, allowing drug companies to creatively bypass national regulatory authorities and emphasize their drug in ways that would normally be illegal.

Being in Japan also afforded me the opportunity to study Japanese vaccine policy both on paper and in practice via interviews with doctors and parents in Tokyo. This resulted in an article co-authored with Professor Akira Akabayashi of the Center for Biomedical Ethics and Law at the University of Tokyo that is due to be published later this year in the *Cambridge Quarterly of Healthcare Ethics*. This article offers a broad outline of Japanese vaccine policy and its history, and compares this policy to that in the United States. We focus on the question of how Japan has achieved what seems elusive in many other countries: high vaccination rates (an important goal of public health officials) under a completely voluntary system (a central concern of public health ethics).

In “Calibrated response to emerging infections” (Doshi 2009a), I reflect upon my observations of the sociology of epidemiological understandings of epidemics using the 2009 influenza pandemic as a case study. I argue that advances in laboratory technology have led to reactions to newly emerging infectious diseases out of proportion with the morbidity and mortality threat of the disease itself.

In an unrelated letter now accepted for publication, I wrote to the *Journal of Infectious Diseases* that the definition of an influenza pandemic must include some connotation of severity. This letter is in response to an historical review article by the director of the National Institute of Allergy and Infectious Diseases and colleagues, which suggested that a pandemic might best be understood as an epidemic with large geographical spread. The problem with this definition, I point out, is that it implies that influenza is a pandemic each and every year, as are many illnesses such as the common cold. If the distinction between “pandemic influenza” and “seasonal influenza” is lost, I argue, what further public policy rationale exists for treating one disease any different than the other?

The Matsushita grant was helpful in advancing my research which, by the end of 2009, resulted in six publications (four published, two in press).

**Bibliography of publications published during 2009**


