CHAPTER 10

The Policy and Politics of Public Health in Pandemics

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1 Introduction

The utility of political science insight and methodology for public health has become increasingly apparent in discussions over policy implementation. In areas such as tobacco regulation (Jarmon, 2018), sugary beverage taxation (Nestle, 2015), and healthy urban design (Corburn, 2009), the

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issue is how to mobilize decision-makers in order to bring about particular kinds of legislation or policy initiatives. Analytical frameworks such as Kingdon's multiple-stream approach (1984) or Sabatier and Jenkins-Smith's Advocacy Coalition Framework (1993) have been particularly useful in helping public health advocates understand how best to navigate the policy-making realm and to push public health initiatives on to the agenda.

These discussions of policy implementation are quite interesting for political scientists because they utilize accounts of agency and advocacy that sit firmly within the discipline. Public health responses to pandemics are qualitatively different, as they are essentially reactive. Pandemic planning requires getting the right goods and services to the right places at the right time. It necessitates clear lines of accurate communication. But it also means decision-making in a context of limited information, a rapidly-changing base of evidence, thoroughgoing uncertainty, and heightened public anxiety.

This chapter was originally presented in June 2019. Its focal point was the claim that the political analysis of public health was too focused on the implementation of health promotion policies, and that it could be useful to think more carefully about another public health context—pandemics—to prepare us better in the off-chance that another pandemic manifested itself. As such, the paper showed remarkable foresight. In the subsequent two years between presentation and publication, however, the focus of this chapter has shifted to an analysis of the ways in which understanding the political response to previous pandemics could have prepared us much better for COVID-19, had there been more interest in this topic. For example, previous pandemics showed us that the crucial aspects of pandemic governance included the coordination of roles and responsibilities within and between jurisdictions; the importance of coordinating messaging across jurisdictions; the need to provide clear information in a context of rapidly-changing scientific understanding; the prioritization of which groups would be vaccinated first; the determination of relative effectiveness and safety of vaccines; and the issue of how to deal with the vaccine-hesitant. But, given the context of limited access to primary and acute care across provinces, an analysis of how to deal with what *might* happen was given low priority compared to those areas generating immediate political dissatisfaction. Neither policy-makers nor policy analysts invested the time to consider events that might or might not occur.

The overarching claim in this chapter is that the evidence-policy-politics nexus in public health differs substantially between the fields of "health promotion" and "disease surveillance and mitigation". In the former, there is often much solid evidence supporting a public health intervention; the difficulty is in getting it on the political agenda. In the latter, the issue is squarely on the political agenda, but the evidentiary base is limited, in flux, and often contradictory. While we discuss the larger decision-making context that characterized the influenza A (H1N1) pandemic (itself a product of the brief Severe Acute Respiratory Syndrome [SARS] pandemic), we will focus more sharply on the decision-making surrounding vaccines and antivirals developed for H1N1. We note that, while pandemic preparedness has increasingly addressed the conditions of hyper-bounded rationality that decision-makers face by establishing clear practices in many areas, the protocols that arose in response to the H1N1 pandemic had many limitations.

2 The H1N1 Pandemic in Nova Scotia

The 2009 global pandemic was caused by the influenza A (H1N1) strain. It was formally identified on 18 March 2009 as originating in central Mexico. A student on a school trip to the Yucatan Peninsula during the first week of April infected three other students at a residential boarding school in Nova Scotia. These were Canada's first confirmed cases of H1N1. On 25 April, the World Health Organization (WHO) declared a Public Health Emergency of International Concern. Two days later, it raised the pandemic alert level to phase four (sustained human-to-human transmission); after two further days, this was raised again to phase five (widespread human infection and imminent pandemic). By this point, there were 13 confirmed cases of H1N1 across Canada. On 9 June 2009, Nova Scotia elected its first NDP government which, in addition to the logistics of governance transition, now had a virulent pathogen to manage. Two days later, on 11 June, the WHO raised its pandemic alert to level six, the highest level, indicating a global outbreak.

The 2009 influenza pandemic manifested itself in two waves: the peak period for the first was between 31 May and 20 June; the second was between 25 October and 14 November. The second wave was much larger than the first, resulting in almost five times more hospitalizations and deaths (Public Health Agency of Canada, 2010). Altogether, 40,185 cases of H1N1 influenza in Canada would be formally confirmed by

laboratory testing: of these, 16.9% would be admitted to an intensive care unit, and 428 people would die (Standing Senate Committee on Social Affairs, Science, and Technology, 2010). In terms of straightforward mortality, the H1N1 pandemic was considered much less severe than the previous 1918 ("Spanish flu"), 1957 ("Asian flu"), and 1968 ("Hong Kong flu") pandemics. However, because many older individuals had been exposed to similar strains in the past, those more likely to be severely infected by H1N1 were younger individuals. Over three-quarters of cases of H1N1 occurred in those under 30, and those between 10 and 19 seemed especially vulnerable (Fineberg, 2014, 1336; Low & McGeer, 2010, 1874). This meant that, calculated in terms of estimated years of life lost, the severity of the H1N1 became more considerable. Worldwide, more than 214 jurisdictions reported over 18,000 lab-confirmed cases of H1N1 resulting in death (Public Health Agency of Canada [PHAC], 2010); estimates for H1N1 deaths not confirmed by lab results have been placed at 201,200 respiratory disease deaths and 83,000 cardiovascular deaths globally (Dawood et al., 2012).

In Nova Scotia, there were 1,334 lab-confirmed cases of H1N1 between April 2009 and January 2010. As only the most serious cases were being lab-tested, it is likely that the number of actual cases was much higher. During the same period, there were 291 hospitalizations resulting from H1N1; of these, 50 were in intensive care units. Seven deaths in the province over this period were directly due to H1N1 (Government of Nova Scotia, 2010, p. 3).

From a public health perspective, the 2009 pandemic was a significant test of the protocol put into place after the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak. Internationally, the 2005 International Health Regulations (which came into effect in 2007) tested the leadership role of the WHO in managing and coordinating an international pandemic. The H1N1 outbreak was also notable insofar as it was the first pandemic where antivirals were widely used, and it was the first time that adjuvanted influenza vaccines were employed in North America. Both of these points will be discussed in more detail below. 50 million doses of the H1N1 vaccine were purchased by PHAC on behalf of the provincial, territorial, and federal governments. Canada's overall vaccination rate was 40%, which was, next to Sweden, the highest vaccination rate for H1N1 in the world. Nonetheless, there were considerable disparities between regions, with Québec, the Atlantic provinces, and the territories achieving vaccination rates of over 50%, and rates in Alberta, Manitoba, and Ontario hovering around 30% (Low & McGeer, 2010).

3 How Was the HiNi Pandemic *Political*?

After 10 August 2010, when the WHO declared that the H1N1 pandemic was officially over, agencies and academics alike evaluated the official response to the pandemic (Fineberg, 2014; Low & McGeer, 2010; Moghadas et al., 2010; Public Health Agency of Canada, 2010; Standing Senate Committee on Social Affairs, Science and Technology, 2010). The assessments generally fell into three categories: decision-making processes, communication, and institutional readiness.

The assessment of decision-making processes focused both on effective vertical command-and-control planning and on horizontal collaboration between units. The overarching strategic plan for the H1N1 pandemic was based on the Canadian Pandemic Influenza Plan, initially developed in 2006 (with the active participation of provinces and territories) in the wake of the SARS epidemic. This document focused on the roles and responsibilities of key players. The overall evaluation was that Canada had acquitted itself during the H1N1 pandemic much better than it had throughout the 2003 SARS epidemic. Nonetheless, given the inherent uncertainty of pandemics, several epidemiological post-mortems agreed on the need for adaptability and scalability in response plans. There was also some recognition in these reports that more stakeholders (such as physicians) would have to be involved more directly in the planning process, and that all jurisdictions would have to endeavour to maintain vigilance and readiness (e.g. through monitoring readiness plans and by committing public health funding for pandemic preparedness) when immediate threats had disappeared.

The analysis of how effective the communication had been was more critical. A major theme in the formal review documents was consistency in information over time, between jurisdictions, and across all units involved in pandemic management both provincially and federally (e.g. in offering a consistent definition of "severity"). In retrospect, many decisions that were made for sound reasons seemed arbitrary and unfair when proclaimed without clear explanations. Several decisions by provincial or federal authorities seemed peremptory and unreasonable when they were announced but, as the review documents noted, when the full reasoning for these decisions was given, there was a clear (although contestable) logic for these choices. There were also examples of mixed messages that seemed to work at counter-purposes. This was, for example, because long-term and short-term objectives were not clearly specified.

Why, for example, was a prioritization schema for vaccinations imposed when PHAC was stating that vaccines would be available for *all* Canadians who wanted them? The answer was that vaccines would eventually be available, but that in the *immediate* term the most vulnerable groups should be prioritized. If adjuvanted vaccines were safe, why were they not being given to pregnant women? The answer to this was that adjuvanted vaccines were not clearly *unsafe* for pregnant women; merely that the safety studies had not involved pregnant women, and so this group was excluded on precautionary grounds until the safety information was better established (see WHO, 2014). Why were first responders not given immediate priority for vaccination? The position here was that vulnerable groups with a high risk of mortality took precedence over first responders; this point had been clearly developed by PHAC in accordance with WHO guidelines. However, critics noted that these stipulations were merely guidelines, and that jurisdictions did have the authority to deviate from them. They also argued that this prioritization, while justifiable in terms of being "evidence-based", was quite "difficult to implement on the ground" (Standing Senate Committee on Social Affairs, Science, and Technology, 2010, p. 34). This illustrates the ambiguous use of "evidence" as the pandemic evolved: given the disparate contexts within which the pandemic was played out, evidence of "good practice" could be (and was) quite variable across locations.

In non-crisis times, the evidence base for best practices can be established gradually and iteratively. The demand for collegial input in the establishment of these practices means that they generally require time for discussion and for widespread input. Crisis management is largely based on the principle of command-and-control, which is effectively top-down decision-making. Yet, to instil confidence in front-line workers, there must be an opportunity for them to advise on whether the accepted evidence-based practices work for *them*. With H1N1, not only was this grassroots input missing, but even the top-down flow of communication was patchy. In some northern and remote areas, for example, providers reported receiving important information via their car radio during their drive in to work (Hodge, 2014).

Because so much attention had been placed on vaccines and antivirals, most evaluations of institutional readiness focused on access to these drugs. In fact, Canada's performance was, in comparative perspective, relatively impressive. As the vaccine used in Canada—Arepanrix—was manufactured in Québec, both the provincial and federal leads were in

constant contact with the company. Thus, Canada was able to negotiate contracts with pharmaceutical manufacturers that ensured that, notwithstanding a few wrinkles (such as packaging), the country had reasonably direct access to these drugs, at lower cost than many other jurisdictions were paying. Yet the provision of vaccines was not straightforward: GlaxoSmithKline (GSK), which produced the vaccine, was also selling to larger markets, and Canada was not always the preferred customer.

Other aspects of institutional readiness included epidemiological planning capacity, the logistics of implementing mass vaccination clinics, health human resources planning (including the way in which the scope of practice for professions such as pharmacists and paramedics could be utilized more effectively during pandemics), the establishment of electronic health IT (such as vaccination records), and the monitoring of pandemic surge capacity.

Nonetheless, none of the pandemic post-mortems squarely addressed the *political* dynamics that made the attempt to negotiate pandemic planning so difficult notwithstanding the existence of the thorough and detailed pandemic planning protocol that had been established post-SARS. Planning protocols are usually based on very quantitative information: how many vaccine doses, syringes, and respirators will be needed? Are there sufficient health care providers with the required skills at the right place at the right time? Are the roles and responsibilities for all responders and decision-makers set out clearly enough? There is in pandemic planning an implicit assumption that the context within which these features are measured and evaluated is operationally neutral; there is little sense of the underlying political dynamics upon which these planning specifications are imposed. Yet establishing emergency measures on a system with underlying tensions can limit the effectiveness of even the best-considered strategies. It is, in fact, when crises descend that the fault lines for such political stressors truly become visible. By understanding where these tensions exist, and how these dynamics manifest themselves, pandemic planning processes can better anticipate where and why established protocol may not be effectively implemented. Even where some of these political dynamics are chronic and intractable, advance recognition of these circumstances can permit greater attention and monitoring in real time.

3.1 Structures and Institutions

The most apparent manifestation of political conflict is influenced by (and reflected in) formal institutional structures. These can include national, provincial, or organizational structural frameworks. At the national level, one obvious tension is related to the distribution of the vaccine and antivirals. Because of the time required to manufacture the products, distribution had to be prioritized. The negotiation for the procurement of vaccines was a federal responsibility, but it was the provinces which were to allocate the vaccines to individuals. But on what basis? Manitoba, for example, was quickly overwhelmed by the H1N1 virus, and the Winnipeg Regional Health Authority declared a state of emergency on 7 June 2009. The province was hit particularly hard because of the high numbers of First Nations residents, who were disproportionately vulnerable to the virus, with a rate of infection 2.8 times higher than non-indigenous populations (Charania & Tsuji, 2010; Hodge, 2014; Kumar et al., 2009; Zarychanski et al., 2010). British Columbia, where the second wave of H1N1 influenza manifested itself more quickly as well, asked to (but did not) receive vaccinations before less-affected provinces (Moghadas et al., 2010). The H1N1 vaccination was, at this point, the largest single vaccination programme in the country's history. Ottawa did provide distribution projections for all provinces, but production challenges meant that the number of doses each province received was subject to change at short notice, with little communication providing forewarning of shortages (Standing Senate Committee on Social Affairs, Science, and Technology, 2010). However, formal distributional protocol was also buttressed by informal collaboration between provinces. After the initial interprovincial allotment of vaccines was determined, for example, extensive discussion amongst the provinces led to a willingness on the part of many provinces to give up part of their allotments to provinces (especially Saskatchewan and Manitoba) with higher Indigenous populations (who were more vulnerable to H1N1).

The federal structure led to tensions in unanticipated ways as well. An attempt was made by the federal government to establish a pan-provincial electronic health registry for vaccinations, as provinces were recording vaccination records on hard copy only. British Columbia was designated as the lead on this initiative, and each province was asked to contribute. Nova Scotia's Department of Health Promotion gave $1 million, but not all provinces would contribute. Québec, as with other

ventures (such as Canadian Blood Services), preferred to develop their own system parallel to, but distinct from, pan-Canadian ventures. And, as other larger provinces contributed a greater proportion of the funding (while enjoying limited control), they calculated that they could develop their own systems with the money that it could cost them (and even do so more cheaply). In the end, the funds collected were retained by British Columbia and eventually used towards the development of that province's own IT systems.

The tracking of adverse events in pharmaceuticals is a complicated and highly political issue in its own right. As Lexchin (2006) notes, the problems with reporting adverse events are well known: "poor quality of submitted reports; significant underreporting of adverse reactions; difficulty in calculating rates because of incomplete numerator data along with unreliable denominators; and limited ability to establish cause and effect". And, as explained below, influenza vaccines—because of the particular way in which they are designed—cannot be tested as rigorously as non-biologic drugs. While the provisional "base" for the vaccines is standard, the "added on" component for each specific variant of influenza is novel. Strain-specific vaccines cannot be produced without the existence of the strain; yet once the strain is identified, there is a serious time-pressure to produce and distribute the vaccine to curb its prevalence. But adverse event reporting with vaccines in general, and during pandemics in particular, is even more fraught with political difficulties. Generally, with adverse events, the precautionary principle—assume a potential problem identified is serious, until proven otherwise—is applied. With vaccines, however, the precautionary principle can heighten public anxiety, undermine public trust, and lead to greater vaccine hesitation. At the same time, epidemiologists have expressed concern that "the five current methods of vaccine vigilance (case reports, case–control studies, active and passive surveillance and randomized controlled trials) are insufficient and further developmental work should be undertaken" (Jefferson, 2000, 402). Thus, good science would, in normal times, dictate an abundance of caution, but in a pandemic such a strategy can inflame public anxiety, leading to depressed uptake of vaccines and the concomitant rise of virus spread. Fragmentation also existed horizontally between federal agencies: for example, during the provision of H1N1 vaccines, Health Canada was responsible for approving the vaccine in an expedited manner. Thus, the H1N1 vaccine was approved on a "rolling" basis, where data was examined as it became available, with "a greater emphasis on post-marketing

commitments" (PHAC, 2010, 67). But, as noted above, post-market collection of possible adverse events is quite poor at the best of times, and in Canada, it was not Health Canada but rather the Public Health Agency of Canada (PHAC) which was responsible for tracking the adverse effects of the vaccine (Standing Senate Committee on Social Affairs, Science, and Technology, 2010, 36). Yet most adverse events tracked were those that appeared within hours or days of vaccination; the problem, as Jefferson (2021) argues, is that there was little careful scrutiny of possible longer-term adverse events, such as neurological damage.

Within Nova Scotia, institutional fragmentation, both vertical and horizontal, tested the capacity of the province to deal effectively with the H1N1 outbreak. When Nova Scotia established nine district health authorities (DHAs) in 2001, these regional units were given the responsibility of managing responses to potential pandemics, with the province becoming involved only when a DHA "could no longer adequately respond to the situation" (Nova Scotia Auditor General, 2009, p. 12). Yet, as there was no central review of district health authority plans, nor a clear sense of whether these plans existed at all, a situation existed which could permit DHAs and provincial departments to attempt to offload responsibility to each other. Because there were regular communication sessions between the Deputy Ministers for the Departments of Health and Health Promotion and the CEOs of the DHAs, there was generally effective cooperation between units on implementation strategy in the province. While some issues of coordination did surface, as this chapter describes, the province was able to contain and minimize the fallout. A somewhat more concerning issue was that information on the available stockpiles of supplies held by DHAs was not readily available, and the province was uncertain whether they could "legally require the DHAs to provide details of their supplies on hand and costs for those supplies" (ibid., 20).

A separate issue was the unclear division of authority between the province's Department of Health and the Department of Health Promotion and Protection. The nature of acute health care demands on the health care system makes it difficult to protect stable, long-term funding for public health and, in a novel administrative move, the Progressive Conservative administration developed a cabinet portfolio for health promotion in 2002. This guaranteed a discrete budget as well as a separate voice for public health in cabinet discussions. The aim of this restructuring was to give public health an opportunity to develop and flourish without

competing with acute health services for direct funding. Ironically, it was precisely a public health crisis which led to the dissolution of the Department and Health Promotion and Protection, and its ultimate reabsorption in a consolidated Department of Health and Wellness in 2012.

The problem, as outlined by the Nova Scotia Auditor General, was that there was no clear command-and-control structure of authority between the Department of Health, the Department of Health Promotion and Protection, and the Emergency Management Office, such that it was "not clear who will be involved in decisions once the response is being managed by multiple entities" (Nova Scotia Auditor General, 2009, p. 10). Communication and planning between the two units were indeed lacking on important matters. On one occasion, for example, the Department of Health Promotion and Protection neither consulted with the Department of Health, nor even gave them advance warning, when they announced a policy of offering free (regular season) flu shots. This had budget implications for the Department of Health, as well as some staffing implications, due to this unknown announcement that had not been anticipated by the Department of Health. However, both departments reported to the Minister of Finance, who was, after this, able to maintain a degree of oversight over the coordination between departments. This underscores the fundamental tension involved in promoting public health objectives: a policy that clearly ring-fences resources for public health and provides a conduit for public health policy champions to achieve long-term goals can, if not carefully monitored, also interfere with immediate public health planning objectives in emergency situations.

Another example of horizontal tensions between institutions was in the competition for scarce resources. Formally, H1N1 vaccines and antivirals were purchased by PHAC on behalf of the Government of Canada and distributed to the provinces and territories, which would then allocate these drugs to their respective populations on their own authority, taking into account guidelines on prioritization that had been developed in consultation between federal, provincial, and territorial representatives. In practice, however, the provinces (as in the case of Nova Scotia) could be circumvented by the DHAs, which were able directly to access the drugs. The IWK Health Centre in Halifax, for example, was able to purchase the antiviral Tamiflu directly, without consultation with the province, leading to considerable tension between agencies.

3.2 Interests

The political tensions between stakeholder interests are less obvious than those at an institutional level, yet arguably led to more acrimony and tension. The most evident tension during the H1N1 pandemic again focused on drugs and addressed the prioritization of recipients for vaccination. The production of the H1N1 vaccine, once it was developed, was first delayed because (following WHO guidelines) companies were asked to complete their production of the seasonal influenza vaccine (which could likely be circulating simultaneously with the H1N1 variant). Thus, while the H1N1 virus was first identified in April 2009, production of the vaccine began in September 2009. The H1N1 vaccine being produced contained an adjuvant, or booster, which was designed to increase the effectiveness of each dose. However, the WHO had advised that pregnant women, a designated highly-vulnerable group, should receive a unadjuvanted vaccine, and so production of the adjuvanted vaccine was halted again to allow for production of the unadjuvanted variant.

The doses that were released thus had to be distributed to designated priority groups first. Priority for vaccination was initially given to children 6 months to five years of age, pregnant women, individuals with certain underlying or chronic medical conditions, and individuals living in rural and remote settings. PHAC's Pandemic Vaccine Task Group collaborated with the provinces and territories to develop these prioritization guidelines, but the provinces and territories were not strictly obliged to follow these guidelines, and so the implementation of the sequencing guidelines varied across regions. This led to public confusion regarding who had first call on the limited number of vaccines. Public health nurses reported that the criteria for priority groups shifted quickly "sometimes changing by the hour during immunization clinics" (Hodge, 2014; Long, 2013, cited in Hodge, 2014).

Across Canada, the media exacerbated the tension, reporting that inmates in penitentiaries and professional sports teams were being allowed to gain preferential access. Another source of controversy was the choice not to include first responders in the initial priority groups. This upset many health care providers, who worried that they were at high risk to contract the virus given that they were in contact with many infected patients, and could not only be infected themselves, but also risked passing the influenza virus on to their families (Hodge, 2014). The decision was a deliberate and arguably defensible one, and it focused on

minimizing illness and death of those most vulnerable in the first instance (Standing Senate Committee on Social Affairs, Science, and Technology, 2010, 34). The prioritization schema, based on WHO protocol, was established fairly quickly at the federal level, but they were simply guidelines, and provinces had full authority to make their own prioritization decisions. Because the vaccines came onstream just before the second peak in October 2009, it was important to vaccinate as many individuals as possible as quickly as possible as "very rapid delivery of vaccination was the only means of optimizing program impact" and, for this reason, some provinces at the outset simply "attempted to get the vaccine out to as many people and as soon as possible, and did not enforce the priorities of the Public Health Agency of Canada" (Low & McGeer, 2010, p. 1876). Nonetheless, the explanation for why certain groups were or were not given precedence was not clearly communicated, leading to considerable resentment and criticism.

The acrimony over prioritization underscored another source of conflict, again focused on vaccines. Physicians in Canada are accorded a relatively high level of autonomy in medical decision-making. The command-and-control protocol of pandemic governance, however, strongly constrained the ability of doctors to make decisions in areas they had historically considered to be within their purview (Nhan et al., 2012). They particularly wanted to determine for themselves who amongst their patients could receive a vaccination, claiming that they were the best judge of who was most vulnerable to the virus. Public health nurses in more remote areas also expressed a level of frustration, based on the observation that they knew more about their geographic areas of practice and the inhabitants within them (Hodge, 2014). Health care providers, in turn, often had to address the antagonism of individuals who were refused vaccinations based on protocol with which the providers themselves did not support.

In Nova Scotia, the discord between physicians and the province was especially fraught, as the province made the decision to direct allotted vaccine supplies to large-scale immunization clinics, run by public health nurses, rather than to GPs' offices, which was standard protocol for seasonal influenza vaccines (Standing Senate Committee on Social Affairs, Science, and Technology, 2010, 34). The doctors took issue with this measure and openly criticized the provincial government's strategy to maximize vaccination rates. In response to this criticism, the Minister of Health responded that:

> Some people have criticized us for not just doing a doctor-based program; I want to explain why that is, why we didn't do a doctor-based program. First of all, it's not what we do traditionally in terms of influenza. Secondly, we want our doctors doing what we need them to do most - treat sick people, number one. Number two, for example if we just took the Capital District Health Authority, 270 doctors times, let's say they can do 50 vaccines a day - at the end of the week, we would have vaccinated 13,500-some-odd people. With the mass community-based clinics, staffed by nurses and docs - we have docs in some of those clinics - we can do 1,000 people per clinic in a day. We have roughly maybe six clinics - 6,000 people a day versus 1,350 people in a week. (Hansard Nova Scotia, 2009)

At the same time, the front-line workers—mainly public health nurses in the immunization clinics—were employed by the District Health Authorities, yet accountable to the Department of Health Promotion (and had no relationship whatsoever with the Department of Health). This leads to a disconnect where Public Health staff were seen as a priority during the pandemic, which resulted in the manifestation of resentment on the part of other health care providers. When the immunization clinic project was completed, for example, the Department of Health Promotion sent each public health office a sum of money to be used on a "thank you" event for staff. This was, however, not well received by those in either the Department of Health or the DHAs. Such tensions contributed to the eventual reintegration of the Departments of Health and Promotion into the new Department of Health and Wellness. The province was engaged in a separate but equally charged political tussle with the health unions. Certain provisions of the unions' collective bargaining provisions were subject to suspension in the event of a pandemic. To address the concerns of the unions, the province negotiated a "Good Neighbour Protocol" to deal with human resource issues during the pandemic period. This protocol addressed issues such as where health workers could be sent, quarantine, liability, temporary licensing, and compensation (Nova Scotia Auditor General, 2009). The protocol, which involved seven unions representing close to 50,000 workers, was expected to be signed in May 2009 (ibid.). However, while the unions accepted in principle the need to facilitate flexibility in the labour supply and to suspend collective bargaining, they were nonetheless concerned about provisions that might require them to drive long distances across the province to report to work. In the end, the parties finally came to an historic agreement—the first of its kind in

Canada—but not until 27 October 2009 (Government of Nova Scotia, 2010).

On another front, the province also had to deal with the Auditor General's Office (AGO). The AGO had begun its audits of the province's pandemic preparedness plans early in the spring, under the Conservative government. The intention of the AGO had been to submit its evaluation in its regular fall report, but subsequent to the April 2009 outbreak, and the declaration of a pandemic in June, the AGO decided to issue a Special Report in July 2009 in order to assist the province to take measures to ensure adequate preparedness (Nova Scotia Auditor General, 2009). Yet the report was a public document, and it was quite critical of some aspects of the province's readiness to deal with the pandemic. Key points included the absence of a central provincial agency responsible for central planning and the lack of an adequate stockpile of supplies needed to address the pandemic. The new NDP government, which was presented with a draft of the AGO's report weeks after assuming office, was concerned that the report would have an incendiary effect on a population that was already alarmed by the growing tide of H1N1, including the first death in the province attributed to H1N1 on 24 July. How much information was it responsible to release in the middle of a pandemic? The original point of the AGO's report was to determine how well placed the province was to deal with another SARS-like epidemic. But health care workers had died in the SARS outbreak in Ontario, and the province was concerned that if the public conflated SARS with the H1N1 pandemic, it would create widespread panic. The province requested that the AGO tone down the report and remove references to SARS and, four days after the province's first H1N1 fatality, the AGO's report was published. While a fairly rare occurrence, the AGO agreed, given the quite exceptional circumstances, to comply with this request.

3.3 Discourses and Narratives

Another level at which political dynamics are played out is in the construction of narratives of reality, which can influence public sentiment to serve the ends of specific stakeholders. The context of a pandemic is particularly precarious, as the volatility of the public mood combined with scientific uncertainty about the nature and extent of the virus (as well as the disruption occasioned by the demands of coordinating a major response) permits interests subtly to frame narratives to their advantage.

One underlying problem with H1N1 was the nature of the new influenza virus. While the scientific community had been preparing for an influenza pandemic for some time, the expected threat was from avian H5N1 influenza, which can lead to a mortality rate of 50% in humans (Fineberg, 2014). A major influenza pandemic was thus anticipated to be one of considerable severity. As the first six months of the H1N1 outbreak began to show far fewer major effects than expected, many Canadians began to exhibit a pronounced indifference to vaccination once the vaccine became available. Then, the same week that the vaccines began to arrive on stream, a healthy, hockey-playing 13-year-old died suddenly. The death was clearly attributable to H1N1, and the public mood suddenly shifted from nonchalance back to panic.

The darker possibility of a *deliberately*-constructed narrative—a narrative of fear—has been suggested by researchers tracking the development of the vaccines and antivirals used in the H1N1 pandemic (Doshi, 2011). In this account, the demand for speed of production and distribution of a pandemic vaccine introduces a higher level of uncertainty regarding safety and effectiveness. But, because of relative risk calculations (the severity of a pandemic outweighing the limited testing of the vaccine) as well as public pressure for governments to take action, most states were willing to enter into confidential advance purchase agreements (APAs) that locked purchasers in, yet exonerated pharmaceutical companies from liability should problems be identified with the vaccines after the fact.

4 How Were Vaccines and Antivirals Addressed by Policy-Makers During H1N1 pandemic, and What Lessons are Relevant for the COVID-19 Pandemic?

The H1N1 influenza was formally identified in Mexico in March 2009. By July 2009, it was clear that the threat level of the virus had been overestimated. H1N1 had nowhere near the mortality rates that had been projected for a H5N1 pandemic. Nonetheless, governments who had entered into APAs with pharmaceutical companies were locked into payment for production, and the vaccines came onstream in October 2009, in time for the "second wave" of the pandemic. Ironically, those countries which—like Canada—were amongst the best-prepared for a pandemic (by virtue of having a purchasing agreement negotiated well

in advance) were also those countries least able to make adjustments as the nature of the H1N1 virus became more apparent.

A major problem with the H1N1 vaccine was that initial risk assessments by Health Canada and other regulators determined that the limited clinical evidence for the safety and effectiveness was outweighed by the potential severity of a novel influenza strain (based on assumptions derived from the H5N1 influenza). Yet, once the mildness of H1N1 had been noted, the regulatory "short cuts" taken to bring the new vaccine into production should have been recalibrated against the reduced mortality threat of the new influenza strain. They were not. It is important to stress that the H1N1 vaccine was largely untested: all H1N1 studies began in September 2009, so that at registration no direct evidence of the effects of the vaccine was available (Jefferson, 2021). Rather, *indirect* markers which inferred effectiveness were used, as was common for the evaluation of regular seasonal influenza vaccines:

> By the definition of the time, the pandemic virus would be a novel virus, against which there was little or no immunity in the population. With no knowledge of what was coming and with the urgency impelled by the doomsday scenario, regulators used serological surrogates (antibodies) as correlates of field protection against influenza, i.e. markers of effectiveness, to kick start production of the vaccines. This was a standard procedure at the time for seasonal influenza vaccines. However, regulators themselves were unsure of the significance of the antibody response surrogate used as a proxy for field effectiveness estimation. These doubts are supported by the observed modest field performance of seasonal vaccines, registered yearly using the same surrogates of effectiveness … None of these doubts were allowed to interfere with the juggernaut unleashed by the pandemic declaration. (ibid.)

Complicating the matter was the use of an adjuvant for most of the vaccines (with a unadjuvanted version produced for specific subgroups, such as pregnant women). Adjuvants, or compounds added to normal vaccines to enhance their effectiveness, "had never been tested in trials against an inert substance in humans", so their relative toxicity was unknown (ibid.). The specific adjuvant used in the H1N1 vaccine had never been used in any licensed vaccines (Low & McGeer, 2010, p. 1877).

How important were these effectiveness and safety concerns? It is instructive to note that levels of vaccination did not correlate with

levels of mortality from H1N1. In Canada, where vaccination rates were high in comparison with other countries (40% overall), the mortality rate was 1.3 per 100,000 population (IPAC, 2014). In France, where vaccine scepticism is quite high, the overall vaccination rate was only 7.1% amongst those 18–60 (Schwarzinger et al., 2010). Nonetheless, the overall mortality rate for H1N1 in France (0.98 per 100,00) was *lower* than that in Canada (Lemaitre et al., 2012). In addition to vaccines, there is considerable evidence to show that the effectiveness of the oseltamivir antiviral stockpiled for use during the H1N1 pandemic ("Tamiflu") was quite minimal (e.g. Kmietowicz, 2017; Jefferson et al., 2014). A Cochrane review of oseltamivir in 2009 determined that the drug reduced complications of illness, but researchers subsequently discovered that this evaluation was based on a small, selective set of the available evidence. A protracted freedom of information request eventually provided 20,000 pages of data on the drug and, when this data was analysed, a 2014 Cochrane review found that there was "insufficient evidence to support claims that oseltamivir reduced lower respiratory tract complications or impeded viral transmission" (Dyer, 2020).

Even more concerning was evidence of toxicity of the Pandemrix H1N1 vaccine. The initial registration trials used to license the H1N1 vaccine employed only a few hundred people. By 2012, when millions of individuals had been vaccinated, a sensitivity analysis found a link between the Pandemrix vaccine (produced in Dresden) and narcolepsy in adults (Schnirring, 2012; Song et al., 2016). Overall, more than 1300 individuals in Europe developed narcolepsy after receiving the Glaxo-SmithKline's Pandemrix vaccine (Vogel, 2015). But narcolepsy was not the only adverse event identified:

> Pandemrix manufactured in Dresden was associated with a higher cumulative rate of harms, serious adverse events, deaths, anaphylaxis, facial palsy, convulsions and miscarriages … Data for these indicators of rare but serious toxicity were available since the end of October 2009, and should have led to immediate action by the competent authorities, either switching to a less toxic pandemic or seasonal influenza vaccine or halting the programme. (Jefferson, 2021)

In the end, there was little investigation of the relative risks posed by the H1N1 vaccine (or the antivirals) in Canada. During the pandemic, the only discussion of medical risk centred on pregnancy. After the

pandemic, Canada's federal structure meant that the agencies responsible for distributing and administering the vaccines—the provinces—had no interest and little authority in the area of drug safety, which comes under the purview of the federal government. But because the federal government was not largely responsible for administering the drug, its main concern was (and remains) adequate supply, not long-term health effects. The federal body responsible for monitoring adverse events related to pandemic drugs, the Public Health Agency of Canada is, formally, charged with the collection of health data related to pandemic vaccines. However, in the case of H1N1, the system was merely a passive one "which only collects adverse event reports that have been submitted by health care professionals, the manufacturer, and in some cases the public" (Standing Senate Committee on Social Affairs, Science, and Technology, 2010, p. 36).

A key lesson of H1N1 is thus that caution should be exercised when developing and approving treatment interventions for COVID-19. There is little likelihood that this lesson will be heeded. The pressing political imperative to develop treatments has led to a greater willingness to sanction shortcuts in data gathering, as well as approval based on limited data. Pfizer's study protocol permitted an interim analysis after 32 cases of COVID-19 occurred in the study population. This meant that it could potentially determine the vaccine to be effective if only six individuals testing positive for the virus were given the vaccine (along with 26 cases in the placebo group): thus, expedited approval could conceivably have occurred if only six people responded favourably to the vaccine (Herper, 2020). Moreover, the definition of "effectiveness" outlined in these protocols had set the bar quite low: for both the Pfizer and Moderna trials, for example, very mild cases of COVID-19 were included. This meant that these vaccines would be considered "successful" even if they only worked on mild cases, and had no effect at all on preventing moderate or serious cases. Any vaccine approved on these terms would give individuals a sense of immunity while providing no protection against severe cases of COVID-19. Beyond the *definition* of effectiveness, the *level* of effectiveness of a vaccine is generally considered, and in the case of potential COVID-19 vaccines, regulators in the United States and Canada have stated publicly that a vaccine showing just 30% effectiveness in reducing symptomatic cases of COVID-19 would be considered to be "beneficial" (Herder & Graham, 2020). Thus, the initial authorization for the vaccines was made, as these authors have noted, on very limited

grounds. As uptake of the vaccines allowed greater corroboration of initial positive statistics, the evidence base provided increasing confidence in the relative safety and effectiveness of the vaccine. But pandemic conditions do underscore the need to provide vaccines (arguably as much for political reasons as medical ones), and the imperative to vaccinate populations as quickly as possible increases the willingness to risk authorization with a much smaller evidence base. Governments have the unenviable task of securing vaccines as quickly as possible while convincing the public (and the larger scientific community) of the safety of these products. Complicating the situation, public trust (especially on the part of the scientific establishment) might have been won had all test data been released to the public. But many pharmaceutical firms (such as Pfizer) rejected this, arguing that it would destroy confidential commercial information. Governments, in no position to negotiate, gave in to the demand for data protection, thereby losing the opportunity to secure wider public trust in the process.

Another concern is that expedited approval for vaccines does not provide sufficient time to establish adverse events that may arise: in the case of Pandemrix, for example, there was a long lag between wide-scale vaccination and the onset of symptoms of narcolepsy. There is also a further issue that pandemic interventions are not tested on the very groups who are the most vulnerable to the disease. Is a vaccine just as effective on the elderly cohort as it is on the young? Are risks to pregnant women greater from the disease or from the vaccine? Again, the assumption that efficacy calculations from full trial populations can be extrapolated to a frailer cohort could lead to serious health outcomes. It is here, too, that a clinical trial protocol, even when made public in its entirely, does not provide sufficient information on the potential effectiveness of a drug, as the trial may have difficulty enrolling participants from these cohorts in practice, notwithstanding an articulation in the protocol that these cohorts should be represented. In such cases, decision-makers are forced to make judgements with limited information. And, while decisions can be made with greater certainty as more data is processed, the about-turns in official public health positions can itself undermine the public trust.

Wider political contexts are also important to consider. Early in the pandemic, most of the focus on expedited approval focused on the United States because of the imperative faced by the executive branch to show immediate progress on COVID-19 interventions. Moreover, regulatory

decisions made in some jurisdictions will have an impact on others: as data is so limited, regulators will keep an eye on progress in other jurisdictions (but some regulators will privilege some information, and other regulators will ignore it, leading to differences in regulatory decisions across jurisdictions). In Canada, the antiviral remdesivir was given expedited approval through the Special Access Program, even though Health Canada did not have access to the manufacturer's clinical study reports that are normally used as the evidentiary basis for drug approval (Edmonds et al., 2021). Another pathway for rapid approval in Canada, the Interim Order, allows the Minister of Health to provide expedited authorization if the treatment has received an authorization for sale in a foreign jurisdiction.

Not only does Canada in this way authorize COVID-19 treatments with a much less robust evidence base than normally expected for drug approval in non-crisis contexts, but it tolerates conflicts of interest in the use of experts used to provide guidance on COVID-19 interventions. This, again, is an echo of the H1N1 experience. Critics point out that the WHO's policy position on the use of antivirals for H1N1 was authored by an influenza expert who was receiving payments from the drug's manufacturer (Godlee, 2010). Similarly, Canada's COVID-19 vaccine task force is co-chaired by one individual who has received funding from three of the major vaccine developers (Novavax, Pfizer, and Johnson & Johnson) and another individual who was CEO of another company competing to develop a vaccine (Sanofi). These commercial relationships were not disclosed until a member of the federal task force resigned due to the lack of transparency governing the task force (Dougherty, 2020).

Thus, the issues underlying the development and regulation of vaccines and antivirals in a pandemic situation are fundamentally political issues which require a sophisticated form of political analysis to comprehend. What is the structural and institutional context through which these interventions are developed, approved, and distributed? How does this institutional framework affect the safety and effectiveness of such treatments in an atmosphere of desperate public demand and (sometimes opportunistic) political response? Who are the agents playing key roles in the roll-out of these interventions, and what interests do they have in pushing one agenda rather than another? How can these interests use context-framing and selective narratives in order effectively to achieve their respective objectives? While the immediate response to pandemics seems to be the development and crystallization of scientific principles,

the wider political context within which this scientific discussion emerges will subtly but substantially shape this discussion.

5 Conclusion

Pandemics pose particular problems for public health. The dynamics of public health politics under pandemic conditions are quite different from the kinds of political dynamics that inform policies geared to health promotion activities. On the one hand, public health actors in pandemic conditions enjoy an obvious advantage, as crises involving virulent pathogens have an immediacy that places them directly on the political agenda, often with the promise of generous funding to match policy initiatives. On the other hand, public health decision-making in pandemic conditions must be formulated in an atmosphere of heightened intensity, with limited or contradictory evidence; and the consequences of these decisions will be serious and immediate. Canada has had the opportunity to think about modern pandemic policy-making in slightly more depth than many other jurisdictions because of two pandemic events that occurred prior to COVID-19. These two events—SARS and H1N1—did establish a useful blueprint for dealing with pandemics. Key points that emerged were the need to develop structures and processes that addressed Canada's decentralized federal model and ensured the clear assignment of roles and responsibilities as well as consistent messaging within and between jurisdictions (Fierlbeck & Hardcastle, 2020).

But a key area of complexity for pandemic management that has *not* been effectively addressed is the development and utilization of pharmaceutical interventions for pandemic diseases. The emergence of SARS in 2003 was quite limited in scope, and the dominant strategy was containment. H1N1 was novel insofar as it was the first time pandemic management included both antivirals and vaccines. The development and utilization of these drugs, as noted above, were problematic for various reasons, but the virulence of H1N1 was relatively limited. With COVID-19, the stakes were much higher. There was a much greater political imperative for governments to be seen to be providing solutions to the crises, and this urgency established a tension with the need to ensure a solid and expansive evidence base for the safety and effectiveness of any intervention.

Political tensions underlie many aspects of the formal response to COVID-19 (Flood et al., 2020), but the pharmaceutical interventions

that many feel hold the key to controlling the disease involve a complex assortment of political relationships that must be scrutinized carefully. The experience of H1N1 gave us a good sense of the kinds of political problems that arise in the development of a pharmaceutical response to pandemics. These include the procurement and distribution of vaccines at the federal level; establishing the precedence for vaccination across groups; setting out the most effective means to administer vaccinations; and monitoring vaccination rates across regions (which, interestingly, were consistent from H1N1 to COVID-19, with the Atlantic provinces and Québec with the highest uptake rates, and the prairie provinces and Ontario having amongst the lowest). To address these issues, one must have a clear sense of the kinds of tensions and obstacles that arise due to the particular institutional structure of the country (e.g. the constraints posed by Canada's federal system of health care governance, or the degree of decentralization in provincial health care institutions). One must also understand the competing interests involved in pandemic management, including competition for vaccines, disagreement over who is best placed to determine prioritization or administration of vaccines, and differences over the relative safety or efficiency of vaccines and antivirals. And one should anticipate the various kinds of narratives, built both on power relationships and more ineffable cultural dynamics, that can influence public behaviour during pandemic situations. The tools of political science, from the analysis of institutional relationships to the illumination of latent power dynamics, can be very useful in navigating these tumultuous waters.

References

Charania, N. A., & Tsuji, L. J. S. (2010). The 2009 H1N1 pandemic response in remote First Nations communities or Subarctic Ontario: Barriers and improvements from a health care services perspective. *International Journal of Circumpolar Health, 70*(5), 564–575.

Corburn, J. (2009). *Toward the healthy city: People, places, and the politics of urban planning*. MIT Press.

Dawood, F., Iuliano, A. D., Reed, C., Meltzer, M. I., Shay, D. K., Cheng, P.-Y., Bandaranayake, D., Breiman, R. F., Brooks, W. A., Buchy, P., Feikin, D. R., Fowler, K. B., Gordon, A., Hien, N. T., Horby, P., Huang, Q. S., Katz, M. A., Krishnan, A., Lal, R., … Widdowson, M.-A. (2012). Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A

H1N1 virus circulation: A modelling study. *Lancet Infectious Diseases, 12*(9), 687–695.

Doshi, P. (2011). *Influenza: A study of contemporary medical politics*. 2011 PhD thesis. http://hdl.handle.net/1721.1/69811

Dougherty, K. (2020, September 21). Leading vaccine developer walks out on federal vaccine task force. *iPolitics*. https://ipolitics.ca/2020/09/21/leading-vaccine-developer-walks-out-on-federal-vaccine-task-force/

Dyer, O. (2020). What did we learn from Tamiflu? *British Medical Journal, 368*, m626. https://doi.org/10.1136/bmj.m626

Edmonds, S., MacGregor, A., Doll, A., Lexchin, J., Eren Vural, I., Graham, J., Fierlbeck, K., Fierlbeck, K., Lexchin, J., Doshi, P., & Herder, M. (2021). Transparency too late? Why and how Health Canada should make clinical data and regulatory decision-making open to scrutiny in the face of COVID-19. *Journal of Law and the Biosciences, 7*, lsaa083.

Fierlbeck, K., & Hardcastle, L. (2020). Have the post-SARS reforms prepared us for COVID-19? Mapping the institutional landscape. In C. Flood, V. MacDonnell, J. Philpott, S. Theriault, & S. Venkatapuram (Eds.), *Vulnerable: The law, policy, and ethics of COVID-19* (pp. 31–48). University of Ottawa Press.

Fineberg, H. (2014, April 3). Pandemic preparedness and response—Lessons from the H1N1 influenza of 2009. *The New England Journal of Medicine, 370*(14), 1335–1342

Flood, C., MacDonnell V., Philpott J., Theriault S., & Venkatapuram S. (Eds.). (2020). *Vulnerable: The law, policy, and ethics of COVID-19* (pp. 31–48). University of Ottawa Press.

Godlee, F. (2010). Conflicts of interest and pandemic flu. *British Medical Journal, 340*(7759), 1256–1257.

Government of Nova Scotia. (2010). *Nova Scotia's response to H1N1: Summary report*. https://novascotia.ca/dhw/publications/H1N1-Summary-Report.pdf

Hansard Nova Scotia. (2009). https://nslegislature.ca/legislative-business/hansard-debates/assembly-61-session-1/61_1_house_09nov03.htm

Herder, M., & Graham, J. (2020, September 15). Canadians need and deserve transparency on COVID-19 vaccines. *Ottawa Citizen*. https://ottawacitizen.com/opinion/herder-and-graham-canadians-need-and-deserve-transparency-on-covid-19-vaccines

Herper, M. (2020, September 28). A layperson's guide to how—And when—A Covid-19 vaccine could be authorized. *STATnews*. https://www.statnews.com/2020/09/28/a-laypersons-guide-to-how-and-when-a-covid-19-vaccine-could-be-authorized/

Hodge, J. (2014). *Canadian healthcare workers' experiences during pandemic H1N1 influenza: Lessons from Canada's response*. National Collaborating

Centre for Infectious Diseases. https://nccid.ca/publications/canadian-healthcare-workers-experiences-during-pandemic-h1n1-influenza/

IPAC. (2014). *2009 H1N1 pandemic*. https://ipac-canada.org/pandemic-h1n1-resources.php

Jarmon, H. (2018). Legalism and tobacco control in the EU. *European Journal of Public Health, 28*(S1), 26–29. https://doi.org/10.1093/eurpub/cky154

Jefferson, T. (2000). Real or perceive adverse effects of vaccines and the media—A tale for our times. *Journal of Epidemiology & Community Health, 54*(6), 402–403.

Jefferson, T. (2021).The European registration of the pandemic influenza vaccine Pandemrix: rushing an untested vaccine to market. In K. Fierlbeck, M. Herder, & J. Graham (Eds.), *Policy gain or confidence game? Transparency, power, and influence in the pharmaceutical industry: Policy gain or confidence game?* University of Toronto Press.

Jefferson, T., Jones M., Doshi P., & Spencer, E. (2014). Oseltamivir for influenza in adults and children: Systematic review of clinical study reports and summary of regulatory comments. *British Medical Journal, 348*, g2545. https://doi.org/10.1136/bmj.g2545

Lexchin, J. (2006, January 17). Is there still a role for spontaneous reporting of adverse drug reactions? *The Canadian Medical Association Journal, 174*(2), 191–192. https://doi.org/10.1503/cmaj.050971

Kingdon, J. (1984). *Agendas, alternatives, and public policy*. Little, Brown.

Kmietowicz, Z. (2017, June 12). WHO downgrades oseltamivir on drugs list after reviewing evidence. *British Medical Journal, 357*. https://doi.org/10.1136/bmj.j2841

Kumar, A., Zarychanski, R., Pinto,R., Cook, D. J., Marshall, J., Lacroix, J., Stelfox, T., Bagshaw, S., Choong, K., Lamontagne, F., Turgeon, A. F., Lapinsky, S., Ahern, S. P., Smith, O., Siddiqui, F., Jouvet, P., Khwaja, K., McIntyre, L., Menon, K., … Canadian Critical Care Trials Group H1N1 Collaborative. (2009). Critically ill patients with 2009 influenza A (H1N1) infection in Canada. *The Journal of the American Medical Association, 302*(17), 1872–1879.

Lemaitre, M., Carrat F., Rey G., Miller M., Simonsen, L., & Viboud, C. (2012). Mortality burden on the 2009 A/H1N1 influenza pandemic in France: comparison to seasonal influenza and the A/H3N2 pandemic. *PLoS One*. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0045051

Low, D., & McGeer, A. (2010). Pandemic (H1N1) 2009: Assessing the response. *The Canadian Medical Association Journal, 182*(17), 1874–1878.

Moghadas, S., Pizzi, N., Wu, J., Tamblyn, S., & Fisman, D. (2010). Canada in the face of the 2009 H1N1 pandemic. *Influenza and Other Respiratory Viruses, 5*, 83–88.

Nestle, M. (2015). *Soda politics: Taking on big soda (and winning)*. Oxford University Press.

Nhan, C., Laprise, R., Douville-Frader, M., Macdonald, M. E., & Quach, C. (2012). Coordination and resource-related difficulties encountered by Québec's public health specialists and infectious diseases/medical microbiologists in the management of A (H1N1). *BMC Public Health, 12*, 115.

Nova Scotia, Auditor General. (2009). *Pandemic preparedness*. https://oag-ns.ca/sites/default/files/publications/2009%20-%20Special%20Report%20-%20Pandemic%20Preparedness.pdf

Public Health Agency of Canada. (2010). *Lessons learned review: Public Health Agency of Canada and Health Canada Response to the 2009 H1N1 pandemic*. https://www.canada.ca/en/public-health/corporate/mandate/about-agency/office-evaluation/evaluation-reports/lessons-learned-review-public-health-agency-canada-health-canada-response-2009-h1n1-pandemic.html

Sabatier, P., & Jenkins-Smith, H. (1993). *Policy change and learning: An advocacy coalition approach*. Routledge.

Schnirring, L. (2012). *French study finds narcolepsy link to H1N1 vaccine in adults*. Center for Infectious Disease Research and Policy, University of Minnesota http://www.cidrap.umn.edu/news-perspective/2012/09/french-study-finds-narcolepsy-link-h1n1-vaccine-adults

Schwarzinger, M., Flicoteaux, R., Cortarenoda, S., Obadia, Y., & Maotti, H.-P. (2010). Low acceptability of A/H1N1 pandemic vaccination in French adult population: Did public health policy fuel public dissonance? *PLOS One*. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0010199

Standing Senate Committee on Social Affairs, Science, and Technology. (2010). *Canada's response to the 2009 H1N1 influenza pandemic*. https://sencanada.ca/content/sen/committee/403/soci/rep/rep15dec10-e.pdf

Song, J. H., Kim, T. W., Um, Y. H., & Hong, S. C. (2016). Narcolepsy: Association with H1N1 infection and vaccination. *Sleep Medicine Research, 7*(2), 43–47.

Vogel, G. (2015). Why a pandemic flu shot caused narcolepsy. *Science*. https://www.sciencemag.org/news/2015/07/why-pandemic-flu-shot-caused-narcolepsy. https://doi.org/10.1126/science.aac8792

WHO. (2014). *Safety of immunization during pregnancy: A review of the evidence*. https://www.who.int/vaccine_safety/publications/safety_pregnancy_nov2014.pdf

Zarychanski, R., Stuart, T. L., Kumar, A., Doucette, S., Elliott, L., Kettner, J., & Plummer, F. (2010). Correlates of severe disease in patients with 2009 pandemic influenza (H1N1) virus infection. *The Canadian Medical Association Journal, 182*(3), 257–264.