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SAME THREAT, DIFFERENT RESPONSES: EXPERTS STEERING POLITICIANS AND STAKEHOLDERS IN 2009 H1N1 VACCINATION POLICY-MAKING

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INTRODUCTION

Why do similar polities facing the same threat enact different response policies? During the H1N1 'swine' influenza pandemic from April 2009 to August 2010 (2009 H1N1), even close-knit European Union (EU) countries pursued divergent responses to the same threat (EC and HPA, 2010; EC, 2010). In particular the approach to vaccination, the key medical intervention against pandemic flu, differed significantly (Mereckiene, et al., 2012; WHO, 2005a). The Netherlands and Denmark are cases in point. Both decided in June 2009 how much vaccine to make available to protect their populations. The Netherlands ordered vaccines for all residents. Denmark ordered vaccines for 28 percent. The article analyzes why these two most-similar countries diverged in this key pandemic response.

Response variations occurred despite international coordination. The World Health Organization (WHO) had facilitated pandemic preparedness since 1997 (WHO, 1999; 2005b). During 2009 H1N1, it pooled information and disseminated guidance (WHO, 2010; 2011b). The EU also sought to coordinate (EC and HPA, 2010; Baekkeskov, 2015). Finally, biomedical specialists and other members of transnational epistemic communities played important roles in responses (Keller, et al., 2012; Baekkeskov, in press [2014]; 2015). National pandemic response decisions thus overrode international isomorphic pressures, including the threat itself and efforts to streamline policies.

As in many crises (Rosenthal, et al., 2001; Boin, et al., 2005), 2009 H1N1 responses were marked by urgent decisions made under uncertainty. Large vaccine quantities take four to six months to develop and produce. Vaccinations had to start during the fall 2009 because flu spreads greatly during late fall and winter. Hence, June orders pushed against limits for timely vaccine deliveries. In addition, pre-pandemic advance purchase agreements (APAs) obliged some countries to order flu vaccines when the WHO declared H1N1 a 'Phase 6' pandemic on 11 June 2009. An APA obliged Denmark to order 2.3 million or



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more doses (SM, May 7 2009). The Netherlands also ordered vaccines in June, to secure timely vaccinations (see case analysis).

This sense of urgency had to be negotiated in an environment of uncertainty (WHO, 2011b, p. 17; Baekkeskov, 2014). Pandemic flu can range from catastrophic to mild. Another H1N1 variant, the 1918 to 1920 'Spanish Flu', infamously caused more fatalities than World War I. A H5N1 'avian' influenza emerged in 1997 and proved fatal to 60 percent of known cases (WHO, 2011a). Public health agencies feared that mutations of H5N1 would generate pandemics (Keller, et al., 2012; MacPhail, 2014; Lakoff, 2015). In contrast, pandemic influenzas in 1957 and 1968 killed relatively few people.

Analyses of 2009 H1N1 vaccination policies show how sharp response divergences can be made. Recent work on 2009 H1N1 argues that responses prepared for H5N1-type flu were implemented by some expert health authorities because "retooling" in the midst of the crisis was too costly (MacPhail, 2014, p. 124; Keller, et al., 2012). This article analyzes four explanations from political studies of crisis management, drug policy and epidemic response (Baldwin, 2005; Boin, et al., 2005; Colgrove, 2006; Vallgårda, 2007; Boin, et al., 2009; Healy & Malhorta, 2009; Reeves, 2011; Meijer, et al., 2013). This analysis will qualify and nuance the line of argument begun by the earlier 2009 H1N1 studies.

Pandemic response can damage public trust in government (health) authority. In 1976, the U.S. vaccinated about 40 million people after a novel H1N1 variant was detected on an army base. Subsequently, Guillain-Barre Syndrome linked to the vaccine struck between 54 and 650 people (Neustadt & Fineberg, 1978, p. 121; Silverstein, 1981, p. 128). In 2009, 5.58 million Swedes and 2.76 million Finns accepted 2009 H1N1 vaccination (MSB, 2011, p. 64; Syrjänen, et al., 2011, p. 2). By 2011, Narcolepsy linked to the vaccines had struck 289 mostly young Swedes and Finns (Post, 2012). Public health experts might ignore such costs because adverse effects strike miniscule fractions of treated populations. But each example above engendered acrimonious public debates. Future crisis governors can mitigate such political hazards by learning how pandemic responses come about.

The next section reviews alternative theories of public health threat response. Methods are described subsequently. Case analyses and discussion follow and assess how well the theories answer why the Netherlands and Denmark had different 2009 H1N1 responses.

## FOUR LOGICS OF PUBLIC HEALTH THREAT RESPONSE

National public health threat responses intersect crisis management (including risk and disaster), medicines policy and epidemic response. Political studies on these themes agree that policy-making actors often have different objectives (reviewed below). The studies disagree on which logic (actor-and-objective) actually steers policy. The thematic review identifies four logics: two for elected leaders (A1 and A2), an interested organizations' (B), and an experts' (C). Explanatory propositions summarize the logics and yield empirical expectations. Finally, the section offers analytical criteria for assessing case evidence for each proposition.

### A1 and A2. Politicians avoid blame or demonstrate value

Elected leaders seeking future office are likely to seek policies that preserve or enhance their popularity (Schumpeter, 1943; Downs, 1957; Budge & Laver, 1986; Strøm & Müller, 1999). This insight has led crisis management studies in two pertinent directions.

First, crises are notoriously risky for politicians because key decisions and perceived outcomes are subject to intense politicization (Boin et al 2005). Consequently, formally responsible elected leaders face great risks popularity damage through blame. Hence, leaders seek to avoid blame (Weaver, 1986; Ellis, 1994; Boin, et al., 2008; Hood, 2011). Similarly, rival politicians may highlight leaders' mistakes and downplay successes. Leaders' anticipation of such framing 'contests' (Boin, et al., 2005; Boin, et al., 2009; Resodihardjo, et al., in press [2015]) may guide their policies. Hence:

*A.1: Formally responsible elected leaders steer responses to clear and present threats; they make policies that are* least *likely to expose them to public blame.*

If true, and given different responses:

a) 2009 H1N1 responses presented known risks of blame to the responsible elected leaders.

b) These risks varied between the Netherlands and Denmark.

c) The selected policies were the options with the lowest blame risk.

Second, crises give elected leaders opportunities to demonstrate their value to contested constituencies. For instance, majority legislators in the U.S., India and Japan have disproportionally favored their own districts with disaster assistance (Healy & Malhorta, 2009; Cole, et al., 2012; Aldrich 2015). Similarly, after U.S. Presidents in 1988 gained unilateral authority to declare disasters, electorally competitive states were twice as likely as noncompetitive states to receive extraordinary Federal disaster funding (Reeves, 2011). Hence:

*A.2: Specific elected leaders* unilaterally *decide responses to clear and present threats; their policies show off their value to key constituencies.*

If true, and given different responses:

a) Identifiable voter groups stood to benefit demonstrably from 2009 H1N1 responses.

b) The Netherlands and Denmark varied in specific elected leaders' unilateral power to make response policy.

c) The selected policies explicitly showed the elected leader's value to targeted voter groups.

<u>B. Interested organizations seek benefits</u>

Political scientists pay close attention to organized interests' influence on policy. Social and economic organizations commonly affect national policies in Northern Europe (Berger, 1981; Esping-Andersen, 1990;

Pierson, 1996). Medicines policy studies confirm that certain stakeholders can sway policies and seek specific benefits (Colgrove, 2006; Wailoo, 2010). Producers promote medicine sales (Abraham, 2002; Autain & Milon, 2010; Meijer, et al., 2013). Medical and nurses' associations promote professional status and discretion (Immergut, 1992; Lewis, 2005). Patient advocates seek greater patient access to care and medicine (Krause, et al., 2010).

Interested organizations can influence policy through formal and informal access. Formal access includes memberships of advisory committees and contract negotiations, where organizations play transparent and legitimate parts. In contrast, informal access easily leads into grey areas where influence is hard to validate. For instance, pharmaceutical firms' real influence on 2009 H1N1 response remains controversial despite formal evaluations and journalistic series. Medical stakeholders' informal access is therefore an oblique focus of many analyses (cf. Carpenter, 2010; Meijer, et al., 2013). For the sake of tractibility within one study and article, this analysis considers stakeholders' formal access and consequent impact on vaccination. It proposes that:

*B: Pharmaceutical businesses, health professional associations and patient advocacy groups with formal policy-making roles actually steer response-making; each seeks to maximize its own gains from the policy.*

If true, and given different responses:

a) Producers, associations or advocates could gain more benefits from one response option than from alternatives (vaccine sales, medical discretion or access to care, respectively).
b) The Netherlands and Denmark varied: - in access for producers, associations or advocates to 2009 H1N1 response-making; - or in these stakeholders' behaviors.
c) The selected response offered high gains to organizations with access.

C. Experts seek 'correct' response

In crises responses, experts often play important roles. Indeed, “expertise and advisory capacities may set the tone of crisis management and have a significant impact on the quality of the decision-making process” (Rosenthal & 't Hart, 1991, p. 353). Epidemiologists, virologists and infectious disease specialists know how to protect population health against viruses (such as flu). Hence, influenza epidemics ‘evoke’ these experts’ advice. In addition, government public health agencies employ such experts to anticipate and undertake epidemic responses (Keller, et al., 2012; Baekkeskov & Rubin, 2014; MacPhail, 2014).

In turn, standards for correct (i.e., ‘appropriate’) care and medication can inform disease experts’ advice. Standards can matter if experts make advice by recognizing and matching problems to appropriate solutions (March & Simon, 1993 [1958], pp. 10-13). In particular, health professionals are trained to use “heuristic” matches between diagnoses and treatments (Gigerenzer & Gaissmeier, 2011, pp. 454, 467-468; Ansell & Gingrich, 2007). This common medical practice suggests that public health physicians may react to limited information by making ‘fast’ heuristic matches, rather than ‘slow’ analyses requiring full information. Similarly, specialized crisis responders of many kinds match recognized problems to prepared “’recipe[s]’ for action” (Leonard & Howlett, 2007, p. 11; Clarke, 1999; Brändström, et al., 2004). Given common reliance on standards in medical and crisis decision-making, particularly when information is limited, public health experts might not start from blank slates. Rather, they may judge crises and their solutions by following standards that match diagnoses and population treatments (i.e., interventions).

The WHO and epistemic communities offer international frameworks for disease diagnoses and interventions. However, actual care and treatment for given diagnoses are established, regulated and implemented nationally (Baekkeskov, 2015). Indeed, comparative studies of epidemic response (to HIV/AIDS primarily) show that policies follow distinct national rather than consensual international standards (Baldwin, 2005; Vallgårda, 2007). Standards link conceptually to ‘logics of appropriateness’, that is, norm-following behavior (March & Olsen, 1989). Hence, public health experts reasoning out epidemic

responses may actually follow national norms that match disease diagnoses with appropriate interventions, and that vary between countries.

Finally, diagnoses and matched interventions may be tenaceous. Scientific training and conventions favor conservative approaches to new data; we reject existing hypotheses only when sufficiently certain (i.e., with high confidence). Viral disease experts (listed previously) are likely to use such reasoning given their scientific training and practices. More generally, scientific communities are reluctant to adopt new paradigms before studies overwhelmingly contradict the old (Kuhn, 1962; Janos, 1986; Hall, 1989). Hence, public health experts' norms are likely to stay 'valid' if not thoroughly disproved.

The points above add up to a proposition:

*C: Government-appointed public health experts actually steer response-making; they follow norms that pair diagnoses to interventions, until and unless these norms can be confidently rejected.*

If true, and given different responses:

a) There were identifiable norms for the pandemic flu 'problem' and a vaccination policy 'solution'.
b) These norms were national and differed between the Netherlands and Denmark.
c) The national responses were consistent with government public health experts' advice, and with the national norms.

The subsequent analysis uses two criteria to assess evidence for the four propositions:

Criterion 1) - The associated actor has an evident role in the national response process. Different theorized actors seek different objectives. Hence, politicians, interested organizations and/or experts needed to participate in 2009 H1N1 response-making to steer response policy (ordered vaccine quantities) toward their objectives.

Criterion 2) - Cases fulfill the expectations developed in this section (a, b, c). More fulfilled expectations mean better empirical support for the associated logic (A1, A2, B or C).

## METHODS: MOST-SIMILAR CASE STUDIES

The 2009 H1N1 pandemic facilitates quasi-experimental analyses of threat responses. The novel H1N1 came to global attention on 25 April 2009 and governments responded. Hence, responses to the H1N1 threat were simultaneous, and disease characteristics and other natural variables were held constant. In addition, European polities had 2009 H1N1 epidemics at similar times (Amato-Gauci, et al., 2011). Yet vaccination responses varied widely. 'Most-similar systems' with different policies can thus be analyzed (Przeworski & Teune, 1970; Peters, 1998).

The Netherlands and Denmark are selected here. The Dutch government decided on 18 June 2009 to protect its whole population and ordered 34.0 million H1N1 vaccine doses from Novartis and GSK (RIVM, 2011, p. 75). The Danish government decided a week later (25 June) to protect 28 percent of its population and ordered 3.1 million doses from GSK (Folketinget, 2009).

National public health conditions might cause response divergences. Hence, the study asked the principal public health professionals involved in Dutch and Danish responses (described below) why their countries made different vaccination policies. *None* mentioned environment, epidemiology or disease. Rather, the two countries share the same predicted flu season (similar fall and winter); close geographical proximity (making flu spread likely); a rich migratory bird area (the Wadden Sea) and intensive agriculture, exposing national populations similarly to zoonotic diseases (such as flu). Hence, technical fundamentals explaining response variations are not indicated.

Further, both polities are mature democracies with proportional representation and, hence, many parties vying for voter approval. Neither held general elections near April to June 2009, so vaccination was no campaign issue. Neither country used domestic vaccine production for H1N1, so no difference in economic stimulus. Both had similar national wealth to afford vaccine (OECD, 2014). Both have capacious

and universal health care where general practitioners conventionally administer vaccinations. Both annually vaccinate at-risk groups against seasonal influenza, rather than general populations.

Due to advance purchase agreements (APAs), the countries had dissimilar obligations toward vaccine producers in June 2009. The Netherlands had no APA and so had complete flexibility (van Dalen, 2014). Denmark's contract obliged an order of 2.3 million doses; but interviewees recalled that producers had offered up to 11 million doses during June 2009, to cover the total population (Jensen, 2013; Pedersen, 2013). Hence, Denmark also had considerable flexibility.

Finally, both countries aimed to immunize vulnerable individuals (Smith, 2013; Gezonheidsraad, 2000). Notably, other similar countries aimed for general immunity, regardless of individual health risk (e.g., Sweden framed general vaccination as societal in addition to at-risk group protection; MSB, 2011; Tegnell, 2014).

These similarities make Dutch and Danish 2009 H1N1 responses useful for study (George & Bennett, 2005). This study was designed to identify the best explanation of the observed policy variation among the four reviewed logics. The Danish Council for Independent Research granted funding. The author conducted field research in the Netherlands and Denmark during 2013 and 2014, which generated interviews and archival evidence that is analyzed in the next section.

Interviews were structured, open-ended, and face-to-face with public health experts, civil servants and elected officials. Individuals inside strategic or daily deliberations on 2009 H1N1 vaccination policies were sought. Contacts were found through observers in academia, consulting and medicine of 2009 H1N1 response processes and by referral. Interview guides were largely identical (adjusted for interviewees' formal positions). Guides were emailed to interviewees one week before interviews. Interviews were audio recorded and fully transcribed.

Six individuals were interviewed in the Netherlands and seven in Denmark. They included senior health ministry civil servants and the heads during 2009 of infectious diseases units at each national public

health agency (NL: *Rijksinstituut voor Volksgezondheid en Milieu* - RIVM; DK: *Sundhedsstyrelsen* - SST). Other interviewees were a Dutch National Health Council (*Gezondheidsraad* - GR) expert, an expert opposing Dutch policy, the Danish Minister of Health during 2009 and two senior officials at Denmark's medicinal research agency (*Statens Seruminstitut* - SSI). All have been able to deny use of their interview and the analysis anonymizes few.

Important recollections may remain unrecorded. Dutch non-respondents included the Minister of Health during 2009, RIVM's current infectious diseases unit head, two public health agency experts, and a regional public health official. Danish non-respondents included two SSI experts, two health ministry civil servants, and a politician who attacked policy.

There may be hindsight or misinformation biases (Mazzoni & Vannucci, 2007). Four to five years had passed and included formal reviews and post-crisis debates. Hence, memories could be distorted. Indeed, interviewees did not perfectly recall events. Exact dates are derived from written documentation. In addition, the timing of information on the Southern Hemisphere's 2009 winter H1N1 flu epidemiology remains unclear. However, recollections point in similar directions for the subsequent analyses.

The study reviewed the legislative records on pandemic vaccination and official post-pandemic evaluations to identify written sources. Additional documents were requested and obtained from interviewees and public authorities. To complement published analyses of Dutch media's H1N1 coverage, all Danish national newspaper articles on H1N1 vaccination were collected, coded quantitatively and content analyzed.

Gaps remain. Minutes and other recordings from internal ministerial and agency meetings were mostly withheld from the study. In addition, 2009 H1N1 vaccine contracts between governments and producers remain mostly confidential. The following analysis of response processes uses several sources in the argument's stages to counter lacunae and possible biases described above.

Processes in 2009 that yielded Dutch and Danish H1N1 vaccine orders had similar but not identical formal contours. The health ministers headed national pandemic response, but had dissimilar real authority. Each health ministry formulated policy (NL: *Ministerie van Volksgezondheid, Welzijn en Sport* - VWS; DK: *Ministeriet for Sundhed og Forebyggelse* - SM). The VWS convened a crisis containment team (*Beleidsteam Crisisbeheersing* - BTCB) to advise Minister Abraham Klink directly on H1N1 response. In turn, Klink could sign national orders for H1N1 vaccines without prior parliamentary approval (van Dalen, 2014; Huijts, 2014). The SM similarly convened a unit to advise Minister Jacob Axel Nielsen. In turn, Parliament's Finance Committee had to grant funding before Nielsen could sign any order (Hansen, 2013; Fisker, 2014; Folketinget, 2009). Hence, Klink decided 2009 H1N1 vaccine availability policy outright, while Nielsen only proposed and shepherded it.

Experts advising each national process had similar responsibilities. Public health agencies and expert panels generated advice. In turn, epidemiologists, virologists and infectious disease physicians led and staffed these bodies. The Dutch BTCB consulted an expert Outbreak Management Team (OMT). The infectious diseases unit at the RIVM supplied the OMT and BTCB with science-based information on H1N1 and intervention options. A GR pandemic influenza expert panel (GR committee) also advised the BTCB. The Danish SM unit similarly consulted the SST. The SST's infectious diseases unit provided H1N1 and intervention information. SSI experts and a pandemic advisory group (PG) also advised the SM unit.

Finally, both governments negotiated with vaccine producers during May and June 2009. In addition, as further described below, the GR committee and PG included professional associations. Hence, politicians, experts and organizations all had some, and mostly similar, formal involvement in the Dutch and Danish 2009 H1N1 vaccine ordering processes. Were theorized logics in evidence?

Evidence on Politicians' Logics (A1 and A2)

Both health ministries were aware of blame risks during work on H1N1 vaccine availability in June 2009. Several Dutch BTCB interviewees recalled unnamed participants proposing that too little vaccine if H1N1 proved widely fatal would produce more blame than spending too much money if the disease proved mild. Nielsen, the Danish former Minister, himself acknowledged blame concerns (2014). SST and SSI experts had persuaded him that H1N1 was not extraordinarily deadly; consequently, the experts recommended and Nielsen favored limited vaccination. But fearing blame for doing too little to protect everyone, he pre-emptively secured broad parliamentary backing for limited vaccination. He invited Parliament's Health Policy Committee to meet with him informally and privately in mid-June 2009. Added were Else Smith, SST's infectious diseases unit head, and Nils Strandberg Pedersen, SSI's Director, to justify limited vaccination and answer committee members' questions (Hansen, 2013; Nielsen, 2014).

In contrast, no evidence indicates favoritism toward swing voters. In the Netherlands, vaccines were ordered for all residents rather than select groups. Hence, though Minister Klink unilaterally decided how many could be vaccinated, his policy did not demonstrate favoritism. Denmark's limited order made targeted vaccinations necessary. But groups eventually targeted for vaccination matched groups defined in pandemic plans from 2006 (SST, 2006a; Nielsen was elected to parliament in 2007). In addition, allocation and priority group deliberations occurred at SST (SST, 2011); interviewees recalled no ministerial interference (Troest, 2013; Smith, 2013).

Did elected leaders steer responses to 2009 H1N1? Elected Ministers of Health were formally responsible in both cases. Both could perceive blame risks surrounding vaccination. In addition, Klink probably expected least risk from general vaccination. In contrast, Nielsen made limited vaccination the lesser risk through political maneuvering. Finally, policy matched each health minister's lowest perceived blame risk. But blame avoidance cannot answer why ministers perceived different blame risks. The leaders'

varied perceptions of blame from the same threat suggest that something else was in control. The discussion will pick up on what this driver of risk perception was.

Evidence on Organizations' Logic (B)

Similar organizations took part in Dutch and Danish 2009 H1N1 vaccine ordering processes. Government officials mostly staffed apparatuses described at the outset of this section. But the two advisory panels included non-governmental organizations. The Dutch GR committee had 14 permanent and three guest members (GR committee, 2009, pp. 8-9). One was a physician representing the Dutch College of General Practitioners. The Danish PG had 14 organizations as permanent members (SST, 2006b, pp. 6-7). These included national associations of physicians and of nurses. Minutes also show that the Danish College of General Practitioners attended some meetings in 2009.

Involved associations had no evident opinions on vaccine orders made in June 2009, however. PG meeting minutes indicate no stands on vaccine availability by its association members (GR committee minutes were unavailable). In addition, interviewees in both countries were asked to recollect contributions from stakeholders. None recalled stakeholders taking stands. National media coverage offers corroboration; content analyses through June 2009 reveal few mentions of organizations voicing H1N1 response positions (Vasterman, et al., 2011, p. 50; Baekkeskov and Öberg, 2015, pp. 19-21). Despite formal access, associations appear to have been little engaged in 2009 H1N1 vaccine orders.

Vaccine producers negotiated with both governments and some won agreements in June 2009 (as previously described). The Dutch health ministry wanted vaccines delivered before H1N1 became widespread (van Dalen, 2014; Huijts, 2014). From H1N1's emergence in April, producers warned Dutch negotiators that later orders would delay deliveries (Vermeend, 2013). In addition, some Dutch interviewees recalled that larger orders meant larger deliveries early on. Producers were allocating vaccine batches in proportion to how much countries ordered, rather than, for instance, national population.

Hence, countries could game the system: ordering more meant having more vaccines before H1N1 became epidemic (a Swedish interviewee anonymously mentioned the same reasoning in Sweden; notably, no interviewee indicated that industry explicitly promoted this rationale).

The Danish government had fewer concerns about early or large deliveries. Producers offered more vaccine than Denmark's APA guaranteed (offer details undisclosed; Jensen, 2013; Pedersen, 2013). However, no Danish interviewee mentioned talk about gaming the system. Rather, they stressed that the Danish 2009 H1N1 vaccine order matched identified needs (Pedersen, 2014).

Unwittingly or not, producers could increase 2009 H1N1 vaccine orders by allocating vaccine production batches by order size. Hence, allocation methods could indirectly lead producers to realize high economic gains. Yet producers had similar formal access in each response process, and took similar apparent actions, as did professional associations. This leaves no evident link between interested organizations and the difference in responses. Rather, the difference between how Dutch and Danish officials reasoned about vaccine deliveries suggests differing priorities. Hence, a quandary for subsequent discussion is why the Dutch prioritized more vaccines earlier and the Danes did not.

Evidence on Experts' Logic (C)

Before H1N1 emerged in April 2009, Dutch and Danish health authorities had developed national norms for pandemic response. Following general WHO guidelines and prompts from the EU, RIVM and SST had led pandemic flu preparations nationally. Between 2003 and 2006, these agencies iteratively wrote national pandemic response strategies (RIVM, 2006; SST, 2006a). The strategies were disseminated to regions and local health care providers (Troest, 2013; Wijngaarden, 2014). In turn, local actors keyed internal guidelines to the strategies. Finally, both countries contractually supported specific vaccination strategies through APAs with producers signed in 2006 and 2007 (though the Netherlands' expired in March 2009). However,

the respective preparations assumed different pandemic flu severities (problems) and vaccination needs (solutions).

The Netherlands prepared for an extraordinarily deadly influenza (the worst case) solved by general mass vaccination. RIVM planning anticipated three threat types: influenza among domesticated birds; human influenza originating domestically; and human influenza that spread to the Netherlands, as happened with 2009 H1N1. The national strategy for this last scenario framed severity: "planning for the [pandemic] situation should be based on a 'worst case' scenario" (RIVM, 2006, p. 1). It described details of highly lethal human-to-human spread of H5N1 (p. 3). Though named, alternative influenzas were not described. An addendum gave "an influenza pandemic such as [the Spanish Flu] in 1918" as a second example. It mentioned three possible severities: a "worst-case", a "realistic case" and a "best case" (p. 42). But 'realistic' and 'best' cases were neither mentioned elsewhere nor described.

Public health experts contributed to preparations as well as advising 2009 H1N1 response. Leading individual experts were Roel Coutinho and Albert Osterhaus in the Netherlands and Else Smith and Nils Strandberg Pedersen in Denmark. The Dutch experts confirmed that the worst case had anchored preparations. Coutinho recalled that before 2009, "all scenarios were based on H5N1", that is, "the idea that this [a pandemic flu] would be a very severe outbreak" (Coutinho, 2014). Similarly, Osterhaus recalled that from 2003 and onward, he had continually advised that the Netherlands was vulnerable to avian influenzas like H5N1 (Osterhaus, 2014).

Matching its worst case, the Netherlands prepared for general mass vaccination. Pandemic flu vaccination aimed to immunize vulnerable individuals (Gezonheidsraad, 2000). But vulnerable groups would be unknown and case numbers large in a deadly flu epidemic (van Dalen, 2014). The national strategy ranked the population into four priority groups, given scarce vaccines (RIVM, 2006, pp. 13-16). But eventually, everyone would be inoculated.

Finally, the Dutch government guaranteed complete population coverage through an APA with Solvay Pharmaceuticals in March 2006 (NRC Handelsblad, 2006). The duration was three years ending in March 2009 (i.e., a month prior to 2009 H1N1). Solvay proved unable to implement a promised new (cell-based) production technology (van Dalen, 2014). Consequently, the Dutch APA lapsed because of unfulfilled contractual terms, rather than any reduced fear of deadly pandemics. Hence, Dutch pandemic planning, leading expert judgment and vaccine contracting prior to 2009 consistently linked general mass vaccination to pandemic flu. This supports that vaccination for all was the appropriate Dutch intervention given a pandemic flu diagnosis.

Danish pandemic flu preparations had focused on the problem as a range of probable, moderately severe influenzas, solvable through limited vaccination. In framing the problem, the single Danish national strategy acknowledged deadly flu as possible (SST, 2006a). But "a coming influenza pandemic virus is most likely to be one of the influenza viruses that have previously caused disease among humans (i.e., H1-3 and N1-2)". Hence, "the extant plan takes all scenarios into account" (p. 11), rather than the worst case only.

Danish experts also recalled focusing on probable rather than worst cases. Nils Strandberg Pedersen, who was involved in Danish biohazard preparations from the late 1990s, explained: "there is a model" in the strategy, "influenced by the need to be flexible because … [with] infectious diseases you never know what will hit you" (Pedersen, 2013). Else Smith, who co-authored the final 2006 national strategy, was more specific: preparedness "starts from: what do we know about this infection, what is the most likely, what has history shown us, what is realistic" (Smith, 2013).

Preparations also prescribed limited rather than general vaccination. The national strategy listed medical risk groups, health care and support workers, and people in critical positions as needing vaccination, or 1.6 million people (29 % of the population; SST, 2006a, pp. 40-41). An otherwise extensive addendum offered the strategy's only few sentences on general vaccination. "Vaccination of everyone" could occur "in a situation with adequate vaccine supplies. Regardless of this ideal situation [*sic*], the task

of health authorities is to plan vaccination in such a way that people [the groups above] will be offered vaccination first" (SST, 2006b, p. 90).

Denmark's APA specified how much vaccination authorities actually thought would be needed. The contract guaranteed between 2.3 and 4.6 million vaccine doses, enough to mitigate several moderate disease scenarios. But the maximum delivery would cover just 42 % of the population (two doses per recipient were planned). The Danish government's principal APA negotiator (2006-2007) recalled that "SST [had] judged: we do not need [vaccines for all]" (Jensen, 2013). Smith led SST deliberations for the APA on vaccine needs, and recalled that "[vaccinate all] has never been a scenario that I have seen in my head as realistic" (Smith, 2013). Hence, Danish plans, expert judgments and contracting consistently matched pandemic flu with vaccination of a population fraction. This supports that vaccination for some was the appropriate Danish intervention to match a pandemic flu diagnosis.

Between the April 2009 H1N1 outbreak and vaccine orders in June, government expert advisors transmitted the national norms into policy deliberations. A Dutch post-pandemic review claimed that the "precautionary principle" (*voorzorgsprincipe;* 'better safe than sorry') encouraged large Dutch vaccine orders (Vermeend, 2013, p. 4; RIVM, 2011). This study qualifies the claim. Some BTCB interviewees had not in June 2009 personally been convinced that H1N1 was deadly. But the worst-case remained possible, and hence, a core concern for the minister making policy (van Dalen, 2014). Roel Coutinho similarly recalled that the worst case could not then be confidently rejected (Coutinho, 2014). The worst-case was rejected in mid-August, when RIVM's infectious diseases unit (which Coutinho led) could identify vulnerable sub-populations. That is, no advisors could reject that 2009 H1N1 would turn deadly in time for their minister's vaccine order.

The key source of the minister's concern was a GR committee memo (Huijts, 2014; van Dalen, 2014). It framed the H1N1 problem: "so far, the virus causes relatively mild symptoms and low mortality"; however, "it is possible that the virus will mutate to a more pathogenic strain" (GR committee, 2009, p. 3).

Two vaccine "policy options" were given (p. 4): "wait and see" until more was known about H1N1; or a prompt purchase of vaccines. Finally, the memo described policy pros and cons. Delaying vaccine orders would save money now; but if purchases became necessary, vaccines could be "delivered too late" (p. 4). Hence, a prompt order would offer "the peace-of-mind and security that in a situation of uncertainty, all that is reasonably possible has been done" (p. 4). Evidently, the Netherlands' leading experts agreed that H1N1 could prove deadly, and that ordering vaccines early was the safest policy.

Albert Osterhaus, a GR committee member in 2009, recalled that between April and June, "our [the GR's] position was that you cannot predict what is going on. At the time we [the Netherlands] ordered [vaccines], it looked like, let's say, a 'medium' pandemic – not a wimpy one, but also not a severe one. But keeping in mind the 1918 [Spanish] Flu [which was mild initially], we said: you don't know. You don't know what's going to happen. So you decide for yourselves. Percentages we cannot give. The most severe situation is the 1918, or perhaps even worse. The milder one is the Asian [as in 1957] or the Hong Kong [as in 1968] Flu. That was more or less the width that we considered" (Osterhaus, 2014).

The Dutch public discourse echoed the worst case. Content analysis shows that media tended to describe 2009 H1N1 as "worrisome" (Vasterman, et al., 2011, pp. 54-55). In addition, media relied on experts' judgments, which constituted 43 % of sources used in H1N1-related newspaper articles and 37 % of sources used in television news stories (p. 51). Experts were more used than civil society (24% and 31%), cabinet members (14% and 8%), health care representatives (12% and 16%) or others. Among individual experts, Osterhaus and Coutinho were cited most (p. 53).

The Dutch case thus shows congruence between the national norm and advice offered by the government's public health experts while 2009 H1N1 pandemic vaccine orders were decided. In particular, norms and advice both assumed that pandemic flu could prove deadly and supported general mass vaccination.

Danish experts found information on H1N1 in June 2009 equally insufficient to reject their (very different) national norms. Else Smith's group started response by taking "the plan off the shelf" (Smith, 2013). Smith further recalled that experts assembled by SST to deliberate on recommendations could find no reasons to abandon the prepared approach. Nils Strandberg Pedersen recalled that information on H1N1 had remained preliminary in June (Pedersen, 2013). He corroborated that available information did not rule out the anticipated moderate-range influenza: "Denmark chose to buy fewer [H1N1 vaccine] doses than the contract [APA] allowed on the background of an analysis of available data on the [2009 H1N1] epidemics in Australia and New Zealand" (Pedersen, 2014).

Where Dutch analysts could not identify vulnerable subpopulations before August 2009, Danish interviewees recalled deliberating in June on who to vaccinate (Troest, 2013; Smith, 2013; Pedersen, 2013). Remarkably, however, SST recommended ordering 1.55 million doses, very near to the 1.60 million doses envisioned in the national strategy (SST, 2009). Indeed, the health ministry wrote to the Prime Minister that "the recommendations are consistent with examples in SST's plan for pandemic influenza of groups that are particularly vulnerable in a pandemic situation" (SM, August 11 2009, p. 1). Evidently, constancy validated policy.

The sanguine view of H1N1 also prevailed in the Danish public discourse. Content analysis of newspaper coverage shows that H1N1 was mostly described as a minor threat (Baekkeskov and Öberg, 2015, pp. 26-27). In turn, as in the Netherlands, media tended to rely on key national experts' judgments. 127 sourced citations related to H1N1 vaccination were identified in Danish newspaper articles from 2009. 48 (37%) were individual experts or expert agencies (p. 20). 25 (apx. 20%) cited Smith (p. 26). No other individual or organization (including politicians) came close to Smith's number. Civil society contributed 27% of citations and politicians 19% (p. 20). The calming portrayal of 2009 H1N1 was no accident. The former minister described a concerted effort from the outset to calm public fears (Nielsen, 2014). Smith recalled that she had sought consistently to present H1N1 publicly as a relatively ordinary flu (Smith, 2013).

The Danish case thus repeats congruence between national norms established for pandemic flu severity and vaccination, and advice of the government's public health experts while 2009 H1N1 vaccine orders were decided. But in contrast to Dutch counterparts, Danish norms and experts' advice both painted pandemic flu as moderately severe and supported limited vaccination.

## DISCUSSION OF RESULTS

The table below summarizes the cases. All theorized actor types took part in each 2009 H1N1 response process. Clearly evident were elected politicians (the ministers of health and various Danish parliamentarians). Experts were equally evident (appointed public health experts who advised response-making and managed H1N1 analyses and information day-to-day). Interested organizations also participated but were less involved in deliberations and decisions. Professional associations in both countries were advisory panel members but evidently took little action. Vaccine producers negotiated contracts but had no seats at policy tables; nor did they contribute notably to public discourses. In terms of access (criterion 1), similar actors had similar access in each case, and politicians and experts had more access than stakeholders. Hence, logic B is less supported than are logics A1, A2 and C (row 1 in the table).

Notably, Danish parliamentarians were involved in decision-making while Dutch were not. As described, this had an evident impact: the Danish minister informally brought Parliament's Health Committee on board to pre-empt blame games; the Dutch minister decided policy, but did not use his unilateral authority to target vaccination at pivotal voters. The contrast aids assessments of A1 and A2, as discussed next.

| | *Proposition A1 (Blame-avoidance)* | *Proposition A2 (Favoritism)* | *Proposition B (Interested organizations)* | *Proposition C (Experts' norms)* |
|---|---|---|---|---|
| 1. *Access: Necessary actor type* | V | V | (V) | V |

| | | | | | |
|---|---|---|---|---|---|
| | *visible* | | | | |
| *2.* | *Expectations:* | | | | |
| *a.* | *Objective evident* | V | X | V | V |
| *b.* | *NL - DK differ* | V | V | (X) | V |
| *c.* | *Logical consistency* | (V) | X | (V) | V |

*KEY:* V = criterion fulfilled, (V) = partially fulfilled, (X) = poorly fulfilled, X = not fulfilled.

The four proposed logics have corresponding policy objectives (2.a). The cases indicate that both health ministers perceived blame risks; the Danish minister's preemption of blame games underscored this. In contrast, there was no evidence for favoritism; this is underscored by the Dutch minister, who had authority to but did not target particular voters. Among involved interested organizations, vaccine producers clearly stood to gain revenue from greater vaccine orders. Finally, each country had pandemic flu norms for experts to follow. Hence, proposition A2 is unsupported, and A1, B and C are supported.

Variation between the cases (2.b) was evident in the blame risks that faced each minister. Less blame was expected from wasted money than from insufficient vaccination coverage in the Netherlands. In Denmark, less blame was expected from limited vaccination. The two ministers also differed in unilateral powers (however, as previously described, A2 is otherwise unsupported). In addition, while the two governments' priorities on delivery size and timing differed, stakeholders with formal roles and their actions were similar. Finally, the two countries had different pandemic flu norms. Hence, propositions A1 and C are supported; B is poorly supported (producers' indirect influence may have varied as expected).

Turning finally to consistency between logics and policies (2.c), congruence exists between health ministers' concerns about blame and their 2009 H1N1 vaccine availability policies. However, as discussed, blame avoidance leaves unanswered why Klink and Nielsen perceived different risks from the same policy options. In addition, producers could make economic gains by increasing vaccine sales. But while producers' allocation mechanism may have interacted with government priorities on early and large

vaccine deliveries, the different government priorities cannot be due to evident stakeholder types or actions.

Norm-based expert advice can explain the policies and can answer the blame avoidance and stakeholder quandaries. As shown, each vaccine order mirrored national norms. Advice by key experts linked the norms to the policies. In addition, different national norms and expert advice can explain why Danish and Dutch politicians saw different blame risks. Expert individuals and agencies can shield politicians from blame for policy mistakes (Ellis, 1994; Hood, 2011). Hence, Klink could credibly believe that general vaccination promised less blame because his experts thought a killer flu was possible. Nielsen (and Danish parliamentarians) could expect less blame for limited vaccination because their experts thought a killer flu was impossible (or very unlikely). Second, experts' advice can explain why the Dutch prioritized earlier and larger deliveries. For killer flu, more vaccinations earlier save innumerable lives. For moderate flu, larger early deliveries matter far less. Hence, C is best supported among the four proposed logics.

## CONCLUSIONS AND PROSPECTS

Dutch and Danish 2009 H1N1 vaccine orders varied because the national public health systems had previously developed different norms for vaccination needs in a flu pandemic, and because their leading experts' recommendations followed these norms. Hence, the cases show that norms linking problems and solutions can shape policy responses to public health threats by way of key experts' policy advice.

At least two implications follow for theory on how governments make public health policy under urgency and uncertainty. First, government-appointed experts' projections of future crises and manifest preparations can steer policy. This finding echoes the general importance of anticipation in risk and crisis management (Wildavsky, 1988), and adds that specific expert bodies develop, rely on and transmit such ideas. It also qualifies and nuances previous findings on uses of fears and information among 2009 H1N1

responders (Keller, et al., 2012; MacPhail, 2014). Second, norms borne by experts can steer policy by shaping other actors' logics. The study found positive evidence that political leaders responsible for crisis management may take decisions with an eye to future blame games. But blame risk can evidently depend on experts' norms, making blame-avoidance a causal mechanism. In addition, producers may indirectly influence what governments buy. But such influence can depend on how key experts understand policy problems and solutions.

Through the study's controlled case selection, the article offers internal validation of the 'national expert norms' theory associated with proposition C. The same policy logic was repeated in both cases, which suggests some external validity. Further external validity is suggested by the effects of national norms on policy shown by comparative studies of responses to other epidemic types (Baldwin, 2005; Vallgårda, 2007). However, subsequent analyses could assess external validity further. For instance, the UK, Belgium, Sweden, Norway and Finland shared the Dutch strategy of ordering vaccines for everybody in 2009. The US and Germany shared the Danish strategy of ordering vaccines for groups.

Future investigations should also address longitudinally how similar countries develop different norms in fields marked by international political and scientific coordination. There may be roots in different past decisions or lessons. For instance, professional recruitment or organizational ethos may vary between states to create different expert analytical strengths or values (such as bias in favor of precaution or probability). Lessons could include experiences with past crises. For instance, a 2003 outbreak of non-lethal H7N7 avian flu infected some Dutch poultry workers (Koopmans, et al., 2004). In contrast, the much-feared H5N1 broke out among domesticated birds in Denmark (Adlhoch, et al., 2014). If direct experiences become expectations, Danish norms for pandemic vaccination might have been relatively more 'precautionary' than the Dutch. Conversely, direct H5N1 experiences may have taught Danish public health authorities to be sanguine about pandemic flu. Hence, case historical studies are warranted (cf. MacPhail, 2014; Lakoff, 2015).

Experts steering policy may make technically optimal solutions more likely. In turn, the scandals stemming from flu vaccination campaigns in the US after 1976 or Sweden and Finland after 2009 illustrate that wrong guesses (e.g., 'crying wolf') threaten trust that experts need to persuade policy-makers and the general population. Uncertainty is inherent in pandemics and other infrequent and variable crises, and anticipating plausible realities facilitates urgent choices while uncertainty lasts. Yet Dutch and Danish health systems might have jeopardized trust less with multiple rather than single prepared levels of pandemic flu severity and vaccination. In addition, even systems advised by savants may become better prepared by understanding why similar systems' preparations and responses differ from their own.

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**Same Threat, DifferentResponses: Experts steering Politicians and Stakeholders in 2009 H1N1 'Swine' Flu Pandemic Vaccination**

ABSTRACT

Why do similar countries facing the same threat respond differently? To answer, this paper analyzes Dutch and Danish vaccinations against the 2009 H1N1 'swine' influenza pandemic (most-similar cases with different outcomes). Policy-making in the cases intersected the politics of crisis management (including risk management and disaster management), pharmaceuticals and epidemic response. Uncertainty and urgency were basic conditions and reduced the potential for evidence-based policy. Public health specialists, elected leaders, and organizations in the economy and society contributed to each national response. Related literatures show that such decision-making can turn on politicians' blame avoidance (A1) or demonstrations of value to swing voters (A2), stakeholders seeking gains (B), or experts following national standards (i.e., norms) for appropriate response (C). While each of these four logics is in some evidence, differences in norms used by national experts advising their governments on pandemic responses best answer the question inthe extant cases.

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