

Multilevel Governance and Complex Threats: The Case of Pandemic Preparedness in the European Union and the United States

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The scale of dangers posed by influenza pandemics, combined with a series of actual outbreaks, has led policymakers in both the European Union (EU) and the United States (US) to frame the issue as a security threat and to call for extraordinary action. In the US, the 2006 and 2010 National Security Strategies identified pandemics as a “catastrophic challenge” while the 2006 US Pandemic Plan argued that “pandemics should be viewed as a national security issue.” The EU’s 2008 review of its own European Security Strategy broadened the scope of threats facing the continent to include pandemic influenza. Identifying an influenza pandemic as a security threat, however, is relatively easily done. More challenging is to act upon that designation, through implementing security strategies in practice and managing governance processes in multi-level governance systems. Drawing upon securitization theory and traditional implementation theory, this article compares the extent to which the EU and the US have turned words into action on pandemic preparation. The findings show that increasingly securitized rhetoric following the H5N1 and H1N1 outbreaks has indeed been followed by new policies, structures, and operational capacities. As such, the article provides preliminary evidence that securitizing a public policy problem can increase political leverage over administrative processes of implementation.

INTRODUCTION¹

The scale of dangers posed by influenza pandemics, combined with a series of actual outbreaks, has led policymakers on both sides of the Atlantic to frame pandemics as a security threat. In the United States (US), the 2006 and 2010 National Security Strategies identify pandemics as a “catastrophic challenge” while the 2006 US Pandemic Plan argues that pandemics should be viewed as a “national security issue.”² The United Kingdom’s (UK) National Security Strategy categorizes an influenza pandemic as the “highest risk” civil emergency.³ France’s White Paper on Security and Defense lists pandemics as a pressing global security threat.⁴ And the European Union’s (EU) 2008 review of its own European Security Strategy broadened its threat scope to include pandemic influenza.

Identifying an influenza pandemic as a security threat is an example of practitioner “securitization” of a public policy problem, as has been widely documented both in the EU and the US and beyond.⁵ Through rhetorical construction of a pandemic as an existential threat, officials find it possible to legitimize extraordinary means to address the perceived problem. In turn, securitization implies real change in governance as officials act upon the dangers implied by the securitized problem – and the need to protect the designated “referent object” through policy and structural change. The theoretical expectation of change

following securitization, however, conflicts with the bleak prospects for implementation implied in the classical implementation literature.⁶ Even the “greatest expectations” of policymakers at high-level, to paraphrase Pressman and Wildavsky, are typically dashed at the local level when it comes to implementation in multi-level governance systems.⁷ From this perspective, we should expect that pandemic preparedness poses a host of troublesome governance issues for the EU and the US, not least in the areas of boosting domestic capacity at the operational level, improving coordination across policy jurisdictions, and enhancing international cooperation.

This article examines whether the EU and the US are turning words into action on the issue of pandemic threats. In doing so, the article offers evidence to help us evaluate whether the expectations of securitization scholars holds in this particular issue, in these particular systems. This article conducts a comparative analysis of EU and US efforts to prepare for, and manage the outbreak of, pandemics, namely in the areas of surveillance, early warning and control. Few extant studies take this comparative approach, particularly in relation to the EU, which, despite its increased relevance for European pandemic cooperation activities, is often neglected in governance studies of global health threats.⁸ Furthermore, few analysts make a direct comparison between the US and EU in the empirical area of pandemic preparedness.⁹

For both the EU and the US cases, we assess strategic rhetoric emanating from political officials and compare those intentions to two key indicators of implementation: policy change and instrument (or capacity) creation. We then identify common patterns of success and failure in EU and US implementation and relate those findings to the challenges of multi-level governance more generally in federal (US) and supranational (EU) systems. We find that the implementation expectations inherent to securitization theory seem to hold in these cases, although both multi-level governance systems show some patterns of ongoing implementation problems. We conclude with a call for more research on complex crisis management in multi-level systems and for practical policy attention to learning lessons across the Atlantic.

COMPARATIVE AND THEORETICAL PERSPECTIVES

Pandemic preparedness and control is the responsibility of a host of public (and private) actors, and in the EU and the US these actors are distributed across multiple levels of governance. Comparison between these two blocs is useful, in that each shares a variety of theoretically relevant characteristics.¹⁰ In both systems, securitization has taken place at the highest political levels. In Europe, this includes the EU-level of governance where both national officials speak collectively and where leaders of the EU institutions (especially the European Commission) have a semi-autonomous voice in European safety and security issues. Through changes to the EU’s governing treaties over the past decades, EU governments have invested more authority at the supranational level to coordinate national responses to health threats and to serve as a common platform for political responses. This explains why

evaluating EU-level rhetoric, in addition to national statements, on pandemics offers a useful indication of securitization processes in action. In the US, the federal level plays a major role in stipulating general frameworks for action, setting standards, and allocating resources, thus giving national officials – ranging from the US Secretaries for Health and Homeland Security to the US President – authority to describe and frame pandemics to the broader public. As we see below, the US, too, has taken part in securitizing the pandemic issue.

In both the EU and the US, the main operational responsibility for public health mostly lies at the local level. The supranational or federal level plays an overarching, but typically indirect, role. In between these layers of governance, states (in the US) and national governments (in the EU) play various roles (with national governments in Europe more powerful, holding the sovereign authority over public safety and security, when compared to US states). Thus each system consists of multiple levels of authority and responsibility, with high level political actors capable of making statements, assertions, and even directives that must be (to varying degrees) digested and implemented at lower levels. As we shall see, then, the two systems offer a useful opportunity to compare the extent to which high level intentions are carried out or dashed at lower levels.

Finally, in both the EU and the US, the exact distribution of authority and responsibility between governance levels is not always clear. In times of crisis, this is especially the case. The problem is exacerbated in the EU, where the EU's common treaties offer only general indications of the EU's role and stipulates public health as a "mixed competence" – where the national level dominates but the supranational level has the authority to issue binding legal instruments in some cases. Moreover, the EU's role in public health per se is qualified by the sometimes overlapping role of international bodies like World Health Organization (WHO)-Europe and collaborative networks like the Global Health Security Initiative and the Global Outbreak Alert Response Network (GOARN), an international team of experts in epidemiology. Despite these small differences, governance efforts in both the EU and the US must contend with shifting patterns of authority.

Similar characteristics between the EU and the US governance systems enables a fruitful comparison of the extent to which words follow action, or more prosaically, the extent to which high-level rhetoric is followed by actual implementation on the question of pandemic preparedness and control. Of course, an article of this length cannot fully explore this phenomenon, but the indicators we sketch out below and the empirics presented allow us to make a preliminary assessment.

Making such an assessment has important theoretical relevance. Scholars focused on "securitization" are concerned with process-oriented conceptions of security, including how an issue is transformed by an actor into a security question.¹¹ This process, which is carried out through rhetoric, framing and other forms of social persuasion (largely intentional, or at least opportunistically) by political leaders, bureaucrats, governments, lobbyists and/or pressure groups must be accepted by an audience as an "existential problem" if securitization is to occur.¹² Once securitization takes place, the theory suggests, extraordinary means can be used in a

seemingly legitimate way to tackle the problem. According to Williams, this can include access to new sources of financing, extra-legislative means of making policy, and arms-length distance from democratic oversight.¹³

More specifically for our purposes here, the act of securitization is linked to the process of executive empowerment. Political leaders are typically in the center of securitization efforts, the effects of which are to lend considerable latitude to politicians in order to solve a perceived problem. The effect, as many studies show, is to empower political leadership and lend additional authority in exacting change.¹⁴ This includes implementation,¹⁵ where “extraordinary means” may be formal edicts (presidential directives, executive orders) but may also be less formal acts including rousing speeches, high-profile agenda-setting and even personal encouragement. The details of the means are less important for our purposes than the theorized effect: as Huysmans argues, securitization can lend weight to new initiatives and motivates subordinate officials into action.¹⁶ From this perspective, securitization should enhance the likelihood of implementation by concentrating minds and motivating extra effort by administrative officials in other governance levels and domains.¹⁷

The hypothesis that securitization paves the way for implementation can be contrasted with findings from more traditional implementation theory. Pressman and Wildavsky’s classic work identified the fact that in federal systems, the generic nature of some policy goals combined with the high number of “decision points” involved in putting intent into action should lead to poor implementation.¹⁸ This decision-focused approach complements a cognitive and social constructivist approach by scholars such as Bachrach and Baratz, who argued in 1970 that conflicting perspectives on policy goals, exacerbated in multi-level systems, is likely to hamper implementation.¹⁹ In general, federal and quasi-federal systems are expected to lead to implementation problems owing to the high number of “veto players,” the diversity of perspectives, the plethora of (usually conflicting) institutional forms, and the lack of direct communication between policymakers and administrators responsible for implementation. From these classical insights, the EU literature has developed a variety of explanations of why the EU’s multi-level system precludes effective implementation.²⁰ Explanations range from veto players to administrative incapacity, and from institutional “misfit” and path dependence. In most cases, therefore, this perspective suggests that we are likely to see significant problems in moving from rhetorical intention to practical action.²¹

To what extent does “action follow talk” in EU and US pandemic preparedness and control measures, particularly against the backdrop of considerable securitization on both sides of the Atlantic? We now turn to the evidence.

EUROPEAN UNION

Over the past decade, public health security cooperation has become an important part of the European Union’s supranational policy agenda. EU governments have made a calculated choice, especially post-SARS (2002) and after the H5N1 “avian flu” (2005) outbreak, to endow the EU level with more responsibilities and coordinating capacity.²² Although member states remain sovereign actors in public health, the EU

role has grown and the EU itself has become a platform for both technical and political coordination during pandemics.

Securitization and Goal Setting

Strategic rhetoric prioritizing pandemic preparedness in a European Union context can be traced back several years. The EU's European Security Strategy (ESS),²³ despite being agreed in the aftermath of the SARS outbreak in 2003, made no mention of pandemics as a security threat, not least because of the all-encompassing shadow cast by the Iraq war at the time.²⁴ Against the backdrop of the H5N1 outbreak, however, a review of the ESS in 2008²⁵ broadened its threat scope to include public health threats, including pandemics, especially in the context of global development. By that time, the European response to H5N1 had occupied the agenda of a number of heads of state and ministerial level council meetings in Brussels, at which they agreed to take a strategic, common approach to combating pandemics. That common approach dates back to a June 2005 meeting of heads of state and government, when leaders emphasized the need to reach a "strong agreement that EU member states need to coordinate efforts in the face of a risk of a human pandemic" and pledged to "ensure strong coordination and information sharing" to tackle the uncertainties involved in a pandemic outbreak.²⁶ They also urged the EU institutions, including the Commission, to ramp up coordination efforts.²⁷ This followed pressure from the European Commission, namely the Commissioner for Public Health and Consumer Protection, to encourage member states to "coordinate at EU level their preparedness for a pandemic, and to work together if a pandemic occurs."²⁸ When the H1N1 flu virus outbreak (or the "swine flu") hit Europe in 2009, health ministers again agreed to increase coordination. A press release from the Commission on its adoption of the strategy paper on pandemics on September 15, 2009 states that "in order to minimize the negative impact of the pandemic, the Commission highlights the importance of close coordination between EU member states in all related sectors affected by the pandemic."²⁹ At a meeting on October 12, 2009, health ministers called for, among other demands, national governments to ensure the availability of medicines throughout the EU and its neighbors.³⁰ Action at the EU level reflected similar strategic statements at national levels.³¹

These texts make clear that European leaders expected heightened prioritization of pandemics as a security threat and increased cooperation on pandemic preparedness; indeed, the threat of a pandemic crossing the EU's internal market seemed to concentrate politicians' minds. More specifically, leaders urged action in a number of fields, including: monitoring national preparedness (issuing warnings where national plans are insufficient), coordinating and streamlining national responses during an outbreak, and ensuring compliance to commonly agreed rules. Assessing implementation, therefore, we would expect to see increased communication and information sharing protocols, the sharing of "best practice" amongst national governments, and the expansion of Commission activities in this area. The following sections empirically evaluate these expectations.

Policies

What kinds of policies have resulted from the EU's securitized rhetoric on pandemics? One should recall that public health and disease control questions have historically been a national concern. However, the intensification of the single market, the increase in the movement of people and goods, and the onset of diseases like SARS and pandemics influenzas such as the avian/bird flu and the swine flu, have exposed shortcomings of cooperation in Europe. This, in turn, led to a surge of EU policy initiatives and proposals in recent years.

EU policy developments can be traced back to the legal grounds for EU cooperation, found in Article 152 of the EC Treaty, which simply states that "Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health." The Lisbon Treaty revised this basis for legislation slightly, with the new Article 168 of the Treaty on the Functioning of the European Union (TFEU) establishing the fight against the major health threats as a Community public health objective. The European Commission adopted its first operational influenza pandemic preparedness policy in March 2004.³² This document outlines the respective roles of the Commission and the member states in preparing for a pandemic and discusses the key measures to be taken at certain phases of pandemic outbreaks. It also calls for closer cooperation between human and animal health authorities and experts in the area of influenza virus infections, including sharing of "best practice" in contingency planning.

In the response to the outbreak of the H5N1 flu virus, the Commission adopted in November 2005 a Communication on Pandemic Influenza Preparedness and Response Planning, which sets out the objectives for each inter-pandemic and pandemic influenza phase and the action to be taken to achieve them at both national and Community levels. In response to the H1N1 flu virus, the Commission adopted a strategy paper on pandemics on September 15, 2009. This strategy focuses the Commission's work on pandemics in five strategic areas: vaccine development, vaccination strategies, joint procurement of the vaccine, communication with the public, and support to non-EU countries.³³ In the Council Conclusions adopted on October 12, 2009 (and previously in October 2008) the Commission was asked to review the EU's influenza preparedness and response plan to update national preparedness plans and strengthen cross-sectoral aspects.

The EU's health security framework accordingly encompasses three main areas of work: prevention of health threats, preparedness, and response to threats. The European Commission also plays a key role in facilitating the coordination at the EU level by supporting authorities in member states in their efforts to address pandemic diseases. This is done in particular through regular coordination with national health authorities meeting in the EU Health Security Committee (see below).³⁴ Research policy represents another area where the EU is taking action on pandemic preparedness.³⁵

These policy developments, although impressive from a relative perspective, still make up a rather small part of pandemic-related policy across the continent.

National planning is still a primary concern. Most EU member states have developed their own pandemic influenza plans, although thoroughness, comprehensiveness, and applicability of those plans are still questioned in some quarters. The EU has encouraged reform of those plans (spurred by the subsequent outbreak of H1N1 flu) but differences remain.³⁶

Capacities

What kind of operational capacities have emerged as the result of the prioritization of pandemic influenza as a security threat? Here we examine four categories prioritized by national leaders and pursued by public health authorities as essential components in pandemic preparedness: surveillance, early alert, decision-making structures, and early response.³⁷

Surveillance: One area where EU governments have entrusted more power to the European level is surveillance. Towards that end, the European Centre for Disease Prevention and Control (ECDC) has been charged to “identify, assess, and communicate current and emerging threats to human health from communicable diseases.”³⁸ Since 2008, this mandate has been stringently pursued, by requiring member states to report influenza outbreaks and by issuing daily situation reports used by member states to coordinate action. During the 2009 H1N1 outbreak, the ECDC was responsible for risk assessment and for providing scientific support and advice on surveillance to member states and the Commission. Member states are reported to have relied heavily on information provided by the ECDC during the pandemic phase.³⁹

In addition to the ECDC’s monitoring role, another EU agency, the European Medical Evaluations Agency (EMA), reviews scientific advice on vaccinations and vaccines, continuously monitoring the safety of centrally authorized pandemic vaccines and anti-viral.⁴⁰ Concurrent to the efforts of ECDC and EMA, the EU’s European Food Safety Agency (EFSA) monitored both the H5N1 and H1N1 outbreaks in relation to animal health and food safety. The Communicable Diseases Network was established to prevent further transmission of the disease to other persons, through epidemiological surveillance and investigation. The network provides the backbone of an elaborate surveillance and early warning network, described in more detail below. The Commission has also set up a number of tools to detect communicable diseases and to support member states to respond to these in a coordinated manner, such as the Medical Information System (MedISys), which provides monitoring and early detection of food and feed hazards.⁴¹

Early alert: Another area of EU operational capacity-building is in the area of early warning and alert. This includes notifying governments of an impending, and sometimes difficult to detect, pathogen. As part of the Communicable Diseases Network (mentioned above), the Commission operates an Early Warning and Response System (EWRS). The EWRS networks national authorities and provides notifications and recommendations for control measures when an outbreak requiring coordination occurs. EWRS is a web-based system linking the Commission, the public health authorities in member states responsible for measures to control

communicable diseases, and the ECDC. Some non-EU countries (Iceland, Lichtenstein and Norway) are also linked to the system. It is designed to provide immediate information on outbreaks with possible cross-border consequences to relevant EU actors. Since 2008, the system also allows its users to connect directly to the WHO.⁴² An assessment demonstrated that the EWRS was largely perceived as helpful by member state officials, but that clarity about its key function and role was lacking.⁴³

Decision-making structures: Decision structures specifically focused on pandemic monitoring and control have been put in place at the EU level, including the Health Security Committee (HSC). The HSC comprises a group of high-level national health officials who meet regularly within the EU's Council of Ministers premises in Brussels. Established by the Council in 2001, the HSC is chaired by the European Commission and consists of officials of EU Members States, officials of the Directorate General for Health and Consumers and other relevant Commission services and agencies (e.g. ECDC, EMA) and holds meetings twice a year. When pandemic influenza becomes increasingly "securitized" throughout the mid- to late-2000s, the HSC's operations came under the spotlight and became increasingly active. During the initial stage of the H1N1 pandemic, the HSC had daily in audio-conference meetings during April and May 2009.⁴⁴ HSC is attributed to having played a key role in harmonizing member state approaches to the pandemic.⁴⁵

Another set of decision structures related to pandemic outbreaks is the Commission's Health Emergency Operations Facility (HEOF), created in April 2009. The onset of both H5N1 and H1N1 pandemics prompted the Commission to build the HEOF, in order to be ensured continuous situation assessments of an outbreak and to provide the decision headquarters for an EU response. This structure includes (especially during the alert phases of an outbreak) a 24 hour on-duty function to provide daily reports on the epidemiological details of a situation. It also coordinates management issues, such as tracking measures being taken and providing recommendations for communication to the public. Similar issues were discussed during regular meetings with member states (via the Health Security Committee, EWRS Committee and their respective sub-groups) during recent outbreaks, with conclusions and recommendations being passed on to the HEOF.⁴⁶

Early Response: EU leaders also signaled a desire to enhance coordinated early response, which would involve actions to stem the tide of an emerging influenza. In this regard, the European Commission has taken steps to boost a common approach to early response, not least by providing common case definitions and recommending common response actions to national authorities. Other examples include: an agreement on advice to persons planning to travel to or returning from affected areas; extension of the surveillance system to identify new cases in the EU; guidelines on case management and treatments and advice on medical countermeasures for health professionals; advice for the general public on personal protective measures; regular public statements by the HSC and through the EWRS contact points regarding school closures and travel advice; and, a statement on "Vaccination strategies: target and priority groups" agreed by the HSC and the EWRS contact points.⁴⁷

Of course, early response takes place (and must take place, considering the dynamics of a spreading pandemic) within a global framework. The WHO's Global Health Security Initiative (GHSI) links together G7 countries, together with Mexico, with the WHO to take quick action. The GHSI group meets with the EU's HSC when necessary, to consider common priorities and challenges.⁴⁸ On a more regular basis, the Commission's DG for Public Health and Consumer Protection follows discussions taking place in the various WHO Committees and then adapts EU and national recommendations in line with WHO action. Moreover, the Commission's HEOF based in Luxembourg monitors and coordinates the flu response from the EU perspective in cooperation with WHO authorities based in Europe. Another key player in early warning and response is GOARN, a network of epidemiologists who are often integrally involved in early communication and diagnoses of problems. Finally, the EU is also committed to promoting the implementation and application of the International Health Regulations (IHR).

UNITED STATES

Like the EU, it took the US federal level some years to prioritize pandemic influenza as a national security threat. Pandemics, for example, were downplayed in the 2002 US National Security Strategy (NSS). Nevertheless, the US eventually raised the fight against a pandemic outbreak to the highest political agenda by the middle of the decade, through a variety of strategic statements encouraging system-wide preparations for a pandemic.⁴⁹

Securitization and Goal Setting

The 2006 version of the US NSS devoted considerable attention to pandemics as a security threat to the United States. It spoke of the importance of fighting pandemics by establishing "a new global partnership of states committed to effective surveillance and preparedness that will help to detect and respond quickly to any outbreaks of the disease." The 2010 Quadrennial Homeland Security Review referred to pandemics as a major security threat, alongside other pressing threats such as terrorism, natural disasters, and organized crime. The review argued that pandemics "can result in massive loss of life and livelihood equal to or greater than many deliberate malicious attacks."⁵⁰

In 2005, the Bush Administration tasked the US Homeland Security Council (HSC), an executive branch coordinating body, with developing a new National Strategy for Pandemic Influenza. This strategy rested on three pillars. The first is "Preparedness and Communication," which includes "activities that should be undertaken before a pandemic to ensure preparedness, and the communication of roles and responsibilities to all levels of government, segments of society and individuals." The second is "Surveillance and Detection," which includes "domestic and international systems that provide continuous situational awareness, to ensure the earliest warning possible to protect the population." The final pillar concerns "Response and Containment," which includes "actions to limit the spread of the

outbreak and to mitigate the health, social and economic impacts of a pandemic.” While the Strategy provides a framework for future US government planning efforts, consistent with the National Security Strategy and the National Strategy for Homeland Security, it also recognizes that preparing for and responding to a pandemic is not just a federal responsibility but also involves state government, local officials, and the private sector. The strategy, released in November 2005, focused specifically on H5N1.

The unprecedented move in the US to view pandemic influenzas as a threat to national security prompts questions. What does such rhetoric imply in terms of implementation of policies and operational capacities? One reading would suggest a greater focus on a “whole of government” approach to tackling pandemics and their knock-on effects, in a long-term perspective (i.e. a national approach all the relevant authorities governments at federal, state and local levels). New policies are likely to be put in place to ensure preparedness at not only the federal level and the state level, but also the international level through increased cooperation. Across the US, we might assume a focus on bringing different geographical regions of the US “up to standard” in identifying and reacting to an emerging pandemic. More coordination of state efforts by federal governments may be in order. The security strategies citing pandemic influenza also imply increased budgets and more resources devoted to pandemic preparedness across government. Such expectations offer analytical “baselines” to guide the following analysis.

Policies

Attached to the 2005 US pandemic strategy is the “Implementation Plan for the National Strategy for Pandemic Influenza,” released in May 2006. The document sought to supplement and detail the broad framework and goals stipulated by the original strategy by outlining specific steps toward achieving goals. As such, the plan includes 324 action items together with expected time frames and measures of performance.⁵¹ In addition to the US national pandemic strategy, the Department of Health and Human Services (HHS) issued its own Pandemic Influenza Plan in November 2005. This document includes an overview of the pandemic influenza threat, a description of the relationship of the plan to other federal documents, including the National Strategy for Pandemic Influenza, and an outline of key roles and responsibilities. Finally, in 2009 the US government developed the “National Framework for H1N1 Influenza Preparedness and Response” to serve as an integrated H1N1 strategy, including timelines for H1N1 preparedness and response readiness based on four pillars: surveillance, mitigation measures, vaccination, and communications and education.

Capacities

What kind of operational capacities have emerged against the backdrop of US strategic rhetoric on pandemics? Similar to the EU section above, we will examine here five categories of actions typically deemed essential to pandemic preparedness:

surveillance, early alert, shared standards, decision-making structures, and early response.

Surveillance: The US Center for Disease Control and Prevention (CDC), headquartered in Atlanta, Georgia, conducts a multi-layered surveillance system for seasonal flu under the HSS administrative umbrella. The components of the system include viral surveillance, physician surveillance for influenza-like illness, hospitalization information, summary of the geographic spread of the flu, death numbers from 122 different geographical locations, and regular recording of laboratory-confirmed threats from flu among children. During the H1N1 flu pandemic, added surveillance components included reports by states on either (a) laboratory-confirmed hospitalizations and deaths from flu, or (b) “syndromic” cases.⁵² The CDC’s system, although complying generally with official strategy, has been criticized as imprecise in its accounting for the total number of deaths and hospitalizations due to the H1N1 flu, prompting a new system based on more precise figures in November 2009.⁵³ It is important to bear in mind that CDC has little in terms of implementation powers and plays largely an advisory role.

Early alert: To prepare against a domestic pandemic outbreak, the US government has provided resources to state and local health departments “to increase the number of...providers and improve laboratory detection at public health laboratories.”⁵⁴ The government is reportedly also working closely with industry to develop rapid diagnostic tests to quickly discriminate pandemic influenza from seasonal influenza or other illnesses. However, federal funding for pandemic preparedness to state and local authorities is fragmented. Most departments and agencies have separate grant programs, which each come with its own funding requirements and objectives. State and local health departments thus face hurdles when seeking to implement early alert capacity at the operational level. In addition to this specific problem, it should be noted that federal funding for pandemic preparedness has on the whole decreased over the past years.⁵⁵

Shared standards: A major step towards shared standards was taken when state and local authorities put together pandemic plans in the aftermath of the H5N1 outbreak, under encouragement from federal officials and with a focus on exercises and training. According to a US Government Accountability Office (GAO) report, by June 2008 all 50 states had developed influenza pandemic plans and conducted pandemic exercises. Congress provided in 2006 \$5.62 billion in federal pandemic funds. Out of this sum, \$600 million was specifically appropriated to state and local planning and exercises.⁵⁶ At the same time, an inter-agency report entitled “Assessment of States’ Operating Plans to Combat Pandemic Influenza” reported in January 2009 that deficiencies exist in many of these pandemic plans.⁵⁷ Since then, work has continued. During the fiscal year of 2009, \$2 billion in emergency supplemental appropriations for the H1N1 pandemic was allocated, and an additional \$5.8 billion made available upon presidential request.

Work on shared standards is also taking place through the national planning scenarios of the “National Preparedness Guidelines,” which contain pandemic influenza as a key scenario to guide planning. The US Department of Homeland Security (DHS) released the National Preparedness Guidelines in September 2007,

as part of the effort to carry out Homeland Security Presidential Directive–8. These guidelines present an “all-hazards” approach to preparedness (i.e. a broad and comprehensive approach). National Planning Scenarios focus on contingency planning for homeland security preparedness work at all levels of government and with the private sector. The scenarios form the basis for coordinated federal planning, training, exercises, and grant investments needed to prepare for all types of emergencies. Another US agency, the Department of Health and Human Services, has also taken steps to coordinate national planning for a pandemic influenza scenario by leading two interagency assessments of states’ pandemic influenza plans. Because of its role as the primary agency for planning and responding to disease outbreaks and its previous efforts to coordinate national planning, HHS could lead the development of federal incident management plans for the pandemic influenza scenario.

Decision-making structures: Strategic statements made at the US federal government level highlighted the need to streamline decision-making in the event of a pandemic. A US “whole of government” approach has proved elusive, however, although some streamlining has taken place. During the H1N1 pandemic flu, the Director of the Department of Homeland Security, Janet Napolitano, assumed the role of lead official in charge of coordinating federal response efforts. As the head of a relatively new governmental agency with limited operational capacities, Napolitano had limited ability to direct the nation’s overall policies, as other agencies and officials maintained influential roles. President Obama boosted the federal role in pandemic response when he declared a national emergency on October 24 2009, and thus allowed “a temporary waiver of certain standard federal requirements ... in order to enable U.S. health care facilities to implement emergency operations plans”⁵⁸ and temporary waivers of certain requirements of Medicare and Medicaid. During the H1N1 pandemic, the National Emergencies Act was used for the first time to enable waivers under section 1135 of the Social Security Act, allowing for patients with flu symptoms to access alternate facilities rather than hospital emergency rooms. However, no presidential declaration was made under the so-called “Stafford Act” (which, allows for federal assistance to state governments), so additional federal intervention was limited.⁵⁹

Another decision-making apparatus relevant to pandemic influenza is the National Response Framework (NRF). In principle, an influenza pandemic could trigger use of the NRF, especially if the appearance of the disease in the US occurs in multiple communities crossing state lines. That would lead to an intense, multi-stakeholder containment effort led by the federal government. The Department of Homeland Security, in collaboration with the Department of Health and Human Services and other response partners, developed the NRF and the associated National Incident Management System (NIMS) pursuant to the requirements of the fifth Homeland Security Presidential Directive, “Management of Domestic Incidents,” in order to prepare for such situations.⁶⁰

Early Response: The National Strategy for Pandemic Influenza sets out goals with regard to vaccine stockpiling: the first is to stockpile enough H5N1 pre-pandemic vaccines to immediately vaccinate 20 million people; the second is to be

able to inoculate the entire US population within six months of a pandemic influenza outbreak. After the outbreak of H1N1 influenza, the US quickly began preparing for H1N1 vaccinations by clearing vaccines for sale and purchasing vaccines. Between May 22, 2009 and September 21, 2009, HHS purchased over \$2.25 billion worth of H1N1 vaccines. The federal government, through the CDC, then distributed the vaccines to states on a per capita basis, beginning in early October. However, considerable delays were encountered in the vaccine supply, complicating the efforts of state and local officials and health care providers to vaccinate people.⁶¹ According to a study commissioned by the Center for BioSecurity, this had partly to do with the limited US vaccine production capabilities. Another reason cited in the study is the huge costs of vaccinating the entire population.⁶² State and local authorities, responsible for developing their own policies and systems for administration of available vaccines, relied heavily on federal information regarding the amount and availability of vaccines. It is also important to keep in mind that it was never the US objective to vaccinate the entire population.

ANALYSIS

As demonstrated, and put simply, the evidence above suggests a considerable amount of “follow through” following political prioritization – and securitization – of pandemic preparedness in both the EU and the US. On the question of securitization, political leaders in both blocs succeeded in prioritizing pandemics as a key security challenge. The EU and the US expressed similar perspectives on pandemics as an issue transcending “politics” and traditional security-related disagreements (such as on the question of Iraq, to use one notable example). As most authors agree that pandemics have been successfully securitized on both sides of the Atlantic, the securitization finding is not surprising. One pattern to note between the EU and the US is the rhetoric deployed in their respective strategic documents. The US appeared more eager to label pandemics a security threat earlier than did the EU. Both see the synergies to be achieved by preparing for pandemics and preparing for other large-scale public health emergencies, such as an anthrax attack.

What truly interests us here, however, is examining the reality of moving from talk to action. The securitization literature, as discussed in the second section above, leads us to believe that a securitized issue will lead to more forceful and deliberate implementation in general terms. Our results seem to bear out this expectation, with considerable progress in the areas of surveillance, early warning, and control witnessed on both sides of the Atlantic. Over the time period studied, EU and US leaders’ intentions were carried out to a considerable degree, with new or revised programs, new instruments, new forms of financial assistance, and newly empowered bureaucratic organizations. The empirics presented above demonstrate this development in a convincing fashion.

Nevertheless, the classical implementation literature, which includes insights that lead us to expect serious implementation problems in multi-level governance systems, may also offer explanatory guidance to some empirical trends identified in the previous section.⁶³ Thus, alongside the implementation “success” predicted by

securitization theory, analysis of both the EU and the US reveal some common problems in turning rhetorical strategies into policy and operational reality. Our study suggests three problems in particular.

First, both the EU and the US encounter problems of institutional overlap and jurisdictional confusion at the horizontal level (e.g. across federal and supranational levels). In the case of the EU, we see problems emerging within the Commission, where different directorates responsible for different aspects of a pandemic outbreak (DG Health, DG Consumer Safety, DG Transport) vie for a share of the policy portfolio, with an often detrimental effect on policy outcomes.⁶⁴ We also see jurisdictional issues emerging between the EU institutions and the World Health Organization in the European region.⁶⁵ In the US, one major source of contention was the issue of leadership at the federal level. Although the US federal government has authority for planning and response for pandemics, effectively coordinating action in a multi-level government setting has proved a considerable challenge. Under current US law, the Director of DHS is the Principal Federal official in charge of coordinating federal response efforts during the pandemic flu incidents while the Secretary of HHS is to lead all federal public health and medical incident response situations. In reality, however, this division of labor is far from clear-cut. The Government Accountability Office (GAO) has noted that in the context of pandemic flu planning “these federal leadership roles involve shared responsibilities between [HHS] and [DHS], and it is not clear how these would work in practice.”⁶⁶ Similar conclusions regarding the potential ambiguity in the leadership roles of DHS and HHS have been drawn by the President’s Council of Advisors on Science and Technology.⁶⁷

Second, our evidence reveals problems of jurisdictional competition at the vertical level (e.g. between governance levels). In the case of the EU, as noted previously, national governments have shown a newfound willingness to delegate authority to EU institutions owing to the fact that pandemics cannot be handled by national governments alone. Nevertheless, a tension remains in the relationship between national and EU level responses to pandemics. A widespread pandemic is an issue that strikes at the heart of national sovereignty, and national governments tend to reserve responsibility. This tendency manifests itself in relations between governments and the Commission, even in areas such as surveillance and early warning (activities that, on the surface, should not generate sovereignty concerns from member states). While national governments tend to agree on the idea of cooperation, they disagree strongly on which policy tools should be used. In particular, legally binding measures (i.e. ones that can be enforced by the Commission and the Court) were also viewed with skepticism by some member states.⁶⁸ In the US, responsibilities for handling pandemic influenza outbreaks have become more centralized in recent years. Those responsibilities now include oversight over incident planning, vaccination schemes, and some aspects of health care, and a direct role in surveillance systems, information sharing, and Medicare/Medicaid spending. However, public health remains primarily a state responsibility, placing a premium on effective, dynamic coordination between federal, state, and local coordination. Some criticism has been lodged against the fact

that lines of responsibility, especially during an acute event, are blurry and sometimes contested.⁶⁹ For example, some state officials express concern over federal intervention, the imposition of new compliance requirements, and “once size fits all” solutions to pandemic response undercutting state rights and civil liberties.⁷⁰ Federal-state/local cooperation appears to have been more successful, however, when it comes to providing federal information regarding the amount and availability of vaccines to state and local authorities during the H1N1 outbreak.

Finally, both the EU and the US display uneven levels of preparedness and response capacities. This stems from the disparate geographical territory covered by each system, but also from the challenges of governing across and through multi-level governance jurisdictions.⁷¹ In the EU, for example, the Commission has frequently noted the lack of operational planning at local levels in Europe and called for more active cooperation. The ECDC has also concluded that the “the existing preparedness plans (both at the national and at the EU level) and systems need to be revised to build in the necessary flexibility to ensure they can be adapted rapidly to differing types and severity of crisis.”⁷² A further problem is that public health crises and in particular expenditure for buying vaccines do not fall within the scope of the EU Solidarity Fund (which provides rapid assistance mainly in cases of major natural disasters with serious repercussions on living conditions, the natural environment or the economy in a member state).⁷³ The H1N1 pandemic flu outbreak has also demonstrated considerable difficulties in the procuring and sharing of vaccines in some EU countries.⁷⁴ Thus, much work remains to be done in regards to getting national governments and EU institutions to work coherently and effectively in the fight against the spread of a major pandemic. In the US, federal funding for state and local pandemic preparedness remains fragmented. This is largely due to the number of federal departments and agencies, each with their own separate grant programs carrying different funding requirements and objectives. Furthermore, it has been argued that US pandemic preparedness plans are not ambitious enough when it comes to setting out objectives for vaccine production and specifying how prioritization methods for vaccination and distribution of anti-virals would be established. Major delays in vaccine supply were encountered on both sides of the Atlantic, owing to production or supply problems. Neither side managed to establish sufficient mechanisms for monitoring progress and implementation of vaccines across all levels of governance. This, too, is a classic problem of governing in complex systems with overlapping jurisdictional responsibilities.⁷⁵ A review of the EU’s response to the H1N1 pandemic in March 2010 found, among other things, that member state priorities for surveillance, safety and evaluation frequently varied⁷⁶ while the US-GAO has repeatedly raised concerns that the National Strategy for Pandemic Influenza and its Implementation Plan lack “a prescribed process for monitoring and reporting on progress” of state and local governments and other non-federal entities engaged in pandemic preparedness.⁷⁷

In sum, while both the EU and the US demonstrated a considerable amount of “follow through” following securitization of the pandemic issue, our results also point towards some serious implementation problems, which classical implementation literature would expect owing to multi-level governance obstacles.

CONCLUSION

In the wake of recent pandemic outbreaks, and against the backdrop of heightened strategic rhetoric on pandemic preparedness, it is critical to assess the extent to which governments are turning words into action. This article assessed both the EU and the US, two complex, multi-level governance systems in which federal (and, in the case of the EU, supranational) officials are taking an increasing role in motivating change in their respective systems. These are two polities in which implementing strategic goals across their governance systems has been historically difficult. Considering the amount of “securitization” that has taken place at the political level on the question of pandemics, however, theoretical insights would suggest a greater degree of implementation than normal. Indeed, we found such patterns common to both blocs.

Both the EU and the US have included pandemics in their respective security strategies, and each has vowed to take extraordinary action to protect societies from a threat that easily sweeps across borders. Moreover, similar policies, structures, and operational capacities focusing on surveillance, early warning and control have emerged in both the EU and the US over the past decade or so. In particular, both have succeeded in establishing some form of minimum standards for pandemic preparedness and response. In short, the evidence suggests that securitization of the pandemic issue indeed allowed for increased political leverage over implementing actors and processes.

Nevertheless, we also found implementation difficulties common to both blocs. First, unclear divisions still exist between different levels of authority and between different institutional actors. In the EU, this includes a complex mix of national governments and EU institutions and agencies. In the US, there are jurisdictional overlaps and potential confusion between federal departments and tension between federal and state and local authorities. Second, local preparedness remains uneven in both the EU and the US, owing to the problem of achieving outcome consistency in territorially diverse systems. Third, EU and US preparedness outcomes suffer from a lack of monitoring on progress. Establishing ambitious implementation plans is only helpful to the extent that these are accompanied by a list of strategic action priorities with clear instruments for monitoring and assessing progress.

In conclusion, our findings demonstrate that both the EU and the US encounter a similar set of governance challenges when confronting new, complex, and boundary spanning security threats such as pandemic influenza. Both blocs have securitized the issue and made it a policy priority, and we have seen a certain degree of follow through from strategic intent to policy and practical capacity building. Thus, implementation in the case of pandemic preparedness reveals less of an implementation gap than the classical literature might suggest. At the same time, a number of complications have emerged in both the EU and the US to shape implementation outcomes, including horizontal coordination problems, vertical jurisdictional disputes, and uneven capacity building across territories. Such realities

remind us of the limitations of motivating change in multi-level systems, even under the unique conditions of pursuing a “securitized” public policy goal.

The task of preparing a vast, multi-level governance system for the onslaught of a complex safety and security problem is a major public policy challenge today. This is as true for the EU as for the US, in which multiple actors operating with considerable latitude and with different kinds of authority can complicate a coherent response. From a practical perspective, policymakers might usefully “learn lessons” from both sides of the Atlantic on such questions as specifying policy goals, building shared perspectives, creating effective oversight mechanisms, and constructing meaningful evaluation processes. From a scholarly perspective, the challenges of implementation under conditions of securitization and urgency require further explanation. Research on key “sticking” points, the specification of how language affects practical implementation and the relative weight of actor, institution or idea-based obstacles to implementation could offer useful insights to take forward the analysis presented in this article.

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² The reference to “catastrophic challenge” is taken from the 2006 US National Security Strategy, pg. 43. The 2010 US National Security Strategy argues that containing an epidemic “has never been so important” (p. 48). The subsequent reference is taken from the *Implementation Plan for the National Strategy for Pandemic Influenza* (Washington DC: Homeland Security Council, 2006), p. 18.

³ Document available at:

http://interactive.cabinetoffice.gov.uk/documents/security/national_security_strategy.pdf

⁴ Document available at: http://www.ambafrance-ca.org/IMG/pdf/Livre_blanc_Press_kit_english_version.pdf

⁵ See Enemark, C. “Is Pandemic a Security Threat?” *Survival*, Vol. 51, 2009, No. 2, pages 191-214; Heymann, D. “The Evolving Infectious Disease Threat: implications for national and global security,” *Journal of Human Development*, Vol. 4, 2003, No. 2; Davies, S. “Securitizing infectious disease,” *International Affairs*, Vol. 84, 2008, No. 2, pages 295–313, March 2008; Youde, J. “Enter the Fourth Horseman: Health Security and International Relations Theory,” Paper prepared for the 44th Annual International Studies Association Convention 17-20 March 2004, Montreal, Quebec; Davies, S. “Securitizing infectious disease,” *International Affairs*, Vol.84, 2008, pages 295-313; Yuk-ping, C. and Thomas, N. “How is health a security issue? Politics, responses and issues,” *Health Policy and Planning*, Vol.25, 2010, No.25, pages 447-453.

- ⁶ Pressman, J. L. and Wildavsky, A. (1973). "Implementation". Los Angeles: University of California Press; for a review of what can be described as the "classical" implementation literature, see Winter, S (2003) "Implementation: Introduction" in Pierre, J & Peters, B.G. (eds.) "Handbook of Public Administration", Sage Publications, London; or Peters, G. (2001). "The Future of Governing". Lawrence: University of Kansas Press.
- ⁷ Selznick, P. (1949). "TVA and the Grassroots".. Berkeley, CA: University of California Press; Pressman and Wildavsky 1973; for a review, see Winter 2003.
- ⁸ However, for a complementary analysis, see Steffen, M. (2005) "Health governance in Europe: issues, challenges, and theories". Milton Park: Routledge Taylor and Francis Group.
- ⁹ For one exception, albeit in a practitioner journal, see Silberschmidt, G. "European Approaches to Global Health: Identifying Common Ground for a U.S.-EU Agenda,". (Washington D.C.: Center for Strategic and International Studies, 2009).
- ¹⁰ There is a considerable body of literature establishing the utility of comparing the US as a federal system of governance with the EU as a quasi-federal or "supranational" system of governance. For a review of that literature, see Menon, A. and Schain, M.A. (2006) "Comparative Federalism: The European Union and the United States in Comparative Perspective". Oxford: Oxford University Press.
- ¹¹ Wæver, O. (1995) "Securitization and Desecuritization". In Lipschutz, R.D. *On Security*. New York: Columbia University Press.
- ¹² Buzan, B. et al. (1998). "Security: A New Framework for Analysis". Boulder: Lynne Rienner Publishers, pages 32, 40.
- ¹³ Williams, M.C. "Words, Images, Enemies, Securitization and International Politics," *International Studies Quarterly*, Vol. 2003, No.47, page 512.
- ¹⁴ See, for example, Buzan, B. et al. (1998). op cit.
- ¹⁵ For the purposes of this paper, we distinguish between "rhetoric" and "action," action being all the political and administrative steps taken in the aftermath of politically articulated objectives. Action includes policies (which in the implementation literature are normally taken as the analytical starting point since they articulate objectives), instruments, tools, and capacities.
- ¹⁶ Huysmans, J. (2006) "The Politics of Insecurity: Fear, Migration and Asylum in the EU". London: Routledge.
- ¹⁷ Research on securitization sometimes has a strong normative element, on account of the fact that a securitized issue is one defined by its removal from policy processes governed by normal democratic accountability mechanisms. The research question in this paper, however, allows us – even requires us – to sidestep such normative questions for the time being.
- ¹⁸ Pressman and Wildavsky op cit.
- ¹⁹ Bachrach, P. and Baratz, M. (1970). "Power and Poverty: theory and practice". New York and London: Oxford University Press.
- ²⁰ Heritier, A. et al. (1996). "Ringling the changes in Europe." Berlin: De Gruyter; Knill, C. "European policies: the impact of national administrative traditions," *Journal of Public Policy*, Vol.18, 1998, No.1, pages 1-28; Boerzel, T. "Toward convergence in Europe?," *Journal of Common Market Studies*, Vol.39, 1999, No.4, pages 573-596.
- ²¹ Hooghes, L. and Marks, G. (2001). "Multi-Level Governance and European Integration." Oxford: Rowman and Littlefield Publishers; Jordan, A. and Liefferink D. (eds.) (2004) "Environmental Policy in Europe: The Europeanization of National Environmental Policy." London: Routledge; Milio, Simona (2010), "Cohesion Policy: A Case Study of Implementation Variation among Member States," in Milio, Simona (ed.). "From Policy to Implementation in the European Union: The Challenge of a Multi-Level Governance System." London: Tauris Academic Studies, pages 23-30.
- ²² This takes place in cooperation with, but largely distinct from, the World Health Organization's regional effort in Europe.
- ²³ Document available at: <http://www.consilium.europa.eu/uedocs/cmsUpload/78367.pdf>
- ²⁴ Biscop, Sven. "The European Security Strategy: Implementing a Distinctive Approach to Security." (Brussels: Royal Institute for International Relations, 2004).

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- ²⁵ Document available at: http://www.eu-un.europa.eu/documents/en/081211_EU%20Security%20Strategy.pdf
- ²⁶ *Press Release EU Council of Ministers* (2005). Informal Meeting of EU Health Ministers, 20-21 October 2005: Pandemic Flu Preparedness, Press Release, Council of Ministers, Brussels.
- ²⁷ Coulombier, D. and Ekdahl, K. "H5N1 Influenza and the Implications for Europe" *British Medical Journal*, Vol.331, 2005, pages 413-414.
- ²⁸ European Voice: "EU Braced for Crisis as Flu Pandemic Threatens." (Brussels: 28 July 2005). At the same time, many European countries have demanded that the EU institutions "respect national prerogatives" and avoid any moves toward binding requirements for cooperation (Press Release EU Council of Ministers, 2005).
- ²⁹ *Press Release Commission adopts EU strategy on Pandemic (H1N1)* (Brussels: European Commission), 2009."
- ³⁰ *Council Conclusions on Pandemic (H1N1) 2009 – a strategic approach* (Brussels: European Council), available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/110500.pdf
- ³¹ Additional strategic statements regarding pandemics can be found in national security strategies in Europe. For instance, the first-ever UK National Security Strategy makes the assessment that the highest risk of public health threats is an influenza-type pandemic. Also the French White Paper on defence and national security mentions pandemics alongside other pressing global security threats.
- ³² EU Commission: *Commission Working Document on Community Influenza Pandemic Preparedness and Response Planning* (Brussels: COM(2004)201 final), 26 March 2004.
- ³³ EU Commission: *Communication from the Commission to the Council... on Pandemic Influenza Preparedness and Response Planning in the European Community* (Brussels: COM(2005) 607 final), 28 November 2005.
- ³⁴ *Pandemic (H1N1) Factsheet*, April 2010 (Brussels: Directorate-General for Health & Consumers), available at: http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/docs/factsheet_h1n1_march2010_en.pdf
- ³⁵ Infectious Disease leaflet (Brussels: Directorate-General for Research), available at: http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/pdf/infectious-diseases-leaflet09_en.pdf
- ³⁶ Martin, R. "The role of law in pandemic influenza preparedness in Europe," *Public Health*, Vol.123, 2009, pages 247-254.
- ³⁷ These categories correspond largely with the WHO's recommendations for pandemic preparedness and response. See, for example, World Health Organization: *Pandemic Influenza Preparedness and Response: a WHO guidance document* (Geneva: WHO, 2009).
- ³⁸ European Parliament and Council: *European Parliament and Council Regulation establishing a European centre for disease prevention and control* (Brussels: No 851/2004), 21 April 2004.
- ³⁹ European Commission (Brussels: Directorate-General for Health & Consumers): *Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009*. 16 April 2010, pp.30-33.
- ⁴⁰ EU Commission: *Communication from the Commission on...Pandemic (H1N1)2009* (Brussels: COM(2009) 481 final), 15 September 2009.
- ⁴¹ Rhinard, M. "European Cooperation on Future Crises: Toward a Public Good?" *Review of Policy Research*, Vol.26, 2009, No.4, pages 439-455.
- ⁴² Kjellén, Z. S. "Rapid Alerts for Crisis at the EU Level" in Olsson, S. "Crisis management in the European Union: Cooperation in the Face of Emergencies" (Stockholm: Swedish Defence Research Agency, 2009), p.68-69.
- ⁴³ European Commission (DG Sanco) op. cit.
- ⁴⁴ Council: *Background on the Health Security Committee and the Early Warning and Response System authorities* (Brussels: MEMO/09/363), available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/363&format=HTML&aged=0&language=EN>

- ⁴⁵ Belgian EU Presidency: *Conclusions of the Conference on lessons learned from the A(H1N1) pandemic* (Brussels, 1-2 July 2010).
- ⁴⁶ See EU Commission: *Commission Health Emergency Operations Facility: for a coordinated management of public health emergency at EU level* (Brussels, 2007). Available at: http://ec.europa.eu/health/ph_threats/com/preparedness/docs/HEOF_en.pdf
- ⁴⁷ These actions were taken, respectively, on May 18, 2009, May 18, 2009, May 18, 2009, May 4, 2009, August 13, 2009, and August 25, 2009. See EU Commission, 2009 op. cit.
- ⁴⁸ EU Commission: *Commission Staff Working Documents: Health Security in the European Union and Internationally* (Brussels: SEC(2009) 1622 final), 23 November 2009.
- ⁴⁹ For example, the President declared, on 23 October 2009, a national emergency in order to address the H1N1 pandemic influenza.
- ⁵⁰ Department of Homeland Security: *Quadrennial Homeland Security Review* (Washington DC: DHS, 2010).
- ⁵¹ U.S. Government Accountability Office: “Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement” (Washington D.C.: GAO, November 2009).
- ⁵² Congressional Research Service: “The 2009 Influenza pandemic: An Overview (Washington, D.C.: CRS, 16 November 2009), p.12.
- ⁵³ BBC News, “US swine flu deaths 'near 4,000',” 12 November 2009, available at: <http://news.bbc.co.uk/2/hi/8358083.stm> Furthermore, European states have also been criticized with respect to reporting crude numbers and predictions of mortality and morbidity.
- ⁵⁴ Homeland Security Council: *National Strategy for Pandemic Influenza Implementation Plan One Year Summary* (Washington D.C. HSC, July 2007).
- ⁵⁵ At the same time, since funding spiked due to the Avian influenza, a decline was expected as the threat perception declines. Thus, the observed decline is not necessarily indicative of a negative trend. See Trust for America’s Health: “Issue Paper “Ready or Not? Protecting the Public’s Health from Diseases, Disasters and Bioterrorism” (Washington D.C., December 2009). Available at: <http://healthyamericans.org/reports/bioterror09/pdf/TFAHReadyorNot200906.pdf>
- ⁵⁶ U.S. Government Accountability Office: *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed* (Washington D.C.: GAO, July 2009). Available at: <http://www.gao.gov/new.items/d09909t.pdf>
- ⁵⁷ Homeland Security Council: *Assessment of States’ Operating Plans to Combat Pandemic Influenza* (Washington D.C.: HSC, January 2009). Available at: http://www.flu.gov/professional/states/state_assessment.pdf
- ⁵⁸ White House: *Press Release* (Washington D.C., 24 October 2009). Available at: <http://www.whitehouse.gov/the-press-office/president-obama-signs-emergency-declaration-h1n1-flu-o>
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- ⁶⁰ Rubin, C.B. and Harrald, J.R. “National Response Plan, the National Incident Management System, and the Federal Response Plan” in “The McGraw-Hill Homeland Security Handbook” (New York: McGraw-Hill, 2006).
- ⁶¹ CNN “CDC: Production of H1N1 flu vaccine lagging,” 17 October 2009, available at: <http://edition.cnn.com/2009/HEALTH/10/16/h1n1.vaccine.delay/index.html>
- ⁶² Center for Biosecurity at UPMC: “Pandemic Flu Preparedness: Lessons from the Frontlines” (July 2009). Available at: <http://healthyamericans.org/report/64/pandemic-flu-frontlines>
- ⁶³ Hooghe, L. and Marks, G. “Multi-Level Governance and European Integration” (Lanham, MD: Rowan & Littlefield Publishers, 2001).
- ⁶⁴ Rhinard, M., 2009 op. cit.
- ⁶⁵ See, for example, van Schaik “Getting better: the European Union’s performance in the World Health Organization,” Global Health Europe Research Paper no. 1 (2009). Available at: http://www.globalhealtheurope.org/images/stories/PDF_Links/Final_researchpaper_01_web.pdf

⁶⁶ U.S. Government Accountability Office: “Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning” (Washington: GAO-07-1257T), 2007. Available at: <http://www.gao.gov/new.items/do71257t.pdf>

⁶⁷ See *Report to the President on U.S. Preparations for 2009-H1N1 Influenza* (Washington D.C.: President’s Council of Advisors on Science and Technology, August 2009).

⁶⁸ At an emergency meeting in April 2009, Health Ministers again reminded the Commission that responses to health risks are a “member state competence.”. Commission reports lament that “member states are protective of national prerogatives and cannot always agree on practical, collective measures.” See EU Commission: *Summary Report of the Health Services Consultation* (Brussels: SEC (2006) 1195/4, 26 September 2006); European Voice: *Swine flu gathers pace, so must EU* (Brussels: 23 July 2009); European Centre for Disease Prevention and Control: *Technical Report: Pandemic Influenza Preparedness in the EU, Status Report as of Autumn 2006* (Stockholm: European Centre for Disease Prevention and Control, 2007).

⁶⁹ For example, it is still uncertain whether a pandemic outbreak would qualify as a “major disaster” under the Stafford Act, thereby enabling further federal intervention. During the recent H1N1 outbreak, President Obama declared the pandemic a national emergency, thus paving the way for increased intervention by the federal level. This declaration allowed the federal government to bypass certain standard federal requirements in order to enhance effective response. Although federal attention to the issue was largely welcome in local and state quarters, some of the federal government’s actions caused a degree of concern at lower governance levels. Of course, the qualification of pandemics as a national emergency also occurs within EU member states. See U.S. Government Accountability Office: *Influenza Pandemic: Further efforts are needed to ensure clearer federal leadership roles and an effective national strategy* (Washington D.C.: GAO, August 2007); Congressional Research Service: “The 2009 Influenza pandemic: Selected Legal Issues (Washington, D.C.: CRS, 15 June 2009).

⁷⁰ For a critical discussion of US pandemic preparedness plans, see Annas, G.J. et al. “Pandemic Preparedness: The Need for a Public Health,” American Civil Liberties Union, January 2008.

⁷¹ Of course, difficulties in producing, procuring and sharing vaccines are not unique to complex multi-level governance settings; they are a global phenomenon.

⁷² European Centre for Disease Prevention and Control: *The 2009 A(H1N1) pandemic in Europe*. (Stockholm: ECDC, 2010). Available at:

http://www.ecdc.europa.eu/en/publications/Publications/101108_SPR_pandemic_experience.pdf

⁷³ EU Commission, 2009 op. cit.

⁷⁴ While some member states had considerable volumes of vaccines, others faced vaccine shortfalls in supplies. To help remedy these differences, EU health ministers agreed during a meeting in Luxembourg in October 2009 on the need for an agreed strategy for sharing stockpiles of vaccines. As a result, EU health ministers agreed to ask the Commission to develop a procedure for allowing them joint purchasing of vaccines at a meeting on 5 July 2010.

⁷⁵ See, for example, Feiock, R.C. and Scholz, J.T. “Self-Organizing Federalism: Collaborative Mechanisms to Mitigate Institutional Collective Action Dilemmas” (New York: Cambridge University Press, 2010).

⁷⁶ Belgian Presidency op. cit.

⁷⁷ U.S. Government Accountability Office, 2009 op. cit.