The Multilevel Regulation of Complex Policy Problems: Uncertainty and the Swine Flu Pandemic

Esther Versluis, Marjolein van Asselt, and Jinhee Kim

This article aims at understanding the challenges of tackling complex policy problems in multilevel governance. In order to better grasp the multilevel regulation of complex policy problems, it is needed to understand how uncertainty and scientific expertise are dealt with. We investigate this via the regulation of pandemics by the EU and the WHO, with the H1N1 pandemic of 2009 as critical case. The analysis of the multilevel practice reveals that the attitude toward uncertainty fundamentally differed between the global (WHO) and the European level. At the global level a classic speaking truth to power approach involved the denial of uncertainty, while at the EU level the assigned role of providing scientific expertise was interpreted as a necessity to openly communicate about uncertainty. While the global approach was heavily criticized, the uncertainty communication at the European level was much appreciated.

KEY WORDS: multilevel governance, problem-solving, uncertainty, expertise, regulation

复杂政策问题的多层次治理: 不确定性和H1N1流感

本文致力理解多层次治理应对复杂政策问题时面临的挑战，为更好地把握复杂政策问题的多层次管理，需要明白不确定性和科学技术是如何加以处理的。笔者以2009年HINI流感爆发作为案例，用欧盟和世界卫生组织(WHO)针对流行病的管理规定进行了调查。通过对多层次实践的分析显示，全球(即WHO)和欧盟对不确定性的态度存在根本差异。在全球层面上，WHO用“对权力说真话”这一经典实践去否定不确定性，而欧盟则运用科学技术，将其作为公开交流不确定性的必备手段。结果则是，WHO实践受到严厉批评，而欧盟对不确定性的公开交流受到赞赏。

关键词: 多层次治理, 解决问题, 不确定性, 专长, 监管

La regulación multinivel de problemas políticos complejos: La incertidumbre y la pandemia de gripe porcina

Este artículo busca comprender los desafíos de abordar problemas políticos complejos en la gobernanza multinivel. Para comprender mejor la regulación multinivel de los problemas políticos complejos, es necesario comprender cómo se aborda la incertidumbre y la experiencia científica. Investigamos esto a través de la regulación de pandemias por parte de la UE y la OMS, con la pandemia H1N1 de 2009 como un caso crítico. El análisis de las prácticas multinivel revela que la actitud hacia la incertidumbre era fundamentalmente diferente entre el nivel global (OMS) y el nivel europeo. A nivel global un método de “decir la verdad al poder” incluía la negación de la
incertidumbre, mientras que a nivel europeo el papel asignado de proporcionar experiencia científica se interpretó como algo necesario para comunicarse abiertamente acerca de la incertidumbre. Aunque la aproximación global fue fuertemente criticada, la comunicación de la incertidumbre a nivel europeo fue muy valorada.

PALABRAS CLAVES: gobernanza multinivel, solución de problemas, incertidumbre, experiencia, regulación

Introduction

Over the last decades, we have witnessed crises and other complex policy problems in very diverse policy fields; think of BSE, GMOs, swine flu (H1N1), E-coli, volcanic ash, the financial crisis, Ebola, or the refugee crisis. Such problems are increasingly transboundary as modern societies are consisting of a tightly woven web of critical infrastructures crossing geographical borders and policy boundaries (Boin, ’t Hart & McConnell, 2009). As a result, risks and crises easily spread over very diverse policy fields, and their regulation is by definition multilevel. In view of the uncertainty inherent to complex policy problems, in the regulation of risk we witness an increasing reliance on scientific knowledge. This embedding of scientific knowledge and expertise in the regulatory system is not always straightforward, however. Let us briefly illustrate this with a well-known case: the BSE crisis (also known as the mad cow disease). Criticism on how this complex policy problem was handled in the 1990s related to the question of how the uncertainty accompanying situations of crisis was tackled and how the scientific expertise played out. Skogstad (2003, 329-330) argued that the BSE crisis was mismanaged, and that we witnessed a “politicization of scientific advice,” because the EU regulatory committee responsible for advising the Commission on BSE underplayed the nature and severity of the crisis. Research by Levidow, Carr and Wield (2005) into the role of UK expert advice in the BSE crisis throws a different light on this politicization of scientific advice. They demonstrated that the scientific advice was framed by policy assumptions. Experts tended to give the “scientific” advice that they knew would be politically acceptable; a phenomenon labeled “serviceable truth” by Jasanoff (2015). The politicized expert advice was presented and used as science to justify political decisions on an uncertain risk.

In line with the theme of this symposium on the challenges of problem-solving in multilevel governance (see the introduction by Thomann, Trein & Maggetti, 2019), this article argues that we need to better understand the crucial role of uncertainty and scientific expertise. Scientific knowledge is needed to understand complex policy problems and facilitate decision making. In that context, scientific expertise is increasingly institutionalized in procedures as well as in agencies and governmental and intergovernmental bodies. At the same time scientific knowledge is by definition limited as uncertainty is a defining characteristic of complex policy problems.

How do the actors involved in the multilevel regulation of complex policy problems deal with uncertainty and scientific expertise? We know that policy
responses to one and the same problem can vary considerably between different
levels (e.g., Ettelt & Hawkins, 2018; Rinscheid, 2015), and thus we analyse the
multilevel handling of a complex policy dossier: the regulation of pandemics via
the critical case of the H1N1 pandemic, concentrating on how EU member states,
EU agencies and the WHO responded to this crisis. The analysis of the multilevel
practice reveals that the attitude toward uncertainty fundamentally differed
between the global and the European level. At the global level a classic speaking
truth to power approach involved the denial of uncertainty, while at the EU level
the assigned role of providing scientific expertise was interpreted as a necessity to
openly communicate about uncertainty. While the global approach was heavily
criticized, the uncertainty communication at the European level was much
appreciated.

Researching Complex Policy Problems

In the most general understanding of the term, a policy problem is a “condi-
tion that some or all citizens (and policymakers) find undesirable” (Peters, 2015,
13). Policy problems are analyzed by a wide variety of scholars, ranging from
public policy scholars, to political scientists and to science and technology schol-
ars. The introduction to this symposium (Thomann et al., 2019) already touched
upon complex problems as “wicked problems.” We argue that in order to get a
better understanding of the challenges of problem-solving in multilevel gover-
nance, we can also learn from the conceptualization of complex problems as
“uncertain risks” and “crises.” In this section we aim to briefly sketch these per-
spectives chronologically, arguing that they all point to uncertainty and scientific
expertise as key issues in the multilevel regulation of uncertain risks.

Complex Policy Problems as Wicked Problems

The early 1970s showed an increasing dissatisfaction with rational-technical
approaches to decision making. This dissatisfaction stemmed from the increasing
belief that the traditional way of thinking about organizational decision-making –
there is a problem, we define the possible decision alternatives, we examine their
potential consequences, and we finally decide – does not capture reality suf-
ciently. This is the time period in which Rittel and Webber (1973) introduced their
work on “wicked problems.” According to this line of thinking simple problems
are those where problem definition and solution to the problem are understood.
Such simple problems are also referred to as “tame” problems. Tame problems
are easy to define, information needed to solve the problem is available, and there
is consensus on both the problem and the solution. Wicked problems are those
where both nature and solution are uncertain and controversial (Durant & Legge,
2006). As Rittel and Webber (1973, 161) put it: “The formulation of a wicked prob-
lem is the problem!” (emphasis in original). Wicked problems occur when institu-
tional complexity, scientific and/or cognitive uncertainty, and social pluralism
(that is, multiple interests and values of stakeholders) reach their maximum values
The article by Fossum (2019) in this symposium provides a clear topical example of how the Brexit can be seen as a prime example of a wicked problem. Because of the crucial significance of uncertainty, scientific expertise is always part of the political game (Rittel & Webber, 1973). More recently, we witness pleas for evidence-based policy-making, in which a solution to wicked problems is sought in an increase in the quality and quantity of information, i.e. evidence. However, as Newman and Head (2017, 423) point out, evidence can never be a cure for wicked problems as there is never an objective solution for such problems; something that we see highlighted in the understanding of complex policy problems as uncertain risks as well. The last couple of years the wicked problems literature has been criticized for its wicked/tame dichotomy, arguing that most policy problems inherently show some wicked elements—“almost any problem is difficult to solve” (Peters, 2017, 386)—and we should better understand complex policy problems as an index of degrees of problematicity or structuredness (Turnbull & Hoppe, 2018, 12).

Complex Policy Problems as Uncertain Risks

In the mid-1980s, around the Chernobyl accident, the risk sociologist Ulrich Beck argued that we live in a risk society where growing uncertainties have to be accepted because they can only be managed and never be completely eliminated (Beck, 1986). The core reason for the inherent uncertainty is that these risks are unforeseen side effects of the industrialized modernity, while science does not provide us with the necessary knowledge to manage them in the current policy framework (Taylor-Gooby & Zinn, 2006). Following Perrow (1984), we have come to realize that the more we depend on complex systems such as nuclear power, the more we need to accept the possibility of accidents. Uncertainty is the product of innovation (Nowotny, 2008). And thus uncertainty becomes a fundamental part of the modern risk society. van Asselt and Vos (2008) (see also van Asselt & Renn, 2011) therefore propose to talk about uncertain risks to refer to complex policy problems which involve potential new hazards rooted in technological and societal developments. Uncertain risks involve suspicions about possible, new and imaginable hazards, with which we have no or only limited experience. They usually involve complex causalities and multiple heterogeneous and long-term effects.

There is no common definition of the concept “risk,” but all attempts at a definition have one commonality: the “distinction between reality and possibility” (Renn, 1998, 50), and as a chance of injury, damage or loss (Slovic, 1999). It was assumed for a long time that risks can be understood as an objective entity whereby a risk equals the probability of an occurrence multiplied by the extent of damage. However, this perspective on risk is past-based and concentrates on hazards which have manifested themselves in the past, hence on familiar dangers. Innovation and globalization, however, influence the levels of complexity and uncertainty, making the reliance on and acceptance of probabilistic calculations increasingly impossible (Taylor-Gooby & Zinn, 2006). Necessary information on
probability and extent of damage is often not available and principally unattainable in the situation of uncertain risks, in turn affecting the role of scientific expertise. At the same time, the higher the levels of ambiguity and uncertainty, the more difficult it becomes for policy-makers to define their preferences, and the more they tend to turn to experts and scientific advice. But all such advice is embedded in prior, socially derived framing assumptions (Jasanoff & Wynne, 1998), so that we need to realize that there is no knowledge without interests (Radaelli, 1999).

How societies handle risks very much relates to institutional, procedural, social, and cultural dimensions. The way in which a country regulates risks is linked to prevailing risk perceptions and levels of uncertainty intolerance (van Asselt & Vos, 2008). This is by no means static. Vogel (2012) for example argued that while in the United States risk regulation was more risk averse than the approach of the European Union in the period of 1960–1990 (particularly in the field of health safety), this relative transatlantic stringency reversed and we arguably witness a more stringent risk regulation in the EU since around 1990. Regulating uncertain risks is complex, particularly in contexts where there is diversity in political cultures, regulatory frameworks, and standards in risk assessment.

**Complex Policy Problems Appear as Crises**

Complex policy problems usually manifest themselves in the societal and political arenas as crises. In defining crises we follow Boin et al. (2009, 83-4) who describe them as “events or developments widely perceived by members of relevant communities to constitute urgent threats to core community values and structures.” A crisis is often triggered by a “focusing event” (Kingdon, 1995), which is an “event that is sudden, relatively rare, can be reasonably defined as harmful or revealing the possibility of greater potential future harms” (Birkland, 2006, 2). Crises are considered to be induced by (in)actions of an organization. Crises are increasingly spanning boundaries (May, Jochim & Sapotichne, 2011) and jump across geographical borders, functional borders, and traditional time borders and are harder to pinpoint in terms of starting and ending time. Crises are therefore labeled as ill-structured problems – i.e. instances where there is no clarity of the definition of the problem, the extent to which it is independent of other problems, and the adequacy of the knowledge base for coping with the problem (Simon, 1973) – or messes (Mitroff, Alpaslan & Green, 2004) and can be conceptualized as manifestations of complex policy problems.

It can be in the interest of certain actors to label something as a crisis, particularly as crises are labeled as willful action or stem from human malfeasance in Birkland’s definition of the concept (Birkland, 2006). Also solutions or problems are no objectively given concepts, but are “constantly changing as they are embedded in cognitive and organizational parameters” (Borràs & Radaelli, 2011, 469). Crises often lead to “politics of urgency” where it is easier to push for certain decisions, as the sense of urgency leads to more readiness for change (Wexler, 2009).
Complex policy problems can be conceptualized as wicked problems, which implies high levels of uncertainty and pluralism, involving uncertain risks, often resulting in crises. Because of the complex significance of uncertainty (van Asselt, 2005), scientific expertise plays a crucial, however ambiguous, role in dealing with complex policy problems. Slovic (1999, 689) summarizes this very nicely, when he states that decision making about complex policy problems, but also in general, is “inherently subjective and represents a blending of science and judgment with important psychological, social, cultural, and political factors.” Boin (2004) argues that in view of uncertain risks and the wicked nature of policy problems, crisis prevention is essentially impossible. Rather than trying to prevent crises, organizations should become resilient and learn to cope with unanticipated dangers and learn to bounce back (Wildavsky, 1988).

Although we realize that the brief synthesis does not do justice to the various rich scholarly bodies of knowledge, it is clear that dealing with uncertainty and scientific expertise is key in dealing with the multilevel governance of complex policy issues. Expertise is not purely objective (Levidow & Carr, 2007), but expert advisers work hard to enact objectivity. Hilgartner (2000) argues that expertise is never purely objective because it is shaped and formed by contextual factors. When expertise would be transparent, it would make this subjectivity visible. Thus experts often “hide,” or “backstage” certain information in order to be able to deliver “serviceable truths” (Jasanoff, 2015) and “plausibility proofs” (van Asselt & Vos, 2008). Supposedly politically and socially neutral input (Millstone & van Zwanenburg, 2001) then serves as a cornerstone in the governance of wicked problems, uncertain risks and crises. We are in danger of a situation that van Asselt and Vos (2008) label as the “uncertainty paradox”: a situation in which uncertainty is acknowledged, but the role of science is still framed as one of providing certainty. Such situations can easily lead to a politicization of uncertainty (Funtowicz & Ravetz, 1990); a process in which uncertainties that relate to their interests are emphasized, amplified, or attenuated by politicians or other relevant stakeholders. In other words, uncertainty is used in political and societal debates to achieve particular ends. So it is not a genuine concern about uncertainty and an attempt to responsibly deal with it, but a particular framing of uncertainty with a certain effect. As a way out of this politicization of uncertainty, it should be much more common practice for governmental actors to provide “uncertainty information.” In other words, “argumentation about which uncertainties are important and why, disclosure of sources of uncertainty, and discussing whether and how uncertainty can be reduced and which interpretations of uncertainty are deemed valid” (van Asselt, 2005, 143).

Having this conceptualization of complex policy problems in mind, how can we better understand the challenges of problem-solving in multilevel settings? We aim to investigate how uncertainty and scientific expertise are dealt with and how this relates to the way in which scientific expertise is embedded in the regulatory
multilevel governance design. To that end, we have selected the H1N1 pandemic as a critical case. In his analysis of the preceding H5N1 avian influenza, DeLeo (2010) labeled this as an “anticipatory-conjectural problem.” These are the type of problems that can be anticipated as a potential threat, but we “rarely know how or when an anticipatory-conjectural problem will occur. Nor can we predict the scope or severity of these problems” (DeLeo, 2010, 151). We follow this characterization of pandemics, although we realize that the H1N1 situation was different from the H5N1 case before in that it was much more fast-moving. Due to the complexity, sensitivity and its scale, this pandemic can be characterized as a typical case of complex policy problems because “by definition, potentially pandemic agents such as H1N1 are novel, complex, variable, and ill-understood... (and) the scientific knowledge produced surrounding pandemic risk therefore tends to be anecdotal (based upon necessarily limited evidence and relatively few initial cases) and theoretically speculative (based on hypothetical models of future spread and pathogenicity)” (Abeyasinghe, 2014, 515). This pandemic represents an anticipatory-conjectural uncertain risk that manifested itself as a crisis. It transcended geographical boundaries, making multilevel regulation a necessity. It is therefore a strategic research site that enables us to investigate the phenomena we are interested in.

Case Study: The H1N1 Pandemic

The influenza first emerged in North America. On 15 April, 2009, infection with this new influenza A virus (then referred to as “swine origin influenza A virus”) was first detected in California, and about a week later Mexico confirmed 120 cases of influenza and 20 deaths (Health Protection Agency (HPA), 2010). At 29 April nine countries reported cases, by 11 June this raised to 74 countries, and on 1 July there were confirmed cases in 120 countries all around the world (Council of Europe, 2010). On 11 June 2009 the global pandemic was officially declared by the World Health Organization (WHO), with the notification that the influenza reached the last phase, Phase 6 of the WHO pandemic scale. The pandemic lasted a little over a year, and on 10 August 2010 the WHO announced its official end. The H1N1 pandemic was a highly complex and challenging event which affected worldwide more than 214 countries, territories and communities, causing over 17,919 deaths (WHO, 2010).

In order to analyse how uncertainty and scientific expertise were dealt with, we examine policy responses by actors at member state level in Europe, the role of the European Union via its specialized agencies, and the actions by the WHO. The WHO is the actor capable of officially declaring a pandemic, and is responsible for advising and guiding countries in developing and implementing their pandemic preparedness plans. The EU agencies involved in this case were particularly the European Centre for Disease Prevention and Control (ECDC) for providing advice on the handling of the pandemic, and to a lesser extent the European Medicines Agency (EMA) for the authorisation of the required vaccines (see Deruelle, 2016 for more insight into the setting up of ECDC). National health
authorities within the EU member states remain responsible for executing their own pandemic preparedness plans and for deciding on potential vaccination strategies. They can thereby rely on advice and expertise provided at both the EU and international level. They also have reporting duties to both the EU agency (ECDC) as well as to the WHO on the national state of affairs regarding the pandemic. In examining the patterns in the behavior and response, we aim to better understand how uncertainty is and can be dealt with in the multilevel governance of complex policy problems.

This case study relies on literature review (analysing scholarly literature on this case) and document analysis. Data were collected via extensive document search, and mostly concentrated on the websites of the ECDC (over 300 relevant documents) and the WHO (around 200 relevant documents). In order to analyse the WHO case, we could resort to 115 situation updates, 23 briefing notes, and 59 guidance documents in nine different categories such as “animal-human interface” or “vaccines.” Of these 197 documents we randomly selected 20, covering the different categories. For the ECDC case a similar strategy was applied. This EU agency published various types of documents, culminating in more than 300 publications. The types of publication include, amongst others, more than 250 “Daily Updates,” “Threat Assessments,” “Risk Assessments,” “Guidance documents,” “Surveillance Reports,” etc. Here we randomly selected 30 documents covering the various categories. Additionally, we could resort to an extensive body of evaluations of the H1N1 pandemic carried out by a variety of actors such as the Council of Europe, the European Commission, the European Parliament, as well as many individual countries around the world (we analysed the 10 most relevant evaluations). These (in total 60) documents were electronically analyzed by applying a keyword search in order to detect and extract relevant text. We initially started with those keywords that directly were related to our research question, i.e. “experts,” “expertise,” “science,” “uncertainty,” “uncertain,” and “complex.” Text using these keywords was analyzed, which led to the identification of additional related keywords: “incomplete,” “gap,” “unknown,” “ill-understood,” “tentative,” “ambiguous,” “limited evidence,” and “anecdotal.” Based on these keywords, relevant text in all documents was identified and analyzed. This research is explorative in nature, and does thus not attempt to provide a detailed insight into the number of times certain words appeared in the text. Our core focus is the behavior of the relevant actors in relation to each other, in order to be able to provide first insights into how in the H1N1 pandemic uncertainty and scientific expertise played out.

The Multilevel Regulation of the H1N1 Pandemic

In order to understand the multilevel regulation of complex policy problems, we analysed how the WHO, the EU-level, and EU member state agencies handled the H1N1 pandemic. For each of the levels we discuss the core steps taken by the institutions, how uncertainty and science played a role in the process, as well as the role played by experts.
The International Level: WHO

The WHO declared the final phase of the pandemic scale, Phase 6, on 11 June 2009, and officially ended the pandemic on 10 August 2010. How did the organization deal with uncertainty and scientific expertise?

Content analysis of WHO documents illustrates that the WHO provided very limited uncertainty information. The policy guidance provided is usually prescriptive of nature, and only occasionally hints at scientific uncertainty. For example in one of its guidance documents (WHO, 2009, 2), it is stated that “this guidance document recognizes several knowledge gaps; e.g. data are limited regarding the risk of transmission associated with procedures that involve manipulation of the respiratory tract,” or in the Outbreak Communication Planning Guide (WHO, 2008, 14), where it is stated that “at the beginning of an outbreak, there are often gaps in information and there may be scientific uncertainty.” However, this uncertainty information rarely becomes specific. We therefore conclude that the WHO documents do not provide uncertainty information.

This observation is consistent with the heavy criticism that the WHO received in various internal and external evaluation reports. During the pandemic, the WHO is claimed not to have been open enough about the uncertainty of the situation, thereby feeding in to the potential overrating of the pandemic. Rather than explicitly addressing the uncertainty, the WHO is seen to have regularly overstated the pandemic’s expected outcome in its communication to the national governments (Council of Europe, 2010, 14). It is stated that “the problem is not so much that communicating uncertainty is difficult, but that uncertainty was not communicated” (BMJ, 2010). The Council of Europe (2010, 9) even goes as far as stating that when looking at the relatively moderate outcome of the pandemic, “the interpretation of scientific and empirical evidence can be seriously questioned”. The criticism on the way the WHO handled the H1N1 pandemic can be summarized by the following remark by the Council of Europe (2010, 1): “Some of the consequences taken and advice given are particularly troubling, as they led to distortion of priorities of public health services across Europe, waste of large sums of public money and also unjustified scares and fears about health risks faced by the European public at large.” The first issue in the most commonly raised concerns boils down to the timing and ease with which the pandemic was defined notwithstanding the inherent uncertainty.

Several institutions state that the pandemic was overrated by the WHO (e.g. Council of Europe, 2010, European Parliament, 2011). Criticism is raised on the WHO moving too quickly to the final phase (Phase 6), as a result of a recent chance in the criteria for pandemic alert. Due to this chance in 2009, the criterion related to the severity of the disease was removed as a precondition for moving to Phase 6. The Council of Europe (2010, 10) argues that the WHO moved to this final phase while already knowing that there was empirical evidence that the influenza was milder than expected. One month prior to moving to Phase 6, Chan
(head of the WHO) actually discussed the moderate severity of H1N1 during a press conference (European Parliament, 2011, 13). In addition, it is stated that the WHO recalled the pandemic too late (European Parliament, 2011).

The second core criticism concerns the role of experts, and more specifically the lack of transparency about internal decision making. The names and declarations of interest of the members of the Emergency Committee, the body advising the director-general on the pandemic, have been kept secret, thus leading to the suspicion of possible influence of the pharmaceutical industry (i.e. leading to the fear of regulatory capture) (Council of Europe, 2010, Davis, Flowers & Stephen son, 2014). Even afterwards, when confronted with this criticism, the WHO did not make this information public. The BMJ (2009) claims that key scientists advising the WHO had done paid work for the pharmaceutical industry working on the relevant vaccines. The Council of Europe (2010, 11) stresses that this lack of transparency can lead to a situation in which uncertainty can be misused and manipulated in favor of commercial interests.

Informed by our content analysis and enriched by the synthesis of evaluations of the WHO performance in the H1N1 case, we conclude that the WHO portrayed uncertainty-intolerant behavior, by not providing uncertainty information which would allow decision makers to reflect on uncertainty and the consequences for policy-making. This handling of uncertainty arguably provided room for what has been referred to as the “politicization of uncertainty” (Funtowicz & Ravetz, 1990).

The European Level: EU Agencies

Although the WHO received considerable criticism on its handling of the H1N1 pandemic, the European agencies involved – and particularly the ECDC – mostly received praise. The Council of Europe, one of the most explicit attackers of the WHO, states that “the rapporteur generally welcomes the realistic approach taken on the pandemic by European institutions involved in public health matters” (Council of Europe, 2010, 18). Comments on ECDC’s handling of the case are generally positive. EU member states valued the risk assessments and evaluation reports by ECDC highly, referring to them as “excellent and reliable,” and describing ECDC as “the entity that provided most information and in a timely manner” (Health Protection Agency (HPA), 2010, 40). The European Parliament states: “With ECDC, the EU has a dedicated agency with regard to the assessment of communicable diseases” (European Parliament, 2011, 14).

In addition, our content analysis of ECDC documents reveals an entirely different approach to providing uncertainty information compared to the WHO. On 24 April 2009 ECDC posted its first threat assessment, and ECDC downgraded the crisis in January 2010 (much earlier than WHO which did so in August 2010). In contrast with the WHO, ECDC provided uncertainty information and kept stressing the uncertainty and highlighted what we do not know yet (“known unknowns”; European Centre for Disease Prevention and Control, 2010, 7). During the starting phase of the pandemic, information on the outbreak “was largely
incomplete” (Greco, Stern & Marks, 2011, 26), and this was clearly acknowledged by ECDC in its documents. In its first rapid risk assessment of 24 April, ECDC concludes that “it is too early to say whether this will lead to a larger outbreak” (European Centre for Disease Prevention and Control, 2009a, 4). Furthermore, when outlining the implications for the EU, ECDC was open and explicit about the scarce data available on the virus. It lists characteristics that help decide the size, speed, and seriousness of a potential pandemic, and in each point ECDC states: “Infectivity: We do not know... At present, it seems as if... but this assessment may change...; Reproduction rate: Unknown...; Immunity: We do not know... etc.” (European Centre for Disease Prevention and Control, 2009a, 2–3). As more data became available, the third update of ECDC’s risk assessment published on 12 June provided more detailed and new information on the virus, and ECDC provided a list of topics that can and cannot be assumed under the name “known knowns” and “known unknowns” (European Centre for Disease Prevention and Control, 2009b, 2). ECDC consistently acknowledged uncertainty, as can be seen in the use of expressions such as “To date there is no evidence...; It is difficult to estimate...; There are as yet no reports of...; It is difficult at this stage to comment on...; Though it seems that...this picture is still unclear...” (European Centre for Disease Prevention and Control, 2009b, 3–5). ECDC is also aware of “unknown unknowns” which describe that “there are always things that surprise about each pandemic.” ECDC presents a menu of possible public health measures that can be adopted by national policy-makers and decision makers during an influenza pandemic in one of its technical reports. Here, the agency stresses that there are “more gaps than certainties... (and) significant holes in our knowledge” and “[t]he evidence base for the use of the measures against influenza is limited and primarily comprises anecdotal observations...” (European Centre for Disease Prevention and Control, 2009c, 9). This report provides specific policy advice regarding several measures for travel, personal protection, public places, antivirals, etc. and in all these proposed measures ECDC clearly states what is known and unknown as well as how much evidence is available. Regarding general mask-wearing in public places, for instance, ECDC states that its effectiveness is unknown as “there is no trial and few other data” (European Centre for Disease Prevention and Control, 2009c, 19). Similarly, when it comes to pandemic vaccines, “there are considerable uncertainties and some risks... and any adverse effects will need to be watched for carefully as there will be no time for ordinary trials” (European Centre for Disease Prevention and Control, 2009c, 31). In sum, ECDC is very explicit in acknowledging what is known and what is unknown, and is thus explicit in providing uncertainty information. Whenever its documentation is offering policy advice, this advice is always phrased in a context. For example, there is explicit recognition of the fact that specific advice is likely to play out differently in different EU member states. As illustrated by the following statement: “…given the above considerations, these plans should have considerable flexibility and command and control structures that will allow changes to be made quickly in the light of new data and experience. ... Because of Europe’s diversity, no single combination of measures will suit every European setting: one
size will not fit all” (European Centre for Disease Prevention and Control, 2009c, 2).

Next to ECDC as the main EU actor involved, the EMA was responsible for deciding on vaccination. There is criticism on the way the EMA authorization procedure worked in this case. Because of the need for quick action, EMA allowed the use of the mock-up procedure that allows fast-tracking (European Centre for Disease Prevention and Control, 2010), i.e., a quick process that skipped clinical testing on vulnerable groups such as children (Council of Europe, 2010). In addition, EMA documents on research protocols, clinical trials, and undesirable effects of medical products are not always accessible to the public (European Parliament, 2011, 8). Also ECDC did not release the names of experts on internal advisory bodies (Council of Europe, 2010), but because the ECDC “merely” provided advice – and was not responsible for the official declaration of the pandemic – this is less criticized than in the WHO case.

Overall we can conclude that in comparison to the WHO documentation, there is much more explicit attention for uncertainty in how the ECDC communicates about the H1N1 pandemic. While we labeled the WHO as uncertainty-intolerant in its communication, the ECDC is seen to provide uncertainty information. As a next step we explore how the EU member states – confronted with this diverging multilevel approach – handle the pandemic.

The National Level: EU Member States

EU member states – the responsible actors for taking the actual decisions on how to handle the pandemic – could resort to information and advice provided by both the WHO and the ECDC, and they were thus confronted with wide diversity in the tone of voice of the documentation provided at these different levels. While the WHO provided rather prescriptive guidance, the ECDC provided more uncertainty information and when it did issue specific guidance, it clearly illustrated how this situation would likely play out differently in different member states. Insight into how EU member states responded to the pandemic reveals that the response was very diversified, particularly regarding the way in which vaccines were handled. In most cases, national governments had predetermined “sleeping contracts,” or “advance purchase agreements,” that oblige countries to buy predetermined numbers of vaccines. There was an automaticity of contracts with industry coming into effect once WHO signals a pandemic of Phase 6 (Baekkeskov, 2016, BMJ, 2010, Council of Europe, 2010). This led to pressure on national governments to speed up their decision making. An additional complication was that because the pharmaceutical industry did not have sufficient time to test the new vaccines, they brought into effect a clause that stipulated that member states making use of these sleeping contracts are liable for the use of the vaccines.

National reactions to the pandemic varied enormously, with some being better prepared than others (Health Protection Agency (HPA), 2010). Within the EU there were several extreme responses, with the reserved attitude of Poland on the
one side, and the pro-active stance of UK and France on the other side. The reserved countries, with Poland as the clearest case, did not automatically initiate vaccination campaigns and did not purchase large quantities of vaccines. The Polish response was handled in close cooperation with the ECDC. The Polish minister for health stated that she took responsibility, and would not accept the conditions imposed by the pharmaceutical industry. The British government, in contrast, started its approach from the worst case scenario and predicted 65,000 deaths (Council of Europe, 2010, 16-17). This in the end led the United Kingdom to spend 1,300 million Euro on H1N1 related actions – compared to around 87 million Euro for an average seasonal influenza (European Parliament, 2011, 13).

As a response, the British actors involved stated that “we had to do what we thought was right at the time” (Davis et al., 2014, 369). In addition, comparative research on the Dutch and Danish vaccination responses to H1N1 reveals that the response resembles the previous national framing of influenza (Baekkeskov, 2016). The Dutch were already preparing for an extraordinarily deadly influenza (worst case), while the Danish focused on a range of probable, moderately severe influenza. This previous Dutch preparedness paved the way for a national policy strategy of mass vaccination, while the Danish opted for limited vaccination.

This differentiated reaction by member states is in line with what De Vries, Verhoeven and Boeckhout (2011) observed, who stated that it often happens that authorities in different countries arrive at different policy recommendations, while basing themselves on the same international scientific data. ECDC provided explicit information about the uncertainty of the severity of the situation. In some countries this uncertainty information did not stop them from adopting a worst case scenario approach, leading ECDC to state that “unfortunately, as is obvious now, many decision makers did not wait for better information to emerge before taking consequential decisions on vaccine strategy on the basis of a worst-case scenario” (European Centre for Disease Prevention and Control, 2011, 31). This indicates that there was a “significant gap between the scientific advice offered by ECDC to member states and the strategic decisions taken by many of them” (European Centre for Disease Prevention and Control, 2011, 32).

**Patterns in the Multilevel Regulation of Complex Policy Problems**

The handling of this pandemic required much multilevel cooperation on all fronts. Between the WHO and the EU counterparts; between national authorities and the EU agencies; between the national authorities and the WHO; between national authorities in different member states. Despite similar exposure to information from international bodies such as the EU agencies and the WHO, national authorities responded very differently to uncertainty and scientific expertise.

Overall, the handling of the H1N1 pandemic was criticized for a disparity between the severity of the crisis and some of the far-reaching actions taken, sometimes even framed as “disproportionate response” (Council of Europe, 2010, 10, European Parliament, 2011, 7). The criticism on the pandemic being overrated, particularly by the WHO, is often substantiated by indicating the estimated
numbers of deaths for this pandemic, compared to the mortality estimates for a “normal” seasonal influenza. The number of deaths caused by H1N1 is estimated to be around 2,900 in Europe, while a seasonal influenza is estimated to lead to 40,000 deaths in a moderate year (European Parliament, 2011, 13).

We furthermore observe that the influenza was constructed as a global health threat (Abraham, 2011). Next to that, WHO’s actions can be characterized as a policy solution waiting for a problem (Cohen, March & Olsen, 1972). The international community was for years anticipating a major pandemic to happen, and many policies were in place already, waiting for the crisis to break out. The 2003 SARS outbreak triggered the WHO to encourage countries to prepare pandemic preparedness plans (Durodié, 2011). Already in 2005, the then US president Bush framed pandemic influenza as a threat requiring emergency funding (Abraham, 2011, 800).

Linking back to DeLeo’s (2010) (see also DeLeo, 2017) capturing of influenza as anticipatory-conjectural problems, we can assume that it was precisely this “anticipatory” nature of influenza that might explain these differentiated responses. Already the H5N1 pandemic before was very much perceived as a problem of preparedness (DeLeo, 2010, 169), and this seems to also capture the way the WHO approached the H1N1 case. The anticipatory building up of national preparedness plans created “a framework or discourse within which a pathogen like H1N1 was almost automatically regarded as a threat warranting a global response” (Abraham, 2011, 809), or as it was framed in the review conducted by ECDC: “it quickly became apparent that this was not the major pandemic that countries had prepared for. [...] This posed some difficulty because the pandemic preparedness plans that were already activated by this time had been prepared to respond to a more severe – or worst case scenario – and it took a lot of effort from the EU/EEA countries” advisors to modify their relatively inflexible plans’ (European Centre for Disease Prevention and Control, 2010, 31). Durodié (2011, 514) also described this difficulty of deviating from premade plans – particularly difficult in already anticipated situations. Even though this new pandemic did not resemble the SARS virus, it was like “old military generals preparing to fight the last war – the responses were largely tailored to the plan, not the virus”. It is always difficult to strike the right balance between applying the precautionary principle – as the proponents of the severe measures used to justify their actions – and the proportionality of the response, but this becomes even more difficult in an anticipated situation where policy solutions are already waiting for a problem.

What does the analysis of the patterns in the multilevel regulation of the H1N1 outbreak teach us about diversified reactions in a situation of scientific uncertainty? The WHO chose the rather classical, positivistic approach of not providing uncertainty information and to use the existing uncertainty as an indicator of risk. This approach has in retrospect been criticized and even characterized as a situation in which politicization of uncertainty took place. At the European level, the ECDC provided uncertainty information, which allowed decision makers to decide about the appropriateness of the response in their context. Both WHO and ECDC were considered as the institutions which serve the role of scientific
expertise in a crisis situation characterized by uncertainty. In a situation in which weighing the uncertainty was crucial for decision makers to decide about the regulation of a complex problem, the approach of ECDC was considered fruitful, while the handling by WHO was heavenly criticized.

Conclusion

Learning from this critical case, we argue that a better understanding of how uncertainty and scientific expertise play out is key to better understand the challenges of problem-solving in a multilevel setting. Our analysis of the multilevel reactions to the H1N1 pandemic illustrates a huge variety in responses to uncertainty. While largely ignored at the international level by the WHO, explicitly acknowledged at the European level by the ECDC, this left EU member states in oblivion on what to make of this uncertainty. In response to the diversity of uncertainty information coming from the various levels, member states seemed to resort to their previous national way of handling things, and in some cases this resulted in a strict following of pre-determined worst case scenarios that turned out not to be entirely apt for the pandemic at hand. This might not be too surprising if we take into consideration that “in a crisis, individuals and institutions often act primarily on the basis of their interpretative frameworks of reality, not solely the information available to them at the time” (Durodié, 2011, 513). This is problematic, because the regulation of complex policy problems then depends too much on local political responses, and misses the opportunity to “inject a much-needed strain of competence and critical intelligence into a regulatory system that otherwise seems all too vulnerable to the demand of politics” (Jasanoff, 1990, 209).

This analysis of the H1N1 outbreak reveals how in the handling of complex policy problems in a multilevel setting, the provision of uncertainty information and a variety of potential policy options is crucial and needs to become standard practice. Without openness about the “known unknowns” and “unknown unknowns,” decision making easily becomes politicized – as here illustrated by the WHO response that seemed to be more in the business of speaking truth to power (Wildavsky, 1979). This case study demonstrates that particularly in multilevel situations the wide variety in national responses can increase the uncertainty about scientific expertise, leading to a situation in which science easily becomes disputed. Following Levidow and Carr (2007), we support the claim that we need to pluralize expertise, and “frontstage” uncertainty and thus show and demonstrate that expertise is never objective but is based on uncertainties and norms. Without explicitly addressing uncertainty, and coordinating this between the various levels involved, there is room for politicization of uncertainty, in other words, actors amplifying uncertainty to further their own interest (van Asselt & Vos, 2008, 291). As stated by De Vries et al. (2011, 495), “risk governance requires uncertainties to be voiced.” Without such a voicing of uncertainty, we run the risk of a negative effect on public trust in science and expertise, as captured in the concerns formulated by the Council of Europe rapporteur, that “there is a real danger of now having cried ‘wolf’ so often that the public will not take
appropriate notice any more when the next infectious disease occurs” (Council of Europe, 2010, 19).

The most important added value of this case study is that we have shown that it is possible for governmental organizations to provide uncertainty information and to be acknowledged for this. We have illustrated how the European agency (ECDC) does explicitly provide uncertainty information, and is highly appreciated for this by the EU member states. As a next step in a more institutionalized acceptance of uncertainty in the regulation of complex policy problems – also to avoid the negative side-effects of a politicization of uncertainty – we need more resilient governmental actors who know how to respond to such “front-staged” uncertainty. The open approach by the European agency should thus be seen as an important first step in more uncertainty tolerance in the governance of complex policy problems, and should be seen as an example for the multilevel regulatory setting.

**Esther Versluis** is Professor European Regulatory Governance at Maastricht University. Her research concentrates on the regulation of risks, and on the implementation of EU policy.

**Marjolein van Asselt** is Professor Risk Governance at Maastricht University. In addition, she is board member of the Dutch Safety Board.

**Jinhee Kim** is a postdoctoral lecturer at Maastricht University. Her research concentrates on the influence of EU agencies.

**Note**

1. ECDC PowerPoint presentation titled “How pandemic differ – and so why they can be difficult to manage or predict.” Available at: http://ecdc.europa.eu/en/healthtopics/Documents/0905_Pandemic_Influenza_Known_Facts_and_Known_Unknowns.pdf.

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