

# **Pandemic Declarations of the World Health Organization as an Exercise of International Public Authority: The Possible Legal Answers to Frictions Between Legitimacies**

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## Abstract

The institutional decisions regarding the 2009–2010 influenza A(H1N1) pandemic displayed how the World Health Organization's (WHO) role as the international organization in charge of coordinating the pandemic response amounts to an exercise of authority. Notably, the 11 June, 2009 Pandemic Declaration was grounded in the WHO's guidelines that do not have a binding nature according to international law. However, this is not an obstacle for considering them as an act of authority, since their effects can constrain the decision-making of States. If these non-binding acts have an authoritative nature, then it is necessary to address various legitimacy issues that may be present. This is where the concept of international public authority (IPA) can prove useful, since it enables to combine the non-binding nature of Pandemic Declarations and the respective guidelines with broad legally-oriented figures such as transparency and accountability.

The controversies surrounding the 2009 Pandemic Declaration illustrate how the strictly technical-scientific elements that led to such a decision were not necessarily harmonious with other aspects more related to political decision making in general, such as transparency and accountability. This can be considered as an example of how so-called 'technocratic legitimacy' sometimes generates friction with *lato sensu* 'political legitimacy'. As the 2009–2010 pandemic period unraveled, it became clear that expertise-based legitimacy is not sufficient in itself to consider the act as generally legitimate. On the contrary, the strongest criticisms directed at the decision-making process of the WHO during this event were leveled against deficits of transparency and accountability. This article purports to discuss the issue of how both types of legitimacies, technical-scientific and political, are necessary components for deeming Pandemic Declarations as legitimate enough, since they amount to an exercise of international public authority.

## A. Introduction

This article focuses on the World Health Organization's (WHO) role in the 2009–2010 influenza A(H1N1) pandemic. The 11 June 2009 Pandemic Declaration of the WHO (2009 Pandemic Declaration) resulted in a series of questions regarding the authority exercised by this organization when this event took place. This was mainly due to accusations of scientifically debatable decision-making, on the one hand, and a lack of transparency and accountability in light of possible wrongdoings, on the other. This calls into

question the legitimacy of the Pandemic Declaration, a matter that is of utmost importance given its consequences.

The first section of this article is devoted to establish how the concept of international public authority (IPA) contributes to the understanding of why the WHO's Declaration of the existence of a pandemic constitutes an activity that entails notable constraining effects for States, even though it is based upon guidelines that are not legally binding under international law. For example, they serve as a basis for activating pandemic preparedness and response mechanisms or 'dormant' contracts with pharmaceutical companies. Pandemic Declarations are an example of the need for a conceptual framework for global governance activities which provides a looking glass for the identification of exercises of authority. In this respect, the concept of IPA can be useful to provide an appropriate response (B.).

Secondly, this article attempts to delve further into some of the features of Pandemic Declarations, and also of the WHO guidelines on pandemics that configure them, contributing to the understanding that they have an authoritative nature. In this respect one needs to distinguish the non-binding Pandemic Declarations from other binding acts, such as a declaration of Public Health Emergency of International Concern (PHEIC) (C.).

Third, once the case has been made that the IPA approach can be useful for the assessment of the authoritative nature of Pandemics Declarations, the subsequent section discusses some of the legitimacy issues related to the 2009 Pandemic Declaration. This Declaration led to questions concerning the scientific grounds for the assessment of the situation, which is a basis for what can be labeled as 'technocratic legitimacy'. It also highlights an underlying friction between the eminently technical elements of the decision and the surrounding 'political' context, a factor that led to controversy due to the (mainly) economic consequences of the Pandemic Declaration (D.).

Finally, the following section addresses the point of how, during the Pandemic Declaration of 2009, there was, and still is, a need to enhance the transparency of the process, along with the WHO's accountability (E.). These are components that lead to these acts being considered as legitimate, especially when these elements are pitted against strictly technical reasons, which themselves cannot be overlooked. The delicate balance between 'scientific' and *lato sensu* 'political' aspects needs to be tackled. Although some improvements are already under way, these discussions are ongoing within the more general debate about the legitimacy of the activities of international organizations, and in the particular context of the more recent Ebola crisis in West Africa, as well as the ongoing Zika epidemic in the Americas.

## B. General Overview

### I. The Concept of International Public Authority as an Analytical Lens

The notion of global governance emphasizes the fact that constraining, authoritative effects do not only emanate from binding legal documents.<sup>1</sup> On several occasions, these effects stem from instruments that are not legally binding, but *de facto* have significant constraining impacts on their addressees, whether they are States or individuals.

Traditional approaches to international law are considered not to be sufficient to take into consideration some of the realities highlighted by the concept of global governance.<sup>2</sup> IPA, by contrast, emphasizes the fact that both formal and informal acts created by public or private entities can be considered as an exercise of authority,<sup>3</sup> insofar as they have

“the legal capacity to determine others and to reduce their freedom, i.e. to unilaterally shape their legal or factual situation”.<sup>4</sup>

<sup>1</sup> The literature on the subject is immense. For a glimpse, see the seminal work of J. Rosenau & E.-O. Czempiel (eds), *Governance Without Government: Order and Change in World Politics* (1992). Focusing on how the term ‘governance’ is used to signify the authoritative effects of rules regardless of their origin, and why ‘global’ is preferred to ‘international’, see J. Peel, *Science and Risk Regulation in International Law* (2010), 5. It is worth mentioning that the multiplicity of understandings of the notion of global governance is the subject of several evolving arguments, since it is in a state of continuous flux. See A. M. Kacowicz, ‘Global Governance, International Order, and World Order’, in D. Levi-Faur (ed.), *The Oxford Handbook of Governance* (2012), 688–692.

<sup>2</sup> See J. Klabbbers, *International Law* (2013), 17, 37–39 [Klabbbers, International Law]. There are several noteworthy approaches that aim at providing an answer to this challenge. Among them are the global administrative law (GAL) approach and the strand of constitutionalization of international law. For the first one, see B. Kingsbury, N. Krisch & R. B. Stewart, ‘The Emergence of Global Administrative Law’, 68 *Law and Contemporary Problems* (2005) 3, 15, 16 *et seq.* For a glimpse at the discussions regarding the second approach, see J. Klabbbers, A. Peters & G. Ulfstein, *The Constitutionalization of International Law* (2009).

<sup>3</sup> J. N. Rosenau, ‘Governance, Order and Change in World Politics’, in Rosenau & Czempiel (eds), *supra* note 1, 3–11.

<sup>4</sup> A. von Bogdandy, P. Dann & M. Goldmann, ‘Developing the Publicness of Public International Law: Towards a Legal Framework for Global Governance Activities’, in A. von Bogdandy *et al.* (eds), *The Exercise of Public Authority by International Institutions: Advancing International Institutional Law* (2010), 3, 11.

Therefore, it is essential that such acts find an appropriate response within the legal domain in order to improve their legitimacy.<sup>5</sup> The purpose is to translate some of the legitimacy challenges of authoritative acts into a cluster of principles that emanate from the broader field of Public Law. This entails that one needs to think about possible restraints to the exercise of authority.<sup>6</sup>

The idea of what is considered as ‘public’ in nature varies significantly between the domestic and the international spheres.<sup>7</sup> In this particular case, the ‘public’ nature of the act is not contested, since the creation of the guidelines that provide the grounds for the Pandemic Declarations was performed by an international organization (namely, the Director-General of the WHO). Additionally, it is grounded on the broad powers granted by its Constitution<sup>8</sup> and on the more specific ones deriving from the 2005 *International Health Regulations* (IHR),<sup>9</sup> which constitutes the core binding instrument for fighting the international spread of disease.<sup>10</sup> Consequently, the WHO’s authority to create pandemic guidelines is considered to be a product of its legal mandate,

<sup>5</sup> *Ibid.*, 11–12.

<sup>6</sup> *Ibid.*, 26. Also, A. von Bogdandy, ‘General Principles of International Public Authority: Sketching a Research Field’, 9 *German Law Journal* (2008) 11, 1909, 1914–1915.

<sup>7</sup> The notions of ‘public’ and ‘private’ at the international sphere are still contested in multiple aspects, since there is no ‘one definition to end them all’, and some borderline cases illustrate their limitations. See T. Risse, ‘Governance in Areas of Limited Statehood’, in Levi-Faur (ed.), *supra* note 1, 705–707. For an overview of the current state of this debate, as well as a proposal for further defining the ‘public’ character of authority, see M. Goldmann, ‘A Matter of Perspective: Global Governance and the Distinction between Public and Private Authority (and Not Law)’, 5 *Global Constitutionalism* (2016) 1, 48, 76–84.

<sup>8</sup> Both the broad nature of the functions described in Art. 2 *Constitution of the WHO*, as well as those stipulations which are perhaps most related to the current analysis, can be witnessed in the following subsections:

“Article 2.

In order to achieve its objective, the functions of the Organization shall be:

(a) to act as the directing and co-ordinating authority on international health work;

[...]

(g) to stimulate and advance work to eradicate epidemic, endemic and other diseases;

[...]

(v) generally to take all necessary action to attain the objective of the Organization.”

<sup>9</sup> This is highlighted in the *IHR*:

“Article 13 Public Health Response

1. [...] WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.”

<sup>10</sup> The *IHR* were approved in 2005 and entered into force in 2007, in the form of a binding ‘regulation’ created under the auspices of an international organization, namely the

which was granted by a political collective,<sup>11</sup> namely the international community of States.

The IPA approach thus provides a conceptual background that allows for the analysis of the creation, development and implementation of Pandemic Declarations. I take the 2009–2010 influenza A(H1N1) pandemic as a case study that sheds light on some of the authoritative features of these acts. The case study also provides an example for dealing with future Declarations of this sort issued by the WHO – whether and when they occur again. It is only through the concrete assessment of a single case, rather than on an abstract basis,<sup>12</sup> that some of the salient issues of WHO’s pandemic policy become visible.

## II. Introducing the Case: The 2009–2010 Influenza A(H1N1) Pandemic

Between the months of February and April of 2009,<sup>13</sup> there were several outbreaks of an influenza virus with the same protein components as the most devastating pandemic known to mankind in terms of fatalities: the 1918–1920 ‘Spanish flu’ caused by the A(H1N1) strain of the influenza virus, believed to have caused between 50 and 100 million deaths.<sup>14</sup> The 2009 A(H1N1)pdm09 virus had a slightly mutated genetic code, and it began spreading throughout nations. This event had been expected to be potentially catastrophic previously

World Health Assembly of the WHO. This is based on the faculties granted by Art. 21 *Constitution of the WHO*.

<sup>11</sup> Von Bogdandy, Dann & Goldmann, *supra* note 4, 13.

<sup>12</sup> R. Wolfrum, ‘Legitimacy of International Law from a Legal Perspective: Some Introductory Considerations’, in R. Wolfrum & V. Röben (eds), *Legitimacy in International Law* (2008), 22.

<sup>13</sup> The basic chronological details of what happened during this period can be consulted in WHO, *Strengthening Response to Pandemics and other Public Health Emergencies: Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza (H1N1) 2009*, 2011, available at [http://www.who.int/ihr/publications/RC\\_report/en/](http://www.who.int/ihr/publications/RC_report/en/), 29 (last visited 14 February 2016); R. Katz, ‘Use of Revised International Health Regulations During Influenza A (H1N1) Epidemic, 2009’, 15 *Emerging Infectious Diseases* (2009) 8, 1165, 1166–1168; B. Bennett & T. Carney, ‘Trade, travel and disease: The role of law in pandemic preparedness’, 5 *Asian Journal of WTO & International Health Law and Policy* (2010) 2, 301, 306–309.

<sup>14</sup> N. P. A. S. Johnson & J. Mueller, ‘Updating the accounts: global mortality of the 1918–1920 “Spanish” influenza pandemic’, 76 *Bulletin of the History of Medicine* (2002) 1, 105, 109–115. Also, D. M. Morens *et al.*, ‘The 1918 influenza pandemic: Lessons for 2009 and the future’, 38 *Critical Care Medicine* (2010) Supplement to 4, e10.

to its emergence<sup>15</sup> but was catalogued ultimately by public health experts as mild<sup>16</sup> given the fact that official reports tallied the fatalities at around 18,500 worldwide.<sup>17</sup> More recent estimates calculate a death toll that was approximately ten times higher due to the persistent under-reporting of many national health systems that complicates determining the exact incidence of influenza.<sup>18</sup> Although these calculations did not modify the overall degree of severity estimated for this event,<sup>19</sup> the pandemic strain of the influenza virus, A(H1N1)pdm09 is currently still spreading through multiple regions.

The mild-to-moderate severity of the 2009–2010 influenza A(H1N1) pandemic led some to believe that the Director-General of the WHO had wrongfully issued a Declaration without having enough factual grounds for it, based on what was considered as ‘biased’ counseling given by the IHR Emergency Committee. There was an ongoing – albeit constrained – discussion of whether the assessment made by these persons was either a hoax<sup>20</sup> or a downright

<sup>15</sup> See P. Doshi, ‘The elusive definition of pandemic influenza’, 89 *Bulletin of the World Health Organization* (2011) 7, 532, 535. Also in that volume, D. J. Barnett, ‘Pandemic influenza and its definitional implications’, 539, and L. Bonneux & W. Van Damme, ‘Health is More than Influenza’, 539–540.

<sup>16</sup> L. Sanders, ‘Of Swine and Men. Scientists study H1N1’s past to predict what the virus has in store’, *Science News* (27 February 2010), 22.

<sup>17</sup> WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 27.

<sup>18</sup> See S. F. Dawood, *et al.*, ‘Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A H1N1 virus circulation: a modelling study’, 12 *The Lancet Infectious Diseases* (2012) 9, 687; L. Simonsen *et al.*, ‘Global Mortality Estimates for the 2009 Influenza Pandemic from the GLaMOR Project: A Modeling Study’, 10 *Public Library of Science: Medicine* (2013) 11, 1, available at <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001558> (last visited 14 February 2016), 10–14.

<sup>19</sup> See the explanation given by then Special Advisor to the Director-General on Pandemic Influenza, Keiji Fukuda, at a press conference on 14 January 2010, available at [http://www.who.int/mediacentre/vpc/transcript\\_14\\_january\\_10\\_fukuda.pdf?ua=1](http://www.who.int/mediacentre/vpc/transcript_14_january_10_fukuda.pdf?ua=1) (last visited 14 February 2016).

<sup>20</sup> This view has been supported, among others, by the former Chair of the Health Committee of the European Council, Wolfgang Wodarg, who basically accused the WHO of acting on the basis of *no* justifiable scientific evidence. The accusation faded away with time, and to this date investigations on the matter have given no additional evidence whatsoever. See ‘Statement presented by Dr. Wolfgang Wodarg, medical expert specialising in epidemiology and former Chair of the Sub-committee on Health and the Parliamentary Assembly’, Social, Health and Family Affairs Committee of the Parliamentary Assembly of the Council of Europe, Strassbourg (26 January 2010), available at [http://www.assembly.coe.int/CommitteeDocs/2010/20100126\\_Statement%20Wodarg.pdf](http://www.assembly.coe.int/CommitteeDocs/2010/20100126_Statement%20Wodarg.pdf) (last visited 14 February 2016).

blunder.<sup>21</sup> Others assume that at the start of the 2009 influenza pandemic, the existing data justified taking such a decision in order to prevent or limit the effects of further outbreaks.<sup>22</sup> A summary report of 18 May 2009, asserted that until that moment, 40 countries had given notice of laboratory-confirmed cases of pandemic influenza.<sup>23</sup>

The main source of concern about the decision-making process that led to the 2009 Pandemic Declaration is related to the possibility of conflicts of interest by some of the members of the IHR Emergency Committee that advised the Director-General in favor of doing so. These conflicts of interest were related to the alleged direct and indirect ties of those members with the pharmaceutical industry, which was seen as promoting the issue of a Pandemic Declaration due to the profits it would entail for the production and selling of antivirals and vaccines.<sup>24</sup> Despite the outcry, the Director-General of the WHO decided not to publicly disclose the names of the Committee's members until after the

<sup>21</sup> See *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe (June 2010), available at [http://assembly.coe.int/CommitteeDocs/2010/20100604\\_H1N1pandemic\\_e.pdf](http://assembly.coe.int/CommitteeDocs/2010/20100604_H1N1pandemic_e.pdf) (last visited 14 February 2016); M. R. Evans, 'The swine flu scam?' (Editorial Comment), 32 *Journal of Public Health* (2010) 3, 296, 297.

<sup>22</sup> With some nuances, such is the position taken in the editorial comment, 'H1N1dsight is a wonderful thing', 28 *Nature Biotechnology* (2010) 3, 182. Also, for a brief recount of the technical process undertaken during the discovery phase of the pandemic for identifying the strain of the virus and its epidemiologic characteristics, see A. Schuchat, B. P. Bell & S. C. Redd, 'The Science behind Preparing and Responding to Pandemic Influenza: The Lessons and Limits of Science', 52 *Clinical Infectious Diseases* (2011) Supplement to 1 January, S9–S10.

<sup>23</sup> See *Summary report of a High-Level Consultation: new influenza A (H1N1)*, WHO Information Note 2009/2 (20 May 2009), available at [http://www.who.int/csr/resources/publications/swineflu/High\\_Level\\_Consultation\\_18\\_May\\_2009.pdf](http://www.who.int/csr/resources/publications/swineflu/High_Level_Consultation_18_May_2009.pdf) (last visited 14 February 2016), 3.

<sup>24</sup> The *Framework of engagement with non-State actors*, approved in Resolution WHA 69.10 at the 69th World Health Assembly (May 2016), stipulates in para. 22 that "[a] conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of WHO's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (WHO's work). The existence of conflict of interest in all its forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. [...]". Available at [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R10-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R10-en.pdf) (last visited 21 June 2016)

maximum pandemic phase was declared to be officially over in a statement published on 10 August 2010.<sup>25</sup>

As a result of the suspicions and inquiries that rose during the pandemic period, the WHO summoned a Review Committee composed of external experts<sup>26</sup> in order to start an investigation regarding the functioning of the *IHR* during the pandemic. This Committee was also meant to evaluate how the process of creating and applying the 2009 pandemic guidelines was conducted.<sup>27</sup> The conclusion of the Review Committee Report ‘cleared’<sup>28</sup> the WHO members of any possible malfeasance stemming from conflicts of interest or hidden agendas.<sup>29</sup>

The Review Committee Report’s observations, as well as the criticisms against the Pandemic Declaration and the guidelines that served as its basis, were taken into account when the WHO issued a new document in 2013 entitled “Pandemic Influenza Risk Management: WHO Interim Guidance”. Currently, this new installment constitutes the decision-making basis in the event of a future Pandemic Declaration until it is replaced by a superseding document.

Given the questions of legitimacy and accountability surrounding the 2009 Pandemic Declaration, it is deemed useful to review the legal framework of Pandemic Declarations. This includes the respective guidelines as well as the mechanisms employed by the WHO that marked the beginning and the end of the official 2009–2010 pandemic period.

<sup>25</sup> The statement declaring the ‘end’ of the pandemic is available at [http://www.who.int/mediacentre/news/statements/2010/h1n1\\_vpc\\_20100810/en/](http://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/) (last visited 14 February 2016). The full list of the names of the Emergency Committee members for the 2009–2010 period is available at [http://www.who.int/ihr/emerg\\_comm\\_members\\_2009/en/](http://www.who.int/ihr/emerg_comm_members_2009/en/) (last visited 14 February 2016).

<sup>26</sup> In accordance with Arts 50–53 *IHR*.

<sup>27</sup> See WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 14–18.

<sup>28</sup> The word is placed between single quotation marks, due to the fact that there is no established mechanism for holding WHO officials responsible for their decision-making, although this is a generalized phenomenon within and across international organizations. See e.g., J. Klabbbers, *An Introduction to International Institutional Law* (2002), 3 [Klabbbers, *International Institutional Law*].

<sup>29</sup> WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 111.

### III. The Close Relationship Between PHEICs and Pandemic Declarations

WHO guidelines can be generally seen as legally non-binding documents<sup>30</sup> designed as recommendations for clinical practice and public health, directed at Member States, WHO officials, health practitioners or experts and “other stakeholders”.<sup>31</sup> Legally, they can complement other formal binding instruments, which in the case of pandemic guidelines consist of the *IHR*, that entered into force in 2007.<sup>32</sup> The *IHR* establish the category of a Public Health Emergency of International Concern (PHEIC),<sup>33</sup> considered by some as the Regulations’ “main governance activity”.<sup>34</sup> During the currently ongoing Zika epidemic (2016), it was considered that a PHEIC must: “(1) constitute a health risk to other countries through international spread; (2) potentially require a coordinated response because it is unexpected, serious, or unusual; and (3) have implications

<sup>30</sup> The role of the guidelines can be considered as a more detailed elaboration of the interpretation and/or application of ‘hard law’, as is argued, e.g., by C. Chinkin, ‘Normative Development in the International Legal System’, in D. Shelton (ed.), *Commitment and Compliance. The Role of Non-Binding Norms in the International Legal System* (2000), 27–31.

<sup>31</sup> WHO, *WHO Handbook for Guideline Development*, 2nd ed (2014), 1, available at [http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf) (last visited 14 February 2016).

<sup>32</sup> For discussions about the binding nature of the *IHR*, see J. P. Ruger, ‘Normative Foundations of Global Health Law’, 96 *The Georgetown Law Journal* (2008) 2, 423, 434–435; D. P. Fidler, ‘From International Sanitary Conventions to Global Health Security: The New International Health Regulations’, 4 *Chinese Journal of International Law* (2005) 2, 325, 385; R. Katz & J. Fischer, ‘The Revised International Health Regulations: A Framework for Global Pandemic Response’, 3 *Global Health Governance* (2010) 2, 2; B. Condon & T. Sinha, ‘The effectiveness of pandemic preparations: legal lessons from the 2009 influenza epidemic’, 22 *Florida Journal of International Law* (2010) 1, 1, 4–5; G. L. Burci & R. Koskenmäki, ‘Human Rights Implications of Governance Responses to Public Health Emergencies: The Case of Major Infectious Disease Outbreaks’ in A. Clapham *et al.* (eds), *Realizing the Right to Health* (2009), 350.

<sup>33</sup> Art. 1 *IHR* defines a PHEIC as “an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response”.

<sup>34</sup> L. Gostin, M. C. DeBartolo & E. A. Friedman, ‘The International Health Regulations 10 years on: the governing framework for global health security’, 386 *The Lancet* (2015), 2222.

beyond the affected country that could require immediate action”.<sup>35</sup> However, the elements of what is considered to be a pandemic are not at all addressed in the *IHR*,<sup>36</sup> but are rather the product of multiple guidelines that have existed since 1999.<sup>37</sup>

In order to elucidate some of the differences between a PHEIC and a Pandemic Declaration, a brief glance at the events that took place during the 2009–2010 is useful. The WHO used both legal bases at the operational level during two separate occasions in 2009: On 25 April, the Director General of the WHO issued a statement declaring that the cases of ‘swine influenza’ reported in Mexico and the United States of America justified labeling the situation as a PHEIC,<sup>38</sup> while the pandemic phase remained at level 3. Later, on 11 June of the same year, the WHO’s Director-General issued yet another official statement, this time declaring that the world “[is] now at the start of the 2009 influenza pandemic”, thereby deciding to raise the pandemic alert phase from 5 to 6, i.e. the maximum possible.<sup>39</sup> Each Declaration differed in scope and consequences. A PHEIC can be limited to a regional area, as occurred on 25 April 2009, when it was emitted on the basis of evidence that the virus was present in Mexico and the United States of America, or more recently during the Ebola crisis in West Africa. By contrast, a Pandemic Declaration, according to both the 2009 and the more recent 2013 guidelines, indicates that there is a considerable risk of the spread eventually reaching a multi-regional and perhaps even planetary dimension. At that moment, approximately 142 WHO Member States had already developed national pandemic plans<sup>40</sup> that were meant to be applied as a consequence of the WHO’s Pandemic Declaration.

<sup>35</sup> D. L. Heymann *et al.*, ‘Zika virus and microcephaly: why is this situation a PHEIC?’, 387 *The Lancet* (2016), 719–720.

<sup>36</sup> Katz & Fischer, *supra* note 32, 11.

<sup>37</sup> The WHO has developed several editions of the pandemic guidelines, in 1999 (*Influenza Pandemic Plan. The Role of WHO and Guidelines for National and Regional Planning*), 2005 (*WHO global influenza preparedness plan. The role of WHO and recommendations for national measures before and during pandemics*), 2009 (*Pandemic Influenza Preparedness and Response*) and 2013 (*Pandemic Influenza Risk Management*).

<sup>38</sup> See this statement available at [http://www.who.int/mediacentre/news/statements/2009/h1n1\\_20090425/en/](http://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/) (last visited 14 February 2016).

<sup>39</sup> Available at [http://www.who.int/mediacentre/news/statements/2009/h1n1\\_pandemic\\_phase6\\_20090611/en/](http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/) (last visited 14 February 2016).

<sup>40</sup> See WHO, *Comparative analysis of national pandemic influenza preparedness plans*, January 2011, available at [http://www.who.int/influenza/resources/documents/comparative\\_analysis\\_php\\_2011\\_en.pdf?ua=1](http://www.who.int/influenza/resources/documents/comparative_analysis_php_2011_en.pdf?ua=1) (last visited 14 February 2016), 4.

The relevant 2013 WHO guidance document states that Pandemic Declarations should be distinguished from the distinct Pandemic phases established elsewhere in the guidelines.<sup>41</sup> The specific components that constitute a Pandemic Declaration are themselves a source of much confusion.<sup>42</sup> On one hand, both the WHO in a 11 June 2009 statement<sup>43</sup> and the Review Committee in its 2011 Report held that the maximum level of pandemic alert (phase 6) is what properly constituted a Pandemic Declaration.<sup>44</sup> However, the latest 2013 WHO guidelines on the matter changed the pandemic alert levels by substituting the six different phases of the 2009 document. Instead, a four-phase system was established, according to which the WHO Director-General may make a ‘declaration of a pandemic’, without specifying the formal details of how such a declaration will be effectuated.<sup>45</sup>

The Director-General of the WHO is in charge of emitting both the PHEIC<sup>46</sup> and Pandemic Declarations.<sup>47</sup> In the case of the PHEIC, this may be done only after convening an Emergency Committee composed of medical experts and receiving its recommendations.<sup>48</sup> By contrast, Pandemic Declarations

<sup>41</sup> WHO, *Pandemic Influenza Risk Management: WHO Interim Guidance*, June 2013, available at [http://www.who.int/influenza/preparedness/pandemic/influenza\\_risk\\_management/en/](http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management/en/) (last visited 14 February 2014), 7. This distinction is also found in Katz & Fischer, *supra* note 32, 7-8.

<sup>42</sup> See WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, Global Influenza Programme (2009, reprinted in 2010), available at [http://www.who.int/influenza/resources/documents/pandemic\\_guidance\\_04\\_2009/en/](http://www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/) (last visited 14 February 2016), 14, Section 2.1. It appears that the only clear component of this criterion for officially declaring the presence of a pandemic (identified with phase 6), was its presence in more than one of the WHO’s world regions. These elements were modified in the latest version, *Pandemic Influenza Risk Management*, *supra* note 41, 7.

<sup>43</sup> See *Emergency preparedness, response. What is phase 6?*, available at [http://www.who.int/csr/disease/swineflu/frequently\\_asked\\_questions/levels\\_pandemic\\_alert/en/](http://www.who.int/csr/disease/swineflu/frequently_asked_questions/levels_pandemic_alert/en/) (last visited 14 February 2016).

<sup>44</sup> WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 37. This is also the position presented in *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, para. 7.

<sup>45</sup> *Pandemic Influenza Risk Management: WHO Interim Guidance*, *supra* note 41, 7.

<sup>46</sup> Art. 12 IHR.

<sup>47</sup> See *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, *supra* note 42, 20; *Pandemic Influenza Risk Management: WHO Interim Guidance*, *supra* note 41, 7.

<sup>48</sup> According to Art. 12(4) IHR. The failure to seek the views of the Emergency Committee is considered by some as a legal requirement that, if ignored, could lead to a case of (formal) responsibility for the WHO and enable affected State parties to the IHR to invoke this

are not subject to such a requirement. Nevertheless, during the 2009–2010 event, the Director-General relied on an opinion of the Emergency Committee to raise the alert phase to level 6.<sup>49</sup>

## C. Pandemic Declarations as an Exercise of International Public Authority

### I. The (Not so) Legal Nature of the WHO's Pandemic Guidelines as the Basis for Pandemic Declarations

A considerable amount of the WHO's activities are made through non-binding recommendations and guidelines.<sup>50</sup> In fact, binding acts issued by the WHO seem to be the exception.<sup>51</sup> This can be due to the additional difficulties in convincing governments to constrain themselves through binding international law, which leads to non-binding acts being a useful tool for reaching agreement on a topic.<sup>52</sup>

As mentioned before, WHO guidelines are legally non-binding documents<sup>53</sup> that consist of a series of steps and/or recommendations for decision-

matter in a dispute. See G. L. Burci & C. Feinäugle, 'The ILC's articles seen from a WHO perspective', in M. Ragazzi (ed.), *Responsibility of International Organizations. Essays in memory of Sir Ian Brownlie* (2013), 187.

<sup>49</sup> This decision has been criticized by D. P. Fidler in 'H1N1 after action review: learning from the unexpected, the success and the fear', 4 *Future Microbiology* (2009) 7, 767, 768.

<sup>50</sup> This tendency has been pointed out, e.g., in G. L. Burci & C.-H. Vignes, *World Health Organization* (2004), 141–142 & 146–152; R. G. Feachem & J. D. Sachs (chairs), *Global Public Goods for Health. Report of Working Group 2 of the Commission on Macroeconomics and Health*, World Health Organization (2002), available at <https://extranet.who.int/iris/restricted/bitstream/10665/42518/1/9241590106.pdf> (last visited 14 February 2016), 55; Burci, & Feinäugle, *supra* note 48, 178, footnote 9.

<sup>51</sup> The 2003 *Framework Convention on Tobacco Control* and the 2005 *International Health Regulations* are the two most notorious cases of binding, 'legislative' regulations adopted by the WHO. See A. L. Taylor, 'Governing the Globalization of Public Health', 32 *The Journal of Law, Medicine & Ethics* (2004) 3, 500, 505; L. O. Gostin, 'Foreword: National and Global Health Law: A Scholarly Examination of the Most Pressing Health Hazards', 96 *The Georgetown Law Journal* (2008) 2, 317, 320; T. van der Rijt & T. Pang, 'Resuscitating a comatose WHO: Can WHO reclaim its role in a crowded global health governance landscape?', 6 *Global Health Governance* (2013) 2, 6–7.

<sup>52</sup> See L. Gostin & D. Sridhar, 'Global Health and the Law', 370 *New England Journal of Medicine* (2014) 18, 1732, 1737.

<sup>53</sup> However, there are also views that consider certain guidelines to have an indirect binding effect, constituting 'hard' international law, since they can be used eventually as a valid

making in health policies both at the international and the national level, based on the viewpoint of what has been labeled by some as “methods of professional practice”.<sup>54</sup> The April 2009 pandemic influenza guidelines are the ones that provided the grounds for the 2009 Pandemic Declaration.<sup>55</sup> These guidelines can also address public health emergencies which, due to the pressing nature of their subject matter, justify a shortened time of elaboration in comparison to other documents of a similar nature.

The guidelines’ status as ‘law’ is contested since they were designed *prima facie* as merely recommendations. Although it can be contested that international law in general lacks a definitive criterion for determining what is law from what is not,<sup>56</sup> a violation of the guidelines is not considered as a breach of international law, at least not in the same manner as those acts that do fall under Article 38(1) *Statute of the International Court of Justice*. Nonetheless, they do function as the source of a line of criticisms – a ‘naming and shaming’

interpretation of the main treaties they are based upon. Such might be the case, for instance, of certain guidelines that are linked to the *Framework Convention for Tobacco Control*, see S. F. Halabi, ‘The World Health Organization’s Framework Convention on Tobacco Control: An analysis of Guidelines adopted by the Conference of the Parties’, 39 *Georgia Journal of International and Comparative Law*, (2011) 1, 121, 126–127.

<sup>54</sup> This label is used in Gostin & Sridhar, *supra* note 52, 1732–1733.

<sup>55</sup> Several clarifications about both the pandemic guidelines and Pandemic Declarations are pending to this date, e.g. whether they would be applicable to diseases other than influenza, such as Ebola and Zika. The wording throughout the document *Pandemic Influenza Risk Management. WHO Interim Guidance* of 2013 suggest these types of Pandemic Declarations are limited to the influenza virus.

<sup>56</sup> The category of *soft law* will not be the core term used in this article, since it is not helpful for establishing sound criteria that can distinguish when a document is binding from when it is not, but rather expresses it as a matter of degree, i.e. one is more or less binding than the other. See Klabbers, *International Law*, *supra* note 2, 38. The broad statement about a lack of consensus regarding the categorical distinction between what is considered ‘hard’ and ‘soft’ law is also present in J. M. Serna de la Garza, *Impacto e Implicaciones Constitucionales de la Globalización en el Sistema Jurídico Mexicano* (2012), 84.

scheme<sup>57</sup> – or a reputational cost<sup>58</sup> in the eventual case of non-observance by national authorities.<sup>59</sup>

Hence, although the WHO guidelines do not hold the same binding legal status as the *International Health Regulations* that entered into force in 2007, both of these instruments are intertwined and share authoritative features that need to be acknowledged and developed. A closer look at the guidelines can illustrate why we should consider them as being authoritative despite them being legally non-binding.

## II. The Authoritative Nature of Pandemic Declarations and Pandemic Guidelines

The fact that the *IHR* are legally binding, as opposed to the pandemic guidelines, also entails that the rules of the WHO Constitution regarding entry into force,<sup>60</sup> interpretation in case of disputes,<sup>61</sup> and obligations of surveillance capacity-building<sup>62</sup> are applicable only to the *IHR*.<sup>63</sup> Yet, the guidelines do have a practical effect. They contain indications for States, which might trigger effects at

<sup>57</sup> See S. E. Davies & J. Youde, 'The IHR (2005), Disease Surveillance, and the Individual in Global Health Politics', 17 *The International Journal of Human Rights* (2013) 1, 133, 135–136.

<sup>58</sup> The idea of 'reputational cost' is useful in this context, since it can be argued that States that do not comply with either the *IHR* or the guidelines will be thought of as being unreliable at future occasions. The purpose of these international documents would be to somehow create expectations about the future behavior and attitudes of States. See A. Guzman, *How International Law Works. A Rational Choice Theory* (2008), 73; Chinkin, *supra* note 30, 23–25. In the context of disease reporting, the WHO's recommendations are only one influential factor amongst many others, such as regional peer pressure in light of a commercial alliance or even what is known as the 'enlightened self-interest' of the reporting State. See S. E. Davies, 'The international politics of disease reporting: Towards post-Westphalianism?', 49 *International Politics* (2012) 5, 591, 608–609; O. Aginam, *Global Health Governance. International Law and Public Health in a Divided World* (2005), 130.

<sup>59</sup> There were some national authorities that deviated from recommendations derived from the WHO guidelines. This is technically a result of the PHEIC and not the Pandemic Declaration, because it occurred after the declaration of 25 April of the presence of a PHEIC. There were no public statements by affected States asking for formal sanctions. See J. G. Hodge Jr., 'Global Legal Triage in Response to the 2009 H1N1 Outbreak', 11 *Minnesota Journal of Law, Science & Technology* (2010) 2, 599, 607–608.

<sup>60</sup> Art. 22 *Constitution of the WHO* & Art. 59 *IHR*.

<sup>61</sup> Art. 56 *IHR*.

<sup>62</sup> Examples include Art. 5(1) & Annex 1(2) *IHR*.

<sup>63</sup> Fidler, *supra* note 32, 385; Condon & Sinha, *supra* note 32, 4–5.

the domestic level. The 2009 Pandemic Declaration caused the implementation of national pandemic plans across the globe, as well as the simultaneous activation of ‘dormant’ contracts with pharmaceutical companies when phase 6 was declared.<sup>64</sup> The guidelines also function as internal operational rules that are to be applied by the WHO when the occasion arises, e.g. with respect to the question of who will issue Pandemic Declarations and when.<sup>65</sup>

Further, both the *IHR* and the guidelines can be viewed as supported by a ‘name and shame’ scheme for promoting States’ compliance.<sup>66</sup> That is, if a State decides not to comply with the regulations or the guidelines, it might incur in reputational costs that may affect its relations with other States.<sup>67</sup> National authorities’ measures that fall outside of the guidelines’ recommendations might also be considered as an obstacle for the containment of an outbreak of a contagious disease. In this line of reasoning, there can be other negative non-legal consequences – be they reputational, economic, etc. – for not observing these recommendations, which emanate from non-binding guidelines.<sup>68</sup> This illustrates how Pandemic Declarations constitute an exercise of international public authority, independently of the *IHR*.

<sup>64</sup> See D. Cohen & P. Carter, ‘WHO and the pandemic flu ‘conspiracies’’, 340 *The BMJ* (12 June 2010) 7759, 1274, 1279; WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 101–102 & 116; *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, para. 10.

<sup>65</sup> These two different types of functions are taken directly from what is branded as ‘international standards’ by M. Goldmann, ‘Inside Relative Normativity: From Sources to Standard Instruments for the Exercise of International Public Authority’, in von Bogdandy *et al.* (eds), *supra* note 4, 661, 695–699 [Goldmann, Inside Relative Normativity].

<sup>66</sup> See G. Rodier, ‘New rules on international public health security’, 85 *Bulletin of the World Health Organization* (2007) 6, available at <http://www.who.int/bulletin/volumes/85/6/07-100607/en/> (last visited 14 February 2016), 428–430; further, Davies & Youde, *supra* note 57, 134–138.

<sup>67</sup> Guzman, *supra* note 58, 73. This dynamic is also present in the PISA rankings, see the explanation in A. von Bogdandy & M. Goldmann, ‘The Exercise of International Public Authority through National Policy Assessment. The OECD’s PISA Policy as a Paradigm for a New International Standard Instrument’, 5 *International Organizations Law Review* (2008) 2, 241, 260.

<sup>68</sup> See Davies, *supra* note 58, 593–595 & 607; T. Murphy, *Health and Human Rights* (2013), 61–62; J. G. S. Koppell, ‘Accountable global governance organizations’, in M. Bovens, R. E. Gooden & T. Schillemans (eds), *The Oxford Handbook of Public Accountability* (2014), 375. For instance, although it was not officially labeled as a legal breach of the 1969 *IHR*, the failure of China to adequately report activities during the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak led to a change in the public discourse within the international community about States’ obligation to make timely reports to the WHO.

The authoritative nature of guidelines can be witnessed in a third manner. Generally speaking, it is accepted that instruments that fall outside the scope of the sources doctrine, i.e., those that do not fit within Article 38(1) *Statute of the International Court of Justice*, cannot entail certain legal ramifications by themselves, e.g., asking for damages or claims before international courts.<sup>69</sup> Nevertheless, ignoring or wrongfully applying the contents of the various pandemic guidelines when issuing Pandemic Declarations can give rise to consequences of another kind. The pandemic guidelines were the target of a substantial part of the investigation of the Review Committee in charge of examining the rightful application of the *IHR* during the 2009-2010 pandemic by the WHO's Director-General and the Emergency Committee.

When assessing the authority of the WHO's guidelines, a complication arises: There is often no evidence in order to unequivocally determine whether a State's actions are the result of a direct compliance with the guidelines, or whether they derive from that State's own understanding of how to deal with the problem.<sup>70</sup> On the more general, theoretical level, it can also be argued that States' actions that happen to be in accordance with the Pandemic Declaration and its guidelines are more than a mere coincidence.<sup>71</sup> There is simply no clear-

<sup>69</sup> This appears to be a broadly accepted account, as is mentioned in Goldmann, 'Inside Relative Normativity', *supra* note 65, 676.

<sup>70</sup> At the outset of the 2009 A(H1N1) pandemic, some of the measures adopted by several States 'deviated', with varying degrees, from the WHO's guidelines and recommendations. These consisted mainly of bans on imports, arrival health screenings in airports and restrictions on flights towards the countries initially affected (U.S.A., Canada and Mexico). Only exceptionally were the more aggressive measures implemented, i.e. quarantines. For a more detailed account, see Condon & Sinha, *supra* note 32, 15–17; also see Katz & Fischer, *supra* note 32, 6–7; additionally, P. Acconci, 'The Reaction to the Ebola Epidemic within the United Nations Framework: What Next for the World Health Organization?' in F. Lachenmann, T. Röder & R. Wolfrum, 18 *Max Planck Yearbook of United Nations Law* (2014), 413.

<sup>71</sup> This is a conundrum present in legal theory and particularly in international law. See M. Goldmann, 'We Need to Cut Off the Head of the King: Past, Present and Future Approaches to International Soft Law', 25 *Leiden Journal of International Law* (2012) 2, 353. According to the 2013 WHO pandemic guidelines, the specific effects that are a direct result from Pandemic Declarations are also a matter of choice. States can choose to consider them as a trigger of particular consequences such as decision-making by national regulatory bodies or the activation of contractual agreements. See *Pandemic Influenza Risk Management: WHO Interim Guidance*, *supra* note 41, 7.

cut causal link between a Pandemic Declaration, the contents of the multiple guidelines, and the actual decisions taken by national governments.<sup>72</sup>

Regardless of the absence of an exact verification of the effects of the guidelines, they show several potential constraining effects that can be examined *ex ante*. This leads to considering them as authoritative in general, and more specifically as exercises of international public authority.

## D. (Some) Legitimacy Issues of Pandemic Declarations

### I. A Workable Concept of Legitimacy

One of the main consequences of viewing Pandemic Declarations as exercises of international public authority is that it opens the floor to a discussion about their legitimacy.<sup>73</sup> Naturally, the very concept of legitimacy is the subject of multiple views that are even opposing at times.<sup>74</sup> For the purposes of this article, legitimacy will be understood as the reasons justifying an exercise of authority.<sup>75</sup> As a caveat, a general assessment of the WHO's degree of legitimacy – based on an institutional-level credibility and integrity as a scientifically reliable entity<sup>76</sup> – requires an analysis that outreaches the scope of this article. This is also a result of the idea that there is no developed legal framework capable of providing a general understanding of international organizations.<sup>77</sup>

The authority exercised by international organizations is often criticized for its 'democratic deficit'. When facing this conundrum, international organizations resort to different ways of legitimizing their actions, which can

<sup>72</sup> There are some illustrative indicators, such as the fact that during the 2009 pandemic, 74% of the countries had already designed a pandemic preparedness plan, and also that phase 6 of the pandemic alert structure activated the advanced-purchase agreements with some vaccine manufacturers. See WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, xix & xxi.

<sup>73</sup> Von Bogdandy, Dann & Goldmann, *supra* note 4, 11.

<sup>74</sup> On the political, and even ideological discrepancies that disrupt the whole idea of legitimacy, see G. C. A. Junne, 'International organizations in a period of globalization: New (problems of) legitimacy', in J. M. Coicaud & V. Heiskanen (eds), *The Legitimacy of International Organizations* (2001), 189, 190–193.

<sup>75</sup> See Wolfrum, *supra* note 12, 6; D. Bodansky, 'Legitimacy of International Governance: A Coming Challenge for International Environmental Law?', 93 *American Journal of International Law* (1999) 3, 596–603.

<sup>76</sup> This line of reasoning was also present during the 2003 SARS outbreak. See D. C. Esty, 'Good Governance at the Supranational Scale: Globalizing Administrative Law', 115 *The Yale Law Journal* (2006) 7, 1490, 1551.

<sup>77</sup> Von Bogdandy, Dann & Goldmann, *supra* note 4, 20–21.

be combined between themselves.<sup>78</sup> One of them is the reliance upon ‘expert-based’ or ‘technocratic’ legitimacy.<sup>79</sup> It will be distinguished from another, even broader category of *lato sensu* ‘political’ legitimacy,<sup>80</sup> which in the present case refers to concerns about transparency and accountability. This type of political legitimacy can be visualized at a general level as a mixture between democratic and procedural aspects, linked directly to the manner in which Pandemic Declarations are made. Even though this is far from being a delineated category, it is useful for the purpose of distinguishing it from the strictly ‘technical’ aspects that comprise expertise-based or technocratic legitimacy.

The main argument that highlights the importance of technocratic legitimacy is that decision-makers consider the scientific nature of some problems to be beyond *lato sensu* political discussions. The issues that are labeled as ‘technical’ may enjoy legitimacy if they are decided in accordance with certain scientific standards and expert knowledge, even though they are not always the result of, and at times not even compatible with, democratic consensus, transparency, accountability and other elements that contribute to political legitimacy.<sup>81</sup> Certainly, technocratic strategies are not limited to international institutions, but have rather been a continuous matter of debate concerning national governments and the European institutions as well.<sup>82</sup>

<sup>78</sup> G. De Búrca, ‘Developing Democracy Beyond the State’, 46 *Columbia Journal of Transnational Law* (2008) 2, 221, 240–245.

<sup>79</sup> Although not identical in its contents, this terminology can be considered as similar to the understandings of this type of legitimacy that are employed by others, as an overall ‘Results-based legitimacy’. See Esty, *supra* note 76, 1517. It is also similar to another type of ‘technocratic’ element, labeled as ‘authority based on knowledge and expertise’, in I. Venzke, ‘International Bureaucracies from a Political Science Perspective - Agency, Authority and International Institutional Law’, in von Bogdandy *et al.* (eds), *supra* note 4, 67, 83–85. Within the specific context of European institutions, see C. Landfried, ‘Beyond Technocratic Governance: The Case of Biotechnology’, 3 *European Law Journal* (1997) 3, 255, 255–262.

<sup>80</sup> The way the generic term ‘political’ is used here is mostly related to the types of legitimacy associated with the ‘good governance’ label. The distinction has already been formulated, albeit with different terminologies and more developed components, in Esty, *supra* note 76, 1511–1512. See also the distinction used in D. Kennedy, ‘Challenging Expert Rule: The Politics of Global Governance’, 27 *Sydney Law Review* (2005) 1, 5, 21–28. This approach has also been criticized in Venzke, *supra* note 79, 86.

<sup>81</sup> This does not only happen in the field of medicine. The dangers of resorting to general discourses about the distinction between science/expertise and political issues have been explored elsewhere. See Landfried, *supra* note 79, 258–259; Kennedy, *supra* note 80, 5, 15–20.

<sup>82</sup> Peel, *supra* note 1, 6 & 14.

The expertise-based or technocratic legitimacy developed in this article encompasses two parallel aspects that can be conceptually distinguished from each other:<sup>83</sup>

a) the participation of independent experts, i.e. of persons endowed with special qualifications in a particular field, and the use of state-of-the-art knowledge in the decision-making process;<sup>84</sup> and

b) the generation of certain results that partly or completely fulfill to a certain extent technically established objectives that were formulated when the decision was initially conceived, or prior to it.<sup>85</sup>

Both of these elements can be considered as part of the technocratic legitimacy equation that is present in Pandemic Declarations: the exercise of authority will be considered to be technically justified if it combines these two elements in a more or less satisfactory way. Regarding the first element, authority is legitimized to a certain extent if it reflects the work of medical experts and incorporates 'state-of-the-art' knowledge produced within the epistemic community in question.<sup>86</sup> As for the second element, if the decision is seen as the cause of a certain desired (health-related) effect in the world, it will enjoy a higher degree of acceptance as legitimate. However, during the 2009–2010 event the inclusion of political factors within a *prima facie* technical decision such as a Pandemic Declaration was arguably the driving force of the controversy surrounding it. It later gave way to suspicions of conflicts of interest by those participating in the decision-making process within the WHO.

Even though the present analysis is mostly limited to the 2009–2010 Pandemic Declaration, it is useful to visualize some of the possible legitimacy issues that might arise in future occasions,<sup>87</sup> so as to look beyond the confines of a particular case. Currently, the 2014 Ebola crisis, that originated in 2013 and

<sup>83</sup> This conceptual division is taken loosely from the classic formulation of 'input-oriented' – as in 'procedural' – and 'output-oriented' – as in 'results' – legitimacy, put forward by F. W. Scharpf, *Governing in Europe: Effective and Democratic?* (1999), 5-11. The distinction between the 'inputs' and the 'outputs' is echoed in the case of international organizations, albeit not in an identical sense, by V. Rittberger & B. Zangl, *International Organization. Polity, Politics and Policies* (2006), 60-61 & 78-87.

<sup>84</sup> De Búrca, *supra* note 78, 242-246; Wolfrum, *supra* note 12, 19.

<sup>85</sup> De Búrca, *supra* note 78, 245-246.

<sup>86</sup> Here, the term 'epistemic community' denotes a widespread consensus of experts in a certain field of knowledge on how to solve a problem. This is borrowed from Rittberger & Zangl, *supra* note 83, 85-86 & 115-116.

<sup>87</sup> Some have already noticed improvements in the decision-making process of the WHO in the case of Ebola and the declaration of a PHEIC. See T. Hanrieder & C. Kreuder-Sonnen, 'The WHO's new emergency powers – from SARS to Ebola' (22 August 2014)

was fully unraveled in 2014, highlights some of the recurrent concerns about how the WHO exercises its authority through non-binding means, even though there was no Pandemic Declaration emitted.<sup>88</sup> And currently, there is a Zika virus epidemic that continues to spread throughout multiple regions and has already been declared a PHEIC.<sup>89</sup>

The following sections provide a closer look at the type of technocratic legitimacy discussed herein. Then, its tenuous relationship with what has been labeled as political legitimacy will be shortly addressed.

## II. The Importance of Being Right: The Issue of the Technocratic Legitimacy of Pandemic Declarations

The WHO's guidelines may enjoy technocratic legitimacy insofar as States can assume that the contents of their regulations are more likely to be technically accurate if they follow the guidelines instead of the conclusions that they may reach on their own.<sup>90</sup> When addressing the technocratic legitimacy of the 2009–2010 Pandemic Declaration, it is helpful to distinguish the two elements of technocratic legitimacy elaborated in the previous section. The first element is *ex ante*. It deals with the issue of whether the available scientific information at the moment of the Declaration justified the decisions adopted considering the degree of scientific uncertainty and the pressing nature of the phenomenon at hand.<sup>91</sup> The highly technical and fluctuating traits of an epidemiological

available at <http://voelkerrechtsblog.org/the-whos-new-emergency-powers-from-sars-to-ebola/> (last visited 14 February 2016).

<sup>88</sup> In the statement of 8 August 2014, the WHO declared the presence of a PHEIC and simultaneously issued several (non-binding) recommendations regarding Ebola. Available at <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/> (last visited 14 February 2016).

<sup>89</sup> The declaration of a PHEIC in the case of the Zika epidemic took place in light of the scientific uncertainty behind the possible link between the virus and emerging clusters of microcephaly cases in affected countries. In this regard, it can be distinguished from previous PHEICs in the cases of A(H1N1) Influenza and Ebola, for which more epidemiological information was already available. See Heymann *et al.*, *supra* note 35, 720.

<sup>90</sup> It has been argued elsewhere that it would have been very risky – and even costlier, if the developments had been more catastrophic – for States not to have invested heavily in vaccines and flu medications, as well as the multiple non-pharmaceutical interventions that were employed. See the editorial comment, 'H1N1dsight is a wonderful thing', *supra* note 22, 182.

<sup>91</sup> For a brief summary of the information gathered at the time of the Declaration, see WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra*

description of influenza and its effects do not allow for a precise forecast of the severity of its incidence at the initial moment of a pandemic, since influenza is widely viewed as a virus with a highly unpredictable nature.<sup>92</sup> Consequently, there is an inherent difficulty in producing the desired effects, hence such a decision benefits from the second element of technocratic legitimacy described in the previous section.

The first element appears to be necessary in the case of Pandemic Declarations. Determining whether there is or is not a new subtype of influenza virus cannot be decided by broad democratic consensus, but is rather dependent on an evaluation of this matter by the medical epistemic community.<sup>93</sup> Thus, the first element of technocratic legitimacy is directly enhanced by the participation of the Emergency Committee, composed solely by experts in the medical field,<sup>94</sup> both in the case of 2009 PHEIC<sup>95</sup> and Pandemic<sup>96</sup> Declarations. In the case of the latter, there is no general, explicit procedural requirement to consult the Committee when raising the pandemic alert. Yet the WHO Director-General nonetheless decided to rely upon these experts' advice when issuing the 2009 Pandemic Declaration.<sup>97</sup>

note 13, xxi. Ultimately, this is the immediate consequence of a prevailing uncertainty in scientific knowledge about influenza, see *Science, H1N1 and society: Towards a more pandemic-resilient society*, Final Report from the Expert Group on 'Science, H1N1 and Society' European Commission (15 June 2011), available at [http://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/sis-heg-final-report\\_en.pdf](http://ec.europa.eu/research/science-society/document_library/pdf_06/sis-heg-final-report_en.pdf) (last visited 14 February 2016), 21-22; Peel, *supra* note 1, 101.

<sup>92</sup> Bennett & Carney, *supra* note 13, 306-308; WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, xv; H. Fineberg, 'Pandemic Preparedness and Response. Lessons from the H1N1 Influenza of 2009', 370 *The New England Journal of Medicine* (2014) 14, 1335, 1341.

<sup>93</sup> This is the source of many debates concerning the alleged 'technical' nature of these decision-making processes, and its friction with the constructivist view that scientific knowledge, including the assessment of risks, is socially built. For a glimpse of this debate, see A. Plough & S. Krinsky, 'The Emergence of Risk Communication Studies: Social and Political Context', 12 *Science, Technology & Human Values* (1987) 3/4, 4, 7-9; M. Thompson & S. Rayner, 'Risk and Governance Part I: The Discourses of Climate Change', 33 *Government and Opposition* (1998) 2, 140-142; Y. Yishai, 'Participatory governance in public health: Choice, but no voice', in Levi-Faur (ed.), *supra* note 1, 528.

<sup>94</sup> In accordance with Art. 48(2) *IHR*.

<sup>95</sup> Art. 12(4c) *IHR*.

<sup>96</sup> WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 37.

<sup>97</sup> Fidler, *supra* note 49, 768.

The first criterion of technocratic legitimacy would entail that influenza guidelines developed by the WHO are more or less flexible in order to adapt general rules to scientific and technological developments, thus accommodating a degree of uncertainty.<sup>98</sup> They may be useful as a reasonable explanation of what is more likely to be the case and what is not, without granting a level of discretion that might pave the way for abuses of power.<sup>99</sup>

The second criterion for assessing technocratic legitimacy – the ‘output’ dimension – is far more difficult to ascertain. The actual impact of issuing a Pandemic Declaration needs to be analyzed *ex post* on a country-by-country basis, given that States are in charge of implementing the medical measures directed at slowing the transmission of the disease. States also need to consider country-specific factors, such as the characteristics of a national health system, or even the natural, social and cultural environments.<sup>100</sup> This can fuel many complications when preparing the pandemic response throughout the various levels of government. States are ultimately the ones with the best knowledge of their national health systems and the extent of their capabilities.<sup>101</sup> Any international regulation therefore needs to leave some room for maneuverability at the national level in order for the mechanisms to be effective.<sup>102</sup>

<sup>98</sup> Morens *et. al.*, *supra* note 14, e14–e16; G. M. Algarra Garzón, ‘Definiendo un escenario de toma de decisiones: El caso de la Influenza humana A(H1N1)’, in I. Brena Sesma (coord.), *Emergencias Sanitarias* (2013), 71; Fineberg, *supra* note 92, 1340–1341.

<sup>99</sup> This can also be the case in the context of terrorist attacks and disasters at the national level. See, e.g., W. K. Mariner, G. J. Annas & W. E. Parmet, ‘Pandemic Preparedness: A return to the rule of law’, 1 *Drexel Law Review* (2009) 2, 341, 365.

<sup>100</sup> L. O. Gostin & B. E. Berkman, ‘Pandemic Influenza: Ethics, Law, and the Public’s Health’, 59 *Administrative Law Review* (2007) 1, 121, 153.

<sup>101</sup> For a more detailed picture of the attempted effects of public health interventions in reducing the spread of the disease, see Condon & Sinha, *supra* note 32, 9. This was also an argument put forward by then Special Advisor Keiji Fukuda, during the 14 January 2010 virtual press conference, in the sense that “we don’t know how many infections and deaths have been avoided or prevented by the actions taken by countries and we don’t know how much these efforts have helped mediate the overall effect of the pandemic [...]”, available at [http://www.who.int/mediacentre/vpc/transcript\\_14\\_january\\_10\\_fukuda.pdf?ua=1](http://www.who.int/mediacentre/vpc/transcript_14_january_10_fukuda.pdf?ua=1) (last visited 14 February 2016).

<sup>102</sup> Hodge, *supra* note 59, 606.

### III. The Friction Between Technocratic and Political Legitimacy in the Case of Pandemic Declarations

In the case of Pandemic Declarations, the so-called technocratic legitimacy collides with other types of legitimacy. In some cases, the *lato sensu* political aspects of a decision – including the democratic element – might operate at the expense of the technical justification of certain assessments,<sup>103</sup> and vice versa. There is a seemingly inescapable tradeoff between the two forms of legitimacy, particularly in the case of pandemic preparedness and response mechanisms. The degree to which the pendulum has swung to either side has been, and will continue to be, a source of disagreements.<sup>104</sup>

The case of the 2009–2010 influenza pandemic is an example of how the technical soundness of a certain act is not impervious to, and needs to be weighed against several underlying political factors as far as possible, since all of them contribute simultaneously to the legitimacy of the act at hand.<sup>105</sup> From this premise, one could then address the view according to which an international organization with eminently technical purposes, like the WHO or its bodies, needs to be ‘insulated’ from political influence in order to gain more legitimacy.<sup>106</sup>

Needless to say, a Pandemic Declaration has to be firmly based first and foremost on scientific grounds.<sup>107</sup> Anything else would result in a seriously flawed approach that, in turn, will eventually lead to myopic decision-making. However,

<sup>103</sup> Plough & Krinsky, *supra* note 93, 7; Peel, *supra* note 1, 10. The Ebola crisis caused disagreements between experts and some electorate-friendly measures taken by some authorities in the U.S.A. that are ill-advised from a scientific point of view. See the Editorial Comment by J. M. Drazen *et al.*, ‘Ebola and Quarantine’, 371 *The New England Journal of Medicine* (2014) 21, 2029, 2029–2030.

<sup>104</sup> Finding the proper balance in this duality is considered to be a core challenge of public health law. See L. Gostin, *Public Health Law. Power, Duty, Restraint* (2008), 41.

<sup>105</sup> For a more detailed account of how this mixture of political and scientific aspects was visible during the 2009–2010 A(H1N1) influenza pandemic, see Algarra Garzón, *supra* note 98, 61.

<sup>106</sup> This view is held, e.g., by the Commission on a Global Health Risk Framework for the Future, see P. Sands, C. Mundaca-Shah & V. Dzau, ‘The Neglected Dimension of Global Security – A Framework for Countering Infectious Disease Crises’, Special Report, *The New England Journal of Medicine* (2016), 6, available at <http://www.nejm.org/doi/pdf/10.1056/NEJMSr1600236>.

<sup>107</sup> A recent proposal by an independent panel, instituted in light of the WHO’s handling of the Ebola crisis, stresses this element in the context of declaring a PHEIC. While the proposal is mainly aimed at delegating this authority to a ‘Standing Emergency Committee’, the reasoning is similar. S. Moon *et al.*, ‘Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM

Pandemic Declarations also need to take into account the multiple underlying political factors within the ever-more crowded international community of States, non-state actors, NGOs, etc. In other words, technocratic legitimacy in Pandemic Declarations is deemed a necessary, but not sufficient element for the purpose of legitimizing its exercise of international public authority.<sup>108</sup> The lengthy discussion that followed the declaration of the maximum pandemic alert level is an example of how decision-making based on purely technical grounds is not at all isolated from the political aspects of a particular field, no matter how sound the scientific data may be.

Among the concerns related to the political legitimacy of Pandemic Declarations is the overwhelming presence of the pharmaceutical sector on the international level and the vested economic interests it holds when dealing with public health emergencies. To put it bluntly: There is no denying that pharmaceutical companies made a big profit after the 2009 Pandemic Declaration was issued, due to the activation of several ‘dormant’ contracts that they had signed with national governments.<sup>109</sup>

Additionally, both pharmaceutical (e.g. the purchase of antivirals and vaccines) and non-pharmaceutical interventions (e.g. quarantine measures or the acquisition of sanitizing gel) directly affect the use of vital economic resources that might be urgently needed for other health-related issues.<sup>110</sup> If the scientific community considers the use of these resources as ‘excessive’, this can also undermine the aforementioned technocratic legitimacy.<sup>111</sup>

In sum, both expertise-based assessments and political considerations taken separately, can only account for part of the legitimacy problems of decisions that lead to Pandemic Declarations.<sup>112</sup> The 2009 Pandemic Declaration demonstrated that regardless of how elaborated or sophisticated the technical justification can be, decisions made by expert-bodies cannot always – if ever – be

Independent Panel on the Global Response to Ebola’, 386 *The Lancet* (28 November 2015), 2212.

<sup>108</sup> Peel, *supra* note 1, 56–57, 109; Esty, *supra* note 76, 1550–1554.

<sup>109</sup> *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, paras 30 & 46–48; Cohen & Carter, *supra* note 64, 1279; WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 101–102 & 116; Algarra Garzón, *supra* note 98, 65–68.

<sup>110</sup> Bennett & Carney, *supra* note 13, 310–311.

<sup>111</sup> For a succinct reading of some of the negative visions about the outcome of the 2009–2010 Pandemic Declaration, see Algarra Garzón, *supra* note 98, 69–71.

<sup>112</sup> Bodansky, *supra* note 75, 623.

politically insulated.<sup>113</sup> More is needed in terms of legitimacy, and that is where transparency and accountability can play a fundamental role.<sup>114</sup>

## E. Addressing the Legitimacy Aspects of Pandemic Declarations: Strengthening the Alarm Button

### I. General Background: The Aftermath of the 2009–2010 Pandemic

During and after the Pandemic Declaration, many objections were leveled not only against the underlying decision-making structure, but also against the accuracy of the assessment of the evidence that led the WHO Director-General and the Emergency Committee to consider it as enough for justifying the implementation of the mechanism.

This has been a source of debate, since the WHO is perceived by some to have misled States in the 2009 Influenza Pandemic by exaggerating the magnitude of the pandemic.<sup>115</sup> A closely related point of inquiry is how the effectiveness of the WHO's decisions is based on the trust it inspires in Member States.<sup>116</sup> This would entail assessing how much trust the WHO maintains after a perceived

<sup>113</sup> Some have already convincingly contested the general idea that certain decisions, particularly concerning risk, can be made on purely technical grounds. See Peel, *supra* note 1, 108.

<sup>114</sup> This was already present in another set of WHO guidelines, where both transparency and accountability were considered as quintessential for building, maintaining and restoring the public's trust, i.e. as a way of improving legitimacy. See *WHO Outbreak communication guidelines* (2005), 2, available at [http://www.who.int/csr/resources/publications/WHO\\_CDS\\_2005\\_28en.pdf](http://www.who.int/csr/resources/publications/WHO_CDS_2005_28en.pdf) (last visited 14 February 2016).

<sup>115</sup> See, e.g., J. Grolle & V. Hackenbroch, 'Interview with epidemiologist Tom Jefferson: "A whole industry is waiting for a pandemic"', in *Spiegel Online International* (21 July 2009), available at <http://www.spiegel.de/international/world/interview-with-epidemiologist-tom-jefferson-a-whole-industry-is-waiting-for-a-pandemic-a-637119.html> (last visited 14 February 2016).

<sup>116</sup> L. Gostin, *Global Health Law* (2014), 203; also, see WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 102.

‘cry wolf’<sup>117</sup> situation in which a Pandemic Declaration might be considered to be an overreaction. But that is beyond the limits of this article.<sup>118</sup>

The following sections will deal with some of the issues related to both technocratic and *lato sensu* political legitimacy of Pandemic Declarations. This will not reduce the analysis to an anecdotal recount of a past event, since it might also provide a better understanding of how the legitimacy of these acts could be enhanced in the future (E.II.). But the question of legitimacy also needs to be translated somehow and to the extent possible into legal principles.<sup>119</sup> This is where the broad concepts of transparency and accountability enter the stage.

## II. The Power of Words: The Price of Choosing a ‘Final’ Definition of Pandemics Amidst Uncertainty

The degree of technocratic legitimacy of a Pandemic Declaration also depends on the soundness of the factual basis. This, in turn, depends on whether there is an acceptable definition or shared understanding of what will be considered as a pandemic for the purposes of activating the respective mechanisms. Several of the critiques directed against the WHO’s guidelines are aimed at the definition of a pandemic and its phases.<sup>120</sup> They could have equally been directed at the current state of epidemiology in general: There is no available, unequivocal definition that exhausts all possible instances – past, present and future – of what is to be deemed as a pandemic at a specific moment.<sup>121</sup>

<sup>117</sup> ‘Push needed for pandemic planning’, 90 *Bulletin of the World Health Organization* (November 2012) 11, 800, 801; *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, para. 68.

<sup>118</sup> Institutional-level assessments of WHO are certainly not uncommon in the literature. For thorough contributions, see D. P. Fidler, ‘The Future of the World Health Organization: What Role for International Law?’, 31 *Vanderbilt Journal of Transnational Law* (1998) 5, 1080-1126; M. J. Volansky, ‘Achieving Global Health: A Review of the World Health Organization’s Response’, 10 *Tulsa Journal of Comparative & International Law* (2002) 1, 223, 248-259; van der Rijt & Pang, *supra* note 51.

<sup>119</sup> Von Bogdandy, Dann & Goldmann, *supra* note 4, 10.

<sup>120</sup> None of the previous guidelines for pandemics contained any precise definition of ‘pandemic’. In the 2009 version, it was attempted, rather unsuccessfully, to discern between one pandemic phase and another. This, of course, has been the source of criticisms leveled against the absence of a workable definition. See Doshi, *supra* note 15, 532-534; also, Gostin, *supra* note 116, 202–203; similarly, S. Abeyasinghe, *Pandemics, Science and Policy. H1N1 and the World Health Organization* (2015), 64-101..

<sup>121</sup> Such a shortcoming is evidently not limited to pandemics or even the medical sciences in general, rather it is well known in the field of legal theory. For instance, see H. L. A. Hart,

It should be kept in mind that choosing between one of any of the available definitions comes at a price: If the conceptual components of a definition are too formal and rigid – for instance, by specifying a rate-of-contagion or a minimum degree of severity<sup>122</sup> as requirements for triggering the alert – this could narrow the kind of diseases that will fall under this category and hamper an effective and rapid response. Such rigidity was the very reason why the previous versions of the *IHR* became ineffective for facing the international spread of contagious diseases.<sup>123</sup> On the other hand, as occurred with the 2009 edition of the Pandemic Guidelines, a more vague and flexible definition may contribute to overcoming many of the obstacles that once plagued the former 1969 *IHR* and its subsequent revisions. But it can also entail giving decision-makers – in this case, the WHO Director-General and the Emergency Committee – too much discretion regarding the evaluation of a situation when determining whether there is an ongoing pandemic or not. With the recent Ebola crisis of 2013–2015, the point of who gets to make this decision in the case of a Public Health Emergency of International Concern (PHEIC) has once again come to the fore.<sup>124</sup>

For the time being, it may be acceptable to have a more or less ‘incomplete’ definition that is vague enough to provide for enough leeway to the WHO for determining whether the international community is facing a pandemic or not.<sup>125</sup> Otherwise, we might as well be demanding of the WHO to correct this

*The Concept of Law*, 2nd ed (1994), 6, 15–17; Klabbbers, *International Institutional Law*, *supra* note 28, 7–8; T. Endicott, *Vagueness in Law* (2000), 48–49 & 181–183; E. Cáceres, ‘The Golden Standard of Concepts with necessary conditions and the Concept of Law’, 6 *Problema. Anuario de Filosofía y Teoría del Derecho* (2012), 39, 41–42.

<sup>122</sup> It is worth noting that the more recent 2013 guidelines do establish severity indicators not as an element of the concept of pandemic itself, but rather as a way to calibrate national responses accordingly. See *Pandemic Influenza Risk Management: WHO Interim Guidance*, *supra* note 41, 22–24.

<sup>123</sup> The explanation of why the former *IHR* were ineffective is relatively widespread, see e.g. Fidler, *supra* note 32, 327–329; Aginam, *supra* note 58, 77; Feachem & Sachs (chairs), *supra* note 50, 56.

<sup>124</sup> In a proposal of July 2015, the Ebola Interim Assessment Panel recommended creating a Centre for Health Emergency Preparedness and Response within the WHO, having ‘full operational authority’. Available at <http://www.who.int/csr/resources/publications/ebola/ebola-panel-report/en/> (last visited 14 February 2016). Other expert groups have agreed with this. See Sands, Mundaca-Shah & Dzau, *supra* note 106, 5; S. Moon *et al.*, *supra* note 107, 2211–2212.

<sup>125</sup> Concerning the necessary balance between the formalization of international public authority and the leeway granted in the case of different modes of decision-making at the international level, see Goldmann, ‘Inside Relative Normativity’, *supra* note 65, 692.

as well as many other medical definitions and their related conceptual problems. This epistemological endeavor might be unsuitable for this organization in light of its goals and institutional features.<sup>126</sup> But a minimum standard of what is to be considered a ‘reasonable’ interpretation of the existence of a pandemic is certainly necessary.<sup>127</sup> The problem in 2009 was the lack of clarity when the pandemic response structures were first formulated by the experts summoned by the WHO. A solution to this was attempted in the 2013 guidelines on pandemic influenza.<sup>128</sup> Nevertheless, the definition to date is still not clear enough, since the analytical distinction between the Pandemic Declaration and the announcement of what is now called the ‘pandemic phase’<sup>129</sup> has not been fully clarified.

In sum, conceptual challenges like those related to the definition of a pandemic imply that decisions have to be made with a varying degree of uncertainty.<sup>130</sup> This epistemological problem also unveils the underlying frictions inherent in technocratic legitimacy and demonstrates the need to resort to political modes of legitimacy in the case of pandemic preparations, such as the principles of transparency and accountability.<sup>131</sup> This might legitimize the discretion granted to the Director-General of the WHO with respect to the application of the pandemic definition.

<sup>126</sup> This stands in opposition to the straightforward recommendation in *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, para. 27.

<sup>127</sup> After all, even though it can be posited that the discretion that comes with vagueness is not in itself synonymous with arbitrariness and cannot by itself be considered to be a deficit in the rule of law, too much discretion could very well entail such a deficit. On the other hand, the determination of what is ‘too much’ can also be the source of major disagreements. Endicott, *supra* note 121, 202–203.

<sup>128</sup> The 2013 pandemic guidelines provide the following definition of ‘influenza pandemics’: “An influenza pandemic occurs when an influenza A virus to which most humans have little or no existing immunity acquires the ability to cause sustained human-to-human transmission leading to community-wide outbreaks. Such a virus has the potential to spread rapidly worldwide, causing a pandemic”, *Pandemic Influenza Risk Management: WHO Interim Guidance*, *supra* note 41, 19. The question of whether a formal Pandemic Declaration can be used in the case of a virus other than influenza is still open.

<sup>129</sup> *Ibid.*, 7.

<sup>130</sup> Another clear example of this particular problem within decision-making is the environmental field, where the indeterminate features of scientific debates are displayed. This is reflected in the ‘precautionary principle’, consecrated throughout several international environmental instruments. See, e.g., Bodansky, *supra* note 75, 622.

<sup>131</sup> Peel, *supra* note 1, 47.

### III. (More) Transparency in the Context of Pandemic Decision-Making

Despite the presence of sound technical expertise within the decision-making process of a Pandemic Declaration, a core question remains: How should decisions be made in the absence of an international democratic consensus?<sup>132</sup>

Indeed, one of the core topics in the Review Committee Report was the fact that there was a high degree of opacity within the process leading to the Pandemic Declaration. This opacity led to inquiries by the Council of Europe regarding the acts of the WHO and the suspicions about conflicts of interest of said Committee's members, as well as health authorities at the European and national levels.<sup>133</sup> At best, this could simply be the result of mishandling the relationship with the media, the main source of access to information regarding the WHO's activities.<sup>134</sup> This is a factor that also needs to be addressed when dealing with general issues of transparency.

Shortcomings in decision-making like the one just mentioned can be identified by focusing on two aspects. On the one hand, it involves scrutinizing the legal basis (in this case: the drafting of the guidelines), and on the other hand, the implementation in each particular case. Such a debate might lean at times more towards *stricto sensu* medical arguments than questions of international law. Yet the problem of pandemics does not always allow for an absolute analytical separation of science and politics, since many of the legal problems can only be properly understood with at least a minimum knowledge of the medical implications. Likewise, labeling political issues as technical questions in order to shut down the debate might further reduce the transparency of decision making.<sup>135</sup>

The fact that the full disclosure of the Emergency Committee's members happened only one year after the initial PHEIC Declaration sheds light on an important dilemma. The publication of the names and backgrounds of the members of the Emergency Committee helped clear the doubts about possible conflicts of interest in the decision that led to the 2009 Pandemic Declaration. The lack of information in this respect greatly contributed to undermining

<sup>132</sup> Bodansky, *supra* note 75, 623.

<sup>133</sup> *The Handling of the H1N1 pandemic: more transparency needed*, Resolution 1749 of the Parliamentary Assembly of the Council of Europe, *supra* note 21, 1.

<sup>134</sup> P. Das & G. Sotomayor, 'WHO and the media: a major impediment for global health?', 383 *The Lancet* (2014) 9935, 2102–2103; also on WHO's communication issues, P. Acconci, *supra* note 70.

<sup>135</sup> The argument has also been held in Landfried, *supra* note 79, 271–272.

its legitimacy to be seen as the result of a trustworthy, scientifically rigorous process, as demonstrated by much-publicized inquiries and complaints.<sup>136</sup> But at the same time, the initial reasons not to disclose the names of members of the Emergency Committee – save for its chair<sup>137</sup> – may have had some grounds to warrant the delay. Beyond any actual ties that have existed between some of its members and the pharmaceutical industry, the delicate nature of the decision could have enabled the exercise of external pressure against the Committee members.

The 2011 Review Committee Report had already argued for a more transparent process for selecting members of an Emergency Committee.<sup>138</sup> More recently, disclosing all of the members of the Emergency Committee in the case of PHEIC statements regarding poliovirus, Ebola and Zika is a sign of a lesson learned for decision-making procedures within the WHO. It is noteworthy that the disclosure was not preceded by a reform of the International Health Regulations. Instead, it resulted from internal discretion. It can be questioned whether decisions related to transparency should be discretionary, and there are already calls for “updating” the IHR on these topics.<sup>139</sup> Yet in the realm of guideline-related decision-making, given their non-binding nature, this discretion could linger.

<sup>136</sup> As a testament of the flexibility and discretion with which the WHO Director-General performs some of the functions, the Declaration of a PHEIC in the case of the spread of wild poliovirus, Ebola and Zika were accompanied by the full disclosure of the members of the Emergency Committee. However, no legal reforms to the *IHR* were needed in order to modify this criterion. For members of the wild poliovirus Emergency Committee, see [http://www.who.int/ihr/procedures/emerg\\_comm\\_members\\_2014/en/](http://www.who.int/ihr/procedures/emerg_comm_members_2014/en/) (last visited 26 April 2016). For the Committee in the case of Ebola, see [http://www.who.int/ihr/procedures/emerg\\_comm\\_members\\_2014/en/](http://www.who.int/ihr/procedures/emerg_comm_members_2014/en/) (last visited 26 April 2016). And for members of the Emergency Committee related to the latest Zika PHEIC declaration, see <http://www.who.int/ihr/procedures/zika-ec-members/en/> (last visited 26 April 2016).

<sup>137</sup> Cohen & Carter, *supra* note 64, 1278.

<sup>138</sup> WHO, *Strengthening Response to Pandemics and other Public Health Emergencies*, *supra* note 13, 117.

<sup>139</sup> L. Gostin & E. A. Friedman, ‘A retrospective and prospective analysis of the west African Ebola virus disease epidemic: robust national health systems at the foundation and an empowered WHO at the apex’, 385 *The Lancet* (2015), 1906.

#### IV. Political and Legal Accountability in WHO Pandemic Decision-Making

For the purposes of the present contribution, the notion of accountability in the context of international or supranational organizations refers broadly to the obligation of these institutions to justify and explain their exercise of international authority.<sup>140</sup> Accountability<sup>141</sup> is to be considered as a key factor for the political legitimacy<sup>142</sup> of Pandemic Declarations.

Since the WHO Director-General is the only person with the power to issue both PHEIC and Pandemic Declarations, there is certainly a need for some sort of accountability with respect to this power. This concentration of authority could constitute an excess of discretionary power in a single official, but it might also be justified in light of concerns about a coherent institutional stance as well as a sufficiently rapid reaction to pandemics. The latter argument does not alleviate the need for the Director-General to justify and explain his or her acts with arguments.

Given that none of the binding legal documents that regulate the WHO's activities explicitly establish what kind of consequences there will be for a possible abuse of authority in case of Pandemic Declarations,<sup>143</sup> one can assume

<sup>140</sup> For discussions about this point, see E. De Wet, 'Holding International Institutions Accountable: The Complementary Role of Non-Judicial Oversight Mechanisms and Judicial Review', in von Bogdandy *et al.* (eds), *supra* note 4, 855, 856; Esty, *supra* note 76, 1507–1508. A more overarching concept of accountability includes the separate concern of transparency in M. N. Shaw, *International Law*, 6th ed (2008), 1317–1318. By contrast, others view accountability as one of the multiple components of the more general principle of transparency, see Gostin, *supra* note 104, 71–72.

<sup>141</sup> The type of accountability discussed within this section should be distinguished from the legal category of responsibility of international organizations, an issue that deals with the breach of (formal) international obligations that would enable a State to invoke the responsibility of the international organization, such as the WHO. See Burci & Feinäugle, *supra* note 48, 186.

<sup>142</sup> Some view the accountability of international organizations, like the WHO, essentially as a problem of legitimacy. See R. O. Keohane & R. W. Grant, 'Accountability and Abuses of Power in World Politics' 99 *American Political Science Review* (2005) 1, 29; Koppell, *supra* note 68, 370–371.

<sup>143</sup> The closest thing is the attribute given to the World Health Assembly in Art. 18(d) of the Constitution of the World Health Organization to "[...] review and approve reports and activities of the Board and of the Director-General [...]". Then again, the World Health Organization's Staff Regulations and Staff Rules establish in Section 10 the figures of "unsatisfactory performance or unsuitability for international service", as well as 'misconduct' that occur, *grosso modo*, when a WHO staff member does not fulfill the respective functions or commits inappropriate acts related to them. This could be

that the response to wrongful acts will have a more informal nature. Internal disciplinary measures seem to be unavailable in this case.<sup>144</sup> This response might therefore consist of, for example, a public request by the World Health Assembly for resignation, an eventual withdrawal of the WHO's main funding by Member States, or other forms of public criticism.<sup>145</sup>

Additionally, there is always the risk of having stringent accountability measures which prove to be too restrictive and untenable. WHO officials often need to act in situations of scientific knowledge gaps. Accusing the WHO's authorities of not being able to accurately predict the development of an influenza pandemic at its initial stage might as well be the equivalent, to some extent, of punishing its personnel for not having clairvoyance abilities.<sup>146</sup>

The publication of the 2011 Review Committee Report, and the recently published assessment by the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response<sup>147</sup> might not be sufficient as stand-alone mechanisms in order to provide accountability for the decisions taken by the WHO during the pandemic. Proposals for additional review mechanisms in order to evaluate not just the governing boards of the Organization, but also its relationship with non-state actors when dealing with potential conflicts of interest, are already under discussion.<sup>148</sup>

## F. Conclusion: The Need for Enhancing the Legitimacy of Pandemic Declarations

The research on global governance has highlighted how the conceptual border between the constraining effects of binding and non-binding acts of international organizations is sometimes blurry. Such is the case in Pandemic Declarations by the WHO, which are legally non-binding but can have a constraining effect on decision-making by States.

applicable to the Director-General as well, although the phrasing of the rules can be considered quite vague.

<sup>144</sup> According to Art. X of the World Health Organization's Staff Regulations and Staff Rules, disciplinary measures are meant to be imposed by the Director-General.

<sup>145</sup> De Wet, *supra* note 140, 863.

<sup>146</sup> See *supra* note 19.

<sup>147</sup> For more information on this Committee, see <http://www.who.int/ihr/review-committee-2016/en/> (last visited 21 June 2016).

<sup>148</sup> It is also useful in this regard to take into account the draft of the *Framework of engagement with non-State actors* presented at the 138th session of the Executive Board, *supra* note 24.

In line with the discussion undertaken in this paper, the international public authority approach is a framework well suited to explain the authority of the WHO guidelines and Pandemic Declarations. It also opens a perspective for exploring the legitimacy gaps of the WHO's Pandemic Declarations. This contribution also sought to illustrate how this endeavor can only be made on a case-by-case basis, since the instances of acts by international organizations that fall under this category help us understand the different legitimacy issues related to the exercise of international public authority.

In the end, a more detailed account of Pandemic Declarations can contribute to a better understanding of the consequences that the 2009–2010 influenza A(H1N1) pandemic will have for future iterations of this WHO mechanism. Additionally, while this article focuses on the case of influenza pandemics, some broader lessons can be shared with the recent Ebola crisis in West Africa initiated in 2013 and the ongoing Zika epidemic in 2016. However, other arguments have to be more case-specific. A comparison between all three of these international epidemiological events could shed light upon how the shortcomings in public health emergency decision-making manifest in every case, which will prove useful for upcoming discussions on how to reform these mechanisms.

By using a very broad and basic distinction between expertise-based or technocratic and political legitimacy, it is possible to formulate an explanation of how international organizations with an aspiration to be viewed as technical institutions have to pay heed to several 'non-technical' aspects like transparency and accountability. Ultimately, the tale of the 2009–2010 influenza pandemic shows that it is better to tackle the political issues before they tackle you.

