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Health Reform Monitor

Pandemic legislation in the European Union: Fit for purpose? The need for a systematic comparison of national laws ^{☆,☆☆}



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ABSTRACT

Sound governance is central to effective pandemic management. Key international legal instruments governing pandemic management in the European Union (EU): the International Health Regulations (2005) and Decision 1082/13 require EU Member States to develop national plans and invite them to establish national legal frameworks to support compliance with this international legislation. Although Member States may design the legal framework as they choose, the strongest instrument of pandemic governance is national legislation.

It is currently unclear what national pandemic governance exists in Member States as it has not been mapped, i.e. identified and collated. Legal analysis and empirical evaluation of implementation and impact have therefore not been possible. We propose comprehensive mapping to create the necessary comparative data for legal analysis assessing national legislation's compliance with international obligations and ethical principles. Empirical research could evaluate its effectiveness in promoting cross-border coherence and robust emergency response. We draw on the U.S. experience with "policy surveillance", the systematic scientific mapping of laws of public health importance. Until national pandemic governance is mapped and evaluated, we cannot know if it is lawful, ethical or effective.

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1. Introduction

A pandemic due to a rapidly transmissible infectious agent has always been a major threat to humanity, and recent outbreaks of Ebola and Zika have heightened interest in ensuring that governments are prepared to respond to this threat. Governance – the assignment of authority and the specification of procedures – is a central pillar of effective pandemic management. Without sound rules in place, ad hoc measures risk being ineffective or unjust, failing to respect human rights and worsening the impact of an outbreak. What is the status of pandemic governance in the EU, a highly developed, densely populated region with largely open bor-

ders, but a variety of languages, legal systems and socio-economic contexts?

At the heart of global pandemic governance is the WHO's International Health Regulations (2005) (IHR), with 194 national signatories, which sets out key principles to guide national preparedness and response. At European regional level, EU Decision 1082/13 is the key legal instrument for cross border threats to health. This explicitly recognises and endorses compliance with the IHR at Articles (6), (12) and (26).

Both the IHR and Decision 1082/13 require signatory states to develop national plans for pandemic preparedness and response [1,2]. Many countries do now have plans in place, which can include controversial, but sometimes necessary, measures such as rationing of resources, enforced isolation or quarantine, or seizure of goods and property. However, given the magnitude of a pandemic threat, both the WHO [3] and the EU (through the ECDC) [4] also encourage the use of legal frameworks to support those plans. "Legal frameworks" may be "legislation, laws, regulation, administrative requirements, policies or other government instruments" [5]. National legislation is "hard law", the strongest and most formal mode of governance.

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Table 1
Number of states not having laws to underpin measures recommended by ECDC [4].

| Measures | Number of EU Member States which reported not having any legal underpinning |
|---|---|
| Quarantine | 6 out of 23 states |
| Requisition of premises | 4 out of 20 states |
| Use of unlicensed antiviral prophylaxis | 7 out of 20 states |
| Use of unlicensed vaccines | 5 out of 19 states |
| School closures | 3 out of 23 states |
| Emergency shifts in essential services | No data collected |

Adapted from: Ref. [8].

2. Knowledge of existing pandemic governance

Given its importance, it is remarkable that laws that support national pandemic governance have yet to be comprehensively mapped, let alone evaluated. “Mapping” in this context means the identification, collation and coding of national laws, for the purpose of individual and comparative analysis and to create data for evaluation. The systematic practice of tracking law over time is called “policy surveillance” [6].

Although law is a matter of public record, information characterising the law across multiple jurisdictions is often unavailable. Katz and Kornblat [7] estimated in 2010 that approximately half of the signatory states to the IHR had put its terms into national legislation. At the same time in Europe, an EU funded research project, PHLawFlu, found that there was “a fragmented legal landscape to support pandemic policy measures” with many Member States not having enacted domestic laws to underpin key measures such as quarantine or requisition of premises [8]. National planning was often outdated, inconsistent with scientific knowledge, and contrary to the ECHR. In some cases measures were underpinned by legislation, in others they were only incorporated in policy or guidance documents. Moreover, national representatives were often unclear of their own relevant national governance, let alone that in neighbouring countries [9] Table 1.

Since the PHLawFlu report in 2010, the EU has grown to 28 Member States, yet there has still been no complete, accessible inventory of national plans or legislation for all Member States. This situation threatens to undermine a coherent and coordinated response.

EU Member States are “strongly encouraged” [10] to publish their national pandemic plans on websites managed by WHO Regional Office for Europe [10] and the ECDC [11] but a simple search shows that many are not accessible due to invalid links or publication only in the national language. Translation into a major language is not a requirement and may be onerous for small states, but it will impact on transparency – a matter of concern when the subject is major cross-border threats to health. There is no equivalent repository for national pandemic legislation and although in a few cases it is referenced in national plans, there are similar problems of accessibility and it is unclear if the legislation is still current. As important, law in the form of text is not easily compared, and not readily usable for evaluation.

3. Importance of a national legal framework for pandemic management

Why is national legislation so important as a mechanism to support effective pandemic preparedness? Legislation is transparent (in the public domain), binding and enforceable. Less formal instruments of policy, such as ministerial decrees or guidelines, tend by contrast to be less accessible and more opaque. The enactment of legislation does not in itself create or demonstrate actual response capacity, but it is the first and necessary step towards compliance: it sets out in the strongest possible form a national commitment

to action, defines clearly the actions to be implemented, and, in so doing, defines tangible measures for evaluation. Legislation is a key tool in the armoury for better compliance, transparency and accountability.

National legislation has another valuable purpose. As legal scholars have noted [12], although described as legally binding, the IHR has no enforcement mechanism. There is no international judiciary that can force a signatory country to carry out its terms, or apply penalties if they do not. Indeed, such enforcement would be politically unacceptable [13]. Peer pressure and even shame, however, are common means to encourage lawmakers to act, but these mechanisms require transparency and ready public access to the compliance “scorecard.”

While EU Member States are encouraged to plan for pandemics within a legal framework, the principle of sovereignty means that each state has the discretion to devise its own unique legal approach within the broad parameters of WHO and EU guidance [14]. While this allows for flexibility in governance, which is culturally and politically sensible, it risks a loss of coherence with neighbouring states and the international response system. National laws that encompass the terms of the IHR and Decision 1082/13 should enable better compliance and enforcement at local level.

4. Measuring and evaluating national pandemic legislation

National legislation can and should be subject to critical legal and scientific scrutiny. From a legal and ethical point of view, we can assess whether the law’s terms comply with international treaty obligations, including both health-related obligations in the IHR and civil and human rights protections in instruments such as the Universal Declaration of Human Rights and the European Convention on Human Rights (ECHR). Since pandemic governance by definition is concerned with the management of cross-border threats, it is also important that laws underpinning governance arrangements are coherent across Member States in order to ensure an effective response.

From the public health perspective, we can examine whether the laws reflect the best scientific evidence and appear to be consistent with, and supportive of, national and international planning standards. Does their implementation depend upon national capacity (infrastructure, resources) which is actually in place, or only aspirational? Legal infrastructure is vital to the effective functioning of health systems, but, as with other elements of the health system, its effectiveness cannot be assumed: evaluation of governance is essential to support strong performance over time [15]. Once new laws come into effect, evaluation of their implementation and actual impact on preparedness and response performance can guide further practice and suggest needed reforms in the law [16]. All these functions require valid data capturing the key attributes of national legislation in a form that can be used by researchers, lawyers, health practitioners, policymakers and the public.

5. Mapping European national laws that support pandemic governance

Considerable time and expenditure has already been incurred in developing measures for pandemic management. It would be absurd if these efforts were to be undermined by a simple failure to record and communicate what is in place, and if planning was unsupported by legislation. An essential first step should be to map the strongest form of governance: national legislation. Not until this has been done will it be possible to make informed recommendations for more effective pandemic governance in Europe.

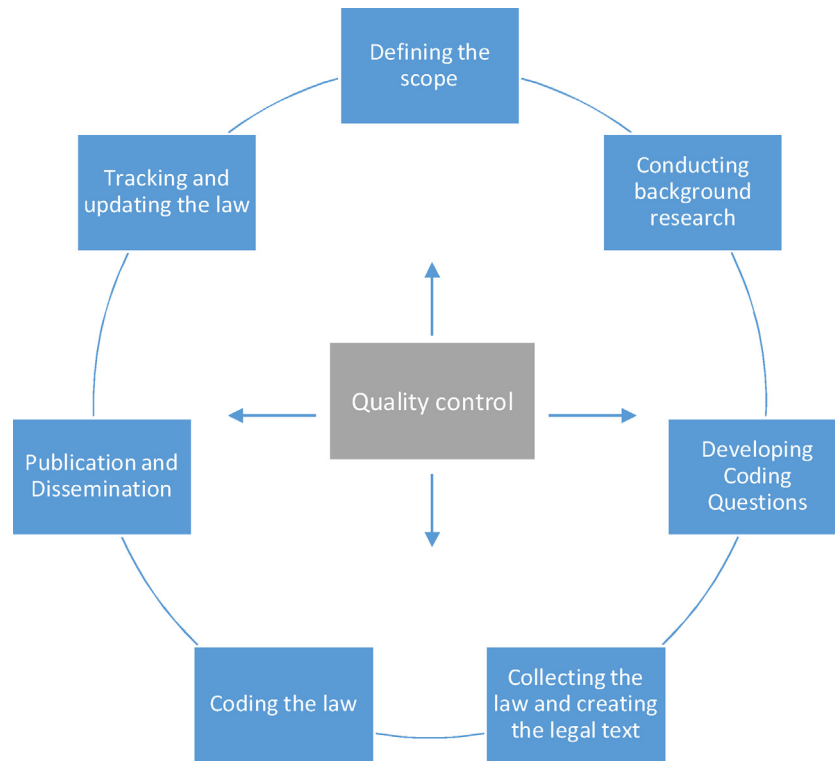


Fig. 1. Overview of the Policy Surveillance Process.

Table 2
Illustrative European Mandates, National Laws, Coding Constructs and Questions.

| European Mandate | Relevant National Legal Texts | Exemplary Construct | Question Examples |
|--|--|--|--|
| Comply with Articles 5 and 13 of the International Health Regulations on Surveillance Capacity | Public health laws and regulations | Authority for surveillance | Does the Member State have a law establishing a surveillance system? |
| | | Obligation to report | Who has a duty to report cases? |
| | | List of reportable conditions | What conditions are deemed reportable? |
| Protect data confidentiality and privacy | Constitution, privacy and public health laws and regulations | Type of health records protected | Does the Member State have a privacy law protecting surveillance data? Under what circumstances may protected data be shared? |
| Participate in European Early Warning System on “serious cross-border” threats | Public health laws and regulations | Definition of “serious cross-border threat” | What are the necessary conditions to declare a “serious cross-sectional border threat”? |
| | | Designation of officer responsible to report | What agency or officials is designated to report a serious cross-border threat to the European Early Warning System? |
| Consult with EU countries prior to initiating emergency response, if possible | Public health laws and regulations | Procedure for declaration of public health emergency | Does the Member State have a process for declaring public health emergencies? Does the procedure include a requirement to consult with the EU? |

6. How to map national legislation

Mapping of EU Member State legislation would be challenging, given the different languages and legal systems, but not impossible. In the US, where many key areas of health and health preparedness are governed by state or even local law, a new practice of “policy surveillance” has emerged in the past decade [6]. Defined as the ongoing systematic, scientific collection and analysis of laws of public health significance, policy surveillance uses rigorous scientific methods to transform the text of law into quantitative data

capturing the content and variation of law over space and time [17]. Policy surveillance resources, like the Alcohol Policy Information System funded by the National Institutes of Health, have been used in dozens of major evaluation studies and have helped shape and improve state alcohol policies [18]. LawAtlas (<http://lawatlas.org>) is a policy surveillance portal funded by the US Robert Wood Johnson Foundation to demonstrate the uses of the practice, and train new practitioners (Fig. 1).

In brief, the procedure entails careful definition of scope and question development before collecting and coding laws for each

jurisdiction. Quality control is important throughout the process, and can be conducted in collaboration with national lawyers and ministries to ensure accuracy in research and coding. Through the use of these methods, documented in transparent protocols, policy surveillance techniques produce data that is highly reliable but also readily usable in evaluation [17]. The process of deciding what to code, and how to code it, is relatively complex, but Table 2 provides an illustration of how laws can be mapped by creating coding constructs and appropriate questions.

Translating legal text into data also facilitates publication of legal information to the internet for use by other stakeholders. Once Member State legislation has been mapped, it can be stored on a publicly accessible and regularly monitored and updated repository. The data can also be downloaded by researchers to begin the task of evaluation to ensure that the legislation does indeed support an effective, ethical pandemic response.

Who should fund or otherwise support the task of collecting, storing and evaluating national legislation? Marks-Sultan et al. make a valid argument for the WHO to take a leadership role in coordinating and overseeing the surveillance of national public health law [19]. As the subject here is national pandemic legislation in EU Member States, the EU could take the lead at regional level.

7. Conclusion

The ultimate aim of pandemic governance is to protect the public. To be effective, and to maintain the support and trust of the public it is imperative that such governance arrangements are lawful, ethical and effective. Without mapping – and subsequent evaluation – of national laws and policy, that cannot be known.

Disclosure statement

EMS and RC have no interests to disclose. SB is a founder of Legal Science, a private company that provides MonQcle software and research services for policy surveillance. There are no competing interests.

Authors' contributions

EMS drafted the manuscript with SB. RC contributed and provided critical review. All authors approved the version for submission.

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