

The Multilevel Dimension of Rules-Based Disease Surveillance beyond the State

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Abstract

The timely availability of accurate information on disease outbreaks with a potential for cross-border spread is a global public good, allowing for a more effective preparedness and response. An ensuing question for national public health authorities is how such information is attained when it is gathered in territories beyond their jurisdiction. International and regional law norms emerge as an option for providing such a global public good. Therefore, the current article examines existing legal frameworks for *ad hoc* disease surveillance beyond the state at the international and regional levels, namely: the World Health Organization's International Health Regulations of 2005; Regulation (EC) No. 851/2004 and Decision No. 1082/2013/EU in the European Union; the Statute of the Africa Centres for Disease Control and Prevention within the African Union; and the Protocol from the Economic Community of West African States, which created the West African Health Organisation. The comparison offers broader insights on the role of rules as a vehicle for securing prompt and reliable information of new and re-emerging communicable diseases, such as Covid-19.

Keywords

international health regulations – European CDC – African CDC – West African Health Organisation – law and ad hoc disease surveillance – Covid-19 pandemic

1 Introduction: Rules for Effective Disease Surveillance beyond States

The timely availability of accurate information on disease outbreaks is a global public good¹ and so systems for disease surveillance created for procuring such information have been considered to be an essential function of public health systems. Like no health crisis before, the Covid-19 pandemic has exposed the need for an awareness of events occurring elsewhere in the world. This raises the question of how public health authorities can conduct disease surveillance and have access to information on events occurring in other territories. That is where the role of disease surveillance beyond the state comes to the fore.

The question for national authorities is how to ensure prompt and accurate disease reporting by authorities from other countries. This is a matter of interest not only for the international community, but also for regional spaces of governance where health security is a component of integration. Here, rules of international and regional-supranational law become entangled. Such rules are meant to foster an exchange of information on disease-related events occurring in multiple territories. The underlying tenets for having rules in place can shed light on the legal goals sought by specific obligations for states for sharing information.

This article focuses on the role of legal rules in addressing ‘passive’ disease surveillance,² namely on mandatory notification by national health authorities to international and regional entities collecting such data. Moreover, ‘passive’ disease surveillance is divided into ‘routine’, on the one hand, and ‘*ad hoc*’ or ‘event-based’, on the other hand.³ This paper focuses on the second category, as it is the one linked to emergency responses such as those for Covid-19. The analysis centres on the rules of four institutions, namely the World Health Organization (WHO) and its International Health Regulations of 2005; the European Centre for Disease Prevention and Control (European CDC) on the basis of both Regulation (EC) No. 851/2004 and Decision No. 1082/2013/EU, as well as the proposed amendments to the former and repealing of the

1 M. Zacher, ‘Global Epidemiological Surveillance: International Cooperation to Monitor Infectious Diseases’, in: I. Kaul, I. Grunberg and M. Stern (eds.), *Global Public Goods. International Cooperation in the 21st Century* (Oxford: Oxford University Press, 1999).

2 For the definition of “passive” disease surveillance, see S. Declich and A.O. Carter, ‘Public health surveillance: historical origins, methods and evaluation’, *Bulletin of the World Health Organization* 72(2) (1994) 285–304, p. 294.

3 World Health Organization (WHO), *Early detection, assessment and response to acute public health events: Implementation of Early Warning and Response with a focus on Event-Based Surveillance, Interim Version* (Geneva: WHO, 2014) pp. 7–8.

latter as part of an ongoing strategy labelled “European Health Union”;⁴ and, in Africa, the continent-wide Africa Centres for Disease Control and Prevention (ACDC) and its Statute; and the subregional West African Health Organisation (WAHO), created through Protocols from the Economic Community of West African States (ECOWAS). Other regional frameworks and institutions where disease surveillance activities are conducted are also mentioned. Nevertheless, in so far as their activities are not conducted on the basis of binding legal rules, they are not at the core of the current analysis.

2 The Normative Foundations of Rules-Based Disease Surveillance

As there is no international or even regional ‘health police’, the question remains of how to guarantee an effective collection and dissemination of data on disease-related events beyond the state. A general belief is that having international and regional rules as the basis for gathering and disseminating such data may lead to increased certainty, while guaranteeing reciprocal relationships between states parties. Accordingly, legal rules would represent a more stable framework compared to reliance on political will, or on self-organising networks.

International and regional legal rules applicable to states cannot, however, deliver a fully comprehensive disease surveillance system. The following lines explore two of the reasons explaining such a limitation. First, universal knowledge of disease-related events in regions, let alone the world, is not feasible in the foreseeable future. Second, underreporting has been a constant feature of the surveillance of communicable diseases and, as discussed below, is likely to continue to be so. Exploring these reasons for the gaps in ad hoc disease surveillance systems could shed light on key obstacles preventing the effective notification of events constituting public health emergencies with a cross-border dimension.

4 As of 31 January 2022, two new Regulations, one to amend Regulation (EC) No. 851/2004 and another one to repeal Decision No. 1082/2013/EU, respectively, have been submitted by the European Commission and is being negotiated through the intergovernmental channels of the EU. The proposed amendment to Regulation (EC) No. 851/2004 is available online at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0726&from=EN>; whereas the proposal for a new Regulation to repeal Decision No. 1082/2013/EU is available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0727>.

2.1 *The Origins of Rules-Based Disease Surveillance beyond States*

Historically, proposals to codify disease reporting by states were first discussed at the International Sanitary Conference in Vienna in 1874.⁵ The focus was on cholera due to its cross-border nature. The creation of a Permanent International Commission of Epidemics was approved at the conference,⁶ but countries did not follow up and the project was abandoned.⁷ This Commission would have received information on the spread of cholera across Europe,⁸ which would then be communicated to the other contracting parties.⁹ Thus, 1874 is the moment where the idea of mandatory information-sharing between states regarding communicable diseases was first formally discussed.¹⁰

The first time that rules of disease notification entered into force was at the International Sanitary Conference of 1893 in Dresden, Germany. There, delegates from European countries approved an obligation to notify through a legally binding international law instrument.¹¹ Yet one of the most eloquent justifications for having such rules had been made during previous negotiations at the International Sanitary Conference of 1881 in Washington, DC.¹² In the opinion of the delegate of Italy, agreeing on legal rules was the best means to ensure clarity among what should be reported, and reciprocity amongst authorities from different states.¹³ Special emphasis was put on the need to report both routine epidemiological data to identify long-term trends and extraordinary events for which urgent action might be needed.¹⁴ Securing such information on disease-related events occurring in other territories was an issue too important to be left to states' flickering political will.

5 N. Howard-Jones, *The Scientific Background of the International Sanitary Conferences, 1851–1938* (Geneva: WHO, 1975) 33.

6 International Sanitary Conference (4th, 1874, Vienna), *Procès-verbaux de la Conférence sanitaire internationale ouverte à Vienne, le 1 Juillet 1874*, 308, available online at <https://apps.who.int/iris/handle/10665/70424>.

7 Howard-Jones, *supra* note 5, 40.

8 International Sanitary Conference 1874, *supra* note 6, 322.

9 *Id.* at 312.

10 N.M. Goodman, *International Health Organisations and their Work* (London: Churchill Livingstone, 1971) p. 60.

11 International Sanitary Conference (8th, 1893, Dresden), *Protocoles et procès-Verbaux de la Conférence sanitaire international de Dresde, 11 1893*, available online at <https://curiosity.lib.harvard.edu/contagion/catalog/36-990015803370203941>.

12 International Sanitary Conference (5th, 1881, Washington, DC), *Proceedings of the International Sanitary Conference provided for by Joint Resolution of the Senate and House of Representatives in the Early Part of 1881*, available online at <https://babel.hathitrust.org/cgi/pt?id=mdp.39015058364046&view=1up&seq=46>.

13 *Id.*, at 37.

14 International Sanitary Conference 1893, *supra* note 11, 92.

In many respects, the perspectives of delegates to the Sanitary Conferences in the 19th Century reflect a bygone era. Thus, caution should be exerted not to read into their views in an anachronistic manner. Nevertheless, it is an insightful display of the normative foundations of rules-based disease surveillance. The justification of rules as a basis for cooperation rests upon the importance of securing a public good beyond the state.¹⁵

2.2 *Facing the Limits of Disease Surveillance*

Since the 19th Century international sanitary conferences, the prevailing limits of disease surveillance have been a constant reason for adjusting expectations on what could be achieved through legal rules. There are two types of obstacles: (1) the medical-epidemiological; and (2) the political (broadly understood). The following subsections explore how these obstacles inform extant rules-based disease surveillance in multiple levels of governance.

2.2.1 The Inevitable Medical-Epidemiological Blind Spots

Rules should not be made based on unrealistic expectations. For a long time, underreporting has been accepted as a reality of medical and public health practices related to epidemiological surveillance.¹⁶ In communicable disease control, the active reporting of cases by medical or public health personnel of an infected patient is clearly necessary. Ideally, the reported cases will be closer to the actual number of cases, understood as the total of such events occurring in society.¹⁷ Basically no healthcare system in the world currently can detect every instance of a disease within its territory; rather, many healthcare systems have deliberately implemented procedures with non-exhaustiveness as their starting point.¹⁸ Such choices are rational decisions based on the realistic assessment of national public health capacities. The challenge is how to frame

15 Zacher, *supra* note 1.

16 M.J. Alter, A. Mares, S.C. Hadler and J.E. Maynard, 'The Effect of Underreporting on the Apparent Incidence and Epidemiology of Acute Viral Hepatitis', *American Journal of Epidemiology* 125(1) (1987) 133–139.

17 C. Gibbons, M.-J.J. Mangen, D. Plass, A.H. Havelaar, R.J. Brooke, P. Kramarz, K.L. Peterson, A.L. Stuurman, A. Cassini, E.M. Fèvre and M.E.E. Kretzschmar, 'Measuring underreporting and under-ascertainment in infectious disease datasets: a comparison of methods', *BMC Public Health* 14 (2014) 147.

18 See the different types of surveillance described in A. Garcia-Abreu, W. Halperin and I. Danel, *Public Health Surveillance Toolkit. A Guide for Busy Task Managers* (Washington, DC: The World Bank, 2002) pp. 9–11; see also N.K. Ibrahim, 'Epidemiologic surveillance for controlling Covid-19 pandemic: types, challenges and implications', *Journal of Infection and Public Health* 13 (2020) 1633–1636, <https://doi.org/10.1016/j.jiph.2020.07.019>.

disease reporting obligations that apply equally to all participating states, or to draft an acceptable differential fulfilment of reporting obligations.

The realisation of the limits of medical and public health practice can allow the gauging of expectations of a rules-based disease surveillance system. As omniscience is not possible, it would make little to no sense to devise rules imposing exhaustive reporting as the only goal. The impracticality of such an obligation applies even to the most robust and well-funded healthcare systems in the world.¹⁹ In the case of systems with lesser resources, the options to address the gaps in reporting become even more complex given that healthcare systems are already overburdened with many activities besides surveillance.

This logic has been incorporated into the WHO's International Health Regulations of 2005. Article 5 enshrines obligations to strengthen different core healthcare capacities, including those for surveillance. In terms of differential treatment, the provision grants different timeframes for countries to shore up their capacities for, among other things, detecting and promptly reporting diseases that may constitute a public health emergency of international concern. By contrast, differential treatment of Member States is not foreseen in any of the European or African rules-based disease surveillance systems.

2.2.2 The Political Disincentives for Disease Reporting

The second major obstacle is related to the persistent political drivers to conceal disease-related events. There are perennial stumbling blocks to effective cooperation by states. What lies beneath is a balancing act between ensuring maximum security against the international spread of disease and the minimum interference possible with cross-border movement and trade.²⁰ Resorting to obligations enshrined in legal rules is intended to overcome the reluctance that national authorities may have for not sharing epidemiological information.

Delegates to International Sanitary Conferences of the 19th century expressed many reasons for sharing epidemiological information on particular disease-related events, but agreed that they should act to reduce the

19 On the disease surveillance system of the United States of America, despite its comparatively high rates of funding for ad hoc disease surveillance, see S. Becker, J. Taylor and J. Sharfstein, 'Identifying and Tracking SARS-CoV-2 Variants – A Challenge and an Opportunity', *The New England Journal of Medicine* 385(5) (2021) 389–390.

20 B. Veilimirovic, 'Do We Still Need International Health Regulations?', *The Journal of Infectious Diseases* 133(4) (1976) 478–482; Y. Beigbeder, *The World Health Organization* (The Hague: M. Nijhoff, 1998) p. 73; D. Fidler, *International Law and Infectious Diseases* (Oxford: Oxford University Press, 1999) p. 104.

risk of creating ‘prejudices against commercial interests’ by other states.²¹ Considering the eventual fate of disease reporting in the following century, these concerns proved to be prescient.

More than 130 years after the rules-based disease surveillance system was first devised, even with the advances in the effective tracing and diagnosis of communicable diseases, the political drivers of underreporting remain key challenges. Several reasons explain why authorities willingly refrain from sharing information. These include reputational costs,²² an absence of transparency standards or fears of overreaction by other states.²³

Reputational costs may be at stake when governments willingly conceal a disease outbreak for fear of appearing ineffective, both towards its own population or towards other countries. Lack of transparency may be at stake whenever states who do not have an ingrained tradition of publicizing information on acts of authority is at stake. Such countries are less likely to deliver at the international level what they fail to uphold nationally. Lastly, perhaps the most visible and longstanding instance of political disincentives to report, mainly at the international level, has been states’ reluctance to convey information promptly and transparently in light of the measures other states may subject them to.²⁴

3 Multilevel Rules on Disease Surveillance: Overlapping Legal Regimes

The three legal regimes chosen for this analysis show an overlap of rules-establishing systems of disease surveillance based on reporting by national public health authorities. How rules are framed in each of these regimes varies, and this is a core determinant of how information is shared with international and regional institutions.

21 International Sanitary Conference (8th, 1893, Dresden), *supra* note 11, at 92.

22 A. Taylor, ‘Controlling the Global Spread of Infectious Diseases: Toward a Reinforced Role for the International Health Regulations’, *Houston Law Review* 33(5) (1997) 1328–1362, pp. 1358–1359.

23 D. Fidler, ‘Return of the Fourth Horseman: Emerging Infectious Diseases and International Law’, *Minnesota Law Review* 81(1997) 771–868, pp. 846–847; A. Kamradt-Scott, ‘WHO’s to blame? The World Health Organization and the 2014 Ebola outbreak in West Africa’, *Third World Quarterly* 37 (2016) 401–418, p. 411.

24 A finding already put forward by a former WHO Deputy Director-General, P. Dorolle, ‘Old plagues in the jet age. International aspects of present and future control of communicable disease’, *British Medical Journal* 789 (4) (1968) 789–792.

3.1 *Global Disease Surveillance: The WHO's International Health Regulations*

The cornerstone of disease reporting at the global level is enshrined in the WHO's International Health Regulations of 2005. The WHO was founded in 1948, superseding both the *Office International d'Hygiène Publique* and the Health Office of the League of Nations and subsuming the Pan American Sanitary Bureau as a regional office, to be renamed the Pan American Health Organisation.²⁵ Article 21 of the WHO's Constitution now granted the World Health Assembly – a body composed of Member States' representatives – the power to issue binding regulations aimed at 'prevent[ing] the international spread of disease'. Under Article 22, after approval at the Assembly, their regulations become binding on all of WHO Member States within a specified time unless they opt out. This is in major contrast to the preceding sanitary conventions which required national ratification²⁶ and a lack of such ratification doomed the International Sanitary Conferences of 1874 and 1881.

The International Sanitary Regulations were approved at the World Health Assembly in 1951 and entered into force in 1952. Article 3 obliged national health authorities to notify the WHO within 24 hours of learning of 'infected local areas' whenever one of six 'quarantinable diseases' was present.²⁷ The term 'infected local areas', as defined by Article 1, denoted instances of epidemics. Afterwards, the International Sanitary Regulations of 1951 were superseded by the International Health Regulations of 1969. The original list of six quarantinable diseases was reduced to three – cholera, plague and yellow fever – but the obligation to notify had a broader scope. Article 1 required states to notify the WHO within 24 hours of 'the first case of a disease subject to the regulations, that is neither an imported case nor a transferred case'. Article 11 required the WHO to share 'with all health administrations [...] all epidemiological and other information which it has received'. Information was then included in periodic publications produced until the 1969 regulations were themselves superseded.²⁸ A list naming each reporting state, the presence of specific diseases and the moment and location of outbreaks was published.²⁹

25 T. Hanrieder, *International Organization in Time. Fragmentation and Reform* (Oxford: Oxford University Press, 2015), pp. 56–58.

26 W. Sharp, 'The New World Health Organization', *The American Journal of International Law* 41(3) (1947) 509–530, p. 525.

27 'Quarantinable diseases' were namely: plague, cholera, yellow fever, smallpox, typhus and relapsing fever. Article 1, International Sanitary Regulations, 1951.

28 See the very last notifications under the International Health Regulations of 1969 in WHO, 'Notifications of diseases received from 9 to 14 June 2007', *Weekly Epidemiological Record* 82 (2007) 209–224, p. 224.

29 On the International Sanitary Regulations of 1951, see, e.g., WHO, Fourteenth Report of the Committee on International Quarantine, EB41/21, 20 December 1967, 9–40; on the

Article 6 of the current International Health Regulations of 2005 obliges states to notify the WHO ‘within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern [PHEIC] within its territory’. A PHEIC is defined in Article 1 as ‘an extraordinary event which [...] (i) constitute[s] a public health risk to other states through the international spread of disease and (ii) [...] potentially require[s] a coordinated international response’. Described as an innovative governance tool at the time,³⁰ declaring a PHEIC allows the WHO to communicate the serious nature of an event to Member States.³¹

3.2 *The Regional Proliferation of Rules-Based Disease Surveillance*

Different systems of regional integration have addressed the matter of disease surveillance. The three regional spaces chosen for study, the European Union, African Union and ECOWAS, display similar reasons behind the creation of disease surveillance through rules. A common denominator in all three is the close relationship between the notification of events and the goals of health security, with the latter being considered a necessary component of regional integration.

Not all regional systems of disease surveillance have been rules-based. Three other frameworks – one in North America comprising Canada, the United States and Mexico; one in the ASEAN region; and one in the Caribbean Community and Common Market (CARICOM) – operate on the basis of political commitments to share information on communicable disease-related events. Thus, these frameworks are studied separately, as the same tenets of interpretation of legal instruments do not apply to them.

3.2.1 Rules-Based *ad hoc* Disease Surveillance in the European Union

Within the legal space of the European Union, Member States are subject to rules for the sharing of communicable disease-related events. The legal backbone of the system is found in Regulation (EC) No. 851/2004 which created the European CDC. Article 3 provides the agency with a mandate to ‘identify,

International Health Regulations of 1969, *see, e.g.*, Functioning of the International Health Regulations (1969) for the period 1 January to 31 December 1978, *Weekly Epidemiological Record* 48 (1979) 369–374, pp. 369–372, as well as its Annex 1.

30 D. Fidler, ‘From International Sanitary Conventions to Global Health Security: The New International Health Regulations’, *Chinese Journal of International Law* 4(2) (2005) 325–392, p. 362.

31 L. Gostin, A. Phelan, A.G. Coutinho, M. Eccleston-Turner, N. Erondy, O. Filani, T. Inglesby, R. Katz, A. Maleche, J.B. Nuzzo, O. Tomori and M. Kavanagh, ‘Ebola in the Democratic Republic of the Congo: Time to Sound a Global Alert?’, *The Lancet* 393 (2019) 617–620, p. 618.

assess and communicate current and emerging threats to human health from communicable diseases'. Article 4 of the Regulation currently in force imposes obligations on Member States to provide the European CDC 'in a timely manner available scientific and technical data relevant to its mission'. There is no clarification provided in the Regulation of what exactly constitutes 'timely'. A proposed amendment of Regulation (EC) No. 851/2004, currently part of the legal package in the strategy known as "European Health Union", would replace the wording in Article 4 with another one obliging EU Member States to notify the European CDC 'of any serious cross-border threats to health ... as soon as detected'.³²

The second legal act underpinning rules-based disease surveillance in the European Union is Decision No. 1082/2013/EU of the European Parliament and of the Council, currently under a process of potential repeal by a new Regulation drafted by the European Commission.³³ Both the Decision and the proposed Regulation in question enshrine an Early Warning and Response System as the operational arm of event-based disease surveillance in the EU, falling under the purview of the European CDC.³⁴ In terms of legally mandatory notifications, Article 6(3) of the Decision in question, and Article 19 of the proposed Regulation to repeal it, enshrine an obligation for EU Member States to convey information on communicable diseases and other "serious health threats" with a potential cross-border dimension. Although Decision No. 1082/2013/EU, in force at the moment of writing, provides no timeline for that notification, the proposed Regulation to repeal said Decision would, if approved, 'fuse' the obligation of Member States to notify the European CDC with the obligation to notify the WHO under Article 6 of the WHO's International Health Regulations of 2005. Thus, under Article 19 of the proposed Regulation to repeal Decision No. 1082/2013/EU, Member States must communicate the corresponding information to the European CDC and, for that matter, the Early Warning Response System within 24 hours after assessing the "serious health threat" in question. If this Regulation is ultimately approved in its current form, it would constitute a unique case of multilevel streamlining of obligations under two separate legal regimes.

32 *Supra* note 4.

33 *Id.*

34 As envisaged in Article 8, Decision No. 1082/2013/EU of the European Parliament and of the Council, 22 October 2013; and in Article 18 of the proposed Regulation to repeal Decision No. 1082/2013/EU.

3.2.2 Rules-Based *ad hoc* Disease Surveillance in Africa

The African region displays the peculiar feature that two institutions operate a rules-based disease surveillance system simultaneously. Both the African CDC and the WHO have been constituted with mandates to collect and disseminate information on communicable diseases spreading in the territories of their Member States. As explained below, ongoing institutional developments aim at combining their activities, wherein WHO's surveillance in West Africa will be part of that conducted by the continent-wide African CDC. Nevertheless, from a legal perspective, rules from each level of governance operate autonomously.

The WHO was created in 1987 through a Protocol adopted by the Member States of ECOWAS³⁵ but it began operations only in 2000.³⁶ Later, it was joined by the establishment of an ECOWAS Regional Centre for Surveillance and Disease Control (RCSDC) created through a Regulation from the WHO Council of Ministers,³⁷ Article 6(2) of which states that ECOWAS Member States 'shall ... [p]rovide ECOWAS – RCSDC with relevant public health information on early warning alert and response activities in Member States on request'. All of these acts stem from ECOWAS legal sources and are thus legally binding upon its Member States.³⁸

Launched in January 2017, the Africa CDC is a specialised technical agency of the African Union focused on preparedness and response to health threats and disease outbreaks.³⁹ It was conceived at the African Union Special Summit on HIV and AIDS, Tuberculosis and Malaria (ATM) in July 2013, and legally established through a Statute approved at the 26th Ordinary Assembly of Heads of State and Government of the African Union.⁴⁰ The African CDC was designed as a decentralised model of governance, with its headquarters relying

35 Protocol A/P.2/7/87 on the Establishment of a West African Health Organisation, 9 July 1987.

36 J. Herpolsheimer, 'ECOWAS and the Covid-19 pandemic: Regional Responses and African Interregional Cooperation', *ReCentGlobe Working Paper Series* No. 42 (Leipzig: ReCentGlobe, 2020) p. 6.

37 Regulations C/Reg. 11/12/15 Establishing and Stating Operating Procedures of the ECOWAS Regional Centre for Disease Surveillance and Disease Control (ECOWAS-RCSDC) Seventy-Fifth Ordinary Session of the Council of Ministers, Abuja, 13–14 December 2015.

38 J. Ukaigwe, *ECOWAS Law* (Cham: Springer, 2016) pp. 33–42.

39 African Union, *African Union Handbook* (2018) p. 173.

40 Statute of the Africa Centres for Disease Control and Prevention (Africa CDC), adopted at the 26th Ordinary Assembly of Heads of State and Government of the African Union, Assembly/AU/Dec.589(XXVI), 31 January 2016.

on the contributions of five Regional Collaborating Centres.⁴¹ The operations distinguish between routine and event-based surveillance and have their own devoted Early Warning Response System.⁴² There does seem to be some overlap as the African CDC's designated Regional Collaborating Centre for West Africa (the Nigerian CDC) and the ECOWAS RCSDC are both in Abuja, Nigeria. Even though they are separate legal entities,⁴³ the purpose is for all reporting activities to be streamlined through both systems.

Just as the SARS-CoV-1 crisis of 2002–2003 created an impetus for the approval of a revision to the International Health Regulations in 2005, the push to reform WAHO and to create an African CDC gained political momentum during the 2014–2016 West African Ebola crisis.⁴⁴ Since its creation, the African CDC has provided constant updates on the Ebola outbreak in the Democratic Republic of the Congo which began in 2018 and the Covid-19 pandemic.⁴⁵ The agency has published regular status updates drawing on reports from Member States. Like in the WHO and in the European CDC, information related to the spread of diseases is published in a non-disaggregated fashion i.e. without revealing more individualised details related to the circumstances of a specific infection.

3.3 *Overview of Legal Regimes for ad hoc Disease Surveillance*

The overlap of rules-based disease surveillance systems beyond the state at the global and regional levels raises the question of to what extent there is a duplication of efforts. Ideally, notifications to international and supranational

41 J. Nkengasong, O. Maiyegun and M. Moeti, 'Establishing the Africa Centres for Disease Control and Prevention. Responding to Africa's health threats', *Lancet Global Health* 5(3) (2017) e246.

42 Assembly of the African Union, Report of the Commission on the Establishment of the African Centre for Disease Control and Prevention, Assembly/AU/4(XXIV), 30–31 January 2015, Annex 5.

43 'Regulations C/REG. 11/12/15 Establishing and Stating Operating Procedures of the ECOWAS Regional Centre for Surveillance and Disease Control (ECOWAS-RCSDC), 14th December 2015', *Oxford International Organizations (OXIO)* 467 (2019), available online at <https://opil.ouplaw.com/view/10.1093/law-oxio/e467.013.1/law-oxio-e467?print=pdf>.

44 16th Extraordinary Session of the African Union Executive Council meeting on Ebola, Addis Ababa, 8 September 2014; E. Ojomo, 'Fostering Regional Health Governance in West Africa: The Role of the WAHO', in: L. Vierck, P. Villarreal and K. Weilert (eds.), *The Governance of Disease Outbreaks. International Health Law: Lessons from the Ebola Epidemic and Beyond* (Baden-Baden: Nomos, 2017) pp. 273–300.

45 Another major communicable disease event, the spread of Ebola in the Democratic Republic of the Congo between 2018 and 2020, did not acquire cross-border transmission.

authorities are not to occur in parallel, hence the European⁴⁶ and African⁴⁷ systems of disease surveillance recognise the WHO’s International Health Regulations as the overarching global framework. The legal rules underpinning each system present a series of features, shown in Table 1.

TABLE 1 Comparison of legal frameworks for passive *ad hoc* disease surveillance

Name of organization	Legal instrument for disease surveillance	Mandatory notification and legal basis	Period of time for notification specified	Legal consequences for breach
World Health Organization	International Health Regulations of 2005	Yes (Article 6 International Health Regulations of 2005)	24 hours	Dispute Settlement between States (Article 56 International Health Regulations 2005)
European CDC	Regulation (EC) No. 851/2004 and Decision No. 1082/2013/EU	Yes (Article 4 Regulation (EC) No. 851/2004; Article 6(3) Decision No. 1082/2013/EU; Article 19 of proposed Regulation to repeal Decision No. 1082/2013/EU)	Legal provisions currently in force: No period for notification specified/Proposed legal provision: “As soon as detected”, and within 24 hours under new Regulations	Infringement Proceedings (Articles 258–259 Treaty on the Functioning of the European Union)

46 Decision No. 1082/2013/EU of the European Parliament and of the Council, 22 October 2013, para. (12); proposed Regulation to repeal Decision No. 1082/2013/EU, para. 8.

47 Assembly of the African Union, Report of the Commission on the Establishment of the African Centre for Disease Control and Prevention, Assembly/AU/4(xxiv), 30–31 January 2015, 6 para. 13(2).

TABLE 1 Comparison of legal frameworks for passive *ad hoc* disease surveillance (cont.)

Name of organization	Legal instrument for disease surveillance	Mandatory notification and legal basis	Period of time for notification specified	Legal consequences for breach
West African Health Organisation	ECOWAS Regulations C/Reg. 11/12/15 Establishing and Stating Operating Procedures of the ECOWAS Regional Centre for Disease Surveillance and Disease Control (ECOWAS)	Yes (Article 6(2) ECOWAS Regulations C/Reg. 11/12/15).	No period specified.	N/A
African CDC	Statute of the Africa Centres for Disease Control and Prevention (Africa CDC), 31 January 2016	No mandatory notification provided.	N/A	N/A

All four rules-based systems of disease surveillance addressed in this study are based on early warning systems, through which individual Member States are notified when reports are received. None of the legal instruments foresees disclosure to the public at large and safeguards are in place so only those with the appropriate clearance may access the system. The WHO's International Health Regulations also establish additional procedural requirements before sharing information. Whenever reports about ongoing disease-related events are received, the organisation's officials must first verify the information with the relevant authorities. No such procedural safeguards are present in the African or European legal instruments.

Concerns have been expressed over the multiplication of disease surveillance systems and the ensuing confusion over exactly who needs to notify

what.⁴⁸ This is compounded by how the jigsaw puzzle of rules may be replicated at the national level. In this sense, on the question of who needs to notify, in a recent report presented at the WHO on the implementation of the International Health Regulations during the Covid-19 pandemic, a Review Committee composed of external experts recommended exploring the role of so-called National Focal Points more deeply.⁴⁹ These are the designated national authorities responsible for transmitting the information to the WHO Secretariat, with similar arrangements existing in regional ad hoc surveillance systems.⁵⁰ Scrutinising the role of these national authorities is needed for a more complete picture of the daily functioning of each system.

3.4 *The Hard Side of Legal Obligations: Facing Non-Compliance*

One of the distinctive features of legal rules is the option to invoke penalties for deviance therefrom. It begs the question of what would happen were states to fail to fulfil the obligations imposed by the International Health Regulations, by the laws issued by the European and African Unions or by ECOWAS. The provisions in all of these instruments are legally binding on states and thus failing to uphold them would represent a breach of the law which could trigger legal consequences. From a hermeneutical analysis of the wording and by looking at some examples, it is possible to extract some of the criteria for determining if and when a breach has occurred.

The wording of Article 6 of the International Health Regulations of 2005 enshrines the conditions in which states should notify the WHO, namely: ‘*within 24 hours* of assessment of public health information, of all events [in their territories] that may constitute a public health emergency of international concern’ (emphasis added). Not following this timetable may itself lead to a breach and, thus, to the responsibility of states for internationally wrongful acts.⁵¹ The question rises of what the evidentiary burden would be to demonstrate the exact time at which authorities ‘assessed’ an event, which is when the 24-hour period begins. Even if a breach were to be established,

48 A. De Ruijter, *EU Health Law & Policy. The Expansion of EU Power in Public Health and Health Care* (Oxford: Oxford University Press, 2021) p. 125.

49 International Health Regulations Review Committee, WHO’s work in health emergencies. Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005), A74/9 Ad.1, 5 May 2021.

50 For example, see Article 5(4), Regulation (EC) No. 851/2004.

51 As enshrined in Article 2 of the International Law Commission’s Articles on the Responsibility of States for Internationally Wrongful Acts.

no sanctions are provided for. There are, nevertheless, some fail-safe actions if cases of non-compliance. Article 10 of the International Health Regulations allows the WHO to publicly share available information when a state fails to report or to respond to requests to do so in a prompt manner. However, the WHO must first engage with the affected state to verify the information received through other means. Proposals to enhance the WHO's role in the oversight of compliance with the International Health Regulations of 2005 include the possibility of 'naming and shaming' those states failing to notify promptly and accurately.⁵² Nevertheless, the WHO has historically been deemed an institution fostering good faith cooperation across its Member States in international health generally, and in the field of *ad hoc* disease surveillance particularly, albeit not always in a successful manner.⁵³ Here, proposals to potentially allow for imposing sanctions on non-compliant states in the field have so far been mostly discarded.⁵⁴ Furthermore, Article 56 of the International Health Regulations gives the option for states to resort to dispute settlement, first through good offices and mediation at the WHO, with the possibility to resort to the Permanent Court of Arbitration. Nevertheless, there has never been any instance of a judicial dispute due to the failure to uphold obligations enshrined in the International Health Regulations.⁵⁵

As for EU law, both the Regulation and the Decision forming the backbone of rules-based disease surveillance in the region constitute legally binding acts for all 27 EU Member States. Non-compliance by Member States with the provisions therein could lead the European Commission or other Member States to launch infringement proceedings at the Court of Justice of the European Union under Articles 258 and 259 of the Treaty on the Functioning of the European

52 On general reputational issues in international law, see A. Chayes and A. Chayes, *The New Sovereignty. Compliance with International Regulatory Agreements* (Cambridge, MA: Harvard University Press, 1995) pp. 124–128; on the specific case of the International Health Regulations of 2005, see Kamradt-Scott, *supra* note 23, at 256.

53 E. Benvenisti, 'The WHO – Destined to Fail? Political Cooperation and the Covid-19 Pandemic', *The American Journal of International Law* 114(4) (2020) 588–597, p. 597.

54 A. Spagnolo, '(Non) Compliance with the International Health Regulations of the WHO from the Perspective of the Law of International Responsibility', *Global Jurist* 18(1) (2018) 11–13; on international trends away from sanctions-based approaches in international law, see S. Sekalala, *Soft Law and Global Health Problems* (Cambridge: Cambridge University Press, 2017) 53.

55 The one time a dispute was initiated was not related to a lack of prompt disease notification, but rather due to excessive measures imposed by other states. WHO, *Sixteenth Report of the Committee on International Surveillance of Communicable Diseases*, 24th World Health Assembly, A/24/B/10, 2 April 1971, available online at https://apps.who.int/iris/bitstream/handle/10665/145207/WHA24_B-10_eng.pdf?sequence=1&isAllowed=y.

Union. The eventual outcome of these proceedings could be the imposition of pecuniary penalties under Article 260(2) of said Treaty. Infringement proceedings were deemed by the European Court of Justice to be the ‘ultima ratio’ for upholding the core treaties at the heart of the EU beyond the wishes of its Member States.⁵⁶ Unlike the International Health Regulations, however, the European legal instruments currently in force do not state a mandatory period for notification. This has led commentators to consider the sharing by EU Member States of *ad hoc* disease surveillance information as being voluntary in nature.⁵⁷ Still, the scenario for disregard of the European CDC’s requests for information could, theoretically, represent a breach of EU law obligations, but there is no existing case law in this area. Other obligations of mandatory notification by EU Member States to the European Commission, such as the one envisaged in Article 193 of the Treaty on the Functioning of the European Union regarding the implementation of environmental measures more protective than those at the EU level,⁵⁸ may not be applicable considering the different nature of information to be submitted. Nevertheless, if the two Regulations to, respectively, amend Regulation (EC) No. 851/2004 and repeal Decision No. 1082/2013/EU enter into force in their current form and a mandatory 24-hour period for notifying serious health threats is foreseen, infringement proceedings could theoretically be initiated against Member States who fail to fulfil the deadline. A different question altogether is whether either the European CDC or, subsequently, the European Commission would have the capacity for constant and comprehensive oversight of numerous notifications and ascertain whether the mandatory period was respected or not in every case.

In the surveillance system under the WHO, the wording of Article 6 of the Regulations establishing the RCSDC indicates that failure by Member States to furnish information as requested might be a breach of legal obligations. Meanwhile, Article 26 of the Statute of the African CDC refers to a cooperative framework between the agency and its Member States. Strictly speaking, no obligations are imposed on states to notify disease-related events, let alone within a specific timeframe. It would therefore be difficult to articulate the argument of a potential breach of obligations by a Member State in case of belated or absent notifications. Thus, unlike the WHO’s International Health

56 L. Prete and B. Smulders, ‘The Coming of Age of Infringement Proceedings’, *Common Market Law Review* 47(1) (2010) 9–61.

57 M. Anderson and E. Mossialos, ‘Time to strengthen capacity in infectious disease control at the European level’, *International Journal of Infectious Diseases* 99 (2020) 263–265.

58 S. Garben, ‘Article 193 TFEU’, in: M. Kellerbauer, M. Klamert and J. Tomkin (eds.), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (Oxford University Press, 2019) pp. 1544–1546.

Regulations, the regional rules-based systems in Africa so far lack a more concise formulation leading to a clear actionable basis on which to establish that a breach has occurred. Nevertheless, the current analysis does not make the argument in favour of punitive enforcement-based approaches.⁵⁹ To the contrary, a cooperative approach between states may have been deemed as pertinent for ensuring the proper functioning of *ad hoc* disease surveillance. Taking non-compliance with rules to their ultimate consequences, or even threatening to do so, may undermine the goals of a closer regional integration, a feature contrasting with the comparatively thin integration between the WHO's Member States.⁶⁰

4 Rules-Based Disease Surveillance beyond States in Practice

Even before the onslaught of reports related to the incidence of Covid-19 starting in 2020, disease surveillance at all levels was a matter of daily practice. For example, in the WHO, hundreds of events were reported through the *ad hoc* surveillance system each year⁶¹ but only public officials with clearance have direct access to the database where they submit reports to the WHO or the corresponding regional authorities and each report is not made publicly available. The full extent of diseases reported to the WHO, the European and African CDCs and WAHO is thus unknown and these systems are mostly 'invisible',⁶² with high-profile diseases constituting PHEICs such as the H1N1 pandemic influenza, Ebola, or Covid-19 being merely the tip of the iceberg.⁶³

59 For the opposite view, see J.H. Duff, A. Liu, J. Saavedra, J.N. Batycki, K. Morancy, B. Stocking, L.O. Gostin, S. Galea, S. Bertozzi, J.M. Zuniga, C. Alberto-Banatin, A. Sena Dansua, C. del Rio, M. Kulzhanov, K. Lee, G. Scaglia, C. Shahpar, A.J. Ullmann, S.J. Hoffman, M. Weinstein and J. Szapocznik, 'A global public health convention for the 21st century', *The Lancet Public Health* 6(6) (2021) e428–e433, p. e429.

60 E. Stein, 'International Integration and Democracy: No Love at First Sight', *The American Journal of International Law* 95(3) (2001) 489–534.

61 For example, at the World Health Assembly of 2019 and before Covid-19, the WHO Director-General reported a total of 484 'public health events' identified in 2018. WHO, *Public health emergencies: preparedness and response. Annual report on the implementation of the International Health Regulations*, A72/8 (April 4, 2019), para. 2, available online at https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_8-en.pdf.

62 P. Villarreal, R. Habibi and A. Taylor, 'Monitoring Compliance with the International Health Regulations', *International Organisations Law Review* (2022) in press.

63 In the WHO's guidance on the matter, events constituting PHEICs were projected to be 'rare' vis-à-vis the total number. WHO, Guidance, 8.

In the case of Covid-19, weekly epidemiological updates by the WHO⁶⁴ and databases by the European⁶⁵ and African CDCs⁶⁶ and the WAHO⁶⁷ are currently operational but the full extent of information poured into those databases is not disseminated. In the WHO, disease-related events may include communicable diseases and other types of health threats such as chemical accidents.⁶⁸ In the case of the European and African CDCs, the systems are exclusively focused on communicable diseases.⁶⁹ Considering their intertwined mandates, it is unclear to what extent mandatory notifications to each of these specialized organisations are duplicated.

The international and regional rules-based systems of disease surveillance overlap with numerous national systems of *ad hoc* surveillance, many of which operate based on national laws mandating notification of events.⁷⁰ Nevertheless, there is no available global mapping of how such legal obligations are framed. Past international attempts by way of a compendium of national health laws were abandoned before completion.⁷¹ A recent report presented at the WHO indicated how effective communication depends on identifying national authorities with the competence to gather the expected information on disease-related events.⁷² Future comparative law studies could yield insights into whether and how national laws mandate authorities from different levels of government to notify diseases to a single administrative unit. This would provide a more complete picture of the numerous chains of compliance involved in *ad hoc* disease surveillance.

As a matter of practice, not all frameworks for epidemiological information-sharing between states are based on legally binding rules, with a central

64 <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

65 European CDC Covid-19 Dashboard, available online at <https://qap.ecdc.europa.eu/public/extensions/covid-19/covid-19.html#global-overview-tab>.

66 African CDC Covid-19 Dashboard <https://africacdc.org/covid-19/>.

67 I. Sombié, E. Johnson, V.I. Lokossou, T. Amouh, A. Sow, N. Ogbureke and S. Okolo, 'How does the West African Health Organisation (WAHO) contribute to the evidence based decision-making and practice during the Covid-19 pandemic in the ECOWAS region?', *Pan African Medical Journal* 37(1) (2020) 20.

68 International Health Regulations (2005), Annex 1.

69 De Ruijter, *supra* note 48; W. Onzivu, 'Globalism, Regionalism, or Both: Health Policy and Regional Economic Integration in Developing Countries, an Evolution of a Legal Regime', *Minnesota Journal of International Law* 15(1) (2006) 111–187, p. 154.

70 A seminal contribution in the field was made by A. Langmuir, 'The Surveillance of Communicable Diseases of National Importance', *The New England Journal of Medicine* 268 (1963) 182–192.

71 WHO, *Joint External Evaluation Tool* (2nd edition, WHO, 2018) 13.

72 WHO, *Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the Covid-19 response*, A74/9 Add. 1, 5 May 2021, para. 19.

institution implementing them. Instead, *ad hoc* global disease surveillance has also evolved in parallel through a variety of governance networks.⁷³ A salient example is the world influenza surveillance network founded in 1947⁷⁴ without new binding rules though, as its title indicates, it was limited to events related to the influenza virus. Afterward, the Global Outbreak Alert and Response Network (GOARN) was formed in 2003 to provide a fast operational response to those events.⁷⁵ No new international law instrument was issued to create it, hence it is not a body holding a legal mandate. Yet GOARN has been touted as a major tool in providing a coordinated response to disease outbreaks, including effective sharing of information on new and re-emerging diseases across multiple territories.⁷⁶

There are also multiple examples of regional cooperation on the notification of communicable diseases not based on legally binding rules. The North American Plan for Animal and Pandemic Influenza is a non-binding offshoot of the North American Free Trade Agreement, itself an international treaty, fostering the exchange of disease surveillance information between Mexico, Canada and the United States.⁷⁷ Similarly, in the aegis of the Association of Southeast Asian Nations (ASEAN), an announcement was made recently about the creation of an ASEAN Regional Center for Public Health Emergencies and Emerging Diseases (ACPHHEED) with proposed terms of reference including receiving reports on disease-related events falling within the purview of the WHO's International Health Regulations.⁷⁸ It is so far unclear whether the proposed ACPHHEED will be endowed with a legal mandate, or rather whether it will rely upon the collaboration by participating states depending on the

73 C. Ansell, E. Sondorp and R. Hartley Stevens, 'The Promise and Challenge of Global Network Governance: The Global Outbreak Alert and Response Network', *Global Governance* 18(3) (2012) 317–337, p. 318.

74 T. Ziegler, A. Mamahit and N. Cox, Influenza, '65 years of influenza surveillance by a World Health Organization-coordinated global network', *Influenza and Other Respiratory Viruses* 12(5) (2018) 559–560.

75 GOARN, <https://extranet.who.int/goarn/about-us>.

76 Ansell, Sondorp and Stevens, *supra* note 73.

77 North American Plan for Animal and Pandemic Influenza (2012), available online at <https://www.publicsafety.gc.ca/cnt/rsrscs/pblctns/nml-pndmc-nflnz/nml-pndmc-nflnz-eng.pdf>. See also D. Avery, 'The North American Plan for Avian and Pandemic Influenza: A Case Study of Regional Health Security in the 21st Century', *Global Health Governance III*(2) (2010), available online at http://www.ghgj.org/Avery_the%20North%20America%20plan%20for%20influenza.pdf.

78 A.V. Miranda, L. Wiyono, I.C.N. Rocha, T.D.D. Cedeño and D.E. Lucero-Prisno III, 'Strengthening Virology Research in the Association of Southeast Asian Nations: Preparing for Future Pandemics', *American Journal of Tropical Medicine and Hygiene* 105(5) (2021) 1141–1143.

existent political will. Lastly, the Caribbean Public Health Agency (CARPHA) was created through an Interagency Agreement of the CARICOM Member States⁷⁹ and operates *inter alia* in the field of public health emergency preparedness and response.⁸⁰ The Agency is currently composed of 26 Member States, who enter by signing the constitutive Agreement. But none of the legal instruments enshrining the mandate of CARPHA provide for the notification of communicable diseases, or other health events with a potential for cross-border spread, by Member States. There is no explicit provision addressing passive *ad hoc* surveillance through notification to the Agency. It is worth noting that this lack of an express legal basis has not prevented CARPHA from offering situation reports on Covid-19, even including countries that are not Member States.⁸¹ In sum, these three regional systems show how rules are not meant to be the exclusive source of information-sharing, both within rules-based integration systems or of purely diplomatic cooperation. Nevertheless, other authors have posited that notifications tend to be higher when they are mandated by law than when they are not.⁸²

In the case of Covid-19, the most widespread database on daily infection and death rates is that developed by Johns Hopkins University⁸³ which offers interactive content and an almost real-time reporting of the pandemic. It is often cited as the most comprehensive and dynamic source of information, potentially representing an evidentiary basis for decisions on pandemic response. Consequently, not only is rules-based (*ad hoc*) disease surveillance not the only game in town, but actually it may not even be the core source of information available for making decisions in response to disease outbreaks. Even if that were the case, it does not mean, however, that these systems are wholly irrelevant. Member States may currently share confidential information which may not be publicly accessible in unofficial databases.

79 CARICOM, Agreement establishing the Caribbean Public Health Agency (CARPHA), June 2011, available online at https://carpha.org/Portals/0/Documents/CARPHA_IJA.pdf.

80 As stated in Article 4 of the Agreement establishing the Caribbean Public Health Agency (CARPHA).

81 CARPHA, *Covid-19 Situation Report No. 209*, 13 December 2021, available online at <https://carpha.org/Portals/0/Documents/Covid%20Situation%20Reports/Situation%20Report%20209%20-%20December%2013,%202021.pdf>.

82 Gibbons *et al.*, *supra* note 17.

83 <https://coronavirus.jhu.edu/map.html>.

5 Rules-Based Disease Surveillance after Covid-19: At the Crossroads?

It is safe to affirm, without venturing into hyperbole, that the Covid-19 pandemic represents a major landmark in the history of disease surveillance. The pandemic's catastrophic dimensions have posed many challenges to contemporaneous surveillance systems. Existing rules meant to provide an effective early warning system are being challenged as unfit for purpose.⁸⁴ Such a juncture could trigger political momentum either for reform, or for strengthening existing frameworks through streamlining efforts and strategic economic investments.

5.1 Reform Debates at the International Level

A series of initiatives are currently being discussed to reform several of the instruments analysed in this paper. In the case of the International Health Regulations, the interpretation of the extent of the obligation to notify the WHO of novel events that may constitute public health emergencies of international concern was at the core of controversies during 2020. The main contention was related to whether China promptly notified the spread of the then-novel SARS-CoV-2 in late December 2019.⁸⁵ Never in the history of the instrument has the international obligation to notify diseases received such attention.⁸⁶ It led to intricate debates on whether the doctrine on international responsibility would be applicable for failing to contribute to the global system of disease surveillance.⁸⁷

There is an ongoing process at the WHO's World Health Assembly⁸⁸ to, among other things, amend the International Health Regulations.⁸⁹ An Intergovernmental Negotiating Body composed of representatives of WHO

84 G. Burci and M. Eccleston-Turner, 'Preparing for the Next Pandemic: The International Health Regulations and World Health Organization during Covid-19', *Yearbook of International Disaster Law* 2(1) (2021) 259–282.

85 S. Singh, C. McNab, R. McKeon Olson, N. Bristol, C. Nolan, E. Bergström, M. Bartos, S. Mabuchi, R. Panjabi, A. Karan, S.M. Abdalla, M. Bonk, M. Jamieson, G.K. Werner, A. Nordström, H. Legido-Quigley and A. Phelan, 'How an outbreak became a pandemic: a chronological analysis of crucial junctures and international obligations in the early months of the Covid-19 pandemic', *The Lancet* 398(10316) (2021) 2109–2124.

86 For a retrospective overview of around forty years of such Regulations, see D. Fidler, *International Law and Infectious Diseases* (Oxford: Oxford University Press, 1999).

87 M. Pappas, 'The Once and Future Law of State Responsibility', *American Journal of International Law* 114(4) (2020), 618–626.

88 WHO, Decision SSA2(5), World Health Assembly Second Special Session, 1 December 2021.

89 Under Article 21 of the Constitution of the WHO, the World Health Assembly may adopt Regulations, which become legally binding for all Member States unless they 'opt out'.

Member States has been given a mandate to consider amendments to the regulations, such as modifying the procedure to notify the WHO.⁹⁰ At the institutional level, the idea to create a Compliance Committee tasked with overseeing the operation of the International Health Regulations has been put forward.

Negotiations on potential amendments to the International Health Regulations of 2005 will be subjected to evolving circumstances related to the Covid-19 pandemic. A recent episode, at the moment of writing, highlights how political disincentives for compliance have endured. In late November 2021, the government of South Africa shared information concerning a new variant of the SARS-CoV-2 virus baptised “Omicron”.⁹¹ On 24 November, the WHO declared this variant, Omicron, to be a variant of concern due to its potential to lead to more severe epidemiological features. Yet, despite having fulfilled an obligation enshrined in Article 6 of the International Health Regulations, the notification led to a series of travel bans imposed against South Africa. Criticisms have been levelled against the imposition of those restrictions, including their potential dissuasive effects on future compliance with obligations to notify the WHO of diseases that may pose a danger to the international community of states.⁹²

5.2 *Reform Debates at the Regional Level*

The onset of the Covid-19 pandemic has generated considerable debate in the European and African Unions and in ECOWAS around reform. In all three cases, despite the creation of new bodies and strengthening of existing ones, the institutional structure for mandatory notifications of diseases to regional health authorities remains mostly unchanged.

In the EU, at the moment of writing,⁹³ Regulation (EC) No. 851/2004 and Decision No. 1082/2013/EU remain in force. A Health Emergency Response Authority was created in September 2021, and negotiations on the approval of the Regulations that will constitute its mandate are being conducted.⁹⁴

90 See the proposal by the United States of America, Executive Board meeting in January 2022.

91 WHO, Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern (26 November 2021), available online at [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern).

92 P. Villarreal, ‘Punishing Compliance with International Law: The Omicron Variant and the International Health Regulations (2005)’, *EJIL:Talk!* (2 December 2021), available online at <https://www.ejiltalk.org/punishing-compliance-with-international-law-the-omicron-variant-and-the-international-health-regulations-2005/> (accessed 30 December 2021).

93 A revised version of this article was submitted on 31 January 2022.

94 See the current stage of the legislative process at <https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-cross-border-threats-to-health>.

Even if all of the proposed Regulations enter into force, Member States will continue to share information on communicable diseases with the European CDC under existing EU law. An increase in the European CDC's budget and more streamlined channels of communication with national reporting authorities are being pursued. Strengthening the core capacities under the WHO's International Health Regulations in EU Member States has been highlighted as a key strategy.⁹⁵

There is also a push to expand the African CDC's and WAHO's operational capacities. It is not clear whether this will entail reforming existing rules but there is ongoing work to consolidate a Regional Integrated Surveillance and Laboratory Network (RISLNET) throughout Africa, encompassing both regional institutions.⁹⁶ It would not lead to the creation of a self-standing body with a new mandate, but rather the sum of pre-existing centres. After the legal reforms fostered in the aftermath of the West African Ebola crisis of 2014–2016, no further proposals have been made for regulating disease surveillance during the Covid-19 pandemic.

In all regional frameworks, an assessment of how notifications by Member States have been made during the Covid-19 pandemic is pending. In-depth inquiries of to what extent states furnished the necessary information as the pandemic progressed will be inevitable for properly overhauling the different regional health agencies tasked with collecting and disseminating epidemiological information. These inquiries can only be undertaken with the forthcoming participation by the corresponding Member States and, considering the way in which rules have been drafted in each regional governance framework, they would not have a punitive objective. Ultimately, based upon the interpretation of existing rules when Covid-19 emerged, there would *prima facie* be no clear legal basis to hold states legally responsible for potentially belated notifications to regional authorities. Nevertheless, providing Member States in ECOWAS, and in the European and African Unions with economic and political incentives for sharing information to the largest extent possible would be a promising path.⁹⁷

95 A. Katz, O. Karvonen, A. Di Caro, F. Vairo, G. Ippolito, R. Grunow, D. Jacob and M. Salminen, 'SHARP Joint Action – Strengthening International Health Regulations and preparedness in the EU', *European Journal of Public Health* 30(Suppl. 5) (2020) ckaa166.606.

96 Africa CDC, Regional Integrated Surveillance and Laboratory Network (RISLNET), available online at <https://africacdc.org/rislnet/>; Herpolsheimer, *supra* note 36, 15.

97 A. van Aaken and B. Simsek, 'Rewarding in International Law', *The American Journal of International Law* 115(2) (2021) 195–241, pp. 240–241.

6 Conclusions: Revisiting the Promises of Legal Rules for Disease Surveillance beyond the State

The overview of existing legal frameworks for event-based or *ad hoc* disease surveillance provided in this contribution sheds light on how rules are one amongst several options for collaboration between states. Further research is needed on the added value, if any, of such rules in fostering the exchange of information between states. At times, the existence of binding obligations to notify international and regional authorities opens the door to the language of compliance when states participating in a surveillance system are not collaborating. Questions on the effectiveness of rules in fulfilling the goals of global health security will be key to debates on the future of pandemic preparedness and responses. At the same time, critical perspectives warning against placing high hopes in legal norms,⁹⁸ as well as against the perils of an overexpansive disease surveillance by states over individuals,⁹⁹ will need to be more thoroughly considered.

The current contribution does not make a case in favour of having legal obligations as the only means to ensure the sharing of disease-related information beyond the state. Ultimately, rules are a means rather than an end. The key goal remains to ensure that information about *ad hoc* or event-based disease surveillance is properly shared through different authorities, be they national, regional or international. Whether mandatory reporting is the best vehicle to secure epidemiological information, as opposed to voluntary cooperation, depends on subjective issues which are difficult to measure. At the same time, once legally enshrined obligations are chosen as the basis for reporting to international and supranational authorities, questions concerning legal interpretation of rules and what their effective implementation entails become inevitable. Any debates on potentially reforming existing legal instruments will have to address the question of whether and to what extent rules offer an added value in guaranteeing effective sharing of information between states.

98 S. Harman, 'Norms Won't Save You: Ebola and the Norm of Global Health Security', *Global Health Governance* VI (2016), available online at <https://blogs.shu.edu/ghg/2016/04/25/norms-wont-save-you-ebola-and-the-norm-of-global-health-security/>.

99 S. Sekalala, S. Dagon, L. Forman and B. Meier, 'Analyzing the Human Rights Impact of Increased Digital Public Health Surveillance during the Covid-19 Crisis', *Health and Human Rights Journal* 22(2) (2020) 7–20, pp. 11–12.

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