How to deal with pandemics

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A. Pandemics: A global governance problem

Pandemics are a threat not only to countries where an outbreak of a new or known virus could be observed. Due to the international travel and trade and its speed of exchange of people and goods pandemics represent a worldwide threat to public health. They represent a global governance problem. Control of infectious diseases - and pandemics are per definition a transnational sub-type - represents a global public good.[1] Every reduction of disease prevalence in one country has benefits in many other countries. Without collective action on a more or less worldwide level a fight against pandemics is not efficient. The legal frame is therefore necessarily an international frame and part of international (public) law.

I. International health law: A long tradition

Although international health law seems to be a relatively new topic in scholarly discussions[2], it has a remarkably long tradition in practise.[3] Early modern attempts to standardise aspects of public health were the International Sanitary Conferences.[4] The first were organised by the French Government in 1851 to standardise international quarantine regulations against the spread of cholera, plague, and yellow fever. Quarantine measures had been the traditional answer to these kinds of threats.

Epidemics were facilitated by technological developments in production, trade, shipping and travelling, which lead to an increased movement of goods and people. The importance of intensified international trade made it more and more inefficient to close boarders and ports and to quarantine people. An important motive for international cooperation emerged.[5] The fourteen conferences, which took place before 1938, are often regarded as providing a sound basis for the institutionalisation of the World Health Organisation in 1948.[6] But the picture is

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1 *Smith* (2009), 124.

2 *Gostin* (2014); *Flood and Lemmens* (2013), 1; *Haffeld, Siem and Røttingen* (2010), 614 et seq.; Compared to the scholarly interest in international trade law the international health law is obviously far less developed; *Condon and Sinha* (2009), 25.

3 Cf. the table with the conventions, treaties etc. in *Fidler* (1999/2000), 17 et seq.

4 *Berend*t (2009).

5 Cf. *Berridge, Loughlin and Herring* (2009), 30 et seq.

6 *Lee* (2009); *Gostin and Mok* (2009).

more complex.[7] The conferences were motivated by concerns about political and economical interests and not really successful until 1903. The Paris Conference was successful insofar as the first convention ratified afterwards was negotiated there.[8] This was obviously fostered by new outbreaks of cholera epidemics (1883, 1897); it was embedded in the internationalisation of nongovernmental and governmental organisations, the development of medical science and practise as well as its institutionalisation on an international level, by social, religious and philanthropic movements during the second half of the nineteenth century.[9]

It was recommended in 1903 to establish the Office International d'Hygiène Publique (OIHP), which was founded in 1907.[10] Its function was to maintain communication with meanwhile established regional sanitary councils and health offices of various countries and collect and disseminate all relevant epidemiological data.[11] *In nuce* this was the institutional and functional blueprint of later schemes: coordination, surveillance, harmonisation of interventions, and communication within a network of public health authorities and public health experts. This architecture was the result of a long process of institutional development, but came into being only after being set up by international law.

This does not mean that international law has been the preferential governance instrument of the WHO.[12] To the contrary, the WHO adopted only four binding international legal instruments, beside the fact, that the organisations itself were institutionalised by law. The International Health Regulations (2005) constitute one of these legally binding instruments.[13] The limited use of international law as instrument may be fostered by the medical-technical professional orientation of this sector and in particular that of the WHO.[14]

But, over time, the governance frame became more and more complex, this orientation became insufficient to solve the underlying political conflicts, and the frame embraced not only nation states and international organisations like the World Health Organization (WHO) but also nongovernmental organisations as well as other private-sector stakeholders.[15] This

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7 *Berridge, Loughlin and Herring* (2009).

8 Conférance sanitaire internationale de Paris, 10 octobre – 3 décembre 1903; documents are available at: http://pds.lib.harvard.edu/pds/view/7482556.

9 *Berridge, Loughlin and Herring* (2009).

10 *Berendt,* (2009), p. 18-24.

11 *Berridge, Loughlin and Herring* (2009).

12 *Taylor, Alvén, Hougendoubler and Buse* (2014), 72 ff.; *Fidler* (1999/2000), 1 et seq.

13 Cf. under B. I. 2.

14 *Fidler* (1999/2000), 21 et seq.

15 *Smith* (2009), 124 et seq.

also poses challenges for the international frame, often discussed under the umbrella of a shift from international to global health governance;[16] this fuelled the scholarly interest in international (public) health law, be it of binding or nonbinding nature.[17]

II. What is a pandemic?

A pandemic is an epidemic occurring worldwide, or in a very wide area, crossing international boundaries and usually affecting a large number of people.[18] New cases of a given disease, in a given human population, and during a given period of time, which substantially exceed what is expected based on recent experience, are called an epidemic.[19] Epidemics occur, at least as far as infectious diseases are concerned, when an agent and susceptible hosts are present in adequate numbers, and the agent can be effectively conveyed from a source to the susceptible hosts.[20] More specifically, an epidemic may result from:

- a recent increase in amount or virulence of the agent,
- the recent introduction of the agent into a setting where it has not been before,
- an enhanced mode of transmission so that more susceptible persons are exposed,
- change in the susceptibility of the host response to the agent, and/or
- factors that increase host exposure or involve introduction through new portals of entry.[21]

To cut it short, epidemics of infectious diseases are generally caused by a change in the ecology of the host population, a genetic change in the parasite population or the introduction of a new parasite to a host population.

III. The importance of knowledge, institutions and international cooperation

The long tradition of fighting infectious diseases internationally reveals some core aspects of the governance frame: the importance of various corpora of knowledge, the need for institutions, be it international, regional or national institutions, and international cooperation.

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16 *Lee* (2009), 99 et seq.

17 *Taylor, Alvén, Hougendoubler and Buse* (2014), 72 et seq.; *Gostin and Taylor* (2008).

18 *Porta* (2008), 179, The WHO uses a similar definition in its 1999 preparedness plan: "The pandemic will be declared when the new virus sub-type has been shown to cause several outbreaks in at least one country, and to have spread to other countries, with consistent disease patterns indicating serious morbidity is likely in at least one segment of the population;" *WHO* (1999).

19 *US CDC* (2012), 1 et seq.

20 The term outbreak, which is often referred to in this context, is used sometimes as a synonym for epidemic or more precise as a term referring to geographically more limited events.

21 *US CDC* (2012), 1 et seq.

1. The importance of knowledge

Not different from other fields of medicine epidemiological evidence is based on experience of the past. This generates a baseline of expectations against which the unusual and unexpected could be observed. Pandemics are not standard. They differ in the virus causing them, the severity, the infectivity and reproductive number, prior immunity and the patterns of spread.[22] New patterns of spread of the same virus among a new host population might be observed, which indicates that local barriers are broken or a variation of the virus occurs with a known or unknown course or a new virus occurs and breaks the animal-human-barrier and human to human infections are identified. Obviously, events of this type would require new knowledge, typically to be generated by science.

First of all, the new virus has to be characterised and analysed. Virological, epidemiological, genetic sequencing and phylogenetic analysis is needed. Samples of blood have to be send to biological safety institutes with a sufficient safety level on a routine basis and in-depth-information of demographic and clinical situations from the environment of origin is necessary to describe the characteristic as well as possible strains of infection.[23]

Secondly, knowledge about the spread of the virus is necessary, which could be based on experience but also on statistics or mathematical modelling by using new knowledge-generating technologies[24], e.g. big data analysis tools.[25] Virus transmission or clinical representation may be altered by differences in cultural practises, the environment, geography, human and animal genetics, social structures in general.[26] Factors that may affect disease activities can be population density, differences in prevalence and spectrum of chronic illness, proximity of young and elderly, low proportion of elderly in the population, low

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22 A brief review of the progress in dealing with infectious diseases is given by *Fauci and Morens* (2012), 454 et seq., emphasising the permanent evolution of the virus and the persistence of problems although substantial progress in medical treatment has been made over the last two decades.

23 Some recent examples are the Zaire Ebola Virus in Guinea (*Blaize et al.* (2014)), the Corona Virus (*Assiri et. al.* (2013), 407 et seq.) Avian Influenza Virus A (H7N9) in China (*Li et. al*. (2014), 520 et seq.; *Writing Committee of the WHO Consultation on Clinical Aspects of Pandemic (H1N1) 2009 Influenza* (2010) 1708 et seq.; *Butler* (2013b); *Buda/Köpke/Haas* (2009).

24 Technology is not used in a technical sense but as a knowledge-generating scientific practice.

25 A vigorously discussed example is Google Flu Trends. The idea behind it is monitoring health tracking behaviours of a large number of users health tracking behaviours online. This data can be analysed to reveal a presence of flu illness in the searched population, compared to historical baseline levels of incidence. Cf. *Ginsberg, Mohebbi, Patel, Brammer, Smolinsky and Brilliant* (2009), 1012-1014; A recent critic reveals a lot of gaps in the algorithm based approach; *Lazar, Kennedy, King and Vespignani* (2014), 1203 et seq.; *Butler* (2013a).

26 *Ortiz, Sotomayor, Uez, Oliva, Bettels, McCarron, Bresee and Mounts* (2009), 1272.

school attendance and even school schedules that may or may not correspond with peak transmissibility season,[27] just to mention a few factors. In computer-based simulation studies other factors came to the fore. Examples are the functioning of the local public health system, the processing of society under stress of a severe event, the behaviour of professionals in situations of an epidemic or a pandemic, the supply of antiviral drugs, airplane schedules and flight routes[28], shipping routes etc., to mention some other factors.[29] And influenza never affects all localities in the same way at the same time. This is true for seasonal influenza surveillance data and is also true for pandemic. The ECDC therefore suggests considering a pandemic as a series of overlapping epidemics that causes problems of its own.[30]

Thirdly, knowledge about the effectiveness of interventions is necessary. This knowledge could again be based on experience but it could also be of scientific nature and derived from mathematical modelling. Basically, this relates to pharmaceutical and non-pharmaceutical measures. Although it might be counterintuitive to the common understanding of the effectiveness of non-pharmaceutical measures, e.g. income travel inspections or quarantine measures it is safe to say that scientific evidence of public health measures contains more gaps than certainties and a review of the scientific studies displays significant holes.[31]

2. The institutionalisation of a surveillance scheme

The process of generating knowledge does not come by itself in the usual proceedings of the science system. The generation has to be organised within the public health system, science and medical professional system and among different actors, be it state or non-state actors. In particular, continuous monitoring and a knowledge-generating infrastructure to identify and analyse possible new threats has to be institutionalised.

Public Health surveillance as a function of every public health system has a very long tradition.[32] In Germany it dates back at least to the work of Johann Peter Frank[33] in the late 17th century, who conceptualised the general overview and control of health as part of the internal security of the state (Polizeiwissenschaft). Other important names might be Edwin

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27 *Ortiz, Sotomayor, Uez, Oliva, Bettels, McCarron, Bresee and Mounts* (2009), 1272.

28 *Butler* (2013b).

29 *Timpka, Eriksson, Gursky, Nyce, Morin, Jenvald, Strömgren, Holm and Ekberg* (2009), 305 et seq.; cf. *WHO* (2011a), 66 et seq.; ECDC (2009), 9.

30 *ECDC* (2009), 10.

31 *ECDC* (2009), 9; see Figure 2 B III.

32 *Choi* (2012); *Declich and Carter* (1994).

33 *Franck* (1779).

Chadwick (1800-1890), William Farr (1807-1883) in England, Louis-René Villermé (1782-1863) in France, Lemuel Shattuck (1793-1859) in the US. But the initial precondition was the upcoming statistics as science and practise of the modern state to generate knowledge, which represents a new form of governance in the second half of the 19th century.[34] Institutional expressions of this development were the register offices and statistical bureaus founded in the 19th century.[35] Important sectors of society were addressed by reporting obligations and one of the most prominent sectors was the medical field,[36] in particular infectious diseases.[37] Surveillance therefore developed as part and factor of the rise of the modern national state and the rationalisation of governance techniques. But, at the same time, the institutes' medical surveillance of the national states, the internationalisation of trade and travel made it necessary to look for international harmonisation at least of interventions and, as a precondition, also an international surveillance mechanism.[38] More and more an international network emerged as the world (!) needs to be monitored, in particular those hot spots where, based on the experience of the past, events of outbreaks tend to occur. The institutionalisation of an international surveillance scheme lies at the heart of international attempts of global health actors dealing with infectious diseases.

Initially, surveillance has to be carried out in a decentralised, local, regional and nationwide approach. The national, regional and local surveillance authorities need knowledge required to carry out the surveillance and to identify possible threats, and they need the resources of medical and epidemiological professionals as well as laboratory capacities to analyse possible threats. There should be a common interest that all necessary corpora of knowledge and resources are available to all those carrying out the surveillance. A mutual exchange of data, information, and knowledge between different layers of surveillance is necessary. And this should work on a routine basis because patterns of the unexpected may not be detected on the national or regional level but sometimes by analyses of cumulated data and vice versa. This surveillance system of different layers and cultures would only be successful if the data and information processed were standardised. [39]

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34 *Desrosière* (2005); *Schneider* (2013) 1 et seq.

35 *Schneider* (2013).

36 *Lee and Schneider* (2005); *Kuhn/Busch*, (2006); *Hüntelmann/Vossen/Czeck*, (2006

37 *Choi* (2012), 12.

38 See under A.I.

39 *WHO* (2013); *Choi* (2012), 8 et seq.

This governance scheme needs adequate resources to function effectively, which cannot be taken for granted as being the case all around the word. In the aftermath of the pandemic in 2009 with the H1N1 virus, it has come to the fore that the existing framework has considerable gaps and represents a geographical bias especially when it comes to Africa and parts of Asia. Systems of surveillance were typically found in the medium and well-resourced countries but rare in less-resourced areas. Before the outbreak of the 2009, pandemics in 54% of the member states of the WHO had no or a very limited seasonal influenza surveillance capacity,[40] for example adequate laboratory capacities.[41] The data collected were often of questionable quality and comparability due to a lack of worldwide standardisation.[42] Although the existence and the effective functioning of a surveillance mechanism seems to be a global public good, the reality of international cooperation and sharing of important capacities and resources is different. One of the challenging problems seems to be a fair distribution of resources, including that of vaccines and antivirals among developed and developing countries.[43]

3. Uncertainty as part of the scheme

Any frame to deal with pandemics is inherently complex as various resources have to be pooled and various actors of the public health systems have to cooperate - be it public or private entities.

And, last but not least, every management of a pandemic faces political and societal challenges of various kinds. The report on the implementation of the International Health Regulations (2005) summarises the problem as follows: "In practice, however, decision-making in a public-health emergency is often based on incomplete information, with uncertainty about the threat and the likely effectiveness of response measures. Plans must typically be adapted to the actual circumstances of the event. There may be competing demands within the health system and other sectors, and constraints imposed by limited resources. In a public-health emergency, decision-makers often face political scrutiny and pressure from the public and media. The ability to take informed action, despite the uncertainty dictated by the speed of events, is the essence of crisis management."[44]

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40 *Briand, Mounts and Chamberland* (2011), 1.

41 *Briand, Mounts and Chamberland* (2011), 8.

42 *Briand, Mounts and Chamberland* (2011), 8.

43 *Krishnamurth and Herder* (2013), 272 et seq.

44 WHO (2011a), 27; for an analysis of the Mexican situation *Condon and Sinha* (2009).

But, it is safe to say, that a high degree of uncertainty is part of the game - even when it comes to the scientific characterisation of a potential threat and possible interventions to reduce the risk of a large-scale dissemination.[45]Again, the information basis is crucial, also for decision-making about interventions, because a biased information basis may lead to an overestimation or underestimation of the severity of an outbreak.

4. Inequalities: The gap between developing and developed countries and between rich and poor

Social determinants, e.g. social and economic factors on an individual and structural level contribute to health disparities.[46] This is also true for pandemics. Various factors are part of the problem: Resources decide about the functioning of a surveillance scheme due to the fact that knowledge of well trained professionals is needed and resources are necessary to exercise these surveillance and monitoring functions. Resources are also decisive for the functioning of the public health system in general and its ability do deal with the consequences of a pandemic. This relates to the distribution of vaccines and antivirals as a typically scarce resource.[47] But it also relates to inequalities in the distributions of burdens and advantages that are important incentives to cooperate within a worldwide mechanism to deal with pandemics. Although the control of infectious diseases might represent a global common good,[48] aspects of social justice are essential preconditions for a functioning of a worldwide mechanism. [49] The fair distribution of resources, medicines and vaccines and a fair commitment to reciprocity are important aspects to deal with pandemics.[50] And it is not only about the social determinants of public health but also about also normative environment, e.g. ethics, individual freedoms, international trade and food regimes and international treaties on intellectual property. The challenge might be that such a goal can only be reached within a complex frame including states, agencies, formal and informal collaborations of states and agencies,[51] international regimes and other public and private actors.[52] The revision of the

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45 *Lipsitch, Cauchemez, Ghani and Ferguson* (2009), 112 et seq.; *Feufel/Antes/Gigerenzer*, (2010).

46 *WHO* (2011b); *Prinja, and Kumar* (2009); *US CDC* (2011); European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU, P7_TA (2011) 0081; European Commission, Report on health inequalities in the European Union, 2013, SWD (2013) 328 final; *Bell, Taylor and Marmot* (2011); *Heywood and Shija* (2010); *Krishnamurthy* (2013).

47 *Brech* (2008); *Buccieri and Gaetz* (2013); *WHO* (2007).

48 *Kickbusch, Hein and Silberschmidt* (2010).

49 *Gostin and Mok* (2010).

50 *Krishnamurthy* (2013).

51 For example initiatives such as the Global Health Security Initiative. The GHSH was founded after 9/11 for fighting bioterrorism. The members of this Initiative comprise the US, Canada, Japan, Mexico, several European states, the EU Commission and the WHO. They intend to

WHO surveillance scheme 2011[53] might be seen as a consequence of the changing role of the WHO as an actor to coordinate the provision of global public goods within this changed regulatory environment.

B. The legal design of the administrative network: the international dimension

The legal design of the international administrative network is complex if all relevant aspects were to be included in the picture. As mentioned above, it is not a single issue to deal with pandemics. A lot of different legal provisions and legal regimes would have to be taken into consideration if a full picture were to be displayed. This would include freedoms as well as security provision, it should include aspects of trade - also international regimes of trade - it should also deal with intellectual property rights as well as with ethical issues of a fair distribution of resources (Figure 1).

Instead, the following part concentrates on the core of the multi-level regulation of pandemics, the surveillance and monitoring system as well as possible interventions. Even this focus will be narrowed to a certain degree. This overview will not include the regulation of animal diseases, which is done under the umbrella of other international organisations such as the FAO and the OI. Although a critique of the existing scheme deals with the institutional split into two different strains of surveillance, it would add even more complexity to the still complex frame.

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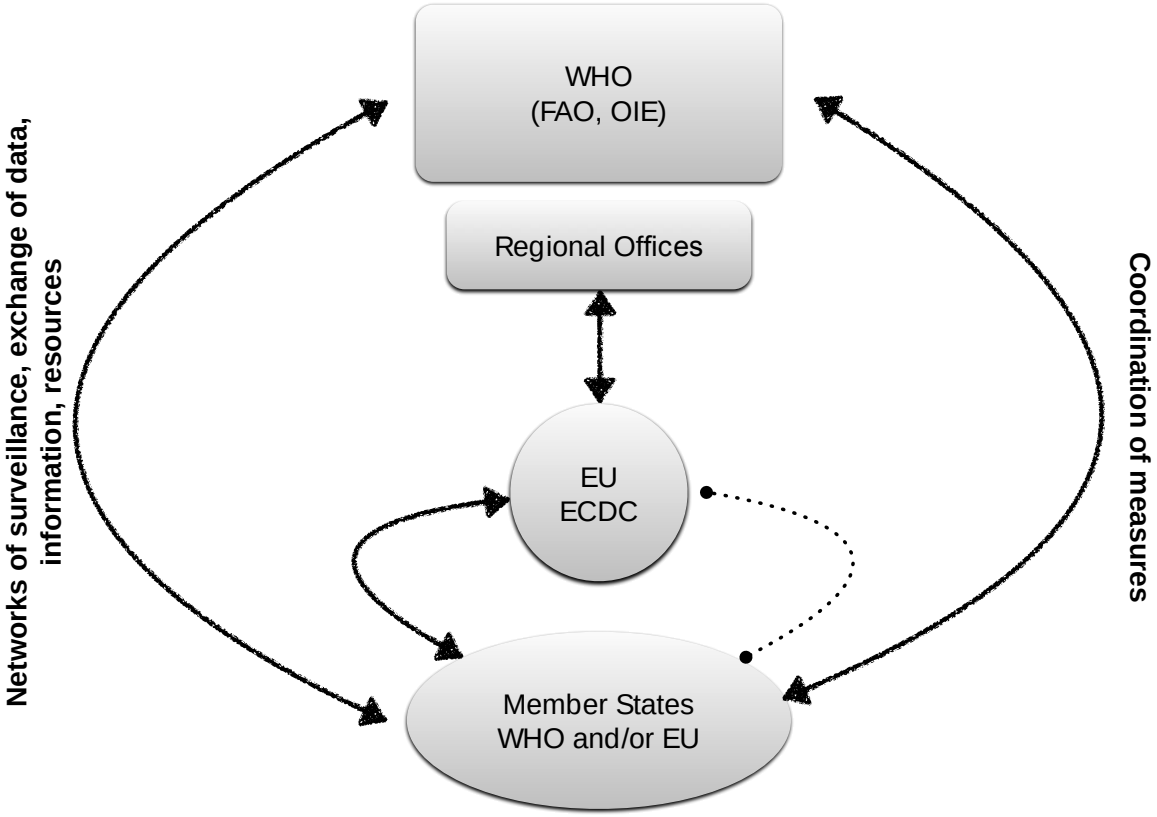
strengthen the preparedness and response to the threat of bioterrorism but have overlapping interest in the strengthening of surveillance instruments and harmonising interventions; http://www.ghsi.ca/english/background.asp.

52 *Kickbusch, Hein and Silberschmidt* (2010).

53 See B. II.



I. The WHO as central node in the international administrative network

Although the regulatory environment of the WHO has changed over the past few decades, the WHO is still the central node in the network of surveillance, monitoring and intervention. Its role and function might have shifted more to a coordinator of a plurality of institutions and a mediator of various interests.

When it comes to the use of law as an instrument it is often argued that the professional orientation of the WHO towards the international medical community[54] was one of the reasons why the WHO did not make use of international law in the past, despite the long tradition of treaties and regulations mentioned above. This might be true, but this orientation could also be read as a precondition for the institutionalisation of an information infrastructure all over the word and for standardising the information to be provided, because the reference to the medical community in the member states could be seen as an instrument to de-politicise an agenda.[55] Of course, there is a dark side of this argument, because some of

54 *Fidler* (1999/2000).

55 The experience of cooperative federalism in Germany provides good examples of the effectiveness of such professional communities, often as administrative communities of practise, operating beneath the radar of politics.

the conflicts about fair distribution of resources and a more technocratic approach to the prioritisation of vaccine and antivirals could be a repercussion of that professional orientation.

1. Constitution of the WHO

The World Health Organization is the central actor within the international administrative network. According to the Constitution of the WHO, its objective shall be the attainment of the highest possible level of health by all peoples (Art. 1 Const. WHO).[56] The functions of the WHO shall be among others to act as the directing and co-ordinating authority on international health work (Art. 2 (a) Const. WHO), to establish and maintain effective collaboration with the United Nations, specialised agencies, governmental health administrations, professional groups and such other organisations as may be deemed appropriate (Art. 2 (b) Const. WHO), to assist Governments in strengthening health services (Art. 2 (c) Const. WHO), to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of governments (Art. 2 (d) Const. WHO), to establish and maintain such administrative and technical services as may be required, including epidemiological and statistical services (Art. 2 (f) Const. WHO), to stimulate and advance work to eradicate epidemic, endemic and other diseases (Art. 2 (g) Const. WHO) and to propose.

According to conventions, agreements, regulations and recommendations with respect to international health matters (Art. 2 (k) Const. WHO Art. 19, 21 Const. WHO), there are basically two provisions for secondary legislation by the WHO. Art. 19 Const. WHO confers the authority on the Health Assembly to adopt conventions and agreements, which will come into force for member states when accepted by it in accordance with its constitutional process. Art. 21 Const. WHO confers the authority on the Health Assembly to adopt regulations, which will - according to Art. 22 Const. WHO - come into force for all members after due notice has been given of their adoption by the Health Assembly except for such members as may notify the Director-General of rejection or reservations within the period stated in the notice.

[56] This wording is also an essential part of the right to health in international covenants; cf. e.g. Art.12 International Covenant on Economic, Social and Cultural Rights, Art. 25 Convention on the Rights of Persons with Disabilities.

2. The International Health Regulations (2005): the basic legal frame

The International Health Regulation 2005[57] is the essential international frame in fighting pandemics. It is based on articles 2 (k), 21 (a) and 22 Const. WHO. The IHR is the result of a long evolution of international law in this field.[58] It is legally binding according to the procedure laid down in Art. 22 WHO Const.

The purpose and scope of this regulation is to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.[59] To this end, the IHR comprises rights and obligations of the member states and the WHO concerning national and international surveillance, assessment and public health response, health measures applied by states parties to international travellers, aircraft, ships, motor vehicles and goods, public health at international ports, airports and ground crossings and many other subjects. The scope of the regulation covers a wide range of risks including biological, chemical or radio-nuclear origin[60] risks and those potentially transmitted by persons, goods, food, animals, vectors or the environment.[61]

The IHR establishes some principles for the implementation.[62] In the context of the rule of law, it is interesting to note that the first principle refers to fundamental freedoms. The implementation of the regulation shall be with full respect for the dignity, human rights and fundamental freedoms of persons.[63] Whether or not this has an impact on the proceedings of the member states remains an open question. The WHO has no mandate for monitoring

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57 *WHO* (2005), The revision of the IHR in 2005 aimed at improving the reporting obligations as well as the harmonization of possible interventions. Member states did often not comply with the IHR (1969) due to the risk of severe economic losses caused by disproportionate intervention from third state parties concerning travel restrictions; *Condon and Sinha* (2009), 10; see also A.III.4.

58 See above.

59 Art. 2 IHR. The reference to traffic and trade represents the long tradition of harmonising interventions. The importance of this aspect for the willingness of a state to report on possible health threats to the WHO is a major concern of states; the economic effects of a pandemic can be serious; cf. *Condon and Tapen* (2009), 2 et seq.; *Congressional Budget Office* (2006).

60 While the majority of the communications are expected to relate to communicable disease outbreaks, the broad scope of the IHR (2005) may require carrying out activities with respect to events arising from non-communicable or unknown etiologies, including chemical or radio-nuclear. Accordingly, the required informational and communications functions and capacities must be established for these areas as well as those concerning communicable disease; cf. *WHO* (2009), International Health Regulations.

61 Art. 1.1 IHR.

62 Art. 3 IHR.

63 Art. 3 Sect. 1 IHR.

violations of human right und does not exercise any supervision on informal basis, as far as it is publicly known.[64]

The second principle is the guidance provided by the UN Charta and WHO Const. The implementation should also consider the goal of the universal application of the IHR for the protection of all people of the world from the international spread of the disease.[65] And the fourth principle highlights state sovereignty in legislating and implementing legislation in pursuance of their health policies. Of course, these principles leave room for discretion in the implementation of the IHR, but they should uphold the purpose of the regulations.

3. The establishment of a public health network

One of the main goals of the IHR (2005) is to establish a surveillance network. As already mentioned global surveillance is an essential precondition for monitoring, analysing and managing pandemics [66] and the underlying dynamics of change of viruses as well as population and other conditions of spread of an epidemic. Systems of surveillance therefore do not only tackle the problems of early warning and the management of an epidemic event but also contribute to the knowledge about pandemics. A reliable and robust *worldwide* network of surveillance is one crucial element in any strategy to deal with pandemics.

a. National IHR Focal Points

A central element of the IHR is the concept of National IHR Focal Points.[67] The National IHR Focal points are institutions accessible at all times for communication, and vice versa the WHO also designates IHR Contact points accessible for communications at any time.[68] The functions of National IHR Focal Points shall include (a) sending to WHO IHR Contact Points, on behalf of the state party concerned, urgent communications concerning the implementation of these regulations, in particular under Articles 6 to 12 and (b) disseminating information to, and consolidating input from, relevant sectors of the administration of the state party concerned, including those responsible for surveillance and reporting, points of entry, public

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64 A critical assessment is given by *WHO* (2011a), 78 et seq. This is in stark contrast to the concerns of international traffic. The first temporary recommendation during the pandemic 2009 dealt with the avoidance of restrictions of international traffic and trade etc.

65 Art. 3 Sect. 3 IHR.

66 *Briand, Mounts and Chamberland* (2011), 1.

67 According to the definition in Art. 1.1 IHR (2005), National IHR "Focal Point" means the national centre, designated by each state party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations.

68 Art. 4 Sect. 2, 3 IHR.

health services, clinics and hospitals and other government departments.[69] Together they form a first layer of the administrative network and they might be called the backbone of the surveillance network.[70]

b. Public Health Emergency of International Concern (PHEIC)

An important term of this network is a *public health emergency of international concern* (PHEIC). This PHEIC is the trigger of many operations within the network. It is defined in the IHR as meaning an extraordinary event constituting a public health risk to other states through the international spread of disease and potentially requiring a coordinated international response.[71] Basically, two different aspects have to be distinguished: Obligations for notification and information of actors within the network do initially not require the determination of a PHEIC but are triggered in cases which may constitute a PHEIC in the near future. Therefore, the frame follows a precautionary approach. Being a trigger to various obligations and a basis of measures it is of importance which node in the network can determine the situation as being a PHEIC.

The determination of a PHEIC lies with the Director-General of the WHO. After a consultation with the state in whose territory the event occurred and which may or may not result in consent about the conditions of a PHEIC, the DG has to follow material and

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69 Art. 4 Sect. 2 a, b IHR. An example of the national legislation might be the case of Germany: Article 2 The National IHR Focal Point within the meaning of Article 4, Para. 1 of the IHR (2005) shall be the situation centre of the Federal Ministry of the Interior. It shall perform the functions cited in Article 4, Para. 2 IHR (2005), in cooperation with the national authorities and institutions which are responsible for preventing and controlling the health risks covered by the IHR (2005), in particular with the Robert Koch Institute as regards preventing and controlling communicable diseases. Article 3 Section 12, Para. 1 of the Protection Against Infection Act of 20 July 2000 (German Federal Law Gazette (BGBl.) I, p. 1045), last amended by Article 57 of the Ordinance of 31 October 2006 (German Federal Law Gazette (BGBl.) I, p. 2407), shall be amended as follows: 1. Sentences 1 and 2 shall read as follows: "Without delay, the local public health office shall notify the competent [German] Land authority, which shall in turn notify the Robert Koch Institute, of the following: 1. the occurrence of a communicable disease, circumstances which point to the occurrence of a communicable disease, or circumstances which may lead to the occurrence of a communicable disease, if, pursuant to Annex 2 of the International Health Regulations (2005) (IHR) of 23 May 2005 (German Federal Law Gazette (BGBl.) 2007 II, p. 930), the communicable disease might constitute a public health emergency of international concern within the meaning of Article 1, Sect. 1. 1 IHR 2. the measures taken, 3. other information which is significant for assessing the circumstances and for preventing and controlling the communicable disease. The Robert Koch Institute shall assess the received information pursuant to Annex 2 IHR and, in accordance with the requirements of the IHR, shall arrange for the communications with the World Health Organization via the National IHR Focal Point."

70 According to the evaluation they function as excellent global communication system; cf. *WHO* (2011a), 67 et seq.

71 Art. 1.1. IHR (2005); *Berendt,* (2009), p. 207 et seq.; Criteria for decision making purposes are defined in Annex II of IHR 2005 relation to three questions: Is the public health impact of the event serious? Is the event unusual or unexpected? Is there a significant risk of international spread? Annex II and its criteria seem to be a very useful tool for constituting and running a surveillance architecture at the member states level; *WHO* (2011a), 68.

procedural requirements, being set up in Art. 12, Art. 49 IHR 2005. The determination is a risk decision. According to Art. 12 Sect. 4 IHR (2005), the DG shall consider information provided by the state (in whose territory the event occurred), the criteria of the decision instrument in Annex II,[72] advice of the Emergency Committee, scientific principles as well as the available scientific evidence and other relevant information and an assessment of the risk to human health and of the risk of international spread of the disease and of the risk of interference with international traffic. The procedure displayed in Art. 49 IHR (2005), referred to in Art. 12 Sect. 2 IHR (2005), constitutes interplay between the DG and the Emergency Committee. This committee is part of a knowledge-generating infrastructure of the WHO. It is set up by the DG with experts from the IHR expert roster of the WHO.[73] It shall be composed of selected experts on the basis of expertise and experience for any particular session (!) with due regard to the principle of equitable geographical representation.[74] Upon request of the DG it has to provide its view on the question whether an event constitutes a PHEIC, whether a PHEIC should be terminated and its view on the proposal or termination of temporary recommendations.[75]

c. Notification, assessment and information

The first obligation is a notification in cases that may constitute a PHEIC.[76] This obligation also includes information about any measure implemented as a response to the event. Subsequent to the notification the state is obliged to continue the communication with the WHO in giving information available in a timely, accurate and sufficiently detailed manner. It includes case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the disease and health measures employed, and, when necessary, the difficulties faced and the support needed in responding to the potential PHEIC.[77] The same obligation applies to evidence of an unexpected or unusual health event within the states

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72 Cf. Fn. 71.

73 Art. 47 IHR (2005); *Berendt*, (2009), p. 154 et seq.

74 Art. 48 Sect. 2 IHR (2005). The members of the EC are recruited on an ad hoc basis and remain anonymous, an often discussed issue of transparency. The reason seems to be a high pressure from pharmaceutical industry as well as from affected states; for a detailed discussion *WHO* (2011a), 78 et seq.

75 Art. 48 Sect. 1 IHR (2005).

76 Art. 6 Sect. 1 IHR (2005). For using the criteria set up Annex II the WHO issued guidance; cf. WHO Guidance for the Use of Annex 2 of the IHR (2005) Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern, 2008.

77 Art. 6 Sect. 2 IHR (2005).

territory irrespective of its source and origin, which may constitute a PHEIC.[78] According to the evaluation of the IHR, the criteria to provide a better reliability and validity could be more detailed.[79] And, there seem to be indications for a delayed notification due to political interference.[80]

Pursuant to Art. 10 Sect. 1 IHR (2005) the WHO has to send in confidence all state parties within the network and, as appropriate, relevant intergovernmental organisations the information it has received under Art. 5-10 IHR (2005) which is necessary for the states to respond to a public health risk. The information it has received under Art. 6, Art. 8, Art. 9 Sect. 2 IHR (2005) - mainly information for verification, assessment and assistance purposes - should only be sent if the event is determined to constitute a PHEIC or information evidencing the international spread of infection or contamination has been confirmed by the WHO in accordance with established epidemiological principles or there is evidence of a failure of control measures or state parties lack sufficient operational capacities or the nature and scope of the international movement of goods and persons require immediate application of international control measures. Under limited circumstances the WHO could also inform the public.

d. Using other sources of knowledge

Given the tendency of states to hide or obscure public health events or to delay information of partners in the network the question might be as to whether the WHO and the network may use knowledge from other sources than that of the respective state in which an event might have occurred. Obviously this is a very sensitive issue as it would constitute bypasses for the state and might cause political interferences, which might also impede the ability to sufficiently respond to a potential PHEIC. This information might stem from other states[81] as well as private sources and they might be used instrumentally. Therefore, Art. 9, Art.10 IHR (2005) open these sources, but establish conditions that must be met before the information can be used within the network. This information, at least in certain cases, its origin is not

78 Art. 7 IHR (2005). In cases in which these conditions are not met the state may nevertheless through its National IHR Focal Point keep the WHO advised and seek consultation (Art. 8).

79 *WHO* (2011a), 69 et seq.

80 *WHO* (2011a), 70; This problem is anything but new. It is an essential part of the efforts to improve reporting obligation; *Condon and Sinha* (2009), 2 et seq.

81 The states are obliged to report to the WHO if they receive evidence of a public health risk outside their territory which may constitute a PHEIC; Art. 9 Sect. 2 IHR (2005).

another state or NFP, [82] has to be assessed by the WHO according to established epidemiological principles and some procedural requirements must be met before using the information within the network and before taking any action. In cases like these, the WHO should try to verify the information and should therefore request a report from the state affected by this event allegedly occurring within its territory. According to Art. 10 Sect. 2 IHR (2005), the state is obliged to reply within 24 hours and make available public health information on the status of events referred to in the request and has to provide information due to the normal assessment procedure laid down in Art. 6 IHR (2005).

e. Temporary recommendations

If it has been determined in accordance with Art. 12 that a public health emergency of international concern is occurring, the DG shall issue temporary recommendations in accordance with the procedure set out in Art. 49 (Art. 15 IHR). [83] Temporary recommendations may include measures for the travel of people, medical inspections, review proof of vaccination or other prophylaxis, vaccination or other prophylaxis, public health observation of suspected persons, implementation of quarantine or other health measures for suspected persons, isolation or treatment, refuse of entry into an area or country, tracing of contacts, entry or exit screening. Also recommendations with respect to baggage, cargo, containers and the like can be issued (Art. 18 IHR). All recommendations have to meet some procedural and substantive criteria, i.e. views of the states directly concerned, scientific principles, principle of proportionality with respect to restrictions on international traffic, international standards.[84]

II. Pandemic Influenza Preparedness Framework (PIP): A new approach

The Pandemic Influenza Preparedness Framework[85] (PIP) is the outcome of a negotiation process between the WHO, member states, industry actors and NGOs in an attempt to fill important gaps of the influenza surveillance and response system that became obvious in the

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82 This seems to be the understanding of the evaluation committee and also be the practise of the WHO: *WHO* (2011a), 71.

83 *Berendt*, (2009), p. 302 et. seq.

84 The compliance of the member states seems insufficient. During the pandemic in 2009, after declaration of a PHEIC, the DG issued temporary recommendations recommending only limited travel and trade restrictions. To the contrary many states applied very restrictive measures causing a lot of economic losses to countries like Mexico; cf. *Condan and Sinha* (2009).

85 Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, WHA 65.4, 2011 (PIP).

follow up and evaluation process of the pandemic response to the 2009 pandemics.[86] The differences between the developed countries and the developing countries about a fair sharing of burden and advantages under the umbrella of distributive justice also played a crucial role, following the Indonesian case in 2006/2007. In 2006, Indonesia resumed sending virus specimens to the GISN due to complaints that scientists used the data derived from the Indonesian samples for publications and an US-based manufacturer sought patent protection for vaccine developed from Indonesian samples.[87] The logic behind this is: The developing countries share the virus samples, the developed countries and the manufactures based in these countries produce vaccines with the information derived from these samples and the developing countries have to pay the price for these vaccines afterwards, which they often cannot afford. This obviously goes along with other aspects like intellectual property law, ownership and mandatory licensing, just to mention a few. To cut it short: The former scheme of GISN was contested as being extremely biased against developing countries.[88]

The PIP scheme was adopted after years of discussion in accordance with Art. 23 WHO Const.[89] and represents a recommendation to the member states and a kind of informal agreement with other stakeholders participating in the negotiation process, e.g. the pharmaceutical industry.[90] PIP is best understood as a complement to the general surveillance network displayed before.

The objective of the Pandemic Influenza Preparedness Framework is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient and effective system on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits.[91] This Framework applies to the sharing of H5N1 and other influenza viruses with

86 *WHO* (2011a).

87 For an in-depth analysis *Krishnamurthy and Herder* (2013), 274 ff.

88 A.III.4.

89 According to Art. 23 IHR the Health Assembly shall have authority to make recommendations to members with respect to any matter within the competence of the organisation.

90 Different from the official WHO Press Release of April 17 2011 "Landmark agreement improves global preparedness for influenza pandemics" following the negotiation process it is not a legally binding legal regime and in particular not for actors other than states. There would be no capacity of the WHA to adopt a legal binding regime vis-à-vis non-state parties. Of course, the WHO may conclude contracts with third parties. The Standard Material Transfer Agreement 2 (SMTA 2) under the PIP (Annex 2) might be seen as a contract.

91 PIP (Fn. 85), 2., p. 6.

human pandemic potential and the sharing of benefits but does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework.[92]

The PIP Framework establishes a network of centres, which function as the WHO global influenza surveillance and response system (GISRS). The centres are basically national facilities working under the umbrella of the WHO frame.

1. GISRS

Global influenza *virological* surveillance has been conducted through WHO's Global Influenza Surveillance Network (GISN) for over half a century. GISN has performed influenza virological surveillance since 1952. The primary aims of the system have been to monitor changes in antigenicity of influenza viruses, to guide the selection of strains for the annual influenza vaccine, and to provide virus samples for use in vaccine production. In recent years, in particular in the follow up of the pandemic 2009 the need for epidemiological data and historical data to complement the virological surveillance became clear. In consequence of this and other identified gaps the overall frame of surveillance was revised. Surveillance is now exercised by the Global Influenza Surveillance and Response Network (GISRS). The new name came into effect following the adoption of the Pandemic Influenza Preparedness (PIP) Framework in May 2011. GISRS means the international network of influenza laboratories, coordinated by WHO that conduct permanent surveillance of influenza, assessing the risk of pandemic influenza and assisting in preparedness measures.

For activities related to pandemic influenza, the WHO GISRS includes four categories of institutions and laboratories:[93] National Influenza Centres,[94] WHO Collaborating Centres,[95] WHO H5 Reference Laboratories[96] and Essential Regulatory Laboratories.[97]

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92 PIP (Fn. 85), 3.1, 3.2., p. 7.

93 For the following cf. PIP (Fn. 85), Annex 5.

94 *National Influenza Centres* or *NICs* mean influenza laboratories authorised and designated by the member state and subsequently recognised by WHO to perform a number of functions including providing PIP biological materials to the WHO GISRS in accordance with the terms of reference (PIP (Fn. 85), 4.3 p. 10). National Influenza Centres collect specimens from suspected cases of H5N1 or other unusual influenza viral infection, perform laboratory diagnosis and analysis, and distribute isolated specimens or viruses to a WHO Collaborating Centre or H5 Reference Laboratory for advanced virological analysis (PIP (Fn. 85), Annex 5, p. 49). They work as the backbone of the international network and a node of a local network and they establish scientific expertise networks in their own country.

95 *WHO Collaborating Centres on Influenza* or *WHO CCs* means influenza laboratories designated by the WHO and supported by national authorities to perform certain roles within the WHO GISRS, and which have accepted formal terms of reference from WHO. In general, they differ

The WHO Global Influenza Programme coordinates the WHO GISRS. Within each category all institutions and laboratories perform functions defined by core terms of reference. The core terms of reference for WHO Collaborating Centres are the minimum requirements that must be met by each WHO Collaborating Centre and the capacity to fulfil these is a prerequisite to designation as a WHO Collaborating Centre. Each laboratory or institution that is formally recogni´sed or designated as a part of WHO GISRS by WHO has accepted to be bound by the core terms of reference applicable to its category.[98]

2. The benefit sharing system

The first general principle of the framework is that member states through their NICs and other authorised laboratories should in a rapid, systematic and timely manner provide PIP biological materials from all cases of H5N1 and other influenza viruses with human pandemic potential, as feasible, to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating member state's choice.[99]

By providing PIP biological materials from National Influenza Centres and other authorised laboratories member states give their consent for the forwarding and use of PIP biological materials to institutions, organisations and entities, subject to provisions in the Standard Material Transfer Agreements.[100] They provide genetic sequence data and analyses, which

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from National Influenza Centres and WHO H5 Reference Laboratories in having global responsibilities and more extensive technical capacities (PIP (Fn. 85), 4.3 p. 10).

96 *WHO H5 Reference Laboratories* means influenza laboratories that have been designated by WHO in order to strengthen national and regional capacity for reliably diagnosing H5 virus infection until this capacity is more widespread; PIP (Fn. 85), 4.3 p. 10 et seq. WHO H5 Reference Laboratories are laboratories that were designated by WHO on an ad hoc basis commencing in 2005, to support the WHO GISRS in response to the emergence and spread of highly pathogenic avian influenza H5N1. These laboratories conduct influenza risk assessment and response by providing reliable laboratory diagnosis of influenza infection in humans, especially those suspected of being associated with avian influenza A (H5) viruses or other influenza viruses with pandemic potential (PIP (Fn. 85), Annex 5, p. 53). They provide laboratory services also to other countries when needed, provide expertise and laboratory support in response to an outbreak, share available gene sequences and build up scientific networks.

97 *Essential regulatory laboratories* means influenza laboratories designated by WHO located in, or associated with, national regulatory agencies and which have a critical role at the global level for developing, regulating and standardizing human influenza vaccines. Such laboratories participate in the WHO GISRS in accordance with their corresponding terms of reference (PIP (Fn. 85), 4.3 p. 10). They have performed their role for nearly four decades within the WHO GISRS, and have thereby contributed to the production of safe and effective influenza vaccines through the selection and development of candidate vaccine viruses. While they previously had no formal terms of reference with the WHO, in practice, they worked closely with both WHO and the influenza vaccine manufacturers (PIP (Fn. 85), Annex 5, p. 57.).

98 PIP (Fn. 85), Annex 5, pp. 43 et seq.

99 PIP (Fn. 85), 5.1.1, p. 12.

100 PIP (Fn. 85), 5.1.2., p. 12.

should also be shared. According to Art. 6 of the SMTA 1, neither the provider nor the recipient should seek to obtain any intellectual property rights on the material.[101] Different from this clause external sources like manufactures of vaccines or antivirals are subject to the SMTA 2, which does not exclude intellectual property rights but includes additional obligations.[102] Obviously this should cause an incentive for collaboration of third parties within the frame.

The second element of the PIP framework is the establishment of a transparent virus traceability mechanism (IVTM) in order to track in real time the movement of biological material within the GISRS together with the reports.[103]

The third element is the constitution of a benefit-sharing system.[104] Member states should, working with the WHO Secretariat, contribute to a pandemic influenza benefit-sharing system and call upon relevant institutions, organisations, and entities, influenza vaccines, diagnostics and pharmaceutical manufacturers and public health researchers to also make appropriate contributions to this system. The PIP Benefit-Sharing System will operate to provide pandemic surveillance and risk assessment and early warning information and services to all countries and provide benefits, including, where appropriate, capacity building in pandemic surveillance, risk assessment, and early warning information and services to member states. It will prioritise important benefits, such as antiviral medicines and vaccines, as high priorities to developing countries, particularly affected countries according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. PIP will build capacity in receiving countries over time for and through technical assistance and transfer of technology, skills and know-how and expanded influenza vaccine production, tailored to their public health risk and needs.

It is important to note, that the WHO will provide candidate vaccine viruses upon request as well as diagnostic reagents and test kits and other necessary elements for testing and producing vaccines. Upon request, member states with advanced laboratory and influenza surveillance capacity are urged to continue to work with WHO and other member states, particularly developing countries, to develop national laboratory and influenza surveillance

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101 PIP (Fn. 85), Annex 1; p. 31. for an in-depth analysis *Krishnamurthy and Herder* (2013), 274 et seq.

102 PIP (Fn. 85), Annex 2, pp. 33 et seq.

103 PIP (Fn. 85), 5.3, p. 13.

104 PIP (Fn. 85), 6., pp. 15 et seq.

capacity. The regulatory capacity of developing countries should be improved by the WHO and developed countries with sufficient capacities. A stockpile of vaccines will be established. The member states should urge influenza vaccine manufacturers to set aside a portion of each production cycle of vaccines for H5N1 and other influenza viruses with human pandemic potential for stockpiling and/or use, as appropriate, by developing countries.

As a measure to improve the affordability for developing countries of pandemic influenza vaccines and vaccines for H5N1 and other influenza viruses with human pandemic potential, and antivirals, member states should urge influenza vaccine and antiviral manufacturers individually to implement tiered pricing for these vaccines and antivirals.[105] As part of this approach, influenza vaccine and antiviral manufacturers should be individually urged to consider the income level of the country. Manufactures of influenza vaccine, diagnostics and pharmaceuticals, using the WHO GISRS, will make an annual partnership contribution to the WHO for improving global pandemic influenza preparedness and response. It is decided that the sum of the annual contributions shall be equivalent to 50% of the running costs of the WHO GISRS.

3. Inclusion of third parties

According to the evaluation report one of the deficits of the existing framework during the pandemics in 2009 was obviously the lack of sufficient resources of vaccines or antiviral drugs, in particular there were not enough affordable drug doses for the least developed countries. The PIP Framework tries to tackle this problem by various means. An essential aspect is the inclusion of third parties into the PIP Framework. Although they cannot be addressed formally by the PIP Framework as a recommendation addressed to member states, third parties could be included into the frame by means of contract. As mentioned before the SMTA 2 is the instrument by which especially producers of pharmaceuticals could be included. Of course, they do have an interest in getting early information about new viruses or variations of known ones to develop early and in time new vaccines or antivirals.[106] The SMTA 2 comprises different options for recipients. They can choose two out of four or six.[107] Options are e.g. a donation of 10% of real time production of vaccine, a reservation of at least 10%ı of real time pandemic vaccine production at affordable prices to WHO, a donation of at least X treatment courses of needed antiviral medicine for the pandemic to WHO, a

105 *Heywood and Shija* (2010), 643.

106 The notion of third parties more than manufacturers of pharmaceuticals; also research institutions and other institutions could be integrated.

107 PIP (Fn. 85), Annex 2, SMTA 2 Art. 4, pp. 33 et seq.

reservation of treatment courses of needed antiviral medicine for the pandemic at affordable prices, to grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect of affordable royalties, taking into account development levels in the country of end use of the products, on technology, know-how, products and processes for which it holds IPR for the production of (i) influenza vaccines, (ii) adjuvants, (iii) antivirals and/or (iv) diagnostics., to grant royalty-free licenses to manufacturers in developing countries [108] or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antivirals products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles. Other options are set for manufacturers of other products than vaccine and antivirals and additional options to consider are also included.

4. Governance aspects

The PIP Framework is coordinated by the WHO, in particular by the DG and is overseen by the WHA with advice from the DG. The Health Assembly acts according to the constitution of the WHO as directing and coordinating authority. The Director-General, consistent with its role and responsibilities, particularly in connection with collaborating institutions and other mechanisms of collaboration, will promote implementation of the Framework within the WHO and among relevant WHO‑related entities.[109]

The advisory group exercises an important function. This independent group works as resource of expertise for monitoring and evaluation purposes. They should provide evidence-based reporting, assessment and recommendations regarding the functioning of the framework. The Advisory Group will comprise 18 members drawn from three member states in each WHO Region, with a skill mix of internationally recognised policy makers, public health experts and technical experts in the field of influenza. The Group is based on equitable representation of the WHO regions and of affected countries, taking into account a balanced representation of developed and developing countries[110] and mirrors core functions of the PIP

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108 The importance of licenses, not at least compulsory licenses for developing countries and the pressure of manufacturing countries is reported in *Condon and Sinha* (2009), 23-24; for an analysis and critique on the basis of considerations about distributional justice *Krishnamurthy and Herder* (2013), 280 et seq.

109 PIP (Fn. 85), 7., p. 23.

110 PIP (Fn. 85), 7. 2.2, 7.2.3, p. 24.

framework, in particular a fair representation and balance of developed and developing countries.

III. Non-pharmaceutical and pharmaceutical measures

Measures to limit transmission of pandemic influenza are broadly divided into those that are pharmaceutical (antivirals and vaccines) and non-pharmaceutical.

The IHR (2005) also comprise provisions dealing with public health measures, which are mainly related to travel and transportation and go along with some basic requirements related to the rule of law. Art. 23 Sect. 1 IHR 2005 states that subject to applicable international agreements and relevant articles of these regulations, a state party may require for public health purposes, on arrival or departure travel information as well as review of the traveller's health documents if they are required under these regulations, medical inspections, non-invasive medical examination which is the least intrusive examination that would achieve the public health objective inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains. Additional measures may be possible but are restricted by express prior informed consent and bound by international law, national law and safety guidelines and international standards.[111] The frame also includes the right of free travel and its restrictions in cases the traveller poses a risk to public health,[112] conditions of health measures relating to entry, in particular conditions for invasive medical examination and vaccination, including respect for dignity, human rights and fundamental freedoms [113] measures for conveyance operators, in particular obligations to comply with health measures recommended by WHO, information obligation vis-à-vis passengers,[114] exemption regulations about transits of ships, aircrafts, lorries, trains and coaches.[115] On the basis of evidence or clinical signs measures such as disinfection or decontamination may be applied, the conditions of free pratique,[116] just to mention a few. It is important to note that states are not excluded from implementing additional and more intense measures, but they have to be justified.[117] According to Art. 43 Sect. 2, state parties shall, in determining whether to

111 Art. 23 Sect. 2-4 IHR (2005).

112 Art. 30 IHR (2005).

113 Art. 31, Art. 32 IHR (2005).

114 Art. 24 IHR (2005).

115 Art. 25, 27 IHR (2005).

116 Art. 28 IHR (2005).

117 This looks like minimum standards and leaves the member states a high margin of discretion to assure an advanced standard of protection. The dark side is the repercussion on third states

implement the health measures referred to in paragraph 1 of this Article or additional health measures under Paragraph 2 of Article 23, Paragraph 1 of Article 27, Paragraph 2 of Article 28 and Paragraph 2(c) of Article 31, base their determinations upon: (a) scientific principles; (b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organisations and international bodies; and (c) any available specific guidance or advice from WHO. In cases of significantly affecting international traffic they shall provide to WHO the relevant scientific information and the public health rationale for it.[118]

Non-pharmaceutical measures are often primarily considered as isolation, quarantines and forms of social distancing. They are focussed especially when it comes to rule of law aspects of fighting infectious diseases. They are not part of the international frame per se but can be recommended by the WHO as a temporary recommendation.[119] Although some of these measures had been applied during the pandemics of the 20th century, their effectiveness has not been systematically evaluated. Measures such as isolation, quarantine, infection control and social distancing were widely used during the outbreak of SARS in 2003. Although SARS highlighted the role such measures can play, their impact during a pandemic was less certain because of influenza's different clinical, epidemiological and virological characteristics.[120] Meta-reviews display a broad zone of uncertainty related to the efficiency of these "classical" instruments.[121] The Evaluation Report of the WHO emphasises this result due to the fact that measures were normally not analysed in an isolated way but in a package so that the relevance of any single measure is hard to evaluate.[122] The ECDC's guide to these health measures displays a remarkably high degree of uncertainty and a lack of sufficient and valid data about the efficiency of the "classical" non-pharmaceutical measures (see figure 2).[123] This might also become relevant with respect to the legal justification of infringements of rights of persons. The principle of proportionality demands for the adequacy of measures in

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and their economy. Whether the obligation to justify is sufficient to moderate these effects is questionable.

118 Art. 43 Sect. 3 IHR (2005).

119 See II. 2.e.

120 Evaluation Report Nr. 191.

121 *Bell et al.* (2006), 81 ff.; *Bitar, Goubar and Desenclos* (2009), 1 ff.; *Kelso, Milne and Kelly* (2009); *Lee, Lye and Wilder-Smith* (2009); *WHO* (2009), 341 ff.; *Schlaich, Sevenich and Gau* (2012), 145 et seq.

122 Evaluation Report Nr. 202 et seq.

123 ECDC (2009).

cases of infringements of rights. Although a margin of discretion would be granted to administrations in cases like this at least according to German law, a complete lack of data justifying most of the measures might be out of limits. Another serious aspect of limited sound scientific data seemed to be the compatibility of restrictions to international travel and trade with other international regimes of law, in particular that of the WTO.[124]

[124] See *Condon and Sinha* (2009), 19 et seq.

Figure 2: Effectiveness of measures

	Quality of evidence	Effective-ness	Direct costs	Indirect costs
International travel				
Travel advice	B	Minimal	Small	Massive
Entry screening	B(m)	Minimal	Large	Large
Border closure	B(m)	Minimal unless complete	Massive	Massive
Personal protective measures				
Hand-washing	B	Probably reduction of transmission	Small	Nil
Respiratory hygiene	B	Unknown but presumed	Small	Small
Mask wearing	C	Unknown	Small	Small
Early self isolation	C	Unknown but presumed	Moderate	Moderate, increased risk to carers, they will be off work
Quarantine	C	Unknown	Massive	Massive, due to lost productivity
Social distancing measures				
Travel restrictions	C (m)	Minor effects	Major	Massive, social disruptions
School closure	B (m) C	Greater effect	Moderate	Massive, children need care
Workplace closure	C (m)	Unknown	Major	Major
Home working etc.	C (m)	Unknown	Moderate	Moderate
Cancelling public gatherings	C	Unknown	Massive	Massive

Vaccination and antivirals				
All those with symptoms	A (transmission and duration of illness only)	Moderate but weak evidence	Massive	Moderate
Health and social care or exposed workers	A	Small	Major	Small
Whole population C (influenza vaccine)	B (m)	Unclear depends of antigenetic type	Massive	Major
Health and social care etc (influenza vaccine)	B (m)	As above	Massive	Major
Children first (influenza vaccine)	B (m)	As above	Massive	Major
Specific pandemic vaccine	B (m)	Minimal in first wave	Massive and prior investment necessary	Small

The table is an extract from a summary table in ECDC, Guide to public health measures to reduce the impact of influenza pandemics in Europe, 2009

The Effectiveness of Evidence is ranked A (strong), B (reasonable), C (poor), (m) signals evidence from modelling.

Pharmaceutical interventions are the application of antiviral drugs and/or vaccines. Here, we also face a problem of efficiency due to general problems of drug control and lack of time. As the latest meta-review by the Cochrane collaboration reveals, the efficiency of Tamiflu is grossly overestimated due to an obviously biased knowledge base provided by a selected publication strategy of clinical studies.[125] This comes very close to a scandal,[126] and throws light on the general problem of drug control and post market surveillance.

The second problem is obviously that until today there is no one drug which serves all pandemics but often the virus changes and there are not enough data about the efficiency of specific vaccines. Therefore, it often takes time to develop these drugs. And, if they are developed in time, it is obvious that not enough doses are at hand to supply the relevant people with the drug. Thus, every drug conception is incomplete and obviously leads to inequalities and injustice. It was mentioned above that the PIP Framework should address the

125 *Jefferson et al.* (2014): "The influenza virus-specific mechanism of action provided by producers does not fit the clinical evidence."

126 Not only loss of trust in the ability to deal with pandemics is on the list of losses. Many governments stockpiled millions of doses to be prepared for the pandemic. The US has spent more than $ 1.3 billion buying a strategic reserve; the UK government spent £ 424 millions for a stockpile. Moreover, this raises serious questions about effective drug regulation as well as public health policy decisions. Cf. The Cochrane Collaboration and BMJ, News Release of 10 April 2014. For a thorough review of the background see *Goldacre* (2014).

problem internationally as a fair balance between developed and developing countries. But of course this also raises questions of prioritisation and justifiable criteria in each country potentially affected by the pandemic.

C. The European dimension: surveillance, assistance and advice

The European Union has only limited competences in this policy field. According to Art. 6 lit. a TFEU, the EU shall have competence to carry out actions to support, coordinate or supplement the actions of the member states.[127] The fields of such action shall be, at European level, i.e. protection and improvement of human health. Furthermore, shared competences between the Union and the member states cover the area of common safety concerns in public health matters, for the aspects defined in the TFEU. According to Art. 168C TFEU Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. Moreover, the treaty emphasises cooperation with third countries and the competent international organisations in the sphere of public health (Art. 168 Sect. 3 TFEU).

Basically, two mechanisms are worth being mentioned: a surveillance system and a rapid alert and response system. According to the Dec. 2119/98/EC the EU, established a network for the epidemiological surveillance and control of communicable diseases in the community.[128] Additionally, a European agency was established as coordinating and advisory body in 2004. An in-depth analysis would also have to take into consideration the EU-citizens right to move and reside freely concerning its restrictions on grounds of public policy, public security and public health.[129]

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127 *Plug* (2013), 100 et seq.; *Schmidt am Busch* (2007), 17 et seq.; 71 et seq.; *Sander* (2004), 168 et seq.

128 Decision No 2119/98/EC of the European Parliament and the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, OJ L 268, 03/10/1998, now repealed by Art. 20 Dec. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5.11.2013.

129 E.g. Art. 29 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens and their family members to move and reside freely within the territory of the member states amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 90/364/EEC and 93/96/EEC, OJ L 158, 30 April 2004, 77.

I. Networks of surveillance, alert and response

According to Art. 1, the objective of the Dec. 2119/98/EC is to set up a network at Community level to promote cooperation and coordination between the member states, with the assistance of the Commission, with a view to improving the prevention and control, in the Community, of the categories of communicable diseases specified in the Annex of the Decision. This network shall be used for the epidemiological surveillance of listed diseases, and as early warning and response system for the prevention and control of these diseases. Epidemiological surveillance is defined as systematic collection, recording, analysis, interpretation and dissemination of data and analysis of communicable diseases and related special health issues in accordance with the WHO and other actors within this field.[130]

The surveillance network shall be established by bringing into permanent communication with one another the Commission and those structures and/or authorities which, at the level of each member state and under the responsibility of that member state, are competent at national level and charged with collecting information on the epidemiological surveillance of communicable diseases, and by establishing procedures for the dissemination of the relevant surveillance data at Community level.[131] This duplicates basically what is also done within the surveillance networks of the WHO.

The early warning and response system shall be formed by bringing into permanent communication with one another the Commission and the competent public health authorities in each member state responsible for determining the measures which may be required to protect public health.

The network relates to a permanent extended set of communicable diseases. It should establish criteria for the selection of diseases to be observed, case definitions, standardise nature and type of data and information to be collected, methods of epidemiological and microbiological surveillance, guideline of protection measures to be taken, guidelines for information of the public.[132] According to Art. 10, the competent authorities of the member states and the Commission shall foster cooperation with non-member countries and international organisations competent in the field of public health, in particular the World Health Organization.

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130 Art. 3 lit d Dec. 1082/2013/EU.

131 The informational network in this field is an example for informational networks within the community administration as a general type of coordinating administrations and creation of a common construction of reality within the community administration; cf. *Heußner* (2007).

132 Art. 3 Dec. 2119/98/EC.

II. European Centre for Disease Prevention and Control (ECDC)

Due to high administrative requirements in running networks with highly specific scientific expertise in 2004 an independent administrative agency was established by the EC, the European Centre for Disease Prevention and Control.[133] In order to enhance the capacity of the Community and the member states to protect human health through the prevention and control of human disease, the mission of the Centre shall be to *identify, assess and communicate current and emerging threats to human health from communicable diseases*.[134] In pursuing its mission the centre shall take full account of the responsibilities of the member states, the Commission and other Community agencies, and of the responsibilities of international organisations active within the field of public health in order to ensure *comprehensiveness, coherence and complementarity of action*. Therefore, the centre's tasks are search for, collection of, collation, evaluation and dissemination of relevant data, provision of scientific expertise, information of relevant policy bodies, coordination of surveillance and expertise networks[135]. The member states therefore shall therefore provide to the centre any relevant scientific and technical data, communicate with the centre and establish support with the networks under the responsibility of the ECDC.[136] The centre also runs an early warning and response system.[137]

III. Adaption of the frame

Following the revision of the IHR in 2005, the establishment of the ECDC, the broad scope of the international health law concerning cross boarder health threats, the need of an enhanced preparedness and response planning coordinated at the European level and the need to adapt the European frame to the role and functions of the WHO leads to a repealing of the Dec.

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133 Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control, OJ L 142 30.4.2004.

134 The mission is broader and comprises not only pandemics and communicable diseases: In the case of other outbreaks of illness of unknown origin which may spread within or to the Community, the centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak which is clearly not caused by a communicable disease, the centre shall act only in cooperation with the competent authority upon request from that authority.

135 Art. 3 Sect. 2, Art. 5 Regulation (EC) No 851/2004; cf. *Haas/Straetmans/Nicoll, (2009).*

136 Art. 4 Regulation (EC) No 851/2004. The ECDC runs for example the TESSy network of surveillance, which was formerly framed by the Dec. 2119/98/EU, repealed now by the Dec. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5 November 2013.

137 Art. 8 Regulation (EC) No 851/2004.

2119/98/EC, [138] including the frame of epidemiological surveillance, preparedness and response planning[139] in order to coordinate and complement national policies. It aims to improve cooperation and coordination of the member states and the Commission. It also defines more clearly the relation to the IHR (2005) and tries to strengthen the implementation of the IHR. It demands e.g. for the implementation of core capacity requirements of surveillance and response as referred to in Art. 5, Art. 13 IHR (2005).[140] Different from the Dec. 2119/98/EC is also covers alert notifications (simultaneously with notification according to Art. 6 IHR) and obligations going along with it, in particular the information, which should be given in a case of alert.[141] Following an alert notification a risk assessment procedure is set up.[142] Moreover, an emergency recognition mechanism is established. According to Art. 12, the Commission may recognise a situation of public health emergency in relation to epidemics of human influenza considered to have pandemic potential, where the Director-General of the WHO has been informed and has not yet adopted a decision declaring a situation of pandemic influenza in accordance with the applicable rules of the WHO or in cases other than that where the DG of the WHO has been informed and has not yet adopted a decision declaring a PHEIC in accordance with the IHR, and where the serious cross-border threat to health in question endangers public health at European Union level, medical needs are unmet in relation to that threat, which means that no satisfactory method of diagnosis, prevention or treatment is authorised in the European Union or, despite the existence of such a method, the authorisation of a medical product would nonetheless be of major therapeutic advantage to those affected. The sole legal effect of an emergency recognition is suspension of some requirements concerning procedures of market permission of vaccines due to the state of emergency.[143] This makes up a kind of a preliminary fast track of market permission – an important tool of producing vaccines in time in case of a pandemic.

The European approach is obviously in line with the WHO approach and partially strengthens the role and requirements of the WHO approach. Pursuant to the policy papers both

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138 Dec. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5 November 2013.

139 Art. 4 Dec. 1082/2013/EU.

140 Art. 4 Sect. 1 d Dec. 1082/2013/EU.

141 Art. 9 Dec. 1082/2013/EU.

142 Art. 10 Dec. 1082/2013/EU.

143 Art. 13 Dec. 1082/29013/EU.

institutions closely cooperate.[144] A benefit of the duplication of some elements of approach may indeed be a better implementation of core requirements by means of the European Law and the reputation of the ECDC within the network. This may be true in particular with the coordination and evaluation of the planning instruments exercised by the ECDC. Whether this is true for the duplicated surveillance networks, remains to be seen. It is not easy to see the benefits of this duplication, as the ECDC could be part of the WHO network. For the time being it adds another layer of coordination to an already complex scheme.

D. The national system: Germany as an example

The basic layer of the multi-level system of global public health administrations is constituted by the national health systems of the member states of the WHO. They carry the burden of the day-to-day exercising of the functions of the international administrative networks.

Basically, there are two major legal acts related to pandemics and epidemics.[145] The first one the Infektionsschutzgesetz (IfSG), the Protection Against Infections Act, and the second is the Gesetz zur Durchführung internationaler Gesundheitsvorschriften und anderer Gesetze (IVG DG), the Law Concerning the Implementation of International Health Regulations (2005) and other laws. As far as the latter is concerned, its content is not being displayed here due to the fact that it is an implementation of the IHR (2005), which is described above with regard to the pandemics problem.

I. The legislative and administrative design in Germany

Some introductory remarks concerning the legislative and administrative design of the German system might be useful. The German federal system is characterised as a complex mix of legislative and administrative competences. According to Art. 74 Nr. 19 BL, the federation has the concurrent legislative powers concerning measures to combat human and animal diseases, which pose a danger to the public or are communicable. Both laws mentioned above are based on this power. Pursuant to Art. 72 Sect. 1 BL the federal states shall have power to legislate as long as and to the extent that the federation has not exercised its legislative power by enacting a law.

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144 European Commission and WHO Regional Office for Europe – Joint Declaration, 2010, http://www.euro.who.int/__data/assets/pdf_file/0011/121601/RC60_edoc12add1.pdf?ua=1; *ECDC and WHO Administrative Agreement*, 2011; *ECDC* (2014), 8.

145 Of course, an intense analysis would have to take a lot of other laws and measures into consideration ranging from intellectual property law, social security law to means of research funding to complete the picture.

The execution of both laws is part of the competence of the federal states. The federal states shall execute federal laws in their own right insofar as the BL does not otherwise provide or permit (Art. 83 BL). An important exemption is the possibility of the federation to establish in addition, autonomous federal higher authorities as well as new federal corporations and institutions under public law by a federal law for matters on which the federation has legislative power (Art. 87 III BL).

1. The Robert Koch Institute (RKI)

Pursuant to this provision the federation is responsible for the Robert Koch Institute, founded in 1891 as scientific department of the Royal Prussian Institute of Infectious Diseases. This institute is responsible for disease control and prevention and is the central federal reference institution for both applied and response-orientated research as well as for the Public Health Sector.[146] The tasks of the RKI include the assessment of scientific results through analysis of current international developments in the respective scientific areas, information of the decision-makers, realisation and coordination of federal health reporting. The RKI therefore communicates and cooperates with partners in the scientific sector, the public health service and the health care sector. The institute has major responsibilities in the field of scientific investigation, epidemiologic and medical analysis and evaluation of dangerous diseases and those with a high prevalence or of increased public or health-related political significance. With the passing of the Law for the Prevention of Infection (Infektionsschutzgesetz, IfSG), the RKI was given the responsibilities of a federal epidemiological centre for infectious diseases, combined with the construction of an expert-based registration system plus other novel and enhanced tools for data generation, prevention, surveillance and research. The RKI is responsible for coordinating and the carrying out the federal health reporting, The science-based approach to pandemics gives the RKI the central position in the national network notwithstanding the fact that the administration of the IfSG lies in the responsibility of the federal states.

2. The responsibility of the federal states

The federal states are responsible for the supervision of numerous facilities such as hospitals, schools, kindergarten, just to mention a few. Therefore, we find additional laws of the federal states concerning the public health service and also other laws relating to the mentioned institutions would be part of an in-depth analysis. Moreover, the federal states are in charge

146 *Schmidt am Busch* (2007), 80 et seq.; *Pflug* (2013), 122 et seq.; for a more general view on knowledge infrastructures see *Groß* (2010), 135 et seq.

for the laws of disasters. They are applicable to any disaster no matter what its origin. In principle, a pandemic can also be a disaster.[147]

These are just some of the aspects worth being mentioned. To get a full picture parts of the social security laws, the hospital laws, organisations of the civil society and of course some professional self regulating bodies, especially the German Medical Association (Bundesärztekammer) and others have to be taken into account. The relevant federal states' institutions - mainly on the community and county level - can exercise their powers according to the law of disaster.

The administrative architecture is complex as well. Inter-federal working groups of ministers and coordination groups of administrative officials of the federation and the federal states form part of this architecture as well as a joint emergency task forces of the federal ministers of the interior and health and different expertise agencies (RKI, Paul Ehrlich Institute, Federal Institute for Drugs and Devices, Federal Institute for Risk Assessment) and representatives of important infrastructure like hospitals and safe and rescue institutions and medical professions.

3. Coordination by emergency plans

To make the plurality of actors in this field work together in a coordinated way and to prepare for pandemics national and federal states' pandemic plans were established in 2005 and revised in 2007.[148] The current national pandemic plan dates from May 2007[149] and should be constantly evaluated and revised if necessary. Although a lot of experience could be gained from the pandemics in 2009, no formal revision has taken place so far. The emergency plan is based on the phase model of pandemics of the WHO and tries to define phase-specific recommendations of actions for the relevant actors (federation, federal states, third parties - be it of public or private nature). A commission of experts and representatives of the federation and the federal states as well as of third parties and the RKI set up the national pandemic plan.

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147 For various reasons it is argued that pandemics are a special form of disasters. The consequence should be that the regulations of the IfSG should be special regulations being prior to the federal state regulations. The relation might be a little more complex than this. First of all, not every pandemic is a catastrophe. Even if a pandemic results in a catastrophe only the prior trigger might be the virus but it might cause secondary catastrophic effects, for example problems of food supply or so. In this case, the provisions of the federal states law are necessarily an important source of measures to cope with it, which cannot be brushed aside just for reason of a clear cut distinction between federation and the federal states.

148 *Pflug* (2013), 175 et seq.; *Haas/Straetmans/Nicoll, (2009)*

149 Nationaler Pandemieplan (2007) http://www.rki.de/DE/Content/InfAZ/I/Influenza/Influenzapandemieplan.html.

The plan is of informal quality with no binding character,[150] although a plan as such is required by Annex 1 of the IHR (2005).[151]

II. The architecture according to the IfSG

Given the complexity of the overall scheme of fighting pandemics at national level all the information, scientific expertise, the scientific uncertainty must be transformed in an administrative design to efficiently cope with pandemics.

1. Emphasis on cooperation

Of course, the purpose of the act is to prevent communicable diseases in human beings, to detect infections at an early point in time and to prevent their spreading (Sect. 1 I IfSG). The regulation starts with an emphasis on cooperation. The participation of and co-operation between authorities at the federal, federal-state and local levels, physicians, veterinary surgeons, hospitals, scientific establishments well as any other parties involved that is necessary for the above purpose shall correspond to the current state of medical and epidemiological science and technology and shall be supported (Sect. 1 II IfSG). As far as the federal aspects are concerned the federal government is in charge of this cooperation. The federal government, by means of a general administrative regulation with consent of the Bundesrat, the upper house of the German parliament, draws up a plan for the mutual information of the federal and federal-state authorities in epidemiologically significant cases in order to prevent the importation of dangerous communicable diseases into the Federal Republic of Germany or to prevent their spread, to initiate the necessary measures wherever a spatial or temporal cluster of a dangerous communicable disease or cases of dangerous illness occurs that may be due to pathogens and is likely to spread beyond one federal state. The administrative regulation may also regulate co-operation between the federal and state authorities and other entities involved (Sect. 5 IfSG).

The individual responsibility of the bodies responsible for and persons in charge of community facilities, food-handling establishments, health facilities and the personal responsibility of each individual in preventing communicable diseases shall be clearly explained and encouraged (Sect. 1 II IfSG). This is a bit unusual to German legal technique.

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150 *Pflug* (2013), 178; *Walus* (2010), 132.

151 IHR (2005), Annex 1 Nr. 2: Each state party shall assess, within two years following the entry into force of these regulations for that state party, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, state parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in Paragraph 1 of Article 5 and Paragraph 1 of Article 13.

But it is an acknowledgement of the situation of a multiplayer architecture. What is missing is the inclusion of the multilevel architecture of an international and European approach at least at this starting point. The second aspect is the reference to the current state of medical and epidemiological science and technology. This is a common technique in German administrative law, which is a reference to a developing state of science enshrining a kind of structural dynamic into the legal frame.

2. Surveillance and notification

The backbone of the surveillance system (also of the international and European parts) is the notification system, which relates to all communicable diseases, covers therefore more than potential pandemics (Sect. Sect. 6 ff. IfSG). In a very detailed way the law regulates notifiable diseases be it on a named-patient-basis or non-named-patient bases, notifiable evidence of pathogens, the persons obligated to notify (mainly physicians, hospitals and other public health entities), the information necessary for notifications on a named-patient-basis or non-named-patient basis, the information procedure between the public health offices of the federal states and the RKI and the notification to the WHO and the ECDC. This is a very subtle regulation of data and information due to the standards of data protection in Germany. No doubt, the data provided on a named-patient-basis could be highly sensitive for the persons infected, not only in cases of a potential pandemic.

3. Possible measures to be taken

Due to the sensitivity of the measures to be potentially taken in an event of communicable diseases the second and more detailed part is the display of measures that could be taken for purposes of prevention and control. The IfSG differentiates between prevention and control of communicable diseases. [152]

a. Measures of prevention

These provisions are modelled along the lines of the traditional general police law[153] of the German federal states but with a shift to a precautionary approach.[154] As far as prevention is

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152 Sect. 16 et seq. IfSG.

153 For those not familiar with the functions and architecture of the police law in the German federal states some basic remarks might be useful: First of all, the name evokes expectations of regulations concerning the armed police forces. This is only true insofar as they are the armed part of what is due to German administrative tradition the administration of public order, which covers nearly every aspect of societal life in cases of a danger to the public order (and in some cases it covers also private rights). To avoid a misunderstanding: public order covers also a violation of persons and private goods like property if this causes a violation of the legal order, not only in cases of a criminal offence. The police law is only applicable, if there is no specific law covering the respective danger, e.g. the IfSG. The police law works on the basis of a broad

concerned the general clause (Sect. 16 IfSG) is as follows: If facts (circumstances) are ascertained which could lead to the outbreak of a communicable disease or if it can be assumed that such facts (circumstances) exist, the competent authority shall take the measures necessary to avert the danger which these circumstances pose to the individual or the public at large. Therefore, as displayed before, no danger is necessary but only facts or assumed facts that an outbreak of a communicable disease exists and these facts pose a danger to the individual or the public for the necessary measures to be taken. The provision does not specify the respective measures. The only requirements are necessity and proportionality. Officers are entitled to inspections of land, houses, facilities and institutions and ask for all information necessary. This is, of course, a restriction to the inviolability of home (Art. 13 BL).

Where articles have been or can be assumed to have been contaminated by pathogens capable of causing a communicable disease subject to notification - thus giving reason to fear that the disease will spread - the competent authority shall take the measures necessary to avert the danger posed. If other measures do not suffice, the destruction of such articles may be ordered. Their destruction may also be ordered if other measures are too expensive when compared with the value of said objects unless the person having an interest in or actual control of them makes an objection and assumes the higher costs (Sect. 17 IfSG). The right to personal freedom (Article 2 Paragraph 2 Sentence 2 Basic Law), the right to freedom of movement (Article 11 Paragraph 1 Basic Law), the right to freedom of assembly (Article 8 Basic Law) and the inviolability of the home (Article 13 Paragraph 1 Basic Law) shall be limited within the framework of Paragraphs 1 to 5.

According to Sect. 65 I IfSG, the destruction of, damage to or otherwise a reduction in the value of objects or any pecuniary prejudice other than an insignificant one, compensation shall be paid in cash; however, no compensation shall be paid to any person whose objects are contaminated with or

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general clause dealing with dangers to the public order. The essential term is danger, which should be determined by a balancing of the probability of a loss and the severity of that loss: The more severe a loss the less probability is needed for an intervention. Eventuality is not enough. Therefore, the term danger should provide a clear cut distinction between risks to be taken by the private individual and the society, detailed on a case by case basis of a more than century lasting judicial practise. If intervention might cause an intense infringement of rights the general clause would not be sufficient and a special normative provision is necessary. Also those who could be addressees are determined in a typical way and the scheme is *in toto* governed by the principle of proportionality.

154 There are some discussions in the German literature whether or not these measures follow the traditional lines or are a new approach. This is misleading insofar as the modern police laws also comprise precautionary measures an aspect discussed for nearly two centuries. The judicial practise follows a police-oriented approach, cf. one of the rare decisions of the Federal Administrative Court BVerwGE 142, 205 et seq.; Trute (2013), 558 et seq.

suspected of being contaminated with pathogens or pests which are presumed to be carriers of such pathogens. Section 254 of the Civil Code shall apply mutatis mutandis.

b. The importance of vaccination

An important measure of protection is vaccination. The German law is first and foremost committed to information about and to voluntary vaccination. The competent higher federal authority, the supreme health authorities of the federal states and the entities charged by them as well as the health offices inform the general public about the importance of vaccinations and other measures of specific prophylaxis against communicable diseases (Sect. 20 I). The Standing Vaccination Commission of the RKI provides recommendations then issued by the health authorities. But in some cases the health authorities may require mandatory vaccination. Sect. 20 VI empowers the Federal Ministry of Health to require by means of an ordinance with the consent of Bundesrat that those segments of the population which are at risk have to undergo the vaccinations or other measures of specific prophylaxis if a communicable disease occurs that takes a severe clinical course or can be expected to take on the proportions of an epidemic. The basic constitutional right to physical integrity (Article 2 Paragraph 2 Sentence 1 Basic Law) can be restricted in this respect. As long as the Federal Ministry does not exercise its power the state governments are empowered to issue such an ordinance (Sect. 20 VII IfSG).

A serious problem arises due to the fact that vaccines are always scarce. Therefore a vaccination scheme is needed to cope with scarcity and to prioritise groups of people. A legal basis for decisions of priority has not yet been developed. Some considerations on possible criteria have been given in the national pandemic plan, [155] although the uncertainty of effects of a prioritisation strategy is acknowledged. The plan differentiates between political-social aspects (vaccination of professional groups necessary to fight the pandemic and to maintain the social order), aspects of optimised reduction of the infection (see criteria in the chart below) and epidemiological-dynamic aspects vaccination of those groups with the highest infection risk and dissemination rate. But different sub-categories might lead to different prioritisation strategies.

Figure 3: Possible prioritisation strategies of vaccination according to the national pandemic plan. [156]

	Criteria		
Priority	Risk of lethal outcome	Fatality rate	Economic benefits
1	risk group 60 +	risk group 16-60	risk group 16-60

155 Nationaler Pandemieplan Teil III (2007), 65 et seq. (Fn. 146).

156 Nationaler Pandemieplan, Teil III (2007), 66 (Fn. 146).

2	non-risk group 60+	risk group 60+	risk group 0-15
3	risk group 0-15	risk group 0-15	non-risk group 16-60
4	risk group 16-60	non-risk group 60+	non-risk group 0-15
5	non-risk group 16-60	non-risk group 16-60	risk group 60+
6	non-risk group 0-15	non-risk group 0-15	non-risk group 60+

The national pandemic plan notes that the federal states have consented to prioritise medical professional groups and those groups necessary to maintain social order (6% of the population). Subsequently, age groups should be vaccinated due to epidemiological-dynamic aspects. This may be justifiable. But there are internationally various approaches of vaccine distribution planning, which might be worth taking into consideration on grounds of ethical and normative as well as efficiency approaches.[157] The legal problem with this kind of consent (which by the way is not documented anywhere) is the lack of any constitutional sound legal basis, although prioritisation is obviously not only a matter of scientific expertise (as it is often seen by experts), but an eminent political question and a distribution of chances to survive in a crisis.

c. Measures to protect

The second bundle of measures is intended to control communicable diseases. The IfSG allows for mandatory investigation of people. Should it occur or should there be reason to assume that a person is ill, suspected of being ill, suspected of being contagious, is a germ carrier, or that a deceased person had been ill, suspected of being ill or a germ carrier, the competent health office shall carry out the necessary investigations, especially with regard to the type, cause, source of infection and spread of the disease (Sect. 25 I IfSG). The basic constitutional rights to physical integrity (Article 2 Paragraph 2 Sentence 1 Basic Law), to personal freedom (Article 2 Paragraph 2 Sentence 2 Basic Law) and to the inviolability of the home (Article 13 Paragraph 1 Basic Law) shall be limited in this respect. The results should be communicated within the surveillance network in cases of a notifiable disease. Should it occur that or should there be reason to assume that a person suffering from a notifiable disease or infected with a notifiable pathogen or that a deceased person who had been suffering from a notifiable disease or infected with a notifiable pathogen, donated his/her blood or any organ or tissue after the presumed date of infection, the competent health office shall, if the disease or infection in question can be transmitted through blood, blood products,

[157] *Buccieri and Gaetz* (2013); *Kaposy and Bandrauk* (2012); *WHO* (2007); *Brech* (2008).

tissues or organs, immediately inform the competent authorities about the result or suspicion. In doing so, it shall report the facts that have come to its knowledge.

The competent authority may also determine all protective measures it deems necessary. As Sect. 28 IfSG states: If persons are diagnosed as being ill, are suspected of being ill or contagious, are diagnosed as germ carriers, or should it occur that a deceased person had been ill, suspected of being ill or had been a germ carrier, the competent authority shall order the implementation of the necessary protective measures, in particular those specified in Sections 29 to 31 in so far as and as long as such action is necessary to prevent the spread of communicable diseases. If the conditions are fulfilled, the competent authority shall be entitled to restrict or prohibit events or other gatherings of large numbers of people and may close public bathing establishments or community facilities as specified in Section 33 or parts of them; it may also force persons not to leave the place they are in or not to enter places specified by it until the necessary protective measures have been taken. A person may not be forced to submit to curative treatment. The basic constitutional rights: The right to personal freedom (Article 2 Paragraph 2 Sentence 2 Basic Law), the right to freedom of assembly (Article 8 Basic Law) and the inviolability of the home (Article 13 Paragraph 1 Basic Law) shall be limited in this respect.

Pursuant to Sect. 29 IfSG persons may be placed under observation and therefore has to permit all investigations necessary with all the rights of inspection of houses etc. and the person has to notify changes in main residence or its usual abode. And, in some cases, the competent authorities may also order that persons are isolated in a hospital or another establishment equipped to handle serious diseases. If these persons do not comply they can be forced and send in a closed hospital or a closed ward of a hospital (Sect. 30 IfSG). Professional activities may be totally or partially prohibited (Sect. 31 IfSG).

Although a detailed regulation of intervention exists and Germans are normally not reluctant to look for judicial control of administrative decisions, only a limited number of decisions from administrative courts can be found.

E. Conclusions

The overall theme and background is situations of emergency and the rule of law. Of course, pandemics are an emergency situation, once they are nascent. Seen against this background prevention and control of pandemics display a slightly different function of the law, be it international, European and national law. The rule of law comes traditionally into play, when it comes to the infringement of individual rights. Procedural and substantive restrictions to

public powers are part of the core of the rule of law. Of course, measures that could be taken in the outbreak of a pandemic might include serious infringements of individual rights. Therefore, we find, in particular at the national level, procedural and substantive requirements, which must be met to take such measures. Interestingly enough, this is only a small part of the law of pandemics. Seen from the perspective of individual rights it is more the right to health, protected by this scheme. Although these rights must be balanced with guaranties of free trade and travel.

At the core of this multilayer architecture lies the institutionalisation of a knowledge generating and disseminating infrastructure and the establishment of international cooperation and a fair distribution of resource necessary to cope with pandemics. This might be seen as a structural precaution approach to protect the individual right to health as far as possible, although this not the only issue of this frame. Hard measures are obviously very rare and, if taken, seldom cause legal conflicts – at least as far as the German situation in concerned. It seems that the incentive to be protected from a pandemic or be cured from illness caused by a virus is strong enough to comply with necessary measures to cope with a pandemic.

More complex are the problems of social and distributional justice, lying behind this scheme. For a long time, they do not come to the fore. But with the changing role of the WHO the conflict between the developed and developing countries they were put on the agenda and it is safe to say, that the new approach, represented by PIP, will not end this conflict. The common interest in controlling infectious diseases is not strong enough as an incentive to assure a fair balance of contribution and advantages.

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