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February 2015

LL File No. 2015-011358
LRA-D-PUB-000114

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Contents

Comparative Analysis 1

Argentina 5

Australia 13

Brazil 29

Canada 39

China 50

Egypt 62

England 66

France 80

Greece 88

India 92

Israel 99

Italy 114

Japan 122

Kenya 137

Lebanon 152

Mexico 156

Nigeria 161

Portugal 175

Russian Federation 187

Senegal 197

South Korea 202

Spain 211

Sweden.....220

European Union 241

World Health Organization.....250

Bibliography 262

Comparative Summary

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This report contains discussions of the regulations addressing health emergencies in twenty-five jurisdictions. The jurisdictional surveys that are included cover countries from six continents and reflect national, regional (European Union, EU), and international (World Health Organization, WHO) approaches to the problem. The report is supplemented by an annotated bibliography that lists recently published English-language monographs and academic articles on issues related to handling public health crises. All surveys included in this report review government structures tasked with delivering public health protection, relevant legislative frameworks for addressing health emergencies, and the powers of government institutions in times of health crises and their ability to mitigate the consequences of such crises. Analyses of the regulation of such issues as disease surveillance and notification systems are also provided. Individual surveys discuss the role of medical and emergency services personnel in responding to public health challenges, the coordination of government activities aimed at minimizing the spread of epidemics, and the cooperation of national health-care institutions with the WHO in implementing pandemic preparedness measures. Measures taken by national governments in response to recent outbreaks of infectious diseases, including the Ebola epidemic in western Africa in 2014, are also described.

I. Introduction

All the countries surveyed recognize the existence of a threat to public health from a variety of infectious diseases, mass illnesses resulting from technological catastrophes or the malicious distribution of viruses, and the potential use of chemical and biological weapons by terrorists. All the reviewed jurisdictions appear to be aware of the importance of maintaining national health care infrastructures to combat public health crises and readily available communications systems that inform the public on preparedness plans and serve as clearinghouses for crisis information.

In addition to the national governments, the WHO performs a critical role in confronting health crises. The WHO coordinates international health work and provides technical and policy assistance to national governments and medical authorities in support of programs to promote health, prevent and control health problems, control or eradicate diseases, and strengthen national health systems. It also keeps communicable and noncommunicable diseases and other health problems under constant surveillance, sets safety standards, issues regulations that are binding on member states, collects and disseminates health data, and carries out statistical analyses and comparative studies concerning various diseases.

The EU survey reflects measures aimed at improving the coordination of Member States' actions. While public health emergencies occurring within the EU fall primarily within the

[*] This comparative summary was originally prepared by Giovanni Salvo and Karel Wennink, former Foreign Law Specialists, in August 2003; it was updated for the purposes of the present report.

domain of the individual Member States, the legal acts of the EU pertaining to public health complement the national policies of the EU members, coordinate their actions, and facilitate communication and the exchange of information among Member States. Addressing existing deficiencies in managing health crises, the EU has passed new legislation expanding the list of threats beyond communicable diseases to include biological, chemical, environmental, and other events that may pose a risk. Three newly established institutions demonstrate the EU's response to health care challenges that emerged with recent epidemics and terrorist attacks: the European Center for Disease Prevention and Control, modeled after the United States Centers for Disease Control and Prevention; the Early Warning and Response System; and the Health Security Committee, which developed into a full-fledged institution in charge of information exchange and response planning from an informal discussion forum on public threats.

The Nordic states take a regional approach toward tackling health crises through cooperative preparedness efforts. These countries have mutual obligations to help each other when necessary and may send their patients to other countries for better treatment. The Baltic states likewise take special actions against contagious diseases jointly. In another example of the regional approach toward managing health care emergencies, members of the Association of Southeast Asian Nations (ASEAN), together with China and Japan, adopted a joint resolution on standard border controls in 2003 during the SARS (Severe Acute Respiratory Syndrome) epidemic to counter the spread of the disease, and also distributed standardized health declaration cards to all travelers at airports. In 2009, following the A/H1N1 (swine flu) virus epidemic, and in 2014, because of the Ebola virus threat, national governments issued guidelines and took measures similar to those suggested by the US Centers for Disease Control and Prevention, another example that demonstrates the increasing interconnectedness of health care management authorities in various countries.

II. Structure of Public Health Crisis Management Systems

In the countries surveyed, the systems of health care and health crisis management are governed by statutory and regulatory measures that reflect general constitutional principles concerning the protection of the public and the health of an individual. Responsibilities for dealing with health crises are distributed among the central or federal governments and regional and municipal authorities to prevent, monitor, and respond to public health emergencies. This distribution prevails regardless of the cause of the health emergency. In the case of terrorism, the intervention of other government authorities may be required. In Germany the legislative power for public health remains with the states; however, the German Federation has concurrent legislative power over measures to combat most public health threats. Decision-making powers and the authority to declare emergencies appear to be concentrated in the hands of specified officials, who are assisted by civil servants from the agencies involved. The participation and cooperation of different agencies and of special units, if they exist, appear to be a common feature in the countries surveyed where the minister responsible for health issues plays a leading role. The appointment of a special commissioner may be an option in certain cases.

Reporting systems for notifiable diseases have been widely adopted so that authorities with decision-making powers can monitor the situation in order to take the appropriate measures. Almost every country reviewed has its own classification of infectious and contagious diseases,

depending on disease severity, as well as relevant national action plans to respond to an outbreak of such diseases.

III. Powers of Public Health Authorities

In the majority of the countries surveyed, the Ministry of Health is the central authority in public health crises and takes appropriate emergency measures to confront such crises. In many countries, separate agencies dealing with epidemic surveillance and sanitary control are subordinated to the Ministry of Health for the duration of a crisis. While in the majority of the countries reviewed such agencies are usually responsible for planning, coordinating, and implementing the response to a crisis, in some countries (e.g., Brazil and Russia) they have the actual power to mobilize resources. In Canada, the Prime Minister and provincial premiers have the authority to declare emergencies for all types of crises, including public health crises. In England, the Secretary of State has broad powers with respect to a health crisis. The power to proclaim a state of emergency is vested in the president in Nigeria and Kenya, according to their constitutions.

In several countries, depending on the type of health crisis, other departments (such as the Departments of Agriculture, Justice, Interior, and Environment), in cooperation with the Ministry of Health, may be involved in the decision-making process. This cooperation is often in addition to the involvement of other agencies' special units, where existing. Public health services at any level are primarily entrusted with the bulk of the measures needed to prevent and control a health crisis. These measures are often preventive in nature, including the power to enter private homes and coercive powers to carry out precautionary measures, including the right to quarantine infected individuals, conduct mandatory inoculations, and examine and monitor diseased persons. In Japan, provincial governors may order the hospitalization of patients, whereas the report on England indicates that public authorities do not have the power to force a quarantined, diseased person to undergo treatment.

A number of reports point out that during a simultaneous outbreak of an infectious disease in several countries, as was the case with SARS in 2003, avian flu in 2005, and the A/H1N1 virus in 2009, or when a threat comes from a disease outbreak outside of the country, as during the 2014 Ebola epidemic, health authorities can impose stricter controls on travelers coming from high-risk areas and require air carriers to provide detailed information regarding their passengers' itineraries. Heath authorities exercise control with the help of health questionnaires, sanitary monitoring, and the mandatory hospitalization of infected persons. Measures necessary to curb a public health crisis may include compulsory health procedures, such as vaccinations, disinfection, quarantine, and travel restrictions. Most of the reports illustrate that measures taken during health crises are, in many instances, in conflict with the constitutional and legal rights of individuals, such as those concerning the inviolability of person and home, freedom of movement, the use of property, peaceful assembly, and the ability to conduct business. In most of the surveyed countries, the constitution permits intrusions into these constitutionally guaranteed fundamental rights to the extent that the intrusive measures are specifically authorized in statutory provisions and are in the public interest, such as for the protection of public health. In Brazil, the government may issue a compulsory license for the use of a patent if a patent holder does not comply with a request for its use, in order to secure the reserve of medicines needed to fight a public health crisis.

The failure to comply with measures taken in a crisis generally results in administrative or criminal sanctions. Medical personnel who fail to provide assistance in emergency health situations, or to act on or report a case, may be more severely penalized. These sanctions are not only set forth in the body of the legislation authorizing the specific measures, but are also included in the criminal codes of a majority of the countries surveyed.

IV. Transparency of Public Health Crisis Management System

Recognizing that a well-informed public is better prepared to deal with an emergency and minimize its impact, education and the disclosure of public health information appear to be important components of the response to public health crises. The need for transparency is emphasized in many of the surveys. The duty to supply information concerning public health finds its basis (with some exceptions) in the countries' constitutions or special laws.

V. Cooperation with the WHO

Recognizing the important role of the WHO in helping its Member States to confront and overcome health crises, the countries surveyed generally cooperate with the WHO. All of the countries have agreed to implement the WHO International Health Regulations of 2005 and are making efforts to comply with the requirements prescribed by that document.

Argentina

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SUMMARY The strengthening of Argentina's Epidemic Surveillance System has been a government priority for the last fifteen years and, although the public health in the country at large has improved, many more resources need to be devoted to reach a higher level of health, especially regarding epidemic prevention and control. In 2002 the declaration of a health emergency required the adoption of urgent measures to ensure the supply of medicines to the population. Following the outbreak of swine flu in Mexico in April 2009, the government declared a health emergency, taking immediate action to ensure the supply of medicines to the population. The current alert on the Ebola virus outbreak is under strict surveillance by health authorities in the country, who are following the World Health Organization's international epidemiology protocols.

I. Government Structure

Argentina's political organization was established by the National Constitution[1] as a Federal Republic consisting of twenty-three provinces and the autonomous city of Buenos Aires. The federal state is headed by a President, who appoints a cabinet and holds the country's executive power. The legislative power is exercised by a bicameral Congress with a Lower Chamber (Cámara de Diputados) and an Upper Chamber (Cámara de Senadores).

Under the National Constitution, each province has its own provincial constitution, legislation, and resolutions. However, provincial legislation may not violate any of the individual rights protected under the National Constitution. The provinces have delegated to the federal legislature the power to enact laws of national scope governing civil, commercial, and other matters.[2]

Although not stated explicitly, the National Constitution guarantees the right to health as a derivative of the right to life.[3] Several provisions also guarantee the right to health, including the right to a healthy environment,[4] the right of consumers to the protection of their health,[5] and in a broader sense, the right to protect collective rights.[6] The constitutional guarantee of health

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[1] CONSTITUCIÓN DE LA NACIÓN ARGENTINA, Dec 15, 1994, http://infoleg.mecon. gov.ar/infolegInternet/anexos/0-4999/804/norma.htm.

[2] *Id.* arts. 121–129.

[3] Daniel Sabsay & Pablo Manili, Constitución de la Nación Argentina y Normas Complementaria, Análisis Doctrinal y Jurisprudencial 1234 (2009).

[4] Constitución de la Nación Argentina art. 41, para. 1.

[5] *Id.* art. 42, para. 1.

[6] *Id.* art. 43, para. 2.

protection may be defined as the right of all individuals to be protected by the state with regard to the prevention and treatment of diseases and the maintenance of health.[7]

II. Structure of Public Health Crisis Management System

The health system has a decentralized structure where many responsibilities have been transferred to the provinces. The Law on Ministries of 1999,[8] as amended by Decree 355/2002,[9] restructured the Ministry of Health (MH), creating two new subdivisions: the Secretariat for Health and Care and the Secretariat for Health Policy and Regulation. The Secretariat for Health and Care has an office of the Undersecretary of Prevention and Promotion Programs, which comprises the National Directorate of Health Programs and the Directorate of Epidemiology (DE).

Under the Law on Ministries, the MH is assigned the responsibility of assisting the President in all health matters, including

- executing plans, programs, and projects related to health;
- medical aspects of immigration and the defense of borders, ports, airports, and international means of transportation;
- coordinating national, provincial, and municipal health services;
- participating in the control of food safety in coordination with the Ministry of Production;
- intervening in the assignment and control of subsidies to solve health emergencies, either unforeseen or not covered by the system in place;
- preparing health statistics and ensuring access to health information for the population;
- developing epidemiology research studies to improve the efficiency and quality of health services;
- managing international health relations, not only with other countries, but also with international health organizations;
- planning health campaigns to eradicate endemic diseases, rehabilitate the ill, and detect and prevent nontransmissible diseases;
- epidemic control and surveillance, including the management of the disease notification system;
- planning national vaccination and immunization programs; and

[7] SABSAY AND MANILI, *supra* note 3, at 1235.

[8] Law 25233, Law of Ministries, Dec. 10, 1999, http://www.infoleg.gob.ar/infolegInternet/anexos/60000-64999/61394/norma.htm (in Spanish).

[9] Decree 355/2002, amending Law 25,233, Law of Ministries, Feb. 21, 2002, http://www.infoleg.gob.ar/infolegInternet/anexos/70000-74999/72483/texact.htm (in Spanish).

- establishing integrated programs to cover specific pathologies affecting groups determined to be at risk because of their geographic location.[10]

In the provinces, health services are provided by a network of provincial primary and secondary care services and by the private sector. The MH establishes basic regulations for the delivery of health services and the operation of health facilities, but most provinces also have an extensive set of regulations. The MH is represented in each province through a Federal Health Council, which constitutes the link between the national MH and the provinces in all health-related matters.[11]

The Federal Health Plan 2010–2016, released by the MH, provides for general guidelines on public health in the country. However, the guidelines are only indicators, since provinces have autonomy in setting their own health policies for the protection of their population. The Federal Health Council, which is made up of the ministers of health of all the provinces and municipalities in the country, facilitates the coordination of health policies and services between the National Health Authority and the provinces. [12]

In 2011, the MH and the Ministry of Planning signed an agreement to integrate hospitals, primary health care centers, integrated community centers, and other health care centers throughout the country into the National Fiber Optics Network,[13] which became operative in August 2014.[14]

III. Powers of Public Health Authorities

The DE and its National Epidemiological Surveillance System are responsible for the registration of diseases subject to obligatory reporting, as established by Law 15465.[15] The Law includes a list of diseases that is updated periodically as needed.[16] The reporting is required not only in confirmed cases but also in suspected cases.[17] Physicians and veterinarians and, when applicable, laboratory technicians and pathologists, dentists, OB/GYNs, and kinesiologists,[18] are

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[10] *Id.* art. 23 ter.

[11] Pan American Health Organization [PAHO], *Argentina*, *in* II SALUD EN LAS AMERICAS, 2007: PAÍSES 53, http://www.paho.org/hia/archivosvol2/paisesesp/Argentina%20Spanish.pdf.

[12] PAHO, *Argentina*, *in* SALUD EN LAS AMERICAS, EDICIÓN DE 2012, at 35–36, http://www.paho.org/saludenlasamericas/index.php?option=com_docman&task=doc_view&gid=186&Itemid.

[13] *Id*. at 37.

[14] Manzur y DeVido Pusieron en Marcha la red federal de Infraestructura Cibersalud, Ministerio de Salud, Aug. 5, 2014, http://www.msal.gov.ar/prensa/index.php/noticias/noticias-de-la-semana/2150-manzur-y-de-vido-pusieron-en-marcha-la-red-federal-de-infraestructura-cibersalud.

[15] Law 15465, on Required Reporting of Diseases, Sept. 29, 1960, http://www.infoleg.gob.ar/infolegInternet/anexos/195000-199999/195093/norma.htm, *regulated by* Decree 3640/64, May 19, 1964, http://www.infoleg.gob.ar/infolegInternet/anexos/195000-199999/195289/norma.htm (in Spanish).

[16] Decree 2771/79, Nov. 1, 1979, art. 2, available on the Legisalud website, *at* http://test.e-legis-ar.msal.gov.ar/leisref/public/showAct.php?id=4140&word (in Spanish).

[17] *Id*. art. 3.

[18] *Id.* art. 5.

all under obligation to report the listed diseases.[19] Noncompliance with this obligation is punishable by a fine and temporary suspension of the professional license to practice for one to three months.[20] The sanctions are determined by the MH or its provincial counterparts when the offense falls under their jurisdiction.[21]

The Advisory Commission on Epidemic Surveillance was also created within the jurisdiction of the DE to provide guidance on procedural and operational aspects of epidemic surveillance actions.[22] The Advisory Commission on Epidemic Surveillance provides technical advice to the provinces contributing to the organization and development of the National Epidemiological Surveillance System, of which it is a part.[23]

The DE also promotes the control of transmissible and nontransmissible diseases and health risks and regulates all activities related to environmental health, including training, research, and control in situ upon request of the different jurisdictions.[24] This system is organized by levels and is comprised of the DE at the national level and epidemiology directorates, departments, and units within ministries of health at the provincial level. The system compiles information on reportable diseases and laboratory data weekly.[25]

The provincial Federal Health Department is in charge of controlling epidemic diseases; this includes diseases subject to quarantine and those that, by their character, danger, or scope, may become a national threat.[26] To this end, the Federal Health Department reports the presence of any such diseases by means of a uniform national procedure and, together with the provincial authorities, carries out epidemic research related to these diseases.[27] Such reporting and communication are confidential. The manner in which the information is reported allows the Federal Health Department to identify and locate the individuals affected and the source of infection.[28] However, the National Health Authority is the only government body with the power to report on this subject abroad.[29]

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[19] *Id.* art. 4.

[20] Law 15465, art. 16.

[21] *Id.* art. 18.

[22] Ministry of Health, Manual de Normas y Procedimientos de Vigilancia y Control de Enfermedades de Notificación Obligatoria (rev. ed. 2007), http://www.snvs.msal.gov.ar/descargas/Manual%20de%20Normas%20y%20Procedimientos%202007.pdf.

[23] *Id*.

[24] *Dirección de Epidemiología: Acciones*, MINISTERIO DE SALUD, http://www.msal.gov.ar/index.php/component/content/article/43-funciones/28-funciones (last visited Oct. 23, 2014).

[25] MINISTRY OF HEALTH, *supra* note 22, at 6–8.

[26] Decree-Law 4143/58, Health Assistance, Apr. 2, 1958, arts. 2 & 7, BOLETÍN OFICIAL, Apr. 16, 1958.

[27] *Id.*

[28] Law 15465, on Required Reporting of Diseases, Sept. 29, 1960, arts. 7, 8.

[29] *Id.* art. 11.

Once the National Health Authority receives the required information or report, it provides all the means necessary to perform clinical and laboratory tests, provide assistance to the sick, and protect public health, including ordering quarantines and other preventive measures.[30]

The Comisión Nacional de Actividades Espaciales (National Commission on Space Activities) concluded an agreement with France's Nationale d'études Spatiales (National Space Studies Center) to develop a panoramic epidemiology system, which allows the prediction and early warning of diseases through the cross-referencing of a combination of satellite-gathered data on such things as vegetation, clouds, rain, rivers, and forests, with traditional data.[31]

Through the Directorate of Health Emergencies, the MH manages catastrophic and emergency situations and provides necessary medical supplies and health assistance throughout the country. The Directorate of Health Emergencies has a permanent communications unit on call for emergencies in coordination with the Federal Emergency System. However, it has been reported that the Federal Emergency System has not been efficiently used in spite of the considerable amount of funds assigned for its operational budget.[32] Since its creation in 1972, the Directorate of Health Emergencies has assisted both in Argentina and abroad in a number of disasters and health emergencies, providing medicine, medical assistance, and transportation when the seriousness of the situation required treatment in a more sophisticated medical facility.[33] The Directorate of Health Emergencies coordinates with the National Directorate for Trauma, Emergencies, and Disasters within the jurisdiction of the Undersecretary of Prevention and Promotion Programs to implement assistance at the national, provincial, and municipal level in cases of emergencies or disasters requiring federal intervention.[34] The National Directorate for Trauma, Emergencies, and Disasters is the authority in charge of the evacuation and reception of victims and the referral of patients, whether individually or in mass, in cases of natural, technological, or other disasters.[35]

The Border Health Program is in charge of maintaining health and epidemic control at the borders and in the international transportation terminals, according to international standards and in compliance with the International Health Regulation.[36]

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[30] *Id.* art. 14.

[31] Nora Bär, *La Argentina Desarrolla una Red de Vigilancia Epidemiológica Satelital*, LANACIÓN (July 14, 2003), http://www.lanacion.com.ar/nota.asp?nota_id=511256.

[32] Daniel Gallo, *El Sistema Federal de Emergencias No se Utiliza*, LA NACIÓN (Apr. 7, 2013), http://www.lanacion.com.ar/1570410-el-sistema-federal-de-emergencias-no-se-utiliza.

[33] For historical data on emergencies in Argentina and abroad covered by the Directorate of Health Emergencies, see *Historia*, DINESA (June 13, 2011), http://www.msal.gov.ar/dinesa/index.php/sobre-dinesa/historia.

[34] *Servicios*, DINESA (June 13, 2011), http://www.msal.gov.ar/dinesa/index.php/actividades/servicios.

[35] Decree 1106/2000 of the Ministry of Health, Nov. 27, 2000, Annex II, http://www.infoleg.gob.ar/infolegInternet/anexos/65000-69999/65187/norma.htm; DP'12 – DOCUMENTO PAIS 2012: RIESGO DE DESASTRES EN LA ARGENTINA 183–84, http://www.msal.gov.ar/salud-y-desastres/images/stories/4-biblio-recursos/pdf/2014-04_documento-pais.pdf.

[36] Decree 1343/2007, Oct. 4, 2007, sched. annexed to art. 2, Secretaria de Politicas Regulaciónes e Institutos, Objetivos 6; Subsecretaria de Politicas, Regulación y Fiscalización, Objetivos 14; Dirección Nacional de Registro, Fiscalización y Sanidad de Fronteras, Acciones 5, 9, 11, http://www.infoleg.gob.ar/infolegInternet/anexos/130000-134999/133099/texact.htm.

As a result of the 2003 worldwide SARS alert, the MH took a number of measures to prevent and eventually control the disease.[37] The Secretariat for Health Policy and Regulation of the MH ordered the strict control over any vessel and its crew entering the country.[38]

The Criminal Code sanctions with imprisonment of three to fifteen years anyone who knowingly propagates a dangerous and contagious illness to human beings.[39] If the propagation is due to negligence or violation of the public authorities' regulations or directives but does not result in the death or infection of someone else, a fine may be imposed. If the propagation does result in death or infection, the offender is subject to imprisonment for six months to five years.[40] Anyone who violates the measures adopted by the designated authorities to prevent the introduction or containment of an epidemic is subject to imprisonment for six months to two years. This crime is punishable even when an epidemic does not occur. If the wrongdoer is a public officer or professional, the sanction will include a special disqualification from his/her post for a period double the length of the penalty.[41]

IV. Transparency of Public Health Crisis Management System

The Statistics and Health Information Directorate is the agency in charge of the collection and analysis of health data on a permanent basis. Its objectives include the identification of health factors that allow the early detection of diseases to prevent their spread and alert the population.[42]

The DE publishes an epidemiological bulletin entitled *Boletín Epidemiológico Periódico*, which is available on the MH webpage.[43] This weekly report includes the latest news on health issues, the current situation on specific illnesses threatening the population, outbreaks of new diseases in the country and abroad, and the epidemic surveillance data provided by the provinces.[44]

V. Management of Health Emergencies

In September 2002, the MH, together with its provincial counterparts, implemented a surveillance system called *unidades centinela* (health watch units) to closely monitor specific

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[37] *See* MINISTERIO DE SALUD, PLAN DE CONTINGENCIA NACIONAL – SÍNDROME RESPIRATORIO AGUDO GRAVE (SRAG) (Apr. 2003), available on the Federación Médica de la Provincia de Buenos Aires website, *at* http://www.femeba.org.ar/fundacion/quienessomos/Novedades/sragministerioabril.pdf.

[38] *Id*. annex D.1.A, at 21.

[39] CÓDIGO PENAL DE LA NACIÓN ARGENTINA*, as amended* (1984 revised text), art. 202, http://www.infoleg.gov.ar/infolegInternet/anexos/15000-19999/16546/texact.htm#22.

[40] *Id.* art. 203.

[41] *Id.* arts. 205, 207.

[42] DIRECCIÓN DE ESTADÍSTICAS E INFORMACIÓN DE SALUD, SISTEMA DE INFORMACIÓN DE SALUD 9 (rev. ed. Sept. 2004), http://www.deis.gov.ar/publicaciones/Archivos/sis2005.pdf.

[43] BOLETÍN EPIDEMIOLÓGICO PERIÓDICO, http://www.msal.gov.ar/saladesituacion/epidemiologia_boletines.php.

[44] *Id*.

health threats like pneumonia.[45] Since 2001, the National Health Statistics Program has been equipped with the proper hardware and software to make the health information collected accessible to all in a timely manner.[46]

In March 2002, the President declared a National Health Emergency[47] as part of an overall public, social, economic, financial, and monetary emergency declared by Law 25561.[48] The social and economic situation in the country was so serious that the provision of medicine and other health and medical supplies, especially those imported, was undermined, causing a genuine crisis and collapse of the national health system. The critical situation of the health sector constituted an exceptional circumstance, rendering it impossible to provide health services according to regular procedures.[49] Under the National Health Emergency, the MH was empowered to take all necessary measures to guarantee the provision of medicine to the population, and to establish the procedures and priorities for its distribution.[50] The MH instituted exceptional procedures to acquire such medicine, authorized special funding for its acquisition,[51] and imposed price controls to avoid excessive price increases.[52] The MH also developed a system that prioritized medical attention during the emergency.[53]

On April 29, 2009, as part of the measures taken by the Argentine government to control the swine flu outbreak that originated in Mexico, all flights incoming from Mexico were suspended until May 5, 2009.[54] At the same time health control points were set up at all points of entry to the country, and sensors to detect fever among the travelers were set up in international airports.[55] Flights from Mexico resumed on May 15, 2009,[56] but measures to check the body temperature of arriving passengers at international airports remained in effect for some time.[57]

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[45] *Id*.

[46] BOLETÍN DEL PROGRAMA NACIONAL DE ESTADÍSTICAS EN SALUD, http://www.deis.gov.ar/Publicaciones/arbol_tematico.asp (last visited Oct. 29, 2014; click on "Boletín del Programa Nacional de Estadísticas en Salud" under "Búsqueda Avanzada").

[47] Decree 486/02 on National Health Emergency of March 12, 2002, http://infoleg.mecon.gov.ar/infolegInternet/anexos/70000-74999/72887/texact.htm (in Spanish).

[48] Law 25561 on National Emergency of Jan. 6, 2002, http://www.infoleg.gob.ar/infolegInternet/verNorma.do;jsessionid=A917C3C78C096E7D9B12CFD246CC3D4A?id=71477 (in Spanish).

[49] *Id.*, intro.

[50] *Id.* arts. 2, 3.

[51] *Id.* art. 9.

[52] *Id.* art. 10.

[53] *Id.* arts. 18–20.

[54] Resolution 201/2009 of the Secretaría de Transporte, Apr. 29, 2009, http://www.infoleg.gov.ar/infolegInternet/anexos/150000-154999/152904/norma.htm; Resolution 214/2009 of May 4, 2009, http://www.infoleg.gov.ar/infolegInternet/anexos/150000-154999/152973/norma.htm.

[55] *Por la Gripe Porcina, el Gobierno suspende los vuelos con México*, CLARÍN.COM (Apr. 28, 2009), http://www.clarin.com/diario/2009/04/28/um/m-01907438.htm.

[56] Mariano Obarrio, *Se reanudan hoy los vuelos a México*, LANACION (May 15, 2009), http://www.lanacion.com.ar/nota.asp?nota_id=1128307.

[57] *Id*.

VI. Current Crisis

On August 7, 2014, the MH issued an epidemiological warning (*alerta epidemiológica*) in the country because of the Ebola virus outbreak in Africa.[58] The warning provides specific instructions and a health protocol to follow in suspicious and confirmed Ebola cases.[59] It further provides information about symptoms to the population at large and specific information for travelers entering the country.[60] On August 20, 2014, the MH published a comprehensive update on the evolution of the Ebola virus in the world, providing an update of the reinforcement prevention, notification and detection measures in compliance with WHO standards.[61]

On September 10, 2014, Argentina announced that the Malbrán Institute of Health in Buenos Aires had developed a biological molecular method for detecting the Ebola virus in less than twenty-four hours.[62] The Minister of Health announced that Argentina was the first country in Latin America that had a diagnosis method for Ebola that had been validated by the WHO. Health authorities have been working in training health staff, acquiring equipment for patients' isolation, and developing and updating a protocol for handling Ebola cases. Currently there are three hospitals in the country already selected and ready to treat Ebola patients.[63]

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[58] DIRECCIÓN DE EPIDEMIOLOGÍA, MINISTERIO DE SALUD DE LA NACIÓN, SEMANA EPIDEMIOLÓGICA 32 (Aug. 7, 2014), http://www.msal.gov.ar/images/stories/epidemiologia/inmunizaciones/11-08-2014-alerta-6-enfermedad-virus_ebola-.pdf.

[59] *Id.* at 2, 3.

[60] *Información sobre la Enfermedad del Virus del Ébola*, MINISTERIO DE SALUD, http://www.msal.gov.ar/index.php/component/content/article/47-epidemiologia/448-informacion-sobre-ebola (last visited Nov. 14, 2014).

[61] Subsecretaría de Política, Regulación y Fiscalización, Ministerio de Salud de la Nación, Refuerzo de los Planes de Contingencia de Salud Pública ante el Riesgo de Ébola: Puntos de Entrada Argentinos (Aug. 20, 2014), http://www.msal.gov.ar/images/stories/epidemiologia/ebola/pdf/10-11-2014-plan-contingencia-puertos-entrada.pdf.

[62] *Argentina Desarrolló un Método para Diagnosticar Casos de Ebola*, TELAM (Sept. 10, 2014), http://www.telam.com.ar/notas/201410/81135-argentina-metodo-diagnostico-ebola.html.

[63] *Id.*

Australia

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SUMMARY Under Australia's federal system, states and territories have primary responsibility for matters related to health care and emergency management. The federal government provides various funding, policy leadership, and coordination assistance in the context of national responses to public health emergencies. It also has quarantine powers and powers related to border management that can be utilized where there is an epidemic or threat of an epidemic. National agreements, as well as the National Health Security Act 2007 (Cth), establish structures and processes for preventing and responding to national health emergencies, with different entities providing oversight and coordination at the national level, and states and territories applying their own laws, jurisdictional responses, and coordination processes. This includes a national notification and surveillance system under which state and territory authorities report on instances of certain diseases to a central authority, which then makes information available for analysis and discussion. In the event of a public health threat, state and territory public health laws provide a range of powers to enable action to be taken by authorities. This can include ordering medical examinations, treatment, and detention of individuals.

The Australian government, along with state and territory governments, has taken a range of actions in response to the 2014 Ebola virus disease (EVD) epidemic in West Africa. This includes enhanced screening of passengers at airports, stopping the processing of visa applications from citizens of affected countries, issuing national guidance to public health units and laboratories, and the development of detailed state and territory response plans. As of October 2014, around twenty people who arrived in Australia from EVD-affected countries had been placed on home quarantine.

I. Introduction

Australia has a federal system of government with powers divided under the Constitution between the Commonwealth government and the country's six states and two mainland self-governing territories.[1] The matters over which the Commonwealth Parliament has legislative powers are listed in sections 51 and 52 of the Constitution.[2] Most of these legislative powers are concurrent, meaning that they are shared with state and territory parliaments. Where there is a conflict between state and federal laws, the federal law will override the state law to the extent of the inconsistency.[3]

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[1] *See generally Making Laws*, PARLIAMENTARY EDUCATION OFFICE, http://www.peo.gov.au/learning/closer-look/governing-australia/making-laws.html (last visited Oct. 28, 2014).

[2] AUSTRALIAN CONSTITUTION ss 51 & 52, http://www.comlaw.gov.au/Details/C2013Q00005.

[3] *Id.* s 109.

Section 96 of the Constitution provides the Commonwealth Parliament with the power to grant financial assistance to any state "on such terms and conditions as the Parliament thinks fit."[4] In practice, this may include tying grants to the implementation of certain policies by the states.[5] Often such policies are the subject of agreements between the state and federal governments, such as through the mechanisms of the Council of Australian Governments (COAG).[6] In addition, state and territory parliaments may refer matters within their legislative powers to the Commonwealth Parliament.[7]

Section 51(ix) of the Constitution provides that the federal government has legislative powers with respect to quarantine. In addition, the commerce and trade powers under section 51 are interpreted broadly, enabling the Commonwealth Parliament to make laws in a range of health-related areas.[8] In general, however, all other matters related to human health fall within the residual powers of the states.

Public hospitals are owned and operated by state and territory governments, which also fund and deliver various health programs and services. However, as a result of long-term funding and policy arrangements, the federal government partially funds public hospitals and "is primarily responsible for health service funding; regulation of health products, services and workforce; and national health policy leadership."[9] Various national agreements impact funding, policy, and implementation arrangements within the health sector.[10]

II. Structure of Public Health Crisis Management System

A. Federal Laws and National Agreements

In addition to the states and territories having residual legislative powers in relation to health care, the management of emergencies is also not generally a matter for which the federal government may give directions to states and territories under the Constitution. Therefore, "cooperative and collaborative mechanisms" between these levels of government are needed for the strategic coordination of responses to national emergencies, including public health crises.[11]

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[4] *Id.* s 96.

[5] Christopher Reynolds, Public and Environmental Health Law 44–45 (2011).

[6] *See About COAG*, COUNCIL OF AUSTRALIAN GOVERNMENTS, https://www.coag.gov.au/about_coag (last visited Oct. 28, 2014).

[7] Australian Constitution s 51(xxxvii).

[8] REYNOLDS, *supra* note 5, at 40–41.

[9] Australian Bureau of Statistics, *Health Care Delivery and Financing, in* 1301.0 – YEAR BOOK AUSTRALIA, 2012, http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/1301.0~2012~Main%20Features~Health%20care%20delivery%20and%20financing~235 (last updated Jan. 21, 2013).

[10] *See Health and Ageing*, COUNCIL OF AUSTRALIAN GOVERNMENTS, https://www.coag.gov.au/health_and_ageing (last visited Oct. 28, 2014).

[11] National Health Emergency Response Arrangements § 3.2 (Nov. 2011), available on the website of the Australian Government Department of Health, *at* http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-response-arrangement-nov11-l (last visited Oct. 29, 2014). For historical information regarding Australia's approach to responding to infectious disease outbreaks see Nigel Brew & Kate Brunton, *Australia's Capacity to Respond to an*

1. National Health Security Act and Agreement

All of the states and territories signed the National Health Security Agreement in 2008,[12] which supports the National Health Security Act 2007 (Cth) and National Health Security Regulations 2008 (Cth).[13] These enactments give effect to the World Health Organization's International Health Regulations (2005).[14] These regulations required Australia to "develop multi-level capacities in the health sector to effectively manage public health threats and to develop, strengthen and maintain the capacity to detect, report and respond to public health events."[15] The objectives of the National Health Security Act include

> (a) to provide a national system of public health surveillance to enhance the capacity of the Commonwealth and the States and Territories to identify, and respond to, public health events of national significance which include:
>
> (i) the occurrence of certain communicable diseases; or
>
> (ii) certain releases of chemical, biological or radiological agents; or
>
> (iii) the occurrence of public health risks; or
>
> (iv) the occurrence of overseas mass casualties; and
>
> (b) to provide for the sharing of information with:
>
> (i) the World Health Organization; and
>
> (ii) countries affected by an event relating to public health or an overseas mass casualty; and
>
> (c) to support the Commonwealth and the States and Territories in giving effect to the International Health Regulations (other than as mentioned in paragraphs (a) and (b)).[16]

The National Health Security Agreement is primarily concerned with strengthening Australia's public health surveillance and reporting system. It sets out the responsibilities of entities at the national and state levels of government with regard to surveillance and reporting of communicable diseases and responding to significant public health events.

2. National Health Emergency Response Arrangements

The Australian government's 2011 National Health Emergency Response Arrangements, referred to as the NatHealth Arrangements, "articulate the strategic arrangements and mechanisms for the coordination of the Australian health sector in response to emergencies of

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Infectious Disease Outbreak (Research Paper No. 3 2004-5, Nov. 16, 2004), AUSTRALIAN PARLIAMENTARY LIBRARY, http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp0405/05rp03.

[12] *See* National Health Security Agreement, available on the website of the Australian Government Department of Health, *at* http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-nhs-agreement.htm (last visited Oct. 29, 2014).

[13] National Health Security Act 2007 (Cth), http://www.comlaw.gov.au/Details/C2014C00121; National Health Security Regulations 2008 (Cth), http://www.comlaw.gov.au/Details/F2013C00171.

[14] WHO, International Health Regulations (2d ed. 2005), http://www.who.int/ihr/publications/9789241596664/en/ (last visited Oct. 28, 2014).

[15] National Health Security Agreement, *supra* note 12, recital B.

[16] National Health Security Act 2007 (Cth) s 6.

national consequence."[17] The document provides a governance structure for coordination, command or control, and information flows during national health emergencies.

Emergencies of national consequence are those that "require consideration of national level policy, strategy and public messaging or inter-jurisdictional assistance, where such assistance is not covered by existing arrangements."[18] The NatHealth Arrangements may be triggered to coordinate a national response to health impacts arising from, for example, natural disasters, acts of terrorism, biosecurity threats, and emergent or re-emergent communicable diseases. They operate in the broader context of Australia's national security framework, which includes various strategic plans and arrangements related to both conventional and nonconventional threats.[19] They may also be utilized for an international health emergency affecting Australian interests or nationals.[20]

B. State and Territory Responsibilities

The National Health Security Agreement recognizes that state and territory governments have "primary responsibility for the public health response" to public health events within their own jurisdictions,[21] while the Commonwealth government has "primary responsibility for international border surveillance and public health events occurring at international borders."[22] Where there is a "Public Health Event of National Significance," a "national health sector response will occur at the request of an affected, or potentially affected, State or Territory."[23] Such a response will be coordinated at the national level in accordance with Commonwealth and state and territory legislation, as well as any established national plans or protocols, and each state and territory will also "undertake its own jurisdictional coordinating processes."[24]

According to the NatHealth Arrangements,

> [s]tate and territory health authorities have well established emergency management legislation, and well rehearsed and integrated emergency management arrangements.
>
> Jurisdictional health authorities have existing command and control structures for the management of health facilities, public health units and pathology laboratory services. Additionally, in some jurisdictions ambulance services also come under the health authority response arrangements.

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[17] National Health Emergency Response Arrangements, *supra* note 11, "Authority."

[18] *Id.*, "Introduction."

[19] *Id*.

[20] *Id.* § 3.3.2.

[21] National Health Security Agreement, *supra* note 12, art. 3.

[22] *Id.* art. 22.

[23] *Id.* art. 14.

[24] *Id.* art. 20.

> Each state and territory is responsible for determining its own internal coordination mechanisms to give effect to the NatHealth Arrangements, both as an affected jurisdiction in requesting national coordination and as an unaffected jurisdiction that may provide resources and assistance.[25]

C. Key National Coordination Entities

1. Australian Health Protection Committee

The Australian Health Protection Committee (AHPC) was established in 2006 by the Australian Health Ministers' Advisory Council (AHMAC). Along with a second new committee, the Australian Population Health Development Committee, the AHPC replaced the previous National Public Health Partnership.[26] It is responsible for "high level cross jurisdictional collaboration in public health protection, planning, preparedness, response and recovery in relation to public health emergencies arising from man made emergencies or natural disasters."[27] Its membership includes the Commonwealth Chief Medical Officer and the Chief Health Officer of each state and territory, as well as health disaster officials, clinical experts, and representatives from the federal Department of Health, Australian Defence Force, and the Emergency Management Australia division of the Attorney-General's Department.[28]

The roles of the AHPC include, among others,

- advising and making recommendations to AHMAC on health protection matters; to mitigate emerging health threats related to infectious diseases, the environment, natural disasters and disasters related to human endeavour in a context of prevention, preparedness, response and recovery;
- advising on national health protection priorities and coordinating the allocation of health resources to these priorities;
- national coordination of emergency operational activity in health responses to disasters and health protection issues of national significance;
- enabling development and adoption by states and territories of national health protection policies, guidelines and standards[.][29]

The AHPC has various standing committees, including the Communicable Diseases Network Australia (CDNA), National Health Emergency Management Subcommittee (NHEMS), and the

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[25] National Health Emergency Response Arrangements, *supra* note 11, § 4.2.

[26] *The National Public Health Partnership*, NATIONAL PUBLIC HEALTH PARTNERSHIP (archived by the Victoria Department of Health), http://www.health.vic.gov.au/archive/archive2014/nphp/ (last updated Feb. 22, 2010).

[27] National Health Emergency Response Arrangements, *supra* note 11, § 4.3.

[28] Presentation, Dr. Robyn Walker, Department of Health and Ageing, RACMA Annual Conference 2011, slide 5 (Oct. 12, 2011), Royal Australasian College of Medical Examiners website, http://files.racma.com.au/conference_racma2011_Walker-135.pdf. For information on Emergency Management Australia, see *Our Organisation*, AUSTRALIAN EMERGENCY MANAGEMENT, AUSTRALIAN GOVERNMENT ATTORNEY-GENERAL'S DEPARTMENT, http://www.em.gov.au/AboutAGD/Ourorganisation/Pages/default.aspx (last visited Oct. 28, 2014).

[29] *Principal Committees*, AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL, http://www.ahmac.gov.au/site/membership.aspx#other (last visited Oct. 28, 2014).

Public Health Laboratory Network (PHLN). The AHPC and these three standing committees receive secretariat support from the Office of Health Protection within the Department of Health.[30]

a. National Health Emergency Management Subcommittee

According to the NatHealth Arrangements,

> [t]he National Health Emergency Management Subcommittee (NHEMS) addresses the operational aspects of disaster medicine and health emergency management in an all hazards context with a focus on preparedness and response. The NHEMS reports to the AHPC. In an emergency the AHPC may task NHEMS to provide advice on operational aspects of the response.[31]

b. Communicable Diseases Network Australia

The CDNA was established in 1989. It "provides national public health co-ordination on communicable disease surveillance, prevention and control, and offers strategic advice to governments and other key bodies on public health actions to minimise the impact of communicable diseases in Australia and the region."[32] The committee meets every two weeks to review information and developments related to communicable diseases surveillance. Its ongoing projects include developing a national communicable disease framework and developing national guidelines for the Series of National Guidelines (SoNGs). Such guidelines are endorsed by the AHPC and "provide nationally consistent advice and guidance to public health units in responding to a notifiable disease event."[33] The CDMA also provides advice on the inclusion and removal of conditions on the Nationally Notifiable Diseases List.[34]

c. Public Health Laboratory Network

The PHLN was first established as part of the previous 1996 National Communicable Diseases Surveillance Strategy in order to complement the CDNA.[35] It is a "collaborative group of pathology and veterinary laboratories, nominated by state and territory health departments,"[36] with the central role of providing "leadership and consultation in all aspects of public health

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[30] *About the Office of Health Protection (OHP)*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-about.htm (last updated Sept. 25, 2014).

[31] National Health Emergency Response Arrangements, *supra* note 11, § 6.5.1.

[32] *About Communicable Diseases Network Australia*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/content/cda-cdna-cdna.htm (last updated Nov. 4, 2013).

[33] *Series of National Guidelines (SoNGs)*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/cdnasongs.htm (last updated Oct. 14, 2014).

[34] About Communicable Diseases Network Australia, *supra* note 32.

[35] *Overview of the Public Health Laboratory Network (PHLN)*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/content/cda-cdna-phln-phln.htm (last updated Feb. 26, 2014).

[36] National Health Emergency Response Arrangements, *supra* note 11, § 6.5.1.

microbiology and communicable disease control."[37] During an emergency of national consequence, the AHPC may seek advice on laboratory diagnostic and surveillance aspects of the emergency from the PHLN.[38]

d. Australian Medical Assistance Teams

The AHPC also oversees multidisciplinary civilian medical assistance teams situated throughout the country. The Australian Medical Assistance Teams (AUSMATs), which are designed to be self-sufficient and have field deployment capabilities, include various volunteer health professionals such as doctors, nurses, paramedics, firefighters, environmental health staff, radiographers, and pharmacists.[39] AHPC may deploy AUSMATs to affected Australian jurisdictions or overseas to assist in the event of health emergencies.[40]

2. Department of Health and Health Emergency Management Branch

According to the NatHealth Arrangements, the federal Department of Health provides leadership and national health sector coordination in the event of an emergency of national consequence. This may include "provision of expert health advice and national policy development, logistical coordination of extra jurisdictional health sector resources (human, equipment and peripherals) and linkages to international health authorities and bodies."[41] The federal budget for the Department of Health includes a specific outcome related to "Biosecurity and Emergency Response."[42]

The Department of Health's Office of Health Protection aims to "protect the health of the Australian community through effective national leadership and coordination and building of appropriate capacity and capability to detect, prevent and respond to threats to public health and safety."[43] It consists of several branches, including the Health Protection Policy Branch, Health Emergency Management Branch (HEMB), and Immunisation Branch.
HEMB is the designated National Focal Point under the National Health Security Act 2007 (Cth) and the International Health Regulations (2005).[44] It undertakes a range of activities related to

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[37] Overview of the Public Health Laboratory Network (PHLN), *supra* note 35.

[38] National Health Emergency Response Arrangements, *supra* note 11, § 6.5.1.

[39] *AUSMAT*, NATIONAL CRITICAL CARE AND TRAUMA RESPONSE CENTRE, http://www.nationaltraumacentre.nt.gov.au/what-we-do/disaster-management/ausmat (last visited Oct. 28, 2014); *Australian Medical Assistance Team*, SA HEALTH, http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/protecting+public+health/emergency+management/australian+medical+assistance+team (last modified Oct. 21, 2014).

[40] National Health Emergency Response Arrangements, *supra* note 11, § 6.5.1.

[41] *Id.* § 4.1.

[42] Australian Budget 2014–15 Health Portfolio Budget Statements, Outcome 9: Biosecurity and Emergency Response (2014), http://www.health.gov.au/internet/budget/publishing.nsf/Content/2014-2015_Health_PBS_sup2/$File/2014-15_Health_PBS_2.09_Outcome_9.pdf.

[43] About the Office of Health Protection (OHP), *supra* note 30.

[44] *Id.*

providing "effective surveillance of current and emerging communicable disease threats" and to monitoring and implementing "effective and sustained responses to national health emergencies and risks."[45] For example, it is responsible for managing the National Incident Room (NIR),[46] which "provides a centralised hub from which responses to national health emergencies are coordinated."[47] The branch also manages the National Medical Stockpile (NMS),[48] administers the Security Sensitive Biological Agents Regulatory Scheme, publishes the *Communicable Diseases Intelligence* journal, and manages surveillance systems for nationally notifiable diseases, among other activities.[49]

D. Notification and Surveillance System

Public health legislation in each state and territory mandates that certain diseases be reported by health care providers to the relevant state or territory health department, while the National Health Security Act 2007 (Cth) requires the establishment and maintenance of a National Notifiable Disease List.[50] Diseases may be added to this list "if the Commonwealth Minister, having consulted State and Territory Ministers, considers that an outbreak would be a public health risk."[51] Diseases may also be added in an emergency where there is not time to undertake consultation.[52]

The federal government operates the National Notifiable Diseases Surveillance System.[53] Where a nationally-notifiable disease is reported at the state or territory level, "[c]omputerised, de-identified unit records of notifications are supplied to the Australian Government Department of Health on a daily basis, for collation, analysis and publication on the Internet, (updated 3 times per week), and in the quarterly journal *Communicable Diseases Intelligence*."[54] The Office of

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[45] *Id*.

[46] *National Incident Room*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-bio-factsht_inc_room.htm (last updated Mar. 4, 2011).

[47] Dr. Robyn Walker, *supra* note 28, slide 9.

[48] *National Medical Stockpile*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-bio-factsht_stckpile.htm (last updated May 14, 2014).

[49] About the Office of Health Protection (OHP), *supra* note 30.

[50] National Health Security Act 2007 (Cth) pt 2 div 5; National Health Security (National Notifiable Disease List) Instrument 2008 (Cth), http://www.comlaw.gov.au/Details/F2008L00800.

[51] National Health Security Agreement, *supra* note 12, definition of NNDL; National Health Security Act 2007 (Cth) s 11(2).

[52] National Health Security Act 2007 (Cth) s 12.

[53] For information on the history and development of the surveillance system, *see* Megge Miller et al., *Evaluation of Australia's National Notifiable Disease Surveillance System*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-2004-cdi2803a.htm (last updated Oct. 30, 2004).

[54] *Introduction to the National Notifiable Diseases Surveillance System*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-nndssintro.htm (last updated Mar. 11, 2014).

Health Protection is the "primary data collection and coordination centre for many communicable diseases."[55]

Under the National Health Security Agreement, where there are one or more cases of certain diseases listed in the National Notifiable Disease List this will be considered a "Public Health Event of National Significance" and must be reported to the National Focal Point. The relevant diseases are

- smallpox,
- poliomyelitis due to wild-type poliovirus;
- human influenza caused by a new subtype;
- severe acute respiratory syndrome (SARS);
- pneumonic plague;
- yellow fever;
- viral haemorrhagic fevers;
- cholera;
- rabies.[56]

The reporting requirement may also be triggered by any other potential "Public Health Event of National Significance or Public Health Emergency of International Concern" depending on the circumstances.[57] Events that constitute a Public Health Emergency of International Concern are defined in Annex 2 of the International Health Regulations (2005).[58]

Notification requirements that may be imposed on others, such as the captains of ships or aircraft entering Australia, are included in the Quarantine Act 1908 (Cth).[59] The Department of Agriculture is notified of ill passengers before a plane lands or a ship docks. In addition, information about where a person has traveled and whether they are feeling ill upon entering Australia may be required.[60] Further information on powers that may be exercised under the Quarantine Act 1908 (Cth) is provided below.

Under the National Health Security Act 2007 (Cth), where a state or territory authority places a traveler who enters, and is in transit, under public health observation while in Australia, the National Focal Point must be notified and provided with certain details.[61]

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[55] *Communicable Diseases Information*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-communic-1 (last updated Oct. 23, 2014).

[56] National Health Security Agreement, *supra* note 12, definition of "Public Health Event of National Significance to be Reported to the NFP."

[57] *Id*.

[58] *Id.*, definition of "Public Health Emergency of International Concern."

[59] Quarantine Act 1908 (Cth) s 22, http://www.comlaw.gov.au/Details/C2014C00612. *See also Fact Sheet: Reporting an Illness or Death*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-quarantine-factsheet (last updated Feb. 17, 2014).

[60] *Quarantine*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-quarantine.htm (last updated Aug. 20, 2014).

[61] National Health Security Act 2007 (Cth) s 17.

III. Powers of Public Health Authorities

A. Vaccinations

As a general rule, there are no diseases for which vaccination is compulsory for persons living in Australia. However, unless an appropriate medical or philosophical exemption has been obtained, children must be assessed as fully immunized in order for parents to be eligible for the federal Family Tax Benefit Part A supplement and other payments.[62] A national childhood immunization register records vaccinations given to children under seven years of age.[63] Parents may be required to keep a nonimmunized child home from school or day care if certain cases of vaccine-preventable diseases occur at that facility.[64]

Furthermore, where cases of quarantinable diseases arise, quarantine officers have the power to require a person who is subject to quarantine to submit to vaccination or prophylaxis if this is considered necessary to prevent the spread of the disease or is specified in the International Health Regulations.[65] The Quarantine Act 1908 (Cth) was amended in 2008 to meet certain requirements under the International Health Regulations (2005) for vaccinations and other health measures related to travelers.[66]

B. State and Territory Public Health Legislation

As noted above, state and territory governments have various powers under their respective public health and emergency management laws. For example, in New South Wales, the largest state in the country, the Public Health Act 2010 (NSW) provides that, where a state of emergency exists under the State Emergency and Rescue Management Act 1989 (NSW), the relevant Minister may take actions or give orders that could include directing all persons in a specified group or area to submit to medical examination.[67]

Furthermore, where a situation exists that is considered a threat to public health, the Minister may take actions to reduce the risk, segregate or isolate people in an area, and prevent access to

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[62] AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, THE AUSTRALIAN IMMUNISATION HANDBOOK, App. 4: "Commonly Asked Questions about Vaccination" (10th ed. 2013), http://www.health.gov.au/internet/immunise/publishing.nsf/Content/appendix4. *See also Immunising Your Children*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HUMAN SERVICES, http://www.humanservices.gov.au/customer/subjects/immunising-your-children (last updated Oct. 24, 2014).

[63] *Australian Childhood Immunisation Register*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HUMAN SERVICES, http://www.humanservices.gov.au/customer/services/medicare/australian-childhood-immunisation-register (last updated July 4, 2014).

[64] The Australian Immunisation Handbook, *supra* note 62.

[65] Quarantine Act 1908 (Cth) s 75.

[66] Quarantine Amendment (National Health Security) Act 2008 (Cth), http://www.comlaw.gov.au/Details/C2008A00068.

[67] Public Health Act 2010 (NSW) s 8, http://www.legislation.nsw.gov.au/maintop/view/inforce/act+127+2010+cd+0+N.

an area.[68] In individual cases, if a certain condition is suspected and a person is considered to be a risk to public health, the Director-General of the New South Wales health department may direct that the person undergo a medical examination and associated tests.[69] Other public health orders are also available to authorized medical practitioners where a person has a condition and is behaving in a way that may be a risk to public health. This might including ordering the person to refrain from certain conduct, submit to supervision, or undergo specified treatment.[70] Where such an order is contravened, the person may be arrested and detained.[71]

In New South Wales, the above public health orders may be made with respect to persons who have the following conditions: avian influenza in humans; Middle East respiratory syndrome coronavirus; Severe Acute Respiratory Syndrome (SARS); tuberculosis; typhoid; viral haemorrhagic fevers; Acquired Immune Deficiency Syndrome (AIDS); and Human Immunodeficiency Virus (HIV) infection.[72]

Similar public health orders and other powers related to notifiable diseases are available under the public health legislation of Queensland, the third largest state. For example, a judge may issue a detention order for a person with a "controlled notifiable condition" whose condition or behavior constitutes an "immediate risk to public health."[73] The person subject to the order must remain at the place of detention for the period stated in the order and undergo ordered medical examination or treatment.[74]

C. Federal Quarantine Law

The Quarantine Act 1908 (Cth) is administered jointly by the Department of Health and the Department of Agriculture. Under the federal statute, in the event of an emergency a proclamation may be issued declaring that "any or all measures of quarantine prescribed by or under any State Act" must cease to have effect for a period of time.[75] In addition, the Commonwealth government may enter into arrangements with states and territories with respect to a range of quarantine-related matters.[76]

The federal government may declare by proclamation the existence of an epidemic or the danger of an epidemic caused by a quarantinable disease. During the period that the proclamation is in force the relevant Minister may "give such directions and take such action as he or she thinks

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[68] *Id.* s 7.

[69] *Id.* s 61.

[70] *Id.* s 62.

[71] *Id.* s 71.

[72] *Id.* sch 1, categories 4 & 5.

[73] Public Health Act 2005 (Qld) s 129, https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf.

[74] *Id.* s 132.

[75] Quarantine Act 1908 (Cth) s 2A.

[76] *Id.* s 11.

necessary to control and eradicate the epidemic, or to remove the danger of the epidemic, by quarantine measures or measures incidental to quarantine."[77] Authorized persons may also exercise such powers in order to implement a coordinated response to a declared epidemic.[78] Failure to comply with a direction given under these provisions is an offense punishable by up to ten years' imprisonment.[79]

In the legislation, quarantine is defined to include measures

> (a) for, or in relation to:
>
> (i) the examination, exclusion, detention, observation, segregation, isolation, protection, treatment and regulation of vessels, installations, human beings, animals, plants or other goods or things; or
>
> (ii) the seizure and destruction of animals, plants, or other goods or things; or
>
> (iii) the destruction of premises comprising buildings or other structures when treatment of these premises is not practicable; and
>
> (b) having as their object the prevention or control of the introduction, establishment or spread of diseases or pests that will or could cause significant damage to human beings, animals, plants, other aspects of the environment or economic activities.[80]

The Quarantine Act 1908 (Cth) provides that persons who may be subject to quarantine include "every person infected with a quarantinable disease or quarantinable pest," or who a quarantine officer reasonably suspects is infected, as well as persons who have been in contact with or exposed to infection from any person or goods subject to quarantine.[81] Quarantinable diseases are listed in the Quarantine Proclamation 1998 (Cth),[82] and are also reflected in the National Notifiable Disease List.[83]

Where a vessel or installation has on board a case of communicable disease, and a quarantine officer certifies that quarantine measures are needed to stop the spread of the disease, such measures may be taken in relation to the vessel itself as well as any persons or goods on board. Those suffering from the disease, which need not be a quarantinable disease, may be ordered into quarantine.[84]

Persons ordered into quarantine may be detained on board the vessel in which they arrived in Australia, on the premises on which they are found, or removed and detained in a quarantine

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[77] *Id.* s 2B(1) & (2).

[78] *Id.* s 3.

[79] *Id.* ss 2B(3) & 3(9).

[80] *Id.* s 4(1).

[81] *Id.* s 18(1).

[82] Quarantine Proclamation 1998 (Cth) reg 21, http://www.comlaw.gov.au/Details/F2014C00294.

[83] National Health Security (National Notifiable Disease List) Instrument 2008 (Cth) div 2.3.

[84] Quarantine Act 1908 (Cth) s 35.

station or other approved place.[85] Persons arriving in Australia may also be placed under "quarantine surveillance" as an alternative to detention.[86]

Various enforcement powers are included in Part VIA of the Quarantine Act 1908 (Cth). These include powers in relation to premises and vehicles, and search and seizure powers.

In July 2014, the Minister for Agriculture announced that the Biosecurity Bill 2014 would be advanced to replace the Quarantine Act 1908 (Cth).[87] The Bill was previously introduced in 2012 but lapsed when Parliament adjourned in 2013.[88] The passage of the Bill would be "the biggest change to [Australia's] biosecurity system in more than one hundred years."[89] Among the changes would be new powers to allow the Commonwealth government to respond to biosecurity risks and to "help state and territory governments manage a nationally significant pest or disease outbreak."[90]

IV. Transparency of Public Health Crisis Management System

As noted above, the Department of Health, through the National Notifiable Diseases Surveillance System, provides online, publicly-available information on notifiable diseases that is updated three times per week. Summary data is available online for each state and territory, and all diseases, dating back to 1991.[91] A quarterly journal that provides detailed information on different diseases and related activities is also published by the Department of Health.[92] The National Health Security Act 2007 (Cth) contains provisions related to information confidentiality, disclosure, and use.[93]

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[85] *Id.* s 45(1).

[86] *Id.* s 34.

[87] Press Release, Hon. Barnaby Joyce MP, Historic Biosecurity Bill 2014 to Safeguard Australia (July 7, 2014), http://www.maff.gov.au/Pages/Media%20Releases/biosecurity-bill-2014.aspx; *Biosecurity Bill 2014*, AUSTRALIAN GOVERNMENT DEPARTMENT OF AGRICULTURE, http://www.agriculture.gov.au/bsg/biosecurity-reform/new-biosecurity-legislation (last updated Oct. 1, 2014).

[88] Biosecurity Bill 2012, http://www.comlaw.gov.au/Details/C2012B00222. *See also Chapter 2 – Managing Biosecurity Risk: Human Health*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-biosecurity-2-human-health.htm (last updated Feb. 20, 2013).

[89] Hon. Barnaby Joyce MP, *supra* note 87.

[90] *Id*.

[91] *National Notifiable Diseases Surveillance System*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www9.health.gov.au/cda/source/cda-index.cfm (last updated Oct. 29, 2014).

[92] *Communicable Diseases Intelligence – Current Issue – June 2014*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/cdi (last updated Aug. 25, 2014). *See also Surveillance Systems Reported in Communicable Disease Intelligence 2014,* AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-surv_sys.htm (last updated June 30, 2014).

[93] National Health Security Act 2007 (Cth) pt 2 div 8.

V. Response to Ebola Virus Epidemic in West Africa

Australian federal and state and territory governments have taken a range of actions in response to the 2014 Ebola virus disease (EVD) epidemic in several countries in West Africa. This includes the appointment of an infectious disease expert to oversee the response.[94] State and territory Chief Health Officers provide weekly updates on their preparedness plans at meetings of the AHPC. Australia's Chief Medical Officer stated in October 2014 that

> [n]ationally and at a local level we have alerted doctors, hospital, paramedics and other health professionals on what to do if they suspect a patient has Ebola.
>
> All States and Territories have their own response plans which include designating specific hospitals to treat suspected cases and ensuring there are adequate facilities and equipment, including personal protection, available.
>
> In addition the Communicable Diseases Network of Australia has produced a series of special guidelines for hospitals, public health units, clinicians and GPs. The guidelines give step by step guidance on identifying and dealing with a suspected case and they are continually under review as new information and experiences from overseas are received.[95]

Enhanced airport screening of passengers traveling to Australia from affected countries started in August 2014, and airport border agencies have been provided with guidance by the Department of Health "to identify and quarantine any passengers presenting Ebola symptoms in flights or at airports."[96] Travelers who have been in EVD-affected countries are asked a series of questions by a Biosecurity Officer "to assess their risk of exposure to EVD."[97] Passengers may then be referred to state health authorities for assessment if required.[98] As at late October, more than nine hundred passengers had been screened at ten Australian airports.[99] Twenty-four people had undergone a full screening process, "including being referred to human quarantine officers."[100]

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[94] Sophie Scott & Brigid Anderson, *Infectious Disease Expert Professor Lyn Gilbert Appointed to Oversee Australia's Response to Ebola Threat*, ABC NEWS (Oct. 23, 2014), http://www.abc.net.au/news/2014-10-23/infectious-diseases-expert-named-as-australias-ebola-tsar/5837000.

[95] Press Release, Australian Government Department of Health, Ebola Health Protection Update (Oct. 17, 2014), http://www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr14-dept-dept010.htm.

[96] Press Release, Australian Health Protection Principal Committee, Australia is Well Prepared to Deal with Ebola (Aug. 15, 2014), http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-ebola.htm//$File/AHPPC-Statement.pdf.

[97] *Ebola Outbreak in West Africa*, SMARTRAVELLER.GOV.AU, http://www.smartraveller.gov.au/zw-cgi/view/travelbulletins/Ebola (last updated Oct. 25, 2014).

[98] Press Release, Hon. Barnaby Joyce MP, Appropriate Biosecurity Measures at Airports to Help Manage Ebola Risk (Oct. 17, 2014), http://www.maff.gov.au/Pages/Media%20Releases/appropriate-biosecurity-measures-airports-ebola-risk.aspx.

[99] Sarah Scopelianos & Tim Leslie, *Explained: Australia's Plan to Tackle Ebola*, ABC NEWS http://www.abc.net.au/news/2014-10-30/ebola-explained-australia-response/5826378 (last visited Oct. 31, 2014).

[100] Dan Harrison, *Australia Shuts Borders to Ebola-Affected Countries*, THE SYDNEY MORNING HERALD (Oct. 28, 2014), http://www.smh.com.au/federal-politics/political-news/australia-shuts-borders-to-ebolaaffected-countries-20141027-11ciut.html.

On October 27, 2014, the Minister of Immigration announced in Parliament that Australian immigration authorities had stopped processing visa applications from citizens from EVD-affected countries.[101] People from these countries who had previously received permanent immigration visas are required to submit to a twenty-one day quarantine period before leaving West Africa, as well as being checked on arrival in Australia.[102] Temporary visas previously granted to people who had not yet traveled to Australia were canceled.[103]

In terms of national guidance and response coordination, the CDNA issued a new SoNG on EVD for public health units in August 2014, which has been updated several times and endorsed by the AHPC.[104] In addition, the PHLN has prepared the National High Security Quarantine Laboratory Guideline for Management of Quarantinable Viral Haemorrhagic Fevers[105] and guidelines on laboratory procedures for samples collected from patients with suspected EVD.[106] The Department of Health provides updates on its website regarding actions being taken by the federal government to "prevent the spread of EVD to Australia in partnership with the States and Territories."[107] For example, it states that "EVD is a quarantinable disease in Australia, and as such can be controlled and eradicated through a range of quarantine measures, including enforcing appropriate disinfection measures on aircraft and ships or port facilities."[108]

At the state and territory level, detailed EVD response plans have been prepared or updated and published by health departments, such as the Victorian Ebola Virus Disease Response Plan[109]

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[101] *Federal Government to Stop Processing Visa Applications from Countries Affected by Ebola*, ABC NEWS (Oct. 27, 2014), http://www.abc.net.au/news/2014-10-27/government-visa-applilcations-ebola/5845048.

[102] Interview, Hon. Scott Morrison MP with Chris Uhlman, ABC AM Programme (Oct. 27, 2014), http://www.minister.immi.gov.au/media/sm/2014/sm218747.htm; Scopelianos & Leslie, *supra* note 99.

[103] Harrison, *supra* note 100.

[104] Australian Government Department of Health, Ebola Virus Disease (EVD): CDNA National Guidelines for Public Health Units (version 1.3, Oct. 24, 2014), http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-ebola.htm/$File/EVD-SoNG.pdf.

[105] *National High Security Quarantine Laboratory Guideline for Management of Quarantinable Viral Haemorrhagic Fevers*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-nhsql-qvhf.htm (last updated Aug. 14, 2014).

[106] *Laboratory Procedures and Precautions for Samples Collected from Patients with Suspected Viral Haemorrhagic Fevers* (Oct. 2014), AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-other-vhf.htm (last updated Oct. 17, 2014).

[107] *Ebolavirus Disease (Ebola) Outbreaks in West Africa*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-ebola.htm (last updated Oct. 31, 2014).

[108] *Ebolavirus Disease (EVD) Outbreaks in West Africa – Important Information for Travellers, Patients and Consumers*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-ebola-info-patients.htm (last updated Oct. 17, 2014).

[109] VICTORIA DEPARTMENT OF HEALTH, VICTORIAN EBOLA VIRUS DISEASE RESPONSE PLAN (version 1, Sept. 15, 2014), http://docs.health.vic.gov.au/docs/doc/F379C2BD968364E8CA257D540008B3CA/$FILE/Victorian%20Ebola%20Virus%20Disease%20Response%20Plan_September%202014.pdf.

and the New South Wales Contingency Plan for Viral Haemorrhagic Fevers.[110] These are read alongside the SoNG issued by the CDNA as well as state and territory legislation.

During October, nineteen people from four families were placed on home quarantine in Queensland for twenty-one days after arriving from affected countries on humanitarian visas.[111] In addition, in September a person in Queensland who had previously traveled to an EVD affected country "was isolated, overseen by infectious disease experts with necessary tests quickly initiated."[112]

The federal government has stated that a team of twenty health care workers is available to be dispatched to Australia's regional neighbors should they request assistance in the event of an EVD outbreak.[113] As at late October 2014, Australia was facing criticism from the affected countries and the United Nations with regard to the new visa restrictions,[114] and from the Australian Medical Association and others for not sending AUSMATs or other Australian health professionals to those countries to provide medical assistance.[115]

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[110] Health Protection NSW, NSW Contingency Plan for Viral Haemorrhagic Fevers (updated Oct. 22, 2014), http://www.health.nsw.gov.au/Infectious/alerts/Documents/NSW-VHF-Plan-Web.pdf.

[111] Paul Osborne, *Aust Closes Door on Ebola-Affected Countries*, THE AUSTRALIAN (Oct. 27, 2014), http://www.theaustralian.com.au/news/latest-news/woman-tests-negative-for-ebola-in-brisbane/story-fn3dxiwe-1227103069235?nk=59548baedb63759428ccdeece45558ba.

[112] Press Release, Hon. Peter Dutton MP, Australia's World Class Preparedness Against Ebola (Sept. 11, 2014), http://www.health.gov.au/internet/ministers/publishing.nsf/content/health-mediarel-yr2014-duttonpd075.htm.

[113] Press Release, Hon. Peter Dutton MP, Ebola – The Facts: Australia is Ready and Able to Assist Neighbouring Countries Across the Region Should Ebola Appear Here (Oct. 22, 2014), http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2014-dutton090.htm.

[114] Greg Dyett, *Australia Criticised Over Ebola Visa Decision*, SBS (Oct. 29, 2014), http://www.sbs.com.au/news/article/2014/10/29/australia-criticised-over-ebola-visa-decision; Matt Siegel, *Australian Ebola 'Tsar' Questions Government's West Africa Visa Ban*, REUTERS (Oct. 29, 2014), http://www.reuters.com/article/2014/10/29/us-health-ebola-australia-idUSKBN0II0CU20141029.

[115] *AMA Head Attacks Australia's Response to Ebola as Shambolic*, THE AUSTRALIAN (Oct. 26, 2014), http://www.theaustralian.com.au/in-depth/ebola-crisis/ama-head-attacks-australias-response-to-ebola-as-shambolic/story-fnpqlos3-1227102521941.

Brazil

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SUMMARY In Brazil, health is a fundamental right under the Constitution and the government has responsibility for the regulation and control of health activities and services, as well as sanitary and epidemiologic surveillance.

A Unified Health System, defined as a body of actions and health services provided by public organs and institutions at all government levels, is in charge of executing epidemiologic surveillance proceedings, including those for the purpose of recommending and adopting preventive measures and the control of diseases.

The Brazilian Penal Code provides for punishing whoever causes an epidemic or fails to comply with public health regulations, and Brazil is currently in the process of incorporating the revised International Health Regulations into its domestic legal system.

Recently, the Ministry of Health updated a Contingency Plan for the Ebola Disease designed to guide government actions to prevent and a possible epidemic in the country.

I. Constitutional Principles – Health

The Brazilian Constitution states that health is a right of all and a duty of the government, guaranteed by social and economic policies aimed at reducing the risk of disease and at the equal and universal access to actions and services for its promotion, protection, and recovery.[1]

It further states that health activities and services are of public importance and it is the government's responsibility to provide, in accordance with the law, for their regulation, supervision, and control. Such activities and services must be carried out directly or through third parties and also by individuals or legal entities.[2] Public health activities and services are part of a regionalized and hierarchical network and constitute a unified[3] system.[4]

According to the Constitution, the Unified Health System (Sistema Único de Saúde, SUS) is responsible, inter alia, for the execution of actions regarding sanitary and epidemiologic surveillance, as well as those relating to the health of workers.[5]

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[1] CONSTITUIÇÃO FEDERAL [C.F.] art. 196, http://www.planalto.gov.br/ccivil_03/Constituicao/Constituicao.htm.

[2] *Id*. art. 197.

[3] *Id*. art. 198.

[4] Article 198 of the Constitution also provides the organizational directives that must be followed by the unified health system.

[5] *Id*. art. 200(II).

II. Unified Health System

The SUS was established by Law No. 8,080 of September 19, 1990,[6] and, pursuant to article 4, is composed of the body of actions and health services provided by public organs and institutions at the federal, state, and municipal levels of direct and indirect administration,[7] and by the foundations maintained by the government. Federal, state and municipal public institutions of quality control, research, and production of supplies and medications, including blood and blood products and health equipment, are also part of the SUS.[8] The private sector can participate in the SUS in a complementary manner.[9]

The SUS's duties encompass, among other things, epidemiologic surveillance,[10] which is defined as a group of actions that provide for the knowledge, detection, or prevention of any change in the determining and conditioning factors of individual or collective health, for the purpose of recommending and adopting measures to prevent and control diseases.[11] Law No. 8,080 also provides for the organization of the SUS at the federal, state, and municipal levels;[12] the attributes of each organization;[13] and their competencies.[14]

A. National Agency of Sanitary Surveillance

Pursuant to the authority in Law No. 8,080,[15] on January 26, 1999, the government issued Law No. 9,782, which further defined the National System of Sanitary Surveillance (Sistema Nacional de Vigilância Sanitária), and created the National Agency of Sanitary Surveillance (Agência Nacional de Vigilância Sanitária, ANVISA).[16]

ANVISA is a federal agency (*autarquia sob regime especial*) linked to the Ministry of Health the institutional purpose of which is to foster the protection of the health of the population by exercising sanitary control over the production and marketing of products and services subject to

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[6] Lei No. 8.080, de 19 de Setembro de 1990, http://www.planalto.gov.br/ccivil_03/Leis/L8080.htm.

[7] Direct Administration is considered to be the body of public administrative services exercised directly by the government (federal, state, and municipal) through government organs, such as ministries and secretaries, which are integrated into the structure of the Executive. Indirect Administration is the body of acts and services rendered by decentralized administrative agencies (*autarquias*) or public entities created by law, in the exercise of their own activities or government functions, through delegation by the government. MARIA HELENA DINIZ, 1 DICIONÁRIO JURÍDICO 123–24 (São Paulo, Editora Saraiva 2005).

[8] Lei No. 8.080, art. 4(§1).

[9] *Id.* art. 4(§2).

[10] *Id.* art. 6(I)(b).

[11] *Id.* art. 6(§2).

[12] *Id.* art. 9.

[13] *Id.* art. 15.

[14] *Id.* art. 16.

[15] *Id.* arts. 6(§1), 15–18.

[16] Lei No. 9.782, de 26 de Janeiro de 1999, art. 3, http://www.planalto.gov.br/ccivil_03/Leis/L9782.htm.

sanitary surveillance, including the environments, processes, supplies and technologies related to them, as well as the control of ports, airports and borders.[17]

The activities of epidemiologic surveillance and vector control related to ports, airports, and borders must be executed by the ANVISA under the technical and normative guidance of the Ministry of Health.[18] In addition, the agency is in charge of regulating, controlling, and inspecting products and services that pose a threat to public health.[19] Law No. 9,782 details the goods and products subordinated to the control and inspection of the ANVISA.[20] Decree No. 3,029 of April 16, 1999 approved the agency's bylaws.[21]

B. Secretariat of Health Surveillance

On August 7, 2013, Decree No. 8,065[22] granted to the Ministry of Health the authority to implement the national health policy,[23] including the coordination and supervision of the SUS;[24] responsibility for taking general preventive measures; and responsibility for the surveillance and sanitary control of borders, ports, and airports.[25]

The Secretariat of Health Surveillance (Secretaria de Vigilância em Saúde, SVS)[26] is one of the many organs within the organizational structure of the Ministry of Health and is composed of

- Department of Surveillance of Transmissible Diseases (Departamento de Vigilância das Doenças Transmissíveis);[27]
- Department of Surveillance of Non-Transmissible Diseases and Health Promotion (Departamento de Vigilância de Doenças e Agravos não Transmissíveis e Promoção da Saúde);[28]
- Department of Management of Health Surveillance (Departamento de Gestão da Vigilância em Saúde);[29]

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[17] *Id.* art. 6.

[18] *Id.* art. 7(§3).

[19] *Id.* art. 8.

[20] Id.

[21] Decreto No. 3.029, de 16 de Abril de 1999, http://www.planalto.gov.br/ccivil_03/decreto/D3029.htm.

[22] Decreto No. 8,065, de 7 de Agosto de 2013, http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2013/Decreto/D8065.htm#art7.

[23] *Id.* Anexo I, art. 1(I).

[24] *Id.* art. 1(II).

[25] *Id.* art. 1(VI).

[26] *Id.* art. 2(II)(e).

[27] *Id.* art. 2(II)(e)(1).

[28] *Id.* art. 2(II)(e)(2). Article 42 of Decree No. 8,065 defines the competence of the Department of Surveillance of Non-Transmissible Diseases and Health Promotion.

- Department of Surveillance, Prevention and Control of Sexually Transmitted Diseases, Acquired Immunodeficiency Syndrome and Viral Hepatitis (Departamento de Vigilância, Prevenção e Controle das Doenças Sexualmente Transmissíveis, Síndrome da Imunodeficiência Adquirida e Hepatites Virais);[30] and
- Department of Environmental Health Surveillance and Worker's Health (Departamento de Vigilância em Saúde Ambiental e Saúde do Trabalhador).[31]

The SVS is responsible for coordinating the management of the National System of Health Surveillance (Sistema Nacional de Vigilância em Saúde), composed of

- National Subsystem of Epidemiologic Surveillance of Transmissible and Non-Transmissible Diseases (Subsistema Nacional de Vigilância Epidemiológica, de Doenças Transmissíveis, e de Agravos e Doenças Não Transmissíveis);[32]
- National Subsystem of Environmental Health Surveillance, including Working Environment Conditions (Subsistema Nacional de Vigilância em Saúde Ambiental, incluindo Ambiente de Trabalho);[33]
- National System of Laboratories of Public Health (Sistema Nacional de Laboratórios de Saúde Pública);[34]
- Health Surveillance Information Systems (Sistemas de Informação de Vigilância em Saúde);[35]
- Programs for the Prevention and Control of Diseases of Public Health Relevance, including the National Program of Immunizations (Programas de Prevenção e Controle de Doenças de Relevância em Saúde Pública, incluindo o Programa Nacional de Imunizações);[36] and
- National Policy on Worker's Health (Política Nacional de Saúde do Trabalhador).[37]

The SVS's duties include, inter alia, preparation and disclosure of information and analysis of health situations enabling the establishment of priorities, monitoring the sanitary situation of the country, assessing the impact of actions taken for the prevention and control of diseases, and

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[29] *Id.* art. 2(II)(e)(3). Article 43 of Decree No. 8,065 defines the competence of the Department of Management of Health Surveillance.

[30] *Id.* art. 2(II)(e)(4). Article 44 of Decree No. 8,065 defines the competence of the Department of Surveillance, Prevention and Control of Sexually Transmitted Diseases, Acquired Immunodeficiency Syndrome and Viral Hepatitis.

[31] *Id.* art. 2(II)(e)(5). Article 45 of Decree No. 8,065 defines the competence of the Department of Environmental Health Surveillance and Worker's Health.

[32] *Id.* art. 40(I)(a).

[33] *Id.* art. 40(I)(b).

[34] *Id.* art. 40(I)(c).

[35] *Id.* art. 40(I)(d).

[36] *Id.* art. 40(I)(e).

[37] *Id.* art. 40(I)(f).

assisting the Ministry of Health with the development of policies.[38] The SVS also coordinates activities related to preventing and controling diseases[39] and participates in preparing and implementing norms, instruments, and methods to strengthen the capacity of the SUS in all three levels of government in the field of health surveillance.[40]

C. Department of Surveillance of Transmissible Diseases

The Department of Surveillance of Transmissible Diseases is responsible, among other things, for

- Proposing norms related to (a) procedures for the prevention and control of transmissible diseases; (b) notification of transmissible diseases; (c) epidemiologic investigation; and (d) epidemiologic surveillance at ports, airports, borders and customs terminals;[41]
- Establishing preventive measures and control of risk factors and diseases;[42]
- Supplementary or complementary coordination of epidemiologic measures and control of diseases in exceptional situations, when (a) the capacity of a State is surpassed; (b) there is the involvement of more than one State; or (c) there is a risk of national dissemination;[43]
- Regulation and definition of technical instruments related to information systems regarding the mandatory notification of diseases and diseases under surveillance;[44]
- Analysis, surveillance, supervision and orientation in the execution of actions for the prevention and control of diseases that are part of a list of diseases requiring mandatory notification, or that may become important for public health;[45]
- Monitoring the epidemiologic behavior of diseases under surveillance;[46]
- Preparing the national list of diseases requiring mandatory notification;[47]
- Preparing a basic mandatory vaccination plan;[48]
- Coordination of investigations related to outbreaks and epidemics;[49] and

[38] *Id.* art. 40(II).

[39] *Id.* art. 40(III), (IV).

[40] *Id.* art. 40(VII).

[41] *Id.* art. 41(I).

[42] *Id.* art. 41(II).

[43] *Id.* art. 41(III).

[44] *Id.* art. 41(IV).

[45] *Id.* art. 41(V).

[46] *Id.* art. 41(VI).

[47] *Id.* art. 41(VII).

[48] *Id.* art. 41(VIII).

[49] *Id.* art. 41(IX).

- Regulation and supervision of the National System of Laboratories of Public Health with respect to health surveillance.[50]

1. Epidemiologic Surveillance Guide

In 1975, the Ministry of Health created the National System for Epidemiologic Surveillance (Sistema Nacional de Vigilância Epidemiológica, SNVE).[51] The SNVE was established by Law No. 6,259 of October 30, 1975, which was regulated by Decree No. 78,231 of August 12, 1976.[52]

Law No. 6,259 provided for the organization of epidemiologic surveillance actions,[53] created the national program of immunizations,[54] and made mandatory the communication of the presence of selected diseases.[55]

In 1977, the Ministry of Health prepared the first Epidemiologic Surveillance Manual (*Manual de Vigilância Epidemiológica*), which gathered all technical norms being used for the surveillance of each disease within the ambit of specific control programs.[56] The manual is still being published by the Ministry of Health and its last updated version was issued in 2009.[57]

With the promulgation of Law No. 8,080 on September 19, 1990, the SUS incorporated the SNVE, which further defined epidemiologic surveillance[58] and re-organized the health system in the country.[59]

2. Rapid Response Center

In 1990, the government merged two agencies in charge of public health and created the National Health Foundation (Fundação Nacional de Saúde, FUNASA),[60] an entity responsible for health promotion and protection,[61] promoting sanitation solutions for prevention and control of

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[50] *Id.* art. 41(X).

[51] MINISTÉRIO DA SAÚDE, GUIA DE VIGILÂNCIA EPIDEMIOLÓGICA 17, 18 (7ª Edição, Brasília, DF, 2009), http://bvsms.saude.gov.br/bvs/publicacoes/guia_vigilancia_epidemiologica_7ed.pdf.

[52] Decreto No. 78.231, de 12 de Agosto de 1976, http://www.planalto.gov.br/ccivil_03/decreto/1970-1979/D78231.htm.

[53] Lei No. 6.259, de 30 de Outubro de 1975, art. 2, http:// www.planalto.gov.br/ccivil_03/Leis/L6259.htm.

[54] *Id.* art. 3.

[55] *Id.* art. 7.

[56] MINISTÉRIO DE SAÚDE, *supra* note 51.

[57] *Id*.

[58] Lei No. 8.080, de 19 de Setembro de 1990, art. 6(§2), http://www.planalto.gov.br/ccivil_03/Leis/L8080.htm.

[59] *Id*.

[60] Lei No. 8.029, de 12 de Abril de 1990, art. 14, http://www.planalto.gov.br/ccivil_03/LEIS/L8029cons.htm#art14.

[61] Decreto No. 7.335, de 19 de Outubro de 2010, Anexo I, art. 2, http://www.planalto.gov.br/ccivil_03/_Ato2007-2010/2010/Decreto/D7335.htm#art6.

diseases, and preparing and implementing actions to promote and protect health related actions established by the National Sub-System of Environmental Health Surveillance.[62]

On August 31, 2000, FUNASA created the Rapid Response Center for Epidemiologic Emergencies (Núcleo de Resposta Rápida em Emergências Epidemiológicas, NUREP)[63] to act in the following cases:

- Epidemics that go beyond the limits of a state
- Epidemics of emerging diseases
- Introduction into the country of an infectious agent that had been eradicated or did not previously exist
- Epidemics of diseases that are part of the International Sanitary Regulation
- Epidemics characterized by an expansion to areas without previous occurrences
- Floods, droughts, and other calamities and/or disasters relevant to public health when insufficient action is demonstrated by a municipality or state[64]

NUREP is also responsible for planning, mobilizing resources, coordinating and implementing actions that reduce or eliminate risks to public health;[65] maintaining information systems regarding human resources and logistics available for mobilization;[66] and preparing procedural manuals for interventions in emergency situations.[67]

III. Patent Breach

In cases of national emergency or public interest, the government may issue a compulsory license for the use of a patent if the owner of the patent or its licensee does not comply with a request for its use.[68] The national emergency must have been declared by an act of the executive branch of the federal government, and the compulsory license must be temporary and non-exclusive, and may not cause prejudice to the rights of the owner.[69]

On October 6, 1999, Decree No. 3,201 was issued to regulate the issuance of compulsory licenses in cases of national emergency and public interest.[70] The decree further: (1) determines

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[62] *Id.*

[63] MINISTÉRIO DE SAÚDE , Portaria No. 473, de 31 de Agosto de 2000, art. 1, http://www.jusbrasil.com.br/diarios/1420127/pg-105-secao-1-diario-oficial-da-uniao-dou-de-04-09-2000.

[64] *Id.* art. 1.

[65] *Id.* art. 2(I).

[66] *Id.* art. 2(II).

[67] *Id.* art. 2(III).

[68] Lei No. 9.279, de 14 de Maio de 1996, art. 71, http:// www.planalto.gov.br/ccivil_03/Leis/L9279.htm.

[69] *Id*.

[70] Decreto No. 3.201, de 6 de Outubro de 1999, http://www.planalto.gov.br/ccivil_03/decreto/D3201.htm.

that in cases of public interest the compulsory license is for noncommercial public use only;[71] (2) defines "national emergency" as an imminent public danger, even if it is only in part of the country;[72] (3) defines "public interest" as the facts related, inter alia, to public health and environmental protection, as well as those of fundamental importance to the technological or socio-economic development of the country;[73] and (4) regulates the procedures that must be observed for the issuance of a compulsory license.[74]

IV. Right to Privacy

According to the Brazilian Constitution, everyone is equal before the law, with no distinction whatsoever, and Brazilians and foreigners residing in the country are guaranteed the inviolate right to life, liberty, equality, security, and property.[75]

As part of the fundamental rights and guarantees established in the Constitution, personal intimacy, private life, honor, and reputation are inviolable, and the right to compensation for pecuniary or moral damages resulting from violations of such rights is guaranteed.[76] In addition, the Constitution provides that an individual's home is inviolable, and no one may enter it without the dweller's consent, except in cases of a flagrant crime (*flagrante delito*) or disaster, or to provide help, or during the day with a court order.[77]

The Brazilian Medical Code of Ethics[78] provides that a medical doctor must keep secret all information that he or she has access to while performing his duties, except in cases provided by law.[79] However, a physician is authorized to disclose information acquired while exercising his or her profession in cases of justified motive (*justa causa*), legal obligation, or written authorization of the patient.[80]

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[71] *Id.* art. 1.

[72] *Id.* art. 2(§1).

[73] *Id.* art. 2(§2).

[74] *Id.* art. 5.

[75] C.F. art. 5.

[76] *Id.* art. 5(X).

[77] *Id.* art. 5(XI).

[78] FEDERAL COUNCIL OF MEDICINE, Resolução CFM No. 1.931, de 17 de Setembro de 2009, http://www.portal.cfm.org.br/index.php?option=com_content&view=category&id=9&Itemid=122.

[79] *Id*. ch. I, no. XI.

[80] *Id*. art. 73.

V. Criminal and Civil Sanctions

The Brazilian Penal Code punishes by up to fifteen years in prison whoever is condemned of causing an epidemic by propagating pathogenic germs.[81] If death occurs, the punishment is doubled.[82]

The breach of government determinations designed to prevent the introduction or propagation of a contagious disease is punished by up to one year in prison and the payment of a fine,[83] and Medical doctors that fail to communicate to health authorities the presence of diseases under the mandatory notification system are punished by up to two years in prison and the payment of a fine.[84]

In addition to the criminal sanctions established in the Penal Code, Law No. 6,437 of August 20, 1977 lists the situations that characterize infringement of federal sanitary laws[85] and their respective penalties.[86]

VI. International Health Regulations

Brazil is a member of the World Health Organization (WHO)[87] and the Pan American Health Organization (PAHO),[88] and follows the International Health Regulations (IHR) adopted by the WHO in 1969 and later amended in 1973 and 1981.

In 1995, the 48th World Health Assembly called for a substantial revision of the Regulations adopted in 1969.[89] After extensive work, on May 23, 2005, IHR (2005) was adopted by the 58th World Health Assembly and on June 15, 2007, it entered into force.[90]

The purpose and scope of the IHR (2005) are "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."[91]

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[81] CÓDIGO PENAL, Decreto-Lei No. 2.848, de 7 de Dezembro de 1940, art. 267, http://www.planalto.gov.br/ccivil_03/Decreto-Lei/Del2848compilado.htm.

[82] *Id*. art 267(§1).

[83] *Id*. art 268.

[84] *Id*. art. 269.

[85] Lei No. 6.437, de 20 de Agosto de 1977, art. 10, http://www.planalto.gov.br/ccivil_03/Leis/L6437.htm.

[86] *Id*. art 2.

[87] WORLD HEALTH ORGANIZATION, http://www.who.int/countries/bra/en/.

[88] PAN AMERICAN HEALTH ORGANIZATION, http://www.paho.org/hq/index.php?option=com_wrapper&view=wrapper&Itemid=2005&lang=en.

[89] WHO, International Health Regulations (2d ed. 2005), http://www.who.int/ihr/ publications/9789241596664/en/.

[90] *Id.* at 1.

[91] *Id*.

IHR (2005) was incorporated into Brazil's domestic legal system through Legislative Decree No. 395/2009.[92]

VII. Recent Developments

On August 8, 2014, the Ministry of Health updated the Contingency Plan for Emergency in Public Health – Disease for Ebola Virus (Plano de Contingência para Emergência em Saúde Pública – Doença Pelo Vírus Ebola),[93] which was designed to guide specific actions against a possible introduction of the Ebola virus in the country.

The Plan defines responsibilities on the federal level and establishes the necessary organization in order to respond to emergency situations related to this disease in Brazil, aiming at the integration of actions and prevention and control.[94]

The objectives of the Plan are as follows:

- Define the operating strategy of the Ministry of Health in line with the definitions of the Response Plan for Public Health Emergencies
- Establish a coordinated response within the scope of the Unified Health System
- Activate Emergency Operation Centers in Public Health to manage a coordinated response
- Adopt measures to prevent the spread of the Ebola virus on an eventual introduction of the virus in the country
- Establish the use of standard protocols and procedures to respond to Ebola[95]

[92] Decreto Legislativo No. 395, de 2009, http://www2.camara.leg.br/legin/fed/decleg/2009/decretolegislativo-395-9-julho-2009-589324-publicacaooriginal-114307-pl.html.

[93] Ministério da Saúde, Secretaria de Vigilância em Saúde, Departamento de Vigilâncias das Doenças Transmissíveis, Plano de Contingência para Emergência em Saúde Pública, Doença pelo Vírus Ebola Versão 5 (Brasília, DF, 2014), http://www.ribeiraopreto.sp.gov.br/ssaude/doencas/ebola/plano_contingencia.pdf.

[94] *Id.* at 4.

[95] *Id*.

Canada

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SUMMARY Emergency measures and emergency management at the federal level in Canada are regulated by the Emergency Act and the Emergency Management Act. However, there is a relatively high trigger for the federal government to take the lead in a health emergency. Therefore, most health emergencies or crises are dealt with at the municipal and provincial level in coordination with the federal government. Most provinces and territories have passed various "health acts" that govern the powers and duties of health officials during a health emergency.

I. Structure of Public Health Crisis Management System

Legislative competence in relation to public health matters is shared by all levels of government in Canada.[1] The Constitution Act, 1867,[2] which defines much of the structure and operations of the Government of Canada, "does not explicitly include 'health' as a legislative power assigned either to Parliament (in section 91) or to the provincial legislatures (in section 92)."[3]

In the 1982 case of *Schneider v. The Queen*, the Supreme Court of Canada stated that

> "health" is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending in the circumstances of each case on the nature or scope of the health problem in question.[4]

Under Section 91 of Canada's Constitution Act, the federal government derives its jurisdiction to directly or indirectly regulate on public health-related issues principally from its powers to legislate on

- quarantine and the establishment and maintenance of marine hospitals;
- criminal matters;
- public debt and property;

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[1] *Background*, PUBLIC HEALTH AGENCY OF CANADA (PHAC), http://www.phac-aspc.gc.ca/about_apropos/back-cont-eng.php (last updated Oct. 9, 2014).

[2] Constitution Act, 1867, 30 & 31 Victoria, c. 3 (U.K.), §§ 91, 92, http://laws-lois.justice.gc.ca/eng/const/page-1.html.

[3] Martha Butler & Marlisa Tiedemann, Library of Parliament, Legal and Social Affairs Division, The Federal Role in Health and Health Care § 1, Pub. No. 2011-91-E (Sept. 2011; revised Sept. 2013), http://www.parl.gc.ca/Content/LOP/ResearchPublications/2011-91-e.htm.

[4] Schneider v. The Queen, (1982) 2 S.C.R. 112, p. 142.

- taxing powers;
- power to pass laws for the peace, order, and good government of Canada; and
- census and statistics matters.[5]

Section 92 of the Act assigns responsibility to the provinces and territories for

- matters relating to the establishment, maintenance, and management of hospitals, asylums, charities, and charitable institutions;
- matters in their province of a local or private nature; and
- municipal institutions.[6]

As stated by the Standing Senate Committee on Social Affairs, Science, and Technology, "[d]ue to this lack of clarity in the constitutional division of powers in relation to health and public health, both levels of government may legislate in these areas."[7]

Canada's public health emergency management system has been described as a "bottom up system,"[8] where the "initial and ongoing responsibility for investigation and response to public health events, including infectious disease outbreaks, occurs at the local/municipal level."[9] Therefore, "depending on the severity, complexity, extent and nature of the public health issue, provincial, territorial and federal systems may be engaged to provide assistance and resources as requested and/or required by local authorities and facilities managing the situation."[10] All levels of government have various forms of legislation to protect and manage public health in a time of crisis.

A. Federal Laws

At the federal level, the Public Health Agency of Canada (PHAC) is primarily responsible for the promotion of health, prevention and control of chronic diseases, prevention and control of infectious diseases, and preparation and response to public health emergencies.[11] The PHAC operates under the Minister of Health and Health Canada. It was established by the 2006 Public Health Agency of Canada Act[12] "for the purpose of assisting the Minister of Health in exercising

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[5] Constitution Act, 1867, § 91.

[6] *Id.* § 92.

[7] STANDING SENATE COMMITTEE ON SOCIAL AFFAIRS, SCIENCE, AND TECHNOLOGY, CANADA'S RESPONSE TO THE 2009 H1N1 INFLUENZA PANDEMIC (Dec. 2010), http://www.parl.gc.ca/content/sen/committee/403/soci/rep/rep15dec10-e.pdf.

[8] *Responding to an Infectious Disease Outbreak: Progress Between SARS and Pandemic Influenza H1N1*, PHAC, http://www.phac-aspc.gc.ca/ep-mu/rido-iemi/index-eng.php#in (last updated Apr. 11, 2012).

[9] *Id.*

[10] *Id*.

[11] *Mandate*, PHAC, http://www.phac-aspc.gc.ca/about_apropos/what-eng.php (last updated June 16, 2011).

[12] Public Health Agency of Canada Act, S.C. 2006, c. 5, http://lois-laws.justice.gc.ca/eng/acts/P-29.5/FullText.html.

or performing the Minister's powers, duties and functions in relation to public health."[13] This statute also established the office of the Chief Public Health Officer "and the related powers, duties and functions."[14]

Federal legislation also mandates public health surveillance activities under the Department of Health Act, the Public Health Agency of Canada Act, and the Statistics Act.[15] The Department of Health Act gives the Minister of Health "the power, subject to the Statistics Act, to collect, analyze, interpret, publish and distribute information related to public health."[16]

The federal government's power to act in a public health emergency is largely governed by two pieces of legislation: the Emergencies Act[17] and the Emergency Management Act.[18] The Emergencies Act gives the government of Canada the authority to "invoke exceptional yet incident-specific powers to deal with emergencies,"[19] including public welfare emergencies. The Emergency Management Act "sets out the leadership role and responsibilities of the Minister of Public Safety and Emergency Preparedness, including "coordinating emergency management activities among government institutions and in cooperation with the provinces and other entities."[20]

The federal government works in collaboration with provinces and territories "to support communities when disasters strike."[21] According to the website of Public Safety Canada, "[t]o this end, *An Emergency Management Framework for Canada* was revised and approved by Federal/Provincial/Territorial Ministers in 2011. The Framework establishes a common approach for a range of collaborative emergency management initiatives in support of safe and resilient communities."[22] The Framework divides emergency management into four interdependent components, which are meant to provide greater clarity of risks "and contribute[]

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[13] *List of Acts and Regulations*, PHAC, http://www.phac-aspc.gc.ca/about_ apropos/act-reg-lois/list-liste-eng.php (last updated May 7, 2013).

[14] *Id*.

[15] Evaluation Directorate, Public Health Agency of Canada/Health Canada, Evaluation of the Surveillance Function at the Public Health Agency of Canada, App. F. Federal, Provincial and Territorial Authorities for Public Health Surveillance, (Jan. 14, 2013), http://www.phac-aspc.gc.ca/about_apropos/ evaluation/reports-rapports/2012-2013/sf-fs/app-ann-f-eng.php.

[16] *Id.*

[17] Emergencies Act, R.S.C., 1985, c. 22, http://laws-lois.justice.gc.ca/eng/acts/E-4.5/.

[18] Emergency Management Act, S.C. 2007, c. 15, http://laws-lois.justice.gc.ca/eng/acts/E-4.56/.

[19] *Emergencies Act*, ALBERTA MUNICIPAL AFFAIRS, http://apsts.alberta.ca/online-courses/bem/chapter-4-legislation/federal-legislation/emergencies-act/ (last visited Nov. 13, 2014).

[20] *Emergency Management*, PUBLIC SAFETY CANADA, http://www.publicsafety.gc.ca/cnt/mrgnc-mngmnt/index-eng.aspx (last updated Mar. 4, 2014).

[21] *Id*.

[22] *Id.*

to a safer, prosperous, sustainable, disaster resilient society in Canada."[23] The components, as explained in the Framework, include the following:

> **Prevention and Mitigation** – to eliminate or reduce the risks of disasters in order to protect lives, property, the environment, and reduce economic disruption. Prevention/mitigation includes structural mitigative measures (e.g. construction of floodways and dykes) and non-structural mitigative measures (e.g. building codes, land-use planning, and insurance incentives). Prevention and mitigation may be considered independently or one may include the other.
>
> **Preparedness** – to be ready to respond to a disaster and manage its consequences through measures taken prior to an event, for example emergency response plans, mutual assistance agreements, resource inventories and training, equipment and exercise programs.
>
> **Response** – to act during or immediately before or after a disaster to manage its consequences through, for example, emergency public communication, search and rescue, emergency medical assistance and evacuation to minimize suffering and losses associated with disasters.
>
> **Recovery** – to repair or restore conditions to an acceptable level through measures taken after a disaster, for example return of evacuees, trauma counseling, reconstruction, economic impact studies and financial assistance. There is a strong relationship between long-term sustainable recovery and prevention and mitigation of future disasters. Recovery efforts should be conducted with a view towards disaster risk reduction.[24]

Canada's federal legislation also includes the Quarantine Act,[25] the purpose of which is "to protect public health by taking comprehensive measures to prevent the introduction and spread of communicable diseases."[26] The Canada Border Services Agency (CBSA) assists the PHAC in the administration of the Quarantine Act and the Quarantine Regulations.[27] The Act is by and large a border-control statute that is applied at entry and departure points.

B. Provincial Laws

Public health activities, including public health crisis management at the provincial and territorial levels, are governed by Public Health Acts (or their equivalent) and related regulations. These Acts usually have provisions on reporting requirements, prevention, inspection powers, emergency measures, and the powers and duties of health officials.

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[23] PUBLIC SAFETY CANADA, AN EMERGENCY MANAGEMENT FRAMEWORK FOR CANADA (2d ed. Jan. 2011), http://www.public safety.gc.ca/cnt/rsrcs/pblctns/mrgnc-mngmnt-frmwrk/index-eng.aspx.

[24] *Id*.

[25] Quarantine Act, S.C. 2005, c. 20, http://laws-lois.justice.gc.ca/eng/acts/Q-1.1/FullText.html.

[26] *Id.* § 4.

[27] CANADIAN BORDER SERVICES AGENCY, MEMORANDUM D19-9-3 (Jan. 16, 2009), http://www.cbsa-asfc.gc.ca/publications/dm-md/d19/d19-9-3-eng.html.

Provinces and territories also have Emergency Management Acts in their respective jurisdictions that provide the legal basis for establishing emergency management organizations (EMOs) and creating provincial/territorial-level emergency management plans to help coordinate a provincial response to an emergency.[28]

II. Powers of Public Health Authorities

A. Federal

1. Emergency Powers

At the federal level, the Emergencies Act authorizes the government of Canada to take special temporary measures through a declaration of a "public welfare emergency," which the Act defines as an emergency caused by a real or imminent disease in human beings, animals, or plants (among others) "that results or may result in a danger to life or property, social disruption or a breakdown in the flow of essential goods, services or resources, so serious as to be a national emergency."[29] However, the federal government's power to issue a declaration of a public welfare emergency can only be triggered after a relatively high threshold is met. According to the Act,

> [t]he Governor in Council may not issue a declaration of a public welfare emergency where the direct effects of the emergency are confined to, or occur principally in, one province unless the lieutenant governor in council of the province has indicated to the Governor in Council that the emergency exceeds the capacity or authority of the province to deal with it.[30]

Therefore, it has been argued that the Emergencies Act essentially "restrains, even denies, federal statutory authority to tackle a disease outbreak while it remains small, manageable, and confined to one province. Rather, federal authority begins only once the outbreak has spread, reaching the out-of-control quality of an epidemic."[31]

While an emergency declaration is in effect, the government has the power to issue orders and regulations on the following matters:

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[28] Emergency Management Ontario Ministry of Community Safety and Correctional Services, Province of Ontario Emergency Response Plan (2008), http://www.emergencymanagementontario.ca/english/emcommunity/response_resources/plans/provinicial_emergency_response_plan.html.

[29] Emergencies Act § 5. Section 3 defines a "national emergency" as "an urgent and critical situation of a temporary nature that": "(*a*) seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it, or (*b*) seriously threatens the ability of the Government of Canada to preserve the sovereignty, security and territorial integrity of Canada." *Id*. § 3.

[30] *Id.* § 14(2). "Governor in Council" is another phrase for the Federal Cabinet.

[31] Amir Attaran & Kumanan Wilson, *A Legal and Epidemiological Justification for Federal Authority in Public Health Emergencies*, 52 McGill L.J. 381, 385 (2007), http://lawjournal.mcgill.ca/userfiles/other/5670367-1219616683_Attaran__Wilson.pdf.

(*a*) the regulation or prohibition of travel to, from or within any specified area, where necessary for the protection of the health or safety of individuals;

(*b*) the evacuation of persons and the removal of personal property from any specified area and the making of arrangements for the adequate care and protection of the persons and property;

(*c*) the requisition, use or disposition of property;

(*d*) the authorization of or direction to any person, or any person of a class of persons, to render essential services of a type that that person, or a person of that class, is competent to provide and the provision of reasonable compensation in respect of services so rendered;

(*e*) the regulation of the distribution and availability of essential goods, services and resources;

(*f*) the authorization and making of emergency payments;

(*g*) the establishment of emergency shelters and hospitals;

(*h*) the assessment of damage to any works or undertakings and the repair, replacement or restoration thereof;

(*i*) the assessment of damage to the environment and the elimination or alleviation of the damage, and

(j) the imposition [of fines] for contravention of any order or regulation made under this section.[32]

2. *Quarantine*

The Quarantine Act "authorizes the Minister of Health to establish quarantine stations and quarantine facilities anywhere in Canada, and to designate various officers, including quarantine officers, environmental health officers, and screening officers."[33] The Act also "authorizes measures that can be taken in respect of international travellers, or other persons at an entry or departure point, who have or might have a communicable disease (one that poses a risk of significant harm to public health)."[34] It also authorizes procedures "that can be taken in respect of conveyances arriving in or departing from Canada, and cargo on those conveyances, which could be the source of a communicable disease."[35]

[32] Emergencies Act § 8(1).

[33] List of Acts and Regulations, PHAC, *supra* note 13.

[34] *Id*.

[35] *Id*.

B. Provincial Powers

1. Emergency Powers

Given the limitations on the federal government to deal with health-related emergencies, responsibility for this matter is largely left to the provinces. All the provinces and territories have their own legislation dealing with emergencies and emergency management. While "[t]here is considerable variation among the provinces and territories with respect to the content, provisions, and the limits of authority defined in the respective legislation,"[36] the laws are more or less the same in terms of powers and organizational structure.[37] For example, they empower "the province or territory, municipalities, individuals, private corporations and/or organizations to formulate emergency plans to prepare for and respond to emergencies or disasters."[38] Other common features of these laws include provisions

- establishing Emergency Management Organizations with assigned powers and duties,
- defining the roles and responsibilities of municipalities and their relationship with the provinces,
- providing "extraordinary power to local government if required,"
- in some jurisdictions requiring local governments "to create and maintain an emergency measures/management organization and program/plan,"
- enabling "provision of Disaster Financial Assistance to victims of all disasters," and
- "provid[ing] exemption from civil liability to all emergency service workers."[39]

2. Quarantine and Other Powers

Health officials in the provinces and territories have extensive powers under various "health acts" to protect the public against pandemics and public health emergencies. For example, section 22 of Ontario's Health Protection and Promotion Act[40] provides that a medical officer of health may, through a written order, "require a person to take or to refrain from taking any action that is specified in the order in respect of a communicable disease" if this officer has "reasonable and probable grounds" to believe

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[36] *Id.*

[37] John Lindsay, *Emergency Management in Canada: Near Misses and Moving Targets*, https://www.training.fema.gov/emiweb/edu/Comparative%20EM%20Book%20-%20Chapter%20-%20Emergency%20Management%20in%20Canada%20-%20Near%20Misses%20and%20Moving%20Targets.doc (last visited Nov. 28, 2014).

[38] NOVA SCOTIA EMERGENCY MANAGEMENT OFFICE, BASIC EMERGENCY MANAGEMENT § 1.6.3 (Jan. 2011), http://0-fs01.cito.gov.ns.ca.legcat.gov.ns.ca/deposit/b10645214.pdf.

[39] *Id.*

[40] Health Protection and Promotion Act, R.S.O. 1990, c. H.7, http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90h07_e.htm#BK26.

(a) that a communicable disease exists or may exist or that there is an immediate risk of an outbreak of a communicable disease in the health unit served by the medical officer of health;

(b) that the communicable disease presents a risk to the health of persons in the health unit served by the medical officer of health; and

(c) that the requirements specified in the order are necessary in order to decrease or eliminate the risk to health presented by the communicable disease.[41]

Such an order can include, but is not limited to,

(a) requiring the owner or occupier of premises to close the premises or a specific part of the premises;

(b) requiring the placarding of premises to give notice of an order requiring the closing of the premises;

(c) requiring any person that the order states has or may have a communicable disease or is or may be infected with an agent of a communicable disease to isolate himself or herself and remain in isolation from other persons;

(d) requiring the cleaning or disinfecting, or both, of the premises or the thing specified in the order;

(e) requiring the destruction of the matter or thing specified in the order;

(f) requiring the person to whom the order is directed to submit to an examination by a physician and to deliver to the medical officer of health a report by the physician as to whether or not the person has a communicable disease or is or is not infected with an agent of a communicable disease;

(g) requiring the person to whom the order is directed in respect of a communicable disease that is a virulent disease to place himself or herself forthwith under the care and treatment of a physician;

(h) requiring the person to whom the order is directed to conduct himself or herself in such a manner as not to expose another person to infection.[42]

In British Columbia, similar protective measures are stipulated under the province's Public Health Act, which includes "quarantine and isolation measures, and closures of public places to help prevent the spread of a disease or health hazard."[43] Under the Act, medical health officers are "empowered to quarantine and isolate individuals who pose a significant risk of spreading serious communicable diseases to others."[44] The Act also allows a quarantine order to be made to a group of people "to expedite the prevention of disease."[45] Medical health officers "can have a person who is spreading disease detained until a court order can be obtained, or during a wide

[41] *Id*. § 22(1) & (2).

[42] *Id*. § 22(4).

[43] *Public Health Act – Frequently Asked Questions*, MINISTRY OF HEALTH, http://www.health.gov.bc.ca/phact/faq.html (last visited Nov. 13, 2014).

[44] *Id*.

[45] *Id*.

spread emergency, the Provincial Health Officer can take command of directing the public health response."[46]

III. Transparency of Public Health Crisis Management System

In the Emergency Management Framework for Canada, the federal, provincial, and territorial governments agreed to the principle of maintaining "clear communications" with the "aim to be as open as possible regarding the work each does in emergency management."[47] The Framework states that, prior to an emergency, emphasis must be on public education in respect to emergency management in order to "enhance awareness of hazards, risks and vulnerabilities; strengthen prevention, mitigation and preparedness measures; and provide information on all aspects of emergency management."[48] Communications during and after an emergency must explain the necessary "response actions" in order to "minimize impacts and to maintain safety and security."[49]

The independent SARs Commission report, which investigated the 2003 outbreak of SARs in Ontario, criticized the "lack of transparency in the adjudication system" during the outbreak and concluded that the lack of transparency "led to confusion over roles and responsibilities" of local Medical Officers of Health in the case review of new probable cases of the disease.[50]

IV. Cooperation with the World Health Organization (WHO)

Canada is a member of WHO and is therefore bound by the International Health Regulations (2005) (IHR). Health Canada "leads Canada's relationship with WHO, while the Department of Foreign Affairs, Trade and Development (DFATD) provides Canada's assessed contribution—about [Can]$14 million [approximately US$12.34 million] per year."[51] The PHAC operates as "the focal point for coordinating the implementation of the IHR in Canada."[52]

According to the DFATD website, "Canada works closely with WHO to reduce global diseases such as polio, HIV/AIDS, tuberculosis and malaria, and to improve maternal, newborn and child health including nutrition."[53] The website also states that Canada is a strong supporter of WHO

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[46] *Id*.

[47] An Emergency Management Framework for Canada, *supra* note 23.

[48] *Id*.

[49] *Id*.

[50] THE HONOURABLE MR. JUSTICE ARCHIE CAMPBELL, THE SARS COMMISSION INTERIM REPORT: SARS AND PUBLIC HEALTH IN ONTARIO 50 (Apr. 15, 2004), http://www.health.gov.on.ca/en/common/ministry/publications/reports/campbell04/campbell04_2.aspx.

[51] *World Health Organization*, FOREIGN AFFAIRS, TRADE AND DEVELOPMENT CANADA, http://www.acdi-cida.gc.ca/acdi-cida/acdi-cida.nsf/en/NAD-321114340-LFU (last updated Aug. 1, 2013).

[52] Responding to an Infectious Disease Outbreak, PHAC, *supra* note 8.

[53] *Id*.

initiatives, such as the Global Polio Eradication Initiative, the Stop TB Partnership, and the Partnership for Maternal, Newborn and Child Health.[54]

Canada also works with WHO to "support national health programs such as those in Haiti and the Polio Eradication Signature Project in Afghanistan and with WHO's regional offices such as the Pan American Health Organization."[55]

There are twenty-six WHO Collaborating Centres operating in Canada.[56]

V. Recent Developments

As of the date of this report there have been no instances of persons with the Ebola virus in Canada.[57] The PHAC has stated that it is working with all levels of government to prevent the disease from spreading in the country. Canadian health authorities have also stated that they have taken the following steps:

- "[E]nforcing the *Quarantine Act* at all international points of entry into Canada. This will help us to identify any sick travellers arriving, and to apply public health measures as appropriate."[58]
- The National Microbiology Laboratory in Winnipeg and provincial laboratories are ready to detect the virus and respond quickly. Experts at Quebec's lab are able to diagnose Ebola and labs in British Columbia, Alberta, Ontario, and Nova Scotia will be next.[59]
- Canadian hospitals "have infection control systems to limit the spread of infection and protect health-care workers."[60]

In early October 2014, the federal Health Minister announced that the government would be taking the additional step of taking "targeted temperature" screenings at Canadian airports. The PHAC also increased the number of staff "at Canadian airports to help with the screening of travelers from Ebola-affected regions."[61] On October 30, 2014, the Canadian federal

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[54] *Id*.

[55] *Id*.

[56] *WHO Collaborating Centres Global Database*, WHO, http://apps.who.int/whocc/List.aspx?cc_code=CAN (last visited Nov. 13, 2014).

[57] *Canada's Response to Ebola*, GOVERNMENT OF CANADA, http://healthycanadians.gc.ca/diseases-conditions-maladies-affections/disease-maladie/ebola/response-reponse-eng.php (last modified Nov. 12, 2014).

[58] *Id*.

[59] *Ebola Preparedness Plan Ready, Canada's Health Officials Say*, CBCNEWS (Oct. 1, 2014), http://www.cbc.ca/news/health/ebola-preparedness-plan-ready-canada-s-health-officials-say-1.2783655.

[60] *Id*.

[61] Helen Branswell, *Canada to Step Up Border Checks for Ebola*, THE CANADIAN PRESS (Oct. 9, 2014), http://www.cp24.com/news/canada-to-step-up-border-checks-for-ebola-1.2046410#ixzz3HjzdnJio.

government announced that it was "suspending visa applications for residents and nationals of countries with 'widespread and persistent-intense transmission' of Ebola virus disease."[62]

[62] Rob Gillies, *Canada Restricts Visas Amid Ebola Scare*, ASSOCIATED PRESS (Oct. 31, 2014), https://news.yahoo.com/canada-restricts-visas-amid-ebola-scare-213729168.html.

People's Republic of China

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SUMMARY China's public health crisis system has been under restructuring since 2003. With the outbreak of a public health crisis, the emergency headquarters set up by the State Council is responsible for leading and commanding the nationwide response to the crisis. The provincial emergency headquarters are responsible for leading and commanding the response to the crisis within their own jurisdictions.

The State Council and its health department, formerly the Ministry of Health and since 2013 the National Health and Family Planning Commission, have the power to declare a crisis involving a statutory infectious disease and draft and implement public health crisis contingency plans. The measures that may be taken when a crisis occurs include the evacuation or isolation of people, the blockade of infectious disease epidemic areas, and the compulsory quarantine and treatment of suspected carriers and people in close contact with them.

In 2010, the ban on the entry into China of aliens with HIV/AIDS or leprosy was lifted. According to the current rules, aliens with serious mental disorders, infectious pulmonary tuberculosis, or other infectious diseases that may significantly endanger the public health may be prohibited from entering China.

I. Legislative and Regulatory Framework

The public health crisis system of the People's Republic of China (PRC or China) has been significantly restructured primarily as a result of the Severe Acute Respiratory Syndrome (SARS) crisis of 2002–2003. Although a statutory and regulatory framework to handle public health emergencies had been in place prior to the SARS crisis, major laws, regulations, and government measures have been amended or newly enacted since then to curb health emergencies.

A. PRC Constitution on States of Emergency

On March 14, 2004, the Constitution of the People's Republic of China was amended[1] to expand the power of the National People's Congress, President, and State Council to declare martial law

[*] This is a revised and updated version of a report authored by Wendy Zeldin, Senior Legal Research Analyst of the Law Library of Congress, in 2003.

[1] XIANFA (1982, as amended on Mar. 14, 2004) (P.R.C.); for the Chinese text, see *Announcement of the National People's Congress of the People's Republic of China: Amendments to the Constitution of the People's Republic of China*, NPCSC GAZETTE (Special Issue, 2004) 1–27 (Mar. 15, 2004). For an English translation, see 16 THE LAWS OF THE PEOPLE'S REPUBLIC OF CHINA [LAWS OF PRC] (2004) 59–91 (Beijing, Law Press 2005). *See also* Cao Kangtai (Head of the State Council Legislative Affairs Office), *Wei Jianli Jinji Zhuangtai Zhidu Tigong Xianfa Yiju* [*Providing a Constitutional Basis for Establishing an Emergency System*], FAZHI RIBAO [LEGAL DAILY], Mar. 25, 2004, *available at* http://www.people.com.cn/GB/14576/15157/2410102.html (in Chinese).

to include declaring states of emergency in cases of serious natural disasters, industrial accidents, public health crises, social unrest, and terrorist attacks.[2]

B. Emergency Response Law and National System of Contingency Plans for Emergencies

For the purpose of preventing and reducing emergent hazards such as natural disasters, industrial accidents, public health crises, and public security hazards, the first PRC Law on Emergency Response (Emergency Response Law) was promulgated and entered into force in 2007.[3]

Since the passage of the Emergency Response Law, the country has established a national system of contingency plans for emergencies, as provided by the Law on Emergency Response.[4] The Law requires the government at all levels, including the State Council and its departments, to formulate contingency plans for emergencies, which these government bodies are to apply according to their level of authority.[5] The central government has set up a webpage on its official website where it publishes the contingency plans for emergencies formulated by the State Council, its departments, and the provinces. The webpage also publishes special project plans.[6]

As part of the national system of contingency plans for public emergencies, the National Contingency Plan for Public Health Emergencies was formulated on February 26, 2006,[7] in accordance with the Health Emergency Regulations, as discussed in Part III(B), below.

C. Regulations on Contingent Public Health Emergencies

A major set of provisions specifically addressing public health emergencies comprise the Regulations on Contingent Public Health Emergencies (Health Emergency Regulations), promulgated by the State Council on May 9, 2003.[8] The Regulations define "public health emergencies" as "major epidemic situations of infectious diseases, broad-spectrum diseases with an unknown cause, major food and occupational poisoning incidents, and other serious public health incidents that occur unexpectedly and cause or may cause grave harm to public health in society."[9]

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[2] XIANFA arts. 67, 80, 89.

[3] Tufa Shijian Yingdui Fa [Law on Emergency Response] (promulgated by the National People's Congress (NPC) Standing Committee on Aug. 30, 2007, effective Nov. 1, 2007), 2007 ZHONGHUA RENMIN GONGHE GUO FAGUI HUIBIAN [FAGUI HUIBIAN] [COMPILATION OF THE LAWS AND REGULATIONS OF THE PEOPLE'S REPUBLIC OF CHINA], 81–97, English translation *available at* Westlaw China (by subscription).

[4] Law on Emergency Response art. 17.

[5] *Id*.

[6] *Guojia Tufa Gonggong Shijian Yuan Tixi* [*National System of Contingency Plans for Public Emergencies*], CENTRAL PEOPLE'S GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.gov.cn/yjgl/2005-08/31/content_27872. htm (last visited Oct. 16, 2014).

[7] *Guojia Tufa Gonggong Weisheng Shijian Yingji Yu'an* [*National Contingency Plan for Public Health Crises*], XINHUA NEWS AGENCY (Feb. 26, 2006), http://www.gov.cn/yjgl/2006-02/26/content_211654.htm.

[8] Tufa Gonggong Weisheng Shijian Yingji Tiaoli [Regulations on Contingent Public Health Emergencies] (Health Emergency Regulations) (promulgated by the State Council, May 9, 2003), *available at* Westlaw China.

[9] *Id*. art. 2.

D. Law on the Prevention and Treatment of Infectious Diseases

Prior to the 2003 Health Emergency Regulations, the primary legislation addressing the prevention and treatment of infectious diseases, including the reporting and releasing of information in epidemic situations, was the PRC Law on the Prevention and Treatment of Infectious Diseases (Infectious Diseases Law), which was enacted in 1989. The Law was significantly revised in August 2004.[10] Effective on December 1, 2004, the new version doubled the length of the former Infectious Diseases Law from forty-one articles to eighty articles.[11]

The Infectious Diseases Law divides contagious diseases into three categories, each requiring the implementation of different preventive and control measures. Category A covers bubonic plague and cholera; category B includes such diseases as SARS, anthrax, AIDS, typhoid, and viral hepatitis; and category C contains such diseases as influenza, leprosy, mumps, and schistosomiasis.[12] The 2004 amendment to the Law added infectious SARS and highly pathogenic avian influenza to category B, thereby increasing the total number of infectious diseases to thirty-seven.[13] Three category B diseases—infectious SARS, pulmonary anthrax, and highly pathogenic avian influenza—are designated to be treated with preventive and control measures applicable to category A diseases.[14]

E. Other Relevant Laws, Regulations, and Government Measures

The prevention, control, and elimination of epidemic diseases among animals are under the general supervision of the State Council's Ministry of Agriculture and regulated under the PRC Law on Prevention of Epidemics in Animals. The Law was enacted in 1997 and amended in 2007.[15] Under the Law, animal epidemics are grouped into three categories, the first of which includes epidemics that menace human beings and animals so seriously that urgent and intensive compulsory measures are required for their prevention, control, and elimination.[16]

Some other major laws and regulations for addressing public health crises include the PRC Food Safety Law[17] and various laws and regulations on quarantine. Under the Food Safety Law, the

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[10] Chuanran Bing Fangzhi Fa [Infectious Diseases Law] (promulgated by the NPC Standing Committee, Aug. 28, 2004, effective Dec. 1, 2004), 6 NPCSC GAZETTE 16–23 (Sept. 15, 2004). For an English translation, see 16 LAWS OF CHINA (2004) 127–55.

[11] *Id*.

[12] *Id.* art. 3.

[13] *Id*.

[14] *Id.* art. 4.

[15] Dongwu Fangyi Fa [Law on Prevention of Epidemics in Animals] (promulgated by the NPC Standing Committee, July 3, 1997, amended Aug. 30, 2007, entered in force Jan. 1, 2008), 2001 FAGUI HUIBIAN 1009–22, English translation *available at* Westlaw China.

[16] *Id*. art. 4.

[17] Shipin Anquan Fa [Food Safety Law] (promulgated by the NPC Standing Committee, Feb. 28, 2009, effective June 1, 2009), http://www.gov.cn/flfg/2009-02/28/content_1246367.htm, English translation *available at* Westlaw China.

State Council is to organize the formulation of a national food safety emergency response plan; the government at or above the county level must also make food safety emergency response plans for its own administrative region.[18]

The central government departments also established the following measures to specifically manage information reporting, transportation administration, and border quarantine when public health crises occur:

- Ministry of Health: Measures for the Administration of Information Reporting in Monitoring Public Health Emergencies and Epidemic Infectious Disease Situations (November 7, 2003; revised August 24, 2006);[19]
- General Administration of Quality Supervision, Inspection and Quarantine: Provisions on the Emergent Response to the Entry-Exit Inspection and Quarantine of Frontier and Port Public Health Emergencies (November 7, 2003);[20] and
- Ministry of Health and Ministry of Transportation: Provisions on Traffic Preparedness and Response to Public Health Emergencies (March 4, 2004; effective May 1, 2004).[21]

In 2007, the State Council passed the Regulations on Open Government Information. Effective from May 1, 2008, information concerning public emergency contingency plans, early warnings, and responses to emergency situations are included in the "key information" that the government at and above the county level must disclose to the public.[22]

II. Structure of Public Health Crisis Management System

A. Central and Local Institutions

The State Council is the highest executive organ and has the power, among others, to direct and administer public health work.[23] In 2013, the Ministry of Health merged with the newly established National Health and Family Planning Commission (NHFPC), a department under the

[18] *Id*. art. 70.

[19] Tufa Gonggong Weisheng Shijian yu Chuanrangbing Yiqing Jiance Xinxi Baogao Guanli Banfa [Measures for the Administration of Information Reporting on Monitoring Public Health Emergencies and Epidemic Situation of Infectious Diseases], MOH Order No. 37, http://www.moh.gov.cn/mohzcfgs/pgz/200901/38689.shtml.

[20] Guojing Kou'an Tufa Gonggong Weisheng Shijian Churujing Jianyan Jianyi Yingji Chuli Guiding [Provisions on Emergent Response to the Entry-Exit Inspection and Quarantine of Frontier and Port Public Health Emergencies], http://www.aqsiq.gov.cn/zwgk/jlgg/zjl/zjl20032004/200610/t20061027_12228.htm.

[21] Tufa Gonggong Weisheng Shijian Jiaotong Yingji Guiding [Provisions on Traffic Preparedness and Response to Public Health Emergencies], *available at* Westlaw China.

[22] Zhengfu Xinxi Gongkai Tiaoli [Regulations on Open Government Information] (promulgated by the State Council, Apr. 5, 2007, effective May 1, 2008) art. 10, 2007 FAGUI HUIBIAN 98, 99, English translation *available at* http://www.epa.gov/ogc/china/open_government.pdf (last visited Oct. 20, 2014).

[23] XIANFA art. 89, item 7, in part.

State Council.[24] The NHFPC is in charge of most health-related matters at the national level. It supervises and administers contagious disease prevention and various aspects of hygiene, organizes and oversees international cooperation and exchanges involving health care, and mobilizes national health care personnel and technical resources to assist local governments and other concerned departments in dealing with outbreaks of epidemics and disease and in taking emergency measures to prevent and control them.[25] A health emergency office, the Public Health Emergency Command Center, is set up in the NHFPC to address public health emergencies.[26]

Once a public health crisis has been identified, the State Council sets up emergency headquarters, over which it exercises unified leadership and command. The national headquarters set up for a crisis is to be composed of relevant departments of the State Council and the Armed Forces, with the competent leader of the State Council as the general director in charge. The NHFPC and other relevant departments of the State Council carry out related tasks within the scope of their duties and responsibilities.[27]

Provincial-level governments are also required to set up emergency headquarters on the outbreak of a public health crisis, with principal provincial leaders as the general directors in charge of handling contingencies in their region. The provincial headquarters are to direct the response to the crisis within their respective jurisdictions. The health departments of local governments at and above the county level are responsible for investigating and managing health crises and organizing medical treatment.[28]

B. Decision Making

With the outbreak of a public health crisis, the emergency headquarters set up by the State Council is responsible for leading and commanding the nationwide response to the public health crisis.[29] The provincial emergency headquarters are responsible for leading and commanding the response to the crisis within their own jurisdictions.[30]

In the case of the SARS crisis, a National SARS Prevention and Control Headquarters was established by the State Council, with the Vice Premier and Minister of Health as the

[24] Guojia Weisheng he Jihuashengyu Weiyuanhui Zhuayo Zhize Neishe Jigou he Renyuan Bianzhi Guiding [Responsibilities, Internal Organs, and Personnel of the National Health and Family Planning Commission] (issued by the State Council by Guo Ban Fa [2013] No. 50, June 9, 2013), http://www.gov.cn/zwgk/2013-06/18/content_2428241.htm.

[25] *Id.*

[26] *Id*.

[27] Health Emergency Regulations art. 3.

[28] *Id.* art. 4.

[29] *Id.* art. 3.

[30] *Id.* art. 4.

chairpersons. Ten special teams (e.g., on prevention and control, quarantine, and rural areas) and a General Office were component units.[31]

C. Reporting and Releasing Information About Emergencies

The state, according to the Health Emergency Regulations, is to establish a system for reporting emergencies. Under the system, the following circumstances may trigger a provincial-level government emergency report to the NHFPC, which must be submitted within one hour after the provincial-level government learns of the emergency: (1) the outbreak and spread, or potential outbreak and spread, of an infectious disease; (2) the occurrence or discovery of a broad-spectrum disease with an unknown cause; (3) the loss of infectious disease bacteria and viruses; and (4) the occurrence or potential occurrence of major food and occupational poisoning incidents.[32] The NHFPC is to promptly report to the State Council any emergency "that may cause significant social repercussions."[33] The Health Emergency Regulations also require that notifications of health emergencies be transmitted from monitoring and medical organizations to local health departments to the local government to higher-level health departments (including the NHFPC), with each organization or department required to transmit the information within two hours of receiving it.[34]

The Health Emergency Regulations also require the reporting and release of information from the NHFPC to other departments under the State Council, to the health departments of provincial-level governments, and to the Armed Forces; from the health departments of provincial-level governments[35] to their counterparts in the neighboring provinces; from provincial health departments to lower-level health departments within the same jurisdiction; and from the governments at the county level and above to their health departments.[36]

In addition, any entity or individual in China has the right to report to the government on the potential danger of a public health emergency, as well as the right to report to a higher level if a local government fails to carry out its duties and responsibilities or carry them out according to regulations. A reporting hotline is also to be established.[37]

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[31] Local SARS headquarters and work mechanisms were also established. Speech of Mr. Gao Qiang, Executive Vice Minister, Ministry of Health, People's Republic of China, WHO Global Meeting on SARS, Kuala Lumpur, 17 June [2003], WHO, GLOBAL ALERT AND RESPONSE (GAR), http://www.who.int/csr/sars/conference/june_2003/materials/presentations/qiang/en/ (last visited Oct. 21, 2014).

[32] Health Emergency Regulations art. 19.

[33] *Id*.

[34] *Id*. art. 20.

[35] The "provincial level" includes provinces, autonomous regions, and municipalities (e.g., Beijing, Shanghai, Tianjin, Chongqing) under the direct control of the central government.

[36] *Id.* art. 23.

[37] *Id.* art. 24.

III. Powers of Public Health Authorities

A. Declaring a Statutory Infectious Disease Outbreak

When an acute infectious disease is newly identified, the health department under the State Council, formerly the Ministry of Health (MOH) and since 2013 the NHFPC, has the power to declare it a statutory infectious disease in accordance with the Infectious Disease Law.[38] Only the State Council itself may declare such a disease to be a category A disease.[39] The NHFPC has the power to declare the addition of a disease to category B or C.[40] The MOH or NHFPC may also, upon approval by the State Council, decide to apply the preventive and control measures applicable to category A diseases to certain category B diseases and other infectious diseases whose outbreak has occurred from unknown causes.[41] Such a decision was made, for example, in the 2009 H1N1 influenza A crisis.[42]

B. Drafting and Implementing Contingency Plans

Under the Health Emergency Regulations, the health department under the State Council, currently the NHFPC, is to draft a national contingency plan for emergencies and submit it to the State Council for approval. On the basis of the national plan, provincial-level governments are to draw up contingency plans for their respective administrative regions.[43]

When a public health emergency occurs, health departments are to organize experts to evaluate and classify it and propose whether a contingency plan should be implemented. Specialized technical organizations designated by health departments at and above the provincial level or by other relevant departments are responsible for investigating emergencies; verifying relevant evidence; and addressing, managing, and assessing such emergencies.[44]

With State Council approval, the NHFPC implements a contingency plan nationwide or across provinces. The decision to implement a contingency plan in a province is made by the provincial government, not the health authorities, and must be reported to the State Council.[45]

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[38] *Id.* art. 30.

[39] *Id*.

[40] Infectious Diseases Law art. 3.

[41] *Id*. art. 4.

[42] Weishengbu Gonggao 2009 Nian Di Ba Hao [MOH Announcement [2009] No. 8, Apr. 30, 2009], http://www.gov.cn/jrzg/2009-05/01/content_1302001.htm.

[43] Health Emergency Regulations art. 10.

[44] *Id.* arts. 26, 29.

[45] *Id.* art. 27.

C. Measures

1. Evacuation, Isolation, and Blockade

Emergency headquarters have the power to evacuate or isolate people and to blockade areas of epidemic infectious disease.[46] Suspected carriers and people in close contact with infected patients who need to be quarantined and treated or put under medical observation must cooperate with the health department or relevant organizations. Compulsory implementation will be carried out with the assistance of the police.[47]

2. Assembling Personnel and Facilities

Emergency headquarters have the power to assemble personnel, materials in reserve, transport vehicles, and relevant facilities and equipment to deal with emergencies.[48] Relevant departments of the State Council and local governments at and above the county level are to ensure the production and supply of medical and rescue equipment, medicine, medical instruments, and other needed materials.[49]

3. On-Site Control

Emergency headquarters may adopt measures to control food and water sources. Government health departments are to adopt measures to control the crisis and provide emergency vaccinations, medicines for preventive purposes, and community-based protection measures to people who are vulnerable to infections or harm.[50]

4. Right of Entry

Specialized technical organizations designated by the NHFPC or other relevant departments of the State Council have the right to enter an emergency scene to conduct investigations, samplings, technical analyses, and tests. The cooperation of the relevant units and individuals is mandatory.[51]

5. Formulating Standards

The NHFPC is to formulate technical standards, specifications, and control measures "as soon as possible" for newly discovered infectious diseases, broad-spectrum diseases with an unknown cause, and major food and occupational poisoning incidents.[52]

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[46] *Id*. art. 33.

[47] *Id*. art. 44.

[48] *Id.* art. 33.

[49] *Id*. art. 32.

[50] *Id.* art. 34.

[51] *Id.* art. 36.

[52] *Id.* art. 37.

D. Sanctions

The Health Emergency Regulations contain administrative sanctions (e.g., written criticism, warnings, demotions, dismissal) for impermissible acts committed by government officials involved in public health emergencies. These include, for example, covering up, delaying reporting, or lying about public health emergencies or instructing others to do so; refusing to cooperate with higher-level government investigations or carry out contingency-related responsibilities; and dereliction of duty. Officials will be dismissed if their acts cause infectious disease contamination, spread, or harm to public health. Medical institutions that refuse to receive and treat patients or fail to promptly adopt control measures are subject to administrative sanctions and may face revocation of their license; officials involved will be disciplined. Responsible units or individuals who fail to carry out reporting duties, obstruct technical or other personnel, refuse to cooperate in investigations, etc., may incur administrative or disciplinary sanctions. If any of the above acts result in a crime, the perpetrator will be investigated for criminal responsibility.[53]

IV. Transparency of Public Health Crisis Management System

The Infectious Diseases Law explicitly makes it illegal for responsible officials and antiepidemic health personnel to conceal the outbreak of contagious diseases or instruct others to do so.[54] It also requires the NHFPC and, under its authorization, provincial-level health departments to promptly release information on and publicly announce an epidemic.[55] The Health Emergency Regulations reinforce the Law. Information on public health emergencies is to be released in a "timely, accurate, and comprehensive way," and no unit or individual is allowed to cover up, delay reporting, or lie about public health emergencies or instruct others to do so.[56]

Despite such provisions, the transparency of the public health crisis management system may be problematic considering that the media is controlled by the Communist Party through government agencies, and that the government may treat infectious diseases as a matter of national security requiring secrecy.[57] Furthermore, the military's health departments supervise and control the prevention and treatment of infectious disease in the People's Liberation Army.[58] For example, in the SARS crisis, the independent administration of the military hospitals made it possible for such hospitals in Beijing to keep secret the number of SARS patients being held in

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[53] *Id*. arts. 45–51.

[54] Infectious Diseases Law art. 37.

[55] *Id*. art. 38.

[56] Health Emergency Regulations arts. 21, 25.

[57] Sin-ming Shaw, *China's Glasnost Moment?*, 25 CHINA REVIEW 9 (Summer 2003); DAVID COWHIG, OPENNESS MANDATED BY PRC LAW, SECRECY IS ILLEGAL: BUT IS NON-GOVERNMENT INFORMATION JUST PUNISHABLE RUMOR, *available at* http://bulldog2.redlands.edu/dept/AsianStudiesDept/cowhig.pdf (last visited Oct. 20, 2014). Cowhig states that perhaps the best example of such government secrecy with regard to health crises is the top secret documents kept by the MOH and the Henan provincial health bureau on the spread of HIV/AIDS throughout Henan during the early to mid-1990s. He notes that some Chinese officials have even contended that health secrecy—for example, keeping secret the incidence of AIDS—protects a locality's collective privacy.

[58] Infectious Diseases Law art. 6.

them, resulting in a major underreporting of cases. Even after the actual number of cases was made known, officials were reportedly not forthcoming with statistics from the PRC's nearly two hundred army hospitals.[59]

Although the 2004 amendment to the Infectious Diseases Law continues to provide that military departments in charge of health are to supervise and control the prevention and treatment of infectious disease in the People's Liberation Army,[60] it now places a reporting requirement on military hospitals. Military hospitals, some of which are open to the public, must report on the epidemic infectious disease situations they encounter when providing medical services to the general public in accordance with relevant NHFPC regulations.[61]

V. Cooperation with the World Health Organization

The PRC is a member of the World Health Organization (WHO), has a WHO representative in Beijing, and is part of the WHO Western Pacific Region. At least sixty-four Chinese health research institutions have been designated as WHO collaborating centers.[62] During the early stages of the SARS crisis, the PRC was dilatory in notifying the WHO of cases and admitting inspectors, and was criticized for its lack of transparency. However, the PRC did issue WHO-compatible health rules for international trade and travel, disinfected conveyances, and required health documents for travelers. Despite its initial failure to cooperate, a senior WHO official later praised the PRC for its "excellent work" in preventing and treating SARS and said that the government accepted advice from international experts and made changes in combating the disease.[63]

Although the PRC's delay in responding to SARS was partially attributed to concerns about economic repercussions, the PRC first treats an infectious disease as a medical problem requiring a medical response. Thus, the delay may have been due in part to (former) bureaucratic procedures that required classification of an infectious disease as a category B disease before local health authorities were required to report it to the central government. It may also have been unclear whether the disease fell under the WHO's International Health Regulations (IHR) framework that makes reporting to the WHO mandatory. Before May 2003, compliance with the IHR was up to the discretion of the Member States; the WHO lacked any enforcement powers and had to rely on persuasion and recommendations to encourage Member States to notify the WHO within twenty-four hours of infectious disease outbreaks. Moreover, only three diseases (plague, cholera, and yellow fever) and no other emerging infectious diseases were covered under the IHR. It was not until late May 2003, during its 56th session, that the WHO adopted a resolution on SARS confirming the WHO's authority to verify disease outbreaks from all

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[59] Gordon Chang, *SARS Crisis: New Disease, New Leaders, Same Old Regime*, 3:8 CHINA BRIEF 5 (Apr. 22, 2003).

[60] 2004 Infectious Diseases Law art. 6(3).

[61] *Id*. art. 30(2).

[62] *See* WHO COLLABORATING CENTERS GLOBAL DATABASE, http://apps.who.int/whocc/ReportDetails.aspx?id=1 (last visited Oct. 21, 2014). The site lists sixty-four institutions as collaborating centers.

[63] *WHO Official: China's SARS Prevention Work 'Excellent,'* XINHUA NEWS AGENCY (June 12, 2003), *available at* http://www1.china.org.cn/archive/2003-06/12/content_1066811.htm; *WHO Experts: China's SARS Surveillance Network Unique*, XINHUA NEWS AGENCY (May 13, 2003), *available at* http://china.org.cn/english/China/64578.htm.

available official and nonofficial sources and to determine an outbreak's severity through on-the-spot investigations.[64]

VI. Recent Developments

A. Entry Ban Lifted for Foreigners with HIV/AIDS

On April 24, 2010, the State Council issued a decree to amend the implementation measures of the Frontier Health and Quarantine Law.[65] The measures were first approved by the State Council in 1986 and amended in 1994. Under the old measures, foreigners suffering from "mental disorder, leprosy, AIDS, venereal diseases, contagious tuberculosis, or other infectious diseases" could be prevented from entering China. The new measures amended this section only, removing the ban on aliens with HIV/AIDS or leprosy, while leaving intact the entry ban on those with "serious mental disorder, infectious pulmonary tuberculosis, or other infectious diseases that may endanger the public health in a major way."[66]

B. Application of the International Health Regulations

On May 14, 2007, the Chinese government declared that the International Health Regulations (IHR), which would enter into force on June 15, 2007, applied to the entire territory of the People's Republic of China, including the two special administrative regions of Hong Kong and Macau. The then MOH of China was designated as China's "national focal point," pursuant to Paragraph 1 of Article 4 of the IHR. The IHR also designated the local health administrative authorities as the health authorities responsible for the implementation of the IHR in their respective jurisdictions, and the General Administration of Quality Supervision, Inspection and Quarantine of China and its local offices as the competent authorities at the points of entry referred to in Article 22 of the IHR.[67]

In this declaration, China vowed to revise its Frontier Health and Quarantine Law to meet the needs of applying the IHR. In the later amendment to the Law on December 29, 2007, the only

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[64] Mely Caballero-Anthony, *SARS:A Matter of National Security*, ASIA TIMES (Apr. 19, 2003), http://www.atimes.com/atimes/Southeast_Asia/ED19Ae01.html (last visited Oct. 24, 2014); *Strategies to Fight World Health Threats, Such As SARS, Receive International Backing*, WORLD HEALTH ORGANIZATION (May 23, 2003), http://www.who.int/mediacentre/news/notes/2003/npwha3/en/.

[65] Guowuyuan Guanyu Xiugai Zhonghua Renmin Gongheguo Guojing Weisheng Jianyi Fa Shishi Xize de Jueding [State Council Decree in Amending the Implementation Measures of the PRC Frontier Health and Quarantine Law] (State Council Decree [2010] No. 574, Apr. 24, 2010), http://www.gov.cn/flfg/2010-04/27/content_1594506.htm.

[66] *Id.*

[67] Zhongguo Zhengfu Shengming: Guoji Weisheng Tiaoli Shiyong yu Zhongguo Quanjing [Chinese Government Declaration: The International Health Regulations Apply to the Entire Territory of China], CENTRAL PEOPLE'S GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA (May 14, 2007), http://www.gov.cn/jrzg/2007-05/14/content_614312.htm.

provision amended was the one on cross-border transportation of corpses.[68] Nevertheless, the Law provides that in the event of any conflicts between it and the IHR, the IHR prevails.[69]

[68] Guojing Weisheng Jianyi Fa [Frontier Health and Quarantine Law] (promulgated by the NPC Standing Committee, Dec. 2, 1986, amended Dec. 29, 2007), 2007 FAGUI HUIBIAN 384–88, English translation *available at* Westlaw China.

[69] *Id.* art. 24.

Egypt

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SUMMARY Law No. 137 of 1958, as amended by Law No. 55 of 1979, regulates the powers of public health authorities in Egypt in the event of an infectious disease outbreak. Additionally, Presidential Decree No. 268 of 1975 defines the Ministry of Health's mission and objectives. The World Health Organization has worked closely with the Egyptian Ministry of Health (MOH) to establish a cooperation strategy to prevent and control public health crises. The MOH posted on its official website an action plan to combat infectious diseases in public places, including schools and medical facilities. While no cases of Ebola have been reported in Egypt, the MOH has issued a precautionary announcement to Egyptians.

I. Structure of Public Health Crisis Management System

Egypt is a low-income, developing country with a per capita GDP of about LE47,050 (approximately US$6,600).[1] The country is divided into twenty-seven governorates. The major provider of health care services is the Ministry of Health (MOH). Health services offered by the MOH are free of charge to all Egyptian citizens. Those services are subsidized by the Egyptian government. The MOH supervises a nationwide health care system that includes outpatient clinics and urban hospitals.[2] The current structure of the health care system was developed during the 1960s under the administration of President Nasser, who adopted socialist economic policies.[3]

II. Powers of Public Health Authorities

Law No. 137 of 1958, as amended by Law No. 55 of 1979 (Combating Contagious Diseases), defines the term "infectious disease" and regulates the powers of public health authorities in the event of an infectious disease outbreak.[4] Article 6 of the Law allows health authorities in any province of the country to require all individuals, including adults, to be vaccinated against any infectious diseases.[5] Article 10 grants the Minister of Health the power to issue necessary

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[1] *The World Factbook: Egypt*, CENTRAL INTELLIGENCE AGENCY, https://www.cia.gov/library/publications/the-world-factbook/geos/eg.html (last updated June 22, 2014).

[2] Ravi P. Rannan-Eliya, Claudio Blanco-Vidal & A.K. Nandakumar, The Distribution of Healthcare Resources in Egypt: Implications for Equity (Boston, Harvard School of Public Health, 2000), https://www.hsph.harvard.edu/ihsg/publications/pdf/No-81.PDF.

[3] HASSOUNA ALI & ABOU ALI, LEGAL ANALYSIS OF THE HEALTH SECTOR POLICY REFORM PROGRAM ASSISTANCE IN EGYPT, Technical Report No. 5, vol. IV (USAID Partnerships for Health Reform Project, Aug. 1996), http://pdf.usaid.gov/pdf_docs/Pnach250.pdf.

[4] Law No. 137 of 1958, *al-Jarīdah al-Rasmīyah*, vol. 27, 11 Sept. 1958, *amended by* Law No. 55 of 1979 (Combating Contagious Diseases), *al-Jarīdah al-Rasmīyah*, vol. 47, 22 Nov. 1979.

[5] *Id*. art. 6.

decisions to monitor and quarantine specific individuals, including individuals coming from abroad if they are suspected of carrying an infectious disease.[6] Furthermore, article 12 requires that any individuals suspected of carrying an infectious disease be reported to health authorities.[7] Article 14 also authorizes health authorities to adopt all measures deemed necessary to curb a public health crisis.[8] Finally, article 15 permits members of law enforcement agencies to inspect houses and places where individuals infected with infectious diseases might be located.[9]

In addition to Law No. 137 of 1958, there is another law governing the area of public health. Presidential Decree No. 268 of 1975 defines the mission and objectives of the MOH. Article 1 of the decree provides that the Ministry's main mission is to protect the health of all Egyptian citizens through preventive and curative services at a centralized level.[10]

The MOH has an array of objectives, which include the following: (1) shaping national health care policies; (2) recording health care data and conducting economic health studies; (3) providing centralized health services, including central laboratories, pharmaceutical services, and manpower training; (4) monitoring the quality of medicine; (5) offering effective management during public health crises; (6) administrating health services and units; and (7) coordinating with domestic medical units on the local level in all governorates.[11]

The administrative structure of the MOH consists of the following departments: (1) health care and nursing, (2) protective affairs and disease, (3) birth control, (4) treatment, (5) training and research, (6) technical support, and (7) provincial health affairs.[12]

III. Transparency of Public Health Crisis Management System

According to an action plan to combat infectious disease issued by the MOH, the Ministry is required to report any outbreak of infectious diseases in public places. The Ministry is also responsible for warning the public about the outbreak and decontaminating the affected places.[13]

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[6] *Id*. art.10.

[7] *Id*. art 12.

[8] *Id*. art 14.

[9] *Id*. art 15.

[10] Presidential Decree No. 268 of 1975, *al-Jarīdah al-Rasmīyah*, vol. 2615, 23 Mar. 1975.

[11] *Id*. art. 2; *see also*, *Objectives of the Ministry of Health*, MINISTRY OF HEALTH [MOH], http://www.mohp.gov.eg/sites/minister/vision/default.aspx (in Arabic; last visited Oct. 16, 2014).

[12] *The Administrative Structure of the Ministry of Health*, MOH, http://www.mohp.gov.eg/about/orgchart/default.aspx (in Arabic; last visited Oct. 16, 2014).

[13] *Health Action Plan to Combat the Outbreak of Infectious Diseases*, AL-WATAN (Oct. 10, 2012), http://www.masress.com/elwatan/59802.

IV. Cooperation with the World Health Organization

Egypt is a member of the World Health Organization (WHO), to which Egypt is obligated to report any outbreak, emergence, or reemergence of infectious diseases.[14] The WHO has also worked closely with the Egyptian MOH to establish a cooperation strategy to assist in the prevention of infectious disease outbreaks. The WHO's local field office in Cairo, Egypt, has contributed to the Cairo Agenda for Action on Aid Effectiveness. According to a WHO progress report, the organization is currently working with health-related sectors, including the Ministry of Agriculture, to prevent an outbreak of the H5N1 influenza virus. It is also sharing expertise with the MOH to prevent and control the spread of hepatitis.[15]

V. Response to the Outbreak of Infectious Diseases

The MOH has posted on its official website an action plan to combat infectious diseases in public places, including schools and medical facilities.[16] According to a WHO report, the MOH is responsible for providing all necessary immunizations and vaccinations to control and prevent the spread of infectious diseases. This strategy has led to a decline in the number of people infected with such diseases as H1N5 and hepatitis.[17]

In an effort to monitor any possible outbreak, the Egyptian health authorities have joined the regional rotavirus surveillance network and launched a national rotavirus surveillance program. The MOH has also established similar surveillance programs for other viruses such as measles, rubella, haemophilus influenza type B, hepatitis, and tuberculosis.[18]

Finally, the MOH has established an active program to control any outbreak of infectious diseases in health care facilities. The Ministry has provided health care facilities across the country with necessary guidelines to deal with such public health crises.[19]

VI. Response to the Ebola Virus Outbreak

While no cases of Ebola have been reported in Egypt, in response to this global health threat the MOH has issued an announcement urging people to take the following precautionary measures:

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[14] WORLD HEALTH ORGANIZATION [WHO], COUNTRY COOPERATION STRATEGY FOR WHO AND EGYPT 2010–2014 (2010), http://www.who.int/countryfocus/cooperation_strategy/ccs_egy_en.pdf?ua=1.

[15] WHO, COUNTRY COOPERATION STRATEGY AT A GLANCE: EGYPT (Mar. 23, 2013), http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_egy_en.pdf.

[16] MOH, GUIDELINES ON COMBATING THE OUTBREAK OF INFECTIOUS DISEASES (2d ed. 2008), http://www.mohp.gov.eg/programs/InfectFight/DocLib/part11.pdf (in Arabic).

[17] Law No. 137 of 1958, *al-Jarīdah al-Rasmīyah*, vol. 27, 11 Sept. 1958, p. 15.

[18] *Id*. p. 16.

[19] Presidential Decree No. 268 of 1975, *al-Jarīdah al-Rasmīyah*, vol. 2615, 23 Mar. 1975.

- Wash hands frequently with soap and water
- Avoid touching any animals, especially sick ones
- Avoid touching any sick person or coming in contact with his/her bodily fluids
- Avoid touching surfaces that have come in contact with the body fluids of a sick person[20]
- Avoid making unnecessary trips to West African countries where Ebola is active[21]

The Ministry has also required international airports to report suspicious cases to the airport medical centers and determined that passengers entering Egypt from countries with suspected infectious disease outbreaks should be quarantined and have their temperature taken.[22]

[20] MOH, IMPORTANT GUIDANCE ON THE EBOLA VIRUS, MOH, http://www.mohp.gov.eg/DocLib/ ebola7.pdf (in Arabic; last visited Oct. 16, 2014).

[21] Press Release, MOH, Health: Tightening Quarantine Measures for the Port of Egypt on Those Arriving from Guinea Following the Outbreak of the Ebola Epidemic, Apr. 3, 2014, http://www.mohp.gov.eg/DocLib/ebola6.pdf.

[22] *Id*.

England

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SUMMARY The public health crisis system in England is based on broadly drafted modernized legislation and regulations. It operates on a local level with primary health care providers using national guidelines to draft emergency plans. Designated agencies or departments are responsible for coordinating local efforts if the crisis becomes national or spills over into more than one local area. Multiagency groups help to coordinate the response. Cooperation and coordination is emphasized as essential to manage public health crises. The legislation regarding infectious diseases has recently been amended to take into account modern-day challenges and scientific knowledge.

I. Structure of Public Health Crisis Management System

A. Government Responsibilities

The Secretary of State has a legal duty to protect public health in England from disease and other dangers.[1] The Secretary has established a number of bodies and programs to meet this duty. The National Resilience Capabilities Programme (NRCP) is the core framework through which the government is preparing for emergencies across all parts of the United Kingdom.[2] This program aims to ensure that the UK has a well-prepared infrastructure that is able to address rapidly and effectively a wide range of emergencies. The program is divided into a number of different groups, one of which includes infectious diseases in humans.[3] The Department of Health is the lead organization in planning for this type of emergency.

The Department of Health, the National Health Service (NHS), Public Health England, and local government authorities[4] are the main organizations responsible for addressing public health crises and, under the NRCP, infectious diseases. These organizations are responsible for

[1] Health and Social Care Act 2012, c. 7, § 11, http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted, inserting § 2A into the National Health Service Act 2006, c. 41, http://www.legislation.gov.uk/ukpga/2006/41/contents.

[2] HM GOVERNMENT, EMERGENCY RESPONSE AND RECOVERY: NON STATUTORY GUIDANCE ACCOMPANYING THE CIVIL CONTINGENCIES ACT 2004, Oct. 2013, ¶ 3.4.2, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253488/Emergency_Response_and_Recovery_5th_edition_October_2013.pdf.

[3] *Id*.

[4] "Local Authority" is defined in section 1 of the Public Health (Control of Disease) Act 1984, c. 22, as district councils, county councils, county borough councils in Wales, the Common Council of the City of London, the Sub-Treasurer of the Inner Temple and the Under-Treasurer of the Middle Temple, and the Council of the Isles of Scilly; *see also UK Resilience, Pandemic Flu*, CABINET OFFICE (Apr. 2008), http://www.cabinetoffice.gov.uk/ukresilience/pandemicflu.aspx.

different aspects of planning for public health crises.[5] Public Health England, an Executive Agency of the Department of Health, is the national public health agency and responsible for fulfilling "the Secretary of State's duty to protect the public's health from infectious diseases and other public health hazards."[6]

B. Department of Health

The Department of Health is involved on an organizational level in the prevention and control of infectious diseases by developing policies and setting standards. It is the lead government department involved in planning for a human influenza pandemic.[7] Responsibility for the functions of the Department of Health rests with the Chief Medical Officer, the government's principal medical advisor.[8]

There are a number of bodies that advise the Department of Health and the NHS on the control and prevention of infectious disease. One of these is Public Health England, an executive agency of the Department of Health.[9] Public Health England's role is to "protect and improve the nation's health and wellbeing, and reduce health inequalities"[10] and its general duty is to fulfil the Secretary of State's statutory duty to protect public health.[11] It works in a number of areas to discharge these functions, such as providing the government, the NHS, public health professionals, and the public with scientific advice; supporting local government with advice on how to protect health; and ensuring that effective local and national arrangements are in place to respond to health protection concerns and emergencies.[12] Public Health England is responsible for the Secretary of State's duties under the Health and Social Care Act 2012. It replaced the

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[5] PUBLIC HEALTH ENGLAND, PANDEMIC INFLUENZA RESPONSE PLAN 2014, ¶¶ 1, 2, 2.3, 3.1, https://www.gov.uk/government/ uploads/system/uploads/attachment_data/file/344695/PI_Response_Plan_13_Aug.pdf. Health is one area that has been devolved to the administrations in Northern Ireland, Scotland and Wales. However, in public health crises, the Department of Health takes responsibility for the response of the entire United Kingdom.

[6] *Id*. at 6.

[7] *Id.*; CABINET OFFICE, DEPARTMENTS RESPONSIBILITIES FOR PLANNING, RESPONSE, AND RECOVERY FROM EMERGENCIES, 2011, at 6, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/61354/lead-government-department-march-2010.pdf. For more information on the role and responsibilities of lead government departments, see CABINET OFFICE: CIVIL CONTINGENCIES SECRETARIAT, THE LEAD GOVERNMENT DEPARTMENT AND ITS ROLE – GUIDANCE AND BEST PRACTICE, 2004, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/61355/lead-government-departments-role.pdf.

[8] *Chief Medical Officer, Professor Dame Sally Davies*, DEP'T OF HEALTH, https://www.gov.uk/government/people/sally-davies (last visited October 21, 2014).

[9] *About Us*, PUBLIC HEALTH ENGLAND, https://www.gov.uk/government/organisations/public-health-england/about (last visited October 21, 2014).

[10] DEP'T OF HEALTH AND PUBLIC HEALTH ENGLAND, FRAMEWORK AGREEMENT BETWEEN THE DEPARTMENT OF HEALTH AND PUBLIC HEALTH ENGLAND, Nov. 2013, at 1, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/259756/DH-PHE_FRAMEWORK_AGREEMENT_FINAL_VERSION_FOR_PUBLICATION_accessible.pdf.

[11] *Id.* ¶ 2.1.

[12] *Id.* ¶ 2.2.

Health Protection Agency as a "category 1" responder[13] under the Civil Contingencies Act 2004 in respect of health hazards and emergencies caused by infectious diseases, chemicals, poisons, and radiation.[14] Public Health England operates in a number of ways to both respond to and help prevent health emergencies, such as by providing advice to the public on how to remain healthy and avoid hazards, conducting surveillance to detect any threats, and preparing plans to ready the nation for any future threats to its health.[15] Its functions are described as combining "public health and scientific knowledge, research and emergency planning within one organization."[16]

C. National Health Service

The National Health Service (NHS) is responsible for the diagnosis and treatment of individuals with infectious diseases, as well as for improving and protecting the health of the population.[17] Regarding the latter two functions, the NHS has a broad array of responsibilities to prevent and control infectious diseases that include implementing health programs, preventing the spread of the disease, surveying the local community, and monitoring any emergence or transmission of infectious disease.

Under the Civil Contingences Act the NHS must demonstrate the ability to effectively respond to an emergency, including infectious disease outbreaks.[18] This type of preparation in England is known as emergency preparedness, resilience, and response (EPRR).[19] To manage its EPRR responsibilities, the NHS has established commissioning boards and clinical commissioning groups.[20] It has also established local health resilience partnerships to coordinate the work and planning for EPRR across all health bodies.[21]

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[13] Category 1 responders are designated by the Civil Contingencies Act; they are "likely to be at the core of the response to most emergencies [and] are subject to the full range of civil protection duties in the Act." They currently include the police, fire and rescue, health bodies, the Maritime and Coastguard Agency, local authorities and the Environment Agency. HM GOVERNMENT, EMERGENCY RESPONSE AND RECOVERY: NON STATUTORY GUIDANCE ACCOMPANYING THE CIVIL CONTINGENCIES ACT 2004, 2013, ¶ 3.2 & Glossary at 217, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253488/Emergency_Response_and_Recovery_5th_edition_October_2013.pdf. *See also* Part I(I), *infra*.

[14] *Id.* ¶ 3.2.22.

[15] Dep't of Health and Public Health England ¶ 6.5.

[16] *Id.* ¶ 6.7.

[17] National Health Services Act 2006, c. 41, §§ 1 and 7, http://www.legislation.gov.uk/ukpga/2006/41/contents.

[18] Civil Contingencies Act 2004, c. 36, § 2 and sched. 1, http://www.legislation.gov.uk/ukpga/2004/36/contents.

[19] NHS ENGLAND, NHS ENGLAND CORE STANDARDS FOR EMERGENCY PREPAREDNESS, RESILIENCE AND RESPONSE (EPRR) (July 2014), http://www.england.nhs.uk/wp-content/uploads/2014/07/eprr-core-standards-0714.pdf.

[20] NHS COMMISSIONING BOARD, NHS COMMISSIONING BOARD EMERGENCY PREPAREDNESS FRAMEWORK 2013, ¶ 1.4, http://www.england.nhs.uk/wp-content/uploads/2013/03/eprr-framework.pdf. As of April 1, 2013, this guidance superseded both *The NHS Emergency Planning Guidance 2005* and the *Arrangements for Health Emergency Preparedness, Resilience and Response from April 2013*.

[21] NHS ENGLAND, *supra* note 19.

D. Local Authorities

Local authorities have a number of statutory obligations and powers to control the spread of infectious diseases under the Public Health (Control of Disease) Act 1984.[22] The types of infectious diseases that trigger the local authorities' powers under the Public Health (Control of Disease) Act are known as notifiable diseases and are specified in the Act and the regulations made under the Act.[23] Additional infectious diseases have been added to the list through regulations, and the Secretary of State has discretion to add more, although the inclusion of any further disease is dependent upon the impact of the disease.[24] Diseases subject to the WHO's International Health Regulations are contained in the list. Doctors and health care providers also have the duty to report other diseases that pose a significant risk to human health.[25]

All incidents of notifiable diseases must be reported to an officer appointed by the local authority.[26] There are no requirements in the legislation as to whom should be appointed, but typically the post goes to the local Consultant in Communicable Disease Control. Doctors and health care providers are under a legal duty to complete the notification form immediately on suspecting or diagnosing a notifiable disease. Lab confirmation of the suspected disease is not needed in order for notification to occur.[27] Once notified, the proper officer must report the case to Public Health England within three days, or twenty four hours for urgent cases.[28]

To ensure that health needs are met on a local level, local authorities can order that a disease not provided for in the Public Health (Control of Disease) Act or in regulations issued by the Secretary of State be labeled a notifiable disease within its designated area.[29] The order must specify the provisions in the Public Health (Control of Disease) Act that apply to the disease and, unless the situation is an emergency, be approved by the Secretary of State.[30]

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[22] Public Health (Control of Disease) Act 1984, c. 22, §§ 1–2, http://www.legislation.gov.uk/ukpga/1984/22/contents.

[23] *Id*. § 10. Current notifiable disease are acute encephalitis, acute infectious hepatitis, acute meningitis, acute poliomyelitis, anthrax, botulism, brucellosis, cholera, diphtheria, enteric fever (typhoid or paratyphoid fever), food poisoning, hemolytic uremic syndrome (HUS), infectious bloody diarrhea, invasive group A streptococcal disease, legionnaires' disease, leprosy, malaria, measles, meningococcal septicemia, mumps, plague, rabies, rubella, severe acute respiratory syndrome (SARS), scarlet fever, smallpox, tetanus, tuberculosis, typhus, viral hemorrhagic fever (VHF), whooping cough, and yellow fever.

[24] Health Protection (Notification) Regulations 2010, SI 2010/695, http://www.legislation.gov.uk/uksi/2010/659/made.

[25] *Guidance: Notifiable Diseases and Causative Organisms: How to Report*, PUBLIC HEALTH ENGLAND (May 1, 2010), https://www.gov.uk/notifiable-diseases-and-causative-organisms-how-to-report.

[26] Health Protection (Notification) Regulations 2010, ¶¶ 2–3, http://www.legislation.gov.uk/uksi/2010/659/made.

[27] *Id*.; *see also* PUBLIC HEALTH ENGLAND, *supra* note 5.

[28] Public Health England, *supra* note 5.

[29] Public Health (Control of Disease) Act 1984, c. 22, § 16(1).

[30] *Id*. § 16(2).

E. Civil Contingencies Secretariat

The Civil Contingencies Secretariat (CCS) assists the government in preparing for public health crises. The CCS was established in 2001 as part of the Cabinet Office to improve the UK central government's ability to prepare for and handle emergencies.[31] The CCS assists relevant organizations, both within the government and outside of it, in planning and preparing responses to emergency situations. The work of the CCS concentrates on four main areas: risk assessment, preparation and planning, response and recovery, and building a resilient society.[32]

F. Department for Environment and Rural Affairs

The Department of Environment, Food and Rural Affairs (DEFRA) plays an important role in any health crisis related to a disease that can be transmitted from animals to humans.[33] The Minister of Agriculture has wide-ranging powers, which are discussed in Part II(E), below.

G. Port Health Authorities

Port health authorities also exist throughout England.[34] During an emergency, their primary function is to control infectious diseases at ports of entry into the country.[35] The port health authorities may be part of a local authority, or in some cases they may be a single authority that conducts the functions across a number of local authorities. The port health authorities work closely with a number of other government bodies.[36]

H. Collection of Public Health Information

Diseases surveillance in the UK is based on statutory reporting required of doctors and other health workers who diagnose or suspect notifiable diseases.[37] Statutory reporting requirements are contained in the Public Health (Control of Disease) Act and the Health Protection (Notification) Regulations 2010. The Act requires registered medical practitioners who become aware or suspect that a patient is suffering from a notifiable disease to submit a certificate containing the patient's details to the local authority.[38] Laboratories that confirm the diagnosis

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[31] Cabinet Office and National Steering Committee on Warning & Informing the Public, *Improving the UK's Ability to Absorb, Respond to and Recover from Emergencies*, http://www.cabinetoffice.gov.uk/ukresilience/ ccs.aspx (last updated Sept. 18, 2014).

[32] *Id*.

[33] *About Us,* DEP'T FOR ENV'T, FOOD & RURAL AFFAIRS, https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs/about (last visited Nov. 5, 2014).

[34] Public Health (Control of Disease) Act 1984, §§ 1–2.

[35] HM GOVERNMENT, *supra* note 2, ¶ 3.2.26.

[36] *Id*. ¶ 3.2.26.

[37] Health Protection (Notification) Regulations 2010, ¶¶ 2–3.

[38] Public Health (Control of Disease) Act 1984, § 11. An example of a reporting form is available online at *Notifiable Diseases: Form for Registered Medical Practitioners*, PUBLIC HEALTH ENGLAND (Feb. 17, 2010), https://www.gov.uk/government/publications/notifiable-diseases-form-for-registered-medical-practitioners.

of a notifiable disease are under a legal duty to inform Public Health England with the details of each case of a notifiable disease.[39] Public Health England then collates this information and publishes reports with an analysis of any trends.[40]

I. Decisions and Decision Makers

In the United Kingdom, the decision makers are determined according to the structure provided by the Civil Contingencies Act 2004.[41] All responder organizations designated as category 1 under this statute follow a nationally recognized structure of three different levels of command—operational, tactical, and strategic.[42] Operational (also known as bronze) command refers to people managing the working elements of the response in such settings as hospital wards or the scenes of major incidents.[43] Tactical (also known as silver) command is responsible for managing an organization's response to an incident. Tactical command must ensure that plans are in place to achieve objectives set by strategic command and that operational command provides an efficient, coordinated response.[44] Strategic (also known as gold) command has overall command of the organization's resources. This level of command liaises with partners to develop strategy and policies and allocates funding to help address incidents.[45]

For incidents and emergencies involving several organizations and agencies, a Strategic Coordinating Group may be convened to coordinate.[46] The NHS's emergency response teams take the form of area Commissioning Boards. In cases of wide-reaching emergencies, the Commissioning Board national team can assume command of all of the resources of the NHS across England, and the regional Commissioning Boards take action based on the commands of that team.[47]

J. Crisis Triggers

In addition to regional procedures for outbreaks of infectious diseases, a general health crisis in England is referred to under the broader term "major incident." The NHS defines the term as

> [a]ny occurrence that presents serious threat to the health of the community, disruption to the service or causes (or is likely to cause) such numbers or types of casualties as to

[39] Health Protection (Notification) Regulations 2010, ¶ 5.

[40] *Notifiable Diseases: Current Weekly Report*, PUBLIC HEALTH ENGLAND, https://www.gov.uk/government/publications/notifiable-diseases-current-weekly-report (last updated Nov. 5, 2014).

[41] Civil Contingencies Act 2004, c. 36, sched. 1, http://www.legislation.gov.uk/ukpga/2004/36/contents.

[42] NHS Commissioning Board, NHS Commissioning Board Command and Control Framework for the NHS During Significant Incidents and Emergencies, Jan. 7, 2013, ¶ 5.1, http://www.england.nhs.uk/wp-content/uploads/2013/01/comm-control-frame.pdf.

[43] *Id.* ¶ 5.2.

[44] *Id.* ¶ 5.2.

[45] *Id.* ¶ 5.2.

[46] *Id.* ¶ 5.3.

[47] *Id.* ¶ 6.1.18.

> require special arrangements to be implemented by hospitals, ambulance trusts or other acute or community provider organisations.[48]

In addition to health crises, major incidents include chemical, biological, radiological, or nuclear incidents; train crashes; and incidents involving terrorism.

II. Powers To Prevent the Spread of Disease

A. Legal Overview

The government was criticized at the turn of the century for not having a clear, coherent legislative and regulatory framework for an effective public health crisis system that could deal with major health risks, particularly the risk of human pandemic diseases.[49] A 2003 report from the House of Lords recommended that the roles and responsibilities of the groups involved in the fight against infectious disease be more clearly defined.[50] The result of this report was the development of the NHS's Emergency Planning Guidance, first published in 2005.[51] This guidance provides general principles on how NHS organizations should handle major incidents, which are defined to encompass "big bang" incidents, such as casualties arising from a terrorist attack, and "rising tide" incidents, such as an infectious disease epidemic.[52]

The primary piece of legislation that addresses public health emergencies is the Public Health (Control of Disease) Act 1984.[53] This Act served to consolidate a number of pieces of legislation from the nineteenth century, much of which was "directly derived from Victorian antecedents."[54] The laws were based on the scientific knowledge and social circumstances of those times and, therefore, did not address modern risks, such as contamination from chemicals or radiation. This Act was reformed in 2009 after the Law Reform Commission recommended that public health legislation was overdue for review,[55] noting that the scientific understanding of disease contagion at the time the laws were drafted were not congruent with today's scientific knowledge. Additional powers to detain individuals suffering from diseases caused concern that the Law would not stand up to a challenge brought under the Human Rights Act 1998, as it

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[48] *Id.* ¶ 1.4.

[49] A STRONG BRITAIN IN AN AGE OF UNCERTAINTY: THE NATIONAL SECURITY STRATEGY, Cm. 7953, 2010–11, ¶ 3.38, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/61936/national-security-strategy.pdf.

[50] HOUSE OF LORDS, SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, FIGHTING INFECTION, FOURTH REPORT, H.L. 138, 2002–03, http://www.publications.parliament.uk/pa/ld200203/ldselect/ldsctech/138/138.pdf.

[51] National Health Service: Department of Health, Emergency Preparedness Division, NHS Emergency Planning Guidance 2005: Underpinning Materials, ¶ 2.2.4, http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_081303.pdf.

[52] *Id.*

[53] Public Health (Control of Disease) Act 1984, c. 22, http://www.legislation.gov.uk/ukpga/1984/22/contents.

[54] THE LAW COMMISSION: NINTH PROGRAMME OF LAW REFORM, March 2005, H.C. 535, http://lawcommission.justice.gov.uk/docs/lc293_9th_Programme.pdf.

[55] *Id.* ¶ 4.4.

would be "difficult [for the government] to argue that exercise of these powers is 'necessary' or even effective in disease control."[56] The Law Reform Commission expressed "fear . . . that the effectiveness of the British response to a major outbreak of contagious disease could be significantly impaired by the defects in the law."[57]

As a result of these concerns, the government enacted the Health and Social Care Act 2008, which repealed a large number of provisions in the Public Health (Control of Disease) Act 1984.[58] The amendments aimed to bring the provisions concerning infections up to date and take into account other concerns, such as radiation and chemical contamination. The updated provisions of the 1984 Act provide two areas under which regulations may be made in relation to diseases. The first relates to in-country provisions and the second to England's international borders.[59]

B. Current Laws and Regulations

Under the Health and Social Care Act 2008, the Secretary of State may make regulations (referred to as "health protection regulations") to prevent, protect against, control, and provide a public health response to an incident or to the spread of infection or contamination in England, even if the threat originated from outside the country.[60] The Law provides examples of powers that the Secretary of State may exercise by regulation, including

- imposing or enabling restrictions or requirements on individuals in the event of, or in response to, a threat to public health; or
- providing local authorities with functions to monitor public health risks.[61]

The restrictions may include keeping a child away from school, prohibitions or restrictions on events or gatherings, a "special restriction or requirement" or "Part 2A order," [62] or requirements

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[56] Robyn Martin, *The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications*, 14(1) MED. LAW REV. 132, 136 (2006), http://medlaw.oxfordjournals.org/content/14/1/132.full. pdf+html. *See also* THE LAW COMMISSION, *supra* note 54, ¶ 4.6.

[57] THE LAW COMMISSION, *supra* note 54, ¶ 4.10.

[58] Health and Social Care Act 2008, c. 14, http://www.legislation.gov.uk/ukpga/2008/14/contents. *See also* DEP'T OF HEALTH, REVIEW OF PARTS II, V AND VI OF THE PUBLIC HEALTH (CONTROL OF DISEASE) ACT 1984: REPORT ON CONSULTATION (Nov. 2007), http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_080384.

[59] Public Health (Control of Disease) Act 1984, c. 22, Part 2A, as inserted by the Health and Social Care Act 2008, c. 14, § 129, http://www.legislation.gov.uk/ukpga/2008/14/section/129. The Health Protection (Notification) Regulations 2010, 2010/659, form part of the in-country regulations.

[60] *Id*. § 45C, as inserted by Health and Social Care Act 2008, c. 14, § 129.

[61] *Id*.

[62] "Special restriction or requirement" is defined in the Act as meaning: "a restriction or requirement which can be imposed by a justice of the peace by virtue of section 45G(2), 45H(2) or 45I(2) of the PHA." *Id*. § 45C(6)(a). Special restrictions may only be imposed in response to a "serious and imminent threat to public health, or . . . contingent on there being such a threat at the time when it is imposed." *Id*. § 45D(4). Part 2A orders are described below.

with regard to the handling and treatment of dead bodies.[63] Any restriction imposed under the provisions of this Act must be proportionate with the aim that it is trying to achieve,[64] in order to comply with human rights principles adopted in the UK.

The Secretary of State may not make regulations requiring that a person receive medical treatment, including vaccinations, as was the case under previous legislation. However, special requirements and restrictions may, if there is a serious and imminent threat to public health, require "medical examinations, removal to or detention in a hospital or other establishment, or isolation or quarantine."[65]

The statute limits the powers and penalties the regulations may confer. The regulations can

- confer functions on local authorities and other persons;
- create offenses, although these cannot be punishable with imprisonment or a fine of more than £20,000 (approximately US$35,000);
- enable courts to order that anyone convicted of an offense under the regulations take or pay for remedial action;
- make regulations that apply to different areas of the country;[66]
- provide for the execution and enforcement of restrictions or requirements imposed;
- provide for a system of appeals from and reviews of decisions made under the regulations;
- allow or prohibit charges to be levied;
- permit or require the payment of incentive payments, compensation, and expenses; and/or
- provide for the resolution of disputes.[67]

To prevent the spread of infection or contamination, the Public Health (Control of Disease) Act provides that Justices of the Peace may impose restrictions and requirements on individuals, premises, groups, and objects through orders, known as "Part 2A Orders." Only local authorities may apply to a Justice of the Peace for a Part 2A Order, and these orders may, in certain circumstances, be made without notifying the individual affected by the Order.[68] Once made, an individual affected by the order, the local authorities, or any other body that is responsible for enforcing or executing the order may apply to have it revoked or varied.[69]

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[63] *Id*. § 45C.

[64] *Id*. § 45D.

[65] *Id*. §§ 45D–E. Health and Social Care Act 2008, Explanatory Notes, ¶ 408, http://www.legislation.gov.uk/ukpga/2008/14/notes/contents.

[66] Public Health (Control of Disease) Act 1984, c. 22, § 45P, as inserted by the Health and Social Care Act 2008, c. 14, § 129.

[67] *Id*. § 45F.

[68] *Id*. § 45M.

[69] *Id*.

Such an order may require that an individual

- submit to medical examination;
- be removed to a hospital or other suitable establishment;
- be detained in a hospital or other suitable establishment (unless otherwise stated, for a maximum period of twenty-eight days);[70]
- be kept in isolation or quarantine (unless otherwise stated, for a maximum period of twenty-eight days);[71]
- be disinfected or decontaminated;
- wear protective clothing;
- provide information or answer questions about their health or other circumstances;
- have their health monitored and the results reported;
- attend training or advice sessions on how to reduce the risk of infecting or contaminating others;
- be subject to restrictions on where they go or with whom they have contact; and
- abstain from working or trading.

The Justice of the Peace may issue the order only if he/she is satisfied that a person may be infected or contaminated, could present significant harm to human health, and there is a risk the person may infect or contaminate others.[72] The Justice of the Peace may also order that the suspected infected or contaminated person provide information about the identity and location of other individuals that may be infected or contaminated who pose a risk to others, to enable "contact tracing" of these individuals.[73]

Justices of the Peace have similar powers to make orders in relation to premises or things that may be infected or contaminated when they could present significant harm to human health and there is a risk that they may infect or contaminate humans.[74]

For items (things), the order may impose a number of restrictions or requirements, including that the thing be seized; retained; isolated; quarantined; disinfected; decontaminated; destroyed; disposed of; or, in the case of dead bodies, cremated or buried.[75] For premises, the order may impose restrictions or requirements, including that the premises be closed, disinfected,

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[70] *Id*. § 45L.

[71] *Id*.

[72] *Id*. § 45G.

[73] *Id*.

[74] *Id*. §§ 45H–I.

[75] *Id*. § 45H.

decontaminated, or destroyed. For conveyances or other moveable structures, the order may require that they be detained.[76]

To enable contact tracing to help prevent the spread of infection or contamination, the order may require the owner or person in control of the thing or premises to provide information or answer questions about the thing or premises.[77]

The Justice of the Peace may also issue additional orders to include "such other restrictions or requirements as the justice considers necessary for the purpose of reducing or removing the risk in question."[78] The order may be conditional; for example, if a person refuses to be decontaminated, he/she must remain in isolation until the risk of contamination or infection has passed.

C. Aircraft and Ships

The Secretary of State has the authority to make regulations to prevent the spread of infection or other contamination through vessels, aircraft, trains, or other conveyances leaving or arriving at any place, or to give effect to any international arrangement regarding the spread of infection or contamination.[79] The regulations may cover issues such as

- detaining conveyances;
- requiring the medical examination, detention, isolation, or quarantine of individuals;
- inspecting, analyzing, retaining, isolating, quarantining, or destroying "things" (objects);
- disinfecting, decontaminating, or using other sanitary measures for conveyances, persons, or things;
- prohibiting or regulating the arrival or departure of conveyances and the entry and exit of persons or things;
- imposing duties on masters, pilots, train managers, and other persons on board conveyances and on owners and managers of ports, airports, and other points of entry; or
- requiring persons to provide information or answer questions (including information or questions relating to their health).[80]

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[76] *Id*. § 45I.

[77] *Id*. §§ 45H–I.

[78] *Id*. § 45K; Health and Social Care Act 2008, c. 14, Explanatory Notes, ¶ 419, http://www.legislation.gov.uk/ukpga/2008/14/contents.

[79] *Id*. § 45B.

[80] *Id*.

D. Sanctions and Fines for Failing to Comply with Requirements

Failing to comply with the requirements of an order without a reasonable excuse can result in a fine of up to £20,000 (approximately US$35,000). Where the court is satisfied that the "failure or willful obstruction constituting the offence has caused premises or things to become infected or contaminated or otherwise damaged them in a material way" by an individual convicted of an offense under the Act, the court may require the individual to take or pay for remedial action.[81] The police may take individuals that contravene an order of detention, isolation, or quarantine into custody and return them to the place specified in the order.[82]

E. Animals and Disease

England's experience with Bovine Spongiform Encephalopathy (BSE) and foot and mouth disease has caused it to introduce numerous pieces of legislation to prevent the spread of such diseases and halt any impact they might have on public health. The Animal Health Act 1981[83] (the 1981 Act) contains broad provisions ranging from requiring the disinfection and cleansing of places where animals reside or visit, to prohibiting animal movement and imports, to requiring vaccinations and the slaughter of animals.

The Minister of Agriculture has wide-ranging powers under the 1981 Act and can issue orders setting standards for the declaration of infected areas that state who can declare an area as infected, as well as the effect, consequence, and duration of such a declaration.[84] The Minister can make orders prescribing the seizure, detention, or disposal of diseased animals, or those suspected of being diseased. To prevent and reduce the risk of spreading any animal disease to humans, the Minister can make an order providing that any provision of the 1981 Act will apply to a specified disease.[85]

Enforcement of the 1981 Act falls to the police, who can arrest and detain any person suspected of, or found committing, an offense under the Act. Punishment is either imprisonment and/or a fine. If a person infects an animal with a disease specified in the 1981 Act, he/she is guilty of an offense and can be fined and/or imprisoned for up to two years, as well as disqualified from keeping or dealing with any animals.[86]

F. Vaccines

The UK currently does not have the capability to produce large numbers of vaccines; most are purchased from France and Belgium.[87] Certain strategic vaccines and drugs are being

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[81] *Id.* § 45O.

[82] *Id.* § 45N.

[83] Animal Health Act 1981, c. 22, *as amended*, http://www.legislation.gov.uk/ukpga/1981/22/contents.

[84] *Id.* § 17, *as amended*.

[85] *Id.* § 29, *as amended*.

[86] *Id.* § 28A–B.

[87] HOUSE OF LORDS, *supra* note 50, ¶ 4.8.

stockpiled; however, owing to concerns that information on these items may prove useful to terrorists, the government has not publicly disclosed any further details. During the outbreak of the swine flu in 2009, the government stated it had enough antivirals on hand to treat thirty-three million people in the UK—half of the population.[88]

III. Transparency of Public Health Crisis Management System

A. Disclosing Information to the Public

There is a duty under the Civil Contingencies Act 2004[89] for those connected with the public health crisis system to disclose information to the public, and the NHS has noted that this is based upon the "belief that a well-informed public is better able to respond to an emergency, and to minimise the impact of the emergency on the community and on NHS services."[90] The NHS follows the Civil Contingencies Act Ten Step Cycle[91] of communications, which helps to provide for effective communication.[92] The Civil Contingencies Act 2004 places two duties on responders to public health crises. The first duty is to warn and inform the public of any likely risks and threats that NHS organizations may address, and of any planned responses to these risks and threats. The second duty is the organization's response to a crisis. The NHS notes that when making information available to the public in crises, the communications must be "simple and easily digestible."[93]

B. Methods of Dissemination

There is no formal emergency broadcast system in England for public health crises, but there are long-standing protocols as to how information should be disseminated. The NHS has implemented a web-based cascade system known as the Central Alerting System that issues "patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others."[94] The NHS notes that the media will play a key role in disseminating information to the public and that there must be clear guidelines for providing clear and accurate information through these means.[95]

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[88] *Statement on Swine Flu/AH1N1,* DEP'T OF HEALTH, http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/MediaCentre/Pressreleasesarchive/DH_098573?PageOperation=email (last updated Apr. 27, 2009).

[89] Civil Contingencies Act 2004, c. 36, http://www.legislation.gov.uk/ukpga/2004/36/contents.

[90] NHS COMMISSIONING BOARD, *supra* note 20, ¶ 12.12.

[91] GOV.UK, CIVIL CONTINGENCIES ACT (2004): DUTY TO COMMUNICATE WITH THE PUBLIC, 2007, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/60906/10_step_cycle.pdf.

[92] NHS COMMISSIONING BOARD, *supra* note 20, ¶ 12.27(h).

[93] *Id*.

[94] *Central Alerting System*, NHS, https://www.cas.dh.gov.uk/Home.aspx (last visited October 29, 2014).

[95] NHS COMMISSIONING BOARD, *supra* note 20, ¶ 12.25.

C. Effectiveness of the Communications System

The BSE crisis, followed by the foot and mouth epidemic, led to a massive loss of public confidence in "official pronouncements about infectious disease issues" from government institutions.[96] This loss of confidence was exacerbated by the government repeatedly stating that certain events pose no risk to the public's health.[97] National Audit Office examinations of debriefs to the media also found that there was a lack of coordination and consultation in disseminating this information, resulting in inappropriate health advice being given to the public.[98]

The communication system during the swine flu outbreak in 2009 appeared to operate effectively, with statistics on individuals who were tested for the flu, as well as those who tested positive, available on the Internet from reliable government pages and distributed via the media.[99]

IV. Cooperation with the WHO

England complies with the WHO's International Health Regulations. The provisions from these regulations were implemented in the Public Health (Control of Disease) Act,[100] as supplemented by regulations.

V. Recent Developments

Public Health England has helped to provide enhanced screening for Ebola at England's main ports of entry (Heathrow, Gatwick, and St. Pancras). "Targeted Passengers" are those identified by the Border Force officers as those who have travelled from Sierra Leone, Guinea and Liberia. These passengers must have their temperature taken and complete a questionnaire that includes information about their current health, travel history, and any contact with Ebola patients. The results of these tests and questions will determine whether the person will be permitted to continue their journey with advice or receive additional checks and possibly be transferred to a hospital.[101]

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[96] HOUSE OF LORDS, *supra* note 50, ¶ 7.20.

[97] Most notably, during government announcements in the midst of the BSE crisis, the government reassured the public that British beef was safe to eat, with the Agriculture Minister feeding his daughter a beef burger to demonstrate the point. In the BSE case, the government later asserted that its statement about British beef being safe to eat did not mean that there was no risk involved.

[98] COMPTROLLER & AUDITOR GENERAL, NATIONAL AUDIT OFFICE, FACING THE CHALLENGE: NHS EMERGENCY PLANNING IN ENGLAND, H.C. 36, 2002–03, at 37, http://www.nao.org.uk/wp-content/uploads/2002/11/020336.pdf.

[99] DEPARTMENT OF HEALTH ET AL., UK PANDEMIC INFLUENZA COMMUNICATIONS STRATEGY 2012, at 15, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213268/UK-Pandemic-Influenza-Communications-Strategy-2012.pdf.

[100] Public Health (Control of Disease) Act 1984, c. 22, http://www.legislation.gov.uk/ukpga/1984/ 22/contents.

[101] Press Release, Public Health England, Department of Health and NHS England, Enhanced Ebola Screening Process Begins (Oct. 14, 2014), https://www.gov.uk/government/news/public-health-england-enhanced-ebola-screening-process.

France

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SUMMARY At the national level in France, the management of a public health crisis caused by a communicable disease is primarily the responsibility of the Ministry of Health, which is aided in its task by public establishments under its supervision such as the Institut de Veille Sanitaire, France's national health monitoring institute. At the local level, the prefects, who are the state representatives, have also been given specific powers in times of epidemic crisis. A reserve health corps was created in 2007.

France drew up its first comprehensive national plan for the prevention and control of an influenza pandemic in 2004, and last updated it in 2011. The plan is aimed at protecting the French population, as well as French citizens living abroad, against a pandemic threat and limiting the social and economic consequences of a pandemic.

Recently, the government has taken steps to prevent or limit the spread of the Ebola virus in France. These steps include screenings at airports in at-risk countries, the preparation of specialized wards in hospitals, and the dissemination of information to both health care professionals and the general public.

I. Introduction

Public health crises can take many forms, such as disease epidemics; large-scale incidents of food or water contamination; and harmful exposure to chemical, radiological, or biological agents. Their causes may be natural, accidental, or deliberate. How France deals with a crisis and which public authorities are involved depends on the nature of the crisis. This report first focuses on the operational management of a public health crisis caused by a communicable disease. It then addresses, as examples, the 2009 national plan for the prevention and control of an influenza pandemic, and measures recently taken in the context of the current Ebola crisis.

The administrative division of France plays a role in how the government prepares for and manages a health crisis. France is divided into twenty-two regions, and there are ninety-six *départements* within metropolitan France. Each *département* has a *préfet* (prefect), who is the representative of the central government. For purposes of emergency planning, France is also divided into seven zones of defense, each under the responsibility of a zone prefect who will manage emergency crises exceeding the boundaries of the *département*.[1] The region prefects are also given specific powers in times of epidemic crisis.[2] Finally, France has incorporated into its

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[1] CODE DE LA DEFENSE art. R.1211-4, http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006071307&dateTexte=20141028.

[2] CODE DE LA SANTE PUBLIQUE art. L.3131-8, http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20141028.

national law the 2005 International Health Regulation adopted by the World Health Organization's (WHO's) Fifty-eighth World Health Assembly on May 23, 2005,[3] which also has an impact on the management of public health crises.

II. Structure of Public Health Crisis Management System

The operational management of a public health crisis caused by a communicable disease principally involves the Ministry of Health; the Ministry of Interior; the Institut de Veille Sanitaire (InVS), which is France's national health monitoring institute; the *préfets* (prefects), who are the state representatives in the *départements*; and the mayors. A reserve health corps was also created in 2007.

A. Directorate General of Health

The Ministry of Health is divided into several directorates. Among them, the Direction Générale de la Santé (DGS, the General Directorate of Health) sets forth health policies and, as a guarantor of health security, may take any measures to prevent or respond to public health crises—in particular, a crisis related to communicable diseases. Following audits and reports prepared after the SARS (severe acute respiratory syndrome) and other health crises, the DGS was reorganized in 2007 to reinforce its action on prevention, to better manage emergencies and health threats, and to improve its governance and performance.[4]

The Health Code provides that when an epidemic threatens the country or part of the country and local means are insufficient to stop it, the Minister of Health may, by means of a ministerial regulation, set forth all appropriate measures and allocate duties to prevent the spread of such disease. The decree may give authority to the prefects to implement one or more of the needed measures.[5] The measures taken are regularly reviewed by the High Council for Public Health (Haut Conseil de la Santé Publique), which checks whether they are appropriate.[6] Created in 2004, this Council comprises six specialized commissions: transmissible diseases; chronic diseases; risks linked to the environment; patient safety; education and promotion of health; and lastly, evaluation and strategy.[7] One of its missions is to provide the necessary expertise for the

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[3] Décret No 2007-1073 du 4 juillet 2007 portant publication du règlement sanitaire international (2005) adopté par la cinquante-huitième Assemblée mondiale de la santé le 23 mai [Decree No. 2007-1073 of July 4, 2007, on the publication of the International Health Regulations (2005) Adopted by the Fifty-eighth Health Assembly on May 23, 2005], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], July 7, 2007, p. 11570, http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=AA3B324B58F8360A41FC03636B303E8A.tpdjo06v_3?cidTexte=JORFTEXT000000467563&categorieLien=id.

[4] Décret No 2007-840 du 11 mai 2007 relatif à l'organisation de l'administration centrale du Ministère chargé de la santé et modifiant le code de la santé publique [Decree No. 2007-840 of May 11, 2007, on the Organisation of the Central Administration of the Ministry of Health, and Amending the Health Code], J.O., May 13, 2007, p. 11240, http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=DF0736163CBBEC68BCF10AE49A507B8E.tpdjo06v_3?cidTexte=JORFTEXT000000427036&categorieLien=id.

[5] CODE DE LA SANTE PUBLIQUE art. L.3131-1.

[6] *Id*. art. L.3131-2.

[7] *Organisation* [*Organization*], HAUT CONSEIL DE LA SANTÉ PUBLIQUE [HIGH COUNCIL FOR PUBLIC HEALTH], http://www.hcsp.fr/Explore.cgi/Hcsp#73 (last visited Oct. 28, 2014).

management of health risks and to evaluate the policies and strategies regarding health prevention and safety.[8]

B. Institut de Veille Sanitaire (InVS)

The InVS's general mission is to constantly monitor the state of the public health. The InVS is under the supervision of the Minister of Health. It was created by Law 98-535 of July 1, 1998, Relating to the Reinforcement of Health Monitoring.[9] Its mission was extended by Law 2004-806 of August 9, 2004, on Public Health Policy to meet new challenges that were highlighted by health crises and emerging risks.[10]

The InVS is, in particular, charged with the following:

- Detecting any threat to public health and alerting the competent public authorities;
- Gathering, analyzing, and developing information on health risks, their causes, and their evolution;
- Taking part in collecting and processing data on the state of public health;
- Carrying out or supporting any action (investigation, study, assessment, etc.) likely to contribute to the monitoring of public health; and
- Helping to manage health crises by proposing to the health authorities the necessary measures and actions to take.[11]

The InVS monitors all fields of public health, including infectious diseases, environmental health, occupational health, chronic diseases, and international and tropical diseases. It participates in international and European cooperation programs, such as the monitoring of AIDS or tuberculosis, or setting forth monitoring systems. It is headed by a General Director. Its 2013 operational expenses were approximately €60 million[12] and it has about 425 employees, mainly scientists.[13]

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[8] Code de la Sante Publique art. L.1411-4.

[9] Loi 98-535 du 1er juillet 1998 relative au renforcement de la veille sanitaire et du controle de la sécurité sanitaire des produits destinés à l'homme [Law 98-535 Relating to the Reinforcement of Health Monitoring and of the Control of the Health Safety of Products Destined for Man], J.O., July 2, 1998, p. 10056, http://legifrance.gouv.fr/affichTexte.do;jsessionid=20D3E80627BA733894E9F14916C2B1F6.tpdjo16v_2?cidTexte=JORFTEXT000000573437&categorieLien=id.

[10] Loi No 2004-806 du 9 août 2004 relative à la politique de santé publique [Law No. 2004-806 of August 9, 2004, on Public Health Policy], J.O., Aug. 11, 2004, p. 14277, http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000787078&categorieLien=id.

[11] *Id.* art. 15; CODE DE LA SANTE PUBLIQUE art. L1413-2.

[12] As of October 29, 2014, the exchange rate for dollars to Euros was US$1.27:€1.00.

[13] INSTITUT DE VEILLE SANITAIRE, RAPPORT ANNUEL [ANNUAL REPORT] 2013 at 68–69, http://www.invs.sante.fr/publications/rapport_annuel/2013/sources/index.htm.

To perform its mission, the InVS has access to a network of seventeen regional centers called Cellules interrégionales d'épidémiologie (CIRE, Inter-regional Epidemiological Units). These CIRE fall under the authority of General Director of the InVS, but are integrated into local Agences régionales de santé (ARS, Regional Health Agencies).[14] ARS were created in 2009 to centralize and better coordinate the various government health-related resources at the regional level.[15] The CIRE investigate and assess potential health safety warning signs,[16] and provide each ARS with methodological support and independent expertise regarding such warning signs.[17]

In addition to the CIRE, the InVS works with a great number of other organizations that contribute to the monitoring of public health, particularly doctors and hospitals.[18] Medical doctors and laboratories (both public and private) must report to their local ARS diseases that necessitate urgent local, national, or international intervention, and diseases that require monitoring for the evaluation of public health policies.[19] A list of the diseases that must be reported is published in the Code of Public Health and is regularly updated.[20] Information must be sent to the ARS and InVS in a manner that protects the patients' privacy,[21] and all those who have access to this information, in whatever capacity, are required to observe the confidentiality of the information.[22] A violation of the confidentiality requirement is punishable by one year of imprisonment and a fine of €15,000 (approximately US$17,000).[23] The Public Health Code does not provide for a penalty when a doctor fails to report a listed disease. However, failure to report may be prosecuted under the provisions governing the risks caused to another[24] or the omission to render assistance[25] when such failure results in the contamination of other individuals either

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[14] *Missions des CIRE* [*Missions of the CIRE*], INSTITUT DE VEILLE SANITAIRE (Apr. 21, 2011), http://www.invs.sante.fr/Regions-et-territoires/Missions-des-Cire.

[15] Loi No. 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires [Law No. 2009-879 of July 21, 2009, Reforming Hospitals and Regarding Patients, Health, and Territories] (July 21, 2009), http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000020879475&categorieLien=id; *Présentation générale* [*General Presentation*], AGENCE RÉGIONALE DE SANTÉ, http://www.ars.sante.fr/Presentation-generale.89790.0.html (last visited Oct. 29, 2014).

[16] *Missions des CIRE*, *supra* note 14.

[17] *Qui sommes nous? Organisation* [*Who Are We? Organization*], INSTITUT DE VEILLE SANITAIRE (Sept. 1, 2014), http://www.invs.sante.fr/L-Institut/Qui-sommes-nous.

[18] RAPPORT ANNUEL, *supra* note 13, at 12.

[19] CODE DE LA SANTE PUBLIQUE arts. L.3113-1 & R.3113-1 to R.3113-4.

[20] *Id*. arts. D.3113-6 & D.3113-7.

[21] *Id*. arts. L.3113-1 & R.3113-2.

[22] *Id*. art. R.3113-5.

[23] CODE PENAL [CRIMINAL CODE] art. 226-13, http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006070719&dateTexte=20141029.

[24] *Id*. art. 223-1. This article provides that "directly exposing another to a risk of immediate death or of wounds likely to result in mutilation or permanent infirmity by the manifestly deliberate violation of a special obligation of safety or prudence imposed by law or regulation," is punishable by one year of imprisonment and a fine of €15,000. *Id*. (translation by the author).

[25] *Id*. art. 223-6.

because they have been in contact with the contaminated subject or have been exposed to the same source of contamination.

The InSV works in close cooperation with the European Center for Disease Prevention and Control.[26] It is part of the Early Warning and Response System that was set up in 1998 under Decision 2119/98/EC of the European Parliament and of the Council.[27] This alert system establishes permanent communication between the EU Member States' public health authorities, enabling them to coordinate their efforts for the prevention and control of communicable diseases.[28]

In February 2001, the WHO opened an office in France to help developing countries detect and control epidemics and emerging diseases.[29] InSV also participates in international epidemic surveillance organizations such as the WHO's Early Alerting and Reporting project[30] and the EpiSouth network, which aims to improve communicable diseases surveillance, communication, and training among the countries of the Mediterranean and the Balkans.[31]

C. Ministry of Health

In cases of severe health threats, especially epidemiological threats, necessitating emergency measures, the minister in charge of health has the authority to impose any proportional measures to prevent and mitigate the dangers to public health.[32] The Minister of Health may also give authority to local prefects to take any measures necessary to apply the minister's decisions.[33]

D. Prefects

The prefect directly represents the Prime Minister and each minister in the *département*. He is, therefore, responsible for most central functions, including internal order, civil safety, security,

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[26] *Activités Européennes* [*European Activities*], INSTITUT DE VEILLE SANITAIRE (Aug. 12, 2013), http://www.invs.sante.fr/Europe-et-international/Activites-europeennes/Projets-europeens-et-contribution-de-l-InVS-a-l-ECDC.

[27] Decision No. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 Setting Up a Network for the Epidemiological Surveillance and Control of Communicable Diseases in the Community, 1998 O.J. (L 268) 1, http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31998D2119&from=EN.

[28] *Id.* art. 1.

[29] *La France et la gouvernance mondiale de la santé* [*France and International Governance on Health*], MINISTÈRE DES AFFAIRES ETRANGÈRES ET DU DÉVELOPPEMENT INTERNATIONAL [MINISTRY OF FOREIGN AFFAIRS AND INTERNATIONAL DEVELOPMENT] (May 2014), http://www.diplomatie.gouv.fr/fr/politique-etrangere-de-la-france/sante-securite-alimentaire/sante/article/la-france-et-la-gouvernance.

[30] *Activités Internationales* [*International Activities*], *Veille Sanitaire Internationale* [*International Health Surveillance*], INSTITUT DE VEILLE SANITAIRE (July 16, 2014), http://www.invs.sante.fr/Europe-et-international/Activites-internationales/Veille-sanitaire-internationale.

[31] *Id.*; EPISOUTH, http://www.episouth.org/home.php (last visited Oct. 29, 2014).

[32] Code de la Santé Publique art. L.3131-1.

[33] *Id.*

and health in his *département*.[34] In a time of crisis of any type, he coordinates all civilian services involved in the management of such a crisis within his *département*.[35] Prefects are authorized to requisition all property or services, in particular the services of any health professionals, if necessary to face a health crisis.[36]

E. Reserve Health Corps

Law 2007-294 of March 5, 2007, established a reserve health corps to help deal with disasters, emergencies, and serious health threats.[37] The Law was incorporated into the Health Code. The reserve corps comprises health professionals, former health professionals, and other individuals whose professional duties, experience, or level of training satisfy the requirements set forth by the Ministry of Health.[38] The contract to serve in the reserve may provide for carrying out international missions.[39]

III. National Plan for the Prevention and Control of the Influenza Pandemic

In 2004, France drew up its first comprehensive national plan for the prevention and control of an influenza pandemic. Its latest version was published in October 2011,[40] and the French government has published an English-language version.[41] The plan is adaptable and aimed at protecting the French population, as well as French citizens living abroad, against a pandemic threat and limiting the social and economic consequences of a pandemic.[42]

The plan sets action guidelines for four different stages of an epidemic's progression in a territory.[43] Responses in the first stage focus on slowing down the introduction of the virus into the territory, thus allowing the government to prepare for the following stages by making vaccines available (if possible), distributing relevant health care products and equipment, and

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[34] *Missions*, PRÉFECTURES, MINISTÈRE DE L'INTÉRIEUR [MINISTRY OF THE INTERIOR] (Oct. 10, 2011), http://www.interieur.gouv.fr/Le-ministere/Prefectures/Missions.

[35] *Id*.

[36] Code de la Santé Publique art. L.3131-8.

[37] Loi 2007-294 du 5 mars 2007 relative à la préparation du système de santé à des menaces sanitaires de grande ampleur [Law 2007-294 of March 5, 2007, on Preparing the Health System to Deal with Large-Scale Health Threats], J.O., Mar. 6, 2007, p. 4224, http://legifrance.gouv.fr/affichTexte.do;jsessionid=C911448ACC0CBA39980BD487A5EA824B.tpdjo14v_3?cidTexte=JORFTEXT000000461266&categorieLien=id.

[38] Code de la Sante Publique art. L.3132-1.

[39] *Id*.

[40] PLAN NATIONAL DE PRÉVENTION ET DE LUTTE «PANDÉMIE GRIPPALE» [NATIONAL "INFLUENZA PANDEMIC" PREVENTION AND RESPONSE PLAN] (Oct. 2011), http://www.sante.gouv.fr/IMG/pdf/Plan_Pandemie_Grippale_2011.pdf.

[41] NATIONAL "INFLUENZA PANDEMIC" PREVENTION AND RESPONSE PLAN (Oct. 2011), http://www.sante.gouv.fr/IMG/pdf/PlanPandemieGrippale-Version_Anglais.pdf.

[42] *Id*. at 4.

[43] *Id*. at 11.

preparing health care facilities for a possible influx of patients.[44] Health checks at the border may be part of the government's response at this stage.[45] Similarly, in the second stage, the authorities act to slow down the propagation of the virus in the territory so as to gain time for the scaling-up of the health care system and/or the preparation of a vaccine.[46] Barrier measures, such as closing nurseries and schools; encouraging the public to use individual means of transport; or restricting collective activities such as performances, sports events, or other major gatherings, may be implemented at this stage.[47] In the third stage, during which the number of affected patients peaks, the authorities try to limit the pandemic's effect—not only from a health care aspect through the treatment of patients, but also from an economic aspect through measures to mitigate the effects of absenteeism and other pandemic-related disturbances.[48] Finally, stage four marks both a transition back to a normal situation, and preparation for a potential second wave.[49]

IV. Responding to the Ebola Crisis

The first case of Ebola infection in Guinea was identified by a French laboratory on March 23, 2014. This prompted French authorities to inform the European Commission and the European Health Security Committee, and to monitor the epidemiological situation in African countries where the virus is present in collaboration with the WHO and the European Center for Disease Control.[50] An interministry task force, including a prefect and representatives from the Ministry of Health and the Ministry of Foreign Affairs, was set up to coordinate the French response to the Ebola threat.[51] The InVS is continuously monitoring the epidemiological situation, both in France and internationally, and special measures were put into place for the early detection and isolation of any person who might be contagious on French territory.[52] Screening processes have been set up at the airports of at-risk countries to assess travelers going to France, and informational brochures have been given to airlines to be distributed to passengers traveling between France and at-risk countries.[53] French citizens are encouraged to postpone any travel to at-risk countries.[54] If a person infected with the Ebola virus is detected in France, that person is

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[44] *Id.* at 39.

[45] *Id*.

[46] *Id*. at 47.

[47] *Id*. at 50.

[48] *Id*. at 55–61.

[49] *Id.* at 65.

[50] *Nous agissons contre Ebola* [*We Are Acting Against Ebola*], MINISTÈRE DES AFFAIRES SOCIALES, DE LA SANTÉ ET DES DROITS DES FEMMES [MINISTRY OF SOCIAL AFFAIRS, HEALTH, AND WOMEN'S RIGHTS], http://ebola.sante.gouv.fr/nous-agissons-contre-ebola/ (last visited Oct. 30, 2014).

[51] Press Release, Premier Ministre [Prime Minister], Le Gouvernement renforce l'organisation interministérielle face à la crise Ebola [The Government Reinforces the Interministry Organization Against the Ebola Crisis] (Oct. 17, 2014), http://www.gouvernement.fr/sites/default/files/document/document/2014/10/17.10.2014_communique_de_presse_de_manuel_valls_premier_ministre_-_crise_ebola.pdf.

[52] Nous agissons contre Ebola, *supra* note 50.

[53] *Id*.

[54] *Id*.

to be transported to a specialized health care facility, where that person will be treated in isolation.[55] The government has published a list of hospitals that have been set up and certified by an ARS to treat Ebola patients.[56] The government has also provided information to medical professionals on the symptoms of the Ebola virus, on the procedures to protect themselves from infection, and on the procedures to alert the health authorities if they come across a potential Ebola patient.[57]

[55] *Id*.

[56] *Id*.; Liste des établissements de santé de référence habilités pour la prise en charge des patients cas possibles ou confirmés de maladie à virus Ebola [List of Reference Health Care Establishments Certified to Take Charge of Possible or Confirmed Ebola Virus Patients], MINISTÈRE DES AFFAIRES SOCIALES, DE LA SANTÉ ET DES DROITS DES FEMMES [MINISTRY OF SOCIAL AFFAIRS, HEALTH, AND WOMEN'S RIGHTS] (Sept. 25, 2014), http://ebola.sante.gouv.fr/IMG/pdf/2014_09_25_-_listingesr_maj_modifidferta-2-2.pdf.

[57] *Id*.

Greece

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SUMMARY The Ministry of Health and Social Solidarity is in charge of public health issues in Greece, such as those related to communicable diseases, weather-related disasters, and others. Two major centers play a central role in coordinating, planning, and fighting the spread of communicable diseases: (a) the National Health Operations Center, and (b) the Center for the Control and Prevention of Communicable Diseases. In response to the Ebola crisis, Greece established a comprehensive plan to fight the virus that involved setting-up a special unit for potential victims and staffing entry points with medical experts to detect suspected cases, among other measures. As a Member of the European Union and the World Health Organization, Greece complies with European Union and World Health Organization legislation on issues related to public health crises and is in constant collaboration with both entities.

I. Introduction

In Greece, public health issues fall within the domain of the Ministry of Health and Social Solidarity. The mission of the Ministry is to promote the health care of citizens; provide a high level of medical, pharmaceutical, and hospital services; and work towards the prevention of diseases, in compliance with European Union (EU) legislation and regulations issued by the World Health Organization (WHO).[1] Greece is required to comply with EU Decision No. 1082/2013 on Serious Cross-Border Threats to Health[2] and is also in close contact with the European Centre for Disease Prevention and Control, established by the EU.[3] In addition, Greece participates in the Early Warning and Response System established in 1998 in order to provide notification of alerts concerning serious public health threats with cross-border implications.[4] The Ministry of Health and Social Solidarity also participates in the Health Security Committee, established at the EU level.[5]

As a WHO member, Greece ratified the revised 2005 International Health Regulations, which entered into force in June 2007 and require WHO Members to provide notification of all events that may constitute a public health emergency of international concern.[6] In February 2014,

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[1] HELLENIC REPUBLIC, MINISTRY OF HEALTH, http://www.moh.gov.gr/articles/ministry/organogramma/45-armodiothtes-toy-ypoyrgeioy-ygeias-kai-koinwnikhs-allhleggyhs (in Greek; last visited Nov. 26, 2014).

[2] Decision No. 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. 2119/1998/ EC, 2013 O.J. (L 293) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0001:0015:EN:PDF.

[3] EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, http://ecdc.europa.eu/ (last visited Nov. 12, 2014).

[4] Decision No. 1082/2013, *supra* note 2, art. 8.

[5] *Id*. art. 17, para. 3.

[6] Law No. 3991/2011 Kyrose tou Anatheorimenou Diethnous Ygeionomikou Kanonismou, tou Pagkosmiou Organismou Ygeias [Ratification of the Revised International Health Regulations Adopted by WHO], EPHEMERIS

WHO designated the University of Thessaly in Central Greece as a WHO collaboration center in order to have support in training activities related to ship inspections and the management of public health events at points of entry.[7]

In 1992, Greece established the Center for the Control and Prevention of Communicable Diseases,[8] which plays a critical role in preventing, controlling, and fighting epidemics, chronic diseases, intentional or accidental disasters from chemical or biological agents, and public health issues associated with a large influx of illegal migrants.[9]

II. National Agencies Responsible for Public Emergencies

At the domestic level, Greece has established two major agencies in order to effectively address public health crises, including natural disasters, communicable diseases, weather-related events, illegal migration, and others.

A. National Health Operations Center

The National Health Operations Center (NHOC) (in Greek, EKEPY) was established in 2004, during Greece's preparations for the Olympic Games. Its headquarters are located in Athens, while four divisions operate in other areas of Greece. The tasks of the NHOC are to assist the public in case of communicable diseases, natural disasters, and weather-related events such as floods or fires, as well as healthcare management associated with illegal migration.[10] It operates at the national level under the aegis of the Minister of Health and Social Solidarity and at the EU level by collaborating with similar institutions in the EU.

TES KYVERNESEOS TES HELLENIKES DEMOKRATIAS [E.K.E.D.] 2011, A:162. http://www.et.gr/index.php/2013-01-28-14-06-23/search-laws (ratifying the WHO International Health Regulations (2d ed. 2005), http://www.who.int/ihr/publications/9789241596664/en/).

[7] *New WHO Collaborative Centre for IHR – Points of Entry in Greece (University of Thessaly)*, WHO PAGNET (July 22, 2014), https://extranet.who.int/pagnet/?q=content/new-who-collaborative-centre-ihr-points-entry-greece-university-thessaly.

[8] Law No. 2071/1992, Eksychronismos kai Organosi Systematos Ygeias [Modernization and Organization of the Health System] art. 26, E.K.E.D. 1992, A:123, http://www.et.gr/idocs-nph/search/pdfViewerForm.html?args=5C7QrtC22wF7YkbUtryc43dtvSoClrL8PD8wzczkG7N5MXD0LzQTLWPU9yLzB8V68knBzLCmTXKaO6fpVZ6Lx3UnKl3nP8NxdnJ5r9cmWyJWelDvWS_18kAEhATUkJb0x1LIdQ163nV9K--td6SIudHO7dAghsLGact9Nmzq9fl479MbV5oRL_W94Evroqqu.

[9] Law No. 3370/2005, art. 5, Organosi kai Leitourgia of Health Services kai Alles Diatakseis [Organization and Operation of Health Services and Other Provisions], E.K.E.D. 2005 A:178, http://www.et.gr/idocs-nph/search/pdfViewerForm.html?args=5C7QrtC22wHrZvzjsKBkq3dtvSoClrL8gb8ZK5B_4Hl5MXD0LzQTLWPU9yLzB8V68knBzLCmTXKaO6fpVZ6Lx3UnKl3nP8NxdnJ5r9cmWyJWelDvWS_18kAEhATUkJb0x1LIdQ163nV9K--td6SIuUjEQ4m-Pl5_5Ndr9ctGV0KgaYdWP7N74CbAY8Bm2sX_.

[10] DR. PANOS EFSTATHIOU, HELLENIC NATIONAL HEALTH OPERATIONS CENTER, NHOC EMERGENCY PLANS AND ACTIONS, http://www.preventionweb.net/files/11564_PANOSEFSTATHIOU.pdf (last visited Nov. 26, 2014).

The NHOC exercises supervision over the Center for the Control of Communicable Diseases, the Hellenic National Center for Emergency Care, and the health districts, which include Greek hospitals.[11]

B. Center for the Control and Prevention of Communicable Diseases

The Center for the Control and Prevention of Communicable Diseases[12] (abbreviated in Greek as KEEL and, as of 2005, as KEELPNO[13]) was established in 1992 and is located in Athens.[14] The mission and tasks assigned to KEELPNO are determined by Implementing Decree No. 358/1992[15] and include the control and prevention of contagious and noncontagious diseases and, if possible, their cure. KEELPNO also makes suggestions and recommendations on national policy concerning diseases to the Ministry of Health and Social Solidarity. In addition, KEELPNO informs the public and disseminates information and circulars to groups that are at high risk of being infected by a disease.[16] KEELPNO has been designated as the national authority to closely communicate with the European Center for Disease Control and Prevention, in particular in the area of developing surveillance responses to health threats, providing scientific opinions and scientific and technical assistance, collecting data and identifying emerging health threats, and conducting public information campaigns.[17]

III. National Response to the Ebola Crisis

In the wake of the Ebola outbreak in West Africa, KEELPNO announced that there is a "very low" risk of the Ebola virus reaching Greece. However, KEELPNO officials have been on the alert and are monitoring the outbreak.[18]

In order to respond to the Ebola crisis in a coordinated manner, Greece established a multifaceted national plan agreed upon jointly by the Ministers of Health and Social Solidarity, of Public

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[11] *Id*.

[12] *Emergency Operations Centre of HCDCP*, HELLENIC CENTER FOR DISEASE CONTROL AND PREVENTION, http://www.keelpno.gr/en-us/managementofpublichealthissuesoperationcenter.aspx (last visited Nov. 26, 2014).

[13] Law No. 3370/2005, art. 20.

[14] Law No. 2071/1992, art. 26, E.K.E.D. 1992, A:123, http://www.et.gr/idocs-nph/search/pdfViewerForm.html?args=5C7QrtC22wF7YkbUtryc43dtvSoClrL8PD8wzczkG7N5MXD0LzQTLWPU9yLzB8V68knBzLCmTXKaO6fpVZ6Lx3UnKl3nP8NxdnJ5r9cmWyJWelDvWS_18kAEhATUkJb0x1LIdQ163nV9K--td6SIudHO7dAghsLGact9Nmzq9fl479MbV5oRL_W94Evroqqu.

[15] Presidential Decree No. 358/1992, Organosi Leitourgia kai Armodiotites tou Kentrou Loimodon Limokseon [Organization, Operation and Responsibilities of the Center of Communicable Diseases], E.K.E.D. 1992, A:179, http://www.et.gr/idocs-nph/search/pdfViewerForm.html?args=5C7QrtC22wF7YkbUtryc43dtvSoClrL8tvmGnUriqnd5MXD0LzQTLWPU9yLzB8V68knBzLCmTXKaO6fpVZ6Lx3UnKl3nP8NxdnJ5r9cmWyJWelDvWS_18kAEhATUkJb0x1LIdQ163nV9K--td6SIuQILCNmEB2x4MHVk-Xgell4tEqkB5I8OkTDDIYS6ToMB.

[16] *Id*. art. 3.

[17] *Competent Bodies*, EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, http://www.ecdc.europa.eu/en/aboutus/Competent%20bodies/Pages/Competent_bodies.aspx (last visited Nov. 26, 2014).

[18] *Greek Disease Control Center Sees 'Very Low' Risk of Ebola Spread but Cautions Travelers*, EKATHIMERINI (Aug. 1, 2014), http://www.ekathimerini.com/4dcgi/_w_articles_wsite1_1_01/08/2014_541879.

Order, and of Shipping designed to deal with Ebola patients; ensure that travelers who may have Ebola and enter Greece either by air, sea, or land are monitored; keep the public informed; and assuage fears among the citizens. To this effect, an intensive care isolation unit specifically equipped to deal with Ebola patients has been established in a hospital in Athens. In addition, a specially trained team of health workers constantly update their training and knowledge of the disease in compliance with guidelines issued by EU and Greek officials.[19]

On October 10, 2014, officials from the Ministry of Health and Social Solidarity, in collaboration with experts from KEELPNO and the NHOC, announced a number of precautionary measures to combat a possible Ebola epidemic in Greece. Priority among the measures was to secure Greece's entry points with an additional thirty medical experts from KEELPNO to provide early diagnoses of any suspicious cases. Airlines were also instructed to distribute questionnaires to visitors traveling from West African countries (via direct flights or in transit) in order to identify persons who may have come into contact with Ebola patients. In addition, Greek and English-language posters have already been placed in Greek airports providing information about the Ebola virus.[20]

[19] *Greece Adopts Preventive Measures Against Ebola Virus*, CHANIA POST (Oct. 11, 2014), http://www.chaniapost.eu/?p=7899; Ioanna Zikakou, *Greek Government Takes Steps to Tackle Ebola Virus*, GREEK REPORTER (Oct. 11, 2014), http://greece.greekreporter.com/2014/10/11/greek-government-takes-steps-to-tackle-ebola-virus/.

[20] CHANIA POST, *supra* note 19; Zikakou, *supra* note 19.

India

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SUMMARY India's Central Government and state governments are empowered to regulate health-related matters. The Epidemic Diseases Act is the main legislative framework at the central level for the prevention and spread of dangerous epidemic diseases. The Act empowers the central government to take necessary measures to deal with dangerous epidemic disease at ports of entry and exit. The Act also empowers the states to take special measures or promulgate regulations to deal with epidemics within their state jurisdictions. In such emergencies the states delegate some of these powers to the deputy commissioners in the districts, typically through state health acts or municipal corporation acts. Thus, responsibility for directly addressing the crisis rests with the deputy commissioner at the district level.

I. Structure of Public Health Crisis Management System

India is a union of twenty-eight states and seven territories, with a constitutional division of legislative responsibilities between the central government and the states. Both the central government (also known as the Union government) of India and the state governments are constitutionally empowered to legislate on matters of public health. The Union law may deal with port quarantine, including in connection with seamen's and marine hospitals.[1] The law may also deal with interstate migration and quarantine. State law may provide for matters relating to public health and sanitation, hospitals, and dispensaries.[2] The central government and state laws may also provide for the prevention of the transmission from one state to another of infectious or contagious diseases or pests affecting humans, animals, or plants.[3] There are several central laws managing the prevention of contagious diseases.

A. Union Laws

1. Epidemic Diseases Act

The preamble to the 1897 Epidemic Diseases Act states that its objective is to provide for better prevention of the spread of dangerous epidemic diseases.[4] The Epidemic Diseases Act empowers the state governments and the central government to take measures as may be warranted or necessary to control the further spread of disease. Thus, any state government,

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[*] This report updates a report originally prepared in 2003 by former Senior Foreign Law Specialist Krishan S. Nehra, which was previously updated in 2009.

[1] INDIA CONST. 7th Sched., List I, Entries 28 & 81.

[2] *Id.* List II, Entry 6.

[3] *Id.* List III, Entry 29.

[4] Epidemic Diseases Act, No. 3 of 1897, pmbl.

when satisfied that any part of its territory is threatened with an outbreak of a dangerous disease, may adopt or authorize all measures, including quarantine, to prevent the outbreak of the disease.[5] Similarly, the central government, when satisfied that there is an imminent threat of an outbreak of an epidemic disease and that the provisions of the law at that time are insufficient to prevent such an outbreak, may take measures and prescribe regulations allowing for the inspection of any ship or vessel leaving or arriving at any port and for the detention of any person arriving or intending to sail.[6]

Any person who disobeys any regulation or order made under the 1897 Act may be charged with an offense under section 188 of the Indian Penal Code.[7] The person in violation of the provision is liable, upon conviction, to a sentence of simple imprisonment for one month, a fine, or both. Notwithstanding anything contained in the Code of Criminal Procedure, such offense, at the discretion of the trial magistrate, may be tried summarily. No suit or legal proceeding lies against any person or authority for anything done, or in good faith intended to be done, under this Act.

Some critics have observed that the Epidemic Diseases Act of 1897 "is a century-old blunt act" that needs a "substantial overhaul to counter the rising burden of infectious diseases both new and old."[8] Some of the issues that require revisiting, they argue, are the "definition of epidemic disease, territorial boundaries, ethics and human rights principles, empowerment of officials, [and] punishment."[9] It appears that India's National Centre for Disease Control (NCDC) is developing a "Public Health Emergencies Act," which is "expected to take care of public health emergency situations in the country arising as a result of disasters and bio-terrorism incidents besides dangerous epidemic diseases including newly emerging infectious diseases."[10] In recent years, the Epidemic Disease Act 1897 was invoked by a number of states in India to deal with the pandemic H1N1 ("swine flu") influenza and other communicable diseases.[11]

2. *Quarantine of Visitors*

For people entering India from abroad, a health officer appointed by the central government is posted at the port of entry.[12] Upon being satisfied that a ship or aircraft is in compliance with the health regulations, the health officer grants pratique to the vessel or aircraft for landing. The

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[5] *Id.* § 2.

[6] *Id.* § 2A.

[7] INDIAN PENAL CODE, No. 45 of 1860.

[8] Binod K. Patro, Jaya Prasad Tripathy & Rashmi Kashyap, *Epidemic Diseases Act 1897, India: Whether Sufficient to Address the Current Challenges?*, 18(2) J. MAHATMA GANDHI INST. MED. SCI. 109, 111 (2013), http://www.jmgims.co.in/article.asp?issn=0971-9903;year=2013;volume=18;issue=2;spage=109;epage=111;aulast=Patro#ref4.

[9] *Id.*

[10] *Centre for Epidemiology and Parasitic Diseases*, NATIONAL CENTRE FOR DISEASE CONTROL, http://nicd.nic.in/index2.asp?slid=496&sublinkid=143 (last visited Nov. 10, 2014).

[11] T. Dikid et al., *Emerging & Re-emerging Infections in India: An Overview*, 138(1) INDIAN J. MED. RES. 19–31 (July 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3767269/.

[12] Aircraft Act, No. 22 of 1934; Indian Aircraft (Public Health) Rules, 1954, R. 2(8).

health officer may demand to see the aircraft journey log book, which shows the places the aircraft visited.[13] He may also inspect the aircraft, its passengers, and its crew, and subject them to medical examinations after their arrival.[14] The officer must follow specific precautions with regard to communicable diseases[15] that require a period of quarantine (such as yellow fever, plague, cholera, smallpox, typhus, and relapsing fever) and other infectious diseases that do not require a period of quarantine.[16]

Except in the case of an emergency constituting a grave danger to public health, an aircraft should not, on account of an infectious disease that does not require a period of quarantine, be prevented by the health officer of an airport from discharging or loading cargo, fuel, or water. However, where any person is required under the rules to be disembarked and isolated for any period, the officer may cause him to be removed to a hospital or another approved place and detain him in quarantine.[17] If necessary, the officer may require the person to report to him at specified intervals during the period of surveillance.[18] The health officer may also remove, cause to be removed, or order the removal of any person, other than someone proceeding on an international voyage, who, in the opinion of the officer, is likely to spread any quarantinable or infectious disease.[19]

When it is brought to the attention of the health officer, he may prohibit the embarkation on any aircraft of any person showing symptoms of any quarantinable disease and any person whom the health officer considers likely to transmit infection because of his close contact with a person showing symptoms of a quarantinable disease.[20] When a case of typhus or relapsing fever occurs at the airport, the person on an international voyage who is considered liable by the officer to spread such a disease must be disinfected.[21] Upon request, the health officer must issue to the commander of an aircraft a certificate specifying the health measures taken with respect to the aircraft, the parts of the aircraft treated, the methods employed, and the reasons why the measure have been applied.[22]

Regulations require that airline staff report any suspected cases or passengers who in their opinion, from observations made in flight, may be suffering from symptoms of a quarantinable disease.

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[13] *Id.* R. 6(2).

[14] *Id.* R. 8(1).

[15] *Id.* R. 9–29.

[16] *Id.* R. 30–32.

[17] *Id.* R. 56.

[18] *Id.* R. 58.

[19] *Id.* R. 61.

[20] *Id.* R. 36(1).

[21] *Id.* R. 39.

[22] *Id.* R. 54.

With respect to Ebola, in early August 2014, the Health Ministry announced that authorities would begin screening "travellers who originate from or transit through affected nations, and track them after their arrival in India."[23] Passengers are informed through in-flight announcements that "mandatory self-reporting is required at immigration."[24] The government also "set up facilities at airports and ports to manage travellers showing symptoms of the disease."[25] The surveillance system will track travelers for four weeks and persons who develop symptoms will be advised to self-report. On August 26, 2014, six Indian nationals were isolated after returning from Liberia but all tested negative for the virus.[26]

Similar quarantine restrictions are provided under the Indian Port Health Rules 1955,[27] pursuant to the Indian Port Act,[28] for passenger ships, cargo ships, and cruise ships.

B. State Laws

In order to prevent the outbreak of smallpox, states have enacted laws in their territories for the vaccination of children under thirteen years of age.[29] For example, the Punjab Vaccination Act makes primary vaccination and revaccination of children compulsory throughout the state. Where the state's Superintendent of Vaccination has reasons to believe that a child was not vaccinated, he may serve notice on the guardian of the child, requiring him to bring the child for vaccination. Upon failure to comply with the notice, a district magistrate may summon the guardian and demand an explanation for noncompliance with the Superintendent's notice. If the explanation is not satisfactory, the district magistrate may require him to produce the child for vaccination and also produce a certification of such vaccination within the period specified.[30]

II. Powers of Public Health Authorities

Every state in India is divided into districts, and the deputy commissioner of each district is not only head of the district administration but also acts as revenue collector and as district magistrate, responsible for the maintenance of law and order in his jurisdiction.[31] He is the key official, and acts as a liaison between the people and the government.

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[23] Nita Bhalla, *India Goes on Alert for Ebola, with Thousands of Nationals in West Africa*, REUTERS (Aug. 8, 2014), http://in.reuters.com/article/2014/08/08/ebola-india-virus-west-africa-idINKBN0G80OA20140808.

[24] *Id.*

[25] *Id.*

[26] Sneha Shankar, *Ebola Alert: Six Indians Isolated at Delhi Airport Test Negative, More People Expected to Arrive and Be Tested*, INTERNATIONAL BUSINESS TIMES (Aug. 26, 2014), http://www.ibtimes.com/ebola-alert-six-indians-isolated-delhi-airport-test-negative-more-people-expected-arrive-1669216.

[27] Indian Port Health Rules, 1955.

[28] Indian Ports Act, No. 15 of 1908, http://www.mumbaiport.gov.in/writereaddata/linkimages/6177609667.pdf.

[29] *E.g.*, Punjab Vaccination Act, No. 49 of 1953.

[30] *Id.* §§ 13–14.

[31] *Introduction*, DISTRICT ADMINISTRATION SANGRUR, http://sangrur.nic.in/html/dcrole.html (last visited Nov. 17, 2014).

In order to meet a health crisis, following the outbreak of an epidemic, the Epidemic Diseases Act gives wide ranging powers to the states.[32] The states, in such emergencies, delegate some of these powers to the deputy commissioners in the districts typically through state health acts or municipal corporation acts. Thus, responsibility for addressing the crisis rests with the deputy commissioner.

A. State and Municipal Governments

If at any time a state government is satisfied that the state or any part of it is threatened with the outbreak of a dangerous disease and that ordinary provisions of the law in force at the time are insufficient for the purpose of addressing the outbreak, it may take, require, or empower any person to take such measures and, by public notice, prescribe such temporary regulations as may be necessary to be observed by the public or by any person or class of persons for the prevention of the outbreak or spread of such disease.[33]

A state government may also take measures and prescribe regulations for the inspection, vaccination, and inoculation of persons traveling by road or rail, including their segregation in a hospital, temporary accommodation, or otherwise, if such persons are suspected by the inspecting officer of being infected with any such disease.[34]

A state government, by general or special order, may also empower a deputy commissioner to exercise, in relation to his district, all the powers under section 2 of the 1897 Act that are exercisable by the state government in relation to the state, other than to determine the manner in which and by whom any expenses are to be defrayed. Many of these powers are prescribed in Municipal Corporation Acts[35] governing "major municipal areas,"[36] or Public Health Acts[37] that also provide municipal-level commissioners or collectors with quarantine or other powers, including the following:

- *Removal of a person to separate premises for medical treatment*: "Persons suffering from such a disease may be removed to any hospital or place for medical treatment, based on an order from the Commissioner or the Collector."[38]

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[32] Epidemic Diseases Act, No. 3 of 1897, § 2(1).

[33] *Id*. § 2(2).

[34] *Id.* § 2(3).

[35] *See*, *e.g.*, Delhi Municipal Corporation Act, 1957, http://mcdonline.gov.in/tri/sdmc_mcdportal/publications/DMC%20Act.v.11..pdf; *and* Chennai City Municipal Corporation Act, 1919 (Tamil Nadu Act IV of 1919), http://www.chennaicorporation.gov.in/images/chennai_city_municipal_corporation_act.pdf.

[36] Monica Dasgupta, *Public Health in India: Dangerous Neglect*, XL(49) ECON. & POL. WEEKLY 11 (Dec. 3, 2005), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1410508&#.

[37] *See*, *e.g.*, Madras Public Health Act, No. 3 of 1939, *available at* http://www.sanchitha.ikm.in/sites/default/files/MadrasPublicHealth_%20Act1939..pdf.

[38] "Municipal Acts of Delhi, Gujarat, West Bengal, Tamil Nadu and Manipur," *Table 1 :Existing Legal Frameworks*, INDIAN J. PUB. HEALTH, http://www.ijph.in/viewimage.asp?img=IndianJPublicHealth_2010_54_1_11_70539_t1.jpg (last visited Nov. 10, 2014).

- *Cleansing or disinfecting any building or part of any building or any articles*: "The cleansing and disinfection of any building or part of it or of any articles in such building which are likely to retain infection, may be required to be cleansed and disinfected based on an order of the Commissioner or Collector to prevent or check the spread of any dangerous disease."[39]
- *Taking special measures in case of the outbreak of dangerous or epidemic diseases*: "In case of an outbreak, the Commissioner or Collector may take special measures and by public notice, give directions to be observed by the public or by any class or section of the public, as he thinks necessary to prevent the spread of the disease."[40]

B. Political and Civil Rights

By its very nature, the ambit of section 2 of the Epidemic Diseases Act is wide enough to allow a state or a lower functionary in the administration, in dealing with an emergency caused by the outbreak of a dangerous disease, to seek or require the cooperation of the public or corporate bodies in the public or private sectors. If the desired cooperation is not forthcoming, a regulation may be imposed. Failure to obey or comply with restrictions imposed by such a regulation constitutes a punishable violation.[41]

Powers of segregation or quarantine that the central government and state governments enjoy may impinge on the political and civil rights of the public. Fundamental rights, as guaranteed by the Constitution of India, are justiciable. The judiciary does not shy away from enforcing these rights or voiding orders that constitute violations of such rights. Quarantine is a measure that adversely affects the fundamental right "to move freely throughout the territory of India."[42] However, this right is to be enjoyed subject to reasonable restrictions that the state may impose in the interest, among others, of the general public.[43] As noted above, section 4 of the Epidemic Diseases Act includes a protection clause that gives state immunity such that "[n]o suit or other legal proceeding" can be brought against "any person for anything done or in good faith intended to be done under this Act."[44]

The right to privacy, as such, is not a fundamental right in India. The Supreme Court of India has found that the right of privacy is an essential component of the right to life, but that it is not absolute and may be restricted to prevent crime or disorder, or to protect health, morals, or the rights and freedom of others.[45]

During the SARS epidemic in 2003, there was concern over the severity of quarantine enforcement measures, the discrimination that patients faced, and the lack of privacy and

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[39] *Id*.

[40] *Id*.

[41] Epidemic Diseases Act § 3.

[42] INDIA CONST. art. 19(1)(d).

[43] *Id*. art. 19(2), (4).

[44] Epidemic Diseases Act § 4.

[45] 'X' v. Hospital 'Z', 1998 S.C.C. 296, para. 28.

confidentiality. There were also reports of shaming of colleagues and neighbors who had been placed in quarantine.[46]

III. Transparency of Public Health Crisis Management System

Within the democratic system, the judiciary in India ensures transparency in government actions and executive orders. The public frequently seeks judicial review of executive orders and regulations. The Parliament of India has also enacted a Freedom of Information Act, requiring transparency in government actions.[47] The Act entitles the public, by filing a written or electronic application, to obtain information from any public authority.[48]

IV. Cooperation with the World Health Organization (WHO)

In 1997 the WHO set up the National Polio Surveillance Project to help provide technical support for the government with surveillance of polio, mass vaccination campaigns, and routine immunizations.[49]

In 2008, WHO, in collaboration with the NCDC, started a pilot project to prevent humans from contracting rabies in five Indian cities. The project "includes training of health professionals in animal-bite management and raising public awareness about the need to seek post-exposure treatment, notably through posting messages on buses and in other public places."[50]

Besides those projects, the WHO is available to provide assistance in all emergencies—for example, earthquakes, epidemics, or disasters resulting from terrorism of any sort that may create a health emergency in the country. The WHO's Regional Office annually conducts ten-day, intercountry training courses on epidemic preparedness and response to develop regional capacity in early detection and response to disease outbreaks. Specifically, the WHO is assisting the National Centre for Disease Control (NCDC) (formerly the National Institute of Communicable Diseases) in the preparation, printing, and distribution of *CD Alert*, a monthly newsletter published by NCDC. The WHO has also been assisting the NCDC in cooperating more closely with neighboring health systems in south and southeast Asian countries through workshops and other meetings.[51]

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[46] Sanjay Nagral, Editorial, *SARS: Infectious Diseases, Public Health and Medical Ethics*, 11(3) INDIAN J. MED. ETHICS (2003), http://ijme.in/index.php/ijme/article/view/861/2020.

[47] Freedom of Information Act, No. 5 of 2003.

[48] *Id*. § 6.

[49] *Surveillance, at the Heart of India's Polio Success Story*, WHO COUNTRY OFFICE FOR INDIA, http://www.searo.who.int/india/topics/poliomyelitis/surveillance/en/. For more information on WHO-India cooperation, see WHO COUNTRY OFFICE FOR INDIA , COUNTRY COOPERATION STRATEGY INDIA 2012–2017 at 29 (2012), http://www.who.int/countryfocus/cooperation_strategy/ccs_ind_en.pdf?ua=1.

[50] Patralekha Chatterjee, *India's Ongoing War Against Rabies*, 87(12) BULLETIN OF THE WORLD HEALTH ORGANIZATION 890–91 (Dec. 2009), http://www.who.int/bulletin/volumes/87/12/09-021209/en/.

[51] K.S. Jayaraman, *India Upgrades Its Disease Surveillance Network*, NATURE (Aug. 17, 2009), http://www.nature.com/news/2009/090817/full/news.2009.825.html.

Israel

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SUMMARY Israel's Ministry of Health (MOH) is generally responsible for public health crisis management. The Minister of Health is authorized to classify specific diseases as "communicable diseases," and to declare a public health crisis caused by such diseases. The Minister may resort to special powers to limit and fight communicable diseases. The Minister's powers include the authority to order quarantine and decontamination of property. Despite the apparent infringement on the basic rights of protection of privacy, confidentiality of medical information, human dignity, and freedom, the law permits the restriction of these rights for the purpose of eliminating public health catastrophes such as epidemics and chemical or biological attacks.

In responding to intentional contamination, the Home Front Command (HFC) of the Israeli Defense Forces is charged with making the first response. The HFC regularly publishes information on threats and on measures that should be taken against contamination. Although data on the spread of communicable diseases is freely available, many aspects of counter biochemical and radiological terrorism are classified out of concern that their disclosure would endanger the public.

Israel develops and implements special plans for preventing the spread of communicable diseases as warranted. For example, Israel's MOH has issued a special memorandum on preparedness for and the prevention of Ebola. Previously, a special directive was issued by the MOH General Manager on May 4, 2009, regarding preparation for A/H1N1 2009 influenza. In 2007 the MOH issued a report titled *Pandemic Influenza Preparedness Plan for the Health System*. The Plan includes specific requirements for reporting and monitoring, as well as a means of responding to a pandemic health crisis in cooperation with the World Health Organization and its regulations.

I. Introduction

Israel's systems of health crises preparedness, disease reporting and surveillance, and alert and response management are under the responsibility of the Ministry of Health (MOH).

The MOH's jurisdiction extends to managing the medical aspects of Israel's preparedness for, and response to, public health crises, including the operation of hospitals and clinics, identification and reporting of health crises, purchase and allocation of vaccines and medications, and distribution of information to the public. Other aspects of addressing health crises, including activating an emergency status, ordering quarantines, maintaining public order, and determining the closing and opening of schools, are handled by the Ministry of Defense through the Homeland Security Command.

The MOH issues new requirements on the spread, prevention, and treatment of disease periodically as needed. Most recently, in August 2014, the MOH published special guidelines on

preparedness for and prevention of the spread of the Ebola virus.[1] In 2007 the MOH issued a detailed report titled *Pandemic Influenza Preparedness Plan for the Health System*.[2]

This report describes the structure of the public health crisis management system in Israel, procedures for the determination of pandemics, and the special powers granted to public health authorities for disease and pandemic prevention. It also discusses the impact of these powers on human rights in Israel as well as the legal requirement for transparency in the public health crisis management system. The report includes information on special prevention programs including preparedness for chemical or biological attacks on the homeland.

II. Structure of Public Health Crisis Management System

Israel's public health crisis system is regulated by law and subsidiary legislation. The MOH is responsible for collecting information and making decisions for the protection of the public and for implementing these decisions and policies.[3] Health services are usually dispensed through companies called health insurance establishments (HIEs) that are partially subsidized by the state.[4] Every resident has a right to health services provided in a manner that protects human dignity, privacy, and medical confidentiality.[5]

A. Declaring a Disease "Communicable"

The statutory framework for dealing with communicable diseases is based on Public Health Ordinance No. 40 of 1940,[6] as amended. A "communicable disease" is defined by the Ordinance as any disease listed in the second appendix to the Ordinance, or one declared by the Head of Health Services or a designee as a communicable disease. The declaration must be made in the official gazette and must specify the area and the period for its application. The list appended to the Ordinance may be amended by the Minister of Health, who is authorized to add or delete diseases from the list through publication in the official gazette.[7]

The list currently includes diseases of international importance requiring immediate notification by the treating physician to the MOH regional office or other MOH offices in accordance with the World Health Organization (WHO)'s International Health Regulations (2005), such as

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[1] State of Israel Ministry of Health [MOH], Memorandum No. 13/14 by Head of Public Health Services (Aug. 7, 2014), http://www.health.gov.il/ hozer/BZ13_2014.pdf (in Hebrew).

[2] MOH, PANDEMIC INFLUENZA PREPAREDNESS PLAN FOR THE HEALTH SYSTEM (updated to June 7, 2007), http://www. health.gov.il/Subjects/emergency/preparation/DocLib/tora/BIO_TORA_PANDEMIC_FLU.pdf.

[3] For information about the Ministry's vision and activities, see *About the Ministry,* MOH, http://www.health.gov.il/English/About/Pages/default.aspx (last visited Oct. 14, 2014).

[4] National Health Insurance Law, 5754-1994, SEFER HAHUKIM [SH] [Book of Laws] (official gazette) No. 1469 p. 156 (5754-1994).

[5] *Id.* § 3.

[6] Public Health Ordinance No. 40 of 1940, ITON RISHMI [IR] (official gazette during the tenure of the Provisional Council of State) 1st Supp. 191 (1940).

[7] *Id.* §§ 11–11(A).

smallpox, Ebola virus, SARS, and yellow fever. Other diseases listed as requiring immediate individual notification similar to that required for diseases of international importance include AIDS and HIV infection; acute hepatitis A, B, and C; West Nile virus; and malaria.[8]

The inclusion of a disease in the list of communicable diseases empowers health authorities in Israel to resort to special measures, including quarantine, to fight the spread of the disease.[9]

B. Declaration of a Serious Health Danger

Public Health Ordinance No. 40 of 1940, as amended, authorizes the Minister of Health to declare the threat or existence of a serious danger to public health in Israel or in neighboring countries. With the publication of the declaration in the official gazette, the head of health services at the MOH may issue regulations regarding any person or HIEs activities, such as house-to-house visits, the provision of medical assistance, medications, housing accommodations, ventilation, and other measures to prevent the spread of the disease.[10]

III. Determination of Pandemics

A. Data Collection: Disease Reporting and Monitoring

1. Reporting

Under the 1940 Public Health Ordinance, doctors treating infected patients, patients' relatives, and possessors of property where infected patients have stayed must inform the regional government doctors of such cases either immediately or within twelve hours of learning that the patients have contracted a communicable disease.[11]

Under the 1994 National Health Law, as amended, HIEs must provide the MOH with medical data necessary for the fulfilment of the Ministry's obligations under the Law upon the Ministry's request. Noncompliance with such a request may cause delay in the provision of governmental subsidies. The Law specifies that medical information will be dispensed only to the extent necessary for the implementation of the Ministry's obligations and for the protection of the privacy of the insured and medical confidentiality.[12]

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[8] Public Health Ordinance (Change of List of Communicable Diseases) Decree (5771-2010), KOVETZ HATAKANOT (Subsidiary Legislation) 5771 No. 6951 pp. 262–72.

[9] Public Health Ordinance No. 40 of 1940, §§ 13–19.

[10] *Id.* § 20. For a discussion of powers provided to public health authorities following the declaration of a serious health danger, see Part IV, *infra*.

[11] Public Health Ordinance No. 40 of 1940, § 12.

[12] National Health Insurance Law §§ 40–41.

2. Monitoring

The Israel Center for Disease Control (ICDC) was established under the MOH in 1994. The ICDC was designed to provide the Ministry with up-to-date information on health issues. The ICDC deals with a large spectrum of health areas and cooperates closely with other departments in the MOH, the Central Bureau of Statistics, HIEs, other health care providers, as well as with research institutions and universities.[13]

According to information posted on the website of the International Association of National Public Health Institutes,

> [t]he ICDC main objectives are to identify health areas which lack essential data, establish new health-related databases, provide ongoing professional support for users of existing databases, undertake applied research in specific areas of public health, carry out national health surveys, report on the health status of the population, present policy alternatives to decision-makers in MOH, and carry out unusual morbidity surveillance. . . .
>
> The ICDC took active part in monitoring the pandemic influenza in Israel on [sic] winter 2009-2010, including syndromic surveillance, serologic surveillance, distribution of weekly reports, regular updates of the pandemia guidelines according to the WHO and other agencies, distribution of the updated guidelines on a daily basis, and activating a hotline for medical teams.[14]

The MOH's 2007 *Pandemic Influenza Preparedness Plan for the Health System* (the Plan),[15] for example, provides for a system of monitoring that relies on information received from the ICDC. According to the Plan, the monitoring of influenza is based on a combination of both laboratory and clinical observations. Laboratory monitoring of influenza is conducted in the MOH's Central Laboratory for Viruses. Samples are received from selected monitoring clinics on a weekly basis. All influenza tests among hospitalized patients and during disease breakouts are sent to the ICDC. The results of influenza tests conducted in two selected hospitals are also routinely delivered to the ICDC. The 2007 Plan further calls for the preparation of additional monitoring clinics and pediatric screening during influenza season and throughout the year as needed.[16] Clinical monitoring is conducted by the MOH Department of Epidemiology, the department for information and digitalization, and the ICDC. The ICDC periodically collects and integrates daily data determined to be indicative of influenza.[17]

The 2007 Plan provides for a specific monitoring program following the issuance of WHO phase 4 and 5 epidemic alerts, which correlate to both limited and significant human-to-human

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[13] *Israel National Disease Control Center*, MOH, http://www.health.gov.il/English/MinistryUnits/HealthDivision/Icdc/Pages/default.aspx.

[14] *Israel Center for Disease Control,* THE INTERNATIONAL ASSOCIATION OF NATIONAL PUBLIC HEALTH INSTITUTES, http://www.ianphi.org/membercountries/memberinformation/israel.html (last visited Oct. 20, 2014).

[15] Pandemic Influenza Preparedness Plan for the Health System, *supra* note 2.

[16] *Id.* at 19–28.

[17] *Id*.

contagiousness. The program calls for the operation of additional monitoring clinics, distributed geographically, and for the testing of a higher number of samples from persons meeting the disease case definition as determined by WHO. In addition, during phases 4 and 5 of the epidemic, a comprehensive epidemiological investigation will be conducted in every case in order to identify all relevant contacts and consider treatment by medication, isolation, and quarantine, as needed.[18]

According to the 2007 Plan, during a pandemic, when contamination is spread worldwide, there is no need for additional monitoring. Samples will be transferred only to the ICDC, which will conduct weekly integration of all the data it receives and disseminate its report to the MOH, health clinics, hospital doctors, and the community at large.[19]

3. Declaration of a Crisis

The 1940 Public Health Ordinance authorizes the Minister of Health to declare in Israel's official gazette that public health is severely threatened by the existence of a communicable disease in Israel or in neighboring countries. The authorization applies "if it seems that part of the country is subject to a danger of a terrible epidemic disease, local or communicable, or is infected with such a disease, such as the plague, cholera, yellow fever, smallpox, typhus, or another disease declared by the Minister of Health in publication in the official gazette, as a dangerous communicable disease."[20] The Ordinance does not describe the decision-making process to be followed by the Minister prior to declaring a disease communicable.

In the case of H1N1 influenza, several cases have been identified in Israel. The declaration concerning H1N1 influenza,[21] however, followed alert announcements by the WHO. Such a declaration forms the basis of the extensive powers granted to the Minister of Health and the Ministry's designees.[22]

IV. Powers of Public Health Authorities

A. General Powers

The Head of Medical Services of the MOH, and a government doctor or a supervisor appointed by the Minister of Health or the Minister of the Environment, whichever is relevant, are provided the authority to

[18] *Id*. at 25.

[19] *Id*. at 26.

[20] Public Health Ordinance No. 40 of 1940, § 20 (in Hebrew; translation by author, R.L.).

[21] Declaration of a Dangerous Communicable Disease, YALKUT HAPIRSUMIM (Notices – Official Gazette) No. 5945 p. 3536 (2009); for procedures to be followed by health teams, see MOH, General Memorandum by the General Manager Regarding Preparedness for 2009 A/H1N1 Influenza (July 1, 2009), http://www.health.gov.il/hozer/mk30_2009b.pdf.

[22] For a discussion of these powers, see Part IV, *infra*.

- inspect and decontaminate areas suspected of being contaminated with communicable diseases;
- examine persons found in suspected contaminated areas; and
- quarantine or transfer infected persons to a hospital.[23]

Specific powers are provided to the Head of Medical Services and to government doctors to order

- the decontamination, reconstruction, repair, or closure of all home water supplies;
- the purification or protection of all private or public water supplies; and
- the removal and destruction of all garbage from private or public premises.[24]

Additional powers include the vaccination of residents of an area suspected of being contaminated in order to stop the spread of the disease.[25]

Any person under an obligation to report communicable diseases, including relatives who stay with the infected person, building managers, and treating physicians, is authorized to carry out temporary quarantine actions ordered by the government doctor.[26]

B. Quarantine Powers

Under the Quarantine Ordinance (New Version) 5741-1981 the General Manager of the MOH is authorized to order a "quarantine service to prevent the penetration of diseases into Israel via land, sea or air, and their transfer from Israel to other countries."[27]

In accordance with the Quarantine Regulations,[28] the MOH is authorized to require a medical examination of every vessel in Israel's waters, to prohibit its contact with the shore or any other vessel, and to impose quarantine and sanitary measures to be followed upon arrival.[29] Vessels suspected of being infected may port only in the ports of Haifa and Tel-Aviv, while those confirmed infected, only in the Haifa port.[30]

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[23] Public Health Ordinance No. 40 of 1940, §§ 13–16.

[24] *Id*.

[25] *Id.* § 19.

[26] *Id*. § 13.

[27] Quarantine Ordinance (New Version) 5741-1981, §1, 35 DINEI MEDINAT YISRAEL (NUSACH CHADASH) (the revised, updated, and binding Hebrew text of legislation enacted before the establishment of the State of Israel) p. 747 (translated by author, R.L.).

[28] Quarantine Regulations, 3 HUKE ERETZ ISRAEL [HEI] [Laws of Palestine] 2170, *as amended*.

[29] *Id.* § 5.

[30] *Id.* § 6.

The Quarantine Regulations specify the procedures to be taken when a vessel arrives at an Israeli port, including the requirement that a health certificate filled out by the vessel's doctor be submitted. The health certificate must include information on events that occurred during travel that are related to public health. The health certificate should specify the health status of the ship's country of origin and all the ports it visited, especially if these places were infected with the diseases listed in the Regulations.[31] Vessels arriving without a health certificate or with an inappropriate health certificate will be subjected to quarantine.[32] Goods and passenger luggage may be subjected to decontamination and possible elimination by burning.[33] Passengers in vessels confirmed as infected will be subjected to quarantine.[34]

Although the Regulations specifically deal with vessels, it is reasonable that similar procedures are applicable to other modes of transportation, such as airplanes, under the general authorization by the Quarantine Ordinance (New Version) 5741-1981.

C. Forced Hospitalization and Seclusion

The 1940 Public Health Ordinance authorizes the head of the MOH or a government physician to force the hospitalization or seclusion of every person who is infected with a communicable disease. This may be done when the conditions of the residence are not suitable for prevention of the spread of the disease. Every person who was in contact with the infected person during the disease's incubation period may also be subjected to forced hospitalization.[35]

D. Powers During Periods of Emergency

As discussed above, the Minister of Health is authorized to publish a declaration that recognizes a dangerous communicable disease as existing or threatening public health. Once such a declaration has been published, the Head of Medical Services is authorized to order, by decrees, directives, or other means, any measures found necessary for preventing or containing the disease, including home visits; the provision of medical help; the distribution of medication; and the provision of clean, ventilated, and decontaminated places of residence.[36] The authorization encompasses the entire country, or designated parts, and applies to all vessels within the territorial waters of Israel.[37]

The Head of Medical Services is further authorized, following the publication of a declaration, to remove or arrest infected persons and subject them to supervision, medical examination, or treatment. Persons in touch with the infected person may also be subjected to this authority.

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[31] *Id.* § 8.

[32] *Id.* § 9.

[33] *Id.* §§ 17–19.

[34] *Id.* § 12.

[35] Public Health Ordinance No. 40 of 1940, § 15.

[36] *Id.* § 20.

[37] *Id.* § 23. An extension to airplanes could be interpreted as applying to territorial air space as well.

Similarly, the Head of Medical Services is also authorized to perform all acts required to obtain samples from such persons for laboratory exam, such as

- entering any private or public premises;
- establishing sanitary supervision;
- seizing, decontaminating, or destroying articles subjected to contamination;
- burying or disposing of the dead;
- taking possession of buildings or land (subject to compensation) to establish temporary hospitals; and
- taking possession of transportation vehicles (subject to compensation) needed to prevent the spread of the disease.[38]

The Head of Medical Services or a government doctor may also order the destruction of any building or shelter used by humans or animals that may provide a center for disseminating disease because of poor sanitary conditions. The owner may be reimbursed, depending on the owner's liability for the unsanitary conditions.[39] In the case of a disease outbreak in a limited area, an order may be made not to allow any person to exit the place. The police may be called upon to assist in enforcing such an order.[40]

E. Enforcement

All legal instruments regulating the handling of a public health crisis provide authorized persons with the power to sanction violations of law and violations of their orders. For example, the failure to inform the government regional doctor of an infected person may result in a one-month term of imprisonment or a fine. Any person under obligation to provide critical information must also carry out the temporary quarantine orders imposed by the regional government doctor.[41]

Certain expenses related to quarantine and decontamination of an infected vessel will be paid by its captain.[42] In addition, penalties are imposed under the Public Health Ordinance on anyone infected with a communicable disease who knowingly exposes himself in a manner that endangers public health or sells or loans clothes and sheets. Persons who transport an infected person without decontaminating the transport vehicle afterward are likewise subject to penalties. Similarly, the parents of a child or a dependent infected with a communicable disease specifically listed in the third appendix of the Ordinance who knowingly or negligently allow the child to visit his school without a medical certificate permitting such a visit are subject to a criminal penalty and a fine. A teacher who knowingly permits such a child to attend school is

[38] *Id.* § 20(2).

[39] *Id.* § 20(4)(a).

[40] *Id.* § 20(4)(b).

[41] *Id.* § 12(2).

[42] *See* Quarantine Regulations, *supra* note 28, § 14.

also subject to penalties. Fines are also imposed on infected persons for engaging in any occupation related to food supply or any other occupation without taking the proper precautions against spreading the disease.[43]

F. Impact on the Protection of Human Rights

The powers exercised by authorities in public health crises appear to conflict with patients' rights guaranteed by the Protection of Patients' Rights Law, 5756-1996,[44] as well as those prescribed by Basic Law: Human Dignity and Freedom.[45] For example, the delivery of information on infected patients contradicts the rights of patients to medical confidentiality. The Protection of Patients' Rights Law, 5756-1996, however, provides that caretakers or medical institutions may provide medical information to others if they are under a legal obligation to do so.[46] The provision of medical information in cases involving communicable diseases is mandatory under the 1940 Public Health Ordinance and, therefore, not in violation of the Protection of Patients' Rights Law.

Removal of persons, forced decontamination, and other measures taken to prevent the spread of disease appear to be in violation of the principle of protecting the life, body, and dignity of a person, guaranteed by Basic Law: Human Dignity and Freedom. Such infringement, however, may be legal under the conditions enumerated in section 8—namely, relevancy and proportionality. The law states that "[t]here shall be no violation of rights under this Basic Law except by a law befitting the values of the State of Israel, enacted for a proper purpose, and to an extent no greater than is required."[47]

It is reasonable to assume that the authority bestowed upon the Health Minister and his designees, specifically those permitting forced entry and quarantine, is one that can be viewed as an authority that is provided "for a proper purpose" in fighting the spread of infectious diseases. Accordingly, orders for forced entry and quarantine that are limited in duration may be considered to meet the requirement that any violation of rights be "to an extent no greater than is required."

V. Actions for Preparedness and Prevention of Pandemics

The MOH issues instructions on preparedness for and the prevention of pandemic diseases as necessary. The following sections provide examples of actions taken by the MOH regarding preparedness for and the prevention of Ebola and pandemic influenza.

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[43] Public Health Ordinance No. 40 of 1940, § 22.

[44] Protection of Patients' Rights Law, 5756-1996, SH 327 (5756-1996).

[45] Basic Law: Human Dignity and Freedom, SH 1391 (9752-1992).

[46] Protection of Patients' Rights Law § 20(a)(2).

[47] Basic Law: Human Dignity and Freedom § 8, SH 5752 No. 1391 p. 150.

A. Preparedness for and Prevention of Ebola

No Ebola cases had been identified in Israel at the time this report was prepared. On August 7, 2014, however, the MOH, issued a recommendation to avoid visiting infected countries to the extent possible. Travelers visiting Guinea, Liberia, and Sierra Leone are required to refrain from having contact with Ebola patients, their excreta, and their personal items. Among other things, they are advised to refrain from visiting health institutions or obtaining medical care in those countries to the extent possible.[48] According to guidelines issued by the Ministry, a patient who develops a temperature of 100.4°F (38°C) within twenty-one days of returning to Israel from any of these three countries must immediately inform hospital authorities prior to their arrival at the hospital in order to receive proper protection instructions.[49]

A memorandum titled *The Ebola Outbreak in West Africa* issued by the MOH on August 7, 2014, provides information on the virus's epidemiologic and microbiologic origin, clinical symptoms, and incubation period and treatment.[50] The Memorandum outlines procedures for the prevention of the spread of Ebola by requiring health care institutions to increase awareness of the potential spread of the virus, identify suspicious cases, and give advance notice to emergency and other health personnel regarding admission and treatment of Ebola patients. Additional requirements on health care institutions introduced by the Memorandum include the duties of issuing emergency alerts for health care personnel,[51] issuing instructions regarding patients' admission, and following the memorandum's guidelines regarding case reporting management and the treatment of patients.[52]

At a minimum, the Memorandum requires the implementation of transmission-based precautions—specifically, regarding contact, droplet, and airborne protections.[53] The following is a summary of relevant procedures and instructions that were issued on the basis of the Memorandum at an exercise conducted in October 2014 at the Tel-Aviv's Ben-Gurion airport.

1. Identification

a. Ebola Patients Arriving at the Airport

According to instructions given at the exercise, a person returning to Israel from the infected countries should be screened. The screening is to include a medical interview and taking the person's temperature. Anyone found to have temperature above 100.4°F is to be immediately

[48] Press Release, MOH, Guidelines and Preparedness of the Health System Following the Outbreak of the Ebola Virus in West Africa (Aug. 7, 2014), http://www.health.gov.il/NewsAndEvents/SpokemanMesseges/Pages/07082014_2.aspx.

[49] *Id.*

[50] Memorandum No. 13/14 by Head of Public Health Services, *supra* note 1.

[51] *Id.* § 1.

[52] *Id.* at 4–9.

[53] *Id.* § 1.

transferred to isolation in a hospital. During the transfer to a protected ambulance, the patient is to be placed on a protected stretcher.[54]

b. Patients' Arrival at Health Facility Following Advance Notice

According to the Memorandum issued by the MOH, every hospital must assign a physician on every shift to answer telephone calls concerning suspicion of Ebola infection. Any patient who has visited a country where the Ebola virus has spread and reports a high fever upon return is to be instructed to appear for an examination at the Emergency Room. The patient must be instructed to minimize risk to others while on route by adopting such measures as covering his/her face, refraining from using public transportation, meeting a health team member who is wearing protective gear, and arriving directly at a secluded area in the admissions department designated ahead of time for this purpose.[55]

c. Patients' Arrival at Health Facility with No Advance Notice

The Memorandum requires the posting of signs at admissions areas instructing patients who have stayed in an Ebola-infected country twenty-one days prior to admission and developed a high fever to immediately report these facts to the receptionist. The receptionist must instruct these patients and people accompanying them to wear protective masks and wait in an isolated area.[56]

The admissions office must immediately report any such cases to the medical team assigned to conduct a brief interview of the patient to determine if it is required that he/she be isolated. While conducting the interview the team will wear an N-95 protective mask, face/eyes protector, a robe, and gloves.[57]

When a patient, who is already being treated either at the ER or at another hospital unit is diagnosed with Ebola, he/she must immediately be transferred to a suitable isolation room. The patient and the treatment team providing care to the patient must wear a surgical mask, and the team must wear protective gear.[58]

2. Treatment Management of Suspicious Cases

The Memorandum requires that the physician and the nurse responsible for managing a suspected case of Ebola will appoint a treatment team that will treat the patient exclusively. Team members must wear full protective gear.[59] Upon admission the patient must be transferred to an isolation room that will be under full supervision to ensure that entry and exit from the

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[54] Itai Gal, *First Publication: This Is How Ebola Patients Will Be Treated in Israel*, YNET (Oct. 20, 2014), http://www.ynet.co.il/articles/0,7340,L-4581372,00.html.

[55] Memorandum No. 13/14 by Head of Public Health Services, *supra* note 1, § 2.1.

[56] *Id.* § 2.2.1.1.

[57] *Id.* § 2.2.1.2.

[58] *Id.* § 2.2.2.

[59] A detailed description of the gear requirements is provided. *Id.* § 3.3.1.

room is in accordance with guidelines. The Memorandum requires the filling out of a special form documenting all persons who were in either direct or indirect contact with the patient prior to the patient's entry into the room.[60]

The Memorandum limits the number of visitors that can be in touch with the patient and requires that they use the same protective gear required of the treatment team.[61] It further provides that after complying with all required measures for preventing contamination, the patient must be diagnosed and treated for any additional dangerous diseases he/she might have, particularly those "common among travelers returning from Africa"—diseases whose symptoms may be similar to those of Ebola, including malaria, typhoid, and hepatitis A.[62]

The Memorandum requires preventing the contamination of materials and equipment as appropriate, by full isolation or by sterilization and fumigation.[63] It also provides specific guidelines for handling and transferring blood and other bodily fluids, for conducting activities that may create aerosols, for procedures involving the use of contained centrifuges, and for the transfer of samples for diagnosing contamination from a patient suspected of having Ebola.[64]

3. Notice Requirement

The Memorandum imposes on the MOH regional physician the duty of immediately reporting by phone every suspicious case of Ebola. The regional physician must immediately transmit the information to the heads of the Ministry's departments of epidemiology and public health services. The Memorandum requires that all announcements be made exclusively via the Ministry's Press Release office.[65]

4. Determination of Treatment Location

Patients must be treated only at hospitals that provide suitable isolation conditions and whose personnel possess the required training and abilities. The MOH management may decide to transfer a patient to another hospital as needed. Such a transfer will be conducted in accordance with the protocol on "Encountering an Unusual Biological Event—the First Hours."[66]

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[60] *Id.* § 3.3.2.

[61] *Id.* § 3.3.3.

[62] *Id.* § 3.3.6.

[63] *Id.* § 3.10.

[64] *Id.* § 5.

[65] *Id.* § 6.

[66] *Id.* § 7; MOH EMERGENCY UNIT, ENCOUNTERING AN UNUSUAL BIOLOGICAL EVENT – THE FIRST HOURS (Aug. 2008), http://www.health.gov.il/Subjects/emergency/preparation/DocLib/tora/BIO_TORA_BIO_EVENT_HOURS.pdf (in Hebrew).

5. Epidemiological Investigation and Follow-Up of Patients and Their Contacts

An epidemiological questionnaire must be filled out for every case where Ebola is suspected. The questionnaire, a copy of which is appended to the Memorandum, includes information identifying the patient and his/her residence address, insurance, treating physician and hospital, clinical symptoms, laboratory results, history of travel, and meetings with any person who returned from a foreign country in the twenty-one days before the onset of symptoms (including meetings to medically treat such a person).[67]

B. Preparedness for and Prevention of Pandemic Influenza

As indicated above, in 2007 Israel's MOH issued its *Pandemic Influenza Preparedness Plan for the Health System*.[68] The Plan provides a list of measures to be employed by HIEs and local and district medical facilities. The Plan also provides special instructions for the Magen David Adom, Israel's national emergency medical, disaster, ambulance and blood bank service.[69]

The Plan lists the following actions to be taken in the community to prevent the spread of disease:

1. Public Health Guidelines

Guidelines regarding the cleanliness of surfaces, personal and respiratory hygiene, and other relevant information related to disease transmission and prevention must be easily accessible to the public via the MOH's website and influenza pandemic site, and through leaflets titled *Hygiene Rules*.[70]

2. Restrictions on Social Gathering

Restrictions on social gathering may be imposed, depending on the scope and duration of the contamination and the conditions of the area where it occurs (open or closed). Schools, day-care centers, and nursery schools may be closed; restrictions may be imposed on the use of public transportation; employees may be encouraged to work from home by phone, fax, computer, etc.; cultural and sports events may be cancelled; and patients may be voluntarily secluded.[71]

3. Limitations on Freedom of Movement

Recommendations to avoid unnecessary travel and restrictions on local and international travel may be issued. In the event of pandemic influenza occurrences involving transmission from human to human, the recommendations of the WHO and the Centers for Disease Control and

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[67] Memorandum No. 13/14 by Head of Public Health Services, *supra* note 1, § 10.

[68] Pandemic Influenza Preparedness Plan for the Health System, *supra* note 2.

[69] *Id.* ch. C(6).

[70] *Id.* ch. C(7)(a)(1).

[71] *Id.* ch. C(7)(a)(2).

Prevention in the United States should be followed. The Plan also provides for preparing control measures for closed or semiclosed facilities, including elderly homes, military facilities, and prisons. To reduce the spread of disease in medical facilities through contact between medical teams, the Plan, among other measures, authorizes the organization of labor teams that work in shifts without meeting each other. The Plan requires the adoption of personal hygiene measures, such as the use of face masks by patients, medical teams, and the public at large.[72]

VI. Transparency of Public Health Crisis Management System

The Department of Epidemiology of the MOH prepares a weekly report based on data received on communicable diseases in the country. The reports have been available to the public in paper or digital form since the year 2000.[73] Israel cooperates with the WHO and provides the organization with data on contagious diseases. Israel protects freedom of the press, and the public may obtain information through any means of communication.

VII. Response to Threats of Chemical and Biological Attacks

Preparing for chemical, biological or radiological attacks is the responsibility of both the Ministry of Defense Home Front Command and the MOH. These Ministries have prepared working procedures; stockpiled vaccines, antibiotics, and other medications; and trained health providers for crisis events. Specific information on such attacks and instructions on how to protect against chemical, biological, and radiological attacks are provided on the website of the Home Front Command.[74]

Information on the state's preparedness for chemical, biological, and radiological attacks is not easily accessible. A 2002 report prepared by the Knesset Information and Research Center in anticipation of the 2003 Iraq War states that the reluctance of the Israeli defense system and its MOH to disclose information on the state's preparedness stems from the concern that this will expose the extent of the state's vulnerability to such attacks.[75] The following is a summary of relevant portions of the report.

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[72] *Id.* ch. C(7)(a)(3)–(6).

[73] *Infectious Disease Unit,* MOH, http://www.health.gov.il/UnitsOffice/ICDC/Units/Infectious_Diseases/Pages/default.aspx (in Hebrew; last visited Oct. 23, 2014); for weekly influenza status reports, see *Weekly Influenza Reports*, MOH, http://www.health.gov.il/UnitsOffice/ICDC/Infectious_diseases/Flu/Pages/FWR.aspx (in Hebrew; last visited Oct. 23, 2014).

[74] *Chemical Weapons*, HOME FRONT COMMAND, http://www.oref.org.il/10648-en/Pakar.aspx (last visited Oct. 23, 2014); *Biological Weapons*, HOME FRONT COMMAND, http://www.oref.org.il/10649-en/Pakar.aspx (last visited Oct. 23, 2014); *Radiological Terror*, HOME FRONT COMMAND, http://www.oref.org.il/10654-en/Pakar.aspx (last visited Oct. 23, 2014).

[75] Y. SHAI, IMMUNIZATIONS AGAINST CHICKEN POX AND ANTHRAX 2, KNESSET INFORMATION AND RESEARCH CENTER (Oct. 20, 2002), http://www.knesset.gov.il/mmm/data/pdf/m00465.pdf (in Hebrew).

A. General Preparedness

The general health system has been reportedly prepared, potential threats identified, and operating procedures formalized for hospitals, health clinics, and localities, including procedures for cooperation among the different bodies. An intensive instruction of thousands of doctors and nurses began at the time the report was issued.[76]

B. Anthrax Preparedness

A health system plan for the treatment of anthrax victims has been prepared. While most of the treatment would be provided by the HIEs, the health system plan includes immunizations and preventive antibiotic treatments for affected persons. The report stated that the authorities had a sufficient supply of antibiotic medications for the treatment of anthrax. The report further recommended not vaccinating the entire population against anthrax because of possible serious side effects.[77]

C. Smallpox Preparedness

It was decided at the time not to vaccinate the entire public against smallpox. Instead, fifteen thousand medical and security personnel were to be vaccinated, some of whom would be among the first teams to come in contact with future patients. Approximately six thousand five hundred persons had been vaccinated by October 2002. These teams would also serve as first reactors from whom antibodies would be extracted to enable countering complications and side effects of the disease.[78]

The report concluded that there was enough vaccine for the country's population. The vaccines and antibiotics are not available at the HIEs, but are kept by the Homeland Command and the MOH. There were several plans for vaccinating the population that were expected to be implemented on the basis of government decisions or the consequences of an event.[79]

At the time of the report, the MOH had requested the Ministry of Education to prepare three hundred schools around the country to serve as smallpox vaccination centers if the need arose.[80]

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[76] *Id*. § 4(B).

[77] *Id.* § 4(C).

[78] *Id.* § 4(D)(1).

[79] *Id.* § 4(D)(2).

[80] *Id.* § 4(D)(3).

Italy

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SUMMARY Italy's Constitution recognizes the protection of health as a fundamental individual right and public interest, and also enshrines the principle of respect for the human personality. Within this constitutional framework, the Consolidated Health Laws and various other legal and regulatory provisions assign responsibility for confronting health crises to national and regional authorities, authorize measures to address infectious and communicable diseases, establish a reporting system, and grant authority for the issuance of special orders when the nation is threatened with an epidemic. The Minister of Health and the National Health Service play leading roles in this field. Freedom of information, including access to public health information, is constitutionally guaranteed. Italy actively cooperates with the World Health Organization, European institutions, and other international organizations.

Given Italy's geographic proximity to Africa, recent parliamentary debates about the Ebola epidemic in Africa have centered on the country's immigration policies. The Health Ministry has now updated its protocols and guidelines concerning preventative and response measures vis-à-vis Ebola. These guidelines set forth measures addressing the treatment of suspected, probable, and confirmed cases of Ebola; sanitation and decontamination; the disposal of waste; and the handling of corpses. Most regions follow the Ebola protocols established at the national level.

I. Government Structure

Italy is a democratic republic whose president is the Head of State. The executive power resides in the Council of Ministers, which is headed by the Prime Minister (officially referred to as the President of the Council of Ministers). Legislative power is exercised jointly by the Chamber of Deputies and by the Senate. The judicial branch is an autonomous order independent from any other power. The territory of the Republic is divided into twenty regions and further into provinces and municipalities.

II. Structure of Public Health Crisis Management System

Health protection and the handling of public health crises in Italy are regulated by statutory and regulatory provisions based on the constitutional principle of the protection of health as a fundamental individual right and a public interest. The Constitution further states that health

[*] This report updates a report originally prepared by former Senior Legal Specialist Giovanni Salvo in 2003, which was previously updated in 2009 by Senior Legal Research Analyst Constance A. Johnson.

treatments may be imposed by law only if they do not violate the principle of respect for the human personality.[1]
Italy's National Health Service, under the Ministry of Health, aims at ensuring the sanitary and epidemiological well-being of the whole population. It assures the coordination of all activities and interventions of agencies, institutions, and services that perform any duty concerning individual and collective health. The central and local governments are jointly responsible for the implementation of the National Health Service. The law provides health authorities with the necessary powers to perform mandatory health controls and treatments.[2]

The Consolidated Health Laws contains specific provisions concerning infectious diseases. It establishes that the Minister of Health may, on the advice of the Superior Council of Health, issue a list of infectious and communicable diseases subject to special procedures and measures.[3] The Act imposes a system of reporting such diseases through the various levels of responsible authorities up to the Minister of Health. It provides for preventative measures, necessary assistance, and disinfection interventions for such diseases. It further grants the Minister of Health, when the nation is threatened with an infectious disease epidemic, the authority to issue special orders for the inspection and disinfection of premises, the organization of special services and medical assistance, and the adoption of protective measures against the spread of such diseases. The ordinances of the Minister are published in the Official Gazette. Under the provisions concerning veterinary regulations, the Act requires coordination between the Municipal Veterinary Office and the Municipal Health Office for the reporting of animal diseases that can be transmitted to humans.[4]

Preventing, monitoring, and responding to public health emergencies including epidemics, even when caused by terrorists, is the responsibility of government officials and civil servants at the central, regional, and municipal levels. The Minister of Health assesses and makes decisions concerning situations of national crisis, and issues the ordinance that triggers the response to a specific emergency.[5] The Civil Protection Department, under the supervision of the Prime Minister or the duly delegated Interior Minister, deals with emergencies that are the result of natural disasters or the consequence of human activities, as well as other events that, because of

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[1] CONSTITUTION OF THE ITALIAN REPUBLIC art. 32, https://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf (English version published by the Parliamentary Information, Archives and Publications Office of the Senate Service for Official Reports and Communication of the Senato della Repubblica, Apr. 2009).

[2] Legge 23 dicembre 1978, n. 833, Istituzione del servizio sanitario nazionale [Law No. 833 of December 23, 1978, National Health Service Institution], GAZZETTA UFFICIALE DELLA REPUBBLICA ITALIANA [G.U.] No. 360, Dec. 28, 1979, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:1978-12-23;833.

[3] *Id*. arts. 9 & 62.

[4] Royal Decree No. 1265 of July 27, 1934, *as amended*, approving the Consolidated Health Law, *in* CODICE DELLA SANITA' (Torino, UTET 1999).

[5] Law No. 833. *See also* Ordinanza 10 Apr. 2003 of the Minister of Health, G.U. No. 89 of Apr. 16, 2003; Decreto-Legge 9 maggio 2003 No. 103, Disposizioni urgenti relative alla sindrome respiratoria acuta severa (SARS) [Decree-Law No. 103 of May 9, 2003, Urgent Provisions Related to the Severe Acute Respiratory Syndrome (SARS)], G.U. No. 108, May 12, 2003, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto. legge:2003;103 (concerning urgent provisions for the SARS syndrome).

their intensity and scope, require the coordinated intervention of public authorities at the central and local government levels.[6]

Under legislation enacted in 1998,[7] urgent interventions in cases of health emergencies can be made by regional and local authorities. The intervention of the central government authorities takes precedence according to the relevance and the magnitude of the emergency.[8] The Prime Minister may appoint a special commissioner when a state of emergency has been declared.[9]

III. Powers of Public Health Authorities

Article 32 of the Italian Constitution states that no one may be forced to receive medical treatment unless provided for by law, and that the law may not violate limits imposed by respect for the human personality. The powers granted to public health authorities to adopt a range of protective measures against the spread of disease in a health crisis, such as mandatory medical treatments, are limited by the constitutional guarantee of respect for the human personality and,

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[6] In addition to the existing body of laws on Civil Protection (Codice della Protezione Civile, Piacenza, La Tribuna, 2002), see Decree of the President of the Republic, Mar. 27, 1992, Course of Action and Coordination for the Regions for the Purpose of Determining Levels of Health Assistance During Emergencies, G.U. No. 76 of Mar. 31,1992; Agreement Between the State and the Regions Approving Guidelines on the Health Emergency System Pursuant to the Decree; Decree of Feb. 13, 2001, on Adoption of General Criteria for the Organization of Health Relief in Disasters; Law No. 401 of Nov. 9, 2001, G.U. No. 262 of Nov. 11, 2001; Legge 9 novembre 2001, n. 401, Conversione in legge, con modificazioni, del decreto-legge 7 settembre 2001, n. 343, recante disposizioni urgenti per assicurare il coordinamento operativo delle strutture preposte alle attivita' di protezione civile [Law No. 401 of Nov. 9, 2001, Conversion into Law, with Amendments, of Decree-Law No. 343, Sept. 7, 343, Concerning Provisions for the Operational Coordination of the Structures of Civil Protection and Improving Logistics of Civil Defense], G.U. No. 262 of Nov. 11, 2001, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2001;401; Decree of Mar. 2, 2002, G.U. No. 66 of Mar. 19, 2002, Establishing the Operational Committee for Civil Protection.

[7] Decreto Legislativo 31 marzo 1998, n. 112, Conferimento di funzioni e compiti amministrativi dello Stato alle regioni ed agli enti locali, in attuazione del capo I della legge 15 marzo 1997, n. 59 [Legislative Decree No. 112 of March 31, 1998, Granting Administrative Powers and Competences of the State to the Regions and Local Entities, in Accordance with Chapter I of Law No. 59, of March 15, 1997], G.U. No. 92, Apr. 21, 1998, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legge:1998-03-31;112vig. *See also* Decreto Legislativo 18 agosto 2000, n. 267, Testo unico delle leggi sull'ordinamento degli enti locali [Legislative Decree No. 267 of August 18, 2000, Approving the Consolidation Act of Provisions Governing Local Administrative Bodies], G.U. No. 227, Sept. 28, 2000, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2000-08-18;267.

[8] Consolidated Health Laws art. 49.

[9] Decreto del Presidente del Consiglio dei Ministri 28 marzo 2003, Dichiarazione dello stato di emergenza in relazione alla tutela della pubblica incolumita' nell'attuale situazione internazionale [Decree of the President of the Council of Ministers of March 28, 2003, Declaration of State of Emergency with Relation to the Protection of Public Safety in the Current International Situation], G.U. No. 74, Mar. 29, 2003, http://www.protezionecivile.gov.it/cms/attach/decreto_28marzo2003.pdf; Ordinanza del Presidente del Consiglio dei Ministri 30 aprile 2003 n. 3285, Concerning Further Measures of Civil Protection for the International Health Emergency, G.U. No. 106, May 9, 2003, http://www.protezionecivile.gov.it/cms/attach/ordinanza3285del30.pdf. *See also* Ordinanza 28 marzo 2003 n. 3275, Disposizioni urgenti di protezione civile per fronteggiare l'emergenza derivante dalla attuale situazione internazionale [Ordinance No. 3275, of March 28, 2003, Urgent Provisions of Civil Protection to Face the Emergency Deriving from the Current International Situation], G.U. No. 74, Mar. 29, 2003, http://www.ambientediritto.it/Onlus/2003/opcm%202003%20n.3275.htm; Ordinanza del Presidente del Consiglio dei Ministri 18 aprile 2003 n. 3282, Disposizioni urgenti di protezione civile [Ordinance No. 3282 of the President of the Council of Ministers of April 18, 2003, Urgent Provisions for Civil Protection], G.U. No. 99, Apr. 30, 2003, http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2003-04-30&atto.codiceRedazionale=03A05416&elenco30giorni=false.

to some extent, in the application of the law protecting privacy.[10] One author has observed that the Italian Constitution appears to favor the collective public health interest as opposed to the individual's interest when it comes to protection from epidemics and infectious diseases.[11]

Health authorities may impose stricter controls on travelers coming from areas at risk, require air or other carriers to provide detailed information regarding their passengers' itineraries, impose health checks, and require hospitalization for infected persons. International preventive measures and public hygiene measures concerning imported goods, travelers, and migrants are carried out by the health authorities set up by the Ministry of Health at the territorial borders, ports, and airports.[12]

Italy's public health laws provide for the imposition of administrative and penal sanctions, including terms of imprisonment, for noncompliance. Punishable conduct includes failure to provide assistance in emergency health situations, especially for health professionals; violations of reporting procedures; and failure to abide by a lawful order of the authority in a health crisis.[13] In addition, the Italian Penal Code makes causing an epidemic by spreading noxious germs a crime punishable by life imprisonment.[14]

IV. Transparency of Public Health Crisis Management System

The right of the public to access official information is a fundamental right provided in article 21 of the Italian Constitution.

Decisions by the Italian Constitutional Court under article 21 have emphasized not only the freedom to provide and divulge news, opinions, and comments, but also the right to obtain information. This interest implies a plurality of sources of information, free access to them, and the absence of unjustified legal obstacles, even temporary ones, to the circulation of news and ideas.[15]

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[10] Legge 31 dicembre 1996, n. 675, Tutela delle persone e di altri soggetti rispetto al trattamento dei dati personali [Law No. 675 of December 31, 1996, Protection of the Person and other Subjects Concerning the Treatment of Personal Data], G.U. No. 5, Jan. 8, 1997, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:1996;675; Decreto Legislativo 11 maggio 1999, n. 135, Disposizioni integrative della legge 31 dicembre 1996, n. 675, sul trattamento di dati sensibili da parte dei soggetti pubblici [Legislative Decree No. 135 of May 11, 1999, Supplementary Provisions of Law No. 675, of December 31, 1996, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:1999;135.

[11] *See generally* La Privacy nella sanità [Privacy in Health], DIRITTO E RISPOSTE, http://www.dirittierisposte.it/Schede/Tutela-della-privacy/Diritti/la_privacy_nella_sanita_id1129480_art.aspx (last visited Nov. 6, 2014).

[12] Regio Decreto 30 marzo 1942, n. 327 Approvazione del testo definitivo del Codice della Navigazione [Royal Decree No. 327 of March 30, 1942, Approving the Final Text of the Navigation Code], G.U. No. 93, Apr. 18, 1942, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:regio.decreto:1942-03-30;327.

[13] CODICE PENALE [C.P.] [PENAL CODE] art. 415, *available at* http://www.altalex.com/index.php?idnot=36766.

[14] *Id.* art. 438.

[15] Italian Constitutional Court, Decision No. 105 of 1972, Consulta Online, http://www.giurcost.org/decisioni/1972/0105s-72.html. In Decision No. 112 of 1993, http://www.giurcost.org/decisioni/1993/0112s-93.html, the Court, referring to its established interpretation of article 21, recognized the existence of a full, individual right to be informed.

The Consolidated Health Laws reserves to the central government the administrative duties and responsibilities concerning the functioning of the national Health Information System. The central government is also required to coordinate (1) the regional information systems in cooperation with public and private entities, (2) statistical analysis of the data disseminated, (3) information to be provided to Parliament, and (4) any other reporting of national relevance.[16] Especially during a public health crisis, the Minister of Health issues directives and disseminates information through any appropriate means, including its website.[17] Health information is further disseminated by newspapers and public and private radio and television stations.

V. Cooperation with the WHO

The Italian government works closely with the WHO in meeting public health crises. The Ministry of Health, through its website, keeps the public informed of international developments and of WHO standards and guidelines.[18]

Italy enacted legislation implementing the International Health Regulations of 1969 as amended in 1973.[19] Italy is also a party to the International Health Regulations of 2005.[20]

VI. Response to Ebola Virus Epidemic in West Africa

A. National Measures

In response to the Ebola epidemic in West Africa, the Italian Ministry of Health issued a Circular on April 4, 2014, recommending the "adoption of all useful surveillance actions related to indirect arrivals" from Guinea and other bordering countries where symptoms of Ebola have been found.[21] While the Circular seeks to minimize the danger of Ebola spreading in Italy, key government ministries and agencies have nonetheless been alerted, including the Italian Red Cross.[22]

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[16] Consolidated Health Laws art. 118.

[17] MINISTERO DELLA SALUTE, http://www.sanita.it (last visited Nov. 5, 2014).

[18] *Id*.

[19] Legge 9 febbraio 1982, n. 106 Approvazione ed esecuzione del regolamento sanitario internazionale, adottato a Boston il 25 luglio 1969, modificato dal regolamento addizionale, adottato a Ginevra il 23 maggio 1973 [Law No. 106 of February 9, 1982, G.U. 87 of Mar. 30, 1982, Approval and Implementation of the International Sanitary Regulations Adopted at Boston on July 25, 1969, Amended by the Additional Regulations Adopted in Geneva on May 23, 1973], G.U. No. 87, Mar. 3, 1982, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:1982-02-09;106@originale.

[20] *States Parties to the International Health Regulations (2005)*, WORLD HEALTH ORGANIZATION, http://www.who.int/ihr/legal_issues/states_parties/en/.

[21] Circolare Ministeriale N° 0026708, Procedure operative per la gestione di casi sospetti, probabili o confermati e contatti di malattia da virus Ebola (MVE) in Africa Occidentale [Operational Procedures for the Management of Suspected, Probable, or Confirmed Cases and Contacts of the Ebola Virus Disease in Western Africa] (Circular) (Oct. 14, 2014), http://www.inmi.it/file/ebola/procedura_ebola_unita_crisi_rev2_16_10_2014.pdf.

[22] *Id*.

On May 14, 2014, the Italian Chamber of Deputies held a parliamentary debate to review the preparedness of Italy's health system to prevent and fight Ebola.[23] The debate highlighted the fact that during the months prior to May 2014, Italy witnessed a growing influx across its southern border of thousands of illegal African immigrants, many of whom came from the Ebola-affected areas of West Africa. During the debates, many participants argued this situation required action from the National Government, in particular from the Health Ministry, to address illegal immigration, as well as to provide the public with transparent and prompt information, especially to protect school children. Some participants in this session proposed that the government impose a sanitary cordon throughout the country to protect the population, but the government has not adopted this proposal.

The Health Ministry responded to the parliamentary inquiry by requiring immigrants arriving at coastal areas of Italy to undergo thorough clinical evaluations to exclude the presence of signs or symptoms of Ebola before they reach immigration centers.[24] Isolation measures are implemented when necessary.[25] Immigration centers are also staffed with sanitary personnel whose function is to ensure the adequate flow of information to and from the Health Ministry, and to adopt immediate measures when specific dangers to public health are involved.[26]

While parliamentary debate has generated new regulations, no specific legislative bills containing extraordinary measures to address the Ebola epidemic have yet been introduced in Italy.

On October 14, 2014, the National Institute for Infectious Diseases (Istituto nazionale per le malattie infettive, Lazzaro Spallanzani), updated its Operational Procedures for the Management of Suspected, Probable, or Confirmed Cases and Contacts of the Ebola Virus Disease in Western Africa (the Procedure).[27] The Procedure contains three parts: the first describes the Ebola virus disease; the second regulates the treatment of Ebola patients; and the third deals with other stages in the treatment of the disease, including disinfection and sanitation, waste treatment, disposal corps, and surveillance of health personnel.

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[23] Camera dei deputati, Session No. 228 (May 14, 2014), Misure sanitarie per tutelare i cittadini in relazione al flusso di immigrati provenienti dal Mediterraneo, con particolare riferimento alla diffusione di un'epidemia del virus ebola in varie aree dell'Africa [Sanitary Measures to Protect Citizens with Relation to the Influx of Immigrants Coming from the Mediterranean, with Particular Reference to the Dissemination of the Ebola Virus in Several Areas of Africa], http://banchedati.camera.it/sindacatoispettivo_17/showXhtml.asp?highLight=0&idAtto=18464&stile=7; XVII Legislatura, Resoconto stenografico dell'Assemblea Seduta n. 228 di mercoledì 14 maggio 2014 [XVII Legislature, Transcript of Assembly Session No. 228, of May 14, 2014], http://www.camera.it/leg17/410?idSeduta=0228&tipo=stenografico#.

[24] Id. See also FAQ – Malattia da virus Ebola (EVD), Question 16, Qual è la situazione in Italia e quali misure sono state prese? [FAQ – What Is the Situation in Italy, and What Measures Have Been Taken?], MINISTERO DELLA SALUTE [HEALTH MINISTRY], http://www.salute.gov.it/portale/p5_1_1.jsp?lingua=italiano&id=184 (last visited Nov. 7, 2014).

[25] *FAQ*, *supra* note 24.

[26] *Id*.

[27] Circular, *supra* note 21.

In the case of suspected patients, health personnel must observe a series of guidelines concerning the sanitation of the areas exposed to the patient, his or her transfer to an isolated room or facility, and his or her immediate treatment by a qualified physician.[28] Suspected patients may be repatriated from overseas or transferred to another specialized facility at the national or regional levels.[29]

The treating physician must issue a diagnostis of the patient as "nonsuspected," or suspected of low or high risk.[30] If the patient is characterized as of low or high risk, he needs to be treated in a facility devoted to the treatment of infectious diseases.[31] The sanitation procedures for the facilities used for the patient must be strictly followed in order to avoid contaminating other patients.[32]

The test for Ebola virus must be carried out only on suspected patients.[33] If the test is negative, and the symptoms remain for at least forty-eight hours, caution must be observed in the handling of the patient until the test is repeated.[34] If the test results are negative a second time, then the patient is moved to a recovery unit.[35]

The Procedure states that there are no international guidelines, criteria, or procedures for the release of patients.[36] However, based on the Institute's experience and observations of comparable scenarios, the Procedure establishes two concurrent criteria that must be met for the release of patients: (i) when the patient is in a good and stable clinical condition; and (ii) when at least two Ebola virus tests have been applied to the patient in a space of at least twenty-four hours, with negative results.[37] Diagnostic activities performed at laboratories must meet specified minimum requirements.[38] Samples taken from the patient are subject to the "rule of triple packaging,"[39] and transportation of samples is subject to stringent rules.[40]

Finally, the Procedure lists stringent measures in case of the death of the patient,[41] and the sanitation and decontamination of health personnel.[42]

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[28] *Id.*

[29] *Id.* at 9.

[30] *Id.*

[31] *Id.*

[32] *Id.* at 12.

[33] *Id.* at 14.

[34] *Id.*

[35] *Id.*

[36] *Id.* at 15.

[37] *Id.*

[38] *Id.* at 17.

[39] *Id.*

[40] *Id.* at 18.

[41] *Id.* at 25.

The Italian Health Ministry is permanently updating its information concerning the Ebola epidemic.[43]

B. Regional Measures

Ebola virus protocols at the regional level follow the guidelines issued by the National Health Ministry. For example, the Lazio Region (where Rome, Italy's capital, is located) has issued a Regional Protocol for the Ebola Virus Epidemics in Western Africa: Indications for Surveillance and Control.[44] This Protocol states that it was written "based on the indications received from the national Health Ministry issued pursuant to a central protocol for the management of suspected/probably/confirmed cases of [Ebola], including their contacts."[45]

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[42] *Id*.

[43] *Eventi epidemici all'estero* [*Epidemic Events Overseas*], MINISTERO DELLA SALUTE, http://www.salute.gov.it/portale/news/p3_2_1_3_4.jsp?lingua=italiano&menu=notizie&p=avvisi&%20tipo=eventiEpidemici (last visited Nov. 7, 2014).

[44] LAZIO REGION, EPIDEMIA DA VIRUS EBOLA IN AFRICA OCCIDENTALE: INDICAZIONI PER LA SORVEGLIANZA E IL CONTROLLO. PROTOCOLLO REGIONALE, http://www.regione.lazio.it/binary/rl_main/tbl_news/Protocollo_Ebola.pdf.

[45] *Id.* at 3.

Japan

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SUMMARY In addition to Japan's general crisis management system, the Japanese government has implemented a health crisis management system. The Ministry of Health, Labour and Welfare, the primary agency in charge of responding to infectious disease outbreaks and other health crises, has issued guidelines for health crisis management. Japan's Infectious Diseases Prevention Act of 1998 provides the legislative framework for the country's response to a potential health crisis caused by infectious disease. The Act classifies infectious diseases covered by the Act into several categories, depending on infectiousness and the severity of symptoms. Under the Act, the Ministry of Health, local governments, and the institutions under them monitor and report on the outbreak of infectious diseases and coordinate their roles to prevent more infections. Medical doctors report incidences of infectious disease to governors through local health centers. Those health centers have broad jurisdiction over health-related issues and play an important role in health crisis management.

Japan has designated hospitals with special facilities to deal with patients who are infected with serious and highly infectious diseases. A governor may order the hospitalization of patients in certain cases. A quarantine system is activated when the outbreak of an infectious disease overseas becomes a threat to the Japanese people. When the system is activated quarantine officers may ask questions of incoming passengers and take their temperatures. When the head of a quarantine station finds or suspects that a person is infected with one of several specified diseases, he or she may isolate the person in an appropriate place.

The Special Measures Act on New Influenza was also enacted in 2012, creating an emergency system specifically for influenza.

I. Government Structure

In Japan executive power is vested in the Cabinet, which consists of the Prime Minister and other ministers. The Prime Minister is designated from among the members of the Diet (Parliament) by a resolution of the Diet. He then appoints the other ministers. Localities are divided into prefectures and municipalities.

II. Structure of Public Health Crisis Management System

A. National Health Crisis Management

The Cabinet has a Deputy Chief Cabinet Secretary for Crisis Management who manages emergency measures when a situation causing significant damage to Japanese people's lives or

assets occurs or is likely to occur.[1] As stated below, the Deputy Chief Cabinet Secretary for Crisis Management chairs the conference of relevant ministries and agencies on Ebola, which is preparing to take coordinated measures among government agencies in case Japanese nationals are infected with Ebola abroad or persons infected with Ebola are found within Japan.

The Ministry of Health, Labour, and Welfare (MHLW) is the primary agency in charge of responding to infectious disease outbreaks and other health crises in Japan.[2] In 1997, the MHLW published the Basic Guidelines in Health Crisis Management[3] and four management implementation guidelines for health crises caused by medicine, infectious diseases, drinking water contamination, and food poisoning.[4] The MHLW has established an electronic health crisis management information system and has also issued guidelines for municipal governments, instructing them to make preparations and develop plans for emergency situations.[5]

The Health Risk Management Office of MHLW is continually gathering domestic and overseas information from related departments and from national research and development institutes. Departments within MHLW exchange information at the Health Risk Management Coordination Meeting held two times per month.[6] A Coordination Meeting can also be convened in an emergency and members may act to establish emergency management headquarters, dispatch staff and experts to the affected areas, and provide citizens with information on health risks.[7]

B. Local Public Health Crisis System

Prefectures are in charge of conducting various on-the-spot measures during a health crisis. In Japan, local government health centers play an important role in local health care management.[8] Prefectures and designated cities have established at least one health center in each of their jurisdictions,[9] resulting in the creation of approximately five hundred health centers throughout

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[1] Naikaku hō [Cabinet Act], Act No. 5 of 2010, *amended by* Act No. 108 of 2013, art. 15.

[2] Ministry of Health, Labor, and Welfare Establishment Act, Act No. 97 of 1999, art. 4, para. 1, items 4 and 19.

[3] MHLW, Kosei rōdō shō kenkō kikikanri kihon shishin [Basic Guidelines in Health Crisis Management], http://www.mhlw.go.jp/general/seido/kousei/kenkou/sisin/index.html (last visited Oct. 8, 2014).

[4] The four health crisis management implementation outlines are available on the MHLW website, http://www.mhlw.go.jp/general/seido/kousei/kenkou/index.html (last visited Oct. 8, 2014).

[5] *Chiiki ni okeru kenko kikikanri ni tsuite* [*Regarding Local Health Crisis Management*], MHLW (Mar. 2001), http://www.mhlw.go.jp/general/seido/kousei/kenkou/guideline/index.html.

[6] MHLW, ANNUAL HEALTH, LABOUR AND WELFARE REPORT 2009–2010, pt. 2, ch. 1, § 9, http://www.mhlw.go.jp/english/wp/wp-hw4/dl/honbun/2_1_9.pdf.

[7] *Regarding Health Emergency Management Measures of the MHLW*, MHLW, http://www.mhlw.go.jp/seisaku/2010/03/01.html (in Japanese; last visited Oct. 10, 2014).

[8] Chiiki kenko kiki kanri gaidorain [Local Health Crisis Management Guidelines], MHLW Circular, Kenso No. 17 (Mar. 30, 2001), I, 1, http://www.mhlw.go.jp/general/seido/kousei/kenkou/guideline/index.html.

[9] Chiiki hoken hō [Local Health Act], Act No. 101 of 1947, *last amended by* Law No. 83 of 2014, art. 5.

the country as of April 2014.[10] The health centers have broad jurisdiction over health-related issues, including administration of food sanitation, administration of medical and pharmaceutical matters, and prevention of infectious diseases.[11]

During a health crisis, the health centers become the center of local health crisis management.[12] The Basic Guidelines Regarding Promotion of Measures to Improve Local Health Issues, issued by the MHLW, recommend that local governments create manuals containing concrete measures for managing a health crisis.[13] The director of the local health department and the heads of health centers manage health crises at the local level. Health centers are to respond to emergency information twenty-four hours a day, seven days a week. Health centers are expected to coordinate services provided by medical service providers.[14]

C. Pandemic Influenza Special Measures

Japan established a system to deal with new influenza when avian flu (H5N1) threatened its citizens. In 2004, the government established the Conference of Relevant Ministries and Agencies to Counter New Influenza and Avian Influenza.[15] The Action Plan to Counter Influenza was approved by the Conference in November 2005,[16] and revised in February 2009.[17] When a new influenza outbreak occurs, the Prime Minister and all Ministers form the Headquarters Against New Influenza, which in turn forms the New Influenza Countermeasures Expert Advisory Committee.[18]

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[10] Jichitai betsu hokenjo secchi sū no suii [Changes of Numbers of Health Centers by Local Governments], as of April 1, 2014, Zenkoku hoken sho chō kai [Japanese Association of Public Health Center Directors], http://www.phcd.jp/03/HCsuii/index.html.

[11] Local Health Act art. 6.

[12] Basic Guidelines Regarding Promotion of Measures to Improve Local Health Issues Based on Local Health Act Article 4, Paragraph 1, MHW Notification No. 374 (Dec. 1, 1994), *last amended by* MHLW Notification No. 464 (July 31, 2012), http://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000049526.pdf (in Japanese).

[13] *Id*.

[14] Local Health Crisis Management Guidelines, *supra* note 8, II 1(4)(5).

[15] Shingata infuruenza oyobi tori infuruenza ni kansuru kankei shōchō taisaku kaigi no secchi ni tsuite [Regarding Establishment of Conference of Relevant Ministries and Agencies to Counter New Flu and Avian Flu], Agreement Among Relevant Ministries (Mar. 2, 2004), http://www.cas.go.jp/jp/seisaku/ful/konkyo.pdf.

[16] Press Release, MHLW, Pandemic Influenza Preparedness Action Plan of the Japanese Government (Summary), (Nov. 2005), http://www.mhlw.go.jp/english/topics/influenza/pandemic01.html.

[17] Shingata Infuruenza taisaku kōdō keikaku [Action Plan to Counter Influenza], Conference of Relevant Ministries and Agencies to Counter New Influenza and Avian Influenza (Feb, 2009), http://www.cas.go.jp/jp/seisaku/ful/kettei/090217keikaku.pdf.

[18] Guidelines for the Prevention and Control of Pandemic Influenza (Phase 4), Introduction, Conference of Relevant Ministries and Agencies to Counter New Influenza and Avian Influenza (Mar. 26, 2009), http://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou04/pdf/09-e01.pdf.

To improve the system, the Special Measures Act on New Influenza was enacted in May 2012.[19] Under the new Act, the government's action plan[20] and guidelines[21] were updated.[22] When an influenza outbreak involving a new strain of influenza occurs, the Prime Minister establishes the New Influenza Countermeasures Headquarters upon a Cabinet decision, unless symptoms of the new influenza are no graver than usual seasonal influenza.[23] The Prime Minister is in charge of the Headquarters[24] and, as such, can declare an emergency when the infection route of the new influenza is not determined by the local governments' investigations or when such investigations reveal that the activities of the person infected or suspected of being infected pose a great risk of widely spreading the disease.[25]

When an emergency is declared, emergency measures can be implemented for up to two years, with the possibility of a one-year extension. The area of the emergency must also be specified.[26] Authorized emergency measures include

- requesting residents to refrain from going outside and requesting entertainment businesses to limit or close their business or events,[27]
- vaccinating residents,[28]
- opening emergency medical facilities,[29] and
- requesting the sale of specified goods to the government.[30]

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[19] Shingata infuruenza tō taisaku tokubetsu sochi hō [Special Measures Act on New Influenza], Act No. 31 of 2012.

[20] Shingata infuruenza tōtaisaku seihu kodo keikaku [National Action Plan for Pandemic Influenza and New Infectious Diseases] (June 7, 2013), English translation available on the Cabinet Secretariat website, *at* http://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/national%20action%20plan.pdf.

[21] Shingata infuruenza to taisaku gaidorain [Guidelines on Countermeasures Against Pandemic Influenza and New Infectious Diseases], Conference of Relevant Ministries and Agencies to Counter New Influenza and Avian Influenza (June 26, 2013), http://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/gl_guideline.pdf.

[22] Government plans are available on the Cabinet Secretariat's website, at http://www.cas.go.jp/jp/seisaku/ful/keikaku.html (last visited Oct. 24, 2014).

[23] Special Measures Act on New Influenza art. 15.

[24] *Id*. art. 16.

[25] *Id*. art. 32; Enforcement Order of Special Measures Act on New Influenza, Order No. 122 of 2013, art. 6.

[26] Special Measures Act on New Influenza art. 32.

[27] *Id*. art. 45.

[28] *Id*. art. 46.

[29] *Id*. art. 48.

[30] *Id*. art. 55.

III. Powers of Public Health Authorities

A. Surveillance

Japan conducts nationwide surveillance of infectious diseases on an ongoing basis. The Infectious Diseases Prevention Law classifies infectious diseases into the following eight categories based on their infectiousness, the seriousness of the symptoms, and types of diseases:

- Category I: Ebola hemorrhagic fever, plague, smallpox, and others.
- Category II: Tuberculosis, SARS (severe acute respiratory syndrome), H5N1 avian influenza, and others.
- Category III: Cholera, bacillus dysentery, E. coli O157 infection, typhoid, and paratyphoid.
- Category IV: Hepatitis E, hepatitis A, yellow fever, anthrax, infantile botulism, avian influenza (excluding H5N1) and others. An infectious disease can be added to this category by Cabinet order.
- Category V: Influenza (excluding avian flu and new influenza), viral hepatitis (excluding hepatitis E and A), AIDS, MRSA (methicillin-resistant Staphylococcus aureus), and others. An infectious disease can be newly added to this category by MHLW ordinance.
- New Influenza.
- Designated Infectious Disease.
- New Infectious Disease.[31]

When physicians make a diagnosis or suspect the incidence of symptoms of one of the diseases in Categories I through IV, or a New Infectious Disease, they must immediately report the incidences to the governors through health centers. In the case of incidences of Category V diseases, physicians have seven days to make such reports.[32] Veterinarians must do the same when they make a diagnosis in monkeys or other designated animals of Ebola hemorrhagic fever, Marburg hemorrhagic fever, and other infectious diseases in Categories I through IV that are designated by a Cabinet order because they are regarded as being infectious to humans as well.[33] The governors must forward such reports to the Minister of MHLW.[34]

Governors designate hospitals and clinics to monitor incidences of (1) specified Category V infectious diseases; and (2) incidences of fever and respiratory problems, and fevers and rashes that are similar to symptoms of diseases in Categories II to IV and some Category V infectious

[31] Kansen shō no yobō oyobi kansenshō no kanja ni taisuru iryō ni kansuru hōritsu [Act on Prevention of Infectious Diseases and Medical Care for Patients of Infectious Diseases] (Infectious Diseases Prevention Act), Act No. 114 of 1998, *last amended by* Act No. 30 of 2008, art. 6, para. 2, items 2–9.

[32] *Id*. art. 12, para. 1.

[33] *Id*. art. 13, para. 1.

[34] *Id*. art. 12, para. 2 & art. 13, para. 3.

diseases. Managers of designated hospitals must report cases treated by their physicians to the governors, and the governors must in turn forward the reports to the Minister of MHLW.[35]

Governors may question doctors and conduct investigations of incidences and suspected cases of infectious diseases in Categories I to V and New Diseases if necessary to determine the cause of the incidences. In an emergency, the Minister of MHLW can do the same.[36]

The National Institute of Infectious Diseases (NIID), under the supervision of the Health Science Division of the MHLW,[37] collects reports of the detection of infectious agents from prefectural public health institutes and those of incidents of infectious diseases from selected clinics.[38] The NIID also maintains and distributes reference materials on matters such as microbial pathogens, antigens, and antisera.[39] In the case of an epidemic or outbreak of an infectious disease, NIID carries out epidemiological investigations and exchanges information with infectious disease surveillance organizations in other countries. To make these activities more efficient, the Infectious Disease Surveillance Center (IDSC) was organized within NIID.[40] IDSC publishes the Infectious Disease Weekly Report and other publications and makes them available online.[41]

B. Infectious Disease Control

A prefectural governor may advise a person who is reasonably suspected of being infected with a Category I, II, or III disease, or New Influenza, to undergo a medical examination.[42] If the person does not voluntarily undergo an examination, the governor may dispatch an officer to examine the person.[43] Except in emergencies, however, the governor must give notice to the person before issuing a medical examination recommendation or dispatching an officer.[44]

When a governor receives a report that a person is infected with a Category I through III disease or New Influenza from a medical doctor, the governor sends a notice to the person prohibiting him or her from engaging in specified jobs, such as chef and waiter positions at a restaurant, for a period of time that depends on the disease.[45]

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[35] *Id*. art. 14; Infectious Diseases Prevention Act Enforcement Ordinance, MHLW Ordinance No. 99 of 2008, arts. 6 & 7.

[36] Infectious Diseases Prevention Act art. 15.

[37] MHLW Organization Order, Order No. 252 of 2000, art. 26.

[38] *Outline – Organization: History*, NIID, http://www.niid.go.jp/niid/en/aboutniid-2.html (last visited Oct. 10, 2014).

[39] *Id*.

[40] *Outline – Organization: Functions*, NIID, http://www.niid.go.jp/niid/en/aboutniid-2.html (last visited Oct. 10, 2014).

[41] *Infectious Disease Weekly Report*, NIID, http://www.niid.go.jp/niid/ja/idwr.html (in Japanese; last visited Oct. 11, 2014). Some publications are available in English at http://www.niid.go.jp/niid/en/idwr-e.html (last visited Oct. 11, 2014).

[42] Infectious Diseases Prevention Act art. 17, para. 1.

[43] *Id.* art. 17, para. 2.

[44] *Id*. art. 17, para. 3.

[45] *Id.* art. 18.

A system of recommended or forced medical diagnosis and hospitalization may be activated when a person is suspected of being infected with certain infectious diseases. A governor may advise a person infected with a Category I or II disease or New Influenza to be hospitalized in a designated hospital. If the person does not follow the advice, the prefectural governor may force the person to stay in a designated hospital.[46] The term of the hospitalization must be seventy-two hours or less initially.[47] If the governor finds during the initial hospitalization that it is necessary to continue to hospitalize the person to prevent the spread of a Category I or II disease or New Influenza, the governor may recommend hospitalization for up to an additional ten days, with the possibility of two ten-day extensions, if necessary.[48] If the person does not follow the advice, the governor may force the hospitalization,[49] but must give the patient and/or his or her guardian an opportunity to state their opinions.[50]

The Infectious Diseases Prevention Act contains provisions aimed at protecting the rights of patients. All measures taken against individuals who are infected or suspected of being infected with certain infectious diseases must be at the minimally required level.[51] A person must be released from the hospital when it is determined that he or she does not have a pathogen. The hospitalized person can request release from hospitalization, whereupon the governor must test the person to determine whether he or she has a pathogen.[52] The governor may seek the opinion of experts before making a decision. Such an opinion is provided by an infectious disease examination council that each health center maintains. When a governor issues a notice that restricts the infected person from engaging in certain jobs, advises hospitalization, and extends the period of hospitalization, as stated above, the council gives its opinion to the governor.[53] A hospitalized person can appeal the governor's decision to the Minister of the MHLW. The Minister then makes a decision in consultation with the MHLW experts' council.[54]

In addition to the examination and hospitalization of persons infected with certain infectious diseases, prefectural governors may take various measures when necessary to prevent incidences or the spread of particular infectious diseases. In order to prevent incidences or the spread of Category I through IV infectious diseases and New Influenza, a governor may order the infected person, the guardian of the person, or the person or organization that manages the place affected to disinfect that place. If such disinfection is not effective, the governor may order a municipality that has control of the site where the patient was or other contaminated places to sterilize such places.[55] A governor may also order a person or organization that manages the site

[46] *Id.* art. 19, paras. 1–3 & art. 26.

[47] *Id.* art. 19, para. 4 & art. 26.

[48] *Id.* art. 20, para. 4 & art. 26.

[49] *Id*. art. 20, paras. 1–3 & art. 26.

[50] *Id*. art 20, para. 6 & art. 26.

[51] *Id*. art. 22-2.

[52] *Id*. art. 22.

[53] *Id*. art. 24.

[54] *Id*. arts. 25 & 26.

[55] *Id.* art. 27.

where rodents or insects contaminated by the pathogen exist to exterminate such rodents and insects. If such extermination is not effective, the governor may order municipalities to exterminate them.[56] Further, a governor may order holders of possibly contaminated food, clothing, bedding, and other items to restrict the movement of, sterilize, or dispose of the items. A governor may also dispatch prefectural officials or order a municipal government to sterilize or dispose of such items.[57]

To prevent incidences or the spread of Category I through III infectious diseases and New Influenza, a governor may restrict the movement of an infected corpse, or require a permit for the burial of an infected corpse. Generally, an infected corpse must be cremated, but with sterilization treatment and a permit, the body can be buried.[58] To prevent incidences or the spread of Category I through III infectious diseases, a governor may restrict the use of water or a water supply that is suspected of being contaminated. In such cases, municipalities must provide clean water for residents.[59]

To prevent incidences or the spread of Category I infectious diseases, stronger measures may be taken. A governor may restrict access to buildings that are contaminated or suspected of being contaminated with a Category I infectious disease,[60] and may also restrict traffic for up to seventy-two hours around the place where the patient is located or the place suspected of being contaminated.[61]

C. New Infectious Diseases or New Threats by Known Infectious Diseases

The Infectious Diseases Prevention Act has provisions to combat new infectious diseases or new threats by known infectious diseases. Where threats of new influenza, or known influenza that poses renewed threats to public health, are recognized, a governor may seek a report of the health conditions, including body temperature, of the person suspected of being infected for a period that is determined after considering the incubation period of the influenza. A governor may also request that such person not go outside of his or her residence, and take other actions that are necessary to confine the disease. In such cases, the governor may provide meals and other necessities for the infected person.[62] Where the influenza is virulent and it is especially necessary to prevent its incidence or spread, the national government can restrict access to a building and control traffic, as stated in the previous section—measures that are normally applied to Category I infectious diseases.[63]

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[56] *Id*. art. 28.

[57] *Id*. art. 29.

[58] *Id*. art. 30.

[59] *Id*. art. 31.

[60] *Id*. art. 32.

[61] *Id*. art. 33.

[62] *Id*. art. 44-3.

[63] *Id*. art. 44-4.

In the case of a new disease other than influenza, the governor may recommend that a person who is suspected of being infected receive a medical examination. If the person does not voluntarily undergo a medical examination, the governor may have a prefectural official examine the person.[64] Other measures used for other categories of infectious diseases under the Infectious Diseases Prevention Act can be used, including mandatory hospitalization and sterilization of the affected building.[65] The governor must consult with the Minister of the MHLW prior to taking these actions, however,[66] and the Minister must give the governor technical advice.[67] When the MHLW has devised effective measures to prevent the spread of a new infectious disease, the government issues an order to make available all measures for Category I infectious diseases under the Act for up to a year in order to prevent the spread of the new disease.[68]

Designated Infectious Disease is a category for a known infectious disease (other than Category I through III infectious diseases and New Influenza) that newly becomes a threat to the Japanese people. The government makes this designation by issuing an order that makes all measures under the Act available for the newly designated disease for up to a year.[69]

For example, severe acute respiratory syndrome (SARS) was designated as a New Infectious Disease on April 3, 2003, and then named a Designated Infectious Disease on June 20, 2003.[70] Later, at the time of the 2006 amendment to the Infectious Diseases Prevention Act, SARS was added to Category II infectious diseases.[71] H5N1 avian influenza was designated as a Designated Infectious Disease on June 2, 2006.[72] Later, at the time of the 2008 amendment to the Infectious Diseases Prevention Act, H5N1 avian influenza was added to Category II infectious diseases.[73]

D. Designated Hospitals

Japan has a designated medical institution system for particular infectious diseases under the Infectious Diseases Prevention Act.

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[64] *Id*. art. 45.

[65] *Id*. arts. 46 & 50.

[66] *Id*. art. 51, para. 1.

[67] *Id*. art. 51, para. 2.

[68] *Id*. art. 53.

[69] *Id.* art. 6, para. 8 & art. 7.

[70] *Jūshō kyūsei kokyūki shōkō gun* [*SARS*], IDSC (Feb. 2005), http://idsc.nih.go.jp/idwr/kansen/k05/k05_06/k05_06.html.

[71] Act to Amend the Infectious Diseases Prevention Act, Act No. 106 of 2006.

[72] Infuruenza (H5N1) o shitei kansenshō to site sadameru tō no seirei [Order Concerning Designation of Influenza (H5N1) as Designated Infectious Disease], Order No. 208 of 2006.

[73] Act to Amend the Infectious Diseases Prevention Act and Quarantine Act, Act No. 30 of 2008.

- A Designated Specified Infectious Disease Medical Institution is designated by the Minister of the MHLW upon the institution's consent, and treats patients stricken with New Infectious Diseases, Category I and II infectious diseases, and New Influenza.[74]
- A Designated Category I Infectious Disease Medical Institution is designated by a governor upon the institution's consent and treats patients with Category I and II infectious diseases and New Influenza.[75]
- A Designated Category II Infectious Disease Medical Institution is designated by a governor upon the institution's consent and treats patients with Category II infectious diseases and New Influenza.[76]

These Designated Medical Institutions must accept patients with the specified diseases for hospitalization, and follow instructions from the Minister of MHLW or the governor.[77]

The MHLW has issued standards for Designated Category I and II Infectious Disease Medical Institutions. The standards for the designated hospital for Category I diseases is significantly higher than the one for Category II diseases. For example, the hospital standards for Category I diseases require that

- the patient's room have air pressure that is lower than the surrounding area so that pathogens will not exit the room;
- there must be a room between the patient's room and hall or other area;
- there must be an independent ventilation system for the patient's room; and
- there must be equipment that sanitizes drained water from the room or the area where the room is located.[78]

As of April 2014, Japan had three Designated Specified Infectious Disease Medical Institutions, forty-four Designated Category I Infectious Disease Medical Institutions, and 335 Designated Category II Infectious Disease Medical Institutions.[79]

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[74] Infectious Diseases Prevention Act art. 6, para. 13 & art. 38, para. 1.

[75] *Id*. art. 6, para. 14 & art. 38, para. 2.

[76] *Id*. art. 6, para. 15 & art. 38, para. 2.

[77] *Id*. art. 38, para. 3.

[78] Kansenshō no yobō oyobi kansenshō no kanja ni taisuru iryōni kansuru hōritsu dai 38 jō dai 2 kō no kitei ni motoduku kōsei rōdō daijin no sadameru kansenshō shitei iryō kikan no kijun [Standards for Designated Infectious Disease Medical Institutions Set by the Minister of MHLW, Based on the Infectious Disease Prevention Law, Article 38, Paragraph 2], MHLW Notification No. 43 (Mar. 19, 1999).

[79] Kansenshō shitei iryō kikan no shitei jōkyō [Statistics of Designated Infectious Disease Medical Institutions], MHLW (Apr. 1, 2014), http://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou15/02-02.html.

E. Quarantine

Two ministries have jurisdiction over quarantines. Human and food quarantine is under the MHLW's jurisdiction. Plant and animal quarantine falls under the jurisdiction of the Ministry of Agriculture, Forestry and Fishery.

Under the Quarantine Law, vessels or aircraft that originated from or visited a foreign country, or encountered and received persons or material from a foreign country, must obtain a Free Pratique, or a Provisory Free Pratique before they enter into ports in Japan, except when they enter into designated quarantine areas.[80] The captains of vessels or aircraft must inform the Chief of the Quarantine Station in advance of matters prescribed in the MHLW ordinances, such as whether patients suffering from or who have died from quarantine infectious diseases have been on board.[81] "Quarantine infectious diseases" refers to Category I infectious diseases, New Influenza under the Infectious Diseases Prevention Act, and other infectious diseases specified by Cabinet order.[82] People on board vessels and aircraft must not leave the designated area until a Free Pratique or a Provisory Free Pratique is issued unless the Chief of the Quarantine Station has confirmed that persons or materials on board are not contaminated by pathogenic microorganisms causing infectious diseases that are subject to quarantine.[83]

When vessels and aircraft enter into the designated quarantine areas, the head of a quarantine office may order quarantine officers to ask questions of the passengers of vessels and aircraft from foreign countries.[84] Quarantine officers may also examine passengers, vessels, and aircraft in order to determine the existence of a pathogen.[85] When swine influenza spread in Mexico, the US, and Canada in 2009, international airports in Japan strengthened their quarantine measures. Quarantine officers went into airplanes arriving from these three countries, distributed health condition questionnaires, and examined body temperatures. Where a passenger was found to have symptoms of swine influenza infection, an instant infection test kit was used for the person.[86]

When a vessel leaves or passes areas where there was a case of a quarantined disease, when a passenger of a vessel was infected with a quarantined disease, or when the existence of mice that were likely infected with plague is confirmed in a vessel, the head of the quarantine office may take the following measures, among others, if necessary:

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[80] Ken-eki hō [Quarantine Act], Act No. 201 of 1951, *last amended by* Act No. 69 of 2014, art. 4.

[81] *Id*. art. 6.

[82] *Id*. art. 2.

[83] *Id*. art. 5.

[84] *Id*. art. 12.

[85] *Id*. art. 13.

[86] *Measures Against New Influenza at Narita Airport Quarantine Office*, 30 INFECTIOUS AGENTS SURVEILLANCE REPORT 257 (Oct. 2009), http://idsc.nih.go.jp/iasr/30/356/dj3561.html (in Japanese).

- Isolate the person infected with a Category I disease or New Influenza;
- Force the person suspected of being infected with a Category I disease or New Influenza to stay at the designated facility or on the vessel, provided that this is necessary to prevent entrance of the pathogen into Japan, and that the infection is recognized in the relevant foreign country and would seriously threaten people's health and lives in Japan;
- Sanitize items and places that are suspected of being contaminated, or discard items if they are not sanitized effectively; and
- Vaccinate people.[87]

Persons who are infected with Category I infectious diseases or New Influenza are isolated at an appropriate, designated medical institution.[88] Persons suspected of being infected with a Category I disease or New Influenza are also kept in appropriate designated medical institutions, but can be kept in other medical institutions or onboard the vessel on which they arrived under special circumstances.[89] Persons suspected of being infected with New Influenza can be kept at a designated medical institution, other medical institutions, hotels, or the vessel on which they arrived.[90] Persons who were isolated or kept at a designated place will be released when a medical professional confirms that the person does not have a pathogen.[91] Other than Category I infectious diseases and New Influenza, when the incidences of other known infectious diseases or a new infectious disease is recognized in a foreign country and the government recognizes the necessity of quarantine to prevent the entry and spread of the disease, the government may apply these measures of isolation and forced stay.[92]

F. Tracking Persons

The head of a quarantine office must report specified information concerning a quarantined person who is infected with a Category II through IV disease, or a Designated or New Infectious Disease, to the governor who has jurisdiction over the person's residence.[93] In addition, when the head of a quarantine office decides not to keep in quarantine a person who might be infected with a Category I disease or New Influenza, the head of the quarantine office must collect information on the person, such as name, address, or place of stay in Japan, and the schedule of his or her travels in Japan, and notify the governor who has jurisdiction over the address or place of stay of this information.[94] The governor who receives such a report may monitor the

[87] Quarantine Act art. 14.

[88] *Id*. art. 15.

[89] *Id*. art. 16, para. 1.

[90] *Id*. art. 16, para. 2.

[91] *Id*. art. 15, para. 2 & art. 16, para. 4.

[92] *Id*. arts. 34-2, 34-3, 34-4.

[93] *Id.* art. 26-3.

[94] *Id*. art. 18, paras. 4 & 5.

condition of the person by asking the person for a report or by dispatching a local health care officer to talk to the person.[95]

G. Animal Quarantine

To prevent infectious diseases of animal origin, the Infectious Diseases Prevention Act provides for animal quarantines and bans.[96] For example, the import of monkeys from Africa is basically prohibited. To import them, special permission from the MHLW and the MAFF are needed,[97] in order to prevent the incursion into Japan of Ebola hemorrhagic fever and Marburg viral disease.[98] In addition, the Rabies Prevention Law provides that dogs, cats, raccoons, foxes, and skunks imported into the country must be quarantined.[99] The Livestock Infectious Diseases Prevention Act also has quarantine provisions for imported livestock.[100]

IV. Transparency of the Public Health Crisis Management System

The MHLW Basic Guidelines makes the administration of health care crises transparent. The guidelines also direct the MHLW to provide and publicize various pieces of information it holds about a given crisis.[101] Health care crisis management by local governments is based on the MHLW's Local Health Crisis Management Guidelines, which identify providing information to the public as one important task of local health centers.[102]

The Infectious Diseases Prevention Act also has provisions to ensure the transparency of public health crisis management information. The Act provides that the national and local governments must educate people with correct information on infectious diseases and provide analytical information on infectious disease trends.[103]

V. Cooperation with WHO

Japan is a member of the World Health Organization (WHO)[104] and complies with the International Health Regulations (IHR).[105] When the MHLW recognizes an incidence of an

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[95] Infectious Diseases Prevention Act arts. 15-2 & 15-3.

[96] *Id*. ch. 10.

[97] *Id*. art. 54; Ordinance to Set Areas from Which Imports Are Banned Based on Infectious Diseases Prevention Act Article 54, Item 1, MHLW & MAFF Ordinance No. 2 of 1999, art. 1.

[98] *What Is Animal Quarantine?*, ANIMAL QUARANTINE SERVICE, MAFF, http://www.maff.go.jp/aqs/english/ (last visited Oct. 19, 2014).

[99] Kyōkenbyō yobō hō [Rabies Prevention Act], Act No. 247 of 1950, *last amended by* Act No. 160 of 1999, art. 2; Kyōkenbyō yobō hō shikō rei [Rabies Prevention Act Implementation Order], Order No. 236 of 1953, art. 1.

[100] Kachiku densenbyō yobo hō [Livestock Infectious Diseases Prevention Act], Act No. 166 of 1951.

[101] Basic Guidelines in Health Crisis Management, *supra* note 3.

[102] Local Health Crisis Management Guidelines, *supra* note 8.

[103] Infectious Diseases Prevention Act art. 3, para. 1 & art. 16, para. 1.

[104] *Countries*, WHO, http://www.who.int/countries/en/ (last visited Oct. 20, 2014).

infectious disease listed in the IHR, it reports the information to the WHO. The MHLW may report information to the WHO even if the disease is not subject to reporting under the IHR Regulations.[106] Japan's National Institute of Infectious Diseases (NIID) has been designated as the Collaborating Center for Influenza along with other WHO-assigned centers and laboratories.[107]

VI. Recent Developments

As discussed in Part II(C), the Special Measures Act on New Influenza was enacted in 2012. That Act created an influenza emergency system.

More recently, a bill to amend the Infectious Diseases Prevention Act was submitted to the Diet in October 2014. Pursuant to the bill, Middle East Respiratory Syndrome (MERS) would be added to Category II infectious diseases. Avian flu (H7N9), which was temporarily added to Category II by Cabinet order designation, would also be added to Category II on a permanent basis. In addition, the bill contains provisions that would enable the governor to collect specimens from persons infected with specified infectious diseases.[108]

In response to the Ebola outbreak in West Africa in 2014, the Japanese government decided to allow the use of a drug approved for influenza treatment in certain situations[109] for Ebola treatment, and to enhance detection and examination of people who arrive at airports in Japan and have been in four African countries where Ebola has spread (Liberia, Sierra Leone, Guinea, and Nigeria).[110] Yasuhisa Shiozaki, Minister of MHLW, said that Japan stockpiles the drug sufficient to treat 20,000 people.[111] On October 27, 2014, Prime Minister Shinzo Abe met with Minister Shiozaki and directed him to set up a meeting of relevant Cabinet members on responses to Ebola.[112] The meeting was approved by the Cabinet on October 28, and the first

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[105] *See About IRH (International Health Regulations)*, WHO, http://www.who.int/ihr/about/en/ (last visited Oct. 20, 2014).

[106] Kansenshō kenkō kiki kanri jisshi yōryō [Infectious Disease Health Risk Crisis Management Implementation Manual], Health Div., MHLW, Mar. 2007, *last amended* Oct. 2013, 3(2) *ko*, http://www.mhlw.go.jp/general/seido/kouse i/kenkou/kansen/index.html.

[107] *Outline – Organization: Functions*, *supra* note 40.

[108] Bill to Amend the Infectious Diseases Prevention Act (submitted Oct. 14, 2014), *available at* http://www.mhlw.go.jp/topics/bukyoku/soumu/houritu/187.html (in Japanese).

[109] Press Release, Toyama Chemical Co., Ltd., The New Drug Application Approval of "AVIGAN® Tablet 200mg" in Japan for the Anti-influenza Virus Drug (Mar. 24, 2014), https://www.toyama-chemical.co.jp/eng/news/news140324e.html.

[110] Ebola taiō kyōgi e kankei kakuryō kaigi . . . shushō ga shiji [Meeting of Relevant Cabinet Members on Responses to the Ebola Virus Disease . . . Prime Minister Directed], YOMIURI NEWSPAPER (Oct. 27, 2014) (on file with author).

[111] Ebora kokunai taisaku, mishōnin yaku 2man nin bun bichiku . . . Kōrōsō [Ebola Measures, Stockpiled Unapproved Drug for 20,000 People . . . MHLW Minister], YOMIURI NEWSPAPER (Oct. 28, 2014) (on file with author).

[112] *Id*.

meeting was held immediately after the Cabinet meeting.[113] The meeting established the conference of relevant ministries and agencies on Ebola, which is chaired by the Deputy Chief Cabinet Secretary for Crisis Management.[114] The goal is to prepare for coordinated measures among government agencies in cases where Japanese nationals are infected with Ebola abroad or persons infected with Ebola are found within Japan.[115]

[113] Ebora shukketsu netsu taisaku kankei kakuryō kaigi no kaisai ni tsuite [Regarding Opening of Meeting of Relevant Cabinet Members on Responses to the Ebola Virus Disease], orally approved by Cabinet Meeting, Prime Minister of Japan and His Cabinet, Oct. 28, 2014, http://www.kantei.go.jp/jp/singi/ebola/youkou.pdf.

[114] Ebora shukketsu netsu ni kansuru seifu no taisei ni tsuite [Regarding System to Counter Ebola Hemorrhagic Fever], Deputy Chief Cabinet Secretary's Office, Oct. 28, 2014, http://www.kantei.go.jp/jp/singi/ebola/dai1/sankou3.pdf.

[115] Ebora shukketsu netsu taisaku kankei kakuryō kaigi [Meeting of Relevant Cabinet Members on Responses to the Ebola Virus Disease], Prime Minister of Japan and His Cabinet, http://www.kantei.go.jp/jp/singi/ebola/index.html (last visited Oct. 28, 2014).

Kenya

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SUMMARY Kenyan officials enjoy broad legal authority to impose various forms of restrictions during public health crises. The Constitution authorizes the head of state to declare a state of emergency and put in place wide-ranging public security preservation measures, including restrictions on movement and assembly, appropriation of private property and labor, and restrictions on entry into the country. However, in order for actions under this authority to remain in place for an extended period of time, they need legislative approval.

Similarly, the Public Health Act (PHA), the primary legislation applicable to matters of public health crises, authorizes public health authorities, particularly the Minister of Health, to take various actions during public health crises, including declaring an infectious disease a "notifiable infectious disease" or a "formidable epidemic, endemic or infectious disease," and taking the necessary prevention and suppression measures to fight the disease. Specific powers accorded to health authorities for the purpose of prevention and suppression of an infectious disease include search, seizure, and detention powers; the power to designate any place as a quarantine area, including ships and aircraft; and the power to restrict or ban immigration into the country.

Kenyan and international laws impose certain transparency requirements on the country's government. Chief among these are the requirement under the PHA to periodically publish information regarding infectious diseases in Kenya, neighboring countries, and around the world, and the obligation under the International Health Regulations to report any public health emergency to the World Health Organization (WHO).

Although Kenya is geographically far from the Ebola-stricken West African region and to this day remains infection-free, the WHO recently declared the country at high risk for an Ebola infection given that it is a transportation hub in East Africa. As a result, the Kenyan government has taken various measures to prepare for an outbreak, including putting in place a contingency plan; establishing an Ebola response advisory task force; partially closing border crossings with Uganda, where there was a recent suspected Ebola death; and instituting a travel ban on persons traveling from the Ebola-stricken countries.

I. Government Structure

Kenya previously had a unitary system of government but recently introduced a system akin to a federation with the adoption of the 2010 Kenya Constitution, which established a two-tiered system of government involving the national and county levels.[1]

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* This report updates a report originally prepared in 2003 by Charles Mwalimu, former Senior Legal Specialist.

[1] CONSTITUTION art. 1 (2010), available on the Kenya Law website, *at* http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=Const2010.

A. National Government

In adherence to the principle of separation of powers, government power at the national level is shared by three branches tasked with constitutionally delimited powers and obligations: the executive, the legislature, and the judiciary.[2]

1. The Executive

The national executive consists of the President, the Deputy President, and the rest of the Cabinet, which includes the Attorney-General, who is the principal legal advisor to the government among other functions, and fourteen to twenty-two Cabinet Secretaries.[3]

2. The Legislature

Another new feature in the country's government structure is the establishment of a bicameral legislative body consisting of a 349-member National Assembly and a sixty-seven-member Senate.[4] The National Assembly enjoys broad legislative and supervisory powers, enacting legislation on any matter over which the national government has jurisdiction under the Constitution, determining revenue allocation between the different tiers of government, appropriating funds for government spending, and exercising oversight over government spending and the conduct of the executive branch of government.[5] The role of the Senate, both in terms of legislative and supervisory powers, is by and large limited to matters that affect the interests of the counties.[6]

3. The Judiciary

The Kenyan judiciary consists of what are known as superior courts (the Supreme Court, the Court of Appeal, and the High Court) and subordinate courts (magistrates' courts, kadhis' courts, the courts marshal, and tribunals).[7] While all of these courts have distinct jurisdictional mandates, for the purposes of this report it is sufficient to point out that the High Court's subject matter jurisdiction includes matters of constitutional interpretation in relation to "constitutional powers of State organs in respect to county governments" and "the constitutional relationship between levels of government," and questions relating to conflicts between national and county-issued laws.[8] This may be significant given that the national and county governments share legislative jurisdiction on public health issues (see below).[9] Decisions of the High Court on

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[2] *Id*.

[3] *Id*. §§ 130, 152 & 156.

[4] *Id*. §§ 93, 97 & 98.

[5] *Id*. §§ 95 & 109.

[6] *Id*. §§ 96, 109–113.

[7] *Id*. § 162; *The Courts*, REPUBLIC OF KENYA, THE JUDICIARY, http://www.judiciary.go.ke/portal/page/courts (last visited Oct. 21, 2014).

[8] CONSTITUTION § 165.

[9] *Id.* § 186.

issues relating to the Constitution may always be appealed to the Court of Appeal and thereafter the Supreme Court.[10]

B. County Governments

Kenya has forty-seven counties, including Nairobi (the capital), which have their own legislative (county assembly) and executive (county executive) organs.[11] The functions of the county assemblies include

- making laws on matters within their legislative jurisdiction (matters specified under the Fourth Schedule of the Constitution);
- exercising oversight over county executive bodies (for instance the county assembly approves the appointments of the governor to the county executive committee, which is the cabinet of the county government); and
- approving management and exploitation plans for the counties' resources, and the development and management of county institutions and infrastructure.[12]

The executive branch of the county government, the county executive committee, consists of the county governor, the deputy county governor, and county executive members.[13]

II. Structure of the Public Health Management System

Ordinarily the national and county governments enjoy concurrent legislative jurisdiction on health-related matters. The national government enjoys legislative jurisdiction on matters relating to "[h]ealth policy" and "[n]ational referral health facilities," while the county governments may legislate on issues relating to county health services, including county health facilities and cemeteries, funeral parlors, and crematoria.[14] While the health issues over which the county governments are accorded jurisdiction appear local in nature, the ongoing Ebola crisis in Liberia reveals that rules on issues such as burial rituals during public health crises may have great ramifications for the prevention and suppression of an infectious disease outbreak.[15]

As noted below, in times of public health crises, the national government has broad, unfettered powers to impose nationally applicable response measures regardless of whether a county government has jurisdiction over the matter.

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[10] *Id*. §§ 163 & 164.

[11] *Id*. §§ 6 & 176.

[12] *Id*. § 185; County Governments Act, No. 17 of 2012, §§ 5 & 8 (July 24, 2012), available on the Kenya Law website, *at* http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=NO.%2017%20of%202012.

[13] CONSTITUTION § 179; County Governments Act § 30.

[14] CONSTITUTION § 186.

[15] *Ebola Cremation Ruling Prompts Secret Burials in Liberia*, THE GUARDIAN (Oct. 24, 2014), http://www.theguardian.com/world/2014/oct/24/ebola-cremation-ruling-secret-burials-liberia.

III. Powers of National Public Health Authorities

A. Declaration of a State of Emergency Under the Constitution

One of the ways that the national government may respond to a public health crisis is through the application of constitutional powers of the executive body. Subject to certain limitations, the President has the power to declare a state of emergency, including when the country is under threat from a "natural disaster or other public emergency" and doing so "is necessary to meet the circumstances for which the emergency is declared."[16] Any law issued under a state of emergency can impose limitations on the rights and fundamental freedoms enshrined in the Bill of Rights, so long as the emergency requires the limitation and it is in keeping with applicable international law.[17]

However, the declaration of an emergency and any laws issued or actions taken by the President are effective for only fourteen days unless extended by the National Assembly.[18] The National Assembly can extend the declaration of a state of emergency by a maximum of two months at a time.[19] While a first extension can be adopted with the support of at least two-thirds of all members of the National Assembly, all subsequent extensions require the support of three-quarters of all members of the National Assembly.[20]

The President is authorized under the Constitution to bring into operation Part III of the Public Preservation Security Act[21] and issue regulations for the purpose of "preservation of public security," including "the securing of the safety of persons and property, . . . [and] the provision of administrative and remedial measures during periods of actual apprehensible national danger or calamity."[22] These regulations may make provisions for

> . . .
>
> B. the registration, restriction of movement (into, out of or within Kenya), and compulsory movement of persons, including the imposition of curfews:
>
> Provided that no person shall be restricted on account of his political beliefs or activities;
>
> C. the control of aliens, including the removal of diplomatic privileges;
>
> D. the censorship, control or prohibition of the communication of any information, or of any means of communicating or of recording ideas or information, including any publication or document, and the prevention of the dissemination of false reports;

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[16] CONSTITUTION §§ 58, 132.

[17] *Id.*

[18] *Id.* § 58.

[19] *Id.*

[20] *Id.*

[21] Preservation of Public Security Act of 1960, 16 LAWS OF KENYA, Cap. 57 (rev. ed. 2012), available on the Kenya Law website, *at* http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%2057.

[22] *Id.* §§ 2 & 4.

E. the control or prohibition of any procession, assembly, meeting, association or society;

F. the control or prohibition of the acquisition, possession, disposition or use of any movable or immovable property or undertaking;

G. the compulsory acquisition, requisitioning, control or disposition of any movable or immovable property or any undertaking;

H. requiring persons to do work or render services, including the direction of labour and supplies, the conscription of persons into any of the disciplined forces (including the National Youth Service) and the billeting of persons;

I. the control and regulation of harbours, ports and the movement of vessels;

J. the control and regulation of transport by land, air or water;

K. the control of trading and of the prices of goods and services, including the regulation of the exportation, importation, production, manufacture or use of any property or thing;

L. amending, applying with or without modification or suspending the operation of any law (including legislation of the East African Common Services Organization) other than this Act or the Constitution;

M. any matter, not being a matter specified in any of the foregoing paragraphs of this subsection, for which provision is necessary or expedient for the preservation of public security.[23]

It is evident that the Preservation of Public Security Act is a catch-all statute that covers all aspects of security in the country including those dealing with a public health crisis or threat, such as bioterrorism, and infectious diseases, such as anthrax, malaria, cholera, leprosy, foot and mouth diseases, and other outbreaks such as severe acute respiratory syndrome (SARS) and Ebola. It appears that in order for a special public security measure to be put in place, the only thing required is the classification of an event as a threat or an act that threatens the security of Kenya.

B. Statutory Regime

1. Powers of Authorities in a Public Health Crisis

Although there are various laws applicable to public health matters, the Public Health Act (PHA) of 1921, including its subsidiary legislation, is the primary law that governs matters of public health crises in Kenya.[24] This law established and regulates the functions and powers of a number of health authorities that deal with public health crises.

The PHA requires that health authorities take all the necessary, lawful actions imposed on them under any law to prevent or deal with an outbreak or the prevalence of "any infectious,

[23] *Id.* § 4.

[24] Public Health Act of 1921, 16 LAWS OF KENYA, Cap. 242 (rev. ed. 2012), http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20242.

communicable or preventable disease, to safeguard and promote the public health and to exercise the powers and perform the duties in respect of the public health."[25]

2. Central Board of Health

The PHA envisages what is called the Central Board of Health (the Board), to be based in Nairobi, which is composed of the Director of Medical Services, a sanitary engineer, a secretary, and up to six additional members, at least three of whom must be medical practitioners.[26] The main function of the Board is to advise the Minister of Health on "all matters affecting public health," including on the prevention of infectious diseases from reaching Kenyan borders and the "prevention, limitation or suppression of infectious, communicable or preventable disease within Kenya."[27] However, sources consulted for this report indicated that the Board has yet to be established.[28]

3. The Medical Department

The PHA also established the Medical Department, which is tasked with a host of responsibilities to prevent and/or play a key role in managing public health crises. The functions of the Department are

> to prevent and guard against the introduction of infectious disease into Kenya from outside; to promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable disease within Kenya; to advise and direct local authorities in regard to matters affecting the public health; to promote or carry out researches [sic] and investigations in connexion with the prevention or treatment of human diseases; to prepare and publish reports and statistical or other information relative to the public health; and generally to carry out in accordance with directions the powers and duties in relation to the public health conferred or imposed by this Act.[29]

The Department is required by law to "obtain and publish periodically" information concerning infectious disease in Kenya and similar information regarding neighboring or other countries, as required by the interests of public health.[30]

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[25] *Id.* § 13.

[26] *Id.* § 3.

[27] *Id.* §§ 8 & 10.

[28] David I. Muthaka et al., Kenya Institute for Public Policy Research and Analysis (KIPPRA), *A Review of The Regulatory Framework for Private Healthcare Services in Kenya* 28 (KIPPRA Discussion Paper No. 35, Mar. 2004), available on the International Finance Corporation (IFC) website, *at* https://www.wbginvestmentclimate.org/toolkits/health-in-africa-policy-toolkit/upload/PNADS076.pdf; TRANSPARENCY INTERNATIONAL-KENYA, THE KENYA HEALTH SECTOR INTEGRITY STUDY REPORT 15 (2011), http://www.gtzkenyahealth.com/blog3/wp-content/uploads/2011/01/TI%20Health%20report.pdf.

[29] Public Health Act § 10.

[30] *Id.*

4. Minister of Health and General Delegated Authority

The Minister may, on the advice of the Board or the Department, order an inquiry regarding any public health matter.[31] A person authorized by the Minister to conduct an inquiry is accorded broad powers under the Public Health Act, which states as follows:

> When an inquiry is directed to be made by the Minister, the person directed to make the same shall have free access to all books, plans, maps, documents and other things relevant to the inquiry, and shall have in relation to witnesses and their examination and the production of documents similar powers to those conferred upon magistrates by the Criminal Procedure Code . . . , and may enter and inspect any building, premises or place the entry or inspection whereof appears to him requisite for the purpose of such inquiry.[32]

5. Notifiable Infectious Diseases (NIDs)

The manner in which the Kenyan health authorities responded to the HIV/AIDS epidemic is illustrative of the process of declaring a disease to be an NID.

HIV/AIDS has impacted Kenya greatly since the first diagnosis of a case of AIDS in Kenya was made in 1984. By August 1993, the Kenya National Aids Control Program estimated that 841,700 persons were infected with HIV.[33] By 2003, there were 1.2 million adults and children living with HIV/AIDS in Kenya.[34] Of these, 1.1 million were adults between the ages of fifteen and forty-nine with an adult rate of 6.7%.[35] Adult women age fifteen to forty-nine accounted for 750,000 of the total number, while 100,000 of the people living with HIV/AIDS were children under the age of fifteen.[36] In the same year, an estimated 150,000 people (including adults and children) are said to have died of AIDS and 650,000 children under the age of seventeen lost one or two of their parents to AIDS in the country.[37]

In response to this health crisis, in July 1987, the Minister declared AIDS an NID under section 17(1) of the Public Health Act.[38] With such a declaration AIDS joined the ranks of other diseases already on the NID list. A disease can be added to this list in one of two ways: by legislative action or ministerial notice.

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[31] *Id.* § 11.

[32] *Id.* § 12.

[33] CENTER FOR REPRODUCTIVE RIGHTS, WOMEN OF THE WORLD: LAWS AND POLICIES AFFECTING THEIR REPRODUCTIVE LIVES. ANGLOPHONE AFRICA 11 (1997), http://reproductiverights.org/sites/crr.civicactions.net/files/documents/WOWAA01.pdf.

[34] UNAIDS/UNICEF/WHO, Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections: Kenya 2 (2004 update), available on the United Nations Program on HIV and AID (UNAIDS) website, *at* http://data.unaids.org/publications/Fact-Sheets01/kenya_en.pdf.

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] Notice of the Minister of Health (July 23, 1987) Gazette Notice, No. 3539, THE KENYA GAZETTE of July 31, 1987, at 110.

Diseases already listed as NIDs under the PHA are

> smallpox, plague, cholera, scarlatina or scarlet fever, typhus fever, diphtheria or membranous croup, measles, whooping-cough, erysipelas, puerperal fever (including septicaemia, pyaemia, septic pelvic cellulitis or other serious septic condition occurring during the puerperal state), enteric or typhoid fever (including para-typhoid fever), epidemic cerebro-spinal meningitis or cerebro-spinal fever, acute poliomyelitis, leprosy, anthrax, glanders, rabies, Malta fever, sleeping sickness or human trypanosomiasis, beri-beri, yaws and all forms of tuberculosis which are clinically recognizable apart from reaction to the tuberculin test.[39]

In addition, the PHA accords the Minister broad powers to list a disease as an NID, designate the geographic area to which the categorization will apply, and dictate the response to the disease.[40] In addition to the 1987 declaration of AIDS as an NID, the Minister has used this authority to add to the list of NID the following diseases:

- Influenza
- Relapsing fever
- Blackwater fever
- Encephalitis lethargica
- Yellow fever
- Kala-azar
- Malaria, microscopically diagnosed within the municipality of Kitale
- Bacillary dysentery and amoebic dysentery (within the municipality of Nairobi)
- SARS[41]

6. Prevention and Suppression of Infectious Disease

Declaration of a disease as an NID triggers reporting as well as prevention and suppression measures whenever the disease is detected or its presence suspected. A person who comes across a case of an NID is required to report it to the nearest medical practitioner.[42] A medical practitioner who comes across such a disease or is notified of its suspected presence is required to inform the nearest medical officer of health and to inform those who live in proximity to or looked after the patient of the infectious nature of the disease and the precautions they need to

[39] Public Health Act § 17.

[40] *Id*.

[41] *Id*.

[42] *Id*. § 18.

take in order to prevent it from spreading.[43] Failure to provide such notice as required by the PHA is an offense.[44]

In addition to the reporting requirements, the suspicion or detection of any infectious disease triggers the application of certain broad powers resembling those accorded to the executive for purposes of preservation of public security. For instance, a medical officer is authorized to search a premises or medically examine any person found there if "he has reason to believe" a person exposed to or suffering from an infectious disease is or was on the premises.[45] In addition, the medical officer may cause other actions to be taken, including

- having the premises exposed to infectious disease cleaned and disinfected;
- having a building, bedding, or other articles exposed to an infection destroyed;
- removing an infected person to a hospital; or
- putting an exposed person in isolation by an order of a magistrate.[46]

The PHA states that the health authority may bear certain cost associated with the suppression or prevention of an infectious disease, including compensating a person for destroyed property and paying for disinfecting premises or other articles.[47] The cost of isolating an infected person is born by the local authority where the person resides.[48]

The PHA criminalizes certain acts that spread infectious diseases. Any infected person who, without proper precautions, willfully exposes himself "in any street, public place, shop, inn or public conveyance, or enters any public conveyance without previously notifying the owner, conductor or driver thereof" commits an offense and is, on conviction, subject to a fine of up to KES 30,000 (about US$337) and/or up to a three-year prison term.[49] The same applies to a person tasked with caring for an infected person who exposes anyone to such person, and to a person who "gives, lends, sells, transmits or exposes" anything exposed to infection without first disinfecting the item.[50] In addition, failure to properly disinfect any mode of transportation or dwelling exposed to an infection before transporting or leasing it to other people is an offense.[51]

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[43] *Id*.

[44] *Id*.

[45] *Id*. § 21.

[46] *Id.* §§ 22, 23, 26 & 27.

[47] *Id*. §§ 23 & 24.

[48] *Id*. § 27.

[49] *Id.* § 28.

[50] *Id*.

[51] *Id*. §§ 29 & 30.

7. Formidable Epidemic, Endemic or Infectious Disease

A number of infectious diseases are categorized as formidable epidemic, endemic or infectious diseases (FEEIDs). These are smallpox, plague, Asiatic cholera, yellow fever; sleeping sickness, and human trypanosomiasis.[52] In addition, the Minister is authorized to declare any infectious disease an FEEID.[53]

Whenever any part of the country is under the threat of an FEEID, the Minister is authorized to issue rules on a variety of measures, including

- quarantining infected areas and preventing anyone from leaving the area without first going through the applicable precautionary measures put in place, including a medical examination, disinfection, or spending time in an observation camp/station;
- removing infected persons and anyone with whom they have been in contact;
- removing corpses; and
- destroying or disinfecting buildings and any other articles that may have been exposed to an FEEID.[54]

The Minister is also authorized to issue rules specifying which areas in the country or vessels within the country's territory are considered infected areas.[55]

In addition, the Director or his representatives are accorded broad powers to deal with FEEIDs. The PHA gives the Director or his representatives the power to enter any premises in order to enforce any rules the Minister issues for the purpose of dealing with an FEEID.[56] The Director also has the power to requisition land, equipment, or any other item for the purpose of dealing with an FEEID in return for reasonable compensation.[57]

The PHA imposes reporting and other requirements on residents and health authorities of a locality during an outbreak of an FEEID. Anyone aware of "any unusual sickness or mortality among rats, mice, cats, dogs, or other animals susceptible to plague" or another FEEID is required to report the matter to the closest medical officer of health; failure to do so is a crime.[58] The medical officer of health in any part of Kenya is bound by law to promptly report to the Director "every notification received" with regard to a suspected case of an FEEID.[59] In

[52] *Id*. § 35.

[53] *Id.*

[54] *Id.* § 36.

[55] *Id.*

[56] *Id*. § 38.

[57] *Id*. § 42.

[58] *Id.* § 40.

[59] *Id.* § 41.

addition, the local medical authority or the medical officer of health must do everything possible to mitigate the spread of an FEEID or execute rules made to suppress the FEEID.[60]

8. Ports and Borders

Unless it is in danger, the master or anyone on board a vessel arriving in Kenya is prohibited from communicating with the shore or other vessels or boats except via a signal until it is granted pratique.[61] When necessary, the Minister may apply this or any other requirement under the PHA to aircraft arriving in Kenya.[62] However, this restriction does not affect the right of any authorized person to approach or board the vessel or aircraft.[63] As a matter of procedure, pratique is granted to an arriving vessel or aircraft via radio communication if the appropriate health officer, based on the information provided by the vessel or aircraft is satisfied that clearing the vessel or aircraft will not result in the introduction of a quarantinable disease (plague, cholera, yellow fever, smallpox, typhus, and relapsing fever) into Kenya.[64] Notification requirements regarding the detection or suspicion of infectious disease discussed above are applicable to vessels or aircraft arriving in Kenya.

Kenyan health authorities are accorded broad powers in dealing with vessels seeking entry into the country. For instance, the port health officer is authorized to board a vessel, inspect any of its sections, and examine and/or ask any person on board any question for the purpose of establishing the existence of an infectious disease.[65] If the health officer suspects the existence of an infectious disease on board a vessel, he may grant conditional pratique or deny pratique and quarantine the vessel.[66] He may have any infected person on a ship, aircraft, vehicle, or train removed and isolated on arrival to Kenya.[67] He may also put anyone exposed to an infectious disease under surveillance and subject the person to medical testing.[68] In addition, he may require a person in charge of a vessel or aircraft suspected of carrying an infectious disease to provide a passenger and cargo manifest as well as a crew list.[69]

The Minister's authority includes regulating immigration into the country for the purpose of preventing the introduction of infectious diseases. Thus, he may issue an order to

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[60] *Id.* § 37.

[61] *Id.* § 58.

[62] *Id*. § 71.

[63] *Id*. § 58.

[64] *Id*. § 59; Public Health (Port, Airport, and Frontier Health) Rules, Public Health Act-Subsidiary Legislation, §§ 2 & 5.

[65] Public Health Act § 60.

[66] *Id.* § 62; Public Health (Port, Airport, and Frontier Health) Rule § 22.

[67] Public Health Act § 66; Public Health (Port, Airport, and Frontier Health) Rule § 7.

[68] Public Health Act § 68; Public Health (Port, Airport, and Frontier Health) Rule § 8.

[69] Public Health (Port, Airport, and Frontier Health) Rule § 14.

> prohibit, restrict or regulate the immigration or importation into Kenya of any person, animal, article or thing likely, in his opinion, to introduce any infectious disease, or impose restrictions or conditions as regards the examination, detention, disinfection or otherwise of any such animal, article or thing.[70]

In addition, the Minister is authorized to engage in foreign relations activities in which he is authorized to enter into agreements with other governments regarding reciprocal notification of outbreaks of any FEEID or any other matter relating to public health relations with other nations.[71]

IV. Transparency of the Public Health Management System

As noted above, the Department is mandated to collect and periodically publish information regarding infectious diseases and other matters of public health concern in Kenya, contagious countries, or any other part of the world.[72] In addition, categorization of a particular infectious disease as an NID via a ministerial order requires publication of a notice in the Gazette.[73] Any medical practitioner who becomes aware that a patient has an NID must inform those people who, due to their proximity to the patient, may have been exposed to the infection.[74] Similarly, the terms or summary of every agreement with another country concerning reciprocal notification of infectious disease outbreaks must be published in the Gazette.[75] In addition, Kenya is required to notify the WHO of any event in its territory that may constitute a public health emergency of international concern within twenty-four hours of detection (see discussion, Part V, below).

V. Cooperation with the World Health Organization

Kenya cooperates with the WHO a great deal with regard to matters relating to public health crises. As a member state to both the WHO and the International Health Regulations (IHR), Kenya is bound by the requirements under the 2005 IHR, an international legal instrument aimed at preventing the spread of disease.[76] Among other things, the IHR require that Kenya "develop, strengthen and maintain . . . the capacity to detect, assess, notify and report" outbreaks of infectious diseases.[77] Accordingly, Kenya has put in place systems for early detection through

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[70] Public Health Act § 63; *see also id*. § 71.

[71] Public Health Act § 72.

[72] *Id*. § 10.

[73] *Id*. § 17.

[74] *Id*. § 18.

[75] *Id.* § 72.

[76] WHO, INTERNATIONAL HEALTH REGULATIONS (2005): A BRIEF INTRODUCTION TO IMPLEMENTATION IN NATIONAL LEGISLATION 1 (Jan. 2009), http://www.who.int/ihr/Intro_legislative_implementation.pdf?ua=1; WHO, International Health Regulations (IHR) app. 1 (2d ed. 2005), http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf?ua=1; *Countries*, WHO, http://www.who.int/countries/en/ (last visited Oct. 24, 2014).

[77] IHR, *supra* note 76, § 5.

what is known as an Integrated Disease, Surveillance and Response Strategy (IDSR).[78] The objectives of this strategy are to

- Strengthen capacity for effective capacity[;]
- Improve use of surveillance information[; and]
- Improve laboratory involvement in epidemic detention.[79]

According to the WHO, the IDSR is "the backbone for communicable disease prevention and control in Kenya" and the WHO provides technical support in its development and expansion.[80] For instance, the WHO is currently assisting in the training of healthcare workers in Kenya in preparation for a possible Ebola outbreak (see discussion, Part VI, below).

Similarly, by simply being a member state of the WHO and IHR, Kenya has agreed to fulfill its obligation under the IHR to notify the WHO of any event that constitutes a public health emergency within twenty-four hours of assessment of such event.[81]

Significantly, the WHO-Kenya 2008–2013 cooperation strategy indicates that providing technical assistance in strengthening Kenya's ability for early detection, diagnosis, management, and control of communicable diseases, including strengthening the country's capacity to prevent and respond to major epidemics and pandemic-prone disease, is one of the main areas of cooperation.[82]

VI. Recent Developments

The Ebola outbreak in West Africa, specifically in Guinea, Liberia, and Sierra Leone, is the most recent public health crisis of global concern. Although Kenya is thousands of miles away from the Ebola-stricken countries in West Africa, in August 2014, the WHO classified the country as a high-risk country for Ebola transmission (level two) due to the fact that it is a transportation hub in East Africa.[83]

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[78] WHO, WHO COUNTRY COOPERATION STRATEGY 2008–2013: KENYA 9 (2009), http://www.who.int/countryfocus/cooperation_strategy/ccs_ken_en.pdf.

[79] Kenya National Council for Science and Technology, *Disease Surveillance and Response in Kenya*, available on the United Nations Office at Geneva (UNOG) website, *at* http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/BFC81C5C68522575C12576460049B118/$file/BWC_MSP_2009_MX-Poster-Kenya.pdf (last visited Oct. 24, 2014).

[80] WHO COUNTRY COOPERATION STRATEGY, *supra* note 78, at 24.

[81] IHR, *supra* note 76, art. 6.

[82] WHO COUNTRY COOPERATION STRATEGY, *supra* note 78, at 33.

[83] *WHO: Kenya at High Risk for Transmission of Ebola*, VOICE OF AMERICA (Aug. 12, 2014), http://www.voanews.com/content/germany-guinea-bissau-react-to-ebola-outbreak/2411822.html.

According to reports, Kenya has put in place a contingency plan (the Plan) to guide health institutions in the event of an Ebola outbreak following the WHO declaration.[84] The Plan, which is intended to serve as a roadmap for preparing and responding to an Ebola outbreak, calls for the establishment of a reference and response information center to "provide accurate information for health workers and the community, provide guidance on key actions to be taken during different phases of the outbreak, prepare clinicians for appropriate action, and identify and mobilise resources for response."[85] As part of the Plan, the Ministry of Health has put together a taskforce, including representatives from various, relevant governmental and nongovernmental organizations, to advise on how to respond to the outbreak.[86] The taskforce is currently coordinating and implementing surveillance through the screening of travelers at entry points, which has been intensified following the WHO declaration.[87]

The Plan also calls for training of various healthcare workers in dealing with an Ebola outbreak.[88] The Kenyan government recently announced plans to train thirty-thousand health care workers on Ebola screening, prevention, control, and case management.[89] This training will take place in all forty-seven counties in the country (it calls for counties to be involved in its implementation) and will target 60% of all health care workers in the country, including clinicians, epidemiologists, health promotion experts, and health workers stationed at airports and border crossings.[90] The government has allocated KES 350 million (about US$3.9 million) for the purpose of implementing the Plan,[91] a large percentage of which will likely be used for the training program. The WHO has deployed training experts to help facilitate the training.[92]

The Plan puts in place procedures for dealing with a person suspected of exposure to Ebola. Those procedures call for isolating persons exposed to Ebola, limiting the number of medical workers that have direct contact with the person, and reserving contiguous rooms for medical personnel to change into protective gear.[93]

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[84] *Action Plan over Ebola Risk*, HEALTH RIGHTS ADVOCACY FORUM (HERAF) (Aug. 21, 2014), http://www.heraf.or.ke/index.php?option=com_content&view=article&id=1352&catid=24?option=com_content&view=article&id=1352&catid=24.

[85] *Id.*

[86] *Id.*

[87] Press Release, WHO Regional Office for Africa, Kenya Steps Up its EBOLA Contingency Plan with Training of Trainers (Sept. 26, 2014), http://www.afro.who.int/fr/kenya/press-materials/item/7053-kenya-steps-up-its-ebola-contingency-plan-with-trainings-of-trainers/7053-kenya-steps-up-its-ebola-contingency-plan-with-trainings-of-trainers.html; *Kenya Intensifies Surveillance to Prevent Ebola Outbreak*, XINHUA (Oct. 24, 2014), http://news.xinhuanet.com/english/africa/2014-08/13/c_133553824.htm.

[88] Press Release, WHO Regional Office for Africa, *supra* note 87.

[89] *Kenya to Train 30,000 Health Workers on Ebola*, XINHUA (Oct. 23, 2014), http://news.xinhuanet.com/english/africa/2014-10/23/c_133735637.htm.

[90] Press Release, WHO Regional Office for Africa, *supra* note 87; HERAF, *supra* note 84.

[91] *Id.*

[92] Press Release, WHO Regional Office for Africa, *supra* note 87.

[93] HERAF, *supra* note 84.

In addition to putting a plan in place, Kenya has also suspended entry of passengers traveling from the three Ebola-stricken West African countries as of August 19, 2014, except for Kenyan citizens and health workers participating in the effort to curb the spread of Ebola.[94] Similarly, following reports of an Ebola-related death in Uganda's Bukwo district, Kenya recently closed the northwest region border crossings with Uganda.[95]

As of the date of this report, Kenya remained free of Ebola. Although there have been a number of cases in which Ebola infection was suspected, all were ruled out after testing.[96] In one of the cases, where the person suspected of having contracted Ebola arrived in an aircraft from West Africa, it appears that the protocols required under the PHA were properly followed. According to Nicolas Muraguri, the Director of Medical Services, the flight crew alerted Kenyan health authorities that one of the passengers was ill, as required by the PHA.[97] The health authorities immediately quarantined the aircraft and screened everyone on board, also in accordance with the provisions of the PHA,[98] and released everyone only after discovering that the suspected person was in fact suffering from other, noncommunicable ailments.[99]

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[94] *Flight Bans from Ebola-hit Countries Will Stay in Effect, Kenya Tells AU*, SABAHI (Sept. 17, 2014), http://sabahionline.com/en_GB/articles/hoa/articles/newsbriefs/2014/09/17/newsbrief-04; *Travel Restrictions, Flight Operations and Screening,* INTERNATIONAL SOS (Nov. 3, 2014), https://www.internationalsos.com/ebola/index.cfm?content_id=435&.

[95] *Kenya Closes Border with Uganda over Ebola Fear*, XINHUA (Oct. 11, 2014), http://news.xinhuanet.com/english/africa/2014-10/11/c_133706916.htm.

[96] *Kenya Rules Out Ebola After Two Tested Negative*, THE NEW INDIAN EXPRESS (Sept. 5, 2014), http://www.newindianexpress.com/world/Kenya-Rules-out-Ebola-After-Two-Tested-Negative/2014/09/05/article2415768.ece; *Kenya Rules Out Ebola Case Following Scare at Airport*, XINHUANET (Aug. 2, 2014), http://news.xinhuanet.com/english/health/2014-08/02/c_133525986.htm; Press Release, WHO Regional Office for Africa, *supra* note 87.

[97] XINHUANET, *supra* note 96; Public Health Act §§ 59 & 71; Public Health (Port, Airport, and Frontier Health) Rule § 5.

[98] Public Health Act § 62; Public Health (Port, Airport, and Frontier Health) Rule § 8.

[99] XINHUANET, *supra* note 96.

Lebanon

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SUMMARY In Lebanon the executive power is vested in a Council of Ministers, of which the Ministry of Public Health is the ultimate authority on matters related to responses to public health crises. The law provides that where such crises are so severe that the capabilities of the Ministry of Public Health are insufficient, that Ministry may seek assistance by proposing the issuance of a presidential decree that defines the assistance needed, the entities involved, and the measures to be taken by each. The Ministry has taken several measures to address the Ebola threat, and thus far has not seen a need to request a presidential decree.

I. Government Structure

Lebanon is a republic that has a centralized parliamentary form of government, with the executive power vested in a Council of Ministers.[1] The Ministry of Public Health is the ultimate authority in charge of all public health matters, including responses to public health crises. The main mission of the Ministry is to protect and improve the status of public health.[2] The Ministry defines its mission as follows:

> To Improve the health status of the population by ensuring an equitable accessibility to high quality health services through a fairly financed universal coverage. And by addressing economic and social determinants of health through trans-sectoral policies.[3]

II. Public Health Crises

Public health crises are generally associated with threats to the health of the population of a geographic area or areas caused by the spread of communicable diseases. Lebanon has enacted a special law, the Law of Communicable Diseases, to deal with these situations when they arise.[4] This law assigns certain duties and responsibilities relating to individual cases of communicable diseases and provides a general framework for the response needed to deal with any outbreak of such diseases that might endanger public health.

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[1] LEBANESE CONSTITUTION arts. 1, 17, http://www.lp.gov.lb/CustomPage.aspx?id=26&masterId=1 (in Arabic).

[2] Presidential Decree 8377 of 1961, art 2, http://www.moph.gov.lb/Rules%20and%20Regulations/Marsoum8377-1961.pdf (in Arabic).

[3] MINISTRY OF PUBLIC HEALTH, http://www.moph.gov.lb/AboutUs/pages/missionandvision.aspx (last visited Nov. 5, 2014).

[4] Law of Communicable Diseases, Dec. 31, 1957, http://ar.jurispedia.org/index.php/%D9%82%D8%A7%D9%86%D9%88%D9%86_%D8%A7%D9%84%D8%A3%D9%85%D8%B1%D8%A7%D8%B6_%D8%A7%D9%84%D9%85%D8%B9%D8%AF%D9%8A%D8%A9_(lb) (in Arabic).

Article 3 of the law provides for combatting communicable diseases by one or more of the following means: reporting or informing about the disease, quarantining or isolating those infected, isolating those who came in contact with those affected and providing them with preventive treatment, disinfection, investigating the source of the disease, making environmental adjustments, and providing general health education.[5]

Treating physicians are required by the law to convey information on cases of listed communicable diseases to the authority designated by an order of the Minister of Public Health.[6]

Family heads, guardians, the *Mukhtar* (an elected local official), and managers of industrial or commercial enterprises (such as a plant, hotel, etc.) and of any public or private organization involved in health or social matters are required to call a physician whenever they suspect they have someone who might be affected by a communicable disease, report the incident, facilitate the reporting of it by the physician, and not hide the incident.[7]

The law gives the Minister of Public Health the power pursuant to a recommendation by the Director General of the Ministry to modify the list of the diseases considered contagious or communicable and for which those affected shall be quarantined.[8]

The law empowers the Ministry at any time to enter and search any place that might be suspected of harboring a case of communicable disease.[9]

All the other means mentioned in article three shall be implemented in accordance with orders of the Minister of Public Health issued separately for each contagious disease.[10]

The measures listed in article three employed in accordance with such orders can be used by the Ministry of Public Health to respond to public health crises. But there are instances where that Ministry might also need outside assistance to deal with a crisis when the spread or the threat of spreading of a contagious disease among the population is overwhelming. To address such instances, the law establishes a general framework for the Ministry to seek needed assistance by proposing a plan to be adopted by a presidential decree. The law specifically provides the following:

> If an epidemic disease threatened all or a part of the territories of the Republic or started to spread within such territories without the local measures being sufficient [to deal with it] the Ministry of Health shall ask for a presidential decree to be issued which shall designate the measures that shall be taken to prevent the spread of the epidemic.[11]

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[5] *Id*. art. 3.

[6] *Id*. art. 4.

[7] *Id*. art. 5.

[8] *Id*. art. 11.

[9] *Id*. art. 12.

[10] *Id*. arts. 6, 7, 8.

[11] *Id*. art. 9.

Such a decree shall designate the role of each authority and body which have been appointed to deal with the crisis, along with the manner by which they are to be established, the limitations on their authority, and the time accorded to them to carry out their duties. The funding cost of such plans shall be borne by the central government paying three-fourths of the cost and the municipalities paying the remaining one-fourth.[12]

It is clear from the foregoing that while the legislature in Lebanon has provided a legal framework to create plans to respond to public health crises, the actual creation of such plans and their attendant details is left to the executive branch of government, to be decided on a crisis-by-crisis basis.

III. The Ebola Threat

Lebanon recognizes the threat caused by the Ebola outbreak in certain foreign countries. The Ministry of Public Health has taken a number of measures to prevent the disease from entering the country, and apparently feels capable to deal with the situation without devising a special plan requiring the issuance of a presidential decree. Among the measures taken by the Ministry of Public Health in this regard are the following:

- Disseminating information about the history, symptoms, and how to avoid contracting the disease. The sources of most of this information are the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (CDC).[13]

- Requiring hospitals in Lebanon to create special units equipped to deal with Ebola cases.[14]

- Requiring all passengers entering the country to fill specially designed cards that allow the Ministry to monitor individual situations and take necessary measures when such measures are warranted.[15]

- Requiring the Airport Authority to advise airlines on how to deal with suspected cases of Ebola on planes.[16]

The Ministry has also decided to assist Lebanese citizens living abroad who might have contracted the Ebola virus or any other communicable disease by providing them with

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[12] *Id*.

[13] This information is posted on the Ministry website and can be accessed individually, *at* http://www.moph.gov.lb/Prevention/Pages/EbolaOutbreak.aspx (last visited Nov. 5, 2014).

[14] Letter of the Minister of Public Health No. 33150/1/14 (Oct. 23, 2014), http://www.moph.gov.lb/Prevention/Documents/2014-1-33150.pdf; Letter of the General Director of the Ministry of Public Health No. 31703/1/14 (Oct. 13, 2014), http://www.moph.gov.lb/Prevention/Documents/Letter14-1-31703.pdf.

[15] Letter of the Minister of Public Health No. 33153/1/14 (Oct. 23, 2014), http://www.moph.gov.lb/Prevention/Documents/2014-1-33153.pdf; Letter of the Minister of Public Health No. 33148/1/14 (Oct. 23, 2014), http://www.moph.gov.lb/Prevention/Documents/2014-1-33148.pdf.

[16] Letter of the Minister of Public Health (July 31, 2014), http://www.moph.gov.lb/Prevention/Documents/Procedures.pdf.

hospitalization and lab exams if they decide to repatriate, on the condition that they inform the Lebanese Embassy in the relevant country in advance.[17]

[17] Letter of the General Director of the Ministry of Public Health No. 24740/1/14 (Aug. 13, 2014), http://www.moph.gov.lb/Prevention/Documents/2014-1-24740.pdf.

Mexico

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SUMMARY Mexico's system for managing public health emergencies is mainly administered by the nation's General Health Council (GHC) and the federal Department of Health (DOH). The GHC has the authority to issue orders that classify communicable diseases that may cause a health emergency as serious threats and subject them to epidemiological monitoring, prevention, and control mechanisms. The DOH has the responsibility to monitor serious communicable diseases listed by law, as well as diseases classified as serious threats by the GHC, to detect and control outbreaks. In cases of actual or potential grave outbreaks of communicable diseases, the DOH has the power to order immediate and appropriate measures to prevent and contain damages to public health, with approval from Mexico's President. Furthermore, the DOH must notify to the World Health Organization of all measures taken in order to address matters related to international health and of any incidence of diseases that may cause an outbreak. Mexico recently signed a Declaration of Intent with the US and Canada on how these countries will exchange public information in times of a health emergency of common interest.

I. Structure of Public Health Crisis Management System

Mexico is a federal republic formed by thirty-one states and a Federal District. Mexico's system for managing public health emergencies is primarily managed by the nation's General Health Council (GHC) and federal Department of Health (DOH), with support from state governments.

The GHC reports directly to Mexico's President and has broad powers on health matters of national importance, including the authority to issue orders that classify communicable diseases that may cause a health emergency as serious threats and subject them to epidemiological monitoring, prevention, and control mechanisms.[1]

The GHC is headed by the Secretary of the DOH, and is comprised of high-ranking government officials (including secretaries and executives from federal and state government departments) and executives from private health institutions, nongovermental organizations, and industry associations.[2]

The DOH has responsibility for establishing and operating the National System for Epidemiological Surveillance (Sistema Nacional de Vigilancia Epidemiológica, SINAVE),

[1] Reglamento Interior del Consejo de Salubridad General [Regulation of the General Health Council] arts. 1, 9(XVII), DIARIO OFICIAL DE LA FEDERACIÓN [D.O.], Dec. 11, 2009. *See also* Consejo de Salubridad General, Acuerdo mediante el cual se determina que la enfermedad transmisible por el virus del Ébola, debe estar sujeta a vigilancia epidemiológica, prevención y control en términos de lo dispuesto por el artículo 134, fracción XIV, de la Ley General de Salud [Order that Determines that the Ebola Virus Must Be Subject to Epidemiological Surveillance, as well as to Prevention and Control Measures], D.O., Oct. 23, 2014.

[2] Reglamento Interior del Consejo de Salubridad General, *supra* note 1, arts. 3, 4.

which monitors serious communicable diseases listed by law, as well as diseases classified as serious threats by the GHC, in order to detect and control outbreaks.[3]

SINAVE is comprised of an extensive national network of health surveillance units (over 20,000 as of May 2014) operating in all public and private health institutions, which monitor and report relevant information on health developments to a central unit managed by DOH's Directorate of Epidemiology (DOE).[4]

The DOE processes this information and prepares reports and health alerts as necessary, which are used to plan and implement appropriate responses.[5]

II. Powers of Public Health Authorities

A. Powers to Control Communicable Diseases

Mexico's General Law on Health provides that certain communicable diseases listed in the law (such as epidemic influenza, viral hepatitis, and AIDS), as well as diseases classified as serious threats by the GHC (such as the Ebola virus, as explained in Part V of this report), are subject to prevention and control measures executed by the DOH and state governments in their respective jurisdictions, with support from other federal government agencies and private health institutions and individuals.[6]

Outbreaks of these diseases must be notified immediately to the DOH, which has at its disposal a number of powers to monitor and control such outbreaks, including

- confirmation of the disease by available clinical means;
- temporary isolation of sick individuals, as well as those who are expected to become sick;
- administration of vaccines and other preventive and therapeutic resources;
- decontamination of areas, living quarters, clothing, utensils, and other objects exposed to viral, parasitic, or microbial contamination;
- inspection of travelers suspected of being infected, as well as their luggage and other belongings that may be contaminated;

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[3] Ley General de Salud [General Law of Health], *as amended through* June 2014, arts. 133(II), 134, D.O., Feb. 7, 1984, available on the website of Mexico's House of Representatives, *at* http://www.diputados.gob.mx/LeyesBiblio/pdf/142_040614.pdf.

[4] *Información Epidemiologica* [*Epidemiological Information*], SECRETARÍA DE SALUD, DIRECCION GENERAL DE EPIDEMIOLOGIA [DEPARTMENT OF HEALTH, DIRECTORATE OF EPIDEMIOLOGY], http://www.epidemiologia.salud.gob.mx/dgae/infoepid/intd_informacion.html (last updated May 2014). *See also* Norma Oficial Mexicana NOM-017-SSA2-2012, Para la vigilancia epidemiológica [Mexican Health Standard NOM-017-SSA2-2012, for Epidemiological Surveillance], D.O., Feb. 19, 2013.

[5] *Id*.

[6] Ley General de Salud arts. 134, 137, 138, 139, 140, 141. *See also* Acuerdo mediante el cual se determina que la enfermedad transmisible por el virus del Ébola, *supra* note 1.

- temporary closure of establishments or gathering locations of any kind; and
- requesting appropriate support from civilian and military authorities, as well as from private individuals, as needed.[7]

B. Department of Health Powers in Health Emergencies

In cases of actual or potential grave outbreaks of communicable diseases, the DOH has the power to order immediate and appropriate measures to prevent and contain damage to public health, including

- issuing sanitary measures governing departures and arrivals of individuals from population centers;
- regulating ground, maritime, and air traffic;
- instructing federal, state, and local authorities and health professionals to support emergency measures, and requiring cooperation from private entities and individuals as necessary;
- using, freely and with priority, radio and television air time, as well as telephone, mail, and telegraphic services.[8]

These urgent measures must ratified by Mexico's President thereafter.[9] In addition, the President may issue an executive order indicating the specific regions that are subject to emergency measures to protect public health.[10] When the health emergency is controlled, the President must order the end of the emergency measures.[11]

III. Transparency of Public Health Crisis Management System

Pursuant to applicable regulations, information generated by Mexico's DOH through the National System for Epidemiological Surveillance (which, as explained above, monitors developments concerning communicable diseases) must be disseminated through reports available electronically and in print in a way that facilitates accessibility to the data contained therein.[12] Consistent with this requirement, a wide variety of data concerning events related to communicable diseases is publicly available on the website of the DOH's Directorate of Epidemiology.[13]

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[7] Ley General de Salud arts. 139, 147, 151, 152.

[8] *Id.* arts. 181, 184.

[9] *Id.* art. 181.

[10] *Id.* art. 183.

[11] *Id*.

[12] SECRETARÍA DE SALUD, DIRECCION GENERAL DE EPIDEMIOLOGIA, *supra* note 4. *See also* Norma Oficial Mexicana NOM-017-SSA2-2012, *supra* note 4, § 10.

[13] SECRETARÍA DE SALUD, DIRECCION GENERAL DE EPIDEMIOLOGIA, *supra* note 4.

With respect to recent measures adopted by the Mexican government concerning the Ebola virus, the DOH provides comprehensive information on this topic on a website that includes general information for citizens and technical information for experts.[14]

At the international level, Mexico recently signed a Declaration of Intent with the United States and Canada that provides principles and guidelines concerning how these countries will exchange public information in the event of a health emergency of common interest.[15] Specifically, the Declaration provides that these countries intend to share with each other plans and statements concerning health emergencies prior to their release to the public.[16]

IV. Cooperation with the WHO

Mexico is signatory to the 2005 International Health Regulations (IHR), which are aimed at helping the international community respond to and prevent severe global public health risks, and provide that signatory countries must report to the World Health Organization (WHO) information concerning certain public health events and outbreaks.[17]

Consistent with the IHR, Mexico's General Law on Health provides that the DOH must notify the WHO about all measures taken in order to address matters related to international health (particularly measures aimed at restricting the transit of persons or cargo due to sanitary reasons), and must also provide information on any case of diseases listed in the IHR that may cause an outbreak.[18]

V. Recent Developments

As of mid-November 2014, no cases of individuals infected with the Ebola virus have been reported in Mexico. However, the Mexican government recently issued guidelines applicable to the treatment of this disease. Specifically, on October 23, 2014, Mexico's GHC issued a directive indicating that the Ebola virus is a matter of public health that may cause a health

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[14] *Todo Sobre el ébola*, SECRETARÍA DE SALUD, http://todosobreelebola.com/ (last visited Nov. 10, 2014).

[15] Press Release, U.S. Department of Health and Human Services (HHS), United States, Canada and Mexico Strengthen Information Sharing in Health Emergencies (May 20, 2014), http://www.hhs.gov/news/press/2014pres/05/20140520a.html; Declaration of Intent to Coordinate Health Emergency Public Communications Between the Department of Health and Human Services of the United States of America, the Public Health Agency of Canada, and the Secretariat of Health of the United Mexican States (May 20, 2014), *available at* http://www.hhs.gov/news/press/2014pres/05/wha-declaration-us-canada-mexico-en.pdf. *See also* Gustavo Guerra, *Mexico; United States; Canada: Agreement on Health Emergencies*, GLOBAL LEGAL MONITOR (July 2, 2014), http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205404053_text.

[16] Press Release, HHS, *supra* note 15; Declaration of Intent to Coordinate Health Emergency Public Communications, *supra* note 15; *see also* Guerra, *supra* note 15.

[17] Norma Oficial Mexicana NOM-017-SSA2-2012, *supra* note 4; WHO, International Health Regulations (2d ed. 2005), http://www.who.int/ihr/publications/9789241596664/en/.

[18] Ley General de Salud art. 359. *See also* Reglamento de la Ley General de Salud en Materia de Sanidad Internacional [Regulation of General Law on Health on International Health] art. 14, D.O., Feb. 18, 1985.

emergency and as a result ordered that this virus must be subject to epidemiological surveillance, as well as to preventive measures.[19]

On October 24, 2014, Mexico's DOH issued a set of measures aimed at controlling health risks caused by the Ebola virus.[20] Those measures include

- confirmation of infections caused by the Ebola virus through lab tests administered by the DOH;
- provision of medical treatment through available means;
- destruction of clothing and equipment utilized by personnel that transport and provide care to infected individuals and those who are suspected of infection;
- requesting support from federal, state, and local authorities, as well as from health professionals, as needed;
- appropriate disposal of human remains of infected individuals, in order to prevent contagion;
- decontamination and sanitization of areas and living quarters exposed to the Ebola virus;
- authority to utilize, freely and with priority, radio and television air time, as well as telephone, mail, and telegraphic services, in order to disseminate guidelines concerning the prevention and control of health risks caused by the Ebola virus;
- authority to regulate ground, maritime, and air traffic;
- authority to request necessary support from international organizations;
- authority to locate and order the quarantine or observation of healthy individuals who have had contact with individuals infected with the Ebola virus;
- acquisition from national or international sources of medical equipment, diagnostic tools, surgical and medical supplies, and any other type of supplies and services necessary to implement measures aimed at controlling health risks caused by the Ebola virus; and
- authority to build and remodel health facilities as necessary.[21]

On October 24, 2014, Mexico's President issued an executive order ratifying these measures.[22]

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[19] Acuerdo mediante el cual se determina que la enfermedad transmisible por el virus del Ébola, *supra* note 1.

[20] Secretaria de Salud, Acuerdo por el que se establecen las medidas preventivas que se deberán implementar para la vigilancia epidemiológica, prevención, control y combate de los riesgos para la salud que implica la Enfermedad por el Virus del Ébola [Order Issued by the DOH Establishing Preventive Measures that Must Be Implemented for the Epidemiological Surveillance, Prevention, Control and Combat of Health Risks of the Disease Caused by the Ebola Virus], D.O., Oct. 24, 2014.

[21] *Id*.

[22] Decreto por el que se Sanciona el Acuerdo por el que se establecen las medidas preventivas que se deberán implementar para la vigilancia epidemiológica, prevención, control y combate de los riesgos para la salud que implica la Enfermedad por el Virus del Ébola [Decree Whereby Mexico's President Ratifies the Order Issued by the DOH Establishing Preventive Measures that Must Be Implemented for the Epidemiological Surveillance, Prevention, Control and Combat to Health Risks of the Disease Caused by the Ebola Virus], D.O., Oct. 24, 2014.

Nigeria

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SUMMARY The legal authority of the Nigerian federal government to take extraordinary measures during public health crises is based on the emergency powers of the president and the legislature under the 1999 Constitution and the authority accorded to the executive body, specifically the health authorities, under the 1926 Quarantine Act. The Quarantine Act gives the president and the country's health authorities broad powers to deal with public health crises. The President is authorized, among other things, to declare any infectious disease a dangerous infectious disease, declare any area in or outside of Nigeria an infected area, and issue regulations to prevent the spread of any dangerous infectious disease. It appears that the power to issue regulations has been exercised only once, with the issuing of the Quarantine (Ships) Regulations, which authorize or require port health officers to take a host of measures to prevent the importation into and spread of infectious diseases within Nigeria.

A bill (SB 210) aimed at replacing the Quarantine Act is currently being considered by the upper chamber of Nigeria's legislature. Among other things, SB 210 seeks to streamline the public health response by establishing a commission that will prepare a plan for prevention and containment of public health emergencies, including ensuring that all tiers of government are duly prepared for such events. It also seeks to introduce transparency in the way that the Nigerian government handles public health crises by requiring the constant dissemination of a specific set of information to the public. In addition, it aims to provide certain protections to persons subjected to isolation or quarantine.

Nigeria's ability to effectively deal with public health crises was tested with a recent outbreak of Ebola in Lagos and Port Harcourt. Nigeria immediately mobilized the relevant government institutions and allocated the necessary funds to take prevention and suppression measures, particularly to conduct wide contact-tracing investigations. This and other factors enabled the country to contain the outbreak quickly with only nineteen infections and seven deaths. As of the date of this report, Nigeria was Ebola free.

I. Government Structure

Nigeria, with an estimated population of over 168 million and a population density of 182.8 people per square mile, is by far the most populous country in Africa.[1] A federation, Nigeria has a three-tiered government structure including the federal government, thirty-six states[2] and a federal capital (Abuja), as well as 768 local government areas within the states.[3]

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[1] *Nigeria*, UNITED NATIONS DATA, https://data.un.org/CountryProfile.aspx?crName=NIGERIA (last visited Oct. 28, 2014).

[2] These are: Abia, Adamawa, Akwa Ibom, Anambra, Bauchi, Bayelsa, Benue, Borno, Cross River, Delta, Ebonyi, Edo, Ekiti, Enugu, Gombe, Imo, Jigawa, Kaduna, Kano, Katsina, Kebbi, Kogi, Kwara, Lagos, Nasarawa, Niger, Ogun, Ondo, Osun, Oyo, Plateau, Rivers, Sokoto, Taraba, Yobe, and Zamfara. CONSTITUTION OF NIGERIA (1999),

Legislative power at the federal level is vested in a bicameral legislative body with a 360-member House of Representatives and a 109-member Senate.[4] At the state level, this power is vested in house assemblies whose seats range from twenty-four to forty members depending on the population of a particular state.[5]

The federal executive power is vested in the president, vice-president, and members of the cabinet, whereas at the state level the same power is exercised by the governor, deputy governor, and commissioners of the government of the state.[6]

The judiciary consists of constitutionally formed courts and other courts. The Nigerian Constitution established what are known as the superior courts of record: the Supreme Court of Nigeria, the Court of Appeal, the Federal High Court, the High Court of the Federal Capital Territory (Abuja), the Sharia Court of Appeal of the Federal Capital Territory, the Customary Court of Appeal of the Federal Capital Territory, a High Court of a State, a Sharia Court of Appeal of a State, and a Customary Court of Appeal of a State.[7] The Constitution permits the federal and state legislatures to establish additional, subordinate courts.[8]

This report focuses on the powers of the federal government in times of public health crises. However, it is important to note that state and local governments do play a key role in matters of public health crisis management. This is particularly true with regard to the issues of disease surveillance and notification systems. Nigeria's National Policy on Integrated Disease Surveillance and Response (ISDR) states that the country's surveillance structure involves the active participation of the three tiers of government and assigns each a specific role in the process of identifying and reporting epidemic-prone diseases (including cholera, meningitis, viral hemorrhagic fevers, and human influenza) and notifiable diseases.[9] For instance, it requires local and state governments to report data collected on epidemic-prone diseases on a weekly basis.[10]

II. Applicable Law

Two sources of legal authority authorize the federal government to take preventative and suppression measures in anticipation of, or during, a public health crisis. The Constitution, which empowers the president to declare a public emergency and curtail certain individual rights

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§ 3(1), available on the International Centre for Nigerian Law (ICFNL), *at* http://www.nigeria-law.org/ConstitutionOfTheFederalRepublicOfNigeria.htm.

[3] *Id*.

[4] *Id*. §§ 4, 47, 48 & 49.

[5] *Id*. §§ 4, 90 & 91.

[6] *Id*. § 5.

[7] *Id*. § 6.

[8] *Id*.

[9] FEDERAL MINISTRY OF HEALTH, NATIONAL POLICY ON INTEGRATED DISEASE SURVEILLANCE AND RESPONSE (IDSR) 3, 5, 13 & 14 (Dec. 2010), http://www.fmh.gov.ng/images/PolicyDoc/FMOH_IDSR_Policy.pdf.

[10] *Id*. at 13, 17 & 27.

(including the right to personal liberty and property) is one source of authority (see discussion, Part III, below). The second is the statutory regime. The 1926 federal Quarantine Act, which remains in force today, is the primary law governing matters concerning public health crises in Nigeria.[11] It is based on the exclusive legislative jurisdiction accorded to the federal government under the Constitution on issues of "quarantine" and "[a]ny matter incidental or supplementary" to it.[12]

The current statutory legal regime is likely to change soon. The upper chamber of the country's legislative body is currently considering a bill, the Nigerian Public Health Bill (SB 210), aimed at replacing the Quarantine Act (see discussion, Part VI, below).[13] SB 210, having passed first and second readings in the Chamber on October 2012 and April 2013, respectively, was referred to the Health and Agriculture Committee.[14] Before it can become law, the bill will need to pass a third reading in the Senate, be passed by the House of Representatives, and be signed by the country's President.[15]

III. Powers of National Public Authorities

A. Constitutional Powers

1. Executive Powers

The President is authorized to unilaterally or at the request of a state governor declare a state of emergency in certain instances, including when

> . . .
>
> (c) there is actual breakdown of public order and public safety in the Federation or any part thereof to such extent as to require extraordinary measures to restore peace and security;
>
> (d) there is a clear and present danger of an actual breakdown of public order and public safety in the Federation or any part thereof requiring extraordinary measures to avert such danger;

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[11] Quarantine Act of 1926, 14 LAWS OF THE FEDERATION OF NIGERIA, Cap. Q2 (rev. ed. 2004), available on the Policy and Legal Advocacy Centre (PLAC) website, *at* http://www.placng.org/new/laws/Q2.pdf. *See also* Oluchi Aniaka, *Law and Ethics of Ebola Outbreak in Nigeria* 2 (Canadian Institute of Health Research, Aug. 8, 2014), available on the Social Science Research Network, *at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2477856 (access restricted).

[12] Quarantine Act of 1926 § 4.

[13] Bill for an Act to Establish the Nigeria Public Health (Quarantine, Isolation and Emergency Health Matters Procedure) Act . . . (Public Health Bill) (2013), available on the Nigerian Senate website, *at* http://www.nassnig.org/nass/legislation.php?id=1316.

[14] *Senate Bill Charts*, POLICY AND LEGAL ADVOCACY CENTRE (PLAC), http://www.placng.org/new/senate-bills-charts.php?page=6 (last visited Oct. 29, 2014).

[15] CONSTITUTION OF NIGERIA § 58; Senate Standing Orders 2007 as Amended § 86, available on Senator Ayo Arise's website, *at* http://www.senatorarise.com/senaterules.html (click on upper-left link to Constitution).

> (e) there is an occurrence or imminent danger, or the occurrence of any disaster or natural calamity, affecting the community or a section of the community in the Federation; [or]
>
> (f) there is any other public danger which clearly constitutes a threat to the existence of the Federation . . . .[16]

The declaration of a state of emergency must be published in the country's Official Gazette, and the President is required to immediately notify the Speaker of the House Representatives and the President of the Senate.[17] Once in place, a state of emergency can be terminated

- if the President revokes it;
- if it is not subsequently endorsed by the federal legislature within two days of its declaration when the legislature is in session or within ten days otherwise;
- after six months of its declaration, but the legislature may extend it for another six-month term; or
- if the legislature, having initially endorsed or extended the declaration, at any time revokes it by a vote of a simple majority in both houses.[18]

The consequences of declaring a state of emergency may take one of two forms. First, the country's legislature may adopt laws that curtail certain fundamental rights guaranteed under the Constitution (see discussion, Part III(A)(2), below). It may also allow the executive to take certain actions that restrict such constitutional rights. For instance, the Constitution appears to permit the executive to temporarily suspend the constitutional protection against forced or compulsory labor "in the event of any emergency or calamity threatening the life or well-being of the community."[19] It is conceivable that this authority could be used to ensure that hospitals and health centers are properly staffed during an outbreak of a deadly infectious disease like Ebola.

President Goodluck Jonathan recently exercised his authority to declare the control and containment of the Ebola virus a national emergency, following the confirmation of seven infections in the country.[20] President Jonathan directed all relevant federal and state authorities to work in concert to make sure that all necessary steps were taken to suppress the spread of Ebola.[21] In addition, he approved a Special Intervention Plan and the immediate release of NGN 1.9 billion (about US$11.5 million) to fight the virus, fast-tracking the disbursement of funds for

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[16] CONSTITUTION OF NIGERIA § 305.

[17] *Id*.

[18] *Id*.

[19] *Id*. § 34.

[20] *Nigeria's Jonathan Declares State of Emergency over Ebola*, REUTERS (Aug. 8, 2014), http://www.reuters.com/article/2014/08/08/us-health-ebola-nigeria-jonathan-idUSKBN0G81WB20140808; *Ebola: Jonathan Declares National Emergency, Approves N2BN Special Intervention Fund*, EMBASSY OF NIGERIA, SEOUL SOUTH KOREA (Aug. 21, 2014), http://www.nigerianembassy.or.kr/ebola-jonathan-declares-national-emergency-approves-n2bn-special-intervention-fund-2/.

[21] EMBASSY OF NIGERIA, SEOUL SOUTH KOREA, *supra* note 20.

Ebola containment efforts.[22] However, no information was located indicating that this authority was used to curtail any constitutionally guaranteed rights.

2. Legislative Powers

As noted above, the declaration of a state of emergency permits the legislature to pass laws that may otherwise be unconstitutional. The Constitution permits the adoption of a law limiting certain constitutionally guaranteed fundamental rights if it is "reasonably justifiable" and done "in the interest of . . . public health."[23] Such a law may impose limitations on the right to privacy; the right to freedom of thought, conscience, and religion; the right to freedom of expression and the press; the right to peaceful assembly and association; and the right to freedom of movement.[24]

Similarly, the Constitution allows the adoption of a law for the compulsory acquisition of movable or immovable property "that is in a dangerous state or is injurious to the health of human beings."[25] In addition, the Constitution permits the adoption of a law imposing restrictions on a person's personal liberty if the person is "suffering from infectious or contagious disease . . . [,] for the purpose of [the person's] care or treatment or the protection of the community."[26]

These constitutional provisions provide the authority for the imposition of statutory limitations on rights otherwise protected under the Constitution during public health crises. This justifies the restrictions imposed on any of the above-stipulated, constitutionally guaranteed rights by the current statutory regime, the Quarantine Act, or any other similar law that may be enacted in the future.

B. Statutory Regime

1. General Provisions

As noted above, the Quarantine Act (the Act) is the primary law governing the prevention and suppression of dangerous infectious diseases. The Act states that it is intended to regulate "the imposition of quarantine and to make other provisions for preventing the introduction into and spread in Nigeria, and the transmission from Nigeria, of dangerous infectious diseases."[27] This includes "cholera, plague, yellow fever, smallpox and typhus."[28] In addition, the Act authorizes the President to declare any infectious or contagious disease as a dangerous infectious disease, an

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[22] *Id.*

[23] CONSTITUTION OF NIGERIA § 45(1)(a).

[24] *Id*.

[25] *Id*. § 44(2)(f).

[26] *Id*. § 35(1)(e).

[27] Quarantine Act of 1926, pmbl., 14 LAWS OF THE FEDERATION OF NIGERIA, Cap. Q2 (rev. ed. 2004), *available at* http://www.placng.org/new/laws/Q2.pdf.

[28] *Id*. § 2.

authority apparently used at least once in the past to categorize sleeping sickness as a dangerous infectious disease.[29] Similarly, the Act authorizes the President to declare any place in or outside of Nigeria to be an infected local area.[30]

The Act further authorizes the President to issue regulations for the purpose of preventing or suppressing a dangerous infectious disease in an infected local area, any other area in Nigeria, or any area outside of Nigeria, stating as follows:

> The President may make regulations for all or any of the following purposes –
>
> (a) prescribing the steps to be taken within Nigeria upon any place, whether within or without Nigeria, being declared to be an infected local area;
> (b) prescribing the introduction of any dangerous infectious disease into Nigeria or any part thereof from any place without Nigeria, whether such place is an infected local area or not;
> (c) preventing the spread of any dangerous infectious disease from any place within Nigeria, whether an infected local area or not, to any other place within Nigeria;
> (d) preventing the transmission of any dangerous infectious disease from Nigeria or from any place within Nigeria, whether an infected local area or not, to any place without Nigeria;
> (e) prescribing the powers and duties of such officers as may be charged with carrying out such regulations;
> (f) fixing the fees and charges to be paid for any matter or thing to be done under such regulations, and prescribing the persons by whom such fees and charges shall be paid, and the persons by whom the expenses of carrying out any such regulations shall be borne, and the persons from whom any such expenses incurred by the Government may be recovered;
> (g) generally for carrying out the purposes and provisions of this Act.[31]

State governors are accorded the same powers as the President to categorize diseases as dangerous infectious diseases, declare a particular location an infected local area, or issue regulations for any of the above-stipulated purposes in the absence of presidential action on a particular matter.[32]

Only one set of regulations, the Quarantine (Ships) Regulations have been issued under this authority to date at the national level.[33] No relevant document issued at the state level was located.

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[29] *Id.*; Subsidiary Legislation, Declaration of Dangerous Infectious Disease, *available at* http://www.placng.org/new/laws/Q2.pdf (scroll to "Subsidiary Legislation," page 3).

[30] Quarantine Act of 1926 § 2.

[31] *Id.* § 4.

[32] *Id.* § 8.

[33] Aniaka, *supra* note 11, at 11.

2. *Quarantine of Ships*

The Quarantine (Ships) Regulations authorize a port health officer to take a number of measures for the purpose of prevention and suppression of infectious diseases. Whenever a person in a ship[34] approaching Nigeria is suffering from an infectious disease or there is suspicion of the presence of an infectious disease onboard, the master must contact the port health authority and provide a specific list of information necessary for the officer to determine, among others, the gravity and origin of an infection, if any.[35] The officer may clear the ship to proceed to its intended destination if, on the basis of the information provided by the master, he is satisfied that the arrival of the ship will not result in the spread of an infectious disease.[36] Until and unless the ship is given clearance, no one may board or leave the ship without the permission of the officer except the pilot.[37]

While the port health officer is authorized to inspect any ship already in the port or on arrival, he is required to inspect all ships that contacted the port health authority about the possible presence of an infectious disease onboard or any other ship present that he has reasonable grounds to believe is carrying a "quarantinable disease."[38] The master of the ship is required to fully cooperate with the officer, including by answering all questions regarding health conditions on board the ship and notifying him of anything that may lead to an infection or the spread of a quarantinable disease.[39]

A ship, which before its arrival had called at a foreign port, is subject to additional requirements. Such ship must submit what is known as the maritime declaration of health (MDH), in a form specified by World Health Organization (WHO) Regulation No. 2, which must be countersigned by the ship's surgeon if it has one.[40] The form requires the listing of all ports of call and contains a number of questions including whether, during the voyage, there were suspected cases of an infectious disease or nonaccidental death.[41] In addition to completing the MDH, the master must submit a Deratting Certificate or Deratting Exemption Certificate, issued under the International Sanitation Regulations.[42] Failure to produce either certificate leads to an inspection by the port health officer.[43]

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[34] A ship includes any "sea-going or . . . inland navigation vessel making an international voyage." Quarantine (Ships) Regulations § 2, Quarantine Act–Subsidiary Legislation.

[35] Quarantine (Ships) Regulations § 10, Quarantine Act–Subsidiary Legislation.

[36] *Id*. § 9.

[37] *Id*. § 14.

[38] *Id*. § 3. A quarantinable disease includes "cholera, plague, relapsing fever, smallpox, typhus or yellow fever." *Id.* § 2.

[39] *Id*. § 4.

[40] *Id*. § 12.

[41] *Id*.

[42] *Id*. § 14.

[43] *Id*.

If the port health officer has reason to believe that a ship may be an "infected ship"[44] or a "suspected ship,"[45] or has experienced a case of quarantinable disease in the last four weeks before its arrival and was not granted clearance in another port, he may direct the ship to a desirable mooring station and must inspect it and everyone onboard.[46] If, upon inspection, the officer discovers that what are known as "additional measures"[47] are required, he may detain the ship in the same place or at another location for as long as needed for the application of the necessary measures.[48] For instance, if a ship is suspected of being infected with cholera, the officer may place anyone who disembarks from the ship under surveillance, require the disinfection of any contaminated area of the ship or article onboard, and/or require the disinfection or removal of any contaminated water onboard.[49]

The port health officer may, on his own volition or upon the request of the master (in which case it is a requirement), examine a person onboard a ship if the person is suffering from an infectious disease or tuberculosis, or has been exposed to an infectious disease. [50] The officer may take a number of actions, including detaining the person for examination in the ship or another location, ordering the person and his belongings to be disinfected, or restricting his movements.[51]

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[44] An "infected ship" is

(a) a ship which has on board on arrival a case of human cholera, plague, small-pox or yellow fever;

(b) a ship on which a plague-infected rodent is found on arrival; or

(c) a ship which has had on board during its voyage-

i. a case of cholera within five days before arrival; or

ii. a case of human plague developed by the person more than six days after his embarkation; or

iii. a case of yellow fever or smallpox, and which has not before arrival been subjected in respect of such case to appropriate measures equivalent to those provided for in these Regulations." *Id*. § 2.

[45] A "suspected ship" is defined as

(a) a ship which has had on board during the voyage a case of cholera more than five days before arrival; or

(b) a ship which, not having on board on arrival, a case of human plague, has had on board during the voyage a case of that disease developed by the person within six days of his embarkation; or

(c) a ship which left within six days before arrival an area infected with yellow fever:

Provided that a ship to which the foregoing paragraph (a) or (b) applies shall not be deemed to be a suspected ship if in respect of such case of human cholera or plague, as the case may be, the ship has before arrival been subjected to appropriate measures equivalent to those provided for in these Regulations." *Id*. § 2.

[46] *Id.* § 15.

[47] Additional measures are stipulated in Schedule Five of the Regulations and are tailored to specific quarantinable diseases. *Id.*

[48] *Id*.

[49] *Id*.

[50] *Id*. § 17.

[51] *Id.*

If the Minister of Health notifies the port health officer of a "grave danger to public health" due to an outbreak of an infectious disease in an area where a ship is docked, the officer is authorized to require anyone disembarking from the ship to provide his personal information and the areas he intends to visit.[52]

In addition to quarantinable diseases, the Regulations require that additional measures (measures stipulated under Schedule Five of the Regulations) be applied to the following:

> (a) any infected or suspected ships;
> (b) any ship on which there is a case of typhus or relapsing fever;
> (c) any ship which has during its voyage been in a local area infected with cholera, plague or yellow fever;
> (d) any suspect for smallpox on a ship other than an infected ship;
> (e) any person on any ship which has come from an area infected with typhus or relapsing fever;
> (f) any ship or any person on board, when the port health officer is satisfied that, notwithstanding the application of sanitary measures to that ship or person at a previous port, an incident has occurred since such previous application which makes it necessary again to apply additional measures, or when the medical officer has definite evidence that the previous measures applied were not substantially effective.[53]

In addition, the Regulations impose a number of requirements and procedures relating to the prevention and suppression of infectious diseases in relation to outgoing ships.[54]

IV. Transparency of the Public Health Management System

Under the current public health regulatory regime, transparency requirements are minimal. Only two types of transparency requirements were located. One mandates that the President (with regard to the declaration of a state of emergency) or the Minister of Health (with regard to the declaration of a particular location as an infected area) issue a public notice via the Official Gazette.[55] The other, which forms part of the country's obligation as a WHO member state, requires that Nigeria notify the WHO of any event that constitutes a public health emergency within twenty-four hours of the assessment of such event.[56]

If the recent Ebola outbreak is any indication, the question of transparency is not a problem in Nigeria. The country's Ministry of Health created a web page dedicated to informing the public about Ebola, including what the virus is, how it spreads, and signs and symptoms of infection.[57]

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[52] *Id*. § 19.

[53] *Id*. § 20.

[54] *Id*. §§ 21 & 22.

[55] CONSTITUTION OF NIGERIA § 305; Quarantine Act of 1926 § 22, 14 LAWS OF THE FEDERATION OF NIGERIA, Cap. Q2 (rev. ed. 2004), *available at* http://www.placng.org/new/laws/Q2.pdf.

[56] WHO, International Health Regulations (IHR) art. 6 (2d ed. 2005), http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf?ua=1.

[57] EBOLA VIRUS INFORMATION UNIT, http://www.health.gov.ng/ebolainfo/ (last visited Nov. 3, 2014).

In addition, the Ministry issued multiple press releases to inform the public about the status of the virus in the country.[58] In fact, a successful information campaign by the government, intended both to educate the public about the disease and inform the public of actions the government was taking for its suppression, is said to have contributed to the country's success in curbing the outbreak.[59]

It is important to note that, if adopted in its current form, SB 210 would require the development of guidelines on mechanisms to communicate with and inform the public during public health crises (see discussion, Part VI, below). It would also mandate that the public health authority provide information to the public regarding

- the declaration or termination of a state of public health emergency,
- the precautions that members of the public need to take in order to protect themselves from the prevailing danger that caused the emergency, and
- the actions that the relevant authorities are taking to address the emergency.[60]

In addition, it would require that the information be disseminated via all of the available modes of communication and languages accessible to the general public, including to individuals with disabilities.[61]

V. Cooperation with the World Health Organization (WHO)

Nigeria is a member country of both the WHO and the International Health Regulations (IHR).[62] As such, Nigeria is bound by the requirements under the International Health Regulations (IHR) (2005), an international legal instrument aimed at preventing the spread of disease.[63] Among others, the IHR require Nigeria "to develop, strengthen and maintain . . . the capacity to detect, assess, notify ad report" outbreaks of infectious diseases.[64] According to the *WHO Country Cooperation Strategy 2008–2013*, strengthening Nigeria's integrated disease surveillance and response and building the capacity of public health facilities for disease control and eradication efforts are among the main focus areas of cooperation with Nigeria.[65]

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[58] *Press Releases*, FEDERAL MINISTRY OF HEALTH, http://www.health.gov.ng/index.php/news-media/press-releases (last visited Nov. 3, 2014).

[59] *Nigeria Is Now Free of Ebola Virus Transmission*, WHO (Oct. 20, 2014), http://www.who.int/mediacentre/news/ebola/20-october-2014/en/.

[60] Public Health Bill § 29, *available at* http://www.nassnig.org/nass/legislation.php?id=1316.

[61] *Id*.

[62] *Alphabetical List of WHO Member States*, WHO, http://www.who.int/choice/demography/by_country/en/ (last visited Oct. 31, 2014); IHR, *supra* note 56, App. 1.

[63] WHO, INTERNATIONAL HEALTH REGULATIONS (2005): A BRIEF INTRODUCTION TO IMPLEMENTATION IN NATIONAL LEGISLATION 1 (Jan. 2009), http://www.who.int/ihr/Intro_legislative_implementation.pdf?ua=1; IHR, *supra* note 56, App. 1; *Countries*, WHO, http://www.who.int/countries/en/ (last visited Oct. 24, 2014).

[64] IHR, *supra* note 56, § 5.

[65] WHO, WHO COUNTRY COOPERATION STRATEGY 2008–2013: NIGERIA 6 & 24 (2009), http://www.who.int/countryfocus/cooperation_strategy/ccs_nga_en.pdf.

In addition, as a member of the WHO and the IHR, Nigeria must cooperate with the WHO by meeting its obligations under the IHR, including a requirement to notify the WHO of any event that constitutes a public health emergency within twenty-four hours of assessment of such event.[66]

VI. Recent Developments

A. Legislative Reform

Nigeria is in the process of reforming its public health crisis legal framework, which is currently governed under a 1926 law. As indicated above, the Public Health Bill (SB 210), aimed at replacing the current health crisis management regulatory regime, is pending in the upper chamber of the country's National Assembly.

A notable provision of SB 210 would establish a public health emergency planning body, the Public Health Emergency Planning Commission. Staffed through presidential appointments, the Commission would prepare a plan for the prevention and suppression of a host of public health emergencies.[67] Its plan would include requirements or guidelines, including on

- communication with and notification of the public during a public health crisis;
- coordinating responses of the different tiers of government during a public health crisis;
- the evacuation and temporary relocation of communities during a public health crisis;
- providing training to public health workers to diagnose and treat infectious diseases; and
- ensuring that all levels of government have made adequate preparations for public health crises, including identifying isolation or quarantine locations, locations for housing and feeding health workers, locations for distributing food to the public, and routes and means of public and material transportation.[68]

Another notable provision seeks to impose a strict reporting requirement, including on all health care providers,[69] coroners, pathologists, and medical examiners, with regard to any disease or illness that may cause a public health emergency.[70] It mandates that any one of the listed professionals who comes across any disease or illness that could possibly cause a public health emergency report it to the public health authority in a prescribed format either electronically or

[66] IHR, *supra* note 56, art. 6.

[67] Public Health Bill §§ 5 & 6, *available at* http://www.nassnig.org/nass/legislation.php?id=1316.

[68] *Id*. § 6.

[69] A health care provider is "any person or entity who provides health care services including, but not limited to, hospitals, medical clinics and offices, special care facilities, medical laboratories, physicians, pharmacists, dentists, physicians assistants, nurse practitioners, registered and other nurses, paramedics, emergency medical or laboratory technicians, and ambulance and emergency medical workers." *Id*. § 3.

[70] *Id*. § 7.

in writing.[71] The same requirements apply to individuals who deal with animals, including veterinarians, livestock owners, and laboratory technicians.[72]

Also notable is part IV of SB 210, which deals with the power of the president to declare a public health emergency, including the mechanics for and consequences of such action. The president may declare a public health emergency whenever there is "an occurrence or imminent threat of an illness or health condition that . . . is believed to be caused by . . . bioterrorism [or] the appearance of [an] . . . infectious agent or biological toxin" that poses a "high probability" of harm to the public.[73] In such instances, the President may declare a public health emergency for a thirty-day period, which he may renew for an indefinite number of thirty-day terms; however, the legislature may terminate the declaration at any time with a simple majority vote if convinced that the underlying threat to public health no longer exists.[74]

A declaration of a public health emergency accords the president certain emergency powers, including the power to suspend laws imposing procedures for the normal functioning of state bodies, and to mobilize "any part of the organized forces."[75] It also authorizes the public health authorities to take certain measures with regard to management of property and protection of persons.[76] For instance, the public authority would have the power to isolate[77] or quarantine[78] individuals or groups, and the failure to follow isolation or quarantine orders would constitute a crime.[79]

The provisions on isolation or quarantine include language for the protection of subjects of such actions. These include the requirement that isolation or quarantine must be imposed in the least restrictive manner and that it must automatically end upon the determination that the person or persons no longer pose a risk of transmission.[80] While SB 210 would allow the public health authority to unilaterally impose a temporary isolation or quarantine in situations in which delay would "significantly jeopardize . . . [its] ability to prevent or limit the transmission of a

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[71] *Id*.

[72] *Id*.

[73] *Id*. §§ 3(m) & 10.

[74] *Id*. § 14.

[75] *Id.* § 12.

[76] *Id*. §§ 15–29.

[77] "Isolation" is defined as the "physical separation and confinement of an individual or groups of individuals who are infected or reasonably believed to be infected with a contagious or possibly contagious disease from non-isolated individuals." *Id*. § 3.

[78] "Quarantine" is defined as "the physical separation and confinement of an individual or group of individuals, who are or may have been exposed to a contagious or possibly contagious disease and who do not show signs of symptoms of a contagious disease, from non-quarantined individuals, to prevent or limit the transmission of the disease to non-quarantined individuals." *Id*. § 3.

[79] *Id*. § 25.

[80] *Id.*

contagious or possibly contagious disease to others," extended isolation or quarantine would be subject to judicial oversight.[81]

B. Ebola Outbreak

The most recent public health crisis in Nigeria came in the form of an Ebola outbreak in two sites in the country. The primary (index) outbreak occurred in Lagos when on July 20, 2014, a person who had contracted the virus in Liberia arrived at the Lagos International Airport.[82] This primary patient was suspected of having potentially exposed seventy-two individuals.[83] The second outbreak occurred in Port Harcourt when the close contact of the primary patient who was under quarantine in Lagos travelled to seek medical attention from a private physician in August 1, 2014.[84] By the time the WHO officially declared Nigeria Ebola free on October 20, 2014, a total of nineteen individuals had been infected with the disease, seven (40%) of whom died.[85]

This was potentially catastrophic in large part because Lagos is far from being an ideal place to contain an infectious disease. Home to twenty-one million people, most of whom live in crowded and unsanitary slums, Lagos is the largest city in Africa.[86] Lagos's population is as large as the total combined populations of Guinea, Liberia, and Sierra Leone, the three West African countries hardest hit by the ongoing Ebola outbreak in the region.[87] In addition, with its air, land, and sea ports of entry, Lagos is the region's transit hub.[88]

According to commentators, these factors make the swift containment of the spread of Ebola in Nigeria with only a few victims a great success story. Sources indicate that this was possible because Nigeria mobilized its resources and took the necessary suppression measures quickly and efficiently. Following the confirmation of the first Ebola case, the Ministry of Health, with the help of the Nigeria Center for Disease Control (NCDC) declared an Ebola Emergency.[89] Nigeria moved quickly to activate the Incident Management Center (now the Emergency

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[81] *Id.* § 26.

[82] Faisal Shuaib et al., *Ebola Virus Disease Outbreak – Nigeria, July–September 2014*, 63(39) MORTALITY & MORBIDITY WEEKLY REPORT (MMWR) 1 (Oct. 3, 2014), available on the Centers for Disease Control and Prevention website, *at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6339a5.htm.

[83] *Id*.

[84] *Ebola Situation in Port Harcourt, Nigeria*, WHO (Sept. 3, 2014), http://www.who.int/mediacentre/news/ebola/3-september-2014/en/.

[85] WHO*, supra* note 59.

[86] *Population*, LAGOS STATE GOVERNMENT, http://www.lagosstate.gov.ng/pagelinks.php?p=6 (last visited Nov. 3, 2014); WHO, *supra* note 59; *Urban Slums in Lagos 'Mega City'*, VANGUARD (Jan. 11, 2014), http://www.vanguardngr.com/2014/01/urban-slums-lagos-mega-city/; *Nigeria: Lagos, The Mega-City of Slums*, IRINNEWS (Sept. 5, 2006), http://www.irinnews.org/report/60811/nigeria-lagos-the-mega-city-of-slums.

[87] WHO, *supra* note 59.

[88] Shuaib et al., *supra* note 82, at 3.

[89] *Id*. at 1.

Operations Center, EOC) to respond to the outbreak.[90] The EOC, as the implementing arm of the national response to the Ebola outbreak, expanded its work beyond Lagos, specifically to Rivers State (where Port Harcourt is located) and Enugu State (for the purpose of monitoring people who had come into contact with the primary patient).[91] Nigeria identified 894 persons who had come into contact with an infected person and contact tracers conducted over 18,000 face-to-face interviews.[92] Individuals suspected of an infection were isolated and those with confirmed cases of an infection were sent to facilities in Lagos and Port Harcourt.[93]

According to the WHO, Nigeria's performance in curbing the spread of Ebola is attributable to a number of factors including

- rapid utilization of public institutions and prompt establishment of an EOC;
- availability of a "first-rate virology laboratory" to make quick and reliable diagnoses;
- availability of qualified contact-tracers who were able to detect infections early and isolate suspected cases;
- full attention of the country's leadership, including that of the head of state;
- generous allocation of resources and their quick disbursement;
- effective public communication campaigns; and
- experience accumulated fighting previous outbreaks such as polio.[94]

As at the date of this report, no new cases of infection have emerged in Lagos or Port Harcourt since August 18 and August 31, 2014, respectively.[95] As noted above, the WHO declared Nigeria Ebola free on October 20, 2014. However, the fact that the Ebola outbreak in the region remains uncontained coupled with Nigeria's geographic proximity to the hardest-hit countries and its extensive borders make Nigeria vulnerable to additional cases.[96]

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[90] *Id*. at 3.

[91] *Id.*

[92] *Id*. at 2.

[93] *Id*. at 2.

[94] WHO, *supra* note 59, at 2.

[95] Shuaib et al., *supra* note 82, at 3.

[96] *WHO: Nigeria is Free of Ebola but Must Remain Vigilant for New Cases*, THE GUARDIAN (Oct. 20, 2014), http://www.theguardian.com/world/2014/oct/20/nigeria-declared-ebola-free-must-remain-vigilant; Okon Bassey, *Health Minister Reiterates Need for Vigilance Despite Clean Bill*, ALLAFRICA (Nov. 2, 2014), http://allafrica.com/stories/201411031718.html.

Portugal

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SUMMARY Constitutional principles guarantee the rights to health protection and protection of personal data in Portugal. A national health system provides healthcare to the population, while a national commission is charged with the power to supervise and monitor compliance with the laws and regulations on personal data protection.

A 1990 law provides the general principles and policies that guide the health sector in the country, the sanitary protection of its borders, and the powers granted to the Minister of Health to manage serious public health emergencies.

Working under the authority of the Ministry of Health are the General Board of Health, which is in charge, inter alia, of regulating, guiding and coordinating the activities of health promotion and disease prevention in the country, including epidemiologic surveillance at national level; and the National Institute of Emergency Medicine, which is responsible for, among other things, collaborating in national civil emergency planning and the development and implementation of specific plans regarding emergencies or disasters.

A system of public health surveillance monitors the health status of the population to determine the risk of transmission of diseases, and a national council performs advisory functions in prevention and control of transmissible diseases.

Additional laws compose the legal framework available to the government to manage public health crises, such as the government's ability to issue compulsory licenses for a patent for public interest reasons; to impose criminal sanctions on persons who spread contagious diseases; and, the adoption, in 2008, of the International Health Regulations.

To respond to a possible Ebola virus outbreak, Portugal is implementing contingency plans.

I. Constitutional Principle – Health

According to the Portuguese Constitution, everyone has the right to health protection and the duty to defend and promote health.[1] The Constitution states that the right to health protection shall be fulfilled

(a) through a universal national health service that, taking into account the economic and social conditions of citizens, will generally be free of charge;[2] [and]

[1] CONSTITUIÇÃO DA REPÚBLICA PORTUGUESA [C.R.P.], (VII Revisão Constitucional (2005)), art. 64(1), *available at* ASSEMBLEIA DA REPÚBLICA, http://www.parlamento.pt/Legislacao/Paginas/ConstituicaoRepublicaPortuguesa.aspx.

[2] *Id.* art. 64(2)(a).

> (b) by creating economic, social, cultural and environmental conditions that will particularly protect childhood, youth and old age; by systematically improving the conditions of life and work and promoting physical fitness and sport at school and among the people; and by developing the people's sanitary education and practices of healthy living.[3]

II. National Health System

A National Health System (Sistema Nacional de Saúde, SNS) was created in 1979 by Law No. 56 of September 15, 1979, through which the government guarantees the right under the Constitution to health protection.[4] The SNS is composed of the organs and services listed in Law No. 56. Its purpose is to provide comprehensive health care to the entire population.[5] The SNS involves all integrated health care, including health promotion, public health surveillance, disease prevention, diagnosis and treatment of patients, and patients' medical and social rehabilitation.[6]

A. Basis of the Health Sector

On August 24, 1990, Law No. 48, the Basic Health Law, was enacted to establish the basis and structure of the health sector in Portugal.[7] Law No. 48 provides the general principles[8] and policies[9] that must guide the country in this area. Failure to comply with the Basic Health Law entails criminal, civil and disciplinary liability.[10]

The Portuguese government promotes the sanitary protection of its borders, in compliance with general rules issued by the competent bodies.[11] The appropriate bodies are charged with studying, proposing, implementing and enforcing necessary measures to prevent the import or export of diseases subject to international health regulations; responding to threats of the spread of transmissible diseases; and promoting all necessary sanitary actions required by the international community.[12]

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[3] *Id.* art. 64(2)(b).

[4] Lei No. 56/79, de 15 de Setembro, art. 1, http://www.parlamento.pt/Legislacao/Paginas/Leis_area_saude.aspx. Scroll down to Section I(2) and click on Lei No. 56/79. *See also* Base XII of Law No. 48/90, *infra* note 7.

[5] *Id.* art. 2.

[6] *Id.* art. 6(2).

[7] Lei No. 48/90, de 24 de Agosto, http://www.parlamento.pt/Legislacao/Paginas/Leis_area_saude.aspx (scroll to Section I(1) and click on "Lei No. 48/90").

[8] *Id.* Base I.

[9] *Id.* Base II.

[10] *Id.* Base III.

[11] *Id.* Base XI(1).

[12] *Id.* Base XI(2).

The organization of the health system is based on the division of the national territory into health regions.[13] The regions can be further divided into sub-regions, according to the needs of the population and the operability of the system.[14]

The health authorities are located at national, regional and council levels to ensure timely and discretionary state intervention in situations of serious risk to public health, and are hierarchically subordinate to the Ministry of Health, through the appropriate general-director.[15] The health authorities are in charge, among other things, of exercising sanitary border surveillance;[16] and requesting services, facilities and the assistance of health professionals in cases of severe epidemics and other similar situations.[17]

In the event of a catastrophe or other serious public health emergency, the Minister of Health is in charge of taking exceptional and indispensable measures, and must coordinate the activities of the central services of the Ministry with the SNS's bodies and the various health authorities.[18] If necessary, the government may request the services of professionals and healthcare facilities of the private sector in cases where such assistance is absolutely indispensable.[19]

All Portuguese citizens are beneficiaries of the SNS.[20] All nationals of Member States of the European Community may receive services of the SNS as well, in accordance with the European Community rules.[21] Foreigners residing in Portugal may receive benefits on a reciprocal basis; stateless persons residing in the country also receive benefits.[22]

Decree-Law No. 11 of January 15, 1993 approved the SNS Statute,[23] which defines, among other things, the ambit of its application;[24] its nature and objective;[25] and the organization and functioning of the SNS.[26] It also provides for the cooperation of the SNS with other entities.[27]

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[13] *Id.* Base XVIII(1).

[14] *Id.* Base XVIII(3).

[15] *Id.* Base XIX(1).

[16] *Id.* Base XIX(3)(d).

[17] *Id.* Base XIX(3)(e).

[18] *Id.* Base XX(1).

[19] *Id.* Base XX(2).

[20] *Id.* Base XXV(1).

[21] *Id.* Base XXV(2).

[22] *Id.* Base XXV(3).

[23] Decreto-Lei No. 11/93, de 15 de Janeiro, art. 1, http://www.sg.min-saude.pt/sg/conteudos/legisaude/legis+sns.htm (scroll to Estatuto do SNS and click on "Decreto-Lei No. 11/93").

[24] *Id.* art. 2.

[25] *Id.* Anexo, arts. 1, 2.

[26] *Id.* Anexo, Capítulo II.

[27] *Id.* Anexo, Capítulo VI.

B. Ministry of Health

The Ministry of Health is the government department responsible for defining and guiding the national health policy, ensuring a sustainable use of resources, and evaluating results.[28] The Ministry of Health is responsible for regulating the SNS.[29] Article 7(2) of Decree-Law No. 124 of December 29, 2011 further provides that all services and public health care providers, particularly groups of health care centers, hospitals(regardless of designation), and local health care units are to be integrated into the SNS.[30]

1. General Board of Health

The General Board of Health (Direção-Geral da Saúde, DGS)[31] is responsible for the direct administration of government within the Ministry of Health.[32] The DGS's mission is to regulate, guide and coordinate the activities of health promotion and disease prevention; define the technical conditions for the provision of adequate health care; plan and program the national policy for quality in the health system, as well as ensure the development and implementation of the National Health Plan (Plano Nacional de Saúde, PNS);[33] and coordinate the international relations of the Ministry of Health.[34]

The responsibilities of the DGS include issuing rules and guidelines, developing and promoting programs on public health and improving the delivery of care in relevant areas of health;[35] and

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[28] Decreto-Lei No. 124/2011, de 29 de Dezembro, art. 1, http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/ministerio/lei+organica/lei+organica3.htm.

[29] *Id*. art. 2(b).

[30] *Id.* art. 7(2).

[31] DIREÇÃO-GERAL DA SAÚDE, http://www.dgs.pt/. The DGS is regulated by Decree No. 14 of January 26, 2012, http://www.dgs.pt/institucional/diplomas-legais-e-organograma.aspx (click on "Decreto Regulamentar No. 14/2012").

[32] Decreto-Lei No. 124/2011, art. 4(c). Pursuant to article 2(1) of Law No. 4 of January 15, 2004, (Lei No. 4/2004, de 15 de Janeiro, http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1561&tabela=leis&ficha=1&pagina=1&), direct administration consists of central and peripheral services which, by the nature of their powers and functions, must be subject to the direction of the respective member of the government. The services included in the direct administration of the state encompass those whose duties arise out of the exercise of sovereign powers, authority, and political representation of the state, or that involve the exercise of functions of study and creation, coordination, support and control, or supervision of other administrative services. *Id.* art. 2(2). In contrast, indirect administration consists of bodies vested with legal personality that are subject to the supervision and authority of the government. Services included in indirect administration are those that, due to their specificity, must not be subjected to the direct administration of the government, and, as a rule, are endowed with administrative and financial autonomy, including those of public institutions, which are governed by Law No. 3 of January 15, 2004 (Lei No. 3/2004, de, de 15 de Janeiro, http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1472&tabela=leis&ficha=1&pagina=1&). *See* MINISTÉRIO DAS FINANÇAS, DIRECÇÃO GERAL DA ADMINISTRAÇÃO E DO EMPREGO PÚBLICO, http://www.dgaep.gov.pt/index.cfm?OBJID=a21efe4b-790e-4b90-8371-0f45231ab4fc.

[33] DIREÇÃO-GERAL DA SAÚDE, PLANO NACIONAL DE SAÚDE (2012–2016), http://pns.dgs.pt/nhp-in-english/.

[34] Decreto-Lei No. 124/2011, art. 12(1).

[35] *Id.* art. 12(2)(a).

coordinating and ensuring epidemiologic surveillance at the national level and Portugal's contribution at the international level.[36]

2. National Institute of Emergency Medicine

The National Institute of Emergency Medicine (Instituto Nacional de Emergência Médica, INEM)[37] is under the supervision and control of the Ministry of Health[38] and is responsible, along with other institutions and organisms, for the indirect administration of the government.[39]

The INEM's mission is to define, organize, coordinate, participate in and evaluate the activities and operation of the Integrated System of Emergency Medicine (Sistema Integrado de Emergência Médica) in order to ensure victims of accidents or sudden illnesses receive prompt and proper health care.[40]

The INEM's responsibilities include, inter alia, collaborating in national civil emergency planning, including developing and implementing disaster relief plans; participating in the national emergency telecommunications network;[41] and developing national and international actions of bilateral or multilateral cooperation.[42]

C. System of Public Health Surveillance

Law No. 81 of August 21, 2009[43] created a System of Public Health Surveillance (Sistema de Vigilância em Saúde Pública, SVSP); a national network to collect information from epidemiologic surveillance; and the National Council of Public Health.

1. System of Public Health Surveillance

The SVSP consists of entities in the public, private and social sectors coordinating public health activities according to their respective statutory duties that prevent, alert, control and respond to transmissible diseases and other risks to public health, to ensure the right of citizens to the defense and protection of health.[44]

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[36] *Id.* art. 12(2)(e).

[37] INSTITUTO NACIONAL DE EMERGÊNCIA MÉDICA, http://www.inem.pt/. The INEM is regulated by Decree-Law No. 34/2012, http://www.sg.min-saude.pt/sg/conteudos/legisaude/legis+leoms.htm (scroll to "Instituto Nacional de Emergência Médica, IP," and click on "Decreto-Lei No. 34/2012").

[38] Decreto-Lei No. 124/2011, art. 5(c).

[39] *Id.* art. 5. For a discussion of the difference between direct and indirect administration, see note 32, *supra*.

[40] *Id*. art. 16(1).

[41] *Id.* art. 16(2)(f).

[42] *Id.* art. 16(2)(g).

[43] Lei No. 81/2009, de 21 de Agosto, http://www.parlamento.pt/Legislacao/Paginas/Leis_area_saude.aspx (scroll to Section 13. 7 and click on Lei No. 81/2009).

[44] *Id.* art. 1(1).

Law No. 81 applies to all entities of the public, private and social sectors that collect, analyze, interpret, and disseminate health data, or perform epidemiologic studies relating to transmissible diseases and other public health risks.[45]

All measures for preventing and containing the spread of transmissible diseases and other risks to public health by public bodies under Law No. 81, including conducting epidemiologic investigations pursued by health authorities and analysis of their risk factors, are subject to the personal data protection requirements discussed below.[46]

The purpose of the SVSP is to monitor the health status of populations across time, evaluate the risk of transmission of any disease, and prevent the entry or spread of disease on Portuguese territory.[47]

2. National Network

The national network includes public health services, laboratories, and other health authorities and bodies in the public, private and social sectors that contribute to a National System of Information of Epidemiologic Surveillance (Sistema Nacional de Informação de Vigilância Epidemiológica, SINAVE).[48]

3. National Council of Public Health

The National Council of Public Health (Conselho Nacional de Saúde Pública, CNSP) performs advisory functions in the area of prevention and control of transmissible diseases and other risks to public health and, in particular, analysis and evaluation of serious conditions, including large-scale disease outbreaks and pandemics. It is responsible for proposing declarations of states of emergency caused by public calamities.[49]

III. Compulsory Patent Licensing

According to the Portuguese Code of Industrial Property, compulsory licenses allowing the use of patented technologies may be granted for reasons of public interest.[50] Such reasons include when increasing or improving the exploitation of the patented technology is of paramount importance for public health or national defense.[51]

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[45] *Id.* art. 2(1).

[46] *Id.* art. 2(2).

[47] *Id.* art. 3(1).

[48] *Id.* art. 1(2).

[49] *Id.* art. 4(1).

[50] CÓDIGO DA PROPRIEDADE INDUSTRIAL, Decreto-Lei No. 36/2003, de 5 de Março, arts. 107(1)(c), 110(1), http://www.pgdlisboa.pt/leis/lei_print_articulado.php?tabela=leis&artigo_id=&nid=438&nversao=&tabela=leis.

[51] *Id.* art. 110(2).

IV. Right to Privacy

A. Constitutional Principle

The Constitution provides that the law must establish effective guarantees against the acquisition and abusive use, or use that is contrary to human dignity, of information concerning individuals and families.[52] Also, the protection of personal data used in connection with information technology is a fundamental right guaranteed by the Constitution.[53]

B. Personal Data Protection

Personal data in Portugal is protected by Law No. 67 of October 26, 1998[54] and supplemented by Law No. 41 of August 18, 2004.[55]

1. Law No. 67 of October 26, 1998

Law No. 67 requires that the processing of personal data be done transparently and with strict respect for subjects' private lives, as well as for fundamental rights, freedoms, and guarantees.[56]

Law No. 67 defines "personal data" (*dados pessoais*) as information of any type, irrespective of the type of media involved, relating to an identified or identifiable natural person.[57]

The "processing of personal data" (*tratamento de dados pessoais*) is defined broadly as any operation or set of operations performed upon personal data.[58]

The processing of various specified types of personal data, including data concerning a person's health or sex life or genetic data, is prohibited under article 7(1) of Law No. 67.[59]

Article 7(2) of the Law determines that the processing of the data mentioned in article 7(1) is allowed if permission is provided by law or authorized, in specific situations, by the National Commission of Data Protection (Comissão Nacional de Protecção de Dados, CNPD).[60]

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[52] C.R.P. art. 26(2).

[53] *Id.* art. 35.

[54] Lei da Protecção de Dados Pessoais [Personal Data Protection Law], Lei No. 67/98, de 26 de Outubro, http://www.pgdlisboa.pt/pgdl/leis/lei_mostra_articulado.php?nid=156&tabela=leis&ficha=1&pagina=1.

[55] Lei No. 41/2004, de 18 de Agosto, http://www.pgdlisboa.pt/pgdl/leis/lei_mostra_articulado.php?nid=707&tabela=leis&ficha=1&pagina=1.

[56] Lei No. 67/98, art. 2.

[57] *Id.* art. 3(a).

[58] *Id.* art. 3(b).

[59] *Id.* art. 7(1).

[60] *Id.* art. 7(2). Article 22(1) of Law No. 67/98 provides that CNPD is the national authority charged with the power to supervise and monitor compliance with the laws and regulations in the area of personal data protection, with strict respect for the human rights and the fundamental freedoms and guarantees provided by the Constitution and the law.

The processing of data relating to a person's health and sex life, including genetic data, is permitted if it is necessary for the purposes of preventive medicine, medical diagnosis, provision of care or treatment, or management of health-care services, provided that those data are processed by a health professional bound by professional secrecy, the CNPD is notified, and suitable safeguards are provided.[61]

2. Law No. 41 of August 18, 2004

Law No. 41 of August 18, 2004, applies to the processing of personal data in the context of networks and electronic communication services available to the public, specifying and supplementing the provisions of Law No. 67.[62]

3. Criminal and Administrative Sanctions

Violations of the privacy provisions discussed above may result in fines and/or imprisonment. For example, some crimes are punishable by up to two years in prison and the payment of a fine, including non-compliance with obligations relating to data protection,[63] unauthorized access to personal data,[64] falsification or destruction of personal data,[65] and breach of secrecy.[66]

4. Data Protection Agency

The National Commission of Data Protection (Comissão Nacional de Protecção de Dados – CNPD) is the agency is charge of controlling and overseeing the enforcement of laws and regulations on the protection of personal data.[67]

C. Personal Health Information

1. Law No. 12 of January 26, 2005

The concepts of health information and genetic information, the flow of information and the intervention on the human genome in the health system, and the rules for the collection and preservation of biological products for the purpose of genetic testing or research are defined by Law No. 12 of January 26, 2005.[68]

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[61] *Id.* art. 7(4).

[62] Lei No. 41/2004, art. 1(2).

[63] Lei No. 67/98, art. 43.

[64] *Id.* art. 44.

[65] *Id.* art. 45.

[66] *Id.* art. 47.

[67] *O que é a CNPD*, COMISSÃO NACIONAL DE PROTECÇÃO DE DADOS, http://www.cnpd.pt/bin/cnpd/ acnpd.htm (last visited Oct. 22, 2014).

[68] Lei No. 12/2005, de 26 de Janeiro, art. 1, http://www.parlamento.pt/Legislacao/Paginas/Leis_area_saude.aspx (scroll to Section II(6) and click on "Lei No. 12/2005").

For the purposes of Law No. 12, health information includes all kinds of information directly or indirectly related to the health, present or future, of a person, whether alive or deceased, and the person's clinical and family history.[69] All such health information is owned by the person. The units of the health system are the custodians of this information, which cannot be used for purposes other than the provision of care, health research, or other purposes specifically allowed by law.[70]

2. Decree-Law No. 131 of August 29, 2014

Law No. 12 is regulated by Decree-Law No. 131 of August 29, 2014, regarding the protection and confidentiality of genetic information, the basis of human genetic data for the purpose of providing healthcare and health research, the conditions of supply and offer of genetic testing and the conditions under which consultations on medical genetics are assured.[71] The release of genetic information related to the health of a person to third parties is prohibited, except as provided in Law No. 67 of 26 October, 1998.[72] Articles 31 to 34 of Decree-Law No. 131 establish the offenses (*contra-ordenações*) that are punishable by a fine and the respective amount of such fines.

3. Law No. 5 of January 23, 2012

Law No. 5 of January 23, 2012 regulates the requirements for processing personal data for the establishment of nationwide files containing health data using information technology resources, including in the context of the SNS.[73] Law No. 5 applies to all public healthcare facilities, to acts performed in private or social establishments that involve charges to the SNS, and to persons who deal with health data of others in the course of their activities.[74]

The personal data and the processing of personal data encompassed by Law No. 5 are subject to authorization of the CNPD, under the terms of Law No. 67 of 26 October, 1998.[75] Everything else that is not expressly regulated by Law No. 5 is applicable the regime provided by Law No. 67 of 26 October, 1998.[76]

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[69] *Id.* art. 2.

[70] *Id.* art. 3(1).

[71] Decreto-Lei No. 131/2014, de 29 de Agosto, art. 1, http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=2214&tabela=leis&nversao.

[72] *Id.* art. 20.

[73] Lei No. 5/2012, de 23 de Janeiro, art. 1, https://dre.pt/application/dir/pdf1s/2012/01/01600/0036000361.pdf.

[74] *Id.* art. 3.

[75] *Id.* art. 11(1).

[76] *Id.* art. 12(2).

4. Portuguese Medical Code of Ethics

Under the Medical Code of Ethics, medical confidentiality must be observed in all circumstances as a result of the inalienable right of all patients to such confidentiality.[77] The confidentiality includes all facts that have come to the attention of a physician in the exercise of his or her profession, and especially comprises:

> a) The facts disclosed by the person directly, by others at the person's request or by a third party who has contacted with the person during care, or because of it;
>
> b) Circumstances perceived by the physician, whether or not originating from clinical observation of the patient or others;
>
> c) The facts resulting from knowledge of supplementary diagnostics and therapeutics related to the patient;
>
> d) The facts reported by another physician or health professional, bound by confidentiality.[78]

The obligation of medical confidentiality exists whether the requested service has been rendered or not and whether paid or unpaid.[79] The obligation to such confidentiality remains after the patient's death.[80] A physician is excused from medical confidentiality in certain situations, such as cases involving diseases that require mandatory notification.[81]

V. Criminal Sanctions

The Portuguese Penal Code punishes with two years in prison and a fine whoever spreads disease that is harmful to plants or animals.[82] If the spread is caused by negligence, the person is punished by up to six months in prison and a fine.[83] In addition, whoever spreads contagious diseases is punished with one to eight years in prison.[84] If the spread is caused by negligence, the person is punished with three years in prison or a fine.[85]

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[77] ORDEM DOS MÉDICOS, CÓDIGO DEONTOLÓGICO art. 86(1), https://www.ordemdosmedicos.pt/?lop=conteudo&op=9c838d2e45b2ad1094d42f4ef36764f6&id=cc42acc8ce334185e0193753adb6cb77.

[78] *Id.* art. 86(2).

[79] *Id.* art. 86(3).

[80] *Id.* art. 86(4).

[81] *Id.* art. 88(d).

[82] CÓDIGO PENAL, Decreto-Lei No. 48/95, de 15 de Março, *as amended by* Law No. 69/2014, de 29 de Agosto, art. 281(1)(a), http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=109&tabela=leis.

[83] *Id.* art. 281(3).

[84] *Id.* art. 283(1)(a).

[85] *Id.* art. 283(3).

VI. International Health Regulations

Portugal is a member of the World Health Organization (WHO)[86] and follows the International Health Regulations (IHR) adopted by the WHO in 1969 and later amended in 1973 and 1981.

In 1995, the 48th World Health Assembly called for a substantial revision of the Regulations adopted in 1969.[87] After extensive work, on May 23, 2005, IHR (2005) was adopted by the 58th World Health Assembly and on June 15, 2007, it entered into force.[88] The purpose and scope of the IHR (2005) are "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."[89]

IHR (2005) was incorporated into Portugal's domestic legal system through Notice 12/2008 issued by the Ministry of Foreign Affairs on January 3, 2008 and published on January 23, 2008.[90]

VII. Current Crisis/Recent Developments

The Portuguese Ministry of Health has been reporting measures that the government has been taking to fight and prevent the spread of the Ebola virus in the country.

On October 10, 2014, the Ministry reported that the National Institute of Medical Emergencies, under the Contingency Plan of Action Against the Infection by Ebola Virus (Plano de Contingência de Atuação Face à Infeção por Vírus Ébola), is prepared to respond to any suspected cases occurring in the continental territory or in case of nationals who are being repatriated and possibly infected with the disease.[91]

A Response Platform to the Ebola Virus Disease (Plataforma da Resposta a Doença por Vírus Ebola), which establishes a hierarchical command that can be adapted according to the evolution of the epidemiologic situation, was approved on October 15, 2014, during a meeting of the National Council of Public Health. The Council also discussed, among other things, the draft of a proposal for a Communication Plan and the legality of measures that may, eventually, limit individual rights.[92]

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[86] WORLD HEALTH ORGANIZATION, http://www.who.int/countries/prt/en/.

[87] WHO, International Health Regulations (2d ed. 2005), http://www.who.int/ihr/publications/ 9789241596664/en/.

[88] *Id.* at 1.

[89] *Id*.

[90] DIREÇÃO-GERAL DE SAÚDE, http://www.dgs.pt/autoridade-de-saude-nacional/regulamento-sanitario-internacional.aspx (click on "Aviso nº 12/2008, Diário da República, 1ª série, nº 16, de 23 de Janeiro de 2008").

[91] *INEM Tem Plano de Contingência para Lidar com Infecções por Vírus Ebola*, PORTAL DA SAÚDE (Oct. 10, 2014), http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/noticias/inem+reforca+equipas.htm.

[92] *Comunicado do Conselho Nacional de Saúde de 15/10/2014*, DIREÇÃO-GERAL DA SAÚDE, http://www.dgs.pt/a-direccao-geral-da-saude/comunicados-e-despachos-do-director-geral/comunicado-do-conselho-nacional-de-saude-publica.aspx (click on "*Abrir Documento*")

On October 16, 2014, the General Board of Health issued Order No. 9/2014 (*Despacho*), which created the Response Platform to the Ebola Virus Disease at the national level.[93] The objective of the Response Platform is the early detection of imported cases, and prevention or minimization of the occurrence of secondary cases and chains of transmission of the disease in the country. The Response Platform also defines, disseminates and operationalizes a Response/Contingency Plan, with guidelines and performance protocols.[94]

The Portuguese Council of Ministers approved on October 23, 2014 the creation of a commission to coordinate the responses to and political decisions on Ebola of all sectors of government. The commission, coordinated by the Ministry of Health, will comprise governmental representatives in charge of Foreign Affairs, National Defense, Internal Administration, Infrastructure and Transportation, and representatives from the regional councils of Azores and Madeira.[95]

[93] Direção-Geral da Saúde, Despacho No. 9/2014, de 15/10/2014, atualizado a 22/10/2014, http://www.dgs.pt/a-direccao-geral-da-saude/comunicados-e-despachos-do-director-geral/plataforma-de-resposta-a-doenca-por-virus-ebola.aspx (click on "*Abrir Documento*").

[94] *Id.* No. 1.

[95] *Governo Cria Comissão Interministerial de Coordenação da Resposta ao Ebola*, GOVERNO DE PORTUGAL, MINISTÉRIO DA SAÚDE (Oct. 23, 2014), http://www.portugal.gov.pt/pt/os-ministerios/ministerio-da-saude/mantenha-se-atualizado/20141023-ms-ebola.aspx#.VE0y0kQoybA.email.

Russian Federation

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SUMMARY The health crisis management system in Russia is regulated by a number of laws and statutory documents issued by federal and regional authorities. The Federal Service for the Surveillance of Consumer Rights Protection and Human Well-Being (Rospotrebnadzor) is the leading government agency in the field and coordinates the activities of military and civilian government agencies and social organizations whose aim is to protect Russia's population and territory from epidemic outbreaks. This report contains a comprehensive analysis of the legislation in force and its implementation.

I. Structure of Public Health Crisis Management System

The Russian health care system is based on a strong governmental role in ensuring the country's sanitary and epidemiologic well-being. The fight against epidemics and overcoming of emergencies are included in the joint jurisdiction of federal and provincial authorities.[1] Government policy in the area of protection from medical emergencies is formulated in a number of federal and provincial legislative acts, presidential decrees, government regulations, and government programs. There is no special legislation aimed at the regulation of issues related to public health emergencies and epidemics. The outbreak of epidemics is considered an emergency situation, and all rules prescribed by the Federal Constitutional Law on Emergency Situations apply.[2] Also, these issues are regulated by the following legislative acts:

- Federal Law on the Protection of the Population and Territories from Emergency Situations of Natural and Technogenic Character[3]
- Federal Law on Civil Defense[4]
- Federal Law on the Sanitary and Epidemiological Welfare of the Population[5]
- Federal Law on the Immunoprophylaxis of Infectious Diseases[6]

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[*] This report was prepared with the assistance of Nerses Isajanyan, Foreign Law Consultant.

[1] CONSTITUTION OF THE RUSSIAN FEDERATION art. 72, *available at* http://www.constitution.ru/en/10003000-01.htm.

[2] Federal Constitutional Law No. 3 on Emergency Situations, SOBRANIE ZAKONODATELSTVA ROSSIISKOI FEDERATSII [SZ RF] [RUSSIAN FEDERATION OFFICIAL GAZETTE], 2001, No. 23, Item 2277, *available at* http://base.garant.ru/12123122/ (in Russian).

[3] Federal Law No. 68 of Dec. 21, 1994 on the Protection of the Population and Territories from Emergency Situations of Natural and Technogenic Character, SZ RF 1994, No. 35, Item 3648, http://base.garant.ru/10107960/ (in Russian).

[4] Federal Law No. 28 of Feb. 12, 1998 on Civil Defense, SZ RF 1998, No. 7, Item 799, http://base.garant.ru/178160/ (in Russian).

[5] Federal Law No. 52 of Mar. 30, 1999 on the Sanitary and Epidemiological Welfare of the Population, SZ RF 1999, No. 14, Item 1650, http://base.garant.ru/12115118/ (in Russian).

- Government Regulation on the Unified State System for the Prevention and Elimination of Emergency Situations[7]

These pieces of legislation determine the powers of Russian authorities in the event of health care emergencies.

The President of the Russian Federation defines public policy and makes the most important decisions related to protecting the population and territory from emergencies. He leads Russia's Security Council and makes decisions regarding the involvement of troops and other militarized units in eliminating the consequences of emergencies. According to the Law on Emergency Situations, the President has the power to declare a state of emergency for thirty days for the entire nation or for sixty days for a particular region when a threat to the health of population exists. Approval of the upper house of the legislature is needed to declare or extend a state of emergency.[8]

Russia's Federal Assembly (the legislature) provides for unified legislation and approves budget allocations to finance activities necessary to manage a health crisis. Parliamentary hearings on related issues can be conducted.[9]

Implementing laws and federal programs aimed at protecting the population from epidemics is the duty of the Russian Federation government. Collecting related information, preparing for emergencies, and managing activities to eliminate crises, on the other hand, are included in the sphere of responsibility of regional executive authorities, who must also make decisions regarding the evacuation or isolation of the population. Each region has its own set of laws on related issues.[10]

The Federal Service for the Surveillance of Consumer Rights Protection and Human Well-Being (Rospotrebnadzor) is the leading government institution in the area of epidemiological security. It reports directly to the government of the Russian Federation and coordinates the efforts of various departments and agencies (the Ministry of Defense, Ministry of Internal Affairs, Federal Security Service, etc.) to prevent and eliminate the consequences of mass epidemics.[11] The Federal Civil Defense Medical Service and the Medical Service Used for Catastrophes were established under the Ministry of Health Protection. They are used depending on the situation—for example, a war, the consequences of an emergency, or the outbreak of an infectious disease.

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[6] Federal Law No. 157 of Sept. 17, 1998 on the Immunoprophylaxis of Infectious Diseases, SZ RF 1998, No. 38, Item 4236, http://base.garant.ru/12113020/ (in Russian).

[7] Government Regulation No. 794 on the Unified State System for the Prevention and Elimination of Emergency Situations of Dec. 30, 2003 (amended Nov. 19, 2012), ROSSIISKAIA GAZETA [RG], No. 271, Nov. 23, 2012, http://base.garant. ru/186620/ (in Russian).

[8] Law on Emergency Situations arts. 4, 7, 9.

[9] Constitution of the Russian Federation art. 105.

[10] Law on Emergency Situations arts. 24, 25.

[11] Statute on Rospotrebnadzor, approved by Government Regulation No. 322 of June 30, 2004, available on the Rospotrebnadzor website, *at* http://64.rospo§trebnadzor.ru/309 (in Russian).

These services provide medical and sanitation services to the population during epidemics and work to prevent adverse consequences.[12]

The Rospotrebnadzor includes administrative offices in the constituent provinces, centers of hygiene and epidemiology, research institutes, and antiplague facilities, and cooperates with sanitary and epidemiological services within the following government agencies: the Ministry of Defense, Ministry of Internal Affairs, Federal Security Service, Federal Protection Service, Directorate of Special Programs Under the President, Federal Penitentiary Service, and Federal Biomedical Agency.[13]

II. Implementation of the Emergency/Crisis Response System

The management of antiepidemic measures is one of the duties of Rospotrebnadzor. These measures may include

- organizing and conducting sanitary and epidemiological monitoring;
- preventing infectious diseases from entering an emergency zone;
- locating, mandatorily isolating, and evacuating patients with infectious diseases;
- locating and monitoring persons with chronic forms of infectious diseases;
- maintaining an antiepidemic regime during medical evacuations;
- disinfection measures;
- preventive and urgent immunization; and
- sanitary education and psychological assistance to the population and responders.[14]

Rospotrebnadzor is in charge of conducting planning and training exercises, which are considered the major actions aimed at preventing emergencies and eliminating their consequences. The main purpose of these planning and training exercises is to ensure the sufficiency and full use of existing resources. The elimination of an emergency's consequences must be conducted by the authorities of Russia's constituent components and the territorial branches of the federal agencies where the emergency has occurred. If necessary, federal resources can be used.[15]

To ensure that all resources are gathered in one place in order to provide the most efficient response, the federal Ministry of Health Protection has designated one hospital in each of Russia's constituent components to respond in case of an infectious disease outbreak. These

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[12] Statute on Medical Service Used for Catastrophes, approved by Government Regulation No. 734 of Aug. 26, 2013, available on the Ministry of Health Protection website, *at* http://static-1.rosminzdrav.ru/system/attachments/attaches/000/012/778/original/Ob_utverzhdenii_Polozheniya.pdf?1389715517 (in Russian).

[13] Statute on Rospotrebnadzor § 8.

[14] *Id.* § 5.

[15] *Id.* § 4.

hospitals focus on treating patients who have been diagnosed with diseases as a consequence of a health crisis. Support is provided to these hospitals by the National Institute of Emergency Medical Services, which conducts research in the field of emergency medical services and supplementary professional education of medical staff. Services of other state and private medical establishments can be enlisted for the duration of an emergency situation.[16]

A quarantine regime can be introduced where danger of an epidemic outbreak appears. The quarantine of a particular territory incurs travel restrictions, mandatory vaccinations, and the cancellation of all mass events. Special procedures are prescribed for the distribution or sale of food and basic commodities, and local authorities can restrict the sale of alcoholic beverages. During the quarantine period, police have extended authority to take quarantine violators into custody.[17]

Implementation mechanisms are prescribed by federal target-program documents, which define means for conducting practical health care activities. Several federal target programs for preventing health care emergencies have been approved, financed, and implemented, including

- emergency measures to ensure the public's sanitary and epidemiologic well-being;
- prevention of the most prevalent diseases;
- disaster medicine;
- protecting the territory from the influence of especially dangerous human, animal, and plant diseases and toxic chemicals; and
- a vaccination program.[18]

Within the vaccination program framework, a one-hundred-million-dose stockpile of vaccines for all major known infectious diseases has been established, and federal control over the vaccines' quality introduced.[19] The federal registration of the producers of products potentially dangerous to humans, the registration of specific kinds of products being imported into Russia for the first time, and the registration of all potentially dangerous chemical and biological substances has been in force since June 2001.[20] The legal basis for the vaccination against major communicable diseases is determined by the Law on the Immunoprophylaxis of Infectious

[16] Order No. 220 of Sept. 17, 1993 of the Russian Federation Health Protection Ministry on the Development and Improvement of the Infectious Disease Service in the Russian Federation, *available at* http://www.consultant.ru/document/cons_doc_law_100796/?frame=3 (in Russian).

[17] Government Regulation No. 529 of Aug. 19, 2005 on Organization and Control for Introducing and Cancelling Quarantine Measures, http://base.garant.ru/12141665/ (in Russian).

[18] Information about ongoing Federal Target Programs is available on the Russian Government web portal at http://www.programs-gov.ru/ (in Russian; last visited Nov. 20, 2014).

[19] V. K. Tatochenko, *Questions and Answers About Federal and Regional Vaccination Programs*, REGIONAL PROGRAMS (No. 5: Sept./Oct. 2005), *available at* http://medi.ru/doc/15b41.htm (in Russian).

[20] Information on the Federal Registry of Potentially Dangerous Chemical and Biological Substances is available on the Rospotrebnadzor website, at http://www.rpohv.ru/ (in Russian; last visited Nov. 20, 2014).

Diseases.[21] The Law recognizes vaccination as a national security instrument. It provides for federal budget funding of all preventive vaccination and states that those who become incapacitated because of postvaccination complications are subject to social security protection. The National Calendar of Preventive Vaccination and deadlines for vaccinating different categories of the population against particular diseases were developed following the adoption of this Law. Enforcement measures can be applied to those who refuse vaccination. These may include a prohibition on traveling abroad, an employment hiring ban, and university admission restrictions. In order to increase incentives, all firms specializing in the research on and production of medical and veterinary vaccines for the purpose of fighting epidemics are exempt from federal property taxes.[22]

All activities related to fighting epidemics are financed by the federal budget from a special reserve fund. In 2000, Russia's Supreme Court confirmed that all services provided by the National Sanitary Service (predecessor of Rospotrebnadzor) to the population are to be free of charge.[23] Budget appropriations for fighting epidemics can be spent on special measures aimed at eliminating outbreaks of epidemic illnesses. One quarter of these funds can be appropriated for unscheduled antiepidemic measures in the event of a threat of an epidemic or increase in morbidity. These funds can be spent by local governments for

- the creation of temporary infectious hospitals, according to a regional executive government resolution if the existing regular hospital network cannot satisfy needs;
- the organization and activities of temporary antiepidemic teams and creation of isolation points;
- the payment of salaries to detailed medical personnel;
- related transportation and communication expenditures; and
- the organization and activities of temporary antiepidemic laboratories.

In 2006, the Government Reserve Fund was used to finance measures aimed at preventing the expansion of the SARS epidemic in Russia. According to a government resolution, an amount equal to US$3 million was allocated for this purpose. This money was divided between the Ministry of Health Protection and the Ministry of Defense.[24]

After the Chernobyl catastrophe when information about radioactive contamination was concealed by Soviet leaders, the management of health- and safety-related information became a sensitive issue regulated by legislative acts. Information on protecting the population from health emergencies consists of data on previously occurring or forecasted emergencies and their

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[21] Federal Law No. 157 of Sept. 17, 1998 on the Immunoprophylaxis of Infectious Diseases art. 4, SZ RF 1998, No. 38, Item 4236, http://base.garant.ru/12113020/.

[22] *Id*. arts. 5.2, 6.

[23] Ruling of the Russian Federation Supreme Court No. GKPI2000-1453 of Feb. 5, 2001, *available at* http://www.consultant.ru/document/cons_doc_LAW_31907/.

[24] Rospotrebnadzor Letter No. 0100/1828 of Feb. 20, 2006 on the Accounting of Expenses Related to Fighting Epidemics, *available at* http://www.businesspravo.ru/Docum/DocumShow_DocumID_113411.html (in Russian).

consequences, and data on the radiation, chemical, medical, biological, explosive, fire, and environmental security of related territories. Information about government activities in this area must be open to public access and cannot be classified.[25]

The concealment or distortion of information about developments, facts, or events endangering human life or health, or the environment, by a person whose duty is to provide such information to the population is a crime punishable by a fine or deprivation of freedom for a term of up to two years, with or without disqualification to hold specified offices or engage in specified activities for a term of up to three years. Stricter punishments are prescribed for the same acts committed by a person holding a post at any level of government.[26]

III. Responsibilities for Failure to Comply with Sanitary Requirements

Russian criminal legislation considers the violation of sanitary rules and creation of health emergencies as attempts on human life regardless of the consequences and punishes the criminal according to the act committed, whether it was a murder or intentionally inflicting harm on health.[27]

The violation of sanitary and epidemiological rules that results in the spread of a disease or poisoning of people is a crime under Russian criminal law. This also applies to individuals who violate quarantine requirements. Such actions are punishable by a fine, disqualification to hold specified offices or engage in specific activities for a term of up to three years, corrective labor for a term of up to one year, or imprisonment for one year. If the death of a person was the consequence, the term of imprisonment extends up to five years.[28]

Also, individuals whose negligence in dealing with dangerous biological agents has inflicted harm on human health are held criminally responsible. Individuals who violate safety regulations for handling microbiological or other biological agents or toxins and thereby cause harm to human health or the spread of an epidemic or disease or other grave consequences are punishable by a fine, compulsory labor for a term of up to two years, or imprisonment for a term of up to two years.[29]

Russian law provides for the possibility of imposing some restrictive measures on foreigners suspected of being infected with a communicable disease. Article 7 of the Law of June 21, 2002 on the Legal Status of Foreign Citizens in the Russian Federation allows authorities to reject a petition or annul previously issued permission for a foreigner to take up temporary residence in Russia if he/she is a drug addict, does not have a document certifying that he/she does not have a

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[25] Federal Law on Information, Information Technologies, and the Protection of Information No. 149 of July 27, 2006, SZ RF 2006, No. 31(1), Item 3448, http://base.garant.ru/12148555/ (in Russian).

[26] CRIMINAL CODE OF THE RUSSIAN FEDERATION art. 237, SZ RF 1996, No. 25, Item 2954 (in Russian).

[27] A.B. BORISOV, COMMENTARIES ON THE CRIMINAL CODE OF THE RUSSIAN FEDERATION 729 (Moscow, 2012) (in Russian).

[28] CRIMINAL CODE OF THE RUSSIAN FEDERATION art. 236.

[29] *Id.* art. 248.

disease induced by the AIDS virus, or is suffering from an infectious disease considered dangerous to other people. The list of these diseases and the procedure for medical evaluation of a person suspected of being infected has been established by the federal government.[30]

IV. Cooperation with the World Health Organization

Russia is a member of the World Health Organization (WHO) and has accepted the obligation to bring its health crisis management procedures in line with WHO requirements. In 2009, the Framework Cooperation Agreement was signed between the WHO and the Ministry of Health Protection,[31] and ongoing developments in the Russian health care sector are tied to WHO strategic goals.[32]

The Ministry of Health Protection has set a goal of bringing Federal Target Programs in line with WHO requirements[33] and, in 2014, the Ministry of Health Protection reported that systemic changes recommended by the WHO had been implemented.[34] Existing Russian rules and procedures for sanitation and epidemiological control do not contradict the requirements of the International Health and Sanitary Regulations of 2005, which were adopted by Russia without reservations, and are followed in case of emergencies.[35]

V. Response to the Outbreak of Infectious Diseases

Recently, Russian authorities have undertaken preventive epidemiologic measures in response to two global health crises, the SARS epidemic in 2006 and the swine flu epidemic in 2009. When the WHO issued an emergency alert in April 2009 because of the spread of the swine flu, the Russian government formed an executive commission on preventing the introduction and spread in Russian territory of diseases caused by flu viruses. The Commission consisted of heads of all relevant government executive agencies. The government decree defined its duty as the coordination and supervision of the activities of federal and regional authorities in this regard.[36]

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[30] Federal Law No. 115 of July 25, 2002 on the Legal Status of Foreign Citizens in the Russian Federation, SZ RF 2002, No. 26, Item 2513, http://base.garant.ru/184755/ (in Russian).

[31] *Russia and WHO Sign Framework Cooperation Agreement*, MEDLINKS.RU (Jan. 21, 2009), *available at* http://www.medlinks.ru/article.php?sid=34871 (in Russian).

[32] Natalia Valkina, *Cooperation Strategy Between Russia and WHO Is Signed*, ARGUMENTY I FAKTY (July 24, 2014), http://www.aif.ru/health/life/1214975 (in Russian).

[33] *Id*.

[34] Press Release, Russian Federation Ministry of Health Protection, Minister Skvotsova Participates in World Healthcare Assembly (May 19, 2014), http://www.rosminzdrav.ru/news/2014/05/19/1839-ministr-veronika-skvortsova-prinyala-uchastie-vo-vsemirnoy-assamblee-zdravoohraneniya (in Russian).

[35] Rospotrebnadzor Order No. 39 of Nov. 29, 2007, *available at* http://www.mossanexpert.ru/view_info.php?id=38 (in Russian).

[36] Government Regulation No. 367 of April 27, 2009, on the Government Commission on Preventing the Spread of Highly Pathogenic Flu in Russia, RG, May 5, 2009, http://www.rg.ru/2009/05/05/virus-dok.html (in Russian).

The Commission ordered

- the surveillance of passengers coming from Mexico and other countries where cases of swine flu had been reported;
- the mandatory checking of the body temperature of all arriving travelers and the creation of quarantine points at the ports of entry;
- the monitoring of disease reporting by regional institutions;
- the allocation of increased funds for select major national research institutes; and
- the stockpiling of antiviral medicines.

In addition, the import of pork from the countries affected by the epidemic was stopped for several days.[37]

In 2006, in order to prevent the spread of the SARS virus, the government ordered the Federal Border Service to close certain checkpoints on the Russian border with Mongolia and China. Airlines were ordered to reduce the number of flights to infection-affected regions, and eleven medical groups consisting of physicians and sanitary control specialists were formed. Placed on trains traveling between Russia and China, these groups conducted medical examinations of more than one thousand suspicious passengers and railroad personnel. A network of federal medical centers was set up in major Russian regional centers with the task of diagnosing the disease and identifying the presence of the virus. Airport terminals in Moscow were equipped with infrared detectors able to determine any traveler's temperature at a distance of fifty yards. In order to protect the capital city, public transport and open markets were disinfected daily, and one million respiratory masks were acquired for public use.[38]

VI. Response to the Ebola Virus Outbreak

Russia's Foreign Ministry announced it had allocated the equivalent of US$3.8 million to help the country prepare for a possible outbreak of Ebola and the equivalent of US$3.95 million for research work.[39] Russia also set aside the equivalent of US$5.2 million in humanitarian aid for the West African countries hit hardest by the outbreak.[40]

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[37] *Id*.

[38] Dmitri Vladimirov, *Cabinet of Ministers Decide to Be Proactive in Fighting Bird Flu*, RG (Apr. 11, 2007), http://www.rg.ru/2007/04/11/medvedev.html (in Russian).

[39] *More Than 3 Million Travelers Checked for Ebola at Russian Airports*, MOSCOW TIMES (Oct. 24, 2014), http://www.themoscowtimes.com/news/article/more-than-3-million-travelers-checked-for-ebola-at-russian-airports/510021.html.

[40] *Russia Allocated 779 Million Rubles to Fight Ebola*, LENTA.RU (Oct. 16, 2014), http://lenta.ru/news/2014/10/16/dorogoivirus/ (in Russian).

Following the outbreak of Ebola in West Africa, a team of epidemiologists, virologists, and bacteriologists was sent by Rospotrebnadzor to Guinea to participate in fighting Ebola.[41] The team delivered a mobile laboratory and took part in diagnosing and treating the Ebola virus.[42] Russia is considering sending additional medics to Africa in order to stop the epidemic spread.[43] The possibility of deploying planes with special medical equipment, including life-support capsules for transporting Ebola-infected patients, is being explored.[44] Protective equipment, such as sealed medical suits, masks, eye shields, and disinfecting materials, was supplied to Guinea.[45] Also, production of a trial batch of the Ebola vaccine Triazavirin has been launched. This vaccine will be sent to Africa for efficacy tests.[46]

The Russian Ministry of Education and Science recommended that universities postpone the academic year for students from Africa because of the Ebola virus.[47] It is estimated that Russia has about two thousand students from the Ebola-affected countries.[48] About five hundred students from West Africa were tested for the virus and placed under observation.[49] They were not isolated, but doctors checked their temperature and other vital signs.[50] No Ebola case was confirmed.[51]

The initiative to check all African residents in Russia for Ebola was discussed by the legislature; however, the Ministry of Health Protection deemed this measure excessive because Africans who already live in Russia do not need to be checked for Ebola, as control border controls are sufficient to keep the disease out of the country.[52]

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[41] *Russia's Putin Vows Closer Cooperation with WHO in Ebola Fight*, SPUTNIK (Oct. 13, 2014), http://en.ria.ru/russia/20141013/194031322/Russias-Putin-Vows-Closer-Cooperation-with-WHO-in-Ebola-Fight.html.

[42] *Russia Offers to Send More Experts to Tackle Ebola in West Africa*, MOSCOW TIMES (Oct. 8, 2014), http://www.themoscowtimes.com/news/article/russia-offers-to-send-more-experts-to-tackle-ebola-in-west-africa/508598.html.

[43] SPUTNIK, *supra* note 41.

[44] *Id*.

[45] Irina Nevinnaia, *Russian Federation and Guinea Will Sign a Memorandum on Ebola Fight*, RG (Oct. 24, 2014), http://www.rg.ru/2014/10/24/golodec-site.html (in Russian).

[46] *Russia Ready to Introduce New Ebola Vaccines in Six Months: Russian Health Minister*, SPUTNIK (Oct. 11, 2014), http://en.ria.ru/russia/20141011/193961655/Russia-Ready-to-Introduce-New-Ebola-Vaccines-in-6-Months-Russian.html.

[47] Gleb Fedorov, *Chances of Ebola Epidemic Reaching Russia Are Slim, Say Researchers*, RUSSIA BEYOND THE HEADLINES (Oct. 13, 2014), http://rbth.co.uk/science_and_tech/2014/10/13/chances_of_ebola_epidemic_reaching_russia_are_slim_say_resea_40553.html.

[48] *Id*.

[49] MOSCOW TIMES, *supra* note 42.

[50] *Id*.

[51] *African Students Hospitalized in Russia Do Not Have Ebola: Russia's Health Watchdog,* SPUTNIK (Oct. 23, 2014), http://en.ria.ru/russia/20141018/194264877/African-Students-Hospitalized-in-Russia-Do-Not-Have-Ebola.html.

[52] *Ebola Checks for African Residents in Russia Unnecessary: Health Ministry*, SPUTNIK (Oct. 23, 2014), http://en.ria.ru/russia/20141023/194495826/Ebola-Checks-for-African-Residents-in-Russia-Unnecessary-Health.html.

From August to October 2014, more than three million passengers arriving at the country's airport from various countries were checked by the Rospotrebnadzor specialists.[53] Of those checked, twenty-two people were hospitalized and examined for signs of Ebola, but all were found to be free of the disease.[54] The agency also introduced a system of registration and mandatory twenty-one-day monitoring of people arriving from Ebola-affected African countries.[55] According to the Ministry of Health Protection, Russia has an active antibacterial system that annually discovers and isolates about two hundred cases of exotic viruses.[56] Reportedly, Russian airports will be provided with additional equipment to increase the effectiveness of examinations.[57]

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[53] MOSCOW TIMES, *supra* note 39.

[54] *Id*.

[55] *On the Ebola Situation (as of 24.10.2014)*, ROSPOTREBNADZOR (Oct. 24, 2014), http://rospotrebnadzor.ru/about/info/news/news_details.php?ELEMENT_ID=2537&sphrase_id=191869 (in Russian).

[56] Fedorov, *supra* note 47.

[57] *Additional Equipment Will Be Installed in Russian Airports in Connection with the Ebola Virus*, TASS (Oct. 17, 2014), http://itar-tass.com/obschestvo/1515553 (in Russian).

Senegal

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SUMMARY Senegal has contained many disease outbreaks and has been particularly credited for keeping its HIV/AIDS epidemics and, recently, the Ebola pandemic at bay. Keys to this success include the involvement of government authorities from the national level to the local level, through a decentralized public health structure; measures aimed at early detection; an extensive use of the media and public information campaigns; and collaboration with the WHO and health-related NGOs for surveillance, immunization, and crisis management.

I. Introduction

Senegal, a West African nation, became independent from France in 1960 and inherited a legal and institutional system that was almost identical to the system prevailing in France. Senegal is a republic with a democratic government. It is regarded as one of the most politically stable countries in Africa.[1] A new Constitution was adopted on January 22, 2001, which guarantees the right to health.[2]

II. Structure of Public Health Crisis Management System

A. The Ministry of Health

Two directorates of the Ministry of Health are primarily involved in the fight against communicable diseases. The Directorate of Health has the task of formulating, implementing, and monitoring health policy and programs. To this end, it is responsible, among others, for the control of communicable and noncommunicable diseases. The Directorate of Prevention formulates, implements, and monitors prevention policy. It is responsible for immunization, monitoring and managing of epidemics, and communicating with the public.[3] In addition, the

[*] This is a revised and updated version of a 2003 report authored by Senior Foreign Law Specialist Nicole Atwill (retired).

[1] *Senegal*, CIA WORLD FACTBOOK, https://www.cia.gov/library/publications/the-world-factbook/geos/sg.html (accessed on Oct. 30, 2014).

[2] CONSTITUTION DE LA RÉPUBLIQUE DU SÉNÉGAL DU 22 JANVIER 2001 (CONSTITUTION) art. 8, JOURNAL OFFICIEL DE LA RÉPUBLIQUE DU SÉNÉGAL [J.O.], Jan. 22, 2001, http://www.gouv.sn/-Constitution-du-Senegal-.html.

[3] Décret No. 2003-466 du 24 juin 2003 portant organisation du Ministère de la Santé, de l'Hygiène et de la Prévention [Decree No. 2003-466 of June 24, 2003 Organizing the Ministry of Health, Hygiene, and Prevention] arts. 1–7 (June 24, 2003), http://www.jo.gouv.sn/spip.php?article284.

Ministry of Health maintains partnerships with several international or foreign organizations including the World Health Organization (WHO), USAID, and the World Bank.[4]

B. Medical Regions

Senegal has eleven medical regions,[5] each divided into sanitary districts, which are operational zones comprising at least one health center around which several health posts have been established. The districts' boundaries do not necessarily coincide with the boundaries of other territorial entities such as municipalities or *départements*.[6] Each district is supposed to cover a population of between 100,000 and 150,000.[7] Each medical region is headed by a doctor and has several bureaus, one of which is specifically in charge of immunization for and the management of epidemics.[8]

C. National Service of Sanitary Information

The National Service of Sanitary Information, attached to the Health Minister's cabinet, collects and analyzes sanitary information. It centralizes and updates all information concerning the sanitary system of Senegal and compiles health statistics. These data are available to other services, researchers, and the Ministry of Health's partners.[9]

D. Notification Requirements

The Public Health Code requires that doctors report to the public health authorities any case that they may come across of a disease listed in a regulation established by the Ministry of Health.[10] Additionally, the head of family, spouse, nearest relative, or any other person residing with or taking care of a sick person is required to report the illness to the public health authorities if they are aware that the patient is suffering from one of the listed diseases.[11] Failure to notify

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[4] *Partenaires* [*Partners*], MINISTÈRE DE LA SANTÉ ET DE L'ACTION SOCIALE [MINISTRY OF HEALTH AND SOCIAL ACTION] (Aug. 21, 2013), http://www.sante.gouv.sn/index.php?option=com_content&view=article&id=1298&Itemid=764.

[5] *Les Régions Médicales* [*The Medical Regions*], MINISTÈRE DE LA SANTÉ ET DE L'ACTION SOCIALE, http://www.sante.gouv.sn/index.php?option=com_content&view=article&id=1294&Itemid=636 (last visited Oct. 31, 2014).

[6] FÉLIX ATCHADÉ, RADIOSCOPIE D'UN SYSTÈME DE SANTÉ AFRICAIN: LE SÉNÉGAL [RADIOSCOPY OF AN AFRICAN HEALTHCARE SYSTEM: SENEGAL] 67, 74 (2013).

[7] COL. MASSAMBA DIOP, LA SANTÉ AU SÉNÉGAL DE 1960 À 2010 [HEALTH IN SENEGAL FROM 1960 TO 2010] at 22 (2011).

[8] Décret No. 2003-466 du 24 juin 2003, arts. 22, 23 & 24.

[9] *Id.* art. 29.

[10] CODE DE L'HYGIENE, Loi No. 83-71 du 5 juillet 1983 portant Code de l'Hygiène [Law No. 83-71 of July 5, 1983, Establishing the Hygiene Code] art. L3 (July 5, 1983), J.O., Aug. 6, 1983, http://www.servicepublic.gouv.sn/assets/textes/code-Hygiene.pdf.

[11] *Id.*

authorities of the disease is punishable by a fine from 9,000 to 18,000 Francs CFA (approximately US$17 to US$35), imprisonment from five to eight days, or both.[12]

III. Powers of Public Health Authorities

A. Mandatory Immunization of Health Care Personnel

All personnel working in public or private health establishments in a capacity where they risk being exposed to certain specified diseases are required to get vaccinated. The Ministry of Health sets forth the list of these establishments and the conditions under which this immunization takes place. The diseases in question are tuberculosis, diphtheria, tetanus, typhoid and paratyphoid fevers, and poliomyelitis.[13]

B. Disinfection Measures

Disinfection measures are mandatory for any of the diseases that must be reported. The Ministry of Health decides which measures should be implemented. The National Hygiene Service carries out the disinfection process.[14] It is unlawful to oppose such measures. The penalties for failing to take such measures are identical to the penalties set forth for failing to notify authorities of a listed disease.[15]

C. Sanitary Controls at the Borders

Sanitary controls at the borders are governed by the World Health Organization's (WHO) International Health Regulations, and any bilateral or multilateral agreement and national regulations in this field, aimed at preventing the spread of communicable diseases by air, sea, or land.[16] Violations of these provisions are recorded either by public health doctors, doctors or officers from the National Hygiene Service, or by other agents specifically commissioned for such a task.[17]

If a civil servant, public agent, or commanding officer of a ship or airplane falsifies or voluntarily conceals information that may compromise the health of the population, he may be punished by a fine of 20,000 to 260,000 Francs CFA (approximately US$39 to US$500), imprisonment from two months to two years, or both.[18]

Senegal, for example, stepped up its vigilance against Severe Acute Respiratory Syndrome (SARS) and took special measures to protect itself when the WHO issued its alerts. Surveillance

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[12] *Id*. art. L75.

[13] *Id.* art. L1.

[14] *Id*. art. L4.

[15] *Id*. art. L75.

[16] *Id.* art. L5.

[17] *Id*. art. L6.

[18] *Id*. arts. L7 & L77.

was reinforced at the Dakar International Airport and at other points of entry. Airport personnel were trained and given the necessary knowledge to be able to identify suspected SARS cases.[19]

IV. Transparency of Public Health Crisis Management System

The Constitution of Senegal recognizes a right to a plurality of information.[20] The government of Senegal has extensively used the media to fight public health crises. In 2003, it launched a radio campaign to heighten public awareness of SARS.[21] Currently, the Senegalese Ministry of Health provides information on the Ebola virus on its website and through a toll-free number.[22]

V. Cooperation with the WHO

Senegal is a member of the WHO. As noted above, it abides by the WHO International Health Regulations dealing with notification of certain communicable diseases and measures to be taken at entry points to avoid the spread of such diseases. Senegal worked with the WHO on precautionary measures to protect its people from SARS. Through the years, the WHO has provided epidemiological, clinical, and logistical support to Senegal. The WHO and the Ministry of Health have worked together in the areas of surveillance, immunization, and coordination with respect to yellow fever.[23]

VI. Recent Crises

A. HIV/AIDS

Senegal also stands as one of the few countries in the region to have succeeded thus far in containing the spread of HIV/AIDS, thanks to a strong surveillance system; an aggressive focus on treatment and support of high-risk groups; extensive information to the general public; and a high level of involvement of local authorities, teachers, soldiers, religious leaders, nongovernmental organizations, and the media to achieve a greater mobilization of the community. Its long democratic experience and the relative freedom of its national press have also resulting in freely debating the problem and publishing information concerning the disease.[24] Senegal has also scaled up access to anti-retroviral treatment and encouraged

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[19] Africa Steps Up Vigilance After Continent's First Probable SARS Case Dies, AGENCE FRANCE PRESSE (Apr. 30, 2003), *available at* Lexis, News Group File.

[20] CONSTITUTION art. 8, http://www.gouv.sn/-Constitution-du-Senegal-.html. The concept of a "right to a plurality of information" is similar to the principle in the European Union Charter that the "freedom and pluralism of the media shall be respected." Charter of Fundamental Rights of the European Union art. 11(2), 2000 O.J. (C 364) 1, http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

[21] AGENCE FRANCE PRESSE, *supra* note 19.

[22] MINISTÈRE DE LA SANTÉ ET DE L'ACTION SOCIALE, http://www.sante.gouv.sn/ (last visited Oct. 31, 2014).

[23] *Country Cooperation Strategy at a Glance*, WHO (May 2014), http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_sen_en.pdf; *Senegal to Launch Pan West-African Campaign to Prevent Yellow Fever*, WHO (Dec. 5, 2007), http://www.afro.who.int/fr/ghana/press-materials/item/74-senegal-to-launch-pan-west-african-campaign-to-prevent-yellow-fever.html.

[24] Mamadou Mika Lom, *Le Sénégal, un modèle de réussite*, 15(1–2) AFRIQUE RELANCE 24 (June 2001).

voluntary counseling and testing. As a result, the country has Africa's lowest HIV prevalence rate, at 0.7%.[25]

B. Yellow Fever

Due to its climate, Senegal is prone to periodic yellow fever epidemics. One such epidemic caused twelve deaths in 2002.[26] In response, the Senegalese authorities organized mass vaccination campaigns, gradually covering the entirety of the country over the next several years. Since 2007, inoculation against yellow fever is routinely given throughout Senegal.[27]

C. Ebola Virus

Senegal has largely been spared by the current Ebola pandemic, despite sharing a border with Guinea, one of the hardest-hit countries.[28] Senegal's response to the Ebola threat has focused on four types of measures: quick testing of individuals suspected of being infected, identifying and monitoring anyone who has been in contact with infected patients, increased monitoring at the country's entry points, and national public awareness campaigns.[29] After Senegalese authorities identified a young man who had arrived from Guinea as being infected, they tracked down seventy-four people with whom he had had contact and screened them for the virus.[30] Additionally, Senegal closed its border with Guinea, and has prohibited aircraft and ships from Guinea, Sierra Leone, and Liberia from landing in the country.[31]

From early on, the Senegalese government has been working closely with the WHO and NGOs such as Doctors Without Borders, both of which have provided Senegal with teams of doctors and epidemiologists to help deal stave off the pandemic.[32]

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[25] *Senegal: A Success Story of AIDS Investments and Impact*, UNAIDS (Oct. 11, 2012), http://www.unaids.org/en/resources/presscentre/featurestories/2012/october/20121011senegal/.

[26] ATCHADÉ, *supra* note 6, at 206.

[27] *Id.*; *Senegal to Launch Pan West-African Campaign to Prevent Yellow Fever*, *supra* note 23.

[28] Karen Weintraub, *From Senegal and Nigeria, 4 Lessons on How to Stop Ebola*, NATIONAL GEOGRAPHIC (Oct. 24, 2014), http://news.nationalgeographic.com/news/2014/10/141024-ebola-nigeria-outbreak-lessons-virus-health/.

[29] Press Release, WHO, WHO Congratulates Senegal on Ending Ebola Transmission (Oct. 17, 2014), http://www.who.int/ mediacentre/ news/statements/2014/senegal-ends-ebola/en/.

[30] *Id.*; Weintraub, *supra* note 28.

[31] Jacque Wilson, *Borders Closing Over Ebola Fears*, CNN (Aug. 22, 2014), http://www.cnn.com/2014/08/22/health/ebola-outbreak/.

[32] *Ebola: le Sénégal sort de la liste rouge de l'OMS* [*Ebola: Senegal Comes Off the WHO's Red List*], LES ECHOS (Oct. 17, 2014), http://m.lesechos.fr/industrie-services/ebola-le-senegal-sort-de-la-liste-rouge-de-l-oms-0203868882831.htm.

South Korea

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SUMMARY The Ministry of Health and Welfare is the government agency responsible for responding to health crises in South Korea. The Korea Centers for Disease Control and Prevention (KCDC) was established by the relevant Minister who delegated certain powers to the KCDC to address infectious disease emergencies.

The aims of the Infectious Diseases Control and Prevention Act include preventing the occurrence and prevalence of infectious diseases and prescribing the necessary measures for their prevention and control. The Quarantine Act provides measures for preventing infectious diseases from spreading inside South Korea and outside its borders.

South Korea has an infectious disease surveillance system. When a person is infected with a specified infectious disease, the person may be treated and hospitalized in designated hospitals.

I. Structure of the Public Health Crisis Management System

The Minister of Health and Welfare is responsible for the administration of affairs related to health, sanitation, and the prevention of epidemics, among other things.[1] The Infectious Diseases Control and Prevention Act was enacted in 2009 "to contribute to the improvement and maintenance of citizens' health by preventing the occurrence and prevalence of infectious diseases hazardous to citizens' health, and prescribing necessary matters for the prevention and control thereof."[2] The Act confers upon the Minister of Health and Welfare various powers and obligations. The authority of the Minister of Health and Welfare stipulated under the Act may be partially delegated to the Director of the Korea Centers for Disease Control and Prevention (KCDC).[3]

The Minister of Health and Welfare formulates and implements a "master plan" for the prevention and control of infectious diseases every five years. The master plan must include the following:

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[*] At present there are no Law Library of Congress research staff members versed in Korean. This report has been prepared by the author's reliance on practiced legal research methods and on the basis of relevant legal resources, chiefly in English, currently available in the Law Library and online.

[1] Government Organization Act, Act No. 1, July 17, 1948, amended by Act No. 11690, Mar. 23, 2013, art. 38, English translation available on Korea Legislation Research Institute's (KLRI) online database, *at* http://elaw.klri.re.kr/eng_service/lawView.do?hseq=27695&lang=ENG.

[2] Infectious Disease Control and Prevention Act, Act No. 9847, Dec. 29, 2009, *amended by* Act No. 11645, Mar. 22, 2013, art. 1, English translation *available at* http://elaw.klri.re.kr/eng_service/lawView.do?hseq=29938&lang=ENG.

[3] *Id*. art. 76(1).

1. Basic objectives of and direction-setting for executing the prevention and control of infectious diseases;
2. Project plans for the prevention and control of major infectious diseases, and methods of executing them;
3. Schemes to train experts and enhance emergency preparedness capability for infectious diseases;
4. Schemes to manage statistics and information on infectious diseases . . . [.][4]

An Infectious Disease Control Committee was established under the Ministry of Health and Welfare (MOHW) to deliberate on major policies concerning the prevention and control of infectious diseases, including the formulation of a master plan and crisis control measures.[5] The Vice Minister of Health and Welfare chairs the Committee.[6] The Minister of Health and Welfare formulates and implements crisis control measures against infectious diseases following Committee deliberations on these matters.[7] The crisis control measures include the following:

1. A response system and roles of each agency at emergency scenes;
2. A determination and decision-making system of emergencies;
3. Schemes of stockpiling and supplying medical supplies . . . ;
4. Education and training schemes, such as citizens' codes of conduct in each case of emergency . . . [.][8]

The Minister of Health and Welfare may establish organizations consisting of private professionals to support infectious disease control projects, the implementation of master plans and implementation plans, and international cooperation in health affairs.[9] The KCDC is one such organization,[10] and contains the following divisions: Infectious Disease Control, Quarantine Support, Infectious Disease Surveillance, Epidemic Intelligence Service, Bioterrorism Preparedness and Response, and Public Health Crisis Response.[11] The Division of Public Health Crisis Response "is in charge of the planning and running of the national emerging disease response, response and management of avian influenza human infection and pandemic influenza, education and training of public health officials, research and development of public health crisis, and international cooperation."[12] The Management Team for Public Health Crisis

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[4] *Id*. art. 7(1). A copy of the master plan was not located.

[5] *Id*. art. 9(1) & (2).

[6] *Id*. art. 10(2).

[7] *Id*. art. 34(1).

[8] *Id*. art. 34(2). A copy of the crisis control measures was not located.

[9] *Id*. art. 8(1).

[10] *See Center for Infectious Disease Control*, KCDC, http://www.cdc.go.kr/CDC/eng/contents/CdcEngContentView.jsp?cid=17908&menuIds=HOME002-MNU0575-MNU0633 (last visited Oct. 29, 2014).

[11] *Id*.

[12] Hye-Young Lee et al., *Public Health Crisis Preparedness and Response in Korea*, 4(5) OSONG PUB. HEALTH RES. PERSP. § 1, 278–84 (Oct. 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3845460/.

Response "supports effective and professional strategy formulation and execution of projects for the crisis caused by emerging infectious diseases of the division."[13]

II. Surveillance

The Infectious Diseases Control and Prevention Act classifies infectious diseases in groups, depending on the speed of transmission or degree of danger and harm:

- Group 1: infectious diseases spread via drinking water or food, with a high risk of mass outbreak, requiring immediate control measures upon their outbreak or prevalence. These diseases include cholera, typhoid fever, paratyphoid fever, bacterial dysentery, colon bacillus infection with enterorrhagia and viral hepatitis A.
- Group 2: infectious diseases that can be prevented and controlled by vaccinations, subject to national vaccination programs. These diseases include diphtheria, pertussis, tetanus, measles, mumps, rubella, poliomyelitis, viral hepatitis B, Japanese encephalitis, varicella, and haemophilus influenza type B.
- Group 3: infectious diseases requiring continuous surveillance and the establishment of control measures against their outbreak. These diseases include malaria, tuberculosis, Hansen's disease, scarlet fever, meningococcal meningitis, legionellosis, vibrio vulnificus sepsis, epidemic typhus, murine typhus, scrub typhus, leptospirosis, brucellosis, anthrax, rabies, hemorrhagic fever with renal syndrome, influenza, AIDS, syphilis and Creutzfeldt-Jakob disease.
- Group 4: infectious diseases, as designated by Ordinance of the MOHW, that have newly broken out or are likely to break out in Korea, or that are epidemics overseas with a risk of transmission to Korea.
- Group 5: infectious diseases that are spread by parasite infection and are designated by Ordinance of the MOHW as requiring surveillance through regular investigations.
- Designated infectious diseases: infectious diseases designated by the Minister of Health and Welfare, other than infectious diseases in Groups 1–5, requiring surveillance to investigate whether they are epidemic.
- Infectious diseases under surveillance of the World Health Organization (WHO): infectious diseases being monitored to prepare for international public health emergencies, as announced by the MOHW.
- Infectious diseases spread through bioterrorism: infectious diseases publicly announced by the MOHW as being among those spread by pathogens through deliberate use or for terrorism.
- Sexually transmitted infectious diseases: infectious diseases announced by the Minister of Health and Welfare as being transmitted by sexual contact.
- Zoonoses: infectious diseases spread by pathogens transmittable from animals to humans and vice versa, announced as requiring surveillance by the MOHW.

[13] *Id*. § 4.3.

- Nosocomial infectious diseases: infectious diseases contracted by people involved in medical activities or undergoing medical procedures, announced as requiring surveillance by the MOHW.[14]

No specific information was located concerning the classification of Ebola in one of the abovementioned infectious disease groups, but it appears that Ebola could be included under "Infectious diseases under surveillance of the WHO" or several other categories.

Under the Infectious Diseases Control and Prevention Act, a medical doctor must report the following infectious disease situations to the head of the medical institution to which he/she belongs or to a competent public health clinic if he/she does not belong to a medical institution:

- A doctor diagnoses a patient as being infected with a disease belonging to any of the groups listed above, or examines the corpse of such a patient.
- A patient infected with a disease from Groups 1–4 dies.[15]

The medical institution that receives such a report from a doctor must forward it to the competent public health clinic.[16]

The Infectious Diseases Control and Prevention Act obligates anyone who becomes aware of a person that he/she suspects is infected with or has died from a disease belonging to any of the groups listed above to inform the head of a competent public health clinic.[17] A definite or suspected case of a Group 1 infectious disease, or a death resulting from a Group 1 disease, obligates the following people either to pursue a medical examination or diagnosis, or to make a report to the public health clinic in their jurisdiction:

- In the case of a family, the head of the household or, in the absence of the head of the household, another member of the household.
- In the case of a school, hospital, government office, company, place of entertainment or worship, vessel, place of business, restaurant, inn, or other place of gathering, the head, manager, proprietor, or representative of the establishment.[18]

Violation of the Act's provisions regarding required medical examinations or reports is punishable by a fine not to exceed ₩2 million (approximately US$1,890).[19]

The head of a public health clinic on receipt of an infectious disease notification must report the details "to the Governor of the competent Special Self-Governing Province or the head of the

[14] Infectious Diseases Control and Prevention Act art. 2.

[15] *Id*. art. 11(1).

[16] *Id*. art. 11(2).

[17] *Id*. art. 12(2).

[18] *Id*. art. 12(1).

[19] *Id*. art. 81.

competent Si/Gun/Gu who shall, in turn, report them to the Minister of Health and Welfare and the competent Mayor/Do Governor."[20] The KCDC receives all such information and creates relevant statistics.[21]

The KCDC conducts an epidemiological investigation when it deems that an infectious disease has broken out and "is likely to prevail subsequently."[22]

III. Powers of Public Health Authorities

A local government may designate a medical institution as an infectious disease control institution. The MOHW Ordinance requires the head of a designated medical institution to establish necessary facilities for preventing infectious diseases and for examining and treating infected patients.[23] The expenses incurred for the establishment of such facilities are subsidized by the local government.[24] In the case of mass infections or difficulty in accommodating all infected patients, the Minister of Health and Welfare and heads of local governments can designate other medical institutions as infectious disease control institutions for a certain period, as well as establish and operate isolation wards, sanatoriums, and clinics.[25]

In August 2014, "the Health Ministry designated a total of 17 hospitals with quarantine units as official facilities to treat patients should Ebola occur in South Korea."[26] However, one expert on infectious disease epidemiology has stated that

> [a]lthough there are 17 government-designated hospitals with quarantine units, these units were constructed for airborne infectious diseases like influenza. As such, currently no hospitals in South Korea are designed to provide one-stop testing and treatment for diseases like Ebola that are transmitted through body fluids.[27]

A person who has contracted a disease specified by the Minister of Health and Welfare as infectious must be hospitalized at the designated infectious disease control institution. If such an institution is full, the Minister of Health and Welfare or the head of the local government may

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[20] *Id*. art. 13(1).

[21] Byungguk Yang, PowerPoint Presentation, Infectious Disease Surveillance System in Korea, Thirty-first Asia-Pacific Advanced Network Meeting, slides 7–15 (Feb. 2011), http://www.apan.net/meetings/ HongKong2011/ Session/Slides/Medical/6-6.pdf.

[22] Infectious Diseases Control and Prevention Act art. 18.

[23] An English translation of the Ordinance is not available.

[24] Infectious Diseases Control and Prevention Act art. 36(1) & (2).

[25] *Id*. art. 37(1).

[26] *South Korea Ill-Prepared for Possible Ebola Outbreak, Say Health Experts*, STRAITS TIMES (Oct. 20, 2014), http://www.straitstimes.com/news/asia/east-asia/story/south-korea-ill-prepared-possible-ebola-outbreak-say-health-experts-201410.

[27] Moran Ki, *What Do We Really Fear? The Epidemiological Characteristics of Ebola and Our Preparedness*, 36 EPIDEMIOLOGY & HEALTH 1, 4 (Aug. 18, 2014), http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4153011/pdf/epih-36-e2014014.pdf.

permit the patient to be hospitalized at another medical institution.[28] The Minister of Health and Welfare or the head of the local government must provide notice to the person to be hospitalized.[29] Refusing hospital treatment is punishable by a fine not to exceed ₩3 million (approximately US$2,790).[30] The Minister of Health and Welfare or the head of the local government may require the relevant public official to conduct an investigation or medical diagnosis by entering the residence, means of transportation (such as a ship, aircraft, or train), or any other place where there are persons infected with a disease from Group 1 or a specified infectious disease from other groups. When a medical diagnosis identifies an infected person, the relevant public official may escort the patient to undergo required medical treatment or hospitalization.[31]

The head of the local government may require any of the following persons to undergo a medical examination or receive a vaccination necessary for the prevention of an infectious disease:

1. Family members of a patient, etc. infected by an infectious disease, or his/her cohabitants;
2. A person suspected of being infected by an infectious disease, who lives in or frequents an area where an infectious disease has occurred;
3. A person suspected of being infected by an infectious disease, as he/she has come into contact with a patient, etc. infected by an infectious disease.[32]

In order to prevent the further spread of an infectious disease once it has broken out, the head of the local government is obligated to take all or some of the following measures:

1. To isolate traffic to places where patients, etc. infected by an infectious disease exist or to the places deemed to have been infected by the pathogen of an infectious disease for a certain period;
2. To keep persons suspected of being infected by the pathogen of an infectious disease hospitalized or in quarantine at an appropriate place for a certain period;
3. To prohibit the use, receipt, transfer, abandonment, or washing of articles infected or suspected of being infected by the pathogen of an infectious disease, or to incinerate or destroy such articles;
4. To order the disinfection of or other necessary measures for places infected by the pathogen of an infectious disease;
5. To prohibit laundry at a specified place, or to order the disposal of waste at a specified place.[33]

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[28] Infectious Diseases Control and Prevention Act art. 41(1) & (2).

[29] *Id*. art. 43.

[30] *Id*. art. 80(2).

[31] *Id*. art. 42.

[32] *Id*. art. 46.

[33] *Id*. art. 47.

IV. Quarantine Act

Means of transport (ships, aircraft, trains, or automobiles), people, or cargo entering or departing from the Republic of Korea must undergo quarantine inspections.[34] No one besides public officials in charge of quarantine is permitted to embark or board a means of transport subject to a quarantine inspection before a quarantine certificate has been issued.[35]

Under the Quarantine Act, diseases subject to quarantine are cholera, pest and yellow fever, SARS, avian influenza, pandemic influenza, and other infectious diseases that break out abroad and are likely to spread within the Republic of Korea, or break out within the Republic of Korea and are likely to spread abroad, and that the Minister of Health and Welfare designates.[36]

The director of the quarantine station conducts quarantine inspections related to any of the following:

1. Progress and current status of health and sanitary conditions of the means of transport;
2. Matters concerning the control and management of quarantinable communicable diseases for passengers, crew members and . . . [pedestrians];
3. The storage status of food and the status of the cargo loaded in the means of transport; [and]
4. Whether vehicles for communicable diseases inhabit [sic] and the state of their breeding.[37]

The director of the quarantine station can take all or some of the following measures:

1. Isolate a patient infected with a quarantinable communicable disease or a patient suspected of being infected with a quarantinable communicable disease . . . ;
2. Supervising or isolating a person who has had contact with patients infected with a quarantinable communicable disease, etc. or who is exposed to the pathogen of a quarantinable communicable disease without any symptom . . . but to whom the quarantinable communicable disease is suspected to break out . . . ;
3. Disinfecting, destructing or prohibiting the movement of cargo contaminated with or suspected of being contaminated with the pathogen of a quarantinable communicable disease;
4. Disinfecting any place contaminated or suspected of being contaminated with the pathogen of a quarantinable communicable disease, and prohibiting or restricting the use of such place;

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[34] Kŏmyŏkpŏp [Quarantine Act], Act No. 1273, Feb. 9, 1963, *amended by* Act No. 11972, July 30, 2013, art. 6, English translation *available at* http://elaw.klri.re.kr/eng_service/lawView.do?hseq=29132 &lang=ENG.

[35] *Id*. art. 13(1).

[36] *Id*. art. 2.

[37] *Id*. art. 12(1).

5. Dissecting any corpse . . . which is contaminated or suspected of being contaminated with a quarantinable communicable disease in order to inspect the corpse;
6. Ordering the head of a means of transport or the owner or manager of cargo to disinfect the means of transport or the cargo, and eradicating the pathogen of a communicable disease;
7. Medically examining or checking persons, deemed necessary to be confirmed whether they are infected with a quarantinable communicable disease; [and]
8. Vaccinating persons who need the prevention of [sic] a quarantinable communicable disease.[38]

The director of the quarantine station may ask the head of the local government to monitor the health status of a person suspected of being infected once that person enters his jurisdiction.[39] If a person is confirmed as being infected with a disease subject to quarantine, the head of the local government must promptly take necessary measures, such as isolation, and immediately notify the director of the relevant quarantine station of the confirmed diagnosis and measures taken.[40]

The Minister of Health and Welfare may request the Minister of Justice to prohibit foreigners infected with a quarantinable communicable disease who are likely to pose a substantial risk to public health from entering or leaving Korea, and to prohibit infected Korean nationals from leaving Korea.[41]

The director of the quarantine station may take any of the following measures with regard to a person who intends to enter or leave Korea when a quarantinable communicable disease is likely to spread:

1. To request information on a travel region and time;
2. To request information on the health status related to a quarantinable communicable disease;
3. To request the documents certifying the vaccination; and
4. To examine or check in order to check [sic] whether he/she is infected with a quarantinable communicable disease.[42]

[38] *Id*. art. 15(1).

[39] *Id*. art. 17(1).

[40] *Id*. art. 17(2).

[41] *Id*. art. 24.

[42] *Id*. art. 26.

V. Recent Developments

After the WHO issued its Statement on the First Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa on August 8, 2014,[43] the Vice Minister of Health and Welfare, Jang Ok-ju, held an emergency meeting with ten relevant ministries and agencies and discussed the WHO's announcement and Ebola prevention and control measures. After the meeting, a special travel advisory was issued, which urged Koreans residing in these Ebola-affected countries to return to Korea and Koreans elsewhere to cancel or postpone nonessential trips to Ebola-affected countries. In addition, the government of South Korea announced that inbound travelers from Nigeria and from the three Ebola-affected countries would be quarantined, undergo thermal screening at the time of entry, and be closely monitored over a certain period of time (for up to twenty-one days) for any Ebola infection. Inbound travelers on direct or transit flights from the four Ebola-affected countries would be quarantined at deplaning gates instead of at general quarantine zones. The government would identify people entering the country after traveling from or through the Ebola-affected countries in advance, through cooperation with the airlines, immigration offices, and embassies in those four Ebola-affected countries, and through voluntary reporting by travelers. Transit passengers from the four Ebola-affected countries would also go through the quarantine process when they enter Korea. Passengers on direct flights from Africa or on flights through a third country from Africa would also undergo enhanced screening.[44]

[43] Press Release, WHO, Statement on the First Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa (Aug. 8, 2014), http://www.who.int/mediacentre/news/statements/ 2014/ebola-20140808/en/.

[44] *Government Steps Up Measures to Prevent Ebola from Entering Korea*, MOHW (Sept. 1, 2014), http://english.mw.go.kr/front_eng/al/sal0101vw.jsp?PAR_MENU_ID=1002&MENU_ID=100201&page=1&CONT_SEQ=304721.

Spain

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SUMMARY The Spanish Constitution recognizes the right to public health and divides such matters between the state and the autonomous communities. Based on this constitutional framework Spain has created an integrated and coordinated network of agencies and institutions to address public health crises and also closely follows World Health Organization standards, alerts, and directives. In cases of public health emergencies, the Ministry of Public Health, Social Services and Equality is the authority in charge of maintaining health and hygiene control over the international transit of people and goods at Spanish ports of entry. The state has the authority to monitor and coordinate public health services with all other local authorities when there is a risk to public health with domestic or international consequences. The National Network of Epidemiological Surveillance and the Carlos III Health Institute are the entities in charge of epidemiological planning, coordination, and research. Information of a personal nature in cases of the declaration of an epidemic remains mainly confidential.

The most recent case of a health crisis impacting Spain was caused by the Ebola outbreak in West Africa. In spite of all the preventive measures taken by the health care authorities, Spain had the first confirmed case of Ebola virus contracted outside Africa after a Spanish nurse came into contact with two Spanish nationals who were infected in Africa. The nurse has now fully recovered.

I. Government Structure

Spain is a parliamentary monarchy[1] with a bicameral Parliament (Cortes Generales) composed of the Senate and the Congress of Deputies.[2] The Constitution recognizes and guarantees the right to autonomy of the regions that comprise the state.[3] Bordering provinces with common historical, cultural, and economic characteristics may accede to self-government and form autonomous communities (*comunidades autónomas*).[4] The country's fifty-two provinces have been grouped into autonomous communities since adoption of the 1978 Constitution.

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[1] CONSTITUCIÓN ESPANOLA art. 1(3), Dec. 27, 1978, BOLETÍN OFICIAL DEL ESTADO [B.O.E.], *English translation available at* http://www.boe.es/legislacion/ documentos/ConstitucionINGLES.pdf.

[2] *Id*. art. 66(1).

[3] *Id*. art. 2.

[4] *Id*. art 143(1).

II. Structure of Public Health Crisis Management System

Spain's Constitution expressly recognizes the right to the protection of public health, stating that it is incumbent upon the authorities to safeguard public health through preventive measures and necessary care and services, which are regulated by law.[5]

The Constitution determines which health matters are reserved for the state and which are to be delegated. The autonomous communities are responsible for regulating social assistance matters and health and hygiene,[6] while the state reserves the exclusive right to regulate matters pertaining to the structure and coordination of the public health system, and to enact legislation on pharmaceuticals.[7] The state is also responsible for regulating matters pertaining to the basic legislation and economic structure of the social security system, even when the services are rendered through the autonomous communities.[8]

Based on the constitutional mandate, Law 14/1986 on General Public Health[9] created a National Health System (NHS) that integrates and coordinates all health services of the autonomous communities, including those rendered at centers and hospitals managed by the municipalities.[10] The Law expressly provides that the state is the exclusive authority over international health relations and agreements and over external health.[11] It further states that matters of external health are those related to vigilance over and control of potential health risks imported and/or exported through the international transit of people or goods.[12]

The Ministry of Public Health, Social Services and Equality (MPH) was recently reorganized under Royal Decree 200/2012,[13] under which the central administration is given the authority to uphold the powers assigned to the state in health matters and to guarantee the population's constitutional right to health protection.[14] The MPH cooperates with other government departments to ensure that the inspection and control of external health matters is coordinated within the government in order to simplify and expedite international transit, in compliance with international agreements.[15] The regulatory directive of Law 14/1986 has been implemented by

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[5] *Id.* art. 43.

[6] *Id.* art. 148(1)(xx), (xxi).

[7] *Id.* art. 149(1)(xvi).

[8] *Id.* art. 149(1)(xvii).

[9] Ley 14/1986, General de Sanidad [Law 14/1986, General Health], Apr. 25, 1986, *last updated* Mar. 28, 2014, http://boe.es/ buscar/act.php?id=BOE-A-1986-10499.

[10] *Id.* art. 50.

[11] *Id.* art. 38.

[12] *Id.* art. 38(2).

[13] Real Decreto 200/2012, Jan. 23, 2012, http://boe.es/diario_boe/txt.php?id=BOE-A-2012-1034.

[14] A. GONZALEZ BUENO, MANUAL DE LEGISLACIÓN FARMACÉUTICA 43 (Aranjuez, 1999).

[15] Ley 14/1986 art. 38.3, *as implemented by* Real Decreto 65/2006, Jan. 30, 2006, http://boe.es/diario_boe/txt.php?id=BOE-A-2006-1916.

Royal Decree 1418/1986,[16] which provides that the MPH has the power to manage relations with other international health and consumer affairs entities through the Ministry of Foreign Affairs;[17] adopt all necessary measures under international agreements on health and consumer affairs to which Spain is a party; and maintain health and hygiene control over, and surveillance of, international traffic at Spanish ports, airports, customs ports, and terminals. The MPH also works in conjunction with the Ministry of Agriculture to oversee the transportation of people, corpses, and human remains, and of animals and animal derivatives. Together with the Ministry of Economy, it oversees the transportation of goods and of any other merchandise that could pose a potential risk to public health.[18]

In the event of an emergency, the MPH has the authority to coordinate international transit that could affect the health of people or their legitimate interests when they may be affected by the international traffic of goods or services.[19]

The Law on General Public Health provides that the state, without prejudice to the authorities assigned to the autonomous communities, is responsible for monitoring and analyzing epidemics and for coordinating the services of the different public health administrations in situations that may create public health risks with domestic or international consequences.[20] It also provides that the state is in charge of setting up a health information system and preparing statistics of general interest to the autonomous communities.[21] The state is also responsible for establishing a network of information and communication between the state and the autonomous communities in health matters.[22]

III. Powers of Public Health Authorities

Health emergencies are declared by the state through the MPH, or by the autonomous communities when such power has been delegated by the state.[23]

Organic Law 3/86 on Special Measures in Matters of Public Health lists the conditions under which the Spanish health authorities may, within their jurisdiction, adopt urgent and necessary public health measures in times of emergencies.[24]

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[16] Real Decreto 1418/1986, June 13, 1986, sobre Funciones del Ministerio de Sanidad y Consumo en Materia de Sanidad Exterior [Royal Decree 1418/1986, on the Powers of the Ministry of Public Health and Consumer Affairs in Matters of External Health] (now the MPH), http://www.boe.es/buscar/act.php?id=BOE-A-1986-18374.

[17] *Id.* art. 2(1.1).

[18] *Id.* art. 2(1.4).

[19] *Id.* art. 2(2.4).

[20] *Id.* art. 40(12).

[21] *Id.* art. 40(13), *implemented by* Decreto 605/2003, May 23, 2003, por el que se Establecen Medidas para el Tratamiento Homogéneo de la Información sobre las Listas de Espera en el Sistema Nacional de Salud [Decree 605/2003, May 23, 2003, Establishing Measures for the Homogeneous Treatment of Information on the Waiting Lists of the National Health System], http://www.boe.es/buscar/act.php?id=BOE-A-2003-11266.

[22] *Id.* art. 40(16), *implemented by* Decreto 605/2003.

[23] *Id.* art. 41.

The government has the authority to declare a state of alert in extraordinary circumstances that make it impossible to keep public order by normal means,[25] and in public health crises, such as an epidemic or situation of serious contamination.[26] Measures taken under a state of alert must be temporary, restricted to a specific area, and limited to those measures necessary to contain the emergency.[27] If the emergency is limited to a specific autonomous community, the community's president may request that the government declare a state of alert in that community.[28] The state or the president of the affected autonomous community serves as the competent authority for purposes of the state of alert.[29] The declaration of a state of alert is enacted through a decree issued by the Council of Ministries.[30]

Under a state of alert, the Minister of Public Health and Consumer Affairs may temporarily order the restriction of the movement of people or motor vehicles; search and seizure procedures; the occupation of facilities or industries (but not private dwellings); the limited consumption or use of necessary food items; and any other measure to fight infectious diseases, protect water and the environment, and protect against forest fires.[31] In these cases, the state may also order the participation of companies and services and the mobilization of their personnel.[32]

The MPH is in charge of the study and management of epidemics, the promotion of health, preventive measures against epidemics, and the surveillance and control of possible health risks derived from the import or export of goods and the international movement of people.[33] The Underdirectorate for the Promotion of Public Health and Epidemiology (Sudireccion General de Promocion de la Salud y Epidemiologia) is in charge of planning, coordinating, and developing strategies for the National Network of Epidemiological Surveillance (NNES) (Red Nacional de Vigilancia Epidemiologica), in conjunction with the Carlos III Health Institute (Instituto de Salud Carlos III), a public research institute created in 1986 to provide scientific and technical support to the MPH and the health services of the autonomous communities.[34] One of the Carlos

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[24] Ley Orgánica 3/1986 de Medidas Especiales en Materia de Salud Pública [Organic Law 3/1986, on Special Measures in Matters of Public Health] art. 1, Apr. 14, 1986, http://www.boe.es/buscar/act.php?id=BOE-A-1986-10498.

[25] Ley Orgánica 4/1981, June 1, 1981, de los Estados de Alarma, Excepción y Sitio [Organic Law 4/1981, June 1, 1981, on States of Alert, Exception and Siege] art. 1(1), http://www.boe.es/buscar/act.php?id=BOE-A-1981-12774.

[26] *Id*. art. 4(2).

[27] *Id.* art. 1(2).

[28] *Id.* art. 5.

[29] *Id.* art. 7.

[30] *Id.* art. 6.

[31] *Id.* arts. 11, 12(1).

[32] *Id.* art. 12 (2).

[33] Ley 14/1986 arts. 8, 38.

[34] *Id.* arts. 111–113, *as implemented by* Real Decreto 375/2001 por el que se Aprueba el Estatuto del Instituto de Salud "Carlos III" [Royal Decree 375/2001, Approving the Bylaws of the "Carlos III" Institute of Health], Apr. 6, 2001, http://www.boe.es/buscar/doc.php?id=BOE-A-2001-8157.

III Health Institute's specific functions is conducting research and studies in epidemiology that are carried out by the Underdirectorate for the Promotion of Public Health and Epidemiology.[35]

The NNES was created by Royal Decree 2210/1995[36] within the NHS to collect and analyze information on epidemics, contribute to the application of individual and collective control measures in cases where a health risk may have national or international consequences, and inform all operational levels about health risks.[37] The National Directorate of Public Health (Dirección General de Sanidad Pública) of the MPH has been established as the Spanish health authority liaison to the World Health Organization (WHO) for tracking and reporting alerts on transmissible diseases.[38]

The NNES is responsible for

- identifying health problems related to epidemics, endemics, and risks throughout the autonomous communities;
- participating in the individual and collective control of public health problems throughout the autonomous communities, and ensuring coordination between surveillance and decision making by the competent health authorities for the prevention and control of public health problems;
- executing epidemiological analysis to identify changes in and the evolution of the abovementioned public health problems, as well as any other epidemiological research;
- providing operative information for planning purposes;
- distributing information to all designated operative levels; and
- contributing the development of related statistics for official use.[39]

The NNES's surveillance activity involves the systematic collection of epidemiological information, its analysis and interpretation, and the distribution of results and recommendations.[40]

The NNES is composed of (1) a basic surveillance system that includes obligatory notifications about diseases, epidemics, and outbreaks, as well as microbiological information; (2) specific systems of epidemic surveillance based on case records, surveys, watch systems, and other methods that could be applicable to the surveillance of AIDS and other preventable immune

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[35] Real Decreto 375/2001 Estatuto del Instituto de Salud "Carlos III" art. 19(6)–(9).

[36] Real Decreto 2210/1995 por el que se Crea la Red Nacional de Vigilancia Epidemiológica [Royal Decree 2210/1995, Creating the National Network of Epidemic Surveillance], Dec. 28, 1995, http://www.boe.es/buscar/act.php? id=BOE-A-1996-1502.

[37] *Id*. art. 1.

[38] Orden Ministerio de Sanidad y Consumo [Order of the Ministry of Health], SCO 3870/2006, Dec. 15, 2006, art. 1 https://www.boe.es/diario_boe/txt.php?id=BOE-A-2006-22360.

[39] Real Decreto 2210/1995 art. 2.

[40] *Id.* art. 3.

diseases; and (3) any other surveillance system that the MPH and the autonomous communities, within their jurisdiction and through the Interterritorial Council of the National Health System (Consejo Interterritorial del Sistema Nacional de Salud), believe necessary to develop in order to control specific problems or use as a complement to other measures.[41]

The basic surveillance system of the NNES includes a list of diseases[42] that are required to be reported. The required report refers to new cases of these listed diseases that appear each week and constitute a concern. Attending physicians both from the public and private sector are the agents responsible for the reporting.[43] The same procedure is applicable at the autonomous communities level, which then transfers all the reported information to the MPH. The information collected must reach the MPH no later than three weeks after the first case is reported.[44]

All practicing physicians and health centers, both public and private, that first detect the outbreak of an epidemic are required to immediately report the outbreak to the MPH.[45] An "outbreak" is defined as a significant increase in the number of cases; the presence of a case in an area that was free of such disease; the presence of cases of acute, collective poisoning due to consumption, handling, or accidental causes; and the presence of any catastrophic incident that may affect the health of the community.[46]
The NNES may also rely on networks of "monitoring physicians," and on networks to trace diseases selected by the designated health authorities in predetermined geographic areas.[47]

Additional regulatory measures have been implemented to address certain diseases, such as AIDS and SARS, that are considered to be or could become an epidemic of serious proportions. Spain created and maintains a national AIDS registry for epidemic surveillance purposes. The autonomous communities also keep registries of AIDS cases in their respective territories and have an obligation to report them to the central health authorities every three months.[48] Although no SARS cases were found in Spain, Real Decreto 350/2003,[49] now superseded,

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[41] *Id.* art. 4.

[42] *Id.*, Annex I. The list includes, among others, botulism, brucellosis, cholera, diphtheria, hepatitis A and B, leprosy, meningitis, malaria, polio, tetanus, and tuberculosis.

[43] *Id.* art. 9.

[44] *Id.* art. 12.

[45] *Id.* art. 16.

[46] *Id.* art. 15.

[47] *Id.* arts. 28–30.

[48] *Id*. arts. 31–36.

[49] Real Decreto 350/2003, Mar. 21, 2003, https://www.boe.es/buscar/doc.php?id=BOE-A-2003-5851 (superseded by Real Decreto 776/2011, de 3 de junio [2011], por el que se Suprimen Determinados órganos colegiados y se establecen criterios para la normalización en la creación de órganos colegiados en la Administración General del Estado y sus Organismos Públicos [Royal Decree 776/2011, June 3, [2011], Dissolving Some Collegiate Entities and Establishing Normalization Criteria for Creating Collegiate Entities Within the General Administration of the State and Its Public Agencies], http://www.boe.es/boe/dias/2011/06/04/pdfs/BOE-A-2011-9736.pdf).

created the Inter-Ministerial Commission for the Surveillance of SARS[50] to coordinate the response to the illness throughout the national territory. The Decree also required coordinated actions and information sharing in case of an outbreak.[51] In addition, the Scientific Committee on SARS[52] was created to provide scientific support and to advise the Inter-Ministerial Commission. By 2011 this Commission was no longer operative.[53]

The NHS is the enforcement authority that manages cases of infectious diseases.[54] Each province and autonomous community has the power to order the isolation of infected individuals and to impose restrictions on their movements to prevent placing others at risk. The same power is assigned to mayors at the municipal level if a case falls under their jurisdiction.[55]

Violations of health safety directives may result in criminal charges for provoking a risk to life, physical integrity, and the health of the population or environment—offenses that are punishable by imprisonment of six months to two years, a fine, and the inability to hold public office or practice a profession for three to six years.[56]

IV. Transparency of Public Health Crisis Management System

The MPH and National Center on Epidemiology,[57] together with the competent provincial councils, are the authorities in charge of declaring an epidemic.[58]

The MPH is the enforcement authority of the NNES, ensuring the coordination and uniformity of information, as well as its evaluation and analysis, throughout the country. Information of a personal nature, managed as a consequence of the application of the NNES, is otherwise to remain confidential.[59] Personal data in databases may be used without the owner's consent only when the information is required in urgent cases or to carry out epidemiological studies.[60] The

[50] *Id*. art. 2.

[51] *Id*. art. 3.

[52] Orden Ministerio de Sanidad y Consumo [Order of the Ministry of Health], SCO/1134/2003, May 6, 2003, B.O.E., May 10, 2003.

[53] Real Decreto 776/2011, Annex, B.O.E. No. 133, June 4, 2011, p. 10.

[54] Real Decreto 1030/2006, Sept. 15, 2006, Annex III, § 5.1(1), http://www.msssi.gob.es/profesionales/prestacionesSanitarias/CarteraDeServicios/docs/RD_1030_2006_act25072014.pdf.

[55] *Id*.

[56] CÓDIGO PENAL Y LEYES PENALES ESPECIALES art. 348 (Navarra, Thomson/Aranzadi 2007).

[57] Real Decreto 2210/1995 arts. 1–5.

[58] *Id.* arts. 15–21.

[59] *Id.* art. 8.

[60] Ley Orgánica 15/1999 sobre el Tratamiento de Datos Personales [Organic Law 15/1999, on the Treatment of Personal Data in Databases] art. 11(2)(f), Dec. 13, 1999, https://www.boe.es/buscar/pdf/1999/BOE-A-1999-23750-consolidado.pdf.

MPH also coordinates such information with the European Union (EU), the WHO, and other international organizations.[61]

The MPH is required to immediately inform the autonomous communities of any epidemic outbreak so that pertinent controls and preventive measures may be set up.[62] Reporting such data also ensures compliance with international health standards, such as the international reporting of diseases subject to quarantine and those subject to special surveillance by the WHO and the EU.[63]

The MPH issues updated press releases to keep the population informed of any health threat. During the latest health epidemic alerts, such as the swine flu outbreak in 2009 and the recent Ebola virus outbreak, the MPH, through the Center for the Coordination of Health Warnings and Emergencies (Centro de Coordinación de Alertas y Emergencias Sanitarias), issued recommendations to the population via the Internet and all other major media, as requested by the WHO.[64]

V. Current Crisis

The MPH, in cooperation with the health authorities of the autonomous communities, the Institute of Health Carlos III (Instituto de Salud Carlos III), and scientific societies, has established a protocol to deal with the Ebola virus.[65] The protocol reflects the recommendations of international organizations and experts to ensure the early detection and diagnosis of possible Ebola cases and to adopt immediate control measures.[66]

The MPH has also established a procedure applicable to all points of entry into the country to make sure that all airplanes and ships coming from Ebola-affected areas meet the applicable health standards.[67] Information pamphlets for passengers coming from these areas, and for any passenger arriving in Spain, have been published and made available online.[68]

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[61] Real Decreto 2210/1995 art. 6(1), (2).

[62] *Id.* art. 19.

[63] *Id.* art. 6(3).

[64] Centro de Coordinación de Alertas y Emergencias Sanitarias, Actualización Epidemiológica: Brotes de Enfermedad por Virus Ébola en África [Epidemiological Update: Outbreaks of the Ebola Virus in Africa] (Oct. 27, 2014), http://www.msssi.gob.es/profesionales/saludPublica/ccayes/alertasActual/ ebola/docs/Actualizacionn 15BIS(27.10.14)EPI-EVE_Africa_2014.pdf.

[65] *Medidas del Gobierno de Espana* [*Measures by the Government of Spain*], GOBIERNO DE ESPAÑA, COMITÉ ESPECIAL PARA LA GESTIÓN DEL ÉBOLA (Oct. 12, 2014), http://infoebola.gob.es/2014/10/10/que-medidas-esta-tomando-el-gobierno-de-espana/.

[66] *Id*.

[67] *Id*.

[68] Información sobre el Brote de Enfermedad por Virus Ébola (EVE), Información para los Ciudadanos/Viajeros [Information on the Outbreak of the Ebola Virus, Information for Citizens and Travelers], MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD, https://www.msssi.gob.es/en/profesionales/saludPublica/ccayes/alertasActual/ ebola/infCiudadanos.htm (last visited Nov. 17, 2014).

In spite of all the preventive measures, Spain had the first confirmed case of Ebola virus contracted outside Africa. The infected woman, a nurse named Teresa Romero, was treated in a Madrid hospital. She had been part of a medical team treating two Spanish missionaries with Ebola, who had been brought back to Spain from Sierra Leone and Liberia. Both died in the hospital in Madrid in August and September 2014. Romero is reported to have entered the room of one of the missionaries who later died.[69] Six other people were also placed in quarantine, while around fifty other healthcare workers were placed under observation because of their interaction with the nurse and the two missionaries who died.[70]

On October 10, 2014, in response to what appears to have been a failure in established protocols, the Spanish government created a Special Committee on the Management of Ebola (Comité Especial en la Gestión del Ébola), headed by the Vice President of the Spanish government, to supervise, coordinate, and manage all actions by and resources from the state necessary for the management of the virus.[71]

The Minister of Health, Ana Mato, informed Congress that the revised procedures applicable for the early detection of Ebola would include the daily monitoring of anyone known or suspected to have come into contact with Ebola victims, and that even minor increases in body temperature would be taken as a likely sign of their being infected.[72]

At the same time, supervision would be tightened in hospitals when staff remove protective body suits, since Romero appears to have been infected when her glove brushed against her face while she was removing her suit. Closed circuit television cameras would also likely be installed in isolation units.[73] On November 5, 2014, Romero was released from the hospital free from Ebola.[74]

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[69] Elisa Silió & Emilio de Benito, *Una Sanitaria de Madrid, Primer Contagio por Ébola Fuera de África* [*A Health Professional in Madrid, First Ebola Infection Outside Africa*], EL PAÍS (Oct. 7, 2014), http://elpais.com/elpais/2014/10/06/ciencia/1412611515_352524.html.

[70] *Id*.

[71] *Santamaría Presidirá un Comité Especial para la Gestión de la Crisis del Ébola* [*Santamaría Will Head a Special Committee for the Management of the Ebola Crisis*], LA VANGUARDIA (Oct. 10, 2014), http://www.lavanguardia.com/politica/20141010/54417805465/santamaria-presidira-comite-especial-gestion-crisis-ebola.html.

[72] *Mato Analizará Esta Tarde con las CCAA los Cambios en los Protocolos Frente al Ébola* [*This Afternoon Mato Together with ACs Will Analyze Changes in the Protocols Applicable in Ébola Cases*], LA VANGUARDIA (Oct. 10, 2014), http://www.lavanguardia.com/local/20141010/54416960358/mato-analizara-esta-tarde-con-las-ccaa-los-cambios-en-los-protocolos-frente-al-ebola.html.

[73] *Los Fallos del Caso de Romero Llevan a Ana Mato a Cambiar en los Protocolos* [*Mistakes in the Romero Case Cause Ana Mato to Change Protocols*], EL PAÍS (Oct. 9, 2014), http://politica.elpais.com/politica/2014/10/09/actualidad/1412838533_047257.html.

[74] T*eresa Romero Recibe Este Miércoles el Alta Hospitalaria Tras Casi un Mes de Ingreso* [*Teresa Romero Is Discharged from the Hospital Wednesday Nearly a Month After Admission*], LA VANGUARDIA (Nov. 5, 2014), http://www.lavanguardia.com/vida/20141105/54418948378/teresa-romero-recibe-alta-ebola.html?rel=rosEP.

Sweden

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SUMMARY Sweden's response to public health crises is governed by statute. Smittskyddslagen (the Communicable Diseases Act) regulates the response to outbreaks and threats of outbreaks of contagious diseases. Power and responsibility for the containment of contagious diseases are shared between state and local authorities. Both individual patients and treating physicians have a duty to report cases of possible contagious disease. Coercive powers such as isolation, quarantine, and restrictions on work and travel are available to the state but only as specified by law and only if there is a serious threat that a dangerous disease may spread. The intentional and negligent spreading of a disease is a crime. The National Board on Health and Welfare is responsible for coordinating with the World Health Organization. Sweden has not had to respond to a public health crisis recently.

I. Structure of Public Health Crisis Management System

A. General Government Structure

The national government,[1] municipalities, and local county councils share power on issues of public health crisis management. Municipal self-governance is fundamental to the Swedish system and is explicitly listed as a right in the Swedish Constitution.[2] The municipalities are generally responsible for health care, education, and elder care.[3]

B. Legislation

1. General Principles

Sweden does not have overarching legislation that deals with all public health crises but instead uses individual acts and regulations that deal with crises in different areas—for instance the Communicable Diseases Act[4] deals with protection against infectious diseases. This report focuses solely on the infectious disease aspect of public health crises and thus only covers the Communicable Diseases Act and its relevant ordinances, procedures, etc.

While Sweden has no overarching legislation it has general guiding principles that apply to all crisis management efforts. These are the principles of responsibility, equal treatment,[5] and

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[1] Note: Swedish authorities and agencies often change names as a result of government changes, and there was such a government change in September of 2014. The names of relevant state authorities used in this report reflect the names in force in October 2014.

[2] REGERINGSFORMEN [RF] [CONSTITUTION] 1:1 para. 2.

[3] For municipalities' general responsibilities, see KOMMUNALLAG (SFS 1991:900), http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Kommunallag-1991900_sfs-1991-900/.

[4] SMITTSKYDDSLAGEN [COMMUNICABLE DISEASES ACT] (Svensk Författningssamling [SFS] 2004:168).

[5] Ch. 2:2 § KOMMUNALLAGEN.

"geographic closeness" (whereby authority is determined by proximity to the crisis).[6] This means that Sweden also has a general division of responsibility between national and local authorities that is similar in all crisis management situations.

2. Smittskyddslagen (Communicable Diseases Act)

The main legislation covering contagious diseases is the Communicable Diseases Act. The Communicable Diseases Act classifies diseases into three different categories: (1) contagious diseases,[7] (2) diseases dangerous to public health,[8] and (3) diseases dangerous to society.[9] *Contagious diseases* are diseases that can be transferred between individuals and that pose more than an insignificant threat to the health of the individual contracting it.[10] *Diseases dangerous to public health* are contagious diseases that can be "life-threatening, result in continuous illness or difficult suffering or cause other serious consequences where there is a possibility of preventing the spread of the disease through measures aimed at the infected individual."[11] *Diseases dangerous to society* are diseases that are dangerous to public health and can spread in society in a manner that would create a serious disruption or imminent risk of a serious disruption of important public functions, and demand extraordinary measures.[12] All diseases classified as dangerous to public health or dangerous to society, and some communicable diseases, are subject to mandatory contact tracing.[13] These diseases are referred to as "diseases that must be reported" or "contact tracing diseases," depending on whether the disease must be traced and reported or only traced.[14]

The government decides how to classify each illness. Currently diseases dangerous to public health include: campylobacteriosis, diphtheria, bird-flu (H5N1), E.coli (EHEC) infection, giardia infection, gonorrhea, hepatitis A-E, HIV infection, infection with HTLV I or II, chlamydia, cholera, infection with methicillin-resistant staphylococcus aureus (MRSA), anthrax, paratyphoid fever, plague, infection with pneumococci with reduced susceptibility to penicillin G, polio, rabies, salmonella infection, shigellosis, smallpox, severe acute respiratory syndrome (SARS), syphilis, tuberculosis, typhoid fever, and viral hemorrhagic fevers except Dengue fever nefropathia epidemica. Diseases dangerous to society include smallpox and SARS,[15] and, as of

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[6] *Tre grundprinciper*, KRISINFORMATION.SE (Dec. 13, 2012), http://www.krisinformation.se/web/Pages/Page____11261.aspx.

[7] Ch. 1:3 para. 1 § SMITTSKYDDSLAGEN.

[8] *Id*. ch. 1:3 para. 2 §.

[9] *Id*. ch. 1:3 para. 3 § (in Swedish: smittsamma sjukdomar, allmänfarliga sjukdomar, and samhällsfarliga sjukdomar) (translation by author).

[10] *Id*. ch. 1:3 para. 1 § SML.

[11] *Id*. ch. 1:3 para. 2 § SML (translation by author).

[12] *Id*. ch. 1:3 para. 3 § SML.

[13] Socialstyrelsens Författningssamling (SOSFS) 2012:2 (M) Föreskrifter, Smittspårningspliktiga sjukdomar [Instructions, Communicable Diseases Which Require Tracing], http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/18593/2012-2-7.pdf.

[14] Ch. 1:3 para. 3 § SMITTSKYDDSLAGEN (translation by author).

[15] SMITTSKYDDSLAGEN add. 1.

October 23 2014, Ebola.[16] Ebola was added to the list by the Swedish government following a request from the National Board of Health and Welfare (NBHW).[17] These classifications determine the lawful measures that the national, municipal, and local representatives may take to intervene to stop the spread of the disease and provide treatment.[18]

3. *International Measures*

Sweden has implemented the World Health Organization's (WHO's) 2005 International Health Regulations into law.[19] The implementing legislation divides responsibility between the municipalities, which are responsible for animal protection, the county councils, which are responsible for human protection, and the NBHW, which is responsible for coordination.[20] All diseases dangerous to society that are listed in the Communicable Diseases Act are also considered international threats to people's health. Currently this list includes smallpox, SARS, and Ebola.[21] The government decides what additional diseases are considered a serious threat to society.[22] All serious diseases are subject to the Communicable Diseases Act.[23]

International public health threats are monitored by the NBHW, and all national and local authorities must report any discovered threat to that Board.[24] The NBHW must in turn inform WHO within twenty-four hours of receiving such reports.[25] In addition, the NBHW must cooperate with international organizations and foreign governments to combat international health threats.[26] Information provided to the WHO should be submitted even if it is covered by domestic secrecy laws.[27]
Compliance with the aforementioned legislation is monitored by the Health and Social Care Inspectorate.[28] Decisions made relying on the authority of the Act can be appealed to the administrative courts.[29]

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[16] Press Release, Regeringskansliet, Regeringsbeslut möjliggör fler skyddsåtgärder mot Ebola [Government Decision Enables Additional Safety Precautions Against Ebola] (Oct. 23, 2014), http://www.regeringen.se/sb/d/14850/a/248949.

[17] *Id*.

[18] *See* Part II(D) & (E), below.

[19] LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA [ACT ON PROTECTION AGAINST INTERNATIONAL THREATS TO PEOPLE'S HEALTH] (SFS 2006:1570).

[20] *Id*. 4–5 §§.

[21] Press Release, Regeringskansliet, *supra* note 16.

[22] 2 para. 3 § LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA.

[23] *Id*. 2 para. 2 §.

[24] *Id*. 10 §.

[25] *Id*. 11 §.

[26] *Id*. 9 §.

[27] *Id*. 12 §.

[28] *Id*. 26 §. For more information on the Health and Social Care Inspectorate, see *About the Health and Social Care Inspectorate*, IVO, http://www.ivo.se/om-ivo/about-health-and-social-care-inspectorate/Sidor/default.aspx (last visited Oct. 31, 2014).

4. Preparedness for Extraordinary Events in Times of Peace

Other legislation related to public health crisis management includes a specific act on how municipalities and county councils should prepare for extraordinary events during peace time,[30] as well as a regulation on emergency preparation and heightened preparedness.[31] Regarding extraordinary events, each municipality has a responsibility to implement a Crisis Management Committee.[32] According to the regulation on Emergency Preparation and Heightened Preparedness, county administrative boards have the overall responsibility for their region's preparedness,[33] but all agencies have joint responsibility to cooperate with each other.[34] Each authority is required to continuously monitor the threat level and make adjustments to their preparedness levels accordingly.[35] The analysis of the threat and weakness level should culminate in a "risk and weakness report" that is sent to the government and the Swedish Civil Contingencies Agency.[36]

C. Responsible National and Local Authorities

1. Responsible National Authorities[37]

On the national level, public health crisis management is divided between a responsible authority that coordinates with national entities, an expert authority that tracks public health threats and builds a planned response, and local authorities that monitor and react to public health threats.[38] The main national actors in public health crisis management are the Ministry of Health and Social Affairs, the National Health and Welfare Agency, the Swedish Civil Contingencies Agency and the NBHW. The responsible government department for public health crisis management is the Ministry of Health and Social Affairs.[39]

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[29] 32 § LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA.

[30] LAG OM KOMMUNERS OCH LANDSTINGS ÅTGÄRDER INFÖR OCH VID EXTRAORDINÄRA HÄNDELSER I FREDSTID OCH VID FÖRHÖJD BEREDSKAP [ACT ON MUNICIPALITIES AND COUNTY COUNCILS MEASURES AHEAD OF AND DURING EXTRAORDINARY EVENTS DURING PEACE TIME AND TIMES OF HEIGHTENED PREPAREDNESS] (SFS 2006:544).

[31] 7 § Förordning om krisberedskap och höjd beredskap [Government Regulation] (SFS 2006:942), http://www.notisum.se/rnp/sls/lag/20060942.htm.

[32] Ch. 2:2 § LAG OM KOMMUNERS OCH LANDSTINGS ÅTGÄRDER INFÖR OCH VID EXTRAORDINÄRA HÄNDELSER I FREDSTID OCH VID FÖRHÖJD BEREDSKAP.

[33] 7 § Förordning om krisberedskap och höjd beredskap.

[34] *Id*. 5 §.

[35] *Id*. 9 §.

[36] *Id*. 9 para. 2 §.

[37] Note that Sweden underwent a change in government in September of 2014 and that the new government may make changes to the organization of its government agencies responsible for public crises. No such changes have yet been announced, however.

[38] Ch. 1: 7-10 SMITTSKYDDSLAGEN.

[39] *Ministry of Health and Social Affairs*, REGERINGSKANSLIET, http://www.government.se/sb/d/2061 (last visited Oct. 31, 2014).

The expert authority on public health crises (infectious diseases) is the National Health and Welfare Agency.[40] It is responsible for monitoring global and national developments in communicable diseases, informing the government and local health care providers of the current state of threats, and proposing actions on how to combat these threats.[41] The Public Health Agency of Sweden is also responsible for all laboratory testing related to the Communicable Diseases Act.[42]

The Swedish Civil Contingencies Agency is responsible for supporting designated agencies with measures and information, and for providing information to the public.[43] Its primary focus is to coordinate efforts and to train personnel in preparedness for national contingencies, as well as to develop better routines for this work.[44] The Agency is also responsible for medical research on how to prevent communicable diseases from spreading.[45]

The NBHW acts with authority from the Ministry of Health and Social Affairs and is the national coordinating authority on communicable diseases, whereas the National Health and Welfare Agency is the expert authority.[46] The NBHW or the government may also issue instructions on responding to public health crises.[47] In September of 2014 the NBHW issued new (nonbinding) guidelines for how suspected Ebola cases should be treated.[48] In addition the NBHW is responsible for reporting pandemic cases to the WHO (IHR).[49]

On the national level, a special working group, the National Pandemic Group, has been created to focus on pandemic threats. The Group consists of the directors for the NBHW, the National Health and Welfare Agency, the Swedish Work Environment Authority, the Medical Products Agency, and the Swedish Association of Local Authorities and Regions. It meets at the discretion of the NBHW.[50]

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[40] Ch. 1:7 para. 2 § SMITTSKYDDSLAGEN.

[41] *Id*.

[42] *Id*.

[43] Förordning med instruktion för Myndigheten för samhällsskydd och beredskap [Regulation with Instruction for the Swedish Civil Contingencies Agency] (SFS 2008:1002), http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Forordning-20081002-med-ins_sfs-2008-1002/.

[44] *Id*.

[45] *Forskning för ett säkrare samhälle*, MSB, https://www.msb.se/Om-MSB/Forskning/ (last visited Oct. 31, 2014).

[46] Ch. 1:7 § SMITTSKYDDSLAGEN.

[47] *Id*. ch. 2:7 §.

[48] NBHW, Rekommendation för handläggning av misstänkta fall av ebola – reviderad version 2014-09-26 [Recommendations for the handling of suspected ebola cases – revised Sept. 26, 2014], http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19458/2014-6-7.pdf.

[49] LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA (SFS 2006:1570).

[50] *Myndigheten för samhällsskydd och beredskap*, KRISINFORMATION.SE (Sept. 8, 2011), http://www.krisinformation.se/web/Pages/Page____72962.aspx.

2. *Responsible Local Authorities: County Councils and County Medical Officers*

On the local level, public health crises are managed by the local health authorities known as the county councils,[51] which are responsible to the municipality and county administrative board. Each county council is overseen by a county medical officer (CMO)[52] and is responsible for health services in general within its region. Local health care providers and the CMO are the points of first contact for most public health crises. Although County Councils are normally only responsible for the residents of their own municipality, all County Councils should cooperate among themselves during extraordinary events.[53] All county councils must provide for the necessary precautions against transmission of disease.[54]. The county councils must also maintain a contingency plan. The local power to take forcible measures against individuals to combat a public health crisis is vested in the CMO.

The CMO has primary responsibility for the prevention and containment of communicable diseases. He or she must "plan, organize and lead the effort and work for efficiency, coordination and consistency."[55] This includes ensuring that local residents have access to information on communicable diseases and the response thereto, providing guidelines and support, ensuring that preventative steps are taken to prevent diseases from spreading, supporting treating physicians, following up on reported illnesses, ensuring that persons who carry a communicable disease get the support and care needed, ensuring that measures are taken to prevent the spread of disease, and continuously following the local status of communicable diseases in the region.[56] CMOs are also required to cooperate with CMOs from other regions and may transfer cases between themselves.[57]

D. Specialized Hospitals

In addition to national and local authorities that follow and monitor potential contagious threats, Sweden also prescribes by law that specialized expertise should be vested in individual public hospitals designated to accept and treat patients from anywhere in Sweden.[58] These specialized hospitals are responsible for national expertise in a specific area and are overseen by the NBHW, which grants a hospital the privilege of being a national hospital and issues the conditions that it needs to follow to maintain that status.[59] The Board's decisions cannot be appealed.[60]

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[51] Ch. 1: 8 § SMITTSKYDDSLAGEN.

[52] *Id*. ch. 1:9 §.

[53] 2b§ HÄLSO- OCH SJUKVÅRDSLAG (SFS 1982:763).

[54] Ch. 1:8 § SMITTSKYDDSLAGEN.

[55] *Id*. ch. 6:1 §.

[56] *Id*. ch. 6:2 §.

[57] *Id*. ch. 6:6 §, ch. 6:8 §.

[58] 9a § HÄLSO- OCH SJUKVÅRDSLAG (SFS 1982:763). For more information, *see Rikssjukvård*, SOCIALSTYRELSEN, http://www.socialstyrelsen.se/rikssjukvard (last visited Oct. 31, 2014).

[59] *Id*. 9b §.

[60] *Id*.

Linkoping University Hospital (a public hospital) is the specialized hospital on infectious diseases with capabilities to care for infectious patients in isolation for a prolonged period of time.[61] The unit is specifically tailored for high-risk diseases such as Ebola and includes three separate "treatment rooms."[62] It also has access to a specialized ambulance as well as airplane transportation.[63] Patients suffering from infectious diseases are transferred to Linkoping from other Swedish hospitals and it must be prepared to transport infected Swedes from anywhere in the world.[64]

E. Nordic Cooperation

1. Nordic Public Health Preparedness Agreement

Sweden cooperates with other Nordic countries on health care.[65] The Nordic Public Health Preparedness Agreement between the Nordic countries signed in Svolvær on June 14, 2002, makes treatment in another Nordic country possible in cases of national crises when Swedish resources are strained. Likewise, Sweden has an obligation to help its neighbors in their time of need.[66] Specifically, the Nordic countries have agreed to "provide assistance to one another upon request";[67] "promptly inform of measures planned or implemented that impact the cooperation";[68] "promote cooperation and insofar as possible remove obstacles in national legislation, regulations, and other rules of law";[69] "provide opportunities for the exchange of experience, cooperation, and competence-building";[70] "promote the development of cooperation in this area";[71] and "inform one another of relevant changes in the countries' preparedness regulations, including amendments to legislation."[72] The Nordic Public Health Preparedness

[61] For information on the operations of the High Risk Unit, see *Högisoleringsenheten*, LANDSTINGET I ÖSTERGÖTLAND (Oct. 14, 2014), http://www.lio.se/Om-landstinget/Vard-i-varldsklass/Hogisoleringsenheten/.

[62] *Id*. (translation by author).

[63] *Linköping i fokus om Sverige får ett ebolafall*, LÄKARTIDNINGEN (Aug. 15, 2014), http://www.lakartidningen.se/Aktuellt/Nyheter/2014/08/Linkoping-i-fokus-om-Sverige-far-ett-misstankt-ebolafall-/.

[64] LANDSTINGET I ÖSTERGÖTLAND, *supra* note 61.

[65] Nordic Public Health Preparedness Agreement, *available at* http://www.nordhels.org/Global/Nordhels/avtal/Nordiskt%20h%C3%A4lsoberedskapsavtal%20-%20engelska.pdf. For example, see information on burn victims at *Brännskadevård vid katastrofläge,* AKADEMISKA SJUKHUSET, http://www.akademiska.se/sv/Verksamheter/Brannskadecentrum/Brannskadevard-vid-katastroflage/ (last visited Oct. 31, 2014).

[66] Nordic Public Health Preparedness Agreement art. 4.1.

[67] *Id*. art. 4.1.

[68] *Id*. art. 4.2.

[69] *Id*. art. 4.3.

[70] *Id*. art. 4.4.

[71] *Id*. art. 4.5.

[72] *Id*. art. 4.6.

Agreement supplements the 1989 Nordic Rescue Service Agreement.[73] Currently, no patients are being treated under the Agreement.

2. *General Nordic Cooperation*

The Nordic countries also cooperate generally in health care.[74] During a meeting in Reykjavik in 2014, fourteen suggestions for deeper cooperation on health care issues were presented.[75] Sweden has general Nordic cooperation with its neighbors through Nordred, a cooperative civil protection agency among the Nordic countries.[76] Only one infectious patient was treated in another Nordic country during the 2005–2007 period.[77]

3. Baltic Sea Cooperation

A special action group against contagious diseases was set up at the Council of the Baltic Sea States (CBSS) meeting in Kolding, Denmark in 2000. Epidemic surveillance, HIV/Aids, tuberculosis, and antibacterial resistance, as well as primary care, were recognized as the most central issues to the region.[78]

II. Powers of Public Health Authorities

A. General

As mentioned above, national and local authorities share responsibilities and powers to act in the face of a public health crisis. The NBHW has the power to seal off and quarantine certain areas and require that individual travelers arriving from certain areas be quarantined.[79] The CMO is responsible for the local response to a public health crisis. As such, the CMO investigates the need for mandatory testing of suspected ill individuals;[80] petitions the courts for mandatory testing of suspected ill individuals;[81] issues, amends, and reviews care instructions for proven ill individuals;[82] and petitions courts for the isolation of infected individuals.[83] In urgent situations,

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[73] *Id*. art. 3.

[74] *See*, *e.g.*, *Nordic Cooperation Following Dramatic Increase in Tick-borne Infections*, UNIVERSITY OF GOTHENBURG (Nov. 28, 2012), http://www.sahlgrenska.gu.se/english/news_and_events/news/News_Detail//nordic-cooperation-following-dramatic-increase-in-tick-borne-infections.cid1108094.

[75] *Fjorton förslag om ökat nordiskt samarbete inom sjukvården*, LIFE-TIME.SE (June, 16, 2014), http://www.life-time.se/2014/06/16/fjorton-forslag-om-okat-nordiskt-samarbete-inom-sjukvarden/.

[76] For additional information see NORDRED, http://www.nordred.org (last visited Oct. 31, 2014).

[77] NORDEN, PATIENT MOBILITY IN THE NORDIC COUNTRIES (June 2011), http://www.nordicinnovation.org/Global/_Publications/Reports/2011/2011_patientMobility_report.pdf.

[78] Prop. 2003/04:30 at 72.

[79] *Id*. ch. 3:8 para. 2 § *and* ch. 3:10 §; *see also* Part II(D)(4), below.

[80] *Id*. ch. 6:3 §.

[81] *Id*. ch. 3:2 §.

[82] *Id*. ch. 4:3 §.

the CMO has the power to place a person in temporary isolation provided that the CMO notifies the court within four days to review the continued isolation.[84] Whereas the NBHW is responsible for designating quarantine areas, the County Medical Officer is responsible for the quarantine of people who are thought to be carriers of an illness and may demand testing of people arriving from abroad.[85] The CMO can also demand information on a patient from other government and local agents who have come in contact with the patient.[86]

B. National Mandatory Notification Systems

The Communicable Diseases Act requires that certain infectious diseases be reported.[87] Reportable diseases include, for example, chlamydia, HIV, and during the 2009 pandemic the A(H1N1) (swine flu) influenza.

1. Responsibilities of Medical Personnel

A treating physician who comes into contact with an infected individual is required to report the disease to the local CMO as well as to the Public Health Agency of Sweden without delay.[88] The provision also applies to pathologists and laboratory physicians.[89] The notification should include:

1. the infected or suspected infected patient's name, Swedish social security number, or government coordination number as well as address;
2. the likely source of the infection;
3. the likely spread of the disease;
4. any and all measures that the physician has taken to prevent the spread of the disease; and
5. other information that will affect the spread of the disease.[90]

"Other information" includes whether or not the individual was a blood donor.[91]

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[83] *Id*. ch. 5:2 §.

[84] *Id*. ch. 5:3 §.

[85] *Id*. ch. 3:8 para. 1 § *and* ch. 3:9 §.

[86] *Id*. ch. 4:9 §.

[87] For full list, see Communicable Diseases Act add. 1 & 2.

[88] Ch. 2:5 § SMITTSKYDDSLAGEN.

[89] *Id*. ch. 2:5 para. 2 §. *See also* Anmälan av anmälningspliktig sjukdom i vissa fall (Socialstyrelsens föreskrifter [SOSF] 2007:1), *as amended*, http://www.socialstyrelsen.se/sosfs/2007-1 (specifically stating in article 3 that A(H1N1) influenza should be reported by treating physicians and a micro-lab technicians, but that pathologists need not report the illness).

[90] Ch. 2:6 § SMITTSKYDDSLAGEN.

[91] Marie Jönsson, Comment 25, Comment to Act 2004:168, *in* 2 KARNOV SVENSK LAGSAMLING MED KOMMENTARER at 2690 (Cecila Bergman et al. eds., 16th ed. 2011/2012).

2. *Mandatory Self-reporting and Information*

A potentially sick person has the obligation to seek medical care to find out whether or not he or she is a carrier for a contagious disease covered by Communicable Diseases Act.[92] The requirement does not include an obligation to undergo treatment for the disease.[93] The patient must, however, inform the doctor of potential sources of the disease and indicate whether other individuals may have been infected.[94]

3. *International*

Captains of ships and airplanes are required to inform Swedish Customs about any potential disease on board and Swedish Customs in turn is required to inform the County Medical Officer.[95]

C. Powers of Disease Control

Once an illness has been diagnosed the local CMO has the power to put in place certain sanctions.[96] These sanctions may not go beyond what is required to contain the disease.[97] The treating physician must, in conjunction with the patient, work out a treatment plan for the treatment and containment of the disease.[98] If this plan is violated the CMO may intervene.[99]

1. *Issuing Individual Formal Instructions to Patients*

After a patient has been diagnosed with a contagious disease the treating physician should create individualized, formal instructions for the patient to follow to minimize the risk of spreading the disease.[100] The instructions may only include the following measures:

> 1. limits on socialization that pertain to work, education, or participation in other activity,
> 2. prohibition on donating blood or organs,
> 3. prohibition on lending or otherwise transferring used injection devices,
> 4. duty to inform caretakers and others, who perform nonmedical procedures on the patient, of the disease,
> 5. duty to inform sexual partners that he/she is carrying the disease,

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[92] Ch. 3:1 § SMITTSKYDDSLAGEN.

[93] KARNOV, *supra* note 91, Comment 27 at 2691.

[94] Ch. 3:4 § SMITTSKYDDSLAGEN.

[95] 16 § LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA.

[96] *See* discussion, Part II(C)(2)–(4), *infra*.

[97] Ch. 1:4 § SMITTSKYDDSLAGEN.

[98] *Id*. ch. 4:2 §.

[99] *Id*. ch. 5:1 para. 1 item 2 §.

[100] *Id*. 4:2 §.

6. duty, during sexual contacts, to adopt a behavior that minimizes the risk of spreading the disease,
7. duty to practice special hygienic routines, and
8. duty to keep in regular contact with the treating physician.

These instructions shall be communicated in writing as soon as possible as well as be included in the patient's health record. The treating physician shall as far as possible make sure that these instructions are followed.[101]

If the formal instructions are not followed the patient may be placed in isolation, if the risk to others requires isolation.[102]

2. Patient Isolation

Patients carrying a contagious disease may be placed in isolation for up to three months, which may be extended by six months at a time.[103] During the isolation period the patient has the right to one hour of outside time per day as well as telephone calls.[104] The patient also has the right to visitors, if visits can be conducted safely.[105] Isolation can only be ordered if there is a violation or risk of violation of the formal instructions or if it is otherwise the only way to contain the disease.[106] There must be a "considerable risk that others may be infected."[107] The European Court of Human Rights has ordered Sweden to pay damages to an HIV patient who was isolated for years, stating that there was not sufficient cause to keep him isolated.[108]

3. Extraordinary Measures

Testing of individuals for a disease at ports of entry is permissible when a person shows signs of illness with a disease that is classified as dangerous to society or when the person is coming from a region of the world known to be suffering from certain contagious outbreaks.[109] In both cases all passengers arriving on the same mode of transportation must undergo testing.[110] However, such tests may not result in deprivation of liberty, or test-taking or other measures that constitute a physical violation.[111]

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[101] *Id*. (translation by author).

[102] *Id*. ch. 5:1 para. 1 item 2 & ch. 5:1 para. 2 §.

[103] *Id*. ch. 5:5 §.

[104] *Id*. ch. 5:9–10 §.

[105] *Id*. ch. 5:10 §.

[106] *Id*. ch. 5:1 §.

[107] *Id*. ch. 5:1 para. 2 §.

[108] Enhorn v. Sweden, App. No. 56529/00 paras. 55–64 (Eur. Ct. H.R. Jan. 25, 2005), http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-68077; *see also* discussion, Part II(G)(3), *infra*.

[109] Ch. 3:8 para. 1 & 2 § SMITTSKYDDSLAGEN.

[110] *Id*.

[111] *Id*. ch. 3:8 para. 3 §.

Individuals who have potentially been exposed to a communicable disease (but who are not showing signs of disease)[112] may be quarantined "within a facility or area."[113] Individuals in quarantine or isolation are not allowed to leave the country.[114] Individuals who harbor a disease but are not under isolation or quarantine may leave the country after first notifying the CMO.[115]

4. Quarantine of Certain Areas, Harbors, and Airports

Specific areas may be designated as quarantine areas.[116] The government, or the agency appointed by the government, decides which ports and airports should be deemed "quarantine ports."[117] However, the government must work together with the county councils and municipalities in this effort.[118] While the government ultimately determines the designation as a quarantine harbor, the county councils and municipalities are responsible for ensuring that the airports and ports in their regions have all the resources they need, as specified by government instruction.[119] The local CMO is responsible for the care of patients and containment of the disease at these harbors.[120] Aircraft and vessels may not be turned away but should instead relocate to the designated quarantine harbor or airport.[121]

D. Powers of Disease Prevention

When the new Communicable Diseases Act was adopted in 2004 its main goal was to emphasize preventing the spread of diseases that are transmitted from human to human.[122] Disease prevention includes vaccination programs as well as educational efforts on how disease is spread.

1. *National Vaccination Program and Seasonal Flu Vaccinations*

Sweden has a comprehensive, voluntary vaccination program for children, which includes vaccinations against Polio, MMR, DTap, IPV, HiB, PCV, and HPV,[123] and administers free seasonal influenza vaccinations for risk groups as well as a general vaccination program for swine flu.[124] Most Swedes are vaccinated against these diseases.[125] The NBHW oversees the

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[112] Prop. 2003/04:158 Extraordinära smittskyddsåtgärder at 105.

[113] *Id*. ch. 3:9 §.

[114] *Id*. ch. 3:12 para. 1–2 §.

[115] *Id*. ch. 3: 12 para. 3 §.

[116] Ch. 3:10 § SMITTSKYDDSLAGEN.

[117] 6 para. 2 § LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA.

[118] *Id*. 6 §.

[119] *Id*. 7 §.

[120] *Id*. 8 §.

[121] *Id*. 18 §.

[122] Comment, Marie Jönsson, *in* KARNOV, *supra* note 91, at 2689.

[123] *Childhood Vaccination Schedule*, EUVACNET, http://www.euvac.net/graphics/euvac/vaccination/sweden.html (last visited Oct. 31, 2014).

[124] Ch. 2:3 SMITTSKYDDSLAGEN.

national vaccination program and makes changes as needed. For a vaccine to qualify for placement on the vaccination programs list, it must be "effective, socioeconomically cost effective and sustainable from an ethical and humanitarian ground."[126] These vaccinations are entered into a "national vaccination database" that tracks the vaccination of Swedish children.[127] The database may be expanded under the supervision and direction of the government to include all vaccinations administered in Sweden.[128]

The NBHW issues recommendations as to who should get a seasonal flu vaccine and has recommended that all pregnant women in their second or third trimester get vaccinated.[129] Other groups who are recommended to get the seasonal flu vaccines include the elderly and those who have underlying conditions, especially respiratory ones.[130]

2. *Mandatory Vaccinations*

Although vaccinations under the national vaccination program and seasonal flu vaccines are not mandatory, the government may mandate vaccination during times of war and/or in other extraordinary circumstances.[131] Failure to comply with such mandated vaccination may result in a fine as well as a court-mandated vaccination by force backed by the penalty of a fine, which can be reissued.[132] Until 1991 the fine was limited by statute to between SEK 5 (US$.68) and SEK 50 (US$6.80) (unchanged since its initial adoption in 1952); following 1991 amendments the amount of the fine is no longer established by law.[133]

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[125] *Id*. For statistics on how many Swedes are actually vaccinated, see *WHO Vaccine-preventable Diseases: Monitoring System, 2014 Global Summary*, WORLD HEALTH ORGANIZATION, http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=SWE (last visited Oct. 31, 2014).

[126] Ch. 2:3d § SMITTSKYDDSLAGEN.

[127] *Vaccinationsregister*, FOLKHÄLSOMYNDIGHETEN (June 27, 2014), http://www.folkhalsomyndigheten.se/amnesomraden/smittskydd-och-sjukdomar/vaccinationer/vaccinationsregister/.

[128] *Frågor & svar*, SMITTSKYDDSINSTITUTET (now FOLKHÄLSOMYNDIGHETEN), http://www.folkhalsomyndigheten.se/documents/smittskydd-sjukdomar/vaccinationer/faq-vaccinationsregistret.pdf?epslanguage=sv (last visited Oct. 31, 2014).

[129] Gravida kvinnor rekommenderas vaccination mot säsongsinfluensa [Pregnant Women Recommended to Get Vaccination Against Seasonal Flu], SOCIALSTYRELSEN, http://www.socialstyrelsen.se/smittskydd/sjukdomar/influensa/gravidakvinnor (last visited Oct. 31, 2014).

[130] *Riksgrupper för årlig influensa* [*Risk Groups for Seasonal Flu*], SOCIALSTYRELSEN, http://www.socialstyrelsen.se/smittskydd/sjukdomar/influensa/riskgrupper (last visited Oct. 31, 2014).

[131] LAG OM SKYDDSYMPNING VID KRIG ELLER KRIGSFARA M.M. [ACT ON PREVENTATIVE VACCINATION DURING WAR OR THREAT OF WAR] (SFS 1952:270); Proposition (Prop.) 2003/04:30 Ny smittskyddslag at 103.

[132] 3 § LAG OM SKYDDSYMPNING VID KRIG ELLER KRIGSFARA M.M.

[133] Prop. 1990/91:68 Om ändringar i brottsbalken (böter) m.m. [Regarding Changes in the Criminal Code (fines) etc.] [Government Bill], http://www.riksdagen.se/sv/Dokument-Lagar/Forslag/Propositioner-och-skrivelser/om-andring-i-brottsbalken-mm_GE0368/ (adopting SFS 1991:271).

3. *Informational/Educational Material*

The county councils are responsible for producing and disseminating information on contagious diseases to the public.[134]

4. *Forcible Screenings and Tests*

A person who is believed to be carrying a communicable disease and opposes testing can be forcibly tested but only at the order of a district administrative court.[135] Only the CMO may petition for the court to issue such an order.[136] Following a petition from the CMO the administrative court must issue a ruling on forcible testing within a week.[137]

E. Sanctions for Noncompliance

Violations of formal instructions[138] required by the Communicable Diseases Act are penalized. A person who intentionally transfers a disease to another can be punished with up to six years in prison.[139] The negligent spreading of a disease is punishable with a fine or imprisonment of up to one year when the person realizes the danger of the spread and does not take precautions to stop it.[140] When no transmission of a disease occurs, the risk alone (if known by the perpetrator) is punishable as "creation of danger to others" with up to two years imprisonment.[141]

F. Compensation

Patients who receive treatment have no separate right to compensation for time spent in isolation, etc., but all health care and all medications are free to the patient and not part of the "maximum payment protection" limit, under which health care is only free following the expenditure of a regulated maximum annual fee that a patient may incur.[142] All vaccinations carried out under the Communicable Diseases Act are also free of charge to the patient.[143]

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[134] Ch. 2:3 § SMITTSKYDDSLAGEN.

[135] *Id*. ch. 3:2 §.

[136] *Id*.

[137] *Id*. ch. 8:5 item 1 §.

[138] *See* discussion, Part II(D)(1), *supra*.

[139] Ch. 13:7 § BROTTSBALKEN [CRIMINAL CODE] (SFS 1962:700).

[140] *Id*. ch. 13: 10 §.

[141] *Id*. ch. 3:9 § BRB; *see also* NYTT JURIDISKT ARKIV [NJA] [SUPREME COURT REPORTS] 2004 p. 176 B4189-03, where the defendant was HIV positive and was indifferent as to the risk of spreading the disease to his sexual partners.

[142] Ch. 7:1-2 § SMITTSKYDDSLAG.

[143] *Id*. ch. 7: 2a § (referencing the national vaccination program).

G. Conflicts with Constitutional Rights of Individuals

Treatments for contagious diseases risk creating a conflict between fundamental human rights and health-care measures, as these interventions may limit the patient's freedoms, including both the treatments in themselves and the collection of personal information used to track and prevent further spread.

1. Treatment of Personal Information/Data

According to the Swedish Personal Information Act, personal information may only be gathered and stored when it is necessary in the practice of preventative care, to make a medical diagnosis, to care for or treat the patient, or to administer health care.[144] The administrator (i.e., the agency that keeps the record of personal information) is required to keep personal information as safe as possible, considering technology, budget, risks, and the sensitivity of the information.[145] When the registration of personal information violates the Personal Information Act, the individual recorded is entitled to damages.[146] Some decisions on the treatment of personal information are appealable to the administrative court system.[147]

The Swedish government collects data on Swedish patients through the vaccination program and also through the sharing of information from the patient's health record when he or she seeks medical treatment. The Act on Public Information and Secrecy prescribes secrecy for such health information.[148]

A person who has contracted a contagious disease is responsible for cooperating in finding the source of the disease as well as containing the spread of the disease and informing his or her health provider of other potential victims of the disease.[149] This information is classified, and may not be divulged. However, patient information may be shared, regardless of secrecy, in international preventative work.[150] Moreover, the CMO may, against the wishes of a contagious patient, inform his or her family that he or she is a carrier of a disease in efforts to prevent further spread of the disease.[151]

Individuals have the right to know what personal information about them is stored and may submit a request for this information at least once a year.[152]

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[144] 18 § PERSONUPPGIFTSLAGEN [PUL] [PERSONAL INFORMATION ACT] (SFS 1998:204).

[145] 31 § PUL.

[146] 48 § PUL.

[147] 51, 52, 53 §§ PUL.

[148] Ch. 1:6 § (for provisions, see chapter 25) OFFENTLIGHETS- OCH SEKRETESSLAG [ACT ON PUBLIC INFORMATION AND SECRECY] (SFS 2009:400).

[149] Ch. 2:2 § *and* ch. 3:4 § SMITTSKYDDSLAGEN.

[150] LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA (SFS 2006:1570).

[151] Ch. 4:8 § SMITTSKYDDSLAG.

[152] 26 § PUL.

2. Quarantine and Isolation

Quarantine and isolation are infringements on human rights. Isolation requires prior approval by the courts or in cases of emergency speedy review by the courts.[153] Because Sweden has signed on to the European Convention on Human Rights it is the European Court on Human Rights that establishes the case law on infringement of human rights.

3. Case Law: Right to Freedom (Enhorn v. Sweden)

Isolation of an individual may result in a violation of the patient's fundamental rights under article 5 of the Convention. In *Enhorn v. Sweden*, the European Court of Human Rights found that placing the plaintiff in isolation was a breach of his right to liberty and security of person, as guaranteed in article 5 of the European Convention on Human Rights.[154] The case involved an HIV-infected man who, after several breaches of conduct that violated the action plan prescribed by the local CMO, was placed under forced isolation.[155] The European Court of Human Rights found that the isolation violated the plaintiff's human rights because no less invasive method of preventing the spread of the disease had been considered.[156]

Even before *Enhorn*, in the legislative history of the 2003 Communicable Diseases Act the Swedish government wrote that the forced isolation of an HIV-positive person is less likely to conform with human rights because transmission of the disease requires intimate contact. It remains unclear whether forced isolation due to a more contagious disease that spreads "by casual contact"[157] is consistent with human rights as guaranteed by the European Convention on Human Rights.

III. Transparency of Public Health Crisis Management System: Publication and Information-sharing Requirements

A. Dissemination of Information to the Public

The government has made available an online platform, Krisinformation.se, that serves as a central clearinghouse for all crisis information.[158]

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[153] See ch. 5:2 § *and* ch. 5:3 § SMITTSKYDDSLAG.

[154] Enhorn v. Sweden, App. No. 56529/00 paras. 55–64 (Eur. Ct. H.R. Jan. 25, 2005), http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-68077

[155] *Id.* paras. 8–26.

[156] *Id*. paras. 55–56.

[157] Prop. 2003/04:30 at 75.

[158] *Vilket ansvar har landstingen när det gäller beredskapen mot ebola*?, KRISINFORMATION.SE (Sept. 2, 2014), http://www.krisinformation.se/web/Pages/Faq/ShowFaqWithLeftMenu___75516.aspx?FaqId=0470029&LangID=SV.

B. Local Contingency Plans

Each county council is required to have a publicly available local crisis preparedness plan,[159] and to have an official on duty twenty-four hours a day, seven days a week to respond to a potential crisis.[160]

C. Transmission of Information

Sweden has a nationally coordinated communications system called the "VMA system" or the "important message to the public system"[161] and a specialized radio system to communicate heightened preparedness in times of peace. Increased preparedness is communicated by radio and television.[162] The highest level of preparedness is announced through a preparedness alarm. The preparedness alarm is an alarm indicating increased preparedness that is transmitted on facilities for outdoor alarms through thirty-second-long signals with a fifteen-second interval between the signals, for a total of five minutes.[163]

IV. Cooperation with the World Health Organization

The National Board of Health and Welfare is responsible for cooperation with the World Health Organization.[164] Sweden also provides support to local initiatives and has provided resources to fight the Ebola epidemic in West Africa of SEK 139 million (about US$18.7 million) this year.

V. Current Crisis/Recent Developments

Sweden has been spared from recent public health crises. The government-run website Krisinformation.se lists events that qualify as recent national crises.[165] Most are environmental (storms) or animal related (such as salmonella in animal fodder) but there are also some public health threats that could have developed into public health crises but did not—specifically the swine-flu outbreak in 2009,[166] and the bird-flu outbreak in 2006. In addition, the current Ebola threat has the potential to develop into a public health crisis.

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[159] *See*, *e.g.*, *Krishanteringsplan*, STOCKHOLMS LÄNS LANDSTING (Apr. 7, 2009), http://www.sll.se/Global/Om%20landstinget/Krisberedskap/krishanteringsplan-stockholms-lans-landsting.pdf.

[160] 53 § Förordning med länsstyrelseinstruktion [Instruction for the County Administrative Board] (SFS 2007:825).

[161] *VMA – Viktigt meddelande till allmänheten*, MSB (Sept. 29, 2009), https://www.msb.se/sv/Insats--beredskap/Hantera-olyckor--kriser/VMA/.

[162] 23 § Förordning om krisberedskap och höjd beredskap.

[163] *Id*. 24 §.

[164] 11 § LAG OM SKYDD MOT INTERNATIONELLA HOT MOT MÄNNISKORS HÄLSA.

[165] KRISINFORMATION.SE, http://www.krisinformation.se (last visited Oct. 31, 2014).

[166] As determined by the government-run site Krisinformation.se. *Influensa A(H1N1) 2009, även kallad svininfluensan*, KRISINFORMATION.SE (Aug. 2, 2012), http://www.krisinformation.se/web/Pages/SubStartPage____72951.aspx.

A. Swine Flu, 2009

Sweden was first informed of the threat of A(H1N1) (swine flu) in the spring of 2009. Initially, vaccination was recommended for risk groups, but this quickly changed after a pregnant woman died. When the WHO updated the classification of the A(H1N1) to a pandemic (level six on their scale) the pandemic vaccination program automatically came into force, requiring county councils to decide how much vaccine they needed.[167] A total of eight million doses were ordered for the entire country.[168] The infections peaked in October of 2009, with vaccinations initiated a week later, resulting in 11,000 laboratory-verified cases of A(H1N1) for all of 2009.[169] The primary prevention focus was on the national vaccination campaign.[170]

In its 2011 evaluation report the NBHW and Swedish Contingency Agency noted several problems with the swine flu response. First, it found that language barriers proved to be a greater obstacle than expected in portions of the population without Swedish as a primary language.[171] Other problems included difficulties in following the transmission of the disease despite classifying the pandemic as a disease that requires a report to a CMO under the Communicable Diseases Act.[172] Only the Stockholm County Council had a working, automated system for keeping track of the disease.[173] Smaller county councils were especially hard hit in meeting the demands of the increased load of patients.[174] Also, determining the distribution priorities of the initial doses of vaccine and how the public should be informed of it was difficult.[175] Reportedly, the NBHW continues to work with how resources should be distributed during the next pandemic.[176]

Another issue noted in the evaluation report was the lack of coordination in the response, as emergency information was transmitted. Problems that occurred included certain county councils running out of vaccines and antiviral medicine and being unaware of where to order more.[177] Long-term effects of the pandemic response included an unexpectedly large number of children diagnosed with narcolepsy following the use of the vaccine Pandemrix. Intensive care saw a steep increase in influenza patients, especially patients suffering from bronchitis and other

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[167] SOCIALSTYRELSEN, INFLUENSA A(H1N1) 2009: UTVÄRDERING AV FÖRBEREDELSER OCH HANTERING AV PANDEMIN 10 (Feb. 2011), http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/18243/2011-3-3.pdf.

[168] *Id*.

[169] *Id*. at 10.

[170] *Id*. at 13.

[171] *Id*.

[172] *Id*.

[173] *Id*.

[174] *Id*. at 14.

[175] *Id*. at 17.

[176] *Id*. at 18.

[177] *Id*. at 73-75.

respiratory problems.[178] The World Health Organization provides a graph of current influenza statistics.[179]

Overall, the evaluation report found the A(H1N1) response was socioeconomically ineffective, which it attributed mostly to the delay in distributing vaccinations.[180] The report did not take the side-effects (predominantly narcolepsy in children and teenagers)[181] into account when estimating whether the response was efficient. In total, 60% of Sweden's population was vaccinated.[182] Thirty-one Swedes reportedly died from the virus.[183]

Earlier this year (2014) it was discovered that a mild variant of the swine flu virus (H1N2) had been transmitted between some farmers in Sweden and their pigs, the first time this is known to have occurred in Sweden.[184]

B. Bird Flu, 2006

Sweden was mildly affected by the bird flu virus in 2006.[185] A number of birds but no humans were infected.[186] The outbreak did, however, spur the response and intervention of national and local authorities, and its treatment resulted in a short report by the Swedish Contingency Agency.[187] Coordinated government responses included setting up a public information website, Fagelinfluensa.info, and a round-the-clock telephone service for bird-flu related information and questions.[188] Overall, the response was considered successful.[189]

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[178] *Id*. at 12.

[179] Chart, *Number of Specimens Positive for Influenza by Subtype – Sweden*, WHO (Nov. 12, 2014), http://gamapserver.who.int/gareports/Default.aspx?ReportNo=1&CountryCode=SE.

[180] SOCIALSTYRELSEN, *supra* note 167, at 93.

[181] For an overview in English, see *Statement on Narcolepsy and Vaccination*, WHO (Apr. 21, 2011), http://www.who.int/vaccine_safety/committee/topics/influenza/pandemic/h1n1_safety_assessing/narcolepsy_statement/en/; *see also* Francesca Poli et al., *Narcolepsy as an Adverse Event Following Immunization: Case Definition and Guidelines for Data Collection, Analysis and Presentation*, ELSEVIER (Dec. 16, 2012), http://www.who.int/vaccine_safety/initiative/BC_Narcolepsy_case_definition.pdf?ua=1.

[182] SOCIALSTYRELSEN, *supra* note 167, at 64.

[183] *Id*. at 57.

[184] *Swedish Farmers Contracted Swine Flu*, THELOCAL.SE (Oct. 22, 2014), http://m.thelocal.se/20141022/swedish-farmers-contracted-swine-flu.

[185] *Utbrottet av fågelinfluensa i Sverige 2006*, KRISINFORMATION.se (Aug. 2, 2012), http://www.krisinformation.se/web/Pages/Page____55168.aspx.

[186] *Fågelinfluens*a, KRISINFORMATION.SE (July 4, 2011), http://www.krisinformation.se/web/Pages/Page____31992.aspx.

[187] *Utbrotten av fågelinfluensa i Sverige 2006*, KRISBEREDSKAPSMYNDIGHETEN (now the Swedish Contingencies Agency) (Dec. 7, 2006), http://www.krisinformation.se/web/Upload/Krisinformation.se/Handelser/F%c3%a5gelinfluensan/utbrotten_av_fagelinfluensa_2006.pdf.

[188] *Fågelinfluens*a, KRISINFORMATION.se (July 4, 2011), http://www.krisinformation.se/web/Pages/Page____31992.aspx.

[189] *Id*. at 36.

C. Current Ebola Threat

On October 23, 2014, the government declared Ebola a disease dangerous to society.[190] Despite declaring itself ready to handle an Ebola patient, the NBHW the same evening refused to admit an international Ebola patient on grounds that it did not know what was needed of it.[191] As of yet no Ebola victim has been confirmed in Sweden.

The country is increasing its spending and preparations for fighting the Ebola virus, currently recruiting additional personnel to be sent to Liberia.[192] Sweden is allocating equipment and funding totaling SEK 489 million (about US$66 million) for 2014 to combat Ebola.[193] Extra funding is also being provided as earmarks to the NBHW budget to help coordinate the effort both locally and abroad.[194] Municipalities have raised their preparedness by issuing local guidelines for health care workers encountering Ebola patients at local, non-hospital, health-care facilities.[195]

The Swedish Armed Forces has reported that it is prepared to fly an Ebola patient from Africa to Sweden within twenty-four hours.[196] The transport would include a custom-made ambulance carried inside a Hercules airplane.[197] There is no information on how long it would take to get the aircraft from Sweden to Africa.

D. National Preparedness and Effectiveness of Routines

A governmental study conducted following the bird flu outbreak resulted in recommendations to improve the cooperation between inpatient care, primary care, and municipal care, and to focus more heavily on logistical aspects, plans to secure resources, and preparedness within the individual communicable diseases units.[198] Also, the European Center for Disease Prevention and Control's (ECDC's) investigation in 2007 found that local preparedness could be

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[190] Press Release, Regeringskansliet, *supra* note 16.

[191] *Landstinget i Östergötland vägrade ta emot ebolasjuk*, CORREN.se (Oct. 24, 2014), http://www.corren.se/nyheter/ostergotland/sverige-ville-inte-varda-ebolasjuk-7455211.aspx.

[192] *Utökade Svenska Insatser i Västafrika*, SOCIALSTYRELSEN (Oct. 9, 2014), http://www.socialstyrelsen.se/nyheter/2014oktober/utokadesvenskainsatserivastafrika.

[193] *Ytterligare 400 miljoner till ebolabekämpning och humanitära kriser* [*Additional SEK 400 Million to the Fight Against Ebola and Humanitarian Crisises*], REGERINGSKANSLIET (Oct. 24, 2014), http://www.regeringen.se/sb/d/18915/a/248832; *Sveriges stöd i kampen mot Ebola* [*Swedish Support in the Fight Against Ebola*], REGERINGSKANSLIET (Oct. 23, 2014), http://www.regeringen.se/content/1/c6/24/88/32/94c6596e.pdf.

[194] *Sveriges stöd i kampen mot Ebola*, *supra* note 193; *Utökade Svenska Insatser i Västafrika*, SOCIALSTYRELSEN (Oct. 9, 2014), http://www.socialstyrelsen.se/nyheter/2014oktober/utokadesvenskainsatserivastafrika.

[195] *See*, *e.g.*, VÅRDHYGIEN ÖSTERGÖTLAND, EBOLA – LOKALT PM FÖR OMHÄNDERTAGANDE AV MISSTÄNKT EBOLA-SMITTAD PATIENT (Oct. 21, 2014), http://vardgivarwebb.lio.se/pages/248565/EBOLA.pdf.

[196] *Förberedda att flyga ebolapatient*, FÖRSVARSMAKTEN (Oct. 9, 2014), http://www.forsvarsmakten.se/sv/aktuellt/2014/10/forberedda-att-flyga-ebolapatient/.

[197] *Id*.

[198] *See* SOCIALSTYRELSEN, *supra* note 167, at 8.

improved.[199] The level of local preparedness was effectively tested during the 2009 response to the potential swine-flu pandemic. The response was investigated and culminated in a report in 2011 in which the experts found that improvement efforts should continue to focus on coordination between national and local authorities.[200]

[199] *Id*.

[200] *See* Part V(A), *supra*.

European Union

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SUMMARY The European Union (EU) Member States are mainly individually responsible for responding to public health and other major emergencies within their borders. The EU's role in the field of public health, as established by the Treaty on the Functioning of the EU, is limited to complimenting the national policies of the EU Members, coordinating their actions, and facilitating communication and the exchange of data between the European Commission and the EU Members.

The most recent health crises in the EU acted as a catalyst for the Commission to reform the 1998 EU legislation. A new decision, Decision No. 1082/2013, expands the type of serious health threats with cross-border implications to also include threats of chemical, environmental, or unknown origin. Events that may constitute public health emergencies of international concern have been added to the list, in compliance with the 2005 revised WHO International Health Regulations, to which EU Members are bound. The Health Security Committee, which acquired formal status by Decision No. 1082/2013, assists the Commission in coordinating public health crises; it also advises the ministers on health of the EU Members and coordinates their actions. In implementing Decision No. 1082/2013, the EU Members have designated national authorities in charge of epidemiological surveillance, alert notification, and taking measures to protect public health.

The European Centre for Disease Prevention and Control (ECDC) plays a vital role in the surveillance, identification, assessment, and communication of current and/or emerging threats to human health. The ECDC has assumed operation of the Epidemiological Surveillance Network and the Early Warning and Response System, both of which were established in 1998 to enhance the EU's ability to respond to public health emergencies.

I. Introduction

The European Union (EU), due to its specific nature as an area with no internal borders and the free circulation of people and goods, faces special challenges in the event of public health crises. Primary responsibility for responding to public health emergencies falls within the domain of the EU Member States. The EU has legal authority in the field of public health based on article 168 of the Treaty on the Functioning of the European Union.[1] In general, EU action in the field of public health is intended to complement the national policies of the EU Members and to coordinate and support their actions. In this regard, the Commission plays a vital role, both in coordinating and exchanging information between the EU Member States and in maintaining the structures and mechanisms that operate at the EU level to address public health crises.[2] In

[1] Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) art. 168, 2012 O.J. (C 326) 47, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT.

[2] *Outbreak of Ebola Virus Disease in Western Africa*, EUROPEAN COMMISSION, DIRECTORATE-GENERAL FOR HEALTH AND CONSUMERS (Oct. 28, 2014; updated Nov. 12, 2014), http://ec.europa.eu/health/ebola/index_en.htm.

addition to twenty-eight EU Members, three non-EU Member countries that participate in the EU Single Market, Iceland, Lichtenstein, and Norway,[3] also cooperate with the Commission in matters involving public health.

At the EU level, several agencies are engaged in preparedness and response planning to combat serious threats to health. The European Centre for Disease Prevention and Control (ECDC),[4] which was established in 2005 and was modeled after the US Centers for Disease Control and Prevention,[5] plays a pivotal role in the field of communicable diseases and other public health crises. Other agencies involved at the EU level include the European Food Safety Authority (EFSA),[6] the European Medicines Agency (EMEA),[7] and the European Environment Agency (EEA).[8] In addition, the European Commission's Health Security Committee, which was established in the aftermath of the September 11, 2001, terrorist attacks on the US (9/11 attacks), acquired formal status by new EU legislation and has been given a specific mandate. The EU has also established two committees to assist the Commission when a scientific opinion is needed: (a) the Scientific Committee on Emerging and Newly Identified Health Risks, and (b) the Scientific Committee on Health and Environmental Risks.[9]

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[3] The European Economic Area (EEC) agreement, which entered into force in January 1994, permits three of the European Free Trade Association (EFTA) countries (Iceland, Norway, and Liechtenstein) to participate in the EU single market. *European Economic Area*, EUROPEAN UNION EXTERNAL ACTION, http://eeas.europa.eu/eea/index_en.htm (last visited Nov. 12, 2014).

[4] EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, http://ecdc.europa.eu/ (last visited Nov. 12, 2014).

[5] The ECDC was established by 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, 2004 O.J. (L 142) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0851:EN:HTML.

[6] In the aftermath of the food crisis in the 1990s, especially the Bovine Spongiform Encephalopathy (BSE) or "mad cow disease" outbreak and dioxin contamination, the EU in 2002 established the EFSA, comprised of European experts who provide risk assessment and risk communication on issues involving food safety. *See* Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002, Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, 2002 O.J. (L 31) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF.

[7] The EMEA is based in London, and is responsible for the authorization and marketing of medicinal products for human and veterinary use. *See About EMEA –Structure*, (last visited Nov. 22, 2014) The EMEA was established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF.

[8] The EEA began operations in 1994 and assists EU institutions and Member States on environmental issues. Council Regulation (EEC) No. 1210/90 of 7 May 1990 on the Establishment of the European Environment Agency and the European Environment Information and Observation Network, 1990 O.J. (L 120) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990R1210:EN:HTML.

[9] The Scientific Committee on Emerging and Newly Identified Health Risks and the Scientific Committee on Health and Environmental Risks were established by Commission Decision 2008/721/EC Setting Up an Advisory Structure of Scientific Committees and Experts in the Field of Consumer Safety, Public Health and the Environment and Repealing Decision 2004/210/EC, 2008 (L 241) 21, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF.

Past experience with public health crises in the EU have clearly demonstrated that such crises affect numerous sectors, including health, food safety, environment, transport, and national security. Thus, the Commission in 2011 initiated new legislation to address the existing deficiencies in tackling health crises.[10] A new decision, Decision No. 1082/2013 on Serious Cross-Border Threats to Health, expands the list of sources of danger to health to include not only communicable diseases but also biological, chemical, and environmental events, or events of unknown origin that may pose a risk to EU citizens.[11]

At the international level, the Commission is engaged in promoting and improving collaborations on global public health issues by participating in the Global Health Security Initiative (GHSI), an international partnership launched in 2001 by the Commission, G7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States), and Mexico.[12] Moreover, the Commission, the ECDC and other agencies have established solid cooperation with the World Health Organization (WHO) through its regional office in Europe (WHO/Europe).[13]

II. Recent Legislation on Serious Public Health Crises

Article 2 of Decision No. 1082/2013/EU on Serious Cross-Border Threats to Health, issued in 2013, recognizes the following categories of serious cross-border threats to health, which may trigger public health measures:

> (a) threats of a biological origin, consisting of:
>
> > (i) communicable diseases;
> >
> > (ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases . . .;
> >
> > (iii) biotoxins or the other harmful biological agents not related to communicable diseases;
>
> (b) threats of chemical origin;
>
> (c) threats of environmental origin;
>
> (d) threats of unknown origin;
>
> (e) events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the categories of threats set out in points (a) to (d).[14]

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[10] Press Release, European Commission, Q&A: Health Security in the EU (Dec. 8, 2011), http://europa.eu/rapid/press-release_MEMO-11-884_en.htm.

[11] Decision No. 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, 2013 O.J. (L 293) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0001:0015:EN:PDF.

[12] *Commission Staff Working Document, Health Security in the European Union and Internationally*, SEC (2009) 1622 final, at 3 (Nov. 23, 2009), http://ec.europa.eu/health/preparedness_response /docs/commission_staff_healthsecurity_en.pdf.

[13] WORLD HEALTH ORGANIZATION/EUROPE, http://www.euro.who.int/en/home (last visited Nov. 21, 2014).

[14] Decision No. 1082/2013/EU, *supra* note 11, art. 2, para. 1.

In exceptional emergency situations, an EU Member State or the Commission may request response coordination within the Health Security Committee for serious cross-border threats to health other than the ones provided above.[15]

Decision No. 1082/2013 introduced the possibility of joint procurement of medical countermeasures, such as vaccines, which could be done through a Joint Procurement Agreement between the EU institutions and those EU Members who wish to participate.[16]

EU Members have the right to maintain or introduce additional measures and procedures to tackle serious threats to health due to biological, chemical, environmental, or unknown origin within their borders.[17] In compliance with Decision No. 1082/2013, EU Members have designated the appropriate competent authorities responsible for epidemiological surveillance,for alert notifications, and for taking the necessary measures to protect public health in times of crisis.[18] The Commission has prepared a template for the national authorities to be used to provide information on preparedness and response planning regarding cross-border threats to health.[19]

III. Overview of Systems Responsible for Crises Management at the EU Level

The various health crises that the EU has encountered thus far, such as mad cow disease, the SARS and flu epidemics, and the ash cloud caused by the eruption of a volcano in Iceland, have demonstrated the need for cross-sector preparedness, monitoring, and response in order to tackle such crises effectively. Therefore, beginning in 1998, the EU established the following critical organizations and systems with the objective of enhancing its own ability and that of its Members to respond to public health emergencies more efficiently.

A. Epidemiological Surveillance Network

Decision No. 1082/2013 extended the scope of the network for the epidemiological surveillance of communicable diseases that was initially established in 1998 to include all the additional sources of threats to public health contained in article 2 (quoted above).[20] This network is operated and coordinated through the ECDC. The national authorities are required to send all authorities connected through the network certain data, including comparable and compatible data related to the communicable diseases and other threats to public health contained in article

[15] *Id*. art. 2, para. 4.

[16] *Id*. art. 5.

[17] *Id.* art. 2, para. 6.

[18] *Id.* art. 15, para. 1(a) & (b).

[19] Commission Implementing Decision 2014/504/EU of 25 July 2014 Implementing Decision No. 1082/2013/EU of the European Parliament and of the Council with Regard to the Template for Providing the Information on Preparedness and Response Planning in Relation to Serious Cross-border Threats to Health (Notified Under Document C(2014) 5180) Text with EEA Relevance, 2014 O.J. (L 223) 25, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.223.01.0025.01.ENG.

[20] *Id*. art. 6, para. 1.

2; updates on the development of epidemic situations; and information on unusual epidemics or new communicable diseases of unknown origin, including those that occur outside the EU.[21]

B. Early Warning and Response System

At the EU level, an Early Warning and Response System (EWRS) was established in 1998, to be used to notify alerts relating to serious cross-border threats to health.[22] Based on this system, the Commission and the national authorities are constantly communicating regarding alerts, assessing public health risks, and deciding on appropriate measures.[23]

Alert notifications are sent either by the Commission or the national authorities to the EWRS when a serious cross-border threat is unusual or unexpected for the specific place where it originated and has the potential to lead to significant morbidity and mortality in humans (or grows larger), affects more than one Member State, and may require a coordinated response at the Union level.[24]

C. European Centre for Disease Prevention and Control

The ECDC is an independent agency, located in Stockholm, Sweden, whose chief mission is to "identify, assess and communicate current and emerging threats to human health from communicable diseases."[25] Specifically, the ECDC has the following tasks:

- Search for, collect, and disseminate scientific and technical data;
- Provide scientific opinions and scientific and technical assistance;
- Provide information promptly to the Commission, Member States, and Community agencies as well as international organizations involved in public health issues;
- Coordinate the actions of the EU networks dealing with public health issues together with those networks or contact points designated by the national authorities, the so-called "dedicated surveillance networks;" and
- Exchange information and expertise, and facilitate the implementation of joint actions.[26]

Since it began its functions in 2005, the ECDC has assumed responsibility for the operation of the Epidemiological Surveillance Network at the Union level and the EWRS, both of which were established in 1998.[27] Since ECDC was established, EU Members have been required to forward to the ECDC any information sent through the EWRS, provide the ECDC with timely scientific

[21] *Id*. art. 6, para. 3.

[22] *Id*. art. 8, para. 1.

[23] *Id*.

[24] *Id*. art. 9, para. 1(a)–(c).

[25] Regulation (EC) No. 851/2004, *supra* note 5, art. 3, para. 1.

[26] *Id*. art. 3, para. 2.

[27] Decision No. 1082/2013, *supra* note 11, art 17, para. 1.

and technical data to enable it to perform its mission, and identify competent bodies and experts in public health who could be available to assist the EU in case of disease clusters or outbreaks.[28]

D. Health Security Committee

Decision No. 1082/2013 granted formal status to the Health Security Committee (HSC), which was first established as an informal forum of discussion of public threats in the aftermath of the 9/11 attacks.[29] The HSC is composed of representatives of the EU Members through their designated person and is chaired by a person appointed by the Commission.[30] The HSC is tasked with (a) supporting the exchange of information between the Commission and the EU Members on practices regarding implementation of Decision No. 1082/2013; and (b) coordinating jointly with the Commission preparedness and response planning, as put together by the EU Members.[31]

IV. Privacy Concerns

Since public health crises often involve the handling and processing of personal data of individuals, EU Members and the Commission are required to comply with EU legislation on the protection of privacy and personal data, as provided for in Directive 95/46/EC,[32] which has been implemented by the EU Members, and Regulation (EC) No. 45/2001 on the Protection of Individuals with Regard to the Processing of Personal Data by the Community Institutions and Bodies and on the Free Movement of Such Data.[33]

In compliance with the EU legislation, which requires that personal data must be collected only for a specific purpose and must be eliminated afterwards, Decision No. 1082/2013 provides that the EWRS system must include a "selective messaging functionality" under which personal data of individuals must be communicated only to national competent authorities responsible for tracing measures.[34] The national authorities will forward such data only to the other EU Members that are involved in the contact tracing measures.[35]

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[28] Regulation (EC) No. 851/2004, *supra* note 5, art. 4.

[29] Decision No. 1082/2013, *supra* note 11, art. 17, para. 1.

[30] *Id*. art. 17, para. 3.

[31] *Id*. art. 17, para. 2.

[32] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 31, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML.

[33] Regulation (EC) No. 45/2001 of the European Parliament and of the Council of 18 December 2000 on the Protection of Individuals with Regard to the Processing of Personal Data by the Community Institutions and Bodies and on the Free Movement of Such Data, 2001 O.J. (L 8) 1, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32001R0045.

[34] Decision No. 1082/2013, *supra* note 11, art. 16, para. 2.

[35] *Id.* art. 16, para. 3.

Any messages that contain personal data can be kept for twelve months and after that period must be automatically erased from the EWRS selective messaging functionality.[36] Decision No. 1082/2013 deems the national competent authorities in charge of preparedness and monitoring public health care crises and the Commission as "controllers" as defined by EU legislation on privacy. Controllers are either natural or legal persons or public authorities that determine the purposes and means for processing personal data.[37] Therefore, they are required to take technical and organizational measures to protect personal data against unauthorized access, accidental loss, or illegal destruction.[38]

V. WHO International Health Regulations and the EU

The collaboration of the EU and the World Health Organization (WHO) is based on article 168 of the Treaty on the Functioning of the EU, which requires the EU and Member States to foster cooperation with international organizations competent in the field of public health.[39] The Commission and the WHO cooperate by exchanging information and sharing experience in assessing health risks, strengthening communicable disease surveillance and improving responses, and developing tools for health monitoring.[40] The ECDC also collaborates closely with the WHO.[41]

In 2005, the WHO revised its International Health Regulations (IHR).[42] The IHR, as an international legal instrument, is legally binding on all states parties, including the twenty-eight EU Members. The revised IHR introduced the concept of public health emergencies of international concern in order to cover existing, new, and old diseases, including health crises due to noninfectious diseases. It entered into force on June 15, 2007, and requires WHO members to implement the regulations gradually by 2016. The EU itself is not a WHO member, and therefore is not a party to the IHR. However, article 57(3) of the IHR recognizes the role of the EU as a "regional economic integration organization" and states that, "[w]ithout prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization."[43]

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[36] *Id*. art. 16, para. 4.

[37] Directive 95/46/EC, *supra* note 32, art. 2(d).

[38] *Id*. art. 16, para. 1.

[39] TFEU, *supra* note 1, art. 168, para. 3.

[40] In 2001, the European Commission and the WHO signed a Memorandum of Understanding to further develop and reinforce their mutual cooperation, and the WHO has also established an office in Brussels. Exchange of Letters Between the WHO and the Commission of the European Communities Concerning the Consolidation and Intensification of Cooperation – Memorandum Concerning the Framework and Arrangements for Cooperation Between the WHO and the Commission of the European Communities, 2001 O.J. (C 001) 7 (Jan. 4, 2001), http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=22001A0104(01)&model=guichett.

[41] *EU in the World, Public Health*, WHO, http://ec.europa.eu/health/eu_world/ international_organisations/who/index_en.htm (last visited Oct. 24, 2014).

[42] WHO, International Health Regulations (2d ed. 2005), http://www.who.int/ihr/publications/97892415 96664/en/.

[43] *Id*. art. 57, para. 3.

In a 2006 Communication on the IHR, the Commission articulated the role that the ECDC and the EWRS can play in implementing the IHR more effectively and coherently in case of public health crises of international concern.[44] In general, preparation and planning for health crises at the EU level follows the general recommendations of the WHO, adapted to particular situations in Europe. If a health emergency, such as pandemic influenza, erupts outside of the EU, the WHO is the organization that identifies the level of emergency and preparedness. The European Commission also has the authority to recognize a pandemic independently of the WHO, based on Decision No. 1082/2013, elaborated above.[45]

VI. Ebola Outbreak

The current Ebola outbreak in West Africa, like the recent polio outbreak in the EU,[46] set in motion the agencies and networks involved in handling such crises, even though, according to EU estimates, the risk of Ebola for EU citizens was low.[47] The European Commission is closely working with the EU Member States within the Health Security Committee to keep them informed about the latest developments and to coordinate approaches on prevention and preparation for Ebola. The Commission's Health and Consumers Directorate-General has been closely monitoring the event in cooperation with the ECDC and the WHO since March 2014, when news of the outbreak first appeared. The ECDC is producing risk assessments, epidemiological updates, and other information. The risk of importation to the EU is considered very low, in particular if returning travelers and health care providers are properly informed and are aware of the risk.[48] Only a few EU health care workers have been infected and have returned to the EU for medical care.[49]

The European Food Safety Agency played an active role in monitoring the Ebola epidemics due to reports of a potential link between Ebola virus found in bushmeat, coming from wild animals native to African forests, and possible transmission to humans. The EFSA experts concluded that the risk from bushmeat consumption and possible infection with Ebola virus is low. Meanwhile, however, the EU has prohibited the import of bushmeat into the EU.[50]

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[44] *Communication from the Commission to the European Parliament and to the Council, on the International Health Regulations*, COM (2006) 552 final (Sept. 26, 2006), http://ec.europa.eu/health/ph_international/ documents / comm_ihr_552_2006_en.pdf.

[45] Decision No. 1082/2003, *supra* note 11, art. 12.

[46] *See* ECDC, TECHNICAL REPORT, DETECTION AND CONTROL OF POLIOVIRUS TRANSMISSION IN THE EUROPEAN UNION AND EUROPEAN ECONOMIC AREA (Feb. 2014), http://www.ecdc.europa.eu/en/publications/Publications/polio-detection-control-EU.pdf.

[47] Press Release, European Commission, Memo, The EU's Response to Help Fight the Ebola Outbreak in West Africa (Sept. 5, 2014), http://europa.eu/rapid/press-release_MEMO-14-520_en.htm.

[48] *Outbreak of Ebola Virus Disease in Western Africa*, EUROPEAN COMMISSION, DIRECTORATE-GENERAL FOR HEALTH AND CONSUMERS (Oct. 28, 2014; updated Nov. 12, 2014), http://ec.europa.eu/health/ebola/index_en.htm.

[49] *Id*.

[50] *EFSA Assesses the Risk of Transmission of Ebola Through Bushmeat*, EUROPEAN FOOD SAFETY AUTHORITY (Nov. 4, 2014), http://www.efsa.europa.eu/en/press/news/141104a.htm?utm_source=feed&utm_medium= rss&utm_campaign=comb.

From the outset of the Ebola crisis, the European Commission has been active with humanitarian aid, expertise, and international coordination. In addition, diplomatic outreach is being done via the Delegations of the EU and other channels in order to facilitate the humanitarian response in the countries concerned and to sensitize governments not to overreact to the crisis with regard to travel restrictions, trade impediments, etc.

As early as March 2014 the European Commission gave €1.9 million (about US$2.4 million) to help contain the Ebola epidemics and to ensure immediate health care for the affected populations. Since then, the Commission has boosted its humanitarian assistance on two occasions, bringing it to a current total of €11.9 million (about US$14.84 million).[51] On September 5, 2014, the European Commission announced €140 million of funding (about US$175 million) for the countries affected by the Ebola virus in West Africa: Guinea, Sierra Leone, Liberia, and Nigeria.[52]

[51] Press Release, European Commission, *supra* note 47.

[52] *Id*.

World Health Organization

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SUMMARY A global approach to addressing health issues and emergencies is provided by the United Nation's World Health Organization (WHO), which was established in 1946. The WHO has a Constitution and issues International Health Regulations (IHR). Its membership is open to all Members of the United Nations and Associate Members. The WHO's objective is the attainment by all peoples of the highest level of health.

Following a severe acute respiratory syndrome (SARS) pandemic in 2003, the WHO and its Member States updated the WHO mechanisms for preventing and controlling pandemics. In 2005, the WHO commenced a Pandemic Preparedness Program that requires the Member States to create national preparedness plans. Also in 2005, the World Health Assembly agreed on new IHR that create an international pandemic risk management system by requiring the Member States to report on an expanded list of diseases and public emergencies, to control the entry and exit of travelers and goods, and to take other precautionary measures in accordance with WHO recommendations. The system was put to the test in the A(H1N1) virus influenza that emerged in Mexico in April 2009 and quickly reached global dimensions. Since that time, the WHO has instituted the Pandemic Influenza Preparedness (PIP) Framework to improve preparedness for and response to pandemic influenza and has replaced the 2009 guidance with the 2013 Pandemic Influenza Risk Management WHO Interim Guidance.

I. Structure of the World Health Organization

The World Health Organization (WHO), established on July 22, 1946, is an agency of the United Nations (UN) responsible for handling global health issues.[1] Any Member State of the UN may become a WHO member by accepting its Constitution.[2] Territories may be admitted to the WHO as Associate Members if an application is made on their behalf by the Member State or

[*] Most of this report was originally prepared by George E. Glos, former Special Group Leader, July 2003; it was supplemented in 2009 by Edith Palmer, former Senior Foreign Law Specialist, and was again updated for the purposes of the present report.

[1] World Health Organization (WHO), Summary Report on Proceedings Minutes and Final Acts of the International Health Conference Held in New York from 19 June to 22 July 22 1946, Official Records of the World Health Organization No. 2, 9 U.N.T.S. 3 (June 1948), http://apps.who.int/iris/bitstream/10665/85573/1/Official_record2_eng.pdf?ua=1.

[2] CONSTITUTION OF THE WORLD HEALTH ORGANIZATION, http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1 (last visited Oct. 29, 2014). The Constitution was adopted as one of the Final Acts of the 1946 International Health Conference; the text is also available in the Summary Report cited above in note 1, *supra*.

other authority responsible for the territory's international relations.[3] At present, there are 194 Member States of the WHO.[4]

The WHO's governing organs are the World Health Assembly, the Executive Board, and the Secretariat.[5]

A. World Health Assembly

The World Health Assembly (WHA), the WHO's supreme decision-making body, is composed of delegates representing the Member States.[6] The WHA meets in a regular annual session and special sessions, as necessary.[7] The WHA is responsible for the WHO's policy-making programs and budget.

The WHA has the authority to adopt regulations concerning sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; nomenclatures for disease, causes of death, and public health practices; standards for international diagnostic procedures; standards for the safety, purity, and potency of biological, pharmaceutical, and similar products moving in international commerce; and the advertising and labeling of biological, pharmaceutical, and similar products moving in international commerce.[8] Regulations come into force for all Members after due notice of their adoption has been given, except for such Members that have notified the Director-General of their rejection or reservations within the period stated in the notice.[9]

The WHA also has the authority to make recommendations to Members on any matter within the competence of the WHO.[10]

B. Executive Board

The Executive Board is the executive organ of the WHA.[11] It is composed of thirty-four health experts designated by, but not representing, their governments.[12] The Executive Board forwards

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[3] *Countries*, WHO, http://www.who.int/countries/en/ (last visited Oct. 30, 2014).

[4] *Id*.

[5] For additional information, see *About WHO*, http://www.who.int/about/en (last visited Oct. 28, 2014), *and Governance*, WHO, http:www.who.int/governance/en (last visited Oct. 28, 2014). *See also World Health Organization Organigram* (Sept. 25, 2014), http://www.who.int/about/structure/WHO_organigram_25092014.pdf?ua=1.

[6] WHO CONSTITUTION art. 10.

[7] *Id*. art. 13.

[8] *Id*. art. 21.

[9] *Id*. art. 22.

[10] *Id*. art. 23.

[11] *Id*. art. 28.

[12] *Id*. art. 24.

recommendations on the Director-General's programs to the WHA,[13] advises on questions referred to it by the WHA, and implements the WHA's decisions and policies. It is also empowered to take emergency measures in case of epidemics or disasters.[14]

C. Secretariat

The Secretariat comprises the Director-General and roughly eight thousand other technical and administrative staff.[15] The Director-General appoints the staff of the Secretariat,[16] and prepares and submits to the Executive Board the financial statements and budget estimates of the organization.[17]

D. Regional Offices

The WHO has six geographical regions: Africa, the Americas, Eastern Mediterranean, Europe, Southeast Asia, and Western Pacific.[18] Each has its own organization consisting of a regional committee representing the Member States and Associate Members in the region concerned, and a regional office staffed by experts in various fields of health.[19]

II. WHO Departments

The WHO departments most directly concerned with responding to health emergencies, including infectious disease epidemics or pandemics, are described below.

The Health Security and Environment (HSE) Department works within the WHO and with partners and countries to strengthen national and global capacities necessary for detecting, being prepared for, preventing, and responding to health security risks and emergencies; to enhance national and global readiness for health security emergencies; and "to provide global leadership and guidance when major infectious disease outbreaks and other health security emergencies occur."[20] The HSE's strategic priorities for 2014–2017 include mounting an effective response to any major new epidemic, pandemic, or food-related health security risk; attaining the core capacities set forth in the International Health Regulations (IHR) by all countries; developing "a global strategic plan for antimicrobial drug resistance with clearly defined roles for all major sectors and WHO and implementing the key roles for WHO"; implementing the Codex Alimentarius and the Pandemic Influenza Preparedness (PIP) Framework; and adopting "a

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[13] *Id*. arts. 26 & 28.

[14] *Id*. art. 28; *see also* WHO, Rules of Procedure of the Executive Board of the World Health Organization as at April 2014, http://www.who.int/governance/EB_rules_of_procedure_rev2014-en.pdf?ua=1.

[15] WHO CONSTITUTION art. 30; *Governance*, *supra* note 5.

[16] WHO CONSTITUTION art. 35.

[17] *Id*. art. 34.

[18] *Regional Offices*, WHO, http://www.who.int/about/structure/en/ (last visited Oct. 30, 2014).

[19] WHO CONSTITUTION arts. 45–47.

[20] *Health Security (HSE)*, WHO, http://www.who.int/about/structure/organigram/hse/en/ (last visited Nov. 5, 2014).

significantly stronger and more effective approach for global surveillance for major pandemic and epidemic infectious disease."[21]

The HIV/AIDS, TB, Malaria and Neglected Tropical Diseases (HTM) Department "helps countries to prevent, reduce and mitigate the health impact of these diseases, which are a major factor affecting development." [22] The department's objectives are "to develop norms, standards and policies to foster new solutions" for prevention of "these high-burden diseases"; to assemble the requisite expertise to combat the diseases; "to develop innovative frameworks for public health action against these diseases" and provide support for strengthening the health system; and to encourage leaders and civil society to promote "increased and sustained investment in countering these diseases."[23]

The Health Systems and Innovation (HSI) Department covers the areas of essential medicines and health products; health statistics and information systems (HSIS); health systems governance and financing; health workforce; knowledge, ethics and research; service delivery and safety; and the WHO Centre for Health Development, Kobe.[24] One example of the activities covered by the essential medicines and health products section was promoting an agreement during the ninth African Vaccine Regulatory Forum (November 3–7, 2014) on a collaborative mechanism to fast-track approvals for clinical trials and registration of potential Ebola therapies and vaccines.[25] The mechanism is to cover the following:

- Clear pathways and timelines for expedited ethical and regulatory review of clinical trial applications and approval of products;
- Agreement on timelines and joint safety and efficacy assessments of the new products to fast-track national registration;
- Endorsement of a panel of safety experts for expedited review of safety data of new products with relevant communication to National Regulatory Authorities . . . ;
- Technical assistance from the [WHO] to facilitate these processes.[26]

The Polio and Emergencies (PEC) Department has among its objectives the worldwide eradication of polio; the coordination and implementation of health responses to humanitarian emergencies and disasters; and the strengthening of the WHO's work "in and with countries, with a special emphasis on fragile states and situations."[27] The department, which is in charge of the WHO's technical assistance to countries, has "the main Organization-wide elements of the

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[21] *Id*.

[22] *HIV/AIDS, TB, Malaria and Neglected Tropical Diseases (HTM)*, WHO, http://www.who.int/about/structure/organigram/htm/en/ (last visited Nov. 5, 2014).

[23] *Id*.

[24] *WHO Headquarters Structure*, WHO, http://www.who.int/about/structure/organigram/en/ (last updated Sept. 25, 2014).

[25] *Essential Medicines and Health Products: African Regulators' Meeting Looking to Expedite Approval of Vaccines and Therapies for Ebola*, WHO, http://www.who.int/medicines/news/AFR_reg_meet/en/ (last visited Nov. 5, 2014).

[26] *Id*.

[27] *Polio and Emergencies (PEC)*, WHO, http://www.who.int/about/structure/organigram/pec/en/ (last visited Nov. 5, 2014).

WHO country support function, that aim at tailoring WHO country collaboration to the needs and capacities of all its Member States."[28] The PEC/POL leads the Global Polio Eradication Initiative, a public-private partnership that has reduced the incidence of polio by 99% over the last two decades.[29]

The PEC also handles the humanitarian aspects of emergency preparedness and response by coordinating activities "to reduce the health impact of emergencies by leading the development of global strategies, identifying best practices, providing evidence to inform global policies, analyzing health trends, and providing technical guidance."[30] In addition, during health emergencies, the PEC is responsible for coordinating the health actors and mobilizing the capacities of WHO and its partners "to ensure the surge to country level of expert staff, logistics, finances, and medicines/supplies for emergency response."[31]

III. Areas of Priority

The WHO has six main priorities for providing leadership. These include universal health coverage; health-related Millennium Development Goals; noncommunicable diseases, such as cancer, heart disease, and mental health disorders; social, economic, and environmental determinants; access to medical products; and the International Health Regulations (2005).[32]

IV. International Health Regulations (2005)

The International Health Regulations (2005) (IHR),[33] which the 194 WHO Member States have agreed to implement, were adopted by the WHA under the authority of the WHO Constitution, which gives the WHA the power to adopt regulations "designed to prevent the international spread of disease," and that thereupon "enter into force for all WHO Member States that do not affirmatively opt out of them within a specified time period."[34]

The IHR are a binding instrument of law developed in response to the exponential "growth in international travel and trade, and the emergence or re-emergence of international disease threats

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[28] *Id*.

[29] *Id*.

[30] *Id*.

[31] *Id*.

[32] *Leadership Priorities,* WHO (undated), http://www.who.int/about/resources_planning/WHO_GPW12_leadership_priorities.pdf?ua=1 (last visited Oct. 29, 2014); Danielle Renwick & Toni Johnson, *The World Health Organization (WHO)*, COUNCIL ON FOREIGN RELATIONS, http://www.cfr.org/public-health-threats-and-pandemics/world-health-organization-/p20003 (last updated Oct. 7, 2014).

[33] WHO, International Health Regulations of 1969, amended in 1973 and 1981, http://whqlibdoc.who.int/publications/1983/9241580070.pdf?ua=1; WHO, International Health Regulations (2d ed. 2005) (in force on June 15, 2007), http://www.who.int/ihr/publications/9789241596664/en/; *see also Alert, Response, and Capacity Building Under the International Health Regulations (IHR)*, WHO, http://www.who.int/ csr/ihr/current/en/ (last visited Oct. 15, 2014).

[34] WHO, Foreword to International Health Regulations (2005), *supra* note 33, at 1; *see also* WHO CONSTITUTION arts. 21(a) & 22.

and other health risks. . . ."[35] Accordingly, the IHR's stated purpose and scope are "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."[36] The IHR require states to enhance their core surveillance of and response capacities to disease threats at all levels—primary, intermediate, and national, and also at designated international ports, airports, and ground crossings. In addition, they provide for a series of health documents, such as ship sanitation certificates and an international certificate of vaccination or prophylaxis for travelers.[37]

V. Monitoring and Alert Systems

The WHO has a monitoring and response system for influenza that, since the adoption of the PIP Framework in May 2011 (described in Part VI(A), below) has been called the Global Influenza Surveillance and Response System (GISRS). (This system was formerly known as the Global Influenza Surveillance Network (GISN), which dates back to 1952.)[38] The system operates through a network of National Influenza Centres, "national institutions designated by national Ministries of Health and recognized by WHO."[39] The GISRS keeps track of the evolution of influenza viruses and offers recommendations on such matters as "laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment," and "also serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential."[40]

In 1997, the WHO established an Outbreak Verification System to gather information, verify reports of, and track infectious disease outbreaks.[41] In addition, the WHO regularly distributes to certain public health officials and scientists an Outbreak Verification List as a means of following up on reports of various outbreaks of disease.[42]

In 2000, the WHO established the Global Outbreak Alert and Response Network (GOARN), which is a network of surveillance systems that "includes a number of formal and informal

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[35] International Health Regulations (2d ed. 2005), *supra* note 33.

[36] *Id*.

[37] *Id*.

[38] *Global Influenza Surveillance and Response System (GISRS)*, WHO, http://www.who.int/influenza/gisrs_laboratory/en/ (last visited Oct. 29, 2014); THE GLOBAL INFORMATION SURVEILLANCE NETWORK, WHO (undated), *available at* http://www.paho.org/hq/images/stories/AD/HSD/CD/INFLUENZA/gisn.pdf (last visited Oct. 29, 2014).

[39] *National Influenza Centres*, WHO, http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/en/ (last visited Oct. 29, 2014).

[40] GLOBAL INFLUENZA SURVEILLANCE AND RESPONSE SYSTEM (GISRS), *supra* note 38.

[41] Thomas W. Grein et al., *Rumors of Disease in the Global Village: Outbreak Verification* 6:2 EMERGING INFECTIOUS DISEASES 97, 97 (Mar. –Apr. 2000), http://wwwnc.cdc.gov/eid/article/6/2/pdfs/00-0201.pdf.

[42] Stephen S. Morse, *Global Infectious Disease Surveillance and Early Warning Systems: ProMED and ProMED-mail*, *in* GLOBAL INFECTIOUS DISEASE SURVEILLANCE AND DETECTION: ASSESSING THE CHALLENGES—FINDING SOLUTIONS, WORKSHOP SUMMARY (Stanley M. Lemon et al. eds., 2007), *available at* http://www.ncbi.nlm.nih.gov/books/NBK52873/#ch2.s2 (scroll down page to view).

sources."[43] The WHO gathers this raw intelligence and converts it into "meaningful intelligence," using six main criteria "to determine whether a reported disease event constitutes a cause for international concern."[44] Information on incoming reports and rumors, their epidemiological significance, and decisions on the actions needed are stored in an electronic event management system. The system "records key information, decisions and actions by WHO and its partners."[45] The Global Alert and Response Team includes "WHO Country Offices, WHO sub-Regional Response Teams, WHO Regional Offices, the Alert and Response Operations Centre team in Geneva and disease specialists."[46] The Team responds to "incoming reports of suspected outbreaks, reports of unknown disease, outbreaks undergoing verification and outbreaks at various stages of containment."[47]

The Department of Pandemic and Epidemic Diseases is responsible for developing "strategies, initiatives, and mechanisms to address priority emerging and re-emerging epidemic diseases, thereby reducing their impact on affected populations and limiting their international spread."[48]

VI. Outbreaks and Responses

A. Pandemic Influenza Preparedness Plan

At the Fifty-sixth Annual Meeting of the World Health Assembly in Geneva on May 28, 2003, the WHO adopted two resolutions concerning SARS and infectious diseases control. Member states were urged to take action to enhance, support, and strengthen national, regional, and international efforts to address the SARS outbreak. The Director-General was requested to take measures falling within the infectious diseases group and take into account reports from sources other than official notification; to alert the international community to the presence of a public threat that may constitute a serious threat to neighboring countries or to international health; and to collaborate with national authorities in assessing the severity of the threat and the adequacy of control measures, and, when necessary, in conducting on-the-spot studies by a WHO team, with the purpose of ensuring that appropriate control measures were being employed.

The first global conference on SARS, held June 18–19, 2003, in Kuala Lumpur, Malaysia, was convened by the WHO to provide technical guidance for the ongoing and long-term response to SARS. At the time, an adequate point-of-care diagnostic test was still not available for SARS and remained a top priority.[49] Even now, although research is being done to develop laboratory

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[43] *Id*.

[44] *Event Verification*, WHO, http://www.who.int/csr/alertresponse/verification/en/ (last visited Oct. 28, 2014). The criteria listed on the webpage are unknown disease, potential for spread beyond national borders, serious health impact or unexpectedly high rates of illness or death, potential for interference with international travel or trade, strength of national capacity to contain the outbreak, and suspected accidental or deliberate release.

[45] *Id*.

[46] *Id*.

[47] *Id*.

[48] *Pandemic and Epidemic Diseases*, WHO, http://www.who.int/csr/disease/en/ (last visited Oct. 28, 2014).

[49] WHO Global Conference on Severe Acute Respiratory Syndrome (SARS): Where Do We Go from Here?, Kuala Lumpur, Malaysia, 17–18 June 2003, http://www.who.int/csr/sars/conference/june_2003/materials/report/en/.

tests to improve diagnostic tests for SARS and other respiratory pathogens, "no specific clinical or laboratory findings can distinguish with certainty SARS-CoV disease from other respiratory illnesses rapidly enough to inform management decisions that must be made soon after the patient presents to the healthcare system," and so early clinical recognition of the disease "still relies on a combination of clinical and epidemiologic features."[50]

Following the pandemic outbreak of SARS in 2003, the WHO member states deliberated on how to prevent and control new pandemics. In 2005, the WHO commenced a Pandemic Influenza Preparedness Plan that required the Member States to devise a national pandemic plan and submit it to the WHO. This plan was last revised in 2009[51] and contains the WHO phases of pandemic alert.[52] They progress from level 1, characterized by animal infections and only a few human infections, to levels 5 and 6, characterized by widespread human infection that, in level 6, reaches global proportions.[53] The system was put to the test in the A(H1N1) influenza virus that emerged in Mexico in April 2009 and quickly reached global dimensions.[54]

On May 24, 2011, the WHA adopted the Pandemic Influenza Preparedness (PIP) Framework.[55] The stated objective of the PIP 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, effective system for, 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.[56]

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[50] Clinical Guidance on the Identification and Evaluation of Possible SARS-CoV Disease among Persons Presenting with Community-Acquired Illness (Version 2) (last updated July 7, 2012), http://www.cdc.gov/sars/clinical/guidance.html; *see also* James McIntosh, *What Is SARS? What Are the Symptoms of SARS?*, MEDICAL NEWS TODAY (last updated Sept. 10, 2014), http://www.medicalnewstoday.com/articles/ 7543.php. For further information on SARS, see *Severe Acute Respiratory Syndrome (SARS)*, WHO, http://www.who.int/topics/sars/en/ (last visited Oct. 28, 2014).

[51] The current version of this plan is published in WHO, PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE: A WHO GUIDANCE DOCUMENT (Apr. 2009), http://whqlibdoc.who.int/publications/2009/9789241547680_eng.pdf?ua=1.

[52] *Id*. For the role of the U.S. government in developing the pandemic phases, *see* J. Montero, *Why is Pandemic Influenza Different*?, 48 NEW HAMPSHIRE BAR JOURNAL 54 (2007), *available at* http://www.lexis.com (by subscription).

[53] PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE: A WHO GUIDANCE DOCUMENT, *supra* note 51, at 29.

[54] E. Eduardo Castillo, *As Swine Flu Spreads, Who Should Get Tamiflu?*, ASSOCIATED PRESS (May 12, 2009), *available at* http://www.utsandiego.com/news/2009/may/12/med-swine-flu-051209/.

[55] WHO, PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS (May 24, 2011), http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf?ua=1.

[56] *Id*. at 6.

The PIP Framework applies to influenza viruses with human pandemic potential, such as H5N1; it does not apply to seasonal flu viruses, noninfluenza pathogens, or other biological material that may be contained in clinical specimens shared under the Framework.[57]

In 2013, the Pandemic Influenza Risk Management WHO Interim Guidance replaced the 2009 Pandemic Influenza Preparedness and Response guidance document.[58] Key features of the new guidance include the following:

- Focus upon risk assessment at national level to guide national level actions
- Revised approach to global phases
- Flexibility through uncoupling of national actions from global phases
- Inclusion of principles of emergency risk management for health
- New and updated annexes on planning assumptions, ethical considerations, whole-of-society approach, business continuity planning, representative parameters for core severity indicators, and containment measures.[59]

As a result of lessons learned from the influenza A(H1N1) 2009 pandemic, the 2013 Guidance revises WHO's approach to global phases of pandemic events.[60] The phases include the interpandemic phase (the period between influenza pandemics); the alert phase (when influenza caused by a new subtype has been identified in humans); the pandemic phase (the period of global spread); and the transition phase (the de-escalation phase).[61] These global phases are to be used to describe a new influenza subtype's spread, "taking account of the disease it causes, around the world," and are "clearly uncoupled from risk management decisions and actions at the country level."[62]

The Guidance points out that "[t]he global phases and their application in risk management are distinct from (1) the determination of a PHEIC [Public Health Emergency of International Concern] under the IHR (2005) and (2) the declaration of a pandemic."[63] The WHO Director-General is responsible for determining a PHEIC, under article 12 of the IHR; that determination leads to the communication of temporary recommendations.[64] The Director-General may also declare a pandemic "during the period of spread of human influenza caused by a new subtype, and appropriate to the situation."[65]

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[57] *Id*. at 7.

[58] PANDEMIC INFLUENZA RISK MANAGEMENT: WHO INTERIM GUIDANCE (June 10, 2013), http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management/en/.

[59] *Id*.

[60] *Id*. at 2.

[61] *Id*. at 7.

[62] *Id*. at 2.

[63] *Id*. at 7.

[64] *Id*.

[65] *Id*.

The Guidance is based on "all-hazards emergency risk management for health" (ERMH) principles, "thereby aligning pandemic risk management with the strategic approach adopted by WHO, in accordance with World Health Assembly resolution 64.10," to strengthen national health emergency and disaster management capabilities.[66] The Resolution, among other measures, urges Member States to (1) strengthen health emergency and disaster risk-management programs as part of their national and subnational health systems, supported by related legislation and its effective enforcement; (2) integrate such programs (including disaster risk reduction) into national or subnational health plans and "institutionalize capacities for coordinated health and multisectoral action to assess risks, proactively reduce risks, and prepare for, respond to, and recover from, emergencies, disasters and other crises; and (3) develop programs "on safe and prepared hospitals that ensure: that new hospitals and health facilities are located and built safely so as to withstand local hazards; that the safety of existing facilities is assessed and remedial action is taken; and that all health facilities are prepared to respond to internal and external emergencies."[67]

B. Recent Developments and Concerns

In 2013, humans were found for the first time to have been infected with the avian influenza A(H7N9) virus. Since providing the first notification of such an infection in late March 2013, China has been reporting to the WHO on cases of subsequent human infection with the virus.[68] The virus is a subgroup of H7 viruses, normally found among birds. Previous reports of human infections with other H7 subgroups (H7N2, H7N3, and H7N7) have come from Australia, Canada, Italy, Mexico, the Netherlands, the United Kingdom, and the United States.[69]

On October 22, 2014, the WHO Emergency Committee, convened by the WHO Director-General under the IHR, held its third meeting on the Ebola virus disease outbreak in West Africa, in advance of the three-month date of expiration of temporary recommendations the WHO had issued on August 8, 2014, and their extension on September 22.[70] The meeting was held because of the increase in the number of cases in Guinea, Liberia, and Sierra Leone, and the incidence of new cases in Spain and the United States.[71] As of the date of the meeting, the number of total cases stood at 9,936, with 4,877 deaths, and "[c]ases continue to increase exponentially in

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[66] *Id*. at 3. A PHEIC is defined under the IHR as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response." IHR art. 1(1). Article 12 of the IHR pertains to determining PHEICs.

[67] Strengthening National Health Emergency and Disaster Management Capacities and Resilience of Health Systems, WHA64.10 (May 24, 2011), at 2–3, http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_R10-en.pdf.

[68] WHO, BACKGROUND AND SUMMARY OF HUMAN INFECTION WITH AVIAN INFLUENZA A(H7N9) VIRUS – AS OF 31 JANUARY 2014, at 1, http://www.who.int/influenza/human_animal_interface/20140131_background_and_summary_H7N9_v1.pdf?ua=1.

[69] *Id*.

[70] Press Release, WHO, Statement on the 3rd Meeting of the IHR Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa (Oct. 23, 2014), http://www.who.int/mediacentre/news/statements/2014/ebola-3rd-ihr-meeting/en/.

[71] *Id*.

Guinea, Liberia, and Sierra Leone" with the situation in these countries remaining to be "of great concern."[72] According to the statement, "[t]he key lessons learned to control the outbreak include the importance of leadership, community engagement, bringing in more partners, paying staff on time, and accountability. WHO, UN partners, and the international community have scaled up their support in these three countries."[73] At the same time, the Committee noted that the Ebola outbreaks in Nigeria and Senegal had been declared over as of October 20 and 17, respectively.

On October 23, 2014, the WHO convened a meeting of high-ranking government representatives from countries affected by the Ebola virus along with representatives from their development partners, civil society, regulatory agencies, vaccine manufacturers, and funding agencies "to discuss and agree on how to fast-track testing and deployment of vaccines in sufficient numbers to impact the Ebola epidemic."[74] The government representatives included officials from the ministries of health and of foreign affairs from Canada, China, the European Union, France, Germany, Guinea, Italy, Japan, Liberia, Mali, Nigeria, Norway, the Russian Federation, Sierra Leone, Switzerland, the United Kingdom, and the United States.[75] The meeting reached consensus on a number of key commitments—namely, (1) results from phase 1 clinical trials of most advanced vaccines are expected to be available in December 2014, and efficacy trials are to begin in the affected countries during this timeframe; (2) pharmaceutical companies developing the vaccines will increase production capacity so that millions of doses will be available in 2015, and regulatory authorities in the countries where the vaccines are manufactured and in Africa will support this goal by working under very short deadlines; and (3) community engagement "should be scaled up urgently in partnership between local communities, national governments, NGOs and international organizations."[76]

At the same time, *The New York Times* reported that "WHO has been badly weakened by budget cuts in recent years, hobbling its ability to respond in parts of the world that need it most. Its outbreak and emergency response units have been slashed, veterans who led previous fights against Ebola and other diseases have left, and scores of positions have been eliminated. . . ."[77] The unit specializing in pandemic and epidemic diseases now "has only 52 regular employees," although the number can be increased during outbreaks, and the WHO's regional emergency outbreak experts, who were experienced in fighting Ebola, "were cut from more than a dozen to three."[78] Moreover, a separate WHO section that handles emergency response "was whittled 'to the bone' during the budget cuts—to 34 staff members from about 94."[79] As a result, Dr.

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[72] *Id*.

[73] *Id*.

[74] Press Release, WHO, WHO Convenes Industry Leaders and Key Partners to Discuss Trials and Production of Ebola Vaccine (Oct. 24, 2014), http://www.who.int/mediacentre/news/releases/2014/ebola-vaccines-production/en/.

[75] *Id*.

[76] *Id*.

[77] Sheri Fink, *Cuts at WHO Hurt Response to Ebola Crisis*, NY TIMES (Sept. 3, 2014), http://www.nytimes.com/2014/09/04/world/africa/cuts-at-who-hurt-response-to-ebola-crisis.html?_r=1.

[78] *Id*.

[79] *Id*.

Margaret Chan, the WHO Director-General stated that "[t]he W.H.O. simply did not have the staffing or ability to flood the Ebola zone with help."[80]

[80] *Id*.

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