DOI: 10.1590/1413-81232015206.06552014

Implementing International Health Regulation (2005) in the Brazilian legal-administrative system

Yara Oyram Ramos Lima [1]
Ediná Alves Costa [1]

Abstract *The scope of this study was to analyze how the International Sanitary Regulation (ISR 2005)has been incorporated into the Brazilian legal-administrative system, in relation to sanitary control measures involving freight, means of transportation and travelers and possible alterations to health surveillance activities, competencies and procedures. This case study has been undertaken using a qualitative approach, of a descriptive and exploratory nature, using institutional data sources and interviews with key-informants involved in implementing ISR (2005). Alterations to the Brazilian legal-administrative system resulting from ISR (2005) were identified, in relation to standards, special competencies and procedures relating to sanitary controls for freight, modes of transportation and travelers. In its present form, the International Sanitary Regulation is an instrument that, in addition to introducing new international and national sanitary control concepts and elements, also helps to clarify questions that are helpful on a national level, relating to the specific competencies and procedures which will, to a certain extent, put pressure on administrative structures in the areas of sanitary control and surveillance.*

Key words *International Sanitary Regulation, Sanitary surveillance, Epidemiological surveillance, Health, Sanitary rights*

[1] Instituto de Saúde Coletiva, Universidade Federal da Bahia. R. Basílio da Gama s/n, Canela. 40110-040 Salvador BA Brasil. oyram@ufba.br

Introduction

The International Sanitary Regulation (ISR), one of the main international documents in the area of public health[1], is closely related to international organisms linked to the United Nations Organization (UNO), the World Trade Organization (WTO) and the World Health Organization (WHO). Its objectives interface between international agreements, such as the Agreement on the Application of Sanitary and Phytosanitary Measures and the Technical Barriers to Trade Agreement.

The interface between the ISR and international organs and agreements involve relations with economic blocks and therefore with the Southern Common Market (Mercosur), which created the Inter-governmental Commission to Implement International Sanitary Regulations. Relationships with Subjects of International Law, WTO, Mercosul, etc. demonstrate an involvement with economic and commercial issues and refer to social production-consumption relationships, especially within the ambit of the free movement of goods, transportation and people[2], which provide an opportunity to reflect on the global risk society[3,4] and the challenges facing sanitary controls.

The wider movement of people and goods around the world favors the spread of health risks, increasing the possibility of the proliferation of diseases which requires the organization of sanitary barriers. In this context of market rule changes, as the question of health gains greater importance, so sanitary regulations tend to become more internationalized[5]. Imposing sanitary control by using the ISR makes it possible to reduce obstacles created by sanitary barriers in favor of a more proactive form of surveillance, which is not limited to controlling infectious-contagious diseases and quarantine measures and the possible harm these can cause. The ISR incorporates the logic of modernity[4], sensitive to the fact that it is impossible to control all events that can give rise to an international sanitary emergency and the need for continual surveillance[6].

When implementing ISR (2005) in Brazil, it is up to the State, among other powers, to guarantee sanitary safety when there is a Public Health Emergency of National Concern (ESPIN), so that this is not transformed into one of international concern (ESPII); to organize legal-administrative measures that limit the exercise of the individual rights and freedom of travelers; and to impose health controls on freight and modes of transportation. Incorporating ISR implies reviewing standards, procedures and specific competencies based on present needs andthe principles of health care laws. The powers required to carry out ISR (2005) are not confined to one organ, but are mainly the responsibility of the public health and epidemiology surveillance agencies that are part of thepublic health system's Public Sector.

Health Law is embodied in the ISR, the regulatory mainstay of which is founded on principles of human rights and basic individual freedoms, inspired by the UN Charter and the Constitution of the WHO. The signatory States should defend public health laws[7,8]; it is up to them to subordinate individual rights in favor of collective rights, while ensuring that the right to health also remains a fundamental individual right; the relationship between public health and human rights seeks to establish a balance between such rights[9]. Thus, the State should continually adapt its structures, so as to maintain the stability ofthese relationships and governability[10,11].

In the international literature, organizing the ISR within the legal-administrative structure in the countries studied is either presented as administrative structuring during certain epidemics, such as SARS and H1N1, and at other times emphasis is given to innovations involving the current version of the Regulation[9,12], or to its implementation characteristics within an administrative framework[13-16]. There were also proposals for mechanisms, such as regional networks, that can be used to adapt these for a legal-administrative system[17], as well as studies that discussed the difficulties involved in organizing a legal system that includes rules that limit freedom in public health situations[18-20].

It was noted that there are still many gaps inthe Brazilian literature about how to incorporate ISR (2005) into the system. Most of the articles addressed: the process of revision[21], relationships between individual freedoms and national sovereignty[22] and how countries responded to the H1N1 pandemic[23]. One article discussed the need to adapt health surveillance in health care[24,25] while another dealt with the implementation of the ISR[26]in the area of epidemiological surveillance.

The aim of this study is to analyze how ISR (2005) has been incorporated into the Brazilian legal-administrative system for sanitary control measures for freight, means of transportation and travelers, and to identify and discuss possible changes to the standards, procedures and competencies pertaining to surveillance activities, based

Ciência & Saúde Coletiva, 20(6):1773-1783, 2015

on the understanding of the actors who are directly involved in its implementation.

Methodological strategy

An exploratory case study was conducted, using a qualitative approach[27-30], to examine how ISR (2005) is being implemented inthe Brazilian legal-administrative system.

The literature review provided input to create a core body of facts and was used as the basis to schedule interviews with key-informants[30], who were selected on the basis of their relationship with the implementation of the Regulation, and involvement with activities related to public health and epidemiological surveillance. The snowball sampling technique was also used[31], based on indications made by the initial interviewees. Fifteen people were selected, based on organizational charts prepared by the Brazilian Health Surveillance Agency (ANVISA) and the National Health Surveillance Secretariat of the Ministry of Health (SVS/MS). Six of the candidates indicated declined and five further nominees agreed to participate in this survey. Four members of ANVISA, who work in the area of Ports, Airports and Frontiers (PAF) in different regions of Brazil, were interviewed, making a total of eighteen key-informants. The interviews took place in Brasilia – DF, in November 2011. These were recorded, transcribed and codified, respecting the anonymity of the participants, each interviewee being given a number and referred to in the male gender. In addition, document analysis was undertaken to establish a relationship between the different views and observations registered, which was more useful as revisionary material rather than being used to construct the core body of facts which, together with information from the interviews, form the basis of the analysis of this article.

The analytical categories defined *a priori* and those that emerged from the field of research were the main changes that have emerged from the implementation of ISR (2005), for standards, competencies and procedures related to the sanitary control activities for freight, modes of transport and travelers.

In this study, the term 'traveler' refers to any person affected by a Public Health Emergency, in cases where the results are unlikely to affect only those in transit, which is the sense of the term ISR (2005). The term "freight" refers to products that are circulating in accordance with health surveillance control regulations and which, due to their specific characteristics, require differential transportation and storage facilities, hygiene and sanitation control management and observance of sanitary legislation.

This research project was approved by the Committee for Ethics in Research of the Institute of Public Health at the Federal University of Bahia – UFBA, and all those taking part signed an Informed Consent Form, in compliance withNational Health Council Resolution Nº 196/96[32].

Findings and Discussion

Changes to Standards

According to fifteen interviewees, new rules resulting from the ISR have been introduced into the legal system while others have been altered. Only one interviewee thought that no changes have been made to existing standards or that others have emerged as a result; two interviewees made no comment. According to one of those interviewed, "some ruleshave been dropped" (E3); according to others, new rules and innumerable adaptations are being made, but even so there are still many gaps in this regulation and things are becoming as fragmented, "as a patchwork quilt" (E14). For some interviewees, the ISR actually serves to apply pressure to ensure that exiting rules are observed, but which have been ignored by the companies operating in the area of the PAF (E1, E10).

The port areas were seen as those that have undergone most changes (E1, E8, E14, E16), while airports have maintained existing international regulations (E1). As regards frontiers – which are still not obliged to observe the ISR – there was only one account given of a proposal for regulation (E1). With regards to travelers, it is understood that significant changes have been made: not exactly involving the creation of new or making alternations to existing regulations (E19, E15), but a proposal for a national policy for travelers, since ANVISA only operates on the basis of the old Resolution (E1). Furthermore, mention was also made of Administrative Rules and decrees, as well as Mercosul rulings which incorporate the ISR (E6, E7, E13, E16).

It was also noted that, during the ISR (2005) implementation process, new rules had been introduced, others revoked and changes made to existing standards, within the areas of health and epidemiological surveillance. The apparent exis-

tence of a normative lacuna, as claimed by some of the actors involved, might have resulted from the inherent limitations of these standards to respond to the overall issues involved, as well as the eagerness of professional health surveillance agents to introduce rules for certain activities.

The ISR is a regulation with a broad scope and it is up to different countries to apply it internally through detailed regulations: Brazil issued Decree Nº 7.616/2011[33], in connection with the Public Health Emergency of National Concern Declaration and which established the National Force of the Unified Health System; the SVS/MS (Ministry of Health) Administrative Rule Nº 104/2011[34], that defines the terminology adopted in national legislation, in accordance with the ISR; and Ministry of Health/MS Administrative Rule No. 1.865/2006[35], which, among other rulings, establishes the SVS as the national Focal Point together with the WHO. Brazil included the ISR as part of Legislative Decree No. 395/2009[36], but even before taking this action, it had organized initial health sector activities, so as to evaluate established basic capacities and respond to public health emergencies, which included holding periodic meetings within the ambit of Mercosur.

A debate arose among the interviewees in connection with this decree; due to the understanding of the Legal Advisory Service (Conjur) at the Ministry of Health to the effect that presidential approval was requiredfor this act to become legally valid. According to one of the interviewees (E9), if such an understanding made it difficult for the SVS to prepare or alter the rules, the same did not occur in the case of ANVISA.

Conjur's position is supported in part by International Public Law with respect to the incorporation of treaties in national legal systems, although it cannot be ignored that the Regulation has been incorporated into non-statutory law. The position of the WHO in relation to their regulations is that signatory countries are given deadlines to establish provisos; if they do not do so, the country in question is required to enforce the regulation in question[6,37]. Brazil did not establish provisos for the ISR, nor were any references found of observations or information being sent to the WHO, to clarify the necessary formalities required to incorporate the ISR. The absence of presidential approval to validate the afore-mentioned decree is more of a formality in the area of law rather than a requirement to carry out suchservices, since administrative activities adhere to the requirements of the instrument, while national rulings are formed on the basis of the ISR text.

Changes in the competencies

According to seven of those interviewed, no changes were made to institutional competencies, while two interviewees believed that changes might occur based on future rulings (E9, E10). Only one interviewee believed that changes had been made, if only a few. One of the interviewees indicated that the Focus Point and the Strategic Information Center for Health Surveillance (CIEVS), represent new capacities that have resulted from the ISR; however, according to this interviewee, the actual attributes have not changed, but risk logic has been incorporated instead, which makes it possible to perform more rationally: "there have been some changes in the way that health inspectors work, but no changes have been made to their competencies per se" (E17). It is understood that ISR (2005) moves forward when it goes beyond a list of diseases and certificates to adopt an approach more centered on sanitary risks, which involves qualified professionals (E2, E13, E15, E17). For some, the competencies have already been established; it was the professionals who found it difficult to understand their work objectives (E2, E15).

Changes to sanitary control competencies involving freight, modes of transport and travelers were not addressed: the interviewees discussed the competencies of ANVISA, the National Health Surveillance Secretariat-SVS and the influence of the ISR, in clarifying questions between the two institutional segments. This issue reveals the complex nature of the organizational structure of the Unified Health System – SUS, especially in surveillance sectors responsible for taking action, often based on common objectives, but which are part of different logical frames and institutional and administrative structures, including the regulatory agency model.

When asked about possible conflicts or changes to competencies and about questions related to activities foreseen in ISR (2005), ten of the interviewees responded politely, admitting that there is a good line of communication between the SVS and ANVISA, reiterating the need for these to work together and to articulate with local epidemiological surveillance services (E1). Even so, they expressed some reservations: the main one being the competency of ANVISA to execute epidemiological surveillance activities in PAF areas, which was the situation prior to the

introduction of the ISR (2005). It appears there are few areas of conflict and many questions about the competency of ANVISA, since, while the SVS has the necessary expertise, it is ANVISA that should execute activities; however, there is still some doubt about "who does what" (E9). Some referred to this particular competency as an "imbroglio" (E2, E11) and said that this must have arisen due to some "misunderstanding," since it is not up to the sanitary surveillance agency to execute epidemiological surveillance activities: since this "[...] was a way to adapt former airport emergency activities" and that "[...] the law that created ANVISA stated that ANVISA operates under Ministry of Health guidelines. Thus, in theory, this gives one agency the responsibility of imposing standards and, the other, the responsibility of carrying these out [...]." For one group of interviewees the changes made involving technicians and managers could well alter the relationship between ANVISA and the SVS (E1, E3, E4, E10, E12) and that this good relationship occurs only between the PAF and SVS (E7), due to the people who are involved in the ISR (2005) implementation process.

A certain tension exists between these two institutional sectors: there appears to be a harmonious relationship between the PAF and SVS, but not between ANVISA and the Ministry of Health, which involves other issues. The matters over which the sanitary surveillance exerts control are crucial to the economic interests of the country and those who carry out examinations exert power[38], however this creates tensions, which are typical of regulatory services. Although ANVISA exerts power though the examinations it carries out – sanitary inspections, the policing powers it holds, etc. – it is really the SVS that controls the system: action based on knowledge, enforced by ANVISA within the PAF ambit; in addition, it is the SVS that is responsible for proposing and formulating the National Sanitary Surveillance Policy.

In Brazil, the sectorial structures that enforce ISR (2005) activities are of a complex nature. The SUS, within the Federal sphere, is an organization that comes under the Ministry of Health and includes, among other components, the SVS and ANVISA, a regulatory agency that has multiple objectives that consolidate the economic and industrial health complex. As well as areas of epidemiological and sanitary surveillance, which are central to sanitary control, the SVS also coordinates environmental health and occupational health, which are not covered in this study.

Sanitary and epidemiological surveillance services are organized according to systems: The National Epidemiological Surveillance System integrates Public Administration directly in its three management areas. However, the National Sanitary Surveillance System (SNVS) is indirectly integrated within the Federal ambit in three states – which have regulatory agencies – and directly so in municipalities and in the remaining states. ANVISA coordinates SNVS, however, in addition to formulating and proposing the Sanitary Surveillance Policy, it is up to the SVS to regulate and accompany the administration contract between ANVISA and the Ministry of Health[39].

From this fragmented format and the separation of practices in different areas as if there were in fact two separate surveillance agencies[2], questions arise that need to be investigated and which involve other management areas. The position of the interviewees from the area of coordination or the senior hierarchical structure of the agencies is centered on maintaining the status quo, whereas in the SVS it is in the sense of errors in this model. In the case of professionals who are working "at the cutting edge," they report difficulties related to their responsibilities in undertaking epidemiological surveillance activities in the PAF, and these professionals even go so far as to refer to a "crisis of identity," since they do not know when a situation calls for epidemiological surveillance or for sanitary surveillance.

Although this was not a question asked, the issue of human resources was emphasized, with repeated issues being raised in relation to the different levels of qualifications that exist, a lack of capacity building, precarious contracts, difficulties related to the quantitative and qualification aspects of personnel. It was claimed that ANVISA professionals need to perform epidemiological surveillance activities that are not exactly within their field of expertise, and that there are huge differences in the level of qualification of PAF professionals, ranging from a primary level of education to others with post-graduate degrees. In the case of the Ministry of Health, the interviewees spoke in particular about insufficient personnel and lack of turnover, the precariousness of their contractual ties, remuneration and a series of critical problems involving human resources policies, both within the MS and in the states and municipalities (E6).

Furthermore, they spoke about the need for capacity building to accompany the changes being made (E6, E10) to install a new logic since, even though this is a legal requirement, this is not

necessarily reflected in changes to practices and services (E17) and in those professionals who seem to be "tied to the past" (E16). It is also understood that the implementation of ISR (2005) "is practically a cultural change" (E8) and that new professionals are needed in the area. This issue arose both in matters related to competencies as well as procedures and converged to form an understanding that changes to competencies require changes in services and qualified professionals, and that the ISR has served to reveal this matter as a result of discussions about the roles that need to be performed in periods of crisis. Such difficulties appear to contribute towards the "identity crisis" experienced by sanitary surveillance professionals, as has already been noted in other studies, since they simultaneously exercise police powers and perform an educational function[40,41].

Changes in procedures

A point of convergence among the interviewees was the need for changes in procedures conducted by the SVS and ANVISA, suggesting that ISR (2005) has helped to find alternatives to overcome weaknesses in the system and bring about changes to strengthen practices and to organize work procedures (E7). Two interviewees did not mention the subject, but three interviewees understood that no changes had been made, but believed that the ISR has helped strengthen the systems of surveillance. The main changes to procedures cited were: changes to the Ship Sanitation Certificate; closure of vaccination points in PAF areas, which favor the creation of state and municipal Travel Information Centers; structuring the CIEVS network; information management: information is administered by formal and informal media channels; as well as improving the response capacity with a network connected to other sectors. According to two interviewees, the main changes were made to procedures relating to the health of travelers (E8, E15).

Freight and means of transportation were not mentioned among the changes made. The main change involving Ports was the adoption of an Exemption Certificate or Ship Sanitation Control Certificate, which is now more directed towards a ship's sanitation risk. This new document is issued by the ports indicated by the signatory country, based on an evaluation of the installed basic capacities (E1, E2, E8, E15). In the case of airports, one of the interviewees highlighted the fact that the ISR (2005) has encouraged the issue of an Onboard Health Declaration, which already existed as an international ruling but was never adhered to (E1). Another ruling to be diligently complied with is the compulsory notification, which is of great importance as a result of the newconcept of a Public Health Emergency.

In the case of frontiers, a tendency to reduce sanitary controls was noted, since the ISR is not obligatory in these areas. As stated by E8: "[...] this trend also shows that frontier areas are practically seen as a single epidemiological area… no longer with so many barriers but rather with controls and an early detection system [...]." This view was confirmed by others who said that this is largely due to the greater awareness shown by the welfare services in detecting cases of Public Health Emergencies, as illustrated by comments made by E13: "[...] the real frontier nowadays is located in the emergency areas, where people go… in the first-aid stations, etc."

One group of interviewees highlighted the SAGARANA/ANVISA Information System, as being responsible for significantly changing work procedures and processes. Another group stressed the CIEVS network organization, coordinated by the SVS, as generating enormous changes in emergency information management. It would therefore appear that incorporating ISR (2005) has led to important changes being made in the management of information in these two institutional sectors.

Another element of change mentioned was the Work Committees, created during the H1N1 pandemic (E9, E6, E13), which resulted in weekly meetings and incorporated new concepts, making problem-solving easier, since these had usually only been held after a problem had occurred and it took time to establish "smooth relationships" (E4). The feeling is that, with a Committee that meets regularly, "time is saved in resolving problems" (E6), and that the involvement of both sectors helps to strengthen relationships, to establish a broader dialogue with other institutional departments and, in particular, to manage information in a more systematic way.

The feeling was that the weaknesses that had emerged during the ISR implementation process, were due to the fact that the Regulation had not been appropriated for purposes other than sanitary and epidemiological surveillance, principally on the part of the welfare services, within both the private and public sectors (E9, E6, E13), as illustrated in the following excerpts: "[...] because many of our cases had already been treated in major hospitals, which did not notify us, did

not tell us and who did not have the same view of what a traveler represents…" (E14).

The ISR is not used either by the states or by the population, as if this tool was limited to "[...] something that only occurs at ports and airports, because it concerns international issues [...]" (E15). It is clear that more information and communication need to be available about the ISR, and that more "[...] work needs to be done to publicize this information so that people can take advantage of it and understand the need for mechanisms that, in some situations, may be very bad individually, but which, collectively, are fundamental [...]" (E12). The broad incorporation of the ISR, especially in health care, is therefore seen as being crucial, since this information boosts contingency preparedness for eventual Pubic Health Emergencies, which is the responsibility of signatory countries, which require articulated internal and international cooperation, so that sanitation safety objectives may be attained[39,42,43].

Failure of the health sector and the general public to incorporate the ISR on a broader basis may well create problems in cases of a Public Health Emergency of National Concern (ESPIN), so that this is not transformed into a Public Health Emergency of International Concern (ESPII). In the case of institutions, this is due to difficulties involved in articulating actions to deal with emergencies. In the case of public or private health care services, this is because it is important to detect emergencies during their initial stages and to establish contingency preparedness for all others; and in the case of the general public, because of the possibility that people will face restrictive measures affecting their freedom.

Changes in sanitary control measures.

On this subject, most of the interviewees talked about travelers, without mentioning freight or means of transportation. Only one interviewee stressed how important it is for public health to impose sanitary control for freight, claiming that the ISR has given the matter little importance. As an example, he mentioned the case of the arrival of used and contaminated hospital material at the port of Suape (State of Pernambco/PE) in 2011, which the exporters had declared to be textile products (E4).

With regards to freedom restrictions applied to travelers, the main arguments put forward were the absence of legal instruments which could be used to impose such restrictions and the binding nature of the Regulation. According to some of the comments made by the interviewees, ISR (2005) left questions unresolved: "[...] quarantine measures that are not clearly defined... 'recommendation' is the magic word introduced by the Regulation; this means that nowadays you are always 'recommended' not to do such a thing…, but, if you wish to do so, you will" (E9); "[...] nothing has been established as being prohibited..." (E10).

The characteristics attributed to the ISR do not take into account the mandatory elements of the Regulation, such as the requirement to indicate a Focal Point within a certain deadline, the need to establish a Liaison Center, rules to control the movement of travelers, etc. It should be highlighted that the Regulation is not designed to prescribe detailed and specific rules to be inserted into the legal systems of signatory countries. The negative view taken of the binding nature of the Regulation may be caused by the desire for rulings that encourage limited action.

Most of the interviewees confirmed that they work inhuman sanitation control in the sense that they are promoting "public awareness" (E1), "to convince others" (E2), that the "[...] SVS does not impose compulsory measures [...]" (E3). According to one interviewee, sanitation awareness is not about imposing restrictions, but about instilling a sense of responsibility in people about private and collective issues.

The question of measures to restrict freedom prompted a heated discussion about individual rights and collective rights, the possibility of conflicts and the responsibilities of the State to protect society, sanitary safety without arbitrariness, and it was argued that in the event of an impasse, individual rights should be put aside in favor of collective rights.

When discussing private and public autonomy, Habermas[44] warns that the issue is not limited to defending the superiority of one over another, since autonomies have a necessary relationship of solidarity – they are co-originators, mutually accepting one another[45]. This is crucial when dealing with sanitary control and the administrative actions of the State, which is based on the idea that the public interest has dominance over private interests and that the public interest is paramount which, among other assumptions, serve pointers to guide the actions of public servants as representatives of the State and, thus, of the population.

With respect to this topic, several interviewees emphasized the need for a specific Law to provide greater clarity regarding the relationship between

measures to restrict freedom and the actions of health surveillance professionals. Some mentioned a legislative bill[25], claiming that discussions about this were interrupted in order to deal with controversial issues such as quarantine and isolation:that laws exist which impose restrictions on freight and means of transportation and even on residential homes, to prevent the spread of dengue fever, but no such restrictions exist for people. One of the interviewees (E12) justified this by saying that countries with more established democracies impose restrictions on freedom[18,19] while Brazil is still "in its infancy" as a democracy and does not even discuss the matter. The question was raised about the possibility of ANVISA applying these measures, based only on ordinances, as illustrated in the following excerpt: "[...] so, the situation always remains unclear. Can we tell a ship not to dock or that no one can disembark on the basis of an administrative ruling? We are interfering in the freedom of movement of people. Can this be done with an ordinance or is a special law required?... At the same time, to have mechanisms capable of guaranteeing collective health actions that can prevent the spread of relevant diseases, right...?" (E6).

It was argued that Law 6.259/75[46], which establishes surveillance of notifiable diseases and creates the National Epidemiological Surveillance System, is outdated and does not even mention municipalities, making it difficult to resolve public health problems, such as measures to be applied to immigrants, and fails to establish practical ways to adopt measures to restrict the freedom of individuals in cases of quarantine and isolation. Furthermore, there are no instruments to ensure compulsory vaccinations; difficulties exist involving the sanitary control of animals, thereby underlining the need for the State to draw up a law that interacts with the ISR ruling.

According to one interviewee, the fact that no such law exists weakens the ISR (2005) implementation process since, in Public Health Emergency situations, management would be exposed to the interference of other sectors, such as the judiciary and the media, who issue responses based on legal generic elements or information from 'pseudo-specialists." As an alternative to this problem, it was suggested that the judicial path should be used to establish the basis to apply measures to restrict freedom, a proposal also mentioned by another interviewee, who thought that this measure would be unfeasible in an emergency situation due to the huge demand.

Although down played by the interviewees, the national legal system, based on Law 6.259/75, already makes it possible to impose restrictive measures, which establishes mandatory vaccination and the Ministry of Health as executor, in cases of national interest or emergencies. In addition, Law 6.437/77[47] prohibits disembarkation or the permanence of foreigners in Brazilian territory, in cases where there has been non-observance or failure to respect sanitary requirements.

If, on the one hand, management can be hampered by the way the legal system and the media approach this matter[37], unlike the health sector, on the other hand, they would be prevented from making it possible to use adequate instruments to carry out the activities of competent professionals, since, in accordance with the principles of legal certainty, lawfulness and the legal reserve[7], the agents of the State can only act on the basis of the law. Thus, we should not forget that the effects of these constraints will be borne by society, which will suffer the consequences of emergency situations and will not receive an adequate response from the State with regard to sanitation issues.

It should be emphasized that the principle of legal reserve[7,8] requires that intervention in the personal sphere, such as restricting right of liberty and property be authorized by law, which does not prevent regulations established by ordinances and resolutions detailing actions to be-applied within the ambit of administrative law. It cannot be ignored that legislative practices to restrict the freedom of individuals, based on issues of collective health, involves a complex area, even when based on truth regimes[38], which help persuade the population to cooperate with measures imposed by the State, since such a regime is based on cohesion, which might cause harm to the individual[48].

In the health sector, the scientific arguments used as truth regimes[49] corroborate to form the basis of decisions related to the ISR and health surveillance agencies. This information shapes the truth regime and validates the imposition of controls on society[38], which makes it possible to raise the level of awareness of the population – which is a strategy used by the two institutional sectors to enable them to apply measures to restrict freedom. Such measures can suffer interference even by the mass media which, in general, presents ideas that are not very coherent as regards their views on health and tend to concentrate more on instrumental logic[50]. This reinforces the need for a coherent institutional system of

Ciência & Saúde Coletiva, 20(6):1773-1783, 2015

communication, which goes beyond the internal scope of such activities[51,52]. Central to this question is the need to restrict individual rights in favor of collective rights, although the importance of the rights of both sides must not be forgotten in the interest of public health.

It was noted that police powers[53] as a State prerogative and as an inherent administrative power for sanitary surveillance[54] was hardly mentioned by the interviewees, who spoke more about using the police themselves to help implement these measures. One wonders if this is due to the so-called absence of laws that support such measures or if this is part of the "identity crisis" experienced by sanitary surveillance professionals between the exercise of police powers and educational activities[50,55].

Freedom restrictions is a reminder of the recent history of Brazilian society, which suffered for many years under a military dictatorship and is therefore wary of the afore-mentioned legal proposal related to public health emergencies[25]. If, on the one hand, difficulties in organizing administrative and practical actions that involve restricting individual freedom should not preclude the need for an open discussion involving civil society, on the other hand, these actions cannot stagnate because it is difficult to establisha minimum level of consensus.

Final Considerations

The incorporation of the ISR (2005) gives rise to discussions, both within the legal ambit as well as within the Brazilian administrative ambit, about questions relating to the State, power, rights, health, among others, all of which are inter-related and none of which are easy to deal with, nor is it easy to construct a single benchmark to understand the subject matter in all its economic, political and sanitary dimensions.

Implementing the ISR involves facing certain difficulties that arise from the complex organization of the administrative structures in the country's health sector, as well as sanitary regulations, which is mainly connected to legal formalities, national sovereignty and aspects of legal security[7,8]. Even so, there are no signs of stagnation in the implementation process and the gaps that still exist, which are of a legal and administrative nature, can find within the Regulation itself the basic elements that need to be addressed. The implications of an economic, political and sanitary nature, even though only mentioned indirectly by the key-actors, are not a secondary issue and help to reveal complex institutional structures that are reflected in standards, competencies and procedures, whichare a concern toits agents.

Surveillance, as an instrument of disciplinary power, is neither good nor bad in character, it is shaped on the basis of how it is used in a social environment[38]; and therefore depends on the values that a given society confers on the exercise of democracy and on health as a matter of individual and collective protection. It may be seen in this study that ISR (2005), as an instrument that serves health surveillance in today's society and, in the case of Brazil, helps to reveal problems that occurred prior to its implementation. This resolution also brings into debate the weaknesses and strengths of the health surveillance systems, and is also seen as a strong promoter of change within the area of standards and practices, as well as a means to strengthen the performance of the sectors and institutions concerned.

The State seeks arrangements to preserve stable internal and external relationships, since the more stable these are the greater the possibility for control; and collective rulings, based on supremacy and precedence of public interest, will encourage the replication of this State. As this is an area prone to disputes and conflicts of interest, the State needs to articulate the relationships involved in individual and collective rights which, due to their characteristics, hamper any *a priori* position in any given situation; perhaps as a result of this difficulty, discussions about measures to restrict freedom tend to lead to too many disputes and too few referrals. The need for specific legislation was one of the main topics discussed; measures restricting freedom are on the international agenda. It is therefore up to the different sectors to use democratic spaces to discuss and register their position on the subject, in accordance with the principle of social participation in the Democratic State of Brazil, one of the core principles of the Unified Health System.

Collaborators

YOR Lima and EA Costa participated on an equal basis in all the preparatory stages of this article.

References

1. Wilson K, McDougall C, Fidler DP, Lazar H. Strategies for implementing the new International Health Regulations in federal countries. *Bull World Health Organ* 2008; 86(3):215-220.
2. Costa EA. *Vigilância Sanitária: proteção de defesa da saúde*. 2ª ed. aum. São Paulo: Sobravime; 2004.
3. Beck U. *La sociedad del riesgo mundial: em busca de la seguridad perdida*. Buenos Aires: Paidós; 2008.
4. Giddens A. *As consequências da modernidade*. São Paulo: UNESP; 1991.
5. Lucchese G. *Globalização e Regulação Sanitária: os rumos da vigilância sanitária no Brasil*. Brasília: Anvisa; 2008.
6. Fonseca VSL. *O Direito Internacional face à saúde e as moléstias transmissíveis* [dissertação]. São Paulo: Universidade de São Paulo; 1989.
7. Aith F. *Curso de Direito Sanitário - A proteção do direito à saúde no Brasil*. São Paulo: Quartier Latin; 2007.
8. Dallari SG, Nunes Júnior VS. *Direito Sanitário*. São Paulo: Editora Verbatim; 2010.
9. Sá MC. Subjetividade e projetos coletivos: mal-estar e governabilidade nas organizações de saúde. *Cien Saude Colet* 2001; 6(1):151-164.
10. Santos MHC. Governabilidade, Governança e Democracia: Criação de Capacidade Governativa e Relações Executivo-Legislativo no Brasil Pós-Constituinte. *Dados* 1997; 40(3).
11. Gezairy HA. Travel epidemiology: WHO perspective. *Int J Antimicrob Agents* 2003; 21(2):86-88.
12. Chamberlain A, Hitchcock P. US accepts 2005 International Health Regulations. *Biosecurity and Bioterrorism-Biodefense Strategy Practice and Science* 2007; 5(1):2-3.
13. Baker MG, Fidler DP. Global public health surveillance under new International Health Regulations. *Emerg Infect Dis* 2006; 12(7):1058-1065.
14. Bennett B, Carney T. Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives. *Aust N Z J Public Health* 2010; 34(2):106-112.
15. Low CL, Chan PP, Cutter JL, Foong BH, James L, Ooi PL. International Health Regulations: Lessons from the Influenza Pandemic in Singapore. *Ann Acad Med Singapore* 2010; 39(4):325-333.
16. Kamradt-Scott A. Disease outbreaks and health governance in the Asia-Pacific: Australia's role in the region. *Australian Journal of International Affairs* 2009; 63(4):550-570.
17. Barata RB. Ethics and epidemiology. *História, Ciências, Saúde – Manguinhos* 2005; 12(3):735-753.
18. Coker RJ, Mounier-Jack S, Martin R. Public health law and tuberculosis control in Europe. *Public Health* 2007; 121(4):266-273.
19. Jacobs AJ. Is state power to protect health compatible with substantive due process rights? *Ann Health Law* 2011; 2(1):113-149.
20. Centers for Disease Control and Prevention (CDC). Public health interventions involving travelers with tuberculosis – U.S. ports of entry, 2007-2012. *MMWR Morb Mortal Wkly Rep* 2012; 61(30):570-573.
21. Menucci DL. O Regulamento Sanitário Internacional (2005) e a vigilância em saúde. *Rev Direito Sanitário* 2006; 7(1-3):54-87.
22. Carmo EH. Regulamento Sanitário Internacional, emergências de saúde pública, liberdades individuais e soberania. *Rev Direito Sanitário* 2007; 8(1):61-64.
23. Velásquez GO. Gerenciamento da pandemia da gripe A (H1N1): uma visão alternativa. *Rev Direito Sanitário* 2012; 13(2):108-122.
24. Aith F, Dallari SG. Vigilância em Saúde no Brasil: Os desafios dos riscos sanitários do Século XXI e a necessidade de criação de um sistema nacional de vigilância em saúde. *Rev Direito Sanitário* 2009; 10(2):94-125.
25. Teixeira MG, Costa MCN, Viana I, Paim JS. Vigilância em Saúde: é necessária uma legislação de emergência? *Rev Direito Sanitário* 2009; 10(2):94-125.
26. Carmo EH, Penna G, Oliveira WK. Emergências de saúde pública: conceito, caracterização, preparação e resposta. *Estud. Av*. 2008; 22(64):19-32.
27. Minayo MCS. O Desafio do Conhecimento: pesquisa qualitativa em saúde. 9ª ed. rev. Aprim. São Paulo, Rio de Janeiro: Hucitec, Abrasco; 2006.
28. Tobar F, Yalour MR. *Como fazer teses em saúde pública: conselhos e ideias para formular projetos e redigir teses e informes de pesquisas*. Rio de Janeiro: Fiocruz; 2001.
29. Yin RK. *Case study research: design and methods*. 2ª ed. New Delhi: Sage Publications; 1994.
30. Minayo MCS, Deslandes SF, Gomes R. *Pesquisa Social: teoria, método e criatividade*. 19ª ed. Petrópolis: Vozes; 2001.
31. Weiss RS. *Learning from stranger: the art and method of qualitative interview studies*. New York: The Free Press; 1994.
32. Brasil. Ministério da Saúde (MS). Conselho Nacional de Saúde. Resolução nº 196 de 10 de outubro de 1996. Diretrizes e Normas Regulamentadoras de Pesquisas Envolvendo Seres Humanos. *Diário Oficial da União* 1996; 16 out.

33. Brasil. Decreto nº 7.616, de 17 de novembro de 2011. Dispõe sobre a declaração de Emergência em Saúde Pública de Importância Nacional - ESPIN e institui a Força Nacional do Sistema Único de Saúde - FN-SUS. *Diário Oficial da União* 2011; 18 nov.
34. Brasil. Portaria SVS/MS nº 104, de 25 de janeiro de 2011. Define as terminologias adotadas em legislação nacional, conforme o disposto no Regulamento Sanitário Internacional 2005 (RSI 2005), a relação de doenças, agravos e eventos em saúde pública de notificação compulsória em todo o território nacional e estabelece fluxo, critérios, responsabilidades e atribuições aos profissionais e serviços de saúde. *Diário Oficial da União* 2011; 26 jan.
35. Brasil. Portaria MS nº 1.865, de 10 de agosto de 2006. Estabelece a Secretaria de Vigilância em Saúde como Ponto Focal Nacional para o Regulamento Sanitário Internacional (2005) junto à Organização Mundial da Saúde. *Diário Oficial da União* 2006; 11 Ago.
36. Brasil. Decreto Legislativo nº 395, de 9 de julho de 2009. Aprova o texto revisado do regulamento sanitário internacional, acordado na 58ª Assembleia Geral da Organização Mundial de Saúde, em 23 de maio de 2005. *Diário Oficial da União* 2009; 10 jul.
37. Ventura D. *Direito e Saúde Global: O caso da pandemia de gripe A (H1N1)*. São Paulo: Dobra Editorial; 2013.
38. Foucault M. *Vigiar e Punir: nascimento da prisão*. 30ª ed. Petrópolis: Vozes; 2005.
39. Plotkin BJ, Hardiman MC. The international health regulations (2005), tuberculosis and air travel. *Travel Med Infect Dis* 2010; 8(2):90-95.
40. Lima YOR. *Trabalho em Saúde: o poder de polícia na visão do profissional de vigilância sanitária* [dissertação]. Salvador: Universidade Federal da Bahia; 2008.
41. Silva ZP. *A Construção de sentidos no discurso do profissional de Vigilância Sanitária. Brasília* [dissertação]. Brasília: Universidade de Brasília; 2004.
42. Katz R, Allen H. Domestic Understanding of the Revised International Health Regulations. *Public Health Reports* 2009; 124(6):806-812.
43. Katz R, Rosenbaum S. Challenging custom: rethinking national population surveillance policy in a global public health age. *J Health Polit Policy Law* 2010; 35(6):1027-1055.
44. Habermas J. *Direito e Democracia: Entre a faticidade e validade*. Rio de Janeiro: Tempo Brasileiro; 2011.
45. Silva FG. A solidariedade entre público e privado. In: Nobre M, Terra R. *Direito e Democracia – Um guia de leitura de Habermas*. São Paulo: Malheiros; 2008.
46. Brasil. Lei 6.259, de 30 de outubro de 1975. Dispõe sobre a organização das ações de Vigilância Epidemiológica, sobre o Programa Nacional de Imunizações, estabelece normas relativas à notificação compulsória de doenças, e dá outras providências. *Diário Oficial da União* 1975; 31 out.
47. Brasil. Lei 6.437, de 20 de agosto de 1977. Configura infrações à legislação sanitária federal, estabelece as sanções respectivas, e dá outras providências. *Diário Oficial da União* 1977; 24 ago.
48. Seale H, McLaws ML, Heywood AE, Ward KF, Lowbridge CP, Van D, Gralton J, MacIntyre CR. The community's attitude towards swine flu and pandemic influenza. *Med J Aust* 2009; 191(5):267-269.
49. Foucault M. *Microfísica do Poder*. 23ª ed. Rio de Janeiro: Edições Graal; 2007.
50. Bensimon CM, Upshur RE. Evidence and effectiveness in decisionmaking for quarantine. *Am J Public Health* 2007; 97(Supl. 1):S44-S48.
51. James L, Shindo N, Cutter J, Ma S, Chew SK. Public health measures implemented during the SARS outbreak in Singapore, 2003. *Public Health* 2006; 120(1):20-26.
52. Kavanagh AM1, Bentley RJ, Mason KE, McVernon J, Petrony S, Fielding J, LaMontagne AD, Studdert DM. Sources, perceived usefulness and understanding of information disseminated to families who entered home quarantine during the H1N1 pandemic in Victoria, Australia: a cross-sectional study. *BMC Infect Dis* 2011; 11:2.
53. Aith F, Minhoto LD, Costa EA. Poder de polícia e vigilância sanitária no Estado Democrático de Direito. In: Costa EA, organizadora. *Vigilância Sanitária: temas para debate*. Salvador: EDUFBA; 2009. Coleção Sala de Aula. p. 37-60.
54. Silva JA. *Curso de Direito Constitucional Positivo*. 23ª ed. rev. atual. São Paulo: Malheiros; 2004.
55. Ng ES; Tambyah PA. The ethics of responding to a novel pandemic. *Ann Acad Med Singapore* 2011; 40(1):30-35.

Article submitted 09/06/2014
Approved 10/08/2014
Final version submitted 12/08/2014