Rev Bras Cir Cardiovasc 2012;27(3):463-8

Analysis of ordinances regulating the national policy of high complexity cardiovascular care

Análise das portarias que regulamentam a Política Nacional de Atenção Cardiovascular de Alta Complexidade

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DOI: 10.5935/1678-9741.20120077

RBCCV 44205-1408

Descriptors: **Heart/surgery. Cardiac surgical procedures. Child care. Health policy. Public Health.**

Descritores: **Coração/cirurgia. Procedimentos cirúrgicos cardíacos. Cuidado da criança. Política de saúde. Saúde pública.**

Ministerial decrees are tools used to create, adapt or regulatory policies established from social demands. The ordinances, subject of this study, inaugurate another moment of care to patients with cardiovascular disease and all forms to the. National Policy of High-complexity Cardiovascular Care

The study that follows is a chapter of dissertation: Evaluation of the National Policy of High-complexity Cardiovascular Care focusing on Pediatric Cardiovascular Surgery, held at the Federal University of Ceará in the Professional Master's Degree Course in Public Policy Evaluation.

We try to analyze the concepts on which the ordinance is based, according to the principles of the Unified Health System (SUS), literature theorizes that such principles, discourses of managers and directors of companies involved in the merits and results of questionnaire applied to cardiovascular surgeons belonging to the Brazilian

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Article accepted on April 7th, 2012
Article approved on September 26th, 2012

Abbreviations, acronyms and symbols	
AHA	authorization for hospital admission
CNRAC	High Complexity National Regulatory Central
DAE/MS	High Complexity Department of Specialized Care/ Ministry of Health
DCCVPed	Pediatric Cardiovascular Surgery Dept.
MS	Ministry of Health
SOP	Standard Operating Procedure
OPM	Orthoses, prostheses and materials
SAS	Department of Health Care
SBCCV	Brazilian Society of Cardiovascular Surgery
SUS	Unified Health System

Society of Cardiovascular Surgery (SBCCV), the sample is calculated by reference to 778 professionals, number provided by SBCCV being distributed in April 2009, as follows: 30 (4%) in the North, 107 (14%) in the Northeast, 68 (9%) in the Midwest region, 437 (56%) and 136 in the Southeast (17%) in the South The sample size for a sampling error of e = 4.87%, was 266 surgeons. Based on this calculation, the sample by region corresponded to ten surgeons in the North, 58 in the Northeast, 25 in the Midwest, Southeast and 43 130 of the South, a total of 266 cardiovascular surgeons.

In January 2003, the Ministry of Health (MS) initiated discussion about comprehensive reform to meet the high complexity and promoted intensive discussion to formulate the so-called: National Policy of High-complexity Cardiovascular Care.

The various specialties were represented by their respective companies, as the Brazilian Society of Cardiology, Brazilian Society of Interventional Radiology and Vascular Surgery, Brazilian Society of Interventional Cardiology, Brazilian Society of Angiology and Vascular Surgery, Brazilian Society of Cardiac Arrhythmias and BSCVS, with its Departments of Cardiac Pacing and Department of Pediatric Cardiovascular Surgery (DCCVPed).

In this scenario, disputes could be observed by medical locus of activity, performance space for hospitals and incorporation of products [1]. The MS proposed to centralize network of university hospitals in the care of high cost and decrease the number of hospitals to the private network, signaling for the development of an exclusionary policy, keeping in view the various requirements for hospitals regarding the physical structure, equipment and human resources, without adequate financial compensation [1].

The SBCCV, during this process, signaled the development of a policy that would meet the regional differences and the fact that it was impossible to meet all the requirements proposed by MS, since most services registered in cardiovascular surgery was experiencing serious financial difficulties [1].

The legal framework came on June 15, 2004 through two devices: the decree No. 1169/GM [2], which established the National Policy of High-complexity Cardiovascular Care, and Ordinance No. 210 SAS / MS [3] regulated the pediatric cardiovascular surgery. This ordinance was amended in some parameters on May 26, 2006, with the publication of the ordinance SAS / MS No 384.

The decree No. 1169/GM/2004 instituted the National Policy of High-complexity Cardiovascular Care considering some requirements, listed below, who gave props to the conceptual elaboration of Ordinance No. 210 and its annexes, which are discussed below.

1. Comprehensive care to patients with cardiovascular pathologies of the Unified Health System - SUS. Integral care consists of the necessary support to those that need treatment. This concept is of great importance, given that comprehensiveness is one of the principles of the SUS.

Integrality is used on an ongoing basis with reference to the guideline of integrated care as the principle of equality of care, seen as a set of actions and, preventive and curative, individual and collective health services at different levels of system complexity [4].

2. Need to organize assistance to those patients on hierarchical and regional services, and based on the principles of universality and integrality of health. Universality is defined as access by all to all services. Integrality is the care that comprises all levels of health care, i.e., the provision of assistance.

However, the ordinance of 2004 did not define how the relationship would take the three levels of care with respect to cardiology and pediatric cardiovascular surgery. In order to the principles of universality and integrality to be effective, it would be necessary to structure the specific model of care for pregnant women and the newborn as well as pediatric monitoring, i.e., the creation of a multidisciplinary care team for the primary and secondary care levels as well as capacitating institutions that provide this kind of assistance with necessary equipment for the diagnosis and monitoring of patients. It was also not established how much and from what sources would be the resources to redress these investments, in addition to determining that all units shall participate in the cardiovascular surgery program, as described in paragraph 1.4 of Annex I.

As for regionalization, Annex IV of Ordinance # 210 established some parameters of territorial operation. In the case of High Complexity Care Units in Pediatric Cardiovascular Surgery, there shall be a ratio of one unit to

serve 800,000 inhabitants (1:800.000), which were also adopted by defining the criteria of article eight of the same ordinance.

In defining the quantitative and geographic distribution of units, such as: population to be served; need for health care coverage, access mechanisms with reference and counter reference, technical and operational services; series of visits, taking into account the pent-up demand; integration with the hospital reference network of emergency care and emergency services with prehospital care, with the High Complexity National Regulatory Central (CNRAC) and other outpatient and hospital care services available in the State. In the same article it was decided that, in the absence of any institution to perform highly complex cardiovascular procedures, the local manager should ensure their achievement by directing the patient through CNRAC.

Thus, these mechanisms would be rational allocation of resources, organized on the basis of technological hierarchy disposition, seeking to expand the capacity of assistance at the entrance of the system, so that other technologies were incorporated to support the needs of each user considering economies of scale and scope. However, it is observed that it is still needed due geographical distribution of health services, human resources and programs, enabling the connection of multiple clinical knowledge and collective health to provide comprehensive care with strategies and mechanisms of articulation and appropriate referencing, sufficient to meet the health needs of specific population base [5].

The structuring of a network of regionalized health care has as its objectives the provision of continuous, integral, quality, responsible and humane health care, articulated according to the complementarity of various densities and technology organized by criteria of microeconomic efficiency in use of resources. This kind of network should be made by the planning, management and financing intergovernmental cooperative and focused on the development of integrated health policy tailored to the population needs of each singular regional space [5]. In complement to what has been defined by MS, Artmann & Rivera [6] i it understood that regionalization requires the allocation of health resources in a given area, in order to facilitate access, offer high quality services, low cost and with better fairness and faster responses to the desires and needs of consumers. The regionalization approach is proposed to find the balance between excessive centralization and complete decentralization of structural health services.

The distance is one of the most important elements to establish the geographical distribution of health institutions within the regionalized system. One cannot help commenting that in a country with vast distances, huge regional differences, especially between the extremes almost depopulated regions and urban centers with overpopulation, we need to think creatively and contextualize parameters through adaptations that bring viable and positive impacts on the problematic situation. The major criterion for the case is access to treatment [6].

In the case of health care, regionalization meets the criterion of priority planning service provision and the need to rationalize the relationship of these dynamics, establishing greater coordination to achieve results in terms of access and equity adequate [6].

Regionalization of care in pediatric cardiology or collaboration among regional centers can not only improve results by focusing the expertise of qualified staff in some institutions, but also to help evaluate the quality due to the increased number of patients [7].

Related to this proposal, interviewed cardiovascular surgeons indicated the establishment of care centers for care of heart disease of higher complexity. Such centers should be distributed in various regions responsible for territorial base previously established, providing quick and skilled care, as in some diseases the delay in care can be the difference in treatment outcome and other long-term survival in patients .

The ordinance in question has adopted the principle of universality, which is access, indiscriminately, of all to all services, based on regional and hierarchical attention. However, the current policy lacks an approach that aims to meet the inequities in cardiovascular care, especially in some regions. Speaking universality it is not the same thing as promoting equity. According to Bottle & Porto [8], “equality is a consequence of the equity. The recognition of differences and suppression of needs make possible the achievement of equality.”

Equity has been interpreted both in official discourse and in the speech of relevance social agents in the arena of health, as a principle of SUS. It is fair that this is so because the universal systems shall seek fairness [9]. According to Neves [10], equity is equal access to health care through its differentiated redistribution: giving more to those who have less and who even have the same conditions, in a regulatory action of inequalities. This is possible only by the principle of solidarity, in which all men redistribute goods among themselves. It suggests the application of two criteria in particular: the medical need, as a factor of rationalization and equal opportunities, as a factor of universal accessibility.

The Standard Operating Procedure (SOP) 96 aimed to promote equity with quality and rationality in spending. In order to avoid cumulative process unfairly by some municipalities, with the increasing dispossession of others, the composition of municipal systems and ratification of agreed schedules in their health councils aimed to

establishments of regional networks for increased access to quality and lower cost [11].

Annex II of Ordinance No. 210 was based on the principle of integral proposed in Ordinance No. 1169/GM, dealing with classification standards and accreditation of units in highly complex cardiovascular care. It was then determined that such units shall offer comprehensive and specialized assistance to patients with diseases of the cardiovascular system and, therefore, it was necessary to: adhere to the criteria of the National Humanization Policy; develop or participate in prevention programs and early disease detection system cardiovascular; offer diagnosis and treatment for the care of patients with disease of the cardiovascular system; develop rehabilitation programs, support and monitoring through specific procedures that promote the improvement of physical and psychological conditions of the patient, besides acting in the preoperative preparation operative or postoperative in addition towards the restoration of functional capacity.

In general, the policy met the principle of completeness when encompassed in care: early diagnosis, treatment, prevention and rehabilitation.

Pauli [12] divides the levels of primary prevention, which is subdivided into health promotion and specific protection; minor in diagnosis with early treatment and limitation of disability, and tertiary prevention to rehabilitation. In none of these directives that comprise the National policy there is reference to the type of action or what kind of disease the primary prevention shall be developed. The determinations merely stipulate that such activities shall be developed in coordination with programs and standards defined by various levels of management.

When it comes to early diagnosis, the policy does not establish standards for adequacy of services to the attention of the segment, which begins in the care of the fetus, neonate and child. On the other hand, it would require physical structure, equipment and specialized professionals in order to such to be met.

The sources of funds for the execution of several actions also represent important gap in politics. It is worth mentioning that early diagnosis points to the scheduled time and treatment in the second article of the decree No. 1169/GM determined that the Secretaries of State for Health establish regional planning and hierarchical network to form the State and / or Regional High-complexity Cardiovascular Care, in order to assist patients with diseases of the cardiovascular system that needed to be subjected to procedures classified as high complexity.

As for rehabilitation, tertiary prevention and other actions to promote integrity, the ordinances do not specify the source of payment, making it infeasible adoption by providers, although these have been signed at the time of accreditation.

3. Ensuring these patients to assistance at various levels of complexity, through multidisciplinary teams, using techniques and specific therapeutic methods. This topic refers to the completeness, and its effectiveness hindered by a lack of coordination between actions at different levels, the lack of infrastructure of services provided to primary and secondary care and tertiary care deficient capacity to meet demand at that level. It is necessary to emphasize that the principle of intersectoriality shall be noted, referring to food conditions, education and leisure, pillars to ensure good cardiovascular health.

4. Need for a new conformation of State Networks and/ or Regional Networks of High-complexity Cardiovascular Care, as well as to determine their role in health care and the technical qualities necessary for the proper performance of their duties.

In order to meet this determination, the second article of the decree No. 210 ordered the secretaries of Health establish regional planning to form a hierarchical Network State and / or Regional Networks of High-complexity Cardiovascular Care. The single paragraph defined the Networks of High-complexity Cardiovascular Care shall be composed of high-complexity cardiovascular care units and referral centers for high cardiovascular complexity. In turn, the high cardiovascular complexity care and referral centers in high cardiovascular complexity conditions shall provide technical, physical facilities, equipment and human resources to provide specialized assistance, develop strong coordination and integration with the local system and regional health care and meet the criteria of the National Humanization Policy. The skills and responsibilities of the departments located in assistance units and referral centers for high cardiovascular complexity care shall be regulated by the Department of Health Care by a specific rule. The minimum parameters of operation of these units were defined in Annex I of Ordinance No. 210.

The same decree No. 210, in the first article of the second paragraph, defined as the Reference Center for High-complexity Cardiovascular Care a High-complexity Cardiovascular Care Unit exercising the auxiliary role of a technical nature, the manager in the policies of care in cardiovascular diseases, must possess attributes such as: be a teaching hospital, certified by the Ministry of Education and MS.

According to the Interministerial ordinance No. 1000 of the Ministry of Education, April 2004, to be a teaching hospital, this should have a territorial base of operations defined, with a maximum of a referral center for every four million inhabitants; participate articulated and integrated with the system local and regional have structure of organized research and teaching, and programs with established protocols, have adequate management structure capable of ensuring the efficiency, efficacy and

effectiveness of actions provided; support the activities of managers in regulation, monitoring, control and evaluation, including quality studies and studies of cost-effectiveness; participate as polo professional development in partnership with the manager, based on the Politics of Permanent Education for SUS, MS, and offers at least four services defined in the fifth article of this ordinance.

Importantly, the requirement for territorial basis of performance (maximum a referral center for every four million inhabitants) was revoked in May 2006 by the third article of the decree No. 384. Already the second article, the first paragraph of this Ordinance provided that, in states with population less than 4,000,000 inhabitants, there should be no more than a reference center, since the unit would meet the requirements. The second paragraph of the same article that preferably should be defined as referral centers enabled public hospitals, private philanthropic and private financial gain, in that order, that would fit in the first article, second paragraph, item I.

Interviewed cardiovascular surgeons of BSCVS considered the technical criteria contained in the annex to the decree No. 210 as not mutually exclusive and that could serve as a bargaining tool for improvement of some institutions. Others considered as a limiting factor in enrollment, especially in the aspects concerning the formation of multidisciplinary teams, the physical structure and the acquisition of costly equipment.

It is understood that the criteria as parameters are needed to provide adequate service to the segment of cardiac patients. However, based on the fact that the target set in the policy was 239 centers and only 66 were actually enabled, this indicates that the policy was limiting access to the institutions.

5. Update the accreditation system and adapt it to provide procedures for High Complexity, High Technology and High Cost.

Article 11 of Decree No 210 incorporated six annexes: Classification Standards and Accreditation of High-complexity Cardiovascular Care Units, Survey Manager Form, MS Survey Form, List of Procedures Included in Tables SIA and SIH / SUS for Cardiovascular Care, Distribution Parameters for Population Assistance Services and Reference Centers for High Cardiovascular Complexity, List of Procedures Excluded from SIA and SIH / SUS Tables. It was created, also, the Table of Compatibility between procedure performed and orthotics, prosthetics and special materials (OPM) and the Cardiovascular Care Procedure Organization.

In the questionnaire applied to cardiovascular surgeons of BSCVS 88.3% of the respondents opined by the need to implement a National Database. They considered that to achieve this it would be necessary to match diagnosis tables, procedures and OPM, using an internationally accepted nomenclature, since the specialty is of high complexity and thus it is essential to be included in the international context.

6. Improving the system of information concerning the Cardiovascular Care.

The sixth article established a deadline of 120 days to deploy management tools, such as the "Brazilian Registry of Cardiovascular Surgery," but until the completion of this survey, in December 2011, it had not occurred.

The arguments mentioned in the interviews of directors of companies as well as the managers of MS, in explanation for the non-implementation of the record were: lack of political will, the inability to formulate DATASUS the database and lack of interest by having doubts SBCCV about how the data will be used. In this regard were clearly identified divergent interests, mainly related to power management to the database can generate. Most cardiovascular surgeons surveyed (91.4%) believes that the database should be managed by the department (DCCVPed) or by BSCVS, while 76.6% believe that the filling should be mandatory and linked to the authorization for hospital admission (AHA) and 93.1% participate in the record even if not compulsory to fill.

Establish mechanisms for the regulation, supervision, control and evaluation of the care provided to these patients.

These mechanisms were effective, in part, by registering cardiovascular surgery. That record, in turn, should equip the actions specified in Annex I of Ordinance No. 210, topic 1.7. Under Annex, maintenance of accreditation services would be conditional: the continued fulfillment of the standards established in the ordinance for unity; evaluation to be performed by periodic audits or recommended by the Department of Health Care (SAS), run by the Department of Health under whose management is unity, and the reports generated should then be forwarded to the General Coordination for High Complexity Department of Specialized Care (DAE / MS) for analysis that would determine the continuation or suspension of accreditation, based on compliance or not the standards established by ordinance, regular reports on the evaluation and annual production. According to the surgeons interviewed, the record could be powered by untrusted data, since they would have among their purposes to support maintenance or suspension of accreditation.

Unfortunately, it remains a challenge to be faced in the fight for effective implementation of policies, in which universal access to effective and resolution should be a guarantee. Overcoming the gap between rule and practice is the way to go for multithreaded interested in solving the ills of this population as specific, as is the scope of notorious intentions contained in ordinances.

The universality, comprehensiveness and equity of health care shall be the goal of health policies that propose to be inducing quality healthcare.

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