

Healthcare regulation and equity promotion: The National Regulation System and the health access in a large municipality

Regulação em saúde e promoção da equidade: o Sistema Nacional de Regulação e o acesso à assistência em um município de grande porte

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ABSTRACT This study aimed to evidence the interface between the municipal healthcare regulation service and the practical realization of the equity principle, based on the experience of the professionals involved in this sector. The methodology was the case study, with techniques of focal group, participant observation and documental analysis, from September to November 2013. The challenges of healthcare regulation were highlighted to effectiveness the principle of equity. The National Regulation System was identified as an instrument to the supply and demand management. In this way, the influence of regulation on the supply and provision of services has the potential to ensure the access to the users and promote the equity.

KEYWORDS Health care coordination and monitoring. Equity. Equity in access. Health management. Public health.

RESUMO O objetivo deste estudo foi evidenciar a interface entre o serviço de regulação em saúde municipal e a efetivação prática do princípio da equidade, a partir da vivência dos profissionais envolvidos nesse setor. A metodologia foi o estudo de caso, com técnicas de grupo focal, observação participante e análise documental, no período de setembro a novembro de 2013. Foram evidenciados os desafios da regulação em saúde para efetivação do princípio da equidade. O Sistema Nacional de Regulação foi identificado como ferramenta para gerenciamento da oferta e da demanda. Assim, a influência da regulação sobre a oferta e a disposição dos serviços tem o potencial de garantir o acesso aos usuários e promover a equidade.

PALAVRAS-CHAVE Regulação e fiscalização em saúde. Equidade. Equidade no acesso. Gestão em saúde. Saúde pública.

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Introduction

The term 'regulation' is associated with acts of regulating, ordering, submitting to rules, and it is related to user satisfaction regarding the fulfillment of their needs. Healthcare regulation has been advancing, as it is an important tool for overcoming the challenges faced by the Unified Health System (UHS) since its inception (OLIVEIRA; ELIAS, 2012). Healthcare regulation is related to the state's function of organizing the distribution of health resources, goods and services, i.e., it is linked to the overcoming of problems such as the provision of health services (OLIVEIRA; ELIAS, 2012; ALBUQUERQUE ET AL., 2013).

Healthcare regulation seeks to achieve the objectives of the UHS by ensuring the right to health, efficient access, efficacy and effectiveness, provision of health services and actions of quality and that are sufficient to attend to the needs of the population, based on available resources (LIMA ET AL., 2013).

The expansion of access to health services and actions is one of the great challenges of the UHS. The solution for this issue requires managers to organize and make available mechanisms that, together, seek to achieve the system's consolidation. Elements considered as facilitators for a good outcome of healthcare actions are: competent Primary Health Care (PHC); appropriate and accurate referrals; assistance protocols; and the structuring of regulatory systems (GAWRYZEWSKI; OLIVEIRA; GOMES, 2012).

In Brazil, in 2008, the National Regulatory Policy was established to regulate three aspects: the health systems; the healthcare; and the access to care (BRASIL, 2008). The latter aims at organizing, controlling, managing and prioritizing access and care flow within the UHS, operating as a sanitary authority to guarantee access based on protocols, risk classification and other prioritization criteria (BRASIL, 2007).

The principle of health equity operates according to two perspectives: first, to

health conditions, which concerns the risk of the worsening of health problems; and the second, the access and use of health services, which addresses the availability of health actions. Both aspects seek to compensate for biological and social variations, balancing the distribution of illness and death in population groups (BARROS; MENDONÇA; SOUZA, 2016). In order to achieve the equitable access that it proposes, the UHS employs the regulatory system as one of its management tools, since it emerges as an important social equalizer capable of attenuating the link between need, demand and supply (VILARINS; SHIMIZU; GUTIERREZ, 2012).

To manage demands, the Ministry of Health provides as a Health Information System (HIS), the Regulation System (Sisreg), which aims to humanize health actions and services, achieve greater control of care access and flow, and optimize the use of financial resources (SISREG, 2008).

Access is understood as the users' reception, admission and referral to healthcare actions that meet their needs. Considering the UHS organization into Health Care Networks (HCN) and its multiple entry routes, the healthcare regulation is responsible for user access availability according to the required need, considering the limits of resources. It aims to manage the prioritizing process of access to healthcare services, ensuring equity within the health system (GAWRYZEWSKI; OLIVEIRA; GOMES, 2012).

The incipient knowledge of the involved professionals limits an effective and satisfactory performance of the regulation services (VILARINS; SHIMIZU; GUTIERREZ, 2012). Health regulation, as a management facilitator and as part of the essential purposes of public health, should be widely discussed in order to qualify health practices and strengthen their institutional capabilities (LIMA ET AL., 2013).

The scarcity of studies in this area indicates the need for scientific investments that address the issue, specially when associated to compliance with the doctrinal principle of

equity. Based on this, a question that arises is: how do the professionals of the health regulation service perceive the connection of their activities with the effectiveness of the equity principle? Thus, the objective of this study was to highlight the interface between the municipal health regulation service and the practical implementation of the equity principle, based on the experiences of the professionals involved in the sector.

Methodology

This was a qualitative study, using the case study as a methodological reference. We used focus group techniques, documentary analysis and participant observation to address the proposed objective. This methodological approach employs qualitative research to map, describe and analyze the context, relationships and perceptions regarding the phenomenon in question, and generating knowledge about significant characteristics of the experienced events (MINAYO, 2013).

The study site was the health regulation sector of a large municipality located in the South of the country. The municipality is known nationally for the good performance of practices in Family Health Strategy (FHS) and public health. The municipal Regulation Center is responsible for managing the regulation of the macro-region, with regard to the regional services in the capital. The macro-region comprises approximately 470,000 inhabitants of the city, and totaling more than one million inhabitants of the metropolitan region (IBGE, 2016).

As the author had no previous professional relationship with the staff in the Regulation Center, a meeting was set up with management to explain the objectives and methodology of the research. Data collection took place from September to November 2013. Initially, the documentary analysis was carried out, to obtain information that clarified questions elaborated by the researcher,

that could not be answered from other data sources (MINAYO, 2013).

After the documentary analysis, participant observation was carried out, which allowed the researcher to identify details, such as work routine, interpersonal relationship among staff members, and special interest of professionals in certain areas of work, all of which are phenomena that can not be addressed by other data collection techniques. Observational meetings allowed the understanding of reality, since in this technique the researcher assumes the position of context analyzer, observing the reality from the same perspective of the subjects and allowing the development of the scientific investigation (MINAYO, 2013).

The researcher was present at the Municipal Health Department (MHD) for 3 days, in full time, in order to observe the genuine dynamics of the staff and the functioning of the MDH regulation sector, and the whole process involved in staff's daily actions. The observations occurred prior to the focus group, in order to equip the researcher on the local work dynamics, to get her familiarized with the context under observation and allow professionals/participants to adapt to her presence.

Participant observation included the work of all 13 employees: seven regulators (five doctors and two dentists), four administrative staff and two nurses, as well as a regulation manager and a director of regulation, control, evaluation and auditing.

Then, the focus group meeting took place. The focus group consists of a qualitative research technique based on interviews applied to small and homogeneous groups and collects information through communication and interactions between the members (MINAYO; MORGAN, 1997). The group was led by the first author of this article, of which its research served as the basis for her master's thesis. All 13 regulation employees were invited by email to participate in the data collection and the invitation was

reinforce personally. Since some were part-time, four were unable to attend the meeting and one remained in the sector during the activity, the final focus group included eight participants: one nurse, four regulators (two physicians and two dentists), and three administrative staff (including the regulatory manager, control and evaluation manager, and the director of the regulation, control, evaluation, and auditing). The meeting lasted 2 hours and had the following guiding question: 'What is the interface of your work in the regulation sector with the principle of equity?'; all those involved participated actively. The speeches were recorded and transcribed verbatim.

For data analysis, the thematic analysis proposed by Minayo (2013) was used, which follows the notion of themes represented by a word, phrase or summary about a certain subject. Thematic analysis took place in three stages: pre-analysis; exploration of the material; and treatment and interpretation of the obtained results (MINAYO, 2013).

The first stage, or pre-analysis, included the familiarization and organization of the material, and formulation/reformulation of hypotheses and objectives, referring to the initial inquiries. The second stage, exploration of the material, included the data classification, aiming to reach the essential understanding of the text. For this, the raw data were coded, reducing the text to significant words or expressions. The categories of analysis were then formulated and the data were grouped according to the theme. Finally, in the third and last stage, the treatment of the results and their interpretation occurred (MINAYO, 2013).

The study led to the construction of three main categories: Health Regulatory Actions; Equity in Health Regulation; and Professional Performance. In this article, we will analyze the second category, Equity in Health Regulation.

The study was submitted to the Research Ethics Committee and to the National

Commission for Research Ethics (CEP/Conep system – Plataforma Brasil), and was approved by means of the Certificate of Presentation for Ethical Appreciation (CAAE): 22230913.0.0000.0121, receiving a favorable feedback for Publication in accordance with Protocol 460.084 / 2013. All the participants were clarified about the research objectives and signed the Informed Consent Term. In order to maintain the confidentiality of the participants, the speeches were identified throughout the text by their professional category and the order in which they manifested themselves.

Results

From the category Equity in Health Regulation, two subcategories were disclosed: 'Sisreg as a tool for supply and demand management' and 'Challenges of health regulation as a manager of the principle of equity'.

Sisreg as a tool for supply and demand management

In this subcategory, data analysis indicated that health regulation for the participants had the following definition: actions which purpose is to guide the supply and production of health actions and services, meeting the needs of the population in order to preserve the UHS fundamental principles of universality, integrality and equity. This understanding was supported by practices observed by the main researcher, which included several discussions among regulators about risk classification of clinical cases. At times, this promoted a better evaluation by the professional, sharing uncertainties and increasing the chances of attending requests in an equitable way.

In this process, Sisreg is identified as the main facilitator of health regulation. It allows the receipt, evaluation, referral and

requests approval, as well as it provides the interface between PHC, caregiver, and health regulation. However, the communication between PHC and the regulatory center is done primarily through e-mail. Many of these messages are requests for prioritization of specific cases. It was found that several of these requests are fulfilled considering the information included in the message, being solved outside Sisreg. This is in line with the recommendation, since only some cases are considered for re-evaluation, while the others continue with the initial prioritization. This difficulty in using the system leads to a deficit in the transfer of relevant information, which hinders the regulation by professionals at the central level. The following statement corroborates this observation:

And another very difficult point that we feel here in regulation: we regulate and prioritize according to what is described there, as the [PHC] professional describes it. We are not seeing the patient. We do not see him, we just read what's in the system. So one of the very difficult points of regulation is still [...] to make them understand that we are a reflection of what is described there, and that regulation begins in primary care. (Regulator 1).

Thus, access protocols are indicated as guiding tools for the regulation process. The development and implementation of access protocols are carried out by regulation professionals in partnership with nurses and sector administrators. They aim to optimize vacancies utilization, establish risk classification criteria where the supply is less than the demand, standardize APS requests and guide the requests' flow to the care provider units. However, the participants revealed the difficulties generated by the lack of access protocols, an instrument that when coupled with the regulator's critical view, tends to qualify the regulatory process, as demonstrated by one participant:

Our traditional problem is the lack of an established [access] protocol: how access to a given exam is accepted, what are the characteristics that allow prioritizing or not. Even for us to provide equity, right? Because treating everyone equally is not possible. Because people are different, each one has different characteristics and different pathologies. So, if you determine in a protocol, it eases the whole process. Of course, it tends to make decisions a little inflexible, but that's what the regulator has to do to see if, at that moment, that person really needs to get ahead, to be prioritized or not. (Regulator 4).

Through the implementation of access protocols, referrals are classified in the health center as routine, priority or urgency. From then on, access for priority and urgent cases is guaranteed, differently from routine appointments, making access more equitable. However, participants demonstrate the difficulty they face with the deficit of previously established access protocols. According to statements, access protocol would facilitate the work of the regulator.

Challenges of health regulation as manager of the principle of equity

From this second subcategory, emerged as the goal for Regulation Management 'to enable Sisreg to be incorporated as a knowledge technology for managers and technicians, and to be capable of making access more equitable. In this context, Sisreg is used as the tool to guarantee access by managing the quota of available services. It was evidenced that the Regulation Management can guarantee through its team of regulators an appointment for all cases that need the application of the principle of equity. At the same time, it evaluates the necessity of supply expansion or the reallocation of resources, based on population demand and impact in collective health indicators, as the statement below confirms:

The ultimate goal of regulation is to match the request with the service. It is not based solely on the expansion of supply. We have to work, also, with the request administration. This is a very troubled marriage. Something that we would have to evaluate also is to what extent the provision of the procedure, consultation or examination is impacting the epidemiological indicators. This is a very complicated part. (Manager 3).

Despite the difficulty that the staff has with handling Sisreg, they pointed out the improvement that the system caused in the health regulation service, as in the subdivision of the service.

The staff demonstrated an understanding of the close relationship between the regulation of health access and the principle of equity, valuing and fostering this principle and perceiving regulation as its potential promoter. The activities in the regulatory sector are motivated by the conquest of the principle of equity, which facilitates the promotion of actions and services accordingly.

Understanding the importance of regulation as a tool to facilitate and achieve equity motivates the professional to act in a committed way in his or her role. The professionals perception of the regulatory activity as a tool for equity can be perceived in the testimonials of professionals of different areas:

Our quest is to always make regulation as equitable as possible. Our pursuit is constant in this. That's why it's so complex. Because queue is not equity, queue is queue. Whoever arrives first, will go in. Regulation is just the opposite. What we try to do is that people who needs the most has more, faster, and is referred in the best way possible. And this is our constant pursuit. Our main motivation is equity. (Nurse 1).

The theory is really this, you give priority to what is priority. You prioritize what really is a priority. Even if there was a place for everyone, still, it

[health regulation] would be necessary because you would still have to give priority. (Regulator 2).

Among the doctrinal principles of UHS, equity is the one that has more to do with us. Basically, that's what you're looking for here. It's kind of the main reason for the regulation. Of course, along with integrity and universality. But if we were to choose one, it would be equity. The one that has more to do with the regulation is equity. (Manager 3).

Furthermore, PHC is indicated as the user's point of entry into the municipal health system. Through it, users are referred to the other levels of the healthcare network according to their care needs, and referred back to it after being assisted in the care levels of greater complexity. According to this logic, the health center in the area of the user's residence is responsible for ordering their access into secondary and tertiary healthcare services. The following statement corroborates these findings:

There is no regulation system in Brazil that, alone, accounts for the repressed demand. Then, because we can not handle the repressed demand, the regulation is what organizes access. It organizes access with the organizing agency, which is primary care. The organizing agency, which demands services for regulation, is the primary care. (Manager 1).

The difficulties of PHC practitioners arise perhaps because it is something new to them. Most of the people who are working, did not even study this in the university, were not sensitized to that aspect. (Regulator 1).

PHC professionals are responsible for identifying the healthcare needs of the user and defining when they should go beyond the primary level and be referred to secondary or tertiary care. According to the participants, the PHC is part of an important

stage of the regulation process, which demonstrates the need for preparing and training these professionals to understand the process and have a better performance when facing the demands, as revealed by the statements:

It is necessary to involve staff, include the unit's coordinator and have him know what is happening. Involve the whole team in the process of getting to know the information system, of understanding the criteria and understanding that it is valuable that everyone knows and everyone participates. (Nurse 1).

The more qualified the primary care, the more training we do, biweekly or weekly, call doctor, call nurse, the more people are trained, the less work we will have, the fewer emails we will respond. The professional will call only when it is an emergency. (Manager 3).

Therefore, the need for preparation and training to develop the knowledge and skills necessary for the correct handling of the system and the realization of equity through health regulation is evidenced.

Discussion

The regulatory sector uses mechanisms to facilitate access to the health system, based on the principles of equity and integrality. The concept of health regulation is linked to the adequacy of healthcare services in relation to the needs of the population, ordering their execution in an equitable and qualified way (LIMA ET AL., 2013).

Regulation is a managing tool that seeks to make all users' access possible in a programmed way. That is, it guides the re-programming of the service's supply by identifying the deficiencies of the population demands. When based on the doctrinal

principles of the UHS, regulation can expand or repress a given supply, according to the impact on health indicators. Thus, the observation of the reality made available by health regulation serves as the basis for a better management of the available financial resources (ALBUQUERQUE ET AL., 2013, LIMA ET AL., 2013). Hence, the literature relates the concept of regulation to the principle of equity, demonstrating that regulation is an important tool for the achievement of this principle (ALBUQUERQUE ET AL., 2013, LIMA ET AL., 2013, GAWRYZEWSKI; OLIVEIRA; GOMES, 2012).

Despite this, gaps are still present between supply and demand in the daily routine of UHS, making the prioritization by regulation insufficient to satisfy the health needs of the population. This scenario allows the formation of repressed demands, known as number of demands constantly above the available supply, a situation that cannot be spontaneously reversed (LIMA ET AL., 2013).

Financial limitation is one of the major problems of the UHS that restrict the actions planned by health management. Whether due to a lack of resources or improper management, this problem is an important barrier to actions and services access to meet the health needs of the population (GAWRYZEWSKI; OLIVEIRA; GOMES, 2012, RIBEIRO, 2015).

The difficulty in space offer to healthcare actions in more complex specialties leads to the image of a 'funnel', in which many people enter and few achieve the goal of 'exiting the funnel', and being effectively cared for (GAWRYZEWSKI; OLIVEIRA; GOMES, 2012). The literature uncovers the need to insert all the requests in a single system, leading to an advance of the regulation process. This would standardize the data sent to the center, allowing data crossing, the attainment of indicators and the structuring of access protocols (ALBUQUERQUE ET AL., 2013).

The use of access protocols, facilitated by Sisreg, leads to an increase in the quality of care provided. The definition of such protocols, considering the organization of care in

networks, defines the flows of assistance and the integration of actions and services, facilitating the regulation process (SOUZA *ET AL.*, 2015).

If all the resources were made available to meet every needs of the population, there would be no health inequities. However, since the UHS has limited resources, the alternative to achieve equity is using certain criteria for prioritizing access proposed by the health regulation system, which seeks to offer health services and actions proportionally to the different needs (ALBUQUERQUE *ET AL.*, 2013; GAWRYZEWSKI; OLIVEIRA; GOMES, 2012; RIBEIRO, 2015). In addition to the contributions related to the increase in access by clinical priority, the regulation also organizes and plans its actions considering the geographical distribution and the social aspects of each region (ALBUQUERQUE *ET AL.*, 2013).

In many cases, priority requests are taken to court with the purpose of assuring the constitutional right of integral access to health. These actions are a prejudice for health equity because legal resources are more accessible among people of higher income and education. In such cases, if the State grants the health care requested for an individual, it does so without considering the other users awaiting the same assistance (GAWRYZEWSKI; OLIVEIRA; GOMES, 2012). The limited knowledge of the system by the judges prevents that the decision taken, although legitimate, favors health equity.

It is necessary to define the criteria to allocate limited resources through public policies based on the principles of social justice, such as equity, integrality and universality. Uniformity and situational action in accordance with agreements are considered alternatives to this problem, leading to the definition of the need to allocate more investments (MURTA, 2015). This study is not criticizing the legal mechanisms to which the citizen is entitled, but it questions the investments in the health sector or within its administration, reinforcing the need to use health regulation to adjust the supply of services according to the demand.

The need for adequate allocation of financial resources is pointed out, since excessive investments in services that are not primordial to the population can compromise the health system structure, which highlights the responsibility of health management for optimizing resources and achieve the highest quality in assistance (RIBEIRO, 2015).

The findings of this study are corroborated by the literature when it states that PHC, as the main gateway to the health system, is responsible for ensuring the user's full access to the needed health services, integrating all available resources (ALBUQUERQUE *ET AL.*, 2013). The regulation is seen as a management tool, a communication channel between health units and promoting agent for the access to health services (ALBUQUERQUE *ET AL.*, 2013; LIMBI *ET AL.*, 2013; ALBIERI, CECILIO, 2015).

The integration of health services of different complexities tends to follow the network system, seeking to ensure continuity of care. Thus, it is noted that health regulation consists of creating networks with the other levels of attention (ALBUQUERQUE *ET AL.*, 2013).

Therefore, in a system with a well-structured PHC, users whose needs are cared for at the primary level are not referred to unnecessary specialized services. Likewise, the integration of the primary care with the regulation service allows the optimization of the available resources for the integral attention of the user. The relationship between primary care and the regulation indicates that the lack of this health management tool would reflect in the disorganization of PHC, which would burden the whole system (LIMA *ET AL.*, 2013; ALBIERI; CECILIO, 2015).

The Permanent Health Education (PHE) promotes the questioning of the current reality and the development of proposals that lead to changes and improvements in the practice of health professionals. The need for PHE investments in the area of health regulation is justified by the high demand of health services in Brazil. This in fact requires the commitment of health

professionals and the encouragement for the development of evidence-based health care, which combines the best scientific evidence with the best possible clinical practice, considering the patient's values in addition to the professional clinical experience. This qualifies the work of healthcare providers, which must be based on decision making capabilities about the most appropriate actions, either clinical or managerial (SILVA ET AL., 2014, JENSEN; GUEDES; LEITE, 2016).

Final considerations

To contribute to an equitable health system, health regulation must tailor supply to demand through evaluation, i.e. it must prioritize cases by means of the classification of

clinical criteria. To do so, it is recommended to use tools that can facilitate this process. Sisreg, currently made available by the Ministry of Health, enables the management of available resources, as well as the verification of the need for expansion or limitation of specific services. Therefore, Sisreg is a significant tool for the management of supply and demand.

PHC is perceived as being responsible for organizing users' access to other levels of health care. Therefore, the full comprehension of the use of Sisreg by the employees of the PHC is essential for the optimal use of this tool. Finally, for future research, it is recommended the development and analysis of educational actions with health network workers to optimize the use of Sisreg and its interface with management indicators. ■

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