Medicina:

Esforço Comum da Promoção da Saúde e Prevenção e Tratamento das Doenças

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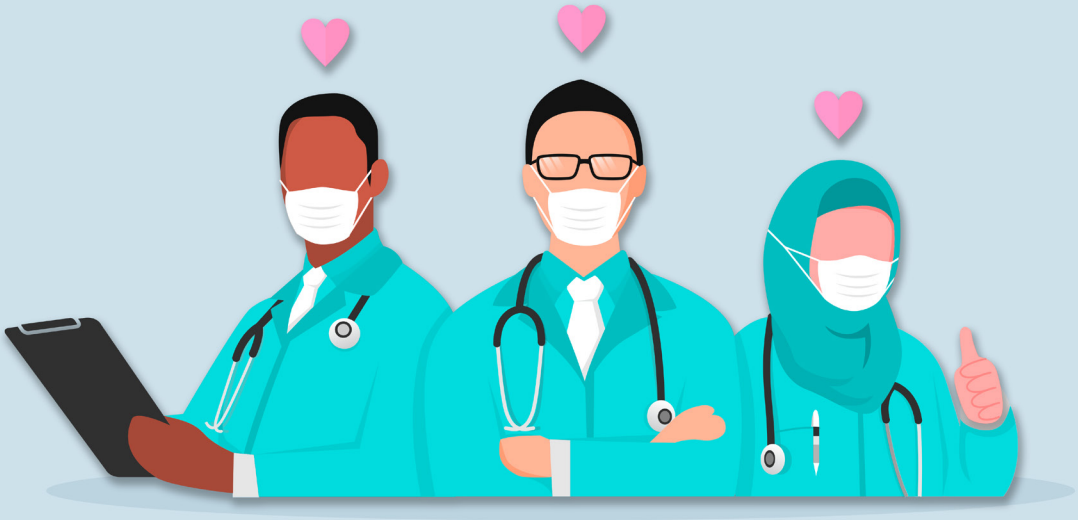

Benedito Rodrigues da Silva Neto
(Organizador)

Atena Editora
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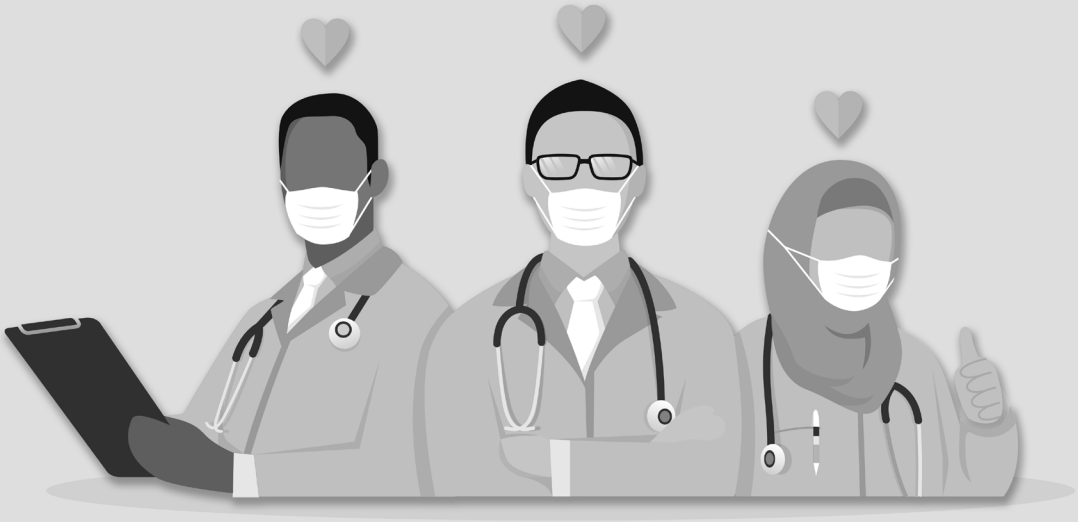

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APRESENTAÇÃO

O esforço presente na comunidade acadêmica e científica com o objetivo comum de promover saúde é uma ação que vai além da Lei orgânica da saúde, se baseando também no compromisso individual dos profissionais da área em oferecer mecanismos que proporcionem saúde à população.

Consequentemente, para se promover saúde em todos os seus aspectos, torna – se necessária cada vez mais a busca por novos métodos de diagnóstico eficaz e preciso para a mitigação das enfermidades nas comunidades. Partindo deste princípio, esta obra construída inicialmente de cinco volumes, propõe oferecer ao leitor material de qualidade fundamentado na premissa que compõe o título da obra, ou seja, promoção da saúde e consequentemente o tratamento das diversas doenças, uma vez que é cada vez mais necessária a atualização constante de seus conhecimentos.

De forma integrada e colaborativa a nossa proposta, apoiada pela Atena Editora, trás ao leitor produções acadêmicas desenvolvidas no território nacional abrangendo informações e estudos científicos no campo das ciências médicas com ênfase na promoção da saúde em nosso contexto brasileiro.

O tratamento, diagnóstico e busca por qualidade de vida da população foram as principais temáticas elencadas na seleção dos capítulos deste volume, contendo de forma específica descritores das diversas áreas da medicina, com ênfase em conceitos tais como ressuscitação cardiopulmonar, exame ginecológico, saúde indígena, telessaúde, dor musculoesquelética, depressão *Aedes aegypti*, prognóstico, morbidade, AIDS, câncer de cabeça e Pescoço, epidemiologia, Ilimaquinona, Saúde da Mulher, tecnologia educacional, lavagem de mãos, infecção hospitalar, mortalidade, atenção psicossocial, covid-19, dentre outros diversos temas relevantes.

Finalmente destacamos que a disponibilização destes dados através de uma literatura, rigorosamente avaliada, fundamenta a importância de uma comunicação sólida e relevante na área médica, deste modo a obra “Medicina: Esforço Comum da Promoção da Saúde e Prevenção e Tratamento das Doenças – volume 5” proporcionará ao leitor dados e conceitos fundamentados e desenvolvidos em diversas partes do território nacional de maneira concisa e didática.

Desejo uma excelente leitura a todos!

Benedito Rodrigues da Silva Neto

SUMÁRIO

CAPÍTULO 12

ORGANIZATIONAL CHALLENGES FACING BY THE BRAZILIAN PUBLIC HEALTH IN TACKLING THE NON-COMMUNICABLE CHRONIC DISEASES BY THE HOMEOSTATIC MODEL

Data de aceite: 01/02/2021

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ABSTRACT: Since its organization in 1990, the Brazilian Universal Health System (SUS) is committed to offer high-quality health care to the entire population. For doing so, the expansion of pharmaceutical care and the free distribution of most NCD medications play an important role in the Brazilian Government's effort to tackle those diseases. While Brazil's national drug policy calls for distribution of essential drugs through the universal public health system, the stocking of these drugs in outpatient facilities is still deficient. Consequently, the drug access through the SUS is still insufficient lacking of affordability and availability creating socioeconomic inequities by the access to public drugs. The state of out-of-pocket added to the much higher prices of medical drugs in Brazil than internationally, is leading the general population to the catastrophic expenditure in health. Hence, despite its accomplishments, the Brazilian health system faces serious financial and organizational challenges. Overall, the onerous expansion of pharmaceutical care and the free distribution of most NCD's medications, has been demonstrated ineffective in controlling these diseases. Underlying the unsuccessful drug therapy in halting and reversing the NCDs epidemic is the ineffectiveness of the used treatment approach of homeostasis. Differently from treating low level targets by drugs (homeostatic model) and generating iatrogenesis, the allostasis model has a more rational goal of intervention. The growing worldwide burden of NCDs demands the implementation of effective population-based strategies in which diet and physical exercise are the pillars of treatment. Costless lifestyle modification programs have, alternatively to homeostatic model, promoted eutrophy and reduced blood hypertension, T2D and Metabolic Syndrome reductions in a community- based adults. Mainly physical activity could be a natural remedy for recovering part of the imbalance caused by modern life-styles, costless and without the side effects of many pharmacological treatments.

KEYWORDS: Non-communicable chronic diseases in Brazil, Brazilian Public Health care, Homeostatic model criticisms, Allostatic model.

1 I IMPORTANCE OF NON-COMMUNICABLE CHRONIC DISEASES

Life expectancy may be abbreviated either by a neonately disease and diarrhea or infections early in the life or, by non-communicable chronic diseases (NCDs) later in the life. Therefore, as a result of the crescent NCD-associated mortality, life expectancy has been predicted to decline for the first time in recent history. Children born today may die at a younger age than their parents (Olshansky *et al.*, 2005). Besides its organic or mental failure,

NCDs affect also patient's autonomy for daily living activities which can be evaluated by the Disability-Adjusted Life Years (DALYS). In Brazil, NCDs responded, in 1998, for 66% of DALYS (Schramm *et al.*, 2004). Hence, it would be difficult to find anyone in our society who is exempt from the devastating effects of one or more chronic diseases. If an individual does not suffer directly from chronic disease, they most likely suffer indirectly as a result of the stress of care giving to others, the death of family members or friends, and/or increased health care costs (Booth *et al.*, 2000).

"Chronic disease" is defined as a disease that is slow in its progress and long in its continuance. Major examples of NCDs are cardiovascular diseases (including hypertension, atherosclerosis, coronary heart disease heart failure, and stroke), obesity, Type 2 diabetes (T2D), some cancers, allergy, osteoporosis, sarcopenia (and frailty), neurodegeneration, cognitive failure and depression. They account for 35 million deaths per year, which is 60% of all deaths globally. In 2007, it was estimated that 72% of all deaths were attributable to NCDs (Schmidt *et al.*, 2011) and increased to 74% in 2010 (Bertoldi *et al.*, 2013). The WHO predicts an increase of 17% in NCDs over the next decade globally (WHO, 2008a). Based on current trends by the present year (2020), NCDs are expected to account for 70% of deaths and 60% of the disease burden (WHO, 2011). The World Health Organization (WHO, 2002) statistics suggests that 80% of these deaths occur in low and middle-income countries. Economically, the World Bank estimated that countries such as Brazil lose more than 20 million productive life-years due to NCDs annually (World Economic Forum, 2008).

1.1 Non-Communicable Chronic Diseases in Brazil

Data sources on NCDs in Brazil are controlled mostly by the Ministry of Health through systems collecting data about morbidity, mortality and risk factors (Plano de ações estratégicas para … Brasil 2011–2022. Brasília: Ministério da Saúde; 2011). The Hospital Information System (SIH-SUS) aggregates patient level data on hospitals while the Ambulatory Information System (SIA-SUS) collects information on screening, treatment and exams. Additionally, there are the Family Budget Survey (POF), a household survey (every 10 yrs) measuring consumption, expenses and income of Brazilian families (since 1974) and the National Household Sample Survey (PNAD) since 1998, that provides periodic surveillance data (every 5 years) on NCDs nationwide. Since 2008 the survey also included information on morbidities caused by chronic diseases. In 2006, it was launched in all capitals the VIGITEL, which is a surveillance system of risk and protective factors for NCDs, through telephone interviews, and has been conducted since then on an annual basis. The most recent government action is the Brazilian Longitudinal Study of Adult Health (ELSA), a multicenter cohort study funded by the Ministry of Health aiming to investigate diabetes and cardiovascular disease incidence, risk factors and complications (Aquino *et al.*, 2012).

Specifically for Blood Hypertension and T2D there is a registration and follow-up system (HiperDia) composed by a computerized system restricted to health system units

that register prospective information on patients with hypertension and diabetes who are registered with a Health Unit or primary health care team (UBS) (Relatório de indicadores das … http://www2.datasus.gov.br/DATASUS/index.php?area=0203&id=6935). Aggregate data and reports (obesity, smoking, physical inactivity, dyslipidaemia) are also accessible on line (Plano de ações estratégicas para … Brasil 2011–2022. Brasília: Ministério da Saúde; 2011). However, evolution of the health care delivered by SUS is still done infrequently , particularly with regard to chronic diseases (Bertoldi *et al.*, 2013).

2 | THE BRAZILIAN PUBLIC HEALTH SYSTEM

Brazil, the world's fifth-largest population and seventh-largest economy, has a Public Health System intended to be free and universal. Since 1990 it has been organized by the Brazilian Unified Health System (SUS-Sistema Único de Saúde). SUS is intended to provide health care free of charge to the whole Brazilian population, financed through direct and undirected sources such as tax revenues, social contributions, out-of –pocket spending, and employers' health care spending. All publicly financed health services and most common medications are universally accessible and free of charge at the point of service for all citizens — even the 26% of the population enrolled in private health plans (Paim *et al.*, 2011; Barros & Bertoldi, 2008).

The SUS comprises public and private health care institutions and providers, financed primarily through taxes with contributions from federal, state, and municipal budgets. Health care management is decentralized, and municipalities are responsible for most primary care services as well as some hospitals and other facilities (Macinko & Harris, 2015). An important arm of the SUS is the Family Health Program (now called the Family Health Strategy, or FHS) evolved into a robust approach to providing primary care for defined populations by deploying interdisciplinary health care teams. The nucleus of each FHS team includes a physician, a nurse, a nurse assistant, and four to six full-time community health agents. Family health teams are organized geographically, covering populations of up to 1000 households each, with no overlap or gap between catchment areas. The households are visited by community health agents at least once a month. Such care is proactive, since the community health agents seek out problems before patients arrive at the health post. Teams also deliver public health interventions, such as contact tracing and immunization campaigns (Macinko & Harris, 2015).

2.1 Organizational Challenges

Despite its many accomplishments, the Brazilian health system faces serious financial and organizational challenges. On the human resources front, rapid expansion of the FHS has led to a physician shortage that Brazil has responded to with the controversial *Mais Médicos* (More Doctors) program, importing nearly 15,000 physicians from Cuba and other countries (Macinko & Harris, 2015).

Since responsibility for managing the FHS lies with the municipalities, there are also large variations in the capacity and quality of the family health teams, including varied availability of basic equipment, varied staffing patterns and availability of different types of health professionals, and varied management and other institutional supports for the teams. Technology use has been severely delayed in the SUS. New developments include proposals for the development of national electronic health records and enhanced access to diagnostic tools in primary care (Macinko & Harris, 2015).

The future of Brazil's FHS, its sustained expansion to the remaining urban centers and the middle classes, and its effective integration into secondary and tertiary care will require continued engagement by health care providers and the public and continued financial, technical, and intellectual investments — all of which ultimately depend on sustained political support (Macinko & Harris, 2015).

2.2 Financing Healthcare

The cost of ill health or illness is not only physical and psychological, but also social and economic: "... illness itself... can threaten people's dignity and their ability to control what happens to them..." (WHO, 2000). Health systems have a responsibility not just to improve people's health, but to protect them against the financial cost of illness..." It stresses on the state's responsibility for investing in health and preventing economic losses due to unexpected disease. The challenge of healthcare financing is to mobilize sufficient funds for the health system and to apply (manage) those funds well. The gap between the health expenditure and health resources is increasing due to mostly three main factors (Laaser & Radermacher, 2006) : a) aging of the population and epidemiological transition to chronic, life-long morbidity; b) fast development of health science and technology and c) incompetent health policy, governance and management.

Mobilizing funds to finance public health interventions is difficult both because health services are becoming more and more costly and because raising revenues in low- and middle-income countries is not easy. Facing this constant increase in the financial deficit, governments worldwide are facing the dilemma: increase in the resources (revenues) or restriction of the expenditures. By restricting the resources for medical care, this may eventually cause decrease in the quality of health services and in the human capacity in health (Shipkovenska *et al.*, 2008).

2.3 Public Investments In Health Care

According to the WHO (WHO-Global Health Expenditure database) US$ 1039 per capita was spent for health expenditures in 2012. In relationship to their GDP (Gross Domestic Product), the Organization for Economic Co-operation and Development(OECD) estimated the amount of money that its country members spent with health as averaging 7.% in 1990 and 8.9% in 2004. During the year of 2004, the expenditure of the US with health care increased by 7.9% (US$ 1.9 trillion) compromising 16% of the GDP (Tanne, 2006).

The Brazilian government expenditure in health achieved 4.1% (in 2000) and 5.4%(in 2007) of its overall expenditures in those years. These figures corresponded to 7.2% and 8.4% of the country's GDP, respectively, a 16.7% increase. The health expenditure per capita was calculated as US$ 202 in 2000 and US$ 348 in 2007. Latter data had showed that Brazil currently spends about $50 annually per person on the FHS program, denoting FHS as extremely cost-effective (Rocha & Soares, 2010). However, according to the Brazilian health care system 40% (year 2000) and 41.6% (year 2007) were expended by the government and the remainder by the private health care (WHO, 2008b). Therefore, although total health spending in Brazil is considered similar to the average (about 9%) of GDP found among the countries of the Organization for Economic Cooperation and Development (OECD), less than half this amount comes from public sources — a proportion that places Brazil far below the OECD average for government share of health expenditures (Macinko & Harris, 2015). Thus, seems that Brazilian government is not playing correctly his expected rule in the "health financial game"!

2.4 Public Investments In Medical Drugs

The Brazilian Universal Health System (SUS) is committed to offer high-quality health care to the entire population, including the distribution free of charge of a list of essential medicines aimed at treating the most prevalent diseases in the population (Bertoldi *et al.*, 2012).

There are three types of medicines available in the Brazilian market: originator brands, generics and similar medicines (Brasil: Agência Nacional de Vigilância Sanitária Decreto n°.3.961, 2001). All generic medicines must be commercialized with no brand. Generics are medicines which are interchangeable with the originator brand (subject to the standard bioequivalence and bioavailability tests) (Brasil: Agência Nacional de Vigilância Sanitária, 2007). Bioequivalence is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same. Birkett (2003) defined bioequivalence by stating that, "two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards"(Birkett, 2003).

Similar medicines are all the others available on the market. This type of medicine is comparable to "branded generics" described in the international literature. Branded generics are generics whose manufacturers launch them with a particular brand name, which can be a 'fantasy' or invented name (protected by trademark law), or the name of the manufacturer

followed by the name of the molecule (Kanavos *et al.*, 2008). Until recently, similar medicines were required to undergo pharmaceutical equivalence, but not bioavailability tests, making them frequently cheaper than generics. However, there was a transition period expired at the end of 2014 enabling them to be on the market without these tests (Brasil: Agência Nacional de Vigilância Sanitária, 2007).

2.5 Medical Drugs Affordability in Brazil

The free distribution of medicines in Brazil began in 1971, focusing on poor population. In 2004, it was created the program "Farmacia Popular"(Popular Pharmacy) as a partnership between the federal government and states/municipalities aiming at increasing access to low-cost essential medications for the Brazilian population (Brasil. Conselho Nacional de ... Brasilia: CONASS, 2011).

The program sells medicines at low prices to the population, particularly those who use private health facilities but who have difficulty in buying their medicines in private pharmacies (Brasil: Ministério da Saúde. Programa Farmácia Popular, 2005). There are two types of "popular pharmacies": (a) those which are run by the state, city governments, universities or other health-related institutions. In these pharmacies, medicines from a list comprising 95 molecules selected on the basis of the most prevalent health problems in Brazil or which are expensive for individuals to acquire, are sold at cost prices. These facilities are considered exclusive "popular pharmacies"; (b) those which are run in partnership with private pharmacies using a system of co-payments. This category was created in 2006 as a means to expand the popular pharmacy program. This strategy was expanded to include private pharmacies and drug stores, named "Aqui tem Farmacia Popular"(Popular Pharmacy is Available Here) (Brasil. Conselho Nacional… CONASS, 2011). As part of this program, the Ministry of Health began subsidizing 90% of the reference price of 24 medicines, whereas the patient pays the remaining 10%. However, only a list of anti-hypertensive, anti-diabetic and contraceptive medicines are sold in this way (Brasil: Ministério da Saúde. Programa Farmácia Popular, 2005). This program covers more than 2,500 municipalities (almost half of the actual existing cities) and is available to 1.3 million Brazilians in need of medication (Plano de ações estratégicas para … (DCNT) 2011–2022. Brasília: 2011).

In September 2006, a law was enacted to ensure the free distribution of diabetic medicines and also the necessary equipment to monitor capillary glycaemia for all SUS insurees. In march 2011, the Brazilian government launched a program called "Saúde não tem preço" (Health has no price) to expand access to medicines for diabetes and hypertension. In this program, the pharmacies and drug stores linked to the Popular Pharmacy network started to offer free medicines for the treatment of hypertension and diabetes in more than 17,500 registered private pharmacies. A month after its launch, more than 3.7 million treatments were distributed representing an increase of 70% in the distribution of medicines for hypertension and diabetes (Plano de ações estratégicas para … (DCNT) 2011–2022. Brasília 2011).

In the first decade of this century(2002-2006), the prescription drug costs was the increasingly large component of overall health care costs of the Brazilian Ministry of Health, varying from 5.4% to 11% of total expenditure. The expenditure with prescription drugs to either chronic or rare diseases increased from US$ 215 million(R$ 516 million) in 2003 to US$ 542 million(R$ 1,3 billion) in 2006. Overall, the increased expenditure with drugs varied from 16.36% in 2002 to 49.7% in 2003 and 45.85% in 2005, summing up 123.9% (2002-2006) (Vieira & Mendes, 2007).

3 I THE BRAZILIAN MEDICATION POLICE CRITICISMS

3.1 Accessibility to Medical Drugs

Effective health systems must provide more than health prevention and promotion activities; they must guarantee access to quality services and goods, especially essential drugs (Nobrega *et al*., 2007). The access to essential medicines is recognized by WHO as one of the five indicators of advanced warranties related to the health rights (Hogerzeil & Mirza, 2011). The insufficient access to medicines is directly associated with illness worsening, more use of alternative therapies, great number of outpatient next-visiting to the Health Services and additional costs to the treatments (Arrais *et al.*, 2005).

At the beginning of the century, it was estimated that one in every three people worldwide would not have access to medical drugs, being the situation even worsened in countries presenting low-middle income, in which the proportion would increase to 50% (WHO, 2001). In these countries only one in every three public institutions have the chance to provide the medical drug looked for the population (Cameron *et al*., 2009). The access to medical drugs occurs through geographical availability, affordability capacity and drug acceptability, all leading to the rational use of the product (CPM, 2003).

3.2 Availability and Affordability

Medicine access relates to both affordability and availability (available stock of essential medicines in pharmacies). While Brazil's national drug policy calls for distribution of essential drugs through the universal public health system(SUS), the stocking of these drugs in outpatient facilities is still deficient (Brasil, Ministério da Saúde. Portaria n° 3.916, 1998). The stocking and continued availability of medical drugs adequately to the population needs has been challenges struggled by the Brazilian authorities since the 90s with implementations of public policies (Política Nacional de Medicamentos-PNM, Política Nacional de Assistência Farmacêutica-PNAF, Política de Medicamentos Genéricos, Programa Farmácia Popular) (Vieira, 2010). International evidence, using data from 36 low and middle-income countries, showed that in the public sector, availability ranged from 29 to 54% (Cameron *et al*., 2009).

Early in 2003, during the Brazilian phase of "*Pesquisa Mundial de Saúde* (PMS)", the prevalence found for drug availability was 87% (Carvalho *et al.*, 2005). Another study revealed an average availability of only 50% of items intended for distribution (Karnikowski *et al.*, 2004). For 71% of medicines the availability of generics was found below 10% (Miranda *et al.*, 2009). Availability, particularly in the public sector, is an issue of considerable concern in Brazil. On average, 40% of the medicines prescribed in public primary health care were not available when needed (Naves *et al.*, 2005; Santos & Nitrini 2004). Thus, the available literature have shown that, almost 30 years after the first Brazilian essential drugs list was created, the essential drugs are only moderately available (Naves & Silver, 2005; Guerra *et al.*, 2004).

The availability of essential drugs in cities of Minas Gerais state presenting Human Development Index (Índice de Desenvolvimento Humano -IDH) lower than 0.699, showed higher availability levels in the private stores(81.2%) compared to Health Public Units(46.9%) (Guerra *et al.*, 2004). Similarly, data from private and public stores and those belonging to the 'Programa Farmácia Popular no Brasil", also had shown in the public sector, the lowerest availability of the medical drugs (Pinto *et al.*, 2010). These results were also replicated in Brazilian southern cities (Bertoldi *et al.*, 2012; Helfer *et al.*, 2012). In 2005, populations from south and northeastern regions of Brazil, had shown that 81.2% of the adult subjects had fully access to the prescribed continued- drugs (Paniz *et al.*, 2008). However, these numbers have to be interpreted carefully because population-based studies about medicines access are scarce in this country and, frequently restricted to specific offers of services and medical drugs which provide higher than the population data (Miranda *et al.*, 2009; Pinto *et al.*, 2010; Bertoldi *et al.*, 2012; Andrade *et al.*, 2010).

Nationwide data from the National Household Sample Survey (2008) analyzing sample consisted of individuals with prescriptions written in the National Health System in the two weeks prior to the interview had shown prevalence of access to medicines as 45.3%. Hence, in spite of SUS relevance in providing free drugs to the population, less than half of those people that had prescribed drugs by the System had obtained fully all the prescribed drugs from the System (Boing AC et al., 2013). This could explain why more than half of studied people had to appeal outside the public sector in order to obtain their desired therapeutic treatment.

3.3 Inequities to Access to Prescribed Drugs

Important advances have been seen with the governmental policy (Política Nacional de Medicamentos and the Política Nacional de Assistência Farmacêutica), that have established definitions and guidelines for the medical drugs access. These policy defined the rules for the utilization of those essentials drugs on the list (RENAME), the generic drug regulation, prices control, incentive to official-laboratories and, production and assistance reorientations by forming and enabling human resources (Brasil: Ministério da Saúde. Portaria nº 399, 2006).

Although access to medicines in Brazil is high, socioeconomic inequities are observed (Bertoldi *et al.*, 2004; Bertoldi *et al.*, 2009). When considered together the public and private sectors, the Brazilian studies had evidenced higher figures for the drugs access but still with deep inequities among users (Arrais *et al.*, 2005; Paniz *et al.*, 2008). Data from the National Household Sample Survey (2008) analyzing sample consisted of individuals with prescriptions written in the National Health System in the two weeks prior to the interview had shown prevalence of access to medicines slightly fewer than half of the sample with prescriptions received the medicines in the public health system; the proportions were higher in the South of Brazil, among black patients, those with less schooling and lower income, and those registered in the Family Health Strategy. When analyzing prescriptions written by the private sector, access to all the prescribed drugs was associated with higher income, higher education, and white skin color (Boing et al., 2013). The referred characteristics of dark skin, lower schooling and lower income is very common in the literature for the people with higher access to the medical drugs (Bertoldi *et al.*, 2004; Aziz *et al.*, 2011).

Higher prevalence of access(around 90%) was detected in higher age, higher income and higher schooling populations; in those presenting chronic diseases and those participating in health promoting groups linked to the Health Basic Units(UBS) and, also in those covered by the Family Health Strategy (Paniz *et al.*, 2008; Carvalho *et al.*, 2005; Bertoldi *et al.*, 2009). The strong and inverse relationship found between socioeconomic status and underutilization of medical drugs points out toward evidences that expressive part of the Brazilian population have the SUS as the only alternative for medicine therapy (Luz *et al.*, 2009). This hypothesis is straightened by the fact that these groups showing more accessibility to SUS medicines have more difficulty in getting them outside the public system. This indicates these people as being of the lower purchase capacity class and therefore with more dependency to the public sector. *The results emphasized the need for policies to decrease inequalities in access to medicines in Brazil (*Boing *et al.*, 2013; Bertoldi *et al.*, 2004; Aziz *et al.*, 2011).

The drug access through the SUS is still insufficient but the System has demonstrated to promote equality. The effective access of population to the medicines will depend upon governmental improvements related to financial capacity, effectiveness in using the public resources and, market regulation (Bermudez *et al.*, 2004). Therefore, besides the obtained rule achievements, further advances will depend upon selection and rational use of medicines, sustained financing, affordable prices and appropriate drug supplying system, overall yet to be consolidated in Brazil (WHO 2004).Thus, strategies are necessary to increase accessibility to medical drugs in order to decrease the inequalities to the drugs access.

3.4 Out-of-pocket

Charging patients for medicines is strictly prohibited in the public system. In real life, however, medicines are often not available when needed. This means that most families must obtain basic pharmacotherapy through one of Brazil's approximately 50 000 private pharmacies. The Brazilian retail market is formed mainly by independent pharmacies (around 90% of the pharmacies). The five main chains of pharmacies represent only 2.8% of the total number of pharmacies in the country, although they were responsible for 23% of the market share of medicines in 2010 (A companhia Mercado de Atuação, 2011).

Retail prices are the result of a series of factors, such as procurement prices. In the public sector, a series of different procurement models is used by governments from developing countries to purchase medicines and other health products. An increasing number of countries have opted to decentralize the procurement process as an effort to answer to local needs. The decentralized purchase involves different levels of responsibility in the procurement process at the federal, state and city levels (WHO, 2011). In Brazil, the procurement of medicines in the public sector is decentralized at different government levels. All purchases are carried out by invitation, following a Federal Law, and usually are made directly from the manufacturers (Brasil: Lei n°. 8.666, 1993).

Considering the heterogeneity of the Brazilian municipalities, regarding size as well as organization, there are relevant differences in the procurement prices of medicines (Ferraes & Cordoni, 2007). However, many Brazilian municipalities are already organized to purchase in large scale, which may lead to better prices (Vieira & Zucchi, 2011). In the private sector, the volume of purchases in the pharmacies is usually low, resulting in purchases from wholesalers, increasing the price for consumers. There is an exception related to the big chains of pharmacies, which can centralize the procurement process decreasing significantly the medicine costs, usually transferring it to the final consumer (Agência Nacional de Vigilância Sanitária. Pós-comercialização / Pós Uso. Regulação de Mercado, 2011). In the wave of deregulation that swept Latin America in the late 1980s and early 1990s, Brazil largely deregulated pharmaceutical prices in 1992. Price is clearly the single, greatest barrier to the population's access to essential drugs (Henry & Lexchin, 2002; Steinbrook 2002; Pecoul *et al*., 1999) and, *it is a key obstacle for consumer access to essential drugs, especially in developing -countries* (Nobrega *et al*., 2007).

The retail price of all drugs on Brazil's Essential Drugs List, July 2000 edition, were compared to the retail price of the same drugs on the Swedish market. For the 132 drugs that were listed on both Brazil's and Sweden's lists, unitary retail prices in Brazil were 1.9 times higher. Of the 94 drugs found on both Brazil's list and the international unit-price indicator, Brazil's national mean unit prices were 13.1 times, more expensive. Conclusively, average retail prices of essential drugs in Brazil are significantly higher than in Sweden (Nobrega *et al*., 2007). Data on prices of 50 medicines were collected in 56 pharmacies

across six cities in Southern Brazil and it was found that in the private sector, prices were 8.6 MPR for similar medicines, 11.3 MRP for generics and 18.7 MRP for originator brands, respectively (Bertoldi *et al*., 2012). Furthermore, international bulk prices indicate that drugs are brought to market by Brazil's private pharmacies at prices that may be excessively high in relation to production costs, creating high profit margins. The expected price-lowering effects of competition were not identified. International evidence, using data from 36 low and middle-income countries, showed that the Brazilian medicine prices for private patients were 9 to 25 times higher than international reference prices for generics and 20 times higher for originator products (Miranda *et al*., 2009; Cameron *et al*., 2009).

3.5 Catastrophic Health Expenditure

Although the majority of the Brazilian population uses SUS, 25% of all families pay for private health insurance, which in Brazil does not cover the costs of medicines used in ambulatory care (Viacava *et al*., 2005). In spite of being considered a free of charge and universal covered Public Health System, the money expended with medicines in private pharmacies is expressive in Brazil (Bertoldi *et al*., 2009). In 2007, Brazilian families spent 10 times more money on medicines than the government (IBGE, 2009).

Despite poor families receiving more medicines free of charge from government-funded sources than the better-off, 25.5% of the medicines obtained by the bottom income quintile of the population are paid for out-of-pocket (Bertoldi *et al*., 2009). In the study analyzing *data from the* National Household Sample Survey *(2008) a*pproximately, two out three subjects consulted by SUS in the previous two weeks of the interview had at least one drug prescribed by the SUS. In this group the prevalence of achieving all the drugs by the SUS was 45.3%. Among those that were unable to receive medicines from SUS, mostly (78.1%) bought at the private sector. The two major causes of not acquiring medicines were lacking of enough money(51.5%) and the inexistence of the drug on that pharmacy(14.6%) (Boing *et al*., 2013). Precluded payment and unavailability of specific drugs on pharmacy stock were, though, the reasons why 13% of prescribed medicines had not being acquired (Carvalho *et al*., 2005; Pinto *et al*., 2010).

The shortage of money as reason for drugs unaffordability was also the determinant factor found in elderly people living in 41 cities from southern and northeastern regions of the country and attended by local Health Basic Units (Paniz *et al*., 2010). It is noteworthy that the migration of SUS users toward private sector or even to the co-payment situation to ensure the medicines access leads to higher income commitment with country's expensive health care, penalizing utmost the poorer population (Silveira *et al*., 2002; Boing *et al*., 2011). Overall, Brazilian families spend 9% of their household income on health, and medicines account for the largest proportion of all health expenses (Silveira *et al*., 2002); 31.5% of monthly health expenses and 2% of monthly family income were shown to be spent on medicines(Bertoldi *et al*., 2011).

Catastrophic health expenditure was defined if a household financial contributions to the health system exceed 40% of income remaining after subsistence needs have been met. This definition was established in a cross-country analysis designed data from household surveys in 59 countries (Xu et al., 2003). In a Brazilian cross-sectional Brazilian study (Pelotas RS, 2003) with representative sample of families covered by the Family Health Program medicines were responsible for 47% of household expenditure with health and about 16% households committed 20% or more of their income with health independent of economic position. Additionally, 12% of the households had health expenditure in excess of 40% of their capacity to pay therefore, reaching the catastrophic health expenditure status (Barros & Bertoldi 2008).

Thus, availability of medicines in the public sector seems not meet the challenge of supplying essential medicines to the entire population, as stated in the Brazilian constitution. This has unavoidable repercussions for affordability, particularly amongst the lower socio-economic strata and taking into account that both the availability of medicines, particularly in the public sector, and their price in the private sector are important determinants of access to medicines in Brazil (Boing *et al.*, 2013; Bertoldi *et al.*, 2012). Therefore, health policy makers have long been concerned with protecting people from the possibility that ill health will lead to catastrophic financial payments and subsequent impoverishment (Barros & Bertoldi 2008).

4 | EFFECTIVENESS OF BRAZILIAN PUBLIC CARE OF NCDS

The dominant form of health care in the U.S. and in many countries throughout the world provides a reactive visit-based model in which patients are seen when they become ill or symptomatic, typically during hospitalizations and at outpatient visits. This model falls short, not just because it is expensive and invariably fails to prevent chronic disease, but because nearly half of all health outcomes are determined by the unhealthy behavioral choices that people make on a daily basis (Schroeder *et al.*, 2007; Asch *et al.*, 2012).

The expansion of pharmaceutical care and the free distribution of most NCD medications play an important role in the Brazilian Government's effort to tackle those diseases (Brasil: Ministério da Saúde. Fundação Oswaldo Cruz. Programa Farmácia Popular do Brasil: Manual Básico, 2005). However, as in other emerging countries there is a lack of nationwide prevalence of NCDs. Fragmentary collected data considered 28.7% of the Brazilian adult population as hypertensive (Picon *et al.*, 2013) and 15.4% as hyperglycemic (Malerbi & Franco, 1991). These would end up as an individual cost of US$ 12.66 for each hyperglycemic (of total expenditure of US$ 195 mi). The estimates of the direct annual cost of treating Hypertension in Brazil varied between U$ 372.9 million (best case scenario) to U$ 1.3 billion (worst-case scenario). When looking at the cost-effectiveness scale it is unquestionable the fact that prevalence of diabetes and hypertension are rising in parallel

with that of excess weight as main NCDs burden in Brazil (Schmidt *et al.*, 2011). In fact, from 2006 to 2010, according to VIGITEL, the self-reported prevalence of diabetes increased from 5.3% in 2006 to 6.3% in 2010, leading to an approximate 20% increase (Bertoldi *et al.*, 2013). Hypertension is estimated to present a 60% increase by the year 2025 (WHO 2002). Projections are that by the year of 2025, 75.0% (or 1.17 billion people) of the people with hypertension in the world will be living in emerging nations (Kearney *et al.*, 2005). Thus seems that besides onerous, the SUS care of NCDs has been demonstrated ineffective in controlling these diseases. Underlying why drug therapy has been largely unsuccessful in halting and reversing the NCDs epidemic would be the ineffectiveness of the treatment approach.

5 I NCD THERAPEUTIC MODELS

Any stimulus, no matter whether social, physiological, or physical, that is perceived by the body as challenging, threatening, or demanding can be labeled as a stressor. The presence of a stressor leads to the activation of neurohormonal regulatory mechanisms of the body(stress), through which it maintains the homeostasis (Dimitrios *et al.*, 2003). These alterations can be viewed as a consequence of general adaptation syndrome and usually return to their normal status once the stimulus has disappeared from the scene (Akhalaya *et al.*, 2006). Both homeostasis and allostasis are endogenous systems responsible for maintaining the internal stability of an organism (Burini 2020, Rahal *et al.*, 2014).

5.1 Homeostasis Model

Homeostasis describes mechanisms that hold constant a controlled variable by sensing its deviation from a “setpoint” and feeding back to correct the error. Based on this model physicians reason that when a parameter deviates from its setpoint value, some internal mechanism must be broken. Homeostasis treats low level targets. Consequently they design therapies to restore the “inappropriate” value to “normal”. By standard pharmacotherapy, drugs can force the response back to the original level, despite continued prediction of high demand, but this compresses responsiveness. While demand stays high, drugs that antagonize key effector mechanisms force the response distribution back toward its initial mean. But this reduces responsiveness and evokes iatrogenic effects. This should be expected because the organism must continue to meet elevated demand but with fewer or weaker effectors(Burini 2020). For these and another reasons, “low-level” pharmacological treatments still face major problems such as “the very high rate of discontinuance or change in medications. These high discontinuance rates are considered to reflect, among other factors, “a combination of adverse drug effects, cost of drugs, and poor efficacy” (Sterling & Peter, 2004; Carretero and Oparil, 2000).

In medicine, major diseases now rise in prevalence, such as obesity, type 2 diabetes, hypertension and metabolic syndrome, whose causes the homeostasis model cannot explain. Coincidentally, they all have evolutionary thriftiness involved in their contemporary origin (McLellan *et al.*, 2011; Burini et al. 2013a; Burini et al. 2013b; Burini et al. 2016; Burini et al. 2017b)

5.2 Allostasis Model

Constancy is not a fundamental condition for life. Most biologists now agree that the true object of all the vital mechanisms is not "constancy" but survival to reproduce. Yet the goal is not constancy, but coordinated variation to optimize performance at the least cost. This is the core idea of allostasis. The concept of allostasis, maintaining stability through change, is a fundamental process through which organisms actively adjust to both predictable and unpredictable events (Burini 2020). This can be carried out by means of alteration in HPA axis hormones, the autonomic nervous system, cytokines, or a number of other systems, and is generally adaptive in the short term (McEwen & Wingfield 2003). Thus, allostasis is adaptation but in regard to a more dynamic balance, it is essential in order to maintain internal viability amid changing conditions (McEwen & Bruce, 1998a; McEwen & Bruce, 1998b).

The allostasis model defines health as optimal predictive fluctuation. A system becomes unhealthy when, high demand predominates for long times, effectors adapt so strongly that they cease to follow promptly when the prediction reverses and, system does not return to the initial state.The allostasis model of physiological regulation, attributes NCDs diseases to sustained neural signals that arise from unsatisfactory social interactions. Consequently, allostasis model attributes the pathogenesis of obesity, metabolic syndrome and its components to prolonged adaptation to hypervigilance and hyposatisfaction. The impact is strongest among populations with the best reasons for vigilance, the narrowest range of satisfactions, and expectations that are least often met. Consequently the allostasis model would redirect therapy, away from manipulating low-level mechanisms, toward improving higher levels in order to restore predictive fluctuation – which under this model is the hallmark of health (Burini 2020; Sterling & Peter, 2004).

5.2.1 Lifestyle Changing

Differently from treating low level targets by drugs (homeostatic model), a more rational goal of intervention would be to shift the predicted distribution of demand back toward its original level. This would allow the effectors to naturally reestablish flexible variation around the predicted lower demand, thus preserving the range of responsiveness. In other words, by rational therapy, when demand is reduced for long periods, the system re-adapts to the initial demand distribution (Sterling & Peter, 2004). Thus, because drug therapy has been largely unsuccessful in halting and reversing the NCDs epidemic, it may

be argued that more emphasis must be placed on novel approaches to enhance current primary prevention guidelines (Burini et al. 2020). Overall, it is known the prevalence of NCDs is rising in parallel with that of excess weight and these increases are associated with unfavorable changes of diet and physical activity (Schmidt *et al.*, 2011).

A prevention or rehabilitation model, focused on forestalling the development or progression of chronic diseases before debilitating symptoms or life-threating events occur (Marvasti & Stafford, 2012) with specific emphasis on those population subsets that are disproportionately affected by the actionable determinants of health (Schroeder, 2007) offers a viable alternative to proactively improve public health. With this model, self-responsibility (e.g., meeting certain health metrics) will become a greater priority, orchestrated in part by incentives and penalties (Sanderasa *et al.*, 2015).

The allostasis model hints that the biggest improvements in health might be achieved by enhancing public life. The guiding principle would be: do everything that promises to reduce the need for vigilance and to restore small satisfactions. Enhance contact with nature by building more parks and by providing communal opportunities to garden – i.e. not just to look at, but to grow flowers and vegetables. Enhance opportunities to walk and cycle by restricting automobile traffic. Prevent this restriction from becoming an annoyance by improving public transportation. Encourage broader participation in sports especially among youth – by constructing public facilities for gymnastics, skating, skate-boarding, climbing, and swimming (Sterling & Peter, 2004).

In a investigation (Li *et al.*, 2018) using data from the Nurses Health Study and Health Professionals Study over a 34-year follow-up, researchers reported that adherence to 5 healthy lifestyle factors (no smoking, body mass index ≤25 kg/m^2, ≥30 minutes of exercise per day, moderate alcohol consumption, healthy diet score) extended the lifespan up to 14 additional years for women and 12 for men. Unfortunately, conventional medical therapies do not address the underlying causes, that is, the most proximal risk factors for chronic disease, including poor dietary practices, physical inactivity, and cigarette smoking and/or exposure to secondhand smoke (Mozaffarian *et al.*, 2008).

Physical inactivity and overweight are common characteristics in Western societies. The growing worldwide burden of NCDs demands the implementation of effective population-based strategies in which diet and physical exercise are the pillars of treatment. Epigenetic studies have shown that the recommended approach to attack their conventional risk factors requires their underlying environmental causes: high-energy dense (sugar and fat) diets and physical inactivity (Burini *et al.*, 2013a; Burini *et al.*, 2013b; Burini *et al.*, 2016; Burini, 2017a; Burini *et al.*, 2017b). Regular exercise is probably the lifestyle intervention with the most profound up regulating effect on tissue maintenance and homeostasis (Fiuza-Luces *et al.*, 2013).

It is well known that exercise satisfies essential requirements for a healthy life. Physical exercise causes alterations in the expression of human skeletal muscle genes, as

a mechanism of adaptation not only to the mechanical load but also to the metabolic stress of exercise. Moreover, exercise raises levels of brain-derived neurotrophic factor and other growth factors known to serve synaptic plasticity and learning (Cotman & Berchtold, 2002). Physical activity could therefore be a natural remedy for recovering part of the imbalance caused by modern life-styles, costless and without the side effects of many pharmacological treatments (Burini 2017b).

The "paradigm shift" needs to move from not only helping patients when they are ill, injured, or sick, to "helping patients help themselves (24/7)." Helping patients improve health outcomes by combatting chronic diseases with cardiorespiratory rehabilitation will not only differentiate primary care physicians as proactive health care providers, but will help move us from the current reactive sick care model to proactive health care. It's time to change our emphasis from disease management/intervention to disease prevention, focusing on the foundational causes of chronic disease. The importance of healthy lifestyle factors, decreased sedentary behaviors, (Diaz *et al*., 2017) and complementary pharmacotherapies, is apparent. Chronic disease, which is responsible for the largest proportion of contemporary health care expenditures (Franklin, 2008).

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ÍNDICE REMISSIVO

V

Medicina:

Esforço Comum da Promoção da Saúde e Prevenção e Tratamento das Doenças

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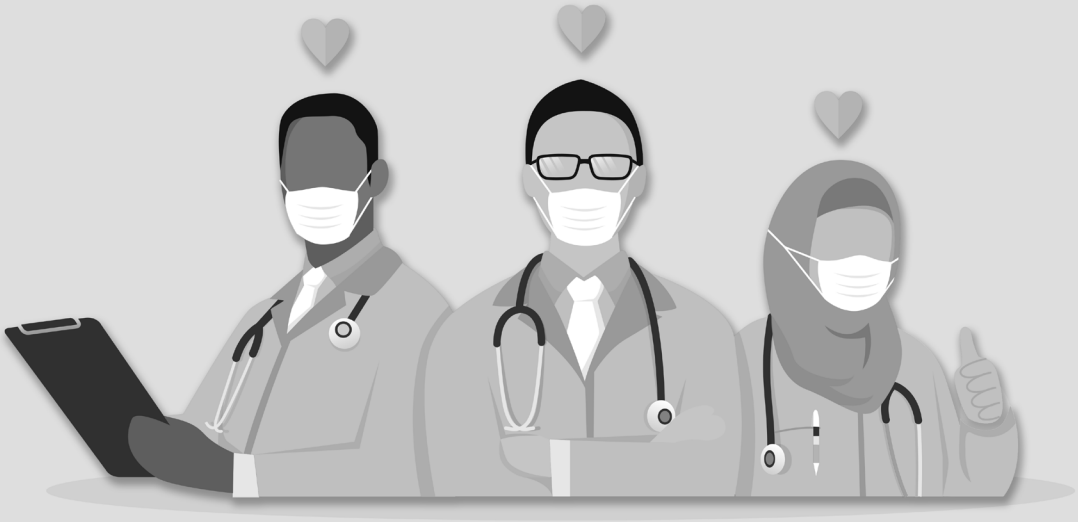

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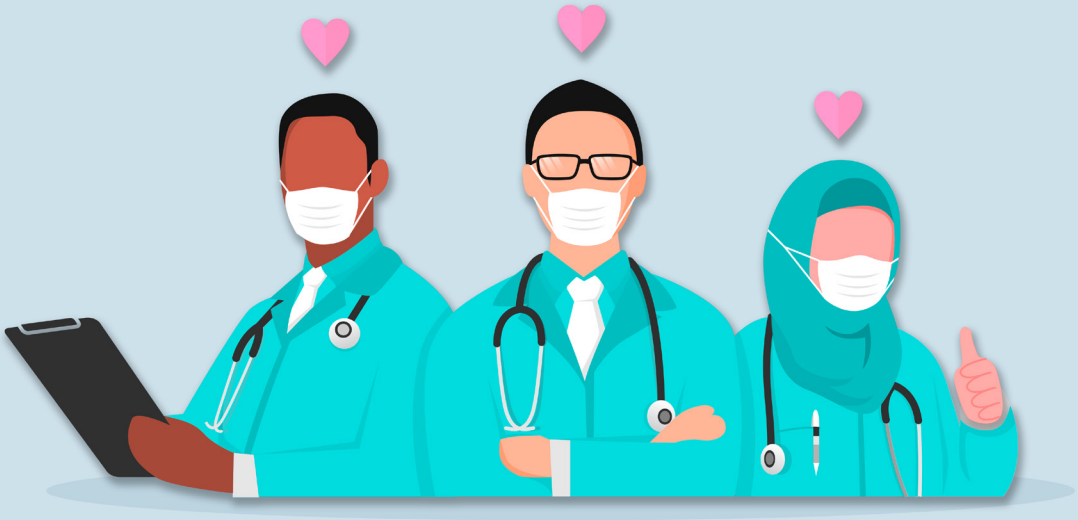

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