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Availability of herbal medicines and medicinal plants in the primary health facilities of the state of São Paulo, Southeast Brazil: results from the National Program for Access and Quality Improvement in Primary Care

Maria do Carmo Gullaci Guimarães Caccia-Bava [1]
Bianca Waléria Bertoni [2]
Ana Maria Soares Pereira [2]
Edson Zangiacomi Martinez [1]

Abstract *This study aims to describe the availability of herbal medicines and medicinal plants in the primary care facilities in the state of São Paulo, Southeast Brazil, from the results of the first cycle of the National Program for Access and Quality Improvement in Primary Care (PMAQ). The PMAQ uses a national cross-sectional multicenter design, with data from 4,249 health facilities distributed among 645 municipalities of the state of São Paulo. Of these facilities, 467 (11%) had herbal medicines and/or medicinal plants. Among the 645 municipalities, 104 (16.1%) had at least one health facility that provided these drugs. We observed that the availability of herbal medicines is greater in larger cities with better social and economic conditions. Furthermore, we found that use of industrialized herbal medicines prevailed over that of vegetal drugs or compounded herbal medicines.*

Key words *Medicinal plants, Herbal medicine, Unified Health System (SUS)*

[1] Departamento de Medicina Social, Universidade de São Paulo. Av. Bandeirantes 3900, Monte Alegre. 14049-900 Ribeirão Preto SP Brasil. mcbava@fmrp.usp.br
[2] Unidade de Biotecnologia, Universidade de Ribeirão Preto. Ribeirão Preto SP Brasil.

Introdução

Brazilian health legislation defines herbal medicines as those obtained through the exclusive use of active plant raw materials whose safety and efficacy are based on clinical evidence and are characterized by their constant quality[1]. This same legislation also covers traditional herbal products obtained with the exclusive use of active plant raw materials whose safety and effectiveness are based on data of safe and effective use published in the technical-scientific literature and that are designed to be used without the supervision of a medical professional for diagnostic, prescription or monitoring purposes[1].

In Brazil, the implementation of herbal medicine in public health services stepped up in the 1980s, and one of the major milestones was the publication of Interministerial Commission for Planning and Coordination (CIPLAN) resolutions, which established supplementary care[2] standards and guidelines. Subsequently, the publication of Collegiate Board of Directors Resolution (RDC) Nº 17 of the National Health Surveillance Agency (ANVISA) in February 2000 sought to standardize the registration of herbal medicines in the Health Surveillance System, establishing guidelines for ensuring the quality, efficacy and safety of these drugs. In turn, the Ministry of Health, through Ordinance Nº 971 of May 2006, approved the National Policy on Integrative and Complementary Practices (PNPMF) in the Unified Health System (SUS), including herbal medicine[3]. In that same year, The National Policy on Medicinal Plants and Herbal Medicines (PNPMF) was approved, which encourages research on medicinal plants and herbal medicines, prioritizing the country's biodiversity and stimulating the use of herbal medicine in public health programs[3-5]. Its general objective was *to ensure the Brazilian population safe access to and rational use of medicinal and herbal plants, promoting the sustainable use of biodiversity, the development of the production chain and the national industry*[3]. The consequent structuring and strengthening of these practices at the level of primary care brought about the need for studies on the knowledge of health professionals about this therapeutic modality and its intended use[6], system users' acceptance[7], the anthropological discussion on comprehensiveness[8], criteria for the population's safe access to medicinal plants[9], as well as other aspects that go beyond the clinical trials required for the regulation of drugs[10] and that involve professionals, population and government agencies. Following enactment of PNPIC and PNPMF, the Ministry of Health, through Ordinance Nº 886 of April 2010, established the *Farmácia Viva* ("Live Pharmacy") within the SUS, which is intended *to perform all stages, from cultivation, collection, processing, storage of medicinal plants, handling and dispensing of magisterial and officinal preparations of medicinal and herbal plants*[11]. Further details on the development of Brazilian legislation on herbal medicines are found in the articles by Batista and Valença[12] and Figueredo et al.[13].

Oliveira et al.[14] conducted a study based on data obtained from the DIRs (Regional Health Directorates, regional management structures), with the purpose of describing the situation of herbal medicine care in the State of São Paulo in 2003, the year prior to the publication of PNPIC. These authors identified that 12 municipalities of São Paulo used herbal medicine with incentive from the Municipal Government in the Public Network (Campinas, Cunha, Guaratinguetá, Herculândia, Pindamonhangaba, Piquete, Roseira, São José do Barreiro, Ribeirão Preto, São Lourenço da Serra, Cruzeiro and Dobrada) and 13 other municipalities developed or had their herbal medicine projects developed by health professionals.

There has been a significant increase in the number of publications on the insertion of herbal medicine in primary care since 2003[15], perhaps stimulated by the legislation regulating the practice in Brazil[4] and with the enactment of PNPIC and PNPMF, both in 2006. In 2014, Oliveira et al.[14] carried out a broad bibliographic survey of journal articles, theses and dissertations on the incorporation of herbal medicine in the Brazilian primary health care actions and programs, and identified 53 original studies on actions, programs and acceptance of herbal medicines and medicinal plants in SUS primary care. This study allowed us to sketch a panorama of the current situation of herbal medicine in the SUS, pointing to the scarce literature on this subject, perhaps as a consequence of a low academic and research promotion agencies interest, of the devaluation of medicinal plants as a research theme and the lack of integration of researchers from different areas of knowledge, aggravated by the fact that herbal medicine is a research area not well developed by Brazilian scholars in the area of collective health. As a result, authors highlighted the need to boost interaction between users and health professionals, as well as to develop a critical view of professionals and the population on the adequate use of these drugs.

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Some recent initiatives that may bring new knowledge for the availability and use of herbal medicines and medicinal plants in primary care include the National Program for Access and Quality Improvement in Primary Care (PMAQ), Ministry of Health[16]. PMAQ was established by Ordinance Nº 1.654 GM/MS of July 19, 2011, and aims mainly to evaluate facilities' infrastructure conditions and primary care quality and to develop technologies for assessing the quality of Brazilian primary care. Its observation module in the Health Facility contains a block of questions about the establishment's availability of medicinal plants or herbal medicines. These issues include information on the availability of dried/fresh plant, compounded or industrialized herbal medicine, as well as on eight herbal medicines from the list of the National List of Essential Medicines (RENAME, 2004 edition) for use in the SUS[17]. These drugs are obtained from the espinheira-santa (*Maytenus officinalis*), guaco (*Mikania glomerata*), artichoke (*Cynara scolymus*), sacred shell (*Rhamnus purshiana*), aroeira (*Schinus terebenthifolius*), devil's claw (*Harpagophytum procumbens*), soy isoflavone (*Glycine max*) and cat's claw (*Uncaria tomentosa*).

Thus, this study aims to describe the availability of herbal medicines and medicinal plants in the primary care facilities of the state of São Paulo based on the results of the first PMAQ cycle developed in 2011 and 2012 and made available in 2014.

Methodology

The evaluation of PMAQ's first cycle health policies, programs or services utilizes a national cross-sectional multicenter design. The tool used to obtain data is organized into three modules[18-19]: Module I – observation of variables to perform an infrastructure census of the primary care facilities; Module II – interview with professionals about the work process of the primary care team and verification of documents in the facility; and Module III – interview with users in the establishment about the experience of use, conditions of access, use of health services and satisfaction. Considering the three modules, the instrument comprises approximately 1,600 variables. The Ministry of Health counts on the partnership of several universities for the operationalization of the project, and data passed on to its partners in a stage prior to national disclosure, which will occur in its second cycle. Authors of this study had access to data because they were collaborators of the initiative.

Module I includes fieldwork with the collection of information on the infrastructure of primary care facilities in local visits, and the person in charge or coordinator of each facility is interviewed. This module's tool organizes this information in different sections, starting with the identification of the health facility, modality and primary care team professionals, external signaling, accessibility of the facility and its actions and services, working hours and structural characteristics. The tool then includes sections on basic pharmacy components, availability of immunobiologicals, diagnostic tests and information technology and telehealth equipment, as well as other materials and supplies. This study mainly uses the section entitled "Basic Pharmacy drugs components" of this tool, which includes the 25-question block on herbal medicines and medicinal plants. In the state of São Paulo, Module I responses can be considered as a census, since its questions were implemented in all basic health facilities.

Module II of PMAQ aims to obtain information about the team's work process and the organization of user care, and includes the verification of documents that will support the evaluation of the implementation of access and quality standards. In the state of São Paulo, professionals from 2,285 facilities from 413 municipalities responded to this module, which contains a block of questions on integrative and complementary practices. Module II is not understood as a census, since participation involves primary health care teams that voluntarily and formally joined the program, by contracting commitments and responsibilities between the teams, the municipal manager and the Ministry of Health. A question of this module asks if the team conducts health education activities addressing the use of medicinal plants and herbal medicines.

Within the PMAQ methodology and seeking greater equity in the certification of participating primary care teams, municipalities are classified into six strata that consider social, economic and demographic aspects, according to the following primary indicators: gross domestic product (GDP) per capita, proportion of the population with health insurance, proportion of the population with *Bolsa Família* (Family Grant), proportion of the population in extreme poverty and demographic density. According to specific weights, these indicators compose an index that assumes values from zero to ten, and strata are defined according to the criteria shown in Chart 1.

As additional information, data on the population size of each city of São Paulo were obtained from the website of the Brazilian Institute of Geography and Statistics (IBGE), according to information from the 2010 demographic census. The Municipal Human Development Index (HDI-M) proposed by the United Nations Development Program (UNDP) was used to characterize São Paulo municipalities according to a composite indicator. The HDI specifies three basic dimensions of development: income (HDI-I), education (HDI-E) and health (HDI-H). We obtained HDI data of São Paulo municipalities from the UNDP website (www.pnud.org.br).

Outcomes

We identified 4,249 health facilities distributed among the 645 municipalities in the state of São Paulo. Of these units, 637 (15%) are health posts, 3,260 (76.7%) health centers or primary health care facilities, 60 (1.4%) health outposts and 292 (6.9%) other type of facility. Only one São Paulo municipality, namely, Bom Jesus dos Perdões, did not participate with a health facility in PMAQ's Module I. We included 427 units in the state capital.

Among the 4,249 São Paulo state's facilities covered in this study, 467 (11%) had herbal medicines and/or medicinal plants, corresponding to 104 (16.1%) of the 645 São Paulo's municipalities. Considering municipalities with 30 or more health facilities, worth outlining are the municipalities of Marília, where 44 of 45 available health facilities had herbal medicines and/or medicinal plants (97.8%), Campinas, with availability recorded in 41 of 63 facilities (65.1%), and Sorocaba, with availability recorded in 15 of the 30 existing facilities (50%).

The map in Figure 1 highlights the municipalities with availability of herbal medicines and/or medicinal plants in at least one health facility. In the municipalities where these items were available, the median population size is 28,440 inhabitants, according to the 2010 demographic census (interquartile range, 7,042 to 87,270). In municipalities that did not provide these drugs in their primary health care system, the median of the population size is 11,290 inhabitants (interquartile range, 4,959 to 30,920). In addition, 46.2% of the municipalities with more than 200 thousand inhabitants have herbal medicines and/or medicinal plants. In the state of São Paulo, therefore, there tends to be a relationship between the availability of herbal medicines and the population size of the municipality.

Coordinators or heads of 24 health facilities reported making the fresh plant available (5.1% of the 467 that make available herbal medicines); these establishments were located in Campinas and Mauá (4 each), Ribeirão Preto and Pindamonhangaba (3 each), São Paulo and Presidente Prudente (two each), and one facility in each of the following municipalities: Cruzeiro, Santos, Presidente Venceslau, Presidente Bernardes, Cabrália Paulista and Marília. The reduced record of the use of *in natura* medicinal plants may be related to the lack of interaction between health and agriculture professionals. This reality can now be changed with the implementation of the *Farmácia Viva* (Live Pharmacy) program regulated by ANVISA[11].

Dry plants are available in 47 health facilities (10.1% of 467 units), of which 16 are lo-

Chart 1. Criteria for classification of municipalities in strata.

Stratum	Stratification criteria
1	Municipalities with scores lower than 4.82 and population of up to 10 thousand inhabitants.
2	Municipalities with scores lower than 4.82 and population of up to 20 thousand inhabitants.
3	Municipalities with scores lower than 4.82 and population of up to 50 thousand inhabitants.
4	Municipalities with scores between 4.82 and 5.4 and population of up to 100 thousand inhabitants; and municipalities with scores lower than 4.82 and population between 50 thousand and 100 thousand inhabitants.
5	Municipalities with scores between 4.82 and 5.85 and population of up to 500 thousand inhabitants; and municipalities with scores lower than 5.4 and population between 100 thousand and 500 thousand inhabitants.
6	Municipalities with population above 500 thousand inhabitants or with a score equal to or greater than 5.85.

Source: http://dab.saude.gov.br/sistemas/pmaq/estratos_para_certificacao.php.

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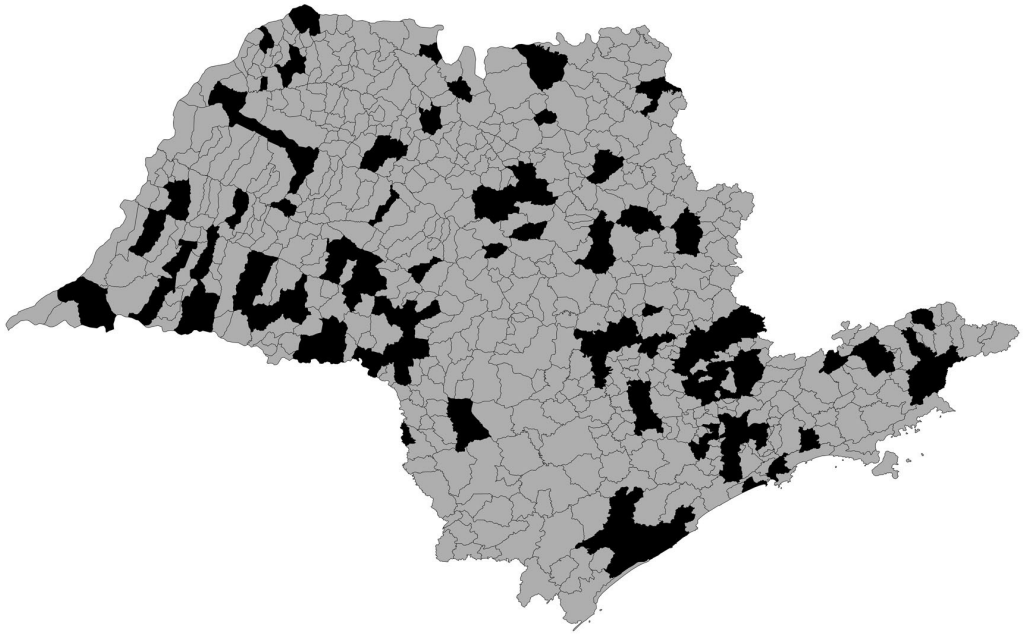

Figura 1. Map of the state of São Paulo highlighting in dark the 104 municipalities where at least one health facility provides herbal medicines and / or medicinal plants.

cated in Campinas, 15 in Marília, three each in Ribeirão Preto and in Mauá, two each in Santos and in Porto Feliz, and in one facility in each of the following municipalities: Borá, Cruzeiro, Lorena, Piracicaba, Santa Bárbara d'Oeste and São Carlos. Compounded drugs are available in 126 health facilities (27% of 467 units) and industrialized medicines are available in 318 facilities (68.1% of 467 units).

The chart of Figure 2 compares, by means of box-plots, the dimensions of the human development index (HDI) of municipalities that provide herbal medicines and/or medicinal plants through at least one health facility, and municipalities where there is no such availability. When comparing median HDI, shown in the lower part of the chart, municipalities with better human development indicators tend to provide herbal medicine.

According to the strata defined by the PMAQ for the process of certification of primary health care teams, in 17 São Paulo municipalities classified in stratum 1, herbal medicines and/or medicinal plants were available in at least one health facility, which is equivalent to 11.3% of the total. This percentage is 11.1% in stratum 2, 33.3% in stratum 3, 13.8% in stratum 4, 14.1% in stratum 5 and 36.0% in stratum 6. These percentages reinforce the trend that availability of herbal medicine is greater in larger municipalities with better social and economic conditions.

Table 1 describes the number of health facilities that provide RENAME's herbal medicines and lists the municipalities that reported availability in at least one facility. In this table, we highlight the municipality of Mauá, located in the Metropolitan Region of São Paulo, which supplied eight RENAME medicines to its population. However, this relationship of municipalities is incomplete, considering that, in 60 municipalities, health facility managers or coordinators reported to the PMAQ that their health establishment provided herbal medicines and/or medicinal plants, but could not specify the name of plants used.

Of the 2,285 professionals of primary health care teams who responded to Module II of the PMAQ, 273 (12%) stated that their team performs health education activities addressing the use of medicinal plants and herbal medicines. These professionals are distributed across 43 municipalities of São Paulo state, including São Paulo, Guarulhos, Campinas, São Bernardo do

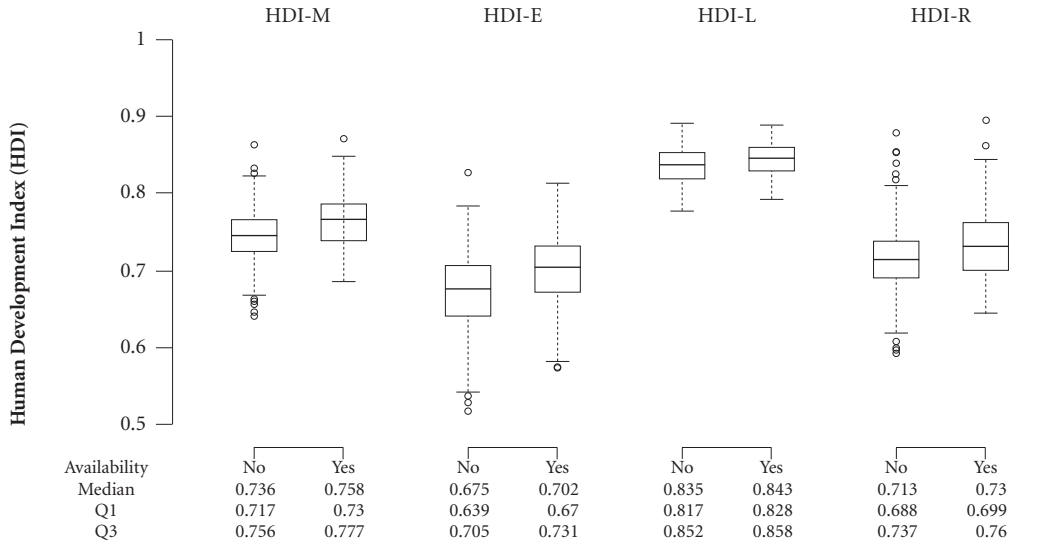

Figura 2. Box-plots for municipal human development index (HDI-M) and its education (HDI-E), longevity (HDI-L) and income (HDI-I) components of municipalities that provide herbal medicine and/or medicinal plants in at least one health facility and municipalities where there is no such availability. At the bottom of the chart, Q1 and Q3 refer to the first and third quartiles, respectively.

Campo, Santo André, Santos, Mauá, São José do Rio Preto, Diadema, Praia Grande, São Carlos, Marília, Jacareí, Araraquara and Presidente Prudente (municipalities with a population of more than 200 thousand inhabitants).

Discussion

PMAQ's results are based on the responses provided by health facilities' coordinators or heads and not on municipal programs that officiate or disseminate the use of herbal medicines. Therefore, in this study, the identification of a municipality with use of herbal medicines in primary care in place may be the reflection of isolated practices from health teams of one or more facilities, not describing official policies that structure such medical practice. However, the results obtained here are sufficient to outline the current situation of the use of herbal medicines in the state of São Paulo and it is suggested that future PMAQ information collection include additional questions about the existence of official programs for a more detailed characterization of these therapeutic practices.

Thus, this study showed that, according to PMAQ data, 104 municipalities in the State of São Paulo provide herbal medicines or medicinal plants. This number is significantly larger than that shown in the study by Oliveira et al.[14], which identified only 12 São Paulo municipalities that used herbal medicine with incentives from the Municipal Government in the Public Network in 2003. The study by Oliveira et al.[14] is prior to the publication of the PNPIC. The availability of RENAME's herbal medicines depends on a number of factors, including the municipality's interest in purchasing these medicines, doctors trained to prescribe them, cost, market availability and even prevalence of diseases that justify their supply in the municipality. The most available herbal medicine is guaco (*Mikania glomerata*) (Table 1), which has a wide tradition of use due to its expectorant and bronchodilator action[20]. There are no restrictions on the raw material of this herbal medicine in the Brazilian market[21], which is produced by several laboratories. The less prescribed drugs were devil's claw (*Harpagophytum procumbens*) and aroeira (*Schinus terebenthifolius*). Devil's claw is a species that does not grow in Brazil and costs of importing its raw material prevent its more intensive use[22]. While aroeira is a native species, it is not yet cultivated on a large scale, and there are not many laboratories producing herbal medicines from this species.

Costa et al.[23] report that herbal medicines are one of the main therapeutic options used by the

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Table 1. Availability of the herbal medicines of the National List of Essential Drugs (RENAME) for use in the SUS in health facilities and in the municipalities of the State of São Paulo.

Drug	Health Facilities		Municipalities that reported availability in at least one health facility	
	nº	%	nº	List
Espinheira santa (*Maytenus officinalis*)	61	13.1	12	Araçatuba, Borá, Cabrália Paulista, Campinas, Juquiá, Laranjal Paulista, Marília, Mauá, Porto Feliz, Registro, Santa Rita do Passa Quatro e São José do Rio Preto
Guaco (*Mikania glomerata*)	200	42.8	35	Adamantina, Anhumas, Araçatuba, Borá, Cabrália Paulista, Campinas, Campo Limpo Paulista, Cândido Mota, Cotia, Cruzeiro, Itariri, José Bonifácio, Laranjal Paulista, Lorena, Marília, Mauá, Narandiba, Ourinhos, Paraguaçu Paulista, Pindamonhangaba, Piracicaba, Pompéia, Porto Feliz, Praia Grande, Presidente Prudente, Registro, Ribeirão Preto, Roseira, Sandovalina, Santa Rita do Passa Quatro, São José do Rio Preto, Sorocaba, Taquaritinga, Teodoro Sampaio e Tupi Paulista
Artichoke (*Cynara scolymus*)	49	10.5	12	Borá, Cabrália Paulista, Campinas, Cruzeiro, Ipauçu, Laranjal Paulista, Marília, Mauá, Paraguaçu Paulista, Registro, Ribeirão Preto e Santa Rita do Passa Quatro
Sacred shell (*Rhamnus purshiana*)	53	11.4	17	Alvinlândia, Borá, Cabrália Paulista, Cândido Mota, Cotia, Ipauçu, Itápolis, Laranjal Paulista, Marília, Mauá, Paraguaçu Paulista, Pindamonhangaba, Piracicaba, Registro, Ribeirão Preto, Santa Rita do Passa Quatro e São Carlos
Aroeira (*Schinus terebenthifolius*)	22	4.7	3	Borá, Mauá e Ribeirão Preto
Devil's claw (*Harpagophytum procumbens*)	23	4.9	4	Cabrália Paulista, Laranjal Paulista, Mauá e Registro
Soy isoflavone (*Glycine max*)	109	23.3	26	Alvinlândia, Anhumas, Borá, Cabrália Paulista, Cândido Mota, Dobrada, Ipauçu, Laranjal Paulista, Lorena, Marília, Mauá, Narandiba, Ouroeste, Paraguaçu Paulista, Porto Feliz, Praia Grande, Presidente Prudente, Registro, Ribeirão Preto, Salto Grande, Santa Rita do Passa Quatro, São Carlos, São José do Rio Preto, Sorocaba, Teodoro Sampaio e Tupi Paulista
Cat's claw (*Uncaria tomentosa*)	49	10.5	9	Cabrália Paulista, Ipauçu, Laranjal Paulista, Mauá, Presidente Prudente, Registro, Ribeirão Preto, Santos e São José do Rio Preto

population of Campinas, which can be explained by the implementation of the Municipal Herbal Medicine Policy, which encourages the use of this treatment and provides access to herbal medicines in municipal pharmacies. Nagai and Queiroz[24] describe that Campinas pioneered the introduction of homeopathy and herbal medicine in primary care, and the first initiatives occurred in the 1990s by pressure from physicians interested in introducing these therapeutic forms into health facilities.

The organization, structuring and strengthening of herbal medicine in the SUS in Campinas are described in detail by Silva[25], who reports that the use of medicinal plants and herbal medicines in the primary care of the municipality is a relevant instrument for establishing links between system users and health professionals, as well as favoring a comprehensive approach to health and resuming and strengthening popular culture. In this study, of the 63 health units in the city of Campinas that participated in the PMAQ, 41 (65.1%) reported the availability of herbal medicines and/or medicinal plants. The survey conducted also in Campinas by Nagai and Queiroz[24] in the first half of 2004 identified that 29.4% of the facilities provided herbal medicine to the population. These numbers demonstrate the expressive growth of this therapeutic practice in this city.

An important factor that certainly contributes to the use of medicinal plants and herbal

medicines in municipalities is municipal laws, which in some way ensure that programs subsist regardless of the change of political management, such as Law Nº 13.888 of July 19, 2010, which provides for the implementation of the Municipal Herbal Medicine Program in the Public Health Network of Campinas, Law Nº 14.903, of February 6, 2009, which provides for the creation of the Program for the Production of Herbal Medicines and Medicinal Plants in the municipality of São Paulo, and Law Nº 8.254 of September 12, 2007 that establishes the implantation of Natural Therapies in the municipality of Sorocaba. This type of policy action is usually a population-led movement and health professionals interested in implementing herbal medicine at the municipal level.

Extrapolating the issues that involve the possibility of cost reduction, advocated by some authors[10,26,27], and increased treatment options in general, and considering that primary care services have the founding value of establishing links between users and health teams and a strong community and family appeal, we also state that the use of herbal medicine is compatible with the premise that knowledge and respect for people's culture adds meaning to the production of care and greater adherence to their practices, singled out for being built from subjects' genuine references.

As an additional comment, it is observed that four other plants were added to the list for use in the SUS in the 2013 edition of the National List of Essential Medicines (RENAME), namely: mint (*Mentha x piperita*), blond psyllium (*Plantago ovata*), willow (*Salix alba*) and aloe (*Aloe vera*)[28]. In the second PMAQ External Evaluation Cycle conducted in 2014 and with databases in the final organization stage by the Ministry of Health, these plants are already included in the conventional primary health care and Family Health Strategy facilities assessment tool. Thus, the use of herbal medicine in the country can be periodically monitored to allow an increased use of this medicinal resource as a health care strategy.

Conclusions

This study evidences an increased use of herbal medicines in the primary healthcare network in the state of São Paulo following PNPIC and PNPMF publications, when comparing the PMAQ results with the previously published studies. In addition, we can observe that the availability of these practices to the population tends to be greater in cities with larger population size and with more favored socioeconomic indicators. This calls for actions that favor greater supply and distribution of herbal medicine considering the size of the state of São Paulo, requiring investments in the training of health professionals in relation to herbal medicine practices, sensitization of managers, joint practices among professionals and institutions, as well as new studies on the acceptance and knowledge of practices among population, professionals and health managers.

In addition, the study also shows that there is a greater use of industrialized herbal medicine in the SUS when compared to vegetal drugs and compounded herbal medicines, which indicates a need for expansion of the Brazilian pharmaceutical industry specialized in the production of herbal medicines, so that the Increasing use of this resource is not compromised by lack of medicines on the market.

Collaborations

MCGG Caccia-Bava and EZ Martinez participated in all stages: concept, design, analysis, data interpretation and paper writing. BW Bertoni and AMS Pereira contributed in the analysis, data interpretation and paper writing.

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