

Access to medication in universal health systems – perspectives and challenges

O acesso a medicamentos em sistemas universais de saúde – perspectivas e desafios

Luciane Cristina Feltrin de Oliveira¹, Maria Angela Alves do Nascimento¹, Isabel Maria Sampaio Oliveira Lima²

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ABSTRACT This study aimed to analyze the challenges of access to medicines in four universal health systems in Australia, Brazil, Canada and the United Kingdom. Critical-reflexive qualitative study through Integrative Literature Review. The great challenge of the systems studied is the incorporation of high-cost drugs, through cost-effectiveness analyses to fulfill the difficult task of reconciling social justice and access equity with economic sustainability. Canada, in particular, despite being a developed country, still deals with the dilemma of how to finance a health system in which access to medicines is also universal. Brazil deals with two problematic realities: first, to grant access to medicines that are already standardized by the Unified Health System (SUS), in the face of insufficient funding. Secondly, similarly to the Australian, Canadian, and English systems, the dilemma of how to incorporate new efficient medicines considering its economic feasibility, as well as the issue of health judicialization, a complex phenomenon resulting from public fragility in the organization, financing, and consolidation of the SUS.

KEYWORDS Access to essential medicines and health technologies. Health systems. Social justice.

RESUMO Este estudo objetivou analisar os desafios do acesso a medicamentos em quatro sistemas universais de saúde da Austrália, do Brasil, do Canadá e do Reino Unido. Estudo qualitativo crítico-reflexivo por meio de revisão integrativa da literatura. Um dos grandes desafios dos sistemas estudados é o da incorporação de medicamentos de alto custo, via análises de custo-efetividade para cumprir a difícil tarefa de conciliar a justiça social e a equidade no acesso com sustentabilidade econômica. Particularmente o Canadá, mesmo sendo um país desenvolvido, ainda vive o dilema de como financiar um sistema de saúde no qual o acesso a medicamentos também seja universal. O Brasil convive com duas realidades problemáticas: primeiro, dar acesso a medicamentos, já padronizados pelo Sistema Único de Saúde (SUS), diante de um financiamento diminuto, segundo, de maneira semelhante aos sistemas australiano, canadense e inglês, vive o dilema de como incorporar novos medicamentos eficazes e com viabilidade econômica, além da questão da judicialização da saúde, um fenômeno complexo resultante da fragilidade pública na organização, financiamento, consolidação do SUS.

PALAVRAS-CHAVE Acesso a medicamentos essenciais e tecnologias em saúde. Sistemas de saúde. Justiça social.

¹Universidade Estadual de Feira de Santana (UEFS) – Feira de Santana (BA), Brasil.
feltrinlc@yahoo.com.br

²Universidade Católica do Salvador (UCSal) – Salvador (BA), Brasil.

Introduction

Medication is an important element in health systems and ensuring its availability, accessibility and rational use, maintaining cost effectiveness and sustainability is a challenge for most countries in the world, especially in the face of increasing demand. This phenomenon occurs due to population aging, inadequate living habits, associated chronic conditions, medicalization of society and pressure from the pharmaceutical market¹.

The availability of essential medicines in the public sector, in many countries around the world, is still considered low. Median availability of medicines in low-income countries in 2016 was 60%, and in middle-income countries was 56%².

The ways of promoting access to medicines for the population differ between countries, as they vary according to the type of health system and the current medicine policy. In universal health systems, based on social justice, whose guiding principles are universality and equal access to health services, access to medicines is expected to be equal and broad. However, the subject of gratuity gives rise to different approaches that are expressed through total gratuity in some countries, gratuity according to the degree of vulnerability of users, and also the co-payment or co-participation system, being part of the expenses covered by the health and social system and the other party by direct disbursement from the user.

In most European countries (United Kingdom, Denmark, Sweden, Finland, Norway, Switzerland, Germany and France), public spending on medicines is higher than private spending, unlike countries like the United States of America, where private expenses are much higher³. In Brazil, free access to full therapeutic care through the Universal Health System (SUS) is the right of all citizens guaranteed by art. 6 of Law n° 8.080/90⁴, which regulates the principle

of universality adopted by the Federal Constitution of 1988.

Access to medicines is a worrying theme and is therefore incorporated into the health-related goals of the Millennium Development Goals of the World Health Organization (WHO) and the 2030 agenda for sustainable development, set by the United Nations (UN)⁵. Furthermore, the theme also integrates national and international studies, especially in the last two decades (2000-2018)⁶⁻⁹. The emergence of this issue comes in the context of an installed economic and humanitarian crisis, a circumstance that has accentuated the barriers of users' access to health services.

Thus, this study aimed to analyze how the theme of the challenges of access to medicines in four universal health systems in Australia, Brazil, Canada and the United Kingdom is addressed in scientific publications.

Material and methods

This is a qualitative study with a critical-reflexive character conducted through an integrative literature review. The descriptors selected were: Access medicines. Access Drugs. Health System. Access to Essential Medicines and Health Technologies. The search was carried out on the following databases: Pubmed, Scientific Electronic Library Online (SciELO), Latin American and Caribbean Center on Health Sciences Information (Bireme), Medline, Latin American & Caribbean Health Sciences Literature (Lilacs), Web of Science and Scopus; and the selected period was from 2008 to 2018.

Initially, 3,168 articles were found: 1,898 were deleted by duplicity in the databases; 1,075, after reading the title and abstract; and 29, because they are editorials, delimiting 166 articles selected for further careful reading. After applying the inclusion criteria, that is, articles published in full in peer review scientific journals; conducted

in countries with universal health systems, resulting from quantitative or qualitative field

research, there were, in the end, 63 articles left to compose the corpus of the study.

Chart 1. Distribution of countries with universal health systems with the highest scientific production on access to medicines published from 2008 to 2018 (N)

Country	(N)
Brazil	40
United Kingdom	9
Canada	7
Australia	7
Total	63

Source: Own elaboration after database survey.

This study is linked to a research project called 'Access to Health as a Right in Universal Systems' of the Center for Integrated Research in Collective Health (Nupisc) of the State University of Feira de Santana (UEFS) – BA, evaluated by the Research Ethics Committee of the UEFS and approved under CAAE n° 65693716.7.0000.0053.

Results and discussions

The access to medicines in Brazil through the SUS occurs in two ways, either through the legal or extrajudicial way, or through the judicial way, in case the right is denied to the citizen. The percentage of access to medicines by SUS by the law between 2003 and 2015 was, on average, 50%^{6,10-12}. The results show that, after 20 years of approval of the National Medicines Policy, free access to medicines through the SUS has increased in recent years. However, considering WHO parameters¹³, this percentage is classified between low and medium, especially in the context of a universal health system such as the Brazilian, in which a political paradox

emerges that indicates flaws in the National Policy on Medicines and Pharmaceutical Assistance, affecting and compromising access to medicines.

When it comes to medicines intended for the treatment of chronic diseases, access through the SUS is around 45%¹⁴⁻¹⁷, and increases for specific chronic diseases such as hypertension and diabetes, reaching 69% for hypertension and 75% for diabetes, without accounting for access through the Brazilian Popular Pharmacy (copayment)¹⁸⁻²³. Increased access to medicines for hypertension and diabetes is mainly due to the increasing prevalence of these diseases in the Brazilian population. This scenario led the Ministry of Health²⁴ to create programs such as HiperDia²⁵ to reorganize attention to the population segments with hypertension and diabetes, with the encouragement of the free distribution of antihypertensive and antidiabetic medicines through the Popular Pharmacy Program and the Health Program has no price²⁶.

After the creation, in 2010, of the Specialized Pharmaceutical Services Component (Ceaf) by the Ministry of Health, SUS started to offer,

through Clinical Protocols and Therapeutic Guidelines (PCDT), access to high cost medicines, with improvements in the access to these medicines²⁷. However, in PCDT, there are limiting barriers to access, such as problems in health system regulation, bureaucratic protocols and difficulties in accessing services for diagnostic tests and consultations to meet their requirements²⁷.

Although access to medicines through the SUS is universal, egalitarian and free to all Brazilian citizens and the result of a historical achievement legally put in practice, it is not yet a reality, as inequalities in access to medicines between the regions of Brazil are visible, especially in the socioeconomically disadvantaged regions that, to a certain extent, reproduce the socioeconomic inequality of the Country. In the South and Southeast regions, the achievement of medicines from the public system is higher^{6,10,18,23}. Regional differences in the organization, structuring and financing of services impact on the pharmaceutical assistance provided.

In Brazil, universal access to medicines by the public sector is still a major challenge, because a large portion of the population still needs to resort to direct disbursement to obtain the medicines necessary for their treatment^{6,15,18,19,23,28}. This reality represents a significant impairment of family income with health expenses and, consequently, characterizes a penalty to the population with lower purchasing power.

Inequalities of access also occur between different population strata^{6,7,19,26,29,30}, segments of the most socially vulnerable population have obtained their medicines through SUS, preferably because SUS is the health care option for this population.

Another way to obtain access to medicines in Brazil through the SUS is the use of judicial protection. It is a way of enforcing rights in the Judicial Branch when the citizen faces difficulties in access. In this case, most actions for requesting medication through the SUS are individual, that is, the decisions resulting

from the demands only ensure the attendance of their applicants, opposing the principles of universality and equity³¹⁻⁴¹.

Likewise, access to justice is also unequal and conditioned by socioeconomic determinants, as evidenced by the predominance of representation of private lawyers in lawsuits and by prescriptions from private health services with plaintiffs, mostly from low-income population strata or no social vulnerability. These data indicate that people with lower purchasing power and unable to afford the lawsuits end up resorting less to judicial means⁴²⁻⁴⁶. We understand that access to medicines through the judicial system in Brazil is reflecting and perpetuating inequalities in Brazilian society by privileging the portion of the population with the best socioeconomic conditions who have access to justice, in addition to reinforcing the individual right of citizens to the detriment of the collective.

In general, the requests for medicines not incorporated into the protocols and programs executed by SUS are high⁴⁶⁻⁵⁰, and the percentage of nonstandard medicines requested ranges from 56.7% to 77%. Most of the time, they are expensive medicines, some not approved by the National Health Surveillance Agency or requested for treatments that are not indicated, the off-label use; or clinical indications for which there is no clinical evidence of its efficacy^{37,50}. In Brazil, the incorporation of new health technologies by SUS passes the National Commission for incorporation of Health Technologies (Conitec)⁵¹, which evaluates new technologies based on evidence of efficacy, accuracy, effectiveness and safety, as well as comparative economic evaluation of benefits and costs in relation to existing technologies, also aiming at the sustainability of the health system.

Finally, access to medicines in Brazil through the SUS involves problems related to the incorporation and supply of new medicines through the system, but mainly due to the difficulties faced by users to have access to medicines already covered.

In the English National Health Service, NHS, as well as Medicare, the Australian public health system, both considered universal systems, access to medicines occurs through a list of standardized medicines, with free access only in specific situations such as hospitalizations; treatments for diseases such as tuberculosis, sexually transmitted disease, mental disorder; elderly patients; pregnant women with children up to 1 year of age; students up to 18 years old; people with disabilities and low-income people. For the rest of the treatments, the provision is mediated by co-payment or co-participation, in which part of the expenses is covered by the health system and the other part comes from the direct disbursement of the user. Currently, in the United Kingdom, co-payment is around £ 8,40 per prescribed item^{52,53}.

In both systems, the main dilemma is the incorporation of new technologies, including new medicines, through cost-effectiveness, safety, effectiveness assessments, in order to balance priorities and maintain equitable distribution of resources⁵⁴⁻⁶².

In the United Kingdom, the National Institute for Health Clinical Excellence (Nice) is a non-departmental public body that publishes guidelines in four areas, among them, the use of health technologies within the NHS, such as the use of new and existing medicines. Nice assessments lead to whether or not new technologies are incorporated into the NHS. Its assessments are based primarily on efficacy, cost-effectiveness and safety and are often used informally in drug price negotiations around the world⁶³. However, decisions based on cost effectiveness are usually associated with a range of more restrictions and delay in approving new technologies, with the average approval time or not of a 2-year medicine in Nice^{59,60}. In this respect, the center of discussion in most universal health systems is cancer treatment drugs, mainly due to the worldwide increase in

the prevalence of the disease and the amount of high-cost cancer drugs⁵⁷.

Nice faces controversy over decisions to deny cancer drugs, mainly, given the lack of therapeutic alternatives for specific cancers. Even using robust methodologies, there is a lack of available evidence on the efficacy of newly launched products compared to those available in the market^{59,62,64}.

Another controversial issue for Nice is the strategy sought to balance competing objectives of patients, taxpayers, in the face of the need to encourage innovation and protect the British pharmaceutical industry. In this case, one form of confrontation has been pharmaceutical price regulation that attempts to establish a fair return on pharmaceutical industry investment and flexible pricing that allows the price of a drug to be raised or lowered according to its evidence of effectiveness⁶¹, but if the medicine fails, the burden remains on the manufacturer, and must take up risk and reimburse the NHS. Another way to make Nice more flexible has been the Patient Access Schemes (PAS), which constitute alternative drug access agreements between the NHS and the high-cost drug manufacturers not yet approved by Nice where the manufacturer provides discounts for a specific patient, but not on the general price list, a fact that may increase the price paid by the NHS and indirectly influence the price of medicines worldwide^{62,65}. However, the NHS is concerned about the high costs of implementing PAS and, at the same time, collecting evidence for approval of new technologies by Nice⁶³. A suggestion by members of the Conservative Party was to improve cooperation between Nice and the pharmaceutical companies, which should better demonstrate the clinical value of the product by shifting the burden of proof from Nice to them⁶⁶.

In the Australian healthcare system, access to medicines is provided by the Australian Pharmaceutical Benefits

Scheme (PBS) which subsidizes the value of preselected medicines to the population. Retirees, the elderly, the unemployed and other vulnerable people pay substantially less than the rest of the population, and medicines given in hospitals are free. To be on the PBS list, medicines must be approved by the Pharmaceutical Benefit Advisory Committee (PBAC), an independent body responsible for evaluating the medicine through cost-effectiveness and clinical needs analysis. However, like Nice, PBAC faces problems regarding the quality and strength of experimental evidence to prove the clinical efficacy of new drugs, especially those for cancer treatment⁵⁴.

The co-payment adopted as the main form of access to medicines by the United Kingdom, Australia and Canada is considered by some authors as a hindrance to access to medicines^{67,68}; and, by others, as a way of maintaining the sustainability of the systems. This maintenance would be achieved by controlling the abuse of medicines, especially in view of the increasing health expenses due to population aging, poor health habits and the increasing prevalence of associated chronic diseases^{63,64,69,70}. However, in Australia, a 24% increase in copayments in 2005 led to a significant reduction in dispensing volumes of 12 drug categories⁷¹, including Parkinson's drugs, platelet antiaggregant drugs and osteoporosis drugs. The reduction was greater for the most vulnerable population, whose copayments are lower than the general population, a serious situation, as discontinuation of the use of drugs for chronic diseases can aggravate the morbid condition of the patient and lead to death.

Since 2000, the expenses of the Australian system with medicines for cancer treatment has increased by 20% per year, the use of cost-effective comparative studies has led to restrictions on access, late approvals and controversies in society, thus, the

PBAC has made difficult choices trying to balance priorities and equitable allocation of resources^{54,55,57}. The evidence-based approach now adopted in Australia is associated with low prices and better accessibility and has the approval of the population⁷². Despite the high prevalence of cancer in Australia, the country has one of the lowest mortality rates among developed countries due to its universal public drug tracking and funding policy⁵⁷.

In Canada, a country which also has a universal health system, each province or territory has its own health system, but is subject to the Canada Health Act⁷³ which establishes the universality of primary health services. However, each province has its own way of operating the system and sets out what is specifically covered beyond primary services. That is, it is not about one health system, but 15. This means that each province can choose how its health system works based on the particular needs of its respective residents.

However, for all provinces, the law does not ensure drug coverage, with the exception of blood products, vaccines, and medicines given in hospitals and outpatients that are fully funded by the system⁷³. With regard to outpatient medications, all Canadian provinces currently fund drug insurance plans that are available to all residents. Citizens with incomes of US\$ 55,000 or more may not receive any financial support for their medicines from government insurance plans. However, one in 10 Canadians who receive a prescription reports cost-related non-adherence, and the lack of drug insurance coverage seems to be one of the main reasons behind this phenomenon^{74,75}.

The use of age-based plans and income-based coverage varies across the country. In addition, each province and, occasionally, different plans within a province use a variety of cost sharing mechanisms, this variation leads to different direct costs for

the same type of patient depending on the province of residence. Finally, the situation of pharmaceutical insurance plans in Canada is that of a ‘patchwork quilt’, with each province having separate medicine insurance plans. This leads to variations in copayment values in all provinces^{74,76,77}

High-cost therapies such as cancer drugs also have varying coverage across provinces. Variations range from medicine eligibility criteria, bureaucratic procedures for access to copayment value; this situation results in cancer patients in different provinces with access to differentiated medicines, which puts equity and equal access at risk^{74,76,77}.

A pungent perspective in the academic literature of Canada is the creation of a National Pharmacy System to replace the current pharmaceutical insurance patchwork

system, a universal system, with public coverage of prescription drugs across Canada, including limited patient copayments and a basic list of medications available to all Canadians. Recent research has shown that the national system could reduce private insurers’ costs by U\$ 8,2 billion and increase costs for public plans by U\$ 1 billion, a total reduction in drug spending of U\$ 7,3 billion. This savings would be achieved through the creation of greater market share, thereby, allowing, lower prices for medicines to be negotiated. The analysis also assumes that a larger market would also be more efficient in medicine selection⁷⁵.

In *chart 2*, we highlight the main challenges and perspectives faced by the Australian, Brazilian, Canadian, and English health systems.

Chart 2. Advances and challenges faced by universal healthcare systems in Australia, Brazil, Canada and the United Kingdom in promoting access to medicines

Country	Advances	Challenges
Australia	<ul style="list-style-type: none"> - Robust new technology assessment system based on cost-effectiveness analysis – PBAC; - Well-defined standardization of covered medicines; - Differentiated co-payments according to the citizen’s vulnerability; - Massive investments in health. 	<ul style="list-style-type: none"> - Uncertainty about the co-payment impact on treatment follow-up; - Difficulty balancing access to medicines x social justification x system sustainability; - Problems regarding the quality of evidence to prove the clinical efficacy of new drugs.
Brazil	<ul style="list-style-type: none"> - Assessment system for new technologies still under consolidation – Conitec; - Standardization of medicines and free distribution of essential and high-cost drugs. 	<ul style="list-style-type: none"> - Expand access to standardized medicines for the entire population; - Difficulty balancing access to medicines x social justification x system sustainability; - Underfunding of health policies; - High judicialization of access to medicines.
Canada	<ul style="list-style-type: none"> - Standardization of medicines by Provinces; - Co-payments for outpatient medicines only. 	<ul style="list-style-type: none"> - Still does not ensure universal access to medicines, fragmented and differentiated access by provinces; - High value co-payments for high cost medicines; - Lack of a national medicine access system to unify provincial policies.

Chart 2. (cont.)

United Kingdom	<ul style="list-style-type: none"> - Robust new technology assessment system based on cost-effectiveness analysis – Nice; - Well-defined standardization of covered medicines; - Co-payment for general population and exemption for vulnerable; - Massive investments in health. 	<ul style="list-style-type: none"> - Difficulty balancing access to medicines x social justification x system sustainability; - Problems regarding the quality of evidence to prove the clinical efficacy of new drugs.
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Source: Own elaboration.

Final considerations

Although the four health systems studied are considered universal, there are major differences between them, especially regarding their structure, management, organization, maturity, financing, size and distribution of morbidities in populations. These differences, whose complexity, *per se*, require analysis, do not allow comparative studies to be carried out, but they do not prevent us from analyzing their main dilemmas and perspectives on the future. The United Kingdom and Australian systems are systems with massive public health financing and investments, where economic rationality is important for their sustainability. In them, access to medicines for the majority of the population is through copayments and it is precisely the issue of incorporating new technologies, such as high-cost medicines, that is the center of attention of these systems.

These systems, through Nice (United Kingdom) and PBAC (Australia), by incorporating medicines via cost-effectiveness analysis, have been trying to fulfill the difficult task of reconciling social justice, equity and equal access with economic sustainability.

Canada, although recognized as a developed country, still faces the dilemma of how to fund a health care system in which access to medicines is also universal, as Canadian health law does not ensure medicine coverage.

All provinces have some type of medicine coverage plan, and the variability is very large, leading to differentiation among Canadian citizens, hurting equality within the system. The problem is greater when it comes to expensive medicines such as anticancer drugs, in which case copayments can be of high value, a circumstance that hinders access for patients.

Brazil, in turn, lives with two problematic realities: the first one regarding the guarantee of access to medicines that are already standardized by the SUS in the face of poor health financing and a growing population; the second, similarly to the Australian, Canadian and English systems, is the dilemma of how to incorporate new effective and economically viable medicines. Added to this is the issue of the judicialization of health, a complex phenomenon that results from public fragility in the organization, financing, consolidation, regulation, supervision and control of the SUS.

This study provided a synthesis of production on access to medicines in Australia, Brazil, Canada and the United Kingdom universal health systems, signaling the main challenges and perspectives of these systems in the task of providing rational and equitable access to their citizens. In this way, it may contribute to the reflection of health managers on the difficulties of balancing the promotion of access to medicines and the sustainability of health systems. In the present integrative review,

despite the careful inclusion of peer-reviewed primary studies, the limitations of the study refer to the sample, since only articles available online and the small number of studies found on access to the study were included. Australia and Canada may have hampered the analysis.

Collaborators

Oliveira LCF (0000-0001-9842-5901)*

contributed to the conception, planning, analysis and interpretation of data; critical review of the content; and approval of the final version of the manuscript. Nascimento MAA (0000-0002-0616-8133)* contributed to the critical review of the content and approval of the final version. Lima IMSO (0000-0002-9833-3721)* contributed to the critical review of the content and approval of the final version. ■

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*Orcid (Open Researcher and Contributor ID).

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