

Access to Guideline-Directed Heart Failure Therapy in Brazil: Methodological and Policy Considerations

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While the study's findings are valuable, some methodological aspects could affect how we interpret them. The analysis is based solely on the presence of medications in Municipal Lists of Essential Medicines (REMUMEs), rather than on actual dispensing records or pharmacy inventory data. However, the fact that a medication is on an official list does not mean that patients can actually receive it in practice. Local procurement rules, supply chain issues, and prescribing practices can significantly affect the availability of drugs when patients need them. Conversely, medications absent from REMUMEs may still be accessible through other mechanisms within SUS. Therefore, relying solely on documentary evidence may not fully reflect the real accessibility of HF therapies. Dispensing records or pharmacy-level availability data could provide a more accurate representation of patient access.

Another important point to consider is how we understand the limited use of newer HF treatments, particularly angiotensin receptor–neprilysin inhibitors and sodium–glucose cotransporter-2 inhibitors. These treatments are often provided through specific national programs, such as the Specialized Pharmaceutical Assistance Component (CEAF), rather than being included in REMUMEs. Consequently, assessing REMUMEs alone may underestimate the availability of these agents within the broader SUS framework. Moreover, the regulatory and reimbursement processes for drugs like dapagliflozin and sacubitril/valsartan have changed quickly in recent years. This makes it especially important to understand how long they have been available.

Moreover, the idea of quadruple therapy warrants careful consideration when applied to the analysis of policies affecting whole populations. Although the four-pillar approach is strongly recommended for patients with HF with reduced ejection fraction, municipal pharmaceutical policies are generally designed to address a wide spectrum of cardiovascular conditions rather than a single HF phenotype. As such, the absence of specific agents in REMUMEs may reflect budgetary prioritization or procurement logistics rather than a direct failure of guideline implementation.

The observed regional differences in the availability of key HF medications, specifically angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, and beta-blockers, remain a concern and warrant policymakers' attention.¹ These disparities could exacerbate regional inequalities in HF outcomes, underscoring the need for unified national strategies to ensure equitable access to essential cardiovascular treatments.

In conclusion, Rocha et al. highlight a significant challenge within the healthcare system, particularly in the management of HF, that warrants attention. To elucidate the precise scope of access disparities and inform the development of more effective strategies for implementing evidence-based HF therapies in Brazil, future research should incorporate medication dispensing data, drug distribution pathways within the healthcare system, and regional health policy considerations.¹⁻⁵

Keywords

Heart Failure; Drug Therapy; Health Services Accessibility

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Reply

*Lidia Einsfeld,^{1,2} Luísa Preiss Marques da Rocha,¹ Diogo Pilger¹**UFRGS,¹ Porto Alegre, RS – Brazil**HCPA,² Porto Alegre, RS – Brazil***Dear Editor,**

We appreciate the interest of our colleagues in our article, “Evidence-Based Pharmacological Treatment for Heart Failure in Brazil”¹, and we welcome the opportunity to respond to their comments and contribute to the scientific debate in the field of pharmaceutical assistance within the context of heart failure (HF) management.

Pharmaceutical assistance constitutes an integral and structural component of the Brazilian Unified Health System (SUS), one of the largest public health systems in the world, which establishes health as a fundamental right and a duty of the state. Within the framework of comprehensive healthcare, this also encompasses the right to access pharmacological therapy.

The literature on pharmaceutical assistance distinguishes between “access” and “availability,” demonstrating that the mere physical presence of medicines within healthcare services represents only one dimension of access. Empirical studies within the SUS indicate that shortcomings in availability undermine the effective realization of access, even when such access is guaranteed at normative and policy levels.² According to the Brazilian National Policy for Pharmaceutical Assistance (PNAF), access to medicines is a multidimensional concept, encompassing not only regulatory guarantees and public financing, but also the organization of services and their effective utilization by patients.³

The Brazilian National List of Essential Medicines (RENAME) therefore works as a structuring instrument for access to medicines. By defining a set of essential medicines prioritized for the population, it guides selection, standardization, and the allocation of funding responsibilities among federal entities.⁴

Based on the RENAME, the PNAF organizes access to standardized medicines considered essential to the health of the Brazilian population. In the specific case of pharmacological therapies for HF, the Specialized Component of Pharmaceutical Assistance includes more recent therapies, particularly angiotensin receptor–neprilysin inhibitors and sodium–glucose cotransporter-2 inhibitors (SGLT2i). Although these are not part of the Basic Component of Pharmaceutical Assistance, they are included in the national essential medicines list and are therefore available through the SUS, subject to predefined inclusion criteria established in the Ministry of Health protocols.

The mechanisms of access and corresponding eligibility criteria are described in Table 2 of the original article. It is important to note, however, that at the time of data collection and manuscript preparation, dapagliflozin had not yet been incorporated into the Brazilian Ministry of Health’s Clinical Protocols and Therapeutic Guidelines

for Heart Failure. Since then, access criteria have been expanded; thus, current regulations are not reflected in the article.

Other evidence-based therapies for HF that are included in RENAME, such as loop diuretics, mineralocorticoid receptor antagonists, and cardioselective beta-blockers, are part of the Basic Component of Pharmaceutical Assistance. Therefore, they fall under municipal responsibility. In accordance with the concept of essential medicines and the SUS principles of regionalization and territorialization, each municipality has autonomy to select medicines for its local lists based on sociodemographic characteristics and the most prevalent conditions affecting its population.

What is observed is the broad availability of medicines for the treatment of hypertension, standardized in municipal essential medicines lists (REMUMEs). In our discussion, we sought to highlight the need to expand this framework to include evidence-based drugs for HF treatment. HF represents the leading cause of hospitalization among individuals over 65 years of age, accounts for annual healthcare system costs exceeding BRL 1.4 billion, and was associated with more than 70,000 deaths between 2018 and 2021, reflecting substantial morbidity and mortality.⁵

The study design did not include an evaluation of the actual provision of these medicines in practice, but rather focused on document-based analysis of municipal REMUMEs, corresponding to the selection and standardization phases of the pharmaceutical assistance cycle. This limitation was acknowledged by the authors from the outset of the methodological design and is described in the study limitations section, along with potential biases related to the use of quadruple therapy, given the absence of phenotypic stratification of HF across municipal populations.

Despite these limitations, the study was conceived as an exploratory investigation aimed primarily at fostering discussion regarding the structural mechanisms that influence access to treatment for HF, a condition characterized by high morbidity and mortality. Beyond identifying process-related weaknesses, the research group’s ultimate objective is to strengthen the SUS as a social institution by reinforcing its regulatory frameworks to better serve patients with HF, whose prevalence continues to rise in Brazil.

We are grateful to the authors for their valuable contributions and constructive feedback. We believe that this academic dialogue significantly enhances the discussion of a critical public health issue in Brazil: access to pharmacological therapy.

Letter to the Editor

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