Annotation Guidelines and Challenges for Automatic Simplification of Portuguese Drug Leaflets

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Abstract

While most essential medicines have become widely accessible across all social strata in Brazil due to government initiatives and market shifts, a significant barrier remains: the technical complexity of medication leaflets. This pragmatic and linguistic gap hinders patient comprehension of critical risks and benefits. Thus, adapting these texts into plain language patterns is crucial for patient safety and treatment adherence. Large language models have been increasingly effective as practical solutions for text simplification, an important Natural Language Processing (NLP) task that serves as a basis for several other linguistic and computational tasks. However, the scarcity of annotated datasets remains a bottleneck for rigorous evaluation. To bridge this gap, we propose a streamlined pipeline for generating simplified medical leaflets and introduce an initial benchmark dataset of 30 expertly annotated samples. Our results, supported by semantic and morphosyntactic evaluations, demonstrate that the proposed method produces high-quality, simplified content suitable for health applications.

1 Introduction

Brazilian government initiatives, most notably the **Farmácia Popular do Brasil**[1] program, significantly expanded access to essential medicines for treating chronic conditions such as hypertension, diabetes, and asthma (Emmerick et al., 2015). However, widespread access must be matched by health literacy; understanding the risks and correct administration of these drugs is vital for therapeutic success. In this regard, the medication leaflet serves as a critical document, particularly for over-the-counter (OTC) drugs that can be purchased without direct medical supervision. Furthermore, each pharmaceutical company can produce a different package insert with different texts, as long as it respects the minimum mandatory content guidelines of **Anvisa** [Agência Nacional de Vigilância Sanitária], the Brazilian federal agency for drug regulations. Therefore, it is possible to have many different leaflets from different companies for the same medicine and/or substance.

The leaflet includes a section titled "patient information" that provides guidance on how the medication works, its dosage, and its risks. While such a section is theoretically intended for the general public, it is often characterized by dense technical terminology, convoluted sentence structures, and complex formatting. This linguistic barrier creates a gap between access to medicine and its safe use (Roseno, 2024). Given the recent breakthroughs in Large Language Models (Sajjadi Mohammadabadi et al., 2025), Automatic Text Simplification (ATS) (Shardlow, 2014) emerges as a viable solution to bridge this gap, democratizing access to clinical information and ensuring that vital health guidance is intelligible to all social strata.

ATS aims to make written information more accessible by reducing linguistic complexity while preserving meaning (Al-Thanyyan and Azmi, 2021). This task is crucial for a broad audience, including language learners, individuals with cognitive or literacy impairments, and citizens navigating complex institutional or legal documentation (Martínez et al., 2024). Traditionally, ATS research has focused on sentence-level simplification (Al-Thanyyan and Azmi, 2021), where complex sentences are rewritten in isolation. Although valuable, it fails to capture broader *discourse-level phenomena*, such as coherence, conciseness, and referential consistency, which are indispensable for comprehending lengthy or technical documents (Vásquez-Rodríguez et al., 2024). Consequently, *document-level simplification* (DS) has emerged as a more practically relevant yet methodologically challenging task. DS requires the seamless integration of summarization, compression,

[1] https://www.gov.br/saude/pt-br/composicao/sectics/farmacia-popular

Proceedings of the 17th International Conference on Computational Processing of Portuguese (PROPOR 2026)
Vol. 2, pages 121–127

and reorganization techniques to sustain global cohesion while ensuring local fluency (Cripwell et al., 2023).

Despite the growing attention toward document-level simplification, most existing research remains restricted to English and relies on a limited set of corpora primarily designed for sentence-level tasks (Ryan et al., 2023). In other languages, particularly Portuguese, the scarcity of structured datasets is a major bottleneck to progress. Pioneering resources such as PorSimples (Aluísio et al., 2008) established a foundation for sentence-level simplification in Brazilian Portuguese; however, there is currently a total absence of *human-annotated* datasets addressing document-level simplification within specialized domains, such as the medical field.

In this work, we present a formal annotation protocol for leaflet simplification and introduce the first human-verified document-level simplification dataset in Portuguese for the medical domain. The dataset was developed using an iterative refinement process: starting from a candidate version initially generated by an LLM, the texts underwent two rigorous rounds of revision. Notably, one of these rounds was conducted by linguists specialized in plain language, ensuring that the simplified versions meet both clinical and accessibility standards. The resulting corpus was then subjected to a two-fold analysis: (i) surface statistics and a readability metric were compared between the original and simple versions and also with an existing simplification dataset, (ii) semantic and morphosyntactic analyses were conducted to automatically assess the quality of the dataset.

This paper makes four main contributions:

1. We propose a simple protocol for annotating simplified medication leaflets by humans.

2. We introduce 30 simplified leaflets, constituting the first human-annotated Portuguese dataset dedicated to document-level simplification in the pharmacological domain. The resource is publicly available for research and educational purposes, adhering to the principles of openness and reproducibility [2].

3. We conduct quantitative analysis of the dataset, comparing its characteristics with those of existing corpora.

4. We assess the quality of the dataset through automatic evaluation using linguistic features.

[2] https://github.com/scalercio/med-simple-docs

2 Annotation Guidelines

This section describes the proposed annotation protocol.

2.1 Starting Point and First Revision

The rules governing the preparation of medication leaflets in Brazil are established in ANVISA Resolution No. 47 of 2009. According to this regulation, patient leaflets must contain three sections: Medication Identification, Patient Information, and Legal Statements. The simplification process was limited to the Patient Information section, which contains nearly all the leaflet's informational content. Under this regulation, the Patient Information section must be organized in a question-and-answer format, consisting of nine questions described in Section 2.2.

Recent studies have increasingly leveraged synthetic data generation to mitigate the scarcity of manually aligned simplification corpora, particularly for low-resource languages and specialized domains (Ghosh et al., 2023; Kaddour and Liu, 2023; Ankinina et al., 2025). Given that Brazilian medication leaflets are typically long documents (Roseno, 2024), we adopted ChatGPT (version 5.2) (OpenAI, 2026) as a starting point for data annotation. This model was selected because of its ability to generate fluent and semantically faithful paraphrases of long documents. The web application was used to generate simplified versions of the texts, and the prompt design was informed by prior work on generating annotated data in the biomedical domain (Attal et al., 2023). The prompt included the following guidelines: (1) Replace technical terms with simpler synonyms; if unavoidable, provide an explanation in parentheses; (2) prefer active voice over passive voice constructions; (3) split long sentences into shorter, simpler ones whenever possible. (4) omit irrelevant sentences; (5) resolve anaphora and ambiguous pronouns; (6) preserve all numerical information, including dosage amounts, frequency, and routes of administration. The automatically generated outputs were subsequently reviewed by one of the non-linguist authors to correct major errors that altered or omitted essential information from the original document. Minor presentation-related adjustments were also performed to ensure clarity and consistency.

2.2 Linguistic Revision

The ATS step applies structural constraints that prioritize shorter sentences and the use of itemized or segmented information to enhance readability. To ensure the leaflets are as clear and accessible as possible, a second review was performed by linguists specialized in plain-language techniques, following experiences of Wives and Finatto (2025) with simplifying texts on cancer for low-educated lay people supported by different LLMs.

To perform the revision, the *primary principle* is to preserve the patient information leaflet in its entirety, in terms of content. Specifically, this involves retaining the nine guiding questions, established by **Anvisa**, about the drug or substance: "1) Para o que este medicamento é indicado?" [What is this medication indicated for?]; "2) Como este medicamento funciona?" [How does this medication work?]; "3) Quando não devo usar este medicamento?" [When should I not use this medication?]; "4) O que devo saber antes de usar este medicamento?" [What should I know before using this medication?] ; "5) Onde, como e por quanto tempo posso guardar este medicamento?" [Where, how, and for how long can I store this medication?]; "6) Como devo usar este medicamento?" [How should I use this medication?]; "7) O que devo fazer quando eu me esquecer de usar este medicamento?" [What should I do if I forget to use this medication?]; "8) Quais os males que este medicamento pode me causar?" [What harm can this medication cause me?]; "9) O que fazer se alguém usar uma quantidade maior do que a indicada deste medicamento?" [What to do if someone takes more than the recommended amount of this medication?].

The revision also aimed to reduce question complexity. For instance, question 8 was reformulated as "Quais problemas este medicamento pode causar?" because *os males* is more complex and the pronoun *me* was considered redundant. Similarly, question 5 was simplified to "Como guardar este medicamento?" [How should this medication be stored?].

The *second principle* was to eliminate excessive information in the simplified version. Such redundancies arise because patient information leaflets in Brazil often contain a lot of topics, as a single leaflet for a given medication or substance may include instructions for treating multiple conditions. For instance, the medication atenolol is indicated for the control of arterial hypertension, angina pectoris, cardiac arrhythmias, myocardial infarction, and early and late treatment after myocardial infarction. Consequently, different patients are required to identify and extract information relevant to their specific condition. Other principles included introducing the lay term before the technical expression, e.g., wheezing (*chiado no peito*), followed by bronchospasm (*broncoespasmo*) in parentheses.

The review further aimed to favor high-frequency lexical choices in Portuguese, such as using "to decrease" (*diminuir*) rather than "to reduce" (*reduzir*), thereby promoting greater clarity and ease of understanding for readers.

3 Drug Leaflets Dataset

This section describes the main characteristics of our initial drug leaflets dataset, which was constructed by simplifying 30 medication leaflets for hypertension drugs included in the Farmácia Popular social program. Ten medications were selected, and for each, three manufacturers were chosen. Appendix A provides the full list of all medications and their respective manufacturers. Appendix B presents an example of the simplification of a drug leaflet. The simplifications were carried out using the protocol described in Section 2.

Surface Statistics Given the absence of other document-level simplification datasets in Portuguese, the dataset was analyzed and compared with the Gov-Lang-BR corpus (Scalercio et al., 2025). Although originally developed for sentence simplification, this dataset also includes multi-sentence examples and texts from the legal domain. The results are shown in Table 1.

		Leaflets	GovLangBR
Original (Source)		30	1,703
Simplified (Target)		30	1,703
Ave. # of sentences	Source	139.0	1.22
	Target	109.7	1.10
Ave. # of words	Source	2,514.5	33.40
	Target	1,571.9	19.35
Ave. # of characters	Source	14,124	181.42
	Target	8,242	104.19

Table 1: Statistics of Leaflets and GovLangBR.

As observed, each instance in our dataset contains substantially more words and sentences than the sentence-level dataset, although both follow the same trend: the simplified version is compressed relative to the original text. While sentence counts decrease modestly (21%), words and characters decrease more aggressively (about 40%).

Document-Level Readability To evaluate the readability of our leaflets dataset, we adopted the Flesch Readability Index (Kincaid et al., 1975), which can be computed without reference data. This metric is grounded in the assumption that shorter words and sentences contribute to easier reading. We employed the version of the formula adapted for Portuguese (Leal et al., 2023). The result is a score, typically between 0 and 100, where higher values indicate easier reading. Table 2 lists the average readability scores of Leaflets and GovLang-BR datasets.

	Leaflets	GovLangBR
Original (Source)	7.3	-12.1
Simplified (Target)	26.5	0.1

Table 2: Comparison of Flesch Readability Index

It can be observed that the gain in average readability for the leaflets dataset is considerably higher than that observed in GovLangBR. Even with a considerable increase in the readability index, the achieved value still indicates that the simplified documents are very difficult to read and are best understood by university graduates. This need for higher literacy levels represents an important challenge. According to the 2024 INAF survey (INAF, 2024), 58% of the Brazilian population has literacy limited to rudimentary and elementary levels, highlighting the strong demand for accessible materials.

The very low readability score of GovLangBR is likely due to the dataset's complexity, characterized by long sentences and technical jargon.

4 Automatic Evaluation

To assess the quality of the dataset, we perform morphosyntactic and semantic analyses.

4.1 Morphosyntactic Evaluation

To evaluate the quality of the simplifications, we employed four reference-free linguistic metrics to assess the examples. They are: (1) Lemma/Token Ratio (LTR) that measures lexical diversity; (2) Ratio of passive to active voice verbs (P/A) to measure more direct constructions; (3) Proportion of adverbial clauses preceding the main clause (AdvL), capturing sentence structure tendencies; and (4) Ratio of fully developed to reduced relative clauses (D/R), reflecting syntactic simplifications. They were developed based on linguistic hypotheses about complexity and are grounded in psycholinguistic research on language processing (Juola, 1998; Gibson, 1998; Charles, 2013; Corrêa et al., 2019). With this approach, we aim to verify that the transformations performed during the simplification process are reflected in the linguistic metrics. Initially, the dataset was annotated morphosyntactically using the UDPipe model, which was trained on a scientific treebank (Straka et al., 2016; de Souza et al., 2021), and, then, we calculated the linguistic metrics.

Dataset	Linguistic Metrics			
	LTR	P/A	AdvL	D/R
Drug Leaflets Set				
Complex	.025	.013	.314	.572
Simple	.032	.003	.482	.647
Simple - reviewed	.029	.003	.427	.697

Table 3: Linguistic Metrics for the Drug Leaflets Dataset

Examining Table 3, with the exception of the LTR metric, all measures follow the expected trend. The slight increase observed in LTR is due to the reduction in the total number of tokens resulting from compression, rather than an increase in the number of lemmas. Regarding the proportion of verbs in the passive and active voices, the first simplification effectivelly eliminates passive constructions, as confirmed by human review. The need to provide explanations and contextualization accounts for the increase in adverbial clauses preceding the main verb in the two simplified versions. Finally, throughout the revision process, the number of reduced relative clauses gradually decreases.

4.2 Semantic Evaluation

To verify semantic consistency between each pair, we employed Sentence-BERT (Reimers and Gurevych, 2019) to compute sentence embeddings. Since the documents consist of multiple sentences, each one was split into smaller chunks, for which individual vector representations were generated. These vectors were then averaged to produce a single embedding per document. We then computed the cosine similarity between the original documents and their linguist-revised simplified versions.

Figure 1 shows the distribution of these scores, along with a kernel density estimation for smoothing the curve. As observed, all the samples in our dataset exhibit a very high semantic similarity to their original documents, which is highly relevant since meaning preservation is a key challenge in document simplification.

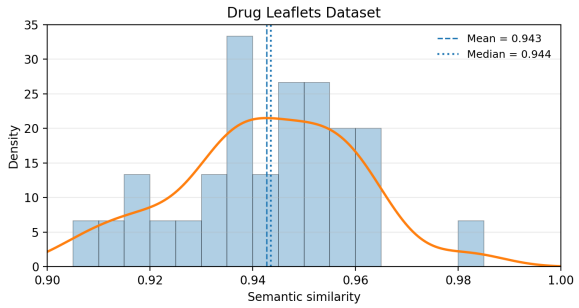

Figure 1: Distribution of Semantic Similarity Scores

5 Conclusions

This work presented a simple annotation protocol for generating simplified medication leaflets, along with an initial dataset of 30 manually simplified leaflets. The main characteristics of the dataset were presented, including an analysis of its readability. Finally, automatic evaluations using linguistic metrics and NLP tools confirmed that the generated simplifications preserve the original content and are simpler than the original leaflets. The main challenge during the annotation process concerns content preservation, given the diversity of existing technical terms and the fact that many spans of text are misspelled and ambiguous. The methodology of human review by specialized linguists ensures that the content is not merely translated by AI, but that it seeks to meet accessibility and clarity standards for the patient. In this regard, we intend to extend the annotation protocol by adding a technical review stage conducted by scholars in the pharmacological field. Other future directions include increasing the number of simplified leaflets, creating an LLM benchmark for document-level simplification, and incorporating different discourse-level metrics into the evaluation framework, such as coherence and cohesion.

Limitations

As mentioned before, the main limitation of our annotation protocol—and consequently of the generated dataset—concerns the lack of a technical review of the simplified leaflets. Without this specialized perspective at all stages, there is a risk that the simplification of the language may simplifying the language may alter or omitt safety. Since preserving the technical and medical content is fundamental for the text simplification task, future work will improve the protocol to include a technical review by pharmaceutical or medical experts, ensuring that, in addition to being easy to read, the text remains clinically accurate and safe. The dataset also presents a limitation in the lack of variety of the selected medications. By selecting only 30 package inserts focused on hypertension medications from the Farmácia Popular program, the study might creates a bias that could compromise the application of the technique in other scenarios. When extending the current dataset, a greater diversity of therapeutic classes will be included to ensure that the simplification protocol works safely and effectively for a wider variety of treatments.

Acknowledgments

This research was supported by CNPq (National Council for Scientific and Technological Development), grant PQ 307088/2023-5, PROBIT and PROBIC FAPERSGS-UFRGS, FAPERJ - *Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro*, processes SEI-260003/002930/2024, SEI-260003/000614/2023, and CAPES. We also thank the support of the CNPq National Institutes of Science and Technology, IAIA (grant 406417/2022-9), TILD-IAR (grant 408490/2024-1) and IAPROBEM (grant 408589/2024-8).

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A Medications and Manufacturers

Table 4 presents the medications and their respective manufacturers for all simplified leaflets.

Medication	Manufacturer
Atenolol 25mg	Germed
Atenolol 25mg	Legrand Pharma
Atenolol 25mg	Sanofi Medley
Besilato de Anlodipino 5mg	Vitamedic
Besilato de Anlodipino 5mg	Novartis
Besilato de Anlodipino 5mg	Achē
Captopril 25mg	Aurobindo
Captopril 25mg	Teuto
Captopril 25mg	Vitamedic
Cloridrato de Propranolol 40mg	1Pharma
Cloridrato de Propranolol 40mg	Globo Pharma
Cloridrato de Propranolol 40mg	Germed
Espironolactona 25mg	EMS
Espironolactona 25mg	Germed
Espironolactona 25mg	Eurofarma
Furosemida 40mg	Neo Química
Furosemida 40mg	Teuto
Furosemida 40mg	Hipolabor
Hidroclorotiazida 25mg	Legrand Pharma
Hidroclorotiazida 25mg	Germed
Hidroclorotiazida 25mg	Teuto
Losartana Potássica 50mg	Cimed
Losartana Potássica 50mg	Legrand Pharma
Losartana Potássica 50mg	Achē
Maleato de Enalapril 10mg	Geolab
Maleato de Enalapril 10mg	Cimed
Maleato de Enalapril 10mg	Biolab
Succinato de Metoprolol 25mg	AstraZeneca
Succinato de Metoprolol 25mg	Neo Química
Succinato de Metoprolol 25mg	Pharlab

Table 4: Medications and Manufacturers of the Simplified Leaflets

B Dataset Example

Below, we present an excerpt from the beginning of the leaflet for enalapril maleate, along with its corresponding simplified version.

Original:

1. PARA QUE ESTE MEDICAMENTO É INDICADO?

Seu médico prescreveu maleato de enalapril para controlar a pressão alta ou melhorar o desempenho do seu coração (tratamento da insuficiência cardíaca). Maleato de enalapril também é usado para a prevenção de insuficiência cardíaca sintomática.

Em muitos pacientes com insuficiência cardíaca que apresentam sintomas, maleato de enalapril retarda a piora da insuficiência cardíaca e reduz a necessidade de internação hospitalar por insuficiência cardíaca. Maleato de enalapril também ajuda alguns desses pacientes a viverem mais. Em muitos pacientes com insuficiência cardíaca em estágio inicial, antes do desenvolvimento dos sintomas, maleato de enalapril ajuda a prevenir o enfraquecimento do desempenho cardíaco e a retardar o aparecimento de sintomas (por exemplo, falta de ar, cansaço após atividades físicas leves, tais como caminhada, ou inchaço dos tornozelos e pés). Esses pacientes poderão precisar de menos hospitalizações por insuficiência cardíaca. Ao tomar maleato de enalapril, alguns pacientes com insuficiência cardíaca podem ter risco mais baixo de sofrer ataque cardíaco (infarto do miocárdio).

Simplified:

1. Para que este medicamento é indicado?

O Maleato de enalapril serve para controlar a pressão alta e para ajudar o coração a funcionar melhor no tratamento da insuficiência cardíaca, quando o coração fica fraco. O Maleato de enalapril também pode ser usado para prevenir os problemas do coração de pessoas que já têm sintomas. Em pessoas que já têm problemas no coração com sintomas, o Maleato de enalapril pode:

- retardar a piora da doença;
- diminuir as internações em hospital;
- aumentar o tempo de vida.

Em pessoas que têm problemas no início e sem sintomas, o Maleato de enalapril pode:

- evitar a perda de força do coração;
- atrasar o aparecimento de sintomas, como falta de ar, cansaço ao caminhar e inchaço nos tornozelos e pés;
- diminuir a necessidade de internações em hospital.

Ao usar Maleato de enalapril, algumas pessoas que já têm insuficiência cardíaca (coração fraco) podem ter menor risco de infarto.