ACTA MÉDICA PORTUGUESA
A Revista Científica da Ordem dos Médicos

Translation and Adaptation of the STOPP/START Criteria Version 3 for Potentially Inappropriate Prescribing in Older People to European Portuguese: A Study Protocol

Tradução e Adaptação Para a Língua Portuguesa da Versão 3 dos Critérios STOPP/START para a Prescrição de Medicamentos Potencialmente Inapropriados em Idosos: Protocolo do Estudo

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Acta Med Port 2024 Dec;37(12):847-852 ▪ https://doi.org/10.20344/amp.21941

ABSTRACT

Introduction: As the global population ages, managing medication use in older adults becomes increasingly complex due to polypharmacy and the associated risks of adverse drug events. To improve the safety and appropriateness of medication use in the older population, tools like the Screening Tool of Older Persons' Prescriptions (STOPP) and Screening Tool to Alert doctors to Right Treatment (START) criteria have been developed. The availability of updated criteria is crucial to better support healthcare professionals in Portuguese-speaking regions. The aim of this study is to translate and validate the STOPP/START version 3 criteria for Portuguese, providing an updated and useful tool for healthcare professionals.

Methods and Analysis: This study will be conducted through four phases: I) translation of the STOPP/START version 3 criteria to European Portuguese; II) collection of sociodemographic, clinical, and medication data; III) intrarater reliability study; and IV) interrater agreement study. This study obtained ethics approval by the Ethics Committee of the Administração Regional de Saúde do Centro, Portugal. The availability of the translated criteria will enable the integration of STOPP/START version 3 into clinical practice in Portugal, facilitating improved medication safety and appropriateness. This integration is expected to lead to better management of polypharmacy and a reduction in adverse drug events, ultimately enhancing patient outcomes and supporting evidence-based prescribing practices.

Keywords: Aged; Drug Prescriptions; Inappropriate Prescribing; Portugal; Potentially Inappropriate Medication List; Practice Patterns, Physicians

RESUMO

Introdução: À medida que a população mundial está a envelhecer, a gestão do uso de medicamentos em idosos torna-se cada vez mais complexa devido à polimedicação e aos riscos associados a eventos adversos relacionados com os medicamentos. Para melhorar a segurança e o uso de medicamentos nesta população foram desenvolvidos critérios como os *Screening Tool of Older Persons' Prescriptions* (STOPP) e *Screening Tool to Alert doctors to Right Treatment* (START). A disponibilização de critérios atualizados revela-se crucial para apoiar os profissionais de saúde portugueses. Este estudo tem como objetivo traduzir e validar a versão 3 dos critérios STOPP-START para a língua portuguesa, disponibilizando uma ferramenta útil e devidamente atualizada para os profissionais de saúde.

Métodos e Análise: Este estudo será realizado através de quatro etapas: I) tradução para a língua portuguesa da versão 3 dos critérios STOPP/START; II) recolha de dados sociodemográficos, clínicos e sobre medicamentos; III) estudo de confiabilidade intra-avaliador; e IV) estudo de concordância inter-avaliador. Este estudo obteve parecer favorável da Comissão de Ética da Administração Regional de Saúde do Centro (ARSC) de Portugal. A disponibilização dos critérios traduzidos permitirá a integração dos critérios STOPP/START versão 3 na prática clínica em Portugal, promovendo uma melhoria na segurança e no uso de medicamentos. Espera-se que esta integração leve a uma melhor gestão da polimedicação e a uma redução nos eventos adversos relacionados com os medicamentos, melhorando os resultados para os doentes e apoiando práticas de prescrição baseadas em evidência.

Palavras-chave: Idoso; Lista de Medicamentos Potencialmente Inapropriados; Padrões de Prática Médicos; Portugal; Prescrição Inapropriada; Prescrição de Medicamentos

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Recebido/*Received*: 13/06/2024 - **Aceite/*Accepted*:** 06/09/2024 - **Publicado *Online*/*Published Online*:** 13/11/2024 - **Publicado/*Published*:** 02/12/2024

KEY MESSAGES

- The translation of the STOPP/START version 3 criteria into European Portuguese is aimed at improving medication safety for older adults by providing healthcare professionals with a robust tool to identify and reduce the use of potentially inappropriate medication.
- This study adapts and validates the criteria specifically for Portuguese healthcare settings, ensuring relevance and applicability in local clinical practice.
- The study follows a well-structured translation and validation process, including forward and backward translations and rigorous reliability testing, to ensure accuracy and consistency.
- Medical guidelines and practices vary between countries and regions, which may require further adjustments of the translated criteria to align with local clinical norms.

INTRODUCTION

World population aging is a significant demographic trend resulting from declining birth rates and increasing life expectancy.[1] An aging population, even with healthy aging, poses a challenge for healthcare systems due to the increased demand for medical services and the need for long-term care.[2]

With aging, there is an emergence of many chronic diseases that require the use of a significant number of medication by the older population.[3] Therefore, polypharmacy, often described as the simultaneous use of five or more drugs,[4] can potentiate the use of potentially inappropriate medication (PIM) in the older population.[5] Inappropriate prescribing occurs when the potential risk of adverse effects exceeds the clinical benefit, especially when there are more effective alternative options available.[6]

Over the years, several criteria have been developed to identify and reduce PIM use in older adults. In 1991, the concept of PIM was first introduced, and the Beers criteria were developed.[7] The American Geriatrics Society (AGS) assumed the responsibility for these criteria and started updating them regularly, in 2012,[8] 2015,[9] 2019,[10] and 2023.[11] The Screening Tool of Older Person's Prescriptions (STOPP) and Screening Tool to Alert to Right Treatment (START) criteria were originally developed in 2008 and adapted to European prescribing standards.[12] Such criteria were designed to help healthcare professionals recognize medication that should be considered for initiation or continuation or that may pose a higher risk of adverse effects or reduced efficacy in older adults. The STOPP/START criteria have also been updated through the years, with version 2 published in 2015,[13] and, more recently, version 3 in 2023.[14] When updating the STOPP/START criteria to version 3, the Delphi consensus panel eliminated three outdated or redundant criteria from version 2 and proposed 93 new criteria. After several rounds of validation, 123 STOPP and 67 START criteria were accepted, increasing the total number of criteria, from 114 (version 2) to 190 (version 3). This rigorous process ensured that the updated criteria incorporated the latest evidence and the best practices for managing medication in older adults. Many other tools have been developed[6]; however, the Beers and STOPP criteria have been the most widely used until today.[15]

Recently, a systematic review found that PIM use among older patients has become increasingly prevalent in the past two decades, with an actual worldwide pooled prevalence rate of 36.7%.[16] In Portugal, several studies found a high percentage of PIM in the Portuguese older population, ranging from 27.7% to 86.4%.[17-27]

In 2022, STOPP-START version 2 criteria were adapted and translated to Portuguese.[28] However, the change in the number of criteria with the publication of the new version demonstrates the need and relevance of updating this tool. Different versions of these criteria have also been translated into other languages, such as French,[29] Spanish,[30] Dutch,[31] and Japanese.[32] To our knowledge, this is the first study intended to translate version 3 of the STOPP/START criteria into European Portuguese. The STOPP criteria were considered more practical to use, more comprehensive, and more sensitive in the assessment of PIM when compared to other tools.[15]

The aim of this study is to translate and validate the English STOPP/START version 3 tool for Portuguese healthcare professionals, ensuring its relevance, accuracy, and applicability in local clinical practice.

METHODS AND ANALYSIS

This study obtained ethics approval on the 23rd of January 2024, by the Ethics Committee of the Administração Regional de Saúde do Centro (ARSC), Portugal (approval number 137-2023). The study's flowchart and timeline can be found in Fig. 1.

Study design

This study will be conducted in four phases: phase I, translation to European Portuguese; phase II, data collection; phase III, intra-rater reliability study; phase IV,

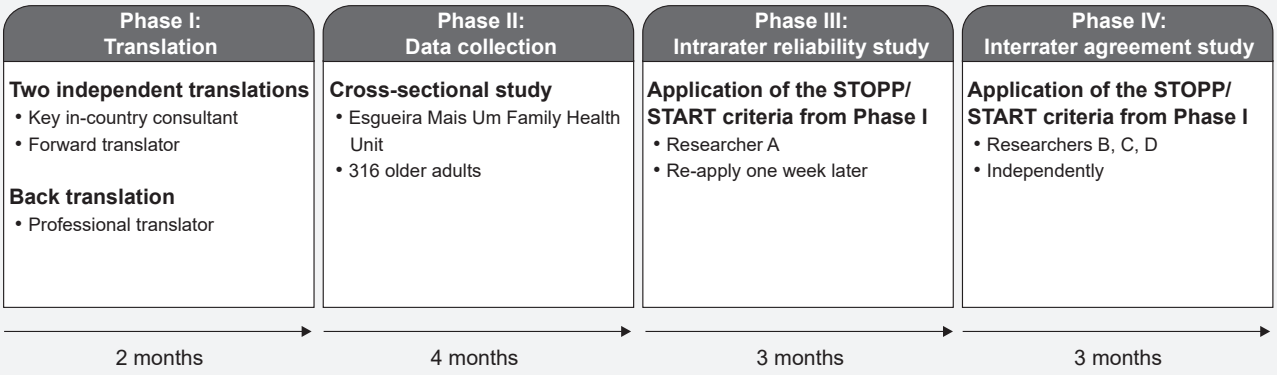

Figure 1 – Study flowchart

inter-rater agreement study.

Study population

The study population will be older adults aged 65 or over. Participants will be excluded if they meet one or more of the following criteria: (i) have dementia; (ii) have severe psychiatric illness; (iii) institutionalized patient; (iv) patient without assigned family physician; (v) have cognitive impairment or physical condition that makes participation in the study impossible and/or (vi) refusal of informed consent to participate in the study.

Phase I: translation to European Portuguese

The translation of the STOPP/START criteria will be carried out in accordance with the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcome (PRO) Measures.[33]

Permission from STOPP/START's authors to translate and validate the tool for Portuguese has already been obtained. Next, we will recruit a key in-country consultant, which is a native Portuguese speaker fluent in English, and residing in Portugal. After that, two independent translations of the criteria will be produced (from English to Portuguese). One will be done by the key in-country consultant and the other by a forward translator, also a native Portuguese and fluent English speaker. The two previous translations will be reconciled by the research team, followed by a back-translation (from Portuguese to English) performed by a professional translator, native English speaker fluent in Portuguese. The next step will be the comparison of the back-translation with the original criteria to detect if there are significant differences or discrepancies. The research team will prepare the final version.

Phase II: data collection

A cross-sectional study will be performed in a primary care center belonging to the Unidade Local de Saúde de Aveiro, in Portugal.

The sample calculation yielded 316 older adults considering the population of 1746 older adults (aged 65 or over) registered at the Unidade de Saúde Familiar (USF) Esgueira Mais, with a confidence level of 95% and margin of error of 5%. Participants will be recruited from the USF Esgueira Mais, ensuring a representative and heterogeneous sample of the older population in primary care. The recruitment strategy will involve the identification of patients aged 65 or older from the electronic health records followed by an invitation from their family physicians. The identified patients will receive an explanation about the study's purpose, procedures, and the importance of their participation. Informed consent will be obtained from all who agree to participate. Researchers will access the electronic health records to retrieve sociodemographic, clinical, and medication data. Specific protocols will be followed to ensure accuracy and consistency, including using predefined data extraction forms for information recording. Structured interviews will be conducted with participants to gather additional data and clarify information from health records. Each patient will be numbered from 1 to 316 to ensure data anonymization and patient protection. The recruitment period will take place between October 2024 and January 2025. In the event of missing data, we will implement appropriate strategies to address this issue that may include imputation methods (such as mean or median imputation), using available data for analyses when possible, and performing sensitivity analyses to assess the impact of missing data on the study's results.

Phase III: intra-rater reliability study

After data collection, a researcher/family physician (named researcher A) will receive training and will apply the translated Portuguese version of the STOPP/START criteria obtained in phase I to the older adult participants considering the data collected in phase II. The researcher will re-apply the STOPP/START criteria to the same users one week later, to measure intra-observer reliability.[34]

Phase IV: interrater agreement study

After receiving training, three researchers/family physicians (named researchers B, C and D) will, independently, apply the translated Portuguese version of the STOPP/START criteria obtained in phase I to older adult participants, to measure inter-observer agreement. Three researchers were considered sufficient since, in studies of interobserver agreement, for dichotomous variables, increasing the number of observers above three had little effect on the power of hypothesis tests or the width of confidence intervals.[35]

Statistical analysis

Data will be stored with Microsoft Excel software. Analyses will be carried out using the Statistical Package for Social Sciences (IBM® SPSS® Statistics version 25) and the software R. Categorical variables will be described using relative and absolute frequencies and percentages, n (%). Continuous variables will be described by the mean and respective standard deviation (mean ± SD) if normally distributed; or by median and interquartile range if not normally distributed. Normality will be assessed by the Kolmogorov-Smirnov test. Intra-rater/inter-rater reliability will be measured using Cohen's κ coefficient and the respective 95% CI.[36] The Cohen's κ coefficient will be interpreted as poor ($\kappa \leq 0.2$), fair ($0.21 \leq \kappa \leq 0.40$), moderate ($0.51 \leq \kappa \leq 0.6$), substantial ($0.61 \leq \kappa \leq 0.8$) and good ($0.81 \leq \kappa \leq 1.00$).[37] Intra-rater/inter-rater agreement will be assessed using agreement proportions and specific (positive and negative) agreement proportions and the respective 95% CI.[36] A *p*-value less than or equal to 0.05 will be considered statistically significant. Adjustment for potential confounding factors will be considered, such as differences in health status, medication-use patterns, and healthcare access, using appropriate techniques like multivariate regression analysis to ensure the robustness and validity of the findings.

Ethics and dissemination

Each participant will sign an informed consent form (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/21941/15548) and will be given a number from 1 to 316 to ensure data pseudonymization, confidentiality, and identity protection. This study obtained ethics approval from the Ethics Committee of the ARSC with the reference number 137-2023. One paper is expected to be published in a related peer-reviewed journal. The results obtained will be disseminated at scientific and professional congresses, to the Portuguese Medical Association, and to political decision-makers for use in healthcare services.

DISCUSSION

With this study it is expected that the availability of the STOPP/START criteria in the Portuguese language will help healthcare professionals to make more informed decisions about prescribing medicines for older adults. This could lead to PIM use reduction, thus enhancing older patient safety.

The translation of the STOPP/START criteria into European Portuguese will make the guidelines more accessible and usable for healthcare professionals and can also help to increase their awareness and knowledge about appropriate medicines use in the older population. By identifying and addressing PIM, healthcare providers can improve medication safety and reduce adverse drug events.

In addition to these clinical benefits, reducing PIM use in the aging population has broader public health implications. Lowering the incidence of medication-related complications can enhance overall healthcare quality and potentially reduce healthcare costs associated with preventable adverse events.[38] Fewer complications mean fewer hospitalizations and treatments, which can significantly decrease healthcare expenditures and improve resource allocation.

Furthermore, by improving medication safety and reducing PIM use, the study contributes, overall, to better patient outcomes. Older adults are particularly vulnerable to medication-related issues,[39] and addressing these through well-validated criteria can lead to a higher quality of life and better management of chronic conditions.

For the successful implementation of these criteria, it will be important to disseminate and integrate the Portuguese version of the STOPP/START criteria into clinical practice guidelines. This integration will ensure that the criteria are effectively utilized in everyday clinical settings, maximizing their impact on patient care. Integrating the translated STOPP/START criteria with existing national guidelines, such as guideline number 018/2016 of 30/12/2016 (updated 01/03/2024) on medication reconciliation,[40] underscores their relevance and alignment with established evidence-based practices. By aligning with these guidelines, the STOPP/START criteria will not only support adherence to best practices but will also contribute to standardizing medication review processes across healthcare settings. This synergy enhances the overall effectiveness of medication management strategies and supports the implementation of high-quality, evidence-based care for older adults.

Moreover, the translated STOPP/START criteria can

also serve as a valuable training tool for healthcare professionals. By incorporating these criteria into training programs, it is possible to increase awareness and knowledge about appropriate prescribing practices for older adults. This will help healthcare providers to better understand and apply evidence-based guidelines, enhancing their ability to identify PIM and make safer prescribing decisions.

To facilitate widespread adoption among healthcare providers, we intend to develop and deliver workshops for healthcare professionals. These sessions will focus on the application and benefits of the STOPP/START criteria, aiming to enhance understanding and practical use in clinical practice. Besides, the incorporation of the STOPP/START criteria into national and local clinical practice guidelines will standardize their use and ensure that they are seamlessly integrated into routine healthcare processes. Therefore, we intend to engage with relevant professional organizations and associations to promote the criteria, encourage its adoption, and facilitate its integration into various healthcare settings.

The expected outcomes from this study can be highly beneficial for healthcare providers, health policy decision-making, and older patients. By enhancing medication safety and improving healthcare quality, the translated STOPP/START criteria will contribute positively to the management of medication use in the older population.

Limitations

Portugal and other Portuguese-speaking countries may have different healthcare systems, availability of medicines and regulatory frameworks, which can affect the applicability of the translated criteria. Besides, medical guidelines can vary between countries and regions, so the translated criteria may need to be adjusted to align with local clinical norms. The study will be conducted at a single primary care center, which may limit the extent to which the findings can be considered representative of the broader Portuguese older adult population. Additionally, participants with conditions such as dementia, severe psychiatric illness, or cognitive impairments will be excluded, which might lead to a sample that does not fully capture the range of medication-related issues experienced by all older adults.

CONCLUSION

The translation and validation of the STOPP/START version 3 criteria into Portuguese represent a crucial step in enhancing medication safety for older adults in Portugal. This initiative is expected to benefit both healthcare professionals and older patients by providing a reliable, evidence-based tool for identifying potentially inappropriate medications and optimizing prescribing practices. For healthcare professionals, the criteria will offer a standardized approach to medication review, improving their ability to make informed decisions and reducing the risk of adverse drug events. For older patients, this means safer medication practices and potentially better health outcomes.

Moreover, by integrating the STOPP/START criteria into clinical practice, it is anticipated that there will be a reduction in medication-related complications and associated healthcare costs. This could lead to improved overall patient care and support the implementation of evidence-based practices across healthcare settings. Additionally, the availability of these criteria may influence health policy decisions and contribute to the standardization of medication review processes in Portugal.

AUTHOR CONTRIBUTIONS

DAR: Study design, data acquisition, writing of the manuscript.

FR, MTH, LM: Study design, critical review of the manuscript.

All authors approved the final version to be published.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

FUNDING SOURCES

This article was supported by National Funds through Fundação para a Ciência e a Tecnologia (FCT), within CINTESIS, R&D Unit. Daniela A. Rodrigues is funded by an individual grant from the FCT (ref 2022.10605.BD).

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