International Journal of Clinical Pharmacy (2019) 41:1562–1569
https://doi.org/10.1007/s11096-019-00920-5

RESEARCH ARTICLE

Patients' clinical information requirements to apply the STOPP/START criteria

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Received: 7 June 2019 / Accepted: 9 October 2019 / Published online: 29 October 2019

Abstract

Background The STOPP/START criteria are an explicit tool to detect potentially inappropriate medications (PIMs). Patient clinical information may not be available in all settings. *Objective* To identify patient clinical information needed to apply the STOPP/START criteria. Setting: Four nursing homes in Portugal. *Methods* First, a theoretical analysis was performed to identify the patient information required to apply the STOPP/START criteria (v2), according to the following categories: patients' current medication, medication history (previous medication and duration), medical records (current and past medical conditions), and laboratory test results. A verification of the information requirements was conducted through a cross-sectional study on a nursing home population with patients over 65 years old. Patients' medical records were appraised to extract only demographic data and current medication profiles. *Main outcome measure* Information requirements of STOPP/START. *Results* For only 29 of the 81 STOPP criteria and 1 of the 34 START criteria, a judgement could be made with only the information in the patient's medication profile. 52 STOPP and 33 START criteria require additional information, (i.e. duration of therapy, previous medication, current and past medical conditions, and laboratory data). The 208 evaluated persons (87 years; 68.75% female) used 1770 medications, with 989 (55.9%) potentially involved in 1629 STOPP criteria. Sufficient information to judge STOPP criteria was available for only 529 (32.5%) potential STOPP criteria situations, with a positive identification of a STOPP PIM in 397 instances (75.0%). *Conclusions* Although STOPP/START criteria can be considered a high-level tool to identify PIMs, their use may be compromised in scenarios where access to patients' clinical information is limited.

Keywords Aged · Clinical patient information · Drug safety · Inappropriate prescribing · STOPP/START criteria

Impact on practice

- The correct use of the STOPP/START criteria requires access to patients' current and past medication profiles and medical records.
- Limited access to patients' clinical information invalidates any comparative analysis of inappropriate prescribing using the STOPP/START criteria.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s11096-019-00920-5) contains supplementary material, which is available to authorized users.

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Introduction

The proportion of people over 65 years old is steadily increasing [1]. In this population, polypharmacy usually leads to an increased chance of drug-drug interactions and adverse drug reactions associated with potentially inappropriate medication use [2]. Potentially inappropriate medications (PIMs) can be defined as medications whose risks outweigh the benefits in older people [3]. In a systematic review, Guaraldo et al. showed that the prevalence of PIMs ranges from 11.5 to 62.5% in community-dwelling aged patients. The use of PIMs is associated with negative clinical outcomes, such as adverse effects, hospitalizations, mortality, and higher health costs [2, 4].

To optimize prescriptions for older people, tools based on implicit or explicit criteria to identify PIM use have been developed in recent decades [5]. Several tools to identify inappropriate prescription in elderly were created, like Beers Criteria [6] or FORTA list [7], and the more recent EU(7) PIM List [8]. These three instruments are considered explicit criteria because their use implies little or no clinical judgement. Among the most commonly used explicit criteria tools are the Screening Tool of Older People's Prescriptions (STOPP) and Screening Tool to Alert to Right Treatment (START) criteria, the second version of which was released in 2014 [9]. The STOPP/START criteria help researchers and practitioners identify 81 PIMs and 34 potential prescribing omissions (PPOs). The STOPP/START criteria are also considered explicit criteria. However, the STOPP/START criteria are more than a simple list of medications to avoid because they aim to identify PIMs under very specific clinical situations that are dependent on the therapeutic context, demonstrating that a medication can be inappropriate in some cases but appropriate in others [9]. Thus, the STOPP/START criteria are excellent tools for use in medication review processes, having demonstrated their capability to improve the quality of prescribing and the clinical, humanistic, and economic outcomes obtained with the medication [10].

However, to properly use the STOPP/START criteria, access to extensive patients' clinical information is required. This access may be limited to some healthcare professionals or in some practice settings [11]. In those situations with limited access to full patients' clinical information, the use of PIM and PPO tools depends on patient self-report, which may produce inaccuracies due to patients' memory and health literacy [12]. Little research has been conducted evaluating the effects of limited access to patients' information on STOPP/START criteria judgement. We recently demonstrated the effect of limited access to information in other well-known explicit PIM tools, namely, the Beers Criteria [13].

Aim of the study

To identify the patients' clinical information requirements to correctly apply the STOPP/START criteria, and identify the potential impact of limited information on the results of this tool.

Ethics approval

This study was approved by the University of Coimbra Medical School Ethics Committee (105-CE-2015).

Method

A two-stage process was designed to first theoretically identify the patient clinical information required to apply the STOPP/START criteria and then verify the consequences of limited access to the required information in a nursing home resident population.

Theoretical analysis

Version 2 of the STOPP/START criteria, released in 2014, was used in this investigation [9]. Two researchers independently appraised the text of the STOPP/START criteria to identify what information sources were needed to evaluate each criterion. The list of information sources considered comprised the following: (a) patients' current medication profile (including the current regime), (b) medication history (including previous medication and duration), (c) medical records (including current and past medical conditions), and (d) test results (including laboratory tests and other measurable parameters).

Verification of the requirements

To evaluate the effects of the lack of information identified in the theoretical analysis, a cross-sectional study was conducted with patients over 65 years old living in 4 nursing homes in Central Portugal that are part of the practice-based research network of the University of Coimbra. Patients' medical records were appraised to extract into an Excel file only demographic data and current medication profiles (international nonproprietary names, dosages, pharmaceutical forms and regime of each medication). Both scheduled medications as well as medications given on an as needed basis (PRN) were considered. Version 2 of

the STOPP/START criteria was applied by one researcher with training in the use of inappropriate medication instruments to the data in the Excel file, with no access to the patient medication records at this stage. The STOPP/START criteria were classified as "applicable" if they could be applied using only the information available or "not applicable" if they could not be applied because of a lack of clinical information. For non-applicable criteria, the missing information required to make a judgment was recorded.

Results

The theoretical analysis of information requirements to apply the STOPP/START criteria demonstrated that of the 81 STOPP criteria, 29 can be judged using only the complete information of the current medication profile: 15 criteria can be immediately judged determined based only on the drug involved, and 14 criteria require information that can be inferred from the other medications currently used by the patient (e.g., medical conditions). The remaining 52 STOPP criteria require the following additional information to be applied (Table 1): duration of therapy (10 criteria); previous medication (8 criteria); current medical conditions (42 criteria); patient medical history (12 criteria); laboratory data (11 criteria); and other measurable parameters (3 criteria). Of the 34 START criteria, only one can be judged when only the current medication is available. The other 33 START criteria require information about the duration of therapy (2 criteria), previous medication (3 criteria), current medical conditions (24 criteria), medical history (6 criteria), laboratory data (1 criterion), and other measurable parameters (6 criteria) (Table 2).

The STOPP/START criteria were applied to the 208 institutionalized older people at the four nursing homes. Their median age was 87 years (IQR = 10), and 68.75% were female. These patients had 1770 prescribed medications (median 8; IQR 5). The most prevalent medications prescribed belonged to the central nervous system, namely, ATC group N (35.81%), and to the cardiovascular system, namely, ATC group C (23.36%). A total of 989 of these medications (55.9%) were amenable to being classified as PIMs because they were included in a total of 1629 STOPP criteria. Sufficient information to judge the existence of a STOPP criterion could be confirmed in only 529 (32.5%) potential STOPP criteria situations, with a positive identification of a STOPP PIM in 397 instances (75.0%). The assessment of the STOPP criteria in the study population is presented in Electronic supplementary material. Regarding the 529 STOPP criteria confirmed as PIM, the most prevalent criteria were K.1.—*benzodiazepines (sedatives that may cause reduced sensorium or impaired balance;* n = 134) and K.2.—*neuroleptic drugs (may cause gait dyspraxia or Parkinsonism*; n = 99). However, 1100 situations considered to be a potential situation amenable to STOPP PIM could not be judged because of a lack of clinical information identified in the theoretical analysis (see "Electronic supplementary material").

Regarding the START criteria, only the criterion E.7.—*folic acid supplementation in patients taking methotrexate* could be judged in the population under analysis using only the information available.

Discussion

This study demonstrates that complete access to clinical information is crucial to judging STOPP/START criteria. Having access only to the patient's current medication profile, only 29 of the 81 STOPP criteria and 1 of the 34 START criteria can be judged. To properly apply the STOPP/START criteria, clinicians and researchers need additional information pertaining to the current medication list, such as the patient's medication history, medical records or clinical examination results.

The STOPP/START criteria are a second-generation explicit criteria for identifying potentially inappropriate medications in the elderly population. In fact, the STOPP/START criteria include more specific situations of inappropriate prescribing, which enhances the robustness of the tool compared to other explicit criteria PIM tools [14]. A common characteristic of all the explicit criteria PIM tools is the capability of being introduced into a clinical decision support system (CDSS) that can be used to reduce prescribing errors and improve the appropriateness of prescriptions [15]. When prescribing software is linked to patient clinical and laboratory data, the appropriateness of prescriptions can be addressed in all potentially relevant dimensions [16]. Too simplistic explicit criteria PIM tools introduced into a CDSS can produce an excessive number of alerts, known as alert fatigue, which are usually ignored by users. The higher complexity of the STOPP/START criteria results in a higher specificity of the alert-generation process. Currently, several attempts to introduce the STOPP/START criteria into CDSS exist: the STRIP assistant [17] and a software application developed within the SENATOR project (https://www.senator-project.eu/).

The other side of the high-specificity issue implies greater patient information requirements. Compared to the EU(7)-PIM list, the STOPP/START criteria require, in addition to the current medication list, information such as the patient's medication history, medical records or clinical examination results [8]. The question of the importance of clinical information has already been addressed by other

Table 1 Patient's clinical information required to apply STOPP criteria

Criteria	Current medication	Indirect application					
		Medication history		Medical records		Test results	
		Duration of therapy	Previous medication	Current medical conditions	Past medical conditions	Laboratory test	Other measurable parameters
A—Indication of medication							
A.1.				X			
A.2.		X					
A.3.	X						
B—Cardiovascular system							
B.1.				X			
B.2.				X			
B.3.	X						
B.4.				X			X (heart rate)
B.5.			X	X			
B.6.			X	X			
B.7.				X		X	
B.8.	XX				X	X (K^+, Na^+, Ca^{2+})	
B.9.	XX			X			
B.10.			X				
B.11.	XX			X		X (K^+)	
B.12.						X (K^+)	
B.13.	XX			X			X (systolic blood pressure)
C—Antiplatelet/anticoagulant drugs							
C.1.		X					
C.2.					X		
C.3.				X			
C.4.				X	X		
C.5.				X			
C.6.				X			
C.7.	X						
C.8.		X		X			
C.9.		X		X			
C.10.	X						
C.11.	X						
D—Central nervous system and psychotropic drugs							
D.1.	XX			X	X		
D.2.			X				
D.3.	XX				X		
D.4.						X (Na^+)	
D.5.		X					
D.6.	XX			X			
D.7.			X				
D.8.	XX			X			
D.9.				X			
D.10.				X			
D.11.	X				X		
D.12.			X	X			
D.13.				X			
D.14.	X						

Table 1 (continued)

Criteria	Current medication	Indirect application					
		Medication history		Medical records		Test results	
		Duration of therapy	Previous medication	Current medical conditions	Past medical conditions	Laboratory test	Other measurable parameters
E—Renal system							
E.1.		X				X (eGFR)	
E.2.						X (eGFR)	
E.3.						X (eGFR)	
E.4.						X (eGFR)	
E.5.						X (eGFR)	
E.6.						X (eGFR)	
F—Gastrointestinal system							
F.1.	XX			X			
F.2.		X		X			
F.3.	XX			X			
F.4.	X						
G—Respiratory system							
G.1.				X			
G.2.				X			
G.3.	XX				X		
G.4.	XX				X		
G.5.				X			X (pO_2, pCO_2)
H—Musculoskeletal system							
H.1.					X		
H.2.				X			
H.3.		X	X				
H.4.		X		X			
H.5.				X			
H.6.		X		X			
H.7.	XX			X			
H.8.	X						
H.9.				X	X		
I—Urogenital system							
I.1.	XX			X			
I.2.				X			
J—Endocrin system							
J.1.	X						
J.2.				X			
J.3.					X		
J.4.					X		
J.5.				X			
J.6.				X			
K—Drugs that predictably increase the risk of falls in older people							
K.1.	X						
K.2.	X						
K.3.				X			
K.4.	X						
L—Analgesic drugs							
L.1.			X				
L.2.	X						

Table 1 (continued)

Criteria	Current medication	Indirect application					
		Medication history		Medical records		Test results	
		Duration of therapy	Previous medication	Current medical conditions	Past medical conditions	Laboratory test	Other measurable parameters
L.3.				X			
N—Antimuscarinic/anticholinergic drug burden							
N.	X						

eGFR: estimated Glomerular Filtration Rate; pO_2: partial pressure of oxygen; pCO_2: partial pressure of carbon dioxide; X: information required from external sources to judge a STOPP criterion; XX: information required to judge a STOPP criterion and can be inferred from current medication used

authors. Differences in the number of PIMs and the number of PIM-qualifying criteria were found when different levels of information were used to judge the Beers Criteria [13]. Ryan et al. reported that without clinical information, PIMs were overestimated and PPOs were underestimated when compared with the number of PIMs and PPOs evaluated by pharmacists with access to clinical data. These authors concluded that the optimal use of the STOPP/START criteria by community pharmacists requires access to patients' full clinical records. Although the version of the STOPP/START criteria used by Ryan et al. [11] was the first version of the STOPP/START tool, the results expected for the new version should not substantially differ. When the creators of the STOPP/START criteria evaluated the interrater reliability between physicians and pharmacists, they concluded that access to the same patient's clinical information was a prerequisite [18]. Gallagher et al. [19] also assessed the interrater reliability among physicians and concluded that more comprehensive clinical and medication details required a higher level of agreement. In a recent study, the STOPP/START criteria were tested to assess medication appropriateness in a resource-limited setting, and hospital and community settings were compared. The authors reported that incomplete documentation in health records was a barrier to the accurate evaluation of PIMs and PPOs, with 53.7% of situations that could not be judged due to the absence of renal function data and 45.9% due to the lack of serum sodium data. The authors concluded that the use of explicit criteria to identify inappropriate prescribing is useful, but the information in medical records should be improved to allow better assessment [20].

Another study that compared two explicit criteria—the PRISCUS list and the STOPP/START criteria—concluded that the PRISCUS tool was more effective when clinical details were unavailable [21]. Nauta et al. tried to computerize the STOPP/START criteria (version 1) using the information contained in an electronic medical record. Similar to our study, the authors could judge only 39 of the 62 STOPP and 18 of the 26 START criteria because of the lack of information about condition severity or complete disease coding. They concluded that having access to laboratory data would address some of these restrictions [22].

With our analysis, we provided a description of the information needed to judge each criterion from the STOPP and START tools. Before using these criteria, a thorough analysis of the availability and reliability of clinical information should be performed. Otherwise, the results of a partial application of any PIM tool may give a false idea of patient safety. In scenarios in which access to patients' clinical information is limited, it is crucial to differentiate between the actual absence of a PIM and the impossibility of judging the existence of a PIM. In general, one should acknowledge that limitation to accessing patients' clinical data may, not only difficult the role of clinical pharmacists, but also hinder the effect of their interventions.

Limitations

The results obtained are limited to the residents of the four nursing homes studied. Although there are no reasons to consider them as a particularly differentiated population, we cannot generalise these results. It is important to note that our aim was to assess the relevance of having full access to patients' medical records in order to correctly use STOPP/START criteria, using for this purpose a scenario where the clinical information was scarce. To internationally validate these results, similar assessment should be repeated in other cohorts of elderly people.

Table 2 Patient's clinical information required to apply START criteria

Criteria	Current Medication	Indirect application					
		Medication history		Medical records		Test results	
		Duration of therapy	Previous medication	Current medical conditions	Past medical conditions	Laboratory data	Other measureable parameters
A—Cardiovascular system							
A.1.				X			
A.2.				X			
A.3.					X		
A.4.				X			X (blood pressure)
A.5.					X		
A.6.				X			
A.7.				X			
A.8.				X			
B—Respiratory system							
B.1.				X			
B.2.				X			
B.3.							X (FEV_1, pO_2, CO_2)
C—Central nervous system and eyes							
C.1.				X			
C.2.				X			
C.3.				X			
C.4.				X			
C.5.				X			
C.6.				X			
D—Gastrointestinal system							
D.1.				X			
D.2.				X	X		
E—Musculoskeletal system							
E.1.				X			
E.2.		X					
E.3.				X	X		X (BMD)
E.4.				X	X		X (BMD)
E.5.				X			X (BMD)
E.6.					X		
E.7.	X						
F- Endocrin system							
F.1.				X		X (proteinuria and microalbuminuria)	
G—Urogenital system							
G.1.				X			
G.2.				X			
G.3.				X			
H—Analgesics							
H.1.			X				
H.2.		X					
I—Vaccines							
I.1.			X				
I.2.			X				

FEV_1: Forced expiratory volume in the first second; pO_2: partial pressure of oxygen; pCO_2: partial pressure of carbon dioxide; BMD: Bone mineral density

Conclusion

Although the STOPP/START criteria can be considered a high-level tool to identify PIMs because of their highly specific criteria, their use may be compromised in scenarios in which access to patients' clinical information is limited. Clinicians or researchers using the STOPP/START criteria should have unlimited access to information on patients' current medication, duration of therapy, previous medication, current medical conditions, medical history, laboratory data, and other measurable parameters.

Funding Marta Lavrador obtained a complete Doctoral grant from the FCT—Fundação para a Ciência e a Tecnologia (SFRH/BD/123678/2016). No other external funding was received for this study.

Conflicts of interest The authors declare that they have no conflict of interest.

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