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#### **RESEARCH ARTICLE**



# Usefulness of STOPP/START criteria to assess appropriateness of medicines prescribed to older adults in a resource-limited setting

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#### Abstract

*Background* There is a dearth of published data from resource-limited settings on appropriateness of medicines in older adults using explicit criteria, but it is unclear if the STOPP/START criteria can be helpful. *Objective* To assess the usefulness of STOPP/START criteria in assessing appropriateness of medicines in a resource-limited setting. *Setting* Medical, diabetic and psychiatric clinics of a tertiary care hospital and elderly living in a selected locality in Colombo district. *Method* A descriptive cross-sectional study was conducted over a 2 months period among adults > 60 years on long-term medicines. 'Screening tool of older person's prescriptions' (STOPP) and 'screening tool to alert doctors to right treatment' (START) criteria were used to assess appropriateness of medicines. *Main outcome measures* Potentially inappropriate medicines (PIMs) and potential prescription omissions (PPOs). *Results* A total of 468 patients prescribed with 2841 medicines were analysed. PIMs were seen among 167 (35.7%) patients, while PPOs were seen among 289 (61.8%) patients. Incomplete documentation in health records, especially the absence of renal function status (53.7%), was a barrier for accurate assessment of PIMs and PPOs. Some criteria could not be assessed due to differences in the healthcare settings and resources available. *Conclusions* Inappropriate prescribing to older adults was a problem in the selected settings. Use of explicit criteria to detect inappropriate prescribing is important, but should be modified to suit the local context. Documentation in medical records should be improved to allow for better assessment of appropriateness of medicines.

Keywords Medicines appropriateness · Older adults · Resource-limited settings · Sri Lanka · STOPP/START criteria

#### **Impacts on Practice**

 Potentially inappropriate medicines are a problem in community-dwelling older adults in Sri Lanka and needs to be addressed.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s11096-019-00786-7) contains supplementary material, which is available to authorized users.

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- Using criteria appropriate to a resource-rich setting has limitations when directly applied to resource-limited settings like Sri Lanka.
- To be meaningful, specific explicit criteria should be developed to assess medicines appropriateness relevant to the healthcare setting in Sri Lanka and other resource limited settings.

#### Introduction

Prescribing for older adults is challenging. Changes in pharmacokinetics and pharmacodynamics that occur with ageing [1], increased potential for polypharmacy [2], limited evidence regarding medicines effectiveness and safety in older and frail patients [3] and the presence of multiple comorbidities, affect the effectivety of medication in older adults. These could lead to inappropriate prescribing (IP). "Appropriateness" of prescribing is subjective and depends on the quality of available evidence, prescriber and



patient viewpoints and goals. Inappropriate prescribing, which includes both under- and over-prescribing, results in increased risks to patients outweighing the potential benefits. Termed "potentially inappropriate prescribing" (PIP), it reflects the limitations of the methods used to identify IP and that the process of prescribing is subjective. PIPs result in increased healthcare costs [4, 5], functional decline and reduced quality of life [5] and adverse drug events (ADEs) leading to hospitalisation and death [6]. The prevalence of PIPs in older adults has been shown to vary from 15 to 44% [7], the variation being due to criteria used to define PIPs and populations studied. A review of 19 studies conducted in different countries found that one in five prescriptions for older adults in primary care was inappropriate [8].

Implicit and explicit criteria help to identify potentially inappropriate prescribing (PIP) and improve therapy. Implicit criteria such as medication appropriateness index (MAI) require interpretation by a clinician and can be time consuming to use [9]. In contrast, explicit criteria such as Beer's and screening tool of older persons' prescriptions (STOPP) and screening tool to alert doctors to right treatment (START) are simple, quick to apply, objective and do not need clinical judgment [9]. Both these explicit criteria are expert consensus derived, but Beer's has not been validated outside North America [10].

STOPP/START (version 1) has 87 indicators which are organised according to the physiological systems to which each relate and refers to classes of medicines rather than specific medications [11]. These features enhance its usability and makes transferability to different healthcare systems easier. STOPP identifies medicines that may have a potential to be discontinued, while START addresses prescribing omissions, i.e. medicines that should be considered for use in certain medical conditions in older adults. Although European based and validated [12], STOPP/START criteria have been used to review the appropriateness of medicines of medical inpatients [13], community-dwelling elderly [14–16] in Asia [13, 16], Europe [15] and North America [14].

Sri Lanka is a low-middle income country in South Asia that has a rapidly ageing population. The population of older adults (> 60 years) which was 2.5 million (12.4%) in 2012 is expected to double (24.8%) by 2041 [17]. Most of these older adults are community dwelling and live with extended families or alone. Therefore, optimising medicines use in this population is an important clinical and public health issue.

Sri Lanka provides free health care to all her people through entirely state-funded healthcare institutions. People may also opt to obtain health care from the private sector. Annually, about 55% of outpatient (similar to General Practice) and > 90% of inpatient care are delivered through state healthcare institutions [18]. The medicines for state healthcare facilities are selected from the Sri Lanka's Essential Medicines list (SL-EML) [19]. The SL-EML is developed based on the World Health Organization (WHO) model list, the health needs specific for Sri Lanka and the cost of medicines. Thus, the medicines and facilities available in state healthcare facilities may differ to those in developed countries. These differences could make it difficult to apply indices and tools developed in such settings effectively. When patients opt to obtain health care from private (non-state funded) institutions, all related expenses must be met either through medical insurance or personal funds. Medicines prescribed in such instances may be different to those in the state healthcare facilities as cost is not a major limiting factor. Such differences in social and healthcare systems and availability of medicines in different countries necessitate country-specific research to identify problems and to plan remedial activities.

#### Aims of the study

We planned a project to develop explicit criteria specific for Sri Lanka for detection of PIPs in older adults. The aims of the initial phase as reported in this paper were to determine the prevalence of PIPs in selected settings using STOPP/ START criteria version 1 and to identify problems and limitations when using these criteria in the selected settings.

#### **Ethics approval**

The study was approved by the Ethics Review Committee of the Faculty of Medical Sciences of University of Sri Jayewardenepura (B.Pharm. 2014/03).

#### Method

#### **Study design**

A descriptive cross-sectional study was conducted over 2 months among community-dwelling older adults ( $\geq 60$  years) on long-term medicines. Age cut-off of 60 years was selected as it is the retirement age for people for state institutions in Sri Lanka.

#### Setting

The study hospital was a tertiary care hospital in the Colombo district with a bed strength of 435 with inpatient and outpatient facilities and an emergency treatment unit. The hospital provides care in all major specialties such as medicine, surgery, paediatrics and obstetrics and gynaecology, and some selected finer specialties such as psychiatry, ophthalmology and ENT. Specialised clinics are conducted regularly, and the patients obtain their

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monthly supply of regular medicines for diabetes, other non-communicable diseases (NCDs) and psychiatric illnesses from these clinics. As there is no screening process in Sri Lanka to attend a hospital, patients with any type of illness can seek treatment from any hospital. The clinics were selected to represent the community-dwelling older adults who would be on long-term medicines for chronic illnesses.

The community study was conducted with the objective of assessing some private sector prescriptions in addition to state sector prescriptions. The selected area was different to the catchment area of the selected hospital to avoid overlap of patients. The selected community had a population of 6000, of which 1370 were  $\geq$  60 years of age and living in the community (data from Grama Niladhari office of the area, personal communications).

Data were collected from older adults aged  $\geq 60$  years, attending medical, diabetic and psychiatric clinics of the study hospital and from older adults on long-term medicines living in the selected community study area. Long-term medicines were defined as prescription medicines that the patient has been taking daily for chronic illnesses for more than 1 month. These were identified from the most current prescription of the patient.

#### Study sample

Since there were no previous studies done in Sri Lanka, we assumed that 50% of older adults would have medicines that are inappropriate. Allowing 10% for missing data, and considering a 95% confidence level, the required sample size was estimated as 400 for each setting. In the hospital sample, the patient numbers from each clinic were calculated according to the proportion of attendance to clinics.

Every third outpatient, 60 years and above in age, who attended the medical, diabetic and the psychiatric outpatient clinics of the selected hospital and had their clinic records with them were selected for the study until the required sample size was obtained. Each patient was included only once as changes to regular prescriptions would be low in clinic settings unless a new compelling indication was identified. In the community, the selected population was divided into clusters according to the divisional map of the area and the cluster with the highest inhabitants of elderly patients was selected as the study area. Every house in a lane with older adults living in it was identified to obtain 400 households for the community study. Of these, older adults on long-term medicines were selected for the study. Those without any health records with them were excluded from the study sample. Written informed consent was obtained from all those who fulfilled inclusion criteria.

#### **Data collection**

Data were collected by two trained pharmacists according to a pre-prepared checklist. This was based on STOPP/START version 1. Each patient's current drugs were identified from the latest prescription in the clinic records with them as these would be the most accurate and up to date. Other relevant medical history was obtained from medical records that were with patients and by taking histories according to the checklist. Both pharmacists were involved in a single patient at a time to avoid variability in data collection.

#### **Data analysis**

PIPs, which included potentially inappropriate medicines (PIMs) and potential prescription omissions (PPOs), were detected according to STOPP and START criteria, respectively. The initial assessment done by the pharmacists was checked and endorsed by a clinical pharmacologist and a clinical pharmacist to ensure accuracy. When there was a difference of opinion, available guidelines and the literature were perused and a consensus was reached.

Statistical Package for the Social Sciences (SPSS) version 20 was used for calculating frequencies of prescribed medicines, total number of PIMs and PPOs and percentages of PIMs. Significance level was set as 0.05.

#### Results

In the hospital sample, all 400 randomly selected clinic attendees (outpatients) had records for the relevant clinic with them. All of them consented for the study and were included in the final analysis. Although 400 households with older adults were visited in the community. only 246 fulfilled the inclusion criteria. Of these, 178 were excluded from the survey as they either refused to consent (N = 144) or did not have any health records with them (N = 34). Only 68 older adults from the community were included in the final analysis of 468 patients.

The most current medicine list of 468 patients which contained a total of 2841 medicines was analysed according to the STOPP/START criteria (version 1).

Demographic data of selected patients are given in Table 1. The mean age (standard deviation) of patients was 69.5 years (6.6), and 61.3% were female.

Common diseases for which patients were on long-term medicines in both settings (N=468) were NCDs such as hypertension (251, 53.6%), type 2 diabetes (208, 44.4%), ischaemic heart disease (209, 44.7%) and bronchial asthma/ COPD (98, 20.9%). Of the 468 selected, 341 (72.9%) were on medicines for multiple NCDs. Although no patients were identified with psychiatric illnesses in the selected

#### Electronic o high results and

	Study setting				
	Hospital N = 4(3)	Community N = 68	Total		
			N = 468		
Sex distribution (N	(%)				
Males	161 (40.3%)	20 (29.4%)	181 (38.7%)		
Females	239 (59 8%)	48 (70.6%)	287 (61.3%)		
Ver distribution ve	ars (N. %)				
(4) . 7()	267 (66.8%)	39 (57.47)	306 (65.4%)		
71-80	119 (29.8%)	22 (32.4%)	141 (30.1%)		
> 81	14 (3.5%)	7 (10.3%)	21 (4.5%)		
Number of preserv patients (N, %)	bed medicines in .	the current medic	rine list of		
Medicines ≤5	195 (48.7%)	26 (38.2%)	221 (47.2%)		
Medicines 6-9	189 (47.3%)	35 (51.5%)	224 (47.9%)		
Medicines ≥ 10	16 (4.0%)	7 (10.3%)	23 (4.9%)		
Median, range	6 (1-13)	7 (1+13)	6.5 (1-13)		

Total N was used as the denominator for calculating percentages; Totals may not add up to 100% due to rounding up

community sample, schizophrenia (50.7%) and depression (34.3%) were the most common diseases among psychiatric clinic attendees (N = 67).

Medicine lists of the majority of patients (456, 97.4%) had PIPs. PIMs were seen in 167 (35.7%) medicine lists, while PPOs were seen in 289 (61.8%). We identified a total of 171 PIMs and 296 PPOs in our sample of medicines (N = 2841,

Table 2 Some potentially inappropriate medicines (PIMs) identified

46.4% of all medicines). Some common PIMs and PPOs identified are shown in Tables 2 and 3, respectively.

We encountered instances where some of the STOPP/ START criteria could not be applied. For example, the START criteria of "Home continuous oxygen with documented chronic type 1 respiratory failure or type 2 respiratory failure" could not be assessed as domiciliary oxygen therapy is not available from state sector hospitals. The absence of documented evidence of renal function (250, 53.7%) and serum Na\* (215, 45.9%) also prevented assessment of some criteria where these were needed.

#### Discussion

Our findings indicate that PIPs are a problem in communitydwelling older adults in the settings studied. PIPs were identified in medicines lists of most patients (97.4%). Out of the 2841 medicines analysed, 16.4% were PIPs (PPOs +PIMs). This is comparable to findings from India (19.8%) [14] and Europe (22%) [15].

Among the 400 medicine lists of patients from the hospital, 83 (20.7%) were identified with PIMs and 173 (43.2%) with PPOs. While the number of medicine lists with PIMs was comparable, those with PPOs were much higher than what was seen in a similar study conducted in a Korean university hospital geriatric clinic. In this study, PIMs accounted for 20.5%, while PPOs accounted for 26.5% of all medicine lists of patients [20]. The higher percentage

STOPP criteria	Study setting	
	Hospital $N = 400^{\circ}$	Community $N = 68^{\circ}$
(A) Cardiovascular system		
Calcium channel blocker with chronic constipation	15 (3.8%)	9 (13.2%)
(B) Central nervous system and psychotropic drugs		
Tricyclic antidepressant with dementia or with glaucoma or with constipation or with pros- tatism or prior history of urinary retention or with an opiate or calcium channel blocker	28 (7.0%)	1 (1.5%)
Anticholinergies to treat extra pyramidal side effects of antipsychotic medications		
Prolong use (>1 week) of first-generation antihistamines		
(C) Gastrointestinal system		
Proton pump inhibitors for peptic ulcer disease at full therapeutic dosage for >8 weeks	37 (9.3%)	3 (4.4%)
Anticholinergic antispasmodic drugs with chronic constipation		
(H) Endocrine system		
Glibenclamide or chlorpropamide with Type 2 diabetes mellitus	14 (3.6%)	5 (8.4%)
Beta blockers in those with diabetes mellitus and frequent hypoglycaemic episodes		
(K) Drugs that adversely affect fallers		
Neuroleptics in patients prone to fall (a fall in the last 3 months)	14 (3.5%)	2 (2.9%)
First-generation antihistamines in patients prone to fall		

All identified PIMs are not shown on this table

<sup>a</sup>The total number of patients (N) in each setting was used as the denominator for calculating percentages

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#### Table 3 Some potential prescription omissions (PPOs) identified

START criteria	Study setting		
	Hospital N=400°	Community N=684	
(A) Cardiovascular system			
Wartarin in the presence of chronic arrial fibrillation	101 (25.5%)	16 (23.5%)	
Aspirin or clopidogrel with a documented history of atherosclerotic coronary, cerebral or peripheral vascular disease in patients with sinus rhythm			
Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease			
ACE inhibitor with chronic heart failure or following acute myocardial infraction			
Beta blocker with chronic stable angina			
(B) Respiratory system	10 (0.001)	6 (8.8%)	
ular inhaled p2-agonist or anticholinergic agent for mild-to-moderate asthma or chronic obstruc- ce pulmonary disease	13 (3.5%)		
(D) Gastrointestinal system	11 (2.99)	1 (5 0%)	
Proton pump inhibitor with severe gastro-oesophageal acid reflux disease or peptic stricture requiring dilation	11 (2.8%)	·+ (J.9 %)	
(F) Endocrine system	110 (20.90)	21 (30.9%)	
Metformin with Type 2 diabetes $\pm$ metabolic syndrome (in the absence of renal impairment)	[19(29.070)	21 (30.5%)	
ACE inhibitor or angiotensin-receptor blocker in diabetes with nephropathy			
Antiplatelet therapy in diabetes mellitus with coexisting major cardiovascular risk factors			
Statin therapy in diabetes mellitus with coexisting major cardiovascular risk factors present			

All identified PPOs are not shown on this table

0

'The total number of patients (N) in each setting was used as the denominator for calculating percentages

of PPOs seen in our study could be due to our clinics being more general in natures and cater for all adults (> 18 years of age). In such situations, unlike in a specialised geriatric clinic, less attention would be devoted to older adults and their special needs.

The majority of the older adults (52.8%, N = 247/468) had more than five medicines in a single medicine list. As PIMs are more likely when more medicines are given to an individual, it is important to regularly assess such medicine lists to determine if all prescribed medicines are needed.

Although first of this nature in Sri Lanka, our study has some limitations. Incomplete documentation in health records was a major barrier for proper application of STOPP/ START criteria version 1. The commonest omission was the biochemical data that were needed to assess renal functions as only 218 (46.3%) had documented evidence of renal function status-i.e. serum creatinine value or the estimated glomerular filtration rate (eGFR). Although it is possible that the relevant investigations have been done, the absence of records prevented analysis of criteria such as the appropriateness of digoxin dose prescribed, use of NSAIDs and whether metformin should be prescribed or not in those with type 2 diabetes in relation to renal function status as given in STOPP criteria. The stage of heart failure according to NYHA classification and the presence/absence of diabetic nephropathy (urine microalbuminuria), serum electrolyte values were the other information that was also not documented in the records and hindered the assessment of some of the STOPP/START criteria.

A special problem encountered in the community sample of older adults was the absence of any health records with them (N = 34). This is due to the practice of retaining some of the health records, mainly the prescriptions/medicine lists, in the hospital clinics, making it difficult to assess the appropriateness as most patients did not know the names of their regular medicines. The problem is further aggravated with medicinal names being stated in English, which is not the primary language of the patients. The absence of up-todate medical records with a patient would create problems if they seek medical care from a different hospital or a healthcare provider. This is a common practice in Sri Lanka as there are no proper referral systems in place.

The study population was from clinics of one hospital and a selected community, and the prescribing practices would reflect only of those practicing in the selected hospital and community. Although it is difficult to generalise, the situation was similar in a previous study done in three different hospitals using a different methodology [21]. It would also be difficult to compare this with prescriptions exclusively from the private sector as prescribing practices differ, depending on the availability of medicines and financial status of patients.

Assessment of one medicine list of a patient using STOPP/START criteria took an average of 10 min. This could pose practical problems if done in a busy clinic with an average of 200 patients a day.

As the STOPP/START criteria were developed in Europe, applying the existing criteria resulted in some limitations. Some of the recommended treatment modalities or drugs are not readily available in the state sector hospitals in resourcelimited settings such as Sri Lanka. This probably led to an increase in the incidence of PIPs which in reality is not the case. Similarly, although it is recommended to avoid tricyclic antidepressants (TCAs) and first-generation antihistamines such as chlorpheniramine in older adults, these may be the only drugs available in state sector hospitals for the given indications as they are cheap and are included in the National List of Essential Medicines of Sri Lanka [19].

### Conclusions

PIPs are a problem for rational drug use in communitydwelling older adults in Sri Lanka. Explicit criteria such as STOPP/START are valuable to detect inappropriate prescribing as they provide consistent means to benchmark quality of prescribing. To be practical and meaningful, the criteria should be appropriate for the healthcare setting. As such, there is a need for development of explicit criteria that are based on the healthcare system of countries such as Sri Lanka where the availability of medicines and therapeutic modalities may be determined by the cost and not by the best recommended option. Such criteria would moist probably have a wider acceptance among the users and the policy makers in resource limited settings.

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

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