

Original Research Article

Prevalence of adverse events due to self-administration errors among patients in a tertiary care hospital: a cross-sectional study utilizing the SAME tool

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ABSTRACT

Background: Self-administration medication errors (SAMEs) are a growing concern in outpatient care, especially among patients with chronic conditions requiring complex medication regimens. Despite perceived competence, many patients may be at risk of medication mismanagement, leading to adverse outcomes.

Methods: A cross-sectional study was conducted among 237 patients with chronic diseases. The SAME tool, a 10-item validated instrument (Cronbach's $\alpha=0.814$), was used to identify self-administration errors and stratify patients into risk categories. Sociodemographic and clinical data, including pill burden and comorbidities, were analyzed for associations with error prevalence.

Results: The prevalence of self-administration medication errors was 31.6%. Forgetting doses (22.4%) was the most frequent error, followed by wrong dose (11.0%) and wrong medication intake (10.1%). Multimorbidity and higher pill burden (≥ 6 pills/day) were significantly associated with higher error rates ($p<0.05$), while age and gender showed no significant correlation. Patients were classified as high risk (17.7%), moderate risk (61.2%), and low risk (21.1%) for medication errors.

Conclusions: Self-administration medication errors are common, especially among patients with multiple conditions and complex regimens. The SAME tool is effective for identifying at-risk individuals. Targeted interventions focusing on medication literacy and regimen simplification are crucial to enhance adherence and safety in outpatient care.

Keywords: Adherence, Chronic disease, Medication errors, Patient safety, Polypharmacy, Risk assessment, SAME tool, Self-administration

INTRODUCTION

Medication errors are a major patient safety concern across healthcare settings globally. These preventable mistakes- ranging from incorrect dosing and timing to confusion of medications- can compromise treatment outcomes, contribute to avoidable morbidity and mortality, and escalate healthcare costs. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as “any preventable event that may cause or lead to inappropriate medication use”.¹ Although traditional research has

focused on errors by healthcare providers, growing evidence underscores that errors during self-administration- errors made by patients themselves- also present a significant risk, especially in outpatient and home settings.

Self-administered medication errors (MSEs) are particularly prevalent among individuals with complex treatment regimens, such as older adults with polypharmacy. In a study of low literate, community dwelling older adults with multiple medications, nearly 70% reported self-administration errors within six months,

with approximately 18% experiencing adverse events following these errors.² Polypharmacy- often defined as the regular use of five or more medications- frequently occurs in aging populations and is associated with higher rates of MSEs due to regimen complexity and cognitive or literacy challenges.^{1,3} A systematic review corroborates that the frequency of self-medication errors across studies ranged from 19% to 59%, with common mistakes including incorrect dosage, forgetting doses, mixing up medications, and taking expired products.⁴ Although many of these errors may not result in severe harm, the potential for escalation to adverse outcomes remains a key concern.

In tertiary care hospitals, the stakes are even higher: patients often manage chronic conditions requiring multiple, potent medications. The need to understand and quantify self-administration errors in this context is critical, yet limited validated tools exist for assessing patient behaviors and vulnerabilities related to self-medication. Existing studies have predominantly focused on medication errors in professional administration- for example, nurses in inpatient wards- rather than patient self-use. Reported prevalence of administration errors by nurses in tertiary hospitals varies widely, often exceeding 15-25%, and is driven by factors like interruptions, workload, and communication breakdowns.⁵ Yet, the outpatient scenario- particularly self-administration- is a distinct domain that demands tailored assessment strategies.

Given this gap, the development and validation of a patient centered instrument to assess self-administration error risk- such as the SAME tool- is timely and essential. Such a tool could enable systematic identification of at-risk individuals, support targeted interventions (e.g., focused education, regimen simplification, reminder systems), and ultimately reduce medication related adverse events in complex care settings. Tertiary care patients frequently contend with chronic diseases, multimorbidity, and high pill burden- a combination that heightens both the likelihood and the implications of self-administration errors.

The present study aimed to estimate the prevalence of self-administration related adverse events among patients in a tertiary care hospital using the validated SAME tool. This objective aligns with the pressing need to address patient safety during transitions of care, particularly when patients assume responsibility for medication management. By applying a rigorously validated, patient-oriented instrument within a tertiary hospital context, this study seeks to fill a critical knowledge gap and inform practical strategies to enhance medication safety for chronically ill populations.

Objective

To estimate the prevalence of adverse events due to self-administration errors in patients of a tertiary care hospital.

METHODS

Study design and setting

This was a hospital-based, cross-sectional observational study conducted at the pharmacy department of the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, a tertiary care teaching hospital in India.

The study was carried out over a 12-month period from May 2023 to April 2024.

Ethical considerations

The study was approved by the institutional ethics committee, JIPMER (Approval No. JIP/IEC-OS/206/2023). Written informed consent was obtained from all participants after providing a detailed participant information sheet. Participation was voluntary, and confidentiality was maintained throughout the study.

Study population

Adult patients attending the JIPMER pharmacy with prescriptions for chronic conditions were considered eligible. These included patients diagnosed with epilepsy, diabetes, hypertension, cardiovascular disease, and other chronic illnesses who were self-administering their medications.

Inclusion criteria

Adults aged ≥ 18 years. Diagnosed with one or more chronic conditions. Prescribed at least two medications for daily use (polypharmacy). Capable of reading and understanding English or Tamil. Willing to provide written informed consent.

Exclusion criteria

Individuals with diagnosed cognitive impairment or severe psychiatric illness. Patients relying entirely on caregivers for medication administration. Incomplete responses to the SAME tool questionnaire.

Sample size calculation

Based on a prior systematic review that reported a 19% prevalence of self-administration medication errors, a sample size of 237 participants was calculated to achieve 80% power at a 95% confidence level and 5% margin of error.³

Sampling technique

Convenience sampling was used to enroll eligible participants from those visiting the outpatient pharmacy for prescription refills during the study period.

Data collection procedure

After informed consent, each participant was administered a structured data collection form by the principal investigator. This form included: Demographics: age, gender, educational status. Clinical information: diagnosis, duration of illness, current medications. Medication details: number and names of drugs, dosage regimen, formulation types. Adverse events: history of side effects, missed doses, or any reported medication error.

Instrument used

The self-administration medication error (SAME) tool, a validated questionnaire developed to assess risks associated with medication self-administration, was used in this study. It includes ten items rated on a 5-point Likert scale, covering dimensions such as confidence, understanding, dosing accuracy, side effects, and emotional burden of medication use.

The tool was previously developed and validated in a tertiary care setting, demonstrating high content validity (S-CVI=1.0), internal consistency (Cronbach's α =0.815), and construct validity through significant Pearson correlations across all items (r =0.492-0.740, p <0.05).⁶

To reduce social desirability bias, participants were encouraged to complete the SAME tool independently. Assistance was provided only when clarification was needed.

Data analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 29.0. Descriptive statistics (mean, SD, frequency, percentages) were used to summarize demographic and clinical characteristics. Reliability of the SAME tool in this cohort was assessed using Cronbach's α . Correlation between variables was explored using Pearson correlation coefficients. Chi-square or Fisher's exact test was used for categorical comparisons where appropriate. A p value <0.05 was considered statistically significant.

Outcome measures

Primary outcome

Prevalence of adverse events attributable to self-administration medication errors.

Secondary outcomes

Frequency of specific self-administration errors (e.g., wrong dose, missed dose). Association between demographic/clinical factors and medication errors. Internal consistency of the SAME tool in this study population.

RESULTS

A total of 237 participants were included in the study. The study included 237 patients (52.7% male, mean age $\approx$ 53.9 $\pm$ 17.4 years). Multi-morbidity was common: 42.6% had $\geq$ 2 chronic diseases.

Table 1: Demographic and clinical characteristics of participants (n=237).

Variables	Category	N	%
Age group (in years)	18-39	68	28.7
	40-59	86	36.3
	$\geq$ 60	83	35.0
Gender	Male	125	52.7
	Female	112	47.3
Primary diagnosis	Epilepsy only	82	34.6
	Hypertension (HTN) only	31	13.1
	Diabetes mellitus (DM) only	23	9.7
	HTN + DM	49	20.7
	Other multi-morbidity*	52	21.9
Number of pills/day	2-3	126	53.2
	4-5	64	27.0
	$\geq$ 6	47	19.8

*Includes combinations with IHD, hypothyroidism, epilepsy + DM/HTN, etc.

Table 2: Reliability of the SAME tool in this cohort.

Statistics	Values
Number of items	10
Cronbach's α (overall)	0.814
Item-total correlations	0.42-0.71
Cronbach's α if item deleted	0.796-0.820

The SAME tool showed excellent reliability and internal consistency for detecting self-administration risk in this cohort (α =0.814), in line with its original validation.

Approximately 31.6% of participants exhibited at least one self-administration medication error as identified by low scores (1 or 2) in forgetting medication, wrong medication intake, or wrong dosage. Forgetting to take medication (Q3) was the most frequent error, affecting 22.4% of participants. Errors involving wrong medication (Q4) and wrong dose (Q5) were less common but still notable, affecting 10.1% and 11.0% respectively. These findings highlight a significant prevalence of medication self-administration challenges requiring clinical attention to reduce errors and improve adherence.

Patients with multiple chronic diseases and those taking $\geq$ 6 pills daily had significantly higher error rates (p <0.05). Age and gender were not significant predictors. Subjectively, many patients still reported confidence in managing their medications, but objective risk items revealed gaps- especially related to pill burden and forgetting doses.

Table 3: Distribution of SAME tool responses (n=237).

Item	SAME tool question (abbreviated)	Mean±SD	% at high-risk**
Q1	Confidence taking medication	3.78±0.86	12.2% (≤2 score)
Q2	Comfort asking provider	3.46±0.92	15.6% (≤2 score)
Q3	Forgot to take medication (freq.)	3.12±1.05	28.7% (≥4 score)
Q4	Took wrong medication (freq.)	2.84±0.94	22.8% (≥3 score)
Q5	Took wrong dose (freq.)	2.77±0.98	24.5% (≥3 score)
Q6	Ease of understanding instructions	3.52±0.80	10.1% (≤2 score)
Q7	Side effects from medication	3.01±0.99	19.0% (≥4 score)
Q8	Meds improve health perception	3.66±0.77	8.0% (≤2 score)
Q9	Negative daily life impact	2.58±0.91	14.3% (≥4 score)
Q10	Overwhelmed by pill burden	2.94±1.06	21.1% (≥4 score)

**High-risk criteria: Positive items (e.g., Q1, Q2, Q6, Q8)- low rating ≤2 = risk. Negative items (e.g., Q3, Q4, Q5, Q7, Q9, Q10)- high rating ≥4 = risk

Table 4: Prevalence of self-administration medication errors (n=237).

Error type	Number of patients	Prevalence (%)
Forgot medication (Q3)	53	22.4
Took wrong medication (Q4)	24	10.1
Took wrong dose (Q5)	26	11.0
Any ≥1 error on Q3 or Q4 or Q5	75	31.6

Table 5: Association between factors and any medication error.

Factors	Category	Error present (%)	Error absent (%)	χ^2	P value
Age group (years)	18-39	54.4	45.6	2.31	0.315
	40-59	58.1	41.9		
	≥60	65.1	34.9		
Gender	Male	58.4	41.6	0.18	0.675
	Female	61.6	38.4		
Diagnosis	Single disease	51.4	48.6	6.42	0.041*
	Multiple diseases	65.8	34.2		
Pill burden/day	2-3	47.6	52.4	15.92	<0.001*
	4-5	62.5	37.5		
	≥6	85.1	14.9		

*Statistically significant at p<0.05.

The observed mean (33.9) supports that most patients have moderate challenges in managing their medications effectively.

Table 6: Overall SAME tool score distribution.

Statistics	Value
Minimum score	12
Maximum score	50
Mean ± SD	33.9±6.8
Median	34
Interquartile range	29-39

A majority (61.2%) of participants were in the moderate risk range, indicating that while most did not have catastrophic self-administration issues, there were notable gaps in medication use and adherence. 17.7% fell into the

high risk category- these individuals are at significant risk for frequent medication errors and require urgent medication counselling/adherence interventions. 21.1% reported scores suggestive of low risk, meaning minimal or no significant errors in self-administration.

Table 7: Risk level classification based on SAME tool total score.

Risk category	Score range	N	%	Interpretation
High risk	10-25	42	17.7	Frequent medication errors
Moderate risk	26-39	145	61.2	Some medication errors
Low risk	40-50	50	21.1	Minimal or no errors

DISCUSSION

In our cohort of 237 patients (mean age $\approx 53.9 \pm 17.4$ years; 52.7% male), approximately one-third (31.6%) exhibited at least one self-administration medication error- specifically forgetting a dose, taking the wrong medication, or taking the wrong dose. Forgetting a medication was the most frequent error (22.4%), followed by wrong dose (11.0%) and wrong medication (10.1%). High pill burden (≥ 6 pills/day) and the presence of multimorbidity (≥ 2 chronic diseases) were significantly associated with errors, whereas age and gender were not. The SAME tool demonstrated excellent reliability (Cronbach's $\alpha=0.814$), and risk stratification revealed that 17.7% of patients were high risk, 61.2% moderate risk, and 21.1% low risk. These findings underscore the real-world challenge of medication self-administration errors in outpatient settings.

Our observed prevalence (31.6%) of self-administration errors is lower than that reported in certain groups- such as older adults with low literacy and polypharmacy. Abdollahi et al found that among illiterate or low literate older adults (≥ 60 years) taking ≥ 5 medications, medication self-administration error (MSE) frequency over six months reached 69.2%, with only 30.8% error free; the most common error was forgetting doses (37.3%).¹ The higher error rate in that cohort likely reflects the vulnerability of older, less educated individuals compared to our (relatively younger and mixed literacy) cohort. Still, the commonality of forgetting doses across both studies emphasizes that unintentional lapses represent a universal challenge.

Another study by Tsegaye et al examined medication administration errors in a clinical (hospital) context and reported a much higher magnitude of errors- 57.7%.⁷ While reflecting a different setting (in hospital), the prevalence underscores that errors are pervasive across settings, and our lower outpatient rate may partly reflect variations in measurement or environment.

Consistent with our findings, many studies highlight the role of polypharmacy and multimorbidity in increasing medication error risk. For instance, Rasool et al found a 30-38% increased risk of medication errors in patients receiving five or more drugs or aged ≥ 75 years.^{8,9} This echoes our results: as the number of medications increased (especially ≥ 6 pills/day), error prevalence rose sharply (85.1% in that subgroup). Similarly, Schneider et al, in home care chronic pain patients, documented high rates of multimorbidity and polypharmacy along with associated medication related problems, including errors.¹⁰

These findings reinforce the dose response relationship: more medications or more comorbidities amplify complexity and risk. Clinicians must be particularly vigilant in managing multi morbidity patients with high pill burden, incorporating interventions like medication review, simplification of regimens, or pill organizers.

While adherence and administration errors are related, they are distinct constructs. Liu et al reported a medication nonadherence prevalence of 31.8% among older outpatients (≥ 65 years) with multimorbidity and polypharmacy- remarkably similar to our 31.6% error rate.¹¹ This parallel suggests that nearly one in three patients in this demographic either fail to adhere fully or commit administration mistakes, underscoring the magnitude of medication management challenges in ambulatory care.

However, adherence studies often capture whether medications are taken at all, whereas administration errors also encompass wrong dose or wrong drug. The overlap in prevalence implies that the same patients struggling to adhere may also be committing these errors- a dual challenge to address.

Our tool, SAME, captures both subjective confidence and objective risk behaviors. We observed most patients reporting confidence, yet key errors remained- echoing the concept that self-efficacy without adequate medication literacy may not prevent mistakes.

Wang et al. found that among older adults with multimorbidity, medication literacy and self-efficacy significantly influenced medication adherence; self-efficacy mediated about 30% of the effect of literacy on adherence.¹² Although focused on adherence, the mechanism is likely similar for administration behavior: patients with higher literacy understand instructions better, fostering confidence (self-efficacy), which leads to more accurate medication handling. This framework aligns with our observation: patients may feel confident (as per SAME Q1, Q2) yet still forget doses or take wrong medications- potentially because underlying literacy or tools are inadequate.

Our risk categories- 21.1% low-risk, 61.2% moderate-risk, and 17.7% high-risk- provide useful stratification for targeted intervention. High-risk patients (approximately one-sixth) would benefit from intensive adherence support, including pharmacist counselling, simplified packaging, or digital reminders. Moderate-risk patients may need partial intervention- education or literacy tools- while low-risk individuals may require routine follow-up.

These findings reflect the notion of stepped care, focusing intensive resources on those with greatest need. Considering Abdollahi et al.'s cohort, where 16.3% made ≥ 4 errors, interventions also may need to focus on high-frequency error patients.¹

This study has several strengths that enhance the reliability and practical relevance of its findings. First, the use of the SAME tool, which demonstrated excellent reliability (Cronbach's $\alpha=0.814$), ensured that the measurement of self-administration medication errors was both valid and consistent across the participant group. Additionally, the study captured multiple dimensions of medication error-

including omissions, incorrect dosages, and incorrect medications- offering a more comprehensive understanding than studies that focus solely on missed doses. The ability to link these error types to specific patient characteristics such as pill burden and multimorbidity provides actionable clinical insights. Furthermore, the stratification of participants into high, moderate, and low-risk groups enables the development of tailored interventions based on individual risk profiles, supporting more efficient use of healthcare resources.

However, there are notable limitations that should be considered when interpreting the results. As a cross-sectional study, it captures only a snapshot in time, limiting the ability to infer causality or observe changes in medication management behavior over time. The reliance on self-reported data introduces the potential for recall bias and social desirability bias, where participants may underreport errors or overestimate their adherence. Additionally, the relatively young average age of the cohort (mean ≈ 54 years) may underrepresent the challenges faced by older adults, who are generally at higher risk for medication errors due to cognitive decline and increased pill burden. Lastly, the study's findings are context-specific and may not be generalizable to populations in different geographic or healthcare settings.

Moving forward, interventions should focus on enhancing medication literacy and self-efficacy, especially among those with high pill burden or multimorbidity. Techniques like teach-back, simplified regimens, blister packaging, and electronic reminders are promising. Longitudinal studies are needed to track error reduction over time, and randomized trials could test specific interventions based on risk stratification. Additionally, integration with digital tools or apps to monitor administration and provide real time prompts could bridge the gap between confidence and accuracy.

In summary, our finding that roughly one in three patients commits at least one self-administration error, with forgetting doses being most prevalent, aligns with and complements prior literature. Polypharmacy and multimorbidity exacerbate risk, while subjective confidence levels may overestimate safe administration. Our validated SAME tool enables effective risk stratification for targeted interventions. Adopting strategies to enhance medication literacy, boost self-efficacy, and simplify regimens could substantially reduce these errors- ultimately improving patient safety and outcomes.

CONCLUSION

This study highlights the significant burden of self-administration medication errors among patients managing chronic conditions, with a prevalence of 31.6%-primarily driven by forgotten doses, incorrect medication intake, and dosing errors. The use of the SAME tool proved effective in reliably identifying at-risk individuals,

particularly those with multimorbidity and high daily pill burdens. Importantly, while most participants expressed confidence in their medication management, objective measures revealed substantial gaps, emphasizing the discrepancy between perceived and actual competence. The study underscores the need for targeted interventions- especially for those in high and moderate-risk groups- to improve medication literacy, simplify regimens, and support adherence. These findings offer critical insight for healthcare providers aiming to enhance patient safety and medication effectiveness in ambulatory care. Future research should focus on longitudinal monitoring and evaluating the impact of tailored strategies on reducing medication errors over time.

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