

Original Research Article

Development and validation of self-administration medication error tool

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ABSTRACT

Background: Medication errors during self-administration pose significant risks to patient safety. The absence of standardized tools to assess and mitigate self-administration errors necessitates the development of a reliable instrument, to identify patients at risk and enhance patient outcomes by reducing adverse drug events.

Methods: This quantitative study was conducted at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, between May 2023 and April 2024. The SAME tool was developed through a literature review, resulting in ten items assessing various aspects of medication self-administration. Content validity was assessed by four experts using a 4-point Likert scale. The Content Validity Index (CVI) was calculated, and the tool was tested on 100 subjects selected by convenience sampling. Internal consistency was measured using Cronbach's alpha, and validity was assessed through Pearson Product Moment Correlation analysis.

Results: The SAME tool included ten items covering confidence in medication administration, understanding instructions, and psychological impact of medication regimens. Validation: All items achieved a CVI of ≥ 0.88 indicating strong content validity. Cronbach's alpha was 0.815, reflecting good internal consistency. Pearson correlation coefficients for individual items ranged from 0.492 to 0.740, all statistically significant ($p < 0.05$), confirming the tool's validity. The estimated prevalence of self-administration errors among participants was 17%, highlighting significant challenges in managing complex medication regimens.

Conclusions: The SAME tool is a valid, reliable instrument for assessing self-administration medication errors in a clinical setting. It can identify patients at risk of medication errors, enabling targeted interventions to improve patient safety and outcomes.

Keywords: Medication adherence, Medication error, Self-administration, Self-medication

INTRODUCTION

Medication errors, particularly those involving self-administration, represent a significant challenge in healthcare systems globally, posing risks to patient safety and leading to adverse drug events (ADEs). The complexity of medication regimens, particularly in patients with chronic illnesses, increases the likelihood of errors during self-administration, such as incorrect dosage, timing, or medication. These errors can result in diminished treatment efficacy, increased hospital admissions, and in severe cases, life-threatening conditions.¹

The prevalence of self-administration medication errors (SAME) is notably high among patients in tertiary care hospitals due to the intricate nature of their treatment protocols. These patients often manage multiple medications, making them particularly susceptible to mistakes. Studies have shown that medication errors in hospital settings can be as high as 5% to 10% among inpatients, with self-administration errors contributing significantly to this statistic.^{2,3} Despite these concerning figures, there is a lack of standardized tools specifically designed to assess and mitigate the risk of self-administration errors in such high-risk populations.

Therefore, developing a reliable and validated tool for assessing self-administration medication errors is imperative. Such a tool could help healthcare providers identify patients at higher risk for these errors and implement targeted interventions to reduce the incidence of ADEs. Existing tools for medication error assessment primarily focus on healthcare provider-administered medications rather than those administered by patients themselves.⁴ Furthermore, these tools often do not account for patients' specific challenges in a tertiary care setting, where the complexity of care is significantly greater.

Given the critical need to enhance patient safety, particularly in the context of self-administration of medications, the development of the Self-Administration Medication Error (SAME) tool is proposed. The rationale behind this initiative is rooted in the recognition that current assessment tools are inadequate in addressing the unique challenges faced by patients in tertiary care hospitals. A tailored tool that can accurately assess and identify potential risks for medication errors in self-administration is essential for improving patient outcomes and ensuring the safe use of medications.

The SAME tool aims to fill the existing gap by providing a comprehensive, validated instrument that healthcare professionals can use to assess the risk of self-administration errors. This tool is expected to be particularly beneficial in tertiary care settings, where patients are often on complex, multi-drug regimens that heighten the risk of errors. By identifying at-risk patients, the SAME tool could facilitate timely interventions, such as patient education, medication review, or reminder systems, thereby reducing the likelihood of ADEs.

The development and validation of the SAME tool are guided by the need to integrate patient-specific factors, such as cognitive function, health literacy, and the complexity of the prescribed medication regimen. The ultimate goal is to enhance patient safety and reduce the burden of medication errors in tertiary care hospitals.

This study aimed to develop and validate the SAME tool in patients of a tertiary care hospital. Also, to estimate the frequency of self-administration errors using the SAME tool in patients of a tertiary care hospital.

METHODS

Study design

This cross-sectional study was a public health, clinical, and socio-behavioural research project conducted in a tertiary care hospital to validate the Self-Administration Medication Error (SAME) tool for identifying medication errors in patients who self-administer their medications.

Study participants

The study included adult patients attending the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) pharmacy in Pondicherry. Participants were selected using convenience sampling from May 2023 to April 2024 and provided written informed consent. No randomisation or blinding procedures were involved in this study.

Sample size

Based on previously published literature, to have robust reliability (based on Cronbach's alpha coefficient of >0.8) and validity, the sample size is 100 participants.⁵

The inclusion criteria for this study were adults aged 18 years or older who have been diagnosed with chronic diseases such as diabetes, hypertension, or cardiovascular diseases. Additionally, eligible participants must be self-administering their medications and must be able to read and understand either Tamil or English. On the other hand, the exclusion criteria were those individuals with cognitive impairments or severe mental illnesses that may affect their comprehension. Furthermore, patients who are unable to provide informed consent were excluded from the study.

Part 1

Development of SAME Tool: The SAME tool was developed through a multi-step process. A comprehensive literature review was conducted to identify common medication errors associated with self-administration. Following this, interviews were conducted with patients suffering from chronic diseases to gather insights on their challenges with medication self-administration. The information from the literature review and patient interviews was synthesized to develop the items of the SAME tool.⁶

Part 2

Validation of SAME Tool: The validation process involved a panel of experts, comprising faculty members from JIPMER, who independently evaluated the relevance of each item in the SAME tool. The experts used a 4-point Likert scale to rate each item, with 1 indicating 'not relevant' and 4 indicating 'very relevant.' Items rated as 3 or 4 were considered 'favorable,' indicating the question was relevant, while items rated 1 or 2 were deemed 'unfavorable,' shown in figure 1. Each item's Content Validity Index (CVI) was calculated, with a cut-off value of 0.78 considered acceptable. The validity of the SAME tool was assessed using Pearson Product Moment Correlation analysis. Additionally, the tool was pre-tested on a sample of 100 subjects to ensure clarity and relevance of the questions.

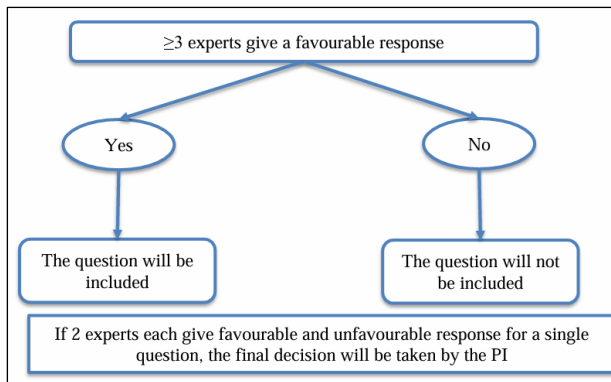


Figure 1: Validation process.

Ethical considerations

All study procedures were deemed acceptable within routine clinical practice. Ethical approval was obtained from the Institutional Ethics Committee of JIPMER before the commencement of the study. IEC approval number - JIP/IEC-OS/206/2023. Participants were provided with an information sheet detailing the study and were informed that they could withdraw at any time without providing a reason.

Statistical analysis

Cronbach's alpha was used to assess the reliability of the SAME tool. Pearson Product Moment Correlation was employed to evaluate the tool's validity. The independent variables analyzed in this study included age, gender, comorbidities and the types of medications used by the participants. The dependent variables were the scores obtained from the SAME tool and the prevalence of self-administration errors. All analysis was performed using SPSS version 29.0.

RESULTS

Part 1: Development of the SAME tool

The Self-Administration Medication Error (SAME) tool was developed through a systematic process involving literature review and patient interviews. The tool was designed to assess various aspects of patients' experiences with self-administering medications, aiming to identify potential areas where errors might occur. The following items were developed as part of the SAME tool: 1) Confidence in Medication Administration: Participants were asked how confident they felt in taking their medications correctly, with responses ranging from "Not at all confident" to "Extremely confident." 2) Comfort with Healthcare Provider Interaction: This item assessed the extent to which participants felt comfortable asking their healthcare providers questions about their medications, with responses ranging from "Not comfortable at all" to "Completely comfortable." 3) Frequency of Forgetting Medications: Participants were asked how often they

forgot to take their medications as prescribed, with options ranging from "Almost every time" to "Never." 4) Incidence of taking the wrong medication: This item explored how often participants accidentally took the wrong medication, with responses ranging from "Almost every time" to "Never." 5) Frequency of Incorrect Dosing: Participants were asked how often they accidentally took the wrong dose of their medication, with responses ranging from "Almost every time" to "Never." 6) Ease of Understanding Medication Instructions: This item assessed how easy participants found it to understand the instructions on their medications, with options from "Very difficult" to "Very easy." 7) Experience of Side Effects: Participants were asked how often they experienced side effects from their medications, with responses ranging from "Almost every time" to "Never." 8) Perception of Health Improvement: This item explored the extent to which participants felt that taking their medications as prescribed improved their health, with responses ranging from "Not at all" to "Completely." 9) Impact of Medication on Daily Life: Participants were asked to what extent they felt that taking their medications as prescribed negatively impacted their daily life, with options ranging from "Very much" to "Not at all." 10) Feeling Overwhelmed by Medication: This item assessed how often participants felt overwhelmed by the number of medications they had to take, with responses ranging from "Almost every time" to "Never."

These items were designed to capture critical dimensions of self-administration of medications, such as confidence, understanding, and the potential for errors. The questions aimed to be clear, concise, and relevant to the challenges patients face managing complex medication regimens. The development of these items was informed by the insights gained from the literature and patient interviews, ensuring that the tool was both comprehensive and targeted to identify key risk areas in self-administration practices (Appendix A-SAME tool).

Part 2: Validation of SAME tool

The validation of the Self-Administration Medication Error (SAME) tool involved scoring by a panel of four experts from the Department of Pharmacology at JIPMER (2 experts) and, PIMS (1 expert), SLIMS (1 expert). Each expert independently evaluated the relevance of the ten items in the tool using a 4-point Likert scale, where 1 indicated 'not relevant' and 4 indicated 'very relevant.' The CVI for each item was calculated based on the scores from the four experts. Items with a CVI of 0.78 or higher were considered to have acceptable content validity.

CVI results

Item-Level CVI (I-CVI): Each item in the tool received an I-CVI of 0.88 or 1.0. This means that all four experts rated each item as either "3" or "4," indicating that they considered all items relevant.

Scale-Level CVI (S-CVI): The Scale-Level CVI (S-CVI) is 1.0, indicating perfect agreement among the experts regarding the relevance of the items in the tool.

As shown in the table 1, all items in the SAME tool achieved a CVI greater than the cut-off value of 0.78, indicating that the tool possesses strong content validity.

These results suggest that the content validity of the tool is excellent according to the expert evaluations.

Cronbach's Alpha: The calculated Cronbach's Alpha is 0.815. This indicates a good level of internal consistency among the items in the SAME tool. Generally, a Cronbach's Alpha value above 0.7 is considered acceptable, and above 0.8 is considered good.

Table 1: CVI scores for the SAME tool based on expert ratings.

Question Number	Expert 1 score	Expert 2 score	Expert 3 score	Expert 4 score	Item-Level CVI (I-CVI)
Q1: Confidence in taking medication	4	4	4	4	1.00
Q2: Comfort asking questions to the healthcare provider	4	4	4	3	0.88
Q3: Frequency of forgetting medication	4	4	4	4	1.00
Q4: Extent of understanding medication instructions	4	4	4	4	1.00
Q5: Confidence in managing medication side effects	4	4	4	4	1.00
Q6: Ability to remember medication schedules	4	4	4	4	1.00
Q7: Perception of medication effectiveness	4	4	4	3	0.88
Q8: Perception of medication improving health	3	4	4	4	0.88
Q9: Perception of negative impact on daily life	3	4	4	4	0.88
Q10: Feeling overwhelmed by the number of medications	3	4	4	4	0.88

Table 2: Pearson correlation between each item of the SAME tool.

Item	Pearson Correlation (r)	P value
Q1: Confidence in taking medication	0.716	0.000
Q2: Comfort asking questions to the healthcare provider	0.532	0.000
Q3: Frequency of forgetting medication	0.551	0.000
Q4: Extent of understanding medication instructions	0.655	0.000
Q5: Confidence in managing medication side effects	0.696	0.000
Q6: Ability to remember medication schedules	0.527	0.000
Q7: Perception of medication effectiveness	0.740	0.000
Q8: Perception of medication improving health	0.492	0.001
Q9: Perception of negative impact on daily life	0.578	0.000
Q10: Feeling overwhelmed by the number of medications	0.673	0.000

Table 2 presents the Pearson correlation coefficients (R-values) and associated p-values for each item in the Self-Administration Medication Error (SAME) tool, indicating the strength and statistical significance of the relationships between the items and the overall construct the tool aims to measure.

The Pearson correlation coefficients (r-values) for the items range from 0.492 to 0.740, indicating moderate to strong positive correlations between the individual items and the overall tool. Items such as "Perception of medication effectiveness" (r=0.740) and "Confidence in taking medication" (r=0.716) show the strongest correlations, suggesting that these items are particularly well-aligned with the overall construct being measured by the SAME tool.

All items have p-values of 0.001 or lower, indicating that the correlations are statistically significant. This means the likelihood that these relationships occurred by chance is very low (less than 0.1% for the least significant item and less than 0.01% for the others).

The consistent significance across all items supports the reliability of the SAME tool and suggests that each item contributes meaningfully to the assessment of self-administration medication errors.

Q7: Perception of medication effectiveness (r=0.740, p=0.000) and Q1: Confidence in taking medication (r=0.716, p=0.000) have the highest correlations, indicating these factors are highly representative of the overall construct of medication management in self-administration. Q8: Perception of medication improving

health ($r=0.492$, $p=0.001$) shows the lowest, though still significant, correlation, suggesting it is slightly less aligned with the other items but still an important aspect of the overall assessment.

Overall, the Pearson Product Moment Correlation analysis provided robust evidence of the SAME tool's validity, reinforcing its utility in clinical settings for identifying patients at risk of self-administration medication errors. The combination of expert scoring and statistical validation supports the reliability and validity of the SAME tool, ensuring that it is both comprehensive and effective in identifying potential medication errors in self-administration.

Table 3: Baseline characteristics.

Variable	Total no of participants (n=100)
Age in years (Mean (SD))	60.03 (10.33)
Gender (%)	
Male	40
Female	60
Comorbidities (%)	
HTN	56
DM	44
Epilepsy	27
Hypothyroidism	17
CAD	12
Polypharmacy (≥ 2 drugs) (%)	
Yes	63
No	37

The baseline characteristics of the study participants shown in table 3 (n=100) reveal a mean age of 60.03 years (SD=10.33), indicating that the study population predominantly consisted of older adults. Gender

distribution showed that 40% of participants were male, while 60% were female. The prevalence of comorbidities was notable, with hypertension (HTN) being the most common, affecting 56% of participants, followed by diabetes mellitus (DM) in 44%, epilepsy in 27%, hypothyroidism in 17%, and coronary artery disease (CAD) in 12%. Additionally, a significant portion of the participants (63%) were on polypharmacy (defined as taking two or more drugs), showing the complexity of their medication regimens and the potential risk for self-administration errors.

The distribution of responses to the SAME tool questions among the study participants highlights varying degrees of confidence, comfort, and perceptions related to medication self-administration is shown in table 4. A majority of participants reported high confidence in taking their medication correctly (Q1: 93% rated 4 or 5), and a similar trend was observed in their comfort level when asking healthcare providers questions about their medications (Q2: 95% rated 4 or 5). However, nearly half of the participants admitted to sometimes forgetting to take their medication as prescribed (Q3: 49% rated 3), indicating a potential area of concern. Most participants found it easy to understand their medication instructions (Q4: 86% rated 4 or 5), and a significant majority felt confident in managing side effects (Q5: 83% rated 4 or 5). The ability to remember medication schedules showed some variability, with 44% rating 3 (Q6). While most participants perceived their medications as effective (Q7: 71% rated 4 or 5), and believed that taking their medication improved their health (Q8: 66% rated 4), there was a notable concern about the negative impact on daily life for 61% of participants (Q9: rated 4). Additionally, 32% of participants reported feeling overwhelmed by the number of medications they had to take (Q10: rated 2), which could indicate potential challenges in managing complex medication regimens.

Table 4: Distribution of responses to each SAME tool question by the participants.

SAME tool question/response	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)
Q1: Confidence in taking medication	0	0	7	54	39
Q2: Comfort asking questions to the healthcare provider	0	2	2	51	44
Q3: Frequency of forgetting medication	0	7	49	22	22
Q4: Extent of understanding medication instructions	0	5	10	32	54
Q5: Confidence in managing medication side effects	0	15	2	20	63
Q6: Ability to remember medication schedules	0	7	44	29	20
Q7: Perception of medication effectiveness	0	12	17	59	12
Q8: Perception of medication improving health	0	5	29	61	5
Q9: Perception of negative impact on daily life	0	12	12	61	15
Q10: Feeling overwhelmed by the number of medications	0	32	15	39	15

To estimate the prevalence of self-administration errors, we used the responses to Q3, Q4, Q5, Q6, and Q10 in the SAME tool, which indicated errors or difficulties in self-administering medications.

Q3: Frequency of forgetting medication → Score 1 or 2 was considered as one event of SAME

Q4: Frequency of wrong medication → Score 1 or 2 was considered as one event of SAME

Q5: Frequency of wrong dose of medication → Score 1 or 2 was considered as one event of SAME

Figure 2 illustrates the estimated prevalence of self-administration errors among the participants is 91%. This high prevalence suggests that a significant proportion of the participants may be experiencing challenges in managing their medications effectively.

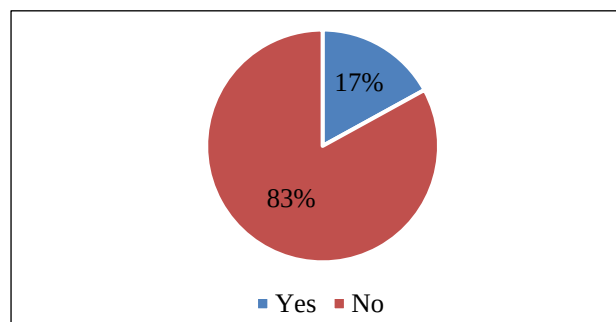


Figure 2: Prevalence of medication errors due to self-administration.

The correlation analysis between independent variables and SAME tool scores in table 5 reveals several significant relationships. Age was moderately correlated with the

number of pills taken ($r=0.42$, $p=0.024$), indicating that older participants tended to take more medications. However, age showed weak and non-significant correlations with confidence in taking medication (Q1, $r=0.15$, $p=0.372$) and the perception of a negative impact on daily life (Q9, $r=0.18$, $p=0.294$). Gender was found to have a moderate correlation with the perception of medication effectiveness (Q7, $r=0.37$, $p=0.019$), with males generally perceiving their medications as more effective, although the correlation with the perception of a negative impact on daily life (Q9, $r=0.28$, $p=0.068$) was not statistically significant. The number of pills taken was strongly correlated with the perception of medication effectiveness (Q7, $r=0.64$, $p<0.001$), suggesting that participants taking more medications perceived them as more effective. However, the correlation between the number of pills and feeling overwhelmed by the number of medications (Q10, $r=0.09$, $p=0.599$) was weak and non-significant. Additionally, there was a moderate correlation between confidence in taking medication (Q1) and feeling overwhelmed by the number of medications (Q10, $r=0.38$, $p=0.013$), as well as between the perception of medication effectiveness (Q7) and the perception of a negative impact on daily life (Q9, $r=0.49$, $p=0.002$), indicating significant interrelationships between these aspects of medication self-management.

Table 5: Correlation between independent variables and SAME tool scores.

Variable	Correlation Coefficient (r)	P value
Age vs.		
Number of pills	0.42	0.024
Q1 (Confidence in taking medication)	0.15	0.372
Q9 (Perception of negative impact on daily life)	0.18	0.294
Gender (Male) vs.		
Q7 (Perception of medication effectiveness)	0.37	0.019
Q9 (Perception of negative impact on daily life)	0.28	0.068
Number of pills vs.		
Q7 (Perception of medication effectiveness)	0.64	<0.001
Q10 (Feeling overwhelmed by the number of medications)	0.09	0.599
Between questions		
Q1 (Confidence in taking medication) and Q10 (Feeling overwhelmed by the number of medications)	0.38	0.013
Q7 (Perception of medication effectiveness) and Q9 (Perception of negative impact on daily life)	0.49	0.002

Table 6: Risk stratification of SAME using SAME tool.

Risk category	Total no of participants (n=100) (%)
Low	57
Moderate	40
High	3

Table 6 presents the risk stratification of self-administration medication error using the SAME tool. The results indicate that the majority of participants (57%) fall into the low-risk category, suggesting that they have a

lower likelihood of experiencing the adverse outcomes associated with SAME. A significant portion (40%) is classified as moderate risk, indicating a moderate likelihood of adverse outcomes. Only a small percentage

(3%) are categorized as high risk, implying they have the highest likelihood of experiencing severe or critical outcomes related to SAME. This stratification helps in identifying and prioritizing individuals who may require more intensive monitoring or intervention based on their risk levels.

DISCUSSION

The development and validation of the Self-Administration Medication Error (SAME) tool represent a significant advancement in the assessment of medication management among patients in a tertiary care setting. The systematic approach employed in creating the SAME tool, including a comprehensive literature review and patient interviews, ensured that the tool addressed the most pertinent aspects of self-administering medications. The resulting questionnaire, composed of ten carefully crafted items, captures essential dimensions such as confidence in medication administration, understanding of instructions, and the psychological impact of managing complex medication regimens.

The validation process confirmed the tool's content validity, with all items receiving a Content Validity Index (CVI) greater than the accepted threshold of 0.78. The high Item-Level CVI (I-CVI) and Scale-Level CVI (S-CVI) indicate strong agreement among the experts on the relevance of the items, demonstrating the tool's appropriateness for the intended purpose. These findings are consistent with the literature, which underscores the importance of content validation in developing reliable and valid instruments for clinical assessment.⁷

The internal consistency of the SAME tool, as evidenced by a Cronbach's alpha of 0.815, further supports its reliability. This level of consistency is in line with established benchmarks, where a Cronbach's alpha above 0.8 is generally considered good, indicating that the items are cohesively measuring the same underlying construct.⁸

The Pearson Product Moment Correlation analysis provided additional evidence of the tool's validity. The strong and statistically significant correlations between items suggest that the SAME tool effectively measures interrelated aspects of medication self-administration. For example, the high correlation between "Perception of medication effectiveness" (Q7) and "Confidence in taking medication" (Q1) indicates that these factors are crucial components of successful medication management.⁹ The consistent significance across all items confirms that each question contributes meaningfully to the overall assessment, reinforcing the tool's utility in clinical practice.

The baseline characteristics of the study population highlight the challenges faced by patients, particularly older adults with multiple comorbidities and complex medication regimens. The high prevalence of polypharmacy (63%) among participants underscores the

necessity of tools like the SAME tool to identify and mitigate medication errors.¹⁰ The distribution of responses to the SAME tool questions revealed that while many participants felt confident and comfortable with their medication management, a substantial proportion reported difficulties such as forgetting medications and feeling overwhelmed by the number of medications they had to manage. These findings are consistent with previous studies that have identified these issues as common challenges in medication self-administration.¹¹

The estimated prevalence of self-administration errors, derived from specific items in the SAME tool, was notably high at 17%. This suggests that some patients in this study are at risk of making errors in their medication regimen, which aligns with existing literature indicating that older adults with multiple medications are particularly vulnerable to such errors.^{12,13}

The risk stratification showed the varying levels of risk for self-administration medication errors (SAME) among participants. The majority (57%) were classified as low-risk, indicating they are less likely to experience errors, while a significant portion (40%) fell into the moderate-risk category, suggesting they may benefit from additional support or interventions. Only a small percentage (3%) were identified as high-risk, emphasizing the need for close monitoring and targeted strategies to prevent severe outcomes. These findings demonstrate the SAME tool's ability to effectively identify at-risk patients, enabling healthcare providers to prioritize resources and interventions for those who need them most. This approach can significantly enhance medication safety and improve patient outcomes in clinical practice.

The correlation analysis between independent variables and SAME tool scores provided further insights into the factors influencing medication management. The moderate correlation between age and the number of pills taken reflects the increased complexity of medication regimens in older adults, a well-documented phenomenon in geriatric care.¹⁴ Gender differences observed in the perception of medication effectiveness highlight the potential influence of demographic factors on medication management, which warrants further investigation.¹⁵

This study has a few limitations to consider. First, using convenience sampling from a single hospital might introduce bias, as the results may not reflect other healthcare settings. Second, the study relied on self-reported data, which can be influenced by memory errors or participants wanting to give socially acceptable answers. These factors could affect the accuracy of the findings.

The SAME tool has been shown to be a valid, reliable, and comprehensive instrument for assessing self-administration medication errors in a clinical setting. Its application can help healthcare providers identify patients at risk of medication errors and implement targeted

interventions to improve patient outcomes. Future research should focus on further refining the tool and exploring its applicability in diverse patient populations.

CONCLUSION

The development and validation of the Self-Administration Medication Error (SAME) tool represent a significant advancement in the assessment and management of medication errors in patients within a tertiary care setting. The SAME tool has been shown to possess strong content validity, reliability, and internal consistency, making it a robust instrument for identifying patients at risk of self-administration errors. The high prevalence of such errors observed in the study underscores the critical need for tools like SAME to enhance patient safety and optimize medication management, particularly in populations with complex, multi-drug regimens. The application of the SAME tool in clinical practice can facilitate timely interventions, reduce the incidence of adverse drug events, and ultimately improve patient outcomes. Future research should focus on refining the tool and exploring its efficacy in diverse healthcare settings and patient populations.

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