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Article

Prevalence, Determinants, and Objective Risk of Unintentional Therapeutic Duplication Among Adults in Saudi Arabia

Yosra Alhindi
Department of Pharmacology and Toxicology, Faculty of Medicine, Umm Al-Qura University, Makkah, Saudi Arabia
Phone number: 00966504530609
ORCID number: https://orcid.org/ 0000-0002-5725-3522
E-mail: yzhindi@uqu.edu.sa

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Abstract:

Background: Unintentional therapeutic duplication represents an underrecognized yet preventable contributor to medication-related harm, particularly in settings characterized by widespread over-the-counter (OTC) medicine use and self-medication practices. **Objective:** To estimate the prevalence of unintentional therapeutic duplication among adults in Saudi Arabia and identify sociodemographic and behavioral predictors associated with increased therapeutic duplication risk. **Methods:** A national cross-sectional study was conducted between February 10 and April 28, 2025, using a structured, self-administered online questionnaire distributed via social media platforms. The survey assessed sociodemographic characteristics, medication-use behaviors, active-ingredient literacy, and duplication risk using both self-reported measures and scenario-based assessments. Multivariable logistic regression was performed to identify independent predictors of elevated therapeutic duplication risk. **Results:** A total of 700 participants were included (mean age 34.2 ± 10.5 years; 58% female). The prevalence of self-reported therapeutic duplication within the preceding 90 days was 43.0%. Paracetamol-containing products were the most commonly implicated (32.0%), followed by nonsteroidal anti-inflammatory drugs (24.0%) and antihistamines (15.0%). The mean ingredient-literacy score was 5.1 ± 2.3 (out of 10), with only 48% correctly identifying duplication scenarios. In adjusted analysis, poor ingredient literacy (AOR 3.12, 95% CI 2.29–4.25), frequent OTC use (AOR 2.41, 95% CI 1.78–3.26), and lower educational attainment (AOR 1.89, 95% CI 1.32–2.71) were independently associated with increased duplication risk ($p < 0.001$). **Conclusion:** Unintentional therapeutic duplication is common among adults in Saudi Arabia and is strongly associated with limited active-ingredient literacy. Targeted interventions focusing on patient education, improved labeling, and pharmacist-led counseling are warranted to mitigate preventable medication harm.

Key Words: Therapeutics; Duplication; Saudi Arabia; public; ingredient.

Introduction

Medication-related harm remains a major safety challenge across outpatient care, and many adverse drug events are preventable when high-risk use patterns are recognized early [1-4]. Among these patterns, unintentional therapeutic duplication deserves more attention than it typically receives in community settings. The problem arises when patients take two medicines with the same active ingredient or overlapping pharmacologic action without realizing that the products are therapeutically duplicative. Because many patients self-select medicines by brand name, symptom label, or advertising cue rather than by active ingredient, duplication can occur even in the absence of intentional misuse [5-8].

Self-medication can improve convenience and support timely symptom relief, but it also shifts a substantial share of medication-selection responsibility to consumers [3,10-14]. In Saudi Arabia, self-medication and OTC purchasing are common, with studies from different regions documenting substantial use of nonprescription medicines and variable understanding of safe medicine use [15-17]. Community pharmacies and family medicine physicians therefore function as a crucial interface between the public and the medication system. Yet evidence from Saudi Arabia also suggests that counseling practices are inconsistent and may not reliably protect against medication-selection errors at the point of purchase [18,19].

Therapeutic duplication is particularly plausible with paracetamol-containing analgesics and combination cold-and-flu products, as well as with NSAIDs and sedating antihistamines. Patients may not recognize that two differently branded products contain acetaminophen/paracetamol or belong to the same class [12-14,20-22]. This matters clinically because paracetamol overdose is a leading cause of acute liver injury and acute liver failure in many settings [15,16], while NSAID therapeutic duplication increases gastrointestinal risk [17-19]. First-generation antihistamines may also impair cognition and psychomotor performance, making inadvertent cumulative use clinically important [20,21].

Ingredient literacy, which is the ability to identify, interpret, and use active-ingredient information during medicine selection is a key construct in the safe use of OTC medicines [5-13]. Lower health literacy and weaker medication knowledge have repeatedly been associated with misunderstanding of labels, reduced ability to distinguish products, and medication-use errors [5,8-12, 23]. Label design also matters: poorly standardized or visually crowded labels may emphasize branding more than active ingredients or critical warnings [6,7,24].

Unlike general self-medication studies, which focus on prevalence and behaviors, this study specifically examines unintentional therapeutic duplication as a distinct and preventable medication-safety risk, incorporating both self-reported behavior and objective scenario-based assessment.

While self-medication, OTC misuse, and medication errors have been widely studied, unintentional therapeutic duplication represents a distinct and underexplored mechanism of medication-related harm. Unlike general misuse, duplication occurs even when patients adhere to labeled instructions but fail to recognize overlapping active ingredients across products. This distinction highlights duplication as a cognitive and informational failure rather than purely behavioral misuse, justifying its independent investigation. Despite the relevance of this issue, national data on therapeutic duplication among adults in Saudi Arabia remain scarce [1-3, 22-26].

The present study therefore aimed to estimate the prevalence of unintentional therapeutic duplication among adults in Saudi Arabia, describe the medication classes most often involved, evaluate active-ingredient literacy, and identify predictors of higher objective therapeutic duplication risk using multivariable analysis.

Materials and Methods

Study design and setting

This national cross-sectional study was conducted in Saudi Arabia between 10 February and 28 April 2025 and was structured in line with STROBE recommendations for observational research. The target population comprised adults aged 18 years or older residing in Saudi Arabia during the study period.

Sample size and sampling

The minimum sample size for a prevalence study was estimated using the standard formula $n = Z^2P(1-P)/d^2$, assuming 50% prevalence, 95% confidence, and 5%

precision, which yielded a minimum of 384 participants. To improve precision and accommodate incomplete responses, 700 participants were included in the final analytic sample. Participants were recruited using online convenience sampling through WhatsApp, X/Twitter, and Telegram.

Inclusion and Exclusion criteria

Inclusion criteria:

- Adults ≥18 years

- Residents of Saudi Arabia

Exclusion criteria:

- Incomplete responses

- Healthcare professionals

Questionnaire development

The questionnaire underwent expert review by two clinical pharmacists and one pharmacology specialist to ensure content validity. A pilot study ($n \approx 30$) was conducted to assess clarity and reliability. Internal consistency of the knowledge and literacy domains was evaluated using Cronbach's alpha, with acceptable reliability defined as $\alpha \geq 0.70$.

Study outcomes

The primary outcome was self-reported unintentional therapeutic duplication during the preceding 90 days. The secondary outcome was elevated objective therapeutic duplication risk assessed through scenario-based items requiring identification of therapeutic duplicative medication use. The ingredient-literacy score reflected respondent ability to identify active ingredients or duplication risk across medicine scenarios. To minimize selection bias, the survey was distributed across multiple platforms targeting diverse demographic groups. However, the use of convenience sampling may limit representativeness. Recall bias was mitigated by restricting duplication reporting to the previous 90 days

Statistical analysis

The data were collected, reviewed, and input into the Statistical Package for Social Sciences version 26 (Released 2019. Armonk, NY: IBM Corp). Descriptive statistics were summarized as frequencies and percentages for categorical variables and mean ± standard deviation for continuous variables. Multivariable logistic regression was used in the source analysis to identify independent predictors of elevated duplication risk. All statistical methods used were two-tailed with an alpha level of 0.05 and were considered significant if the p-value was less than or equal to 0.05.

Ethics and consent

The source manuscript states that participation was voluntary, anonymous, and preceded by electronic informed consent. Ethical approval was obtained from the Biomedical Ethics Committee of the Faculty of Medicine at UQU, Makkah, KSA (approval number HAPO-02-K-012-2026-04-344); the study was conducted in accordance with the Declaration of Helsinki. Electronic informed consent was obtained from each participant prior to administering the questionnaire. Confidentiality was ensured. The names or phone numbers of the participants were not collected.

Results

A total of 700 participants were included in the final analysis. The mean age was 34.2 ± 10.5 years. Females accounted for 58.0% of the sample, 65.0% had university-level education or higher, and 54.0% reported frequent OTC medication use (Table 1).

The prevalence of self-reported unintentional therapeutic duplication within the previous 90 days was 43.0% (301/700). The most frequently implicated medication groups were paracetamol-containing products (32.0%), NSAIDs (24.0%), and antihistamines (15.0%), with smaller contributions from combination cold/flu remedies, gastrointestinal medications, and other classes (Table 2, Figure 1).

Medication literacy appeared suboptimal. The mean ingredient-literacy score was 5.1 ± 2.3 out of 10, and only 48.0% of respondents correctly identified duplication scenarios. Taken together with the high rate of frequent OTC use, these findings suggest a pattern in which access to medicines is not consistently matched by the ability to recognize overlapping products (Figure 2).

In the reported multivariable model, poor ingredient literacy was the strongest predictor of elevated duplication risk (AOR 3.12, 95% CI 2.29–4.25; $p < 0.001$). Frequent OTC medication use was also independently associated with higher risk (AOR 2.41, 95% CI 1.78–3.26; $p < 0.001$), as was lower

Table 1. Sociodemographic and medication-use characteristics of the study sample (N = 700).

Variable	Category	n	%
Age (years)	Mean ± SD	34.2 ± 10.5	—
Gender	Female	406	58.0
	Male	294	42.0
Education	University or higher	455	65.0
	Secondary or lower	245	35.0
OTC medication use	Frequent	378	54.0
	Occasional/rare	322	46.0
Self-reported duplication, past 90 days	Yes	301	43.0
	No	399	57.0

Values are presented as frequency (%) unless otherwise indicated.

Table 2. Reported medication classes involved in unintentional therapeutic duplication (n=700)

Medication class	n	%
Paracetamol-containing products	224	32.0
Nonsteroidal anti-inflammatory drugs (NSAIDs)	168	24.0
Antihistamines	105	15.0
Combination cold/flu products	84	12.0
Gastrointestinal medications	63	9.0
Other classes	56	8.0

educational attainment (AOR 1.89, 95% CI 1.32–2.71; $p < 0.001$) (Table 3). The magnitude and precision of these effect estimate support ingredient literacy as the most important modifiable determinant among the measured factors.

The observed discrepancy between high OTC medication use (54%) and relatively low therapeutic duplication recognition (48%) suggests a clinically relevant gap between access to medicines and the ability to safely interpret medication information. This mismatch highlights the importance of functional medication literacy as a determinant of safe self-medication practices.

Discussion

This study demonstrates that unintentional therapeutic duplication is both common and clinically significant among adults in Saudi Arabia, affecting 43% of respondents within a 90-day period. This prevalence is notably high for a preventable medication-use error and highlights an underrecognized dimension of medication safety in community settings [3. 22-24].

Importantly, the findings position therapeutic duplication not merely as a subset of self-medication behavior, but as a distinct and cognitively driven safety issue that warrants independent investigation. Unlike general medication misuse, therapeutic duplication can occur even when patients adhere to labeled instructions, reflecting a failure to recognize overlapping active ingredients across products [5-13]. This distinction is critical, as it shifts the focus from behavioral non-compliance to informational and cognitive limitations in medication selection. In this context, the current findings contribute to the literature by identifying duplication as a specific mechanism of harm embedded within otherwise acceptable self-care practices.

A key contribution of this study is the identification of ingredient literacy as the strongest predictor of duplication risk. Ingredient literacy may be conceptualized as a domain-specific extension of health literacy, referring to the ability to identify, interpret, and apply active-ingredient information during medication decision-making [13-16]. Within patient safety frameworks, this aligns with cognitive processing models in which errors arise from misinterpretation rather than intentional misuse [17-19]. The strong association observed in this study (AOR 3.12) suggests that duplication risk is fundamentally rooted in deficits in how medication information is processed, rather than solely in access or behavior.

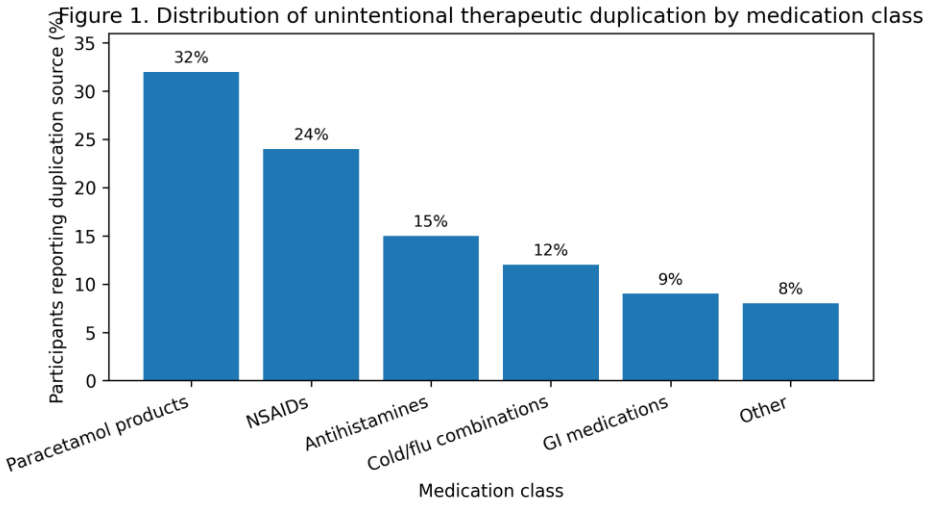

Figure 1. Distribution of reported unintentional therapeutic duplication by medication class among study participants (n=700) expressed as percentages of total reported duplication cases.

Paracetamol-containing products were the most frequently reported source of duplication, followed by NSAIDs and antihistamines.

Table 3. Multivariable logistic regression analysis of factors associated with elevated therapeutic duplication risk (n=700).

Predictor	Adjusted odds ratio	95% CI	p-value
Poor ingredient literacy	3.12	2.29–4.25	<0.001
Frequent OTC medication use	2.41	1.78–3.26	<0.001
Lower educational attainment	1.89	1.32–2.71	<0.001

AOR = adjusted odds ratio; CI = confidence interval.

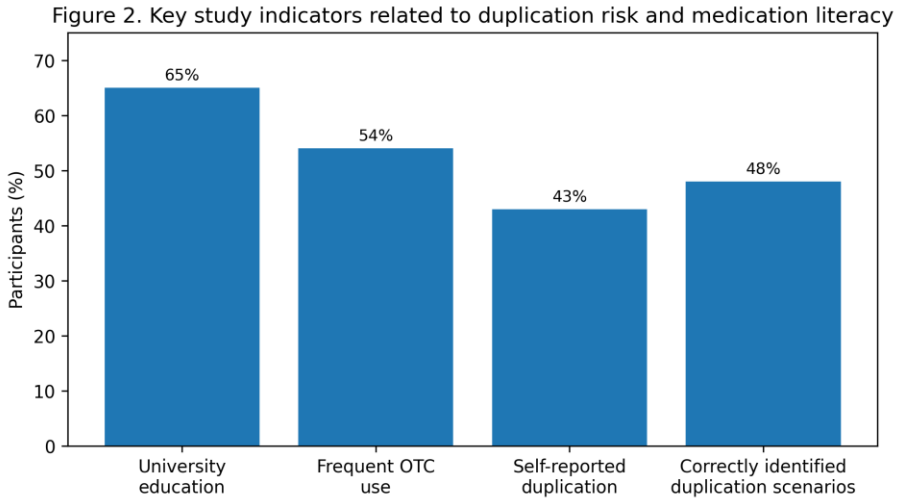

Figure 2. Key study indicators related to therapeutic duplication risk and medication literacy (n=700) expressed as percentages of total reported duplication cases.

The coexistence of frequent OTC use, moderate educational attainment, low scenario recognition, and high self-reported duplication highlights a mismatch between medicine access and medicine-use literacy.

The observed discrepancy between high OTC medication uses and relatively low recognition of therapeutic duplication scenarios further supports this interpretation. Participants demonstrated the ability to self-manage symptoms but lacked the functional literacy required to safely interpret pharmacological equivalence across products [20, 21]. This mismatch reflects a broader systems-level issue in which increasing accessibility to medications is not accompanied by adequate support for safe decision-making.

The pattern of therapeutic duplication across medication classes reinforces this interpretation. Paracetamol-containing products were the most frequently implicated, consistent with their widespread availability in both single-ingredient and combination formulations [3. 25]. However, rather than reiterating well-established toxicity risks, this finding highlights a structural vulnerability in OTC markets, were multiple branded products obscure shared active ingredients. Similarly, NSAID therapeutic duplication reflects not only patient behavior but also a lack of clear differentiation at the point of selection, while antihistamine duplication underscores the clinical relevance of cumulative sedative effects even at therapeutic doses [25,26].

These findings are broadly consistent with emerging international concerns regarding OTC-related medication errors, particularly in increasingly consumer-driven and digitally influenced medication environments [27-30]. However, most prior studies have focused on general misuse, adherence, or labeling comprehension, with limited attention to therapeutic duplication as a distinct outcome. The current study therefore addresses a critical gap by quantifying therapeutic duplication risk and linking it to measurable cognitive determinants, thereby extending existing literature on medication safety.

From a clinical and public health perspective, the results suggest that interventions should prioritize improving ingredient literacy as a core component of safe medication use. While traditional approaches emphasize reading labels and consulting healthcare providers, these findings indicate that such strategies may be insufficient unless patients are specifically trained to interpret active ingredients and recognize duplication risk [6–9]. Among potential interventions, pharmacist-led counseling represents a high-impact opportunity. Community pharmacists can play a critical role by proactively assessing concurrent medication use and emphasizing active ingredients rather than brand names during patient interactions [24–26].

In addition, system-level interventions are warranted. Medication labeling should be redesigned to enhance the visibility and comparability of active ingredients across products, using standardized formats and plain-language approaches [6,7,29]. Digital solutions, such as barcode scanning or mobile applications that identify overlapping ingredients, may further support real-time decision-making and reduce duplication risk. These approaches align with broader patient safety strategies that aim to reduce cognitive burden and support informed medication use [9,30].

Despite its strengths, this study has several important limitations. The use of online convenience sampling likely resulted in overrepresentation of younger and more educated individuals, potentially underestimating duplication risk in populations with lower health literacy [11,23]. This limits the generalizability of the findings and suggests that the true burden may be even greater in less digitally engaged groups. Additionally, the cross-sectional design precludes causal inference. Although the study incorporated scenario-based assessments to enhance objectivity, self-reported data remain subject to recall and reporting biases.

Furthermore, the study did not assess clinical outcomes such as adverse drug events or healthcare utilization, limiting the ability to directly quantify the clinical impact of therapeutic duplication [1–3]. Future research should aim to link duplication behaviors with measurable health outcomes and evaluate the effectiveness of targeted interventions, including educational, pharmacist-led, and digital strategies.

In conclusion, unintentional therapeutic duplication represents a prevalent and preventable medication-safety issue that extends beyond traditional models of medication misuse. By identifying ingredient literacy as a central determinant, this study provides a conceptual and practical framework for addressing duplication risk through targeted educational and system-level interventions.

Conclusion

Unintentional therapeutic duplication represents a common yet preventable medication-safety issue among adults in Saudi Arabia. The strong association with limited active-ingredient literacy highlights the need for targeted educational and system-level interventions. Improving medication labeling, strengthening pharmacist-patient communication, and enhancing public awareness of active ingredients may significantly reduce duplication-related risks.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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This study did not receive any funds.

Artificial Intelligence (AI) Disclosure

The authors declare that artificial intelligence (AI) tools were used solely to assist with language editing, grammar refinement, and clarity of expression. No AI tools were used for data generation, data analysis, or interpretation of results. All scientific content, study design, analysis, and conclusions were developed and verified by the authors.

Supporting Information

S1 Questionnaire. Study questionnaire domains and item structure. https://doi.org/10.70957/uqu.edu.sa/s.toxicology.s/stj2026-4-3-s1

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