

Original Research

Screening of herbal-drug interactions during dispensing: A simulated patient study in community pharmacies

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Abstract

Background: Community pharmacists play a pivotal role in ensuring safe and effective self-medication. In Hungary, national guidelines require structured questioning and risk assessment during consultative dispensing, however Real-world adherence is uncertain. Herbal products such as St. John's wort, which has well-documented interactions with antidepressants and hormonal contraceptives, represent a high-risk area where inadequate counselling may have serious clinical consequences. **Objective:** This study aimed to assess the quality of consultative dispensing in Hungarian community pharmacies, with a particular focus on the identification and management of clinically relevant drug–herb interactions. **Methods:** A simulated patient study was conducted between January and April 2024 in pharmacies across Csongrád-Csanád County, Hungary. A standardized scenario involved a young woman requesting St. John's wort while taking escitalopram and an oral contraceptive. After each visit, a structured questionnaire recorded the information elicited by pharmacy staff (pharmacist, technician, or pharmacy student, based on name tags), recognition of clinically relevant interactions, and whether dispensing, counselling, or referral occurred. Descriptive statistics were used to evaluate adherence to guideline-based counselling. Outcomes were classified as: (1) dispensed without warning/referral; (2) dispensed with warning and/or referral; (3) not dispensed with correct justification (interaction(s) recognised and communicated); (4) not dispensed with incorrect or unclear justification. **Results:** A total of 110 pharmacies (81.5% of all pharmacies in the county) were visited. In 89 cases, staff initially intended to dispense St. John's wort without further questioning. After disclosure of escitalopram and oral contraceptive use, dispensing was correctly refused in 62 cases (56.4%); however, only 52 refusals (47.3%) were supported by appropriate clinical reasoning. Correct performance was observed in 41.0% of pharmacist-led and 28.6% of technician-led encounters. Interactions with escitalopram and oral contraceptives were identified in 35.2% and 27.4% of cases, respectively, and physician referral occurred in 43.6%. Lack of structured questioning frequently resulted in missed safety risks. **Conclusion:** This study reveals substantial gaps between guideline recommendations and real-world pharmacy practice. Inadequate questioning of patients and failure to recognize clinically significant interactions highlight the need for better implementation of guidelines to improve patient safety when dispensing OTC and herbal medicines.

Keywords: Patient Simulation; Pharmaceutical Services; Drug-Herb Interactions; Hypericum perforatum; Escitalopram; Contraceptive Agents

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INTRODUCTION

The role of community pharmacists today extends far beyond the traditional dispensing of medicines. Pharmacies are often the first and last point of contact for patients seeking healthcare, and patients expect prompt, professional, and empathetic help with their concerns¹. In this environment, the role of the pharmacist is crucial. They not only recommend and dispense medicines, but also take responsibility for patient safety and the effectiveness of

therapy, and if necessary, refer patients to physicians².

Pharmaceutical care is based on appropriate patient communication, using a structured questioning technique to explore the background of the problem³. The five most important questions about a patient's medication habits are: what, how much, when, why and how⁴. Of particular note is the increasing use of herbal products and supplements by patients, who often believe them to be completely harmless. However, these substances can also trigger drug-herb interactions that affect the absorption, metabolism, or elimination of drugs⁵. This is particularly true for example in the cases of chronic diseases, anticoagulant treatment, immunosuppressive or hormonal therapy, where even seemingly simple herbs can have serious consequences on health⁶. Structured questioning and personalized advice by pharmacy staff often reveal background information that makes referring the patient to a medical doctor the most responsible step, rather than recommending an over-the-counter (OTC) medicine. This may include persistent, worsening, recurrent complaints, or not responding to OTC treatment, unusual symptoms, underlying medical conditions, or drug therapies that preclude self-management. Therefore, pharmacists play a key role not only in recommending therapy, but also in acting as a screening point in the healthcare system. They can help to prevent complications arising from inappropriate self-medication, and identify when a patient's condition requires further investigation⁷. All of this contributes



to safe patient care, relieves the burden on the healthcare system, and enhances the professional image of pharmacies.

Although it has always been clear that pharmaceutical counselling is a fundamental part of safe medicine supply, the development of consultative dispensing in its current form is the result of recent decades. The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established the legal foundation for mandatory pharmacist counselling in the United States. Under OBRA '90, pharmacists were required to offer patient counselling at the point of dispensing, ensuring that patients receive essential information about the proper use of their medications, potential side effects, and drug interactions⁸. This act represented a shift from product-oriented to patient-centered pharmacy practice. In 1992, the International Pharmaceutical Federation (FIP) created standards for pharmacy services titled "Good pharmacy practice in community and hospital pharmacy settings." This document was submitted to the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 1994. Taking into account the recommendations of the committee, the joint FIP/WHO document on good pharmacy practice (GPP) was officially published in 1999⁹. According to the 2011 edition of the GPP guideline, "pharmacists should ensure patient confidentiality at the point of dispensing medical products and should provide advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment"¹⁰.

In Hungary, the Guideline on Medicinal Safety Monitoring in Pharmacies as Part of Direct Medicinal Supply to the Public laid down the foundations for consultative dispensing. According to the definition, consultative dispensing is a healthcare service that includes the dispensing of prescription and nonprescription medicines, as well as other pharmacy products relevant to the consultation; professional monitoring in terms of patient safety, drug safety, and cost-effectiveness, as well as providing information tailored to the patient's individual needs. In addition, using appropriate methodology, it emphasizes counseling that improves patient cooperation (adherence), the identification of drug-related problems, and problem-solving pharmacist interventions. When dispensing OTC medicines, the dispensing personnel (pharmacist or specialized pharmacy technician) must address five basic drug safety issues: 1) who needs the medicine; 2) what symptoms exactly does the medicine need to treat; 3) is it necessary at all; 4) are there any other medications being taken, any chronic diseases; 5) is the patient/customer aware of any drug sensitivities¹¹.

The aim of our work was to evaluate, within the framework of a simulated patient study, the extent to which the objectives of the Hungarian guidelines on consultative dispensing, which focus on drug and patient safety, are being achieved.

METHODS

Design of the situation

The standardised situation was constructed jointly by the members of the research team and tested on ten pharmacists. Following the pilot, the situation was modified according to the pharmacists' recommendations. The situation was designed to evaluate consultative dispensing, paying particular attention to drug-herb interactions. In each visit, the same standardised scenario was presented: a young woman diagnosed with depression, receiving escitalopram as monotherapy and concurrently using oral contraceptive wishes to buy a St. John's wort (*Hypericum perforatum* L.) product. She expresses that the current treatment was insufficient and that she seeks an additional remedy. Each visit was started with the following statement: "I would like to buy a St. John's wort product for myself." The combination of St. John's wort and escitalopram (a selective serotonin reuptake inhibitor) is considered a clinically significant and potentially serious drug interaction, therefore, concurrent use is strictly contraindicated. Also, the interaction between St. John's wort and hormonal contraceptives is clinically significant and is therefore contraindicated due to an increased risk of unplanned pregnancy. Responses to the questions posed by pharmacy staff were provided according to the predefined background. When essential information was not requested, it was offered proactively by the investigator.

Scenario progression followed a predefined algorithm (Figure 1), which included a standardized trigger point for proactive disclosure when concomitant medication use was not obtained.

Data collection

The primary outcome was the proportion of encounters in which dispensing of St. John's wort was correctly refused because at least one clinically relevant interaction (with escitalopram and/or with hormonal contraceptives) was recognised and communicated. The secondary outcomes included identifying the escitalopram and contraceptive interactions, referral behaviour (recommending a consultation with a physician/psychiatrist), extent of guideline-concordant information gathering, and the association between staff qualification and performance. We hypothesised that correct refusal would be suboptimal overall and more frequent in pharmacist-led than technician-led encounters. Simulated patient visits were carried out between January and April 2024.

A pre-designed online questionnaire (filled out immediately after each visit) documented the sequence of questions and information exchanged, the dispensing decision, counselling content, referral advice, and any stated justification. Data that could identify the dispensing personnel or the pharmacy were not collected. We only recorded the educational level of the dispensing staff based on the mandatory name tag (pharmacist/technician/pharmacy student), the type of pharmacy (public/branch/hospital-based community), and the type of settlement (city/village). Encounters were classified as: (1) dispensed without warning/referral; (2) dispensed with warning and/or referral; (3) not dispensed with correct justification (interaction(s) recognised and communicated); (4)



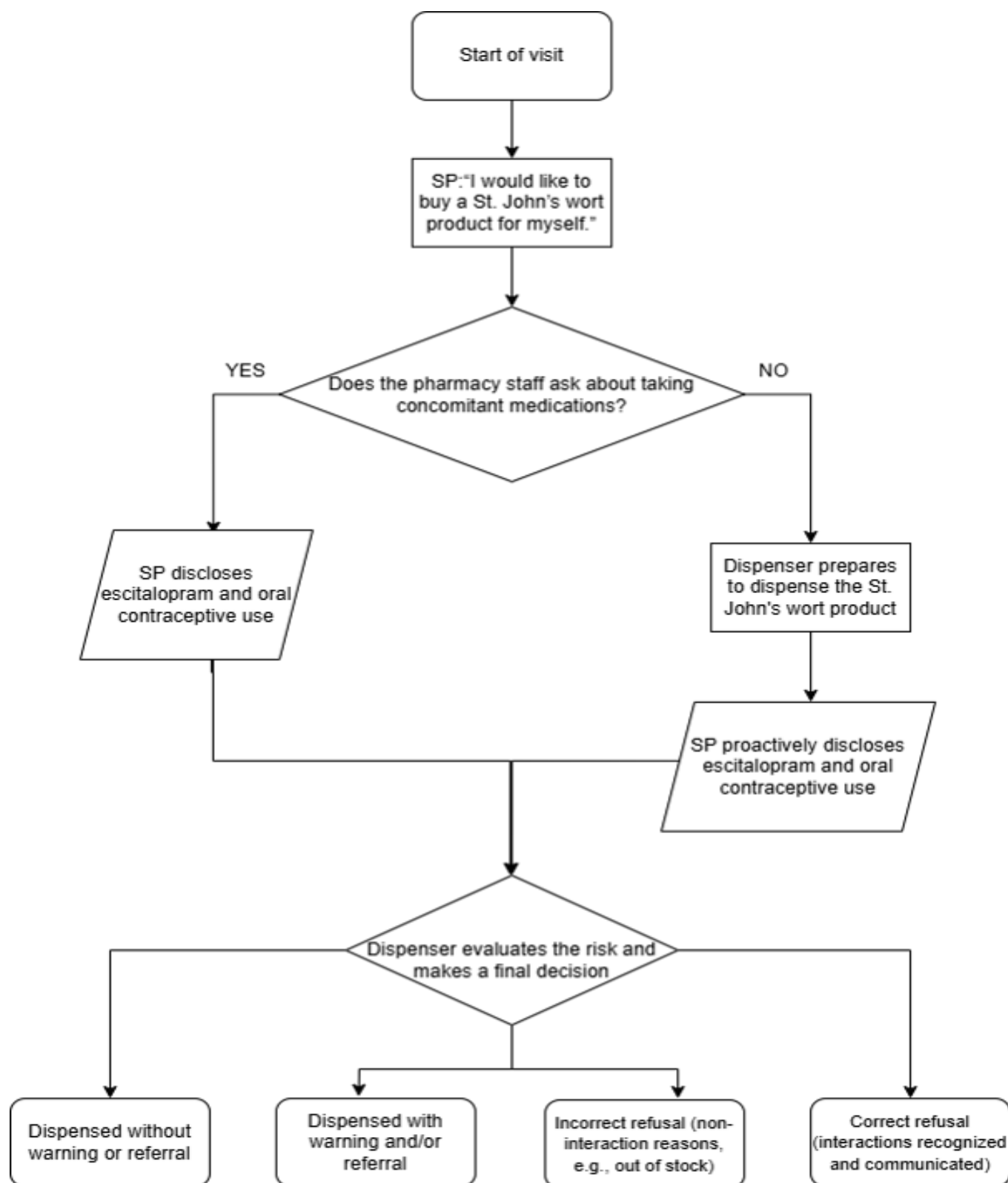


Figure 1. Flowchart of predefined algorithm of scenario progression and disclosure rules used in the simulated patient visits.

not dispensed with incorrect or unclear justification (e.g., stock shortage or non-interaction reasons).

Sample size/participants

Data were collected in Csongrád-Csanád County, Hungary, by visiting community pharmacies. The pharmacies to be visited were not informed in advance of the visit. In this County there are a total of 135 pharmacies, including 113 community pharmacies, 16 branch pharmacies, and 6 hospital-based community pharmacies. We planned to visit at least 80% of the pharmacies in Csongrád-Csanád County, Hungary.

Statistical analysis

Each visit was followed by the completion of a pre-prepared questionnaire. The resulting data were subsequently analysed using Microsoft Excel. Visualizations were created using the online tool SankeyMATIC¹².

RESULTS

During the study, 110 pharmacies were visited, located in 36 different settlements. A total of 97 community pharmacies, 4 hospital-based community pharmacies and 9 branch pharmacies were visited during our study. Data collection covered 81.5% of pharmacies in the county. All visits were eligible for analysis.

In 39 mystery shopping cases, dispensing was performed by a pharmacist and in 14 cases by a pharmacy technician. The remaining 57 cases are classified as 'other' categories: in 43 cases, it was not possible to identify the dispensing personnel; in 11 cases, more than one person was involved in the consultation; and in 2 cases, pharmacy students were dispensing.

In 89 cases, the situation would have been handled incorrectly, and the product would have been dispensed without further question (Figure 2).

Thereafter, if pharmacy staff did not inquire about concomitant medication use, the customer informed the dispensing personnel that she was regularly taking escitalopram for major depressive disorder and oral contraceptives. Even with this information, in 48 of the 89 cases (43.6%) the dispensing personnel were still willing to incorrectly dispense products containing St. John's wort (Figure 3).

In a total of 62 cases (56.4%), the dispensing of products containing St. John's wort was correctly refused, and in 52 cases (47.3%) this was done with appropriate justification, based on the interactions with other medications being taken or refers the patient to doctor, specialist. In a total of 48 cases (43.6%), the patient was referred to a specialist or a medical doctor (Table 1).

In 10 cases, the preparation was not dispensed to the patient due to stock shortage or other invalid reasons (for example, by stating that St. John's wort is not intended for the treatment of depression). The average time spent on counselling was 10 minutes.

Examining the cases from the perspective of the dispensing healthcare professional's qualifications, we found that pharmacists acted correctly in 41.0% of cases, while dispensing technicians did so in 28.6% of cases. The outcome was correct in 90.9% of cases when several people were involved in the dispensing.

The dispensing personnel rarely (2.7%) asked spontaneously about the concomitant medication use. Of the cases where the customer's regular drug therapy was identified (escitalopram and an oral contraceptive), the potential interaction between St. John's wort and escitalopram was detected in 35.2% of cases (n=37), while the potential interaction between St. John's wort and the oral contraceptive was noted in 27.4% of cases (n=26).

The quality of dispensing is influenced by many factors, such as the number of people waiting at the pharmacy¹³. In cases where the patient was alone in the pharmacy during the entire dispensing process or at the beginning, the dispensing personnel was more likely to refer her to a specialist. When the patient was alone in the pharmacy during the entire dispensing process, she was referred to a psychiatrist in 50.0% of the cases. In cases where the patient was initially alone and others arrived at the pharmacy later, referral to a doctor occurred in 57.1% of cases (n=14). If there were other patients in the pharmacy but they were being served by another pharmacist, referral to a clinician occurred in 26.7% of cases, while if there was a queue behind the test purchaser, referral to a doctor happened in 39.3% of cases.

In many cases, the patient was recommended to use alternative methods in addition to or instead of medicines containing St. John's wort. The most common recommendations were St. John's wort tea and herbal drops (n=26). In 13 cases, the patients were encouraged to visit non-pharmacy drugstores to purchase for example lemon balm-based products. In 10 cases, solutions such as starting to exercise, listening to music, and dancing were recommended.

DISCUSSION

To the best of our knowledge, this is the first simulated patient study to examine the dispensing of St. John's wort in community pharmacies. The significance of this research lies in the fact that St. John's wort is a popular herbal product whose potential interactions require increased attention on the part of dispensing staff.

In Hungary, the dispensing of nonprescription (over-the-counter, or OTC) medications is part of pharmaceutical care, which requires standardised patient counseling before



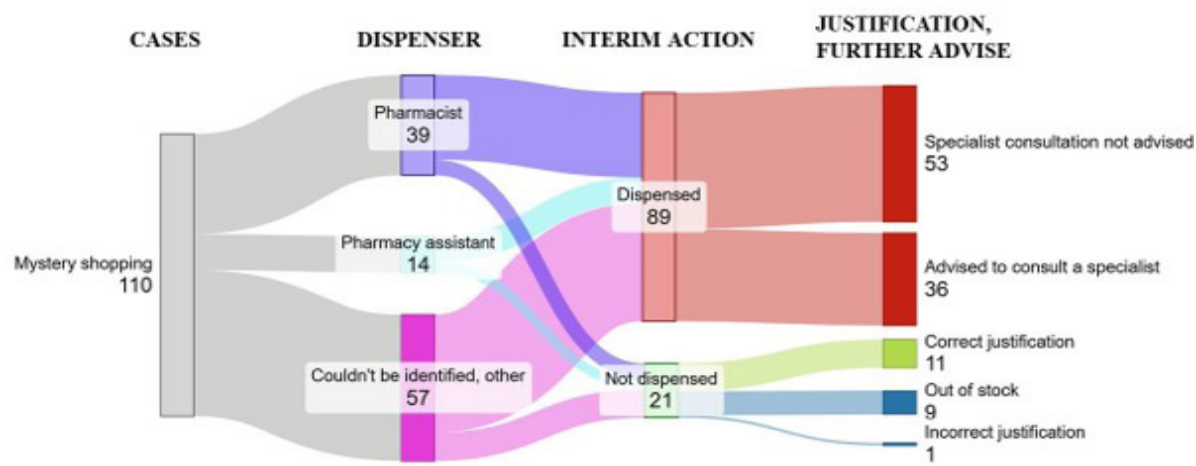


Figure 2. Flowchart of interactions between patients and dispensing personnel (edited with sankeyMATIC.com)

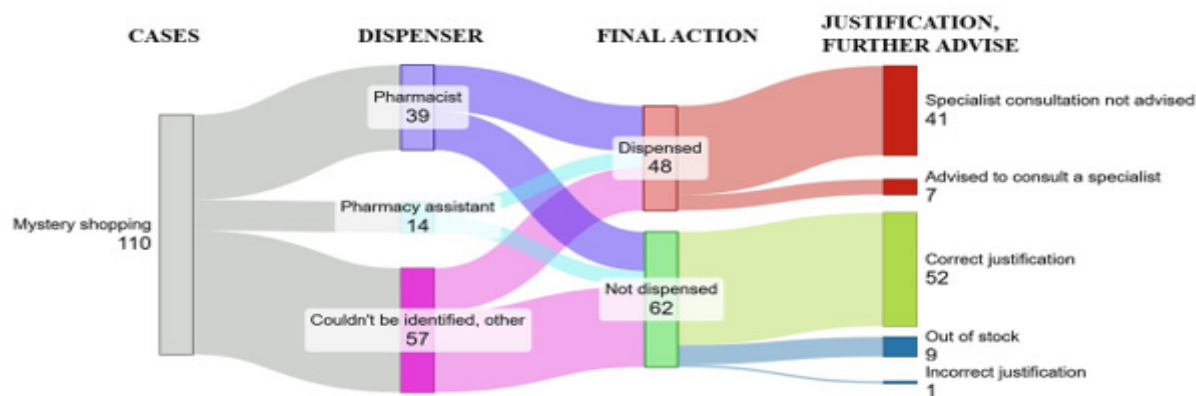


Figure 3. Flowchart of interactions between patients and dispensing personnel in cases where the patient has provided information about concomitant medication use (edited with sankeyMATIC.com)

Table 1. Correctly justified cases according to type of the dispenser, recognition of interactions, and referral to a doctor/specialist						
Type of the dispenser	Recognised the interaction with escitalopram	Recognised the interaction with hormonal contraceptives	Refer to doctor/specialist	Cases	%	95%CI
					(n _{total} = 110)	
Pharmacist	☒	☒	☒	3	2.7	0.93:7.71%
	☒	☒	☒	1	0.9	0.16:4.97%
	☒	☒	☒	4	3.6	1.42:8.98%
	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	3	2.7	0.93:7.71%
Pharmacy technician	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	3	2.7	0.93:7.71%
Couldn't be identified, other	☒	☒	☒	6	5.5	2.52:11.39%
	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	11	10	5.68:17.02%
	☒	☒	☒	3	2.7	0.93:7.71%
	☒	☒	☒	4	3.6	1.42:8.98%
	☒	☒	☒	2	1.8	0.5:6.39%
	☒	☒	☒	2	1.8	0.5:6.39%
Total correct cases				52	47.3	38.19:56.54%

dispensing. The official quality standards of the Hungarian Chamber of Pharmacists' require pharmacy staff to perform a comprehensive safety check. This procedure is designed to support appropriate self-medication and minimise patient risk and includes the collection of crucial patient data through targeted questioning. The most important questions focus on the user of the medicine (including age and other characteristics), symptoms, concurrently used medicines, and medical history¹⁴. This long-standing practice was confirmed by the official guideline published in 2024¹¹.

Several studies have pointed out that targeted questioning and informing of patients is important for safe medication supply. This has been addressed in various test purchase studies. A Dutch study examined the quality of advice that was provided in community pharmacies on allergic rhinitis (i.e. hay fever). Community pharmacies performed well in responding to requests for treatment of allergic rhinitis, providing appropriate advice in 96.0% of cases. However, their performance dropped significantly for symptom-based requests, with only 21.1% to 41.2% of pharmacies dispensing the correct antihistamine¹⁵.

A test purchase study conducted in Perth, Australia, revealed that pharmacies performed sub optimally in terms of patient assessment and counselling when dispensing non-prescription asthma relief medication (salbutamol). Both aspects fell short of recommended practice when the medication was supplied in a community pharmacy setting¹⁶. Another study was a secondary analysis of a survey conducted in the United Kingdom that aimed to identify factors that influence the dispensing of over-the-counter medicines in accordance with guidelines. The study showed that the likelihood of supplying non-prescription medicines in accordance with the guidelines was significantly greater when presenting symptoms than when presenting conditions or products ($p<0.001$). The likelihood of an appropriate outcome increased further with greater information exchange and when consultations involved pharmacists rather than medicine counter technicians¹⁷.

No prior studies in Hungary have assessed the quality of dispensing. This study is the first to reveal the strengths and limitations of dispensing practices, paying particular attention to drug-herb interactions. In Hungary, pharmacists and

dispensing pharmacy technicians are permitted to dispense medication legally, and they should always wear nametags to make them identifiable. In 43 cases (39%), this requirement was not met. Moreover, important questions were often left out during the dispensing process, raising concerns about medication safety. In our study, we divided the problems caused by inadequate questioning into two main categories. The first category includes cases where the dispenser did not find out that the patient was already receiving antidepressant treatment (in which case St. John's wort cannot be taken at the same time). The second category includes cases where the interaction between St. John's wort and oral contraceptives was not identified, which should also have led to the refusal of dispensing.

The interaction between *Hypericum perforatum* and escitalopram is clinically relevant. Two mechanisms are involved in this interaction. First, at the pharmacodynamics level, St. John's wort increases serotonin levels in the central nervous system similarly to escitalopram. This may lead to serotonin syndrome, a potentially life-threatening state (reaction), which can cause symptoms such as confusion, agitation, tremor, muscle spasms, tachycardia, and this interaction is clinically relevant¹⁸. A case series reported symptoms of serotonin syndrome in five patients taking SSRI antidepressants¹⁹. Second, from a pharmacokinetic point of view, hyperforin, a characteristic component of St. John's wort, is a moderate inducer of the CYP3A4 enzyme system and the P-glycoprotein (P-gp) in the liver. This mechanism accelerates the breakdown and elimination of escitalopram, and reduces bioavailability, resulting in a decrease in blood levels and reducing the effectiveness of antidepressant treatment. However, this theoretical interaction has not been confirmed in reliable clinical trials and case reports. Overall, in particular due to the increase in serotonin levels, the combined use of escitalopram and St. John's wort may be a source of high-risk interactions²⁰.

The concomitant use of St. John's wort and hormonal contraceptives is contraindicated due to an increased risk of unplanned pregnancy. The main mechanism of this interaction is the induction of CYP3A4 which leads to the decrease of plasma level of the contraceptive hormone level. These reduced hormone levels impair contraceptive effectiveness, increase the risk of breakthrough bleeding during the cycle, and can potentially lead to ovulation²¹. The relevance of this interaction is supported by case reports of unwanted pregnancies^{22,23}.

Our investigation showed that proper questioning of patients is essential for safe medication use, even in the case of OTC products. The fact that in most cases, dispensing personnel did not identify the reasons why they should have refused to dispense products containing St. John's wort draws attention to the fact that guidelines and daily practice in pharmaceutical care do not coincide.

Limitations

This study has several limitations. Firstly, the data were collected in a single county, so the results may not be generalisable to other regions of Hungary or other countries. Secondly, only one high-risk scenario was assessed (St. John's wort in interaction with escitalopram and hormonal contraception); performance may differ for other products or interaction types. Thirdly, the simulated patient recorded the outcomes immediately after each visit, which may have introduced observer bias despite the use of a standardised questionnaire and training. Fourthly, we did not systematically assess the underlying clinical reasoning beyond what was verbally communicated during the encounter. Finally, although the covert design minimises reactivity, the Hawthorne effect cannot be fully excluded if staff suspected the assessment.

CONCLUSIONS

To our knowledge, this is the first study in Hungary to use the test purchase technique to examine the knowledge of pharmacy dispensing personnel regarding drug interactions, particularly herbal-drug interactions. Our results suggest that much more attention should be paid to detailed questioning of patients. This should include their regular medication and dietary supplements. It should also include an assessment of the patient's condition. If necessary, the patient should be referred to a specialist or doctor. Following appropriate protocols and guidelines could be very useful in addressing these shortcomings, and regular training and education could help in the practical application of lexical knowledge and increase the patient safety.

AUTHOR CONTRIBUTIONS

Credit Taxonomy

Conceptualization: D.C.

Methodology: D.C., B.T., M.M., R.S.

Investigation: G.Á., M.M.

Writing—original draft preparation: Z.S.

Writing—review and editing: Z.S., G.Á., D.C., B.T., R.B., M.M.

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CONFLICTS OF INTEREST

Authors declare no conflicts of interest.



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