



The quality of non-prescription medicine counselling in Finnish pharmacies – a simulated patient study

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ABSTRACT

Background: Medication counselling provided by pharmacists is important for ensuring the safe use of medicines.

Objective: To assess the quality of non-prescription medicines counselling in Finnish pharmacies.

Methods: Three scenarios using simulated patient methodology were conducted: the patient requesting a specific brand name Burana® (ibuprofen, OTC medicine), Pronaxen® (naproxen, behind-the-counter (BTC) medicine) and a nasal spray. The visits were conducted in 146 pharmacies by trained simulated patients. Each pharmacy was visited twice. The quality of counselling was defined as poor (1–2 points), moderate (3–4 points), or high (5–6 points) based on developed scenario-based scoring criteria.

Results: The total number of conducted visits was 292, of which only 29 received high quality counselling. The quality was high in 20% of the cases for Pronaxen® and in 7% of the cases for Nasal spray scenarios. In the Burana® scenario, counselling quality was high only in 2% of the cases. Patients who requested a nasal spray were often asked questions about their symptoms (93%). In the Pronaxen®-scenario, the most frequently asked questions were related to contra-indications and drug interactions (56%). The most often given instructions varied between the scenarios, being follow-up in the Burana® and Nasal spray scenarios (17% and 70%, respectively) and how to use the medicine in the Pronaxen®-scenario (63%).

Conclusions: Non-prescription medicine counselling is rarely performed with high quality. However, the quality of counselling depends on the medication in question. There is room to improve medication counselling and the assessment of the necessity and suitability of treatment, especially when a patient requests an OTC pain medicine by its brand name.

1. Introduction

A trend is evident in that the number of over-the-counter (OTC) medicines available for self-medication keeps increasing across Europe.¹ Such deregulation increases the autonomy of individuals. Even though OTC medicines have been assessed as being safe for self-medication, studies demonstrate that the use of OTC medicines is often associated with drug-related problems such as adverse effects, drug-drug interactions and overdose.^{2–4} Patients consider easily available OTC medicines to be safe, and consequently often underestimate their potential risks.^{3,4} Safe self-medication requires that a medicine is used for its intended purpose and usually only for a short period of time. As trusted and easily accessible healthcare professionals, community pharmacists are often the first contact for patients with minor symptoms. Medication counselling provided by pharmacists is especially important when OTC medicines are purchased without first contacting other healthcare professionals.^{5,6} In many European countries, customers can purchase OTC medicine only from

pharmacies.⁷ However, there are also exceptions. For example, in the United Kingdom (UK) there are two different OTC medication categories.⁸ Pharmacy medicines (P) can only be bought from pharmacies and under a pharmacist's supervision, while General Sales List medicines (GSL) can be bought also from retail stores. When it comes to the Nordic countries, in Finland and Iceland OTC medicines are pharmacy-only whereas in Sweden, Norway and Denmark, customers can also purchase OTC medicines outside the pharmacy.

Several studies have been conducted about the pharmacist's role in customer service and the sale of OTC medicines in pharmacies. Many studies have used the simulated patient method, but only a few have assessed the quality of counselling using a scoring system.^{9,10} The quality has been measured using different scoring systems that incorporate different areas such as counselling content (questions pharmacists should ask, information pharmacist should give), written instructions used, and manner of counselling (counselling spontaneity, counselling comprehensiveness, eye contact). The quality of counselling has been classified for example as

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unsatisfactory, satisfactory or excellent; basic or good practice; or by defining the score that adequate advice ought to reach.^{9,11,12} The wide variety in methods used in these studies for assessing the quality of counselling makes it difficult to summarize their results. There is some evidence to show that patients receive higher quality counselling when they ask for help for symptoms compared to a situation where they make a direct request for a specific product.^{2,9,13–16} Nonetheless, many of these studies conclude that there is much room for improvement in the quality of OTC counselling in pharmacies.^{11,13–15,17}

More research is needed on the quality of OTC medication counselling. Only a few previous studies have assessed the quality by scoring the counselling given to simulated patients. In Finland, a previous study evaluating the quality of OTC medication counselling was conducted more than ten years ago.¹⁷ According to that study, the amount and quality of counselling varied greatly between the different scenarios used, thus, there was room for improvement in the quality of OTC medication counselling in Finnish pharmacies. After that, there has been attempts to improve the OTC medication counselling in community pharmacies, but evaluation has not been conducted.

The aim of this study was to assess the quality of non-prescription medication counselling in response to three scenarios in Finland.

2. Methods

2.1. Context

In Finland, medicines are classified into prescription medicines, over-the-counter medicines (OTC), and since 2015, medicines requiring additional information (behind-the-counter, BTC). The sale of all OTC and BTC medicines, is limited to pharmacies.¹⁸ BTC medicines can be purchased only with special guidance provided by pharmacists according to a pre-determined protocol supplied by the marketing authorization holder. At the moment, there are 78 active OTC substances in self-care, of which six (ulipristal acetate, sumatriptan, naproxen, orlistat, levonorgestrel, 5000 ppm fluoride toothpaste) are BTC medicines.

OTC medicines are usually placed in pharmacies' self-service sections, where pharmacists are available for giving advice. Only pharmacists (either a 5-year MSc (Pharm) or a 3-year BSc (Pharm) university education) are allowed to dispense medicines or give any medicine counselling. Later in this article, the term "pharmacist" refers to both MSc and BSc educated pharmacists. Medication counselling by community pharmacists has been mandated by law since 1983. Currently, medication counselling is defined in law at a general level, and there are no national quality criteria for non-prescription counselling in Finland.

2.2. Data collection

A random sample of 150 pharmacies was taken from all Finnish pharmacies ($n = 627$), excluding the province of Lapland for resource reasons ($n = 33$). Three pharmacies were excluded from the sample because they had ceased operation and one pharmacy in Åland was excluded for resource reasons. This resulted in the final sample of 146 pharmacies. Pharmacies in the sample were found to represent Finnish pharmacies relatively well in size and geographical location.¹⁹

The simulated patient method was used in this study to examine simulated patient and pharmacist interactions, and the quality of medication counselling provided. The simulated patient method is a commonly used method for measuring the outcomes of medication counselling in pharmacies and for identifying areas for improvement.^{20–22} Simulated patients are people who have been trained to make covert visits to pharmacies to enact specific scenarios and report on the behavior of pharmacy staff without the staff being aware that they are being evaluated.

For each scenario was defined specific time for simulated patient visit over a period September 2016 and May 2018. All pharmacies were visited twice during the study period with the same scenario, at the same time in different years. The Pronaxen® (naproxen) scenario was conducted during

the influenza season and the nasal spray scenario in the spring at the typical allergy time in Finland. Altogether 292 visits were completed.

The visits were conducted by a company specialized in the simulated patient method. They trained each simulated patient in the method, as well as the current study cases and observation forms. Altogether 41 trained simulated patients, between ages 30 and 70 years, with previous experience of conducted simulated patient visits, both male and female, carried out the visits. Each of the scenarios had its own observation form, developed by the research team. The simulated patient waited for pharmacy staff to make contact and if not approached, asked for help. The simulated patient did not provide any information, unless asked. As the observations were to be realistic, the simulated patient purchased the medicines. Immediately after each visit, the simulated patient documented the counselling process electronically. Most items were designed to enable a structured yes/no answer. However, open-ended questions were also utilized to allow the simulated patients to describe the visit in their own words. In the scenario of Pronaxen® (naproxen), the use of written material was documented. Visits were not recorded.

2.3. Scenarios

The research team developed three simulated patient scenarios (Table 1). Scenarios 1 and 2 were direct product requests: the patient requesting a specific brand name Burana® (ibuprofen, OTC medicine) and Pronaxen® (naproxen, BTC medicine). In scenario 3, the patient requested a nasal spray.

2.4. Scoring

Scoring criteria for each of the scenarios differed. For Scenario 1 (Burana®, ibuprofen) the scoring criteria was developed by the research team. The scoring criteria for Pronaxen® scenario was developed by research team based on the BTC-protocol provided by the marketing authorization holder which sets the requirements in medicine counselling. Finally, the scoring criteria for the nasal spray scenario are a modified version of previous criteria developed to investigate the quality of medication counselling.¹⁷ This scoring system was originally based on the United States Pharmacopeia Medication Counselling Behavior Guidelines.²³

The quality of counselling is usually measured through two main elements; questioning and advice-giving.^{20–22} In this study, the scoring criteria for the quality of medication counselling were inductively developed using two categories: need assessment and instructions for use, which were further divided into subcategories (Table 2). Need assessment category included the questions that pharmacists should ask the patients. The Instruction for use category included information and advice about the medicine that pharmacists should give to the patients. The questions and advice were based on the data, i.e., they were questions that the pharmacists had asked and advice they had given to the simulated patient.

For scenario 1 (Burana®, ibuprofen) included questions and instructions for the use of the medicine that are needed to ensure medication safety (Table 2). For scenario 2 (Pronaxen®, naproxen) included questions and instructions required by marketing authorization holder. Scoring criteria for scenario 3 (nasal spray) were included questions and instructions for the use of the medicine that are prerequisites for medication safety.

Each subcategory was scored 1, if at least one question was asked or piece of advice was given, and 0 if no questions were asked or no advice was given. Total scores and scores for the two categories, i.e. Need assessment and Instructions for use, were calculated for each visit. The quality of medication counselling was defined as being poor with scores 1–2, moderate with scores 3–4, and high with scores 5–6.

2.5. Pilot study

All three scenarios and observation forms were piloted three times, each in a different pharmacy resulting in nine pilots altogether. Scenarios 1

Table 1

Description of the simulated patient scenarios used in the study.

Scenario 1:**The simulated patient enters the pharmacy and asks for a 30-tablet pack of Burana® (ibuprofen, OTC medicine) 400 mg**

The scenario was selected because ibuprofen is a commonly sold OTC medicine. A patient asking for a product by brand name is a typical situation in a pharmacy. The scenario was conducted in October 2016 and 2017.

The simulated patient gives the following information only if asked:

Identify patient:

- the medicine is for the simulated patients own use

Symptoms

- Headache for a long time, for several weeks
- Other symptoms: muscle pain in the shoulders

Possible cause of symptoms:

- Working on the computer

Previous self-treatment of symptoms

Ibuprofen 2 to 3 tablets a day for several weeks

- Not yet seen a doctor

Other medicines and illnesses

- No other medicines in use
- No other diseases, such as asthma

Scenario 2:**The simulated patient enters the pharmacy and asks for a 10-tablet pack of Pronaxen® (naproxen, BTC medicine) 250 mg.**

During the time of the study, BTC medicine category had recently been introduced in Finland. The scenario was conducted in February–March in 2017 and 2018. These months are the typical for influenza in Finland.

The simulated patient gives the following information only if asked:

Identify patient:

- for an adult family member

Symptoms:

- High fever of over 38 degrees Celcius
- Headache and muscle pain started the same day

Possible cause of symptoms:

- A child in the family has had influenza (as determined by a doctor). The child is already recovering from the disease

Previous self-treatment of symptoms

- The child was prescribed naproxen in liquid form, and it was good for the influenza symptoms
- Patient would like to buy the same medicine for the adult family member who has the same symptoms

Other medicines and illnesses

- No other medicines, illnesses or allergies

Scenario 3:**The simulated patient enters the pharmacy and asks for a nasal spray**

The scenario was utilized in a previous simulated patient study conducted in Finland in 2003.¹⁷ The scenario was conducted in April – May in 2017 and 2018. April–May is the beginning of the typical allergy time in Finland.

The simulated patient gives the following information only if asked:

Identify patient:

- the medicine is for the simulated patients own use

Symptoms:

- A runny nose and a mild flu
- Symptoms make sleeping difficult

Previous self-treatment of symptoms

- Has used nasal spray (Otrivin® xylometazolin) occasionally

Other medicines and illnesses

- No other medicines, illnesses or allergies

(Burana®) and 3 (nasal spray) were piloted in September 2016 and scenario 2 (Pronaxen®) during the influenza season in January 2017. A few minor changes were made to the observation forms based on the pilot study. Pilot visits were not included in the study data.

2.6. Statistical analysis

The collected data was analyzed using the statistical software SPSS (25.0). Data on pharmacy visits were evaluated using the scoring criteria described in Table 2. The total scores for each subcategory were calculated. In addition, mean total scores and standard deviations (SDs) for each scenario as well as mean total scores and standard deviations (SDs) for the categories in each scenario were calculated.

2.7. Ethical issues

All Finnish community pharmacies were informed by email of the simulated patient study five months before the study. The pharmacies didn't have the opportunity to refuse to participate the study. The pharmacies were blinded regarding the dates of the visits and details of the scenarios. The pharmacies were informed that all data would be anonymous and strictly confidential. At the end of the study, a summary of the results was sent to all Finnish pharmacies. Furthermore, the visited pharmacies were informed by email of their participation in the study and they had the opportunity to obtain the observation forms concerning the visit to their pharmacy.

This study was approved by The Committee on Research Ethics of the University of Eastern Finland in March 2016.

3. Results

The quality of patient counselling was high (scored 5 or 6 points) only in 29 of all visits: 2% of Burana® scenario 1, 20% of Pronaxen® scenario 2 and 7% of nasal spray scenario 3.1 respectively (Table 3). On the other hand, 68%, 13% and 1% of the pharmacies provided no counselling at all in scenarios 1, 2 and 3, respectively. In general, quality was higher in the Pronaxen® and nasal spray (3.1) scenarios compared to the Burana® scenario. Mean scores for the need assessment -category was the highest in the nasal spray scenario (1.47, range 0–3) and for the instruction for use category in the Pronaxen® scenario (1.45, range 0–3).

In the Pronaxen® scenario, 48% of pharmacists used written material. This increased the quality of medical counselling, as 32% of the pharmacists who used written material and 10% of those who did not use written material scored between 5 and 6 points (high quality counselling), respectively. All pharmacists who used written material received at least 1 point. Furthermore, 77% of those who used written material, scored at least 3 points (45% moderate quality, 32% high quality). On the other hand, 25% of pharmacists who did not use written material received 0 points (no counselling at all).

In general, the need assessment was best conducted in the Pronaxen® scenario (Table 4) where 19% of pharmacists asked at least one question from each subcategory and 16% provided at least one instruction for use from each subcategory. However, the pharmacists assessed the patient's symptoms most often (93% of the pharmacists) in the nasal spray scenario. Need assessment was conducted the weakest in the Burana® scenario. Similarly, the instruction for use were given best in the Pronaxen® scenario. The most often given instructions varied between the scenarios, being follow-up in the Burana® and nasal spray scenarios (17% and 70%, respectively) and how to use the medicine in the Pronaxen® scenario (63%).

In the Pronaxen® scenario, the use of written material increased the number of questions asked in the need assessment category. 70% of the pharmacists who used written material and 37% of those who did not use written material asked who the medicine is for. The questions related to other medical conditions were also asked more frequently by those who used written material (85%) compared to those pharmacists who did not use written material (27%).

4. Discussion

In this study, only a few pharmacies performed high quality medication counselling indicating that there is room for improvement in the quality of non-prescription medicines counselling in Finnish pharmacies. This result is in accordance with the previous ones reported in other studies conducted with similar methods in community pharmacies in different countries.^{11,13–15,17} In this study, non-prescription medicines counselling was most often of high quality in the scenario involving a direct product request of a BTC medicine, and especially, when the pharmacist utilized written material, i.e., followed the

Table 2

The scoring criteria for the scenarios used in the study.

Scenario 1: The simulated patient enters the pharmacy and asks for Burana® (ibuprofen, OTC medicine) 400 mg a pack of 30 tablets			
CATEGORY	SCORE FOR SUBCATEGORY	SUBCATEGORY	QUESTIONS AND ADVICE
NEED ASSESSMENT	1	Identify patient	Who is the product for?
	1	Contraindications and drug interactions	Any other medication? Allergies? Other medical conditions?
	1	Symptoms	What symptoms are present? How long have symptoms been present?
	1	Previous treatment	What is the possible cause of the headache? Have you used the product before? Have you tried any other treatments? Have you seen another health professional?
INSTRUCTIONS FOR USE	1	How to use the medicine	Dosage Dosing
	1	Follow-up	Duration of medicine use What to do if symptoms persist
TOTAL SCORE	0–6		
Scenario 2: The simulated patient enters the pharmacy and asks for Pronaxen® (naproxen, BTC medicine) 250 mg a pack of 10 tablets			
CATEGORY	SCORE FOR SUBCATEGORY	SUBCATEGORY	QUESTIONS AND ADVICE
NEED ASSESSMENT	1	Identify patient	Who is the product for?
	1	Contraindications and drug interactions	Other medical conditions?
	1	Symptoms	What symptoms are present?
INSTRUCTIONS FOR USE	1	How to use the medicine	Dosage
	1	Follow-up	Duration of medicine use
	1	Restrictions in use	Other NSAIDs should not be taken at the same time
TOTAL SCORE	0–6		
Scenario 3: The simulated patient enters the pharmacy and asks for a nasal spray (a scoring criteria developed by the research team)			
CATEGORY	SCORE FOR SUBCATEGORY	SUBCATEGORY	QUESTIONS AND ADVICES
NEED ASSESSMENT	1	Identify patient	Who is the product for?
	1	Symptoms	Are the symptoms due to allergy or flu? What symptoms are present? How long have the symptoms lasted?
	1	Previous treatment	Have you used nasal sprays before? Have you tried any other treatments?
INSTRUCTIONS FOR USE	1	How to use the medicine	Dosage Dosing
	1	Adverse effects	Harmful effects of long-term use Consequences of long-term use
	1	Follow-up	Duration of medicine use
TOTAL SCORE	0–6		

* Each subcategory was scored 1, if at least one question was asked or piece of advice was given, and 0 if no questions were asked or no advice was given.

Table 3The quality of patient counselling in Finnish pharmacies ($n = 292$) in three simulated patient scenarios.

Total score	Quality of medication counselling	Scenario 1 (Burana®, ibuprofen, direct product request, OTC medicine) $n = 96\%$ (n)	Scenario 2 (Pronaxen®, naproxen, direct product request, BTC medicine) $n = 98\%$ (n)	Scenario 3 (nasal spray) $n = 98\%$ (n)
0	No counselling	68 (65)	13 (13)	1 (1)
1–2	Poor quality	19 (18)	32 (31)	42 (41)
3–4	Moderate quality	11 (11)	35 (34)	50 (49)
5–6	High quality	2 (2)	20 (20)	7 (7)
Maximum score 6		1 (1)	5 (5)	0 (0)
Mean score		mean (\pm SD)	mean (\pm SD)	mean (\pm SD)
Mean total score 0–6		0.81 (1.45)	2.82 (1.80)	2.67 (1.14)
Mean score for the categories:				
Need assessment		0.55 (1.04) ^a	1.37 (1.08) ^b	1.47 (0.71) ^b
Instructions for use		0.26 (0.55) ^a	1.45 (1.05) ^b	1.20 (0.87) ^b

^a Score range for the Need assessment 0–4, Instruction for use 0–2.^b Score range for the Need assessment 0–3, Instruction for use 0–3.

pre-determined protocol provided by the marketing authorization holder. The poorest quality medication counselling was performed in the scenario involving a direct product request of an OTC pain medicine ibuprofen: counselling quality was either poor or there was no

counselling at all in all participating pharmacies. The counselling quality were better in the nasal spray scenario compared to the scenario of an OTC pain medicine ibuprofen, most likely due to the fact, that the request was not focused on a specific product. Counselling has been

Table 4

Summary of the percentages of pharmacies that received scores in the subcategories of need Assessment and instruction for use categories (N = 292)*.

CONTENT OF PATIENT COUNSELLING		SCENARIO 1: BURANA® (ibuprofen)	SCENARIO 2: PRONAXEN® (naproxen)	SCENARIO 3: NASAL SPRAY
Category	Subcategory	n = 96% (n)	n = 98% (n)	n = 98% (n)
NEED	Identify patient	13 (12)	53 (52)	39 (38)
ASSESSMENT	Symptoms	14 (13)	29 (28)	93 (91)
	Previous treatment	14 (13)	NA	15 (15)
	Contraindications and drug interactions	16 (15)	56 (55)	NA
	<i>High quality of need assessment -category</i> (One question from each subcategory asked)	2 (2)	19 (19)	6 (6)
INSTRUCTION FOR USE	How to use the medicine	9 (9)	63 (62)	26 (25)
	Adverse effects	NA	NA	24 (24)
	Follow up	17 (16)	37 (36)	70 (69)
	Other NSAIDs should not be taken at the same time	NA	45 (44)	NA
	<i>High quality of instruction for use -category</i> (One instruction for use from each subcategory provided)	5 (5)	16 (16)	7 (7)

* see the scoring criteria in Table 2, NA = not applicable for the particular scenario.

shown to be even higher in quality when the patient asks for help for symptoms compared to a situation where the patient makes a direct product request.^{2,13–17,24}

In this study, the quality of need assessment of a patient requesting pain medicine was low. Pharmacists did not ask patients adequate questions to ensure the suitability and safe use of the medicine in question. Our results are in accordance with previous results regarding direct product request for pain medicines.^{11,14} In the scenario involving a direct product request of an OTC pain medicine, only less than one-fifth of the pharmacists asked questions aiming to identify possible contraindications and drug interactions. On the other hand, in the scenario involving a direct product request of a BTC medicine, pharmacists asked these questions more often.

The use of written material was related to higher quality of medication counselling in the scenario with a direct product request of a BTC medicine. Vast majority of those pharmacists, who used written material, asked about other medical condition to ensure contraindications. On the other hand, almost half of pharmacists did not use written material. These pharmacists did not often enough ensure the safe use of the medicine. These findings are concerning because interactions between nonsteroidal anti-inflammatory drugs (NSAIDs) and some other commonly used medicines are common problems with OTC medication⁴ and patients should be informed about these possible interactions. A special emphasis should be given to ensure adequate counselling.

In Finland, a national high-risk OTC medication list was published in 2017 to prevent severe risks related to OTC medication.²⁵ Since then it has been implemented in practice in Finnish pharmacies.⁴ Of NSAIDs, the list identifies acetylsalicylic acid, ibuprofen, ketoprofen, naproxen and paracetamol/acetaminophen as high-risk OTC medicines. The list includes their key safety risks (e.g., drug–drug interactions) and a checklist to support identification of at-risk patients to prevent drug related problems. Pharmacies have been provided with educational material on the usage of the list and encouraged to provide counselling more actively when selling high-risk OTC medications. However, the current study was conducted before this list was implemented. Consequently, further studies are needed to assess whether the quality of high-risk OTC medication counselling has improved in Finnish pharmacies.

Pharmacists asked questions about symptoms most often from patients who requested a nasal spray. In contrast, when presented with a direct product request of either an OTC or a BTC pain medicine, less than a third of the pharmacists asked questions about the patient's symptoms. This is understandable as the pharmacist must find out the symptoms for which the nasal spray is used for, for flu, allergy symptoms or to moisturize a dry nose, in order to select the right treatment for the patient. Discussing the patients' experience of their symptoms as well as the use of other medications are examples of patient-centered counselling content that should be frequently asked. Pharmacists play an important role in the prevention of drug-related problems, and especially medication counselling of high-risk medicines in self-medication should be developed.⁴

According to this study, the quality of instructions given regarding the use of medicines was low in all investigated scenarios. The most frequently provided instructions were on how to use a medicine and follow up advice, both of which are in accordance with the most frequently provided information reported in previous studies.^{13,15,26–28} Another finding of the current study was that side-effects are rarely discussed which is also in line with previous studies.^{13,15,26–28} The quality of instructions given about how to use a medicine was the highest when pharmacists were presented a direct product request of a BTC medicine. This is not a surprise as pharmacists are required to give counselling according to the protocol provided by the marketing authorization holder. However, the results show that, in general, even the sales protocol was relatively poorly followed as it was fully followed only by 5 % of the pharmacists, which is in accordance with results of a previous study.²⁹ Furthermore, the use of written material increased the quality of OTC medication counselling in this study and the amount of medication counselling in a previous study.³⁰ Those who used written material asked more questions than those who did not use the material to support counselling. Thus, pharmacists should be encouraged to use written material to support medication counselling.

In Finland, OTC medication counselling has been undergoing major development in pharmacies since the previous simulated patient study (2003). During this development process, new sources of information and quality indicators were produced for pharmacies including: an electronic drug information database on prescription drugs, therapeutic guidelines on self-medication and a handbook on communication skills.^{31,32} Furthermore, the Current Care Guideline for Self-Medication was published in 2016.³³ Efforts have been made to bring these new sources of information and training to the day-to-day practice of pharmacies. But based on the results of this study, it is evident that more has to be done. It is the responsibility of pharmacy owners to ensure that pharmacists have the information sources as well as the skills needed for high quality medication counselling in their pharmacies. In the future, the development of OTC medication counselling will continue in Finnish pharmacies. A new project named VALO (2021–2026) has been launched, aiming to develop medication safety and medication counselling as part of it.³⁴

The simulated patient method has been found to give a more reliable picture of pharmacy OTC medicine counselling compared to results collected using a non-covert non-participant observation.³⁵ In order to maximize the reliability of the results, it is important to record the findings in a structured way. The standardization of the data collection was assured by utilizing electronic observation forms by the research team and furthermore, by training the simulated patients to thoroughly understand the cases and how to fill in the observation forms. Forms, which were designed to be easy to complete with structured questions. Most items included a yes/no scale for assessment. The observation forms were developed by the research team and piloted before use. Audiotaping would have given a better understanding of the counselling situation.³⁶ However, the visits were not recorded, which is a limitation of this study.

In this study, altogether 41 simulated patients with previous experience of the method carried out the visits. According to the systematic literature review, the number of simulated patients used has varied between 1 and 625.²¹ It has been argued that using multiple simulated patients will gain more generalizable results, if the visits are well standardized.³⁷ However, large number of simulated patients could contribute to variability in performance by the pharmacy staff. Furthermore, each simulated patient makes their own individual interpretations of the content of the counselling, which could not be verified due to the lack of recording. The observation forms were completed only after the visit, so the possibility of memory bias exists when filling out the form.

According to systematic literature reviews, the assessment criteria of medication counselling quality has been based on published guidelines, recommendations and standards, other published studies, criteria developed by the authors or basing their criteria on mnemonic acronyms, most commonly on WWHAM method (W = Who is the patient? W = What are the symptoms? H = How long have the symptoms been present? A = Action taken. M = Medication being taken).^{9,10} In this study, the evaluation criteria were inductively developed and they based on different requirements in each of the three cases. Authors developed assessment criteria for the Burana® and nasal spray scenarios based on their expertise. In the Pronaxen® scenario, the criteria were based on the protocol provided by the marketing authorization holder.

The generalizability of the results is restricted only to the types of medication counselling that have been evaluated in this study. The provision of counselling is affected by several different factors such as which symptoms or medication one selects as examples for the study and whether the patient is seeking help for symptoms or asking for a specific product. There are other simulated patient studies of OTC pain medicines, but they have used different criteria and quality assessment methods.^{11,12,14,29} The results are only comparable to the results of previous studies if the same scenario and scoring criteria are utilized. In the future, it is important to follow the quality of medication counselling in Finnish pharmacies with the same scenarios allowing the evaluation of the medication counselling quality over time. This is especially important taking into account the national activities that have aimed to improve the quality of medication counselling, as these activities have been conducted after the data collection for this study.

5. Conclusions

This simulated patient study revealed that there is variation in the quality of non-prescription medicines counselling provided in Finnish pharmacies. Only a few pharmacies performed high quality medication counselling. Counselling was of high quality most often when pharmacists were presented a direct product request of a BTC pain medicine, and especially, when the pharmacist utilized written material. Medication counselling had lowest quality when pharmacists were presented a direct product request of an OTC pain medicine.

There is room for improvement in medication counselling in assessing the need for treatment and the instruction for use, especially when a patient requests an OTC medicine using its brand name.

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CRediT authorship contribution statement

Niina Alastalo: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Visualization. **Piia Siitonen:**

Conceptualization, Methodology, Writing – review & editing. **Johanna Jyrkkä:** Methodology, Data curation, Writing – review & editing. **Katri Hämeen-Anttila:** Conceptualization, Methodology, Data curation, Writing – review & editing, Supervision, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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