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Original Research

The practice of OTC counseling by community pharmacists in Parana, Brazil

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ABSTRACT*

Background: In order to provide appropriate advice to the patient at the time of dispensing and over-the-counter (OTC) medication counseling, community pharmacists need access to current and reliable information about medicines. Brazilian pharmacists have assumed new functions such as prescribing medication, in a dependent model, based in protocols.

Objective: To examine the practice of community pharmacists in a Brazilian State, focusing on OTC recommendation.

Method: A cross-sectional survey of community pharmacists in a state of Brazil was conducted from October 2013 to January 2014, with data collection through a pre-piloted self-administered anonymous survey via Survey Monkey® platform. Following ethical approval, the online instrument was sent to 8,885 pharmacists registered in Parana State, Brazil, focusing on professionals working in community pharmacies. The questionnaire assessed the community pharmacy setting, the search for information, the knowledge of the evidence-based practice, the important factors to consider when recommending an OTC medicine, and the pharmacist prescribing. Responses were imported into SPSS® (version 22.0) for analysis. Nonparametric tests were used to assess the association between responses and demographic information with a significance level less than 5% ($p < 0.05$).

Results: Of the pharmacists, 97.4% dispensed medications and counseled patients for a median of six hours per day. Product's efficacy (97%) and adverse effects (62.3%) were the most important factors taken into account when counseling a nonprescription medicine. Few pharmacists knew the meaning of terms related to evidence-based health. Most respondents agreed that pharmacists have the necessary training to prescribe.

Conclusion: Over-the-counter medication counseling is a daily practice among Brazilian pharmacists. Learning needs exist for community pharmacists in relation to evidence-based practice. Thus, sources of information with good evidence could be used daily by community pharmacists, especially as regards nonprescription medication counseling.

Keywords: Nonprescription Drugs; Professional Practice; Pharmacies; Evidence-Based Practice; Brazil

INTRODUCTION

Pharmacists in community pharmacies are placed in a position of trust, especially in how they relate directly to patients and are readily available to provide advice and information.¹ In Brazil, according to the National Health Surveillance Agency (ANVISA), a regulatory agency similar to the Food and Drugs Administration (FDA) in the United States of America, community pharmacists can dispense medicines with the presentation of a prescription and they can recommend nonprescription medicines for patients' symptoms.^{2,3} In this context, pharmacists should educate and counsel patients about nonprescription medicines and provide pharmaceutical services, established by ANVISA², such as determining blood pressure, administration of injectable drugs, and verification of blood glucose.

Community pharmacies in Brazil are not required by law to be owned by pharmacists. However, pharmacists are required to be present in pharmacies during opening hours, and all must be registered with the Regional Pharmacy Council of the State where they live. The working hours of community pharmacists is 44 hours per week. In pharmacy setting there is no requirement for a space to meet seated patients, although this is important for more quality in dispensing process. The existence of computers with access to the internet, although not mandatory, it is important to carry out research and consultations on medicines.

According to the World Health Organization (WHO), nonprescription medicines are drugs approved by health authorities to treat minor ailments and symptoms. Internationally known as over-the-counter (OTC), they are available without prescription because of their safety and effectiveness, if used in accordance with the guidelines available on the package inserts and on labels.⁴ However, these medications are not without risk. Therefore, it is important the pharmacist counseling at the time of purchase to promote the safe use of these medicines. In Brazil, most pharmacies stores OTC medicines behind the counter, although ANVISA allow them to be on the shelves within reach of customers. Thus, to be purchased is necessary to have the pharmacist's advice.

Therefore, in order for the pharmacist to provide appropriate counseling to the patient at the time of dispensing medication and OTC in the best way, he needs access to current and reliable information about medicines. Access to sources of information about medicines and participation in continuing education are essential in this context. Thus, the

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main objective of continuing professional development is to improve the quality of services provided by community pharmacists.¹

Thereby, it is important for pharmacists in the OTC counseling not only consider their own experiences, but also the scientific information arising from the ability to analyze scientific data published, as recommended by evidence-based practice (EBP). In this context, we highlight the published clinical trials evaluating the efficacy and safety of medicines.

Currently, in Brazil as in other countries, community pharmacists have assumed new functions such as prescribing medications, a practice seen as a way to reduce the costs of healthcare, improve patients' access to this⁵, decrease the number of non-urgent visits to the emergency services⁶, and further emphasize the importance of the pharmacist to society.

However, among countries, there are differences in pharmacist prescribing model⁷, as well as the interpretation of the term. The model adopted in Brazil is dependent prescribing. The Resolution of the Federal Council of Pharmacy (Pharmaceutical Society of Brazil), number 586 of 2013, was published establishing that pharmacists could prescribe drugs based on the needs of the patients and the best scientific evidence. The resolution considers this as a clinical pharmacist assignment; prescribing medications whose dispensation does not require a prescription by a physician (OTC). Still, the pharmacist has the ability to prescribe medications that require a prescription from a physician, on the condition of previous diagnosis and only when provided in protocols.⁸ In this scenario, pharmacists need to qualify through postgraduate courses.

Prescribing medicines is not a simple task; it requires significant experience to apply skills regarding drug therapy, though this kind of knowledge pharmacists can develop.⁹

In the present study, we examined the practice of community pharmacists in Parana - Brazil, focusing on OTC recommendation.

METHODS

Design and Setting

The study is descriptive, cross-sectional, with data collection through a self-administered anonymous survey via Survey Monkey® platform. The study was conducted in Parana State, Brazil. Ethical approval for the study was obtained from the State University of Ponta Grossa Ethical Committee on June 26, 2013.

Sampling

The online instrument was sent to all pharmacists registered in Parana State, Brazil, focusing on pharmacists working in community pharmacies. Parana is a state located in southern Brazil, with about 11 million inhabitants.¹⁰ The Pharmacists Association in the State of Parana (CRF-PR)

provided a list of 12,401 email addresses of pharmacists registered in the state.

Instrument

The questionnaire, with closed and open questions, assessed the community pharmacy setting, the search for information, the knowledge of the EBP, the important factors to consider when recommending an OTC medicine, and the opinion about pharmacist prescribing. Before the investigation began, the instrument was piloted to eliminate potential confounders for the subjects and to determine whether the same approach did not generate biases. The 10 pharmacists for this test selected made suggestions, which were analyzed by the team that developed the instrument. These pharmacists were excluded from the final analysis of results.

Data collection

The survey was launched on October 2013 and closed January 2014. We sent an email invitation to pharmacists explaining the purpose of the study. A link to the online survey was included in this email, along with a consent form. From the moment the participant read the consent form and clicked on the option to continue consent was deemed to have been given. If there was disagreement with the content of the term, the participant could click on the exit option. After agreeing, the interviewee was taken to an electronic sequence of questions. A reminder email was sent after three weeks to encourage participation by pharmacists who had not responded.¹¹

Regarding the question about the search for information, participants could respond "never", "sometimes" or "always" for each item. To establish a score for the behavior in seeking information, a point was assigned for each answer, with 1 being the value of "never", 2 "sometimes", and 3 "always". Thus, the score ranged from 6 to 18 points, and the higher its value, the greater the tendency of the pharmacist to search for information in the cited sources.

Similarly, we established a score relating to knowledge of the terms associated with the EBP. In this case, we considered the number of answers "I have a good understanding of this term and could explain it to others," with the value of one point, referring to the greater degree of knowledge about the terms. Other answers did not score.

Data analysis

The questionnaire responses were imported into SPSS® (version 22.0) for analysis. Since the data did not have normal distribution, nonparametric tests (Mann-Whitney, Kruskal-Wallis and Chi-square tests) were used to assess the association between responses and demographic information with a significance level less than 5% ($p < 0.05$). The graphs were constructed in graphPad PRISM® (version 5.00).

Table 1. Characteristics of pharmacists in this study.	
Characteristics	n (%)
Gender	
Male	163 (30.6%)
Female	370 (69.4%)
Community pharmacy experience	
1 year or less	20 (3.7%)
2 to 5 years	164 (30.8%)
6 to 10 years	143 (26.8%)
11 to 15 years	80 (15%)
16 to 20 years	58 (10.9%)
> 20 years	68 (12.8%)
Degrees	
Graduation	265 (49.7%)
Professional postgraduate course	245 (46%)
MSc	20 (3.7%)
PhD	3 (0.6%)
Type of pharmacy worked in	
Local pharmacy chain	174 (32.6%)
State pharmacy chain	49 (9.2%)
National pharmacy chain	97 (18.2%)
Independent	213 (40%)

RESULTS

The 12,401 electronic addresses obtained were imported into Survey Monkey®. After removal of duplicates, the instrument was sent to 9,837 e-mails. Of these, 952 were returned, generating a total of 8,885 available e-mails.

Of the 8,885 pharmacists contacted via email, 1,851 (20.8%) accessed the questionnaire, but only 533, who were also community pharmacists, the subjects of this study, completely responded to the questionnaire. Considering in the State of Parana currently has 6,294 pharmacists working in community pharmacies, the response rate was 8.5%.

The average age of respondents was 35.2 years (SD=9.3), with ages ranging between 23 and 71 years. Table 1 presents characteristics of the participants in this study.

The number of women responding was more than twice the number of men. More than half of participants (54.7%) graduated between 2005 and 2010 and 61.3% had up to 10 years of experience in retail pharmacy. Significantly, more women (54%) had a postgraduate qualification than men (41.7%), either *lato* or *stricto sensu* (chi-square=6.888; p=0.009).

With regard to the community pharmacy setting, 89.3% of pharmacies had internet access, 68.9% had a waiting room, and 52.2% had a private or semi-private area for care of seated clients. With regard to their job positions, 43.7% of participants were pharmacists in charge (technical directors) and 21.4% were pharmacy managers; 31.3% were pharmacy owners. Most participants (60%) worked in local, state or national pharmacy chains.

Participants worked a median of 44 hours per week (interquartile range 40-48), and 97.4% of the pharmacists dispensed medications and counseled patients for a median of six hours per day (interquartile range 4-7). Respondents reported giving advice a median of 30 times per day (interquartile range 20-50), with about 12 minutes

Table 2. Important factors to consider when making decision about a nonprescription medicine to the patient	
	% respondents
Cost of product to the customer	46.0%
Efficacy	97.0%
My previous experience with the product	54.8%
Customer's preference	21.2%
Adverse reactions	62.3%
Product profit	18.8%

for each advice. Of all advice, 33.3% was OTC medication counseling.

There was no significant difference in OTC medication counseling among pharmacists working in pharmacy chains and those working in independent pharmacies (chi-square=0.061; p=0.806), or in the number of times counseling was given (p=0.360). Likewise, there was no difference in OTC medication counseling by gender (chi-square=0.813; p=0.367), or among the graduate and postgraduate pharmacists (chi-square=0.801; p=0.371).

Pharmacists were questioned about the important factors to consider when making decision about a nonprescription medicine to the patient. For this, it was necessary to point out three of the six exposed alternatives (Table 2).

Professionals with community pharmacy experience of less than 10 years were significantly more likely to consider customer preference an important factor to choose a nonprescription medicine, compared with those with more than 10 years of experience (chi-square=20.243; p<0.05). There was observed no difference in relation to pharmacists with graduate and postgraduate qualification and the factors considered important for counseling a nonprescription medicine (p>0.05).

Pharmacists were asked about search for information: "When you have a question or a problem in your day-to-day work, how often do you query each resource below?" (Figure 1). In total, 62.2% responded that they always used search engines like Google, 49.5% always consulted technical books, for example, pharmacology and medication guides, while 37% always took the advice of healthcare colleagues. On the other hand, 23.6% of pharmacists never consulted the manufacturers of drugs and 21.6% never consulted the websites of regional and national pharmaceutical societies. Considering the score referring to behavior in seeking information, it was observed that pharmacists with postgraduate qualifications were significantly more likely to seek information in the resources, because of the higher score, listed in relation to graduate pharmacists (p<0.002).

Participants were asked to rate their knowledge of a variety of concepts associated with research work related to the EBP. We presented the answers in four categories according to Table 3.

For 6 of the 10 presented terms (meta-analysis, the number needed to treat, confidence interval, publication bias, cohort study, p-value <0.05), most pharmacists responded that they did not know the

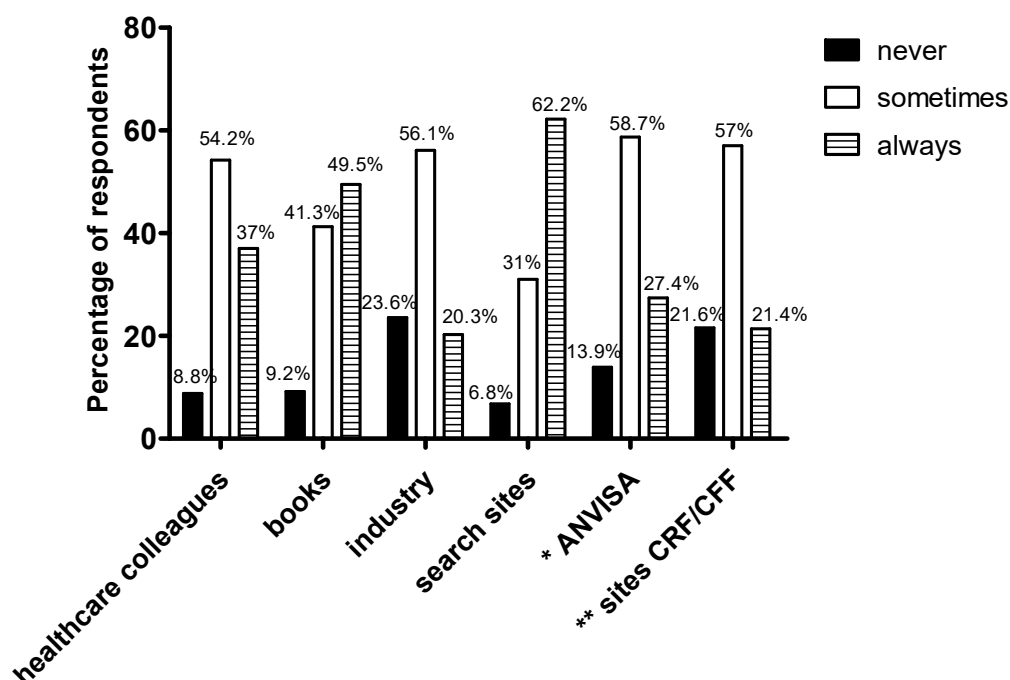


Figure 1. Responses of pharmacists when asked about the sources of information in case of doubts.

*ANVISA: National Health Surveillance Agency (regulatory agency in Brazil).

*CRF/CFF: Parana Pharmacists Association / Brazilian Pharmacists Association.

meaning, but would be interested in knowing. A considerable proportion of respondents (21.4-49.7%) had some understanding of the terms, but could not explain them to others.

Pharmacists with postgraduate qualifications demonstrated higher knowledge scores as regards the term related to EBP ($p < 0.05$), as well as respondents whose community pharmacy experience was less than or equal to 10 years ($p < 0.05$). Moreover, this score had no correspondence to the criteria set as the most important in OTC medication counseling ($p > 0.05$).

When asked about continuing education, 43.7% of respondents said they had been on some short course in the last 12 months, not considering professional postgraduate courses, with a median duration of 20 hours (interquartile range 8-40).

Pharmacists who undertook continuing education courses had higher score of knowledge about issues related to EBP in comparison with those who did not ($p < 0.05$). Similarly, there was a positive correlation ($r = 0.224$ e $p = 0.001$) between the time duration of these courses and the highest score of knowledge in EBP. Respondents who had been on continuing education courses for the past 12 months also showed higher scores related to search for information than those who did not ($p < 0.05$). On the other hand, there was no significant correlation ($p = 0.310$ e $r = 0.067$) between time duration of continuing education courses and score information search.

Participants were asked about pharmacists prescribing (Figure 2) in view of the recent regulation in Brazil.⁸ The answers were in the form of Likert scale of three points: "agree", "neither agree nor disagree", "disagree".

Table 3. Knowledge of the terms related to Evidence-Based Health (number and percentage of respondents).

	I do not know what this term means and think it would not be helpful to know it	I do not know what this term means, but I would like to	I have some understanding of this term	I have some understanding of this term and could explain it to others
Randomized controlled trial	22 (4.1%)	172 (32.3%)	260 (48.8%)	79 (14.8%)
Systematic review	22 (4.1%)	207 (38.8%)	243 (45.6%)	61 (11.5%)
Meta-analysis	30 (5.6%)	315 (59.1%)	145 (27.2%)	43 (8.1%)
Number needed to treat	39 (7.3%)	343 (64.3%)	117 (22%)	34 (6.4%)
Confidence interval	25 (4.7%)	229 (43%)	191 (35.8%)	88 (16.5%)
Relative risk	20 (3.8%)	166 (31.1%)	265 (49.7%)	82 (15.4%)
Publication bias	36 (6.8%)	339 (63.6%)	114 (21.4%)	44 (8.2%)
Case-control study	24 (4.5%)	147 (27.6%)	249 (46.7%)	113 (21.2%)
Cohort study	30 (5.6%)	267 (50.1%)	178 (33.4%)	58 (10.9%)
p-value < 0.05	34 (6.4%)	302 (56.7%)	147 (27.5%)	50 (9.4%)

- I. Pharmacists have the necessary training to prescribe medicines that do not require a prescription by a physician.
- II. The regulation of pharmacist prescribing is an important step towards the recovery of the entire profession.
- III. Regulating pharmacist prescribing would not be necessary because the pharmacist could always recommend over-the-counter medication.
- IV. The pharmacist prescribing should not exist, because the professional who must prescribe is only the physician.

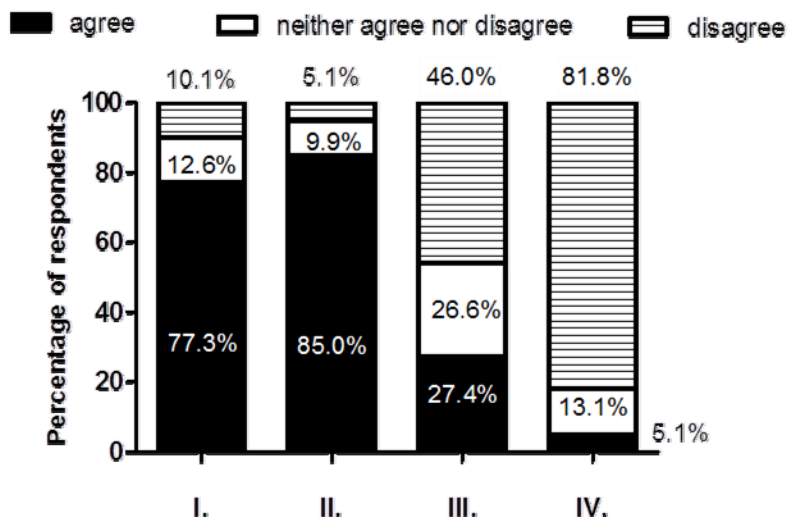


Figure 2. Comparison of participants' responses in relation to pharmacists prescribing medications whose dispensation does not require a prescription by a physician.

DISCUSSION

This is the first study to evaluate the practice of community pharmacists in a Brazilian State focusing on OTC medication recommendation. Important data were found, such as poor knowledge about the issues related to Evidence Based Health and the main factors considered to choose an OTC medicine for a patient.

More than half of pharmacies have a private or semi-private space for care of seated clients, which favors proper advice regarding the use of the drugs dispensed. Our result is higher than in a study conducted in another state in southern Brazil, which showed that only 11.4% of pharmacies had this kind of space.¹²

In terms of pharmacists' advice, 1 in every 3 is OTC medication recommendation and counseling. There was no difference regarding the number of OTC medication recommendation between pharmacy chain and independent. There seems to have been no client's preference for a particular type of pharmacy. The State of Parana currently has 6,294 pharmacists working in community pharmacies and the results of this work show that they make about 300 OTC medication recommendations per month. It is estimated that this practice is performed about one million and 800 thousand times per month, which reflects its importance in the daily work of pharmacists.

When asked about the factors considered important to OTC medication recommendation, pharmacists could choose three of the six alternatives: 97% considered the product's efficacy, 62.3% reported adverse reactions, and 54.8% considered their

previous experience with the product. The profit from the product was considered an important factor for 18.8% of pharmacists. In the study by Hanna and Hughes, safety was considered the most important factor (67.6%), followed by effectiveness (36.8%), patient choice, cost, and product popularity.¹³

Despite considering the efficacy and adverse reactions as important factors for an OTC medication recommendation, pharmacists demonstrated a lack of understanding of the technical terms used in EBP. In relation to the interpretation of scientific studies, such as those that verify efficacy and safety, knowledge of technical terms is essential and a key element in evidence-based practice. This result is consistent with studies of other health professionals¹⁴⁻¹⁷, who demonstrated partial understanding of the terms used in EBP. Perhaps for this reason, more than half of the participants took into account their previous experience with the product. Moreover, it is noteworthy that knowledge about EBP does not always result in behavior change in practice, according to a paper published in 2004.¹⁸

In one study, evidence of efficacy was not the key determinant for selection of nonprescription medicine. The respondents pointed to the lack of evidence associated with such products. These pharmacists therefore tended to make decisions based on personal experience shaped by patient feedback and the medicine's ability to cause harm.¹⁹

Pharmacists with postgraduate qualification demonstrated higher scores of knowledge about the terms related to the EBP, as well as those who undertook continuing education courses in the last 12 months. This can be attributed to the deficiency

of the content in the curriculum of courses on pharmacy, reinforcing the importance of continuing professional development, which is a crucial part in the formation of professionals.

Hanna and Hughes suggested that universities should put more emphasis on how and where to find the best sources of current evidence.²⁰ On the other hand, in a study involving pharmacists who received training on EBP at university, the authors concluded that it seems to have limited influence on decision-making regarding the choice of an OTC product. The study also emphasized that more work is needed to ensure that an evidence-based approach is routinely implemented. A systematic review concluded that education should go beyond the classroom, to the clinical practice, involving the EBP, in order to promote improvements in the skills, attitudes, and behaviors of professional.¹⁸

There is clearly a need to increase the critical thinking of pharmacists, so look for updated information, based on sound scientific evidence and free from conflicts of interest in order to improve practice in community pharmacy. Thus, it highlights the importance of continuous professional development with the need for continuing education through postgraduate courses and participation in conferences.

In the last two decades, pharmacists around the world have received authorization to prescribe a growing range of drugs. In some countries, including the United Kingdom, United States of America, Canada, and New Zealand, pharmacists can now legally prescribe various medications previously prescribed only by physicians.⁹ Currently in Brazil, pharmacists can prescribe medications whose dispensation does not require a prescription by a physician. Although, the pharmacist also has the ability to prescribe medications that require a prescription from a physician, on the condition of previous diagnosis and only when provided in protocols, they need an extra qualification through postgraduate courses.⁸

When asked about this, most respondents agreed that pharmacists have the necessary training to deal with nonprescription drugs and agreed that this regulation is an important step for the development of their profession. These results are in agreement with the figure of 81.8% who disagreed that prescription should not exist, because the physician is the only professional who should prescribe. Notably, some pharmacists have further questions about the applicability of this resolution, since the OTC product recommendation by a pharmacist is already practiced. The list of OTC drugs in Brazil is restricted compared with other countries.⁴ Thus, in Brazil pharmacists have the need to expand the possibilities of prescribing medications beyond those previously established.

The main limitations of this study relate to the methodology of online data collection and the response rate. Indeed, 20.8% of pharmacists in the State of Parana accessed the questionnaire. However, some answered incompletely and were discarded, while others were non-community

pharmacists, and not within the inclusion criteria of this study. Thus, the response rate obtained (8.5%) was similar to other studies in the literature using the same methodology.²¹⁻²⁸

As the study was conducted with community pharmacists in only one Brazilian State, this further limits the generalizability of the findings for the whole country. Therefore, the low response rate obtained (although expected by the methodology used) raises the possibility of non-respondent bias.

The online survey of research type has advantages such as low cost, flexibility in application, control over incorrect reporting, the ability to reach a large number of people, and the requirement of complete responses. Moreover, it also has some disadvantages such as lower response rate than other methods of applying a questionnaire, presence of incorrect emails, and some servers receiving the email as "junk". We can even cite lack of interest in responding to the questionnaire and the fact that it reached only those individuals with access to a computer, although most pharmacists have access to the internet at home, at work or at both locations. Edwards *et al.* demonstrated that offering incentives increases the response rate, although, for ethical reasons, this strategy was not used.¹¹ Studies show that inquiries like web surveys have lower response rates compared with other forms of surveys.²⁹⁻³² However, there was no reliable way to collect data from resident pharmacists throughout the state under study.

CONCLUSIONS

Over-the-counter medication counseling is a very common practice in the daily work of Brazilian pharmacists. Our study highlights a problem; that is, the poor knowledge of terms related to evidence-based practice among community pharmacists, which compromises understanding of scientific studies. This practice could be implemented in undergraduate pharmacy studies. Thus, it is intriguing to determine how the efficacy and safety of drugs are taken into consideration for counseling on OTC medications. The sources used for information are related to weak scientific evidence. Moreover, respondents considered that pharmacists are able to prescribe, although they have divergent opinions on the OTC medication prescription.

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We wish to thank the survey respondents for their time and the Regional Pharmacy Council of Parana for providing the email addresses of pharmacists.

CONFLICT OF INTEREST

Conflicts of interest: The authors have no conflicts of interest.

Financial support was provided by the authors, and there was not corporate involvement.

LA PRÁCTICA DEL ASESORAMIENTO EN OTC POR FARMACÉUTICOS COMUNITARIOS DE PARANÁ, BRASIL

RESUMEN

Antecedentes: Para proporcionar asesoramiento adecuado al paciente en la dispensación de medicamentos *over-the-counter* (OTC), los farmacéuticos comunitarios necesitan acceso a información actual y fiable sobre medicamentos. Los farmacéuticos brasileños han asumido nuevas funciones, tales como la prescripción de la medicación, en un modelo independiente basado en protocolos.

Objetivo: Examinar la práctica de los farmacéuticos comunitarios en un estado de Brasil, centrándose en las recomendaciones de OTC.

Métodos: Se realizó un estudio transversal de farmacéuticos comunitarios en un estado de Brasil entre octubre 2013 y enero 2014, con recogida de datos mediante un cuestionario auto-administrado, pre-pilotado y anónimo en una plataforma Survey Monkey®. Después de la aprobación ética, se envió el instrumento online a 8.885 farmacéuticos registrados en el estado de Paraná (Brasil), centrándose en los profesionales que trabajan en farmacia comunitaria. El cuestionario evaluaba el establecimiento de la farmacia comunitaria, la busca de información, el conocimiento de las prácticas basadas en la evidencia, los factores importantes a considerar cuando se recomienda un medicamento OTC, y la prescripción del farmacéutico. Las respuestas se importaron a SPSS®

(versión 22.0) para su análisis. Se usaron pruebas no paramétricas para evaluar la asociación entre respuestas y la información demográfica con un nivel de significancia de menos del 5% ($p < 0,05$).

Resultados: El 97,4% de los farmacéuticos dispensaba medicamentos y aconsejaba a pacientes durante una mediana de seis horas por día. Los factores más importantes a tener en cuenta cuando se aconsejaba un medicamento sin receta eran la eficacia del producto (97%) y los efectos adversos (62,3%). Pocos farmacéuticos conocían el significado de los términos relacionados con la práctica basada en la evidencia. La mayoría de los respondentes estaban de acuerdo con que los farmacéuticos tienen la formación necesaria para prescribir medicamentos.

Conclusión: El asesoramiento en medicamentos *over-the-counter* es una práctica diaria entre los farmacéuticos brasileños. Existen necesidades formativas de los farmacéuticos comunitarios en relación a la práctica basada en la evidencia. Así, los farmacéuticos comunitarios podrían usar a diario las fuentes de información con buena evidencia, especialmente relativas al asesoramiento de medicación sin receta.

Palabras clave: Medicamentos sin Prescripción; Ejercicio Profesional; Farmacias; Práctica Clínica Basada en la Evidencia; Brasil

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