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Development of a community pharmacy-based intervention for patients with uncontrolled asthma

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ABSTRACT

Background: Achieving asthma control is often difficult, despite the availability of effective medications. Because of their expertise, regular contact with patients, and accessibility, community pharmacists can play an important role in helping patients manage uncontrolled asthma.

Objective: To develop a community pharmacy-based intervention for improving asthma control in patients with uncontrolled moderate to severe asthma.

Methods: A qualitative study involving two focus groups with six and five community pharmacists, respectively, five individual interviews with community pharmacists, and three individual interviews with asthma patients was conducted using semi-structured interview guides. Focus groups aimed to develop the first prototype of the intervention and the topics included criteria to identify patients with uncontrolled asthma, content of the intervention to manage uncontrolled asthma, and potential logistical issues. Interviews were subsequently conducted with individual pharmacists and asthma patients to evaluate the prototype and finalize the intervention. The interviews and focus group transcripts were analyzed thematically, using an iterative process.

Results: In focus groups and interviews, the pharmacists discussed how they screen patients with uncontrolled asthma using prescriptions refills, their needs for a convenient tool to assess asthma control, the necessity to identify causes of uncontrolled asthma to guide asthma management strategies, and the importance of patient follow-up. During interviews, patients shared their interest for the commitment of pharmacists to managing asthma. The final intervention consists of structured face-to-face counselling sessions at community pharmacies, with six steps: screening of patients with potential uncontrolled moderate to severe asthma, assessment of asthma control, identification of the causes of uncontrolled asthma, strategies for controlling asthma, an optional follow-up at the next prescription refill, and a follow-up 3 months after the initial intervention.

Conclusions: The patients and community pharmacists reached consensus on the intervention's key elements and provided support for implementing the intervention in community pharmacies.

1. Introduction

Asthma affects >334 million people worldwide,¹ including 2.5 million Canadians aged ≥ 12 years.² Despite international and Canadian clinical practice guidelines^{3,4} and the availability of effective medications to control asthma symptoms and reduce the risk of exacerbations, the prevalence of uncontrolled asthma remains high in many countries.^{5,6} Canada is no exception with 90% of Canadians with asthma having poor disease

control,⁷ even if asthma medications are covered by private and public drug insurances. Healthcare providers, including community pharmacists (CPs), show low adherence to asthma management guidelines, contributing to uncontrolled asthma among their patients.^{8–12} Patient-related factors, such as poor inhaler technique, low adherence to medications, comorbidities, exposure to asthma triggers, and poor understanding of the disease also contribute to uncontrolled asthma.^{3,8,9,11,13–15} In addition, healthcare

Abbreviations: ACT, Asthma Control Test; CP, community pharmacist; FG, focus group; RESP, *Registre de données en Santé Pulmonaire*; SABA, short-acting β_2 -agonists.

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providers and patients often overestimate asthma control, which leads to lack of intervention to improve it.^{10,16–18}

Currently, physicians are the main healthcare providers responsible to evaluate and manage asthma, but in the province of Quebec in Canada, access to a family physician or a pulmonologist can be difficult and often requires a long waiting time, leaving patients to rely on acute care settings. On the other end, CPs are accessible since they are responsible for dispensing medication prescriptions and refills, and have the expertise and responsibility to monitor pharmacotherapy, including the evaluation of medication adherence and the teaching of inhalation technique. Moreover, CPs can use patients' pharmacy records to identify treatment adherence issues such as underuse of asthma controllers (e.g., inhaled corticosteroids) and overuse of asthma relievers (e.g., short-acting β_2 -agonists [SABA]).^{13,19–21} Therefore, CPs are well placed to act as key stakeholders to manage asthma in primary care.

Three systematic reviews support the effectiveness of CP-delivered interventions for improving asthma control.^{22–24} As described in another systematic review, these interventions include one or more of the following components: patient completion of an asthma control assessment tool, pharmacotherapy review and counselling including demonstration of inhaler use, disease and treatment education, provision of educational materials, setting goals with patients, or referring patients to their treating physician to seek further medical advice.²⁵ However, as concluded by Crespo-Gonzalez et al., for most of the interventions listed above,^{26–33} the few, if any, implementation outcomes (i.e., indicators of the frequency or level of deployment of the intervention and its specific components) reported do not allow the identification of the interventions or components that are most likely to be successfully implemented by CPs in clinical practice.²⁵ Therefore, it may be inappropriate to develop a new intervention only based on those results if it will be implemented in a different community pharmacy environment. Indeed, the legislative context surrounding the profession of CPs as well as the organization and structure of the healthcare system may greatly vary between provinces and countries. In addition, although interventions have been shown to improve asthma control, there are still barriers to overcome to implement them in community pharmacies, including CPs' lack of time to intervene with patients, unclear definition of tasks and procedures to manage asthma, and low patients' expectations regarding the involvement of CPs in asthma management.^{34–36}

Consequently, as recommended by the Medical Research Council's guidance, a British organization whose main mission is to encourage and support research to improve human health, to develop a new intervention that fits into CPs' routine practice, is adapted to patients' priorities, and is likely to be successfully implemented in clinical practice, it is necessary to ensure that the context specific needs of its end-users (i.e. asthma patients and CPs) and barriers to its implementation are considered at the time of development.^{37,38} The Medical Research Council also suggest to publish an article to provide a comprehensive description of the rationale guiding the development of the intervention to enable other investigators to evaluate its likelihood of a successful implementation in clinical practice in terms of acceptability, feasibility, efficacy and sustainability.

Despite these recommendations, none of the interventions included in the systematic reviews referenced above were designed in collaboration with both asthma patients and CPs. Moreover, the development process was published for only one intervention that was successfully implemented in community pharmacies in the United States and that includes three telephone calls with patients based on a communication guide developed in collaboration with CPs but not with asthma patients.^{29,39} This intervention targeted patients living in rural areas and enrolled in a prescription drug program funded by the Federal government.

The aim of this study was to develop a community pharmacy-based intervention for improving asthma control in patients with uncontrolled moderate to severe asthma in collaboration with CPs and asthma patients to maximize its likelihood to be successfully implemented in Quebec community pharmacies located in urban areas. This article presents the processes involved in developing the intervention and its final design. The

implementation of the intervention is in progress and its results will be published in another article.

2. Methods

2.1. Study design

This qualitative study involved an iterative approach with three sequential parts: (1) Focus groups (FGs) with CPs; (2) individual interviews with CPs; and (3) individual interviews with asthma patients. Once the analysis of FGs was completed and data saturation reached (i.e., when no new information emerged from data collected in FGs according to all study investigators), CPs were recruited for interviews until a sufficient number of interviews were completed to reach data saturation. Finally, asthma patients were recruited for interviews until a sufficient number of interviews were completed to reach data saturation. The FGs aimed to develop the first prototype of the intervention and individual interviews aimed to present the prototype to CPs and asthma patients, further evaluate the prototype and finalize the intervention with the CPs and asthma patients' recommendations. The study was approved by the research ethics committee at the *Centre Intégré Universitaire de santé et de services sociaux du Nord-de-l'Île-de-Montréal* (approval number: 2019–1643). The participating CPs and patients signed an informed consent form for disclosure of anonymized interview data before FGs and interviews. For FGs and face-to-face interviews, the informed consent form was signed in person. For telephone interviews, the informed consent form was emailed to participants, they signed it and returned it by email to study investigators.

2.2. Recruitment of participants

CPs were eligible to participate in the FGs or interviews if they were registered with the Quebec Order of Pharmacists, were practicing as a CP in Quebec, and were fluent in French. A convenience sampling method was used, leading to the inclusion of CPs working near the *Université de Montréal*. More specifically, CPs were recruited by calling community pharmacies of retail chains in ascending order according to their distance from the *Université de Montréal*, selected from a list obtained from the Ministry of Health and Social Services of Quebec website.⁴⁰ CPs working as managers/owners and those working as employees/staff participated in different FGs in order to avoid potential influence of hierarchy or relationships on the information shared or preventing freedom of speech.⁴¹ CPs that were not interested in participating in a FG were invited to participate in an individual interview, and if they were interested, they were told that the research team would contact them to schedule the interview after the completion of the FGs. For FGs and interviews, a total of 122 CPs were contacted by phone, and 66 were interested to participate. For FGs, a link to access an availability questionnaire was emailed to CPs interested to participate in the study, and recruitment calls were made until there was a time slot for which at least five CPs were available for each FG. The CPs received financial compensation of 75\$CAD for participating in a FG or interview, and lunch was offered during FGs.

Patients with asthma were recruited from a research registry, the "*Registre de données en Santé Pulmonaire (RESP)*", comprising adults with asthma or chronic obstructive pulmonary disease treated at outpatient respiratory clinics of the *Hôpital du Sacré-Coeur de Montréal* or the *Centre hospitalier universitaire de Sherbrooke*. At the time of registration in RESP, the patients gave informed consent to be contacted for future research projects. A purposive sampling strategy was used by calling patients who fulfilled the following eligibility criteria according to their disease recorded in RESP: asthma diagnosis confirmed by a pulmonologist; moderate to severe asthma defined as the prescription of a combination of inhaled corticosteroid and long-acting β_2 -agonist as maintenance therapy³; uncontrolled asthma defined as ≥ 2 prescription refills of SABA in the last year³; fluent French speaker; and no diagnosis of chronic obstructive pulmonary disease. A total of seven patients were contacted by phone, and three agreed

to participate. Patients were offered a financial compensation of 25\$CAD for participating in the interviews.

2.3. Data collection

FGs took place at the *Université de Montréal*. CPs and patients' interviews took place at the *Université de Montréal* or by telephone to accommodate participants who did not want to travel to the University and thus minimize refusals to participate. Before FGs and interviews, the CPs completed a questionnaire documenting demographic characteristics, including their age and number of years of practice in community pharmacies. For FGs and face-to-face interviews, the questionnaire was completed in person. For telephone interviews, the questionnaire was emailed to participants and they had to return it completed to the investigators by email.

The FGs were designed to identify essential components to include in the intervention, leading to the development of a prototype adapted to the CPs' daily practice. This prototype was then presented to CPs and asthma patients in interviews to finalize the intervention. Two FGs were conducted in February 2019, with planned duration of 60–90 min involving 5–6 employee CPs (staff) or owner CPs (manager), respectively. Five interviews with CPs, lasting 30–45 min, were conducted in April and May 2019, of which three were by telephone and two were face-to-face. Three interviews with asthma patients, one face-to-face and two by telephone, lasting 30–45 min, were conducted in June 2019.

All FGs and interviews were conducted in French and followed a semi-structured interview guide (see electronic supplementary material S1) addressing three topics: (1) criteria to identify patients with uncontrolled asthma in community pharmacies; (2) content of the intervention to manage uncontrolled asthma; and (3) practical and logistic issues of the intervention, including the involvement of pharmacy technicians and how to successfully implement the intervention in daily pharmacy practice. The interview guide was developed based on current asthma management guidelines³ and a targeted literature review covering community pharmacy practice, the management of uncontrolled asthma by CPs and the perceptions that CPs have of their role in asthma management. The interview guide was revised by four members of the research team: two CPs, including one who specializes in respiratory diseases, one pulmonologist, and one researcher who specializes in the pharmacoepidemiology of respiratory diseases. Through an iterative process,⁴² new ideas could be integrated in the next FG or interviews by adapting the interview guide according to the results from the previous FG or interviews. For instance, the subjects for which there was more divergence among CPs who participated in the FGs were more specifically and deeply addressed during individual interviews. Moreover, during individual interviews, the prototype of the intervention developed in FGs was presented to CPs and asthma patients and the interview guide was adapted to focus on the components of the intervention.

The FGs were conducted by a female moderator who is the laboratory coordinator (RFD) and a female study coordinator (CT), both trained in qualitative research. The interviews with CPs and patients were conducted by two female moderators (CT and a research assistant who is also a laboratory technician in a community pharmacy or CT and RFD). The study investigators did not personally know the participants, apart from the research assistant who knew two of the CPs who participated in the interviews. All FGs and interviews were audio-recorded for the analysis with permission from the participants.

2.4. Analysis

Audio recordings were transcribed in verbatim. By reading the transcripts and listening to the recordings repeatedly, investigators familiarized themselves with the information collected. Investigators then performed a thematic analysis, as described by Braun & Clarke.⁴³ This is a method of identifying, analyzing and reporting themes from data using a coding process to generate a coding framework that reflects the elements emerging from the data set. By following an inductive approach with no predefined

coding frameworks before data collection (i.e. the interview guide was not used to elaborate a preliminary coding framework), thematic analysis involved dissecting the transcripts using a coding process,⁴⁴ to target and highlight relevant excerpts that captured key elements regarding the intervention, and generated initial codes that could be attributed to those highlighted excerpts. As described by Braun & Clarke, investigators then created categories by associating codes that covered common or similar topics, and formed themes by combining related categories.

Each step of the analysis was performed in parallel by the same two investigators who conducted the FGs or interviews. In the last phase of the analysis, investigators pooled the results of their analysis by comparing their themes and codes. Differences in coding between investigators were discussed thoroughly to reach consensus regarding the final codes and themes and their interpretation to guide the development of the intervention. Three final coding frameworks covering similar themes were obtained for the FGs, the interviews with CPs, and the interviews with patients, whereby the codes or themes were gradually refined as the FGs and interviews progressed due to the iterative process. Dedoose Software (version 8.0.42) was used for the qualitative analysis. The analysis was conducted in French and excerpts were translated after the analysis from French to English by CT and were validated with back translation by CT and revised by an English professional linguistic reviser to ensure accuracy.

3. Results

3.1. Participants' characteristics

Six staff CPs and five owner CPs attended the first and second FGs, respectively. CPs' characteristics presented in Table 1 show that the majority were women (83%) for staff CPs and men (60%) for owner CPs. Five of the 11 (46%) CPs who participated in the FGs had >15 years of work experience in community pharmacies. Five other CPs participated in interviews, including one owner (20%) being the only CP with >15 years of work experience in community pharmacies.

Three asthma patients participated in the interviews and their characteristics are presented in Table 2. Two (67%) were women and had at least one emergency visit due to asthma in the previous year. Two patients were < 30 years old and one (33%) was >60 years old.

3.2. Emerging themes

Six themes related to the development of the intervention were identified from the thematic analyses of the FGs and interviews. Data saturation

Table 1
Characteristics of the community pharmacists (n = 11).

Characteristics	Focus group 1	Focus group 2	Interview
	n (%)		
CP's position			
Staff	6 (100)	0	4 (80)
Owner	0	5 (100)	1 (20)
Women	5 (83)	2 (40)	3 (60)
Age (years)			
<30	1 (17)	0	0
30 to 39	2 (33)	2 (40)	3 (60)
40 to 49	2 (33)	2 (40)	0
50 to 59	1 (17)	1 (20)	2 (40)
Work experience in community pharmacies (years)			
<5	2 (33)	0	2 (40)
5 to 15	2 (33)	2 (40)	2 (40)
>15	2 (33)	3 (60)	1 (20)
Average working hours in community pharmacies per week			
<30	0	1 (20)	1 (20)
30 to 35	6 (100)	1 (20)	3 (60)
36 to 40	0	1 (20)	1 (20)
41 to 45	0	2 (40)	0

CP community pharmacist.

Table 2
Characteristics of the patients (n = 3).

Characteristics	Interview n (%) [*]
Age in years (mean ± SD)	48 ± 16
Women	2 (67)
Caucasian	3 (100)
Non-smoker	3 (100)
≥ 1 emergency visit in the last year due to asthma	2 (67)
Medication insurance type	
RAMQ Public Drug Insurance	1 (33)
Private insurance	2 (67)
Atopy	3 (100)

SD standard deviation; RAMQ Régie de l'assurance maladie du Québec.

* Unless otherwise specified.

for each of the three sequential parts of the study was respectively reached with the second FG, the fifth CPs' interview and the third patients' interview. Because there were no new relevant themes that emerged from interviews compared to FGs, the results of interviews are presented together with the results of FGs. Table 3 presents each theme together with the main quotes from the participants that were translated from French to English. These themes were used to develop the intervention presented in Fig. 1.

3.2.1. Theme 1: Identification of patients with uncontrolled asthma

The CPs discussed how they screen patients to identify those with uncontrolled asthma. They use prescription refill data from the patients' pharmacy records to identify frequent or early refills for a SABA. In addition, they mentioned looking for a recent prescription of oral corticosteroids, which are commonly prescribed for asthma exacerbation and used as a marker for uncontrolled asthma.

"(...) it is the [excessive] use of bronchodilators that mostly guides us. That is really what will get our attention and make sure that we will either question the patient (...) or perform an intervention either on the spot or provide one with the management."

[Pharmacist 1, staff, woman, 12 years' experience]

"(...) the use of an oral corticosteroid, seen in the [patients'] records can be a thing too. Some people refill prescriptions for oral corticosteroids every 2 months because of asthma attacks, thus this is a factor associated with uncontrolled asthma."

[Pharmacist 2, staff, man, 4 ½ years' experience]

Accordingly, the following criteria were developed to identify patients with potentially uncontrolled asthma as targets for the intervention: too frequent SABA refills or a recent prescription for an oral corticosteroid (e.g., prednisone) (Patient recruitment: Selection criteria in Fig. 1).

3.2.2. Theme 2: Assessment of asthma control

The CPs highlighted their need for a convenient and valid tool to assess asthma control and assist them with managing asthma patients. They also wanted the tool to be quick to administer due to the limited time available for assessing patients.

"(...) I tell the patients that they can assess themselves, and then I give them self-administered questionnaires. In the case of asthma, that could be a good tool, but it would really be [for] targeted patients, once the dialog opens up at the time of the counselling."

[Pharmacist 8, owner, man, 18 years' experience]

The Asthma Control Test (ACT), a five-item questionnaire,⁴⁵ was proposed because it was the shortest and the simplest validated tool for assessing asthma control in clinical practice. The asthma patients reported that the questionnaire is easy to understand and complete at the pharmacy.

"(...) I liked the questionnaire because it really allowed me to see what level I am with the control of my asthma and that, in specific situations I use my pumps more than usual. Thus, yes, I found the questionnaire to be very very indicative."

[Patient 3, woman, 50 years old]

Therefore, Step 1 of the intervention (Fig. 1) involves the assessment of asthma control using the ACT for patients who are identified by the CPs as having uncontrolled asthma.

3.2.3. Theme 3: Cause(s) of uncontrolled asthma

First, the CPs emphasized the importance of a proper inhaler technique for optimal asthma control, because a poor inhaler technique prevents the medication from achieving maximum effectiveness.⁴⁶ The CPs also discussed adherence to asthma controller medications as a key factor for achieving asthma control. Several CPs reported how patients overuse their SABA due to their misunderstanding of the role of controller medications.

"(...) either it is a problem of adherence (...) often there is an aspect like the high cost (...) People do not see [the effect of good adherence] or are relieved of immediate symptoms but do not understand corticosteroids."

[Pharmacist 12, staff, man, 8 years' experience]

Moreover, the CPs reported that they often question patients about their lifestyle habits and environment, to identify potential asthma triggers or comorbidities that may contribute to poor asthma control. They want to identify the causes and triggers of uncontrolled asthma by questioning patients about allergens, sports, and cigarette smoking, for example. The patients revealed that they would be comfortable discussing their environment or comorbidities with their CPs to help find a way to improve asthma control.

"(...) Personally, I have no problem because [the pharmacist] is already teaching me when they give me a new prescription. Moreover, there is the [pharmacy] record, so I think so, yes automatically, there is no problem discussing [environment, comorbidities, tobacco, allergies, colds, lifestyle habits] with them."

[Patient 2, woman, 62 years old]

Because the CPs mentioned that they should identify the causes of uncontrolled asthma to guide asthma management, Step 2 (Fig. 1) involves identification of at least one of the following potential causes of uncontrolled asthma: inadequate inhaler technique, poor adherence to controller medications, asthma triggers or comorbidities, and the need to adjust controller medications.

3.2.4. Theme 4: Management of the patient with uncontrolled asthma

According to CPs, Step 3 (Fig. 1) involves managing patients by focusing on the causes of uncontrolled asthma. They also discussed the importance of trust in their relationship with patients in order to implement the intervention and the need for an approach that will help patients feel comfortable with answering questions regarding their health in order to improve the therapeutic outcomes.

In patients with poor inhaler technique, CPs would teach them the appropriate technique. Some CPs mentioned that pharmacy technicians could provide guidance on correct inhaler technique if they are experienced and familiar with the devices. All three asthma patients expressed willingness to demonstrate their technique at the request of the CP, but only one patient was in favor of the pharmacy technicians' involvement; the other two clearly preferred CP involvement. Therefore, as indicated in Fig. 1, guidance on correct inhaler technique could be provided by a pharmacy technician who has received the necessary training from a CP, at the discretion of the CP and the patient. The CPs recognized that the use of a spacing device for a metered dose inhaler could be helpful for patients with poor inhaler technique, because it facilitates medication intake. The two patients

Table 3
Quotations relevant to the main themes and codes emerging from the focus groups and interviews.

Themes	Codes	Study Stage	Quotations ^a
Identification of patients with uncontrolled asthma	Use of asthma medications	Focus groups	<p>“(…) it is the [excessive] use of bronchodilators that mostly guides us. That is really what will get our attention and make sure that we will either question the patient (…) or perform an intervention either on the spot or provide one with the management.”Pharmacist 1, staff, woman, 12 years' experience</p> <p>“[As an indicator for patients in need of an intervention], a refill for short-acting bronchodilators, <30 days each month and no refill for a corticosteroid….”Pharmacist 7, owner, woman, 25 years' experience</p> <p>“(…) the use of an oral corticosteroid, seen in the [patients'] records can be a thing too. Some people refill prescriptions for oral corticosteroids every 2 months because of asthma attacks, thus this is a factor associated with uncontrolled asthma.”Pharmacist 2, staff, man, 4 ½ years' experience</p>
Assessment of asthma control	Questionnaire	Focus groups Interviews	<p>“(…) I tell the patients that they can assess themselves, and then I give them self-administered questionnaires. In the case of asthma, that could be a good tool, but it would really be [for] targeted patients, once the dialog opens up at the time of the counselling.”Pharmacist 8, owner, man, 18 years' experience</p> <p>“(…) I liked the questionnaire because it really allowed me to see what level I am with the control of my asthma and that, in specific situations I use my pumps more than usual. Thus, yes, I found the questionnaire to be very very indicative.”Patient 3, woman, 50 years old</p> <p>“I think this is in all asthma programs, this is (…) the simplest.”Patient 1, man, 31 years old</p>
Cause(s) of uncontrolled asthma	Inadequate inhaler technique	Focus groups	<p>“Well yes, [inhaler] technique is essential, for sure if at the beginning they don't even know how to use [the inhaler device] well, for sure you won't have an effect. This is the basis [for controlling asthma].”Pharmacist 3, staff, woman, 19 years' experience</p> <p>“(…) we will take the time to look at the [inhaler] technique, especially if we see that patients refill the SABA quite frequently.”Pharmacist 9, owner, man, 20 years' experience</p>
	Poor adherence to controller medications	Interviews	<p>“(…) also, if you see in the record that the person refills the bronchodilators only and never refills their corticosteroid or leukotriene (…) it is related. Also, I try to make adherence interventions because it is the basis of controlling [asthma].”Pharmacist 3, staff, woman, 19 years' experience</p> <p>“When we talk about asthma being uncontrolled, it is because behind that, what makes me ring a bell all the time is that there is a big adherence problem.”Pharmacist 8, owner, man, 18 years' experience</p>
	Asthma triggers or comorbidities	Focus groups Interviews	<p>“(…) either it is a problem of adherence (…) often there is an aspect like the high cost (…) People do not see [the effect of good adherence] or are relieved of immediate symptoms but do not understand corticosteroids.”Pharmacist 12, staff, man, 8 years' experience</p> <p>“(…) I always tell them 'I give you lines of thought, that's your answer (…)', it is not my curiosity to know your [lifestyle habits], I am just giving you some ideas to think about, see where the problem comes from: is it the environment, is it where you work, is it at home, what is triggering, maybe it is an allergenic component.”Pharmacist 4, staff, woman, 6 years' experience</p> <p>“(…) there are the questions, does the patient still smoke, does the patient exercise, does the patient have a healthy lifestyle (…)?”Pharmacist 9, owner, man, 20 years' experience</p> <p>“(…) Personally, I have no problem because [the pharmacist] is already teaching me when they give me a new prescription. Moreover, there is the [pharmacy] record, so I think so, yes automatically, there is no problem discussing [environment, comorbidities, tobacco, allergies, colds, lifestyle habits] with them.”Patient 2, woman, 62 years old</p>
Management of patients with uncontrolled asthma	–	Focus groups	<p>“I use a psychological formula. I say 'I am worried about you. Ok, I am not judging.’”Pharmacist 4, staff, woman, 6 years' experience</p> <p>“(…) we tend to act a bit like the police but the relationship of trust [with the patient] is not built that way. The patient needs, in my opinion, clear objectives (…)”Pharmacist 9, owner, man, 20 years' experience</p> <p>“Absolutely [the pharmacists should be more active in their intervention rather than being passive]. Because this is what we have been doing for a long time, to hand out written information and then say okay, if you have any questions call me.”Pharmacist 8, owner, man, 18 years' experience</p>
	Inhaler technique	Interviews	<p>“(…) I would like to add the correct [inhaler] technique because if [the patient] does 'psssh psssh' like a perfume at the store (laughs), for sure they will empty their pump in 10 days, so insisting on [using] a spacing device and then [using] the correct technique from the beginning so that at least they benefit from their medication.”Pharmacist 3, staff, woman, 19 years' experience</p> <p>“I sometimes involve [pharmacy technicians], because sometimes, just for techniques with spacing devices, I sometimes send my technicians who know the devices well to go and explain (…)”Pharmacist 8, owner, man, 18 years' experience</p>
	Adherence	Focus groups Interviews	<p>“(…) But I use [my spacing device] mostly at night when I have (…), let us say I wake up from an asthma attack, it was wonderful for that.”Patient 1, man, 31 years old</p> <p>“(…) you really have to educate the patient (…) about adherence, the knowledge facet of adherence, it is huge. So, asthmatics who refill their short-acting bronchodilators every month, it is because (…) their symptoms have improved [after using their short-acting bronchodilators], they do not understand that first it increases palpitations, it increases their chances of heart disease and secondly, their disease continues to progress. It is important (…) that they still have the information to understand the issues of not taking their preventive medication (…)”Pharmacist 7, owner, woman, 25 years' experience</p> <p>“(…) when adherence is problematic, it can be misinformation, but it can also be the person must be convinced. This is the human aspect as a pharmacist (…), we may be people worthy of trust, they listen to us, we are able to stir them up a little too, which must be done.”Pharmacist 8, owner, man, 18 years' experience</p> <p>“(…) a thing I can do is remind them for instance about their inhaled corticosteroid. Well, it is their number 1 treatment and it is not the blue pump”Pharmacist 13, staff, man, 2 years' experience</p>
	Asthma triggers or comorbidities	Focus groups	<p>“(…) We target these patients and (…) with what we currently have as tools, that is to say the prescription, smoking cessation. For example, a patient on a pump when we take their history at the beginning when entering data, if the patient is a smoker we will target them and then we will work with them at each refill to encourage smoking cessation.”Pharmacist 9, owner, man, 20 years' experience</p>

(continued on next page)

Table 3 (continued)

Themes	Codes	Study Stage	Quotations ^a
	Pharmaceutical opinion	Interviews	<p>“So for [pharmaceutical] opinion, precisely we were talking about someone who uses the blue pump too much, or an oral corticosteroid due to hospitalization for asthma. Often I will try to check the treatment after that (...), increase the dose, double the dose, switch from a low to moderate to high dose as needed, basically increase doses within the [asthma treatment] guidelines.” Pharmacist 2, staff, man, 4 ½ years' experience</p> <p>“If we had a standard [pharmaceutical] opinion specific to asthma that the doctors would be aware of, because when we make opinions it takes time, and if there was a standard (...) with specific criteria (...), it would be easy and the interventions would be faster.” Pharmacist 7, owner, woman, 25 years' experience</p> <p>“(…) I noticed that, in order to have a good response rate to a pharmaceutical opinion, you should not write a lot but use checkboxes instead.” Pharmacist 12, staff, man, 8 years' experience</p>
Educational materials	Information leaflet to bring home	Focus groups Interviews	<p>“(…) The fact of having the information quickly [accessible] at home, also if [patients] feel unwell, they are able to check their symptoms immediately. I think that can help and it is also useful to direct them to us.” Pharmacist 10, owner, woman, 9 years' experience</p> <p>“It would have to be practical (...), having questions such as ‘are you out of breath?’ etc., so that [patients] themselves can detect their lack of asthma control, and that they can better understand the importance of adherence (...), that the disease does not progress and that [the patient] does not have long term effects as they get older (...) and potentially life-threatening illnesses.” Pharmacist 7, owner, woman, 25 years' experience</p> <p>“I say [an information leaflet] is useful because unfortunately there are still people that, when you explain something to them now, they do not remember it later. They cannot capture all the information, so if it is written, it will help (...) I think that providing written information will save time because people do not necessarily listen 90% of the time.” Patient 3, woman, 50 years old</p>
	–	Interviews	<p>“(…) [The type of information in the leaflet] should be limited to asthma medications, and good utilization, I would not have a problem with that. After that, if they tell me (...) to pay attention to my breathing (...), I can understand all the advice, I will take it. In fact any advice is positive.” Patient 1, man, 31 years old</p> <p>“(…) If my patient, is kind of open to [an asthma management follow-up appointment], I find seeing them again a month later is some kind of positive reinforcement. (...) Just to encourage them until the next refill. (...) Would it be [necessary] to redo the entire [asthma control] questionnaire? I think it should after 3 months, the impact of which is to reinforce [the advice given to] the patient, this I would do it at the next refill (...)” Pharmacist 12, staff, man, 8 years' experience</p> <p>“When you are very, very busy, it is very difficult to do a follow-up. Sometimes, what I do, in the evening when it is not too busy [at the pharmacy], I call [the patient].” Pharmacist 14, staff, woman, 5 years' experience</p> <p>“Basically, pharmacists always followed up with me about my medications. When my controller medication has been changed, ‘How did you like it, does it react better?’ (...) I also think that it can give confidence to people (...) we often feel alone in our fight and are not always seeing the doctor, so it can be a little stressful. So to have another specialist [like the pharmacist], who is able (...) [to do] some kind of follow-up (...), yes it could be nice.” Patient 1, man, 31 years old</p>

^a Quotations were translated from French to English by CT.

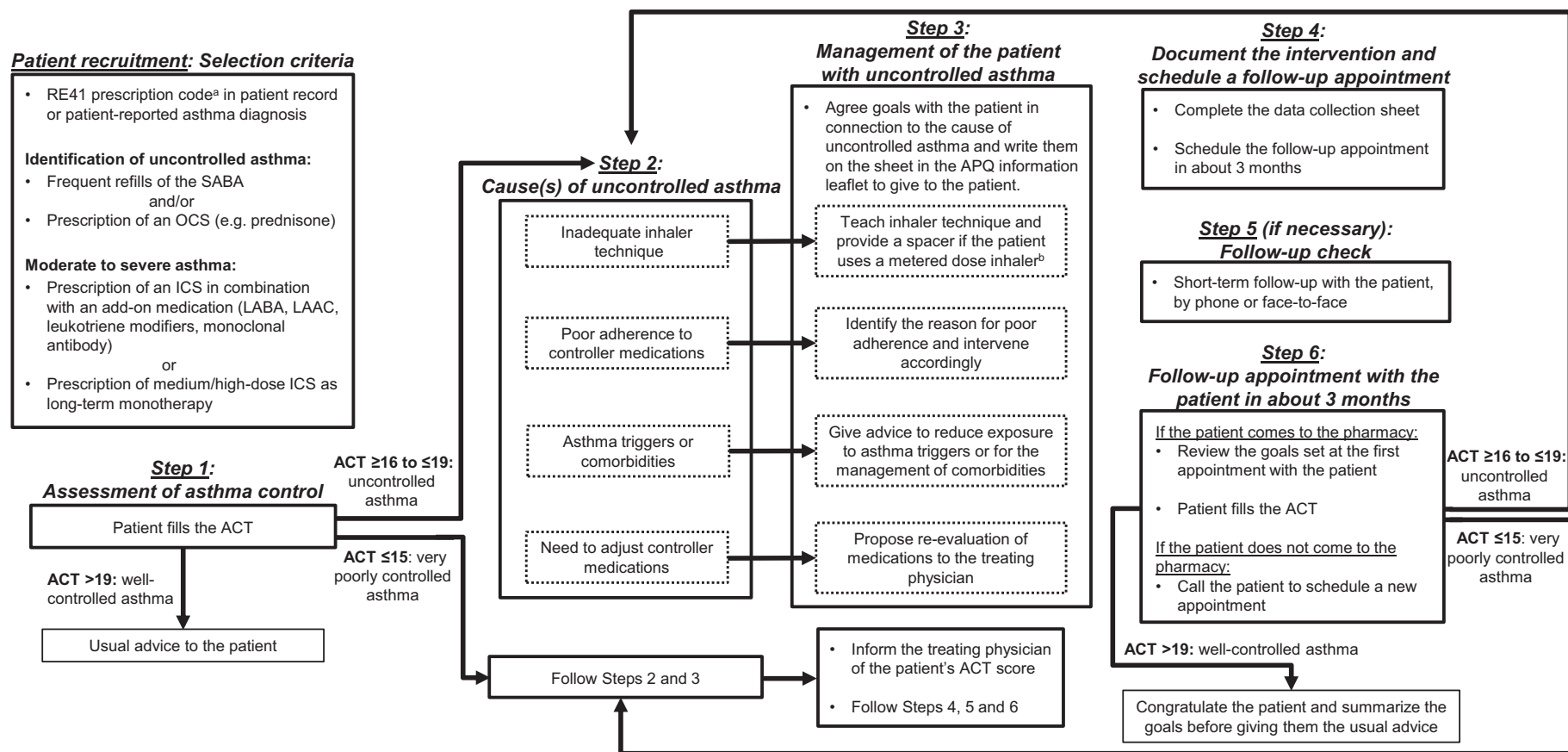


Fig. 1. Overview of the community pharmacy-based intervention aimed at identifying patients with uncontrolled moderate to severe asthma and providing support to improve asthma control. ^aRE41 is a code added by the prescriber to the prescription of a combination of ICS and LABA (classified as an exception drug by the RAMQ; i.e., not covered by the public drug insurance plan) to allow a patient whose asthma remains uncontrolled despite the use of an ICS to obtain confirmation regarding the coverage of the exception drug by the public drug insurance plan (RAMQ). ^bSupport can be provided by a member of the technical team who has received the necessary training from the pharmacist participating in the study. ACT Asthma Control Test; APQ Association pulmonaire du Québec (Provincial Pulmonary Association); ICS inhaled corticosteroid; LAAC long-acting anticholinergic; LABA long-acting β 2-agonists; OCS oral corticosteroid; RAMQ Régie de l'assurance maladie du Québec; SABA short-acting β 2-agonists.

who were using a spacing device confirmed that they are easy to use and were effective for medication delivery.

“(...) But I use [my spacing device] mostly at night when I have (...), let us say I wake up from an asthma attack, it was wonderful for that.”

[Patient 1, man, 31 years old]

Regarding adherence to controller medications, the CPs stated that they should identify the reason for poor adherence in order to provide appropriate advice to their patients. Limited understanding of how controller medications work and the absence of immediate relief, like the one provided by a SABA, might decrease the likelihood of patients taking their controller medications as prescribed. The CPs also emphasized the importance of providing patients with education on the role of each asthma medication to highlight the importance of medication adherence to improve asthma control.

“(...) you really have to educate the patient (...) about adherence, the knowledge facet of adherence, it is huge. So, asthmatics who refill their short-acting bronchodilators every month, it is because (...) their symptoms have improved [after using their short-acting bronchodilators], they do not understand that first it increases palpitations, it increases their chances of heart disease and secondly, their disease continues to progress. It is important (...) that they still have the information to understand the issues of not taking their preventive medication (...).”

[Pharmacist 7, owner, woman, 25 years' experience]

If the reason associated with uncontrolled asthma is related to the patient's environment, lifestyle or comorbidities, the CPs reported that they should provide advice aimed at reducing exposure to asthma triggers (e.g., smoking cessation counselling) or manage comorbidities (e.g., medication for seasonal allergies).

The CPs also mentioned that they sometimes communicate with the treating physician via a “pharmaceutical opinion” (a letter sent to the treating physician regarding a drug-related problem) to suggest a treatment adjustment for patients who frequently experience asthma symptoms. Additionally, the CPs expressed their interest in a pharmaceutical opinion template with checkboxes specific to asthma that can be rapidly completed.

“If we had a standard [pharmaceutical] opinion specific to asthma that the doctors would be aware of, because when we make opinions it takes time, and if there was a standard (...) with specific criteria (...), it would be easy and the interventions would be faster.”

[Pharmacist 7, owner, woman, 25 years' experience]

3.2.5. Theme 5: Educational materials

The asthma patients felt that some educational materials, such as information leaflets, would be useful tools to ensure they have reliable information that is easily accessible at home. They suggested that the information leaflet should be in format that is easy to carry.

“I say [an information leaflet] is useful because unfortunately there are still people that, when you explain something to them now, they do not remember it later. They cannot capture all the information, so if it is written, it will help (...) I think that providing written information will save time because people do not necessarily listen 90% of the time.”

[Patient 3, woman, 50 years old]

The CPs agreed with the usefulness and relevance of providing patients with reliable educational materials.

“(...) The fact of having the information quickly [accessible] at home, also if [patients] feel unwell, they are able to check their symptoms immediately. I think that can help and it is also useful to direct them to us.”

[Pharmacist 10, owner, woman, 9 years' experience]

Therefore, in Step 3 (Fig. 1), an information leaflet from the “Association Pulmonaire du Québec” (Provincial Pulmonary Association) containing general information about asthma and its control should be given to patients.⁴⁷

3.2.6. Theme 6: Follow-up appointment

All CPs indicated that a follow-up with the patient after the initial counselling session would be necessary. Five CPs reported that it is quite difficult to do it over the phone and they would prefer to do it when the patient visits the pharmacy for a prescription refill. However, two CPs stated that they were already doing occasional short follow-ups by telephone.

The CPs were divided regarding the timing of the follow-up appointment: some CPs recommended a follow-up at 1 month and others proposed a follow-up at 3 months. This issue was discussed comprehensively during the interviews, and the CPs reported that a short follow-up at the next refill, about 1 month after the initial counselling session, would be necessary for some patients.

“(...) If my patient, is kind of open to [an asthma management follow-up appointment], I find seeing them again a month later is some kind of positive reinforcement. (...) Just to encourage them until the next refill. (...) Would it be [necessary] to redo the entire [asthma control] questionnaire? I think it should after 3 months, the impact of which is to reinforce [the advice given to] the patient, this I would do it at the next refill (...).”

[Pharmacist 12, staff, man, 8 years' experience]

All three asthma patients agreed with having follow-up appointment with a CP as part of the management of their uncontrolled asthma.

“Basically, pharmacists always followed up with me about my medications. When my controller medication has been changed, ‘How did you like it, does it react better?’ (...) I also think that it can give confidence to people (...) we often feel alone in our fight and are not always seeing the doctor, so it can be a little stressful. So to have another specialist [like the pharmacist], who is able (...) [to do] some kind of follow-up (...), yes it could be nice.”

[Patient 1, man, 31 years old]

Therefore, Step 4 (Fig. 1) involves scheduling a follow-up appointment 3 months after the initial counselling session, Step 5 (Fig. 1) consists of a follow-up at the next prescription refill if deemed necessary, and Step 6 (Fig. 1) involves the follow-up appointment 3 months after the initial counselling session at the time scheduled in collaboration with the patient on Step 4. This follow-up appointment consists of CPs assessing again asthma control using the ACT, and if applicable, identifying the causes of uncontrolled asthma and managing patients by focusing on the identified causes.

4. Discussion

In this study, an intervention was developed in collaboration with CPs and asthma patients that enables CPs to identify and manage patients with uncontrolled moderate to severe asthma at community pharmacies. The fact of having involved CPs as well as asthma patients throughout the development of the intervention enabled to obtain an in-depth understanding of the context in which the intervention will be implemented, and to choose intervention components adapted to the needs of patients and routine practice in community pharmacies in the province of Quebec. The intervention consists of structured face-to-face counselling sessions between CPs and individual patients at the pharmacy, and includes six steps: Step 1, screening of patients with potentially uncontrolled moderate to severe asthma; Step 2, assessment of asthma control; Step 3, identification of the cause(s) of uncontrolled asthma; Step 4, asthma control management strategies; Step 5, a short-term follow-up at the next refill of any medication if deemed necessary; and Step 6, a follow-up at 3 months after the initial counselling session.

Because limited time and heavy workloads are common in community pharmacies, the CPs reported that the intervention needs to be simple and quick to apply to maximize the likelihood that it will be successfully implemented in clinical practice. Therefore, even though there were some disagreements about the involvement of pharmacy technicians to provide inhaler technique guidance to patients, it could be considered useful to optimize the limited time CPs have to intervene with patients. Chui et al.⁴⁸ demonstrated with a qualitative study conducted with CPs that expanding pharmacy technicians' responsibilities would be an important factor to favor a successful implementation of such interventions in community pharmacies. In another study conducted by René-Henri et al.,⁴⁹ results showed that 62% of the interviewed CPs reported that there were enough skilled and experienced pharmacy technicians at their pharmacy to help them to implement interventions with asthma patients. Moreover, CPs suggested that the intervention should include a screening step to target patients with inadequate asthma control, instead of targeting all asthma patients. The availability of dispensed prescriptions data in patients' pharmacy records provides CPs with an opportunity to identify patients with potentially uncontrolled asthma based on the type and frequency of asthma drugs dispensed.⁵⁰ Consistent with the criteria for uncontrolled asthma derived from the CPs' suggestions in this study, van Boven et al.¹⁹ previously reported that high use of a SABA or filled prescriptions for an oral corticosteroid without a controller medication could be useful indicators of suboptimal asthma pharmacotherapy that justify intervention. Moreover, other studies conducted in community pharmacies have demonstrated the feasibility of CP-provided interventions to patients who refill their prescriptions for a SABA too frequently,^{13,20,21} since dispensing refilled prescriptions provides CPs an opportunity for regular and frequent contacts with patients in community pharmacies. Prior studies have also shown that one-on-one sessions with patients at pharmacies are more frequent than CPs delivering asthma interventions via telephone,^{25,50} suggesting that face-to-face interventions provide the most favorable approach to manage asthma patients, as reported by the CPs who participated in the study.

The CPs also expressed the need for a questionnaire that allows them to objectively measure asthma control and validate their judgment. To reduce the burden on patients and promote their willingness to accept the intervention, the CPs suggested using the ACT that could be completed by patients at the initial contact and about 3 months later. The results of the ACT will allow CPs to tailor the management strategies to fit the patients' level of asthma control, as recommended by the Canadian Thoracic Society Asthma Guideline.⁴ The ACT has been used in other studies of asthma management conducted in community pharmacies,^{16,32,50–52} confirming that CPs can play a role in assessing asthma control by using a quick and valid tool. Moreover, a study demonstrated a high correlation between the ACT and the Global Initiative for Asthma classification of asthma control, and found it to be an appropriate screening tool with a cut-off score of ≤ 17 for suboptimal asthma control.⁵³

The CPs identified four main causes of uncontrolled asthma to which they can apply specific management strategies to help patients achieve asthma control: inadequate inhaler technique; poor adherence to controller medications; asthma triggers or comorbidities; and the need to adjust controller medications. Asthma management focusing on the specific causes of uncontrolled asthma allows the intervention to focus on patients' needs. Patient education was highlighted as a relevant management strategy that could be used to address most of these causes. The CPs also emphasized that they must work collaboratively with patients to raise their health awareness and improve their understanding of asthma treatment. The causes of uncontrolled asthma and the corresponding management strategies shown in Fig. 1 are consistent with prior reports. A systematic literature review conducted by Crespo-Gonzalez et al.²⁵ showed that the most common components of asthma management interventions delivered by CPs include assessing and educating patients on appropriate inhalation techniques, providing patients with suitable educational materials,

referring patients to the prescribing physician to suggest a medication review, and providing counselling sessions covering topics such as how to avoid asthma triggers and addressing low adherence to medications. In light of this literature, the results of the present study demonstrated that these management components also fit into the specific context of community pharmacies located in urban areas of the province of Quebec.

Although these management strategies were considered as part of the usual role of CPs by some participating CPs, the results of this study showed that CPs are usually not sufficiently proactive in asthma management. Indeed, they have reported that the lack of time resulting from heavy workloads and the lack of tools at their disposal to objectively measure asthma control were barriers to uncontrolled asthma management in community pharmacies. By developing the intervention in collaboration with CPs and patients, the investigators were able to address barriers that need to be overcome in current practice in community pharmacies and produce an intervention that is easy to integrate in the pharmacy workflow and likely to be successfully implemented. Therefore, CPs' interest in the development of this intervention resided in its capacity to better target patients with uncontrolled asthma and assist them to intervene more efficiently to optimize their counselling time.

An Australian study suggest that the lack of confidence of CPs in their asthma management skills is a factor limiting interventions,³⁶ but it did not appear to be an important issue among CPs participating in this study. In addition, provisions of the Quebec Health Insurance Law allow CPs to be reimbursed by the *Régie de l'assurance maladie du Québec* for some pharmaceutical services embedded in the intervention, namely recommending an over-the-counter medication to manage a comorbidity (e.g., antihistamines to treat seasonal allergies) or an asthma trigger (e.g., treatment for smoking cessation), sending a pharmaceutical opinion to the treating physician or providing a spacing device to the patient. While the lack of financial incentives was reported as a barrier to deliver interventions in community pharmacies,⁵⁴ it should be reduced by the reimbursement possibilities in Quebec.

The findings of this study suggest that patients are interested in a commitment by CPs for asthma management, including their role in teaching appropriate inhaler technique and monitoring asthma medications. Besides improving asthma outcomes, a potential benefit of the intervention for patients is the development of a stronger relationship with their CP. Similar results were obtained in a qualitative study conducted by Olufemi-Yusuf et al.⁵⁵ in Canada, in which asthma patients highly valued the education delivered by CPs related to their inhaler technique and medication use. They also reported that collaborative and trusting relationships between CPs and patients were necessary to ensure patients become actively engaged in asthma management.⁵⁵

A triangulation strategy, by combining FGs and interviews, helped convergence and complementarity of the findings.⁵⁶ Although a small number of patients with asthma were interviewed, the interviews provided further insights and validated the information collected from CPs by triangulation.^{56,57} Triangulation was also achieved by including two investigators for data collection and analysis, thus accounting for interobserver variations in the interpretation of the same data. Reaching data saturation provides reassurance regarding the adequacy of the sample size and the content validity of the intervention developed.⁴² Overall, this approach limits research bias and increases the reliability of the findings.

However, this study has some limitations which mainly affect the external validity of the intervention and its future implementation. First, only those CPs working in the Montreal area (the largest city in the province of Quebec, Canada) were enrolled, which limits the transferability of the findings to CPs working in rural or remote areas where the pharmacy practices may differ. Moreover, the transferability of the findings to other provinces of Canada or countries is limited due to the legislative context surrounding the profession of CPs as well as the organization and structure of the healthcare system that may considerably differ from the Quebec context. Second, the CPs who agreed to participate are potentially more

interested in asthma management, which might reduce the transferability of the intervention to all CPs. Limited transferability may also apply to patients because the participants were recruited from a research database; patients already participating in research may be different to patients in routine practice in terms of their interest in improving asthma control and receptivity to have their asthma managed by CPs.

5. Conclusions

In this study, investigators collaborated with CPs and asthma patients to develop an intervention aimed at targeting and managing patients with uncontrolled moderate to severe asthma in community pharmacies. The patients and CPs reached consensus regarding the intervention's key elements, supporting the future implementation of the intervention in community pharmacies. The findings of this study highlight the expertise of CPs for screening patients with suboptimal asthma control, to identify the cause of poor control, to promote medication adherence and optimal prescribing, and to provide patient education about asthma and guidance on correct in-haler technique. The next step is to finalize the study assessing the feasibility of implementing the intervention in community pharmacies and explore its impact on asthma control and medication adherence.

CRedit authorship contribution statement

Claudie Turcotte: Formal analysis, Validation, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Project administration. **Rébecca Fénélon-Dimanche:** Conceptualization, Methodology, Formal analysis, Validation, Investigation, Data curation, Writing – review & editing, Project administration. **Catherine Lemière:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Marie-France Beauchesne:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Bachir Abou-Atmé:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Isabelle Chabot:** Writing – review & editing, Supervision. **Lucie Blais:** Conceptualization, Methodology, Validation, Resources, Writing – review & editing, Supervision, Funding acquisition.

Declaration of Competing Interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.rcsop.2022.100167>.

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