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**TITLE PAGE:**

**Characterization of pharmacists' interventions on asthma management: a systematic review.**

**Authors:**

Carmen Crespo-Gonzalez. MPharm, BPharm.

PhD candidate.

Graduate School of Health

University of Technology Sydney, Sydney

Australia

Fernando Fernandez-Llimos. PhD, PharmD.

Assistant Professor.

Institute for Medicines Research (iMed.Ulisboa), Department of Social Pharmacy,

Faculty of Pharmacy, University of Lisbon, Lisbon,

Portugal.

Inajara Rotta. PhD, PharmD.

Clinical Pharmacist.

Pharmacy Service, Hospital de Clínicas,

Federal University of Parana, Curitiba,

Brazil.

Cassyano J. Correr. PhD, PharmD.

Associate Professor.

Department of Pharmacy,

Federal University of Parana, Curitiba,

Brazil.

Shalom I Benrimoj .PhD, BPharm (Hons).

Professor, Head of School.

Graduate School of Health.

University of Technology Sydney, Sydney

Australia

Victoria Garcia-Cardenas PhD, MPharm, BPharm.

Senior Lecturer.

Graduate School of Health

University of Technology Sydney, Sydney

Australia

**Correspondence:**

Carmen Crespo-Gonzalez.

Graduate School of Health

University of Technology Sydney

City Campus, Broadway, Building 7, Lvl 4, WS04.02161

PO Box 123, Broadway NSW 2007 Australia

Telephone: +61 2 9514 9223

Email: [Carmen.crespogonzalez@student.uts.edu.au](mailto:Carmen.crespogonzalez@student.uts.edu.au)

**Disclosure:**

The author(s) declared no potential conflicts of interest with the respect to the research, authorship, and/or publications of this article.

**Funding support:**

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

**Previous presentation:**

This work was presented as a poster at the SIMPODADER international congress, Granada (Spain) June 23th to 25th 2016.

**Word counts:**

Abstract: 296 words.

Main text: 3.841 words.

## **ABSTRACT**

**Objective:** Pharmacists have adopted an active role on asthma management. We aimed to analyze the intervention dose, understood as the “amount of program delivered”, and core components of the intervention provided by pharmacists on asthma management.

**Data sources:** A literature search was conducted in December of 2016 at PubMed since its inception.

**Study selection:** A two stage approach was used. At the first stage systematic reviews of pharmacists’ interventions on asthma management were identified. At the second stage primary studies included in the systematic reviews were selected.

**Data extraction:** The DEPICT-2 (Descriptive Elements of Pharmacist Intervention Characterization Tool) was used for data extraction. In addition GINA (Global Initiative for Asthma) guidelines were used as a reference to classify the interventions’ core components.

**Results:** 31 studies were included .In most of the studies the pharmacist-patient intervention occurred at the community pharmacy setting (n=22). The most common core components used in pharmacists’ interventions were the provision of drug information and patient counselling (n=27). Pharmacists’ interventions frequently were target at assessing and improving the use of patient’s inhaler technique (n=27). Educational materials and written action plans were the materials most commonly used in the interventions (n=20). The duration (n=13) and the frequency (n=16) of the intervention were the most frequent information about the intervention dose measure reported.

**Conclusion:** Pharmacists’ interventions in asthma management are complex. Structured educational programs and patient counselling appear to be the most frequent core component of the pharmacist’s interventions. Interventions were focused on the provision of information about the condition and on inhaler technique assessment and training. However, the majority of studies failed to report the intervention dose sufficiently to be reproduced. The reporting of this indicator is crucial to ensure the reproducibility of the interventions assessed and their implementation in practice. (Registration number CRD42016029181).

## **KEY POINTS**

### **Background:**

- Asthma is a major health problem affecting 300 million people worldwide with a high prevalence in developed countries.
- Complex interventions, defined as “interventions that contain several interacting components”, delivered by health care professionals are used as a strategy to reduce the burden of chronic diseases.
- Pharmacists have an important role in the treatment of the condition to achieve positive outcomes. However the intervention complexity is difficult to report. Therefore, their core components and dose remain heterogeneous.

### **Findings:**

- Most of pharmacists’ interventions are targeted at providing information about the condition and inhaler technique assessing and training.
- Medication adherence is an essential core component that should be included in all asthma management intervention delivered by pharmacists.
- There is a lack of reporting of the intervention dose, making reproducibility into practice difficult.

## INTRODUCTION

Asthma is a major health problem affecting 300 million people worldwide with a high prevalence in developed countries.<sup>1</sup> Ineffective management of the disease is common, mostly due to medication non-adherence, poor inhaler technique or exposure to triggers.<sup>2,3</sup> The Global Initiative for Asthma (GINA) is a leading medical guidelines organization whose main objective is to reduce asthma prevalence, morbidity, and mortality, providing the foundation for asthma guidelines worldwide. Since its first report in 1993 it has been updated on a yearly basis with a major significant update in 2006, signaling a paradigm shift in asthma management, from asthma severity to asthma control. Consistent education delivered by a healthcare provider, with patient active participation, is a critical component recommended by GINA for effective asthma management and good asthma control.

Following these recommendations, different health care providers including pharmacists have adopted an active role in the management of the condition through the provision of complex interventions.<sup>4,5</sup> Complex interventions have been defined as “interventions that contain several interacting components”.<sup>6</sup> The complexity of these interventions may be driven by the number and variability of the intervention’s components, the number of individuals targeted by the intervention, the level of behavioral change required in the provider and patient, and/or how the interventions’ components interact.<sup>6</sup> There is an increasing body of evidence supporting the positive impact of these interventions for asthma patient care in controlled studies.<sup>7-9</sup> When these evidence-based complex interventions are replicated or finally implemented into routine practice, it is crucial not only to know whether they are effective, but also which interventions’ core components (i.e. “active ingredients of the intervention”), are essential in making them effective. Thus, if an intervention is not achieving its expected outcomes, an evaluation can be made to understand whether the intervention is ineffective in nature or whether it was not implemented correctly. However, as researchers often select different sets of indicators to describe the interventions’ core components,<sup>10</sup> replication in practice and comparison across studies can be challenging. From an implementation science point of view, intervention dose (understood as the “amount of program delivered”,<sup>11</sup> i.e. intensity and frequency of the intervention) is also crucial to understand its effectiveness and in achieve successful implementation. The intervention dose has been found to be a potential moderator of an intervention’s intended outcomes.<sup>12</sup> Therefore, some interventions proven to

be effective in controlled studies may not achieve their desired outcomes in daily practice if they are not being delivered with the correct intervention dose.

Although pharmacists' interventions have a positive effect on a range of different asthma outcomes,<sup>13</sup> there seems to be a high heterogeneity in the core components and characteristics of the interventions delivered. The identification of the interventions' core components and their dose is needed to provide a foundation for the design of new pharmacist interventions on asthma management and successfully implement interventions proven to be effective in impact studies. Furthermore, how pharmacists are reporting information about the core components will be useful to detect what information is essential to replicate these interventions and what information could be missing.

Therefore, our objective was to analyze the core components and the dose of the interventions provided by pharmacists in asthma management.

## **METHODS**

### **Literature search and screening**

A systematic review was conducted following the reporting and methodological standards recommended by PRISMA<sup>14</sup> and Cochrane.<sup>15</sup> A two-stage literature search was undertaken in December of 2016. The first stage aimed to identify systematic reviews on pharmacists' interventions of asthma management. A PubMed search, which includes MEDLINE, PubMed Central, and other NIH databases, was conducted since its inception (table 1). Two researchers (CCG and FFL) independently screened all titles and abstracts to exclude irrelevant records. Next, a full-text eligibility process was undertaken using the following exclusion criteria: 1) non-systematic and systematic reviews assessing pharmacists' interventions on patients with other conditions different to asthma.

During the second stage, all the primary studies included in the systematic reviews selected during the first stage were gathered. A full-text analysis was independently performed by two researchers (CCG and VGC). The following exclusion criteria were applied: 1) papers screening or assessing asthma control without further management, 2) papers in which the intervention was provided simultaneously by a pharmacist and another health care professional, 3) papers in which a clinical asthma outcome was not assessed, 4) letters, notes, editorials, and

commentaries, 5) papers reporting interventions provided to patients with other respiratory conditions different to asthma, 6) papers not written in languages with roman characters. Duplicate papers were removed. This review was registered in the PROSPERO International prospective register of systematic reviews database (registration CRD42016029181).

### **Data extraction and synthesis**

The DEPICT-2 (Descriptive Elements of Pharmacist Intervention Characterization Tool)<sup>16</sup> was used to guide the data extraction. The DEPICT-2 is a tool that aims at guiding authors when describing and characterizing pharmacists' interventions. It is composed by 146 items grouped into eleven domains: contact with recipient, setting, focus of the intervention, clinical data sources, variables assessed, action(s) taken by the pharmacist, timing of action(s), materials that support actions, repetition, communication with recipient, and changes in therapy and lab tests.<sup>16</sup> Two DEPICT-2 domains, 'Action undertaken by the pharmacist' (8 items) and 'Materials that support actions' (9 items) (table 2) were used to extract the information on the interventions' core components. To better characterize the interventions delivered, GINA guideline was used as a reference due to the fact that it is updated yearly and used worldwide. In 2006 GINA as stated above, adopted a new asthma management approach, based on asthma control rather than asthma severity or symptoms. In this update, the relevance of establishing a patient-doctor partnership, the importance of setting individual treatment goals, patient self-management, avoiding trigger factors and the appropriate treatment of other comorbidities were also introduced. Therefore, the interventions' core components were classified in two groups: (1) core components of interventions delivered prior 2006 and (2) core components of interventions delivered since 2006. The figure 2 summarizes the general characteristics of the pharmacists' interventions on asthma management. The information about the studies included and the intervention dose is retrieved in appendix 1 available on JAPhA.org as supplemental content.

### **RESULTS**

Initially, twenty-six records were identified. Three of them were systematic reviews of pharmacists' interventions on asthma patients.<sup>13,17,18</sup> These three systematic reviews included forty-nine papers. After the screening process, forty-two articles were selected for full-text review and 31 studies were included in the analysis (Figure 1). These studies were conducted in different countries, including Australia,<sup>19-27</sup> United States,<sup>28-31</sup> Germany,<sup>32,33</sup> Canada,<sup>34,35</sup>



Finland,<sup>36</sup> Belgium,<sup>37</sup> France,<sup>38</sup> Spain,<sup>39</sup> Sudan,<sup>40</sup> India,<sup>41</sup> Denmark,<sup>42</sup> Bulgaria,<sup>43</sup> Italy,<sup>44</sup> Chile,<sup>45</sup> Taiwan,<sup>46</sup> United Kingdom,<sup>47</sup> Brazil,<sup>48</sup> and New Zealand.<sup>49</sup>

## **Core components of the interventions performed by the pharmacists**

### **Core components of interventions delivered prior 2006**

#### ***A. Structured educational programs***

Two studies comprised of structured patient educational programs.<sup>29,43</sup> One of them<sup>29</sup> focused on asthma disease, asthma treatments, the use of asthma devices, and inhaler technique. The other<sup>43</sup> was based on providing information about the condition, possible asthma complications, and adverse drug reactions. In addition, pharmacists explained to patients the effects of obesity and nicotine in this disease. Inhaler technique training and peak flow meter use were used as part of the program. The patients received a self-monitoring device, educational material and written instructions on inhaler technique,<sup>29</sup> or educational material and a self-monitoring patient diary.<sup>43</sup>

#### ***B. Drug information provision or patient counselling***

In fourteen studies, pharmacists delivered counselling sessions.<sup>23,28,31-36,42,44-47,49</sup> Information about the disease,<sup>31-33,35,36,42,47</sup> the way to recognize and manage asthma trigger factors<sup>23,31,35,44,47</sup> as well as asthma symptoms,<sup>31,36,44,47</sup> the medication used to treat the disease<sup>31,33,35,42</sup> and the adherence to treatment<sup>23,42</sup> were the topics covered in these sessions. The main actions performed by the pharmacists within the studies were: goal setting with the patients,<sup>23</sup> assessing and correcting the patients inhaler technique,<sup>23,28,31-34,36,42,44-47</sup> and instructing the patients in the used of the peak flow meter.<sup>23,31-33,35,36,44,46,47</sup> In order to reinforce the counselling session, some materials were provided such as diaries to record peak flow measures and asthma symptoms,<sup>23,31-33,35,36,42,44,46,49</sup> portable peak flow meters,<sup>31-33,35,36,42,44</sup> handouts with information about different asthma issues,<sup>34,45-47</sup> or in one case written instructions about the devices used to treat the disease.<sup>34</sup>

### ***C. Referral to other HCP***

Pharmacists referred patients to other health care professionals in 5 studies.<sup>32,34,42,44,49</sup> In some of the interventions referrals were made when the patients needed additional drug therapy,<sup>32</sup> change of their treatment,<sup>44</sup> or if the pharmacist suggested to patients to visit their physician for reassessment.<sup>34</sup> A referral letter<sup>49</sup> and a medication list<sup>34</sup> with the referral letter were given to the patient in two studies.

### ***D. Change or suggestion for change in therapy***

In seven studies pharmacists made recommendations to other HCPs to suggest a more appropriate treatment or a different dosage of the patient's medication.<sup>23,32,33,35,36,44,47</sup> Pharmacists recommended a treatment modification when they identified a more appropriate inhaler device or when clinical asthma outcomes signaled medication ineffectiveness.<sup>23,32,33,35,44</sup> The pharmacist recommended a change of treatment directly to the patient in one study.<sup>47</sup>

### ***E. Monitoring results report***

In one study, pharmacists monitored patient asthma control indicators and provided the information obtained to the physician.<sup>27</sup> No further materials were used.

## **Core components of interventions delivered since 2006**

### ***A. Structured educational programs***

In one study<sup>25</sup> the pharmacist provided an educational program based on asthma, its management, and the medication used. The correct use of the inhaler device was taught. Moreover, the pharmacist provided a written asthma action plan and the relevant information in pamphlets and leaflets.<sup>25</sup>

### ***B. Drug information provision or patient counselling***

Thirteen studies performed counselling sessions.<sup>19,20,22,24,26,27,30,37-41,48</sup> Information about asthma pathology<sup>19,22,27,37,40,41</sup> and the medication used to treat it<sup>19,22,24,30,37,40,41</sup> was provided in some of them. The adherence to the treatment<sup>19,22,24,37,39</sup> as well as asthma triggers<sup>22,27,37</sup> and symptoms<sup>37</sup> were other topics included in their counselling sessions.

Goal setting in collaboration with the patient was another action performed by the pharmacists in some studies,<sup>19,20,22</sup> moreover they identified patient's drug-related problems.<sup>19,30</sup> Smoking cessation advice was included as part of the session in one study.<sup>27</sup> The materials used in some sessions were wordbooks with information about the disease and in which patient's goal were settled,<sup>20</sup> cards to records patient symptoms,<sup>40</sup> written personalized instructions for each patient,<sup>38</sup> protocol based intervention,<sup>39</sup> and a portable spirometer.<sup>27</sup>

### ***C. Referral to other HCP***

In seven interventions the pharmacists referred their patients to other health care professionals.<sup>19-22,27,30,37</sup> They were referred if they didn't have an asthma action plan,<sup>19, 22</sup> or if they had a suboptimal spirometry exam.<sup>19,22,37</sup> Other causes for referring were if a medication review was needed<sup>20,22</sup> or if they hadn't had any review six months before the intervention.<sup>19,22</sup> When severe asthma related-problems were identified<sup>30</sup> or if a new prescription was needed,<sup>27</sup> the pharmacists suggested to the patient to visit their physician .A referral letter was used in two studies.<sup>21,22</sup>

### ***D. Change or suggestion for change in therapy***

In three studies, pharmacists made recommendations to other HCPs to suggest a more appropriate treatment or a different dosage of the patient's medication.<sup>27,40,48</sup> Pharmacists contacted other HCPs if they identified medication ineffectiveness<sup>27</sup> or if they wanted to inform them about a more effective dosage or treatment for the patients.<sup>40,48</sup> Medication reconciliation lists were provided to the physician in one study.<sup>48</sup>

### ***E. Monitoring results report***

The pharmacists monitored patient asthma control indicators and provided feedback to the patient and the physician.<sup>27</sup> No further materials were used.

In one study, the intervention was based on a computer program installed in several pharmacies without a direct interaction between the pharmacist and the patient.<sup>21</sup> Based on this program, educational material about asthma, a referral letter for the patient general practitioner, and the patient's medication list with the medications patients was generated and sent to the patient.

### **Intervention dose**

Twenty-seven out of thirty-one studies reported some information about the intervention dose.<sup>19,20,22-25,27,29-34,36-49</sup> The duration (n=13; 48.19%)<sup>20,22-25,29,31,38,42,45-47,49</sup> and the frequency (n=16 ; 59,26%)<sup>19,20,23,24,30-33,36,37,39-44</sup> of the intervention were the most frequent intervention dose measurements reported. Other content reported about the intervention dose was: the percentage of patients referred to another HCP (n=4; 14.81%),<sup>19,27,34,49</sup> the number of patients receiving different types of goals (n=3; 11.11%),<sup>19,20,23</sup> the number or percentage of patients who were the recipients of the different types of interventions delivered (n=3; 11.11%),<sup>19,34,48</sup> the percentage of patients with medication changes (n=2; 7,40%),<sup>27,36</sup> number of interventions related to changes in patients medications (n=2; 7,40%),<sup>40,48</sup> the number of the different types of the intervention delivered (n=1; 3.70%),<sup>40</sup> and time spent reviewing the medication (n=1 ; 3.70%,).<sup>22</sup> A description of the intervention dose can be found in appendix 1, available on JAPhA.org as supplemental content.

The use of statistical techniques to correlate intervention core components, intervention dose and asthma outcomes was attempted. However, this analysis could not be performed due to the high heterogeneity in the core intervention components and asthma outcome indicators reported.

## **DISCUSSION**

Thirty-one studies reporting pharmacists' interventions on asthma management were analyzed. The type of interventions delivered varied between studies. However, many of them had similar characteristics. Interventions were primarily conducted during one-to-one sessions.<sup>19-24,26-28,30-42,44-49</sup> Whether individual interventions are more likely to optimize an improvement in patient's health outcomes remains unknown. Nevertheless, it allowed providers to focus on individual patient's needs and target them more effectively with their intervention. The interventions were mainly delivered in a community pharmacy setting,<sup>29,30,32-36,41-49,52-54,57-59</sup> suggesting community pharmacists can be a feasible point-of-asthma care education due to their accessibility, regular contact with the patient and proven effectiveness in asthma care.

The DEPICT-2 was used to systematically extract and analyze the interventions core components of the studies included, providing more consistency to our results. This reliable tool has been previously tested and used to analyze 269 randomized controlled trials describing pharmacist's interventions in the management of other chronic diseases. Drug information provision and patient counselling were the most common core components used in

pharmacists' interventions.<sup>19,20,22-24,26-28,30-42,44-49</sup> It is highly likely these types of actions are the most suitable to be delivered by pharmacists in primary care settings. They fit with the current role of pharmacists in the management of chronic conditions, they have proven to have positive effect on patient outcomes, and they are well accepted by patients, making them feasible to be implemented. They are focused on several important aspects of the disease and are usually modified to be targeted at the patient's needs. Counselling and drug information sessions cover essential information about the disease and its management, such as the way in which asthma medications should be used and the problems arising from their improper use. Moreover, they are usually focused on improving self-care behaviors, providing patients with the fundamental skills to self-manage their condition. Patient's self-efficacy has been proven to be fundamental to prevent the worsening of asthma symptoms and asthma exacerbations.<sup>50</sup> This is usually caused by drug related problems including inappropriate use of inhalers or medication non-adherence. Inhaler technique assessment and training<sup>19,22-47</sup> was identified to be a core target in most of the interventions in the studies included in this review. This seems reasonable as there is extensive evidence linking poor inhaler technique with improper asthma control.<sup>51-53</sup> Interestingly, a high percentage of the studies reported patient referral to another health care professional.<sup>19-22,27,30,32,34,37,42,44,49</sup> This result may be explained by the evolution towards a more integrated multidisciplinary model of care, in which different health care professionals interact to improve patient care. In the case of pharmacist-physician collaboration, it seems reasonable that these interactions can contribute to an optimization of clinical outcomes and health care costs.

In regards to the educational resources used during the interventions assessed, pharmacists used different types of educational materials or written action plans in most of the studies.<sup>20,21,23,25-31,34,38,39,41,43-48</sup> It can therefore be assumed that the use of these resources may improve the patient's understanding of the recommendations provided ensuring they follow them once the interaction with the pharmacist is over. We recommend the use and provision of educational materials that align with the interventions' core components. The use of these materials can reinforce the intervention delivered and can guide the patient once the interaction with the HCP is finished.

The latest version of GINA guidelines<sup>54</sup> state interventions for asthma management should include: the provision of information about the disease, how to avoid trigger factors, the assessment and training of inhaler technique as well as the promotion of patient self-

management skills with the use of asthma action plans according to patients' needs. In our review we found there were minimal differences in the core components of those interventions reported prior to 2006 with those reported since 2006. In the last decade, pharmacists' role in asthma management has evolved towards a more active and patient centered care. However, the implementation and integration of those changes into routine practice seems to be a slow process. Medication adherence, it is currently one of the most important core components for asthma management, reaching a significant relevance since the GINA report in 2006.<sup>55</sup> Surprisingly this core component was only delivered in two<sup>23,42</sup> studies before the year 2006 and five<sup>19,22,24,37,39</sup> after the year 2006. It is now widely known that medication adherence to maintenance therapy is essential to the achievement of asthma control. Therefore any pharmacist intervention on asthma management should incorporate this core component, identifying practical and behavioral specific barriers and addressing them accordingly in an individualized and targeted manner.<sup>54</sup>

As previously reported, most of the studies reported some information about the intervention dose.<sup>29,30,32-35,37,39-44,46-59</sup> The intervention dose measurements most frequently reported were the duration<sup>20,22-25,29,31,38,42,45-47,49</sup> and the frequency<sup>19,20,23,24,30-33,36,37,39-44</sup> of the intervention. However, these intervention dose measurements differed in the way they were reported. A good example of the intervention dose reporting is the study conducted by Stergachis<sup>31</sup> et al, who assessed the percentage of patients receiving different intervention's components and their duration. Other important intervention dose measurement used included the number of different types of interventions provided,<sup>40</sup> the percentage of patients who were the recipients of the different types of interventions delivered,<sup>19,34,48</sup> and the number of patients receiving different types of goals.<sup>29,30,33</sup> The reporting of this information can assist researchers and implementers in evaluating the impact of each intervention component on different clinical outcomes, the suitability of the intervention according to the patient's characteristics, or even in allowing its replicability during the implementation phase. Furthermore, it can guide authors on targeting asthma interventions according to the patient's needs, which appears to be a more effective approach for achieving optimal outcomes than standard strategies. The percentage of patients referred<sup>29,37,44,59</sup> was another intervention dose measurement used which can prove the importance of inter-professional collaboration in optimizing patient care, showing how often pharmacists can screen and refer patients when required. Due to their regular interaction with asthma patients, pharmacists are in an excellent position to identify drug related problems and refer patients when the intervention of another HCP is needed to address them. However,

effective referral criteria and referral systems should be developed and implemented. In addition, the number of interventions made to change or modify patients therapy<sup>40,48</sup> or the number of patients that actually got a change in their therapy<sup>27,36</sup> were intervention dose measurement used in some studies. This information is essential in terms of the study outcomes, since it may be able to influence some of the outcomes achieved. However, some studies included in our systematic review did not report any dose indicators for this type of intervention.<sup>26,31,33,40</sup>

Adequate reporting of health interventions is an essential process contributing to the practice of any health care profession. It allows the replicability and implementation of effective evidence-based interventions. However, poor reporting of complex interventions targeted at different medical conditions seems to be a common problem. For example, an in depth analysis of studies published in nursing research journals showed that most authors failed to provide a comprehensive description of the intervention to allow its replication.<sup>56</sup> The same issue is usually identified when reporting the intervention dose. This was highlighted in a recent systematic review aimed at summarizing the evidence of pharmacists' interventions on patients with chronic kidney disease and at assessing their implementability.<sup>57</sup> The authors concluded that additional information should be reported in order to facilitate the implementation of those interventions in practice. This included an in depth description of the resources used to develop the intervention, the materials provided to both patients and practitioners, and the intervention's protocol and procedures. A similar problem was highlighted in another systematic review summarizing asthma management interventions provided by different health care professionals. The authors found there was a lack of information on both the duration and frequency of the interventions provided and a high variability amongst the training characteristics and the materials provided.<sup>58</sup> Moreover, the identification of the interventions' core components remained a challenge, also suggesting there is a lack of consensus on the most effective education strategies in asthma management.

As it has been suggested,<sup>59</sup> reporting intervention core components would allow the identification of its "effective ingredients" and its optimization over time. In addition, the intervention dose should also be standardized. The more detail in the dose reporting, the more reproducible an intervention will be. Reporting the number of patients undergoing a specific procedure is probably the minimum dose indicator required. However, reporting the number of

patients receiving a specific time or number of a given action would allow creating a clearer picture of what the intervention consisted of.

## **LIMITATIONS**

In our systematic review, primary studies were identified through previously published systematic reviews of pharmacist's interventions on asthma management. Some studies not included in these reviews could be missing in our analysis. Moreover some factors could have influenced the amount of information reported in the studies analyzed, including the word limit of some journals, but it is important to highlight the main reason to publish a study is ensuring the reproducibility of the intervention performed.

## **CONCLUSION**

Pharmacists' interventions in asthma management are complex and include several interacting components. Structured educational programs and patient counselling appear to be the most frequent component of the pharmacist's interventions. These sessions were focused on the provision of information about the condition and on inhaler technique assessment and training. Following GINA guidelines, the interventions' core components reported prior 2006 with those reported since 2006 do not present major differences. However, medication adherence was not included as core component in most studies. Intervention's frequency and duration were the intervention dose measurement most commonly used. The majority of studies failed to report the intervention dose sufficiently to be reproduced. The reporting of this indicator is crucial to ensure the reproducibility of the interventions assessed and their implementation in practice.

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