

M. CAMINATI<sup>1</sup>, G. SENNA<sup>1</sup>, N. SEGALA<sup>2</sup>, M. BACCHINI<sup>2</sup>, G. STEFANIZZI<sup>1</sup>, C. BOVO<sup>3</sup>,  
M. SCHIAPPOLI<sup>1</sup>, G.W. CANONICA<sup>4</sup>, G. PASSALACQUA<sup>4</sup>

## Evaluation of asthma control in the pharmacy: an Italian cross-sectional study

<sup>1</sup>Asthma Center and Allergy Unit, Verona University and General Hospital, Verona, Italy

<sup>2</sup>Pharmacists' Association, Verona, Italy

<sup>3</sup>Medical Direction, Verona University and General Hospital, Verona, Italy

<sup>4</sup>Allergy and Respiratory Diseases, IRCCS San Martino-IST, University of Genoa, Italy

### KEY WORDS

Community pharmacy services;  
asthma; Asthma Control Test;  
asthma control; asthma comorbidities

### Corresponding author

Marco Caminati  
Asthma Center and Allergy Unit  
Verona University and General Hospital  
Piazzale Stefani 1, 37126 Verona, Italy  
E-mail: ma.caminati@gmail.com

### Doi

10.23822/EurAnnACI.1764-1489.03

### Summary

**Background.** In Western countries a large proportion of asthmatic patients remain uncontrolled, despite the availability of effective drugs. An involvement of pharmacies / pharmacists in asthma management has been suggested in guidelines, since this could provide a relevant support. **Objective.** The present cross-sectional study aimed at assessing the level of asthma control, by using ACT questionnaire, in the community pharmacies in the County of Verona, North East of Italy. **Methods.** A call for participation was sent by Verona Pharmacists' Association to all the pharmacies located in the Verona municipality. Patients with a medical prescription and an asthma exemption code were recruited in pharmacies. They were asked to fill the ACT questionnaire and to answer some additional questions on asthma treatment, smoke habits and comorbidities. **Results.** Thirty-seven community pharmacies recruited 239 patients. According to the ACT score, more than 50% of patients had a controlled asthma but 20% of them were totally uncontrolled and 12% were using oral steroid. Only 2.9% of patients had received an asthma action plan. Asthma was intermittent in 17.6% of patients, mild persistent in 13.8%, moderate persistent in 63.1% and severe in 5.4%. Discordance was observed between the self-perceived asthma control and objective parameters, when available. Of note, in the severe asthma group, most patients had an ACT > 20. **Conclusion.** This is the first Italian pharmacy-based study on asthma control. A better asthma control was recorded in this study in comparison with other trials, but about 50% of patients were insufficiently controlled. The community pharmacies can play a relevant role in the preliminary assessment of asthma control by using easy and not time consuming tools, such as ACT.

### Introduction

Asthma is overall poorly controlled in Western countries (1,2) despite the availability of effective drugs (3). Many reasons may account for this finding, such as a low adherence to the treatment, observed in every chronic condition, the fear of systemic side effects related to the long term treatment with inhaled corticosteroids (ICS), the switch to Complementary Medicines, the inadequate knowledge of the disease (4-7). However, a relevant drawback is the limited time for consultation in the GP's office,

and the difficult access to in-hospital follow up. As reported in a recent Italian survey, the majority of patients receive no more than one visit / year, and spirometry is rarely performed (6,7). The Asthma Control Test (ACT<sup>TM</sup>) is a standardized questionnaire, representing as a fast and easy tool for assessing asthma control in every setting (8). However, according to the available data, it is routinely used only by 20% of GPs and by 42% of specialists, mainly because it is considered time consuming (7). Though asthma is usually managed in medical settings, the involvement of community pharmacies could provide a significant

support, as demonstrated by the growing interest in this topic (9). Several pharmacy-based studies evaluating the control of asthma have been performed in Europe, but no similar studies have been carried out in Italy. Aim of this cross-sectional study was to assess the level of asthma control by the ACT administered in pharmacies in the county of Verona, in the North East of Italy.

Methods

Community pharmacies

Community pharmacists underwent a two-session seminar performed one month before starting the study, where information about bronchial asthma and about the study design were provided. Subsequently, a call for participation was sent by the Verona Pharmacists' Association to all the community pharmacies in Verona territory. The study lasted seven months, from February the 1st to July the 31th 2015, and was approved by Verona Pharmacists' Association Ethical Committee.

*Patients.* The only inclusion criterion of consenting patients was the presence of the payment exemption related to asthma diagnostic procedures and treatments (code 007 present on the medical prescription). In Italy, the exemption code is released to the patient by the National Health Service only to subjects provided with a diagnosis of bronchial asthma, relying on the clinical history and the positivity to metacholine test and/or bronchodilator test.

Evaluations

Asthma control was evaluated by ACT™ (8). The questionnaire was self-completed by the recruited patients on site in pharmacies. ACT is a validated questionnaire including five questions. The possible answers are scored from 5 (best) to 1 (worst). The final score ranges from 5 to 25, and the higher is the score the better is the asthma control: ACT = 25, totally controlled asthma; ACT = 20-24, well controlled; ACT < 20, insufficiently controlled; ACT < 15, uncontrolled asthma. The pharmacists were instructed to address patients to immediate referral to GP or specialist if the ACT score was below 15. Some additional information was also collected together with the ACT: demography, work occupation, smoking habit, characteristics / doses of asthma medications, having an action plan. These data were reported by patients on a separate standard questionnaire. Asthma severity was deduced on the basis of the treatment used.

Results

Thirty-seven pharmacies (27% of all pharmacies in the Verona municipality) adhered to the observational study, and 239 patients were consecutively recruited. Among the responding sub-

jects there was a slight female prevalence (54%), the mean age of study population was 50.6 yrs (20% of subjects were retired), and 27.6% were older than 65 years. Their characteristics are summarized in **table 1**. According to the ACT score, the prevalence of uncontrolled asthma was 20%, and in other 26% of patients the control was insufficient (**table 2**). However, the majority of patients were under control, 11% being totally controlled (**figure 1**). According to ACT overall analysis, about one in five patients (19.7%) suffered from night awakenings and used short acting bronchodilators more than three times a week (18.8%). However, a discordance was observed between the ACT questions, exploring the self-perceived overall asthma control, and the other questions, investigating more objective parameters. For instance, among the patients marking with a low score the questions on night awakenings and short acting bronchodilators use, 10.6% declared a total asthma control (**table 2**). In the severe asthma group, all patients had an ACT score higher than 20 (**figure 2**). Asthma severity was evaluated on the basis of concomitant treatment, as per GINA recommendations (10). According to this criterion, asthma was intermittent in 17.6% of patients, mild persistent in 13.8%, moderate persistent in 63.1%, and severe in 5.4%, but 12% of patients were on regular oral steroids (thus severe by definition). Only 7 patients (2.9%) had received a written asthma action plan, to manage exacerbations (**table 2**). In the study population, 36% of patients were never smoker, 30% were current smokers, and the remaining 33% were ex smokers. The mean ACT of these three categories did not differ

Table 1 - Demographic data of patients.

SUBJECTS N	239 (100%)
MALE/FEMALE	110/129
MEAN AGE (SD)	50.8 (19.8)
AGE RANGE	4-88
SMOKING STATUS	
Current smoker (%)	72 (30.0%)
Ex-smoker (%)	79 (33.2%)
Never smoker (%)	88 (36.8%)
WORKING HABIT	
Retired	57 (23.8%)
Student	20 (8.4%)
Unemployed	3 (1.3%)
Employee	55 (23%)
Workers	78 (32,6%)
Other	26 (10,9%)

**Table 2** - ACT results and clinical characteristics.

ACT SCORE	
ACT < 15	48 (20.1)
ACT 15-19	62 (25.9)
ACT 20-24	101 (42.3)
ACT = 25	28 (11.7)
Question 5 > 4 (self evaluation) <sup>1</sup>	5/47 (10.6%)
Question 3 < 3 (nocturnal awakenings)	47/239 (19.7%)
Question 4 < 4 (rescue medications)	45/239 (18.8%)
ACT SCORE ACCORDING TO SMOKE	
Current smoker	17.5 (± 3.82)
Never smoker	19.2 (± 4.90)
Ex smoker	19.1 (± 4.99)
CONCOMITANT RHINITIS	42 (17%)
HAVING A WRITTEN ACTION PLAN	7 (2.9%)
USE OF ORAL CS (burst or daily)	11 (4.7%)
MEDICATIONS	
ICS	18 (7.5%)
SABA	14 (5.9%)
ICS+LABA	147 (61.5%)
Leukotriene modifiers	15 (6.3 %)
ICS + Leukotriene modifiers	3 (1.3%)
ICS + LABA + Leukotriene modifiers	8 (3.4%)
SABA + Leukotriene modifiers	1 (0.4%)

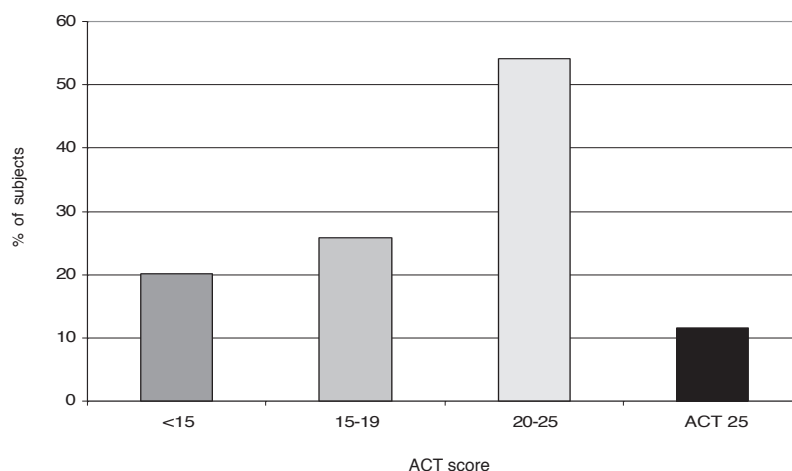
<sup>1</sup>Only those patients who had an ACT score < 15

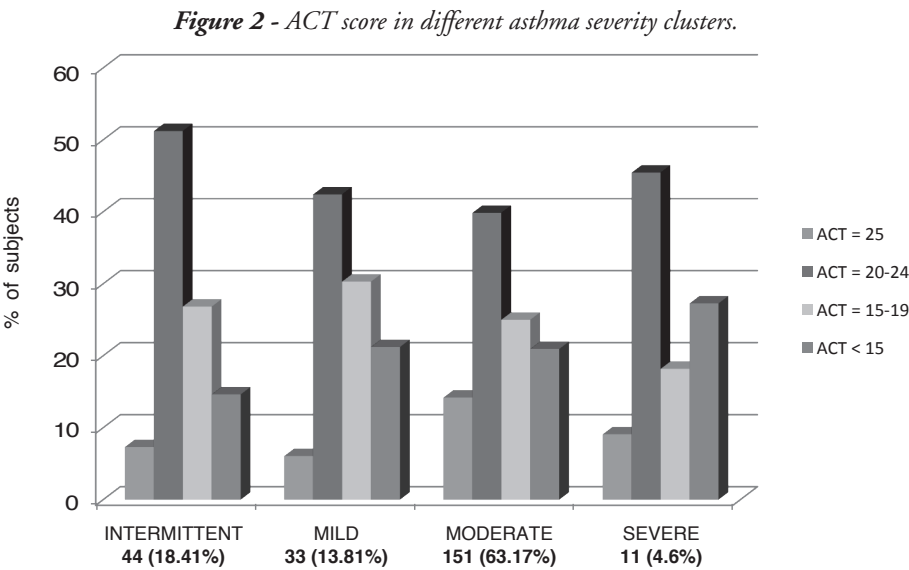
significantly, being slightly lower among smokers. Concomitant rhinitis was reported in 17.7% of patients.

## Discussion

The level of asthma control recorded in this Italian population sample is overall higher than that reported in recent studies carried out in medical settings in Italy (11,12), as well as in community pharmacies in other countries (**table 3**) 13-25. In fact, more than 50% of patients were controlled according to the ACT score, being a total control present in more than 10% of the whole population. This finding is indirectly confirmed by the low percentage of asthmatics with night awakenings or using frequently short acting beta agonists. However, among the patients marking with a low score the ACT questions on night awakenings and short acting bronchodilators use, 10.6% answered the last ACT question on the overall perceived control by marking the maximum score, and in the severe asthma group, most of patients had a total ACT score higher than 20. The discordance between the self-perceived asthma control and more objective parameters is a well-known phenomenon (26,27). For these reason, a careful and global evaluation should be part of the regular asthmatic patients' follow-up, and cannot be managed by the pharmacists only. However, the community pharmacies can play a relevant role in the preliminary assessment of asthma control and in advising the patient to the medical evaluation.

Non-atopic asthma seemed to be prevalent in our population, owing to the mean age over 50 years and to the low prevalence of concomitant rhinitis. Previous studies reported a lower control of asthma in comparison with the present one, but in those studies the number of adolescents and young adults

**Figure 1** - ACT- based level of asthma control in the study population.



was prevalent (13-25). Therefore, it is conceivable that a worse control of asthma is more common in younger ages. Moreover, the older age of our patients raised the problem of the differential diagnosis with COPD. However, we overcame this confounding factor selecting only patients with a diagnosis of asthma proved by pulmonary function test, and confirmed by

the exemption code. Of note, in our study population, around one out of three patients (27.6%) was older than 65 years. As highlighted by other reports (28,29) asthma in the elderly is not a rare disease, and its detection and management in that specific population deserves the highest consideration. Furthermore, the treatment choices should be carefully evaluated

**Table 3 - Level of asthma control reported in published studies performed in community pharmacy setting.**

First Author (Ref)	N. patients	Country	Questionnaire used	Controlled asthma %	Uncontrolled asthma %
Nishiyama (13)	306	UK	JMA	50	50
Laforest (14)	1.559	France	ACT	28	72
Mehuys (15)	166	Belgium	ACT	51	49
Laforest (16)	1.048	France	ACT	30	70
Armour (17)	396	Australia	JMI	21	79
Mehuys (18)	201	Belgium	ACT	52	48
Mendes (19)	5.551	Portugal	ACT	39	61
Giraud (20)	727	France	ACQ6	49	51
Saini (21)	570	Australia	JMI	23	77
Garcia-Cardenas (22)	336	Spain	ACQ	34	66
Armour (23)	570	Australia	JMI	23	77
Le May (24)	354	Australia	PACS	23	77
Laurenco (25)	224	Portugal	CARAT	13	87

in the light of the complex comorbidity frame, which often characterizes the older patients.

The duration of this study is shorter than one year, and therefore it does not cover the whole pollen seasons. However, the time-frame from January to July includes the pollination of cypress, olive tree, birch and grass, which are the most relevant seasonal allergens in our region. We did not include a PEF measurement in the study design. However, PEF assessment is very useful in the monitoring of the disease over the time, but it is less relevant as an isolated measurement (30).

One potential flaw of our study is that the Verona County is not representative for the whole country. Nevertheless, this is the first Italian report assessing the level of asthma control in the community pharmacy setting.

In other studies, the preliminary cross-sectional evaluation of asthma control was followed by longitudinal interventions with different outcomes, such as PEF monitoring, control of asthma, quality of life, asthma education and assessment of the inhalation technique. In most of these studies an increase of the knowledge of asthma (17,18,21), an improvement of asthma control (18,20) and quality of life (17,21), a better technique in the use of the devices (18,21) was observed, whereas conflicting results were reported about the lung function improvement (18,21,31). In our study, the very low number of patients with an asthma action plan to be used in case of asthma exacerbations, can be considered a relevant drawback in the current management of asthma, as well as the not negligible proportion of subjects reporting SABA as the only reference treatment. The absence of a regular anti-inflammatory treatment has been described in literature as the result of both poor adherence and, in some cases, inappropriate prescription (32). However, the overuse of SABA has been identified as a risk factor not only for severe exacerbations, but also for fatal asthma attacks (33,34). The UK National Review of Asthma Deaths (32) and a recently published Italian fatal asthma case series (35) described the use of SABA alone as a key recurrent finding. A strong educational action is thus mandatory, which involves all the health care providers, including pharmacies.

However, though the positive results of pharmacy interventions suggest their feasibility in real life, the possible drawbacks are the costs of the training courses as well as the waste of time for pharmacists (36). Differently from other countries such as Australia, in Italy there is an easy access to the medical facilities. For these reasons, on practical ground the community pharmacies interventional role can be focused on less time consuming outcomes, such as the assessment of asthma control or the inhaler technique verification. Furthermore, an active role in asthma management can be feasible for a limited number of pharmacies, maybe through the creation of dedicated networks (37).

A regular inclusion of spirometry testing was recently promoted in the pharmacy-based assessment of asthma, on the basis of positive results registered in several studies (38). However, the interpretation of this test needs specific background and expertise, and therefore the inclusion of spirometry in the pharmacy facilities must be carefully evaluated.

In conclusion, to our knowledge this is the first Italian pharmacy-based study on asthma control. The community pharmacies can play a relevant role in the preliminary assessment of asthma control, by using easy and not time consuming tools, such as ACT. A higher asthma control level has been observed in the present study in comparison with other trials, nevertheless it has to be noticed that one out of two patients are still insufficiently controlled. Thus, there is room for an active role of pharmacists in the management of asthma. In particular, the implementation of the inhalation technique and the educational support in order to improve the knowledge of the disease, could represent areas of intervention. However, a careful cost / effective evaluation should be performed for every interventional plan involving other health care providers, and the central role of the GP and of the specialist in the management of asthma should not be neglected.

## References

1. Cazzoletti L1, Marcon A, Janson C, Corsico A, Jarvis D, Pin I, et al. Asthma control in Europe. A real world evaluation based on an international population-based study. *J Allergy Clin Immunol.* 2007;120:1360-7.
2. Slejco GS, Ghushchyan VM, Sucher B, Globe DR, Lin SL, Globe G, et al. Asthma control in the United States, 2008-2010: indicators of poor control. *J Allergy Clin Immunol.* 2014;133:1579-87.
3. Bateman ED, Boushey HA, Bousquet J, Busse WW, Clark TJ, Pauwels RA, et al. Can guideline-defined control be achieved? The Gaining Optimal Asthma Control study. *Am Resp Crit Care Med.* 2004;170:836-44.
4. Howell G. Non adherence to medical therapy in asthma : risk factors, barriers and strategy for improvement. *J Asthma.* 2008;45:723-9.
5. Chen W, Fitzgerald JM, Rousseau R, Lynd LD, Tan WC, Sadatsafavi M. Complementary and alternative asthma treatments and their association with asthma control. *BMJ Open.* 2013;3:e003360.
6. Canonica GW, Baena-Cagnani C, Blaiss MS, Dahl R, Kaliner MA, Valovirta EJ, GAPP Survey Working Group. Unmet needs in asthma: Global Asthma Physician and Patient (GAPP) survey: global adult finding. *Allergy.* 2007;62:668-74.
7. Caminati M, Magnoni MS, Rizzi A, Braido F, Foresi A, Bettoncelli G et al. Asthma management among different specialists: results from a national Italian survey. *Eur Ann Allergy Immunol.* 2014;46:74-82.
8. Nathan RA, Sorkness CA, Kosinski M, Schatz M, Li JT, Marcus R, et al. Development of the asthma control test : a survey for assessing asthma control. *J Allergy Clin Immunol.* 2004;117:59-65.
9. Reddel HK, Bosnic-Anticevich SZ, Armour CL, Basheti I. Pharmacy intervention in asthma. *Eur Resp J.* 2008;32:812.



10. From the Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2015. Available from: <http://www.ginasthma.org/>. (accessed 31 Nov 2015).
11. Corrado A, Renda T, Polese G, Rossi A. Assessment of asthma control : the SERENA study. *Resp Med*. 2013;107:1659-66.
12. Caminati M, Bettoncelli G, Magnoni MS, Rizzi A, Testi R, Passalacqua G et al. The level of control in mild asthma in general practice: an observational community-based study. *J Asthma*. 2014;51:91-6.
13. Nishiyama T, Chrystyn H. The Jones Morbidity Index as an aid for community pharmacists to identify poor asthma control during the dispensing process. *Int J Pharm Pract*. 2003;11:41-6.
14. Laforest L, Van Ganse E, Devouassoux G, Chretien S, Bauguil G, Pacheco Y, et al. Quality of asthma care: results from a community pharmacy based survey. *Allergy*. 2005;60:1505-10.
15. Mehuys E, Van Bortel L, Annemans L, Remon JP, Van Tongelen I, Van Ganse E, et al. Medication use and disease control of asthmatic patients in Flanders: a cross-sectional community pharmacy study. *Respir Med*. 2006;100:1407-14.
16. Laforest L, Van Ganse E, Devouassoux G, Osman LM, Brice K, Massol J, et al. Asthmatic patients' poor awareness of inadequate disease control: a pharmacy-based survey. *Ann Allergy Asthma Immunol*. 2007;98:146-52.
17. Armour CL, Lemay K, Saini B, Reddel HK, Bosnic-Anticevich SZ, Smith LD, et al. Using the Community pharmacy to identify patients at risk of poor asthma control and factors which contribute to this poor control. *J Asthma*. 2011;48:914-22.
18. Mehuys E, Van Bortel L, De Bolle L, Van Tongelen I, Annemans L, Remon JP, et al. Effectiveness of pharmacist intervention for asthma control improvement. *Eur Respir J*. 2008;31:790-9.
19. Mendes Z, Madeira A, Suzete C, Sonia I, Marianela V, Artur TA, et al. Asthma Control Assessment using Asthma Control Test in Portuguese Pharmacies. *Rev Port Imunoalergologia*. 2010;18:313-30.
20. Giraud V, Allaert FA, Roche N. Inhaler technique and asthma: feasibility and acceptability of training by pharmacists. *Respir Med*. 2011;105:1815-22.
21. Saini B, LeMay K, Emmerton L, Krass I, Smith L, Bosnic-Anticevich S, et al. Asthma disease management - Australian pharmacists' interventions improve patients' asthma knowledge and this is sustained. *Patient Educ Couns*. 2011;83:295-02.
22. Garcia-Cardenas V, Sabater-Hernandez D, Kenny P, Martinez-Martinez F, Faus MJ, Benrimoj SI. Effect of pharmacy intervention for asthma control. A cluster randomised trial. *Resp Med*. 2013;107:1346-55.
23. Armour CL, Reddel HK, LeMay KS, Saini B, Smith LD, Bosnic-Anticevich SZ, et al. Feasibility and effectiveness of an evidence-based asthma service in Australian community pharmacies: A pragmatic cluster randomized trial. *J Asthma*. 2013;50:302-09.
24. Le May KS, Armour CL, Reddel HL. Performance of a brief asthma control screening tool in community pharmacy: a cross-sectional prospective longitudinal analysis. *Prime Care Resp J*. 2014;23:79-84.
25. Lourenco O, Calado S, Sa'-Souza A, Fonseca J. Evaluation of allergic rhinitis and asthma control in a Portuguese community pharmacy setting. *J Manag Care Pharm*. 2014;20:513-22.
26. Boulay ME, Boulet LP. Discordance between asthma control clinical, physiological and inflammatory parameters in mild asthma. *Respir Med*. 2013;107:511-8.
27. Caminati M, Caimmi C, Dama A, Schiappoli M, Passalacqua G, Senna G. What lies beyond Asthma Control Test: suggestions for clinical practice. *J Asthma*. 2016;53(6):559-62.
28. Scichilone N, Ventura MT, Bonini M, Braido F, Bucca C, Caminati M, et al. Choosing wisely: practical considerations on treatment efficacy and safety of asthma in the elderly. *Clin Mol Allergy*. 2015;13(1):7.
29. Lombardi C, Raffetti E, Caminati M, Liccardi G, Passalacqua G, Reccardini F, et al. ; ELSA Study Group. Phenotyping asthma in the elderly: allergic sensitization profile and upper airways comorbidity in patients older than 65 years. *Ann Allergy Asthma Immunol*. 2016;116(3):206-11.
30. Brusasco V. Usefulness of peak expiratory flow measurements : is it just a matter of instrument accuracy. *Thorax*. 2003;58:375-6.
31. Mangiapane S, Schulz M, Muhlig S, Ihle P, Schubert I, Waldmann HC. Community pharmacy-based pharmaceutical care for asthma patients. *Ann Pharmacother*. 2005;39:1817-22.
32. Royal College of Physicians. Why asthma still kills: the National Review of Asthma Deaths (NRAD) Confidential Enquiry report. London: RCP, 2014.
33. Al-Dorzi HM, Al-Shammary HA, Al-Shareef SY, Tamim HM, Shammout K, Al Dawood A, et al. Risk factors, management and outcomes of patients admitted with near fatal asthma to a tertiary care hospital in Riyadh. *Ann Thorac Med*. 2014;9:33-8.
34. Gonzalez-Barcala FJ, Calvo-Alvarez U, Garcia-Sanz MT, Bourdin A, Pose-Reino A, Carreira JM, et al. Characteristics and prognosis of near fatal asthma exacerbations. *Am J Med Sci*. 2015;350:98-102.
35. Vianello A, Caminati M, Crivellaro M, El Mazloum R, Snenghi R, Schiappoli M, et al. Fatal asthma. Still an epidemic? *World Allergy Organ J*. 2016; in press.
36. Van Mil JW, Tromp TF. European barriers to the implementation of pharmaceutical care. *Int J Pharm*. 2001;9:163-8.
37. Berry TM, Prosser TR, Wilson K, Castro M. Asthma friendly pharmacies : a model to improve the communication among pharmacists, patients and health care providers. *J Urban Health*. 2011;88(suppl 1):113-25.
38. Cawley MG, Warning WJ. Pharmacists performing quality spirometry testing: an evidence based review. *Int J Clin Pharm*. 2015;37:726-33.