Original Research

Monitoring and screening COPD in community pharmacies: experimentation in Italy

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Abstract

Objective: COPD is one of the most important causes of morbidity and mortality worldwide. The health and economic burden of COPD may in part be reduced by early disease case finding and a correct therapy. This study aimed to investigate the feasibility of a community pharmacy programme for COPD case finding among previously undiagnosed subjects and for monitoring and enhancing adherence to prescribed pharmacological therapies among patients with confirmed COPD. **Methods:** The intervention was conducted in hundred community pharmacies in Piedmont (northwest Italy) and developed in two different arms: a case finding one through the administration of a specific questionnaire and the spirometry measurement and the adherence one through the administration of a questionnaire exploring the impact of the disease and the therapy adherence. Persons considered at risk to develop the COPD disease or non-controlled patients were referred to the GP or were invited to return in the pharmacy for a follow-up interview. **Results:** Overall, 844 subjects, out of 934 enrolled, completed the baseline interview. 103 subjects (25.7% of the 401 enrolled in the case finding arm) were considered at risk of suffering from COPD. Lower educated subjects and those without social support were more frequently at very high risk. Five returned to the pharmacy with a confirmed medical diagnosis. Among the 443 patients interviewed we found non-adherence value (depending on the drug) varying from 31% to 46%. A significant protection from non-adherence to bronchodilators was found among patients with comorbidities and among people living alone. **Conclusions:** We showed that opportunistic screening for COPD is feasible in community pharmacies. Concerning adherence to therapy in pharmacies, it would be necessary to identify different methods of enrolment in order to involve only those patients who are less adherent or who have difficulties in the management of therapy and chronic pathology.

Keywords: community pharmacy; adherence; case finding; counselling; COPD

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is one of the most important causes of morbidity and mortality both in Italy and worldwide.[1] The reported prevalence is variable; indeed, its assessment may vary depending on diagnostic criteria, age, gender, smoking habit. The values reported by different studies range from 5 to 15 %.[2-4]

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In Italy, about 3.5 million people are affected with COPD and its prevalence is estimated to be about 6%.[5] Its distribution is uneven: it is higher in smokers and ex-smokers compared to non-smokers, in men and in people aged over 40.[1] On average in Piedmont, the Italian region where this study takes place, 1,700 people die every year due to COPD.[6]

COPD is associated with significant economic and social burdens. It is estimated that in the European Union, 6% of the annual health budget is spent on direct costs for respiratory diseases, more than half for COPD. The costs of COPD are mostly due to the exacerbations of the disease and their consequences (e.g. hospitalization, need for oxygen). Indirect costs may also be huge in terms of loss of productivity and workplaces.[1] COPD is also one of the diseases that more frequently causes disability.[7]

Despite all these considerations, the disease is not diagnosed in more than half of affected patients and, when it is, it is not treated properly.[8-11]

It is therefore important to put in place firstly measures aimed at the prevention and the early diagnosis of the disease. Prevention is possible through the identification and reduction of exposure to risk factors (primarily through intervention aimed at avoiding smoking initiation or early cessation of cigarette smoking). Early diagnosis must be enhanced by targeting screening particularly towards at-risk individuals.[1]

Secondly, it is important to power up measures aimed at preventing exacerbations of the disease. At this regard, the

GOLD strategy (Global Initiative for Chronic Obstructive Lung Disease) recommends that COPD patients be subjected to strict control of drug therapy, including verification of adherence to therapeutic prescriptions and of correct use of inhalers.[1] Recent observations show that both adherence and inhalation techniques are insufficient in many patients with COPD,[12-18] thus affecting clinical conditions, quality of life, and healthcare costs.[19]

Previous studies demonstrated that actions like the above-mentioned may be carried out also in community pharmacies.[20-25] Indeed, community pharmacies are widespread and easily accessible on the territory, and the entrance and the counselling are free of charge.[26,27] More than 19,000 community pharmacies are present in Italy. Since 2012, the Piedmont Orders of Pharmacists, Federfarma Piemonte and the University of Turin have launched a number of projects aimed to counteract the negative effects of non-communicable diseases thanks to targeted measures applied in the community pharmacies.[27-32]

As part of the aforementioned programme, the Italian Health Ministry funded a project on diabetes[32,33] and on COPD.

We report the results of the COPD intervention, whose main objectives were: 1. Identification, among customers of community pharmacies of those at increased risk of COPD, who can benefit from early referral to the physician, and 2. Monitoring and enhancing adherence to prescribed pharmacological treatment among patients with confirmed COPD. In this article we also aimed at assessing the feasibility and the impact of the intervention of the pharmacists on the previous actions.

METHODS

Study population and protocol of the intervention

The intervention was conducted in Piedmont, a northwest region of Italy. All community pharmacies of the territory (about 1,600) were invited to participate in the project on a voluntary basis. The first one hundred who agreed were trained through a course on COPD (conducted by a senior pulmonologist). Participants were informed on the study procedures and instruments to ensure that all pharmacists collected data homogeneously. Every pharmacy was equipped with a portable spirometer (Air Smart Spirometer - Pond Healthcare Innovation, Sweden -), that houses disposables mouthpieces and turbines. It can be connected with a jack cable to a smartphone, and allows to perform a basic spirometry and to receive in seconds a result visible through a dedicated APP and sharable as any photo or pdf (e-mail, MMS, whatsapp). The device, CE marked, detects FEV1 and FVC values, and FEV1/FVC ratio. Pharmacists were trained on its use and helped participants to perform a correct assessment of spirometry.

The intervention consisted of two arms: the first one focused on COPD case finding and the second on adherence to therapies. Each arm was carried out in two different steps: a cross-sectional survey and a follow-up assessment. The operating phases took place as described below.

COPD case finding

Every day, over the period October 2017 - February 2018 the first two costumers' men and the first two costumers' women over 40 years old who entered a participating pharmacy in the first opening hour in the morning and the first opening hour in the afternoon, without known lung diseases ascertained by a pharmacist's direct question, were informed of the aims of the study and invited to participate. Those who agreed gave their written informed consent to be interviewed and followed-up. The participants were interviewed by the pharmacists in a consultation room within the premises of the pharmacy.

A questionnaire based on the GOLD criteria[34] was administered to identify subjects potentially suffering from COPD. The questionnaire consisted of five dichotomous questions concerning: coughing frequently, frequently having phlegm in the bronchus, having difficulty breathing compared to peers, being over 40 years old, being a current or past smoker.

Furthermore, information on education, social/family support, and household composition were collected. Educational level, measured as the maximum attained degree, was categorized in three classes: low, including no formal education and primary school (corresponding to the UNESCO International Standard Classification of Education 1997 (ISCED97) levels 0-1); medium, i.e. middle and vocational school (ISCED97 levels 2-3C); and high, including high school and university degrees (ISCED97 levels 3A, 3B, 5 and 6).[35] Social/family support and household condition were described by two dichotomous variables indicating whether the subject could receive help in case of need and lived alone or not.

The pharmacists asked the questions to participants and then entered the answers into a specific software. The questionnaires used are reported in the appendix 1. All data were electronically collected and stored in a central database.

All individuals with at least three positive responses in the GOLD Questionnaire, were invited to take a free FEV1 measurement in the pharmacy. Those with a FEV1 score less than or equal to 80% received counselling from the pharmacists about the importance of reducing their behavioural risk factors and keeping them under control. Furthermore, they were referred to their general practitioner (GP) for possible further controls, and were invited to repeat the interview in the same pharmacy after 3 months, to assess any change or any new diagnosis made by GPs. (Appendix 2)

COPD adherence to therapies

Over the period June 2017 - December 2017 all persons over 40 years who entered a participating pharmacy with a personal prescription for medicines from pharmaceutical categories related to COPD, and affected by chronic respiratory failure (recognized by a specific code on the prescription) were informed of the aims of the study and invited to participate. Patients who had their first prescription or with asthma (recognized by a code on the prescription) were excluded. Those who agreed, gave their written informed consent to be interviewed and followed-up.

The impact of the disease on the patient life was assessed through the CAT (COPD Assessment Test) questionnaire.[36] The test consists of eight questions with a Likert scale (values 0 to 5) concerning different aspects of the impact of COPD: coughing, having phlegm in the chest, feeling a constriction in the chest, being breathless when climbing stairs or walking uphill, having limitations in carrying out household activities, being confident leaving home despite the lung condition, being able to sleep soundly, having energy. The score is categorized into four levels: <10 corresponding to the lowest impact of the disease on the patient's life, 10-19 medium, 20-29 high, and 30-40 for the highest impact.

Adherence to prescribed drug therapies was investigated using a 4-item scale, developed from the Italian version of the original 8-item Morisky scale.[37] It consists of four dichotomous questions asking if the patient had ever omitted taking the medicine because of forgetfulness, inattention, interruption of therapy in the event of remission, or worsening of symptoms.[38] A patient with a score of the 4-item questionnaire>0 was considered non-adherent to the prescribed pharmacological therapies. In addition, the survey enquired whether the patient suffered of dyslipidaemia, hypertension, diabetes or heart failure, and investigated any COPD flare in the last period of time. Patients were also asked about the duration of COPD. Finally, patients were asked whether they know how to use their inhalation devices and were asked to demonstrate how they used it.

Information on education, social/family support and household composition have been collected as described in the above section on *COPD case finding*.

The pharmacists asked the questions to participants and then entered the answers into a specific software. The questionnaires used are reported in Appendix 1. All data were electronically collected and stored in a central database.

All the participants were interviewed in a consultation room within each pharmacy and then invited to repeat the interview three times in the same pharmacy every 3 months, to assess any change. (Appendix 3)

All individuals resulting non-adherent to prescribed therapies received counselling on correct medicine taking. Moreover, patients who were not able to correctly use the inhalation device were trained about it and invited to bring an empty inhaler with them to the next appointment in order to exercise.

Satisfaction questionnaires

A short online questionnaire was administered at the end of the project to collect the opinion of the pharmacists. They were asked to point out three positive aspects and three negative aspects of each arm of the project. Furthermore, suggestions for future studies were requested. All the items were free-text open questions. (Appendix 4).

Statistical analysis

The descriptive analysis encompasses the distribution of prevalence of COPD risk and drug adherence by individual characteristics. Differences were evaluated by means of exact Fisher tests to account for small numbers; a 2-tail p-value less than 0.05 was considered statistically significant.

Determinants of COPD risks and drug adherence were investigated performing robust multivariable Poisson regression models, estimating prevalence rate ratios (PRR) with their 95% confidence intervals (95% CI). All statistical analyses were performed using SAS-ver.9.3.

RESULTS

One hundred pharmacies took part in the training course with at least one pharmacist. Of these, 94 participated in the programme.

Overall, 908 subjects were invited to take part in the study. Sixty-four of them (7.0%) refused to participate; the final study populations consisted of 401 subjects for the case finding arm and 443 for the adherence arm.

COPD case finding

Table 1 shows the characteristics of the 401 interviewed subjects. Men were 45% of the population and almost half were over 64 years old. Participants appeared to be in a medium-high socioeconomic position: 44% were highly educated, and the great majority did not live alone (85%) and could receive help in case of need (96%).

Table 1. Characteristics of the enrolled subjects divided into the two arms of the projects		COPD case finding		COPD adherence to therapy	
		SUBJECTS (n=401)		PATIENTS (n=443)	
		n	%	n	%
Gender	Women	221	55.3	171	38.6
	Men	180	44.7	272	61.4
Age	41-54	116	28.9	26	5.8
	55-64	108	26.7	69	15.6
	≥65	177	44.4	348	78.6
Educational level	Low	75	18.7	182	41.4
	Medium	148	36.9	171	38.8
	High	178	44.4	87	19.8
Living alone	Yes	61	15.2	96	21.9
	No	340	84.8	342	78.1
Social network	No	16	4.2	27	6.1
	Yes	385	95.8	416	93.9
Duration of COPD (years)	<1			52	13.4
	1-5			156	40.4
	5-10			92	23.4
	>10			87	22.5
Comorbidities	Yes			382	87.0
	No			57	13.0
CAT score (impact on patient's life)	0-9 (low)			97	22.1
	10-19 (medium)			173	39.5
	20-29 (high)			138	31.5
	30-40 (very high)			30	6.9

Two hundred forty-one subjects resulted at risk of suffering from COPD according to the GOLD questionnaire (score≥3, 60.1%) and were invited to undergo spirometry in pharmacy (table 2). Out of 220 who accepted, 103 subjects (prevalence=46.8%, corresponding to 25.7% of the initial sample) had a FEV1 measurement ≤80%, and therefore were counselled by the pharmacist, invited to follow-up, and referred to their GPs. The prevalence of the different levels of COPD risk by subject characteristics are displayed in table 2. About 24% of individuals resulted at moderate risk, 25% at high risk and 12% at very high risk. The prevalence of COPD risk was generally higher among men and the elderly, particularly in the very high-risk group. Overall, the prevalence of risk according to the GOLD score was evenly distributed across the sociodemographic categories, but lower educated subjects and those without social support were more frequently at very high risk (with a prevalence of 15% and 25%, respectively). This is also reflected in the prevalence of subjects with FEV1≤80%, which almost doubled among the most disadvantaged subjects compared to their more advantaged counterparts: the percentage of individuals with low expiratory volumes is in fact 67% among the less educated subjects (vs. 38% in the higher educated group) and 89% among those without social support (vs. 45%). On the contrary, the prevalence of a low FEV1 score did not change across the levels of risk identified by the GOLD questionnaire.

In the multivariable model (table 3), a low educational level and the lack of a social network remained significantly associated to the risk of low expiratory volumes, with 64% and 69% excess of risk compared to their more advantaged counterparts, respectively.

Of the 103 subjects with FEV1 ≤80% invited to follow-up, only 42 (40.8%) returned to the pharmacy for the second interview. Five reported a confirmed COPD diagnosis, corresponding to 4.9% of the subjects considered at risk by spirometry, 2.1% of those at risk according to the GOLD criteria, and 1.2% of the total subjects enrolled. Confirmed cases were 3 men and 2 women, all were over 60 years old, had low education and a GOLD score showing a high or very high risk.

COPD adherence to therapies

Table 1 shows the characteristics of the 443 COPD patients enrolled. Men were 61% of the population and almost 80% were over 64 years old. About half of the patients had a duration of COPD shorter than 5 years and 87% had at least one comorbidity; most of them (78%) had a CAT questionnaire score revealing a medium-high impact of the disease on the patient's life. Coherently with the epidemiology of the disease, only 20% had a high educational level; however, the vast majority did not live alone (78%) and could receive help in case of need (94%).

The prevalence of non-adherence varies depending on the prescribed pharmacological therapy. As reported in table 4, non-adherent patients were 37% for bronchodilators, 31% for steroids, and 46% for mucofluidifiers; only 6% of inhaler users did not use it correctly.

In the univariate analysis, we found that the only statistically significant difference was among bronchodilators users, with higher non-adherence among people without comorbidities. Although not statistically significant, there is a tendency to greater non-adherence among younger, highly educated and patients not living alone. The pattern of non-adherence is similar for the other classes of drugs, but the numbers are too small to be analysed further.

Table 2. Number of cases and prevalence (%) of COPD risk by level of risk and subject characteristics											
		RISK ACCORDING TO GOLD CRITERIA								RISK ACCORDING TO FEV1 (≤80%)		
		TOTAL (score ≥3)		Moderate risk (score=3)		High risk (score=4)		Very high risk (score=5)				
		N	Prev %	N	Prev %	N	Prev %	N	Prev %	N	Prev %	Fisher p
TOTAL		241	60.1	95	23.7	99	24.7	47	11.7	103	46.8	
Gender	Women	126	57.0	49	22.2	57	25.8	20	9.0	57	50.9	0.227
	Men	115	63.9	46	25.6	42	23.3	27	15.0	46	42.6	
Age	41-54	68	58.6	28	24.1	28	24.1	12	10.3	25	39.7	0.366
	55-64	62	57.4	25	23.1	24	22.2	13	12.0	27	47.4	
	≥65	111	62.7	42	23.7	47	26.6	22	12.4	51	51.0	
Educational level	Low	47	62.7	13	17.3	23	30.7	11	14.7	29	67.4	**0.005**
	Medium	86	58.1	34	23.0	33	22.3	19	12.8	36	47.4	
	High	108	60.7	48	27.0	43	24.2	17	9.6	38	37.6	
Living alone	Yes	37	60.7	14	23.0	18	29.5	5	8.2	17	50.0	0.712
	No	204	60.0	81	23.8	81	23.8	42	12.4	86	46.2	
Social network	No	10	62.5	2	12.5	4	25.0	4	25.0	8	88.9	**0.014**
	Yes	231	60.0	93	24.2	95	24.7	43	11.2	95	45.0	
COPD risk (based on GOLD score)	Moderate									40	46.5	0.984
	High									42	46.7	
	Very high									21	47.7	

Table 3. Factors associated to FEV1≤80%		PRR	95% CI
Gender	Women	1	
	Men	0.86	0.64 – 1.14
Age	41-54	1	
	55-64	1.20	0.80 – 1.82
	≥65	1.12	0.76 – 1.65
Educational level	High	1	
	Medium	1.22	0.86 – 1.72
	Low	**1.64**	**1.13 – 2.38**
Living alone	No	1	
	Yes	0.97	0.66 – 1.41
Social network	Yes		
	No	**1.69**	**1.24 – 2.31**
COPD risk (based on GOLD score)	Moderate		
	High	0.95	0.69 – 1.29
	Very high	0.92	0.63 – 1.34

After the multivariable adjustment, a significant protection from non-adherence (i.e. higher adherence) to bronchodilators was confirmed among patients with comorbidities (PRR=0.55), and was also detected among people living alone (PRR=0.63) (Table 5).

After three months, only 210 patients (47.4%) returned for the first follow-up interview. This percentage decreased further at the second (31.4%) and third (23.9%) follow-up. The planned impact evaluation was therefore unfeasible.

Satisfaction questionnaires

Forty pharmacists filled the satisfaction questionnaires at the end of the study. Most of them underlined that the project has contributed to value the professional role of the pharmacist and to establish an increasingly close relationship with the afferent population. Regarding the case finding arm, pharmacists judged that an easy-to-implement service such as this, which would allow early diagnosis of chronic diseases, may be very important to public health. As for the adherence arm, pharmacists reported that they felt very helpful in showing

Table 4. Number of cases and prevalence of non-adherence to therapy and devices by patient characteristics													
N		Bronchodilators users (n=396)			Steroids users (n=261)			Mucofluidifiers users (n=92)			Inhaler users (n=408)		
		N	Prev %	Fisher p	N	Prev %	Fisher p	N	Prev %	Fisher p	N	Prev %	Fisher p
TOTAL		145	36.6		80	30.7		42	45.7		24	5.9	
Gender	Women	59	39.9	0.332	37	33.9	0.343	16	51.6	0.508	8	5.3	0.829
	Men	86	34.7		43	28.3		26	42.6		16	6.3	
Age	41-54	9	47.4	0.539	4	33.3	0.826	1	33.3	0.474	0	0.0	0.758
	55-64	19	33.3		10	26.3		11	57.9		3	5.2	
	≥65	117	36.6		66	31.3		30	42.9		21	6.4	
Duration of COPD (years)	<1	13	28.3	0.422	6	21.4	0.573	1	12.5	0.121	2	4.0	0.420
	1—5	52	36.1		26	31.7		19	55.9		10	6.9	
	5—10	38	43.7		21	35.6		10	47.6		6	6.9	
	>10	26	32.9		18	26.5		6	31.6		2	2.4	
	unknown	16	40.0		9	37.5		6	60.0		4	9.8	
CAT score (impact on patient's life)	0-9	11	36.7	0.808	5	20.8	0.673	5	41.7	0.564	2	6.9	0.441
	10-19	50	40.0		34	34.0		16	53.3		11	8.5	
	20-29	53	34.6		29	29.9		14	37.8		7	4.4	
	30-40	31	35.2		12	30.0		7	53.9		4	4.5	
Comorbidities	No	28	58.3	0.001	11	31.4	1.00	7	53.9	0.561	2	3.8	0.754
	Yes	117	33.6		69	30.5		35	44.3		22	6.2	
Educational level	Low	57	34.3	0.640	31	27.4	0.515	15	42.9	0.859	12	7.1	0.626
	Medium	57	37.3		35	31.8		19	48.7		9	5.6	
	High	31	40.3		14	36.8		8	44.4		3	3.9	
Living alone	Yes	24	28.2	0.098	16	24.6	0.277	6	40.0	0.779	5	5.5	1.00
	No	119	38.5		64	32.8		36	46.8		19	6.0	
Social network	No	8	34.8	1.00	3	20.0	0.565	2	66.7	0.590	0	0.0	0.384
	Yes	137	36.7		77	31.3		40	44.9		24	6.2	

Table 5. Factors associated to non-adherence to bronchodilators		PRR	95% CI
Gender	Women	1	
	Men	0.84	0.69 – 1.12
Age	41-54	1	
	55-64	1.05	0.49 – 2.28
	≥65	1.38	0.53 – 1.21
Duration of COPD (years)	<1	1	
	1—5	1.14	0.68– 1.89
	5—10	1.12	0.64 – 1.97
	>10	1.41	0.84 – 2.37
CAT score (impact on patient's life)	0-9	1	
	10-19	1.05	0.76 – 1.50
	20-29	1.04	0.70 – 1.54
	30-40	0.87	0.47 – 1.64
Comorbidities	No	1	
	Yes	**0.55**	**0.41 – 0.74**
Educational level	High	1	
	Medium	0.97	0.70 – 1.42
	Low	0.87	0.57 – 1.31
Living alone	No	1	
	Yes	**0.63**	**0.42 – 0.95**
Social network	Yes	1	
	No	1.02	0.54 – 1.92

the correct use of the inhaler and that patients increased their awareness about their disease. On the other hand, the main drawbacks were difficulties in recruiting clients, dedicating time to the interviews and services offered, getting clients back for follow-up, and communicating with GPs.

DISCUSSION

As reported in other studies, pharmacies are confirmed to be a good setting to conduct investigations of public health because of the profitable pharmacists' participation and the possibility to intercept a large number of subjects.[25]

COPD case finding

We can support that an opportunistic screening for COPD is feasible in community pharmacies and may lead to the identification of both people at high risk of developing COPD and previously unknown cases of COPD. Indeed, more than half of the enrolled were found to be at risk according to the GOLD questionnaire and a quarter according to the FEV1 measurements.

Only five persons returned to pharmacies reporting a confirmed medical diagnosis. On the one hand, this number represents only the rate of the diagnosed subjects who came back to the pharmacy, and therefore it has to be considered as the minimum number of confirmed new COPD cases detected thanks to the

intervention; it is very likely that the actual number is greater. On the other hand, the enrolment criteria may have been too wide, resulting in a low specificity of the screening procedure. Therefore, we deem there is space to improve the efficiency of the program by restricting the recruitment criteria, such as enrolling actual or past smokers and older subjects.

Other studies reported similar results. In Australia, 21 community pharmacies assessed subjects' risk of COPD using questionnaires and spirometry, and subsequently diagnosing about 10% of the subjects, particularly in the rural areas.[23] Other surveys demonstrated that pharmacies may play an essential role in all steps of an integrated COPD patient care pathway acting from early disease detection to the all support in the full-blown disease.[24-39-42]

We found that low educated subjects are at higher risk of lower expiratory volumes. Similar social gradients emerged in other studies, where more disadvantaged people are more likely to be hospitalised with COPD.[43-45] Therefore, our results may suggest a possible impact of the intervention in moderating socioeconomic inequities, by anticipating diagnosis and early treatment in more disadvantaged subjects.

COPD adherence to therapy

In the populations covered by the study, we found rates of adherence to prescribed pharmacological treatments and capability to use correctly inhalers, considerably higher than expected. Indeed, patients considered adherent to the pharmacological therapies were, on average, between 55 and 70%. Figures from AIFA (the Italian Medicines Agency) show a different scenario, with high adherence to drugs for obstructive disorders of the airways respiratory in 20% of the cases and low adherence in about 50%.[46] Since it stands to reason that the subjects entering a pharmacy are intrinsically more adherent than those who don't even go to a pharmacy to collect their prescribed medicines, our results are not directly comparable with and generalizable to the whole population. Therefore, unlike other studies,[18,47-49] the planned impact assessment, could not be carried out.

We observed the highest non-adherence to bronchodilators among people without coamorbidities and those who do not live alone. This is inconsistent with the literature showing a greater likelihood of being less careful to a specific drug regimen when undergoing polytreatment,[50-52] and in general, of being less careful to the management of a chronic disease among those who live alone.[50,51,53,54] However, as discussed above, in our study we have captured a selected sample of highly adherent patients, who also report good social support in 94% of cases. It is therefore likely that in this sample, patients with comorbidities and living alone are not particularly disadvantaged (e.g. because cared for by non-cohabiting family members), which would lead to this unexpected result.

We have not performed an economic evaluation, but other studies have shown the cost-effectiveness of this type of intervention.[55] It would be interesting to evaluate the cost-effectiveness of an intervention such as the present one in order to assess the likely savings in terms of costs and in terms of health also in Italy.

Satisfaction questionnaires

An interesting result, which emerged from the satisfaction questionnaires, is the positive perception by pharmacists of this activity that enhances the profession as well as the relationship with patients. The actions included in both arms of the programme were considered by pharmacists useful for the patients' health. On the other hand, they reported difficulties in the interaction with the GPs, and complained about the presence of some critical issues which should be taken into account for the development of future studies: the lack of time within the daily workload, the need for adequately trained staff, and the need for economic recognition within the health service.

Other surveys report analogous results: pharmacists feel that screening for potential health risks and supporting patients to enhance drug adherence are within their role, and are useful for patients and for learning new skills.[56-60] The results about possible barriers are also consistent with what has been reported in the same studies.

LIMITATIONS

Some limitations of the study may have affected the results. Firstly, as discussed above, patients entering a pharmacy are intrinsically more adherent than the overall patients, which undermines both the representativeness of the sampled population and the efficiency of interventions aimed to improve drug adherence in the pharmacy setting. Furthermore, patients who can go to the pharmacy are selected to be in a less severe stage of the disease. In our case, this can also be linked to the particular timing of the intervention, which was conducted during the winter. Therefore, the possible effect of seasonality on the frequency of access to pharmacy, the results of the spirometry, and of the CAT questionnaire (e.g. less respiratory disease control due to allergies in spring) should also be assessed in future studies. Another limit concerning the adherence questionnaire is the possible social desirability bias in the answers.

A further constraint was the low participation in the follow-up and the little involvement of GPs, which forbade a full assessment of the impact of the intervention.

CONCLUSION

This study aimed to identify, among customers of community pharmacies, those at increased risk of COPD, who can benefit from early referral to the physician, and those with confirmed COPD who can benefit from monitoring and enhancing adherence to prescribed pharmacological treatment.

We showed that opportunistic screening for COPD is feasible in Italian community pharmacies. Since an early diagnosis is very important in order to start therapy as soon as possible and this can reduce the impact of the disease both on the patient and on public spending, it could be useful to implement these services in community pharmacies.

As regards activities to enhance adherence to therapy in pharmacies, it would be necessary to identify different methods of enrolment in order to involve only those patients who are less adherent or who have difficulties in the management of therapy and chronic pathology (e.g. those who need education in the use of inhalers, help in monitoring the worsening of the symptoms).

Finally, this study has provided us with some important information to take into account when planning future interventions in Italian community pharmacies. First, the activities of pharmacies should be integrated with those of other primary healthcare professionals in the territory. Above all, it would be useful to implement cooperation with GPs through the direct sharing of patients' data, to ensure that GPs are always informed about what their patients discuss with the pharmacists, such as possible risk factors or critical aspects in the management of a chronic disease. Furthermore, all pharmacists need to be fully trained in the prevention and management of chronic diseases, to avoid that they themselves are not aware of many topics, as sometimes reported.[61]

ETHICS STATEMENT

The study "The pharmacy of services for the control of chronic diseases: experimentation and transfer of a model of prevention intervention on type 2 diabetes " has been evaluated and authorized by the Italian Ministry of Health as part of the CCM (National Center for Disease Prevention and Control) program on 11 September 2015 (Directorate General for Health Prevention, protocol 0027843-11/09/2015-DGPRE-MDS-P). The official documentation is available on the CCM website.[62] The adaptation of the diabetes intervention protocol to another chronic disease (COPD) has been approved in objective 8 of the study. The project according to Italian legislation, does not require further evaluation. Nonetheless, the same workflow had been approved by the "Azienda Sanitaria Locale ASLTO2" Ethics Committee, Approval Protocol n°46480 / 2013.[33]

Data were stored and analysed in an anonymous manner.

AUTHOR'S CONTRIBUTIONS

Francesca Baratta: investigation, writing – original draft preparation, writing – review & editing; Irene Pignata: investigation, writing – original draft preparation, writing – review & editing; Roberta Onorati: investigation, data curation, writing – review & editing; Giuseppe Costa: conceptualization, funding acquisition; Roberto Gnavi: conceptualization, investigation, data curation, writing – review & editing; Paola Brusa: conceptualization, investigation, project administration; Teresa Spadea: conceptualization, investigation, data curation, writing – review & editing

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DATA AVAILABILITY STATEMENT

Derived data supporting the findings of this study are available from the last author [TS] upon request.

DISCLOSURE

The author reports no conflicts of interest in this work.

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APPENDIX 1

S1. Patient questionnaires

SOCIO-DEMOGRAPHIC CHARACTERISTICS			
Gender		M	F
Age (in completed years)		-----	
How many people does your family consist of (excluding yourself)?		-----	
		YES	NO
In case of need, can your family count on the personal help of other non co-habiting people?	Relatives		
	Friends		
	Neighbours		
	Others on a voluntary basis		
	Others for a fee		
What is your highest educational qualification?	None		
	Primary school diploma		
	Middle school diploma		
	2-3 yrs. High school diploma		
	4-5 yrs. High school diploma		
	University degree or more		

GOLD QUESTIONNAIRE		
Do you cough several times? Most days?	yes	no
Do you bring up phlegm or mucus most days?	yes	no
Do you get out of breath more easily than others your age?	yes	no
Are you older than 40 years?	yes	no
Are you a current smoker or an ex-smoker?	yes	no

CAT QUESTIONNAIRE *							
	0	1	2	3	4	5	
I never cough							I cough all the time
I have no phlegm (mucus) in my chest at all							My chest is completely full of phlegm (mucus)
My chest does not feel tight at all							My chest feels very tight
When I walk up a hill or one flight of stairs I am not breathless							When I walk up a hill or one flight of stairs I am very breathless
I am not limited doing any activities at home							I am very limited doing activities at home
I am confident leaving my home despite my lung condition							I am not at all confident leaving my home because of my lung condition
I sleep soundly							I don't sleep soundly because of my lung condition
I have lots of energy							I have no energy at all

* *There is no licence fee associated with the use of the CAT for research purposes.

| ADHERENCE TO PHARMACOLOGICAL THERAPIES		
Which medicines do you use?	YES	NO
Bronchodilators		
Do you sometimes forget to take your bronchodilators?		
Have there been days in the last two weeks when you have not taken bronchodilators (not because you forgot)?		
When you feel that the disease is under control, do you stop taking bronchodilators?		
Have you ever decreased your doses or stopped taking bronchodilators without telling your doctor because you felt worse when you were taking them?		
Inhaled steroids		
Do you sometimes forget to take your inhaled steroids?		
Have there been days in the last two weeks when you have not taken inhaled steroids (not because you forgot)?		
When you feel that the disease is under control, do you stop taking inhaled steroids?		

|		
Have you ever decreased your doses or stopped taking inhaled steroids without telling your doctor because you felt worse when you were taking them?		
Mucofluidifiers		
Do you sometimes forget to take your mucofluidifiers?		
Have there been days in the last two weeks when you have not taken mucofluidifiers (not because you forgot)?		
When you feel that the disease is under control, do you stop taking mucofluidifiers?		
Have you ever decreased your doses or stopped taking mucofluidifiers without telling your doctor because you felt worse when you were taking them?		

USE OF THE INHALER DEVICE		
Do you know how to use the device?	YES	NO
The pharmacist asks the user to show how he/she usually uses the device. Was the demonstration correct?		

COMORBIDITY			
Do you take medicines for other chronic diseases?	Does not know/does not remember	YES	NO
If yes, what disease? arterial hypertension heart failure diabetes mellitus dyslipidaemia other			

APPENDIX 2
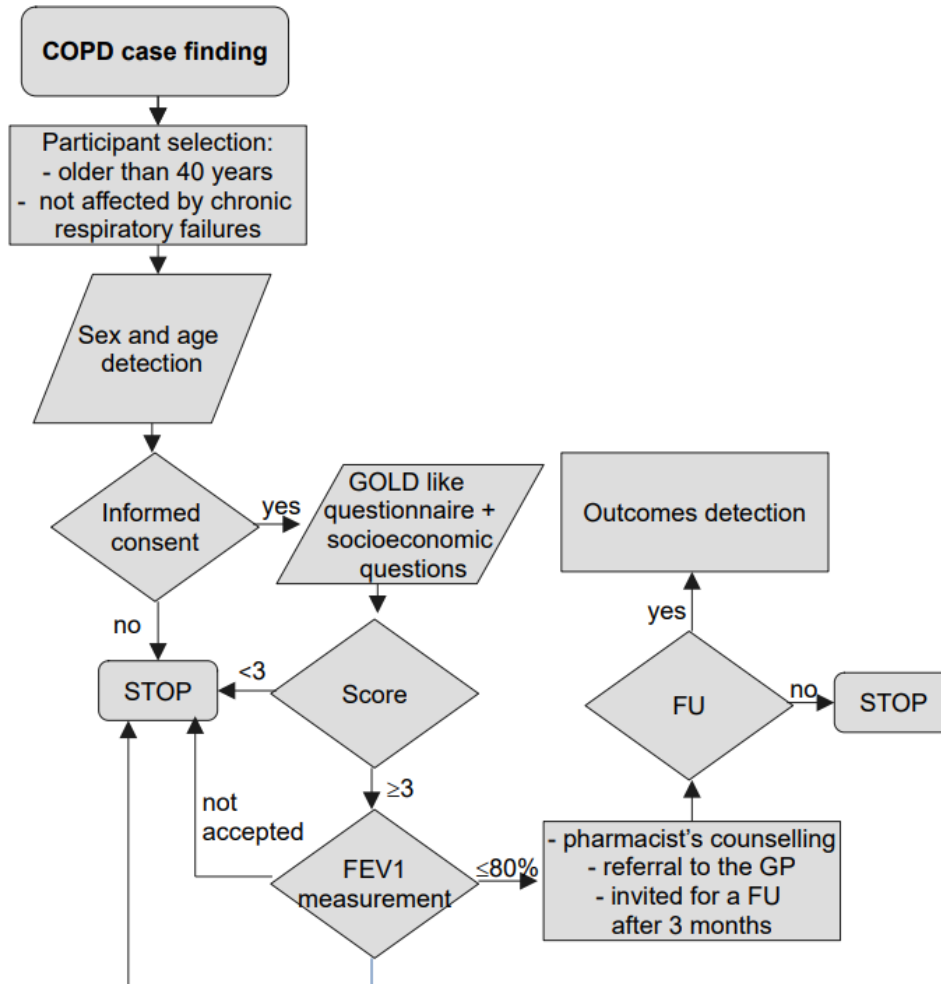
APPENDIX 3
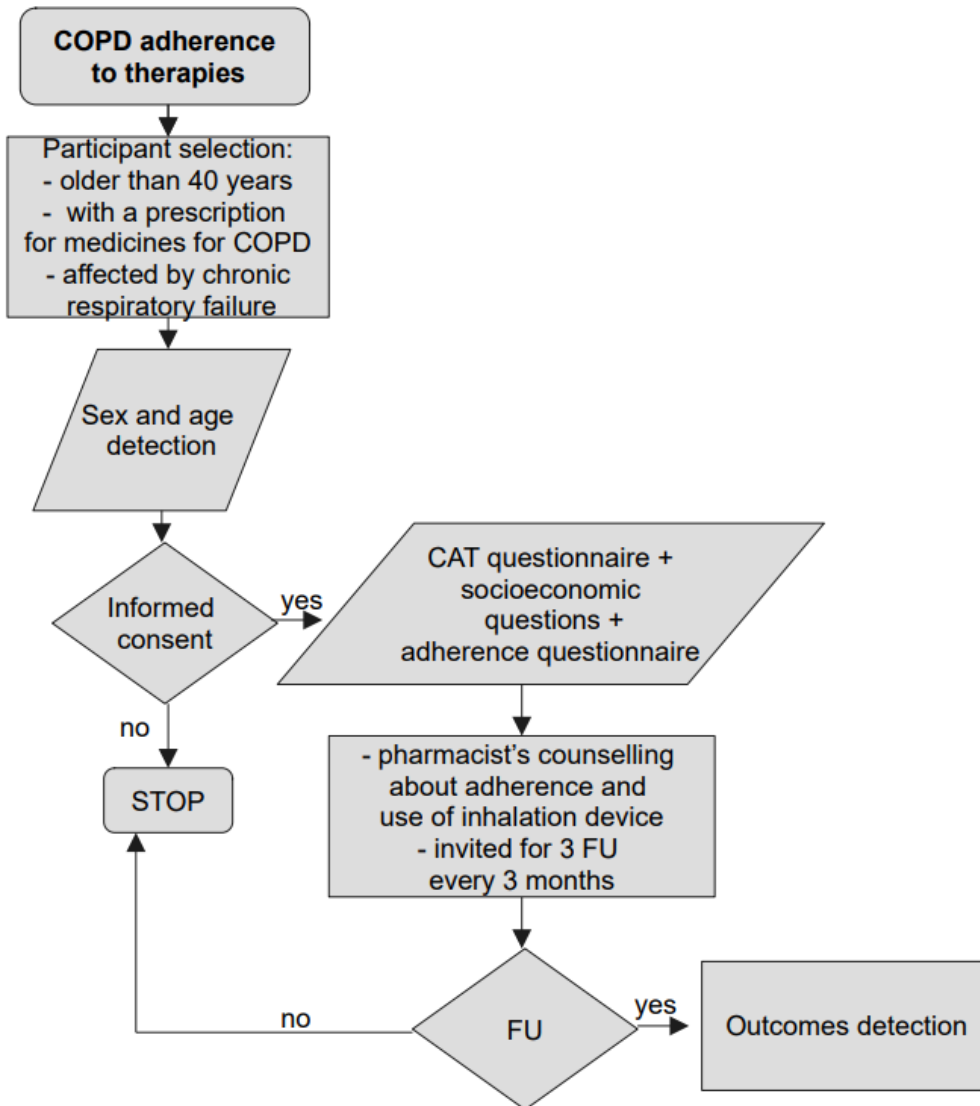
APPENDIX 4

S2. Pharmacists satisfaction questionnaire

- Indicate 3 positive aspects regarding this project:

1………………….

2………………….

3………………….

- Indicate 3 negative aspects regarding this project:

1………………….

2………………….

3………………….

- Do you have any suggestions for improving the process? _____
_____