STUDY REPORT SUMMARY (ABSTRACT)

Observational multicenter non-interventional study of management strategies in patients with COPD at the moment of hospital discharge and during 12 months of follow-up in the outpatient setting

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Background/Rationale: Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide, increasing significant economic and social burden. In the Russian Federation (RF) in 2009 COPD was the most common disease (55%) among all respiratory conditions, followed by bronchial asthma (19%) and pneumonia (14%) [3]. COPD exacerbation (periodic escalations of symptoms of cough, dyspnea, and sputum production) is a major contributor to lung function worsening, life quality impairment, need for urgent care or hospitalization, and cost care increase in COPD; severe exacerbations are the main cause of mortality in COPD patients [14; 15].

Treatment of diagnosed COPD is based on pharmacotherapy. Global initiative for chronic obstructive pulmonary disease guidelines (GOLD 2014) were intended to harmonize diagnostic approaches and methods of COPD management. Until now, information on pharmacological treatment of patients with severe and very severe COPD in the Russian Federation remains scarce. The rationale for this study is the need to describe the treatment choices after hospital discharge from the hospital for patients with frequent COPD exacerbations.

Objectives and Hypotheses: Primary objective. To describe methods of pharmacological management (including different schemes of glucocorticoids use) for subject with severe and very severe COPD, according to GOLD 2014 recommendations, including methods of exacerbations management and therapy changes for the following periods of time: during one year prior to hospitalization, at the moment of hospital discharge, and for the following 12 months of follow-up in the outpatient setting.

Secondary objectives:

1. To evaluate demographic characteristics (birth year, race, gender), social and economic status data (education, profession, family status, housing conditions, income level) of the subjects with severe and very severe COPD hospitalized due to COPD exacerbation.

2. To evaluate the following information about subjects with severe and very severe COPD hospitalized due to COPD exacerbation: year of initial diagnosis, significant concomitant diseases, including allergic reactions, rhinitis, atopic reactions, gastroesophageal reflux disease, as well as eosinophil count, reversibility of airflow limitation, frequency of exacerbations, pneumonias, hospital admissions, number of emergency medical service calls and number of clinical visits for the reasons related to COPD during one year prior to current hospitalization.
3. To evaluate clinical status (significant concomitant diseases, including allergic reactions, rhinitis, atopic reactions, gastroesophageal reflux disease, as well as eosinophil count, reversibility of airflow limitation) after 3, 6, 9, and 12 months of outpatient follow-up.
4. To evaluate smoking status of subjects with severe and very severe COPD hospitalized due to reason of COPD exacerbation at the moment of hospital discharge and after 3, 6, 9, and 12 months of outpatient follow-up. To assess number of pack-years for these subjects at the moment of hospital discharge
5. To describe treatment regimen for severe and very severe COPD, including different schemes of glucocorticoid usage according to GOLD 2014 recommendations for the following periods: prior to hospitalization (according to medical history) and at the moment of hospital discharge.
6. To describe changes in treatment schemes for severe and very severe COPD (prescribed at the moment of hospital discharge) after 3, 6, 9, and 12 months of outpatient follow-up, including different schemes of glucocorticoids usage. To clarify reasons for therapy changes (in case of any) and to compare them to GOLD 2014 recommendations.
7. To evaluate life quality in subjects with severe and very severe COPD using the EQ-5D questionnaire at the moment of hospital discharge and after 3, 6, 9, and 12 months of outpatient follow-up and compare the dynamics of EQ-5D changes with therapy regiments, including different schemes of glucocorticoids usage.
8. To perform CAT assessment in subjects with severe and very severe COPD using the EQ-5D questionnaire at the moment of hospital discharge and after 3, 6, 9, and 12 months of outpatient follow-up.
9. To define phenotypes of subjects with COPD, including asthma-COPD overlap syndrome, hospitalized due to COPD exacerbation.

Methods: This was an observational multicenter descriptive study. 1250 subjects were planned to ne enrolled at approximately 35 study sites where lung function test (LFT) was a routine procedure. The study subjects were treated according to the routine practice for their disease in RF. The study included male and female patients who signed Informed Consent Form, ≥40 years old and with smoking history >10 pack-years with severe and very severe COPD hospitalized due to COPD exacerbation into departments of pulmonology or general therapy. 5 visits every 3 months were planned during the study. Demographics and socioeconomic status were to be assessed once at the moment of hospital discharge as well as medical history of COPD and significant concomitant diseases, instrumental assessments (anthropometry and spirometry) were to be performed every 6 month during subject's visit to the study site, information about COPD pharmacotherapy, smoking status, occupational status, health status and life quality, and newly diagnosed significant concomitant disease were to be gathered every 3 month during both subject's visit to the study site and by phone contacts.

During the study following outcomes were assessed:

Primary endpoint:

Percentage of subjects with severe and very severe COPD who received therapy prescription, including different schemes of usage of inhaled glucocorticoids, according to the main principles of COPD therapy (GOLD 2014 recommendations) at the moment of discharge and after 3, 6, 9, and 12 months of follow-up.

Secondary endpoints:

1. Description of social status, demographics and economic status of subjects with severe and very severe COPD hospitalized due to COPD exacerbation.
2. Percentage of subjects with severe and very severe COPD for whom scheme of inhaled glucocorticoids usage was changed after 3, 6, 9, and 12 months of follow-up (outpatient setting after hospital discharge).
3. Frequency and reasons for treatment scheme correction during follow-up after its prescription at the moment of hospital discharge.
4. Percentage of subjects with severe and very severe COPD who during the follow-up period attended medical institution for the correction of treatment scheme prescribed at the moment of hospital discharge.
5. Percentage of subjects with severe and very severe COPD, who received treatment with short acting anticholinergic drugs, short acting beta-agonists (SABA), long acting beta-agonists (LABA), long acting muscarinic antagonists (LAMA), oral corticosteroids (oral CS), fixed drug combinations (FDC), phosphodiesterase type 4 inhibitors, theophylline during one year prior to the current hospitalization (medical history data).
6. Percentage of subjects with severe and very severe COPD, who received treatment with short acting anticholinergic drugs, short acting beta-agonists (SABA), long acting beta-agonists (LABA), long acting muscarinic antagonists (LAMA), oral corticosteroids (oral CS), fixed dose combinations (FDC), phosphodiesterase type 4 inhibitors, theophylline at the moment of hospital discharge as well as after 3, 6, 9, and 12 months of follow-up.
7. Percentage of subjects with asthma-COPD overlap syndrome (ACOS) among all subjects with severe and very severe COPD hospitalized for the reason of COPD exacerbation.
8. Percentage of subjects with asthma-COPD overlap syndrome who received treatment with inhaled glucocorticoids both at the moment of hospital discharge and after 3, 6, 9, and 12 months of follow-up.
9. Percentage of subjects with severe and very severe COPD, who received treatment with short acting anticholinergic drugs, short acting beta-agonists (SABA), long acting beta-agonists (LABA), long acting muscarinic antagonists (LAMA), oral corticosteroids (oral CS), fixed dose combinations (FDC), phosphodiesterase type 4 inhibitors, theophylline at the moment of discharge and after 3, 6, 9, and 12 months of follow-up, among all subjects with asthma-COPD overlap syndrome (ACOS).

10. EQ-5D results at the moment of discharge and after 3, 6, 9, and 12 months of follow-up.
11. CAT results at the moment of discharge and after 3, 6, 9, and 12 months of follow-up.

Descriptive statistical analysis of the obtained data was performed using the software SAS® 9.4 and MS Excel® 2016. Demographics, anthropometry and other parameters of the study population were described using the following values: N (quantity), mean value, standard deviation, standard deviation (SD), median, lower and upper quartile (Q1, Q3), minimal and maximal values and interquartile range (IQR) for quantitative variables. Qualitative variables were described using frequency tables. No formal hypothesis was tested in the study.

Results:

Study participation

The study covered almost all Federal Districts of the Russian Federation. Full analysis set (FAS) comprised of 1029 subjects hospitalized due to COPD exacerbation into departments of pulmonology or general therapy. However, not all data required for analysis were available for all subjects. Therefore, PP-population was extracted based on patients who completed all visits according to the study protocol, had full dataset of COPD medications prescribed at the moment of discharge and received at least once during follow-up, for whom exact start and stop dates of COPD treatment were indicated, and for whom full EQ-5D and CAT dataset were available. 852 patients were included in the PP population. PP population was used to assess primary endpoint and secondary endpoints which implied analysis of outcome dynamics during the study course. Demographic, anthropometric, socioeconomic status and COPD status parameters of PP population were similar to those of the full analysis set (FAS).

Demographic characteristics and socioeconomic status

Mean age of study population was about 64 years (63.92 (95% CI 63.34 – 64.71) and 64.08 (95% CI 63.53 – 64.61) in the PP population and the FAS population respectively), with higher proportion of male subjects (83.33% and 85.13% in PP and FAS population, respectively) compared to general population of the Russian Federation (48%). Mean BMI was 25.87 (25.50 – 26.24) and 25.72 (25.39 – 26.06) in PP and FAS population respectively. The majority of subjects were married (81.9% and 80.6%, PP and FAS respectively), without higher education (52.6% finished high school and about 31% finished college in both PP and FAS populations), and had a low income rate (75% of patients who provided corresponding information (464 in PP and 543 in FAS) had income < 15000 rub/month versus 30% for general population of the Russian Federation). About 13% of the study population lived in houses with stove heating which conforms to the proportion of households with stove heating for the general population of the Russian Federation.

Smoking status

Average smoking history was 39.02 pack-years (37.75 – 40.30) and 38.46 pack-years (37.33 – 39.58) in PP and FAS respectively. Percentage of smokers at the moment of discharge was about 51% in both populations and remained about 50% during the course of the study.

Phenotypes of subjects with COPD

The most prevalent COPD phenotypes was Chronic Bronchitis phenotype (55.16% and 55.3% in PP and FAS), Frequent Exacerbator phenotype comprised 46.1% and 46% in PP and FAS, Emphysema phenotype comprised 33.8% and 34.6% in PP and FAS, Pulmonary Cachexia phenotype comprised 10.7% and 11.1% in PP and FAS, COPD-Bronchiectasis Overlap phenotype comprised 3.9% and 3.6% respectively, and frequency of Asthma-COPD Overlap Syndrome was 13.9% and 12.6% in PP and FAS, respectively.

Primary objective

About 95% patients received treatment following GOLD 2014 recommendations during the course of the study.

	At discharge N (%)	**Month 3 N (%)**	**Month 6 N (%)**	**Month 9 N (%)**	**Month 12 N (%)**
Complied with GOLD 2014 recommendations	806 (94.60%)	807 (94.72%)	808 (94.84%)	809 (94.95%)	810 (95.07%)
Non-complied with GOLD 2014 recommendations	46 (5.40%)	45 (5.28%	44 (5.16%)	43 (5.05%)	42 (4.93%)

The most popular medications were ICS, which were received at least once during 12 months of follow-up period by 85.8% subjects with severe and very severe COPD (either as monotherapy or as a fixed dose combination).

Medications related to COPD treatment were classified by international non-proprietary names (INN) and pharmacological class. Following table provides percentage of patients who received COPD-specific INN at least once during 1 year prior to hospitalization and during 12 months of follow-up:

Pharmacological class Total* N (%)**	**Drug INN***	**FAS (N=1029)**	
		1 year prior to hospitalization N (%)**	**Follow-up** N (%)**
ICS		**157 (15.26%)**	**283 (27.5%)**

Pharmacological class Total* N (%)**	**Drug INN***	**FAS (N=1029)**	
		1 year prior to hospitalization N (%)**	**Follow-up** N (%)**
	Budesonide (Pulmicort®)	48 (4.66%)	136 (13.22%)
	Budesonide (Other)	33 (3.21%)	78 (7.58%)
	Beclomethasone	81 (7.87%)	85 (8.26%)
	Mometasone	1 (0.1%)	5 (0.49%)
	Ciclesonide	0	3 (0.29%)
	Fluticasone	5 (0.49%)	5 (0.49%)
FDC/ICS+LABA		**507 (49.27%)**	**805 (78.23%)**
	Beclomethasone+Formoterol	7 (0.68%)	43 (4.18%)
	Budesonide+ Formoterol (Simbicort®)	207 (20.12%)	385 (37.41%)
	Budesonide+ Formoterol (Foradil Combi®)	114 (11.08%)	204 (19.83%)
	Fluticasone+Vilanterol	1 (0.1%)	1 (0.1%)
	Fluticasone+Salmeterol	189 (18.17%)	265 (25.75%)
FDC/SABA+SAMA		**583 (56.66%)**	**572 (55.59%)**
	Fenoterol+Ipratropium bromide	619 (56.46%)	572 (55.59%)
	Salbutamol +Ipratropium bromide	2 (0.19%)	0
FDC/LAMA+LABA		**0 (0%)**	**13 (1.26%)**
	Olodaterol+Tiotropium bromide	0	10 (0.97%)
	Indacaterol+Glycopyrronium bromide	0	1 (0.1%)
	Vilanterol+Umeclidinium bromide	0	2 (0.19%)
SABA		**233 (22.64%)**	**198 (19.24%)**
	Fenoterol	118 (11.47%)	124 (12.05%)

Pharmacological class Total* N (%)**	**Drug INN***	**FAS (N=1029)**	
		1 year prior to hospitalization N (%)**	**Follow-up** N (%)**
	Salbutamol	114 (11.08%)	75 (7.29%)
	Orciprenaline	1 (0.1%)	0
LABA		**73 (7.09%)**	**113 (10.98%)**
	Formoterol (Oxis Turbohaler®)	60 (5.64%)	51 (4.96%)
	Indacaterol	16 (1.55%)	64 (6.22%)
SAMA		**63 (6.12%)**	**88 (8.55%)**
	Ipratropium bromide	63 (6.12%)	88 (8.55%)
LAMA		**334 (32.46%)**	**780 (75.8%)**
	Glycopyrronium bromide	8 (0.78%)	107 (10.4%)
	Tiotropium bromide	329 (31.78%)	693 (67.35%)
PDEI		**2 (0.19%)**	**12 (1.17%)**
	Roflumilast	2 (0.19%)	12 (1.17%)
MX		**29 (2.82%)**	**67 (6.51%)**
	Theophylline	8 (0.78%)	7 (0.68%)
	Aminophylline	25 (2.43%)	61 (5.93%)
	Theophedrin	1 (0.1%)	0
Oral CS		**133 (12.93%)**	**219 (21.28%)**
	Dexametasone	12 (1.17%)	45 (4.37%)
	Prednisolone	122 (11.76%)	190 (18.46%)

*Each patient might receive more than one medication.

**Note: data for 1 year prior to hospitalization were collected from the medical history, whereas data for 1 year of follow-up were prospectively collected.

***Number and percentage of patients who received any medication of certain pharmacological class at least once during 1 year prior to hospitalization and during follow-up.

Secondary objectives

Clinical status of subjects with COPD

FAS population comprises 795 (77.26%) GOLD3 patients and 234 (22.66%) GOLD4 patients, PP population comprises 661 (77.58%) GOLD 3 patients and 191 (22.42%) GOLD4 patients.

38 new significant concomitant diseases occurred within the first 3 months of follow-up, 125 – from Month 3 to Month 6, 33 – from Month 6 to Month 9, and 63 – from Month 9 to Month 12. About half of all conditions accounted for allergic reactions and reversibility of bronchial obstruction, frequency of rhinitis and gastroesophageal reflux disease did not exceed 10% and 7%, respectively, and abnormal eosinophil count was registered only within Month 3-6 period and comprised 4.8% of all conditions.

Treatment regimen for severe and very severe COPD, including different schemes of glucocorticoid usage according to GOLD 2014 recommendations for the following periods: prior to hospitalization (according to the medical history) and at the moment of hospital discharge

During 1 year prior to hospitalization frequency of usage of COPD-specific pharmacological classes was as follows (in descending order): FDC (78.05%); LAMA (30.16%); SABA (19.84%); Oral CS (13.5%); LABA (7.5%); SAMA (6.34%); Theophylline (0.47%); PDEI (0.23%).

Changes in treatment schemes for severe and very severe COPD (prescribed at the moment of hospital discharge) after 3, 6, 9, and 12 months of outpatient follow-up, including different schemes of glucocorticoid usage. To clarify reasons for therapy changes (in case of any) and to compare them to GOLD 2014 recommendations

During 12 months of follow-up frequency of usage of COPD-specific pharmacological classes was as follows:

Pharmacological class	**At discharge**	**Month 3**	**Month 6**	**Month 9**	**Month 12**
	N (%)	**N (%)**	**N (%)**	**N (%)**	**N (%)**
SABA	135 (15.85%)	133 (15.61%)	134 (15.73%)	138 (16.2%)	132 (15.49%)
LABA	89 (10.45%)	81 (9.51%)	84 (9.86%)	91 (10.68%)	79 (9.27%)
SAMA	62 (7.28%)	40 (4.69%)	43 (5.05%)	44 (5.16%)	37 (4.34%)
LAMA	634 (74.41%)	701 (82.28%)	632 (74.18%)	639 (75%)	616 (72.3%)
PDEI	8 (0.94%)	5 (0.59%)	6 (0.7%)	5 (0.59%)	5 (0.59%)

Pharmacological class	At discharge	Month 3	Month 6	Month 9	Month 12
	N (%)	N (%)	N (%)	N (%)	N (%)
Oral CS	88 (10.33%)	18 (2.11%)	23 (2.7%)	55 (6.46%)	12 (1.41%)
Theophylline	4 (0.47%)	4 (0.47%)	4 (0.47%)	6 (0.7%)	3 (0.35%)
FDC	742 (87.09%)	725 (85.09%)	726 (85.21%)	728 (85.45%)	704 (82.63%)

At the moment of discharge inhaled corticosteroids (ICS) including fixed dose combination ICS+LABA were prescribed to 731 (85.79%) patients in the PP-population. Therapeutic scheme of ICS usage was changed for 89 (10.45%) patients within the first 3 months of hospital discharge. During 3-6 months of follow-up changes in the therapeutic scheme of ICS usage were registered for 31 (3.64%) patients, during 6-9 months of follow-up – for 25 (2.93%) patients, and during 9-12 months of follow-up – for 49 (5.75%) patients in the PP population.

In the course of follow-up methods of COPD management was changed for 503 (34.5%) subjects. 1091 reasons for treatment scheme correction were identified during 12 months of follow-up. All reasons for therapeutic scheme corrections were categorized into 14 classes. Most frequently, therapy was corrected because of COPD exacerbation (about 29%), the next frequent reasons were high cost of medications (25.4%) and absence of the drugs in subsidized drug list (21%). Other reasons were as follows (presented in descending frequency order): emergency physician's decision (3.9%); advice of friends/relatives/people with similar diagnosis (2.6%); absence of the drug in the pharmacy (2.4%); advice of the pharmacist (1.8%); inconvenient scheme of drug application (1.6%); inconvenient inhaler (1.2%); pneumonia (1%); idiosyncrasy/allergic reactions (0.3%). Total number of reasons was 1091.

Treatment of severe and very severe COPD (prescribed at the moment of hospital discharge) after 3, 6, 9, and 12 months of outpatient follow-up among all patients with asthma-COPD overlap syndrome

Addressing possible variations in methods of COPD management depending on COPD heterogeneity, subjects with asthma-COPD overlap syndrome (ACOS) were analyzed separately. Percentage of subjects treated with ICS was slightly higher among subjects with ACOS (N=118) compared to PP population (N=852) (94.9% vs 86.0% respectively), percentage of subjects treated with LAMA was slightly lower among subjects with ACOS compared to the PP population (60-65% vs 72 -82% during 12 months follow-up, respectively). Increased usage was observed for oral CS at hospital discharge (17.0% vs. 10.3% in ACOS and PP respectively). Then during Month 3 – 12 percentage of patients receiving oral CS was similar in the PP population and in ACOS subjects.

Life quality assessment in subjects with severe and very severe COPD using the EQ-5D questionnaire at the moment of hospital discharge and after 3, 6, 9, and 12 months of outpatient

follow-up and compare the dynamics of EQ-5D changes with regiment of therapy, including different schemes of glucocorticoid usage

Health status assessed with EQ-5D questionnaire as well as VAS demonstrated slight improvement after the first 3 months of follow-up compared to hospital discharge (0,60 (95% CI 0,58 - 0,61) vs 0,55 (95% CI 0,54 -0,57) respectively) and then remained unchanged for Month 3-12 period. Analysis of EQ-5D dynamics in comparison to COPD treatment regiment demonstrated slight improvement trend of EQ-5D index score over the course of follow-up (0,56 (0,54-0,58), 0,60 (0,58-0,63), 0,61 (0,59-0,63), 0,62 (0,60-0,64), 0,60 (0,58-0,62) at discharge and after 3, 6, 9, and 12 months of follow-up, respectively) in group of patients who received COPD treatment complying with GOLD 2014 recommendations during the whole study period for whom COPD treatment regimen remained unchanged or was changed due to non-medical reasons. At the same time, EQ-5D remained unchanged in the group of patients treated in compliance with GOLD 2014 during the whole study period but for whom COPD treatment scheme was modified due to health conditions (COPD exacerbation or pneumonia or emergency physician's decision). Group of patients with treatment non-complying to GOLD 2014 recommendations during the whole study period demonstrated no EQ-5D trend during follow-up due to high variability of EQ-5D index score.

CAT assessment in subjects with severe and very severe COPD using the questionnaire at the moment of hospital discharge and after 3, 6, 9, and 12 months of outpatient follow-up

Mean CAT score slightly improved after the first 3 months of follow-up compared to hospital discharge and then remained unchanged within Month 3-12 period:

CAT	At discharge	Month 3	Month 6	Month 9	Month 12
Mean (95% CI)	22.87 (22.39-23.36)	21.29 (20.82-21.77)	21.67 (21.18-22.16)	21.18 (20.70-21.66)	21.57 (21.10-22.04)

Safety evaluation

According to Sponsor requirements, only the following cases which occurred during therapy with AstraZeneca drugs, were registered in electronic Case Report Forms:

- COPD exacerbation without hospitalization;
- COPD exacerbation requiring hospitalization;
- pneumonia without hospitalization;
- pneumonia requiring hospitalization;
- individual intolerance/allergic reaction;
- events leading to death.

There were 14 cases of AEs (without serious AEs) including 13 cases of COPD exacerbations and 1 case of pneumonia – all of them without hospitalization. One episode of pneumonia was associated with current drug therapy (lack of therapeutic efficacy). Patient was treated with

Tiotropium bromide (Spiriva®) and Budesonide (Pulmicort®); AE severity decreased after dose reduction. One episode of COPD exacerbation was also associated with current drug therapy (lack of therapeutic efficacy). Patient was treated with Budesonide+Formoterol (Symbicort Turbuhaler®); AE severity also decreased after dose reduction. Thus there were only two episodes of adverse drug reactions according to the investigator`s opinion. All of the 14 AEs resulted in improvement (11) or complete recovery (3). One patient with COPD exacerbation died later from decompensation of discirculatory encephalopathy, which was registered as SAE (see below).

There were 86 serious AEs (SAEs) reported during the study including 54 cases of COPD exacerbations, 9 cases of pulmonary infection exacerbation, 8 deaths, 6 cases of pneumonia, 2 cases of suffocation, 2 cases of decompensated CHF, 2 cases of respiratory failure, 3 cases of cardiopulmonary failure, 1 case of myocardial infarction, 1 case of anaphylactic shock, 1 case of thromboembolism, 1 case of decompensation of discirculatory encephalopathy. There were 4 patients with two serious AEs: COPD exacerbation and pneumonia (3), COPD exacerbation and cardiopulmonary failure (1).

There were two cases of COPD exacerbation with bronchial asthma in patients with asthma-COPD overlap phenotype. According to the investigator`s opinion all of the SAEs were not associated with current drug therapy and resulted in improvement (50), complete recovery (15), recovery with consequence (1) or fatal outcome (20).

The causes of fatal outcomes (20) were anaphylactic shock (1), myocardial infarction (1), chronic heart failure (2), acute cardiopulmonary failure (3), respiratory failure (2), suffocation (2), decompensation of discirculatory encephalopathy (1), suicide (hanging) (1), thromboembolism (1), and 6 deaths without exact cause.

All investigated therapeutic methods of management of subjects with COPD at the moment of hospital discharge and during 12 months of follow-up in outpatient setting were proved to be safe. All but 2 adverse events were unrelated to the therapy with AstraZeneca drugs. None of SAEs was associated to the therapy with AstraZeneca drugs.

Conclusion:

- High proportion of the subjects with severe and very severe COPD hospitalized due to COPD exacerbation into departments of pulmonology or general therapy were non-graduated married man with low and very low income, with average smoking history of 39 pack-years;

- 95% of pharmacological treatment prescribed for COPD during 12 months of follow-up complied with first/alternative choice in management of severe and very severe COPD recommended by the International guidelines (GOLD 2014);

- About 86% of pharmacological treatment prescribed for COPD during 12 months of follow-up included inhaled corticosteroids either as monotherapy or as a component of

fixed dose combination. ICS were combined with long-acting bronchodilators accompanied by on-demand use of short-acting bronchodilators;

- COPD therapy prescribed at the moment of hospital discharge was changed in about 59% of all subjects during 12 months of follow-up. The most significant reasons for therapeutic scheme change were COPD exacerbation, absence of the drug in subsidized drug list and high cost of medications;

- Life quality of enrolled patients slightly improved after the first 3 months of follow-up and then remained almost unchanged during the next 9 months of follow-up. Improvement was attributed to group of patients treated in compliance with GOLD 2014 for the whole study period for whom COPD treatment regimen remained unchanged or COPD treatment regimen changes were unrelated to health conditions.