INTRODUCTION
Chronic obstructive pulmonary disease (COPD) is a devastating condition that leads to respiratory disability and a considerable reduction in the comfort of living. In Poland, COPD is observed in over 20% of the population at risk (smokers over the age of 40). As in many other countries, the percentage of detected cases is very low. The progressive course of the disease and its manifestations, including dyspnea and reduced exercise tolerance, have a considerable impact on patient activity, and the disease negatively affects all aspects of the patient’s life. Subjective assessment of health state by patients themselves is increasingly included in research studies of treatment outcomes. Therefore, the quality-of-life (QoL) studies in COPD patients are gaining significance as a complement to objective evaluation of the patient’s clinical condition (e.g., spirometry). They are also an important component of the clinical assessment of treatment outcomes and, more importantly, of treatment acceptability. The relationship between the severity (stage) of the disease and reduced comfort of living has been demonstrated in numerous studies.
One of the largest studies confirmed that health state is significantly impaired in COPD patients across all stages, even in milder disease. However, there is little difference in the degree of impairment between patients with stage 1 and 2 according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), and a wide variation in patients’ health-related QoL (HRQL) within each GOLD stage is observed. However, there are sparse data concerning the relationship between the severity of the observed abnormalities (on the basis of which the stage of the disease is established) and how patients with COPD in Poland perceive their health. The current study was designed and conducted in 2000s to assess this association. To our knowledge, there have been no such large-scale studies that would use the generic HRQL questionnaire to study patients with all stages of COPD in Poland. Thus, the objectives of our study were to assess the negative effect of COPD on patients in Poland, to describe the QoL of patients with COPD, and to support the Polish data on health economics assessment by providing the measures of health outcomes determined with the use of a HRQL questionnaire, EQ-5D.

**Patients and Methods** The study was designed as an epidemiological study involving a representative cross-sectional population of patients diagnosed with COPD, who remained under the care of specialists or family doctors in numerous centers across Poland. COPD patients were defined as those who had chronic symptoms (dyspnea, cough, wheezing in the chest), together with irreversible airflow limitation (post-bronchodilatation forced expiratory volume in 1 second to forced vital capacity ratio [FEV1/FVC] ratio less than 0.7) and a history of exposure to noxious agents (most often smoking or occupational exposure). Stage of the disease was defined according to FEV1% predicted using the GOLD 2007 criteria. The only requirement for inclusion in the study was the diagnosis of COPD (during the current visit or in the past) together with spirometry assessment of disease severity. Subjects with asthma were excluded from the study. Exact spirometry data were not collected. The target sample size (about 10,000) seems to be representative, considering epidemiological data on the prevalence and awareness of COPD in Poland.

The study was conducted in the form of a survey supplemented by spirometry between the fourth quarter of 2008 and the first quarter of 2009 and between the third and the fourth quarter of 2009 (winter and autumn were selected, as the seasons with the greatest frequency of visits for COPD patients). A total of 630 specialists in respiratory medicine and specialists in family medicine providing medical care to patients with COPD were invited to participate in the study. The study included men and women aged 35 or older with the diagnosis of COPD (established on the basis of clinical manifestations and the spirometric criterion of irreversible airway obstruction) of any severity, with no previous treatment with tiotropium, and currently managed on an outpatient basis. There were no patients using a long-acting anticholinergic (tiotropium) in the study population. This resulted from the aims of the study, one of which was to assess the comfort of living among patients who were not receiving this medication, for possible future comparisons. The severity of COPD was determined on the basis of the most recent spirometry conducted after administration of a bronchodilator in accordance with the relevant GOLD guidelines and the 2006 guidelines of the Polish Respiratory Society.

Patients who were considered unable to fulfill the study requirements by the investigator were excluded from the study.

The survey used in the study consisted of 2 parts. Part 1 covered the patient’s demographic data and general COPD-related data, and was completed during or directly after the patient interview. Part 1 included questions on the symptoms that had prompted the patient to seek medical attention, as well as on smoking, medications, frequency of doctor visits, and the severity of dyspnea (Medical Research Council scale). Part 2 consisted of the EQ-5D questionnaire (page 2 of the survey) in the form of a sheet to be completed by the patient.

EQ-5D is a standardized, well-characterized instrument for assessing the course of health processes. One of the components of EQ-5D is self-assessment, which involves describing health state in 5 aspects: mobility, self-care, everyday activities, pain (discomfort and anxiety), and depression. Each of these aspects is assigned 3 degrees of severity perceived by the patient (limitations). The other component of EQ-5D is intended for the assessment of health parameters using a visual analogue scale (VAS) in the form of a 20-cm vertical line where the endpoints are labeled the “best imaginable health state” (at the top of the scale) and the “worst imaginable health state” (at the bottom of the scale). These extremes are assigned numeric values of 100 and 0, respectively. Such questionnaire has already been used in patients with COPD and was also validated in the Polish population.

No extra data input was made. The percentages in the tables concern the total number of the available values. Categorical variables were characterized by their frequencies and percentages, while continuous variables were presented as means, standard deviations, minimum and maximum values. To verify the correlation between variables a $\chi^2$ test was applied. The differences of dependent variables in the 2 groups were verified by means of a $t$-test for independent samples. The verification of differences between $k$-groups ($k >2$) for dependent variable expressed on a quantitative scale was conducted using the one-way analysis of variance (ANOVA). Post-hoc tests were used for the multiple comparison of differences between the individual groups.
The effect of dependent variables on continuous variable was verified by means of the regression model using dichotomous and continuous predictor. We chose a 99% 2-tailed confidence level. All statistical analyses were performed using Statistica 9.0 PL (StatSoft, Inc. 2010. STATISTICA v. 9.1., www.statsoft.com).

Because the study was purely observational and was not associated with any medical intervention or did not violate the privacy of patients, who participated voluntarily, we did not apply for permission to any ethical committee.

### RESULTS

A total of 9310 patients with COPD were enrolled into the study, but the QoL data were obtained from 8537 patients (records provided without the answers to the question on severity of COPD or VAS reading or the EQ-5D questionnaire were excluded).

Thus, the subsequent analysis involved the group of 8537 patients. The mean age was 64.41 ±9.86 years. Men constituted 64% of the study population. The duration of COPD at baseline was 8.95 ±6.87 years (ranging from 0 in newly diagnosed patients to 61 years). The association between COPD and occupation was declared by 503 patients.

The majority of patients in the study population had moderate disease (4603; 53.9%). Severe (2265; 26.5%) and very severe (327; 3.8%) COPD was present in less than one third of the study population. Mild stage of the disease was detected in 1342 respondents (15.7%).

The majority of patients had already been treated for COPD at baseline. The most common drugs were long-acting β₂-agonists and short-acting anticholinergics. More than half of the patients were on long-term inhaled glucocorticosteroids and a similar percentage of patients used theophylline derivatives. The study population included 106 patients receiving home oxygen therapy (1.2%). The percentage of patients treated with particular drug classes (some of the patients were using more than 1 agent; 8537 subjects = 100%) are summarized in Table 1.

Smoking, a common risk factor for the development and progression of COPD, was reported by 91% of the patients (46% of the patients were current smokers during the study). The average exposure among smokers was about 30 pack-years.

Dyspnea was the most common symptom that had prompted patients to seek medical attention and was reported as the most important symptom that led to the diagnosis of COPD (53.6%). Cough as the major symptom was reported by 38.2% of the patients. Expectoration was a significant problem for 7.9% of the patients. Wheezing was reported by 6.0% of the patients. Other, nonspecific symptoms resulting in the diagnosis of COPD were reported by a mere 0.7% of the patients.

The most troublesome symptoms prompting patients to start treatment was dyspnea (reported by 66.3% of the patients) and cough (26.7% of the patients). Expectoration and wheezing prompted 6.4% and 3.1% of the patients, respectively, to start treatment.

Exacerbations, defined as requiring antibiotic or systemic steroid therapy in the past 12 months, were reported by 6677 (78.2%) and 3608 (42.3%) of the respondents, respectively. In 3014 cases (35.3%), 1 or more hospitalizations were observed in the preceding year. The frequency and intensity of contacts with health care professionals and services were proportionate to the severity of the disease assessed on the basis of the clinical status and spirometry. Figure 1 summarizes the mean annual values related to the numbers of medical visits, emergency services received, hospitalizations for exacerbations, and courses of antibiotics and systemic glucocorticosteroids (online supplement, Table 1).

At least 1 coexisting disease was reported by 6422 patients (75.2%); in 47.1% of the cases cardiac disorders (heart failure, ischemic heart disease, or arrhythmias) were reported as comorbidity. Detailed data on the rate of comorbidities (heart failure, ischemic heart disease, cardiac arrhythmias, other cardiovascular diseases, endocrine disorders, gastrointestinal disorders, kidney/urinary tract disorders, other diseases) are presented in Table 2.

Responses to the EQ-5D questions according to COPD stage are summarized in Figure 2 (descriptions of individual categories reflect exactly the responses from the form describing the severity of symptoms in a given aspect). The exact numeric values are provided in the online supplement.
(2) – I have moderate pain or discomfort
(2) – I have some problems with performing my usual activities
(3) – I am extremely anxious or depressed

The most common patterns were 22222 (17.7%) and 11111 (15.8%) suggesting moderate or no limitations, respectively. The remaining patterns were much less common (online supplement, Table 7).

After responding to the questions, patients were asked to place a mark on the VAS reflecting their perceived health state, where 0 meant the “worst imaginable health state” and 100 meant the “best imaginable health state”. The results are summarized in Figure 3.

Detailed data on VAS responses are provided in Table 3. The differences between the responses in the subgroups of disease severity were statistically significant (ANOVA, $F[3.8533] = 1280.605; P < 0.001$). Post-hoc tests (comparisons in twos with correction for Bonferroni’s multiple comparisons) showed significant differences between every individual group – classification of COPD.

Patterns in which the predominant number was “1” corresponded to the VAS scores of 64 or more. Patterns in which the predominant number was “2” and in which none of the 5 aspects were rated “3” corresponded to the VAS scores ranging from 47 to 63. The occurrence of “3” in any of the 5 aspects was associated with much lower VAS scores (below 38). The most common patterns of responses with the VAS results are presented in the online supplement (Table 8).

Of note, the perceived health state did not differ significantly between the particular domains of life affected by the disease (e.g., patients with patterns 11212 and 21211 reported similar perceived health states with the VAS scores of 63.62 and 63.42, respectively). It may also be concluded that patients with pattern 21221 (a mean VAS score of 60.75) perceived their health state twice
showed that certain states had extremely high importance in the description of the sample (and population). The implemented model matched the data $F(11.8525) = 782.817, P < 0.001$ with the constant value of 77.075 $t(8525) = 258.091, P < 0.001$ and explained 50% of the variance of dependent variable. The comparison of standardized $\beta$ coefficients showed the highest negative effect of moderate/severe occurrence within “mobility” – M2 ($\beta = -0.176$), “usual activities” – UA2 ($\beta = -0.171$) and “anxiety/depression” – AD2 factor ($\beta = -0.174$). Interestingly, the lowest effect was shown by the “pain or discomfort” factor ($\beta = -0.079$).

A regression analysis allowed us to establish a statistically significant relationship describing the association between the EQ-5D results and VAS scores. Abbreviations and classification for descriptive variables according to specific answers were adopted (details in the online supplement) and after the variables had been recoded, the regression model was tested. The methodology and results are described in the online supplement (Tables 9, 10).

Research on EQ-5D showed that certain states had extremely high importance in the description of the sample (and population). The implemented model matched the data $F(11.8525) = 782.817, P < 0.001$ with the constant value of 77.075 $t(8525) = 258.091, P < 0.001$ and explained 50% of the variance of dependent variable. The comparison of standardized $\beta$ coefficients showed the highest negative effect of moderate/severe occurrence within “mobility” – M2 ($\beta = -0.176$), “usual activities” – UA2 ($\beta = -0.171$) and “anxiety/depression” – AD2 factor ($\beta = -0.174$). Interestingly, the lowest effect was shown by the “pain or discomfort” factor ($\beta = -0.079$).
To investigate the effect of sex, age, smoking habits, the number of comorbidities, and stage of COPD (severe/nonsevere) on the health state determined by the VAS from 0 to 100, a linear regression analysis was performed. The proposed model explained 35.3% of the variance of the dependent variable – the assessment of the health state. The linear model was a good fit to the data (F(5.1502) = 163.938, \( P < 0.001 \)) and post-hoc tests showed a noticeable and appreciable effect of current smoking on the health state of patients with COPD. In each case, the relationship between the other predictors and the dependent variable was significant and negative. The greatest effect on the health state was observed for severe or very severe stage of COPD (β = –0.448). The weakest predictor in the model was the number of comorbidities (β = –0.139).

Patients with a history of exacerbations (who required antibiotic or steroid treatment during the past 12 months) marked significantly lower values on the VAS scale compared with patients without exacerbations (56.7 ±18.9 vs. 64.3 ±21.6, respectively) (t(2483.196) = 13.364, \( P < 0.001 \)).

**DISCUSSION**

To our knowledge, this is the first study on the QoL in patients with COPD in Poland conducted on such a large scale. The study showed a noticeable and appreciable effect of COPD on the perceived health state of patients, even of those with mild disease. The study group was numerically representative for COPD patients. The distribution of disease severity differed slightly from the results of population studies conducted in Poland, although the percentage of patients with severe and very severe disease was similar to that observed in other studies involving this population. The great majority of patients (91%) were smokers, which is a risk factor for the development of COPD. The remaining 9% were nonsmokers and were included in the study due to the symptoms of irreversible airway obstruction, exposure in the workplace, and lack of asthma symptoms. Nearly 6% of the patients reported a link between their occupation and the development of COPD, although the design of the survey did not allow us to investigate this issue more thoroughly (no objective risk markers in the workplace).

The management of COPD in the study population involved mainly bronchodilators. Two

### TABLE 3: Visual analogue scale scores

| Severity of COPD | n  | min | max | mean | lower limit of the 95% CI for the mean | upper limit of the 95% CI for the mean | SD   |
|------------------|----|-----|-----|------|----------------------------------------|----------------------------------------|------|
| mild             | 1342 | 0   | 100 | 73.04 | 72.16                                  | 73.92                                  | 16.357 |
| moderate         | 4603 | 0   | 100 | 60.12 | 60.08                                  | 63.03                                  | 16.447 |
| severe           | 2265 | 0   | 90  | 45.56 | 43.89                                  | 45.22                                  | 16.072 |
| very severe      | 327  | 0   | 90  | 32.05 | 30.19                                  | 33.91                                  | 17.062 |

"0" means “the worst imaginable health state” and 100 “the best imaginable health state” (the analysis of variance, F(3.853) = 1280.605; \( P < 0.001 \)).

Abbreviations: CI – confidence interval, others – see FIGURE 1 and 3
thirds of the patients were using long-acting β₂-agonists and a similar percentage of patients were using short-acting anticholinergics. It is surprising that nearly half of the patients were on long-term treatment with inhalation glucocorticosteroids and methylxanthine derivatives, because only 30% of the patients were diagnosed with severe COPD, which is an indication to receive such treatment, according to the guidelines that were in force at the time of the study (GOLD 2007–2009). There were no patients using a long-acting anticholinergic (tiotropium) in the study population. We excluded these patients because one of the objectives of the study was to assess the comfort of living in patients who did not receive this medication, and possibly make future comparisons with patients receiving tiotropium. This may explain a relatively high percentage of patients using a short-acting anticholinergic.

Dyspnea was reported as the symptom that was the most troublesome and that prompted patients to seek medical attention. Cough and expectoration were reported much less frequently. This explains why mild COPD, in which cough predominates and dyspnea usually develops only during forceful exercise, was a rare diagnosis in the study population.

Health care resource utilization, expressed by the frequency of medical visits, hospitalizations, and necessary pharmacological interventions (courses of antibiotics and systemic glucocorticosteroids), increased with the severity of the disease. Of note, even patients with mild-to-moderate disease required treatment with antibiotics and glucocorticosteroids at least once a year, most probably due to exacerbation of the underlying condition, which is also consistent with the observed epidemiology of COPD exacerbations. However, the proportion of patients who required treatment with antibiotics was surprisingly high (78%).

The analysis of the 5 domains of living with EQ-5D showed an increase in perceived discomfort with the increasing severity of the disease. Even in mild disease, which is commonly ignored both by patients (due to low severity of symptoms) and by doctors (due to only minor impairments of lung function with FEV₁ >80% predicted), we observed a deterioration in the comfort of living in nearly one third of our patients, which mostly concerned the ability to walk about, discomfort, and anxiety.

In the group of patients with moderate COPD, nearly half declared some degree of limitation of physical activity caused by the disease and associated discomfort. Also the mean VAS scores represented two thirds of the maximum scores possible, which means that these patients’ well-being was far from ideal. This is consistent with the studies which showed that even in patients with milder disease the phenomenon of dynamic hyperinflation is present and worsens during slight exertion associated with usual activity.

This supports the need for bronchodilator treatment, which reduces this phenomenon in these cases and improves patients’ well-being by increasing their exercise tolerance.

Patients with very severe COPD significantly more commonly reported problems in the domains associated with physical activity (walking about, self-care, usual daily activities), which was not always paralleled by a proportionate deterioration in discomfort or depression. This results, most likely, from the development of tolerance to the troublesome symptoms in chronically-ill patients with a long duration of illness.

Patients usually declared that the degree of impairment in the examined domains was the same or similar. Among the most common patterns of responses (online supplement, TABLE 8) there were none that would include “1”, “2”, and “3” at the same time. The VAS scores in patients with mild disease ranged from 60 to 90 (mean ± standard deviation). The scores in patients with moderate COPD were on average 10 points lower (with most scores within the range of 46–79, which was nearly identical to the range of FEV₁ values corresponding to this stage of the disease). Between moderate and severe COPD, we observed the highest drop in the VAS scores of 18 on average. Patients with very severe COPD reported the VAS scores that were nearly twice as low compared with patients with moderate disease. The VAS score results in all stages of COPD were similar to those in other countries presented by Fletcher et al.

Severe or very severe stage of COPD was the strongest predictor of low health state; however, the VAS scale results were also dependent on the presence of comorbidities, particularly heart failure. In line with other studies, history of exacerbation was associated with poorer health state.

Limitations of the study The study was conducted using the questionnaire and all information on medical events are derived exclusively from the surveyed patients, and are not supported by the analysis of objective data from medical records or hospital databases (exacerbations, hospitalizations). There were no separate questions about cancer (past or present), and it was not a criterion for exclusion. Database analysis revealed only 52 cases with reported cancer (majority treated in the past). The percentage of respondents with cancer seems to be small enough (0.6%) to exclude it from statistical consideration. We did not have access to the results of spirometry, so it was impossible to verify the quality of spirometry. COPD severity classification was conducted by a doctor who completed the questionnaire, but without giving the exact value of FEV₁ and FEV₁/FVC ratio, so it was not possible to investigate a direct correlation between lung function and the degree of discomfort felt by a patient.
Our results suggest a clear relationship between the perceived deterioration of the health state and the severity of the disease assessed with the objective parameter of FEV₁, by spirometry. The VAS score was also associated with the reported degree of perceived deterioration in the domains of life examined with EQ-5D. Of note, in all domains of life, the general perceived health state was similar if the sum of points in all the responses was similar. When analyzing the most common responses, it may be concluded that the disease limits all domains of life to a similar degree (both those associated with physical exercise and mental discomfort). Of note, also in milder stages of the disease, patients report significant limitations in the various aspects of life.

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REFERENCES

1. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2010. http://www.goldcopd.org/uploads/users/files/GOLDReport_April112011.pdf. September 2011.

2. Zielinski J, Bednarek M, Gorecka D, et al. Increasing COPD awareness. Eur Respir J. 2006; 27: 833-852.

3. Zielinski J, Bednarek M.; Knew the Age of Your Lung Study Group. Early detection of COPD in a high-risk population using spirometric screening. Chest. 2001; 119: 731-736.

4. Nizankowska-Mogilnicka E, Mejia F, Buist AS, et al. Prevalence of COPD and tobacco smoking in Malopolska region-results from the BOLD study in Poland. Pol Arch Med Wewn. 2007; 117: 402-410.

5. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet. 2009; 374: 721-732.

6. Stahl E, Lindberg A, Jansson SA, et al. Health-related quality of life is related to COPD disease severity. Health Qual Life Outcomes. 2005; 3: 56.

7. Bak-Draciak K, Zora D. [Quality of life in chronic obstructive pulmonary disease]. Pneumonol Alergol Pol. 2004; 72: 128-133. Polish.

8. van Schayck CP, Dompeling E, Rutten MP, et al. The influence of an inhaled steroid on quality of life in patients with asthma or COPD. Chest. 1995; 107: 1199-1205.

9. Baeztes E, Geo J, Ferrer J, et al.; PAC-COPD Study Group. Factors affecting the relationship between psychological status and quality of life in COPD patients. Health Qual Life Outcomes. 2010; 8: 108.

10. Voli-Aamerud M, Eagan TM, Plana E, et al. Respiratory symptoms in adults are related to impaired quality of life, regardless of asthma and COPD: results from the European community respiratory health survey. Health Qual Life Outcomes. 2010; 8: 107.

11. Yorgancioglu A, Havluco Y, Celik P, et al. Relation between quality of life and morbidity and mortality in COPD patients: Two-year follow-up study. COPD. 2010; 7: 248-253.

12. Habraken JM, van der Wel WM, Ter Riet G, et al. Health-related quality of life and functional status in end-stage COPD: longitudinal study. Eur Respir J. 2011; 37: 280-288.

13. Jones PW, Brusselle G, Dal Negro RW, et al. Health-related quality of life in patients with COPD severity within primary care in Europe. Respir Med. 2011; 105: 57-66.

14. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2007. http://www.goldcopd.com. Accessed February 2011.

15. [Polish Society of Lung Diseases Guidelines for Spirometry]. Pneumonol Alergol Pol. 2006; 74 (Suppl 1): 1-44. Polish.

16. Fletcher CM, ELMES PC, FAIRBARRN AS, WOOD C. The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population. Br Med J. 1959; 2: 257-266.

17. EQ-5D Value Sets: Inventory, Comparative Review and User Guide. 1st ed. Dordrecht: Springer; 2007.

18. Golicz D, Jakubczyk M, Niewada M, et al. Valuation of EQ-5D health states in Poland: first TTO-based social value set in Central and Eastern Europe. Value Health. 2010; 13: 289-297.
ARTYKUŁ ORYGINALNY

Stan zdrowia i jakość życia chorych na przewlekłą obturacyjną chorobę płuc w Polsce

Badanie z wykorzystaniem kwestionariusza EQ-5D

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SŁOWA KLUCZOWE
EQ-5D, jakość życia, przewlekła obturacyjna choroba płuc

STRESZCZENIE

WPROWADZENIE
Przewlekła obturacyjna choroba płuc (POChP) jest ciężką chorobą, która prowadzi do inwalidztwa oddechowego, znacznie obniża komfort życia oraz wpływa na wszystkie aspekty aktywności pacjenta.

CELE
Celem pracy była ocena jakości życia (quality of life – QoL) u chorych na POChP za pomocą kwestionariusza jakości życia związanej ze zdrowiem, EQ-5D, jako narzędzia badawczego.

PACJENCI I METODY
Przeprowadzono badanie przekrojowe w dużej grupie chorych na POChP (n = 9310). Dane pozyskiwano, stosując opracowany do tego celu kwestionariusz.

WYNIKI
Większość badanej populacji stanowili chorzy na łagodną i umiarkowaną postać POChP (stadium 1 i 2 wg Global Initiative for Chronic Obstructive Lung Disease, odpowiednio 16% i 54%). Wykazano odczuwalne dla chorych pogorszenie jakości życia w każdym stadium choroby, w tym także u pacjentów z łagodną lub umiarkowaną POChP. Stwierdzono istotne różnice między grupami chorych stratyfikowanymi według wyniku badania spirometrycznego dotyczące odczuwanego stanu zdrowia ocenianego za pomocą kwestionariusza i wizualnej skali analogowej (visual analogue scale – VAS), przy czym wyniki EQ-5D korelowały z wynikami VAS. Wykazano statystycznie istotny wpływ chorób współistniejących (zwłaszcza niewydolności serca) i ciężkiej (lub bardzo ciężkiej) postaci POChP na odczuwany stan zdrowia (model regresji liniowej, p <0,001). Pacjenci z zaostrzeniami w wywiadach wskazywali istotnie niższe wyniki na skali VAS (p <0,001).

WNOSKI
Jako się wydaje, kwestionariusz EQ-5D oraz skala VAS to przydatne narzędzia do oceny stanu zdrowia chorych na POChP. Należy podkreślić, że stwierdzono istotne dla chorych ograniczenia dotyczące różnych sfer życia, także w łagodniejszych stadiach choroby.
**ONLINE SUPPLEMENT**

**TABLE 1** Mean annual values of medical events related to chronic obstructive pulmonary disease in groups according to disease severity

|                     | COPD |            |            |            |
|---------------------|------|------------|------------|------------|
|                     | mild | moderate   | severe     | very severe|
| appointed visits    | 4.94 | 5.7        | 3.37       | 7.13       |
| emergency visits    | 2.11 | 2.37       | 2.93       | 3.8        |
| hospitalization     | 1.53 | 1.41       | 1.87       | 2.5        |
| related to COPD     | 1.94 | 2.24       | 3.01       | 3.83       |
| courses of antibiotics | 1.76 | 1.97       | 2.68       | 3.92       |

Abbreviations: COPD – chronic obstructive pulmonary disease

**TABLE 2** Number and percentage of patients reporting problems with mobility

| Mobility                              | COPD |            |            |            | Total |            |            |            |
|---------------------------------------|------|------------|------------|------------|-------|------------|------------|------------|
|                                       | mild | moderate   | severe     | very severe|       | mild       | moderate   | severe     |
| I have no problems in walking about   | n    | 931        | 1584       | 123        | 8     | 2646       |            |            |
|                                       | %    | 69.4       | 34.4       | 5.4        | 2.4   | 31.0       |            |            |
| I have some problems in walking about | n    | 409        | 2999       | 1983       | 194   | 5585       |            |            |
|                                       | %    | 30.5       | 65.2       | 87.5       | 59.3  | 65.4       |            |            |
| I am confined to bed                  | n    | 2          | 20         | 159        | 125   | 306        |            |            |
|                                       | %    | 0.1        | 0.4        | 7.0        | 38.2  | 3.6        |            |            |
| total                                 | n    | 1342       | 4603       | 2265       | 327   | 8537       |            |            |
|                                       | %    | 100        | 100        | 100        | 100   | 100        |            |            |

χ²(6) = 2981.59; P < 0.001

Abbreviations: see **TABLE 1**

**TABLE 3** Number and percentage of patients reporting problems with self-care

| Self-care                          | COPD |            |            |            | Total |            |            |            |
|------------------------------------|------|------------|------------|------------|-------|------------|------------|------------|
|                                    | mild | moderate   | severe     | very severe|       | mild       | moderate   | severe     |
| I have no problems with self-care  | n    | 1222       | 3274       | 550        | 46    | 5092       |            |            |
|                                    | %    | 91.1       | 71.1       | 24.3       | 14.1  | 59.6       |            |            |
| I have some problems washing or dressing myself | n    | 119        | 1304       | 1554       | 165   | 3142       |            |            |
|                                    | %    | 8.9        | 28.3       | 66.6       | 85.5  | 36.8       |            |            |
| I am unable to wash or dress myself| n    | 1          | 25         | 161        | 116   | 303        |            |            |
|                                    | %    | 0.1        | 0.5        | 7.1        | 35.5  | 3.5        |            |            |
| total                              | n    | 1342       | 4603       | 2265       | 327   | 8537       |            |            |
|                                    | %    | 100        | 100        | 100        | 100   | 100        |            |            |

χ²(6) = 3108.7; P < 0.001

Abbreviations: see **TABLE 1**
### TABLE 4  Number and percentage of patient reporting problems with usual activities

| Usual activities (e.g., work, study, housework, family, or leisure activities) | COPD | Total |
|---|---|---|---|---|---|
| | mild | moderate | severe | very severe |
| I have no problems with performing my usual activities | n | 1034 | 2262 | 228 | 17 | 3541 |
| | % | 77.0 | 49.1 | 10.1 | 5.2 | 41.5 |
| I have some problems with performing my usual activities | n | 306 | 2237 | 1551 | 115 | 4209 |
| | % | 22.8 | 48.6 | 68.5 | 35.2 | 49.3 |
| I am unable to perform my usual activities | n | 2 | 104 | 486 | 195 | 787 |
| | % | 0.1 | 2.3 | 21.5 | 59.6 | 9.2 |
| total | n | 1342 | 4603 | 2265 | 327 | 8537 |
| | % | 100 | 100 | 100 | 100 | 100 |

$χ^2 (6) = 3122.012; P <0.001$

Abbreviations: see **TABLE 1**

### TABLE 5  Number and percentage of patients reporting problems with pain or discomfort

| Pain/discomfort | COPD | Total |
|---|---|---|---|---|---|
| | mild | moderate | severe | very severe |
| I have no pain or discomfort | n | 935 | 2091 | 385 | 44 | 3455 |
| | % | 69.7 | 45.4 | 17.0 | 13.5 | 40.5 |
| I have moderate pain or discomfort | n | 402 | 2471 | 1711 | 204 | 4788 |
| | % | 30.0 | 53.7 | 75.5 | 62.4 | 56.1 |
| I have extreme pain or discomfort | n | 5 | 41 | 169 | 79 | 294 |
| | % | 0.4 | 0.9 | 7.5 | 24.2 | 3.4 |
| total | n | 1342 | 4603 | 2265 | 327 | 8537 |
| | % | 100 | 100 | 100 | 100 | 100 |

$χ^2 (6) = 1638.814; P <0.001$

Abbreviations: see **TABLE 1**
### Table 6: Number and percentage of patients reporting problems with anxiety or depression

| Anxiety/depression | COPD | Total |
|--------------------|------|-------|
|                     | mild | moderate | severe | very severe |
| I am not anxious or depressed | n 952 | 2470 | 445 | 45 | 3912 |
|                     | % 70.9 | 53.7 | 19.6 | 13.8 | 45.8 |
| I am moderately anxious or depressed | n 381 | 2040 | 1545 | 194 | 4160 |
|                     | % 28.4 | 44.3 | 68.2 | 59.3 | 48.7 |
| I am extremely anxious or depressed | n 9 | 93 | 275 | 88 | 465 |
|                     | % 0.7 | 2.0 | 12.1 | 26.9 | 5.4 |
| total               | n 1342 | 4603 | 2265 | 327 | 8537 |
|                     | % 100 | 100 | 100 | 100 | 100 |

χ²(6) = 1593.112; P < 0.001

Abbreviations: see Table 1

### Table 7: The most common response patterns (see text for description)

| Response pattern | Number of responses | Percentage, % |
|------------------|---------------------|---------------|
| 22222            | 1514                | 17.7          |
| 11111            | 1352                | 15.8          |
| 21111            | 533                 | 6.2           |
| 21222            | 511                 | 6.0           |
| 21221            | 295                 | 3.5           |
| 22221            | 291                 | 3.4           |
| 21121            | 286                 | 3.4           |
| 21211            | 264                 | 3.1           |
| 21122            | 261                 | 3.1           |
| 11121            | 251                 | 2.9           |
| 22322            | 248                 | 2.9           |
| 11112            | 219                 | 2.6           |
| 21212            | 181                 | 2.1           |
| 11122            | 179                 | 2.1           |
| 21112            | 178                 | 2.1           |
| 22212            | 157                 | 1.8           |
| 22211            | 155                 | 1.8           |
| 11211            | 145                 | 1.7           |
| 11222            | 145                 | 1.7           |
| 11221            | 109                 | 1.3           |
| 22223            | 105                 | 1.2           |
| 11212            | 90                  | 1.1           |
| others            | 1068                | 12.5          |
| Response pattern | n   | VAS (mean) | SEM  |
|------------------|-----|------------|------|
| 11111            | 1352| 77.58      | 0.373|
| 11121            | 251 | 73.08      | 0.790|
| 11112            | 219 | 70.04      | 1.086|
| 21111            | 533 | 69.94      | 0.593|
| 11211            | 145 | 68.64      | 1.072|
| 11122            | 179 | 66.74      | 0.960|
| 11221            | 109 | 66.05      | 1.339|
| 21121            | 286 | 65.24      | 0.757|
| 11212            | 90  | 63.62      | 1.564|
| 21211            | 264 | 63.42      | 0.814|
| 22121            | 62  | 63.19      | 1.574|
| 21112            | 178 | 62.82      | 1.038|
| 22111            | 50  | 62.50      | 2.098|
| 21221            | 295 | 60.75      | 0.790|
| 21122            | 261 | 58.89      | 0.848|
| 11222            | 145 | 58.47      | 1.421|
| 22211            | 155 | 56.88      | 1.224|
| 21212            | 181 | 55.54      | 0.991|
| 22221            | 291 | 53.86      | 0.796|
| 21222            | 511 | 52.57      | 0.638|
| 22222            | 63  | 52.32      | 1.708|
| 22222            | 1514| 48.08      | 0.368|
| 22212            | 157 | 46.78      | 1.291|
| 22322            | 248 | 37.67      | 0.807|
| 22332            | 34  | 35.88      | 2.523|
| 32322            | 37  | 33.16      | 1.540|
| 22223            | 105 | 32.92      | 1.270|
| 22323            | 63  | 32.41      | 1.509|
| 23322            | 40  | 30.03      | 1.634|
| 22333            | 38  | 29.86      | 2.881|

Abbreviations: SEM – standard error of the mean, VAS – visual analogue scale
### Table 9: Regression model: an assessment of the associations between EQ-5D responses and visual analogue scores

| Model | Unstandardized coefficients | Standardized coefficients | t     | Sig.  |
|-------|-----------------------------|---------------------------|-------|-------|
|       | B   | SEM  | β    |       |       |
| (constant) | 77.075 | .299 | 258.091 | .000 |
| M2     | -7.487 | .399 | -.176 | -18.775 | .000 |
| M3     | -4.681 | 1.056 | -.044 | -4.432 | .000 |
| SC2    | -5.214 | .414 | -.130 | -12.604 | .000 |
| SC3    | -6.152 | 1.072 | -.058 | -5.739 | .000 |
| UA2    | -6.856 | .408 | -.171 | -16.792 | .000 |
| UA3    | -5.733 | 1.003 | -.084 | -5.716 | .000 |
| PD2    | -3.159 | .377 | -.079 | -8.377 | .000 |
| PD3    | -3.560 | .986 | -.033 | -3.611 | .000 |
| AD2    | -6.868 | .368 | -.174 | -18.860 | .000 |
| AD3    | -7.597 | .915 | -.088 | -8.300 | .000 |
| N3     | -3.716 | 1.022 | -.063 | -3.635 | .000 |

Abbreviations: see Table 8

The following abbreviations and classification for descriptive variables have been adopted:

- **M2** = 1 if the response to the question about mobility was ≥2 and 0 if another response was provided
- **M3** = 1 if the response to the question about mobility was ≥3 and 0 if another response was provided
- **SC2** = 1 if the response to the question about self-care was ≥2 and 0 if another response was provided
- **SC3** = 1 if the response to the question about self-care was ≥3 and 0 if another response was provided
- **UA2** = 1 if the response to the question about usual activities was ≥2 and 0 if another response was provided
- **UA3** = 1 if the response to the question about usual activities was ≥3 and 0 if another response was provided
- **PD2** = 1 if the response to the question about pain/discomfort was ≥2 and 0 if another response was provided
- **PD3** = 1 if the response to the question about pain/discomfort was ≥3 and 0 if another response was provided
- **AD2** = 1 if the response to the question about anxiety/depression was ≥2 and 0 if another response was provided
- **AD3** = 1 if the response to the question about anxiety/depression was ≥3 and 0 if another response was provided
- **N3** = 1 if any response was 3 and 0 if another response was provided

After the variables had been re-coded as follows, the regression model was tested.

It was shown that the descriptive values significantly affected (were related to) the VAS scores describing health state (well-being). The following table shows the estimated values on the basis of the model and allows for a comparison with the actual values obtained in the study population.
### TABLE 10  Mean visual analogue scale scores in the study population and in the regression model

| Combinations of highest importance | N  | Mean (estimation from data) | Mean (estimation from regression model) | Difference |
|-----------------------------------|----|-----------------------------|----------------------------------------|------------|
| 11112                             | 219| 70.041                      | 70.207                                 | −0.2       |
| 11113                             | 4  | 63.750                      | 58.894                                 | 4.9        |
| 11121                             | 251| 73.076                      | 73.916                                 | −0.8       |
| 11131                             |    |    | 66.64                    | −          |
| 11133                             |    |    | 52.175                  | −          |
| 11211                             | 145| 68.641                      | 70.219                                 | −1.6       |
| 11312                             |    |    | 53.902                  | −          |
| 12111                             | 23 | 66.739                      | 71.861                                 | −5.1       |
| 13311                             |    |    | 49.404                  | −          |
| 21111                             |    |    | 69.588                  | −          |
| 22222                             | 1514| 48.082                     | 47.491                                 | 0.6        |
| 23232                             | 6  | 48.667                      | 34.063                                 | 14.6       |
| 32111                             |    |    | 49.121                  | −          |
| 32223                             | 3  | 29.333                      | 31.497                                 | −2.2       |
| 32313                             |    |    | 28.923                  | −          |
| 33223                             | 27 | 21.148                      | 19.612                                 | 1.5        |
| 33333                             | 67 | 15.731                      | 16.052                                 | −0.3       |