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COPD in Ukraine: overview of the status and prospects for improvements and developments in health care system

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ABSTRACT

Chronic Obstructive Pulmonary Disease (COPD) is an actual problem for healthcare systems in different countries taking in account it`s high morbidity, mortality, impact on quality of life and related costs. COPD in Ukraine could be one of the most valuable medical and socio-economic problems as for developing country, the human capital affected by COPD is the most important national asset. The access to drugs is critical especially for COPD patients, medications for basic therapy are very expensive, while intended for use permanently. This study was performed to investigate the status with COPD in Ukraine and determine possible ways for improvements and developments in COPD management and related processes in healthcare system in Ukraine. The following areas were investigated: epidemiological data, data in COPD management, health economics data and targeted literature review. Results showed that very limited epidemiological COPD data are available in Ukraine. There are favorable conditions for good COPD management in Ukraine because of availability of the adopted guidance and the unified clinical protocol that cover prophylaxis, diagnostics, treatment and rehabilitation of COPD patients. Ukrainian clinical guidance in COPD management has external validity and is expected to be updated on regular basis. There were several country-specific Health Economic studies focused on COPD but these studies have limitations due to substantial assumptions and extrapolations from small to large populations. More Health Economics large-scale studies needs to be performed in Ukraine. Results of current study, also, showed that COPD is a relevant topic for pulmonology research in Ukraine.

BACKGROUND

To investigate the status of COPD in Ukraine and determine possible ways for improvements and developments in COPD management and related processes in healthcare system in Ukraine.

METHOD

Overview of the following data was performed: data from Ukrainian epidemiological statistical reports and studies in COPD, health care legislative documents for COPD management, literature publications in international scientific database.

Search strategy: e-search was performed using the following key words and word combinations in Ukrainian and English languages: COPD in Ukraine; COPD prevalence in Ukraine; COPD morbidity in Ukraine; COPD mortality in Ukraine; health care for COPD patients in Ukraine; COPD costs in Ukraine.

Resources for e-search: Informational Portal of the Ministry of Health of Ukraine (https://www.moz.gov.ua/ua/portal/); web-database in healthcare standards of the State Expert Center of Ministry of Health of Ukraine (http://www.dec.gov.ua/mtd/index.html); web-database of the National Institute of Phthisiatry and Pulmonology (http://www.ifp.kiev.ua/index_ukr.htm); Ukrainian governmental legislative portal (http://zakon4.rada.gov.ua/laws); Embase (http://www.embase.com/).

Search period: 8-20 May 2015.
Search depth: Five full-scale years (2010-2015).

In addition, with the aim to assess the level of topicality and importance of the problem with COPD in Ukraine the targeted literature review was performed. For this purpose the "Ukrainian Pulmonology Journal" was selected as the web-database with the most relevant Ukrainian publications in pulmonology science in Ukraine. This journal is the only one that is selectively specialized in pulmonology area in Ukraine. Journal is established by the National Institute of Phthisiatry and Pulmonology n.a. V. Komisarenko. This institute is the core scientific institution of Ukrainian healthcare in phthisiatry and pulmonology. Search period: 1-2 June 2015. The search depth of three full-scale years (2012-2015) was selected with the aim to review and analyze the topics and key results of the recent publications are being considered as actual for today. Scope of search included results of the cost, economic, epidemiology and clinical studies.

RESULTS

Epidemiological data

The first official data on COPD prevalence, morbidity and mortality were introduced in 2010. It was 2009 report of the National Center of Medical Statistics had been created from 2009 data. Report was followed by the 2010 prevalence data in 2011. These reports are cumulative and included case data from the state (public) healthcare institutions (data from private healthcare providers were not included). COPD patient registries are not established in all state healthcare institutions in Ukraine, so statistical reports do not contain data from patient registries.

Unfortunately, no official reports were published after 2011 until now. Nevertheless, the presented reports did not contain the disease-related information on number of specialists' consultations (outpatient visits), number of disability days and hospitalizations frequency and lasting. According to the data from the National Center of Medical Statistics of the Ministry of Health of Ukraine (MoH), in 2009 the COPD prevalence was about 0.9% in Ukraine. The

number of COPD cases in population aged 18 and over was 377 267 with prevalence 998.70 for 100 000 population. In 2009 there were 29 928 first-diagnosed COPD cases. Average lasting of COPD hospitalization was 12.57 days with hospital mortality rate 0.88 for 100 000 [1]. In 2010 the National Center of Medical Statistics registered 420 083 COPD cases in population aged 18 and over.

According to opinion of the Ukrainian leading pulmonologists, COPD is under-diagnosed in Ukraine and it`s prevalence rate could reach 6% in general adult population [11]. Thus number of COPD patients in Ukraine could reach 1 930 000 patients.

Some epidemiological data were obtained from the prospective modeling for 2012-2020 are available in literature [8]. 2012-2020 dynamics of the key socioeconomic and COPD-related epidemiological indicators for general Ukrainian population were modeled based on data collected from MoH reports and data from World Health Organization (WHO). The best fit (least square) linear regression forecast was applied for that modelling. Results showed that in general population number of COPD patients could reach 1 731 332 in 2020. Cumulative 2012-2020 number of new COPD cases and COPD related deaths could be 1 230 750 and 56 207, respectively.

Data in COPD Management

COPD patients are being managed in Ukraine by GPs and Pulmonologists on outpatient and hospital levels of medical care. Management of COPD in Ukraine is regulated by the decree of MoH 555 from 27 Jun 2013 "About the approval and implementation of medical and technological documentation in standardization of medical care in Chronic Obstructive Pulmonary Disease". This decree implemented the adopted clinical guidance "Chronic Obstructive Pulmonary Disease" and unified clinical protocol of primary, secondary, tertiary (highly specialized) medical care and rehabilitation "Chronic Obstructive Pulmonary Disease". This decree required that the unified clinical protocol to be adopted locally in health care institutions throughout the Ukraine.

Clinical guidelines were adopted by Ukrainian multidisciplinary work group mostly from the following documents:

- GOLD (Global Initiative for Chronic Obstructive Lung Diseases (updated 2011))

- NICE 101 (Chronic obstructive pulmonary disease. Management of COPD in primary and secondary care (Jun 2010)).

Adopted guidance covers COPD diagnostics, management of stable COPD and exacerbation management. In addition, this document states the key measures to be implemented in healthcare system such as:

- diagnostic in age group over 35 years with appropriate clinical symptoms;
- confirmation of bronchial obstruction with post-bronchodilator spirometry;
- open access for spirometry;
- smoking cessation;
- treatment with effective bronchodilators;
- access to lung rehabilitation for any patient who needs it;
- usage of non-invasive ventilation in cases of COPD exacerbations with sustain lung hypercapnic insufficiency;
- appropriate exacerbation prevention (decrease the exacerbation frequency with inhaled corticosteroids, bronchodilators and vaccines) and adequate management (minimization of injury from exacerbation with: advises for early self-reporting of symptoms by patients; start of appropriate oral corticosteroids and/or antibiotics; use of non-invasive ventilation; inpatient-outpatient care combinations and early discharges);
- treatment by the multidisciplinary specialists.

Unified clinical protocol was created based on adopted clinical guidance for the following expected users: physicians, nurses and doctor-assistants, healthcare decision makers, patients and patient-support groups, authorized organizations and service providers. The aims of the protocol are: to ensure the quality, efficiency and access to medical care of COPD patients, according to evidence based medicine principles; to establish unified requirements for prophylaxis, diagnostics, treatment and rehabilitation in accordance with the guidance created with evidence based approach; to justify the human and material resources for healthcare institutions; to determine indicators for medical care quality assessment with the purpose of monitoring and audits of healthcare institutions. Date of creation: May 2013. Planned revision date: May 2016. Protocol

defines obligatory and desirable measures to be performed by healthcare professionals with appropriate justifications and reference to the adopted clinical guidelines.

Health Economics data

Some studies to determine socio-economic impact of COPD in Ukraine were performed by members of Ukrainian chapter of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). They were obtained in result of the literature e-search and are described below.

COPD data collection study with the Cost of Illness analysis were performed as a pilot project [9, 19]. Multi- center retrospective analysis (data from 12 months) of medical records (90%) and subjects' interview-lists (10%) was performed in three regions of Ukraine. Target population included patients with II-III severity stage COPD. The main objective was to collect data is required for direct and indirect costs calculation: medical care (including routine practice for treatment) and services utilization data (Table 1). Tariffs for COPD related medical services were collected from the state (public) health care institutions. For tariffs, medians were calculated due to presence of outlier values and skewed data distribution (Table B). In result, total (direct + indirect) COPD costs were calculated for 2011. Direct costs included outpatient costs, hospitalization and inpatient care costs. Indirect costs included productivity loss (taxes from the lost average annual personal income and lost average annual income of companies) and disability compensations. Costs were calculated for 377 267 COPD patients from "Economically-active" age group by multiplying of cost units (Table 2) with the corresponding discounts.

Table 1.
Results of retrospective analysis of COPD related data from Ukrainian healthcare

Mean number of GP visits per 12 months (±SD)	2.63 (±1.45)
Mean number of Pulmonologist visits per 12 months (±SD)	1.18 (±1.1)
Number of lost working days due to COPD per patient, per 12 months	12.63
Frequency of COPD-related hospitalizations	0.53
Average duration of COPD-related hospitalization (days)	12.75

Table 2.
Direct costs units (tariffs) and indirect cost units (2011)

Unit	Price, €
GPs or specialists visit	0.61
Spirometry	3.59
Chest X-ray	4.17
Complete Blood Cells	2.92
ECG	2.27
Bacteriological Sputum Analysis	7.21
Hospital service (per person, per day)	11.52
1 lost working day	0.19
Disability compensation (per person, per day)	5.12
Annual Productivity loss because of presentism* (per person)	20.84

Total annual COPD costs were estimated as € 38 870 506 (€ 103.03 per patient) with € 28 448 213 (73.80% from total) direct medical costs and € 10 422 293 (26.20% from total) indirect costs in Ukraine.

The assessment of 2012 and projected 2020 COPD-related direct and indirect costs was performed [8]. Result showed that in 2012 in Ukraine direct COPD costs could be in 68.57% higher than indirect COPD costs and could reach € 326 367 598 vs. € 193 607 579.90, respectively. In 2020 indirect COPD costs may 1.47% exceed the direct costs and may reach € 496 997 427.80 vs. € 489 796 409, respectively. So, COPD-related productivity loss is expected to increase due to expected increase of economically active population proportion in general Ukrainian population.

Cost Benefit Analysis for salmeterol and tiotropium compared to standard intervention mix (routine practice of GPs) in economically active population with COPD was performed [10]. Results showed that per 1000 employed economically active COPD patients total annual COPD costs could reach € 498 052.34, € 441 697.07 and € 508 983.73 for usual COPD treatment practice of GPs, salmeterol and tiotropium, respectively. Reduction of annual exacerbation-related COPD costs compared to usual practice could amount €85 698.78 for salmeterol and € 114 380.78 for tiotropium per 1000 economically active COPD patients. Cost-benefit ratio for salmeterol calculated as 5.15 and for tiotropium as 4.45. Results of sensitivity analysis showed that in case of 27 % price drop salmeterol could become to be more beneficial than tiotropium.

Targeted literature review

The Ukrainian Pulmonology Journal reflects the whole spectra of scientific interests on Ukrainian pulmonology field. Articles had been published in 2012-2015 time-period were reviewed and sorted based on disease specificity (Table 3).

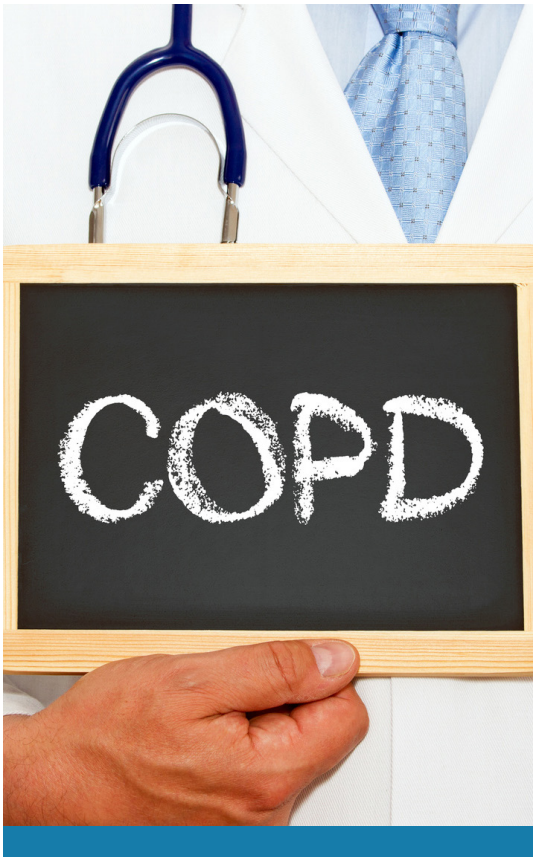

Table 3.
2012-2015 publications in Ukrainian Pulmonology Journal

Disease	2015/Q1	2014	2013	2012	Total
TBC	2	25	5	6	38
COPD	3	34	8	25	70
Sarcoidosis	1	3	1	-	5
Pneumonia	1	8	10	9	28
Asthma	3	6	2	10	21

The majority of articles (70 in total) are related to COPD as primary topic. Key messages/results from the articles have been written by lead Ukrainian experts in pulmonology are briefly described below:

Y. Feschenko noted [11] that according to official statistics, prevalence of COPD in Ukraine is about 1% of, but, according to local epidemiological studies, the prevalence of COPD in Ukraine can reach 6%. The main cause of this discrepancy of data is the low rate of early-diagnosed cases.

On the other hand, Y. Mostovoy presented data, according to which, the cause of prevalence data discrepancy could be inconsistencies in the forms of statistical reporting in inpatient and outpatient treatment levels of healthcare system [12].

T. Pertseva et al. [13] found that inflammation markers – cytokines and thromboxanes play an important role in the occurrence and development of COPD. Among them promising for the study is a factor lipoxins A4 as a marker of anti-inflammatory reserves of an organism.

N. Gorovenko et al. investigated the polymorphic marker for of adrb2, nr3c1, mdr1 genes relation with improvement of ICS/LABA therapy effect in COPD patients. Method could be used for prediction of ICS/LABA treatment efficiency in COPD patients [14].

L. Yudina in the study considered the antibiotics should be used for infectious COPD exacerbation. Author concludes that ciprofloxacin should be the medication of choice in cases of severe infectious COPD exacerbation with risk of P. aeruginosa colonization [15].

Current status and trends of disability of workable age population due to COPD and asthma is presented in the study of V. Shevchuk, et al [16]. In the conclusions authors stated that the average level of disability due to COPD in workable age population was 1.4 times lower than in Asthma. Analysis of disability due to COPD and Asthma revealed the lack of modern evidence-based health and social rehabilitation programs.

The article of K. Gashynova [17] provides factors that determine the prognosis of COPD. They are: the presence of systemic manifestations of the disease and comorbidities. Concomitant diseases increase the risk of hospitalization and death, increase the cost of medical care for such patients and reduce the quality of life. It was stated by the author that the majority (83.90%) of patients with COPD suffered from at least one concomitant disease. The most common comorbid conditions were cardiovascular diseases.

At the same time, A. Dovgan et al. [18] stated that COPD was associated with a development of somato-psychic disturbances – frequent neurosis 79.70%, reactive anxiety 41.80%, personal anxiety 76.70% and depression 23.30%.

DISCUSSION

For today in Ukraine, there is no appropriate COPD epidemiological statistical regular data that could be used to represent sufficiently the current COPD status in Ukraine [1,11,12]. Results of modeling could be used [8] but these data could have substantial level of uncertainty. Therefore, today, it is possible to perform only approximate assessment of prevalence morbidity and mortality levels when make the decisions in health care system in Ukraine. In addition, regular data about healthcare COPD-related resource utilization and tariffs for related medical services are not available and could be obtained

from the surveys or targeted analyses [9,19]. It could be useful to change the statistical datasets in regular reports with the purpose of support decision makers with the information required for efficient decisions on different levels of Ukrainian healthcare system.

To make clinical decision within the COPD management healthcare professionals in Ukraine have the adopted guidance and the unified clinical protocol as the tools are being powered by legislation. That documents are directly related to guidelines are being used throughout the world. Therefore, evidence-based part of prophylaxis, diagnostics, treatment and rehabilitation measures for COPD patients in Ukraine, in general, comply with other European countries.

The first economic assessment showed that total annual COPD costs in 2011 were estimated as € 38 870 506 (€ 103.03 per patient) with majority of direct costs 73.80% from total [8]. Results from cost study "Economic analysis of the Confronting COPD survey" was performed in U.S.A., Canada, the U.K, Spain, Italy, France and the Netherlands were published in 2003 [20]. In this study total per patient societal COPD costs ranged from $5646 in the U.S.A. to $1023 in the Netherlands. In all countries, except the France, direct costs dominated. The Countries had a particularly high proportion of indirect costs were the following: France, the Netherlands and the U.K., with 67%, 50% and 41% from overall costs, respectively. Compare to developed countries, Ukraine, as a country that is under developing, has lower incomes rates and lower rates of prices and tariffs. As result, there is substantial difference between per patient COPD-related costs between Ukraine and EU countries, U.K., USA, Canada.

The health economic studies on COPD [8,9,10,19] are only starting and need to be developed now in Ukraine. The importance of those studies is extremely high. Results of Cost of Illness studies could valuate the losses related to COPD in money equivalent. Cost-Benefits analyses and Budget Impact analyses will show the possible benefits from purposeful implementation of different health technologies and will help to understand the real needs for reimbursement. However, conducting of costs studies requires appropriate datasets, which to be specific for Ukraine. Economic appraisals have been performed before [8,9,10,19] used substantial amount of assumptions and extrapolations from small to large populations. On the other hand, the cost structure and information collecting approaches were developed and implemented could be used as methodological basis for further studies.

Analysis of the specific publications showed that COPD is under active research in Ukraine. Large number of original publications on the epidemiology, pathogenesis, diagnostics, treatment and prevention of this disease are available for review. The lead Ukrainian experts in pulmonology are actively involved in research process [1,2,11-18]. Taking in account the majority in pulmonological disease-related publications, we can conclude that the problem of COPD in Ukraine is one of the most important in pulmonology. This indicates that COPD is not only a medical problem, but also social and economic. Today, scientists are looking for modern and effective methods for the treatment and diagnostic of COPD. Increase of COPD prevalence makes clinical, social and economic impact onhealth care system of Ukraine. Moreover, from publications we can see that COPD in Ukraine represents an enormous health problem for the community, affecting patients, state budget, employment sector, institutional network and hence society as a whole.

CONCLUSIONS

Statistical reports in Ukrainian Health care system should be changed with the aim to support healthcare professionals with COPD-related epidemiological and healthcare resource utilization information. These changes could increase the efficiency of COPD-related decisions in Healthcare system of Ukraine;

Ukrainian clinical guidance in COPD management has external validity and is expected to be updated on regular basis;

More Health Economics large-scale studies need to be performed in Ukraine. It will support healthcare system with important information and can help to establish reimbursement for COPD basis-drugs and improve patient's access to treatment.

COPD is actual problem for Ukraine that was confirmed by analysis of COPD-related publications in highly specialized Ukrainian scientific journal.

LIMITATIONS

Current review was performed using the e-search. Documents and articles were not published officially or were issued only on paper source are out of scope of current review. Literature search for 2015 year included only articles were published within the 1st quarter 2015. Journals specialized in internal medicine specialties other than pulmonology were not included in literature review.

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