COPD Czech National Research Database of COPD

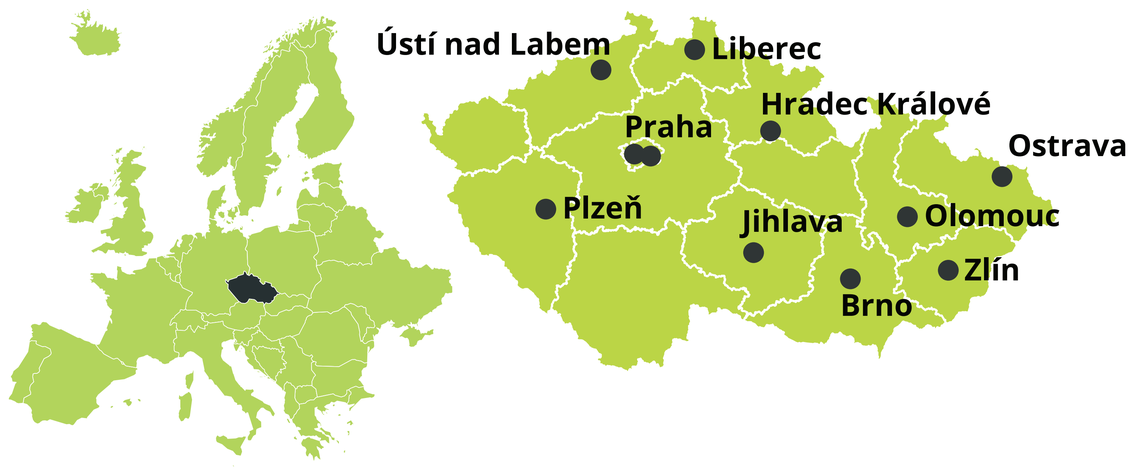
Hejduk K.[1], Koblížek V.[2], Novotná B.[2], Zbožínková Z.[1], Uher M.[1], Mertová J.[1], Dušek L.[1]

[1] Institute of Biostatistics and Analyses of the Masaryk University, Brno, Czech Republic
[2] Pulmonary Department, Faculty of Medicine in Hradec Kralove, Charles University in Prague and University Hospital Hradec Kralove, Hradec Kralove, Czech Republic

The Czech Multicentre Research Database of COPD is a national clinical registry for multicentre longitudinal observational monitoring of severe COPD (post bronchodilator FEV1 ≤ 60%). The design of this study is based on the official diagnosis and treatment guidelines of The Czech Pneumological and Phthiseological Society (CPPS) of the Czech Medical Association (CzMA). The registry was created in March 2013 and the official launch date was in August 2013 after a period of testing and harmonisation.

INTRODUCTION

The estimated prevalence of COPD in the Czech Republic is 7% of adult population. It is estimated that in the Czech Republic, 16.000 patients were hospitalized and 2.500 died last year (2012) as a consequence of COPD. The electronic database of COPD was created in 2013 as a result of cooperation between the Czech Pneumological and Phthiseological Society and the Institute of Biostatistics and Analyses of the Masaryk University in Brno.
In the Czech Republic, patients with severe COPD are treated mainly in large University hospitals, which act as 'pneumological treatment centres'. The involvement of regional hospitals is not of less importance for the coverage of the entire population. At present, 11 pneumological centres are involved in the project.



PROJECT OBJECTIVES

Primary outcome measures	Secondary outcome measures	Other outcome measures
Assessment of all-cause mortality in an unselected group of consecutive patients with severe COPD (post-bronchodilator FEV1 ≤ 60%).	Assessment of morbidity in an unselected group of consecutive patients with severe COPD (post-bronchodilator FEV1 ≤ 60%).	Monitoring of lung function decline (post-bronchodilator FEV1) Monitoring of prognostic indices COPD categories and quality of life assessment Evaluation of activity of daily living Assessment of therapeutic compliance Analysis of extra-pulmonary impairment during

The outcomes of the registry are essential for the dealings of the Czech Pneumological and Phthiseological Society with national authorities such as the State Institute for Drug Control, The Ministry of Health or Insurance companies.

CRITERIA

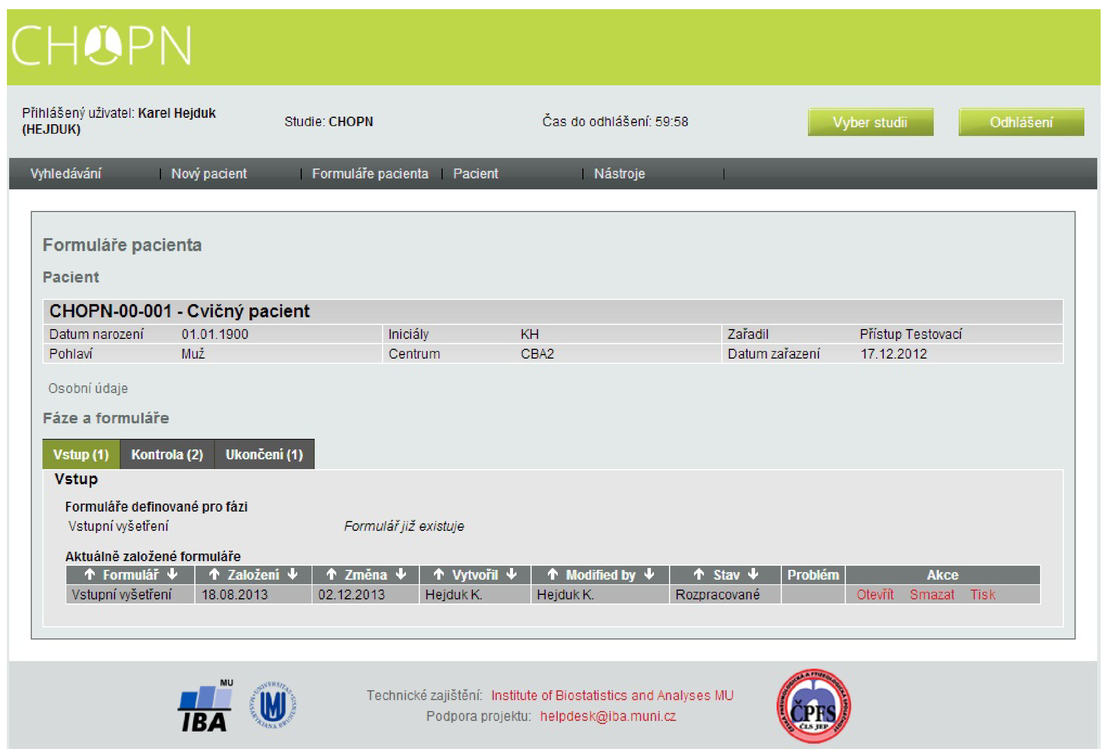
Inclusion criteria	Exclusion criteria
Post-bronchodilator FEV1/VC < LLN and post-bronchodilator FEV1 ≤ 60% of the predicted value (VC – Vital Capacity, LLN – Lower Limit of Normal) Definite clinical diagnosis of COPD (can be overlap of: COPD + asthma / COPD + bronchiectasis) Stable course of COPD (≥ 8 weeks free of acute exacerbations and/or free of any acute conditions) Informed consent	"Pure" bronchial asthma without COPD "Pure" bronchiectasis without COPD Cystic fibrosis End-stage of COPD Non-curable malignancy Total non-compliance Immobility

STRUCTURE OF THE CZECH COPD REGISTRY

Time schedule

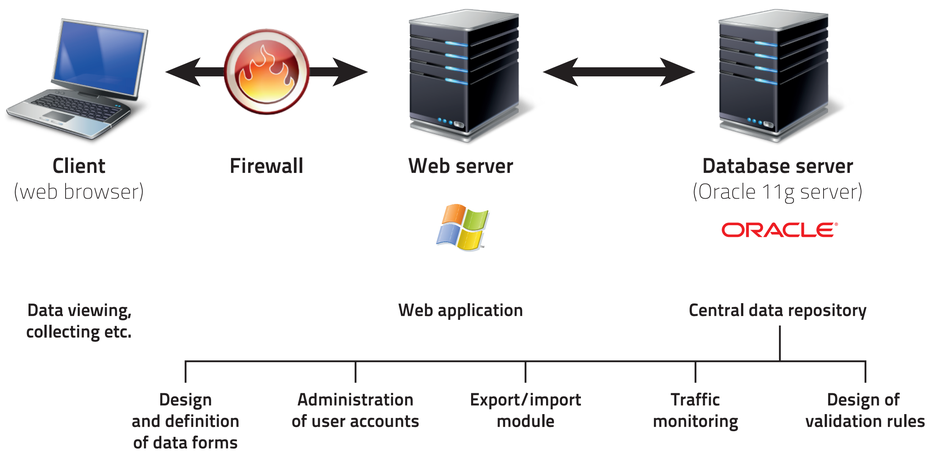
Appointment type	Admission appointment (stable COPD)	Planned appointment (stable COPD)	Emergency appointment (emergency hospitalisation)
Appointment interval	**Registry admission**	**Every 6 months**	**In the event of emergency hospitalisation (NOT planned hospitalisation)**
Appointment number	1st	2nd–11th	E1. E2. E3. etc.
Informed consent	X		
Patient history	X		
Demographic data collection	X		
Risk factors	X	X	
Respiratory symptoms (CAT, mMRC)	X	X	
Quality of life assessment (SGRQ)	X	X	
Current medications	X	X	
Physical examination	X	X	
ECG	X	X*	
Laboratory tests	X		
Frequency of exacerbations /year	X	X*	
ORL symptoms (SNOT – 22)	X	X	
Lung function°	X	X	
Arterial blood gases	X	X	
6MWT	X	X	
Pedometer and ADL°°	X	X*	
Depression scores (Zung, Beck)	X	X	
Chest HRCT	X	X§	
Echocardiography	X	X**	
DEXA	X		
Anthropometry	X	X*	
Compliance assessment	X	X*	
Blood, urine (-70°C) "BIOBANKING"	X		
Reason for sudden hospital admission			X
Patient development during admission			X
Cause of death			
5 year survival			

Notes:
* once a year
**during the 3rd and 5th year of study
° FEV1, FVC, VCmax, RV, TLC, RV/TLC, IC/TLC, DLCO
°° monthly average
§ during the 5th year of study



METHODS

The electronic database has been designed as an on-line application that is accessible to its users via a web browser after a proper authentication. The system has been developed to serve as a robust base for the collection of data from numerous clinical centres. Any communication between the client and server is realized via the secure protocol HTTPS, using the SSL (Secure Socket Layer) encryption.
All data are analysed in the form of de-identified records, ruling out the possibility of any direct or indirect identification of patients. Data quality is ensured by continuous data validation.
Standard descriptive statistics will be used in the analysis; all results will be described by number of samples in the base for given computation; valid N will be also reported in case of missing values in continuous variables. Median supplemented by 5th–95th percentile range will be used for continuous variables; parametric description will be adopted as supplementary descriptive statistics. Mean supplemented by standard deviation or 95% confidence interval will be adopted for continuous variables when normality of data will be proven by means of Kolmogorov-Smirnov test; geometric mean and its 95% confidence interval will be adopted for log-normally distributed data. Categorical data will be described using absolute and relative prevalence (frequencies) of categories.
Factors influencing attainment of satisfactory results of endpoint will be analysed using logistic regression for binary endpoints and general linear models for quantitative endpoints with proven confounding factors as covariates.
The a = 0.05 will be used as a level of statistical significance in all analyses; all alternative hypotheses will be two-sided. Analyses will be performed using SPSS 20.0.0 (IBM Corporation, 2011) and R.



RESULTS

After 2 months of enrolment, 125 patients are currently enrolled in the registry (data from 2. December 2013). The COPD project is currently in the initial stage of data collection. Study completion date is estimated on December 2019. Publications of the first outputs (baseline data) are planned in 2014. The analyses will serve for monitoring of patients with COPD and as a basis for publications in scientific journals and conferences. All analytical outputs are subject of approval by the Scientific Board of the project.

CONCLUSIONS

Up-to-date and precise clinical and epidemiological data describing the situation in the Czech Republic is currently unavailable. Additionally there are no data on the representation of different phenotypes among the COPD patients. Registration of parametric data of patients with COPD on a centralized level pursues not only scientific objectives: its practical impact on everyday clinical practice is also very important. An agreement on parametric assessment of the treatment process has made it possible to establish methodical standards, and to assess treatment response in a methodically correct manner. The system has been designed and continuously developed in a way that makes it possible to extend it, for example to monitor patients with specific conditions. Special subprojects focused on monitoring of specific parameters can be easily created.

The COPD project is registered on ClinicalTrials.gov under the identifier NCT01923051.