COVER PAGE

Official Study Title:
Quality of Life Among People Living With Chronic Obstructive Pulmonary Disease Visiting the Spirometry Center of Tribhuvan University Teaching Hospital, Kathmandu, Nepal

NCT Number:
Unavailable

Unique Protocol ID:
353 (6-11) E2 077/078

Sponsor:
Institute of Medicine, Maharajgunj Medical Campus

Principal Investigator:
Abhishek Kumar Shah
Principal Investigator
Institute of Medicine, Maharajgunj Medical Campus

Document Type:
Study Protocol, Statistical Analysis Plan, and Informed Consent Form

Document Date:
November 29, 2025

Version:
Version 1.0

Team Members:

Abhishek Kumar Shah, MBBS (PI), Institute of Medicine, Kathmandu, Nepal

Dr. Narayan Prasad Neupane, MBBS, Institute of Medicine, Kathmandu,Nepal

Nishant Neupane, MBBS, Institute of Medicine, Kathmandu,Nepal

Dr. Bishal Bashyal, MBBS, Institute of Medicine, Kathmandu, Nepal

Suhana Chaulagain, MBBS, Patan Academy of Health Sciences, Kathmandu, Nepal

Dr. Niraj Bam, Associate Professor, Institute of Medicine, Kathmandu, Nepal

Title
Quality of life among people living with Chronic Obstructive Pulmonary Disease- visiting spirometry center of Tribhuvan University Teaching Hospital, Kathmandu Nepal: A cross-sectional study.

Project Background

Chronic obstructive pulmonary disease (COPD) is characterized by airflow limitation that is not fully reversible. The study "Quality of life among people living with Chronic Obstructive Pulmonary Disease- visiting spirometry center of Tribhuvan University Teaching Hospital, Kathmandu Nepal" aims to assess the quality of life (QOL) of COPD patients and the factors affecting it.

A cross sectional study will be performed among the patients visiting Spirometry center of Tribhuvan University Teaching Hospital, Kathmandu Nepal using Convenience Sampling. Ethical approval will be obtained from Institutional Review Board (IRB) of TUTH and written/verbal consent for data collection will be obtained from Teaching hospital authority as well as the respondents. St. George's respiratory questionnaire (SGRQ) will be used to assess quality of life and the Medical Research Council questionnaire will be used to assess the severity of dyspnea. Data management and analysis will be conducted through Epi-Data version 3.1 and Statistical Package for Social Sciences (SPSS) version 26.0.

Introduction

Chronic obstructive pulmonary disease (COPD) represents a complex respiratory disorder characterized by chronic airflow limitation and an increased inflammatory response of the airways (1) The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines define COPD as a disease state characterized by airflow limitation that is not fully reversible, is usually

progressive, and is associated with an abnormal inflammatory response of the lungs to inhaled noxious particles or gases,. Globally, 10%–20% of the population older than 40 years (an estimated 80 million) are COPD sufferers, resulting in more than 3 million deaths each year (2, 3). In Nepal, COPD accounts for 43% of the non-communicable disease burden, and 2.56% of hospitalizations (4, 5).

Though tobacco smoking is established as the primary cause of COPD, indoor air pollution from biomass and/or traditional fuels is estimated to be associated with 0.4 million deaths from acute symptoms of COPD (6). Studies have shown that smokers in Nepal have a 70% greater chance of developing COPD (4). In Nepal, more than 85% of households (98% in rural areas) still rely on biomass fuel (7). Nepalese women are at higher risk of developing COPD through exposure to indoor air pollution; additionally, about 15% of women also smoke tobacco (8, 9).

Health-related quality of life (HRQOL) may have a major impact on COPD patients. They may have restriction of activities, decreased social functioning and loss of independence (10). Co-morbidities are frequent in COPD and significantly impact on patients' quality of life, exacerbation frequency, and survival (1, 11). Quality of life and self-reported health status decrease with an increasing number of co-morbidities in patients with COPD (11,12,13). The distinction between co-morbidities and systemic manifestations of COPD is, at present, unclear. Systemic features of COPD include cachexia, skeletal muscle abnormalities, osteoporosis, depression, anemia, and cardiovascular disease (1).

COPD is a major public health problem because of its high prevalence, adverse impact on quality of life (QoL), (14) and large social and economic costs. (15) Psychological and behavioral factors may influence individual perceptions of symptom severity, and strategies used by patients to cope with the burden of symptoms and disability are still incompletely understood. (15)
Acceptance of the disease has a significant impact on the level of assessment of quality of life in patients with COPD — the higher acceptance, the higher rating of quality of life. (16) COPD as a chronic illness has effects on social, psychological, and economic spheres of life. It has several significant extra-pulmonary effects, such as skeletal muscle impairment and exercise intolerance, which have an important effect on the daily life activities of patients with this disease (17, 18).

Lower self-reported walking times are related to worse markers of disease severity in COPD (19). Moreover, reduced levels of physical activity have been found to be related to an increased risk of hospital admissions and mortality in COPD (20, 21). The American College of Sports Medicine recommends that older adults should perform at least 30 min of physical activity of moderate intensity, such as walking, most days of the week in order to maintain or develop fitness. (22)

The Bagmati province of Nepal consists of a privately-run medical college and many public hospitals, of which the TUTH is the referral center within the public hospital/health facility network in the province. Assessment of visits made to the TUTH helps identify the number of COPD cases. Therefore, the purpose of this study is to identify the quality of life among Chronic Obstructive Pulmonary Disease in Nepal through a cross-sectional study in TUTH.

Rationale

Despite the increasing trend of burden of COPD, little efforts have been made to combat Chronic Obstructive Pulmonary Diseases (COPD). There is very scare information in about the quality of life among COPD patients.

Quality of life (QOL) is an important aspect for measuring the impact of chronic diseases. HRQOL measurement facilitates the evaluation of efficacy of medical interventions and also the detection of groups at risk. Many studies have been conducted across the world to study the HRQOL of COPD patients and the factors affecting it. However, studies from Nepal are far fewer in number. To fill this gap, we have proposed this research which would be helpful to find out the association between quality of life and chronic disease. Moreover, this will be useful to compare QOL of COPD patients of Nepal with other countries

General Objective

To assess the quality of life and identify its associated factors among people living with Chronic Obstructive Pulmonary Disease (COPD) visiting the spirometry center of Tribhuvan University Teaching Hospital, Kathmandu, Nepal.

Specific Objectives

1. To describe the socio-demographic, clinical, and exposure profiles of COPD patients.

2. To assess the quality of life of COPD patients using the COPD Assessment Test (CAT) and determine the prevalence of different impact levels (low, medium, high).
3. To analyze the relationship between quality of life (CAT score) and key clinical factors, including dyspnea severity (mMRC grade), lung function (FEV$_1$% predicted), and GOLD stage.
4. To identify the factors independently associated with poor quality of life (defined as a CAT score >20) using multivariate logistic regression.

Methodology
Study design
A cross-sectional study design employing quantitative research method will be done to fulfill the research purpose. The study will be hospital based and will be carried out in Institute of Medicine, Tribhuvan University Teaching Hospital, Maharajgunj, Kathmandu, Nepal.

Sampling
Non probability sampling will be done for four months visiting the spirometry center of TUTH. According to the spirometry center report average 30 patients visit in a month. Considering the non-response rate 20% we can collect data of 24 patients in a month. Considering this and duration of data collection, study aims to collect data from 96 patients.

Data collection
Data collection will be carried out by trained medical interns at the spirometry center. Following the provision of informed consent, participants underwent a face-to-face interview using a structured questionnaire to gather information on socio-demographics, smoking history, and biomass fuel exposure. Dyspnea severity was assessed using the modified Medical Research Council (mMRC) scale, and health-related quality of life was measured using the COPD Assessment Test (CAT). Anthropometric measurements and vital signs were recorded for each participant. Spirometry was performed pre- and post-bronchodilator administration in accordance with standard 4 guidelines to confirm COPD diagnosis and severity classification; all spirometric values were directly recorded onto a standardized data sheet. Medical Modified Research Council (mMRC) will be used to assess dyspnea scale. Spirometry report card will be observed and recorded for assessing the following parameters:

a. Forced expiratory volume in the first second (FEV$_1$) pre and post bronchodilator. Forced vital capacity (FVC).

b. FEV$_1$/FVC ratio.

c. Peak expiratory flow rate (PEFR).

d. Forced expiratory flow at 25%- 75% of maximal lung volume ($FEF_{25-75\%}$).

Table 1: Tools and techniques of the data collection

Techniques	Tools	Participants	Data generated
Structured interview	CAT Questionnaire	Sample Population	Health related quality of life (HRQOL)
Anthropometric measurement	Digital weighing machine, measuring tape and portable standard stature scales	Sample Population	BMI, waist circumference
Observation and structured interview	Spirometry report card	Sample population	FEV1% and FEV1/FVC
Structured interview	Medical Research Council (mMRC)	Sample Population	Assess dyspnea scale

Data collection and analysis plan

Data collection will be carried out by trained medical interns at the spirometry center. Following the provision of informed consent, participants will undergo a face-to-face interview using a structured questionnaire to gather information on socio-demographics, smoking history, and biomass fuel exposure. Dyspnea severity will be assessed using the modified Medical Research Council (mMRC) scale, and health-related quality of life will be measured using the COPD Assessment Test (CAT). Anthropometric measurements and vital signs will be recorded for each participant. Spirometry will be performed pre- and post-bronchodilator administration in accordance with standard guidelines to confirm COPD diagnosis and severity classification; all spirometric values will be directly recorded onto a standardized data sheet.

For statistical analysis, the parameters from the datasheet will first be entered into an Excel spreadsheet (Microsoft Corp., 2019). All analyses will be conducted in the Statistical Package for the Social Sciences (SPSS), version 29.0 (IBM Corp., Armonk, N.Y., USA). Descriptive statistics will be presented as means ± standard deviations for continuous variables and as frequencies and percentages for categorical variables. Bivariate analyses will be conducted using Pearson's or Spearman's correlation coefficients for continuous variables, independent samples t-tests for dichotomous comparisons, and one-way ANOVA for comparisons across multiple groups. Multivariable analyses will include a linear regression to identify factors associated with the continuous COPD Assessment Test (CAT) score and a logistic regression to determine predictors of poor quality of life (defined as a CAT score > 20). Assumptions for all regression models will be checked and must be met. A two-tailed p-value of < 0.05 will be considered statistically

significant. All figures, including the participant flow diagram, distribution plots, and scatter plot, will be generated using R software (R Foundation for Statistical Computing).

Ethics

Ethical approval will be taken from Ethical Review Board of the Nepal Health Research Council(NHRC) and Institutional Review Board (IRB) of TUTH . Written informed consent will be taken from the study participants. The study participants will be informed about the confidentiality of information collected and their right to withdraw from the study at any time. Preventive and promotional counseling will be given to the study population after the data collection and healthy tips for promoting quality of life will be shared.

Potential impact of the project

Our research is closely aligned with goal 3, target no. 4 of Sustainable Developments Goals (SDG): reducing the premature mortality of NCDs and Nepal's Multi-sectorial action plan for the prevention and control of NCDs.It has spelled out the need to reduce the premature death due to NCDs with focus on prevention and treatment as well as decreasing the risk factors of NCDs. As COPD is the major burden of NCDs in Nepal, it can play crucial role in generating evidence and which ultimately helps in formulation and execution of plans and policies. In Institute of Medicine(IOM), we students celebrate many health related days and make patients aware of the healthy life.This research can help us to focus about different factors affecting COPD. This research will set the baseline information for developing patients based intervention for the prevention and management of COPD and uplifting the quality of life among them.

So, the design and implementation of intervention package following the study will be conducted jointly by different organization available under Institute of Medicine, TUTH.

Project Schedule

Task to be performed

Preparation and submission of research proposal
Ethical clearance from NHRC
Orientation to enumerators
Data collection
Data analysis
Report writing and dissemination of preliminary study findings to IRC and TUTH
Submission of final report to IRC and TUTH, IOM

Budget

S.N.	Budget head	Justification	#units (days/months)	Rate	Total (NRs)
Phase I: Study design and development					
1.1	Human resources				
1.1.1	Research team	Includes cost for data analysis, report writing and monitoring research work for research team members	15 working days	1000	15000
1.1.2	Field supervisor	Allowance	1 persons*4days	1000	4000
1.1.3	Field enumerators	Includes cost for field allowance	2 * 32	500	19000
			Subtotal (1.1)		**30,000**

1.2	Study tools and training				
1.2.1	Stationery	For literature review and field level data collection	Lump sum	-	5000
1.2.2	Questionnaire	For literature review and field level data collection	1	2000	2000
1.2.3	Training for enumerators	For data collection	2 days	25,00	5,000
			Subtotal (1.2)		**12,000**
Phase II: Field work organization					
2.2	Communication expenses		Lump sum		1000
			Sub total (2)		**1,000**
Phase III: Data management					
3.1	Data analysis		-	-	-
3.2	Report preparation	Printing and binding	Lump sum	-	3000
3.4	Miscellaneous	other contingency costs	Lump sum	-	1000
			Sub total (3)		**4,000**
			Subtotal (1.1+1.2+2+3)		**52,000**
	Ethical approval cost				1000
		Grand Total			**53,000**

References
1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of COPD; 2014. Available from: http://www.goldcopd.org/. Accessed June 5, 2014.

2. Longmore JM. *Oxford Handbook of Clinical Medicine*. 8th ed. Oxford,UK: Oxford University Press; 2010.

3. World Health Organization. *Chronic Obstructive Pulmonary Disease*. Geneva, Switzerland: Office of Health Communications and Public Relations; 2007.

4. Nepal Health Research Council. *Prevalence of Non Communicable Disease in Nepal: Hospital Based Study*. Kathmandu, Nepal: Nepal Health Research Council; 2010.

5. Department of Health Services. Annual report. In: *Ministry of Health and Population*. Kathmandu, Nepal: Department of Health Services; 2009/10.

6. COPD-International.com. COPD statistical information. Available from:http://www.copd-international.com/library/statistics.htm. Accessed October 24, 2011.

7. Winrock International Nepal. Household energy, indoor air pollution and health impacts: status report for Nepal 2004. Available from: http://pdf.usaid.gov/pdf_docs/PNADO853.pdf. Accessed February 23, 2012.

8. Pandey MR. Health effects of indoor air pollution. Available from:http://www.arecop.org/publications/glow/zip/glow200302vol29.pdf. Accessed February 23, 2012.

9. Ministry of Health and Population. Brief profile on tobacco control in Nepal. In: *Government of Nepal*. Kathmandu, Nepal: Ministry of Health and Population; 2010.

10. Cleland JA, Lee AJ, Hall S. Associations of depression and anxiety with gender, age, health-related quality of life and symptoms in primary care COPD patients. Fam Pract. 2007;24:217–23.

11. Putcha N, Puhan MA, Hansel NN, Drummond MB, Boyd CM. Impact of co-morbidities on self-rated health in self-reported COPD: an analysis of NHANES 2001–2008. COPD. 2013;10(3):324–332.

12. van Manen JG, Bindels PJ, Dekker EW, et al. Added value of co-morbidity in predicting health-related quality of life in COPD patients. Respir Med. 2001;95(6):496–504.

13. Yeo J, Karimova G, Bansal S. Co-morbidity in older patients with COPD: its impact on health service utilisation and quality of life, a community study. Age Ageing. 2006;35(1):33–37

14. Miravitlles M, Ferrer J, Baró E, Lleonart M, Galera J. Differences between physician and patient in the perception of symptoms and their severity in COPD. *Respir Med*. 2013;107(12):1977–1985.

15. Vestbo J, Hurd SS, Agustí AG, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. *Am J Respir Crit Care Med*. 2013;187(4):347–365.

16. Beata Jankowska-Polańska, Maria Kasprzyk, Anna Chudiak, Izabella Uchmanowicz : Effect of disease acceptance on quality of life in patients with COPD ; *Pneumonol Alergol Pol 2016;84(1):3-10*

17. Vestbo J, Hurd SS, Agustí AG, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. Am J Respir Crit Care Med. 2013;187:347–365. [PubMed] [Google Scholar]

18. Agustí AGN, Noguera A, Sauleda J, Sala E, Pons J, Busquets X. Systemic effects of chronic obstructive pulmonary disease. Eur Respir J. 2003;21:347–360. [PubMed] [Google Scholar]

19. Ramon MA Esquinas C, Barrecheguren M, Pleguezuelos E,et al . Self-reported daily walking time in COPD: relationship with relevant clinical and functional characteristics. 2017 Apr 13[PubMed] [Google Scholar]

20. Garcia-Aymerich J, Lange P, Benet M, Schnohr P, Antó JM. Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study. Thorax. 2006;61:772–778. [PMC free article] [PubMed] [Google Scholar]

21. Garcia-Rio F, Rojo B, Casitas R, et al. Prognostic value of the objective measurement of daily physical activity in patients with COPD. Chest. 2012;142:338–346. [PubMed] [Google Scholar]

22. Chodzko-Zajko WJ, Proctor DN, Fiatarone Singh MA, et al. American College of Sports Medicine position stand. Exercise and physical activity for older adults. Med Sci Sports Exerc. 2009;41:1510–1530.[PubMed] [Google Scholar]

\

Informed consent form

"Quality of life among people living with Chronic Obstructive Pulmonary Disease- visiting spirometry center of Tribhuvan University Teaching Hospital, Kathmandu Nepal: A cross-sectional study."

Maharajgunj Medical Campus, Tribhuvan University Teaching Hospital, Institute of Medicine

Maharajgunj, Kathmandu, Nepal

I, ... , a male/female of .... years of age, have received information regarding this research to be conducted by .... by reading and/or listening to the attached 'Information Sheet/Booklet' and through a question-and-answer session.

- I understand that my participation in this research work depends entirely on my personal will, and that I can withdraw from this research process at any time if I wish. I have been made to understand that I do not need to provide any reason for this, and it will not affect the services I receive or my legal rights.
- I understand that no personal identifying information about me will be published in the report of this research or in any related publications.
- Knowing and understanding all these points, I voluntarily agree to participate in this study-research and hereby provide my signature on this Informed Consent Form.

[Participant's]

Signature : ....

Full Name : ....

Date : ..../....../...... (YYYY/MM/DD)

Participant's Thumbprint

Right　　　　　**Left**

[Witness's]

Signature : ....

Full Name : ....

Date : ..../......./....... (YYYY/MM/DD)

[Researcher's]

Signature : ....

Full Name : ....

Date : ..../......./....... (YYYY/MM/DD)