

Lung cancer registry and monitoring: Feasibility study and application (fars lung cancer registry project)

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Background: Lung cancer (LC) is the second most common and deadliest cancer in the world. Despite the control of the progressive course of LC in developed countries, studies indicate an increase in the incidence of the disease in developing countries. We designed a stepwise approach-based surveillance system for registering LC in our region (fars lung cancer registry “FaLCaRe” Project). **Materials and Methods:** A questionnaire was designed and agreed upon by the steering committee using the Delphi method. Variables in nine fields were divided into three groups based on their importance: core, expanded core, and optional. The web-based data bank software was designed. The informative site about LC and team services was designed and launched for professional and community (www.falcare.org) educational purposes. **Results:** 545 variables in nine fields were designed (20 core variables). Primary data of 39 LC patients (24 men and 15 women) with a mean age of 62 years were analyzed. Twenty-six patients had a history of smoking. Moreover, 39% and 26% of patients had a history of hookah smoking and opium use, respectively. Adenocarcinoma was the most prevalent pathologic findings in cases. More than 80% of patients were diagnosed in stages 3 and 4 of cancer. **Conclusion:** FaLCaRe Project with the capabilities seen in it can be used as a model for national LC registration. With continuous valid data registry about LC, it is possible to make decisions at the national level for control and management its consequences while drawing the natural history of the LC.

Key words: Disease registration, Fars province, Iran, lung cancer, pleural malignancy, surveillance

How to cite this article: Fallahi MJ, Baghaei A, Rezvani A, Hosseinzadeh M, Jalli R, Mohammadianpanah M, *et al.* Lung cancer registry and monitoring: Feasibility study and application (fars lung cancer registry project). *J Res Med Sci* 2023;28:48.

INTRODUCTION

Lung cancer (LC) is the second most commonly diagnosed cancer worldwide. Irrespective of cutaneous malignancies, LC is the second and the third most common cancer in men (after prostate cancer) and women (after breast cancer), respectively. The estimated 1.8 million deaths per year (nearly 18% of all cancer-related deaths) of LC indicates the first rank of this cancer in mortality higher than other malignancies in the world.^[1]

In addition to the high rate of mortality, a high level of metastasis and disability of LC patients contributes to

the increased treatment and care costs, decreased quality of life, and several social consequences for the health system, society, and families of patients.^[2]

The costs of research focused on it's the prevention, treatment, and follow-up of LC are much lower than those of other cancers. In the United States, the funding for research on LC was \$1.6 million versus nearly \$60 million for research on breast cancer in 2017. In the same year, LC-related mortality was three times higher than that of breast cancer.^[3]

By implementing some preventive policies, several developed countries have successfully controlled

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10.4103/jrms.jrms_760_22

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Submitted: 29-Oct-2022; **Revised:** 12-Feb-2023; **Accepted:** 22-Feb-2023; **Published:** 12-Jun-2023

the risk factors of LC by decreasing smoking and other factors such as industrial pollutants. These countries have moderated the increasing annual incidence of this disease or have reduced its incidence in some cases during the last 30 years. On the other hand, the rate of LC patients has increased in underdeveloped or developing countries, with the highest increasing incidence of LC being reported in East Asian countries.^[4]

There is a direct relationship between the incidence of LC and the rate of smoking, while it is inversely related to the gross national product and human development indicators. The process of epidemiologic changes in the past 10 years indicates the increasing and decreasing incidences of LC among women and men, respectively.^[5]

In terms of prevalence, LC ranks the fifth among other types of cancers in Iran. However, the studies of LC epidemiology in the world indicate that the change in the age pyramid of Iranian society toward old age, the significant rate of tobacco consumption (25% of men and 3% of women), and environmental pollutants will expectedly increase the incidence of LC and its burden on the health system of Iran.^[6-8]

LC registration in the form of national programs for cancer registration with a holistic approach and merely the registration of its diagnosis has been implemented in previous years. Health system planning, however, aims at the epidemiologic survey of conditions and access to documented and trusted data to represent the disease distribution pattern and predict the process of its changes and related risk factors through statistic modeling. This strategy needs a systematic and targeted collection of data in the form of a dynamic registration and monitoring (surveillance) system.

The World Health Organization defines the registration of a patient as a document containing a specific patient's information collected with a systematic and comprehensive method to be used for scientific and clinical aims or in the health system policy-making.^[9]

The up-to-date accessibility of disease-related epidemiology and the assessment of indexes and factors affecting the burden of diseases on the health system provide the data for decision-making by the health system trustees for the prioritization and management of diseases.

The distribution and diversity of disease-related indicators, especially multifactorial ones, can be compared with other geographic areas to raise research questions in clinical and basic studies in the management of diseases for medical sciences researchers.

Providing localized clinical approaches for prevention, treatment, and rehabilitation based on the model of incidence, progression, and complications of diseases in each region will be accessible relying on documented data from the surveillance system.

The determination of the natural history of diseases in Iranian LC patients will aid to design basic and clinical studies in the mentioned fields.

Fars and Isfahan provinces have been introduced as hot zones of LC, which necessitates the need to plan the survey of patients' conditions more than ever.^[10]

In this study, a model is proposed for the registration and follow-up of LC. The presented model allows for providing a regional and national program for developing a surveillance system of LC to realize the mentioned aims.

The main goal is planning and setting up hospital-based lung and pleural cancer registry and monitoring (surveillance) in Iranian Population. For achieving this goal, we should design data collection tools and process based on stepwise approach in disease registration (localization and customized based on our setting), design and conduct web-based national ongoing data collection system. After that, we will be able to illustrate the natural history of lung and pleural malignancy in our community, estimate the disease burden and disease epidemiology in our community for making decision in our health services. Furthermore, it is possible to make a valid source of data for planning new studies in LC research fields and educational content for health-care providers and make a network of LC patients and their families for education and improve their skills in managing the disease.

MATERIALS AND METHODS

The design and launch of a registration and monitoring system for lung and pleural cancer in an action research were planned based on the stepwise approach to surveillance [Figure 1]. This project was designed in three phases, and the data were exclusive to hospital registration and offices of collaborating physicians.

- Phase 1: Designing
- Phase 2: Pilot study and data entry
- Phase 3: Evaluation and presentation of a model for the project development and continuation.

Phase 1: Designing

The formation of a steering committee

This committee consists of specialists in the fields of pulmonology, hematology, radiation oncology, radiology, pathology, thoracic surgery, and epidemiology. Table 1 shows the duties of this committee.

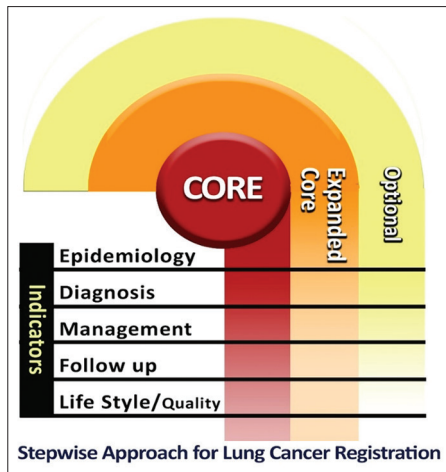


Figure 1: The stepwise approach for LC registration. LC: Lung cancer

Table 1: Duties of the steering committee of the project

Survey and approval of data collection tools and classification of variables in the core, expanded core and optional forms
Survey and approval of the definitions and exclusion and inclusion criteria of registered items
Monitoring and approval of data analyses for registration items
Monitoring and approval of the disease monitoring and surveillance protocols
Participation and supervision of the output documents of the LC registration system
Supporting and providing a suitable platform for consolidating patient's data
Providing a program for obtaining the comments of national and international authorities related to the subject of this study and its implementation

LC=Lung cancer

Preparation of the framework and coordinates of lung tumor registration forms

A set of variables and indexes related to the registration of LC were categorized into nine groups [Table 2]. Variables were defined according to stepwise approach in the following fields: epidemiology, diagnosis, management, follow-up, and lifestyle [Figure 1].

Providing the project and format of the data collection form based on the stepwise approach to surveillance

It is necessary to classify data based on the written and oral comments of authorities since all disease-related variables are of dissimilar importance and priority and there are limited financial and human sources for collecting all variables. To achieve this aim, the comments of the steering team and other scientific advisors were collected, analyzed, and categorized based on the opinions of the steering committee by the Delphi method. Then, the variables were divided using the methods for summarizing the expert panel's views. Finally, a table was prepared through the consensus among the committee members.

First category: Core variables

These include those variables whose absence in the registration form results in the exclusion of the case or patient from the registration system; in other words, it is the minimum necessary for the registration of patients' data of such as age, gender, and smoking.

Second category: Expanded core variables

It includes the minimum data that should be collected for the analysis of results, decision-making about the distribution of disease, and surveying the related reasons and factors based on the steering committee's comments. Although missing this part of the data complicates the final analysis, it can be managed and processed by statistical methods and specific analyses (data processing and missing analysis, including family history, the location of birth, and the number of chemotherapy sessions).

Third category: Optional variables

Currently, these variables are only used in the field of research or, in terms of evidence, do not have a specific position in the diagnosis and treatment process and are considered in special cases such as positron emission tomography scan and specific genetic and molecular tests.

Finalization, completion of the forms, and the final development of the data collection protocol

The definitions of the registration system, the processes of the registration of cases, the definitive diagnosis criteria, the conditions for the entry of a sample into the data bank, development and determination of exclusion criteria, development of follow-up protocols and their indices, development of a reporting plan and a result analysis plan, development of a process evaluation plan, and quality control of data registration were presented in this step (www.falcare.org).

Phase 2: Implementation

Designing and preparing the comprehensive software for pleural and lung cancer registration

The software and data bank of patients were designed and produced according to the forms and questionnaires designed in the first phase of the project for the registration and follow-up of LC patients. The web-based data bank can retrieve data for analysis in statistical software. The time intervals for patients' follow-up and presentation of time series in the follow-up of variables are considered in this program (<https://panel.rabit.ir/q/FaLcaRe.html>).

To realize the professional and community educational purposes of LC and make a relationship between the coworkers of this study to facilitate the implementation of processes, the services and educational subjects are

Table 2: The classification of studied variables in the lung cancer registration system

Class	Titles	Number of variables (core)
Demographic	Age, gender, socioeconomic status	25 (4)
Health and disease condition	Risk factors	60 (5)
	Associated diseases	
	Examination findings	
Diagnosis of disease	Type of cancer	120 (5)
	Clinical findings	
	Time of diagnosis	
	Laboratory, imaging, scopy, pathology, molecular medicine and genetics findings	
Disease status (severity of disease)	Surveying disease severity and the patient's performance	40 (-)
Complications of the disease	Complications of the disease on the body's organs	110 (-)
	Metastasis	
	Socioeconomic difficulties and consequences	
Information on hospitalization	Cancer-related hospitalization	10 (-)
Treatment regimens	Type of treatment regimen (surgery/radio/chemotherapy)	100 (4)
	Treatment protocols	
	Complications of treatment and causes of changes in the treatment regimen	
Lifestyle and rehabilitation	QOL and the patient's performance	60 (-)
Monitoring and follow-up	Diagnostic and treatment findings and complications in the disease process	20 (2)
	Mortality and morbidity	

QOL=Quality of life; LC=Lung cancer

uploaded on the webpage (www.falcare.org), which are updated continuously.

Data entry into the software and pilot study

Sources of data

Available resources (patients)

- Patients with medical records in an LC clinic.

New cases of the disease

The information of new cases referring to the coworker physicians' offices of the project was continuously entered as registry forms into the software at 1-month intervals based on the coordination with the project coworkers.

Data collection method

Selection of patients

The patients referred to the cancer clinic at Motahari Medical Center affiliated with Shiraz University of Medical Sciences were visited by the project team, and primary data were recorded in the disease registration form. To develop the statistical society and increase the number of registered cases, a fast patient registration system has been designed on the internet (accessible from the project site) in which coworkers and physicians register the patient's primary characteristics. For the completion of data, the project data collection team follows up and calls for the patients.

All referred patients with positive pathology for lung or pleural cancer are accepted in the registry plan. The only criterion for removing the sample is the absence of one of the specified variables as core variables.

The follow-up team for the completion of data as registry forms

This team was composed of educated human resources at the LC clinic, where the forms were completed based on the set protocol for a specific time frequency. The items of the provided protocol included the contact procedure, question design procedure, answering the patients, entering the answers, verifying the data, and the requirements for data confidentiality and security, and the safety and assurance by physicians to prevent ambiguity and doubt in their patients about the treatment process and the subsequent referrals.

The quality control and data process

Quality control takes place on two levels: quality control of processes and quality control of data. Patient selection and referral processes and data recording and analysis methods are carried out in different stages by reviewing standards and periodic audits. Ten percent of the registered data are randomly verified by the representatives of the steering committee, and if there is a registration error of more than 10%, while reporting the cases and correcting them, the performance of the questioners will be reviewed.

Phase 3: Evaluation

Based on the measured variables, ongoing reports on the epidemiology of lung tumors will be presented, annually. The process was evaluated by reviewing registry protocols and forms to provide a method for removing obstacles and proposing a method for improving the project implementation and monitoring of patients. It was presented on the project website to be used by the project coworkers. The data were analyzed to report the analysis of collected indicators in the form of core and optional variables.

RESULTS

A questionnaire including 545 variables in nine fields was designed by consolidating the comments of the project team and the steering committee. Twenty core variables were selected based on the stepwise approach in the surveillance system. After the entry of data from 39 patients into the prepared software, the data entry and analysis system was revised to amend the defects.

During implantation phase (January 2021 to October 2021), the university medical centers introduced 39 patients (24 men and 15 women with a mean age of 62.6 ± 6.3 years) to the LC clinic.

Twenty-six patients (67%, 23 males and three females) had a history of smoking, with 23 cases (90%) having a history of smoking at least 100 cigarettes. The smokers stated an average of 33 years of smoking history, during which they used an average of 13 cigarettes per day. Smoking continued by nearly 90% of patients up to 1 month before the diagnosis of their LC.

Moreover, 39% and 26% of patients had a history of hookah smoking and opium use, respectively. A history of alcohol use was stated by only three patients.

Out of 39 registered patients, bronchoscopy was conducted for 21, 16 cases of which were diagnosed definitely, and five patients needed another invasive diagnostic procedure. Among 23 patients who underwent transthoracic biopsy, only one case was not diagnostic and needed resampling.

Adenocarcinoma was the most prevalent finding in the pathology report of the studied samples [Table 3].

In addition, 66% and 15% of LC patients were, respectively, diagnosed in stages 4 and 3 of cancer, and only two patients were in stage 1. At the time of diagnosis, metastases to the brain and bone were recorded in nine and four patients, respectively. Chronic cough was the most prevalent symptom of the patients registered in the data registration system [Table 4].

The interval between the incidence of symptoms and the final diagnosis was an average of 8 weeks, and the shortest diagnosis interval (2 weeks) belonged to the symptom of hemoptysis.

The most frequent primary locations of the tumor were in the upper lobes of the right (11 cases) and the left (10 patients) lungs, respectively. Three patients died during this period.

After designing the project website (www.falcare.org), the entry ports into the data registration system were

Table 3: The pathology frequency in the studied cases

Pathology	Frequency
Adenocarcinoma	22
Squamous cell carcinoma	6
Neuroendocrine	3
Small cell carcinoma	3
Others	5

Table 4: The frequency of symptoms reported by the lung cancer patients

Symptom	Frequency (%)
Asymptomatic	6
Cough	88
Shortness of breath	56
Fatigue	53
Weight loss	41
Chest pain	41
Hemoptysis	38
Anorexia	41

introduced to the project coworkers. The educational subjects for the patients and their families, as well as the physicians and nurses related to the patients are uploaded and updated on this website.

DISCUSSION AND CONCLUSION

The launch of the Fars LC Registration and Monitoring fars lung cancer registry (FaLcARe) program aims to collect data about LC cases in this area to provide a national model. The stepwise registration system approach used in this project allows for recording the minimal variables in the required fields along with complementary data for use in LC-related studies.

Similar to previous studies, the analysis of limited data entered into the pilot phase of this project shows the role of smoking as the most widespread risk factor. The close ratio of females and males in our registered cases justifies the lower frequency of smoking in this study (65%) than the prevalence of smoking among LC patients in other studies (90%).

Our data indicated that 66% of the registered patients were in the fourth stage of the disease, and only two cases were diagnosed in the first stage. These statistics for metastatic and localized cases in the first stage were 57% and 17%, respectively, in advanced countries from 2010 to 2016.^[11]

It seems that LC screening in high-risk people will reveal an increase in the early diagnosis of LC in the following years.^[12]

The previous studies indicate the role of increasing age in the incidence of LC. The mean age (63 years) of the

registered patients in this study was significantly lower than that of diagnosed patients (70 years) in developed and developing countries.^[13]

Although our analyzed data do not represent the main society and have only been based on hospital registration cases, this level of difference needs to be confirmed through more studies to unveil the possible reasons.

In this study, another diagnostic procedure was necessary for the confirmation and finalization of the type of tumor in five out of 21 patients who underwent bronchoscopy. White light bronchoscopy is reported to have a diagnostic ability of nearly 70% for invasive lung tumors.^[14]

The selection procedure of patients for bronchoscopy in our center and access to alternative methods for the referral of patients led to a higher rate of cases diagnosed by bronchoscopy.

Adenocarcinoma was the most frequent malignancy among the registered patients, similar to that of extensive epidemiologic studies. Among other LC types, the increasing relative prevalence of adenocarcinoma has been reported in recent decades. Upper lobes of the lungs as the same as other studies are the typical sites of malignancies.^[15]

The most important factor limiting the proper implementation of the registry plan is the lack of allocation of sufficient funds for skilled human resources to participate in the process of calling patients and recording data. Efforts were made to define and use joint human resources with other work departments in the form of LC clinic in the university-affiliated medical center. The continuation of the project requires the allocation of necessary financial resources.

Quality control of data and adherence to standards in collecting and reporting results requires active and continuous participation of steering committee members and scientific advisors of the project, which is followed up in the form of regular meetings.

Following up patients and getting their family's cooperation in completing the registry data is also one of the limitations and problems of project implementation.

The limitation of access to standard questionnaires translated into Farsi for use in some parts of the registry is managed by the implementation of supplementary plans for the validation of questionnaires.

Although the FaLcaRe currently registers hospital cases, the preparation of a suitable electronic platform in

cyberspace will lead to the participation of researchers in the registration of disease cases and movement toward the national disease registration system. The development of the FaLcaRe requires the support of medical universities in the country and scientific associations related to the subject of the project.

The consolidation of data from different regions aids in the assessment of the minimum incidence and prevalence of LC in the country as well as presenting the natural history of the disease and estimating its burden in this geographical region. The design of clinical trials and cohort studies in the registered population presents applicable and more precise information for implementing suitable methods of patients' diagnosis, treatment, and follow-up and the screening of at-risk societies.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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