Chapter 10

SPIROMETRY MONITORING AND PREVENTION USING SPIROLA SOFTWARE

EVA HNIZDO, PhD*; and CARA HALLDIN, PhD†

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*Epidemiologist, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888

†Epidemiologist, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888

INTRODUCTION

Several medical and case studies indicate a potential association between military deployment-related environmental exposures and postdeployment chronic respiratory conditions among US Army service members. Pulmonary conditions and diseases of concern include obstructive airways disease, symptom of breathlessness, asthma, bronchiolitis, and interstitial pulmonary disease.[1,2] Suspected attributable exposures include high concentrations of particulate matter generated by various sources, including smoke from oil well fires,[3] sand exposure from sandstorms,[4,5] smoke from burn pits, and smoking.[6,7] Data from the Millennium Cohort Study suggest a >25% increase in chest symptoms among US Army service members after deployment compared with predeployment.[8] Nevertheless, there is still lack of conclusive epidemiological evidence on an association between adverse respiratory health effects and deployment airborne exposure and on the severity of the associated respiratory outcomes, especially their longer term effect on pulmonary function and general fitness. The lack of conclusive evidence is at least in part from lack of systematic data on baseline (predeployment) and postdeployment respiratory health status in individuals and on respiratory exposure to particulate matter during deployment.

Prevention of environmental and lifestyle exposures that may lead to chronic airway diseases, such as chronic obstructive pulmonary disease (COPD) and asthma, are important because these diseases often profoundly diminish the affected individual's quality of life and are associated with premature functional impairment and disability, early retirement from work, and increased future morbidity and mortality.[9–13] Fortunately, most respiratory diseases can be prevented through early recognition of the risk and effective interventions directed at controlling known risk factors, including environmental, occupational, and lifestyle exposures.[14–18]

In general, the respiratory health status of a population at risk can be established using respiratory questionnaires and spirometric measurements of pulmonary function. Although baseline and periodic spirometry for the whole deployed military population may be logistically challenging, periodic evaluation by spirometry and questionnaire could be done for groups or individuals a priori known to be likely at risk of exposure to harmful respiratory agents. This would help to identify hazardous exposures, establish their effect on the prevalence and severity of respiratory conditions, and provide information for prevention. Also, to ensure that there are no longer term consequences of the observed adverse respiratory health effects, the exposed or affected individuals, or smaller representative groups, may be included in a postdeployment periodic spirometry monitoring for at least 5 years to investigate the longer term consequences of the various exposures or deployment-related respiratory conditions.

Computerized spirometry data and appropriate software can be used to assist healthcare providers manage and interpret periodic spirometry data and thus help in achieving the full potential of spirometry monitoring in disease prevention and management. In this chapter, an easy-to-use visual and analytical tool known as SPIROLA (Spirometry Longitudinal Data Analysis) software (Morgantown, WV)[19]—designed for use by healthcare providers as an aid in spirometry monitoring—is described. The SPIROLA methodology and functions are outlined, and results from its application in ongoing monitoring programs are presented. Software and instructions for use can be downloaded free of charge from the Internet.[19]

RESPIRATORY HEALTH EVALUATION AND SPIROMETRY MONITORING

Monitoring of spirometric measurements in occupational settings is widely accepted as a key step in recognizing the early (preclinical) obstructive and restrictive lung diseases and in maintaining respiratory and general fitness to wear respiratory protection.[20,21] Spirometric measurements of forced expiratory volume in 1 second (FEV_1) and forced vital capacity (FVC), as well as the ratio of FEV_1:FVC are most commonly used for establishing and monitoring respiratory health in at-risk populations (eg, firefighters, cotton dust-exposed workers, miners, construction workers exposed to silica dust, and diacetyl-exposed workers[22]). Professional recommendations emphasize several key steps in achieving the full potential of spirometry monitoring in disease prevention and management. These recommendations include

- maintaining acceptable spirometry quality and accuracy through adherence to American Thoracic Society (ATS) and European Respiratory Society (ERS) standards;[23]
- maintaining acceptable longitudinal data precision (ie, low variability of lung function measurements over time in individuals);[24–26]
- applying interpretative strategies that have good sensitivity, yet sufficient specificity, to identify individuals at risk of experiencing excessive loss of lung function and developing functional impairment;[25] and
- using health monitoring results (including symptoms) to target and monitor intervention, including medical treatment.[20,21,27]

METHODS OF LONGITUDINAL SPIROMETRY DATA EVALUATION

Generally, the main objective of spirometry monitoring is to identify individuals at risk of developing lung function impairment (ie, those with abnormally low lung function or those with excessive decline in lung function). Identification of individuals with low lung function has been described elsewhere in detail[23] and will not be covered here. In healthy working populations, including the military, most individuals are likely to have normal lung function, but may develop—in response to hazardous exposures—adverse changes in the lungs that may lead to excessive decline in lung function and long-term consequences. Thus, one of the objectives in workplace spirometry monitoring is to characterize the time-related pattern of lung function decline to identify individuals whose lung function decline is excessive and may be at risk of developing lung function impairment. This section briefly describes methods recommended to identify individuals whose decline in lung function is greater than expected and the method for monitoring longitudinal spirometry data precision and quality.

The most suitable of the spirometry measures for evaluation of lung function changes over time is FEV_1 because it is least prone to measurement error and is decreased in both obstructive and restrictive impairment. In healthy adults who never smoked and have normal body weight, FEV_1 declines at about 27 mL/yr (starting at around 27 years of age), and the decline appears to be linear over the working lifetime.[28]

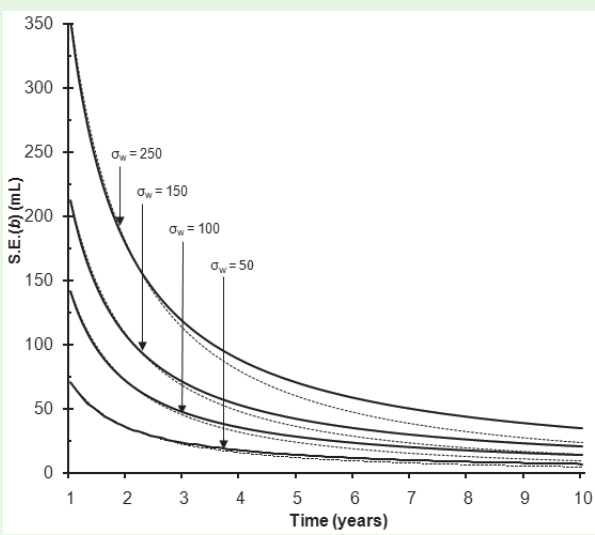


Figure 10-1. Decline in SE(*b*) in relation to follow-up time and varying within-person variation s_w. *Solid line* is based on two measurements (ie, baseline and a measurement at a specific year). *Dotted line* is based on all annual measurements.
SE: standard error

However, because of inherent within-person variability in the spirometry measurements, it generally takes 5 or more years to establish the rate of lung function decline in individuals reliably.[25,26,29]

It can be shown with simple linear regression model statistics why at least 5 years of follow-up are needed, and how the longitudinal data variability affects the duration of follow-up needed to estimate the rate of decline with sufficient precision. The rate of decline in FEV_1 with age can be estimated using a simple linear regression model:

$$(1) \quad FEV_1 = a + b \times \text{age},$$

where slope b represents the rate of FEV_1 change (eg, mL/yr).[28,29] In addition, the variability of longitudinal FEV_1 measurements around the predicted line, as measured by its standard error, SE(b), then determines the precision of the estimated rate of decline (b). Figure 10-1 shows how the estimated SE(b), shown for four individuals with varying inherent within-person variation (from a low of 50 mL to a high of 250 mL), decreases with increasing years of follow-up. The solid line is based on two measurements (ie, baseline and a test taken at a specific year), and the dotted line is based on annual measurements. The one-sided 95% upper confidence limit (95% UCL) for the person's rate of decline measured by slope b is then calculated as

$$(2) \quad 95\%\ \text{UCL} = b + 1.645\ \text{SE}(b).$$

Given that the rate of decline usually ranges from about 20 to 90 mL/yr, it takes approximately 5 to 8 years to estimate an individual's rate of decline with sufficient precision, depending on the magnitude of the individual's within-person variation.

Figure 10-1 demonstrates two important aspects in longitudinal spirometry data evaluation. First, it is important to maintain good quality of the spirometry tests to keep the longitudinal data variability as low as possible so that the signal from the effect of environmental exposure or disease process can be detected. Second, in prospectively collected spirometry data where testing is done on an annual or less frequent basis, the slopes provided by the linear regression model during the first 5 years are generally imprecise and may not provide a reliable estimate of the "true" rate of decline which, on average, ranges around 30 mL/yr in healthy people who never smoked.[25,29–32] Nevertheless, during the early period of spirometry monitoring from 0 to 5 years, there is a need to determine whether a person's observed decline in lung function exceeds what would be predicted based on an expected rate of decline and expected FEV_1 data variability.[30,31,33] The ATS recommends a limit of annual

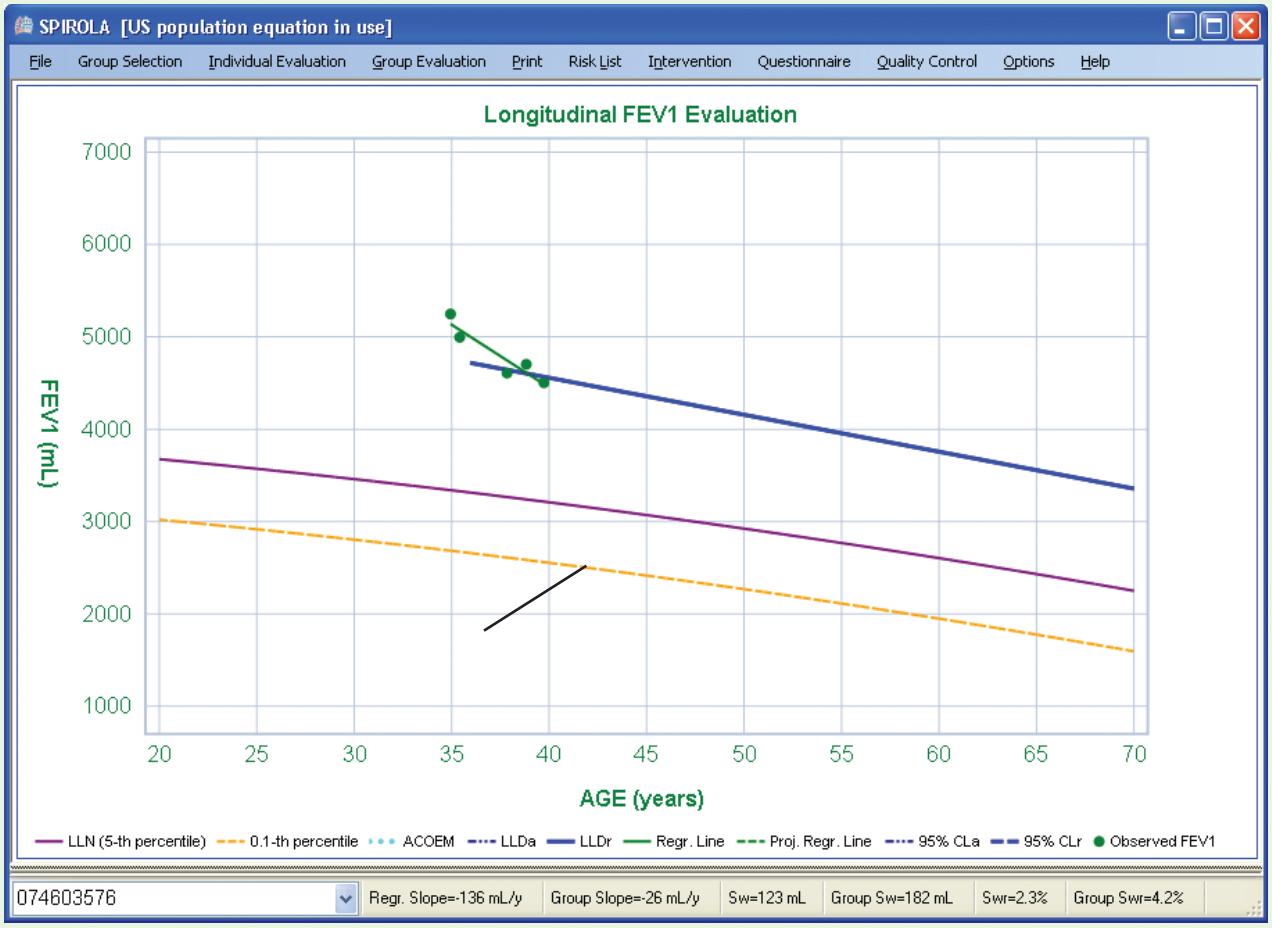


Figure 10-2. Screen capture of a SPIROLA chart that shows longitudinal FEV_1 data for an individual plotted against age, in relation to cross-sectional lower limit of normal (LLN; *purple line*), the limit of longitudinal decline (LLD; *blue line*), and the lower 0.1th percentile (approximately comparable to 60% predicted; *yellow line*).
ACOEM: American College of Occupational and Environmental Medicine; CLa: absolute confidence limit; CLr: relative confidence limit; FEV1: forced expiratory volume in 1 sec; LLDa: absolute limit of longitudinal decline; LLDr: relative limit of longitudinal decline; Proj.: projected; Regr.: regression; Sw: within-person variation; Swr: relative within-person variation; y: year

decline for FEV_1 of 15% as a clinically significant decline.[33] The American College of Occupational and Environmental Medicine (ACOEM) has proposed a longitudinal reference limit based on a 15% annual FEV_1 decline for working populations.[21] However, the fixed limit of 15% may be too wide for maintaining acceptable data precision in a relatively healthy workforce, and has low sensitivity to detect acute adverse effects in some workplace situations where excessive decline over a short period of time has been observed (eg, diacetyl-exposed workers).[34,35]

Computer software, such as SPIROLA, helps to maintain acceptable longitudinal data precision through monitoring of longitudinal data variability. Knowing the variability of the existing data also allows the user to tailor the limit of longitudinal decline (LLD) so that it reflects existing data precision. With increasing data precision, the longitudinal limit can be made more sensitive than the ACOEM recommended 15%. If an individual's FEV_1 decline exceeds LLD, a first step in the evaluation should include an increase in precision of the longitudinal measurements by review of data quality or retesting in the near future, before further steps are taken. Generally, after 5 to 8 years of follow-up, the individual's own regression slope reaches sufficient precision and can be used for decision-making.[25,29,34] Figure 10-2 shows a screen capture from SPIROLA with an example of longitudinal spirometry data for an individual with 5 years of follow-up data, plotted in relation to the estimated lower 5th percentile (lower limit of normal or LLN) for a person of the same age, height, gender, and race, and in relation to the LLD. Although the observed FEV_1 values are within the "normal" range (ie, they are above the LLN), the decline in FEV_1 is excessive when evaluated in relation to LLD.

SPIROLA SOFTWARE FUNCTIONS AND METHODS OF EVALUATION

SPIROLA provides functions for group and individual data evaluation. Group data evaluation is designed to help maintain good spirometry data quality, low within-person variation for the longitudinal FEV_1 and FVC data, and stable mean lung function values for the group over time. Individual data evaluation helps to identify individuals with low lung function values or those with excessive lung function decline or variability.

The following sections demonstrate each function and usefulness of SPIROLA to healthcare providers and provide examples of the application of SPIROLA to data from several ongoing monitoring programs.

Functions for Evaluation of Data at a Group Level

Monitoring Longitudinal Data Precision

Monitoring the program's within-person variation, overall and by individual technicians or centers, helps to maintain longitudinal data precision at an acceptable level and allows prompt investigation into the source of increased variation (eg, instrument malfunction, procedural errors, effects of exposure on lung function, and technician-related errors).[36,37] The program's data variation can be monitored on an annual basis using the absolute or relative pair-wise, within-person variation statistics.[34]

Example Data. Application of SPIROLA in 2005 for the evaluation of data precision in a monitoring program conducted on about 2,500 firefighters prompted concerns about spirometry quality. Figure 10-3 shows that the annual values of absolute (left axis) and relative (right axis) pair-wise, within-person variation for FEV_1 had declined gradually from the program's inception in 1988 until 1999—indicating improving data quality and precision—but then the statistics indicated a marked increase in data variability from 2000. At that time, a volumetric spirometer, used since 1988, had been replaced by a new flow-based spirometer. Usage of the new spirometer resulted in a marked increase in spirometry data variability after 2000. Application of SPIROLA in 2005 led to recognition of the problem and prompted intervention to improve spirometry quality and involved the following measures:

- replacing a flow-based spirometer with a volumetric spirometer in December 2005;
- using a computerized central-quality control by a senior technician from September 2006; and
- monitoring of SPIROLA's indicators of spirometry quality and data variability from January 2008.

Taken together, the interventions resulted in a substantial decrease in the relative within-person variation from 2006 to 4%. The relative within-person variation of about 4% from 2006 to 2011 (Figure 10-3, red line and right axis) signifies acceptable data precision and corresponds to an annual LLD value of ≈10%.[19]

Monitoring Spirometry Quality Control

Monitoring test quality grades assigned by a spirometer at a testing session indicates what percentage of tests adheres to the ATS/ERS recommendations. To help optimize the spirometry quality control for the monitoring program and individual technicians, SPIROLA analyzes the quality grades assigned by a spirometer at a testing session[19,38,39] and monitors on a quarterly basis the percentage of tests that meets the ATS/ERS criteria for acceptability and repeatability, and the percentage of tests that meets repeatability criteria only (ie, ≤150 mL between the two best FEV_1 and FVC measurements).[19]

Example Data. Figure 10-4 shows a SPIROLA chart generated from the analysis of the firefighters' data: quality indices as assigned by a spirometer; within-test repeatability; and relative pair-wise, within-person variation. The figure shows the percentage of tests of acceptable quality (ie, grades A, B, and C); the unacceptable quality includes grades D and F. In this example, data are summarized across all technicians by quartiles. The charts of individual technicians can also be shown. From the onset, a large percentage of FVC tests did not meet the ATS/ERS criteria of quality. Additional training in 2008 helped to improve acceptability of FVC measurements by 2010; most of the unacceptable tests failed to fulfill the end-of-test criteria. Reviewing the charts of individual technicians prompted technician-specific tailored guidance toward improvements.[36]

Monitoring the Group Mean Forced Expiratory Volume in One Second and Forced Vital Capacity Values

Time trends in mean FEV_1 and FVC are displayed to help identify effects taking place at a group level (eg, because of an occupational hazard or a smoking cessation program). To adjust for time-related changes in a group's demographics, SPIROLA also monitors the mean-predicted values estimated from standard or user-supplied reference equations and the z-score. The z-score reflects the mean difference between the observed and predicted values in standard deviation units.

Example Data. Improved spirometry quality and longitudinal data precision resulted in more accurate and precise

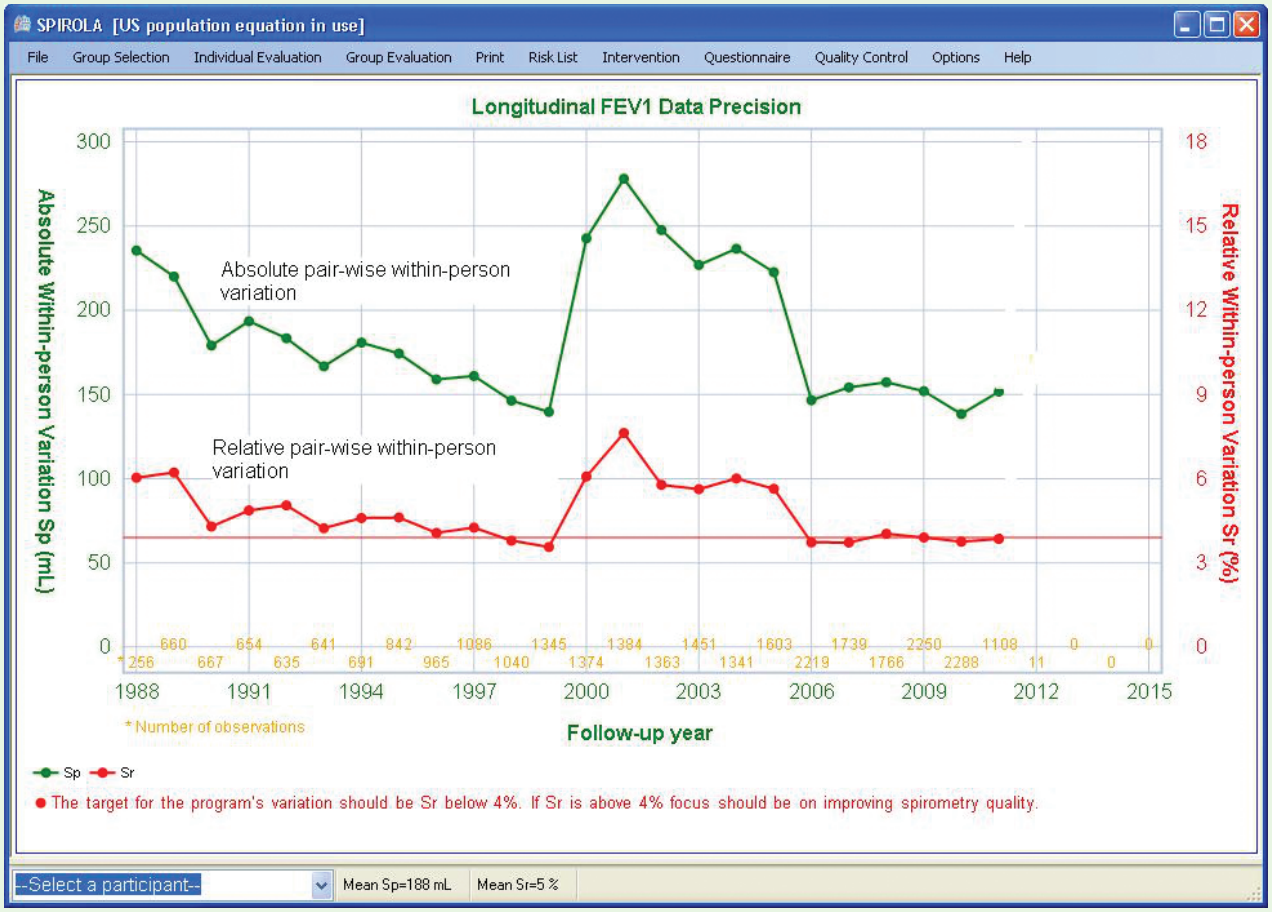


Figure 10-3. Screen capture of a SPIROLA chart for evaluation of longitudinal FEV_1 data precision measured by pair-wise, within-person variation (absolute in mL, *green line*; relative in %, *red line*). Within-person variation of 4% is the desirable level of precision.
FEV1: forced expiratory volume in 1 sec; Sp: absolute within-person variation; Sr: relative within-person variation

lung function values. Figure 10-5 shows the observed mean FVC values plotted against time (green line) in relation to the mean predicted values (yellow line) and the z-score (red line). Because there were no changes in the employment or hiring pattern since the intervention onset in 2005, the increase in the observed means in relation to the predicted means and the increase in the z-scores (red line) was mainly from the improvement in spirometry quality.

Screening for Individuals With Abnormal Results

The individuals identified to have abnormal lung function results appear in the Risk List function, which provides summary statistics on the number screened and found with a specific type of abnormal results. The summary results from one of the monitoring programs (Figure 10-6) show that there were 5,632 workers who had at least one spirometry test during the screening period. The Risk List then shows the number of workers identified with a potential abnormality in lung function: the last observation below LLN, and excessive decline or variation in FEV_1 or FVC. The healthcare provider can then choose participants with a selected condition and click on the "Evaluate" button to assess data for the chosen individuals.

Functions for Evaluation of Data at an Individual Level

Evaluating the Most Recent Spirometry Test Results

As recommended by the ATS, ERS, and ACOEM, the most recent best FEV_1, FVC, and FEV_1/FVC values are compared with US population-based reference values

(default) [21,23,40] or with user-defined reference values. Individuals whose values are below the LLN (ie, values that have a 5% probability of being normal in a healthy nonsmoker population) are identified for further evaluation and recorded in the Risk List.

Evaluating Longitudinal Changes in Forced Expiratory Volume in One Second and Forced Vital Capacity

Time trends for FEV_1, FVC, and their percentage of predicted values and the FEV_1/FVC ratio are displayed graphically. During the first 7 years of follow-up, SPIROLA applies the LLD criterion to identify FEV_1 and FVC measurements that decline excessively from the baseline measurement(s). The LLD can be specified in absolute values or in relative values as percentage, or as the ACOEM limit based on the annual limit of 15%.[20,21] Beginning with 4 years of follow-up, changes in the rate of FEV_1 decline from each longitudinal data point are monitored graphically. The latter function is useful in monitoring the effect of intervention or identification of events leading to deterioration in the rate of decline. Beginning with 8 years of follow-up, SPIROLA evaluates whether an individual is at risk of developing FEV_1 values that have a low probability of being normal (ie, <0.1 percentile, which is comparable with 60% predicted, as defined by ATS as moderate impairment), based on the level of FEV_1 and the rate of FEV_1 decline.

Evaluating Longitudinal Forced Expiratory Volume in One Second and Force Vital Capacity Data Variability

Within-person variation in FEV_1 and FVC is calculated when there are three or more longitudinal measurements and evaluated for the probability of being normal.

Figure 10-4. Screen capture of a SPIROLA chart that shows the percentage of tests that meet the ATS/ERS criteria for acceptability and repeatability for FVC (*green squares*) and FEV_1 (*green circles*); repeatability (respective *blue lines*); and relative pair-wise, within-person variation (*red line*). This is also a summary chart by all technicians and quartiles. ATS: American Thoracic Society; ERS: European Thoracic Society; FEV1: forced expiratory volume in 1 sec; FVC: forced vital capacity; QG: quality grade; Rep: repeatability; Sp: absolute within-person variation; Sr: relative within-person variation

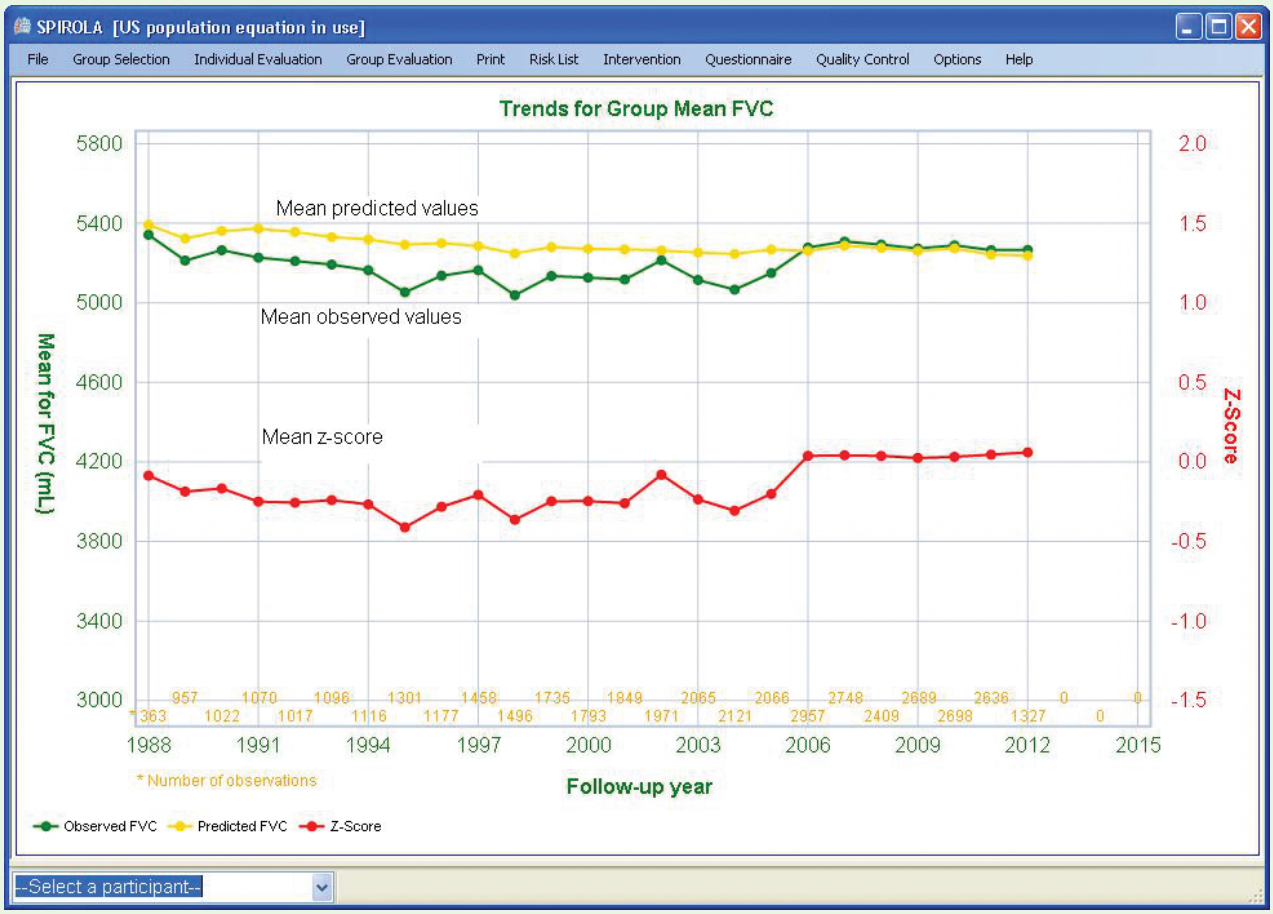


Figure 10-5. Screen capture of a SPIROLA chart that shows group means for observed FVC data (*green line*) and the predicted (*yellow line*) and z-scores (*red line*), by year.
FVC: forced vital capacity

Reporting an Individual's Results

An individual's reports display results of data analyses together with demographic data. If there are abnormal findings, the individual report suggests steps to be considered in further evaluation. These steps include the following:

- assessment of the individual's longitudinal data—obvious outliers can be excluded temporarily from the analysis;
- review of the baseline and most recent spirometry tracings and test quality;
- retesting in the near future to confirm the results; and
- recommendation of further steps, such as medical evaluation and intervention on potential risk factors, but only if abnormal test results are confirmed.

Tagging Individuals for Further Evaluation

The SPIROLA software enables the user to create a list of individuals for quality control or retesting and intervention.

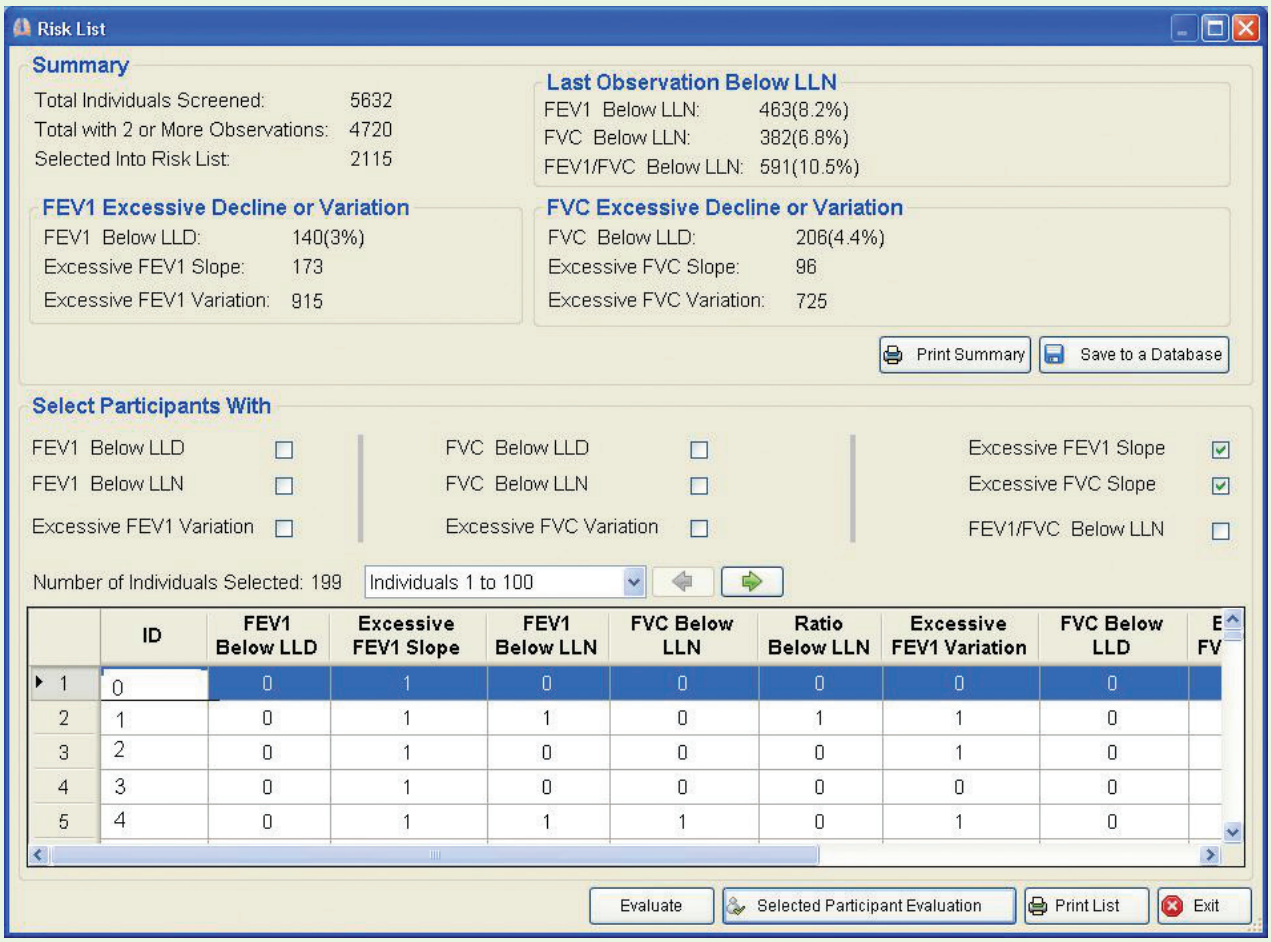
Examples of an Individual's Data Evaluation

The first step in the evaluation of an individual's data is to view the longitudinal trends. Figure 10-7 shows SPIROLA's multiple charts of longitudinal data for FEV_1, FVC, and the FEV_1/FVC ratio for an individual with less than 8 years of follow-up. Although the most recent lung function values were above the LLN (ie, the lung function levels are within normal limits), the FEV_1 and FVC are below LLD for the last two measurements, indicating excessive decline for both FEV and FVC.

Figure 10-8 shows longitudinal data for an individual with

8 or more years of follow-up. The individual was identified as having an excessive decline based on the regression slope and an increased risk of developing moderate impairment (ie, FEV_1 value that has <0.1% probability of being normal when compared with the US population of healthy nonsmokers). The 0.1% corresponds to 60% predicted (ie, moderate impairment).

The first step in the evaluation is to confirm the results by reviewing the longitudinal data, the quality of the baseline and last tests, and retesting, if needed, to increase longitudinal data precision. If an obvious outlier is observed, a data point can be temporarily deleted from the analysis. If the abnormal findings are confirmed, the individual should be referred for further medical evaluation to investigate whether there is respiratory abnormality because of a specific condition or disease and, if needed, intervention on potential risk factors should be initiated. Results should be discussed with an individual to motivate participation in interventions directed at controlling occupational and nonoccupational risk factors. Because of confidentiality issues, an individual's results should not be made available to the employer; only group summary findings should be provided to the healthcare provider to motivate preventive measures in the workplace.



	ID	FEV1 Below LLD	Excessive FEV1 Slope	FEV1 Below LLN	FVC Below LLN	Ratio Below LLN	Excessive FEV1 Variation	FVC Below LLD
1	0	0	1	0	0	0	0	0
2	1	0	1	1	0	1	1	0
3	2	0	1	0	0	0	1	0
4	3	0	1	0	0	0	0	0
5	4	0	1	1	1	0	1	0

Figure 10-6. Screen capture of the SPIROLA Risk List function. Summary results from automatic screening for individuals at risk for having abnormal lung function or excessive decline in lung function. De-identified data obtained from spirometry monitoring program conducted on firefighters.
FEV1: forced expiratory volume in 1 sec; FVC: forced vital capacity; ID: identification; LLD: limit of longitudinal decline; LLN: lower limit of normal
Data source: Hnizdo E, Hakobyan A, Fleming J, Beeckman-Wagner L. Periodic spirometry in occupational setting: improving quality, accuracy, and precision. *J Occup Environ Med.* 2011;53:1205–1209.

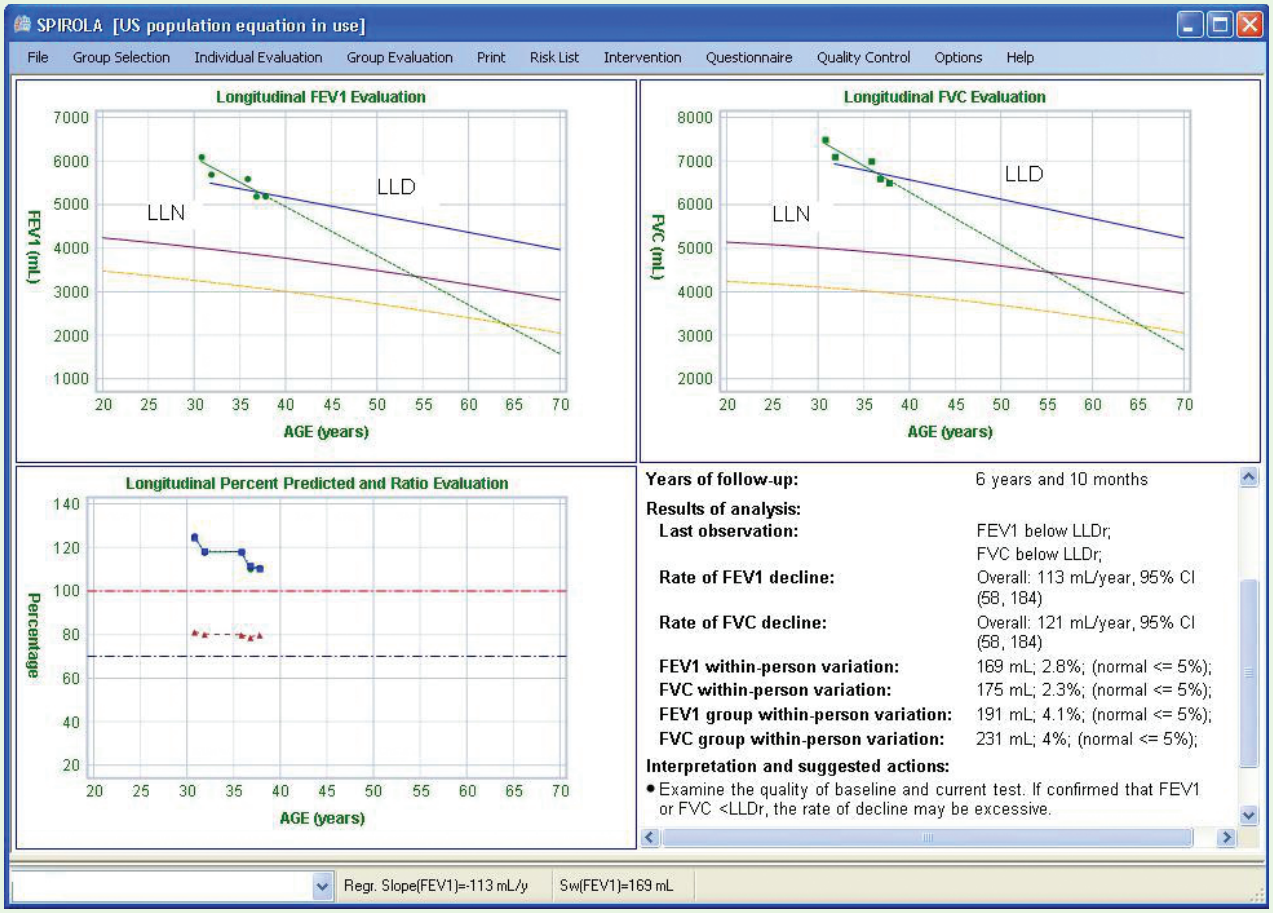


Figure 10-7. Screen capture of SPIROLA multiple charts for an individual with <8 years of follow-up. Longitudinal FEV_1, FVC, and the percentage of predicted values are plotted against age and the report summarizing findings. FEV_1 and FVC are below LLD, indicating an excessive decline. De-identified data obtained from spirometry monitoring program conducted on firefighters.
CI: confidence interval; FEV1: forced expiratory volume in 1 sec; FVC: forced vital capacity; LLD: limit of longitudinal decline; LLDr: relative limit of longitudinal decline; LLN: lower limit of normal; Regr.: regression; Sw: within-person variation; y: year
Data source: Hnizdo E, Hakobyan A, Fleming J, Beeckman-Wagner L. Periodic spirometry in occupational setting: improving quality, accuracy, and precision. *J Occup Environ Med.* 2011;53:1205–1209.

Software Environment and Data Requirement

SPIROLA runs on the PC and requires Microsoft Windows 2000/XP/Vista/Windows 7, Microsoft .NET Framework 2.0, and Microsoft Database Engine (which are Microsoft default options). The User Guide, available on the Internet[19] or from SPIROLA's Help menu, describes the installation procedure, data input, functions, and theoretical background on which the data analysis is based. The SPIROLA databases should be kept in a secured folder or in a secured shared folder, if needed.

At a minimum, SPIROLA requires the following data:

- a unique personal identifier,
- age,
- height,
- race/ethnicity,
- best FEV_1 and FVC test values, and
- date of test.

Where the spirometry system assigns quality grades from each testing session (i.e., quality grades for acceptability and repeatability), these data can be also uploaded into the SPIROLA database and analyzed by SPIROLA. Data for intervention decision-making (eg, weight, occupational exposure factors, smoking data, and questionnaire responses) can be included in the database for display in individual records. Also, a direct link can be created between a spirometer and SPIROLA.[19]

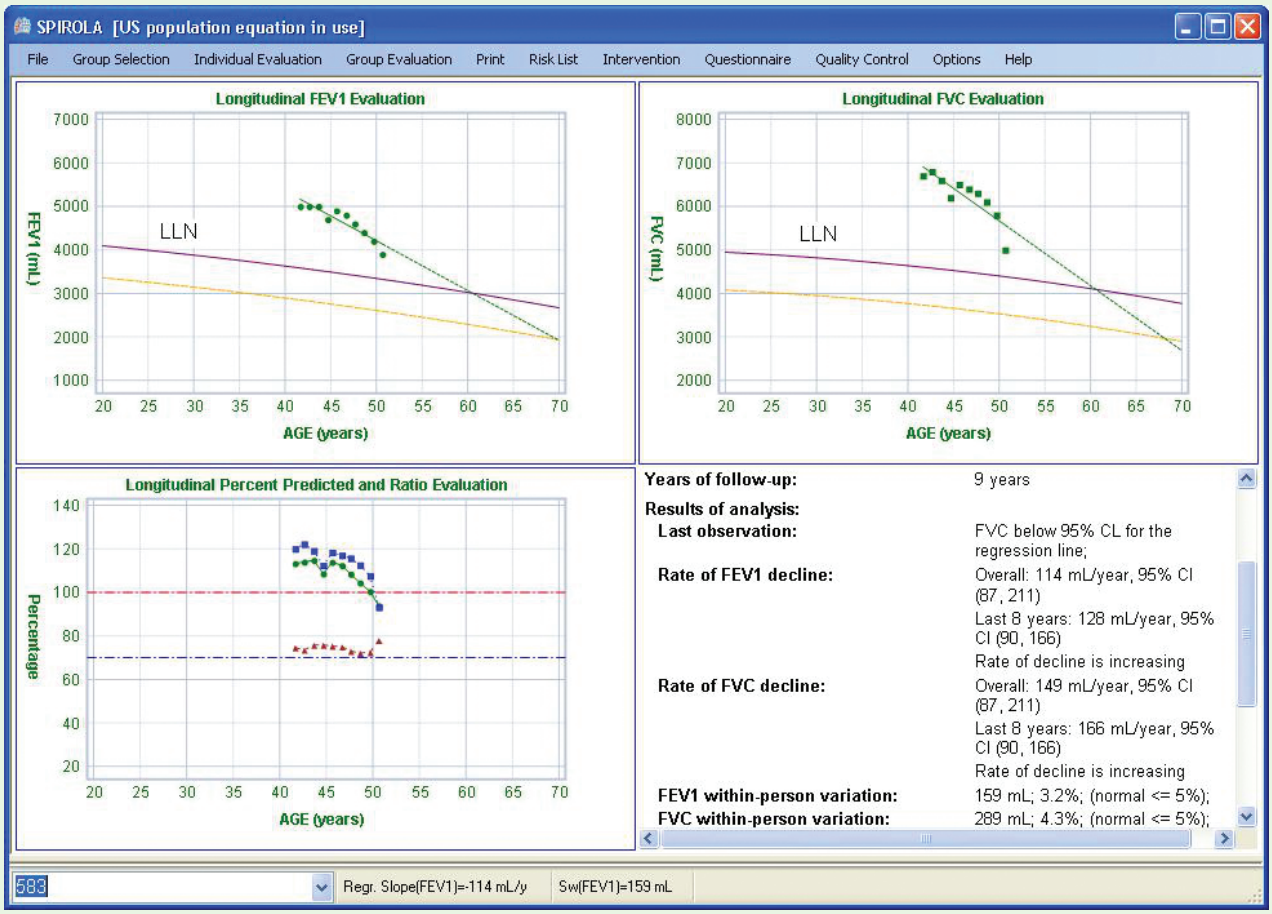


Figure 10-8. Screen capture of a SPIROLA chart shows results for an individual with >8 years of follow-up. Regression lines for FEV_1 and FVC can be projected to indicate whether the person is at risk for developing moderate airflow obstruction based on the LLN and 0.01th percentile. De-identified data obtained from spirometry monitoring program conducted on firefighters.
CI: confidence interval; CL: confidence limit; FEV1: forced expiratory volume in 1 sec; FVC: forced vital capacity; LLN: lower limit of normal; Regr.: regression; Sw: within-person variation; y: year
Data source: Hnizdo E, Hakobyan A, Fleming J, Beeckman-Wagner L. Periodic spirometry in occupational setting: improving quality, accuracy, and precision. *J Occup Environ Med.* 2011;53:1205–1209.

SPIROLA's main menu options are easy to operate and allow for a spirometry file selection, a group selection and evaluation, evaluation of an individual's data, monitoring of longitudinal spirometry data precision and tests quality scores, and automatic selection of individuals whose tests need review because of abnormal findings.

DISCUSSION

Periodic spirometry is often recommended for individuals with actual and potential exposures to respiratory hazards.[20,21] To achieve the full potential of spirometry-based medical monitoring in detecting a signal due to adverse health effects, it is necessary to maintain acceptable test quality and apply interpretive strategies that have high sensitivity and specificity in identifying individuals at risk of developing lung function impairment. Longitudinal data precision determines how soon and how reliably a "true" excessive decline can be identified (Figure 10-1).[34]

SPIROLA software was developed as a visual and analytical tool to assist healthcare professionals in addressing challenges arising from monitoring the respiratory health of individuals potentially at risk.[19] The software is intended to assist the user in assembling the information required to make medical decisions; however, it cannot

be substituted for competent and informed professional judgment.

To assist in the evaluation of the practical utility of SPIROLA, managers of several ongoing spirometry-based health surveillance programs have adopted use of the software. The results from monitoring programs conducted on US workers reported here demonstrate that the information displayed by SPIROLA on longitudinal data precision can assist the healthcare professionals in determining potential sources of excess variability (eg, a change in spirometry systems and procedural errors) and recognizing when an intervention on data quality is needed and, subsequently, whether the intervention improved longitudinal data precision (Figures 10-3, 10-4, and 10-5). SPIROLA can also aid in optimizing the performance of individual technicians through the spirometry quality grades analysis (Figure 10-5). Although appropriate equipment, trained technicians, knowledgeable professional oversight, and comprehensive procedure manuals are basic components of a quality testing program,[20,21] data precision can vary over time for various reasons, and such changes may not be noticeable on individual tests.[36]

The estimate of data precision provided by the software affords additional benefits during the interpretation of longitudinal change for individuals. It facilitates determination of an appropriate limit of longitudinal decline, LLD, a criterion applied by SPIROLA software to maintain longitudinal data precision and detect early (within 8 years) excessive lung function decline. The LLD method increases flexibility to develop stringent quality control and to increase sensitivity for detecting long-term excessive decline or acute respiratory effects under different monitoring conditions.[34] The knowledge of group longitudinal data precision and data quality increases the likelihood of discerning whether an observed change in lung function is from procedural error or incipient lung disease. However, workplace or environmental factors may be responsible for increased FEV_1 and FVC variabilities by causing respiratory illness.

Because COPD is a preventable disease that usually takes many years to develop, early recognition of abnormal pulmonary function decline followed by an effective intervention is important in disease prevention.[14] The longitudinal assessment over all follow-up years based on evaluation that takes into account data variability, as done by SPIROLA, helps to improve the accuracy of recognition of the development of respiratory disease. By helping to improve longitudinal data precision, SPIROLA improves the precision of the estimated rate of decline and identification of those with a true excessive rate of decline. Furthermore, the Risk List function helps the healthcare provider to identify individuals whose spirometry results may be abnormal and who may need further evaluation; this function is especially useful in occupational settings where a large number of workers undergo spirometry monitoring.

A limitation of this work is that the long-term implications of the application of SPIROLA for disease prevention have not yet been fully evaluated in ongoing monitoring programs.

All the data presented in this chapter are from a project that has been approved by the NIOSH Human Subject Review Board.

SUMMARY

Prevention of environmental and lifestyle exposures that increase the risk of lung function impairment and disease is important because these conditions often profoundly diminish the affected individual's quality of life. These conditions are also associated with premature functional impairment and disability, early retirement from work, and increased future morbidity and mortality.

Prevention through early recognition and effective interventions directed at controlling known risk factors—including environmental, occupational, and lifestyle exposures—is possible in spirometry monitoring of at-risk populations.

SPIROLA software is designed to assist healthcare providers in managing and interpreting periodic spirometric measurements. Thus, this helps to achieve the full potential of spirometry monitoring in disease prevention and management.

Application of SPIROLA in an ongoing spirometry monitoring program has helped to identify previously unrecognized increases in longitudinal data variability from equipment and procedural problems. It also helped to demonstrate that subsequent data quality interventions resulted in improvement in spirometry quality, longitudinal data precision, and validity.[36]

By organizing and analyzing longitudinal spirometry data, SPIROLA software has helped to improve the use of periodic spirometry data in disease prevention and to improve the wellness of construction workers potentially exposed to respiratory hazards.[27]

Collection of spirometric measurements can be costly; thus, it important that the measurements are of recommended quality and that the data are effectively used for its purpose. Computerized monitoring of data quality and precision, and ongoing data analysis help to achieve the full potential of spirometry monitoring in clinical, occupational, or other settings.

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