Clinical Application of Spirometry Longitudinal Data Analysis (SPIROLA) Software in an Occupational Health Clinic and Office Setting

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Conflict of Interest

• I hereby certify that, to the best of my knowledge, no aspect of my current personal or professional situation might reasonably be expected to affect significantly my views on the subject on which I am/we are presenting.
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  » United States Navy
  » U.S. Naval Hospital Guam
• No financial or organizational interests to disclose.
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Acknowledgements

• Dr. Wesley Boose, MD, MPH
• Dr. Christopher Rendina, DO
• Suzanne Cabrera, MN, RN, COHN-S
• Kathryn Henzler, BSN, RN
• Occupational Health Technicians:
  » Teresita Ann Julao   » Patrick Powell
  » Livian Lucy Sanchez   » Jamiel Morris
  » Garry Phillip   » Ariel Parris
• Administrative / Medical Records Clerks:
  » Esther Fergison   » Jesse Munoz
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  - Jesse Munoz
GUAM: “Where America’s Day Begins”
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Image Source: https://earth.google.com/
Occupational Health Clinic

- Joint Region Marianas
- Naval Hospital Guam
- Naval Base Guam
- Naval Weapons Magazine
- Naval Comm’s Station
- Andersen AirForce Base Assets
- Force Protection (Police/ Security)
- Fire and Emergency Services
- U.S. Coast Guard Sector Guam

- Naval Special Warfare - Detachment 1
- Explosive Ordinance Disposal - Mobile Unit 5
- Submarine Squadron 15
- Seabees (NMCB 11, NMCB 133)
- Military Sealift Command (MSC)
- Helicopter Sea Combat - 25
- Naval Facilities Marianas
- Guam Army National Guard, 94th Civil Support Team
How does your occupational health practice evaluate for excessive lung function decline?
Learner Outcomes

• Understand the American Thoracic Society (ATS) recommendation for longitudinal monitoring of pulmonary function tests to detect early signs of excessive lung function decline
• Describe lung function decline and it’s clinical implications
• Describe the process to set up and apply SPIROLA in an Occupational Health Clinic and Office Setting
• Review case studies to assess longitudinal spirometry and identify evidence of excessive lung function decline
History of Spirometry

  - Cotton dust exposure
  - Byssinosis (aka brown lung disease or Monday fever), bronchitis, and asthma
  - Impairment, disability, and premature death
  - Industry required to comply with new guidance to reduce exposure → regulatory requirements
  - Periodic medical surveillance must include spirometry
  - Persons administering PFTs must be certified by completing a NIOSH-Approved Spirometry Course (reproducibility)

Image Source: https://www.trustedclothes.com/
History of Spirometry

  » Coal and silica dust exposure
  » Coal Worker’s Pneumoconiosis (CWP), Silicosis, also called “black lung,” COPD
  » Impairment, disability, and premature death
  » Industry required to comply with new guidance to reduce exposure → regulatory requirements
  » Coal Workers’ Health Surveillance Program (CWHSP)
    ▪ Periodic chest radiographs
  » Periodic medical surveillance to include:
    ▪ Spirometry
    ▪ Standardized respiratory questionnaire

Purpose of Spirometry

- Occupational medical surveillance tool
- Cross-sectional (single point in time) or longitudinal (over time) analysis
- Measures how much (volume) and how fast (flow) air moves into and out of lungs
- Early identification of lung disease caused by occupational hazards
- Identify workers with excessive FEV1 decline
  - Respiratory morbidity
  - Loss of productivity at an earlier age
  - Mortality

Image Source: https://www.cdc.gov/niosh/topics/cwhsp/coalminerhealth.html
Spirometry Overview

• Flow-volume curve
  » Emphasizes the **start of test**
  » Rising rapidly to sharp peak
  » Descending to zero flow

• Volume-time curve
  • Emphasizes the **end of test**
  • Rising rapidly
  • Gradually flattening out to plateau

Image Source: https://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/ACOEM%20Spirometry%20Statement.pdf
Spirometry: Measurements

- **FVC – Forced Vital Capacity**
  - Maximum volume of air that can be exhaled forcefully after a maximal inspiration
  - Reduced in restrictive disease and severe obstructive disease

- **FEV1 – Forced Expiratory Volume in 1 second**
  - Volume of air exhaled forcefully during the first second of expiration after a maximal inspiration
  - Best indicator of air moving through airways
  - Reduced in obstructive disease or if FVC is reduced

- **FEV1/FVC – Ratio of FEV1 to FVC**
  - Expressed as a percent (%): \((\text{FEV1}/\text{FVC}) \times 100\)
  - In healthy people, >70% of FVC exhaled in first second
  - Reduced in obstructive disease, best indicator of obstructive disease

*Image Source: https://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/ACOEM%20Spirometry%20Statement.pdf*
Spirometry: Reference Values

• Lower Limit of Normal (LLN)
  » Threshold below which a value is considered abnormal
  » 5% of reference population is below the LLN
  » ATS/ERS recommend using LLN to differentiate between normal from abnormal rather than using a fixed value (e.g., 80% of predicted FEV1 or FVC and 0.70 for the observed ratio of FEV1/FVC)

• Longitudinal Limit of Decline (LLD)
  » Relative limit set for longitudinal annual FEV1 decline
  » Limit is calculated using statistical methods (software available)
  » Facilitates interpretation of annual longitudinal changes in FEV1
  » If FEV1 < LLD, then observed FEV1 decline may be excessive
ATS Recommendations

• FEV1 decline of **15% or more over a year (15% rule)** in otherwise healthy individuals is considered “significant,” beyond what would be expected from typical variability
• In 2014, the ATS recommended three approaches for longitudinal analysis
• Approaches to detect **excessive FEV1 decline**:
  1. A 15% decline from baseline FEV1, plus expected age-related loss
  2. Limit of Longitudinal Decline
  3. Linear Regression
Calculating Excessive FEV1 Decline

Approaches:

1. A 15% decline from baseline FEV1 (plus expected age-related loss)
   - **Percent Predicted Method**
     - **Calculation of threshold**: Baseline (initial) FEV1% predicted minus current FEV1% predicted
     - **Interpretation**: If ≥15%, then observed decline in FEV1 may be excessive
   - **Volume Method**
     - **Calculation of threshold**: Baseline (initial) predicted FEV1 minus current predicted FEV1 plus (0.15 x baseline FEV1)
     - **Interpretation**: If observed change in FEV1 (FEV1 baseline minus FEV1 follow up) > threshold, then FEV1 decline may be excessive
Calculating Excessive FEV1 Decline

Approaches (continued):

2. Limit of Longitudinal Decline (LLD)
   - **Calculation of threshold:** Calculate LLD using available software
   - **Interpretation:** If current FEV1 < LLD threshold, then FEV1 decline may be excessive

3. Linear Regression
   - **Calculation of threshold:** Use linear regression software to calculate FEV1 slope (ml/yr) using all available spirometry results over time
   - **Interpretation:** Compare observed rate of FEV1 decline with rates of decline associated with adverse health outcomes (>60-90 ml/yr)
Lung Function Decline

• Primary measurement for assessment is FEV1
  » FEV1 is less affected by technical factors than FVC
• Lung function normally increases during childhood, before reaching a maximum
• Lung function begins to decline in the mid-20s to mid-30s
Lung Function Decline

- Average rate of decline
  - 29 ml/yr
  - Affected by:
    - Occupational exposures
    - Cigarette smoking
    - Weight gain
    - General lack of fitness
    - Gender
    - Age

- Accelerated lung function decline
  - >60-90 ml/yr
  - Associated with:
    - ↑ morbidity
    - ↑ mortality
Lung Function Decline Over Time

Source: https://www.aafp.org/afp/2006/0215/p669.html
Clinical Implications for Longitudinal Evaluation

- Detect *excessive* decline in lung function
- Early identification to an exposure
- Early identification of an underlying condition
- Detect progressive lung disease at an earlier stage
- Help providers make decisions about respiratory health
- Help providers make decisions about the need for medical referrals
- Prevent increased respiratory morbidity, loss of productivity at an earlier age, and increased mortality
Intervention Measures

• Individual
  » Inhalation of hazardous particulates and gases
    ▪ Smoking cessation
    ▪ Occupational exposures to resp hazards (engineering controls, administrative controls, PPEs)
  » Weight Gain (BMI >25)
  » Education and Training

• Group / Company
  » Integrated worksite health and safety program
    ▪ Healthy workforce
    ▪ Smoking cessation
    ▪ Weight management
  » Education and Training
How does your occupational health practice evaluate for excessive lung function decline?
Voice of the Customer

• **Patient:** “I have confidence that the doctor would know if I was developing a lung problem.”

• **Occ Health:** I’m not confident that with the current 15% analysis method, I can predict a dangerous trend in a patient’s lung condition.”

• **Commanding Officer:** “I wonder if our Occupational Health Clinic is using the latest techniques for spirometry analysis to keep our firefighters healthy.”

• **Pulmonology:** “Longitudinal data analysis would give us further perspective into the disease process.”
Gaps in Clinical Practice

- In 2014, ATS recommends longitudinal lung function monitoring to detect early signs of excessive lung decline.
- Efficient clinical tool for longitudinal lung function monitoring is available for clinical application.
- Limited educational resources to train providers on how to evaluate and interpret longitudinal spirometry.
- Lack of knowledge of a tool available for clinical application to lung function longitudinal monitoring.
Existing Solutions

• Manually plotting trends
  » Time consuming, increase chance of error/inaccuracy

• 15% method – compare current data to baseline
  » May miss subtle lung disease presentations

• Linear regression – compare current data to baseline
  » Requires building database and calculating best-fit line
  » Does not provide group comparison or program quality analysis.
  » Time consuming, not practical in a busy clinic.

• Spirometry analysis software – calculate LLD and linear regression
Existing Solutions
(Current Methodology)

- 48 yo M Firefighter presents for annual physical exam
- PMH/PSHx: Nothing significant
- Meds: None
- Allergies: NKDA
- Soc Hx: 5 smoking pack years, quit in 20s
- Occ Hx:
  » Federal CIV Firefighter for 24 yrs
  » Air Force Active Duty Firefighter for 4 yrs
Existing Solutions
(SPIROLA Analysis of Same Patient)

- 48 yo M Firefighter presents for annual physical exam
- PMH/PSHx: Nothing significant
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<td>Years of follow-up</td>
<td>19 years and 3 months</td>
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**Results of analysis:**

- **Last observation:**
  - Rate of FEV1 decline:
    - Overall: 3.5 mL/year, 95% CI (9, 44)
    - Last 8 yrs: -2 mL/year, 95% CI (-60, 56)
    - Rate of decline is decreasing
  - Rate of FVC decline:
    - Overall: 26 mL/year, 95% CI (9, 44)
    - Last 8 yrs: -21 mL/year, 95% CI (-60, 56)
    - Rate of decline is decreasing
- **FEV1 within-person variation:** 206 mL, 4.1%, (normal <= 5%)
- **FVC within-person variation:** 202 mL, 3.2%, (normal <= 5%)
- **FEV1 group within-person variation:** 197 mL, 5.6%, (normal <= 6%)
- **FVC group within-person variation:** 217 mL, 5.4%, (normal <= 5%)

**Interpretation and suggested actions:**

- No abnormal findings
Existing Solutions  
(SPIROLA Analysis of Same Patient)

**Color Key**

- Lower Limit of Normal (LLN)
- Limit of Longitudinal Decline (LLD)
- Regression Line
- Projected Regression Line
Existing Solutions

- No specialized off-the-shelf commercial applications available
- SPIROLA Software developed by NIOSH
  » Designed to perform longitudinal lung functional analysis in clinic and office setting
    ▪ Calculates limit of longitudinal decline (LLD)
    ▪ Most accurate with 5+ years of follow up data
    ▪ Can assess individuals and groups
    ▪ Can compare testing quality across PFT testers
Root Cause Analysis

• Why is there currently no longitudinal analysis of spirometry data?
  » Current system has no function for regression analysis – all done manually with pen and paper
  » **No enforcement (audit) for longitudinal data analysis**
  » No clinical training in regression analysis
  » Network restrictions on new software
  » No available commercial programs with direct application to spirometry

Source: U.S. Navy Medicine
Why is there no longitudinal data analysis?

- **HQ**
  - No Audits
  - No Tracking of Longitudinal Data
  - No initiatives for new software
  - Implementation would require high workload — quality control
  - Change is inconvenient

- **IT**
  - No system for electronic regression analysis
  - Spirometer has no function for longitudinal tracking
  - No appropriate documentation that Health Promotions Dept was notified
  - Why no longitudinal analysis of Spirometry Data?
  - Network regulation issues
  - Spirola Software not authorized with .mil

- **Support Staff**
  - No training in data analysis
  - Little knowledge about regression analysis
  - Manual tracking of data is cumbersome and slow

- **Provider**
  - No tracking of longitudinal data
  - Why no initiatives for new software
  - Implementation would require high workload — quality control
  - Change is inconvenient

Lack of awareness about alternatives
Prioritized Solutions

• Prioritized Solutions
  » Install SPIROLA Software
  » Manually Perform linear regression analysis
  » Continue using 15% rule
  » Do nothing

• Determine Measures of Success
  » % of patients that receive longitudinal data analysis

• Identify Expected Results
  » Short term
    ▪ Earlier detection of lung disease
    ▪ Earlier identification of workplace exposures
    ▪ Earlier identification of PPE effectiveness or compliance concerns
    ▪ Safer workplace
  » Long term: Protect the worker from further excessive lung function decline
Gap and Target

• No efficient, accurate method for longitudinal analysis
• No existing program in our industry with an efficient and accurate method
• Failure to track a patient's lung function could result in delayed diagnosis and treatment
• ATS guidelines recommend implementing a system to longitudinally follow the lung function of patients at risk for developing occupational related lung disease
• Target for an affordable, effective, practical, and sustainable solution
  » In search for existing solutions, SPIROLA was identified
SPIROLA

- SPIROLA identified as best solution for longitudinal data analysis
  - Low Cost ➔ free for use by public
  - Accuracy ➔ testing in clinic using actual data
  - Reliability ➔ pilot testing shows high reliability
  - Testability ➔ all systems were testable prior to complete conversion
  - User-Friendly ➔ easy to install, application requires no special training
  - Usability on Network ➔ DHA approved for use on DoD network

Image Source: https://www.cdc.gov/niosh/topics/spirometry/spirola-software.html
SPIROLA

• **FREE** downloadable Longitudinal Data Analysis Software (NIOSH)
• Integrated visual, quantitative tool for monitoring lung function over time
• Monitors quality of spirometry test
• Monitors longitudinal data precision
• Determines if an individual has excessive lung function decline
• Collect information on potential risk factors
• Plan, record, and evaluate the effect of intervention strategies

Image Source:
https://www.cdc.gov/niosh/topics/spirometry/spirola-software.html
SPIROLA

• Individual Evaluation
  » FEV1 and FVC changes over time
  » Most recent spirometry test results
  » Longitudinal changes in FEV1
  » Longitudinal FEV1 data variability
  » Individual report
  » Tags individuals for further evaluation

• Group Evaluation
  » “Risk List” – screens for and provides statistics on individuals in groups whose lung function level, decline, or variability may be abnormal
  » Monitors for
    ▪ Longitudinal data precision
    ▪ Group mean FEV1 and FVC values
    ▪ Spirometry quality control
    ▪ Screening for individuals with abnormal results
Risk List

- Screens for Individuals with excessive lung function decline or variation
- Screens for individuals whose most recent lung function values fall below LLN
- Identifies individuals at risk of developing respiratory impairment
# Implementation Plan

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<th>ACTION</th>
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<td>Search for viable solutions</td>
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<td><strong>Network approval process (DHA)</strong></td>
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<td>SPIROLA database build</td>
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<td>Build SOP and staff training</td>
<td>Clinic Manager</td>
<td>13 Apr 17</td>
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<td>Quality check data entry</td>
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<td>29 Dec 17</td>
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<td><strong>Request Occupational Medicine Form Change</strong></td>
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<td>Begin Patient Consults with SPIROLA</td>
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## Stages of Implementation

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## Implementation Timeline

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Initial Referral to Occ Health

Registration at Front Desk

Job-forms Labs X-rays

Assign Spirometry Tech

Medical Restrictions?

Spirometry test

Test Good?

OCC Health RN Quality Assurance

Paper results placed in medical file

Medical Restrictions?

Yes 97%

NO 3%

Discharge from Occ Health Clinic with appropriate F/U

Yes 98%

NO 2%

Pulmonology exam and treatment

Current MD Review does not included longitudinal analysis

All records and analysis of spirometry test are paper

MD review spirometry data w patient

Problems?

START

1 week lead

.7 hrs-- cum .7 hrs

.2 hrs-- cum 2.7 hrs

.3 hrs-- cum 2.5 hrs

.6 hrs-- cum 3.3 hrs

END

1 week lead

.1 hrs-- cum .1 hrs

2 hrs-- cum 2.1 hrs

.1 hrs-- cum 2.2 hrs
(Ideal) State After Implementation

START

1. Initial Referral to Occ Health
2. Registration at Front Desk
3. Job-forms
4. Labs
5. X-rays
6. Medical Restrictions?
   - Yes 3%
   - No 97%

END

Discharge from Occ Health Clinic with appropriate F/U

Results of Spirometry test entered manually into SPIROLA database

MD Review includes full longitudinal analysis

Test Good?
   - No 10%
   - Yes 90%

MD review spirometry data w/ patient

OCC Health RN Quality Assurance

Spirometry data entered into SPIROLA

Paper results placed in medical file

Spirometry test

Medical Restrictions?
   - Yes 3%
   - No 97%

Discharge from Occ Health Clinic with appropriate F/U

Pulmonology exam and treatment

PCM evaluation of medical issue

1 week lead

.1 hrs - cum .1 hrs

.2 hrs - cum 2.7 hrs

.3 hrs - cum 2.5 hrs

.6 hrs - cum 3.3 hrs

1 week lead

.1 hrs - cum .1 hrs

2 hrs - cum 2.1 hrs

1 hrs - cum 2.2 hrs

Pulmonology exam and treatment

MD Review includes full longitudinal analysis
Access Database

- Database View
- Form View
  - Customized Fields
  - Data Entry Legend
Results and Follow Up

• By Dec 2017 (13.5 months)
  » All patient spirometry data entered
  » 100% of patients scheduled received longitudinal data analysis using SPIROLA
  » Data control plan involved QC of data entry
Implementation Benefits

• Supports Organization goals of personnel readiness, health and safety
• Efficient and cost-effective
• Approach may be applied at any Occupational Health Clinic (DoD or Civilian)
Recommendations for Future Implementation

• Obtain SPIROLA Software from NIOSH
  » SPIROLA Web-Based Application in pilot stages

• Contact local IT for installation on network
  » Already approved and authorized for DoD use

• Building the Database
  » Approximately 30 days and 80 man-hours
  » Quality check every record after build

• Train all clinic personnel
  » Approximately 30 days

• Start Clinical Use
CASE STUDIES
Color Key

• Lower Limit of Normal (LLN)
• Limit of Longitudinal Decline (LLD)
• Regression Line
• Projected Regression Line
Case 1

- 47 yo Firefighter presents for annual physical
- PMH/PSHx: GERD
- Weight gain: 19lbs, BMI: 31
- Meds: Vitamins
- Allergies: NKDA
- Soc Hx: Never smoked, chewing tobacco
- Occ Hx:
  - Federal CIV Firefighter for 22 years
  - Work Exposures: Nothing significant
- CXR: Normal
- % Predicted and LLN with Asian Ethnic Correction:
  - FVC: 4.00 (95%), FEV1: 3.17 (96%), FEV1/FVC%: 79.2%
  - LLN: FVC = 3.44, FEV1 = 2.65
Case 1
Case 1

Sex: Male
Race: Asian-American
Age: 47 years old
Height (Mean): 172.2 cm
Date of last test: 10/10/2017
Years of follow-up: 21 years and 10 months

Results of analysis:

Last observation: FVC below 95% CL for the regression line;
Rate of FEV1 decline: Over 20 mL/year. 95% CI (41, 39)
Last 8 years: 66 mL/year, 95% CI (-55, 185)
Rate of decline is increasing

Rate of FVC decline: Overall: -1 mL/year, 95% CI (41, 39)
Last 8 years: -69 mL/year, 95% CI (-55, 185)
Rate of decline is increasing

FEV1 within-person variation: 335 mL, 9% (normal <= 5%)
FVC within-person variation: 545 mL, 12.7% (normal <= 5%)
FEV1 group within-person variation: 186 mL, 5.3% (normal <= 5%)
FVC group within-person variation: 214 mL, 5.2% (normal <= 5%)

Interpretation and suggested actions:

- The within-person variation for FEV1 or FVC > 5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase data variability.
- If confirmed that FVC < 95% CL for the regression line, consider re-testing in near future.

2018 NATIONAL CONFERENCE | APRIL 16-18, 2018
Case 1
(excluding 4/2012 observation from analysis)
Case 1
(excluding 4/2012 observation from analysis)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male</th>
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<tbody>
<tr>
<td>Race</td>
<td>Asian-American</td>
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<tr>
<td>Age</td>
<td>47 years old</td>
</tr>
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<td>Date of last test</td>
<td>10/10/2017</td>
</tr>
<tr>
<td>Years of follow-up</td>
<td>21 years and 10 months</td>
</tr>
</tbody>
</table>

**Results of analysis:**

**Last observation:**

**Rate of FEV1 decline:**
- Overall: 28 mL/year, 95% CI (3, 20)
- Last 8 years: 31 mL/year, 95% CI (11, 52)

**Rate of FVC decline:**
- Overall: 12 mL/year, 95% CI (3, 20)
- Last 8 years: 34 mL/year, 95% CI (11, 52)

**FEV1 within-person variation:** 92 mL, 2.5% (normal <= 5%)
**FVC within-person variation:** 113 mL, 2.6% (normal <= 6%)
**FEV1 group within-person variation:** 186 mL, 5.3% (normal <= 5%)
**FVC group within-person variation:** 214 mL, 5.2% (normal <= 5%)

**Interpretation and suggested actions:**
No abnormal findings
Case 2

- 54 yo Firefighter presents for annual physical
- PMH/PSHx: 1966 LTBI s/p INH Tx, HLD
- Weight gain: 13lbs, BMI: 30
- Meds: Crestor
- Allergies: NKDA
- Soc Hx: 10 smoking pack years
- Occ Hx:
  - Federal CIV Firefighter for 27 years
  - Work Exposures: 1991 Occupational back injury
- CXR: Normal
- % Predicted and LLN with Asian Ethnic Correction:
  - FVC: 3.29 (94%), FEV1: 2.84 (105%), FEV1/FVC%: 86.4%
  - LLN: FVC = 2.81, FEV1 = 2.12
Case 2
Case 2

Sex: Male
Race: Asian-American
Age: 64 years old
Height (Mean): 162.6 cm
Date of last test: 8/9/2017
Years of follow-up: 27 years and 9 months

Results of analysis:
- FVC below 95% CL for the regression line
  - Overall: 18 mL/year, 95% CI (4, 17)
  - Last 8 years: 57 mL/year, 95% CI (27, 87)
  - Rate of decline is increasing
- Rate of FVC decline:
  - Overall: 7 mL/year, 95% CI (4, 17)
  - Last 8 years: 72 mL/year, 95% CI (27, 87)
  - Rate of decline is increasing

**FEV1 within-person variation:** 130 mL, 3.7% (normal <= 5%)
**FVC within-person variation:** 202 mL, 5.1% (normal <= 5%)
**FEV1 group within-person variation:** 186 mL, 5.3% (normal <= 5%)
**FVC group within-person variation:** 214 mL, 5.2% (normal <= 5%)

Interpretation and suggested actions:
- The within-person variation for FVC > 5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase FVC variability.
- If confirmed that FVC < 95% CL for the regression line, consider re-testing in near future.
Case 3

- 45 yo M Firefighter presents for annual physical exam
- PMH/PSHx: DM2, HTN, HLD
- Weight gain: 85 lbs, BMI: 43
- Meds: Metformin, Glipizide, Lisinopril, Lipitor
- Allergies: NKDA
- Soc Hx: Approx 28 smoking pack years, quit in 2014
- Occ Hx:
  - Federal CIV Firefighter for 25 years
  - Work Exposures: Nothing significant
- CXR Normal
- % Predicted with Asian Ethnic Correction:
  - FVC: 66%, FEV1: 63%, FEV1/FVC%: 75%
Case 3
Case 3

**Longitudinal FEV1 Evaluation**

**Sex:** Male  
**Race:** Asian-American  
**Age:** 45 years old  
**Height (Mean):** 170.2 cm  
**Date of last test:** 8/17/2016  
**Years of follow-up:** 24 years and 9 months

**Results of analysis:**  
- FEV1 below LLN  
- FVC below LLN

**Rate of FEV1 decline:**  
- Overall: 51 ml/year, 95% CI (29, 55)  
- Last 8 years: 88 ml/year, 95% CI (54, 123)  
- Rate of decline is increasing

**Rate of FVC decline:**  
- Overall: 42 ml/year, 95% CI (20, 55)  
- Last 8 years: 85 ml/year, 95% CI (54, 123)  
- Rate of decline is increasing

**FEV1 within-person variation:** 202 ml, 6.2%, (normal <= 5%).  
**FVC within-person variation:** 215 ml, 5.0%, (normal <= 5%).

**Interpretation and suggested actions:**  
- The within-person variation for FEV1 or FVC > 5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase data variability.  
- If confirmed that FEV1/FVC < LLN and FVC < LLN, results indicate low vital capacity.  
- If confirmed that predicted FEV1 declines to 0.1th percentile (<60% predicted FEV1), results indicate increased risk of developing moderate impairment.  
- Examine the spirometry quality and retest to confirm the results. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
Case 4

- 42 yo M Firefighter presents for annual physical exam
- PMH/PSHx: Nothing significant
- Weight gain: 0, BMI: 24
- Meds: None
- Allergies: Dimetapp, Shellfish
- Soc Hx: Never smoked
- Occ Hx:
  - Federal CIV Firefighter for 7 years
  - Work Exposures: Nothing significant
- CXR Normal
- % Predicted and LLN with Asian Ethnic Correction:
  - FVC: 4.30 (87%), FEV1: 3.16 (81%), FEV1/FVC: 73.6%
  - LLN: FVC = 4.03, FEV1 = 3.14
Case 4
Case 4

Longitudinal FEV1 Evaluation

Results of analysis:
- Last observation: FEV1 below LLD; FVC below LLD.
- Rate of FEV1 decline: Overall 108 mL/year; 95% CI (134, 327).
- Rate of FVC decline: Overall 231 mL/year; 95% CI (134, 327).
- FEV1 within-person variation: 149 mL, 5.8% (normal = 5%).
- FVC within-person variation: 330 mL, 5.3% (normal = 5%).

Interpretation and suggested actions:
- The within-person variation for FVC > 5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase FVC variability.
- Examine the quality of baseline and current test. If confirmed that FEV1 or FVC < LLD, the rate of decline may be excessive.

Examine the spirometry quality and retest to confirm the results. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
Case 5

- 36 yo M Firefighter presents for annual physical
- PMH/PSHx: None
- Weight Gain: 23lbs, BMI 33
- Meds: Multivitamins
- Allergies: NKDA
- Soc Hx: Non-Smoker
- CXR: Normal
- Occ Hx:
  - Federal CIV Firefighter for 11 years
  - Work Exposures: Nothing significant
- % Predicted and LLN with Asian Ethnic Correction:
  - FVC: 3.73 (84%), FEV1: 3.29 (92%), FEV1/FVC: 88.2%
  - LLN: FVC = 3.65, FEV1 = 2.91
Case 5
Case 5

Sex: Male
Race: Asian-American
Age: 35 years old
Height (Mean): 175.0 cm
Date of last test: 5/24/2017
Years of follow-up: 11 years and 4 months

Results of analysis:
Last observation:
Rate of FEV1 decline:
Overall: 66 ml/year, 95% CI (25, 116)
Last 8 years: 85 ml/year, 95% CI (61, 110)
Rate of decline is increasing

Rate of FVC decline:
Overall: 70 ml/year, 95% CI (25, 116)
Last 8 years: 80 ml/year, 95% CI (61, 110)
Rate of decline is increasing

FEV1 within-person variation: 227 ml, 5.9% (normal <=5%)
FVC within-person variation: 287 ml, 6.5% (normal <=5%)
FEV1 group within-person variation: 186 ml, 5.3% (normal <=5%
FVC group within-person variation: 214 ml, 5.2% (normal <=5%)

Interpretation and suggested actions:
- The within-person variation for FEV1 or FVC >5 % can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase data variability.
- If confirmed that FEV1/FVC<LLN and FVC<LLN, results indicate a low vital capacity.
- If confirmed that projected FEV1 declines to 14-th percentile (<60% predicted FEV1), results indicate increased risk of developing moderate impairment.
- Examine the spirometry quality and retest to confirm the results. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
In Summary

• Spirometry is an important medical surveillance tool
• ATS recommends longitudinal data analysis to identify excessive lung function decline
• Implementation of longitudinal data analysis software such as SPIROLA in an occupational health clinic and office setting is feasible
• Spirometry longitudinal data analysis helps to identify evidence of excessive lung function decline
• Consider data and spirometry quality in longitudinal data analysis, interpretation, and intervention
• Implementation supports occupational health goals of worker readiness, health and safety
Acknowledgements

• Dr. Wesley D. Boose, MD, MPH
• Mr. Bradford Jensen, MBA, CSSBB
• Dr. Bennett Shapiro, MD
• Occupational Health Department Staff at the U.S. Naval Hospital Guam
Un Dangkulu na Si Yu'us Ma'ase! Thank you very much!
References

Questions and Answers