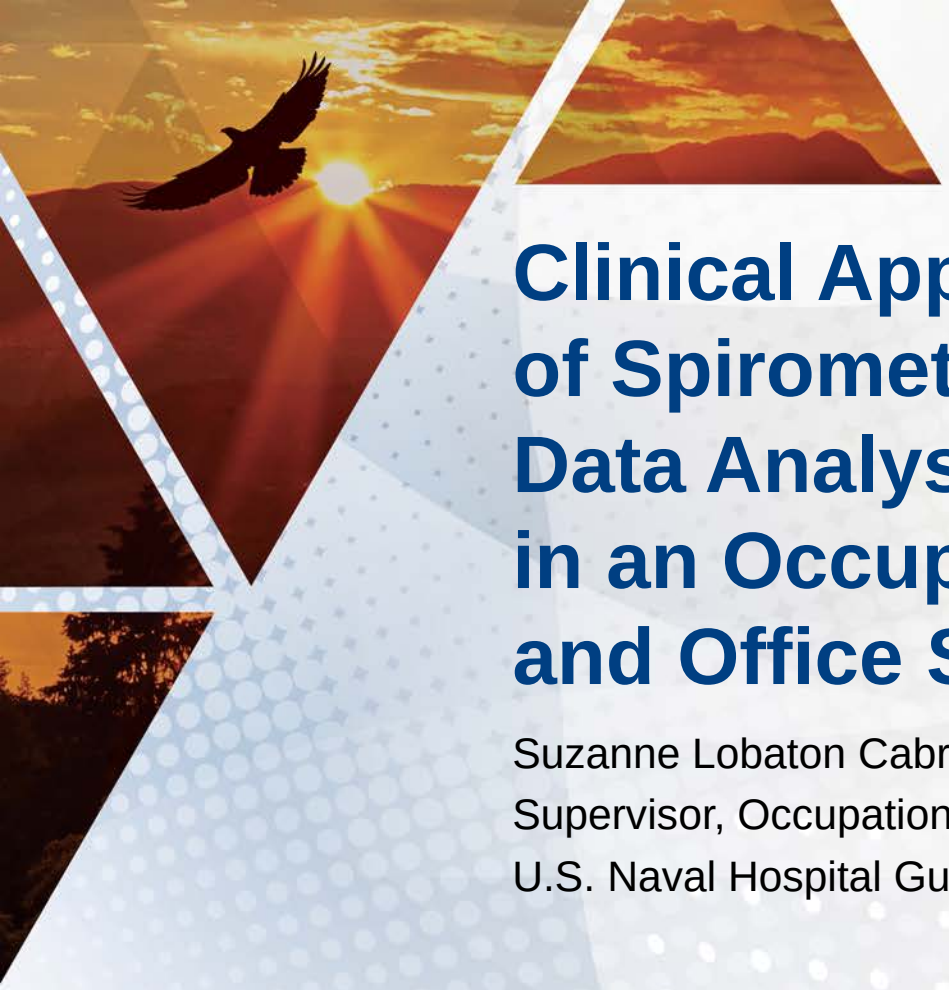

Clinical Application of Spirometry Longitudinal Data Analysis (SPIROLA) Software in an Occupational Health Clinic and Office Setting

Suzanne Lobaton Cabrera, MN, RN, COHN-S
Supervisor, Occupational Health Nurse
U.S. Naval Hospital Guam

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.
- The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the policy of:
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- No financial or organizational interests to disclose.
- All images, graphs, and reports, unless otherwise cited, are courtesy of and property of U.S. Naval Hospital Guam Occupational Health Clinic

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- Kathryn Henzler, BSN, RN
- Occupational Health Technicians:
  - » Teresita Ann Julao
  - » Livian Lucy Sanchez
  - » Garry Phillip
  - » Patrick Powell
  - » Jamiel Morris
  - » Ariel Parris
- Administrative / Medical Records Clerks:
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  - » Jesse Munoz

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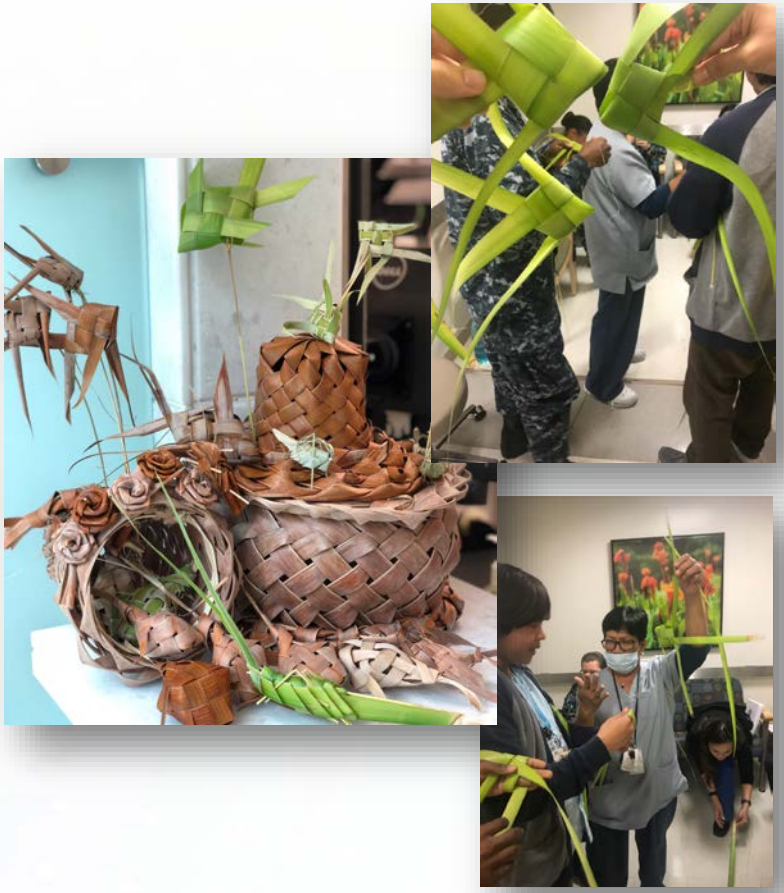


GUAM: *"Where America's Day Begins"*

GUAM: *"Where America's Day Begins"*

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

- Brown Lung, the Textile Industry, and the Cotton Dust Standard (29CFR 1910.1043), 1978
  - » 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

- Black Lung, Mining Industry, Coal Act of 1969, and the Mine Act of 1977
  - » 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

Image Source: https://www.cdc.gov/niosh/mining/UserFiles/works/pdfs/2010-128.pdf

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

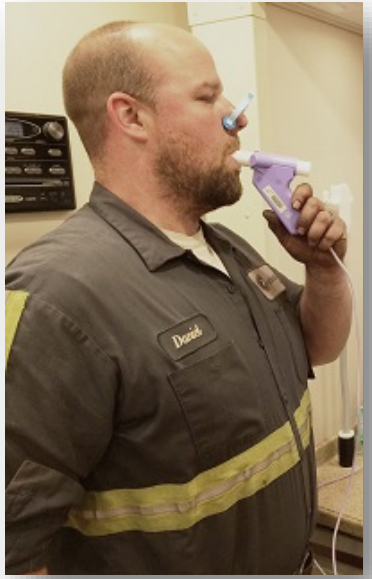
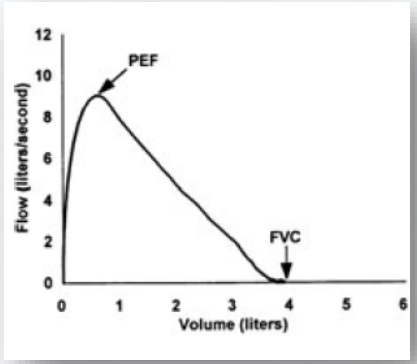


Image Source: https://www.cdc.gove/niosh/topics/cwhsp/coalminerhealth.html

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

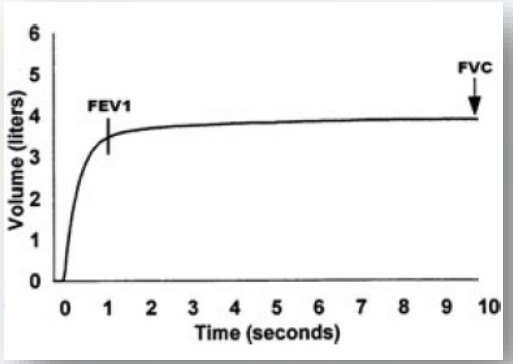
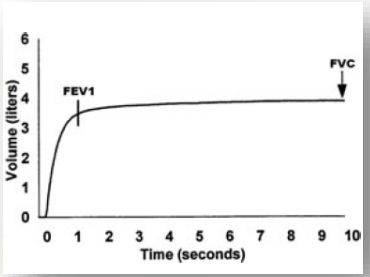


Image Source: https://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/ACOEM%20Spirometry%20Statement.pdf

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
  - » Voume 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 (%): (FEV1/FVC)x100
  - » In healthy people, >70% of FVC exhaled in first second
  - » Reduced in obstructive disease, best indicator of obstructive disease



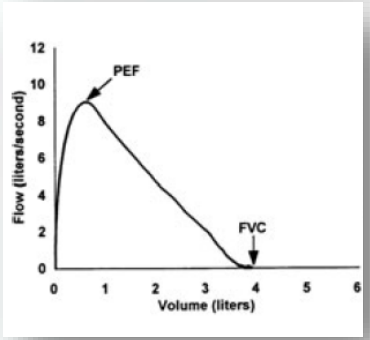


Image Source: https://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/ACOEM%20Spirometry%20Statement.pdf

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 FEV_1
  - 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)

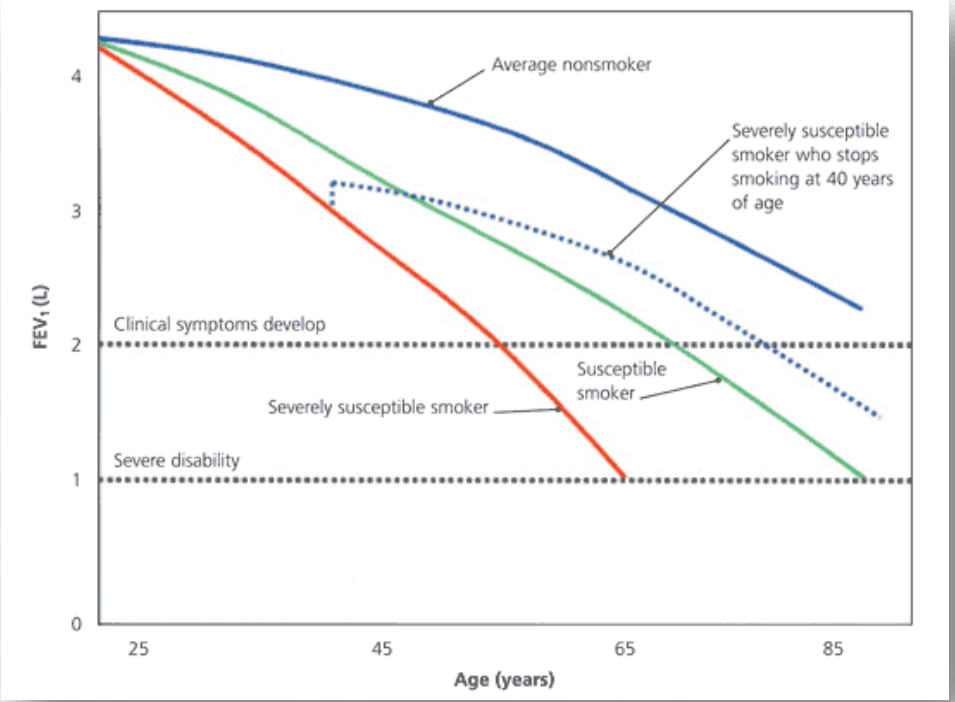
Lung Function Decline

- 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

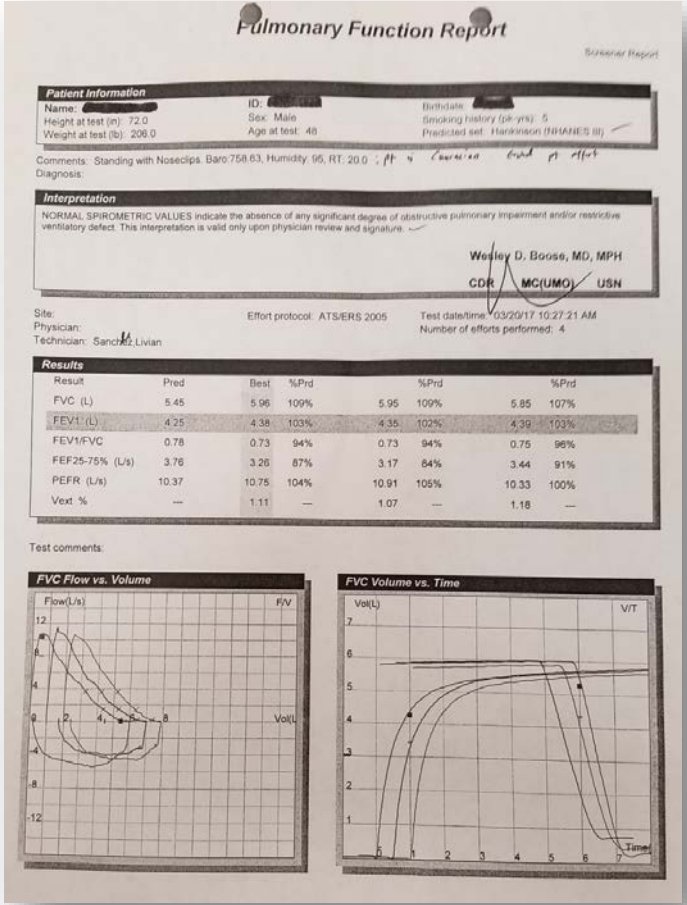
Existing Solutions

- 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



Pulmonary Function Report

Screener Report

Patient Information

Name: [redacted]
Height at test (in): 72.0
Weight at test (lb): 206.0

ID: [redacted]
Sex: Male
Age at test: 48

Birthdate: [redacted]
Smoking history (pk-yrs): 5
Predicted set: Hankinson (NHANES III)

Comments: Standing with Noseclips. Baro:758.63, Humidity: 95, RT: 20.0 ; pt ↓ Coached good pt effort
Diagnosis:

Interpretation

NORMAL SPIROMETRIC VALUES Indicate the absence of any significant degree of obstructive pulmonary impairment and/or restrictive ventilatory defect. This interpretation is valid only upon physician review and signature.

Wesley D. Boose, MD, MPH
CDR MC(UMO) USN

Site:
Physician:
Technician: Sanchez, Livian

Effort protocol: ATS/ERS 2005

Test date/time: 03/20/17 10:27:21 AM
Number of efforts performed: 4

Results

Result	Pred	Best	%Prd		%Prd		%Prd
FVC (L)	5.45	5.96	109%	5.95	109%	5.85	107%
FEV1 (L)	4.25	4.38	103%	4.35	102%	4.39	103%
FEV1/FVC	0.78	0.73	94%	0.73	94%	0.75	96%
FEF25-75% (L/s)	3.76	3.26	87%	3.17	84%	3.44	91%
PEFR (L/s)	10.37	10.75	104%	10.91	105%	10.33	100%
Vext %	---	1.11	---	1.07	---	1.18	---

Test comments:

FVC Flow vs. Volume

FVC Volume vs. Time

Existing Solutions

(SPIROLA Analysis of Same Patient)

- 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
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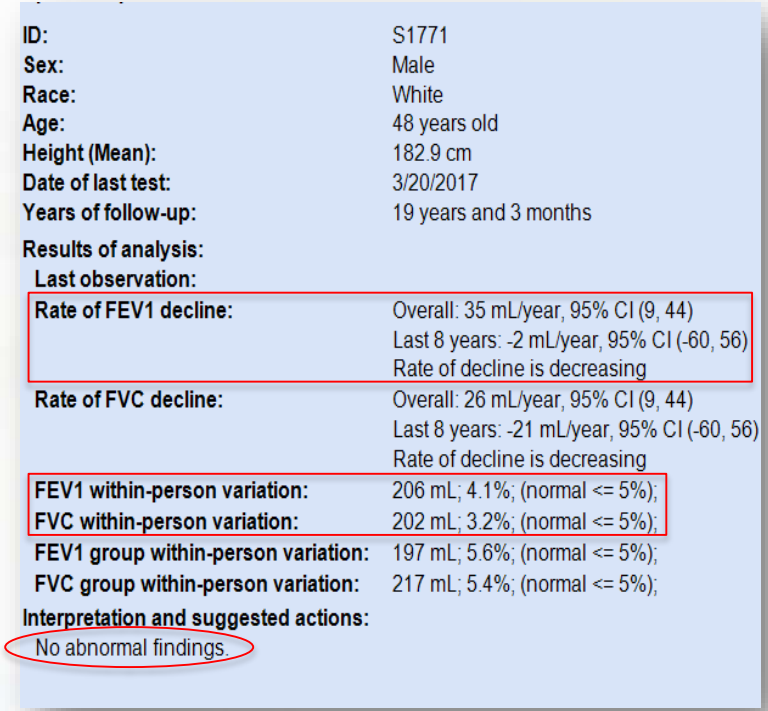


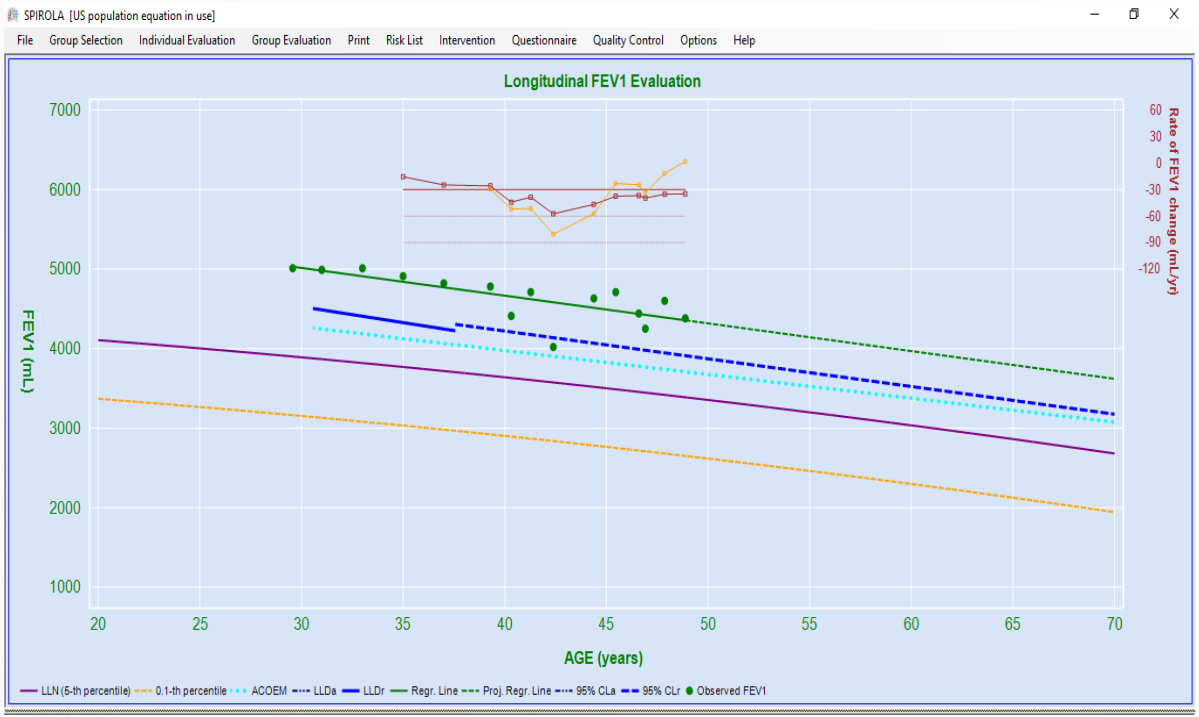
ID:	S1771
Sex:	Male
Race:	White
Age:	48 years old
Height (Mean):	182.9 cm
Date of last test:	3/20/2017
Years of follow-up:	19 years and 3 months
Results of analysis:	
Last observation:	
Rate of FEV1 decline:	Overall: 35 mL/year, 95% CI (9, 44) Last 8 years: -2 mL/year, 95% CI (-60, 56) Rate of decline is decreasing
Rate of FVC decline:	Overall: 26 mL/year, 95% CI (9, 44) Last 8 years: -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 <= 5%);
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

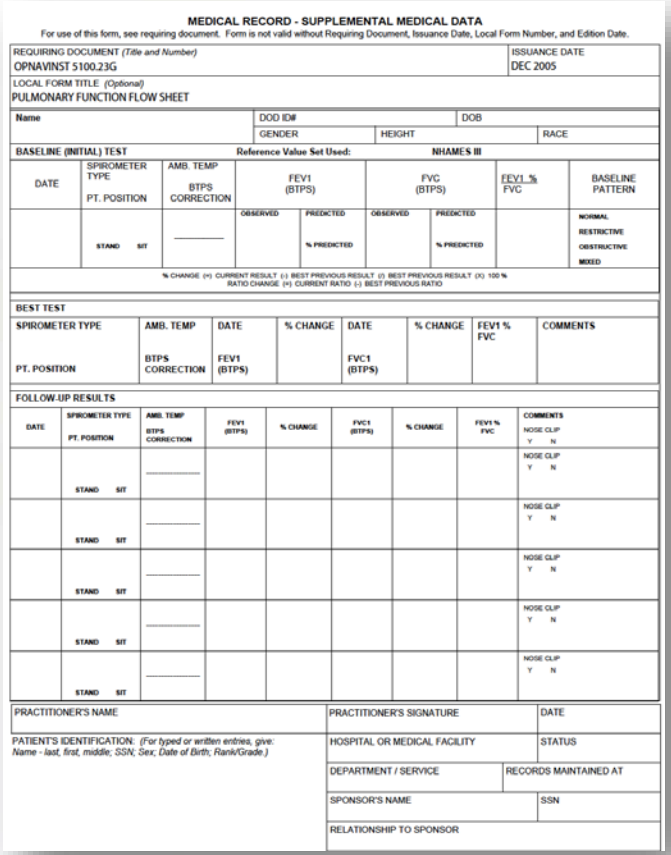


Existing Solutions

- 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



MEDICAL RECORD - SUPPLEMENTAL MEDICAL DATA

For use of this form, see requiring document. Form is not valid without Requiring Document, Issuance Date, Local Form Number, and Edition Date.

REQUIRING DOCUMENT (Title and Number)	ISSUANCE DATE
OPNAVINST 5100.23G	DEC 2005

LOCAL FORM TITLE (Optional)
PULMONARY FUNCTION FLOW SHEET

Name	DOD ID#	DOB
	GENDER / HEIGHT / RACE	

BASELINE (INITIAL) TEST — Reference Value Set Used: NHANES III

DATE	SPIROMETER TYPE / PT. POSITION	AMB. TEMP / BTPS CORRECTION	FEV1 (BTPS) OBSERVED	FEV1 (BTPS) PREDICTED / % PREDICTED	FVC (BTPS) OBSERVED	FVC (BTPS) PREDICTED / % PREDICTED	FEV1 % FVC	BASELINE PATTERN
	STAND SIT							NORMAL / RESTRICTIVE / OBSTRUCTIVE / MIXED

% CHANGE (+) CURRENT RESULT (-) BEST PREVIOUS RESULT (/) BEST PREVIOUS RESULT (X) 100 %
RATIO CHANGE (+) CURRENT RATIO (-) BEST PREVIOUS RATIO

BEST TEST

SPIROMETER TYPE / PT. POSITION	AMB. TEMP / BTPS CORRECTION	DATE / FEV1 (BTPS)	% CHANGE	DATE / FVC1 (BTPS)	% CHANGE	FEV1 % FVC	COMMENTS

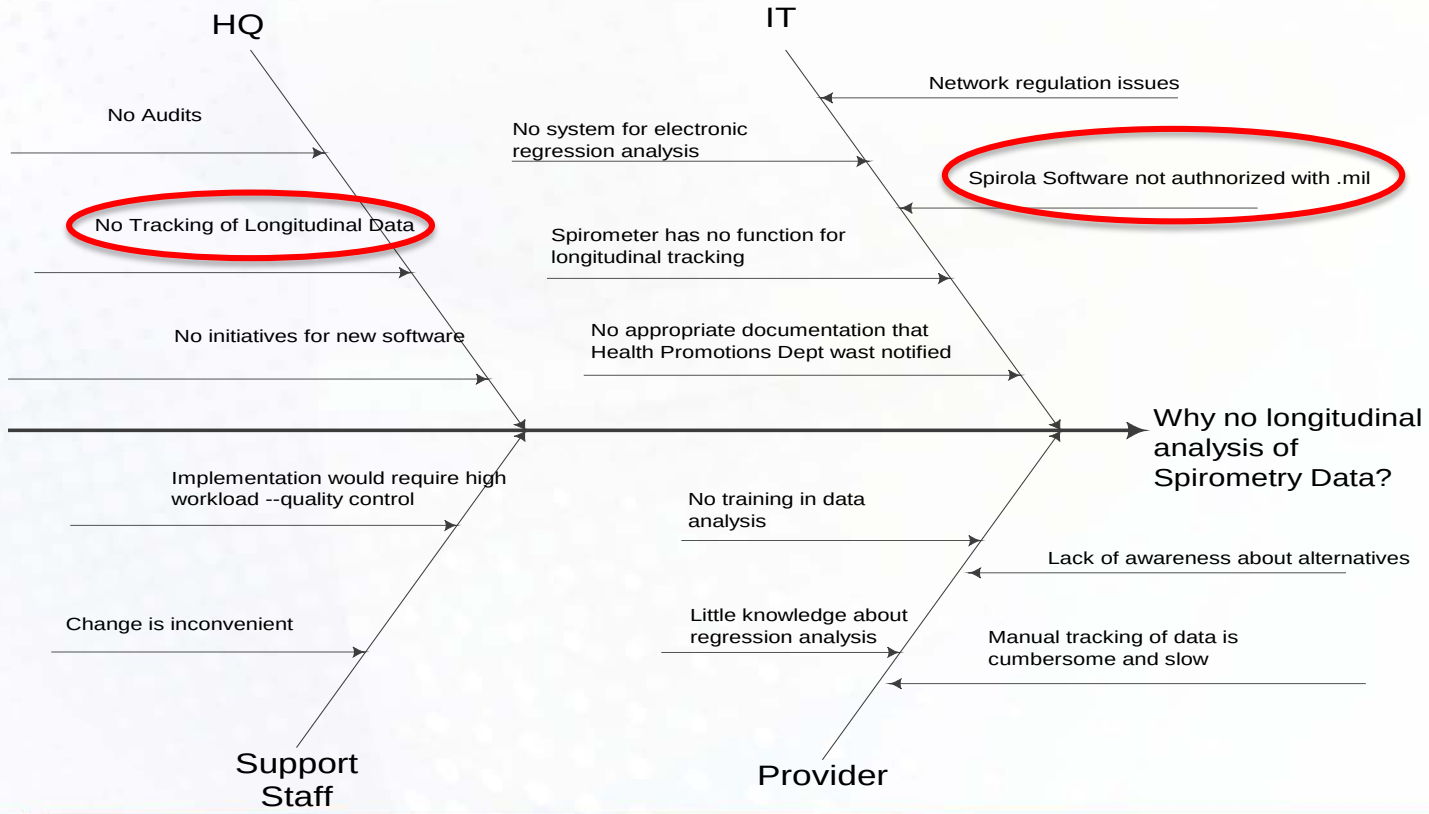
FOLLOW-UP RESULTS

DATE	SPIROMETER TYPE / PT. POSITION	AMB. TEMP / BTPS CORRECTION	FEV1 (BTPS)	% CHANGE	FVC1 (BTPS)	% CHANGE	FEV1 % FVC	COMMENTS / NOSE CLIP Y N
	STAND SIT							NOSE CLIP Y N
	STAND SIT							NOSE CLIP Y N
	STAND SIT							NOSE CLIP Y N
	STAND SIT							NOSE CLIP Y N
	STAND SIT							NOSE CLIP Y N

PRACTITIONER'S NAME	PRACTITIONER'S SIGNATURE	DATE
PATIENT'S IDENTIFICATION: (For typed or written entries, give: Name - last, first, middle; SSN; Sex; Date of Birth; Rank/Grade.)	HOSPITAL OR MEDICAL FACILITY	STATUS
	DEPARTMENT / SERVICE	RECORDS MAINTAINED AT
	SPONSOR'S NAME	SSN
	RELATIONSHIP TO SPONSOR	

Source: U.S. Navy Medicine

Why is there no longitudinal data analysis?



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**

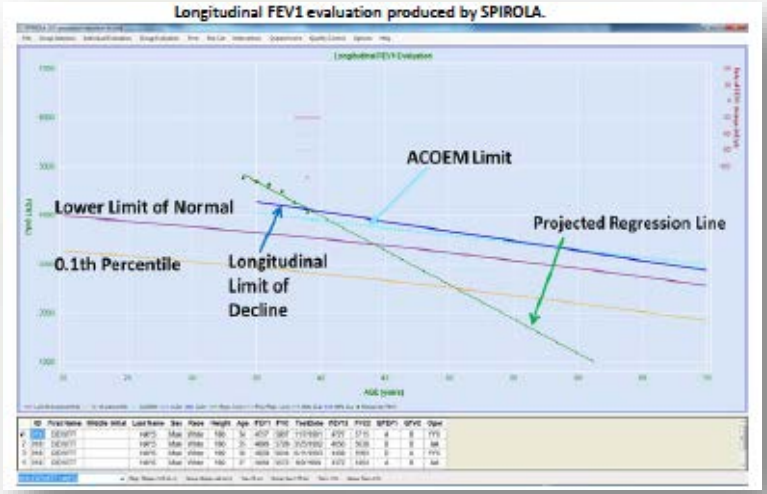


Image Source: https://www.cdc.gov/niosh/topics/spirometry/spirola-software.html

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

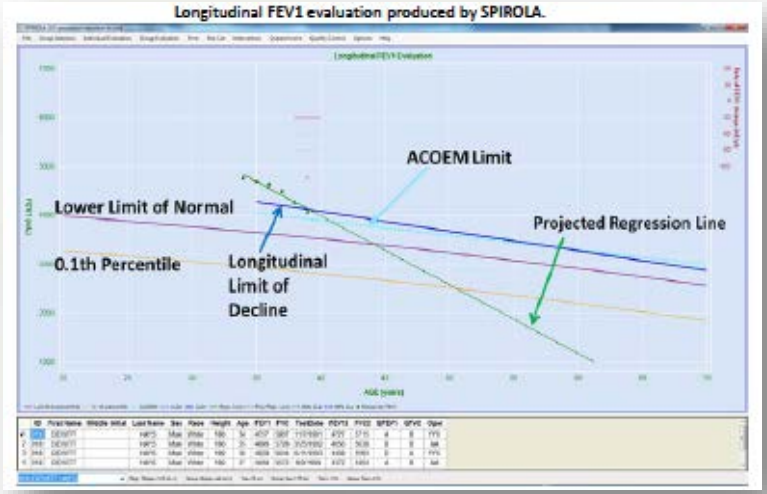


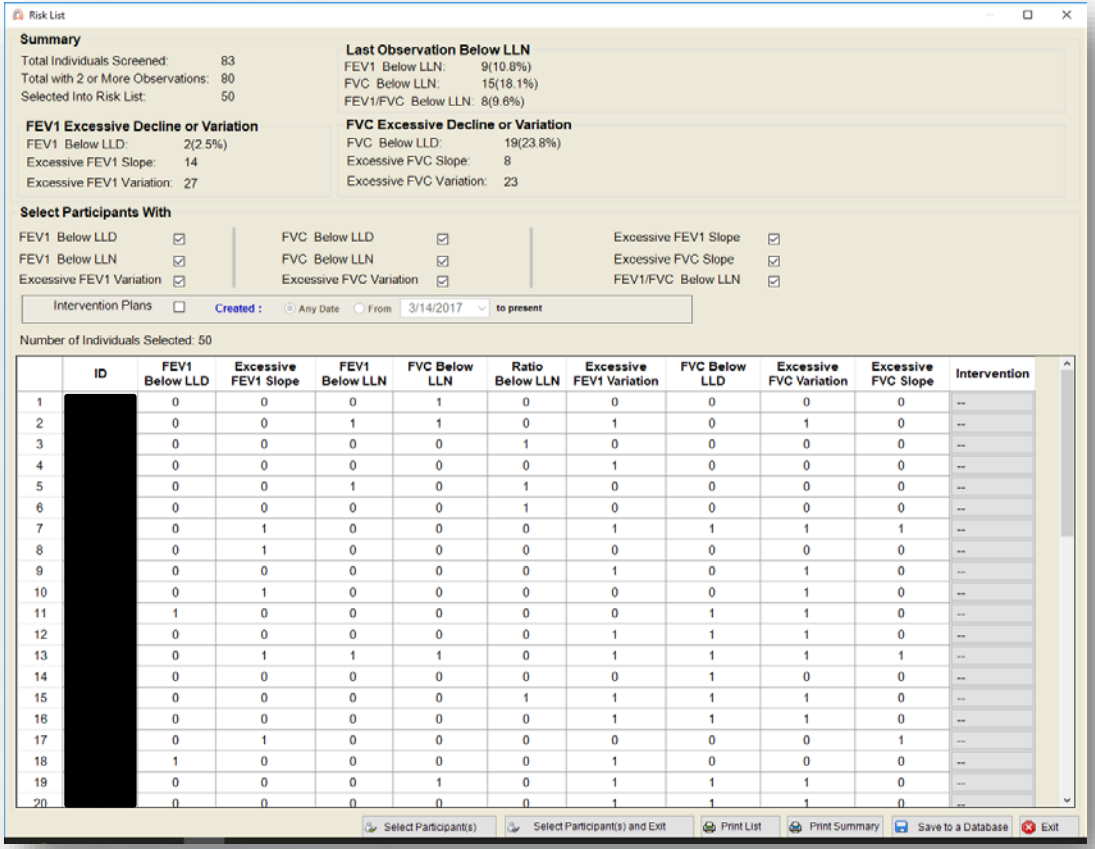
Image Source: https://www.cdc.gov/niosh/topics/spirometry/spirola-software.html

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

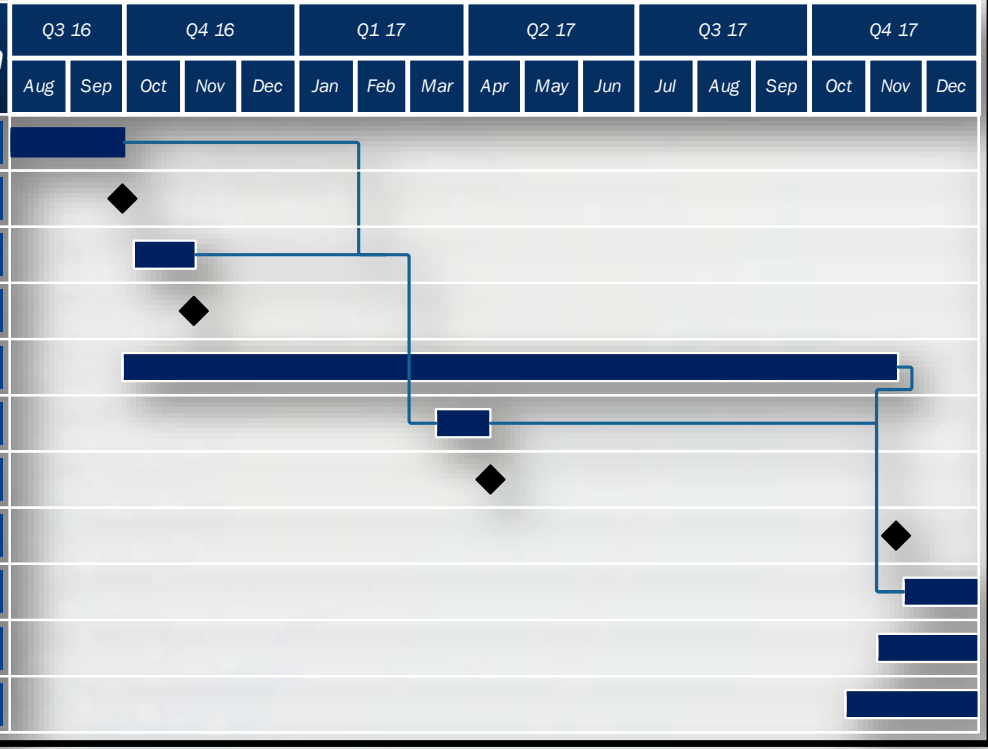
ACTION	RESPONSIBLE	DUE DATE
Search for viable solutions	Department Head	30 Sep 16
Network approval process (DHA)	**Department Head**	**16 Nov 17**
SPIROLA database build	Department Head	07 Nov 16
Build SOP and staff training	Clinic Manager	13 Apr 17
Quality check data entry	Clinic Manager	29 Dec 17
Request Occupational Medicine Form Change	**Clinic Manager**	**31 Dec 17**
Begin Patient Consults with SPIROLA	Occ Med Providers	29 Dec 17

Stages of Implementation

STAGE	DATE	LENGTH OF TIME (months)
SPIROLA Software Network Approval	**30 Sep 16 – 16 Nov 17**	**13.5**
Database Build	06 Oct 16 – 07 Nov 16	1
Staff Training	16 Mar 17 – 13 Apr 17	1
Database QC	06 Nov 17 – 05 Dec 17	1
Occupational Medical Matrix Forms Change Request (to NMCPHC and NMW)	**20 Oct 17 – Present**	**Pending**

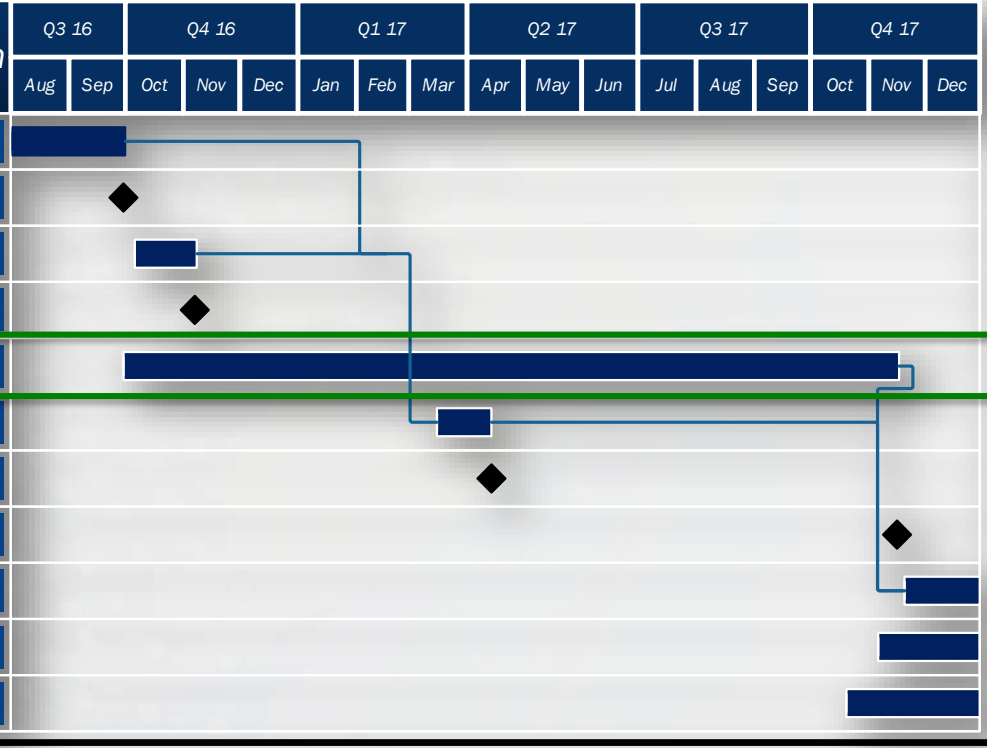
Implementation Timeline

ID	Task Name	Start	Finish	Duration
1	Search for Solution	8/2/2016	9/30/2016	8.8w
2	Milestone DECISION	9/30/2016	9/30/2016	0w
3	Building Data Base	10/6/2016	11/7/2016	4.6w
4	Data Base Complete	11/7/2016	11/7/2016	0w
5	Network Approval	9/30/2016	11/16/2017	59w
6	Staff Training	3/16/2017	4/13/2017	4.2w
7	Training Complete	4/14/2017	4/14/2017	0w
8	Installed on Network	11/16/2017	11/16/2017	0w
9	Consults w SPIROLA	11/20/2017	12/29/2017	6w
10	Quality Control Data	11/6/2017	12/29/2017	8w
11	OccMed Form Change	10/20/2017	12/31/2018	62.4w



Implementation Timeline

ID	Task Name	Start	Finish	Duration
1	Search for Solution	8/2/2016	9/30/2016	8.8w
2	Milestone DECISION	9/30/2016	9/30/2016	0w
3	Building Data Base	10/6/2016	11/7/2016	4.6w
4	Data Base Complete	11/7/2016	11/7/2016	0w
5	Network Approval	9/30/2016	11/16/2017	59w
6	Staff Training	3/16/2017	4/13/2017	4.2w
7	Training Complete	4/14/2017	4/14/2017	0w
8	Installed on Network	11/16/2017	11/16/2017	0w
9	Consults w SPIROLA	11/20/2017	12/29/2017	6w
10	Quality Control Data	11/6/2017	12/29/2017	8w
11	OccMed Form Change	10/20/2017	12/31/2018	62.4w



Implementation Timeline

ID	Task Name	Start	Finish	Duration
1	Search for Solution	8/2/2016	9/30/2016	8.8w
2	Milestone DECISION	9/30/2016	9/30/2016	0w
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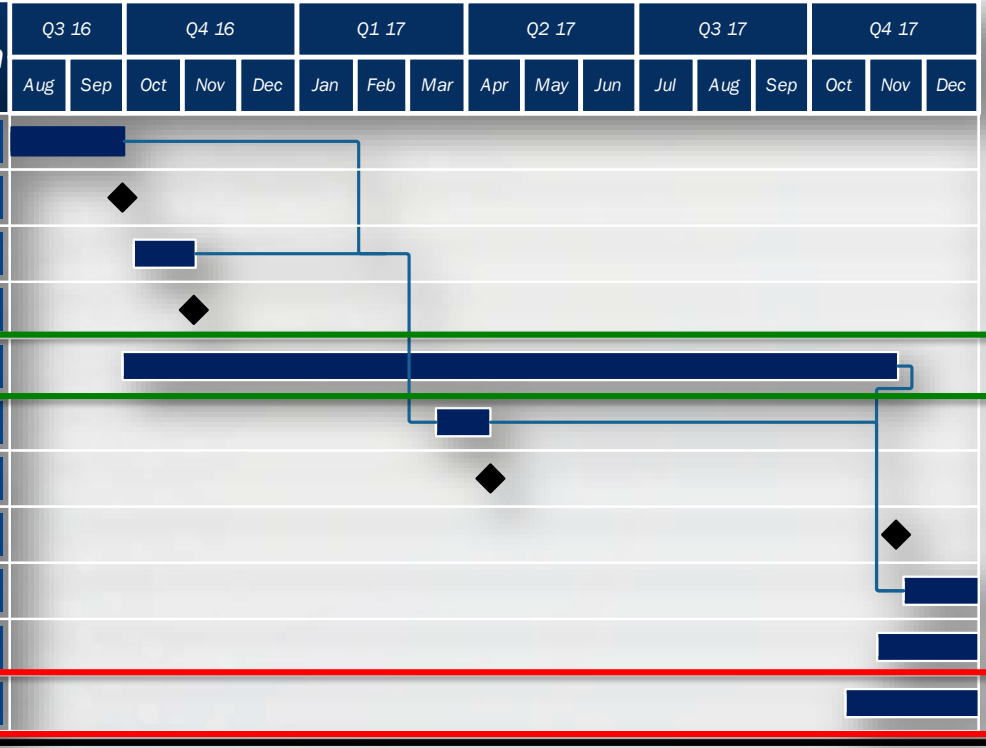
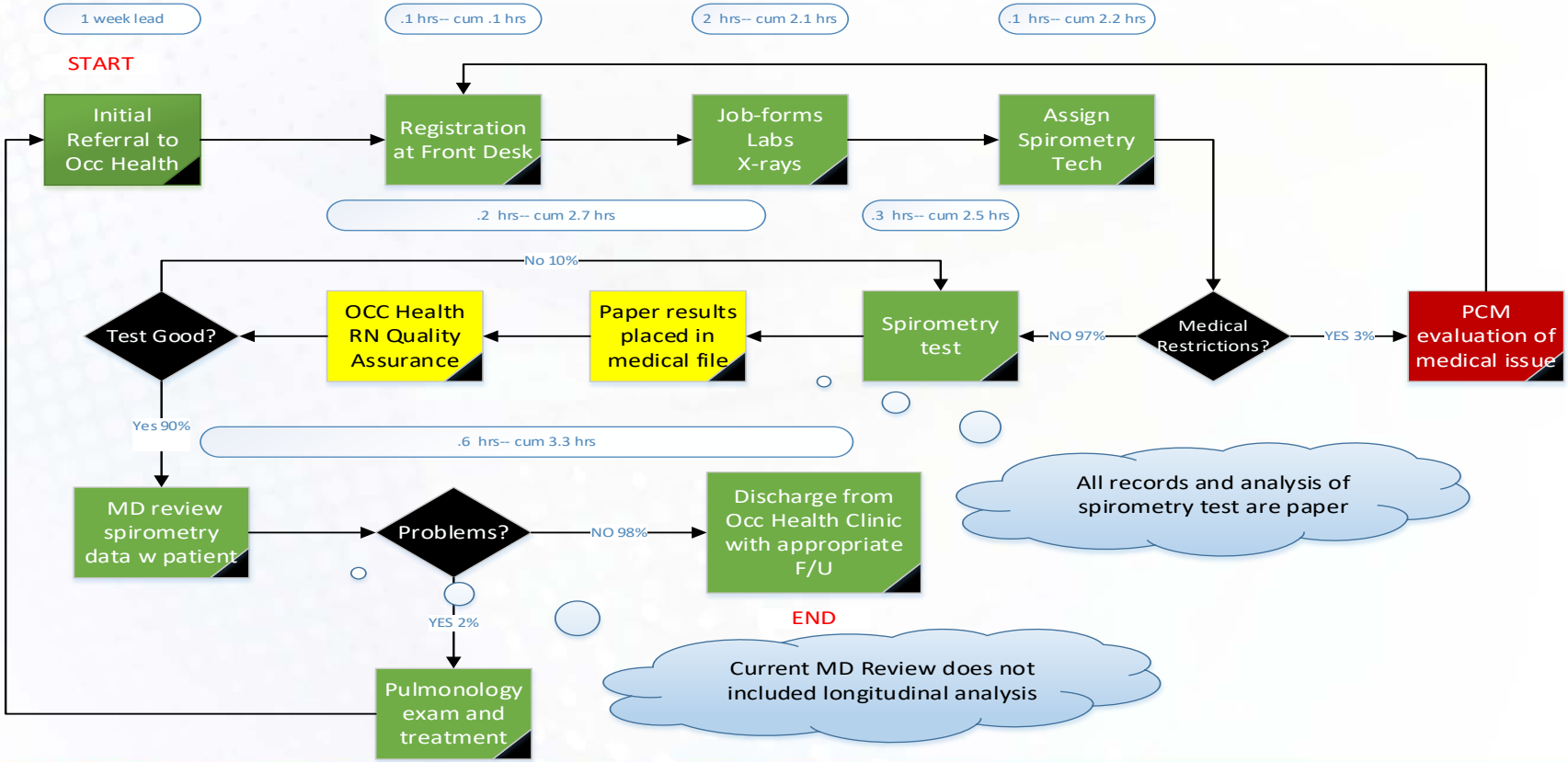
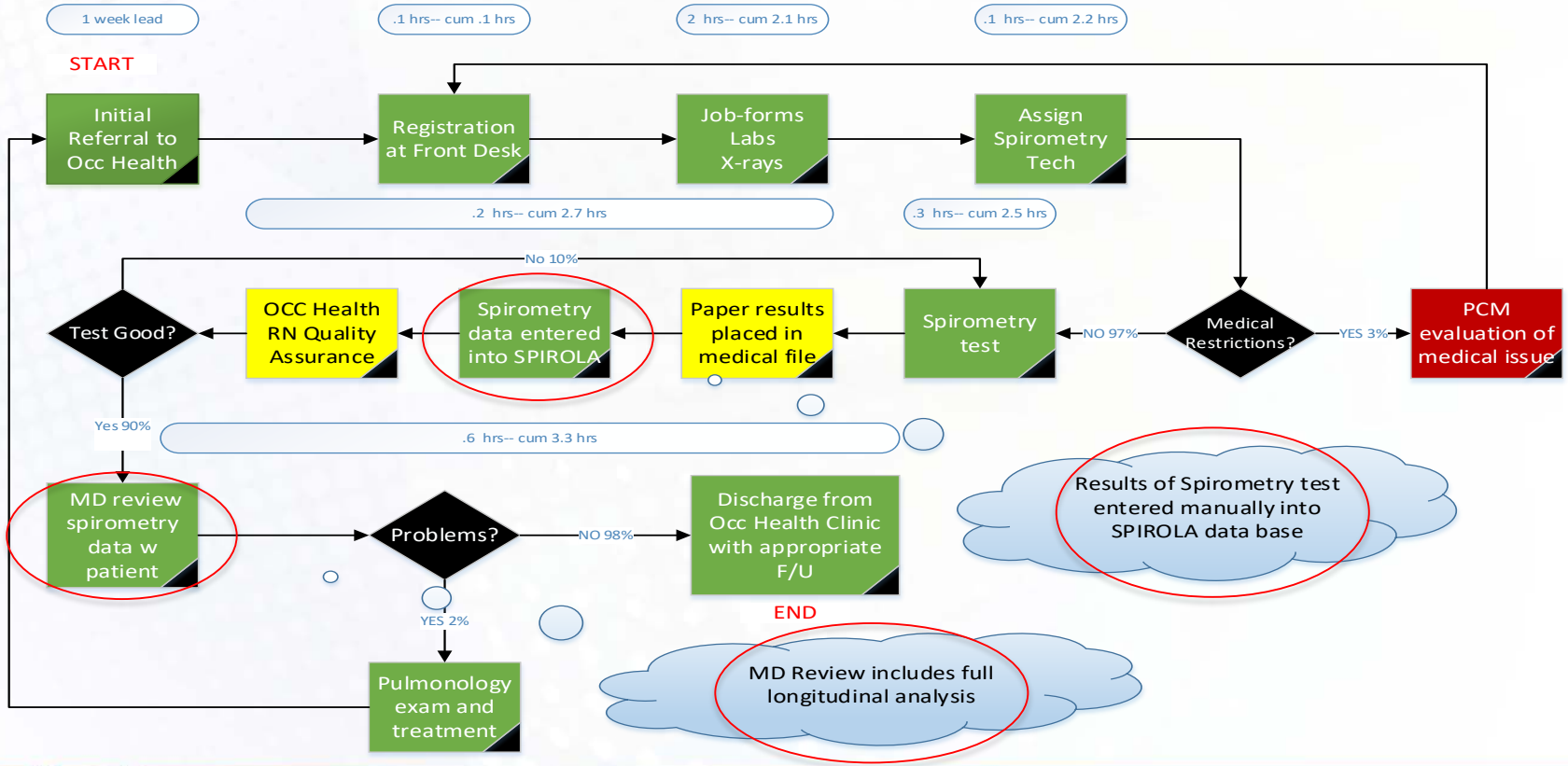
6	Staff Training	3/16/2017	4/13/2017	4.2w
7	Training Complete	4/14/2017	4/14/2017	0w
8	Installed on Network	11/16/2017	11/16/2017	0w
9	Consults w SPIROLA	11/20/2017	12/29/2017	6w
10	Quality Control Data	11/6/2017	12/29/2017	8w
11	OccMed Form Change	10/20/2017	12/31/2018	62.4w



State Before Implementation

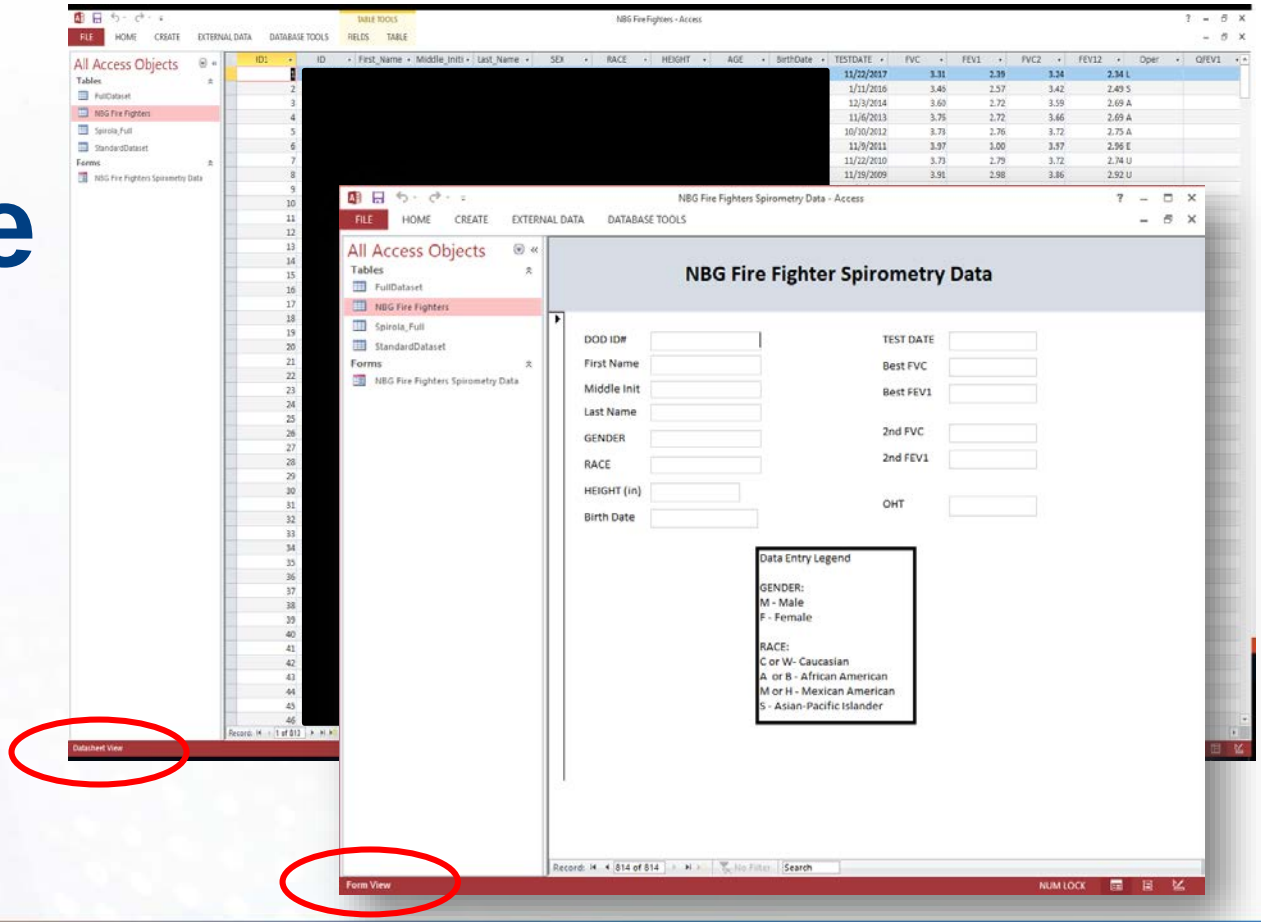


(Ideal) State After Implementation



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

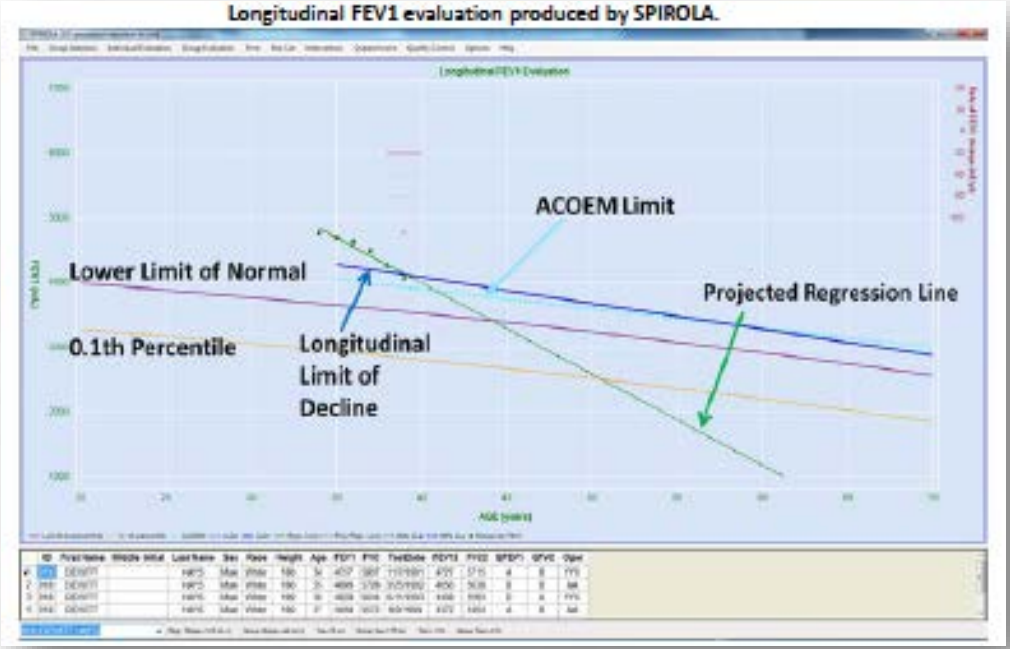
- Obtain SPIROLA Software from NIOSH
  - » SPIROLA Web-Based Application in pilot stages
- Contact local IT for installation on network
  - » Already approved and authorized for DoD use
- Building the Database
  - » Approximately 30 days and 80 man-hours
  - » Quality check every record after build
- Train all clinic personnel
  - » Approximately 30 days
- Start Clinical Use


Family

CASE STUDIES

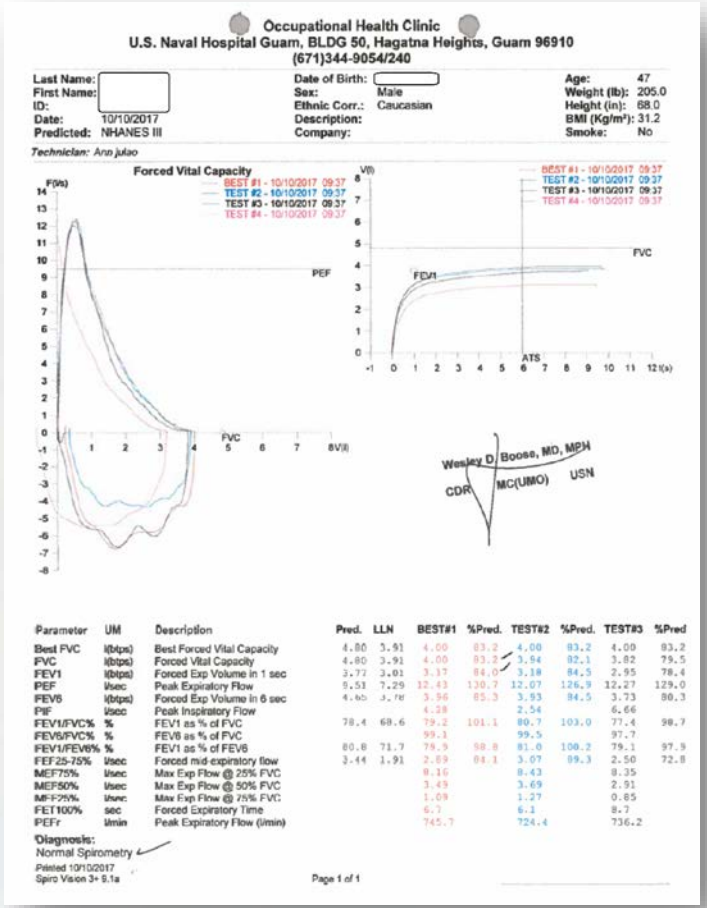
Color Key

- 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



Occupational Health Clinic
U.S. Naval Hospital Guam, BLDG 50, Hagatna Heights, Guam 96910
(671)344-9054/240

Last Name:
First Name:
ID:
Date: 10/10/2017
Predicted: NHANES III
Date of Birth:
Sex: Male
Ethnic Corr.: Caucasian
Description:
Company:
Age: 47
Weight (lb): 205.0
Height (in): 68.0
BMI (Kg/m²): 31.2
Smoke: No

Technician: Ann julao

Forced Vital Capacity

BEST #1 - 10/10/2017 09:37
TEST #2 - 10/10/2017 09:37
TEST #3 - 10/10/2017 09:37
TEST #4 - 10/10/2017 09:37

PEF
FEV1
FVC
ATS

Wesley D. Boose, MD, MPH
CDR MC(UMO) USN

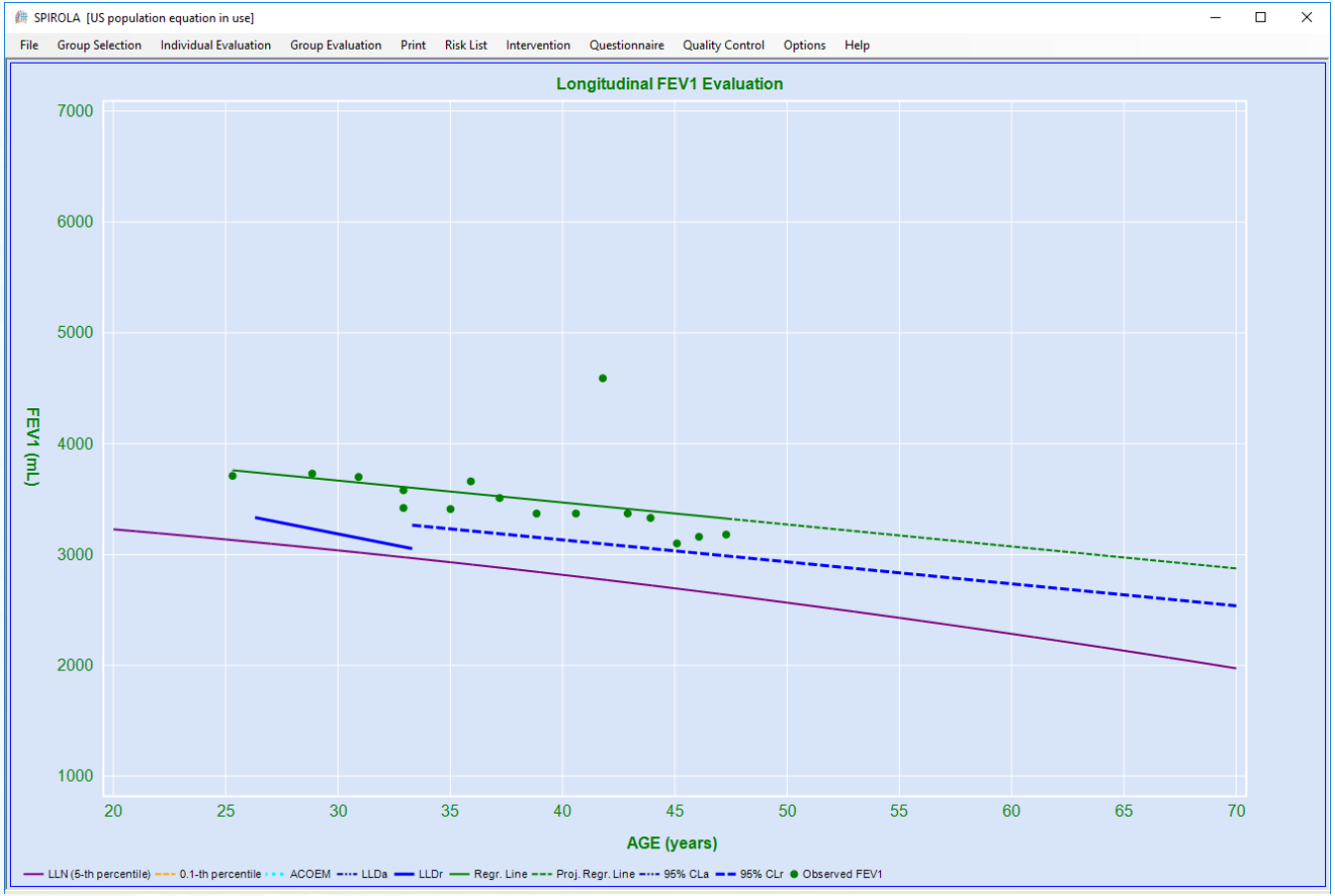
Parameter	UM	Description	Pred.	LLN	BEST#1	%Pred.	TEST#2	%Pred.	TEST#3	%Pred
Best FVC	l(btps)	Best Forced Vital Capacity	4.80	3.91	4.00	83.2	4.00	83.2	4.00	83.2
FVC	l(btps)	Forced Vital Capacity	4.80	3.91	4.00	83.3	3.94	82.1	3.82	79.5
FEV1	l(btps)	Forced Exp Volume in 1 sec	3.77	3.01	3.17	84.0	3.18	84.5	2.95	78.4
PEF	l/sec	Peak Expiratory Flow	9.51	7.29	12.43	130.7	12.07	126.9	12.27	129.0
FEV6	l(btps)	Forced Exp Volume in 6 sec	4.65	3.76	3.56	85.3	3.93	84.5	3.73	80.3
PIF	l/sec	Peak Inspiratory Flow			4.38		2.54		6.66	
FEV1/FVC%	%	FEV1 as % of FVC	78.4	68.6	79.2	101.1	80.7	103.0	77.4	98.7
FEV6/FVC%	%	FEV6 as % of FVC			99.1		99.5		97.7	
FEV1/FEV6%	%	FEV1 as % of FEV6	80.8	71.7	79.9	98.8	81.0	100.2	79.1	97.9
FEF25-75%	l/sec	Forced mid-expiratory flow	3.44	1.91	2.89	84.1	3.07	89.3	2.50	72.8
MEF75%	l/sec	Max Exp Flow @ 25% FVC			9.16		8.43		8.35	
MEF50%	l/sec	Max Exp Flow @ 50% FVC			3.49		3.69		2.91	
MEF25%	l/sec	Max Exp Flow @ 75% FVC			1.09		1.27		0.85	
FET100%	sec	Forced Expiratory Time			6.7		6.1		8.7	
PEFr	l/min	Peak Expiratory Flow (l/min)			745.7		724.4		736.2	

Diagnosis:
Normal Spirometry

Printed 10/10/2017
Spiro Vision 3+ 9.1a

Page 1 of 1

Case 1

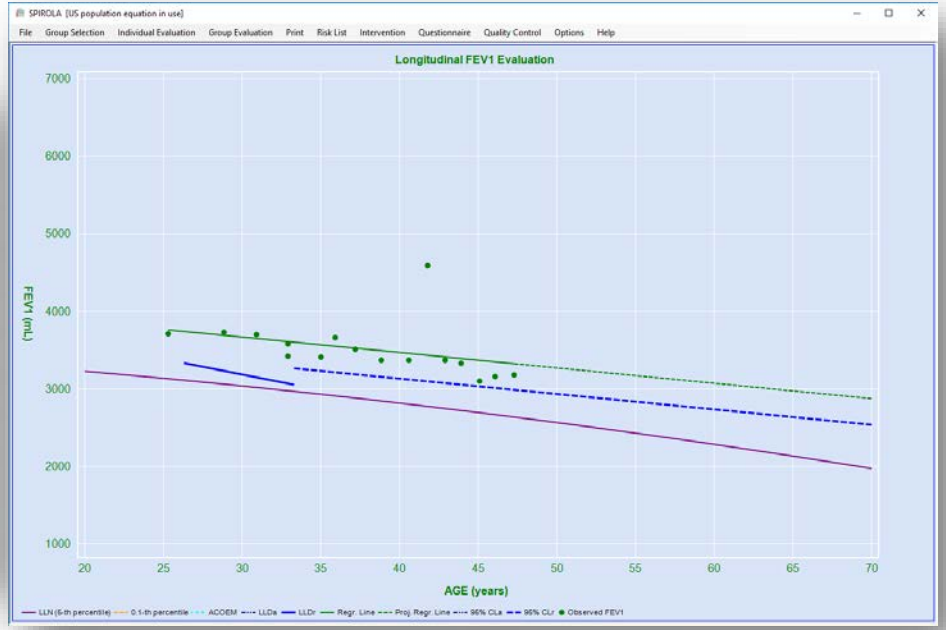

SPIROLA [US population equation in use]
File
Group Selection
Individual Evaluation
Group Evaluation
Print
Risk List
Intervention
Questionnaire
Quality Control
Options
Help
Longitudinal FEV1 Evaluation
FEV1 (mL)
7000
6000
5000
4000
3000
2000
1000
20
25
30
35
40
45
50
55
60
65
70
AGE (years)
LLN (5-th percentile)
0.1-th percentile
ACOEM
LLDa
LLDr
Regr. Line
Proj. Regr. Line
95% CLa
95% CLr
Observed FEV1

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:	Overall: 20 mL/year, 95% CI (-41, 39)
	Last 8 years: 65 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: 90 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%);

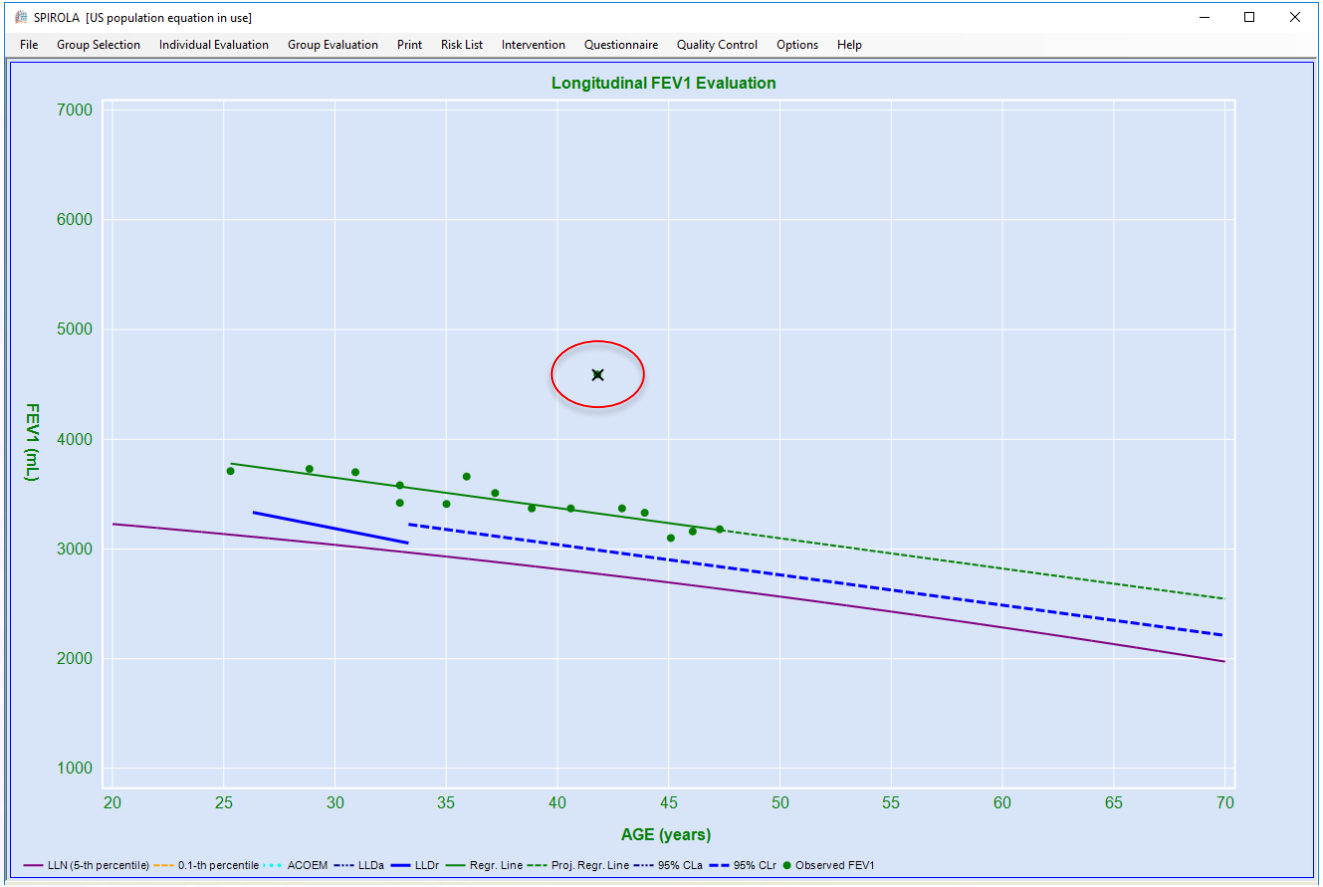
Interpretation and suggested actions:

- 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.



Case 1

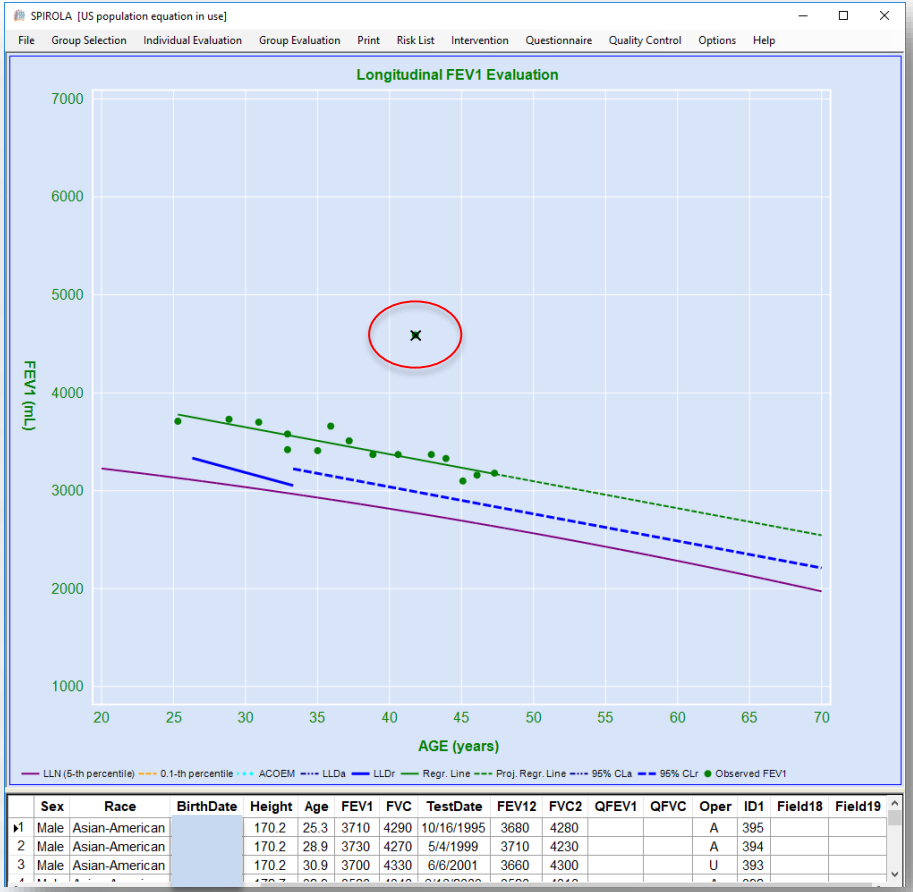
(excluding 4/2012 observation from analysis)



Case 1

(excluding 4/2012 observation from analysis)

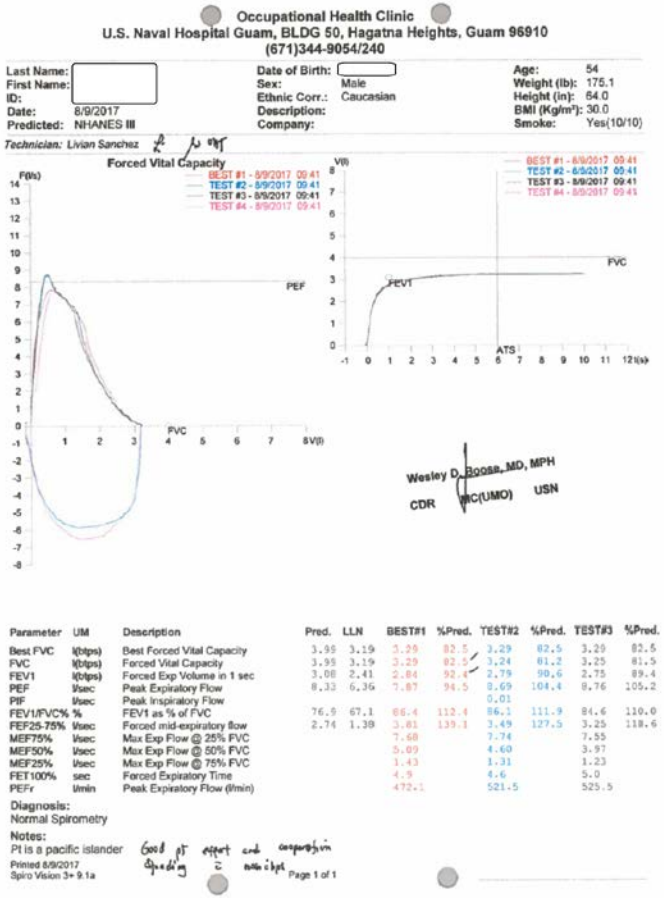
Sex:	Male
Race:	Asian-American
Age:	47 years old
Height (Mean):	172.2 cm
Date of last test:	10/10/2017
Years of follow-up:	21 years and 10 months
Results of analysis:	
Last observation:	
Rate of FEV1 decline:	Overall: 28 mL/year, 95% CI (3, 20) Last 8 years: 31 mL/year, 95% CI (11, 52) Rate of decline is increasing
Rate of FVC decline:	Overall: 12 mL/year, 95% CI (3, 20) Last 8 years: 34 mL/year, 95% CI (11, 52) Rate of decline is increasing
FEV1 within-person variation:	92 mL; 2.5%; (normal <= 5%);
FVC within-person variation:	113 mL; 2.6%; (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:	
No abnormal findings.	



	Sex	Race	BirthDate	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper	ID1	Field18	Field19
▸1	Male	Asian-American		170.2	25.3	3710	4290	10/16/1995	3680	4280			A	395		
2	Male	Asian-American		170.2	28.9	3730	4270	5/4/1999	3710	4230			A	394		
3	Male	Asian-American		170.2	30.9	3700	4330	6/6/2001	3660	4300			U	393		

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



Occupational Health Clinic
U.S. Naval Hospital Guam, BLDG 50, Hagatna Heights, Guam 96910
(671)344-9054/240

Last Name:
First Name:
ID:
Date: 8/9/2017
Predicted: NHANES III
Date of Birth:
Sex: Male
Ethnic Corr.: Caucasian
Description:
Company:
Age: 54
Weight (lb): 175.1
Height (in): 64.0
BMI (Kg/m²): 30.0
Smoke: Yes(10/10)

Technician: Livian Sanchez

Forced Vital Capacity

BEST #1 - 8/9/2017 09:41
TEST #2 - 8/9/2017 09:41
TEST #3 - 8/9/2017 09:41
TEST #4 - 8/9/2017 09:41

F(l/s) PEF FVC 8V(l)
V(l) FEV1 FVC ATS 12t(s)

Wesley D. Boose, MD, MPH
CDR MC(UMO) USN

Parameter	UM	Description	Pred.	LLN	BEST#1	%Pred.	TEST#2	%Pred.	TEST#3	%Pred.
Best FVC	l(btps)	Best Forced Vital Capacity	3.99	3.19	3.29	82.5	3.29	82.5	3.29	82.5
FVC	l(btps)	Forced Vital Capacity	3.99	3.19	3.29	82.5	3.24	81.2	3.25	81.5
FEV1	l(btps)	Forced Exp Volume in 1 sec	3.08	2.41	2.84	92.4	2.79	90.6	2.75	89.4
PEF	l/sec	Peak Expiratory Flow	8.33	6.36	7.87	94.5	8.69	104.4	8.76	105.2
PIF	l/sec	Peak Inspiratory Flow					0.01			
FEV1/FVC%	%	FEV1 as % of FVC	76.9	67.1	86.4	112.4	86.1	111.9	84.6	110.0
FEF25-75%	l/sec	Forced mid-expiratory flow	2.74	1.38	3.81	139.1	3.49	127.5	3.25	118.6
MEF75%	l/sec	Max Exp Flow @ 25% FVC			7.68		7.74		7.55	
MEF50%	l/sec	Max Exp Flow @ 50% FVC			5.09		4.60		3.97	
MEF25%	l/sec	Max Exp Flow @ 75% FVC			1.43		1.31		1.23	
FET100%	sec	Forced Expiratory Time			4.9		4.6		5.0	
PEFr	l/min	Peak Expiratory Flow (l/min)			472.1		521.5		525.5	

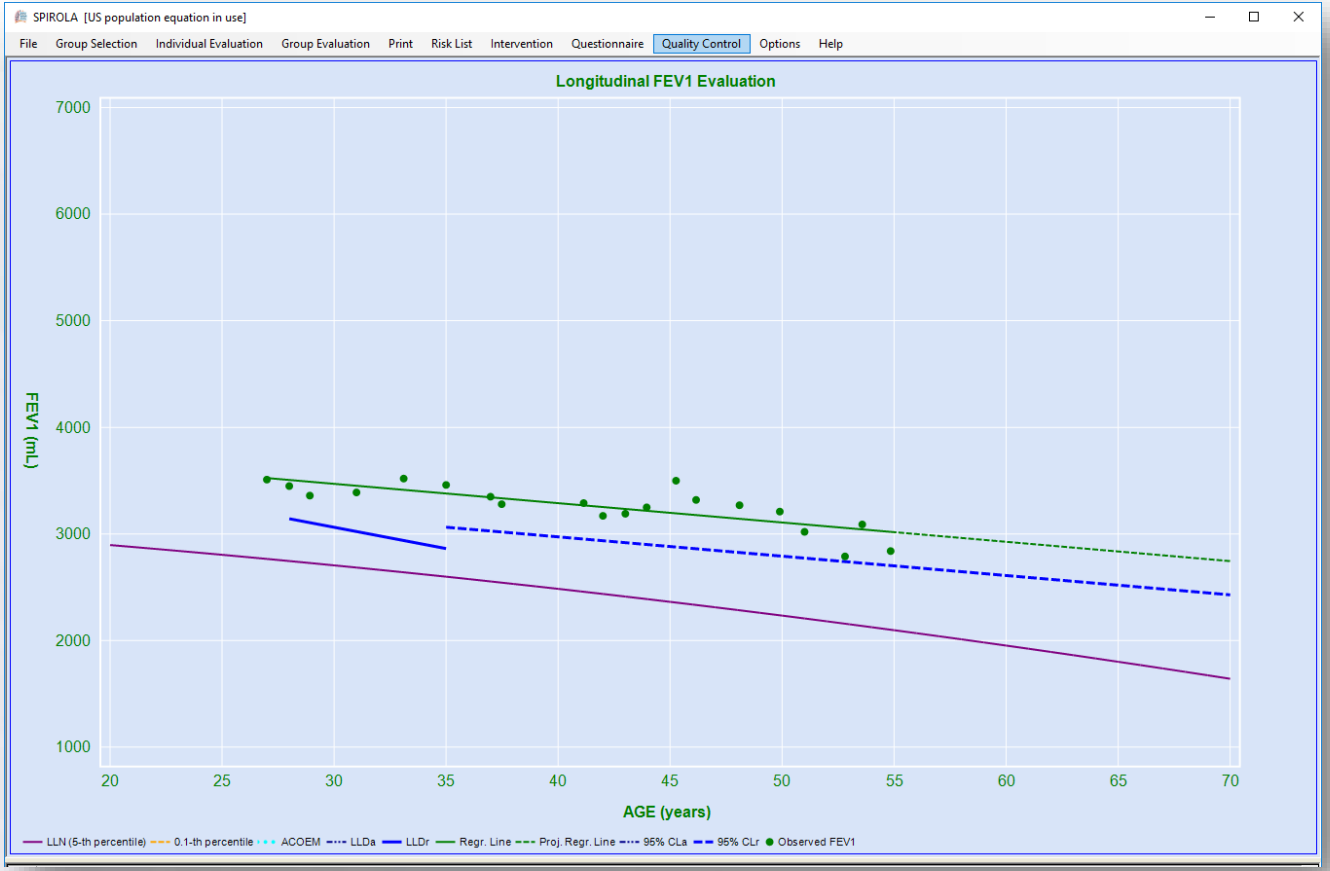
Diagnosis:
Normal Spirometry

Notes:
PI is a pacific islander

Printed 8/9/2017
Spiro Vision 3+ 9.1a

Page 1 of 1

Case 2

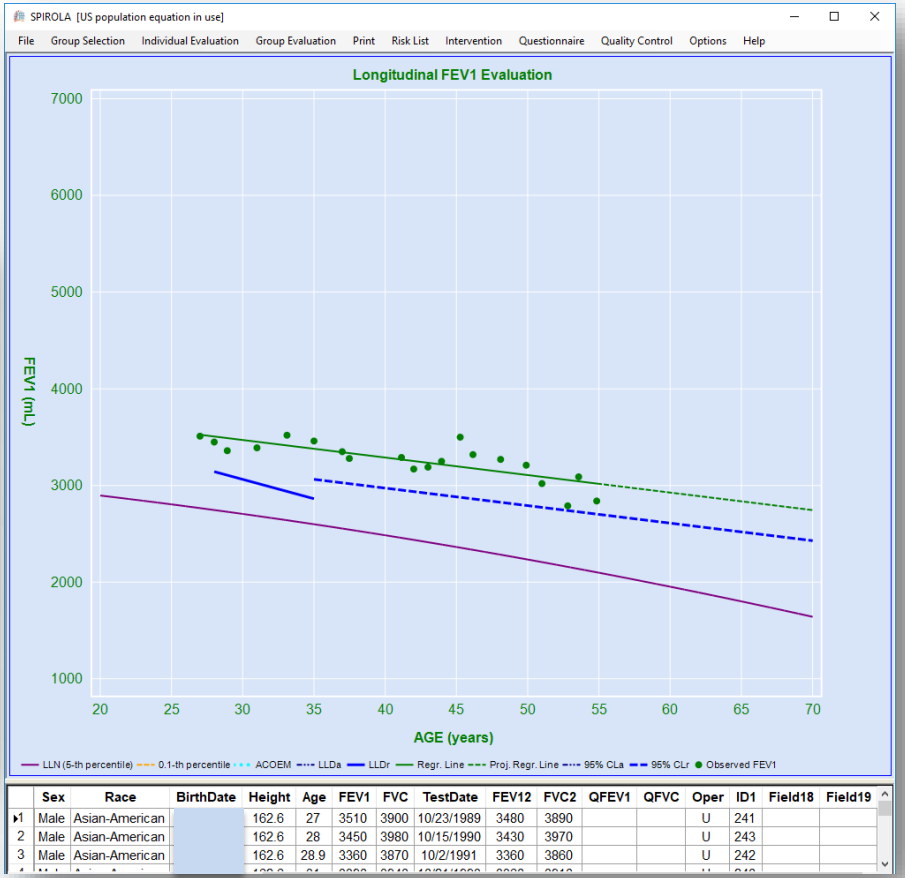

SPIROLA [US population equation in use]
File
Group Selection
Individual Evaluation
Group Evaluation
Print
Risk List
Intervention
Questionnaire
Quality Control
Options
Help
Longitudinal FEV1 Evaluation
FEV1 (mL)
7000
6000
5000
4000
3000
2000
1000
20
25
30
35
40
45
50
55
60
65
70
AGE (years)
LLN (5-th percentile)
0.1-th percentile
ACOEM
LLDa
LLDr
Regr. Line
Proj. Regr. Line
95% CLa
95% CLr
Observed FEV1

Case 2

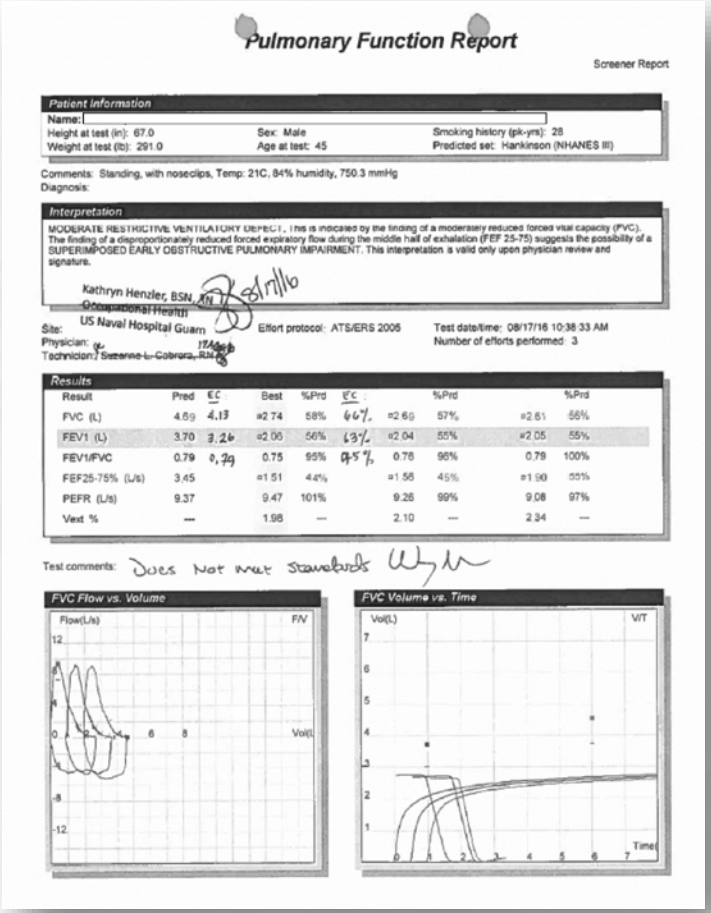
Sex:	Male
Race:	Asian-American
Age:	54 years old
Height (Mean):	162.6 cm
Date of last test:	8/9/2017
Years of follow-up:	27 years and 9 months
Results of analysis:	
Last observation:	FVC below 95% CL for the regression line;
Rate of FEV1 decline:	Overall: 18 mL/year, 95% CI (-4, 17) Last 8 years: 57 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.



	Sex	Race	BirthDate	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper	ID1	Field18	Field19
▶1	Male	Asian-American		162.6	27	3510	3900	10/23/1989	3480	3890			U	241		
2	Male	Asian-American		162.6	28	3450	3980	10/15/1990	3430	3970			U	243		
3	Male	Asian-American		162.6	28.9	3360	3870	10/2/1991	3360	3860			U	242		



Pulmonary Function Report

Screener Report

Patient Information

Name:

Height at test (in): 67.0 | Sex: Male | Smoking history (pk-yrs): 28

Weight at test (lb): 291.0 | Age at test: 45 | Predicted set: Hankinson (NHANES III)

Comments: Standing, with noseclips, Temp: 21C, 84% humidity, 750.3 mmHg

Diagnosis:

Interpretation

MODERATE RESTRICTIVE VENTILATORY DEFECT. This is indicated by the finding of a moderately reduced forced vital capacity (FVC). The finding of a disproportionately reduced forced expiratory flow during the middle half of exhalation (FEF 25-75) suggests the possibility of a SUPERIMPOSED EARLY OBSTRUCTIVE PULMONARY IMPAIRMENT. This interpretation is valid only upon physician review and signature.

Kathryn Henzler, BSN, RN
Occupational Health
US Naval Hospital Guam

Site:

Physician:

Technician: Suzanne L. Cabrera, RN

Effort protocol: ATS/ERS 2005

Test date/time: 08/17/16 10:38:33 AM

Number of efforts performed: 3

Results

Result	Pred	EC	Best	%Prd	EC		%Prd		%Prd
FVC (L)	4.69	4.13	#2.74	58%	66%	#2.69	57%	#2.61	56%
FEV1 (L)	3.70	3.26	#2.06	56%	63%	#2.04	55%	#2.05	55%
FEV1/FVC	0.79	0.79	0.75	95%	95%	0.76	96%	0.79	100%
FEF25-75% (L/s)	3.45		#1.51	44%		#1.56	45%	#1.90	55%
PEFR (L/s)	9.37		9.47	101%		9.26	99%	9.08	97%
Vext %	---		1.98	---		2.10	---	2.34	---

Test comments: Does Not Meet Standards

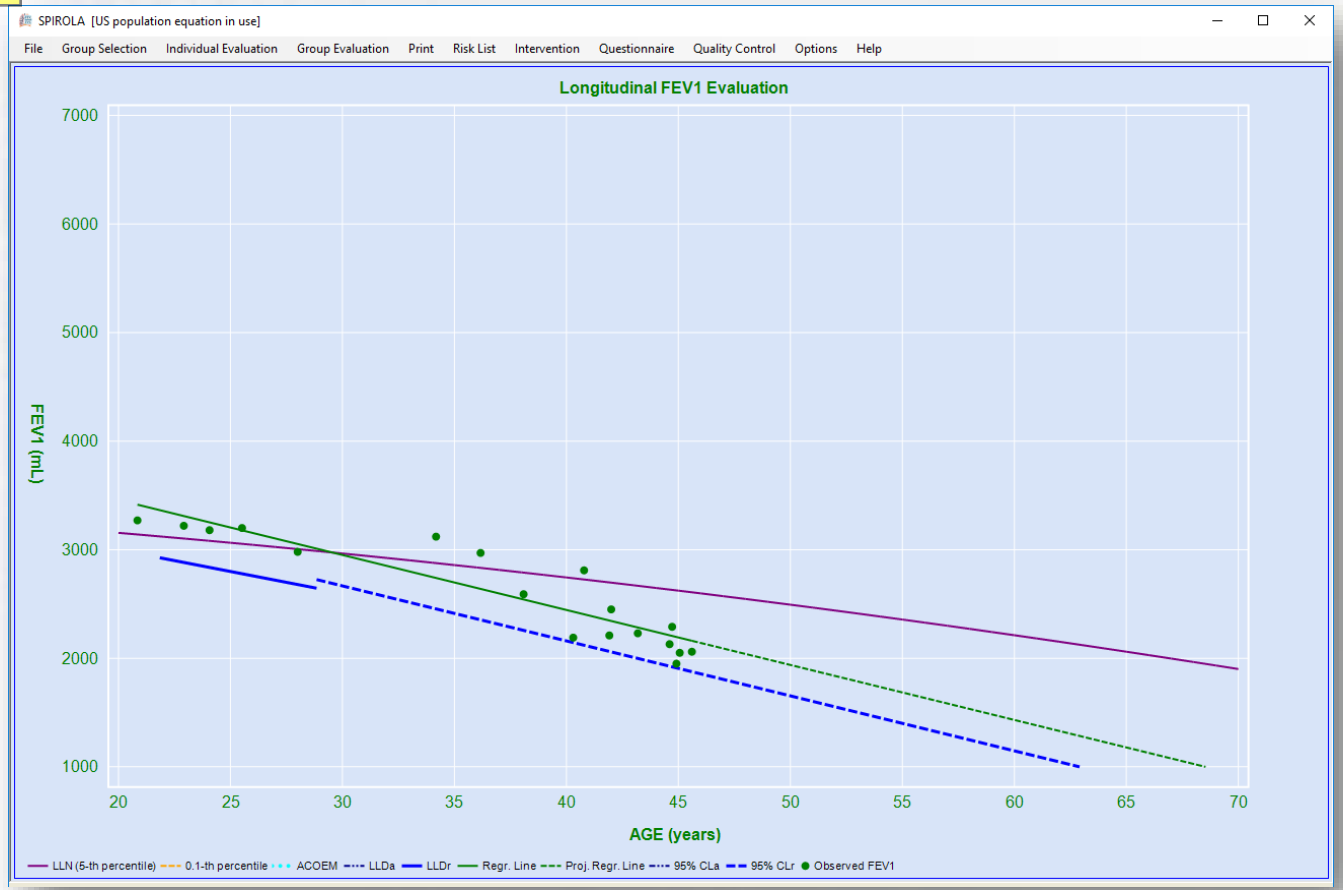
FVC Flow vs. Volume

FVC Volume vs. Time

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


SPIROLA [US population equation in use]
File
Group Selection
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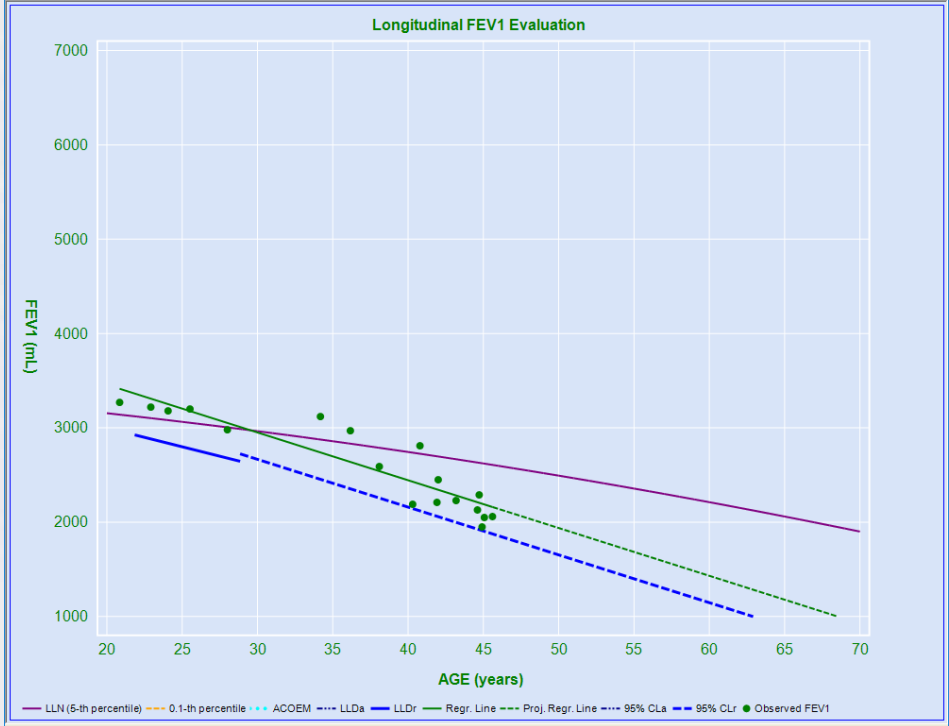
Longitudinal FEV1 Evaluation
FEV1 (mL)
7000
6000
5000
4000
3000
2000
1000
20
25
30
35
40
45
50
55
60
65
70
AGE (years)
LLN (5-th percentile)
0.1-th percentile
ACOEM
LLDa
LLDr
Regr. Line
Proj. Regr. Line
95% CLa
95% CLr
Observed FEV1

Case 3

SPIROLA [US population equation in use]

File | Group Selection | Individual Evaluation | Group Evaluation | Print | Risk List | Intervention | Questionnaire | Quality Control | Options | Help



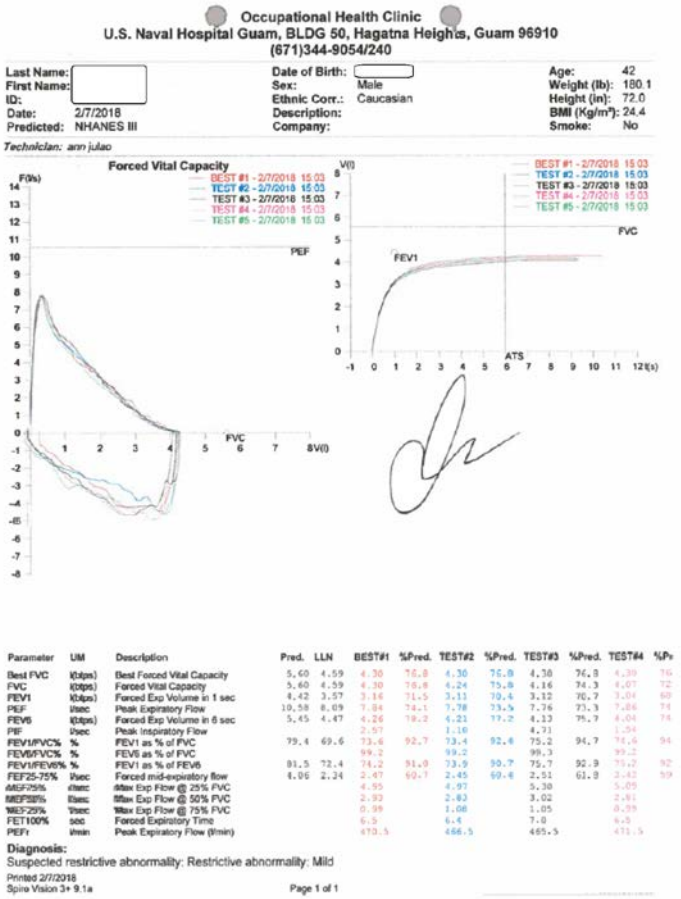
	Sex	Race	BirthDate	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper	ID1	Field18	Field19
▸1	Male	Asian-American		170.2	20.8	3270	3670	11/15/1991	3160	3670			U	480		
2	Male	Asian-American		170.2	22.9	3220	3630	1/7/1994	3180	3590			U	479		
3	Male	Asian-American		170.2	24.1	3180	3630	2/3/1995	3140	3620			A	478		

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:	
Last observation:	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 (29, 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; 5.9%; (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 0.1-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.



Occupational Health Clinic
U.S. Naval Hospital Guam, BLDG 50, Hagatna Heights, Guam 96910
(671)344-9054/240

Last Name:		Date of Birth:	Age: 42
First Name:		Sex: Male	Weight (lb): 180.1
ID:		Ethnic Corr.: Caucasian	Height (in): 72.0
Date: 2/7/2018		Description:	BMI (Kg/m²): 24.4
Predicted: NHANES III		Company:	Smoke: No

Technician: ann julao

Forced Vital Capacity

BEST #1 - 2/7/2018 15:03
TEST #2 - 2/7/2018 15:03
TEST #3 - 2/7/2018 15:03
TEST #4 - 2/7/2018 15:03
TEST #5 - 2/7/2018 15:03

F(l/s) PEF FVC 8V(l)

V(l) FEV1 FVC ATS 12t(s)

Parameter	UM	Description	Pred.	LLN	BEST#1	%Pred.	TEST#2	%Pred.	TEST#3	%Pred.	TEST#4	%Pr
Best FVC	l(btps)	Best Forced Vital Capacity	5.60	4.59	4.30	76.8	4.30	76.8	4.30	76.8	4.39	78
FVC	l(btps)	Forced Vital Capacity	5.60	4.59	4.30	76.8	4.24	75.8	4.16	74.3	4.07	72
FEV1	l(btps)	Forced Exp Volume in 1 sec	4.42	3.57	3.16	71.5	3.11	70.4	3.12	70.7	3.04	69
PEF	l/sec	Peak Expiratory Flow	10.58	8.09	7.84	74.1	7.78	73.5	7.76	73.3	7.86	74
FEV6	l(btps)	Forced Exp Volume in 6 sec	5.45	4.47	4.26	78.2	4.21	77.2	4.13	75.7	4.04	74
PIF	l/sec	Peak Inspiratory Flow			2.57		3.16		4.71		1.94	
FEV1/FVC%	%	FEV1 as % of FVC	79.4	69.6	73.6	92.7	73.4	92.4	75.2	94.7	74.6	94
FEV6/FVC%	%	FEV6 as % of FVC			99.2		99.2		99.3		99.2	
FEV1/FEV6%	%	FEV1 as % of FEV6	81.5	72.4	74.2	91.0	73.9	90.7	75.7	92.9	75.2	92
FEF25-75%	l/sec	Forced mid-expiratory flow	4.06	2.24	2.47	60.7	2.45	60.4	2.51	61.8	2.42	59
MEF75%	l/sec	Max Exp Flow @ 25% FVC			4.55		4.47		5.30		5.09	
MEF50%	l/sec	Max Exp Flow @ 50% FVC			2.93		2.83		3.02		2.91	
MEF25%	l/sec	Max Exp Flow @ 75% FVC			0.99		1.08		1.05		0.99	
FET100%	sec	Forced Expiratory Time			6.5		6.4		7.0		6.5	
PEFr	l/min	Peak Expiratory Flow (l/min)			470.5		466.5		465.5		471.5	

Diagnosis:
Suspected restrictive abnormality: Restrictive abnormality: Mild

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Spiro Vision 3+ 9.1a

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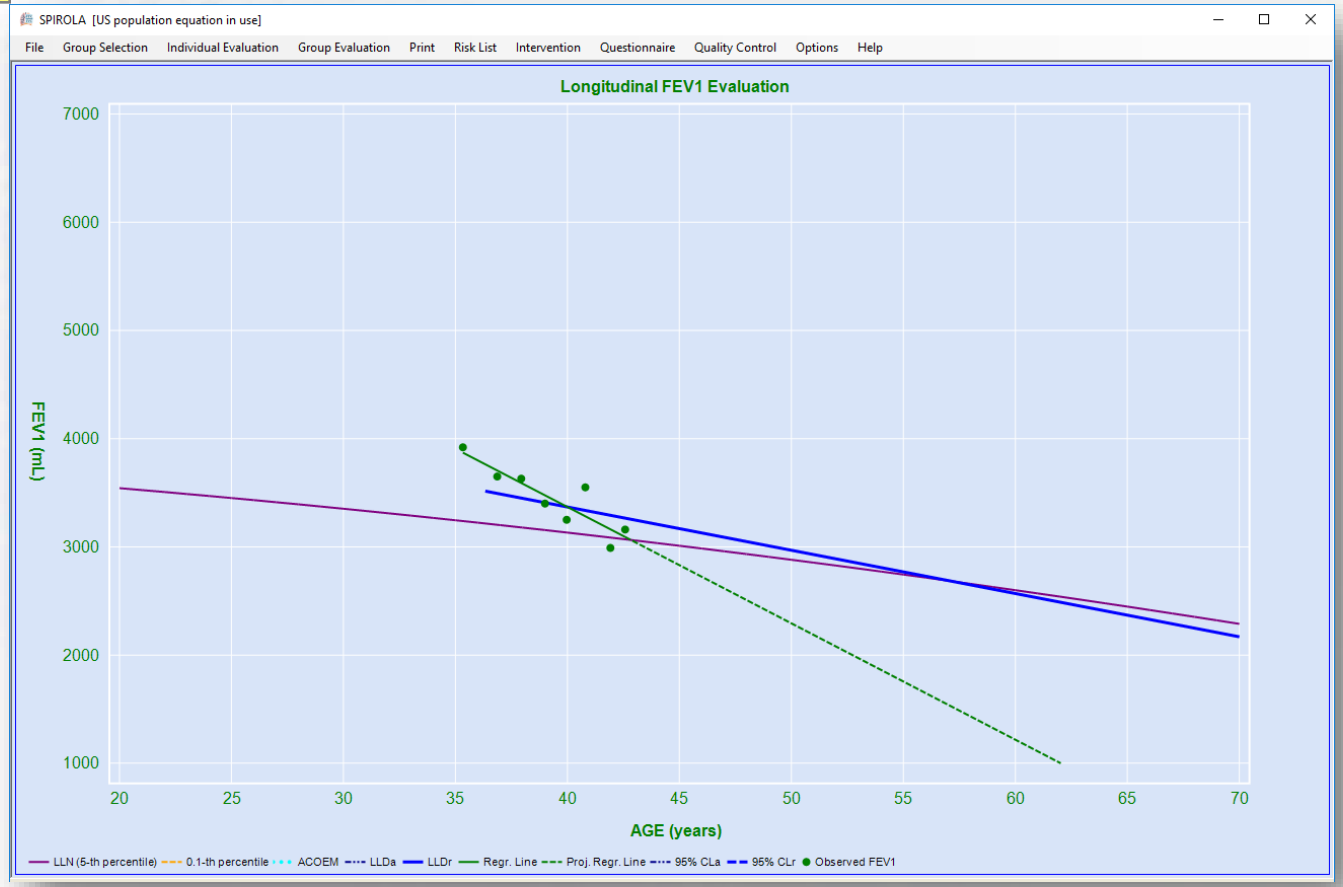
Case 4

- 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


SPIROLA [US population equation in use]
File
Group Selection
Individual Evaluation
Group Evaluation
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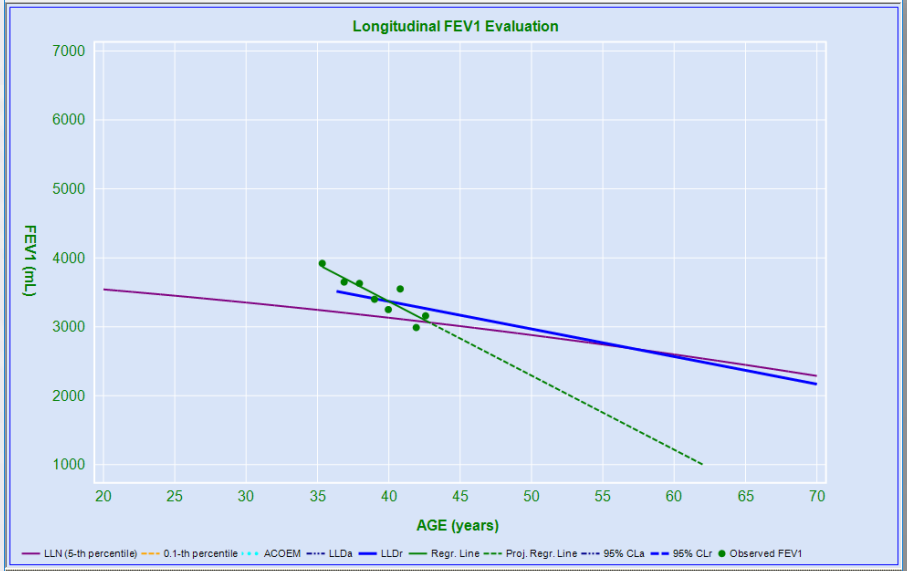
Risk List
Intervention
Questionnaire
Quality Control
Options
Help
Longitudinal FEV1 Evaluation
FEV1 (mL)
7000
6000
5000
4000
3000
2000
1000
20
25
30
35
40
45
50
55
60
65
70
AGE (years)
LLN (5-th percentile)
0.1-th percentile
ACOEM
LLDa
LLDr
Regr. Line
Proj. Regr. Line
95% CLa
95% CLr
Observed FEV1

Case 4

SPIROLA [US population equation in use]

File | Group Selection | Individual Evaluation | Group Evaluation | Print | Risk List | Intervention | Questionnaire | Quality Control | Options | Help



	Sex	Race	BirthDate	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper	ID1	Field18	Field19
▸1	Male	Asian-American		180.3	35.3	3920	6210	11/10/2010	3860	5180			A	161		
2	Male	Asian-American		180.3	36.9	3650	4980	5/23/2012	3550	4820			A	160		
3	Male	Asian-American		180.3	37.9	3630	5150	6/19/2013	3570	5100			A	159		
4	Male	Asian-American		180.3	39	3400	4710	7/16/2014	3310	4510			A	158		
5	Male	Asian-American		180.3	40	3250	4610	6/29/2015	3240	4550			A	157		
6	Male	Asian-American		180.3	40.8	3550	4870	4/28/2016	3550	4830			A	156		
7	Male	Asian-American		182.9	41.9	2990	4040	6/12/2017	2910	3940			A	798		
8	Male	Asian-American		182.9	42.6	3160	4300	2/7/2018	3110	4240			Ann	809		

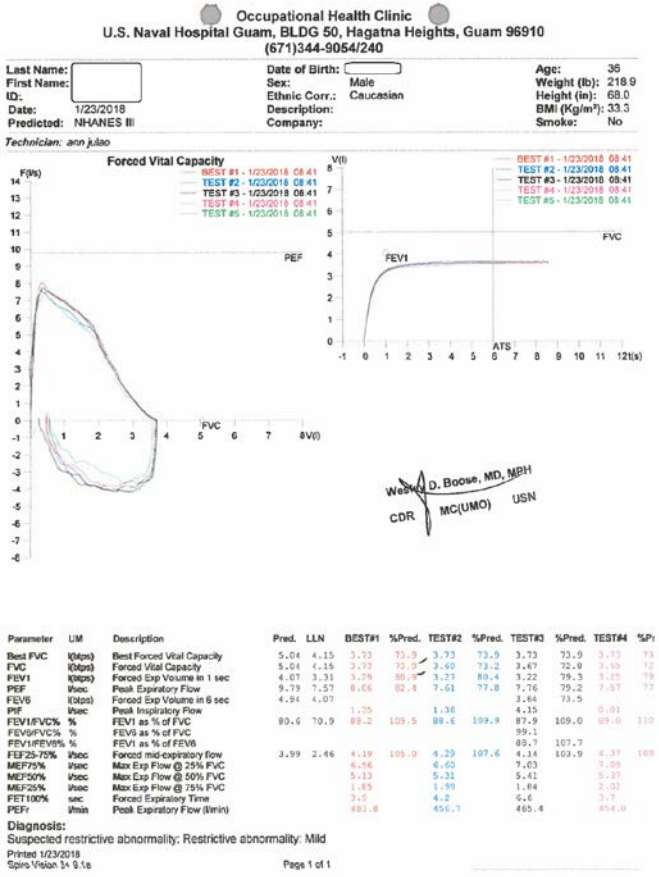
Sex:	Male
Race:	Asian-American
Age:	42 years old
Height (Mean):	181.0 cm
Date of last test:	2/7/2018
Years of follow-up:	7 years and 2 months
Results of analysis:	
Last observation:	FEV1 below LLDr; FVC below LLDr;
Rate of FEV1 decline:	Overall: 108 mL/year, 95% CI (134, 327)
Rate of FVC decline:	Overall: 231 mL/year, 95% CI (134, 327)
FEV1 within-person variation:	149 mL; 3.8%; (normal <= 5%);
FVC within-person variation:	330 mL; 5.3%; (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.
- Examine the quality of baseline and current test. If confirmed that FEV1 or FVC <LLDr, 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



Occupational Health Clinic
U.S. Naval Hospital Guam, BLDG 50, Hagatna Heights, Guam 96910
(671)344-9054/240

Last Name:
First Name:
ID:
Date: 1/23/2018
Predicted: NHANES III

Date of Birth:
Sex: Male
Ethnic Corr.: Caucasian
Description:
Company:

Age: 36
Weight (lb): 218.9
Height (in): 68.0
BMI (Kg/m²): 33.3
Smoke: No

Technician: ann julao

Forced Vital Capacity

BEST #1 - 1/23/2018 08:41
TEST #2 - 1/23/2018 08:41
TEST #3 - 1/23/2018 08:41
TEST #4 - 1/23/2018 08:41
TEST #5 - 1/23/2018 08:41

PEF
FVC
FEV1
ATS

Wesley D. Boone, MD, MPH
CDR MC(UMO) USN

Parameter	U/M	Description	Pred.	LLN	BEST#1	%Pred.	TEST#2	%Pred.	TEST#3	%Pred.	TEST#4	%Pr
Best FVC	l(btps)	Best Forced Vital Capacity	5.04	4.15	3.73	73.9	3.73	73.9	3.73	73.9	3.73	73
FVC	l(btps)	Forced Vital Capacity	5.04	4.15	3.72	73.8	3.60	73.2	3.67	72.9	3.69	72
FEV1	l(btps)	Forced Exp Volume in 1 sec	4.07	3.31	3.29	80.8	3.23	80.4	3.22	79.3	3.25	79
PEF	l/sec	Peak Expiratory Flow	9.79	7.57	8.06	82.4	7.61	77.8	7.76	79.2	7.57	77
FEV6	l(btps)	Forced Exp Volume in 6 sec	4.94	4.07					3.64	73.5		
PIF	l/sec	Peak Inspiratory Flow			1.35		1.36		4.15		0.01	
FEV1/FVC%	%	FEV1 as % of FVC	80.6	70.9	88.2	109.5	88.6	109.9	87.9	109.0	88.0	110
FEV6/FVC%	%	FEV6 as % of FVC							99.1			
FEV1/FEV6%	%	FEV1 as % of FEV6							88.7	107.7		
FEF25-75%	l/sec	Forced mid-expiratory flow	3.99	2.46	4.19	105.0	4.29	107.6	4.14	103.9	4.37	109
MEF75%	l/sec	Max Exp Flow @ 25% FVC			6.56		6.60		7.03		7.08	
MEF50%	l/sec	Max Exp Flow @ 50% FVC			5.13		5.31		5.41		5.37	
MEF25%	l/sec	Max Exp Flow @ 75% FVC			1.85		1.99		1.84		2.02	
FET100%	sec	Forced Expiratory Time			3.5		4.2		6.6		3.7	
PEFr	l/min	Peak Expiratory Flow (l/min)			483.8		456.7		465.4		454.0	

Diagnosis:
Suspected restrictive abnormality: Restrictive abnormality: Mild

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Spiro Vision 3+ 9.1a

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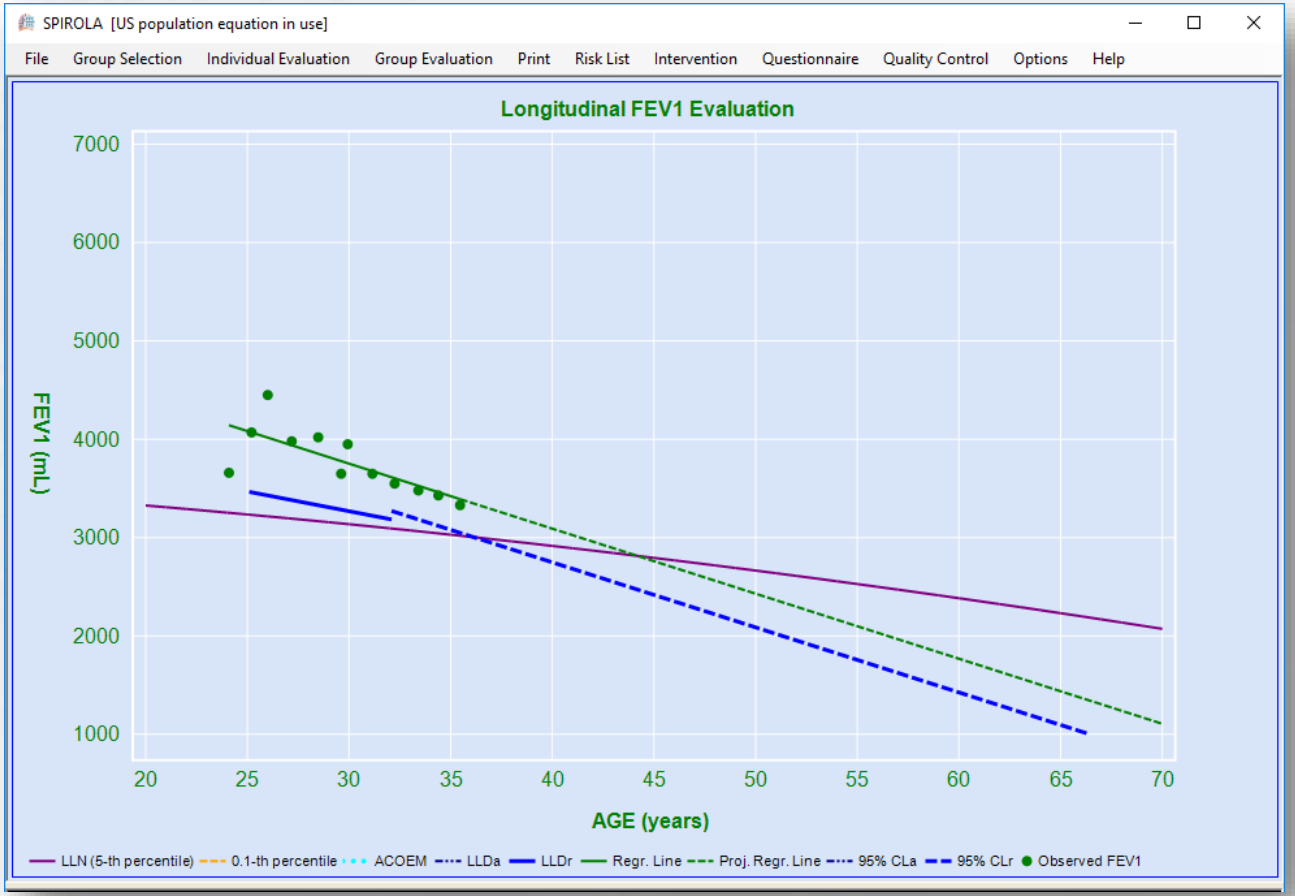
- 36 yo M Firefighter presents for annual physical
- PMH/PSHx: None
- Weight Gain: 23lbs, BMI 33
- Meds: Multivitamins
- Allergies: NKDA
- Soc Hx: Non-Smoker
- CXR: Normal
- Occ Hx:
  - Federal CIV Firefighter for 11 years
  - Work Exposures: Nothing significant
- % Predicted and LLN with Asian Ethnic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

Case 5


SPIROLA [US population equation in use]
File
Group Selection
Individual Evaluation
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Intervention
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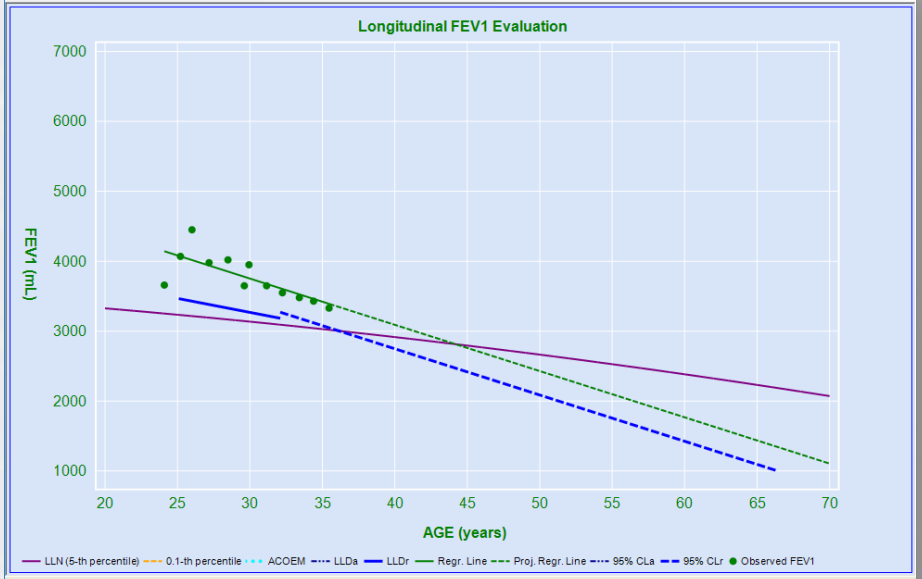
Quality Control
Options
Help
Longitudinal FEV1 Evaluation
FEV1 (mL)
7000
6000
5000
4000
3000
2000
1000
20
25
30
35
40
45
50
55
60
65
70
AGE (years)
LLN (5-th percentile)
0.1-th percentile
ACOEM
LLDa
LLDr
Regr. Line
Proj. Regr. Line
95% CLa
95% CLr
Observed FEV1

Case 5

SPIROLA [US population equation in use]

File | Group Selection | Individual Evaluation | Group Evaluation | Print | Risk List | Intervention | Questionnaire | Quality Control | Options | Help



	e	Sex	Race	BirthDate	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper	ID1	Field18	Fi
▸1		Male	Asian-American		175.3	24.1	3660	4110	1/10/2006	3580	4000			U	113		
2		Male	Asian-American		175.3	25.2	4070	4700	2/20/2007	4070	4680			U	112		
3		Male	Asian-American		175.3	26	4450	5030	12/11/2007	4450	4970			U	111		
4		Male	Asian-American		175.3	27.2	3980	4420	2/11/2009	3880	4360			U	110		
5		Male	Asian-American		175.3	28.5	4020	4410	6/2/2010	3980	4260			U	109		
6		Male	Asian-American		175.3	29.6	3650	3940	7/19/2011	3550	3850			A	108		
7		Male	Asian-American		175.3	29.9	3950	4580	11/14/2011	3900	4440			A	107		
8		Male	Asian-American		175.3	31.2	3650	4210	1/31/2013	3650	4190			E	106		
9		Male	Asian-American		175.3	32.2	3550	4080	3/5/2014	3570	7060			A	105		

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:	FVC below LLN
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 0.1-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
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- Occupational Health Department Staff at the U.S. Naval Hospital Guam

Un Dangkulu na Si Yu'us Ma'ase! *Thank you very much!*

References

- Hnizdo, E., Yan, T., Hakobyan, A., Enright, P., Beeckman-Wagner, L. A., Hankinson, J.,…Lee Petsonk, E. (2010). Spirometry Longitudinal Data Analysis Software (SPIROLA) for Analysis of Spirometry Data in Workplace Prevention or COPD Treatment. *Open Med Inform J, 4*, 94-102. doi:10.2174/1874431101004010094
- Hnizdo, E., Sircar, K., Yan, T., Harber, P., Fleming, J., & Glindmeyer, H. W. (2007). Limits of Longitudinal Decline for the Interpretation of Annual Changes in FEV1 in Individuals. *Occup Environ Med, 64*(10), 701-707. doi:10.1136/oem.2006.031146
- National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. (2016). *Spirometry Longitudinal Data Analysis User Manual, Version 3.0.3.* Retrieved from http://www.cdc.gov/niosh/topics/spirometry/files/spirola-user-manual.pdf.
- Occupational Safety and Health Administration (OSHA). (2013). *Spirometry Testing in Occupational Health Programs, Best Practices for Healthcare Professionals*. OSHA 3637-03. Retrieved from https://www.osha.gov/Publications/OSHA3637.pdf.
- Redlich, C. A., Tarlo, S. M., Hankinson, J. L., Townsend, M. C., Eschenbacher, W. L., Von Essen, S. G., …Weissman, D. N. (2014). Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting. *Am J Respir Crit Care Med, 189*(8), 983-993. doi:10.1164/rccm.201402-0337ST
- Townsend, M. C. (2000). ACOEM Position Statement. Spirometry in the Occupational Setting. American College of Occupational and Environmental Medicine. *J Occup Environ Med, 42*(3), 228-245.

Questions and Answers