UNIT SIX: COMPARING OBSERVED TO PREDICTED NORMAL VALUES

A. "Normal" Spirometry

Lung function increases rapidly with growth during childhood and adolescence, reaches a peak sometime between the ages of 18 and 35, and then begins to slowly decline, even in healthy persons (29).   Persons who grow relatively tall also have relatively large lungs when compared to those who are shorter in stature. Women on average, have lungs that are about 20% smaller than men of the same height and age (30). For a given standing height, African-American men, on the average, have longer legs than Caucasian men, and a correspondingly shorter trunk size; and therefore slightly smaller lungs (29,31,32,33) explaining most of the differences between predicted values for Caucasian and African-American men. All of the above factors mean that to optimally interpret spirometry results (observed values), you must first know the employee's age, height, gender, and race or ethnicity.

Before performing spirometry, record on a worksheet, or enter directly into a computer, the following information about the employee (at a minimum):

1. The employee's date of birth (DOB), and their age calculated from the date of testing and their DOB. Ask the employee their age, in order to verify the calculation.

2. The employee's standing height in stocking feet should be measured using a stadiometer, and recorded in feet and inches, to the nearest half inch. Verify this height with the employee. Their height should then be converted to centimeters by multiplying their height in inches by 2.54.

3. The employee's weight (in stocking feet) should also be measured to the nearest pound, using a scale which is accurate to within one pound. The computer should convert their weight to kilograms (multiply pounds by 0.4536) and then calculate and display their body mass index (BMI) in kilograms per meter squared. A BMI greater than 30 Kg/m^2 indicates that the employee is overweight. Body weight is not used to calculate spirometry reference values, but obesity can lower the measured lung volumes, and changes in body weight can result in small changes in lung function.

4. An attempt should be made to determine and record the employee's race or ethnicity. Often this can be done with adequate accuracy merely by observation. If in doubt, ask the employee, explaining that race affects the reference values used for the test. If the employee considers the question objectionable, or if their race or ethnicity does not clearly fit the limited categories available, just record "unknown" and use Caucasian reference equations (no race correction or race-specific reference value).

B. Spirometry Reference Studies.

There have been dozens of studies published in the medical literature which have determined spirometry reference values from groups of relatively healthy persons. The OSHA Cotton Dust Standard, published in 1978 (10), mandated that spirometry reference equations, determined from healthy persons in Tucson, Arizona, and published by Knudson, et. al. in 1976 (32,33,34) be used

when performing spirometry testing to detect lung disease in employees working in the cotton textile industry. Because the Knudson-1976 study did not include African-Americans, a "race correction factor" of 0.85 times the Knudson-1976 Caucasian reference value is recommended in the Cotton Dust Standard [10]. However in 1983, Knudson et. al. (35) published revised reference equations for their 1976 published values. See Appendix E for more information about the Cotton Dust Standard. The use of the Knudson equations to determine predicted normal values was adopted during the 1980s by many other industries for spirometry testing done in the occupational setting. However, the instruments and techniques for performing spirometry have improved and the American Thoracic Society (ATS) has published updated detailed recommendations for the interpretation of spirometry in the clinical setting, most recently in 1991 (30) and 1995 (1). When spirometry is being performed to comply with current regulations, the reference equations that are specified in the regulation must be utilized, such as Knudson 1976 in the OSHA Cotton Dust Standard. When interpretation of spirometry is not specified by regulation, NIOSH recommends following the most recent update of the ATS recommendations for interpretation of spirometry and selecting reference values based on the third National Health and Nutrition Examination Survey (NHANES III), published in 1999 (29).

It may be necessary to consult with the manufacturer of some older model spirometry systems to update the software to include the NHANES III spirometry reference equations for adults. The use of older spirometry reference values when testing employees in the age range of 18-65 years of age may result in slightly lower predicted values for FEV_1 and FVC when compared to using the NHANES III equations (29).

Racial Differences in Spirometry.

The NHANES III study (29) provides a separate set of spirometry reference equations for men and women of African-American, Caucasian, and Mexican-American ethnic groups. The NHANES III study did not provide spirometry reference equations for Asian-Americans, American Indians, East Indians, or other ethnic groups. Other investigations suggest that spirometry results are not substantially different for American Indians when compared to Caucasians living in the United States (36,37); therefore, NIOSH recommends that when testing American Indian employees, the reference equations for Caucasians be used. Large studies of Asians outside of the U.S. (39, 40) suggest that Asian FEV_1 and FVC values are, on average about 15% lower than Caucasians of the same age, gender, and standing height. However, smaller studies of Asian-Americans living in the U.S. (40,41) suggest that Asian-American FEV_1 and FVC are approximately 6 to 7 % lower than Caucasians. Therefore, until separate reference equations are published and accepted for Asian-American and East Indian ethnic groups, the NHANES III reference equations for Caucasians should be used, but a correction factor of 0.94 should then be applied to the predicted values for FVC and FEV_1. Note that the **predicted values** are multiplied by the correction factor, not the observed values.

C. The Lower Limit of the Normal (LLN) Range.

The predicted value calculated from spirometry reference equations is the *average* or mean value observed from many healthy persons of the same age, gender, height, and race as the employee being tested. The predicted value is actually in the middle of a rather wide, bell-shaped

distribution (range) of normal values. For instance, some healthy persons may have FVC values as much as 20% lower than the predicted value.

The lower limit of the normal range (LLN) is the threshold below which a value is considered abnormal - usually the value is set so that 95% of a "normal" population will have values above the LLN value and correspondingly, 5% of a "normal" population will have values below the LLN. The LLN is about 80% of the predicted value for FEV_1 and for FVC, but about 90% of the predicted value for the FEV_1/FVC ratio, and about 60% of the predicted value for the FEF25-75%. However, these are only rough "rules of thumb" and the exact LLN should be determined using the reference equations. If a race correction factor is used (0.85), the same race correction factor should be applied to the LLN value.

What is Considered Abnormal?

Abnormalities detected by spirometry may show one of three patterns: obstructive, restrictive, or mixed obstructive and restrictive. Employees with obstructive lung diseases, such as emphysema or chronic asthma, often have an abnormally low FEV1/FVC and a low FEV1 (below the LLN). Employees with fibrotic lung diseases, such as asbestosis, often have an abnormally low FVC, but their FEV1/FVC will generally be above the LLN. Persons exposed to certain dusts, such as silica or coal mine dust, can develop either pattern of abnormality, or a mixed pattern with reductions of both the FEV1/FVC ratio and the FVC below the LLN.

Occasionally, spirometry results from a worker without any apparent health problems are found to be slightly below the LLN. In contrast, it is not unusual to have high FVC or high FEV1 spirometry values. In fact, when they begin working, a majority of individuals in blue collar jobs have lung function that is considerably above average, a phenomenon called the "healthy worker effect". Young adults who were competitive athletes in high school, trade school, or college (while their lungs were still growing) may have a percent predicted FVC above 120%. On the other hand, it is unusual to have a percent predicted value above 140%, so if this occurs, be sure to check that the employee's age or height was measured, recorded, transcribed, and entered correctly. If an unusually high percent predicted value cannot be explained by an error, you should check the calibration of your spirometer.

D. How to Determine Predicted Values Using Look-up Tables.

There are several methods available to calculate spirometry reference values, percent predicted values, and the LLN's for an employee: 1) using a calculator, 2) using a nomogram, 3) using "look-up" tables, 4) using a personal computer or automated spirometry system which has already been programmed with the appropriate reference equations.

There are two times when it is useful to determine spirometry predicted values without using a computer: 1) when learning about them (using this workbook); and, 2) when verifying (checking) the accuracy of the reference equations which have been programmed into a spirometry system that you are using for the first time.

Abbreviated tables based on the NHANES III reference equations are provided in Appendix L for

the purpose of completing the examples given in this workbook and for verifying the accuracy of a spirometry system for computing the predicted values. However, these small tables will not be adequate for the routine testing of employees, because the range and intervals of heights are limited. Also, there may be slight differences ($\pm$ 0.02 liters), depending on whether a reference calculator, nomogram, or table is used.

The steps for determining the predicted normal and the LLN values from the tables are:

1. Choose the appropriate table from the six tables in Appendix L, based on the employee's gender and race. Use the employee's height and age to find the predicted normal values and LLNs for the FVC, FEV_1, and FEV_1/FVC%.

2. Use a pocket calculator to determine the percentage of the predicted values as follows:
    a. Divide the observed FEV_1 and FVC by the predicted result.
    b. Multiply the answer by 100. Round to one decimal place.

An Example:

A 30 year-old woman is a firefighter in Miami. She is 4 foot 11 inches tall, 135 pounds, and states that she is a Mexican-American. To determine her spirometry predicted values, choose Table 6 from Appendix L for Mexican-American women. Then note that her height is listed as 150 cm in the first column. Find age 30 on the second vertical column and use a straight-edged ruler to underline the row of predicted values for 30 year old women of this height. Move over to the third vertical column labeled "FVC Pred" and read the value 3.21 L. This is the predicted FVC in liters (BTPS) for this employee. Also record the lower limit of the normal value for the FVC as 2.60 liters, and the other predicted and LLN values for this employee from same row.

Her FVC was measured (observed) as 2.85 liters (BTPS) and her FEV_1 was 2.28 liters. Use a pocket calculator to determine that her FEV_1/FVC was 80.0% To determine her FEV_1 percent predicted value:

$$\%Pred\ FEV1 = 100.0 \times \frac{Observed\ FEV1}{Predicted\ FEV1}$$

Note that her FVC and FEV_1 were both above the LLNs and both above 80% of the predicted values. Her FEV_1/FVC was also above the LLN. Her results would be interpreted as normal, since all three of these values were within the normal ranges.

EXERCISES:

1. What is the predicted FVC value for a 60 year old, Caucasian male steelworker in Pittsburgh. He is 71 inches tall and weighs 220 pounds.

2. What is the predicted and LLN for FEV_1 for a 40 year old African-American man, who is a

supervisor at a petrochemical company in Alabama. He is 170 cm tall and weighs 170 pounds.

3.   A 20 year old, third-generation Japanese-American man, working at an electronics plant in San Jose, has an FVC of 4.00 L. He is 5 feet 11 inches tall and weighs 135 pounds. What is his percent predicted FVC?

4.   What is the predicted FEV_1 for a 40-year old African-American man, 170 cm tall, using the reference value recommended in the Cotton Dust Standard? The Knudson 1976 (Cotton Dust) FEV_1 reference value for a Caucasian subject of the same gender, age and height is 3.56 liters.

FEEDBACK:

1.   His predicted FVC is 4.92 liters, based on a height of 180 cm. Note that weight is not considered when calculating spirometry reference values.

2.   His predicted FEV_1 is 3.23 liters, with a lower limit of 2.47 liters.

3.   Since there are no tables for Asian-Americans, use table 1 for Caucasian men who are 5 feet 11 inches (180 cm) tall. Reading from the table, the predicted FVC for a 20 year old Caucasian man of this height is 5.75 liters. Then multiply this value by the suggested Asian-American correction factor of 0.94 to estimate the predicted value for this employee as 5.41 liters. Divide his observed FVC of 4.80 liters by the predicted value of 5.41 to obtain his percent predicted FVC as 88.7%. He clearly has a normal vital capacity since his percent predicted FVC is greater than 80% and his FVC is above the LLN value of 4.51 liters (0.94 x 4.80 = 4.51).

4.   The Cotton Dust standard recommends that a "correction factor" of 0.85 be multiplied times the FEV_1 reference value from the Knudson-1976 study of Caucasians. The predicted FEV_1 for a Caucasian male from Knudson-1976 is 3.56 liters. Therefore, the predicted value for this African-American worker would be 0.85 x 3.56 = 3.03 liters.