Progress Report of the Medical Devices Committee

Recommendations for Spirometers

By Reed M. Gardner, *Chairman*

The past two years have been busy and intense ones for the Medical Devices Committee of the American Thoracic Society. Development of recommendations for spirometry has been tedious and, at times, frustrating, but the Committee is convinced that only through effort and discipline can the best standards be developed for the pulmonary medicine community. Results of this effort are soon to be published in the *American Review of Respiratory Disease* as an ATS Statement, "Snowbird Workshop on Standardization of Spirometry."

Development of recommendations for spirometers has given us insight into the process of writing recommendations and getting medical consensus. Following are some of the key things we have learned in this process.

1. In general, there are few medical instrument recommendations or standards currently available, especially for pulmonary medicine.

2. Many times experimental work must be done before recommendations can even be suggested.

3. It is tempting, but undesirable, to use one instrument as the "gold standard."

4. Rationale for making recommendations at times is based only on an expert consensus and not on detailed quantitative experimental evidence.

5. Consensus in establishing instrument recommendations is important. Each issue must be resolved and, at times, the majority must rule and the consensus won't be unanimous. This process is time-consuming, frustrating, and sometimes antagonizing.

6. Once preliminary recommendations are determined, they require the tempering of the ideal with the practical. For example, it may be desirable to have a spirometer with ±0.1 per cent of reading accuracy. However, this is not available with today's technology, nor are there testing devices and methods available to test such an instrument.

7. One must be reasonable in establishing recommendations so that the ever-increasing cost of medical care is not compounded. For example, if a $100 spirometer can achieve the same clinical effectiveness and reliability as a $5,000 spirometer, standards should not be promulgated to rule out the use of the less expensive device.

8. As soon as recommendations are developed, they are applied to all instruments —old and new. More than likely, there are old devices which will not meet the new recommendations. This raises the question of what should be done with the old device. We see four alternatives:

A. The device could be upgraded to meet the recommendations.

B. The implementation of the recommendations could be delayed for a time.

C. The device could be relegated to a less demanding function.

D. The device may have to be discarded.

9. Manufacturers of devices which do not meet the standards are placed in a vulnerable position. Most manufacturers of medical devices are honest, conscientious, and interested in the use of their devices in the practice of medicine. Unfortunately, until recent years there have been few standards for medical devices, and the manufacturer may find himself pushed out of the marketplace because his device does not meet a new standard. If the device is very inferior, he should be pushed out of the marketplace and required to develop better instrumentation. However, if his device is marginal, there should be some method to give him time to upgrade his instrument.

As the art of medicine becomes more quantitative, these issues and others similar to them will be facing the medical community. If organizations such as the ATS don't take an active role in this process then it will be up to government and industry to establish the standards which will then regulate how the medical profession practices medicine. It is the feeling of the Medical Devices Committee that professional organizations need to take a leadership role in establishing these standards.

Standards need to be developed not only for manufacture of new instruments but also for periodic testing of performance and quality of available instruments. One of the goals of the Medical Devices Committee is to establish simple testing procedures that the medical community can utilize to test devices in use. Establishment of quality control is just as important for the practicing physician as it is for the manufacturer of medical devices.

To help the medical user, publications are in preparation which will outline test procedures that are simple and inexpensive yet effective in testing spirometers.

Development of these methods followed extensive testing done as a follow up of the Snowbird Workshop on the Standardization of Spirometry (ATS NEWS, Summer 1977). Major conclusions of this testing were:

1. The testing methods proposed at Snowbird can be applied to commercially available spirometers.

2. Most of the commercially available spirometers meet or exceed the Snowbird recommendations.

3. Results from any of the spirometers which meet or exceed the Snowbird recommendations can be used interchangeably without concern for instrumentation differences.

4. Most of the defects we found can be detected by simple testing procedures outlined below.

A. The first step in evaluating a spirometer should be a comparison of manufacturer-stated specifications with the ATS Snowbird recommendations (ATS NEWS, Summer 1977). It is important to observe that a 10-liter spirometer, which has an accuracy specification of ± 3 per cent of full scale or ± 300 milliliters, will *not* meet the ATS Snowbird accuracy requirements of ± 3 per cent of reading.

B. Check for any leaks in the tubing or spirometer. This is particularly important for volume measuring devices.

C. Simulate a normal and an obstructed patient by injecting air from a 3-liter syringe into the spirometer in approximately 2 seconds (normal) and 6 seconds (obstructed). Also, observe if there is adequate recorder volume sensitivity. The FVC's in both instances should fall within the ATS Snowbird accuracy recommendations.

D. Perform an FVC maneuver using yourself as the subject while taking particular care to achieve relative low flow rates at the end of the maneuver. Notice if the spirometer prematurely terminates the maneuver or if it continues to show an increase in volume when you approach your residual volume. This test is particularly important for flow measuring devices.

E. Check the start of test determination for any unusual sensitivity to noise. Some spirometers have a tendency to false start timing for the FEV_1 when the subject is shaking the mouthpiece and tubing while straining to completely inhale. When this occurs, the FEV_1 will be zero, or unusually low.

F. The recorder timing accuracy should be checked with a stopwatch by simply observing the time displacement over

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an appropriate time period. Three-liter syringes with attachments for measurement and computation of $FEF_{25-75\%}$ are now becoming available. These syringes provide the best method to test the entire system's volume and time accuracy.

G. The automatically-determined FEV_t should be compared with several hand-determined FEV_t's from the chart record, using the back extrapolation methods (on human FVC's). This comparison is necessary to insure that the instrument is using a start of test determination method which is equivalent to the back extrapolation method.

H. Check to make certain that the manufacturer provides simple and complete calibration procedures, including how to correct for room air syringe volume testing. These procedures should be simple enough for a technician to follow and complete enough to insure that the instrument is functioning within ATS recommendations.

These eight steps will adequately evaluate most spirometers currently manufactured. To use these methods, the manufacturer will have to provide the appropriate "multiplying" factors to compensate for the effects of using "cool," "dry" air in the syringe rather than the human breath.

Three-liter syringes which have National Bureau of Standards traceability are currently available from multiple sources.

1. A-M Systems Inc., Box 7332, Toledo, Ohio 43615.

2.Warren E. Collins Inc., 220 Wood Road, Braintree, Mass. 02184.

3. SRL Medical Inc., 2676 Indian Ripple Road, Dayton, Ohio 45440.

4. Med-Science Electronics Inc., 1455 Page Industrial Blvd., St. Louis, Mo. 63132.

5. LSE Corporation, 6 Gill Street, Woburn, Mass. 01801.

Obituary

Jay Arthur Myers, M.D., recipient of the Will Ross Medal in 1964 and former ALA president, died September 11, at age 89, in Minneapolis, Minnesota. Dr. Myers had retired in 1957 as professor emeritus of internal medicine and public health at the University of Minnesota. He had authored 23 books, among them several on tuberculosis.

COURSES AND WORKSHOPS

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Daily Decisions in Lung Diseases—California Thoracic Society 1979 Annual Postgraduate Course, February 21-23, 1979, Red Lion Motor Inn, Sacramento, Calif. For information contact the California Thoracic Society, 424 Pendleton Way, Oakland, CA 94621.

Alaska Lung Conference, February 23-25, 1979, sponsored by the Alaska Lung Association and the Alaska Thoracic Society. For information contact Leo C. Kaye, Executive Director, Alaska Lung Association, 406 "G" St., Anchorage, AL 99501, or phone (907) 272-2332.

Seventh Annual Taos Lung Disease Symposium, February 23-25, 1979, sponsored by the New Mexico Thoracic Society. For information contact the New Mexico Thoracic Society, 216 Truman Avenue, N.E., Albuquerque, NM 87108.

International Conference on Occupational Lung Disease, February 27-March 2, 1979, San Francisco, Calif., sponsored by the American College of Chest Physicians. For information contact the ACCP at address given above.

Postgraduate Courses on Clinical Management and Control of Tuberculosis, March 4-10, 1979, and June 3-9, 1979, Denver, Colo. Presented by the National Jewish Hospital and Research Center with the cooperation of the University of Colorado Medical School, Denver Health Department, Colorado State Health Department, Fitzsimons Army Medical Center, American Lung Association of Colorado, and the American Thoracic Society. For information write to Paul T. Davidson, M.D., Chief, Tuberculosis and Chest Section, Dept. of Medicine, National Jewish Hospital and Research Center, 3800 E. Colfax Ave., Denver, CO 80206.

Postgraduate courses sponsored by the American College of Chest Physicians in March, 1979:

Fifth Annual Sugarbush Course—Cardiology for the Practitioner, March 7-9, 1979, Warren, Vt.

Exercise Testing and Exertional Dyspnea, March 29-31, 1979, Palm Springs, Calif.

For information contact the ACCP at address given above.

International Conference on Tuberculosis, March 22-24, 1979, Orlando, Fla., sponsored by the American College of Chest Physicians. For information contact the ACCP at address given above.

Pediatric Pulmonary Conference—Lung Injuries and Emergencies, March 28-29, 1979, Indianapolis, Ind. For information contact the Indiana University School of Medicine, Division of Postgraduate Medical Education, 1100 West Michigan St., Indianapolis, IN 46202, or phone (317) 264-8353.

Postgraduate courses sponsored by the American College of Chest Physicians in April, 1979:

Pulmonary Care—The Full Spectrum—Diagnosis, Care, Prevention, April 2-6, 1979, Denver, Colo.

Lung Pathology, April 25-28, 1979, Chicago, Ill.

For information contact the ACCP at address given above.

15th Annual Arizona Chest Symposium, April 6-8, 1979, Doubletree Inn, Tucson, Ariz. Main topics of the symposium will be mycotic, occupational, and interstitial lung diseases. Sponsored by the Tucson Medical Center, Pulmonary Section, University of Arizona, College of Medicine, Division of Respiratory Sciences. For information contact Linda Alpert, R.N., Symposium Coordinator, Arizona Chest Symposium, Tucson Medical Center, P.O. Box 6067, Tucson, AZ 85733, or phone (602) 327-5461 ext. 341.

International Symposium on Exercise in Cardiac and Pulmonary Rehabilitation, April 17-19, 1979, Cambridge, Mass., sponsored by the American College of Chest Physicians. For information contact the ACCP at address given above.

Pulmonary Medicine 1979—A Practical Approach, April 18-20, 1979, Marriott Hotel, City Line, Philadelphia, Pa., sponsored by the Pennsylvania Lung Association, Pennsylvania Thoracic Society, and the Delaware Valley Chapter of American Association for Respiratory Therapy. For information contact Joyce C. Waite, Pennsylvania Thoracic Society, Hershey Community Center, Chocolate and Cocoa Aves., Hershey, Pa. 17033, or phone (717) 533-6851.

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