A Cleaning and Calibration Method for the SpiroPro Portable Spirometer's Pneumotachometer Tube in a Remote Field Study

Matthew R Baldwin MD, William Checkley MD PhD, Robert A Wise MD, Subarna K Khatry MD, Steve C LeClerq, and Keith P West Jr DrPH MPH

BACKGROUND: We developed a systematic method of cleaning and calibration-checking for the pneumotachometer tube of the SpiroPro portable spirometer; this method maximized spirometry accuracy in a population-based study in a remote area of Nepal. METHODS: We tested 10 factory-calibrated pneumotachometer tubes. Each use consisted of a full set of spirometry maneuvers, per the American Thoracic Society (ATS) spirometry criteria. RESULTS: The pneumotachometers remained accurate, per the ATS criteria, for 5–9 disinfections, but began to drift toward inaccuracy after the first disinfection. All the pneumotachometers had become inaccurate, per the ATS criteria, after 10 disinfections. CONCLUSIONS: In a remote field setting the SpiroPro pneumotachometer tube can be cleaned and reused 5–9 times before it becomes inaccurate per the ATS criteria. Rigorous rinsing in distilled water and repeated calibration checks, at various flows up to 12 L/s, are essential for precise and accurate spirometry with the SpiroPro. Reusing the SpiroPro pneumotachometer in a remote setting may impose measurement bias. Single use of SpiroPro pneumotachometers, albeit more costly, will provide better data. *Key words: spirometry, portable; pneumotachometer; calibration; accuracy; disinfection.* [Respir Care 2010;55(4):443–452. © 2010 Daedalus Enterprises]

Introduction

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) jointly issued guidelines for the standardization of spirometers and lung-function testing. A spirometer must be capable of collecting volume readings for ≥ 15 s and measuring volumes of ≥ 8 L (at body temperature and pressure saturated gas) with an accuracy of at least ± 3% of the reading or ± 0.050 L, whichever is greater, at flows up to 14 L/s. In addition, the syringe used to check the volume calibration must have an accuracy of ± 0.015 L or ± 0.5% of the full scale.[1]

In the developing world, public-health interventions have traditionally focused on transmittable and malnutrition-related diseases. Accordingly, many developing-world populations are now living longer, and thus there is a transition toward detecting and treating non-communicable diseases.[2,3] There appears to be an increasing amount of exposure-induced respiratory illness, such as chronic obstructive pulmonary disease (COPD), asthma, and interstitial lung disease,[4] so there is an emerging need for precise and accurate lung-function testing in large populations in remote settings.

Portable spirometry is an important screening tool in the office and field study settings.[5] Portable spirometry was found suitable for long-term patient-administered testing,[6] and found reliable in a multi-country study of COPD prev-

Matthew R Baldwin MD is affiliated with the Division of Pulmonary, Allergy, and Critical Care, College of Physicians and Surgeons, Columbia University, New York, New York. William Checkley MD PhD and Robert A Wise MD are affiliated with the Division of Pulmonary and Critical Care, School of Medicine, The Johns Hopkins University, Baltimore, Maryland. Subarna K Khatry MD is affiliated with the Nepal Nutrition Intervention Project, Sarlahi, National Society for the Prevention of Blindness, Kathmandu, Nepal. Steve C LeClerq and Keith P West Jr DrPH MPH are affiliated with the Center for Human Nutrition, Department of International Health, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland.

The research was partly supported by the Bill and Melinda Gates Foundation, Seattle, Washington (grant 614) and the Sight and Life Research Institute, Baltimore, Maryland.

Correspondence: William Checkley MD PhD, Division of Pulmonary and Critical Care, Department of Medicine, School of Medicine, The Johns Hopkins University, 1830 Monument Street, Fifth Floor, Baltimore MD 21205. E-mail: wcheckl1@jhmi.edu.

alence.[7] There are no published data or experience, however, on the stability of the accuracy of portable spirometers in remote settings such as rural areas of the developing world. The accepted standard calibration of a spirometer is usually performed by the manufacturer or an independent laboratory, and requires a computer-controlled air pump that produces 24 standard waveforms.[1] In many hospital-based pulmonary-function laboratories, technicians perform daily calibration checks with the assistance of a computer program that delivers flows up to 12 L/s, but that equipment is expensive and not widely available.

We conducted the present study in a rural area in the southeast plains of Nepal, known as the Terai. The population of the Terai is agricultural, remote from developed infrastructure, poor, and chronically undernourished. Running water and electricity are limited, and non-industrial air pollution from biomass fuel is common year-round. We sought a handheld, portable spirometer that would withstand the conditions of field work in the Terai, and we chose the SpiroPro (Jaeger/Cardinal Health, Hoechberg, Germany). The most attractive feature of the SpiroPro is that the manufacturer provides factory-calibrated pneumotachometer tubes, which obviates calibrating the spirometer before each use.

We used the SpiroPro to assess lung function in a cohort of children whose mothers participated in a double-blind placebo-controlled vitamin A supplementation trial, before, during, and following pregnancy,[8] and in a cohort of adolescents and young adults, 15–23 years of age, who had been enrolled in a vitamin A supplementation trial while they were less than 5 years of age.[9]

The manufacturer says that the SpiroPro pneumotachometer tube can be reused 20 times, after proper disinfection each time,[10] but the stability of this pneumotachometer's accuracy had never been tested in a remote and resource-poor setting. Accordingly, to ensure maximum accuracy, we used a new pneumotachometer tube with each subject in the larger field study. Concurrent with the start of that larger field study, we were interested in determining the feasibility of cleaning, disinfecting, and reusing the pneumotachometer tubes, under controlled but difficult field conditions. Determining whether the pneumotachometer tubes can be reused in a remote setting has important implications for planning future spirometry field studies. We devised a systematic cleaning method to maximize pneumotachometer accuracy and precision with repeated use, and measured the stability of the pneumotachometer's accuracy after repeated uses over a 2-week period with 10 volunteer subjects who were separate from the aforementioned larger field study.

Methods

The Committee on Human Research at The Johns Hopkins School of Public Health, and the Nepal Nutrition Intervention Project Sarlahi, approved this study. As part of the preparation and testing of methods for use in the large field studies, this field test protocol was approved by the institutional review boards of Johns Hopkins and the Institute of Medicine, Tribhuvan University, Kathmandu, Nepal.

Fig. 1. SpiroPro handheld spirometer with extra pneumotachometer with mouthpiece. (Courtesy of Jaeger/Cardinal Health, Hoechberg, Germany.)

Equipment and Facilities

We used only one SpiroPro spirometer (Fig. 1) for all the measurements in this study. We used a 3-L syringe (5530, Hans Rudolph, Shawnee, Kansas), which has the ATS-recommended accuracy of ± 0.5% (± 0.015 L for a 3-L syringe), for all the calibrations. The SpiroPro's dimensions are 150 × 9 × 40 mm, and it weighs 0.20 kg. It has a rechargeable 3.6-volt lithium-ion battery that provides 10 continuous hours of operation, and a touch-sensitive display with a menu-guided graphical user interface. Patient data can be transferred to a computer (and vice versa) via the spirometer's serial interface. The disposable pneumotachometer tube houses a screen that works as a pressure transducer. The spirometer converts pressure to volume and flow readings, with a volume accuracy of ± 3% (or 0.05 L) in the volume range 0.1–8.0 L, and a flow accuracy of ± 3% (or 0.4 L/s) in the flow range 0.1–16 L/s.

The ATS criteria require that a spirometer have an accuracy of ± 3% of the reading or ± 0.050 L, whichever is greater,[1] and that calibration checks occur daily, with a 3-L syringe discharged at least 3 times, at multiple flows

between 0.5 L/s and 12 L/s, and with 3-L injection times of approximately 6 s and < 0.5 s.[1] Taking into account the permitted error of the spirometer and calibration syringe, the volume reading after each syringe injection should meet the ATS accuracy requirement of ± 3.5% of a reading.[1] Thus, in this study the required volume accuracy of the pneumotachometer is ± 0.11 L (ie, 3.5% of the 3.0-L syringe volume).

New SpiroPro pneumotachometers are calibrated by the manufacturer, who assigns each pneumotachometer a calibration code that is entered into the spirometer prior to making measurements. The calibration code for each new pneumotachometer corresponds to correction factors derived from the manufacturer's calibration check. We wanted to determine if the SpiroPro's pneumotachometer remained accurate by ATS criteria over the 2-week period when we took repeated measurements with 10 pneumotachometer tubes assigned to 10 volunteers. Accordingly, each day we first performed a calibration check with each pneumotachometer and compared the generated calibration code from our calibration check to that assigned by the manufacturer. All the new pneumotachometers tested accurate by ATS standards, so none needed to be returned to the manufacturer. To further ensure accuracy, we recorded the ambient temperature and relative humidity and entered those into the spirometer just prior to all measurements. The average ambient temperature and average relative humidity at our field office in Sarlahi, Nepal, in October, during which all the experiments took place, were 32.1°C and 64%, respectively.

The field office has electricity from a generator, and a few water faucets. Passive building ventilation is via open windows, without screens. Laboratory personnel share a single faucet equipped with a water distiller and demineralizer (Eurogard Classic, Eurogard, West Midlands, United Kingdom). There are no traditional laboratory sinks or ventilation hoods. We used germicide solution (Cidex, Johnson & Johnson, Jharmajiri Baddi, India) to disinfect the pneumotachometer tubes, per the manufacturer's recommendation. The technician in charge of cleaning and disinfecting the pneumotachometer tubes wore a mask, protective lenses, laboratory apron, and copolymer plastic gloves that covered his forearms.

Determination of a Rinsing Method to Maximize Pneumotachometer Accuracy

We prepared 10 L buckets with lids for the cleaning and disinfection of the pneumotachometer tubes. When not being used, all the buckets were kept covered. The pneumotachometer screens calcify in tap water, so we used only distilled water to rinse and fill the buckets.

To disinfect the tubes we poured an entire 3.8-L bottle of disinfectant into a bucket that had been cleaned and rinsed with distilled water. We disinfected the tubes daily, for the manufacturer-recommended maximum of 14 days, after which the bucket was rinsed with distilled water and refilled with new disinfectant. We cleaned the pneumotachometer tubes in sets of 15 for the precision and accuracy experiments, and in sets of 10 for the stability experiments, because those were the numbers of pneumotachometer tubes being used in those experiments, respectively. However, we found that as many as 20 tubes could be cleaned at once, because this was the maximum number of tubes that could be completely and simultaneously submerged in the 3.8 L of disinfectant.

We rinsed the tubes in a bucket with approximately 3.8 L of distilled water. After each rinsing of a set of tubes, we discarded the rinse water and rinsed the bucket with distilled water before refilling it. In developing our method of post-disinfection rinsing that maximized pneumotachometer accuracy, we tested the pneumotachometers after "active" rinsing and "passive" rinsing. Active rinsing involved submerging the tubes in the distilled water for 5 min, then lifting each tube in and out of the water 10 times, alternating which end of the tube the water flowed out. Passive rinsing involved soaking the tubes in distilled water for 10 min, without further intervention. We sterilized the tubes by submerging them in disinfectant for 15 min. We then gently lifted each tube in and out of the disinfectant 10 times, as during active rinsing.

The pneumotachometer tubes used in the larger field study sometimes returned covered with dust, so we decided that if the tubes were to be reused, they should be actively rinsed to remove dust prior to disinfection. The tubes used in the precision and accuracy experiments and in the stability experiments were separate from those used in the larger field study, and hence only acquired minimal dust from the ambient air in the field office. However, to ensure that our findings would be applicable to the tubes used in the larger field study, we also actively rinsed the tubes in both the precision and accuracy experiments and the stability experiments, prior to disinfection.

By trial and error we developed a method of rinsing that maximized pneumotachometer accuracy (Fig. 2). First we disinfected and passively rinsed a set of pneumotachometer tubes and tested their accuracy. Then we re-tested the tubes' accuracy after re-disinfection with active rinsing, re-rinsing alone, or no further intervention, which served as a control. We used 2 rinse buckets filled with distilled water when we actively rinsed the tubes twice. We then left the tubes to dry standing upright on a table covered with newspaper, in the center of the room, approximately 2 m from unscreened windows on 2 sides. We calibrated each pneumotachometer the next day, after 16–24 h of drying.

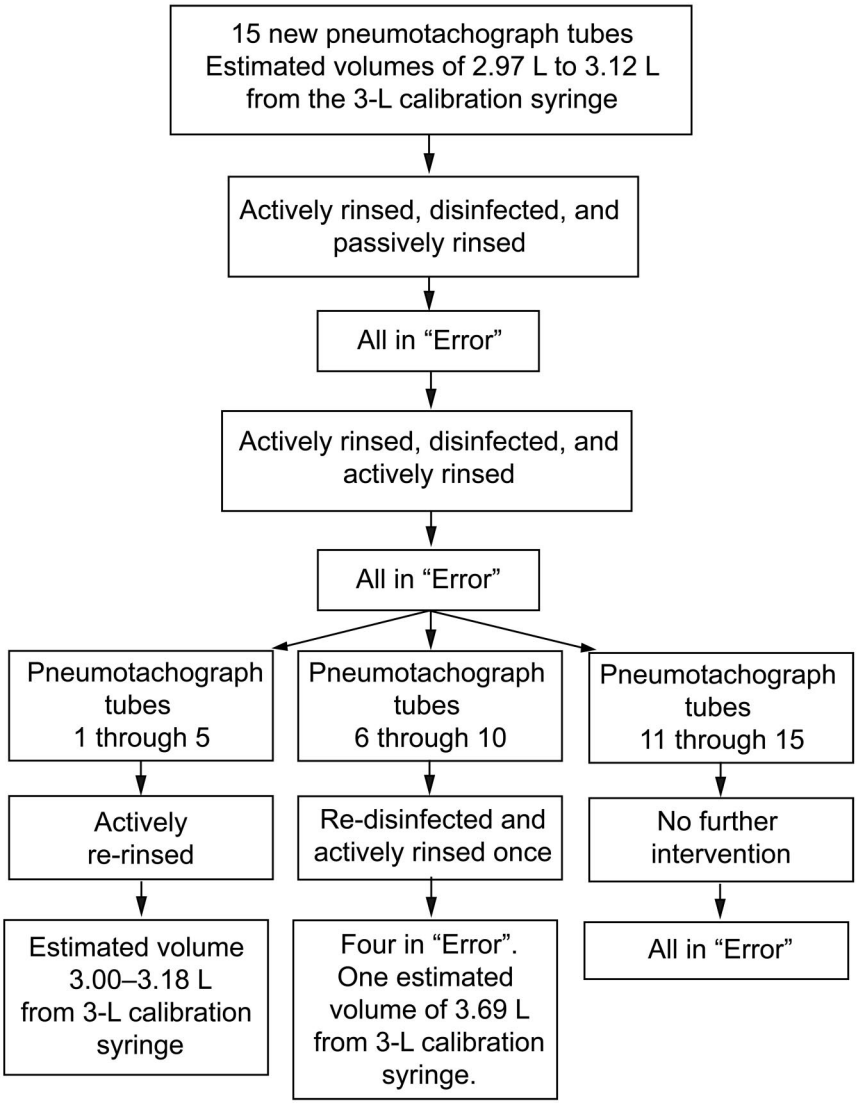

Fig. 2. Comparison of pneumotachometer tube cleaning methods. The calibration checks were done with a 3-L syringe. New pneumotachometer tubes were first calibration-checked, then immediately disinfected and rinsed (ie, not used for spirometry before disinfection and rinsing), then calibration-checked again. All the pneumotachometers grossly overestimated the calibration volume after being passively rinsed once, and after being actively rinsed once. When the inhaled volume reading was < 2.52 L or > 3.70 L or the exhaled volume reading was < 2.45 L or > 3.70 L, the SpiroPro display indicated that the calibration was in "error." After active re-rinsing the pneumotachometers labeled 1 through 5 measured the 3 L from the calibration syringe in the range 3.00–3.18 L, which is a difference range of zero to 0.16 L from the measured calibration volumes for inhalation and exhalation prior to disinfection and rinsing.

Determination of a Reliable Calibration Check Method

The calibration check of the SpiroPro's pneumotachometer requires that the 3-L syringe be discharged 4 times. This is in compliance with the ATS recommendation to discharge the syringe at least 3 times during calibration.[1] For calibration, the spirometer derives the inhalation and exhalation correction factors: 3 L divided by the volume calculated from 3 L of flow through the pneumotachometer.

The technician pumped the syringe from end to end, accelerating the flow during syringe discharge and slowing the flow just prior to finishing the discharge, to comply with the ATS recommendation of varying the flow between 0.5 L/s and 12 L/s.[1] However, during the calibration checks for the disinfection and rinsing experiments we observed that the maximum flow was often less than 6 L/s. The SpiroPro's calibration check program does not ensure that the flow varied from 0.5 L/s to 12 L/s prior to calculating a correction factor. After the disinfection and rinsing experiments, with the pneumotachometers labeled 9 and 10

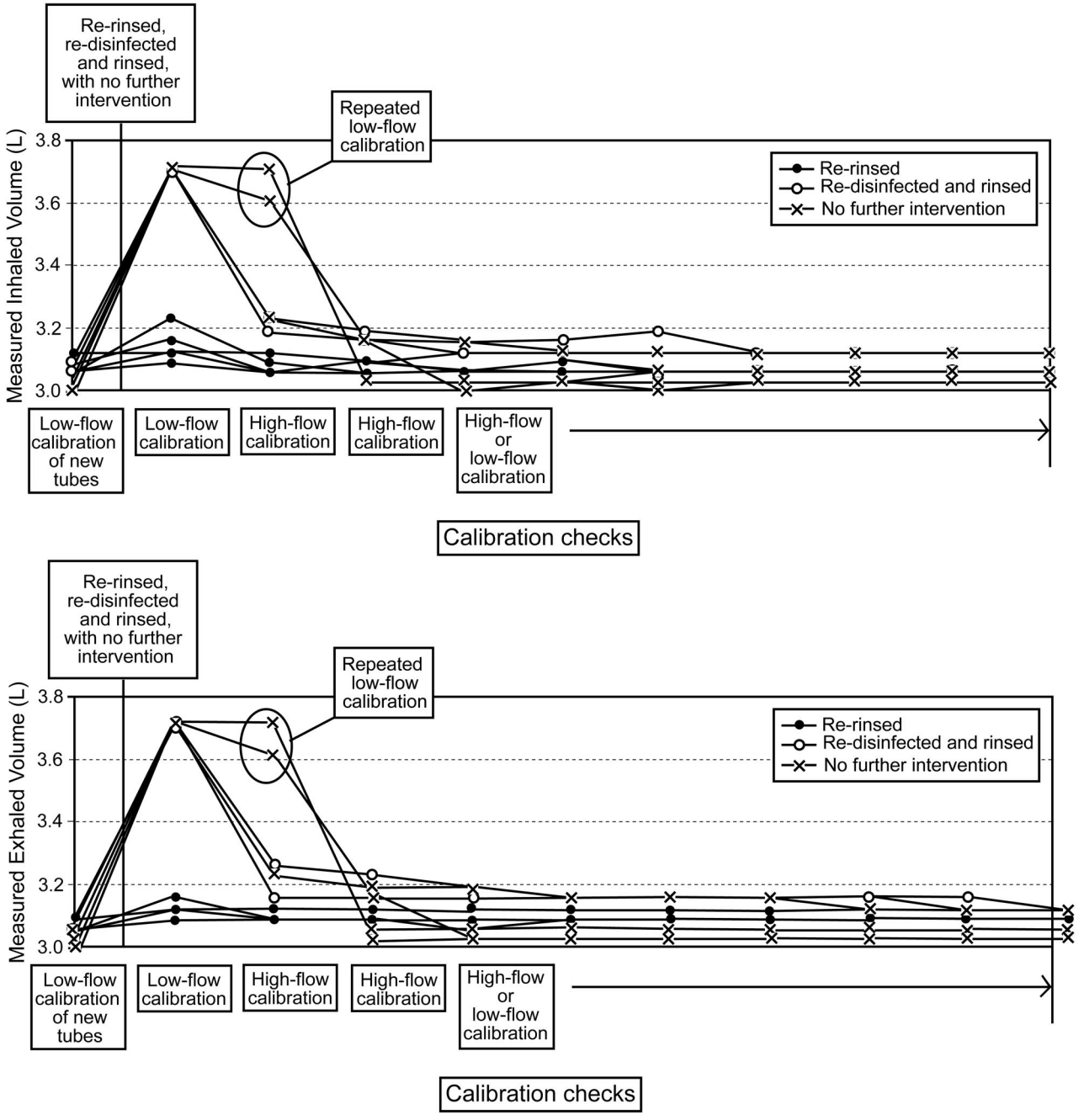

Fig. 3. Inhaled and exhaled volumes measured with the SpiroPro spirometer, with flow delivered from a 3-L syringe after high-flow (6–12 L/s) and low-flow (< 6 L/s) calibration checks. When the inhaled or exhaled volume reading was > 3.70 L the SpiroPro display indicated that the calibration was in "error." For graphic display, "error" calibrations are given as 3.71 L for inhaled volumes and exhaled volumes. All pneumotachometers were actively rinsed in these experiments. The high-flow calibration check can correct volume overestimation due to inadequate rinsing or dust particles on the pneumotachometer screens, to be within ATS accuracy criteria.

we repeated the calibration checks with syringe discharge flows ≥ 6 L/s but still less than the ATS-recommended 12 L/s, which required much more vigorous syringe discharge. To achieve 12 L/s, the 3-L injection time needed to be 0.25 s. After the calibration checks with discharge flows of 6–12 L/s, the calibration correction factors (ie, calculated volumes) went from being in "error" to being within the ATS limit of ± 3.5% (0.11 L). We then tested pneumotachometer precision and accuracy by comparing 10 repeated calibration checks at both lower (< 6 L/s) and higher (6–12 L/s) maximum flows on the remaining 13 pneumotachometers (Fig. 3). The mea-

surements are reported as volumes calculated from the correction factors.

Determination of Pneumotachometer Stability of Accuracy

To test the pneumotachometers' stability of accuracy after repeated disinfections, we assigned one pneumotachometer to each of 10 volunteers, for repeated uses over a 2-week period. The volunteers reused the pneumotachometers up to 10 times. The volunteers were healthy non-smoking co-workers who did not have asthma, COPD, or other known lung disease. We chose not to use one-way-valved disposable mouthpieces, for 2 reasons. First, we wanted to examine the inspiratory component of the flow-volume loop. Deep and fast inspiration is an important component of the spirometry maneuver and ensures better quality spirometry. Second, the spirometry technicians traveled via motorbike to subjects' households and carried an entire day's supply of pneumotachometer tubes with them, so they had little to no capacity to carry any more equipment than they already had.

With his or her assigned pneumotachometer, the volunteer first performed a deep and fast inhalation maneuver, then the forced vital capacity (FVC) maneuver, to meet the ATS within-maneuver criteria:

- The spirogram must be free from artifacts such as cough or glottis closure.
- The back-extrapolated volume must be $< 5\%$ of the FVC or < 0.150 L.
- Complete expiration (ie, the volume-time curve showed no change in volume [< 0.025 L] for ≥ 1 s).
- The subject exhaled for ≥ 3 s if the subject is < 10 years old, or for ≥ 6 s if the subject is ≥ 10 years old.

The between-maneuver criteria are:

- 3 acceptable spirograms, and
- The 2 largest FVC values must be within 0.2 L of each other, and
- The 2 largest forced expiratory volume in the first second (FEV_1) values must be within 0.2 L of each other, or
- A total of 8 maneuvers were performed.

Accordingly, in each use, the volunteers performed 3 to 8 forced expiration maneuvers. Of note, the latest ATS/ERS criteria, published in 2005, require that the 2 largest FVC and FEV_1 values be within 0.15 L of each other. However, our spirometers were programmed with the 1994 ATS criteria that require that the 2 largest FVC and FEV_1 values be within 0.2 L of each other. The current version of the SpiroPro uses the 2005 ATS/ERS spirometry criteria.

For the stability-of-accuracy testing we used the method of disinfection, rinsing, and calibration that we determined best preserved pneumotachometer accuracy and precision. Specifically, four 10-L buckets were prepared for cleaning and disinfection. One bucket was used for disinfection, and 3 were used for rinsing. We first actively rinsed the tubes once, and then disinfected them. We then actively rinsed the tubes twice, then air-dried them for 16–24 h. We then calibration-checked the tubes with maximum flows of 6–12 L/s during each syringe discharge. We varied the 3-L discharge times from approximately 6 s to 0.25 s, to ensure we achieved both the minimum and maximum flows in the ATS-recommended range. We repeated the calibration-check process up to a maximum of 4 times, until consecutive calibrations yielded the same inhalation and exhalation correction factors. If the correction factor continued to change after 4 calibration checks, the pneumotachometer was considered inaccurate and discarded.

Results

Determination of a Rinsing Method that Maximizes Pneumotachometer Accuracy

We compared pneumotachometer accuracy after different rinsing methods (see Fig. 2). We rinsed, disinfected, and passively rinsed once 15 pneumotachometer tubes that had never been used. During subsequent calibration every pneumotachometer grossly overestimated the volume (range 4–7 L). When the inhaled volume reading was < 2.52 L or > 3.70 L, or when the exhaled volume reading was < 2.45 L or > 3.70 L, the SpiroPro's display indicated that the calibration was in "error." The 15 tubes were again disinfected and actively rinsed once, but again every pneumotachometer had readings of 4–7 L and the display indicated that the calibration was in error.

The pneumotachometer tubes labeled 1 through 5 were then actively re-rinsed, those labeled 6 through 10 were disinfected and actively rinsed once, and those labeled 11 through 15 were set aside as a control group for repeated calibration. The re-rinsed tubes estimated the volume within 0.18 L of the measured volume prior to disinfection and rinsing. All but one of the tubes labeled 6 through 10 continued to grossly overestimate the volume, and the display again indicated that calibration was in error. Pneumotachometer number 7 measured an inhalation and exhalation volume of 3.69 L with the 3-L syringe calibration. While that measurement is within the range that the spirometer still estimates a volume during calibration, it substantially overestimated the inhalation and exhalation volumes, by 0.60 L and 0.63 L more than the initial volumes, respectively.

Table 1. Differences in Inspiratory and Expiratory Volume Measurements by SpiroPro Pneumotachographs Before and After Rinsing and Calibration Procedures With Maximum Flows of 6–12 L/s*

Pneumotachograph Number	Inhaled Volume Measurement When New (L)	Exhaled Volume Measurement When New (L)	Disinfection, Rinse, and Calibration Procedures	Inhaled Volume Difference Between Low-Flow and High-Flow Calibration Checks (L)	Inhaled Volume Difference Between Initial Measurement and Last High-Flow Calibration Check (L)	Exhaled Volume Difference Between Low-Flow and High-Flow Calibration Checks (L)	Exhaled Volume Difference Between Initial Measurement and Last High-Flow Calibration Check (L)
1	3.06	3.06	Pneumotachographs 1–5 actively re-rinsed, then 10 calibration checks with the 3-L syringe	–0.06	0.00	–0.03	0.03
2	3.09	3.06		–0.10	–0.03	–0.07	0.03
3	3.06	3.06		–0.16	0.00	–0.07	0.03
4	3.06	3.06		–0.03	0.00	0.00	0.03
5	3.12	3.09		0.00	0.00	0.00	0.03
6	3.09	3.09	Pneumotachographs 6–8 re-disinfected, actively rinsed, then 10 calibration checks with the 3-L syringe	"Error" and 3.12†	0.03	"Error" and 3.12	0.03
7	3.09	3.06		–0.58	0.03	–0.58	0.06
8	3.06	3.06		"Error" and 3.12	0.06	"Error" and 3.12	0.06
11	3.00	3.03	Pneumotachographs 11–15 disinfected once, actively rinsed, then 10 calibration checks with the 3-L syringe.	"Error" and 3.06	0.06	"Error" and 3.06	0.03
12	3.00	3.00		"Error" and 3.03	0.03	"Error" and 3.03	0.03
13	3.03	2.97		"Error" and 3.03	0.00	"Error" and 3.03	0.06
14	3.00	3.00		"Error" and 3.03	0.03	"Error" and 3.03	0.03
15	3.00	3.00		"Error" and 3.03	0.03	"Error" and 3.06	0.06

* Repeated calibration with maximum flows of 6–12 L/s in pneumotachographs numbered 6 through 8 and 11 through 15 demonstrates that volume overestimation due to inadequate rinsing can be corrected to be within ATS accuracy criteria. However, accuracy after high-flow calibration in once-rinsed pneumotachographs 6 through 8 and 11 through 15 was less than in twice-rinsed pneumotachographs 1 through 5 (0.03–0.06 L versus 0.03 L).
† "Error" on spirometer's display.

Determination of a Reliable Calibration Check Method

A high-flow calibration check at 6–12 L/s, following a low-flow calibration check at < 6 L/s, yielded more accurate inhaled and exhaled calibration volumes with 12 of the 13 pneumotachometer tubes (Table 1). These pneumotachometers then remained accurate with repeated high-flow and low-flow calibration checks (see Fig. 3). With pneumotachometer 5, re-rinsing followed by a low-flow calibration check yielded measured inhaled and exhaled volumes of 3.12 L and 3.12 L, respectively, and these volumes did not change with subsequent high-flow calibration checks, but they were already identical and 1% more than initial measured volumes, respectively. After 10 repeated calibration checks at either high or low flow, pneumotachometer tubes 1 through 5 were accurate within ± 1% (± 0.03 L) of their initial measured inhaled and exhaled volumes, and precise within ± 1% (± 0.03 L) following the first high-flow calibration. Furthermore, once identical inhaled and exhaled volumes were obtained on consecutive calibration checks, accuracy and precision thereafter remained within the same range as when high-flow calibration was repeated 10 times.

High-flow calibration checks of the tubes labeled 6 through 8 and 11 through 15 demonstrated that volume overestimation due to inadequate rinsing can be corrected to be within ATS accuracy criteria. The tubes labeled 6, 8, and 11 through 15 overestimated the measured inhaled and exhaled volumes such that the spirometer read the calibration as being in error. High-flow calibration of the pneumotachometer labeled 7 decreased both inhaled and exhaled measured volumes by 0.57 L. Accordingly, the new inhaled and exhaled volumes were 0.03 L and 0.06 L greater than the initial measurements, respectively. After 4 repeated high-flow calibration checks of the tubes labeled 6 through 8, the inhaled and exhaled volumes either remained the same or changed no more than ± 0.03 L during 6 more calibration checks at high or low flow. This is the same range of precision found in the tubes labeled 1 through 5. However, accuracy after high-flow calibration checks in once-rinsed tubes 6 through 8 and 11 through 15 was less than that of twice-rinsed tubes 1 through 5 (± 0.03–0.06 L versus ± 0.03 L). Accordingly, actively rinsing the tubes

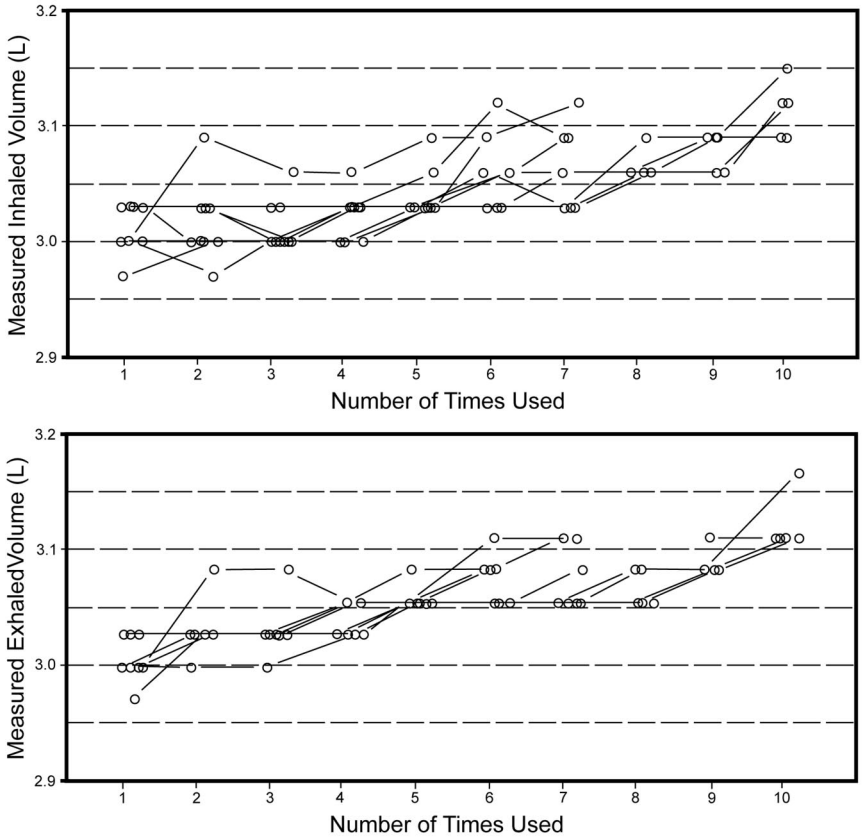

Fig. 4. Inhaled and exhaled volumes measured with the SpiroPro spirometer, with flow delivered from a 3-L syringe, with repeated use (ie, one set of spirometry maneuvers per the American Thoracic Society [ATS] criteria). The ATS recommended volume accuracy is ± 3.5%, as measured by the pneumotachometer, so, when testing the spirometer with a 3-L syringe, the volume should be within 0.11 L of 3.0 L. All the SpiroPro pneumotachometers were accurate after being used 5 times, but showed a trend toward overestimating the volume. After 10 uses all the pneumotachometers overestimated the exhaled volume, outside the ATS-recommended accuracy ± 0.11 L. The pattern is similar for the inhaled volume, but 2 of the 5 pneumotachometers used 10 times remained within the ATS-recommended accuracy, albeit while demonstrating a similar trend toward inaccuracy by progressively overestimating volume.

twice, followed by calibration with maximum flows of 6–12 L/s until consecutive calibrations yielded the same correction factors, up to a maximum of 4 times, provided the highest precision (99%, or ± 0.03 L) and accuracy (99%, of ± 0.03 L).

Determination of Pneumotachometer Stability of Accuracy

All 10 tubes used in this part of the study had unchanged correction factors in 4 calibration checks, so none was discarded.

Five of the volunteers used their respective pneumotachometer tubes 10 times; 3 used their pneumotachometer tubes 7 times; and 2 used their pneumotachometer tubes 6 times. Figure 4 shows the inhaled and exhaled volumes in the 3-L syringe calibration checks after each use and disinfection. All the pneumotachometers remained accurate within the ATS-recommended volume accuracy of ± 3.5% (0.11 L), but 4 of the 10 pneumotachometer tubes showed a trend toward overestimating volume even after one use. Between 6 and 10 uses all the pneumotachometers overestimated the 3.0 L calibration volume by more than 0.11 L, and hence became inaccurate by ATS criteria. Four of the 5 pneumotachometer tubes used 10 times measured volume within the ATS accuracy criteria after 9 uses, albeit with substantial volume overestimation. After 10 uses, all 5 of those pneumotachometers became inaccurate by ATS criteria, overestimating the exhaled volume by 0.12–0.18 L. The inhaled volume measurement remained slightly more accurate but demonstrated a similar drift toward volume overestimation. Two of the 5 pneumotachometers were still within the ATS accuracy criteria after 10 uses, overestimating the inhaled volume by 0.09 L. The remaining 3 pneumotachometers overestimated the inhaled volume by 0.12–0.15 L, which is beyond the ATS-recommended accuracy range of ± 0.11 L with a 3.0-L calibration volume.

Discussion

Portable spirometry can provide high-quality data for epidemiologic field studies in developing countries, but little is known about spirometry quality obtained with reused pneumotachometer tubes after repeated disinfections. SpiroPro pneumotachometers showed a drift toward overestimating volume with repeated use in our remote, cross-sectional study setting. To avoid temporal bias, each volunteer used one assigned pneumotachometer tube for repeated measurements over a 2-week period. Each use consisted of a set of spirometry maneuvers (ie, 3 acceptable spirograms from a maximum of 8 attempts) per ATS criteria, and after each use the pneumotachometer tubes were disinfected and calibration-checked. The pneumotachometers remained accurate by ATS criteria for only 5–9 reuses (see Fig. 4), which is much less than the 20 times the manufacturer claims these tubes can be reused before becoming inaccurate by ATS criteria. Active re-rinsing and repeated calibration checks with maximum flows of 6–12 L/s were essential to maximize pneumotachometer accuracy and precision after disinfection and repeated use (see Table 1 and Figs. 2 and 3). Accordingly, limited reuse of SpiroPro pneumotachometer tubes is feasible in a cross-sectional study, where the temporal effect is small. However, pneumotachometer stability of accuracy in a longitudinal study could impose measurement bias, so extensive reuse is not recommended.

Given that the pneumotachometer tubes progressively overestimated volume implies that the resistance across the flow-measurement screens increased with repeated use. Actively re-rinsing the tubes lowered the volume overestimation, which suggests that dried disinfectant, subject secretions, or dust particles not initially rinsed off the flow-measurement screens may have been blocking flow during calibration. In addition, substantial correction of volume overestimation with re-rinsing suggests that we had adequately distilled the local water.

Conducting the calibration checks with maximum flows of 6–12 L/s also decreased volume overestimation and improved accuracy by at least 0.57 L with the pneumotachometer tubes rinsed once, and by up to 0.18 L with the tubes rinsed twice. That flow correction was not observed with maximum calibration flows < 6 L/s. There are 3 reasons that high flow provides a more accurate calibration check. Regardless of the rinsing method, all the pneumotachometer tubes were left to dry for 16–24 h, standing upright on a table in a room with open unscreened windows. First, perhaps flow-limiting dust particles that settled on the pneumotachometer screens while drying were cleared by the higher calibration flow. Second, repeated high-flow calibration also corrected gross volume overestimation when rinsing was inadequate. The tubes that were rinsed once initially overestimated volume outside the spirometer's calculating range, but became accurate (within 0.03–0.06 L of original measured volume) with repeated high-flow calibrations. This suggests that flow-limiting dust or disinfectant not washed away by rinsing may be cleared by high calibration flows, to achieve an accuracy only 1% ($\pm$ 0.03 L) less than that of the twice-rinsed tubes repeatedly checked with higher flows. Third, while the tubes that were allowed to dry for 16–24 h appeared dry upon macroscopic inspection, perhaps the pneumotachometer screens still retained flow-limiting macroscopically invisible water droplets that were expelled or dried by the higher flows. Accordingly, repeated calibration flows of 6–12 L/s can be used to confirm whether a pneumotachometer has been adequately rinsed and dried, and maximizes accuracy when combined with active re-rinsing. This finding also underscores the fundamental importance of the ATS recommendation to vary the calibration flows between 0.5 L/s and 12 L/s. We found that a vigorous syringe discharge was required to achieve a flow of 6–12 L/s.

The tubes rinsed only once were as precise as the tubes rinsed twice ($\pm$ 1% or $\pm$ 0.03 L) after 4 high-flow calibrations. In the twice-rinsed tubes, after identical inhaled and exhaled volumes were obtained on consecutive calibration tests, the accuracy and precision thereafter remained within the same range as when calibration was repeated 5–9 times (ie, $\pm$ 1% percent, or 0.03 L, and $\pm$ 1% or 0.03 L, respectively). Accordingly, to maximize precision and accuracy with repeated pneumotachometer use in this remote setting, the pneumotachometer tubes were actively rinsed twice after disinfection and then repeatedly calibrated, up to 4 times or until consecutive calibration tests yielded identical inhaled and exhaled volumes. We adopted the policy that if the volume estimations continued to differ after 4 high-flow calibration tests (as with the tubes rinsed only once), the tube would be considered inaccurate and imprecise, and would be discarded, but that never occurred with the repeatedly used tubes in this study.

While we did not test whether active rinsing alone prior to disinfection affects accuracy, we presumed that pre-rinsing would further facilitate dust removal from the pneumotachometer screens and minimize dust that would otherwise accumulate in the disinfectant that was used for 14 days. The manufacturer recommends soaking the tubes in the disinfectant for 15 min. At the end of the disinfection period we lifted the tubes in and out of the disinfectant (as in the rinsing procedure) to facilitate removal of dust from the pneumotachometer screens, but we did not specifically test whether this affected the stability of pneumotachometer accuracy.

A drift toward volume overestimation was first observed in 4 of the 10 pneumotachometer tubes after a single use (ie, 3–8 spirometry maneuvers per ATS criteria) and disinfection (see Fig. 4). This drift caused the pneumotachometers to become inaccurate by ATS criteria in as few

as 5, and as many as 9, uses. Our finding that the SpiroPro's pneumotachometer tubes can be reused only 5–9 times before becoming inaccurate probably reflects challenges specific to the remote field setting of the study. The increasing flow resistance across the pneumotachometer screen may be due to inadequate rinsing (due to lack of a laboratory sink), inadequate drying, and using the pneumotachometer tubes in the dusty ambient air. Our active rinsing process probably mimics the flow of water across the pneumotachometer screens when rinsed in a laboratory sink that is filled and then drained. Repeated high-flow calibration checks corrected the increased pneumotachometer resistance, regardless of the rinsing method. For inadequately rinsed tubes the high-flow calibration may blow out disinfectant and dust that remains after rinsing, and thus decrease the volume overestimation. Given that repeated high-flow calibrations also corrected (albeit to a lesser degree) volume overestimation in the twice-rinsed tubes suggests that additional rinsing may improve accuracy. Volume overestimation may also be due to dust that settles on the pneumotachometer screens while drying, and we were in a dusty environment that lacked the ventilation system of a modern laboratory. High-flow calibration may blow this dust off the pneumotachometer screens and thereby improve accuracy.

A previous study found that an ultrasound-based spirometer used in a multi-national house-by-house spirometry survey remained accurate within ATS criteria and did not drift with repeated use.[7] Calibration was done with a 3-L syringe, and measured volume was minimally affected by the calibration peak flow or emptying time (0.1% of the variation in the volume measured by the spirometer). In contrast, our study demonstrates that calibration peak flows of 6–12 L/s are essential to maximizing spirometry precision and accuracy when reusing the SpiroPro's tubes.

Previous studies that reported on the stability of accuracy of portable spirometers included between 22 and 357 subjects.[6,7] Our field study involves approximately 5,000 subjects, so maximizing repeated use of the pneumotachometer tubes would substantially reduce study costs. The cleaning and calibration protocols we developed to maximize spirometry precision and accuracy with repeated pneumotachometer use may be important for planning future large-population spirometry studies in remote settings. However, the time and effort spent disinfecting and calibrating pneumotachometer tubes in the field may not be worth the risk of inaccurate data, given that reuse is limited to 5–9 times with the SpiroPro's tube, and drift toward inaccuracy may begin after a single use. Accordingly, using a tube once and disposing of it (as the manufacturer also suggests) may be the more costly but more accurate way to pursue studies in remote and resource-poor settings.

Conclusions

The burden of exposure-induced respiratory illness is increasing in the developing world,[4] and little is known about the specific challenges of performing spirometry in large populations in remote settings. We found that, in our remote study setting, the SpiroPro's pneumotachometer tube can be reused 5–9 times before it becomes inaccurate by ATS criteria. Rigorous rinsing in distilled water and repeated calibration flows of 6–12 L/s are essential to obtaining precise and accurate measurements with this pneumotachometer in this environment. Accordingly, disposing of the SpiroPro pneumotachometer tube after one use, though more costly, may be the correct approach for obtaining high-quality data. Reusing SpiroPro pneumotachometer tubes in a longitudinal study in a remote setting may impose additional measurement bias, and therefore is not recommended.

REFERENCES

1. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J 2005;26(2):319-338.
2. Tunstall-Pedoe H. Preventing chronic diseases: a vital investment. WHO Global Report. Geneva: World Health Organization; 2005: 200. http://www.who.int/chp/chronic_disease_report/en. *Accessed February 3, 2010.*
3. Anderson GF, Chu E. Expanding priorities: confronting chronic disease in countries with low income. N Engl J Med 2007;356(3):209-211.
4. Lopez AD MC, Ezzati M, Jamison DT, Murray CJL, Measuring the global burden of disease and risk factors, 1990-2001. In: Lopez AD MC, Ezzati M, Jamison DT, Murray CJL, editors. Global burden of disease and risk factors. Washington DC: The World Bank and New York: Oxford University; 2006:1-13. http://files.dcp2.org/pdf/gbd/gbdfm.pdf. *Accessed February 3, 2010.* DOI: 10.1596/978-0-8213-6262-4/.
5. Ferguson GT, Enright PL, Buist AS, Higgins MW. Office spirometry for lung health assessment in adults. Chest 2000;117(4):1146-1161.
6. Dirksen A, Madsen F, Pedersen OF, Vedel AM, Kok-Jensen A. Long-term performance of a hand held spirometer. Thorax 1996; 51(10):973-976.
7. Perez-Padilla RV-GJ, Marquez MN, Jardim JR; on behalf of the PLATINO Group. The long-term stability of portable spirometers used in a multinational study of the prevalence of chronic obstructive pulmonary disease. Respir Care 2007;51(10):1167-1171.
8. West KP Jr, Katz J, Khatry SK, LeClerq SC, Pradhan EK, Shrestha SR, et al. Double-blind, cluster randomised trial of low-dose supplementation with vitamin A or beta carotene on mortality related to pregnancy in Nepal. BMJ 1999;318(7183):570-575.
9. West KP, Katz J, LeClerq SC, Pradhan EK, Tielsch JM, Sommer A, et al. Efficacy of vitamin A in reducing preschool child mortality in Nepal. Lancet 1991;338(8759):67-71.
10. Jaeger. SpiroPro instruction manual V, article 780987. Viasys HealthCare. Hoechberg, Germany; 2005:110.