

Predictive equations for spirometric reference values in a healthy adult suburban population in Tanzania

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Abstract: This study was conducted in Kinondoni district, Dar es Salaam, Tanzania, with the objectives to generate prediction equations for forced expiratory volume in 1 second (FEV1), forced expiratory volume in 6 seconds (FEV6), FEV1/FEV6 ratio and peak expiratory flow (PEF) from a non-symptomatic sample of the population, and to compare these equations to published reference values. The study included adults aged ≥ 15 years who were recruited by use of community based, multistage cluster random sampling. Participants performed spirometry and answered questionnaires regarding respiratory symptoms and socioeconomic conditions. Anthropometric data were collected. Selection of subjects for generation of reference values followed American Thoracic Society (ATS) recommendations. Data were analyzed using multiple regression techniques. Fifty two men and 98 women were selected to the reference value group. FEV1, FEV6, FEV1/FEV6 and PEF were regressed against age, height and weight. For men a curvilinear model was chosen when predicting FEV1, FEV6 and PEF, and a linear model predicted FEV1/FEV6. For women a linear model was used in the regression equations. The reference values generated from our study were lower than in several previously published studies. Our study suggests that assessment of respiratory function should be based on reference values generated from the same population as those being assessed.

Keywords: reference values, spirometry, lung function, adults, Tanzania

Introduction

Availability of appropriate reference values is a necessity for interpretation of pulmonary function tests and in assessment of lung function and respiratory diseases. According to American Thoracic Society (ATS) recommendations, such reference values should be based on healthy people with the same anthropometric characteristics and ethnic origin as the subjects being tested (Brusasco *et al.*, 2005). Nevertheless, many low-income countries are faced with scarce documentation regarding national prediction equations and must rely on foreign reference values adjusted with estimated ethnic correction factors (Myers, 1984; White *et al.*, 1994; Goldin *et al.*, 1996; Louw *et al.*, 1996). This assumption may lead to artificially low ethnic standards, and may possibly result in a high false negative rate and missed diagnosis of respiratory diseases (Myers, 1984; White *et al.*, 1994; Goldin *et al.*, 1996; Louw *et al.*, 1996).

In this paper we present prediction equations generated from a non-symptomatic adult population in Dar es Salaam, Tanzania, and compare these equations to already published reference values. Both sitting and standing height have been measured and included as part of presumptive determinants of lung function, to allow for comparison of study results across countries and ethnicity (Myers, 1984; American Thoracic Society, 1991; Goldin *et al.*, 1996; Louw *et al.*, 1996; Mokoetle *et al.*, 1994; Brusasco *et al.*, 2005).

Materials and Methods

Study design and participants

The study was based on a descriptive cross-sectional design. The source population comprised all adults above the age of 15 years in Kinondoni district, Dar es Salaam, Tanzania, with a population of about 1.1 million according to the 2002 Population and House Survey in Tanzania (URT, 2003). The main goal of the study was to determine prevalence of respiratory symptoms and obstructive lung disease (separate analysis not yet published). Thus, the basis for the sample size calculation was the assumed frequency of COPD of 12 - 15% (Buist *et al.*, 2007). Estimating prevalence of COPD to 15% and accounting for reduced precision due to cluster sampling through use of a design effect at 1.5, the minimum sample size required was calculated to 300 participants (95% confidence level, precision set at 5%).

Participants were recruited by multistage cluster random sampling. In the first stage, two out of 27 wards of Kinondoni district were selected. At next stage, two areas in each ward were chosen. Each ward consisted of five areas. Finally, four ten-cell leaders were selected from each area, conducting to a total of 16 clusters. The term 'ten-cell leader' refers to the smallest administrative unit in Tanzania, and one ten-cell leader has the responsibility for approximately 10-12 households (Mfinanga *et al.*, 2003).

Primary sampling unit comprised all households under the selected ten-cell leaders. Recruiting study subjects was accomplished by informing the selected ten-cell leaders about the aim of the study and seeking their approval to collect the necessary data. Next, a mobile testing team carried out a knock-on-door approach to the households under their selected ten-cell leaders. Subjects within the target age group were included in the study with the exception of participants having conditions contraindicating spirometric testing (known heart disorder, present tuberculosis, recent chest/abdominal/eye surgery or last trimester of pregnancy) (Miller *et al.*, 2005). Subjects with negative responses to core questions from the American Thoracic Society - Division for Lung Disease (ATS-DLD) questionnaire regarding smoking history, respiratory symptoms and doctor diagnosed heart/chest illnesses were considered eligible for generating reference values. The predictive equations for reference values presented in this paper are based on this subsample of never-smoker, non-symptomatic study participants.

Data collection

Spirometry was performed using the *ndd EasyOne* spirometer (ndd Medizintechnik AG), which has proven to be suitable in field work as it operates on batteries and requires no calibration while achieving a high degree of accuracy and reliability (Buist *et al.*, 2005). The following parameters were measured; peak expiratory flow (PEF), forced expiratory volume in one second (FEV1), and forced expiratory volume in six seconds (FEV6). All study subjects performed a minimum of three and a maximum of eight tests, and the best FEV1, FEV6 and PEF were selected and used in further analysis. The spirometric testing was performed by trained assistants following a standardized procedure adherent to ATS/ERS guidelines (American Thoracic Society, 1991; Miller *et al.*, 2005).

The test subjects performed spirometry without nose clips, and sitting position was allowed if participants found the manoeuvre in standing position to be exhausting. All

spiromgrams were reviewed by an experienced chest physician, where ATS acceptability and reproducibility criteria were followed for selection of best pulmonary function curve with forced exhalation time exceeding a minimum of 6 seconds or show a plateau of the volume-time graph (Miller *et al.*, 2005). Further, each participant should display at least two acceptable reproducible manoeuvres with both FEV1 and FEV6 within 200ml and with absence of cough during the first second of the manoeuvres. Participants not fulfilling these criteria were excluded from the reference sample.

Anthropometric data, including weight, standing height and sitting height were obtained using robust equipment easy to transport in the field. Standing height was measured using a metal tape-measure and with heels, shoulders and occiput positioned against the tape. Sitting height was measured with a tape-measure affixed to a vertical wooden plank with the subjects sitting on a firm wooden chair with buttock, shoulder-blades and occiput touching the plank. Age was recorded as birth-date or as mid-year in the year of birth.

Respiratory symptoms were recorded using the ATS-DLD validated questionnaire, which was translated into Kiswahili, then back-translated to English prior to data collection, to ensure that questions and the phrasing used were adherent to the original format. Questions regarding socioeconomic status were derived from a culture specific questionnaire used in the Tanzania Demographic Health Survey from 1999 and 2002 (United Republic of Tanzania, 2002).

Data analysis

Questionnaire data were double entered, cleaned and coded using Epi data version 3.1 (Centre for Disease Control and Prevention, Atlanta, GA, USA), and were exported to SPSS for the statistical analyses. The spirometric data were automatically stored in the spirometres used, and were electronically exported to SPSS. Data were analyzed using standardized and hierarchical multiple regression techniques. Both linear and curvilinear formulae were obtained, and the model best fitted for the present data were chosen. The following dependent variables were applied; FEV1, FEV6, PEF and FEV1/FEV6, and regressed in separate models for sex, against the following independent variables; age, height and weight. The explanatory variables were assessed in terms of highest contributing R statistic, variable significance at $p < 0.05$, partial correlation coefficients and lowest SEE values. The lower limit of normal (LLN) was defined as the 5th percentile, estimated as $1,645 \times \text{SEE}$, for each of the dependent variables.

Reference values were compared to previously published predictions by use of paired t-tests. The Independent-Sample T-test was used to compare continuous variables, and Pearson Chi square and Wald statistic tests were used to compare group differences for categorical variables. Descriptive statistics are reported as means and standard deviations (SD) when normally distributed, skewed data are expressed in medians and percentiles. Calculations were done using the Statistical Package for the Social Sciences version 15 (SPSS Inc., Chicago, IL, USA).

Ethical considerations

Approval was obtained from the Ethical Committee of Western Norway (REK-Vest) and the Medical Research Coordinating Committee of Tanzania National Institute for Medical

Research. After subjects eligible for participation were informed of the nature and purpose of the study, and had given their informed consent, they were enrolled providing inclusion criteria were met. If disease that needed medical attention was found in any study participant, the person was aided with a referral to proper medical care.

Results

Of the 16 selected clusters, 14 were visited, and a total of 552 subjects were eligible for the main study. The response rate attained was 66% as 135 subjects in the visited households were absent at the time of testing and 41 participants were excluded from the study due to conditions contraindicating spirometry testing. Further, 11 subjects refused to participate, and the final population sample for the main study was 365, 159 (43.6%) men and 206 (56.4%) women. After evaluating the spirometric measurements, 39 study participants (19.7%) did not accomplish test results in compliance to quality criteria, and were excluded from analysis regarding spirometric lung indices. On the basis of the selection criteria, a total of 150 subjects, 52 men (34.7%) and 98 women (65.3%) were selected to the reference value group (Table 1). Median age for the selected men and women was 34 years. Table 1 summarizes the age distribution and descriptive statistics regarding anthropometry and spirometry parameters.

Table 1: Age distribution and descriptive statistics of the reference sample

Variable	Men (n=52)	Women (n=98)	
Age category N (%)	<20	7 (13.5)	12 (12.2)
	20-29	16 (30.8)	34 (34.7)
	30-39	11 (21.1)	25 (25.5)
	40-49	10 (19.2)	13 (13.3)
	50-59	4 (7.7)	10 (10.2)
	60-69	3 (5.8)	3 (3.1)
	70+	1 (1.9)	1 (1.0)
Height in cm (mean±SD)	166.4±7.9	157.2±6.0	
Sitting height in cm (mean±SD)	81.5±3.6	78.1±3.4	
Weight in kg (mean±SD)	65.6±11.5	61.5±15.0	
FEV1 (mean±SD), L	3.02±0.65	2.24±0.51	
FEV6 (mean±SD), L	3.59±0.68	2.71±0.56	
FEV1/FEV6 (mean±SD)	0.840±0.079	0.825±0.070	
PEF (mean±SD), L	7.98±2.32	5.48±1.38	

Key: N= number of responders; %= proportion of responders; SD= standard deviation

Age, height and sitting height correlated significantly with the dependent variables FEV1 and FEV6 for both sexes in bivariate analysis while FEV1/FEV6 was correlated to age alone among women and age and weight among men (Table 2). The regression analyses were performed separately for males and females. The exponential variable height square was entered into the equation together with age, height and weight, to assess whether a linear or curvilinear model produced best fit. Weight turned out non-significant in the male strata, and showed only a minor contribution to the variability of the regression models, and was excluded from the formulas. For women weight had a part correlation coefficient of 0.178, when regressed against PEF, explaining an additional 3.17% of the total R square ($P = 0.05$),

and was retained in the final model when standing height was part of the independent variables. For the dependent variables FEV1, FEV6 and FEV1/FEV6, weight was non-significant, and was removed from the equations in further analyses. Height, and height square in the exponential equations for men and women, entered all the regression models with the exception of the model predicting FEV1/FEV6, as it did not provide a significant contribution to the variance in the present sample and only showed a marginal improvement of the R statistics and the corresponding SEE values.

Table 2: Bivariate correlations (Pearson) between potential explanatory variables and spirometric outcomes

Sex	FEV1, L	FEV6, L	FEV1/FEV6	PEF, L
Men (N=52)				
Age (years)	-0.461**	0.333*	-0.415*	-0.205
Height (cm)	0.536**	0.603**	0.026	0.416**
Sitting height (cm)	0.475**	0.621**	-0.109	0.482**
Weight (kg)	-0.007	0.136	-0.294*	0.202
Women (N=98)				
Age (years)	-0.738**	-0.628**	0.557**	-0.397**
Height (cm)	0.405**	0.467**	-0.044	0.258*
Sitting height (cm)	0.383**	0.426**	-0.008	0.314**
Weight (kg)	0.142	0.153	0.009	0.195

** correlation is significant at the 0.001 level (2-tailed); * correlation is significant at the 0.05 level (2-tailed)

Table 3: Multivariate prediction equations for spirometric outcomes in the reference sample based on standing height

Mode	R ²	SEE	5 th Percentile*
Men			
FEV1 = 33.173 – 0.0203 × A – 0.394 × H + 0.00130 × H ²	0.491	0.477	0.785
FEV6 = 37.052 – 0.0149 × A – 0.444 × H + 0.00148 × H ²	0.479	0.503	0.827
PEF = 94.661 – 0.0314 × A – 1.143 × H + 0.00377 × H ²	0.222	2.108	3.468
FEV1/FEV6 = 0.920 – 0.00231 × A	0.72	0.073	0.120
Women			
FEV1 = – 1.133 – 0.0261 × A + 0.0270 × H	0.658	0.317	0.521
FEV6 = – 2.031 – 0.0288 × A + 0.0350 × H	0.553	0.385	0.633
PEF = 104.066 – 0.0386 × A – 1.286 × H + 0.00419 × H ² + 0.0179 × W	0.239	1.229	2.022
FEV1/FEV6 = 0.920 – 0.00282 × A	0.310	0.058	0.095

A = age in years, H = height (cm), H² = height square, W = weight; *5th percentile is obtained by subtracting given value (1.645 × SEE) from an individual predicted

Tables 3 and 4 summarize the prediction equations generated. All the spirometric parameters were negatively related to age, and all increased with height, with exception of FEV1/FEV6. The lower limit of normal (LLN) is presented as – 1.645 × SEE, which is the age and height specific estimated 5th percentile for the reference sample.

The prediction equations derived from our sample are compared to those of Mokoetle, reference values generated from a healthy South African University workforce (Mokoetle *et al.*, 1994) and with Hankinson's equation (The National Health and Nutrition Examination Survey [NHANES iii] of African-American above 20 years of age (Hankinson *et al.*, 1999). Reference values for the male strata are also compared to Louw's equations of

Black and White South African men and to the predictions of Mustafa of Northern Sudanese but also tested to fit Tanzanian men (Louw *et al.*, 1996; Mustafa, 1977). Mustafa’s predictions (generated in 1977) are included in the comparison of published equations to assess possible secular changes in predicted lung volumes. Figure 1 and 2 present scatter plots of predicted FEV1 for men and women applying the equations of Mokoetle, Hankinson and Louw.

Table 4: Multivariate prediction equations for spirometric outcomes in the reference sample based on sitting height

Mode	R ²	SEE	5 th Percentile*
Men			
FEV1 = 29.530 – 0.0222 × A – 0.713 × SH + 0.00486 × SH ²	0.446	0.498	0.819
FEV6 = 30.233 – 0.0168 × A – 0.753 × SH + 0.00531 × SH ²	0.508	0.489	0.804
PEF = – 15.682 – 0.0289 × A + 0.303 × SH	0.264	2.030	3.339
Women			
FEV1 = – 0.0196 – 0.0253 × A + 0.0398 × SH	0.614	0.319	0.525
FEV6 = – 0.762 – 0.0232 × A + 0.0544 × SH	0.502	0.401	0.660
PEF = 51.653 – 0.0359 × A – 1.267 × SH + 0.00883 × SH ²	0.236	1.225	2.015

A, age in years; SH, sitting height (cm); SH², sitting height square

*5th percentile is obtained by subtracting given value (1.645xSEE) from an individual predicted

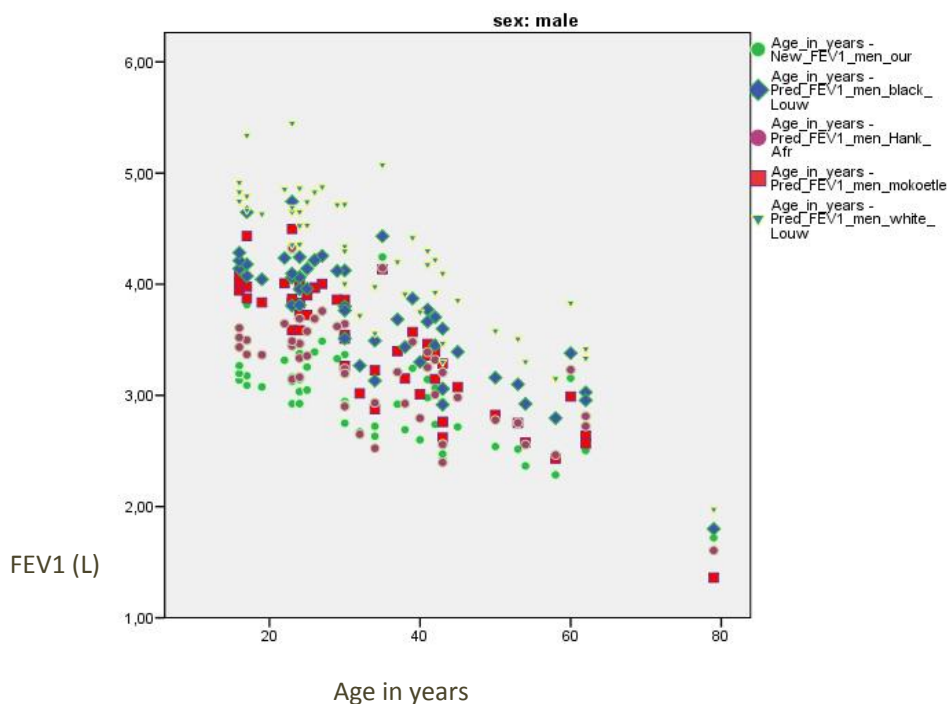


Figure 1: Scatter plot of predictive FEV1 values in male strata applying equations of Louw, Hankinson, Mokoetle and those generated in the present study, which shows consistently lower values for all age groups

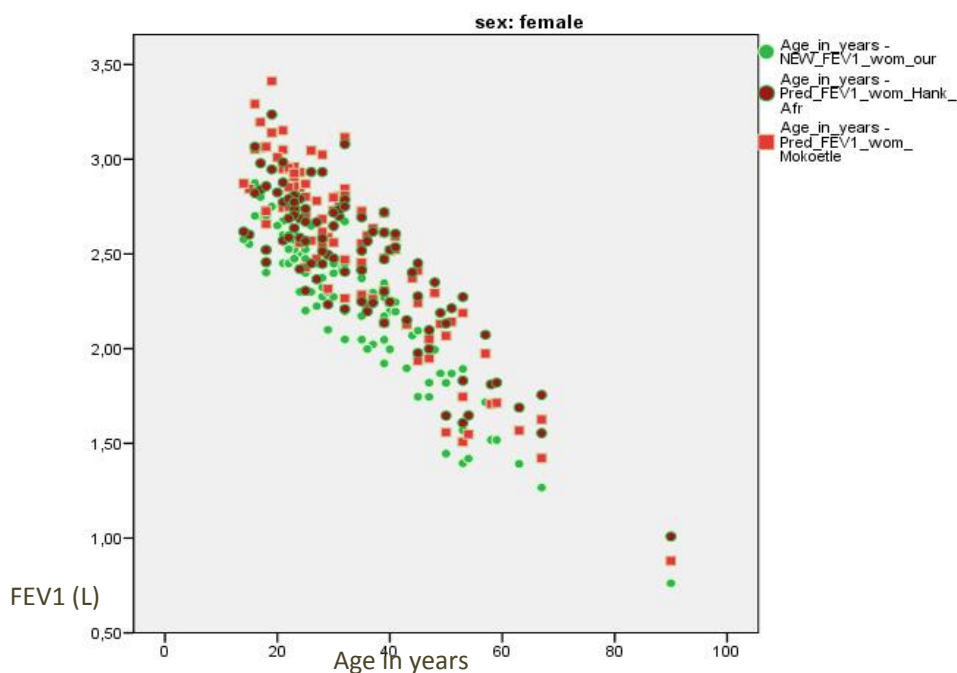


Figure 2: Scatter plot of predictive FEV1 values in female strata applying equations of Mokoetle, Hankinson and those generated in the present study, which shows consistently lower values for all age groups

Discussion

We have generated prediction equations for the following pulmonary parameters; FEV1, FEV6, FEV1/FEV6 and PEF from a non-symptomatic subsample of the study participants. As recommended by GOLD and ATS guidelines the selected lung function indices are frequently used in pulmonary testing and in assessment of respiratory diseases (Brusasco *et al.*, 2005; Miller *et al.*, 2005). When we used Mokoetle's and Louw's equations of Black South African men to predict FEV1 in our male strata we obtained larger values of FEV1 than when we used the equations derived from our study, thus overestimating normal values of FEV1 in our sample population. This was also evident when using Hankinson's equation of African-American adults above 20 years of age, though the mean difference to our predictive equations was smaller.

Louw's reference values of White South African men, showed an even larger mean difference in FEV1 at 1.2 litres when compared to our study values. Applying equations using sitting height as a proxy estimate of height reduced this difference to 1.0 litre. This is in accordance with previous publications, where ethnic differences in lung volumes are thought to be partly due to difference in body build and that Blacks have smaller trunk-to-leg ratio than Whites (Miller *et al.*, 2005). Accounting for this by using sitting height reduces these ethnic differences (Myers, 1984; Goldin *et al.*, 1996; Louw *et al.*, 1996; Miller *et al.*, 2005; Brusasco *et al.*, 2005).

The predicted FEV1 values for the women in our study were also significantly lower compared to those of Mokoetle and Hankinson, with a mean difference of 0.30 and 0.23 litres respectively. Louw did not generate reference values for women in his study. Both Mokoetle and Louw used occupation based samples in their studies, which have proven to generate higher lung volumes than studies deriving reference values from a community source (White *et al.*, 1994). This healthy-worker bias, might explain some of the variation in mean FEV1 values, but also possible differences in socio-environmental conditions for the study populations must be considered (Myers, 1984; Goldin *et al.*, 1996; Louw *et al.*, 1996; Miller *et al.*, 2005; Buist *et al.*, 2005; GOLD, 2008). In addition, the altitude in Johannesburg is 2000m above sea level, which can account for up to 400ml according to the study of White *et al.*, published in 1994 (White *et al.*, 1994).

Comparing our equations to those of Mustafa in 1977, we found very similar predicted values for FEV1 (Mustafa, 1977). The Sudanese site was situated at 400m altitude, and the sample was derived from an urban community source. Thus we find little evidence of a birth-year cohort effect on the spirometric measurements, though possible differences in socio-environmental conditions for the study populations may be present. Alternatively, the present sample size might not have been sufficiently large to detect differences in lung volumes as a result of changes in determinants, like nutrition, health status and environmental factors. Our data also failed to demonstrate any association between lung volumes and socioeconomic factors (analyses not shown).

We have chosen to present prediction equations for FEV6 rather than the Forced Vital Capacity (FVC). The FEV6 test has been shown to be advantageous in epidemiological fieldwork due to shorter exhalation time making it easier for the subject to reach end of test criterion. The FEV6 has also been demonstrated to display less test variability when compared to the FVC (Miller *et al.*, 2005; Vandevoorde *et al.*, 2006). Several studies have shown a sensitivity of 89-95% and a specificity of 97-98% of the FEV6 test compared to FVC (Akpınar-Elci *et al.*, 2006; Pedersen, 2006; Jing *et al.*, 2009). Hankinson found that differences between FEV6 and FVC values were small in younger adults but increased with age (Hankinson *et al.*, 1999). In our sample, FVC and FEV6 were identical in 42% of the subjects and showed a difference less than 50ml in an additional 55% of the subjects, supporting the view that FEV6 is an acceptable surrogate for the FVC test (Swanney *et al.*, 2000; Pedersen, 2006; Lundgren *et al.*, 2007; Jing *et al.*, 2009).

We believe that the main advantage of using FEV6 is that less costly and easier-to-use spirometric devices, where FEV6 is used instead of FVC, can broaden the practice of diagnostic screening for COPD in low income countries. Even in the USA, the National Lung Health Education Program (Ferguson *et al.*, 2000) recommends the 6-second spirometric manoeuvre for this purpose. It is therefore important to establish reference equations based on FEV6, possibly even more importantly in developing countries.

One of the strengths of our study is that strict adherence to ATS/ERS acceptability criteria was followed when assessing the manoeuvres with the exception of the 150ml reproducibility criteria. Previous ATS acceptability criteria have used a 200ml limit and in the present study this was chosen so as to avoid an exaggerated exclusion of subjects. However, of the 150 subjects only 29 had repeatability of FEV1 poorer than 150ml. It would seem unlikely that this choice of criterion should affect the reference values significantly as the best FEV1 and the FEV6 were used in the final analysis.

Our study sample was selected randomly, through a multistage cluster technique. However, difficulties in obtaining a correct sampling frame prior to the selection, and thus ensuring selection probabilities proportionate to size at the different stages, may limit the extent to which the results can be generalised. Due to time and capacity restraints, the two last clusters were not visited. This also has implications for the generalisability of the study outcomes and may slightly increase the overall sampling error. The available sample in the non-symptomatic group was small, particularly in the male strata. Thus, the power to detect differences between the subgroups and sex strata might not have been sufficient.

Also, correlations between the selected pulmonary parameters and explanatory variables might have been weakened and in some cases falsely negative due to a small sample size.

In conclusion, the differences in predicted lung volumes derived from our study compared to values obtained by using previously published equations, emphasise the importance of using appropriate reference values in clinical assessment of respiratory illness, based on the same population as those being tested. The reference values generated in this study will be immediately applicable for use in the sub-urban and semi-rural population of Tanzania.

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