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Feasibility and Preliminary Validity of Mobile Spirometry in Pediatric Asthma

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Children who frequently miss clinic visits or do not have access to a specialty clinic may not receive consistent lung function assessments, resulting in missed changes in lung function that may impact both diagnosis and treatment in pediatric asthma^{1,2}. The recent COVID-19 pandemic has underscored the utility of mobile health solutions (mHealth) in monitoring symptoms at home to reduce hospital visits and exposure risk. Peak-flow meters and portable spirometers are not equipped for real-time monitoring, conveniently sized/shaped, nor cost effective (i.e., portable spirometers). Mobile spirometry offers a solution to these barriers by 1) providing a cost-effective way to obtain spirometry measurements and 2) facilitating remote monitoring and the provision of digital lung function feedback to patients and providers via a mobile application³.

The present study addresses a gap in the literature by assessing the feasibility, acceptability, and preliminary validity of mobile spirometry by demonstrating consistency between laboratory-based spirometry and repeated measures of mobile spirometry. We also examined the feasibility and acceptability of telehealth training by respiratory therapists (RTs).

Participants meeting eligibility requirements (i.e., ages 12-17, diagnosed with moderate- or severe-persistent asthma), provided written assent/consent, and completed a demographic form and an in-person baseline visit. Participants completed baseline spirometry in the pulmonary function laboratory (Carefusion Vmax Encore™) and with the mobile spirometer (MIR Spirobank Smart™). RTs provided feedback until effort and technique on laboratory-based and mobile spirometry until lung function tests were comparable. Participants were provided with 1) a mobile spirometer and 2) a cell phone with a prepaid data plan and the MedaCheck Habit™ app required for spirometry for the duration of the 18-week study.

The MIR Spirobank Smart™ mobile spirometer (Spirobank Office; MIR; Rome, Italy) is an app-based bi-directional digital turbine system that simultaneously records FVC, FEV1, FEV1/FVC, and FEF₂₅₇₅. The precision and accuracy of the MIR Spirobank Smart™ meets or exceeds the European Respiratory Society (ERS) and American Thoracic Society (ATS) standards.⁴ This spirometer is calibrated by the manufacturer and does not require calibration unless damage occurs. Only acceptable and physiologically possible efforts were included in statistical analyses. Lung function data from the pediatric PFT lab and the mobile spirometer were reported as percent predicted for age, sex, race, and height based on reference equations by Wang⁵ as these are the reference values utilized in the pulmonary function lab. Participants were not limited in number of attempts, and the highest values were selected as the final value for each week.

The MedaCheck Habit™ app was used with the MIR Spirobank Smart™ to track spirometry data and uploaded data for the participant and study staff. The app provided weekly reminders to complete mobile spirometry via push notification and provided specific feedback to participants to re-perform mobile spirometry when readings were unacceptable. One week post-baseline, participants completed a telehealth training session with their RT to assess mobile spirometry technique and provide instruction. If mobile spirometry data were not deemed acceptable or reproducible, the participant received a second telehealth session.

Mean percent predicted was calculated for each metric of lung function for each participant. To assess preliminary validity, percent differences were calculated for each metric of lung function to assess the difference between mobile spirometry at baseline with 1) laboratory-based spirometry, 2) initial at-home mobile spirometry, and 3) average mobile spirometry throughout the study using $\leq 10\%$ difference for FVC, FEV1, and FEV/FVC and $< 25\%$

1 difference for FEF_{2575} as benchmarks based on ERS/ATS guidelines for standardization of
2 spirometry^{4,6}. To assess feasibility, we examined 1) participants requiring additional telehealth
3 training and 2) the ratio of acceptable mobile spirometry readings to the number of mobile
4 spirometry recordings completed. Acceptability was determined by the ratio of completed mobile
5 spirometry recordings to the number of requested recordings.

6 Participant demographics and spirometry values and comparisons can be found in Table 1
7 and 2, respectively. Baseline PFT laboratory and mobile spirometry value differences were
8 within the expected range for FVC (10.74%), FEV1, FEV1/FVC (<10%), and FEF_{2575} (16%).
9 Initial mobile spirometry values were also within the expected ranges of baseline mobile
10 spirometry for FVC, FEV1, FEV1/FVC (<10% difference), and FEF_{2575} (17%). Average mobile
11 spirometry readings over time were within 12% difference of baseline mobile spirometry ($\leq 12\%$
12 for FVC, FEV1, FEV1/FVC, and 19% for FEF_{2575}).

13 All participants completed telehealth training with an RT, and 93% of participants
14 demonstrated appropriate mobile spirometry technique at the first session. Seven percent of
15 participants required a second RT telehealth visit to ensure adequate technique. Feasibility data
16 indicates that participants completed technically acceptable mobile spirometry for 95%
17 (SD=14.33%; range: 27.2%-100%) of readings provided during the study, with 83% of
18 participants providing all acceptable readings. Acceptability results revealed that participants
19 provided 44% of the requested weekly spirometry measurements.

20 Overall, mobile spirometry values at baseline were similar to those obtained in the
21 pulmonary function laboratory, initial home mobile spirometry values, and average mobile
22 spirometry values over time, suggesting preliminary validity of mobile spirometry. Values were
23 most consistent for FEV1 percent predicted and FEV1/FVC, suggesting that adolescents were

1 able to perform these lung functions most reliably, which is commonly seen in pediatric
2 patients⁷. Results also support the feasibility of mobile spirometry with participants completing
3 technically acceptable mobile spirometry for nearly all measurements. The acceptability of
4 *weekly* mobile spirometry participants was less than optimal in the racially and socio-
5 economically diverse sample included in this study; however, participants were able to provide
6 mobile spirometry approximately every other week. Future studies should 1) determine an
7 acceptable frequency (e.g., monthly) for mobile spirometry that optimizes patient participation
8 and allows for routine remote lung function monitoring and 2) assess the efficacy of mobile
9 spirometry in improving additional digital assessments of asthma control. Finally, this study
10 supported the feasibility and acceptability of RT telehealth training for spirometry. Future studies
11 should assess the impact on patient access to RTs and sustained, proper use of a mobile
12 spirometer. Overall, the integration of mobile spirometry and telehealth utilized in this study has
13 the potential to improve health-related outcomes, encourage patient self-management, reduce
14 asthma symptoms, and strengthen patient-provider communication^{8,9}.

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Table 1. Participant Demographics (N=29)

Characteristic	Mean (Standard Deviation) or N (%)
Age in years	14.69 (1.61)
Sex	
Male	15 (51.7%)
Female	14 (48.3%)
Race	
White	17 (58.6%)
Black	11 (37.9%)
More than one race	1 (3.4%)
Asthma severity	
Moderate	15 (51.7%)
Severe	14 (48.3%)
Prescribed inhaled corticosteroid	
Dulera	21 (72.4%)
Advair	3 (10.3%)
Symbicort	2 (6.9%)
Flovent	1 (3.4%)
Asmanex	1 (3.4%)
Breco	1 (3.4%)
Family insurance coverage	
Private	14 (48.3%)
Public	11 (37.9%)
Don't Know	3 (10.3%)
Self-pay	1 (3.4%)

Table 2. Comparison of Baseline Mobile Spirometry to Clinic-Based Mobile Spirometry and At-Home Mobile Spirometry After Telehealth (N=29)

	Baseline Mobile Spirometry M(SD)	Clinic-Based Spirometry M(SD)	% Difference M(SD)	Initial Mobile Spirometry^a M(SD)	% Difference M(SD)	Average Mobile Spirometry^b M(SD)	% Difference M(SD)
FVC percent predicted	110.77 (22.04)	105.52 (15.05)	10.74 (17.80)	108.19 (19.15)	8.04 (10.58)	104.39 (23.38)	12.00 (12.76)
FEV1 percent predicted	95.25 (18.00)	94.97 (18.13)	6.78 (5.50)	92.57 (18.24)	7.26 (8.04)	88.33 (20.42)	11.14 (7.06)
FEV1/FVC	76.71 (13.24)	78.17 (9.85)	7.73 (10.98)	75.65 (10.72)	9.32 (16.87)	74.58 (10.50)	10.22 (20.71)
FEF ₂₅₇₅	81.13 (27.03)	76.38 (25.50)	16.30 (15.12)	76.33 (25.96)	16.95 (20.17)	70.05 (23.59)	18.54 (13.18)

Note. ^aThis column displays the average of the sample's initial spirometry value obtained right after telehealth training was complete (either 1 or 2 sessions); ^bThis column displays the average of all at-home spirometry values obtained over the course of the study beginning with the spirometry value obtained right after telehealth until the end of the study.