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RESEARCH PAPER

Effectiveness of Spirometry Fundamentals™ for increasing the proper use of spirometry in patients with asthma and COPD

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Abstract

Aim: To examine whether exposure to the Spirometry Fundamentals™ CD-ROM results in improved quality of spirometry testing in primary care.

Methods: Spirometry tests performed in 20 intervention and 19 control practices were analysed using American Thoracic Society grades A and B for 'passing' and grades C, D and F for 'failing'. Intervention effects on spirometry quality were assessed using random effects multivariate logistic regression.

Results: Adjusted analyses revealed no intervention effect. The likelihood of passing tests was higher in paediatrics-only practices (adjusted odds ratio (AOR) 2.60, 95% confidence interval (CI) 1.32 to 5.12; p=0.01). Hospital or university-based clinics had a lower performance than private or community-based practices in unadjusted analysis (7% vs. 22% passing tests; p=0.05). However, this relationship was not significant in adjusted analyses.

Conclusions: Spirometry Fundamentals™ is insufficient to improve the quality of spirometry in primary care, suggesting the need for more comprehensive multifaceted training resources.

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Introduction

The initial diagnosis and severity of illness for asthma and chronic obstructive pulmonary disease (COPD) are frequently underestimated without the use of diagnostic spirometry.[1,2] Such misclassification can lead to inappropriate treatment[1,3] and increased use of acute healthcare services.[4–6] Evidence-based guidelines state that spirometry is mandatory for the diagnosis of COPD. In the USA, published guidelines for asthma recommend routine spirometry or serial peak flow readings as the medical standard for diagnosis and ongoing management of patients in primary care.[7–9]

Despite its clinical utility, only 52% of family physicians and paediatricians in the USA report using spirometry in clinical practice and, of this group, only 21% routinely use spirometry for all guideline-recommended clinical situations.[10] As a result, 'usual care' for asthma and COPD typically does not include routine spirometry. The following four barriers to the use of spirometry in primary care are frequently cited: (1) absence of properly trained staff; (2) lack of time/administrative support to fit spirometry into scheduled visits; (3) no spirometer; and (4) general practitioners' lack of confidence in interpreting results.[10,11]

To address these barriers, we developed a multimedia CD-ROM entitled "Spirometry Fundamentals™: A Basic Guide to Lung Function Testing", a 70-min tutorial with an interactive action-orientated delivery involving video, audio, animation, and

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text.[12,13] The Spirometry Fundamentals™ tutorial has undergone expert review and is organised into 10 short individual learning modules (2–11 mins each) on topics including: introduction to spirometry, the spirometric manoeuvre, volume/time curves, flow/volume curves, preparing to do spirometry, patient preparation and coaching, acceptability and reproducibility of tests, reference and percentage predicted values, interpretation for clinical use, and pre/post-bronchodilator response. Each module concludes with a short series of content-based questions and immediate feedback on response correctness. This format gives learners flexibility to pace their learning and review individual modules as needed. The development of the CD-ROM was funded by the Centers for Disease Control and Prevention.

This paper presents data from a randomised controlled trial (RCT) that assessed whether exposure to the Spirometry Fundamentals™ CD-ROM resulted in improved quality of spirometry testing sessions.

Methods

Eligibility criteria

Primary care practices belonging to one of three groups were eligible to participate in the study: (1) those who purchased an an EasyOne Diagnostic™ spirometer made by new diagnostic designs (ndd) Medical Technologies (spirometer producer and distributor) during the previous year (March 2006 to March 2007) and had returned their warranty card to the company; (2) those who purchased an EasyOne Diagnostic™ spirometer between March 2007 and March 2008; and (3) those who belonged to one of two practice-based research networks and decided to either purchase or borrow a spirometer from the project team in order to take part in the study.

Enrolment process

Enrolment occurred over a 12-month period from March 2007 to March 2008, during which time period 51 practices agreed to participate. A number of methods were used to recruit practices into the study. Most were recruited through various practice-based research networks across the USA and other sites were recruited through ndd sales representatives or their customer warranty mailing list.

Practices were randomised at the time of enrolment. The research coordinator determined randomisation by retrieving the next envelope from a box of envelopes containing consecutive study group assignments. These assignments were determined before beginning enrolment using a random number generator. The randomisation resulted in 25 control practices and 26 intervention practices.

Each office assigned two people as study subjects, one as the spirometry test interpreter (most commonly a physician) and the other as the spirometry coach (most commonly a medical assistant or registered nurse). Study subjects consented to participate using a University of Washington Human Subjects Protection Committee-approved protocol. This trial was also registered under ClinicalTrials.gov (#NCT01152320).

Once enrolled, all practices (intervention and control) that needed to purchase or borrow a spirometer in order to participate received their unit from ndd and were provided with standard training on its use by the vendor. Practices already owning an EasyOne Diagnostic™ spirometer did not receive any additional training by the vendor beyond that received when they initially purchased their unit. All practices also received spirometry curve uploading software developed by Biomedical Systems called EasyData to facilitate transmission of de-identified spirometry testing session data to the project team on a weekly basis during their participation in the study. Practices were individually trained on the installation and use of the EasyData software by project staff. Twenty-two practices already had an EasyOne Diagnostic™ spirometer and 29 practices either purchased a spirometer from ndd or borrowed a spirometer from project staff.

Procedures for intervention practices

Shortly after enrolment, intervention sites received two copies of the Spirometry Fundamentals™ CD, an enrolment survey, and a letter instructing the interpreter and coach to view the CD at his/her convenience within a 3-week period. The letter also included instructions on how to access the study website in order to complete an evaluation survey after viewing the CD. The enrolment survey provided the study team with descriptive characteristics for the providers and their practices. These characteristics included: type of professional training (e.g. medical doctor), years since completing professional training (0–5 years, 6–10 years, >10 years), exposure to prior spirometry training (none/some), prior experience with conducting or interpreting spirometry tests (yes/no), practice type (paediatrics-only vs. 'other'), practice structure (hospital/university-based clinic vs. private/community-based clinic), type of community (urban, suburban, rural), and years of spirometry use in the practice (never used, <1 year, 1 year, >1 year).

We assumed that a site had watched the CD upon receipt of the completed evaluation survey or at the end of the 3-week period (whichever occurred first). At that point, each site was instructed to perform spirometry as clinically indicated and to upload their spirometry testing session data to a secure website on a weekly basis. Intervention sites submitted data from their spirometry testing sessions for 4 months. Once they had completed 4 months of data collection, their participation in the RCT was complete.

Procedures for control practices

Similar to the intervention group, descriptive data on the control providers and their practices was obtained via the enrolment questionnaire. Three weeks after receipt of their spirometer and/or installation of the EasyData software, control sites were instructed to perform spirometry as clinically indicated and to

upload their spirometry testing data to a secure website on a weekly basis for a total of 4 months. At the end of 4 months they were sent two copies of the Spirometry Fundamentals™ CD to thank them for their participation. The mailing also included a letter with instructions on how to access the study website in order to complete the evaluation survey after viewing the CD. This concluded their participation in the RCT.

Transmission and analysis of spirometry data

All transmitted spirometry testing sessions included a quality grade (A, B, C, D, or F) that was automatically calculated by the EasyOne spirometer. Because these automated grades are frequently inaccurate compared with visual inspection, each transmitted testing session was also over-read by a physician member of the project team (KS) who was blinded to study group allocation. Over-reading involves visual inspection and letter grade assignment based on criteria established by the American Thoracic Society (ATS). A and B grades are considered clinically interpretable and of high quality. For this analysis, grades A and B were equal to ATS test performance standards and were considered as 'passing' or acceptable quality and other grades (C, D, and F) were not.

Statistical analysis

The primary outcome compared between the control and intervention practices was the percentage of spirometry testing sessions collected during the 4 months of study participation which were assigned a 'pass' grade (i.e. the over-reader assigned an ATS grade of A or B to the testing session). Bivariate comparisons between control and intervention groups were performed using the χ^2 test and logistic regression.

Kappa statistics were calculated to examine inter-rater reliability of the grading system, comparing grades assigned by the blinded project physician and those assigned by a registered respiratory therapist who was also blinded to study group allocation. A kappa value of 0.50 indicated moderate inter-rater reliability.[14]

In bivariate analyses we examined whether characteristics of the coach (e.g. gender, years since completing professional training), characteristics of the practice (e.g. practice type, years of spirometry use in practice), or frequency of spirometry use were associated with the percentage of acceptable quality testing sessions conducted by the office. Characteristics of individuals responsible for interpreting the spirometry tests were not examined in this analysis because the percentage of testing sessions with acceptable quality was a product of the interaction of the coach with the patient.

One-way analysis of variance (ANOVA) was used to compare the means for the percentage of acceptable quality testing sessions for each independent variable with multiple categories. Pearson correlation coefficient was used to assess the relationship between the number of spirometry tests performed and the percentage of high-quality spirometry testing sessions.

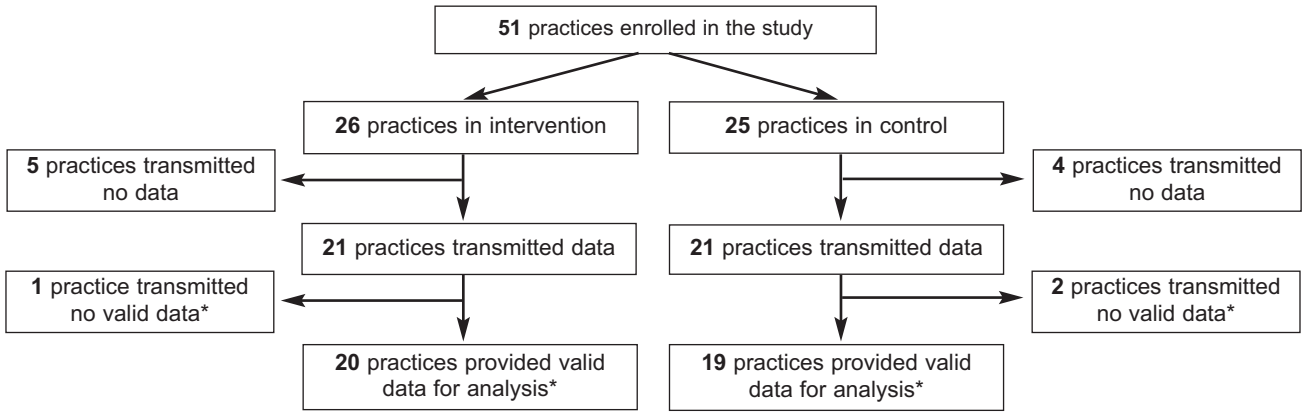
We analysed the effect of the intervention on the quality of spirometry testing using a random effects multivariate logistic regression model, taking into account clustering within practices. We included variables in the model that were related to the outcome of interest at a $p<0.10$ level in bivariate analyses. All statistical analyses were performed using Stata/SE 10.1 (Stata Corporation). Hypothesis tests were considered statistically significant only if they produced two-sided p values of <0.05. Intention-to-treat analyses included all spirometry testing session grades for intervention practices, regardless of their completion of the Spirometry Fundamentals™ training CD.

Results

Practices and coaches

Fifty-one practices were initially enrolled in the study, 39 of which provided complete/interpretable spirometry testing session data over the study period (20 intervention and 19

Figure 1. Enrolled practice attrition



*valid data = transmission of 3 curves/session

control practices; Figure 1). For data to be considered complete/interpretable, practices had to submit three spirometry curves per testing session. Three practices sent incomplete testing session data that included only one spirometry curve per testing session and thus could not be graded using ATS criteria. Nine practices did not transmit any spirometry testing session data during the course of the study.

Of the 39 practices with interpretable spirometry testing session data, 20 were paediatrics-only sites and 19 were 'other' sites (15 family medicine, 2 internal medicine, 1 pulmonology, and 1 allergy/immunology). The 20 intervention sites, comprising 11 paediatrics-only sites (55%) and nine 'other' sites (45%), submitted 943 spirometry testing sessions. The 19 control sites, comprising nine paediatrics-only sites (47%) and 10 'other' sites (53%), submitted 537 spirometry testing sessions. Sites in the intervention group submitted an average number of 47 testing sessions (standard deviation (SD) 96, median 17, range 2–443) over a 4-month period and control sites submitted an average number of 28 testing sessions (SD 34, median 17, range 5–138) over a 4-month period (Table 1).

Table 1. Performance of spirometry testing session by intervention status

	Intervention	Control	p value*
Number of sites sending spirometry testing session data	20	19	
Total number of testing sessions transmitted	943	537	
Mean (SD) number of testing sessions transmitted	47.2 (96.3)	28.3 (34.3)	0.42
Range of spirometry testing sessions transmitted	2–443	5–138	
Mean percentage acceptable quality testing sessions transmitted	20.9 (15.9)	19.4 (16.2)	0.77

*Calculated using t test; SD=standard deviation.

Table 2. Coach and practice characteristics by intervention status

Characteristics		Intervention status N (%)		p value
		Intervention (N=20)	Control (N=19)	
Coaches	*Gender*			
	Male	0	1 (5.3)	
	Female	20 (100)	18 (94.7)	0.30
	Years of professional experience			
	0–5	4 (20.0)	5 (26.3)	
	6–10	3 (15.0)	4 (21.0)	
	>10	13 (65.0)	10 (52.6)	0.73
	Any spirometry training courses?			
	None	5 (25.0)	3 (15.8)	
	Some	15 (75.0)	16 (84.2)	0.62
	Past experience with conducting spirometry tests?			
	No	12 (60.0)	10 (52.6)	
	Yes	8 (40.0)	9 (47.4)	0.64
Practices	*Practice type*			
	Other	9 (45.0)	10 (52.6)	
	Paediatrics-only	11 (55.0)	9 (47.4)	0.63
	Practice structure			
	Private/community	18 (90.0)	16 (84.2)	
	Hospital/university	2 (10.0)	3 (15.8)	0.59
	Type of community			
	Urban	7 (35.0)	6 (31.6)	
	Suburban	10 (50.0)	9 (47.4)	
	Rural	3 (15.0)	4 (21.1)	0.88
	How long has the practice been doing spirometry?			
	Not at all	6 (30.0)	6 (31.6)	
	<1 year	1 (5.0)	5 (26.3)	
	1 year	3 (15.0)	0	
	>1 year	10 (50.0)	8 (42.1)	0.12

Enrolment surveys were completed by 26 interpreters and 25 coaches from intervention sites and 20 interpreters and 21 coaches from control sites. More intervention site coaches had completed training >10 years ago (65% vs. 52% for controls) and almost all intervention sites were private or community-based practices (90% vs. 84%). More than half of the intervention and control coaches reported no experience with spirometry at the time of study enrolment (60% vs. 53% for controls; Table 2).

Quality of spirometry testing

The overall quality of the spirometry testing sessions conducted in the sample was poor (Table 1). The average percentage of acceptable quality spirometry testing sessions for intervention sites was 20% (SD 16%) compared with 19% (SD 16%, p=0.77) for controls. There was no correlation between the frequency of spirometry use and the percentage of acceptable quality testing sessions (r=–0.17; p=0.30).

Quality of spirometry testing session and coach/practice characteristics

Unadjusted bivariate results examining the relationships between intervention status and the quality of spirometry testing sessions indicated no intervention effect (Table 3). Similarly, results examining the unadjusted relationships between coach and practice characteristics and quality of spirometry testing sessions found no relationship in most cases (Table 3). However, we found that both practice type and practice structure were significantly related to the quality of spirometry tests performed. Compared with coaches in the 'other' sites, coaches in paediatrics-only sites had a significantly higher frequency of spirometry testing sessions of acceptable quality (15% vs. 26%; p=0.03; Table 3). Hospital and university-based practices had a significantly lower percentage of spirometry testing sessions of acceptable quality than private and community-based practices (7% vs. 22%; p=0.05; Table 3).

Adjusted analyses showed no intervention effect. Coaches exposed to the Spirometry Fundamentals™ CD-ROM had the same odds of performing high-quality spirometry tests as coaches who were not exposed to the CD-ROM (adjusted

Table 3. Unadjusted relationships between percentage of acceptable quality spirometry testing sessions and coach/practice characteristics

Characteristics		N	Mean (SD) percentage of acceptable quality spirometry testing sessions*	p value
Coaches	*Gender*			
	Male	1	35 (0)	
	Female	38	19.8 (15.8)	0.35
	Years of professional experience			
	0–5	9	12.7 (13.8)	
	6–10	7	16.7 (16.7)	
	>10	23	24.2 (15.7)	0.15
	Any spirometry training courses?			
	None	8	25.2 (13.8)	
	Some	31	18.9 (16.3)	0.32
	Past experience with conducting spirometry tests?			
	No	22	22.1 (17.6)	
	Yes	17	17.7 (13.3)	0.39
Practices	*Practice type*			
	Other	19	14.6 (17.7)	
	Paediatrics-only	20	25.5 (11.9)	0.03
	Practice structure			
	Private/community	34	22.1 (15.7)	
	Hospital/university	5	7.3 (10.1)	0.05
	Type of community			
	Urban	13	17.2 (13.1)	
	Suburban	19	21.0 (16.5)	
	Rural	7	13.6 (19.7)	0.94
	How long has the practice been doing spirometry?			
	Not at all	11	22.1 (15.9)	
	<1 year	6	12.0 (15.3)	
	1 year	3	24.0 (29.7)	
	>1 year	17	21.0 (13.9)	0.59

*ATS grades A or B as assessed by the over-reader. SD = standard deviation.

Table 4. Adjusted association between acceptable quality spirometry testing sessions and intervention status

Variable	Adjusted odds ratio (95% CI)	p-value
Intervention group status	1.15 (0.59 to 2.26)	0.68
Practice type		
Paediatrics-only	2.60 (1.32 to 5.12)	0.01
Practice structure		
Hospital/university	0.38 (0.10 to 1.45)	0.16

odds ratio (AOR) 1.15, 95% confidence interval (CI) 0.59 to 2.26; p=0.68; Table 4). However, coaches in paediatrics-only practices had a significantly higher odds of performing acceptable quality spirometry testing sessions than coaches in 'other' practices (AOR 2.60, 95% CI 1.32 to 5.12; p=0.01; Table 4). In adjusted analyses, coaches who practised in hospital or university-based clinics had a similar odds of conducting acceptable quality testing sessions as those in private or community-based practices (AOR 0.38, 95% CI 0.10 to 1.45; p=0.16; Table 4).

Discussion

We tested the effectiveness of the Spirometry Fundamentals™ CD-ROM for teaching primary care physicians and their staff to conduct high-quality spirometry testing sessions that conform with ATS standards. Spirometry Fundamentals™ as a single intervention was found to be ineffective in improving the quality of spirometry testing in the primary care setting. A more interactive and multifaceted training programme is probably needed to improve the quality of spirometry testing.[15,16]

Previous intervention studies including an active in-person training component have demonstrated significant improvements in the quality of spirometry testing in primary care.[17–21] However, the need for in-person training calls into question the disseminability of these interventions. Additionally, one study based quality assessments on the automated grade assigned by the ndd EasyOne spirometer. We have found that, when comparing grades assigned by the ndd device with grades assigned by a human over-reader, the grades are frequently discordant with the ndd device generating superior grades to those assigned by the over-reader. Leuppi *et al*.[19] also considered an ATS grade C as acceptable, in contrast to our analytical approach where only grades A and B were counted as acceptable. These differences in approach might explain the higher percentage pass rate observed by Leuppi *et al*.

Our findings are consistent with previous research suggesting that the quality of spirometry testing in primary care is poor.[2,22] We postulate that a logical sequence of reasons helps to explain the poor spirometry performance in primary care. The forced expiratory manoeuvre required for office-based spirometry represents a technique-dependent set of psychomotor skills. Coaching an individual through a technique-dependent test is typically improved with increased frequency of practice, and with the help of a mentor providing specific feedback and encouragement to the coach.

Spirometers often arrive and are initially used in a general office practice without any formal training in proper performance or interpretation of the test. Practices are thus faced with three choices: (1) to seek training from a local clinical expert or through an in-person programme; (2) to administer and interpret spirometry without training; or (3) to shelve the device eventually if acceptable results are not achieved because the need for training is often not recognised until a practice begins administering spirometry. In those offices choosing to implement spirometry, our experience in the current study indicates that the procedure is generally performed <10 times per month and feedback from an experienced colleague is usually not available. A recently published paper on spirometry standards suggests that office staff who have been trained in spirometry should conduct at least five tests a week (20/month) to maintain competence in conducting the tests.[9] Given these challenges, the poor quality of spirometry in primary care is not surprising.

Limitations of the study

The relatively small sample size in our study may have affected our ability to determine whether exposure to the Spirometry Fundamentals™ training CD-ROM is effective in improving the quality of spirometry testing in primary care. To detect a difference of 15 percentage points in the proportion of spirometry tests with acceptable quality grades after exposure to the CD-ROM, we needed to recruit 34 practices per study arm. Our final sample size fell short of this goal. However, to detect a 20% difference in performance after exposure to the CD-ROM with 80% power and α=0.05 required that we enroll 19 practices per study arm, a sample size that we achieved. Another potential limitation was our inability directly to validate that participants in the intervention arm actually viewed the CD-ROM in its entirety. However, all intervention group participants were asked to complete and return a web-based evaluation survey which asked them their impressions about specific content included in the CD-ROM. Thus, although this represents a proxy measure, return of the completed evaluation survey by all intervention participants raises our confidence that most – if not all – viewed the CD-ROM.

Participation in this study to evaluate a spirometry training tool was voluntary. The results may therefore not be generalisable to the quality of spirometry testing in other primary care settings with less motivated providers.

Implications for policy and practice

This study contributes to a growing body of research suggesting that the quality of spirometry testing in primary care is poor. Since

clinical guidelines and national quality standards encourage the use of spirometry in primary care settings, it is essential that spirometers meet minimum feature standards and comply with ATS and European Respiratory Society specifications. Individuals conducting spirometry should undergo training and competency testing for performing (and ideally interpreting) the tests. This training should also be subject to assessment according to national or international standards. There is a need to develop systems for ongoing surveillance and quality control.[9]

If performed properly, incorporating routine spirometry testing into standard practice is likely to improve the diagnosis and monitoring of both asthma and COPD. Improvement in these processes should in turn reduce the burden of pulmonary disease on patients and their families.

Conclusions

Simply viewing the Spirometry Fundamentals™ CD-ROM is insufficient to improve the quality of spirometry testing in primary care. Standard vendor training – if provided at all – is also not sufficient. To address the poor quality of spirometry testing in primary care effectively, a more interactive and multifaceted training programme is clearly needed.

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Statistical review

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Conflicts of interest

The authors declare that they have no conflicts of interest in relation to this article.

Contributorship

Ms Latzke-Davis and Drs Stout and Mangione-Smith contributed to the conception and design of the study, analysis and interpretation of the data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, supervision and technical support.

Dr Smith contributed to the analysis and interpretation of data, provided critical revision of the manuscript for important intellectual content, and provided technical support.

Drs Solomon and Garrison provided analysis and interpretation of data, statistical expertise, and technical support.

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