Lay Health Coaching to Increase Appropriate Inhaler Use in COPD: A Randomized Controlled Trial

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ABSTRACT

PURPOSE Poor adherence to medications is more prevalent for chronic obstructive pulmonary disease (COPD) than for other chronic conditions and is associated with unfavorable health outcomes. Few interventions have successfully improved adherence for COPD medications; none of these use unlicensed health care personnel. We explored the efficacy of lay health coaches to improve inhaler adherence and technique.

METHODS Within a randomized controlled trial, we recruited English- and Spanish-speaking patients with moderate to severe COPD from urban, public primary care clinics serving a low-income, predominantly African American population. Participants were randomized to receive 9 months of health coaching or usual care. Outcome measures included self-reported adherence to inhaled controller medications in the past 7 days and observed technique for all inhalers. We used generalized linear models, controlling for baseline values and clustering by site.

RESULTS Baseline adherence and inhaler technique were uniformly poor and did not differ by study arm. At 9 months, health-coached patients reported a greater number of days of adherence compared with usual care patients (6.4 vs 5.5 days; adjusted \( P = .02 \)) and were more likely to have used their controller inhalers as prescribed for 5 of the last 7 days (90% vs 69%; adjusted \( P = .008 \)). They were more than 3 times as likely to demonstrate perfect technique for all inhaler devices (24% vs 7%; adjusted \( P = .01 \)) and mastery of essential steps (40% vs 11%; adjusted \( P < .001 \)).

CONCLUSIONS Health coaching may provide a scalable model that can improve care for people living with COPD.

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) affects more than 14 million US adults and is a leading cause of 30-day hospital readmissions in the United States. Use of inhaled medications is recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) international guidelines and is associated with reduced exacerbations, decreased hospitalizations, fewer symptoms, better disease control, and longer survival. Adherence to medications is worse for COPD than for most other conditions, however, with multiple large, claims-based studies estimating adherence rates of 23% to 43%. Contributors to poor adherence for inhaled COPD medications include complex medication regimens, polypharmacy, poor understanding of the disease and how inhalers relieve symptoms, confusion about prescribed regimens, high costs of inhalers, current smoking, poor clinic attendance, comorbid illness, depression, and poor trust in the clinician.

Even for patients using their medications, poor inhaler technique can result in underdosing. More than 70% of patients use their inhalers incorrectly, and this rate has remained unchanged in 40 years. Barriers to effective inhaler use include the complexity and diversity of devices, which require correct execution of 6 to 8 steps that may be contradic-
Poor adherence and errors in technique are even more pronounced for low-income and minority patients and those with lower educational attainment. These factors may contribute to greater disease severity, poorer disease-related quality of life, more hospitalizations, and a greater risk of dying from COPD.

Multiple recent reviews have found a dearth of studies of interventions that improved adherence for COPD. The few interventions to successfully improve medication adherence or inhaler technique for COPD relied on pharmacists or nurses.

Health coaching is a patient-centered, team-based model of care. Health coaches facilitate shared decision making and equip patients with the knowledge, skills, and confidence to manage their conditions. Although health coaching for COPD has been delivered with some success by nurses and respiratory therapists, these resources are rarely available in the context of primary care, particularly in resource-limited settings. Lay health coaches have been efficacious at improving medication adherence and disease control for other conditions.

The Aides in Respiration (AIR) health-coaching study sought to improve disease-related quality of life, reduce exacerbations, and increase exercise capacity for people living with COPD. As previously published, improvements in these primary outcomes did not reach statistical significance. In this article, we report on secondary outcomes related to inhaler adherence and technique. We explored the efficacy of health coaching using trained, unlicensed personnel to improve adherence to and technique in using inhalers among a low-income, predominantly African American population living with moderate to severe COPD.

METHODS

The AIR health-coaching study was a multisite, single-blinded randomized controlled trial. The study protocol was approved by the UCSF Human Research Protection Program (approval no. 14-12872) and registered with clinicaltrials.gov (NCT02234284). The study protocol and primary outcomes have been previously published.

Setting

This study was conducted at 7 urban, county-operated primary care clinics, including 2 academic residency teaching practices, that primarily serve a low-income, publicly insured patient population. Pulmonary specialty care was available through the public hospital that was part of the health network and could be accessed via an electronic consultation system.

Participants

Enrollees were English- or Spanish-speaking patients at least 40 years old who were contactable by telephone and planned to continue to receive care at 1 of the 7 study sites. Clinical eligibility included having COPD, confirmed by a post–bronchodilator spirometry ratio of forced expiratory volume in 1 second (FEV₁/FVC) of less than 0.70, or by review by a pulmonologist, that was moderate to severe as defined in published study protocol. Health coaches for this study held bachelor’s degrees from 4-year colleges but were not licensed health care professionals. Both health coaches were fluent in English and Spanish.

Identification and Recruitment

Potential recruits were identified from targeted diagnoses in billing records or hospital census data, as well as referrals from clinicians at specialty and primary care sites. Medical chart review and primary clinician review were conducted to determine eligibility based on clinical criteria. Research assistants (RAs) contacted potentially eligible patients by telephone using a recruitment script or by letter.

Enrollment and Randomization

RAs met with eligible patients to secure consent, verbally administered a questionnaire, and observed inhaler techniques. Participants received up to $30 at baseline and $60 at 9 months in acknowledgment of their study participation. A random binary sequence, created by the project manager and stratified by site, was used to order study arm assignment into sequentially numbered envelopes in a 1:1 ratio. Once baseline measures were complete, the RA asked the patient to open a sealed envelope with a randomization card indicating assignment to usual care or health coaching. Study investigators and the data safety monitoring board were blinded to assignment until analyses were finalized.

Health-Coaching Intervention

Health coaches received more than 100 hours of training using a health-coaching curriculum supplemented by COPD-specific content. The curriculum covered active listening and nonjudgmental communication, navigating health care systems, creating self-management goals, and use of teach-back (closing the loop) methods. COPD-specific training delivered by pulmonary specialists included inhaled medications.
Health coaches worked with patients for 9 months, with a maximum caseload of 30 patients at any given time. They accompanied patients to visits with primary care clinicians, pulmonary clinicians, or both; met with them individually in the community or at their home; and conducted telephone calls between in-person visits. Health coaches addressed barriers to medication adherence and conducted teach-back to improve inhaler technique. The minimum frequency of contact was once every 3 weeks. Patient interactions were documented in a database created for the study, including date, time, topics discussed, and relevant notes. Health coaches met with a supervising pulmonary specialist nurse practitioner at least weekly.

**Usual Care**

Patients randomized to usual care received any resources provided by their clinic as part of standard care. These resources included but were not limited to visits with their primary care clinician, pulmonary clinician, or both; COPD education classes; pulmonary rehabilitation; and smoking cessation resources.

**Measures**

On enrollment and at 9 months, RAs reviewed each inhaled medication presented by the patient. They asked patients to demonstrate how they used their inhalers, and recorded inhaler technique using a standardized checklist to mark successful completion of each step of inhaler use. Checklists were adapted from those developed by Melani and colleagues and modified by the pulmonary specialist members of the team to match standard inhaler education instructions for the most commonly used device types, including Diskus (GSK), HandiHaler (Boehringer Ingelheim), Respimat (Boehringer Ingelheim), and variations for metered dose inhalers for open- and closed-mouth techniques and use of a spacer. Patients using more than 1 type of device were asked to demonstrate use of each. Patients used their own inhalers when available; demonstration inhalers were available for patients who did not bring their own inhalers. Medication adherence was assessed by reading the dosing instructions and asking, “In the past 7 days, how many days did you take this medicine exactly as it was prescribed?”

**Outcomes**

Perfect inhaler use was defined as successful completion of every essential step required for medication delivery, for every inhaler for which use was demonstrated. Finally, a continuous, weighted score was created by assigning 2 points for each essential step and 1 point for each additional step completed successfully. Weighted scores for each inhaler were normalized on a 100-point scale, and a mean was generated across inhalers demonstrated by each patient.

Medication adherence was analyzed, per a previously published protocol, both as a continuous variable and as 2 dichotomous variables: perfect adherence, defined as having taken every controller inhaler as prescribed every day for the past 7 days, and good adherence, defined as having taken controller inhalers as prescribed for an average of at least 5 of the past 7 days.

**Quality Assurance**

Before study launch, the project manager conducted skills checks with each RA to ensure that she consistently captured correct information about technique through the inhaler checklist. Spot checks were conducted periodically thereafter to ensure compliance to the study protocol.

**Statistical Analyses**

Analysis of inhaler technique was restricted to patients using at least 1 inhaler at baseline, and analysis of medication adherence to patients using at least 1 controller inhaler at baseline. Baseline patient characteristics were compared between study arms and tested for significance using the chi² test for categorical variables, t tests for normally distributed continuous variables, and non-parametric tests for non-normally distributed continuous variables. Outcomes were compared by assignment arm (intention-to-treat approach) using generalized linear models with a normal distribution, with identity link for continuous outcomes and binomial distribution with logit link for binary outcomes. Hypothesis tests were 2-sided with P values <.05 considered statistically significant. A robust standard error was used to account for clustering and accommodate missing data under the assumption that the outcomes were missing at random. In all models, the baseline level of the outcome was included as a predictor and the follow-up level as the dependent variable.

We tested for differential attrition between study arms with logistic regression models for a preidentified set of variables (age, sex, disease severity, smoking status, substance abuse, and homelessness) with participation at 9 months as the dependent variable and independent variables including study arm, the
variable, and an interaction term of study arm by the variable. We conducted subgroup analysis for adherence to long-acting muscarinic antagonists (LAMAs). Two planned sensitivity analyses were conducted. First, we imputed missing values in a subset of data using variables from the current analysis, examining 10 iterations and aggregated results; second, we adjusted for season of enrollment, patient age, race, and sex as well as baseline variables that differed between study arms at \( P < .10 \). Statistical analyses were run using Stata 13.0 (StataCorp, LLC) and multiple imputation using the SPSS Multiple Imputation Procedure (IBM).

## RESULTS

Of 282 patients identified as eligible for the study, 192 (68%) were enrolled and randomized to receive health coaching \((n = 100)\) or usual care \((n = 92)\) (Figure 1). Of the 178 using a rescue or controller inhaler at baseline, 138 (78%) provided data at 9 months; of the 126 using a controller inhaler, 98 (78%) provided data at 9 months. Loss to follow-up was greater for the health-coaching arm than for the usual-care arm for the subsample included in the inhaler technique analysis (29% vs 14%; \( P = .02 \)). There were no significant differences between the study arms in baseline demographics or disease severity for patients who dropped out of the study. None of the patients participating in the study used oral medications for their COPD.

Participating patients had a mean age of 61 years, and the majority (66%) were male (Table 1). More than one-half (57%) were African American and about one-fifth (17%) reported Hispanic ethnicity.
Thirty-two percent had less than a high school education, and 37% reported needing at least some help with health information (not shown). Participants were primarily publicly insured (56% MediCal and 35% Medicare). Thirteen percent were affected by homelessness or housing insecurity. Most (93%) reported high levels of COPD symptoms. Patients were prescribed a mean of 1.4 controller inhaler medications.

Table 1. Participant Characteristics, by Study Arm (N = 192)

| Characteristic | All (N = 192) | Health-Coaching Arm (n = 100) | Usual-Care Arm (n = 92) | P Value |
|---------------|--------------|------------------------------|------------------------|---------|
| **Demographics** |              |                              |                        |         |
| Age, mean (SD), y | 61.3 (7.6) | 60.7 (8.0) | 61.9 (7.2) | NS |
| Male, % (No.) | 65.5 (126) | 67.0 (67) | 64.1 (59) | NS |
| Works full/part-time outside the home, % (No.) | 17.8 (34) | 16.0 (16) | 19.8 (18) | NS |
| Income <$10,000/y, % (No.) | 45.7 (84) | 45.8 (44) | 45.5 (40) | NS |
| Black/African American race, % (No.) | 56.8 (109) | 53.0 (53) | 60.9 (56) | NS |
| Hispanic/Latino ethnicity, % (No.) | 16.7 (32) | 13.0 (13) | 20.7 (19) | NS |
| Preferred language is not English, % (No.) | 12.6 (24) | 7.0 (7) | 18.7 (17) | .02 |
| Education less than high school, % (No.) | 31.9 (61) | 34.0 (34) | 28.3 (26) | NS |
| Had visit with pulmonary specialist in 12 months before enrollment, % (No.) | 31.3 (60) | 34.0 (34) | 28.3 (26) | NS |
| **Severity of COPD** |              |                              |                        |         |
| GOLD classification, % (No.) |              |                              |                        | NS |
| Gold A (low symptoms, low risk) | 4.2 (8) | 5.1 (5) | 3.3 (3) | NS |
| Gold B (high symptoms, low risk) | 46.3 (88) | 46.5 (46) | 46.2 (42) | NS |
| Gold C (low symptoms, high risk) | 3.2 (6) | 4.0 (4) | 2.2 (2) | NS |
| Gold D (high symptoms, high risk) | 46.3 (88) | 44.4 (44) | 48.4 (44) | NS |
| FEV1 % of predicted, mean (SD) | 58 (20) | 55 (19) | 60 (20) | NS |
| High COPD symptom score: CAT ≥10, % (No.) | 92.7 (177) | 90.9 (90) | 94.6 (87) | NS |
| Ever smoked, % (No.) | 96.3 (184) | 99.0 (99) | 93.4 (85) | .04 |
| Current smoker, % (No.) | 53.8 (99) | 54.6 (54) | 52.9 (45) | NS |
| Asthma diagnosis, % (No.) | 27.6 (53) | 29.0 (29) | 26.1 (24) | NS |
| **Inhaled medications** |              |                              |                        |         |
| Uses any inhaler (rescue or controller), % (No.) | 92.7 (178) | 95.0 (95) | 90.2 (83) | NS |
| Uses controller inhaler, % (No.) | 65.6 (126) | 67.0 (67) | 64.1 (59) | NS |
| Number of controller inhalers prescribed, mean (SD) | 1.4 (0.9) | 1.5 (0.9) | 1.3 (0.9) | NS |
| **Types of medications prescribed** |              |                              |                        |         |
| Short-acting β agonist (SABA), % (No.) | 88.5 (170) | 90.0 (90) | 87.0 (80) | NS |
| Short-acting anticholinergic, % (No.) | 34.4 (66) | 32.0 (32) | 37.0 (34) | NS |
| Long-acting β agonist (LABA), % (No.) | 56.8 (109) | 57.0 (57) | 56.5 (52) | NS |
| Long-acting muscarinic antagonist (LAMA), % (No.) | 51.6 (99) | 59.0 (59) | 43.5 (40) | .03 |
| Inhaled corticosteroid (ICS), % (No.) | 76.0 (146) | 76.0 (76) | 76.1 (70) | NS |
| Correctly identified rescue inhaler, % (No.) | 88.5 (161) | 90.7 (88) | 85.9 (73) | NS |
| Number of uses of rescue inhaler/day, mean (SD) | 2.5 (1.9) | 2.7 (2.0) | 2.3 (1.8) | NS |
| **Inhaler use** |              |                              |                        |         |
| Metered dose inhaler, % (No.) | 91.8 (168) | 90.7 (88) | 93.0 (80) | NS |
| Closed-mouth technique | 66.1 (111) | 63.6 (56) | 68.8 (55) | NS |
| Open-mouth technique | 8.9 (15) | 10.2 (9) | 7.5 (6) | NS |
| Use with a spacer | 25.0 (42) | 26.1 (23) | 23.8 (19) | NS |
| HandiHaler, % (No.) | 40.2 (70) | 42.9 (39) | 37.4 (31) | NS |
| Diskus, % (No.) | 19.4 (35) | 13.7 (13) | 25.9 (22) | .04 |
| Respimat, % (No.) | 12.0 (22) | 14.4 (14) | 9.3 (8) | NS |

COPD = chronic obstructive pulmonary disease; CAT = COPD Assessment Test; FEV1 = forced expiratory volume in 1 second; GOLD = Global Initiative for Chronic Obstructive Lung Disease; NS = not significant.

a According to the 2014 GOLD guidelines.58
b Either alone or in combination with another inhaled medication.
At baseline, the usual care arm had a higher proportion of patients whose preferred language was not English (19% vs 7%), and the health-coaching arm had more patients with a history of smoking (99% vs 93%) (Table 1). Patients in the health-coaching arm were more likely to have been prescribed a LAMA (59% vs 44%) and less likely to use a Diskus device (14% vs 26%) at baseline. Baseline adherence to controller inhalers and correct inhaler use did not differ by study arm.

At 9 months, patients in the health-coaching arm reported a significantly greater number of days of adherence to controller inhalers compared with counterparts in the usual-care arm (6.4 vs 5.5 days; Table 2) and were more likely to have taken all of their medications as prescribed for 5 of the last 7 days (90% vs 69%). Patients receiving health coaching were 3 times as likely to demonstrate perfect technique of all inhaler devices (24% vs 7%), and their weighted inhaler technique score was about 11 points higher (Table 3). When considering the essential steps of inhaler use required for medication delivery, 40% of health-coached patients vs 11% of usual-care patients could demonstrate adequate use at 9 months.

The same pattern of results persisted when using imputed values or adjusting for season of enrollment; patient age, race, and sex; and baseline variables that differed between study arms. A subgroup analysis for LAMAs yielded similar results (not shown).

**DISCUSSION**

**Key Findings**

To our knowledge, this is the first study to demonstrate that unlicensed, trained health coaches may...
improve inhaler adherence and technique over usual care for patients with COPD. In this low-income, predominantly minority population living with moderate to severe COPD, 9 months of health coaching resulted in greater patient-reported adherence to inhaled controller medications and a threefold increase in correct observed inhaler technique. Our health-coaching model is responsive to recent calls to incorporate attention to shared decision making and collaborative care into efforts to improve adherence to inhalated medications for COPD. In a systematic review of interventions to improve adherence to COPD controller medications, Bryant and colleagues observed that shared decision making—shown to improve medication adherence for other conditions, including asthma—was missing from the literature on interventions for COPD. Our study addresses this gap, as our intervention, health coaching, is grounded in the principles of shared decision making, for example, selection of devices based on patient capabilities and preferences.

Collaborative care models using unlicensed team members to assist patients with navigation or education have improved quality of care and adherence to treatment in populations with other complex conditions and comorbidities. Our model is aligned with a recently proposed model for COPD collaborative care, which includes as core tenets access, teamwork, disease management, and coordination of care. Health coaching addresses each of the pillars of this model, providing a point of contact to facilitate access; additional time from a new team member who plays a key role in activating the patient as a core member of the team (teamwork); proactive review of treatment plans and preventive care to improve disease management; and active coordination of care among primary care, specialty care, and inpatient care. One key technique in health coaching that may have contributed to improved inhaler technique is closing the loop, or asking patients to demonstrate use of their inhalers and providing targeted feedback to improve use, which has been shown to improve technique in several small COPD studies. Use of closing the loop in practice is uncommon, with only 27% to 50% of patients reporting that their health care team has ever observed them use their inhalers. It is estimated that effective inhaler instruction using closing the loop requires approximately 5 minutes for devices such as the Diskus and 8 minutes for metered dose inhalers, time that may be more feasible in a collaborative model wherein health coaches share responsibility for patient care.

The direction of change for the primary outcomes in the AIR study, such as disease-specific quality of life and exacerbations, were positive for the coached group, but differences did not reach statistical significance over usual care. This result may suggest that improved inhaler technique and adherence are only one of the factors required to move outcomes.

**Limitations**

Our study was conducted in an urban, low-income population with moderate to severe COPD, generalizability of the intervention to other settings requires additional evaluation. The prevalence of people with COPD who had never smoked tobacco is consistent with that in other studies conducted in clinical settings but lower than estimates for the general population. Loss to follow-up was greater in the health-coaching arm than in the usual-care arm but did not appear to differ by study arm for baseline characteristics. Adherence was self-reported. Like other studies of inhaler technique, our study is limited by a lack of standard definitions for critical errors and common checklists. Although inhaler adherence has been linked to improved outcomes in other studies, the AIR study was not able to demonstrate reduced adherence in patients who received health coaching.

### Table 3. Inhaler Technique for Controller and Rescue Medications at Baseline and 9 Months, by Study Arm (N = 138)

| Measure | Health-Coaching Arm (n = 67) | Usual-Care Arm (n = 71) | Difference, % | Adjusted Difference, % (95% CI) | P Value |
|---------|-----------------------------|-------------------------|---------------|---------------------------------|---------|
| Perfect use of all inhalers, % (No.) | 4.5 (3) | 23.9 (16) | 1.4 (1) | 7.0 (5) | 16.9 | 24.8 (4.2-42.6) | .01 |
| Adequate use of all inhalers, % (No.) | 9.0 (6) | 40.3 (27) | 5.6 (4) | 11.3 (8) | 29.0 | 40.0 (20.7-59.2) | <.001 |
| Weighted inhaler technique score, mean (SD) | 71.9 (15.7) | 88.9 (10.2) | 72.9 (15.3) | 77.7 (13.2) | 11.24 | 11.61 (8.18-15.04) | <.001 |

Note: Includes only patients with data for baseline and 9 months (ie, patients on controller or rescue inhalers at both time points). See Table 1 footnotes for definitions of use and score details.
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Conclusions
Patients who received 9 months of health coaching reported greater adherence to their COPD inhaled medications and were directly observed to use their inhalers correctly more often than patients receiving usual care. Given that COPD is a leading cause of hospital readmissions, health systems have a financial incentive to provide support for self-management of this disease, which may include improvement of inhaler use as a component strategy. Health coaching such as that provided in the AIR study may provide a scalable model to improve inhaler use for people living with COPD.

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Key words: health coaching; self-management; patient education; medication adherence; inhalers; inhaler technique; chronic obstructive pulmonary disease; chronic illness; shared decision making; practice-based research; primary care

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