

Aides in Respiration (AIR) Health Coaching Study Research Protocol

Background and Description

The Aides in Respiration research protocol is a detailed description of the protocol for a randomized controlled trial of health coaching for Chronic Obstructive Pulmonary Disease (COPD). This protocol describes identification, recruitment, introduction of the program, assessment tools, tracking, and follow up of patients with COPD for this program.

Instructions

These protocols and forms may be adapted and used by sites that are launching health coaching programs for COPD.

UCSF Center for Excellence in Primary Care

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Section A: Patient Recruitment and Baseline Measures

1. Eligibility criteria

To be enrolled in the study, patients must have chronic obstructive pulmonary disease (COPD) of at least moderate severity, and they must meet non-clinical requirements for participation.

Criteria A: COPD. The determination of COPD is made based on spirometric criteria of ever having FEV1/FVC<.7 post-bronchodilator (indicating a fixed obstruction) or diagnosed by the study pulmonologist using all available clinical data (e.g., disease history, smoking status, CT scans, X-rays and PFTs).

Criteria B: At least moderate severity. Moderate to severe COPD was defined as meeting at least one of the following criteria:

- At least one hospital admission in the last 12 months due to COPD-related diagnosis;
- At least two emergency department visits in the last 12 months due to COPD-related diagnosis;
- Current prescription of anti-cholinergic inhaler;
- Current prescription of combination medication (LABA/ICS);
- Prescription of short term oral steroids (at least 40 mg for at least 5 days but <21 days) in the last 12 months;
- Prescription of home oxygen therapy at any time;
- FEV1<80% of predicted (post-bronchodilator) at any time;
- Resting O2 Saturation <= 88% at any time (outpatient);
- Arterial blood gas (ABG/PPO2) <=55 mm Hg at any time (outpatient);

Criteria C: Meet non-clinical requirements for participation. Other eligibility criteria include:

- Age at least 40 years;
- Goes to one of the seven study sites for primary care, and had at least one outpatient visit within last year;
- Plans to seek care at a study primary care clinic for at least the next 9 months;
- Does not plan to be out of area for at least 3 months in next 9 months;
- Plans to be in the San Francisco area at 9 months (and therefore able to meet for the 9 month survey);
- Can be reached by telephone;
- Speaks Spanish or English; and
- Willing to attempt spirometry.

Patients may be **ineligible** for the study based on any ONE of the following conditions:

- Primary care clinician determines not able to work with a health coach due to serious physical condition, terminal illness, cognitive dysfunction, serious psychiatric illness, or uncontrolled substance use;
- Unable to come into clinic due to severity of COPD;
- Does not identify as having a breathing problem.

2. Identification of Potentially Eligible Patients

Patients who are potentially eligible for the study will be identified through four channels:

- Search through DPH billing records (THREDS search) for patients with any of the target ICD9 codes (Figure A) in the last 24 months (any number of visits in ED, Hospital, and outpatient clinics with one of target codes*);
- List of patients referred to the Chest Clinic;
- List of patients admitted with any of the target ICD9 codes (hospital census); or
- Referral from providers of study site (or identification through their chronic disease registry) through email, paper referral, or direct introduction in clinic.

* Target diagnostic codes of interest: 491, 492, 496, 490+305.1, 493+305.1, 786+305.1)

Chart review. Research Associates (RAs) will conduct chart review to gather clinical measures to determine eligibility ([Appendix A](#)).

Provider review. The list of potentially eligible patients will be given to clinic primary care providers (See **Provider Review Form**). The providers will be instructed to identify patients who would not be eligible for the study based on defined exclusion criteria such as untreatable cancer or serious psychiatric disease.

3. Recruitment of Study Participants

All patients identified as potentially eligible will be assigned to an RA using the **Recruitment Tracking Database**. RAs will contact patients by letters and/or telephone using the **Recruitment Script (Appendix B)**. They will identify themselves as members of a study team working on a project at their clinic to improve COPD care and indicate that the patient's provider suggested that they might be appropriate for the study. If the patient is interested, they will ask a series of screening questions to confirm that the patient meets non-clinical eligibility criteria. Patients who are interested in the study and meet non-clinical criteria will be invited to meet with a research assistant in person in a private setting so the study can be explained and informed consent obtained. Spirometry and the 6 minute walk test must be performed in a clinical setting with a nurse or clinician who can respond in the event of an exacerbation. Surveys may be conducted in another setting if preferred by the patient.

RAs will track attempts to contact their patients, using the Recruitment Database. The general rule is to call at least 5 times, with at least one attempt on each of three timeframes: weekday mornings (9 AM - noon), weekday afternoons (noon - 6 PM), and weekday evening 6 - 8 PM). It is not required to leave a message on voicemail for each call, but it is requested to leave at least 2 messages before ceasing attempts to contact the patient.

A recruitment flyer will be posted in Spanish and English in the clinic as another method of recruiting potentially eligible patients. The flyer will instruct interested patients to contact the study team. Contact information for the study team will be shared with staff and providers at the sites, and flyers will be available for clinical care teams to share with patients.

The **Recruitment Tracking Database** will be used to document the outcome of the recruiting process (e.g., not eligible, not interested, or enrolled).

4. Patient Consent and Enrollment

Interested and eligible patients will meet with a research assistant at their clinic (or another designated clinical site where privacy is possible) to be consented and enrolled (see **Appendix C** for recruitment supply checklist). Prior to meeting with the patient, the RA will pick up a consent package in the patient's language of choice. The consent packet includes the following forms:

- Consent forms (2; one copy is for patient)
- HIPAA forms (2; one copy is for patient)
- HIPAA form for ER/hospital visit (for all patients -- in the event of a report of a hospitalization/ED visit during the study period)

- Future contacts form
- Post-survey chart review form
- Intake form (only used if patient is assigned a health coach, to assist with hand-off)
- Randomization card in sealed envelope

The RA will consent patients using the IRB-approved **Consent Form** (English or Spanish) and have patients sign the consent form, regular **HIPAA form**, AND the **ER HIPAA form**. The RA will give the patient a copy of the Consent Form and HIPAA Form for his or her records.

The RA will outline key points of the documents and then will give the potential participant a choice: a) The RA may read the entire consent and HIPAA forms for the patient; or b) The patient may review the documents himself or herself. The RA may use the **Study Flow Diagram (Appendix D)** to explain the research study.

In the event that a patient is **visibly impaired from the use of drugs or alcohol**, the RA will reschedule the patient for another day and explain that the testing needs to be done at the time when the patient has not had a drink or consume substances.

5. Spirometry

The RA will perform spirometry to determine eligibility for the study if the patient does not already meet criteria for COPD (see section 1c above) and/or to secure baseline measures for patients who are eligible for enrollment but have not had a spirometry in the previous 3 months. Consent will be secured prior to conducting spirometry, even if the eligibility of the patients is not yet determined. All spirometry results will be reviewed by the Director of the Community Spirometry program to determine quality based on American Thoracic Society (ATS) guidelines (See **Appendix E** for spirometry workflow).

Patients are allowed a maximum of 10 attempts at either pre- or post-bronchodilator spirometry. If a patient feels unable to complete the test, the RA should terminate attempts and refer them to the pulmonary function testing (PFT) lab or to a respiratory therapist for testing.

Screening for contraindications. The RA will take the patient’s vitals (Blood pressure, O2 sat, heart rate) after a patient has been sitting for at least 5 minutes and before conducting spirometry. The RA will also ask a series of screening questions to identify contraindications (see **Enrollment form – Appendix F**). See table below for response to positive screen on contraindications.

Contraindication	Response
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Contraindication	Response
Patient has had heart attack in the last month	Absolute contraindication. Do NOT conduct spirometry.
Patient has had surgery on eye or torso in last month	Absolute contraindication. Do NOT conduct spirometry.
Patient shows signs of distress (e.g., gasping for air)	Absolute contraindication. Do NOT conduct spirometry.
Systolic Blood Pressure \geq 200	Measure again after 5 minutes of rest. If it is still high, do NOT conduct spirometry.
Diastolic Blood Pressure \geq 120	Measure again after 5 minutes of rest. If it is still high, do NOT conduct spirometry.
O2 saturation < 92%	Measure again after 5 minutes of rest. If \leq 88% do NOT conduct spirometry. Refer patient to triage nurse for assessment. If it is < 92% but > 88%, ask patient: <ul style="list-style-type: none"> • Do you know what your oxygen saturation usually is? • How are you feeling? Refer patient to triage nurse for assessment. If nurse confirms that patient is okay to proceed and patient feels okay, then may attempt spirometry.
Pulse \geq 120 beats/minute	Measure again after 5 minutes of rest. If it is still \geq 120 beats/minute, do NOT conduct spirometry.
Patient has a bad cold or respiratory infection	Ask the patient how bad the cold is and whether they feel able to attempt the test. If they wish to attempt the test, then check in after each attempt to ensure no distress. If their first 3 curves show signs of coughs/mucus, stop and reschedule for another day.
Patient reports feeling faint if he/she breathes out hard	Instruct patient not to bear down but rather to keep head up and squeeze air out of lungs using their abdomen. Attempt a trial run. If patient is experiencing problems, stop.

Post-bronchodilator spirometry. Post-bronchodilator spirometry is conducted when there is no documentation of spirometry showing an FEV1/FVC < .7, but the patient is otherwise eligible.

RAs may conduct post-bronchodilator spirometry if all of the subsequent conditions are satisfied:

- The clinic and study investigators have signed the Study Operating Procedures allowing the RAs to conduct post-bronchodilator spirometry on site and standing orders for use of albuterol for the test; and
- RAs have demonstrated competence on the **SABA administration checklist (Appendix G)**, as confirmed by observations by the study investigators and project manager.

When post-bronchodilator spirometry is needed, the RA will not conduct pre-bronchodilator spirometry.

Use of inhaler study stock. The RA may provide albuterol from the study to the patient and record the inhaler number, date, and Study ID on the **Albuterol Logsheet**.

When an albuterol inhaler from the study supplies is used, this inhaler may be re-used under the following circumstances, as approved by SFGH infection control:

- The patient has not placed their mouth on the inhaler boot, but rather has used a spacer; and
- The boot is removed from the inhaler, washed in warm, soapy water, and allowed to dry completely before reassembly.

Pre-bronchodilator spirometry. If the patient has post-bronchodilator spirometry indicating obstruction on record and is eligible base on one or more severity criteria (see section 1. Eligibility, Criteria B) and does not have a record of spirometry in the past 3 months, the RA will conduct spirometry without use of a bronchodilator (pre-bronchodilator spirometry) as a baseline measure.

Acceptable time range for spirometry to be considered part of baseline

Measure	Acceptable range for completion
Baseline spirometry	91 days (3 months) before to 61 days (2 months) after enrollment

Pulmonologist review of cases. A pulmonologist review of a case may be required in circumstances in which a patient is unable to complete spirometry but appears that they may have at least moderate COPD:

- The patient does not have post-bronchodilator spirometry on record showing $FEV1/FVC < .70$;
- AND the patient meets ONE of the following criteria:
- The patient has two “use with caution” tests with $FEV1/FVC \leq .75$ conducted during for study recruitment; OR
 - The patient is unable to complete the maneuver; OR
 - The patient has completed post-bronchodilator spirometry with an overread grade of A, B, or C, and the $FEV1/FVC \geq .7$ and $< .75$.

The pulmonologist may recommend exclusion or inclusion from the study based on existing data. He may also identify additional testing that could be useful for determining whether a patient is likely to have moderate COPD.

Materials needed for the pulmonologist review are summarized in **Appendix H**.

Reporting spirometry results to PCP

Patients not identified as having COPD. In the event that post-bronchodilator spirometry shows obstruction, a person who does not have COPD listed in the chart and is not prescribed an anticholinergic inhaler (e.g., ipratropium or tiotropium) or combination beta agonist/inhaled corticosteroid (e.g., fluticasone propionate and salmeterol), the RA should alert the Principal Investigator (PI) with patient information and spirometry results. The PI will follow up with the PCP.

Reporting results when test does not meet reproducibility criteria. When a test receives a grade of “use with caution” or “not interpretable” because there are not at least two tests meeting acceptability and reproducibility criteria in the overread, the results should NOT be given to the provider.

In the event that the patient had pre-bronchodilator and received a “use with caution” grade for the over read, the patient will not be required to redo the spirometry test.

In the event that the patient had post-bronchodilator and received a “use with caution” rating, additional attempts to secure better spirometry results will be made under the following conditions:

- The available FEV1/FVC < .75;
- The RA believes that the patient can understand instructions and take part in the maneuver; and
- The patient is willing to coming in for another appointment.

If results meeting ATS criteria (with grade A/B/C) cannot be secured, the RA will send a TE to the provider that states, “Spirometry was performed, but we were unable to secure an interpretable test. This patient may benefit from pulmonary function testing. If you feel that this would be appropriate, you may wish to refer them to the PFT lab at SFGH.”

Additional points

Spirometry will not be conducted more than two times for the study, even if both attempts result in a “Use with caution” grade. For patients eligible for additional attempts at spirometry, the RA will speak to the patient at least once and attempt one additional contact. If a patient schedules an appointment but does not reschedule or show up for it, then the RAs will only attempt to reschedule if they believe that there were extenuating circumstances and that additional attempts will result in the patient’s participation.

The FEV1/FVC and FEV1 % predicted for “Use with caution” tests will be included in the study data, labeled as “use with caution.”

When a patient is asked to come in a second time for spirometry for the study, the patient is eligible to receive an additional \$10 incentive.

Baseline Survey

All patients who consent to participate will be verbally administered the **Patient Baseline Survey** in person by an RA, either in English or Spanish, based on the patient preference (**see Appendix I for Survey measures**). Spirometry readings, outcomes from the 6 minute walk test, weight, height, blood pressure, pulse, and O2 saturation will be recorded on the **Enrollment Form (Appendix F)**. Survey and enrollment form data will be entered in the **RedCap Survey Database**.

6. Six minute walk test

The 6 minute walk test (6MWT) measures the distance a patient can walk in a period of 6 minutes on a flat, hard surface. This self-paced test assesses the sub maximal level of functional capacity. Most patients do not achieve maximal exercise capacity during the 6MWT. Instead they choose their own intensity of exercise and are allowed to stop and rest during the test. However, because most activities of daily living are performed at sub maximal levels of exertion, the 6MWT may better reflect the functional exercise level for daily physical activities.

Contraindications:

Absolute contraindications include unstable angina or myocardial infarction during the previous month or angina with walking (on either level or up hill).

The RA will ask:

- Have you had a heart attack in the last month?
- When you walk, do you get chest pains?

If the answer to either of these questions is "yes," then the RA will not conduct the 6 minute walk test.

Additionally, the RA will not conduct the test if any of the following conditions apply after the patient has been sitting for at least 5 minutes:

- Pulse above 120
- Systolic blood pressure ≥ 200
- Diastolic blood pressure ≥ 110
- O2 saturation $< 92\%$
- Patient shows signs of distress (e.g., gasping for air)

If a patient has blood pressure, pulse, or O2 saturations readings that exceed these thresholds, the RA will re-measure them after the patient has been sitting for at least 5 additional minutes. If the measures are below the threshold, the test may proceed.

If after the second measure, the patient has a blood pressure 200 or greater systolic or 110 or greater diastolic or if the O2 sat is < 92%, the RA will notify the appropriate member of the clinic staff. A patient may attempt the 6MWT if their only contraindication is O2 sat<92% but >88%, the patient reports that this is normal for them and they feel okay, and the triage nurse conducts an assessment. If the blood pressure is above the stated thresholds, the 6MWT should not be conducted on that day. The patient may attempt the test again in two weeks if the blood pressure is below the threshold at that time. If the patient does not attend the appointment or does not wish to conduct the test, the RA does not need to make another appointment. The 6 minute walk test must be done within 61 days of enrollment to be included as a baseline measure.

If the patient is not able to walk (e.g., in a wheelchair), he or she should not do the test.

Equipment Needed:

1. Stopwatch
2. Measuring Tape
3. Two small cones to mark the turnaround points
4. A chair than can be easily moved along the walking course
5. Worksheets
6. Omron automated blood pressure cuff
7. A pulse oximeter
8. A marker to place where patient stops at the end of the test.

Preparation before the patient arrives:

1. Check in with charge nurse and alert him/her that you will be doing the 6 minute walk test with a patient.
2. Measure/mark course.
3. Set up chair and equipment.

Patient Preparation:

1. The patient should be wearing comfortable clothing and appropriate shoes.
2. Patients should use their usual walking aids during the test (cane, walker, etc.).
3. The patient's usual medical regimen should be continued. This may include oxygen and the use of rescue inhalers before or during walking.
4. The patient should not have exercised vigorously within 2 hours of beginning the test.

Procedure:

1. The 6MWT can be performed indoors, along a long, flat, straight, enclosed corridor with a hard surface. The walking course for this study should be 15 meters (49 feet, 2.5 inches) in length, whenever possible. When there is not a sufficiently long enough space, the distance may be shorter, but the RA should carefully note this and adjust

accordingly when calculating total meters walked. It is preferable to have a shorter but straight course than to have a course that requires turning a corner or otherwise navigating obstacles. The turnaround points should be marked with a cone. A starting line, which marks the beginning and the end of the lap, should be marked.

2. The patient should sit at rest in chair located near the starting point for at least 10 minutes before the test starts. During this time check for contraindications, measure SpO₂, heart rate, and blood pressure.
3. Instruct the patient using the standardized instruction sheet (Scripted Instructions below).
4. Position the patient at the starting line. Tell the patient to start when they are ready.
5. Start the time (stop watch) when the patient begins walking.
6. Do not talk to the patient during the walk except for the scripted comments (Scripted Instructions below) unless you are concerned the patient is in distress or may need to stop. Watch the patient. Do not get distracted and lose count of the laps. Each time the patient returns to the starting line, mark the lap on the worksheet.
7. At the end of each minute advise the patient of the time remaining in an even tone using the script (Scripted Instructions below)
8. If the patient stops walking during the test and needs to rest do not stop the timer. Let the patient rest until they can continue.
9. Reasons for immediately stopping a 6MWT include the following: chest pain, intolerable dyspnea, leg cramps, staggering, and pale or ashen appearance.
10. If the patient stops before the 6 minutes are up and does not wish to continue (or you decide that they should not continue), bring the chair for the patient to sit on, discontinue the walk and note on the worksheet the distance, the time stopped and the reason for stopping prematurely. Record the distance walked at the time the test was stopped
11. When the 6 minutes are complete, ask the patient to stop. Walk over to them (take the chair to the patient if necessary) and note where they stopped.
12. Ask patient to sit down and record SpO₂, heart rate, and BP.
13. Using the worksheet, complete the distance calculation.
14. Congratulate the patient and offer a drink of water if needed.

SCRIPTED INSTRUCTIONS

Introduce the test and give instructions using the following script.

“The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You may get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. If you feel you can't or don't want to continue let me know and we can stop the test at any time. Because this test requires you to exert yourself, I encourage you not to try to have a conversation while you do this test. I will not talk to you until the test is over except to let you know how many minutes have passed. However, if you need help, just tell me or wave at me.

"Do you typically use oxygen or an inhaler before or during exercise? If so, you may use them today as you usually do.

"You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.

"Are you ready to do that? Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Also, try not to talk during the test and I will not talk to you except to let you know how many minutes are remaining.

"Start now, or whenever you are ready."

During the test, use the following scripted comments

At 1 minute tell the patient "You are doing well. You have 5 minutes to go."

At 2 minutes, tell the patient "Keep up the good work. You have 4 minutes to go."

At 3 minute tell the patient "You are doing well. You are halfway done."

At 4 minutes tell the patient "Keep up the good work. You have only 2 minutes left."

At 5 minutes tell the patient "You are doing well. You have only 1 minute to go."

When the timer is 15 seconds from completion, say this: "In a moment I'm going to tell you to stop. When I do, just stop right where you are, and I will come to you."

At 6 minutes say "Stop! Great job. You are done!"

Walk over to the patient. Take the chair to the patient if the patient looks tired. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor.

During the test, do not use other words of encouragement (or body language) to speed up the patient.

If the patient stops walking during the test and needs a rest, say this: "You can lean against the wall if you would like; then continue walking whenever you feel able." Do not stop the timer. If the patient stops before the 6 minutes are up and does not wish to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

For the purpose of marking the 6MWT status in the tracking database, the following definitions apply:

- Attempted – includes cases where patient did at least part of test, even if they stopped before the 6 minutes were up because they were tired

- Ineligible – includes patients in wheelchairs, people who have contraindication, or people who are too sick or in pain to take part in the test
- Refusal – Patient elected not to take part in test
- RA terminated test – includes cases where patient attempted test and would have continued, but RA terminated test because concerned about patient’s welfare
- Pending

Other Baseline Clinical Measures (not used for eligibility determination)

Weight. Weight will be measured using one of the two research study scales. The RA will measure weight of all patients in clothes including footwear, but without overcoats.

Height. The RA will measure height of all patients in stocking feet using a supplied tape measure and architect’s right angle triangle.

Blood pressure. The RA will measure the blood pressure of all patients using the blood pressure cuff provided (Omron automatic cuff). Blood pressure will be measured in the left arm after the participant has been sitting for at least 5 minutes.

O₂ Saturation and pulse. The RA will measure O₂ saturation and pulse using a Nonin Onyx 9500. The oximeter may be used on either hand on the index or middle finger. If it is not possible to use either of these fingers, make a note about the finger used on the enrollment form. Pulse will be measured after the participant has been sitting for at least 5 minutes.

7. Urgent issues arising during enrollment

The RA will alert triage nurse and the project manager if any of the following symptoms occur.

- Shortness of breath (lasting more than 5 minutes)
- Dizziness
- Chest pain
- Loss of consciousness
- Pulse rate <50
- Pulse rate >100 for more than 5 minutes
- BP ≤ 90/50 or ≥ 200/110
- Signs of distress (e.g., gasping for breath)
- Intention to harm self or others

In the event that a patient's score on the PHQ is ≥ 15 , or the patient expresses emotional distress, the RA will offer to introduce the patient to a behaviorist and/or share the patient's score on the PHQ with their provider. Whenever possible, the RA will conduct the referral through a "warm handoff" in which the RA introduces the patient to the behaviorist in person. The RA may also fill out a behavioral health referral form or send a TE to the team nurse or the provider, depending on the protocol of the clinic site. If the patient does not wish to speak with a behaviorist or PCP regarding these symptoms, the RA will remind them that they may speak with their provider if they change their mind, but the RA will not report the score to a provider without the patient's permission. Behavioral health referrals should be reported to the project manager. A study investigator should also be alerted when an urgent issue has arisen, and the event should be logged in the Issue log for the study.

8. Randomization & forms

After obtaining baseline measures, patients will be randomized to one of the two study arms (health coaching and usual care) the patient will be given the next envelope in sequence and asked to open the envelope to learn if they will receive health coaching or usual care. The randomization cards are in sequentially numbered, sealed envelopes. Each card assigns patients either to a health coach or to the usual care arm of the study.

Patients randomized to the intervention group will be assigned a Health Coach. If possible, patients will meet their health coach the same day as enrollment in the clinic, with a "warm handoff" from the research assistant to the health coach. If it is not possible to introduce the patient and the health coach in person, the health coach will contact the patient to arrange a meeting at the clinic. Whether the patient is transferred through a warm handoff or a referral, the RA will complete the top section of the **Intake Form (Appendix J)** and deliver this to the assigned Health Coach.

The RA will complete the **Future Contact Form (Appendix K)**. The RA will provide a card to the patient and instruction him/her to ask his/her emergency contacts to contact the study team if the patient has any health complications like going into the hospital.

An additional HIPAA authorization form will be secured for emergency visits or hospitalizations outside of the network.

The RA will provide an incentive to patients of \$30 for completing this baseline survey and assessment (\$10 for the survey, \$10 for spirometry, and \$10 for the 6 minute walk test). In the event that a patient completes spirometry but is not eligible for the study, the RA will provide the patient with an incentive of \$10 as a thank you for their time.

Patients will be told that they will be contacted in 9 months to complete a survey (similar to the survey administered at the beginning of the study). Additionally, they will receive a brief call at 3 and 6 months to complete a 5 minute phone survey.

9. After Enrollment

Return consent materials. The RA will return all study forms, to the research office as part of the consent packet. The RA will review the consent packet prior to filing it to identify any missing paperwork or signatures. The **Consent Form, HIPAA form(s), Future Contact Form, Enrollment Form,** and Randomization Card will be filed together.

Update database. The RA will enter the participant’s enrollment information, including study ID, enrollment date, and study arm into the **Recruitment Database.** (The **Recruitment Database** will be used to generate weekly progress reports on recruitment activities and outcomes, enrollment, and comparison to target numbers for a monthly dashboard.)

Survey data. The RA will enter survey data into Redcap.

Provide results of 6MWT with PCP. The results of spirometry and the 6 minute walk test will be shared with the primary care provider. When a patient receives a health coach, the health coach will send the message. When a patient does not receive a health coach, the message will come from the RA.

10. Post-enrollment electronic health record (EHR) abstraction

RAs will review patients’ charts to determine and record medications prescribed at time of enrollment, as well as medical conditions and procedures, using the **Post-Enrollment Chart Review Form** (see **Appendix A** for list of measures).

RAs are responsible for completing the post-survey chart review. At baseline, the post-survey chart review form examines:

Variable group	Abstraction decisions
COPD-related medications being taken on the last visit with a primary care provider prior to enrollment	<ul style="list-style-type: none">• Include the following dispositions: Taking, Not taking, Start, Refill, Continue, Increase, or Unknown. Do not include the dispositions Discontinued or Stop.• If no COPD-related medications, move on the next section
Anti-smoking medications taken in the 6 months prior to enrollment	Medications for smoking cessation: <ul style="list-style-type: none">• Nicotine Replacement Therapies (e.g., Nicorette)• Bupropion/Zyban/Wellbutrin• Chantix/Varenicline• Rx doesn’t have to be started in the 6 month period, just active in that period

Variable group	Abstraction decisions
	<ul style="list-style-type: none"> • Bupropion is marked as Zyban and Wellbutrin. The formulation Zyban is specifically for smoking cessation. Include Wellbutrin only if note states that it is prescribed for smoking cessation.
Co-morbidities <u>on the problem list</u> and ICD9 or ICD10 codes	<ul style="list-style-type: none"> • Include only diagnoses on the problem list (do not include if only found in progress note) • Do not include substance abuse if in remission
Insurance	<ul style="list-style-type: none"> • MediCal • Medicare • Healthy San Francisco • Private • Other

In addition, RAs will identify any medications indicative of potential exacerbation in the period of 12 months prior to enrollment, including:

- Prednisone
- Doxycycline
- Cephalexin/Keflex
- Septra/Trimethoprim sulfamethoxazole/TMP-SX
- Amoxicillin
- Augmentin/amoxicillin-clavulanate
- Meds starting with cef-
- Ciprofloxin
- Levofloxin
- Moxifloxin and
- Azithromycin
- Clarithromycin
- Erythromycin

RAs will pull all ED and hospital visits for that period and abstract chief complaint and discharge diagnoses. These records will be reviewed by a study investigator to determine if they are indicative of a COPD exacerbation.

11. Study attrition

Attrition from the study may occur because of unanticipated circumstances (e.g., moving away, severe illness) or participant decision not to continue involvement in the study. The reason for attrition will be recorded in the Recruitment Database. The following definitions apply:

- **Declining intervention:** A participant assigned to the coaching arm may elect not to continue meeting with a coach, but they may still take part in the end-of study measures if they wish to do so;
- **Dropping out of study:** A participant may decide to discontinue all future contacts with the study, including survey or clinical measures. Enrollment data will be retained to help identify characteristics of people who dropped out of the study;
- **Loss to follow up:** If a participant moves, becomes seriously ill, or is otherwise unable to be reached at 9 months, then they are considered lost to follow up.

1. Required activities

In the 9 months following their enrollment, the health coach will do the following minimally required activities with each patient to whom they have been assigned:

- Conduct an initial visit within 2–3 weeks of enrollment with the goal of rapport building and understand the patients' motivations, strengths, and barriers to self-management;
- Conduct medication reconciliation and the COPD Assessment Tool prior to the first primary care visit;
- Consult with the COPD nurse practitioner specialist to determine recommendations based on GOLD criteria;
- Conduct a primary care visit with the patient and the primary care provider in the study with goal of discussing primary care provider and patient priorities for COPD management, reviewing GOLD criteria recommendations, reviewing preventive care needs, and establishing a COPD Action Plan;
- Meet with the patient at least once every two months;
- Attend clinic primary care provider visits with the patient at least three times during the study to assess and support chronic care medication adherence, discuss care maintenance, set behavioral change action plans, and ensure understanding of provider's instructions;
- Call patients to follow up on action plans and medication changes two weeks after each clinic visit; and
- Call the patient at least once every three weeks to provide self-management support.

2. Documenting health coaching activities

The Health Coach will complete a **Health Coach Interaction Form** (within their **Health Coaching Database**) each time they interact with a patient to document the time, nature, and topics covered in the interaction. For the sake of this study, an interaction is defined as any kind of substantive interaction with a patient about study or non-study topics. This may include such interactions as:

- Taking part in a medical visit or follow-up call
- Talking with a patient about non-study-related topics (e.g., job, family) – this is considered psychosocial support
- Assisting a patient who cannot make it to an appointment to understand walk-in appointments – this is considered navigational assistance

- Assisting a patient with needed paperwork
- Note: A reminder call about an appointment would NOT be considered a health coach interaction, unless the call transforms into one in which information is being shared or other topics are discussed

Additionally, Health Coaches will keep an **Issue Log** of significant situations that arise that could (e.g., if a patient loses housing or experiences the death of a family member).

3. Communicating with the PCP

Health coaches will communicate non-urgent information to PCPs via Telephone Encounters in the eClinical Works electronic health record. The standard principle for communication is that coaches will only communicate information that might lead to a change in treatment decision or a request to bring the patient in before their next scheduled visit. If a PCP asks to receive additional "for your information" notes (e.g., action plan, positive change of status, content of health coaching sessions), the health coach may communicate these, but this is not required.

Urgent issue	Non-urgent, actionable issue
<p><i>Actions:</i></p> <ol style="list-style-type: none"> 1. Patient should be directed to clinic nurse, urgent care, emergency department. 2. Page study investigator. 3. Inform primary care team (most often team nurse) via TE of issue and action taken. 4. Alert project manager. 	<p><i>Action: Health coach will create a telephone encounter for the primary care team - most often the team nurse. TE will include brief summary of issue and offering options of scheduling visit with PCP or communicating something back to patient.</i></p>
<p><u>Examples:</u></p> <ul style="list-style-type: none"> • Anything on COPD action plan yellow or red flags • Shortness of breath (lasting more than 5 minutes) • Dizziness • Chest pain • Loss of consciousness • Signs of distress (e.g., gasping for breath) • Intention to harm self or others 	<p><u>Examples:</u></p> <ul style="list-style-type: none"> • Major life change for patient • Missed appts or tests and actions taken (e.g., rescheduled) • Patient stopped taking medications or facing barrier to securing medications • ED/Hospital visits to <u>non-SFGH</u> facilities (PCPs receive automatic notification of ED visits and hospitalizations at SFGH)

Common questions

1. **If a patient is having symptoms that fall within the "urgent issues" list but refuses to call 911 or the NAL, is there ever a time that I would override their wishes and call 911 on their behalf?**

The only case in which we would override the wishes of a patient is if there is evidence that they are not mentally competent to make decisions (e.g., disoriented, loss of consciousness). In that case, we would first ascertain the location of the patient. Then we would ask if there is someone with the patient that we can speak with (who may be able to assist and call on their behalf). If there is no one present to help, and the patient shows signs of lack of mental competence, then the health coach may call 911 on their behalf. The health coach should describe the location of the patient, the symptoms of concern, and the perceived lack of ability to make decisions.

2. **What kinds of assistance may health coaches offer to primary care providers? What are they not allowed to do?**

Assistance that health coaches may offer to PCPCs	Assistance that health coaches may NOT offer
<ul style="list-style-type: none"> • Review medications and how to take them • Help with medication related challenges, such as calling pharmacy upon request to discontinue old medications • Share information about lung disease • Making an emergency breathing plan • Ask questions and list to patient’s experience of lung disease • Come to visits with doctor and meet with patient alone to help support self-management of condition • Make personalized plans to be more active, manage stress, or meet other personal goals • Meet with patient outside of clinic, including at home • Remind patient of appointments • Help identify resources to meet social needs 	<ul style="list-style-type: none"> • Recommend changes to medications • Assess symptoms or diagnose disease • Provide direct help in a medical emergency • Give medical advice • Take the place of a doctor or other health professional

3. If a change in treatment is recommended by the pulmonary specialist, who will communicate with the PCP?

In the event that the pulmonary team recommends a change in medication management based on their review of a patient case, the pulmonary advanced nurse practitioner (ANP) will reach out to the patient's primary care provider with the suggested change in medication.

4. Home visits

Home visits can serve several functions. The most general is to get a sense of where the patient lives, both the home and the neighborhood. Home visits also allow the health coach to learn more about how the patient spends his or her day typically, who else is around, and to meet caregivers.

Home visits should be conducted as soon as possible when appropriate, but it is important that the patient does not feel pressured and is in control of the timing and agenda.

When conducting home visits, it is very important to first take time to connect personally. Take time to check in, follow up on news in the person's life, or comment on family photos before you start talking about COPD or related topics.

Health coaches should present a menu of options for how to use the visit and should engage the patient in deciding how to use the time together. This menu could include reviewing medications, providing COPD-related information, following up on action plans, or reviewing the home for triggers (in the case that allergies are an issue).

The **home visit form** can serve as a tool to guide visits.

To ensure safety, the following protocols should be followed:

- Home visits may only be conducted during **daytime hours**, and sufficient time should be allowed to get back to the office before dark;
- The first home visit should always be conducted with a **second person**, and subsequent visits may also be conducted in pairs when the coach feels it is desirable;
- If the coach has any concerns about safety in the house or environment, she should immediately terminate the visit;
- A person who is not part of the home visit (a "**safety**") should be advised of the location, contact information of the patient, and the estimated departure time from the visit;
- The coach conducting the visit must have a **charged cell phone and a watch** so as to be able to receive and make calls and monitor time;
- The coach must carry the **hard copy phone number of the safety** in a place that is separate from the phone;
- The coach must text or call the safety prior to entering the patient's home.
- The coach should **contact the safety immediately by phone or text** upon leaving the house or when the estimated departure time is reached.
- If the coach does not contact the safety by 15 minutes after the estimate departure time, the safety will take the following sequential actions until the coach is reached:
 - Attempt to contact the coach by cell phone;
 - Attempt to contact the patient;
 - Continue attempting to contact the coach and patients for 15 minutes;

- Page one of the study investigators and call the project manager; Clearly state in the message the name and location of the coach, the agreed upon departure time, and any other actions taken;
- If contact with the coach has not been reestablished within one hour of scheduled end of visit, a call to the police will be made. If the project manager or study investigator has been reached, one of these individuals will call the police. If they have not been reached, the safety will call the police directly.
- As soon as contact with the coach has been re-established, immediately contact the study investigator, project manager, and police if necessary.

Policy for patients who leave the clinic

Patients who leave their clinic during the study period will remain part of the study. If they have a health coach, and they leave the clinic completely, then health coaching will cease. However, if they do not entirely leave the clinic (e.g., they experience insurance problems that they are working to resolve), then health coaching may continue (even if remotely). In either case, a health coach may periodically check in with the patient to make sure that he/she has not returned to the clinic.

Section C: Three and Six-Month Patient Survey

Three and six months after a patient is enrolled in the study, regardless of whether they are assigned to the health coaching or the usual care arm, the RA will call them to complete a brief survey over the phone or in person. The **three and six month patient surveys** include a subset of measures from the baseline survey (see **Appendix I** for survey measures).

Acceptable range for 3 & 6 month surveys

Survey	Acceptable range for completion
3 month follow up survey	61-122 days (2-4 months)
6 month follow up survey	152-213 days (5-7 months)

For the 3 and 6 month surveys, a minimum of 3 calls should be made to try to get in contact with patient.

Section D: Nine Month Patient Follow Up

Research assistants may call the patient between 8-12 months post-enrollment to set up an interview time for the nine-month survey (see **Appendix I** for survey measures).

Acceptable range for 9 month surveys

Survey	Acceptable range for completion
9 month follow up survey	243-365 days (8-12 months) NOTE: ALL measures must be secured in this time frame, including spirometry, 6MWT.

For the 9 month surveys, at least 9 calls should be made unless a patient actively declines to take part in the survey. In addition, a letter should be sent to the patient and the RA should determine if the patient has an appointment that she can show up at to invite them to take part in the survey.

The RAs will set up a time to conduct the survey and whatever clinical measures were conducted at baseline (spirometry and/or the 6 minute walk test). Blood pressure and weight will be recorded. The same method of measurement and type of spirometry (pre or post) will be used at baseline and follow up. Whenever possible, the same 6 minute walk course will be used as at baseline.

If a patient did not have spirometry results updated at baseline, there is no need to complete spirometry or measure height and weight at 9 months. If a patient did do a 6MWT at baseline, he or she does not need to complete it at 9 months.

In the event that a patient cannot complete spirometry or the 6 minute walk test on the day of the interview, the RA will still conduct the nine month survey. Patients will receive \$20 for completing the survey, \$20 for completing spirometry, and \$20 for completing the minute walk test, for a total of up to \$60.

Chart review. Chart review will occur at 9 months in order to abstract the prescribed medication list, visit history, antibiotics indicating possible exacerbations, and smoking cessation medications (see **Appendix A** for measures) at the time of the 9 month survey (using the medication list from the visit immediately prior to that date).

In addition, the RA will collect dates for visits to the primary care clinician, pulmonary specialists, and urgent care for the year prior to enrollment and the 9 months of enrollment in the study. The RA will identify any dates as which medications associated with exacerbations were prescribed. These cases will be reviewed by the study investigator to determine if the patient experienced an exacerbation. In addition, the RA will indicate if medications for smoking cessation were prescribed in the period 3-9 months after chart review.

Section E: Qualitative data on providers, health coaches, and patients

In depth qualitative interviews lasting 20-60 minutes will be conducted with patients who received health coaches, primary care clinicians and specialists working extensively with coaches, and the study health coaches by two trained interviewers who are not part of the original study team. Interviewers will use a semi-structured interview guide (Appendix L). Interviews will be audio recorded and transcribed verbatim.

Health coaches will identify 10 patients with significant barriers and 10 patients without significant barriers to be recruited for interviews. Primary care providers and specialists with the highest counts of visits with a patient receiving health coaching will be invited to take part in the study.

The two interviewers, along with 3 other members of the study team, will read a subset of de-identified transcript and meet to develop a codebook reflecting emerging ideas.

Section F: Utilization of Services and Other Data

In addition to patient-reported measures, data on service utilization will be gathered for each patient in the study. This data will be gathered from several sources for a period of 1 year prior to enrollment to 9 months after enrollment.

ED/ Hospital records

RAs will look for emergency department and hospital visits at the home hospital through the Lifetime Care Record. When cases are found, the RA will print out discharge summaries or visit notes. Emergency department and hospital visits occurring outside of the home system will be identified by patient report, with the patient asked at enrollment, 3 months, 6 months, and 9 months. A records request will be faxed to the corresponding medical records department. If a patients' emergency visit results in admission to the hospital, both the emergency department and hospitalization notes will be reviewed.

Cases in which a patient left without being seen will be excluded.

The study investigator will review all emergency department and hospital records to identify discharge diagnoses and determine whether the visit reflected a COPD exacerbation. The study pulmonologist will review a subset of cases to confirm decisions.

Participation in Better Breathers or Smoking Cessation programs

We will compare our list of enrolled patients to records kept by Better Breathers and the smoking cessation program to identify patients who took part in these programs in the 12 months prior to enrollment and during their enrollment in the study.

Primary care, specialty, and urgent care visits

Visits to a primary care clinician, pulmonary specialist, or urgent care will be tallied by the RA during chart review at 9 months after enrollment. Visits to the primary care clinic for labwork, nursing visits, or classes will be excluded if they do not also entail a visit to a clinician.

Checklists and decision support

RAs will use checklists, protocols, and scripts as facilitators for recruitment. Some of these include:

- Recruitment script (**Appendix B**)
- Spirometry workflow (**Appendix J**)

Ensuring spirometry quality

Calibration of the Vyntus spirometry system will be conducted daily using a 2 liter syringe. In the event of error messages, the RA will consult with the Director of Community Spirometry and the representative from the Vyntus system to try to resolve the issues.

All spirometry curves will be reviewed (overread) by the Director of Community Spirometry, who will grade the tests based on American Thoracic Society guidelines. Tests with a grade of A, B, or C are considered to have “passed” ATS criteria and may be uploaded in to the electronic health record and shared with the primary care clinician, whereas tests with a grade of “Use with caution” will not be uploaded as part of the medical record. Use with caution results will be recorded in the dataset, and the grade will be noted for purposes of sensitivity analyses.

ATS grade	Meaning
A	3 attempts met quality standards and variance \leq 150 ml
B	2 attempts met quality standards and variance \leq 150 ml
C	2 attempts met quality standards and variance \leq 200 ml
Use with caution	Only one spirometry curve was secured that met ATS criteria
Not interpretable	No spirometry curves were secured that met criteria

For predicted values, the Crapo algorithms are used to derive predicted values, as this was the standard of the hospital system when the study began. In the last months of the study, the hospital system changed to GLI algorithms. Crapo algorithms rely on height, age, and gender.

Unlike GLI algorithms, Crapo does not take into account race/ethnicity or other demographic factors.

After overreads are complete, the study pulmonologist will review each case for interpretation. Reports with interpretation for spirometry meeting ATS criteria will be uploaded into the electronic health record and shared with the primary care clinician and any pulmonary clinicians providing care.

Data Review

The Project Manager is responsible for ensuring the quality of the data. This includes merging new batches of information with existing batches and systemically checking incoming data for quality. The Project Manager will maintain a **Logbook for Data Cleaning** in which she identifies discrepancies and/or missing data, actions taken, and decisions made. The PM is responsible for communicating questions not addressed in the data dictionary to the AIR study team for decisions.

Section H: Protecting Patients' Health

Given that the patient population for this study has chronic obstructive pulmonary disease and may be susceptible to respiratory illnesses, the study team will take the following additional precautions to prevent spread of infection to these patients:

If the study team member has a fever, vomiting, or severe respiratory symptoms, she will not meet with patients. She may trade meetings when appropriate (e.g., RAs covering for each other if possible) or reschedule the visit.

If the study team member has a mild cold, she may meet with patients, but will be asked to take measures to prevent spread to patients, such as:

- Keeping a distance;
- Maintaining doors open as much as possible;
- Using hand sanitizer liberally; and
- Offering to use a face mask.

When the study team member reaches patients for a reminder call, she will alert them if she is experiencing a cold. In the event that a patient expresses concern about catching illness, the RA or health coach will acknowledge the importance of the patient's concerns and offer to reschedule the meeting.

Section I: Usual Care Consultations

As an added service to usual care patients, after the period of study participation is complete (after the 9 month survey and measures), usual care patients are eligible to receive limited consultations with a health coach (See <http://cepc.ucsf.edu> for form and instructions).

- After a usual care patient completes their 9 month survey, RAs may offer the patient a chance to consult with a health coach on a “one-time basis.” All usual care patients are eligible for this service.
- Usual care consultations will be provided as time allows for the health coaches.. In the event of a special situation that appears to be urgent, the RAs may ask the coaches about their availability to do the consultation at an earlier date.
- The “usual care consultation” may include the following:
 - Up to two interactions between the health coach and the patient, including one in person meeting
 - A consultation between the health coach and pulmonary Advanced Nurse Practitioner (ANP) regarding medications and other care plan strategies & communication back to the provider in the event of recommendations
 - Depending on the patient’s need, the consultation may include activities such as medication reconciliation, review of inhaler use, reviewing the COPD action plan, and connecting the patient to resources

Appendix A: Chart review - information and sources

The following information will be abstracted from medical records.

Information	Used to determine eligibility (severity marker)	Baseline	9 months	Pulmonologist review
Pulmonary function tests	X	X		X
Arterial blood gas -- PO2 (PPO2/ABG)≤55 mg Hg	X			X
Pulse oximeter - O2 Sat	X			X
Use of Home oxygen	X			X
Diagnoses (COPD, chronic bronchitis, emphysema, chronic airway obstruction)		X	X	
Co-morbidities (Coronary artery disease, heart failure, diabetes, asthma, obstructive sleep apnea, pulmonary hypertension, tobacco use, schizophrenia, schizo-affective disorder, bipolar, alcohol abuse, opioid abuse, sedative abuse, cocaine abuse, other stimulant abuse, hallucinogen abuse, other drug abuse)		X		
Prescribed inhalers	Prescription for anticholinergic or combination medication indicative of moderate severity	X	X	X
Past medications - short term oral steroids	X	X	X	X
Past visits to pulmonary/ chest clinic	X	X	X	X
CT scan				X
Chest radiographs				X
Other PFT tests (e.g., DLCO)				X
Prescribed smoking cessation medications		X	X	
Insurance status		X		

Appendix B: Recruitment script

[Note: This is the script that the research assistant will use to screen potential subjects who have been recommended by their providers and identified as potentially eligible for the study. The purpose of this screening is to determine if the patient is interested in participating in the AIR Health Coach Study. Patients who decline to talk or those who are ineligible will be thanked for their time.]

Hello. My name is __ [study team member] ____, and I am a researcher calling from UCSF and (name of clinic). I am calling you to let you know about a research study we are doing about whether health coaching would help people with lung conditions, such as COPD. **I received your information from your provider at (your clinic) and they thought you might be interested.** Is this something that you might be interested in? *[If yes, proceed]*

As I mentioned before, the purpose of this study is to find out if a health coach can help people with lung conditions, like COPD, better manage their condition. I would like to ask you a few questions to see if you might be eligible in the study, and then if you are interested in participating in this study, I will talk to you about the next steps. Is that OK? *[If yes, proceed]*

1. As far as you know, do you plan to continue to come to your clinic in the next 9 months?
 Yes
 No → **INELIGIBLE**
2. Do you plan to be out of town for more than 2 months in the next year?
 Yes → If so, do you know when?: _____
 No
3. How old are you? *[Check against anticipated age; if it does not match, check birthdate to make sure you have the right person]*
 40 years of age or younger → **INELIGIBLE**
 At least 40 years of age
4. Is this the best number to reach you at in the future?
 Yes
 No → If not, is there another number where we can reach you at in the future?: _____
5. Do you have a lung condition such as Chronic Obstructive Pulmonary Disease, or COPD?
 Yes
 No → **INELIGIBLE**

*If any of the response above are marked as "ineligible," then the patient is ineligible. You can **terminate** the call by saying: From the answers that you gave me, it sounds as if you are not eligible to take part in*

this study. Thank you for taking the time to talk with me. Do you have any questions for me before I let you go?

If individual is eligible based on responses above, then assess interest (below).

Great! It sounds like you may be eligible to take part in this study. Let me tell you a little more about it to see if you are interested in participating.

This is a research study. We want to understand if having a health coach can help people improve their COPD. A health coach is someone that works with your doctor or nurse when you come for an appointment. They would meet with you before your visit, stay with you during your visit, and meet with you afterward to make sure you understand what to do next. They will also call you at least once a month. A health coach might do things like help you better understand your COPD, help you achieve your health goals, or to make sure you know how to take your medicines.

If you choose to take part in this study, you will have a 50-50 chance of receiving a health coach for the next 9 months. The other 50% of the patients who participate will continue to receive their usual care.

Would you like to participate in this study and possibly receive a health coach for the next 9 months?

Yes

No → **INELIGIBLE**

If you participate in this study, you will be asked to complete a survey about your health habits, your health, and your visits with your doctor or nurse. You will take this survey when you begin to take part in the study and then again at 9 months. I will also be calling you at 3 months and 6 months to ask you some follow up questions. Each time you take the survey or answer the questions, you will receive \$10. In addition you will be asked to do a breathing test to test your lungs and to do a walking test at the beginning of the study and after 9 months. Each time you do these tests, you will receive an additional \$20.

6. Are you willing to take four surveys in total about your health and to take part in the lung test?

Yes

No → **INELIGIBLE**

*If the person is **NOT** interested in participation (response of “no” to either of the questions above), you can **terminate** the call by saying: From the answers that you gave me, it sounds as if you are not interested in taking part in this study. That is okay, and I want to be sure that you know that you can continue to go the San Francisco General Hospital General Medicine Clinic and Family Health Center/ Southeast Health Center/ Mission Neighborhood Health Center/Silver Avenue Family Health Center/Maxine Hall Health Center/Castro Mission Health Center just like you did before. Thank you for taking the time to talk with me. Do you have any questions for me before I let you go?*

*If individual **IS** interested in participating in the study, you can continue: Thank you! From the answers you gave me, it sounds like you are interested in taking part in this study and you are probably eligible. That’s great! Let me tell you a little more about the next steps.*

In order to find out if you are eligible for this study, we will need to measure your lungs using that lung test I told you about – spirometry. This will not only enable you to take part in the study, but it will also help your provider better take care of your medical needs.

7. Have you ever had a spirometry test done before?
 - Yes → If yes, do you remember when or where: _____
 - No
8. (If yes) Would you happen to have the results?
 - Yes → Great! Do you think that you could bring them with you when we meet?
 - No → To save you some time, would you be okay with allowing us to access these results? This would require that you sign a medical release form giving the facility your permission to let us see the results.

I'd like to set up a time for you to come into the clinic to take the survey and make sure we have everything we need to get you enrolled in the study. This meeting would take about two hours. Remember that I will pay you \$10 to take part in the breathing test, \$10 for the survey, and \$10 for the walking test. If you are assigned a health coach, I can introduce you to your health coach at that time.

When you come in to meet with me, be sure to bring your COPD/breathing medications (including your inhalers) or a list of your medications and how you take them. Additionally, since we will be doing the 6 minute walk test, make sure that you wear comfortable shoes and clothing.

I will call the day before to remind you about your appointment. Is this the best number to reach you or to leave a message for you?

If you need to reach me, you can call: _____

General supplies

- BP monitor + large cuff
- Scale
- Tape measure
- Cones x 2
- Oximeter
- Stopwatch

For Spirometry

- Vyntus equipment
- Syringe
- Mouthpieces
- Filters
- Noseclips
- Placebo meds

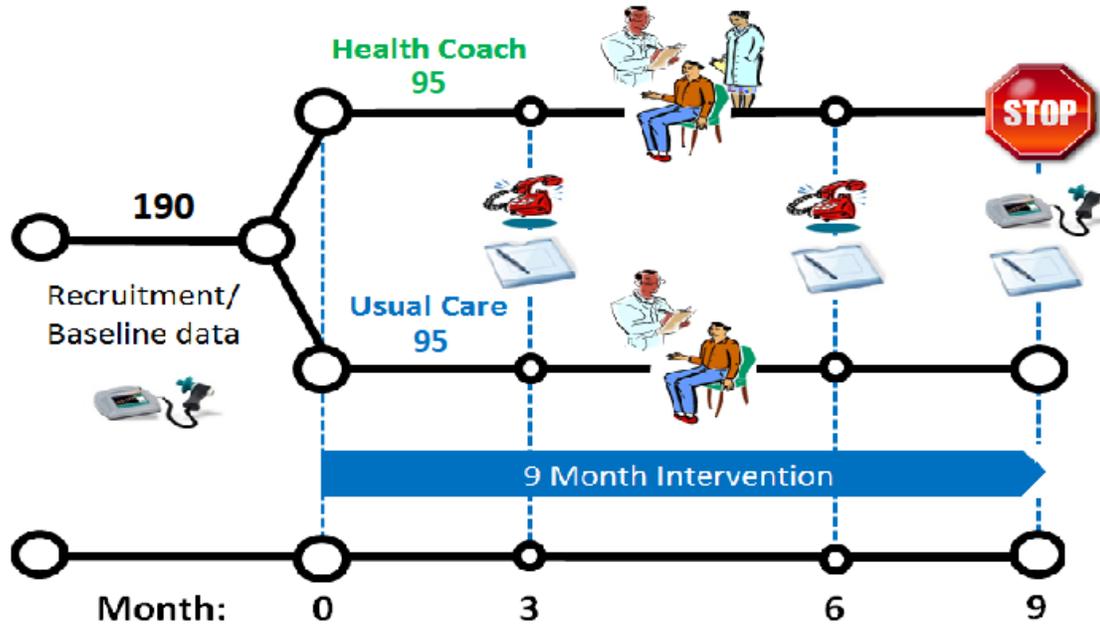
Forms

- Consent packets + randomizations cards
- Hard copies survey
- Flashcards
- Money and signature forms
- Blank enrollment forms
- Health coach cards and photos
- Card with info on BP, 6MWT

Other supplies

- Clear tape
- Batteries (AA)
- Batteries (AAA)

Aides in Respiration (AIR) Health Coach Study



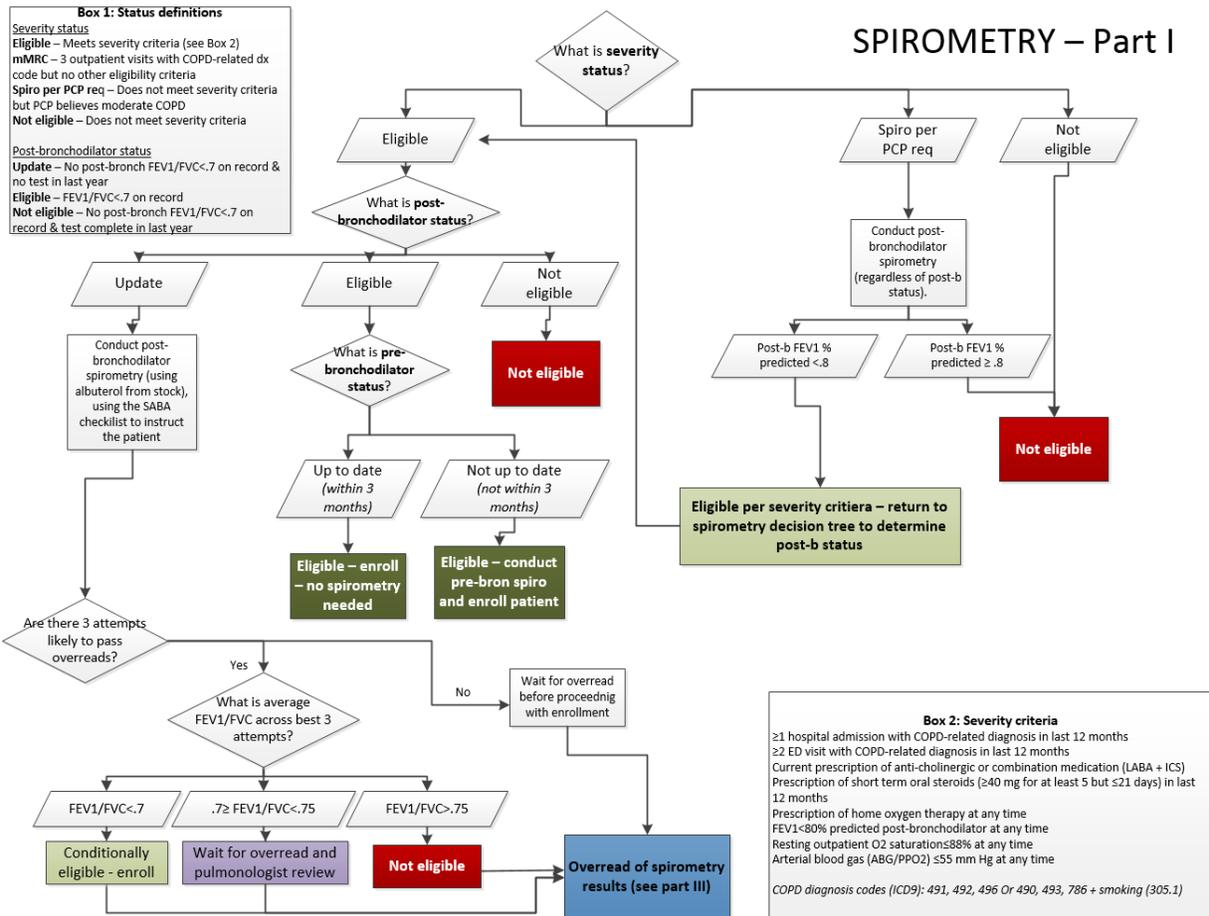
Study Investigators: David Thom, George Su, Stephanie Tsao, Danielle Hessler

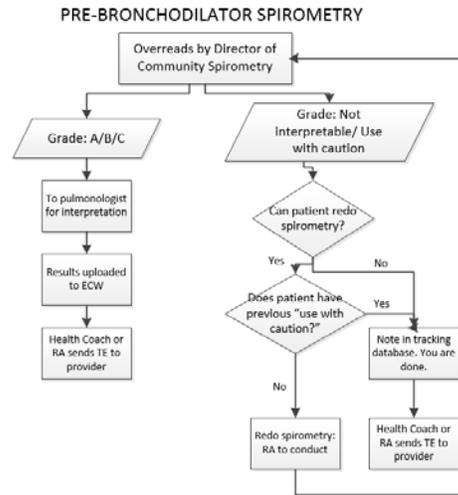
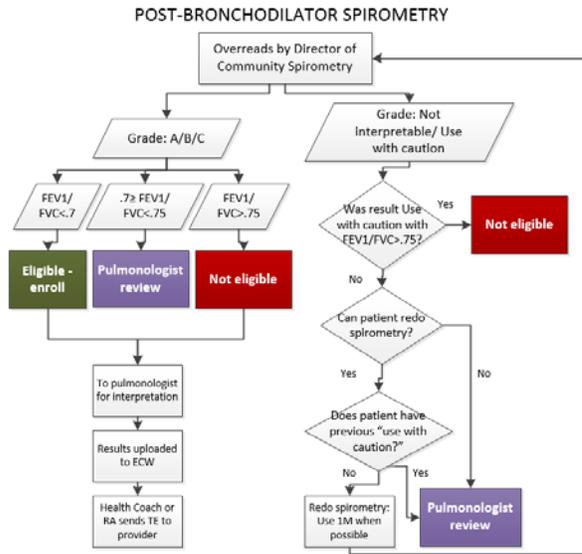
Time period: September 2014 → December 2016

Sites: Maxine Hall Health Center, Silver Avenue Family Health Center, Southeast Health Center, General Medicine Clinic, Family Health Center, Potrero Hill Health Center, Castro Mission Health Center



Appendix E: Spirometry workflow





Enrollment form

Background information

MRN	Name	DOB	Age									
Language	Gender	PCC	PCP									
Status Post-B Spirometry Severity Pre-B Spirometry <input type="checkbox"/> Flag Alert PCP (No dx)		Past spirometry results <table border="1"> <thead> <tr> <th>Date</th> <th>Pre-bronch</th> <th>Post-bronch</th> </tr> </thead> <tbody> <tr> <td></td> <td>FEV1/FVC FEV1 % predicted</td> <td></td> </tr> <tr> <td></td> <td>FEV1/FVC FEV1 % predicted</td> <td></td> </tr> </tbody> </table>		Date	Pre-bronch	Post-bronch		FEV1/FVC FEV1 % predicted			FEV1/FVC FEV1 % predicted	
Date	Pre-bronch	Post-bronch										
	FEV1/FVC FEV1 % predicted											
	FEV1/FVC FEV1 % predicted											

Clinical measures at baseline

Spiro date: Time:

1. Height: _____ ft _____ inches

2. Weight: _____

3. Gender Female Male Other: _____

4. Inhalers used today? No Yes

Inhaler name: _____ Time used: _____

5. What race do you most identify with?
 Asian White/caucasian
 Black/African America Pacific islander
 Native American Other: _____

6. Are you of Latino/Hispanic ethnicity?
 Yes No

Smoking history

1. Have you smoked more than 100 cigarettes in your life? No-->Stop Yes

1a. At what age did you start smoking? _____

2. Have you smoked a cigarette, even a puff, in the last 30 days? Yes--> 2b. How about how: how many packs a day have you smoking in the past week? _____ No--> 2a. At what age did you stop smoking? _____

Screen for contraindications

A. Have you had a heart attack in the last month? Yes --> DO NOT DO 6MWT OR SPIR No

B. When you walk, do you get chest pains? Yes --> DO NOT DO 6MWT No

C. Have you had surgery in last month? Yes --> DO NOT DO SPIROMETRY IF ON EYE OR TORSO No

D. Do you have a bad cold? Yes --> PROBE No

E. Do you faint if you breathe out hard? Yes --> PROBE No

Pack years calculation

_____ yrs smoking cigarettes

X _____ avg packs/day

_____ PACK YEARS

[CALCULATE - years from start to stop = _____ yrs

2c. Between [age started] and [aged stopped], there are _____ yrs. How many of those years did you smoke? _____

2d. On average during the periods you smoked, how many packs a day did you smoke? _____

Ask for everyone with smoking history!

Blood pressure: _____ / _____

Cuff # _____

Arm for BP: _____

Heart rate: _____

O2 saturation: _____

Enrollment form

6 Minutes Walk Test

1. Location of test: _____
2. Inhaler used w/i 30 minutes of test?
 No
 Yes --> Inhaler name: _____ Time used: _____
3. Supplemental oxygen used during test?
 No
 Yes --> Flow: _____ lpm
4. Have you smoked in the last hour? No Yes
5. Have you eaten a large meal in the last two hours? No Yes
6. Have you consumed alcohol in the last 4 hours? No Yes

REMINDER: Do NOT conduct the 6MWT if contraindicated (questions above) OR if any of the following conditions apply:

- Pulse \geq 120
- SBP \geq 200
- DPB \geq 110
- O2 sat (at rest) $<$ 92% *
- Patient shows signs of distress (e.g., gasping for air)

* If $>$ 88% and nurse examines patient, okay to proceed with

PRE-TEST	POST-TEST
Time: _____	Time: _____
Blood pressure: _____ / _____	Blood pressure: _____ / _____
Cuff # _____	
Arm for BP: _____	
Heart rate: _____	Heart rate: _____
O2 saturation: _____	O2 saturation: _____

Lap counter: cross out each lap completed. A lap is 30 meters - to the end of the hall and back.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

9. Rescue inhaler used during test? No Yes
10. Was test completed? No Yes
 Explain in comments below
11. Total distance walked in 6 minutes: _____ laps x 30 meters/lap = _____
 + _____ meters on last lap
 Enter this --> = TOTAL METERS
12. Did the patient experience any pain or discomfort during test?
 No
 Yes --> Explain: _____
13. Comments: _____

 RA signature: _____

Study ID: _____

Study arm: Health coach

Usual care

Appendix G: SABA administration checklist

RA: _____

Observer: _____

Date: _____

Preparation & Greeting	
<input type="checkbox"/>	RA has new albuterol canister
<input type="checkbox"/>	RA has cardboard spacer
<input type="checkbox"/>	RA determines if patient has own albuterol with a dose counter <ul style="list-style-type: none"> <input type="checkbox"/> Patient does not have albuterol <input type="checkbox"/> Patient has albuterol with dose counter → RA instructs patient to use own albuterol <input type="checkbox"/> Patient has albuterol, but no dose counter → If it is not, RA provides new albuterol canister
<input type="checkbox"/>	RA determines if patient has spacer <ul style="list-style-type: none"> <input type="checkbox"/> If patient does, RA instructs patient to use own spacer <input type="checkbox"/> If not, RA provides cardboard spacer
Talk through for MDI	
<input type="checkbox"/>	RA asks patient to describe how they take their inhaler (but NOT to take a dose)
<input type="checkbox"/>	RA uses checklist to record observations
Instructions on Albuterol administration	
<input type="checkbox"/>	RA asks patient to shake albuterol 10 times
<input type="checkbox"/>	RA asks patient to attach albuterol to spacer
<input type="checkbox"/>	RA describes and demonstrates following steps <ul style="list-style-type: none"> <input type="checkbox"/> Sitting up straight <input type="checkbox"/> Breathing out fully <input type="checkbox"/> Making a tight seal around the spacer with lips <input type="checkbox"/> Breathing in slowly for 3-5 counts <input type="checkbox"/> Holding breath for 10 seconds (or as close as possible) <input type="checkbox"/> Breathing out
<input type="checkbox"/>	RA asks patient to breathe out fully
<input type="checkbox"/>	RA asks patient to place spacer in mouth
<input type="checkbox"/>	RA asks patient to press down on inhaler as they breathe in slowly
<input type="checkbox"/>	RA counts for periods of inhale (3-5 seconds) and breath hold (10 seconds)
<input type="checkbox"/>	RA ensures that patient takes 4 doses, 1 minute apart
<input type="checkbox"/>	RA times patient for 20 minutes
<input type="checkbox"/>	RA conducts spirometry at 20 minutes

Signature

Date

Appendix H: Pulmonologist Review Checklist

RA Use
DD BH

Filled out by RA (circle one):

Patient information (RA fills out as much as known)		Date:	
MRN		Reason(s) flagged	
Name		ED/Hosp visits with major dx (12 M)	
DOB		Oxygen – Home O2, PO2<55%, O2 sat<88% (ever)	
Age		FEV1<80% pred (ever)	
Pack years		Anti-chol or combo med (current)	
Current meds (name only)		Oral steroid burst (12M)	
		3 outpt visits – major Dx (12 M)	
Tests available (print results for ALL tests listed)			
Test	Available?	ALL Dates of testing	
		Date	Location
		Grade?	Post-b FEV1/FVC?
Spirometry	<input type="checkbox"/> Yes <input type="checkbox"/> No	<i>George would like to see reports with all curves. For VMax, can print it out as a report. For Vyntus, will need to show curves on the computer. For “use with caution” results, George would like to see the error codes.</i>	
Other PFT results (e.g., diffusion capacity)	<input type="checkbox"/> Yes <input type="checkbox"/> No		
CT Scan of chest	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Chest x-ray	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Progress notes (print progress notes available – looking for recent reports with good description of symptoms and history. Preference for chest clinic if available.)			
Clinic	Available?	ALL Dates of testing/Notes	
Chest clinic provider	<input type="checkbox"/> Yes <input type="checkbox"/> No		
PCP	<input type="checkbox"/> Yes <input type="checkbox"/> No		

Appendix I – Survey questions

Timing of survey item administration

	BL	3	6	9
Self-rated health	X			X
Self-efficacy	X			X
SF-CRQ	X	X	X	X
Medication concordance	X			X
Inhaler demonstration	X			X
Morisky medication adherence	X			X
Rescue inhaler	X			X
COPD assessment test	X			X
Smoking status and history	X	X	X	X
Trust in physician	X			X
PACIC	X			X
Satisfaction with provider and clinic	X			X
PHQ	X			X
Generalized Anxiety Disorder scale (GAD)	X			X
COPD knowledge	X			X
Visits to the hospital and emergency room (ED, Hosp, UC, Exacerbations)	X	X	X	X
Bed days	X	X	X	X
Demographics	X			
Health literacy	X			
6MWT	X			X
Smoking cessation assistance				X
CPAP question				X

Study ID: _____

Date: _____

Interviewer: _____

Language: _____

COPD Health Coaching Primary Care Study
Patient Survey to be administered at baseline, 9 and 15 months
To be administered by research assistant in interview with study patients

Medical Conditions and Medications (MCMD)

1. Have you ever been told by a doctor or nurse practitioner that you have COPD?
₁ No
₂ Yes → **Skip to Q3**
₉ Do not know

2. Have you ever been told by a doctor or nurse practitioner that you have a chronic lung condition?
₁ No → **Not eligible for study**
₂ Yes
₃ Do not know → **Not eligible for study**

3. For how many years have you had this condition?
_____ years or _____ months (if < 1 year)
₉ Do not know

Self-rated health (SRH)

1. In general, would you say your health is. . .
₁ Excellent
₂ Very good
₃ Good
₄ Fair
₅ Poor

Self-efficacy (SE)

We would like to know how confident you are in doing certain activities related to caring for your **COPD/lung condition**. For each of the following questions, please choose the number that corresponds to your confidence that you can regularly do the tasks related to your condition. 1 means “not confident at all” and 10 means “totally confident.”

On a scale from 1 to 10, 1 being not confident at all and 10 being totally confident...

1. How confident are you that you can keep the **FATIGUE** caused by your COPD/lung condition from interfering with the things you want to do?

1 2 3 4 5 6 7 8 9 10

2. How confident are you that you can keep the **PHYSICAL DISCOMFORT OR PAIN** of your COPD/lung condition from interfering with the things you want to do?

1 2 3 4 5 6 7 8 9 10

3. How confident are you that you can keep the **EMOTIONAL DISTRESS** caused by your COPD/lung condition from interfering with the things you want to do?

1 2 3 4 5 6 7 8 9 10

4. How confident are you that you can keep **ANY OTHER SYMPTOMS OR HEALTH PROBLEMS** you have from interfering with the things you want to do?

1 2 3 4 5 6 7 8 9 10

5. How confident are you that you can do the different tasks and activities needed to manage your COPD/lung condition so as to **REDUCE YOUR NEED TO SEE A DOCTOR?**

1 2 3 4 5 6 7 8 9 10

6. How confident are you that you can do things **OTHER THAN JUST TAKING MEDICATION** to reduce how much your COPD/lung condition affects your everyday life?

1 2 3 4 5 6 7 8 9 10

Short-Form Chronic Respiratory Disease Questionnaire (SF-CRQ)

1. How much shortness of breath have you had during the last 4 weeks **WHILE WALKING ON A FLAT SURFACE?**

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
Extremely short of breath	Very short of breath	Quite a bit short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath

2. How much shortness of breath have you had during the last 4 weeks **WHILE SLEEPING?**

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
Extremely short of breath	Very short of breath	Quite a bit short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath

3. How often over the last 4 weeks have you felt **WORN OUT OR SLUGGISH?**

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

4. How much **ENERGY** have you had in the last 4 weeks?

<input type="checkbox"/> 1 No energy at all	<input type="checkbox"/> 2 A little energy	<input type="checkbox"/> 3 Some energy	<input type="checkbox"/> 4 Moderate energy	<input type="checkbox"/> 5 Quite of bit of energy	<input type="checkbox"/> 6 Very energetic	<input type="checkbox"/> 7 Full of energy
---	--	--	--	---	---	---

5. In general, how much of the time during the last 4 weeks have you felt **FRUSTRATED OR IMPATIENT?**

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

6. In general, how much of the time did you feel **UPSET, WORRIED, OR DEPRESSED** during the last 4 weeks?

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

7. How often during the last 4 weeks did you have a feeling of **FEAR OR PANIC** when you had difficulty getting your breath?

- | | | | | | | |
|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 |
| All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | Hardly any of the time | None of the time |

8. How often over the last 4 weeks did you feel you had **COMPLETE CONTROL** over your breathing problems?

- | | | | | | | |
|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 | <input type="checkbox"/> 6 | <input type="checkbox"/> 7 |
| None of the time | Hardly any of the time | A little of the time | Some of the time | A good bit of the time | Most of the time | All of the time |

Date complete: _____
***If no meds, put today's date.**

Medication concordance (MedConc)

[Review medications to check for medications for COPD, including steroids for COPD exacerbations, even if patient denies taking medications for these conditions]

Patient takes no medications for COPD (as verified by medication review) → **Skip to next section**

	Copy from Bottle	Copy from Bottle or ask patient how prescribed if directions not available		Ask patient: In the last 7 days, how many days did you		Ask patient: What happened in the other __ days?		Validated?	Every day or as needed?	Rx changed in last week?
		# pills per dose (N/A if inhaler)	# doses per day	... take this medication EXACTLY as prescribed?	... take NONE of this medication?	# days taken LESS than prescribed (doses or pills)	# days taken MORE than prescribed (doses or pills)			
1								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
2								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
3								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
4								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
5								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
6								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
7								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No
8								<input type="checkbox"/> Validated <input type="checkbox"/> Self-report	<input type="checkbox"/> Every day <input type="checkbox"/> As needed	<input type="checkbox"/> Yes <input type="checkbox"/> No

Rescue inhaler

1. Could you show me which of these is your **RESCUE INHALER** (the one you take when you are feeling short of breath)?

_____ (name of inhaler)

.₈ Patient does not report having a rescue inhaler → **Skip to next section**

.₉ Do not know → **Skip to next section**

2. In the past two weeks, on average, **HOW MANY TIMES A DAY** have you used your rescue inhaler?

._{0.5} Less than once a day

.₁ 1 time a day

.₂ 2 times a day

.₃ 3 times a day

.₄ 4 times a day

.₅ 5 times a day

.₆ 6 times a day

.₇ 7 times a day

.₈ 8 times a day

.₉ 9 times a day

.₁₀ 10 times a day

.₁₁ More than 10 times a day

.₋₉ Do not know

Demonstration of MDI inhaler technique (MDI)

1. **[RA: Does patient use metered dose inhaler? If not clear during medication concordance, show example and ask if they use an inhaler like that.]**

.₁ No → **SKIP to next section**

.₂ Yes

.₉ Do not know → **SKIP to next section**

2. What method do you most often use to take your inhaler?

.₁ Open mouth technique

.₂ Close mouth technique

.₃ Spacer

.₄ Other: _____

3. **[RA: Determine method used for demonstration. Usually this will be the method used most often, but if a patient uses a spacer but does not have it and also frequently uses another method, they may use that secondary method.]**

- ₁ Open mouth technique
- ₂ Close mouth technique
- ₃ Spacer

Checklist for MDI use	
4. Shake inhaler	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
5. [Spacer] Attach spacer	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes <input type="checkbox"/> ₈ Not applicable because NOT using spacer
6. Breathe out fully before firing	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
7. Inhaler upright during firing (w/i 30°)	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
8. One inhalation for one actuation	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
9. [Open mouth technique] Place mouthpiece before open mouth (aimed at mouth, with no blockage by tongue or teeth)	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes <input type="checkbox"/> ₈ Not applicable because using spacer or closed mouth technique
10. [Closed mouth technique or spacer] Close lips around mouthpiece to establish a good seal	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes <input type="checkbox"/> ₈ Not applicable because using open mouth technique
11. [Open or closed mouth technique] Actuation in the first half of inhalation	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes <input type="checkbox"/> ₈ Not applicable because using spacer
12. After actuation continue breathing in slowly and deeply for 3-5 seconds until total lung capacity	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
13. [Spacer] Slow breath does NOT cause spacer to whistle.	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
14. Hold breath for at least 4 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
15. Hold breath for at least 10 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
16. Breathe out away from device	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
17. Close mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes

18. **[RA: Did patient use simulated or real inhalation?]**

- ₁ Simulated inhalation (no actuation and/or breath through device)
- ₂ Real inhalation

Demonstration of handihaler technique

1. **[RA: Does patient use handihaler? If not clear during medication concordance, show example and ask if they use an inhaler like that.]**

- ₁ No -> **SKIP to next section**
- ₂ Yes
- ₉ Do not know -> **SKIP to next section**

Checklist for handihaler use	
2. Lift up mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
3. Remove capsule from blister and place in chamber	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
4. Turn mouthpiece to closed position	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
5. Holding inhaler upright, press green button inward on base of inhaler once and release to pierce the capsule	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
6. Breathe out away from the mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
7. Close lips around the mouthpiece to establish a good seal	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
8. Breathe in forcefully and deeply enough to make capsule rattle, until total lung capacity	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes <input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
9. Hold breath for at least 4 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
10. Hold breath for 10 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
11. Breathe out gently away from mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
12. Take a second breath	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
13. Open mouthpiece and remove pierced capsule, tipping it into the trash without touching it	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
14. Close mouthpiece cap	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes

15. **[RA: Did patient use simulated or real inhalations?]**

- ₁ Simulated inhalation (no real capsule and/or breath through device)
- ₂ Real inhalation

Demonstration of diskus inhaler technique

1. **[RA: Does patient use diskus? If not clear during medication concordance, show example and ask if they use an inhaler like that.]**

- ₁ No -> **SKIP to next section**
- ₂ Yes
- ₉ Do not know -> **SKIP to next section**

Checklist for diskus use	
2. Open using thumb grip	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
3. Holding horizontally device while loading (w/i 30°)	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
4. Load dose by sliding lever until it clicks	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
5. Breathe out away from the mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
6. Close lips around the mouthpiece to establish a good seal	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
7. Breathe in forcefully and deeply for 1–2 seconds until total lung capacity	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
8. Hold breath for at least 4 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
9. Hold breath for 10 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
10. Breathe out gently away from mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
11. Close cover until to click	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes

12. **[RA: Did patient use simulated or real inhalation?]**

- ₁ Simulated inhalation (no loading of medication and/or breath through device)
- ₂ Real inhalation

Demonstration of soft mist inhaler

1. [RA: Does patient use soft mist inhaler? If not clear during medication concordance, show example and ask if they use an inhaler like that.]

- ₁ No -> **SKIP to next section**
- ₂ Yes
- ₉ Do not know -> **SKIP to next section**

Checklist for soft mist inhaler use	
2. Hold inhaler upright (within 30 degrees)	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
3. Turn the clear base in the direction of the white arrows on the label until it clicks (half a turn)	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
4. Flip the orange cap until it snaps fully open	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
5. Breathe out away from the mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
6. Close lips around the mouthpiece to establish a good seal, without covering the air vents	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
7. Press the dose release button in the first half of the breath	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
8. Breathe in slowly and deeply for 3–5 seconds until total lung capacity	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
9. Hold breath for at least 4 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
10. Hold breath for 10 seconds	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
11. Breathe out gently away from mouthpiece	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes
12. Close cover until to click	<input type="checkbox"/> ₁ No <input type="checkbox"/> ₂ Yes

13. [RA: Did patient use simulated or real inhalation?]

- ₁ Simulated inhalation (no loading of medication and/or breath through device)
- ₂ Real inhalation

Medication Adherence (MedAd)

.8 Patient takes no medications for COPD (as verified by medication review) → **Skip to next section**

These questions ask you about medications you take for **COPD/Lung condition**. It can be difficult to take medicines every day, and we are interested in your experiences. There is no right or wrong answer.

	Yes	No
1. Do you sometimes forget to take your COPD/Lung condition medicines?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
2. Over the past two weeks, were there any days when you did not take your COPD/Lung condition medicine?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
3. Have you ever cut back or stopped taking your COPD/Lung condition medication without telling your doctor because you felt worse when you took it?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
4. When you travel or leave home, do you sometimes forget to bring along your COPD/Lung condition medications?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
5. Did you take your COPD/Lung condition medicine yesterday?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
6. When you feel like your COPD/Lung condition is under control, do you sometimes stop taking your medicine	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your COPD/Lung condition treatment plan?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
8. How often do you have difficulty remembering to take all your COPD/Lung condition medication?		
__ A. Never/rarely - code as no (2)		
__ B. Once in a while – code as yes (1)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
__ C. Sometimes– code as yes (1)		
__ D. Usually– code as yes (1)		
__ E. All the time– code as yes (1)		

COPD Assessment Test (CAT)

For each question, select the number that best describes how you feel.

1	I never cough	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	I cough all the time
2	I have no phlegm (mucus) in my chest at all	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	my chest is completely full of phlegm (mucus)
3	My chest does not feel tight at all	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	My chest feels very tight
4	When I walk up a hill or one flight of stairs I am not breathless	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	When I walk up a hill or one flight of stairs I am very breathless
5	I am not limited doing any activities at home	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	I am very limited doing activities at home
6	I am confident leaving my home despite my lung condition	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	I am not at all confident leaving my home because of my lung condition
7	I sleep soundly	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	I don't sleep soundly because of my lung condition
8	I have lots of energy	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	I have no energy at all

Primary Care Provider

1. Do you have a primary care provider?

(Define if needed: A primary care provider is a doctor, nurse practitioner, or physician's assistant at the clinic who you usually see if you need a check-up, want advice about a health problem, or get sick or hurt.)

₁ No => What is the name of the last physician, nurse practitioner or physicians' assistant you saw at the clinic 2. _____

₂ Yes => What is the this person's name? 2. _____

₃ Do not know => What is the name of the last physician, nurse practitioner or physicians' assistant you saw at the clinic 2. _____

Trust in Physician (TIP)

[Note to RA: many patients refer to their primary care provider as their doctor, regardless of whether they are a physician, nurse practitioner or physicians' assistant. In that case, simply use the term doctor without distinguishing their professional title.]

The following questions ask about [name of PCP or last provider saw from previous question]

Please indicate how much you agree or disagree with each of the following statements.

	Totally disagree	Disagree	Neutral	Agree	Totally agree
1. I think that my provider/doctor really cares about me as a person.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
2. My provider/doctor is usually considerate of my needs and puts them first.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
3. I trust my provider/doctor so much that I always try to follow his/her advice.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
4. If my provider/doctor tells me something is so, then it must be true.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
5. ^R I sometimes distrust my provider/doctor's opinions and would like a second one.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
6. I trust my provider/doctor's judgments about my medical care.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
7. ^R I feel my provider/doctor does not do everything he/she should about my medical care.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

	Totally disagree	Disagree	Neutral	Agree	Totally agree
--	------------------	----------	---------	-------	---------------

- | | | | | | |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| 8. I trust my provider/doctor to put my medical needs above all other considerations when treating my medical problems. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 9. My provider/doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 10. I trust my provider/doctor to tell me if a mistake was made about my treatment. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| 11. ^R I sometimes worry that my provider/doctor may not keep the information we discuss totally private. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |

"R" indicates items to be reverse coded.

Health Care Team Support (PACIC)

Staying healthy can be difficult when you have a chronic condition. We would like to learn about the type of help with your COPD/Lung condition you get from your health care team. This might include your regular doctor, your lung specialist, clinic nurse, medical assistant, nutritionist or health coach. Your answers will be kept confidential and will not be shared with your physician or clinic.

Over the past 6 months, when you received care for COPD/Lung condition, how often were you...

	None (1)	A Little of the time (2)	Some of the time (3)	Most of the time (4)	Always (5)	Not applicable (-8)
2. Given choices about treatment to think about.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
5. Satisfied that your care was well organized.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
8. Helped to set specific goals to improve your eating or exercise.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
9. Given a copy of your treatment plan.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
10. Encouraged to go to a specific group or class to help you cope with your chronic condition.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
11. Asked questions, either directly or on a survey, about your health habits.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
13. Helped to make a treatment plan that you could carry out in your daily life.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
14. Helped to plan ahead so you could take care of your condition even in hard times.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
15. Asked how your chronic condition affects your life.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
16. Contacted after a visit to see how things were going.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	
19. Told how your visits with other types of doctors, like an eye doctor or surgeon, helped your treatment.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₋₈

Satisfaction with provider and clinic (SPC)

1. How likely are to recommend **YOUR DOCTOR** to your friend or relative?

- ₁ Definitely not
- ₂ Probably not
- ₃ Not sure
- ₄ Probably would
- ₅ Definitely would

2. How likely would you recommend **YOUR CLINIC** to your friend or relative?

- ₁ Definitely not
- ₂ Probably not
- ₃ Not sure
- ₄ Probably would
- ₅ Definitely would

PHQ-8 (PHQ)

I would like to ask you questions about your mood and mood changes over the **last 2 weeks**. I will read a statement and ask you how much what I just read bothers you. For example, if you feel that a particular item has not been a bother or a problem for you, answer “Not at all”. If it has been bothersome to you nearly every day, you might answer “Nearly every day.”

	Not at all (0)	Several days (1)	More than half the days (2)	Nearly every day (3)
1. Little interest or pleasure in doing things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
2. Feeling down, depressed, or hopeless	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
3. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
4. Feeling tired or having little energy	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
5. Poor appetite or overeating	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
7. Trouble concentrating on things, such as reading the newspaper, watching television	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

Generalized Anxiety Disorder scale (GAD)

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all sure (0)	Several days (1)	Over half the days (2)	Nearly every day (3)
1. Feeling nervous, anxious, or on edge	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
2. Not being able to stop or control worrying	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
3. Worrying too much about different things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
4. Trouble relaxing	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
5. Being so restless that it's hard to sit still	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
6. Becoming easily annoyed or irritable	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
7. Feeling afraid that something awful might happen	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

COPD knowledge (KN)

We would like to ask you a few questions to learn what you know about your COPD/lung condition. For each of the following questions, please tell us if you think it is true or false.

1. It is okay to get short of breath when you exercise, as long as the feeling goes away within a minute or two of stopping the exercise?
 - ₁ False
 - ₂ True

2. Once you have COPD/a lung condition, there is really no benefit to stopping smoking.
 - ₁ False
 - ₂ True

3. It's not a good idea to be on oxygen for a long period of time because you can become addicted to it.
 - ₁ False
 - ₂ True

4. Smoking can help your breathing if you have COPD/a lung condition.
 - ₁ False
 - ₂ True

What would you be most likely to do if you had each of the following symptoms?

5. Shortness of breath when sitting that lasts for more than 5 minutes.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____
6. Having a runny nose.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____
7. Fever or shaking chills.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____
8. Feeling confused and very drowsy.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____
9. Coughing up yellow or green mucus.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____
10. Using your quick relief inhaler more than usual.	<input type="checkbox"/> ₁ Go to my doctor	<input type="checkbox"/> ₂ Go to the ER, urgent care, or hospital	<input type="checkbox"/> ₃ Take care of it myself	<input type="checkbox"/> ₄ Other: _____

Emergency Department visits (ED)

How many times have you visited the emergency room for a problem in the past 6 months? _____ times → **If zero, skip to next section**

FOR NON-SFGH VISITS ONLY, NOTE:

Which emergency room did you go to?	What was the primary reason that you went?	What was the approximate date of the visit?

Hospital visits

How many times have you been hospitalized for a problem in the past 6 months? _____ times → **If zero, skip to next section**

FOR NON-SFGH VISITS ONLY, NOTE:

Which hospital did you go to?	What was the primary reason that you went?	What was the approximate date of the visit?

Urgent care visits

How many times have you visited urgent care for a problem in the past 6 months? _____ times → **If zero, skip to next section**

FOR NON-SFGH VISITS ONLY, NOTE:

Which urgent care did you go to?	What was the primary reason that you went?	What was the approximate date of the visit?

Exacerbations

1. In the **last 6 months**, how many times have you **been prescribed oral steroids** because your breathing got worse? _____

Bed Days (BD)

1. During the **past 4 weeks**, how many days did health problems keep you in bed for all or most of the day? _____ days
2. During the **past 4 weeks**, how many days did you cut down on your activities because of health problems? _____ days

Demographics (DEM)

1. What is your primary language?

- ₁ English
- ₂ Spanish
- ₃ Other: _____

2. Were you born in the U.S.

- ₁ No -> in total, how many years have you lived in the U.S.? ____ years
- ₂ Yes

3. Are you currently married or in a long-term relationship?

- ₁ No
- ₂ Yes

4. Do you live alone?

- ₁ No
- ₂ Yes

5. Is there someone who helps you with your COPD or lung condition?

- ₁ No
- ₂ Yes

6. What is the highest level of school that you have completed?

- ₁ Never went to school
- ₂ Between 1st and 5th grade
- ₃ Between 6th and 8th grade
- ₄ Some high school
- ₅ High school graduate or "GED"
- ₆ Some college
- ₇ College graduate

7. Which of the following best describes your current working status?

- ₁ Working full time for pay (more than 30 hours per week)
- ₂ Working part time for pay (less than 30 hours per week)
- ₃ Homemaker
- ₄ Unemployed
- ₅ Retired
- ₆ Other _____

8. Which of the following categories best describes your total annual household income? (Please remember, this survey is confidential).

- ₁ Less than \$5,000 per year
- ₂ More than \$5,000 per year but less than \$10,000 per year
- ₃ More than \$10,000 per year but less than \$20,000 per year
- ₄ More than \$20,000 per year but less \$40,000 per year
- ₅ More than \$40,000 per year

8a. How many people are supported on this income? ____

Other Measures (OM)

1. How long have you been coming to your clinic for your care? ____ years or ____ months (if less than 1 year)

2. In the past 6 months, have you received information about COPD/Lung condition through any of these sources?

a. COPD class like Better Breathers	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
b. Friends or family	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
c. Internet	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
d. COPD/Lung specialist, like a doctor, nurse, or respiratory therapist	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
e. Pulmonary rehabilitation	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
f. Other : _____	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes

3. Do you use oxygen at home?

- ₁ No → **Skip to Q4**
- ₂ Yes

3a. When do you use oxygen at home? (select all that apply)

- ₁ When sleeping
- ₂ When awake

4. Do you use oxygen when you leave home?

- ₁ No
- ₂ Yes, sometimes
- ₃ Yes, almost all the time or all the time

5. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?
- ₀ None of the time
 - ₁ A little of the time
 - ₂ Some of the time
 - ₃ Most of the time
 - ₄ All of the time
7. Do you have internet access **at home**?
- ₁ No
 - ₂ Yes
8. Do you have **text messaging** on your phone?
- ₁ No
 - ₂ Yes
9. Do you have internet access **outside your home**?
- ₁ No
 - ₂ Yes
10. Do you use CPAP at home all or most of the time at night?
- ₁ No
 - ₂ Yes
11. **Since you were enrolled in the study** (about the past 9 months), have you been offered any help to stop smoking?
- ₁ I have not smoked in the past 9 months
 - ₂ I have smoked in the past 9 months but have not received any help to stop smoking
 - ₃ Yes ---- If so, which of these resources?

a. Been referred to a quit smoking class	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
b. Been referred to a quit line	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
c. Received medications to help you stop smoking, such as a pill or nicotine patch, gum, or lozenges	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
d. Received counseling on stopping smoking	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes
e. Other : _____	<input type="checkbox"/> ₁ No	<input type="checkbox"/> ₂ Yes

9 Month survey for Intervention arm

For each of the following statements, please choose the number that corresponds to how much you agree with the statement. 1 means “Completely agree” and 4 (or 5) means “Completely disagree.”

Trust in Health Coaches

	Totally disagree	Disagree	Neutral	Agree	Totally agree
1. I can tell my health coach anything, even things that I might not tell anyone else.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2. My health coach pretends to know things when s/he is not really sure	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3. My health coach cares as much as I do about my health	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4. I doubt that my health coach really cares about me as a person.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
5. I trust my health coach so much I always try to follow his/her advice	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6. If my health coach tells me something is so, then it must be true	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
7. I sometimes distrust my health coach’s advice	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
8. I feel my health coach does not do everything he/she can do for me	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
9. I sometimes worry that my health coach may not keep the information we discuss totally private.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
10. My health coach listens well so he/she understands my concerns	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
11. My health coach is considerate of my needs and puts them first	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
12. All things considered, how much do you trust your health coach? Not at all <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 Completely					

Interactions with Health Coaches

	Never (1)	Sometimes (2)	Usually (3)	Always (4)
1. Are you able to contact your health coach when you need to?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
2. Has your health coach adjusted his or her ways of doing things to be helpful in meeting your changing needs?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
3. Has your health coach asked what would be helpful to you in managing your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
4. Has your health coach helped you set specific goals to manage your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
5. Has your health coach helped you learn skills or improve your skills to achieve your goals?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
6. Has your health coach helped you solve problems that arise in managing your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
7. Has your health coach helped you figure out how to deal with stress?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
8. Has your health coach provided support that built your confidence to manage your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
9. Has your health coach helped you get support from your family?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
10. Has your health coach helped you get support from your friends?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
11. Has your health coach helped you get support from others besides your family and friends?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
12. Has your health coach encouraged you to get regular care for your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
13. Has your health coach helped you get the care you need from doctors and nurses?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
14. Has your health coach helped you find other resources in your community to help you take care of your health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
15. Has your health coach helped you communicate	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

	Never (1)	Sometimes (2)	Usually (3)	Always (4)
with your doctor or nurse about your health conditions?				
16. Has your health coach helped you get lab tests done?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
17. Has your health coach helped you understand your lab results?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
18. Has your health coach helped you solve problems in getting your medicines from the pharmacy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
19. Has your health coach helped you understand how to take your medicines the way they were prescribed?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
20. Has your health coach helped you to prepare for your visits with your doctor through reminders about appointments, bringing your medicines to clinic or helping you to remember what you want to talk about in your visit?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

Medication Concordance

Medication concordance is the process of reviewing the medication that a patient knows they have been prescribed in order to determine if they are taking the medication as indicated.

Which medications are we interested in?

Include	Do not include
Any kind of inhaler Nebulizer treatments If in doubt, include the medication; we can remove it later if needed.	Medication for allergies (e.g., Singulair, Flonase) Antibiotics Over the counter remedies (e.g., Vapor rub) Oxygen Medications that the patient thinks are for COPD, but that we know are not

* at least 40 mg for at least 5 days but <21 days

Acquiring inhalers or medication list

If screening over the phone, near the end of the call when you are scheduling the appointment, ask the patient to please bring their current inhalers and other COPD medications with them. Tell them that if they cannot easily bring their medications for any reason to please write down on a piece of paper the name of the medication. Tell patient if they are unsure what a medication is for to bring it to the appointment

If a patient does not have their inhalers with him/her at the time of the survey:

- Ask patient if they have a list of their medication written that they carry with them
- And/or ask if they can tell you (verbally) the names and doses of the medication. The RA may use the inhaler guide as a tool if patients recognize their inhalers. If they have the information memorized or written down, continue to go through the medication concordance process.
- If patient does not know medication or does not appear confident (hesitates), arrange a time to call them at home when they will have their medications. In this case do not complete medication concordance at the appointment, but wait to conduct over the telephone.
 - When you call, ask them to first locate all of their medications that they take for COPD (inhalers, discus, and pills). Then ask them to read or spell the name of the medication and the dosage.
 - Medication concordance must be completed within 30 days of the baseline survey.

Conducting medication concordance portion of survey

Take all of medications out and separate medications for COPD from other medications. Separate one (relevant) inhaler from the rest and place it in front of the patient. Record the name and strength.

- Say, “This is your [fill in name].”
- If dosing information is on the inhaler, record number of times/day that the inhaler is prescribed. Say to patient, “This says you take this inhaler XX times per day.”
- If a patient says that they are taking a medication every XX hours, use the following guide to record the dosing as times/day

	Times/day
Every 4 hours	4
Every 6 hours	3
Every 8 hours	3
Every 12 hours	2

Now you are going to ask the patient some questions to determine how often they took this medication in the past 7 days. Say to patient, “Sometimes it is hard for people to take their medications exactly as they were prescribed. I’m going to ask you some questions about your experiences. There are no right or wrong answers and I want to remind you that your answers are not shared with your doctor.”

- Ask patient, “In the past 7 days, how many days did you take this medicine EXACTLY as it was prescribed, meaning you took it XX times per day?” Record the number 0-7.
- Ask patient, “In the past 7 days, how many days did you take NONE of this medicine?” Record the number 0-7.
- **STOP to look at their responses to these two questions.**
 - Make sure that they do not add up to more than 7. If sum is more than 7, ask the patient to clarify.
 - If the sum of these two items adds up to 7, there is no need to ask any other questions about this medication. Fill in 0’s for the remaining columns and go on to the next medication.
 - If the sum of these two items adds up to less than 7, then proceed.

What does “the last seven days” mean?

The “last seven days” always ends yesterday. For example, on a Wednesday, the prompt would state, “Thinking about the last 7 days, that is, from last Wednesday through yesterday...”

- **Subtract the sum of these two items from the number 7 to find the number of remaining days.**
For example, if a patient said that took their medication exactly as directed 4 of the days and not at all 1 of the days, then that would be $7-4-1=2$. This is the number of remaining days that aren't "all" or "nothing." We are interested in knowing more about what happens on these remaining days. The last two columns ask you to have the patient think just about these remaining days (in our example, the 2 days).
- Say to patient, "Now I'd like you to think about the remaining (fill in e.g., 2) days last week. On those days, how did you take your medication?"
 - You will categorize their response into two columns – *number of days took more than prescribed* and *number of days took less than prescribed*.
 - You do not need to repeat the final numbers back to the patient (they are confusing – because they can add up to more than 7).
- Mark "validated" if you saw a bottle or a medication list. Mark "self-report" if the patient told you the dosage in person or over the phone. If the patient says something like, "I know the bottle says 2 times/day but my doctor told me to take it one time/day," then write down what the patient says and mark "self report."

How do I handle medications taken "as needed" (PRN)?

When a medication is taken as needed (e.g., rescue inhaler taken only when breathing is harder), record the maximum dosage that can be taken. For example, if rescue inhaler is taken "2 puffs, up to 4 times per day as needed," I would write "2" for *Number of pills or units* and "4" under *Number of times per day*.

The only other column that you need to fill out for "as needed" medications is for *more than prescribed*. You can skip the columns for *exactly as prescribed*, *none*, and *fewer than prescribed*.

Move that medication to your other side. Pull out a new medication and begin again. Repeat until you have covered all of the relevant medicines (those for COPD).

After you have talked about all of the medications, ask the patient if there are any other medications that they think might be for their breathing that they haven't brought with them today.

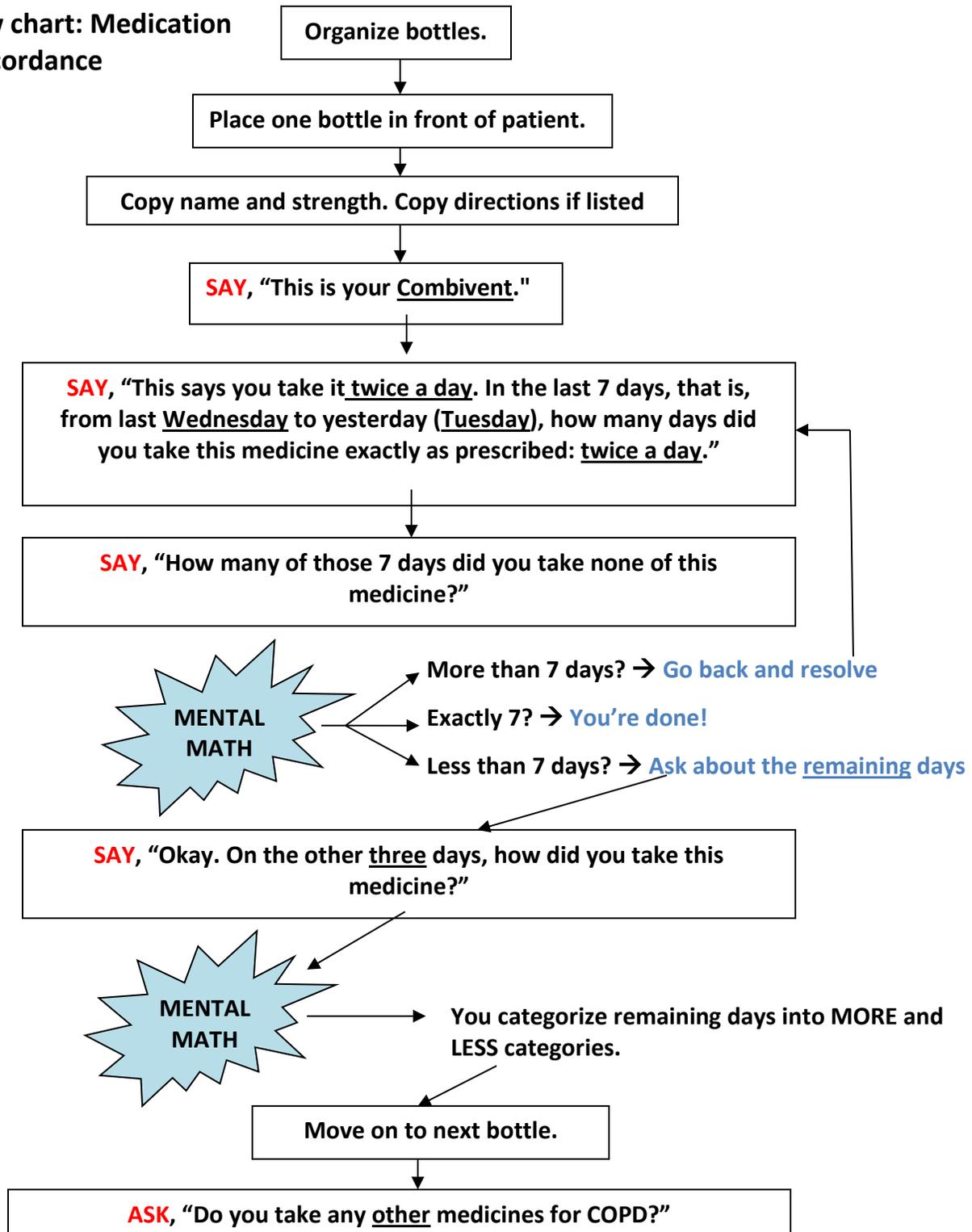
Common questions

- a. **The prescription has been taken for less than one week:** In the event that patients have been on meds for less than once a week, the RA will write down the name and dose but will not answer adherence questions. Mark off check-box for "new Rx."
- b. **What date should we list for medication concordance if patient only has some of medications?** Use the **Bulk of the information principle** when deciding what date to use for medication concordance: For example, if you get most of the medication concordance done but have a few outstanding questions that you need to call back to determine, use the date when MOST of the medication concordance was done.

- c. **You can't get all of the meds through follow-up calls?** Use **the one month rule**: At the end of one month after you complete the enrollment survey, finalize the survey, even if medication concordance is not complete. Any medication concordance information not collected within a month will be considered missing data.

- d. **The patient says something that you know is wrong?** Use **the confidence principle**: If a patient says, "I take aspirin 80 mg, once a day," write it down as a self-reported medication (aspirin, 80 mg), even if you just so happen to know that aspirin is always sold as 81mg or 325 mg. If the patient says, "I take aspirin. I can't remember how many mg. Maybe 20? 30?" then you could suggest that you call later when they can check their bottle. The bottom line: If they are sure, write it down just as they say it. If they are not sure, you can suggest a check-in later by phone.

Flow chart: Medication concordance



Observing inhaler technique

RAs will ask patients to show them how they use each of their inhaler types and will use standardized checklists to mark off whether patients conducted each of the defined actions. This may include metered dose inhalers, dry powdered inhalers, handi-halers, and/or respimats. The RA will ask the patient to bring their medications with them. If the patient is able to wait to take their controller medications until they meet with the RA, then the RA may ask them to demonstrate use of each device as they would routinely use it. If the patient has already taken their dose for the day, then patients may simulate a breath rather than taking a real breath.

If the patient does not bring in their inhalers, a sample inhaler may be used for the purpose of demonstration. If enough sample inhalers are available (that have never been used), then the patient may demonstrate using the sample and putting their mouth on it, taking a breath, etc. as they normally would. In this case, the sample should then be discarded after the visit. If extra samples are not available, the patient may use a placebo inhaler to demonstrate steps, but they should not put their mouth on the inhaler.

When a patient does a simulated demonstration of how they use their inhaler (eg. does not demonstrate actuation such as pressing down on MDI or turning soft mist inhaler), but if they state the step (e.g., “Then I would press the green button here”), mark it as “Yes.”

Health coach interaction questions (9 month survey)

The last section of the nine-month survey asks about the patient’s experience with their health coach (coaching arm only). If the patient had no contact or cannot remember contact with their health coach, then skip the rest of the questions.

Appendix K: Survey Sources

Section	Sources
Self-rated health	DeSalvo KB, Fisher WP, Tran K, Bloser N, Merrill W, Peabody J. Assessing Measurement Properties of Two Single-Item General Health Measures. <i>Qua Life Res</i> 2006;15:191-201
Self-efficacy	Adapted from: Lorig K, Ritter PL, Laurent DD, Plant K. Internet-Based Chronic Disease Self-Management A Randomized Trial. <i>Med Care</i> 2006;44: 964–971
SF-CRQ	Tsai C-L, Hodder RV, Page JH, Cydulka RK, Rowe BH, Camargo CA. The short-form chronic respiratory disease questionnaire was a valid, reliable, and responsive quality-of-life instrument in acute exacerbations of chronic obstructive pulmonary disease. <i>J Clin Epidem</i> 2008;489-9. Guyatt GH, Berman LB, Townsend M, Pugsley SO, Chambers LW. A measure of quality of life for clinical trials in chronic lung disease. <i>Thorax</i> 1987;42:773e8.
Medication concordance	Thom DH, Willard-Grace R, Hessler D, DeVore D, Prado C, Bodenheimer T, Chen E. The impact of health coaching on medication adherence in patients with poorly controlled diabetes, hypertension, and/or hyperlipidemia: A randomized controlled trial. <i>JABFM</i> 2015;28(1):38-45.
Inhaler demonstration	Melani AS, Canessa P, Coloretti I, DeAngelis G, DeTullio R, del Donno M. Inhaler mishandling is very common in patients with chronic airflow obstruction and long-term nebulizer use. <i>Resp Med</i> 2012;106:668–76.
Morisky medication adherence	Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. <i>J Clin Hypertens</i> 2008;10(5):348-54. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. <i>Med Care</i> . 1986;24(1):67-74.
Rescue inhaler	Developed by study team
COPD assessment test	Jones PW, Harding G, Berry P, Wiklund I, Chen WH, Kline Leidy N. Development and first validation of the COPD Assessment Test. <i>Eur Respir J</i> . 2009 Sep;34(3):648-54. Tsiligianni IG, van der Molen T, Moraitaki D, Lopez I, Kocks JW, Karagiannis K, Siafakas N, Tzanakis N. Assessing health status in COPD. A head-to-head comparison between the COPD assessment test (CAT) and the clinical COPD questionnaire (CCQ). <i>BMC Pulm Med</i> . 2012 May 20;12:20
Smoking status and history	Developed by study team
Trust in physician	Anderson LA, Dedrick RF. Development of the trust in physician scale: a measure to assess interpersonal trust in patient-physician relationships. <i>Psychol Rep</i> 1990;67:1091-100. Thom DH, Ribisl KM, Stewart AL, Luke DA. Further validation and reliability testing of the Trust in Physician Scale. <i>The Stanford Trust Study Physicians</i> . <i>Med Care</i> . May 1999;37(5):510-517.
PACIC	Gugiu PC, Coryn C, Clark R, Kuenh A. Development and evaluation of the short version of the Patient Assessment of Chronic Illness Care instrument. <i>Chronic Illness</i> 2009;5:268–

Section	Sources
	76 Glasgow RE, Wagner EH, Shaefer J, Mahoney LD, Reid RJ, Greene SM. Development and Validation of the Patient Assessment of Chronic Illness Care (PACIC). <i>Med Care</i> 2005;43:436–44
Satisfaction with provider and clinic	Reichheld FF. The one number you need to grow. <i>Harvard Bus Rev.</i> 2003;81(12):46-54.
PHQ	Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. <i>Journal of General Internal Medicine</i> 2001;16(9):606-13.
Generalized Anxiety Disorder scale (GAD)	Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. <i>Arch Intsern Med.</i> 2006;166:1092-1097.
COPD knowledge	Developed by study team
Visits to the hospital and emergency room (ED, Hosp, UC, Exacerbations)	Developed by study team
Bed days	Schillinger D, Handley M, Wang F, Hammer H. Effects of Self-Management Support on Structure, Process, and Outcomes Among Vulnerable Patients With Diabetes. <i>Diabetes Care</i> 2009;32:559–66.
Demographics	Developed by study team
Health literacy	Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. <i>J Gen Intern Med.</i> 2008;23(5):561-566.
6MWT	Guyatt GH, Sullivan MJ, Thompson PL et al. The six minute walk: a new measure of exercise capacity in patients with chronic heart failure. <i>Can Med Assoc J</i> 1985;132:919–923. Ingle L, Shelton RJ, Rigby AS, Nabb S, Clark AL, Cleland JGF. The reproducibility and sensitivity of the 6-min walk test in elderly patients with chronic heart failure <i>European Heart Journal</i> (2005) 26, 1742–1751
Smoking cessation assistance	Developed by study team
CPAP question	Developed by study team



INTAKE FORM

RA Use

Filled out by RA (circle one): DD BH

Patient information (RA fills out as much as known) Date: _____

Name: _____

DOB: _____ Patients identify with:

MRN: _____ Lung condition

COPD

Asthma

Other: _____

Clinical values	Value	Date
FEV1/FVC		
FEV1 predicted		
6 minute walk test		

Contact information

Phone number (in order of preference)	Type	Best day and time to reach
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	

Emergency contact information – if your phone doesn't work, who can we call to find you?

Name	Relationship	Phone number	Other information

Comments/Notes

Health Coach use

Assigned Health coach (circle one): CC JW

Preferred name: _____

Preferred language- Speaking: English Spanish

Reading/writing: English Spanish

<input type="checkbox"/> Yes <input type="checkbox"/> No	Is it okay for me to send you appointment reminders or check on you via text message?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is it okay for your health coach to leave voicemails identifying themselves as your health coach?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is it okay to leave message for you with people at your house and identify themselves as your health coach?

Health literacy (how often needs help reading instructions, pamphlets, or other written material from your doctor or pharmacy): Never Rarely Sometimes Often Always

Any other providers? If yes, who?: _____

Current smoker?

Any allergies? If yes, to what?: _____

Immediate needs:



INTAKE FORM

Anything else you'd like us to know:

Next appointment in LCR: _____ ----> If not, review chart. When requested? _____

Possible questions for conversation:

- Just to get to know each other a little bit more, what do you like to do for fun?
- Tell me about the things that are most important in your life. How does having COPD affect those things?
- Tell me about how you take care of your health. Who or what helps you take care of your health?
- Tell me about the things that make it hard to take care of your health.
- What are your goals for your health?
- What do you feel would most benefit you in managing your health?
- What expectations do you have from me?

Introduce health coaching using brochure.

- In what ways do you think that I can help you to take care of your health? *(If patient has specific ideas of how to improve their health, you can ask if they would like to make an action plan.)*

Notes:

Confirmed or set up appointment with PCP as per chart instructions; if more than 1 month from enrollment

If PCP appointment is more than 2 weeks away, set up time to meet to discuss goals and meds

Post visit:

- Enter patient information in Health Coaching database in Access
- Fill out Health Coach Interaction form
- Email provider – patient has been assigned a health coach, next appointments

Future Contact Form

Participant Study ID _____ Name _____

Contact information

Phone number <i>(in order of preference)</i>	Type	Best day and time to reach
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	
	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work <input type="checkbox"/> Other:	

Primary mailing address	Secondary mailing address

Email: _____

If your phone doesn't work, who can we call to find you?

Name	Relationship	Phone numbers	Address

Appendix N: Home visit form

Home visits can serve several functions. The most general is to get a sense of where the patient lives, both the home and the neighborhood. It is also a way to find out more about how the patient spends his or her day typically, who else is around, and perhaps to meet with any caregiver who is there. If time allows, review medications and inhaler usage in the home, as it is more likely that the patient will be able to produce all medications than at a visit.

Section 1: General topics

Topic	Not applicable	Not assessed	Notes (if assessed)
Description of home			
Description of neighborhood (does patient feel safe)			
Who lives there in home?			
Is there a care taker in home?			
Where does patient keep medications? (cleanliness of space, mouthpieces & nebulizer cups)			
Does anybody in the household smoke? (If so, who smokes? Where do they smoke?)			

Comments:

Section 2: Questions when screening for environmental triggers for dyspnea or allergies

Does patient have history of asthma?

Does patient have a history of hay fever?

Does patient notice more shortness of breath or cough when at home?

Does patient notice more shortness of breath or cough at night or in the morning when sleeping at home?

If yes to above, does it happen less when away from home including nights away from home.

Does patient feel that anything in his or her home triggers a cough or shortness of breath? If so, what.

If you suspect there are environmental triggers in the home then complete next 2 sections

Section 3: Screening for common triggers in the home

Assessing for mold	No	Yes	If yes, location	Notes
Moldy smell				
Visible mold				
Areas of dampness/water damage				
Shower curtain				
Assessing for dust/dust mites (Focus on bedroom & other rooms where patient spends majority of time)				
Visible dust				
Many dust-collecting surfaces (including clutter)				
Carpeting (How often vacuumed, type of vacuum)				
Area rugs				
Upholstered furniture				
Fabric curtains				
Pets				
Are their pets in the home? (What type? Where do they reside?)				
Pests				
Visible cockroaches or rodents in the past 30 days?				

Section 4: Mitigation of common triggers in the home

Mold mitigation	Discussed	Not discussed	Notes
Wash away mold using soapy water with vinegar			
Correct cause of any water leaks or areas of wetness			
Dry (wipe down) shower curtains after showering			
Use fan or open window when showering			
Keep furniture at least 2 inches away from the			

Mold mitigation	Discussed	Not discussed	Notes
wall			
Keep windows open for 5-15 minutes each day to release excess moisture			
Do not use a humidifier unless recommended by your doctor			
Dust mitigation			
Use HEPA air filter			
Damp mop hard surface floors weekly			
Replace carpet with hard flooring			
Vacuum carpets 2 times per week using microfiltration bags or a HEPA filtered vacuum*			
Vacuum both sides of area rugs*			
Wash area rugs monthly*			
Vacuum upholstered furniture weekly*			
Replace old upholstered furniture with vinyl covered furniture			
Replace fabric curtains with washable shades			
Dust all surfaces weekly with a damp cloth*			
Store items in containers or cabinets to reduce the number of items and surfaces that collect dust			
Wash sheets and bed blankets in hot water every 1-2 weeks			
Encase pillow, mattress in dust mite covers			
Wash curtains frequently in hot water and dry in a dryer at high temperature			
Pet Mitigation			
Getting rid of pet(s)			
Keeping pet(s) out of bedroom			
Wash hands after petting			
Pest Mitigation			
Do not leave food or garbage out or uncovered			
Use traps and poison baits			
Vacuum up cockroach bodies or droppings			
Fix leaky plumbing			
Remove sources of water			

* Person with allergies/asthma should avoid dusting/vacuuming; if this is not possible, they should wear a dust mask.

AIR Health Coaching Study

Interview guide (Patient)

Self-management

1. In what ways has your lung/breathing condition impacted your life?
2. What have been the most challenging things about managing your condition?
3. What gets in the way of managing your condition?
 - a. What else in life is stressful for you? Are there non-COPD problems you're dealing with?
 - b. *Circle back later:* We've learned from talking with our health coaches that there are some common things that make it difficult for people to manage their condition like problems with housing, problems with money, family issues, etc. What do you think of that?

What you expected versus what you found

(To set the stage, preface this part with: closing your eyes, think back to before you were involved in this study...)

4. When you first heard about the AIR Health Coaching study, what interested you about it?
5. Before you met your health coach, what did you expect working with a health coach would be like?
 - a. Were your expectations met? What parts of health coaching were like what you expected?
 - b. What was most surprising to you about health coaching?

Experience in working with a health coach

6. What is a typical interaction with your health coach like?
7. **Tell me about a time when your health coach helped you. What did she do that was helpful?**

Probes (if yes, ask for examples):

- Are there any problems that your health coach helped you solve?
- To what extent do you feel that your health coach helped you communicate better with your provider? Could you give me an example?
- To what extent do you feel that your health coach helped you understand how to better manage your lung condition? Could you give me an example?
- To what extent do you feel that your health coach helped you manage your medications? Could you give me an example?
- To what extent did your health coach help you live more healthfully, like quitting smoking, getting more physical activity, or taking better care of yourself? Could you give me an example?

- To what extent do you feel that your health coach helped you use clinic or community resources, like getting connected with a social worker or finding a class to help you? Could you give me an example?
 - To what extent do you feel that your health coach helped you feel personally supported? Could you give me an example?
8. **[Card sort activity – pre-made + some to fill in with their ideas]** Of all of the things that your help coach did, which do you think was the most important? The least important?
- a. Is there anything else your health coach did that is not on here?
9. Did you trust your health coach, and if so, why?

Opinions about health coaching

10. (Remind patient about confidentiality) What do you wish you could change about the health coaching experience?
11. Do you know someone who has your lung condition who might be helped by having a health coach?
- a. Have you talked to them about what you've learned from your health coach?
 - b. What advice would you give him/her about working with a health coach?
12. What do you think it takes to become a good health coach? Can anyone learn to become a health coach?

Health coaching as transformation

13. As you look back, how do you think that you have changed how you manage your lung condition as a result of having a health coach? How has how your management of [insert challenges patient mentioned in questions 1-2] changed?
14. What changes have you maintained since you graduated from health coaching? How do you sustain those changes?
15. *For patients who have not made changes:* Have you made a lifestyle change in the past, for example exercising more, changing your diet, etc.?
- a. What helped you make that change? Who helped you?
 - b. How could a health coach have helped with that change?
16. Is there anything that I didn't ask you about health coaching or your lung condition that you'd like to share?

AIR Health Coaching Study

Interview guide (Provider)

What you expected versus what you found

1. What drew you to working in the safety net?
2. Prior to working with coaches from the AIR Health Coaching study, had you worked with health coaches before?
 - a. In what context?
 - b. How was your experience?

Challenges of COPD for patients and their providers

3. Thinking about your patients with lung conditions like COPD, what are some the challenges that they face in managing their lung conditions.
 - a. What are the disease-specific challenges?
 - b. What are some of the more general challenges (e.g., social needs)?
4. As a provider, what are some of the challenges that you face in supporting your patients with lung conditions like COPD?

Working with health coaches

5. What was your understanding of the qualifications of the health coaches?
6. How did the health coach(es) work with you and your patients around management of their lung condition?
 - c. What did the coaches do that was most helpful?
 - d. Were there any challenges to working with health coaches?
7. Tell me about one of your patients who changed during the course of health coaching. How did that person change? What do you think led to this change?
8. Tell me about one of your patients who was unable to improve his/her health despite having a health coach. What do you think contributed to the lack of change?
 - e. Is there anything a health coach could do to further facilitate change?
9. In general, what characteristics might make a patient most likely to benefit from working with a health coach?
 - *If asked to define "benefit," state "to experienced improved health and/or well-being"
10. Did you receive recommendations regarding medications or other aspects of care management for patients who had a health coach?
 - f. (If yes) If so, did you receive those recommendations directly from Stephanie Tsao, the pulmonary nurse practitioner or through the health coach?
 - g. (If via health coach) How did you feel about receiving recommendations via the health coach compared to directly from a nurse practitioner specialist or a pulmonologist?

Closing

11. If you had a colleague whose health center was considering starting a health coaching program, what advice would you give him/her?
12. Is there anything that I didn't ask you about that you'd like to share?

AIR Health Coaching Study

Interview guide (Health Coach)

What you expected versus what you found

1. When you first heard about this job, what attracted you to it?
2. What parts of health coaching were like what you expected?
3. What was most surprising to you about health coaching?

Working with patients

4. What builds good strong patient-health coach relationships?
 - a. How did you establish trust?
 - b. How did you define boundaries?
5. Tell me about one of your patients who changed during the course of health coaching. What was different about that person? What do you think contributed to the change in his/her life?
6. Tell me about one of your “challenging” patients. What was difficult about coaching this patient? What did you find worked?
7. ***[Card sort with roles—what were most important? Least? What is missing?]***
 - c. Tell me about a time when you helped your patient better communicate with their provider.
 - d. Tell me about a time when you helped a patient better understand how to manage their lung condition.
 - e. Tell me about a time when you helped a patient better manage their medications.
 - f. Tell me about a time when you helped a patient make a lifestyle change such as quitting smoking, becoming more active, eating more healthfully, or do something else to improve their health.
 - g. Tell me about a time when you helped a patient better navigate clinic or community resources.
 - h. Tell me about a time when you helped a patient feel personally supported.
 - i. Tell me about other ways in which you supported patients as a health coach.
8. If you knew from the beginning of your coaching experience what you know now, what would you do differently in your coaching?

Health coaching as transformation

9. If you met someone who wanted to start a health coaching program for COPD at their clinic, what advice would you offer them?
 - a. What words of caution would you give them?
 - b. What is most rewarding about the experience?
 - c. What do you think it takes to become a good health coach?
10. As you look back, how do you think that you’ve changed personally as a result of becoming a health coach?