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Access to Breathing Medications in an Uninsured and Underinsured Patient Population

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Cover Page Footnote

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Introduction

Despite provisions made by the 2010 Affordable Care Act to expand Medicaid and make health insurance more available, many low-income individuals remain uninsured or underinsured.^{1,2} Lack of insurance can be a barrier to receiving needed healthcare.¹ Chronic respiratory diseases, such as asthma and chronic obstructive pulmonary disease (COPD), disproportionately impact people with low incomes, with factors such as smoking or exposure to secondhand smoke, air pollution, and occupational dust and chemicals increasing the risk of disease.^{3,4} A variety of breathing medications exist to control these diseases and manage symptoms, such as oral and inhaled bronchodilators, oral and inhaled corticosteroids, as well as leukotriene receptor antagonists and selective phosphodiesterase-4 inhibitors. However, prescription cost can be a major financial burden for patients without adequate insurance coverage.²

A study examining cost-related medication nonadherence in Medicare beneficiaries by Castaldi et al. (2010) found that patients paying more than twenty dollars per month for inhalers were at a significantly higher risk for cost-related nonadherence compared to those who had no out-of-pocket inhaler costs.⁵ Nonadherence to breathing medications can lead to uncontrolled respiratory disease, which may result in expensive emergency department (ED) visits and hospitalizations. A retrospective cohort study by Hasegawa et al. (2014) found that lower socioeconomic status was significantly associated with a higher frequency of ED visits for acute exacerbation of COPD.⁶ Similarly, a cross-sectional study of outpatient asthma-related ED visits by Wang et al. (2014) identified that the majority of patients in their sample were low-income, defined as $\leq 200\%$ of the federal poverty level.⁷ Prescription-related issues after hospital discharge, most often not filling discharge prescriptions, have been found to be especially common among patients with Medicare HMO coverage, Medicaid, or no insurance, and in patients prescribed an inhaler.⁸

A patient's medication plan should be developed based on his or her access to resources and consideration of the cost of the medications and interventions.⁹ According to a physician survey by Reichert et al. (2000), while most prescribers recognize that medication cost is important, few have easy access to drug cost information and even fewer have received formal training about the cost of medications.¹⁰ Prescribing clinicians should consider cost information when selecting potential breathing medications so that the most affordable drug is prescribed to best meet the patient's therapeutic goals.

Pharmacists can promote utilization of assistance programs for patients who are uninsured and underinsured. These patients may include those who exceed Medicaid coverage or for whom Medicaid coverage is pending, those without any health insurance or without a prescription drug benefit, those for whom the planned drug therapy is not covered by insurance or covered inadequately (copay not affordable), and those enrolled in charity programs.¹¹ However, in our experience, even pharmacists who work with the underserved daily may struggle to provide breathing medications due to the lack of consistency in the types of assistance programs available for each breathing medication, as well as specific patient qualifications that impact a patient's eligibility to receive medications through these routes. The challenge of breathing medication access for the uninsured and underinsured needs to be characterized so that key stakeholders, such as prescribers and payers, can understand the magnitude of the issue and the options for improved breathing medication access.

Purpose. The purpose of this study was to explore access to breathing medications in an uninsured and underinsured patient population and identify needs related to additional medication access resources. Specific aims included describing the population of patients who are relying on a charitable pharmacy to provide access to breathing medications, identifying methods utilized by a charitable pharmacy to provide breathing medications, and describing individual patient experiences with their respiratory health.

Setting. At the Charitable Pharmacy of Central Ohio, we provide medications at no charge for patients in Franklin County who are at or below 200% of the federal poverty level and are either uninsured or underinsured. Patients are

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considered underinsured if they meet financial eligibility and have insurance but cannot afford their medications despite insurance coverage. We utilize several access routes to provide medications to our patients including manufacturer bulk-replenishment programs, drug repositories, charitable distributors, and purchase with our own pharmacy funds. Table 1 contains descriptions and comparisons of each access route utilized by our charitable pharmacy. Despite having multiple resources available for our underserved patients, we still struggle to consistently provide some medications to our patients, particularly breathing medications. Inhalers are especially costly, which can result in patients going to the ED for care and potentially suffering from poor quality of life due to uncontrolled breathing conditions.

Methods

This was a descriptive study approved by the Ohio State University Institutional Review Board that used a sequential, exploratory design. In order to describe access issues for uninsured and underinsured patients who require breathing medications, we collected quantitative data from a retrospective records review (Phase I) and then summarized individual patient experiences with breathing medications and respiratory health (Phase II).

Phase I. In Phase I, a dispensing report utilizing our dispensing software system (QS/1[®]) was generated to identify patients who filled medications at the Charitable Pharmacy of Central Ohio during the three-month time period between December 11, 2014 and March 11, 2015. Patients who filled breathing medications during this time were separated out for further analysis. Quantitative data was collected from the dispensing report, financial database, and medical records review for these patients. Objective data gathered from the dispensing report included number and types of breathing medications prescribed, routes from which breathing medications were obtained, and number of prescribers for breathing medications. Data collected from the financial database and medical records review included patient demographics, respiratory diagnoses, and issues detailed in patient charts related to access to prescribed breathing medications.

Phase II. In Phase II, patients were telephoned by a study investigator and invited to participate in a patient interview to share their experiences about obtaining breathing medications and their respiratory health. They were offered a \$10 grocery store gift card incentive to participate in the interview either in-person or via telephone. Patients verbally consented to participate in a semi-structured interview which gathered information including respiratory disease history, payer situation, perception of respiratory health, modifications to breathing regimens (both provider-initiated and patient-initiated), and any ongoing access issues with

breathing medications. Appendix A contains specific interview questions utilized during the interview. Interviews were audio-recorded, transcribed by a third party, and analyzed by investigators to determine themes. These themes were determined by identifying common experiences between all or most patients and patients' experiences with breathing medication access.

Statistical Analysis. Analyses were performed in SAS version 9.2 (SAS institute, Cary, NC). The study was exploratory in nature and not powered to detect specific differences; no formal hypothesis testing was conducted. All demographic and interview data was summarized using descriptive statistics. Categorical variables were expressed using frequencies and percentages. Continuous variables were expressed using means and standard deviations.

Results

Phase I. Overall, 777 patients filled a prescription during the study period, and 181 (23.3%) of those patients filled a breathing medication totaling 494 breathing medications dispensed. The majority of patients with documented race were African American (n=90, 52.9%) and Caucasian (n=69, 40.6%). The most common respiratory diagnoses were asthma (n=75, 41.4%) and COPD (n=65, 35.9%). Detailed demographic data is displayed in Table 2.

Most patients were prescribed an "as needed" breathing medication (n=151, 83.4%), while nearly half were prescribed a "controller" medication (n=88, 48.6%). Examples of "as needed" and "controller" breathing medications are shown in Table 3. Medications were obtained through purchase (41.1%), manufacturer bulk-replenishment (38.5%), repository (10.5%), and a charitable medication distributor (9.9%). A total of 50 patients (27.6%) reported utilizing routes in addition to the charitable pharmacy to access their breathing medications within the past year. Figure 1 conveys per-patient data regarding number of breathing medications dispensed, access routes utilized, and number of prescribers of breathing medications.

Phase II. Five patients verbally consented to and completed a semi-structured interview regarding their experience with breathing medication access and respiratory health. Each patient had a different prescription insurance status, including uninsured (n=1), Medicare with Part D coverage (n=1), Medicare without Part D coverage (n=1), Medicaid (n=1), and private insurance (n=1). Analysis of transcribed interviews revealed common themes. All patients (n=5) reported poor perception of respiratory health, history of ED visits or hospitalizations due to uncontrolled respiratory disease that decreased in frequency after receiving breathing medications from the charitable pharmacy, and incorrect use

of inhalers to extend their duration of use. All patients (except n=1 insured by Medicaid) reported going without breathing medications for some period of time prior to coming to the charitable pharmacy. Additionally, all patients (except n=1 insured by Medicare with Part D coverage) reported that the charitable pharmacy had to request a medication change due to access issues or was unable to obtain the prescribed breathing medication. Table 4 contains patient case summaries.

Discussion

This descriptive research study identified characteristics of patients who are relying on a charitable pharmacy to provide their breathing medications, and summarized themes regarding the challenges and consequences patients have faced while struggling to obtain prescribed breathing medications.

We found that respiratory disease is particularly common in our patient population, with almost a quarter of our total pharmacy population filling a breathing medication during the study period. The prevalence of respiratory disease in our charitable pharmacy appears to be high compared to the prevalence generally reported in the United States. According to a 2013 National Health Interview Survey, 7% of adults in the United States have asthma, while we found that 12.7% (n=99) of our total pharmacy population has either asthma or a combination of asthma and COPD.¹² A 2011 Behavior Risk Factor Surveillance System identified 7.1-9.3% of adults in Ohio as having COPD, while 11.5% (n=89) of our total pharmacy population has COPD or a combination of asthma and COPD.¹³ The increased prevalence of respiratory disease in our population may be due to asthma and COPD disproportionately affecting people of low socioeconomic status.^{3,14} Our pharmacy population's prevalence of respiratory disease aligns with that identified by the Kaiser Commission, which found that 23% of Medicaid beneficiaries have a chronic respiratory illness according to 2009 Medicaid Expenditure Panel Survey data.³ While only a small percentage of our patients who filled breathing medications were Medicaid beneficiaries, the prevalence data provided by the Kaiser Foundation may be considered a relevant comparison due to the low-income status of the patients utilizing the charitable pharmacy.

Another reason we may have observed a higher prevalence of patients with respiratory disease at our charitable pharmacy is because breathing medications are often expensive compared to many medications for other chronic conditions. Effective December 31, 2008, the US Food and Drug Administration banned the use of chlorofluorocarbon (CFC) albuterol inhalers due to environmental harm through ozone-depletion.^{15,16} This act prompted the production of new

inhaler designs with new patents and higher costs.¹⁶ Currently, there are no generic inhalers in the United States. The high cost of breathing medications may be driving our low-income patients with breathing conditions to seek medication assistance.

While patients included in this study were able to fill at least one breathing medication through the charitable pharmacy, our findings suggest several medication access challenges remain. The charitable pharmacy utilized bulk-replenishment programs, drug repository, and a charitable medication distributor for access. However, 41% of all breathing medications dispensed during the study period had to be purchased by the charitable pharmacy. The charitable pharmacy will only purchase medications as a last resort if the medications are not available through any other access route. Since most community pharmacies do not have the resources of the charitable pharmacy, 41% of the inhalers we dispensed may have otherwise been unobtainable for our patients had they filled their prescriptions elsewhere.

Further investigation revealed that the charitable pharmacy had to utilize two or more access routes for nearly one-third of its patients in order to obtain prescribed breathing medications. Reasons for using more than one route may be due to route-specific drug availability or patient eligibility issues (see Table 1). For example, a patient underinsured with prescription insurance would only be eligible for repository drugs or drugs purchased by the charitable pharmacy, thus limiting resources available to him/her. Uninsured patients are eligible to receive medications through a larger number of access routes, but the issue of drug availability remains. Bulk-replenishment programs, for example, only provide certain brand-name medications. If there is not a manufacturer assistance program for a particular inhaler, a patient must wait for the medication to be donated to the charitable distributor or rely on financial availability for the medication to be purchased through the charitable pharmacy's operating budget. These limitations make navigating available medication access routes particularly challenging.

In cases where the prescribed breathing medication was not available through any access route, the charitable pharmacy requested therapeutic substitution from physicians when possible via telephone or fax communication. One of the interviewees shared that the charitable pharmacy had to not only request an alternative inhaler which was more readily available, but also a nebulizer because the necessary class of breathing medications was most affordable through a nebulized solution formulation. Another interviewee shared that he/she had to go without his/her inhaled breathing medication on several occasions because the physician was

unwilling to accept the therapeutic alternative recommended by the pharmacist. Our data indicated that the majority of patients had only one physician writing prescriptions for the patient's breathing medications, so education opportunities about cost and access may be manageable. It is important that health care professionals be cognizant of medication costs and access, particularly if the prescribed breathing medications are financially unobtainable for their patients.

The medical records review showed that 27.6% of patients filling breathing medications used a resource in addition to the charitable pharmacy to obtain their breathing medications within the last year. Alternative resources might include EDs, drug samples through physician offices, medication assistance programs, 340b drug pricing, or retail purchase (with or without insurance) at community pharmacies. In the case of retail purchase, the interviewees were asked how much money they would be able to spend per month on breathing medications. Answers ranged from being able to pay very little for their breathing medications to fifty dollars per month (see Table 4). Considering that 44.2% of the study patients were taking two or more breathing medications, monthly inhaler costs would likely be significantly higher than what most patients could afford.

Ultimately, lack of access to breathing medications can lead to cost-related nonadherence and poor disease control. A common theme from patient interviews was history of using inhalers incorrectly to extend their duration of use. Two interviewees reported spreading out the doses of their inhalers to make them last longer when unable to obtain their breathing medications. Another interviewee admitted to using a family member's or friend's inhalers, which did not contain the correct medication for the patient's diagnosis and therefore did not work properly to control his/her disease.

All interviewees shared frequenting the ED and/or hospital more often prior to coming to the charitable pharmacy due to lack of breathing medication access. One interviewee admitted to going to the ED whenever his/her inhaler ran out so that the interviewee could get a new one because the ED was the only reliable access route for breathing medications. According to a study by Dalal et al. (2011), mean costs for COPD exacerbation ED visits in 2008 were \$647, while mean costs for COPD exacerbation hospital admissions ranged from \$7,242 to \$44,909 depending on complexity.¹⁷ Unfortunately, the high cost associated with lung disease is not expected to decrease any time soon. According to researchers at the Centers for Disease Control and Prevention, national annual COPD medical costs are projected to increase from \$32.1 billion in 2010 to \$49 billion by 2020.¹⁸

While this study identified several important challenges facing underserved patients utilizing breathing medications, there are limitations to consider. One limitation is that the study data is from a "snapshot" three-month time period. It is possible that results could be different depending on the time of year studied, with seasonal variation accounting for differences in inhaler needs. For example, more patients could be filling inhalers during the spring due to seasonal allergies. However, the purpose of the study was to describe characteristics of the population that relies on a charitable pharmacy for breathing medications, and the study investigators did not feel that the overall characteristics of the population would significantly change. Three months was chosen versus a shorter period of time in order to capture patients who may have only been prescribed an "as-needed" or "rescue" medication, since the patient may not need to get a new inhaler every month if using the medication infrequently.

Another limitation is that Phase I relies on a retrospective chart review, so the accuracy of the data is dependent on accurate record-keeping at the pharmacy. This study only accounts for breathing medications that were filled at the charitable pharmacy, so the 27.6% of patients who utilized resources outside of the charitable pharmacy had unaccounted for experiences regarding those breathing medications. Additionally, much of the data in the medical chart is patient-reported, including diagnoses, insurance status, and a portion of the information gathered from the medical record review. In regard to insurance status, it is possible that some uninsured patients were eligible for affordable income-based coverage and were unaware, which would overestimate the magnitude of the problem regarding access to breathing medications. It is also possible that if some patients had assistance in selecting their insurance plans, they may be able to better afford their breathing medications at a reasonable price. However, the data presented in this study conveys the reality that in practice it may not always be possible to optimize each patient's insurance plan prior to granting access to charitable pharmacy resources.

The small sample size and selection of interviewees in Phase II is a limitation as well. Patients were selected based on their insurance status and are not a true representation of the entire population of patients filling breathing medications at the pharmacy. However, the purpose of Phase II was to share individual patient experiences regarding their respiratory health and medication access issues, so the research investigators focused on the quality of stories gathered. The patient interview data was used to support the quantitative data collected and personalize the issue of medication access in the underserved population.

Opportunities exist for further exploration into breathing medication access issues. Respiratory disease-related ED and hospital admission rates of patients at a charitable pharmacy could be compared to the general population or a population of similar low income status. In addition, respiratory disease-related ED and hospital admission costs could be compared to the costs of breathing medications. As poor perception of respiratory health was a common theme among our interviewees, a future study could examine factors that contribute to health perception in uninsured or underinsured patients with respiratory disease. Therapeutic regimens could be analyzed for appropriateness based on current respiratory guidelines in uninsured or underinsured patients. In addition, pharmacist collaboration with prescriber offices in assisting with the selection of accessible breathing medications could be explored, as could partnerships with other members of the health care team to explore eligibility and optimization of a patient's health plan selection.

Conclusion

Use of breathing medications was common in our population, and access remains a significant challenge regardless of insurance status or the available expertise and resources of a charitable pharmacy. The majority of breathing medications were prescribed for common diagnoses, but controller medications were seen in less than half of the patients. While this charitable pharmacy utilizes several routes to access breathing medications, over a quarter of the patients needed to seek outside resources to obtain therapy. Most commonly, the charitable pharmacy still had to purchase breathing medications. Collaborative, team-based efforts are needed to ensure that vulnerable populations can consistently access necessary breathing medications.

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Table 1. Description of Medication Access Routes Commonly Utilized by a Charitable Pharmacy

Access Route	Description	Patient Eligibility Criteria	Pros	Cons
Bulk-replenishment programs	Drug manufacturer provides certain brand-name medication at no cost to patients who qualify	Income and insurance criteria depend on particular program, but typically must be U.S. citizen and have no prescription insurance	Brand-name medications readily available	Eligibility requirements; supply limited to certain brand-name drugs only
Drug repository	Unused drugs donated from nursing homes, long-term care facilities, and wholesalers	Resident of Ohio and no prescription insurance or must be a patient of a nonprofit clinic	Variety of drugs potentially available; may qualify even if has insurance if patient of nonprofit clinic	Inconsistent drug supply based on donations
Charitable distributor	Organization provides donated medications from manufacturers and health systems	At least 18 years-old, $\leq 200\%$ federal poverty level, and no prescription insurance	Variety of drugs potentially available	Must be uninsured to be eligible; inconsistent drug supply based on donations
Purchase	The Charitable Pharmacy of Central Ohio (CPCO) uses its own operating budget to purchase medication for patients who cannot access it from any alternative route	Must be qualified as a patient of CPCO (i.e. >18 years, resident of Franklin county, and $\leq 200\%$ federal poverty level and having difficulty affording prescriptions)	Any patient of CPCO is eligible to have access to drugs purchased by CPCO	CPCO operating budget is limited, so it can only provide relatively low-cost drugs and is often route of last resort

Table 2. Demographic Data	
	Mean ± SD (range), or n (%)
Age	57.9 ± 10.7 (21.7 – 83.6)
Gender	
Male	82 (45.3%)
Female	99 (54.7%)
Race	
Caucasian	69 (40.6%)
Black	90 (52.9%)
Other	11 (6.5%)
Insurance status	
Uninsured	84 (46.4%)
Medicare A & B	30 (16.6%)
Medicare A, B, & D	38 (21.0%)
Medicaid	12 (6.6%)
Private	9 (5.0%)
Other	8 (4.4%)
Pulmonary diagnosis	
Asthma	75 (41.4%)
COPD	65 (35.9%)
Asthma and COPD	24 (13.3%)
Unknown	11 (6.1%)
Other	6 (3.3%)

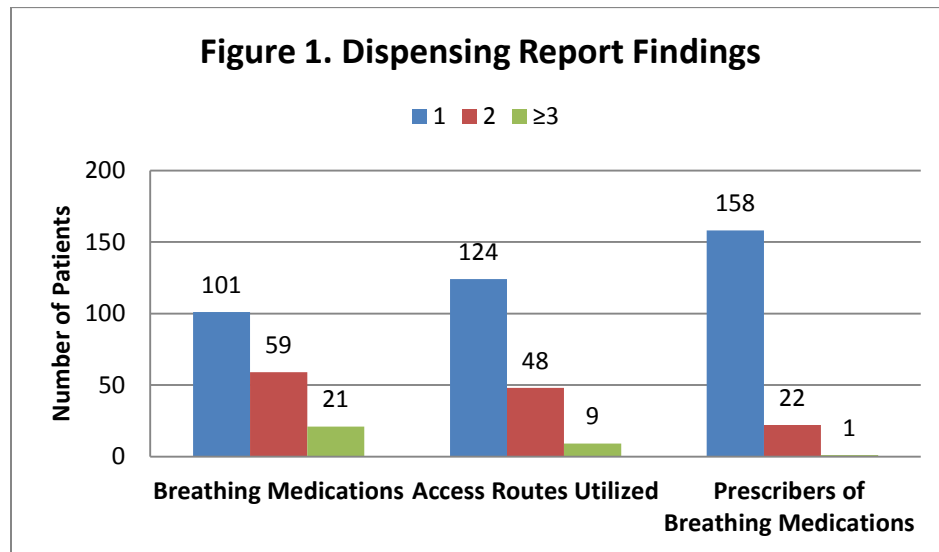
Table 3. Examples of “As Needed” and “Controller” Breathing Medications

As Needed: albuterol (ProAir [®] , Proventil [®] , Ventolin [®]), ipratropium/albuterol (Combivent [®])*, levalbuterol (Xopenex [®])	Controller: acclidinium (Tudorza [®]), beclomethasone (Qvar [®]), budesonide (Pulmicort [®]), budesonide and formoterol (Symbicort [®]), fluticasone (Flovent [®]), fluticasone and salmeterol (Advair [®]), mometasone (Asmanex [®]), mometasone and formoterol (Dulera [®]), montelukast (Singulair [®]), roflumilast (Daliresp [®]), salmeterol (Serevent [®]), theophylline ER, tiotropium (Spiriva [®])
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*Combivent[®] may be used “as needed” or regularly as a “controller” medication. It was categorized as an “as needed” breathing medication for study purposes.

Table 4. Patient Case Summaries

Table 4. Patient Case Summaries	
Patient 1	Patient with history of smoking was diagnosed with asthma and chronic obstructive pulmonary disease (COPD) over twenty years ago during hospitalization for acute bronchitis. Before coming to the Charitable Pharmacy of Central Ohio (CPCO), patient reported scraping money together to get whatever inhalers patient could afford, though patient always found a way to get long-acting anticholinergic inhaler and referred to it as “magic stuff.” Patient reported having to make a decision between medication and food. When asked how much patient could spend on breathing medications, patient reported \$50 maximum per month. Patient reported taking long-acting anticholinergic inhaler differently than prescribed at times by skipping doses to make it last longer when CPCO was unable to provide this medication.
Patient 2	Patient with history of childhood asthma also diagnosed with COPD. Before coming to CPCO, patient reported purchasing breathing medications at the cheapest retail price patient could find. When asked how much patient could spend on breathing medications, patient reported \$20-\$40 per month. Patient reported that CPCO has had to call physician in the past to switch the brand of prescribed inhalers to inhaler more readily available through the pharmacy’s access routes. Patient also reported CPCO requested nebulized medications for patient due to access issues.
Patient 3	Patient with a strong family history of asthma was diagnosed as an adult. Patient struggled to afford breathing medications and used family member’s or a friend’s inhalers which did not work well because the other inhalers were prescribed for COPD. Uncontrolled asthma greatly interfered with daily tasks and ability to perform job. Patient reported that CPCO had contacted physician to change one of patient’s inhalers due to uncontrolled asthma, and breathing was much better on the new regimen. When asked how much patient could spend on breathing medications per month, patient said patient would be unable to afford them because they are very expensive.
Patient 4	Patient with history of smoking was diagnosed with COPD upon a routine physician visit due to shortness of breath. Patient reported going without breathing medications often before coming to CPCO. Patient went to emergency room if unable to tolerate shortness of breath. Patient has tried to “spread out” doses of inhalers to make them last longer but reports they do not work as well when taken this way. When asked how much patient could spend on breathing medications per month, patient responded that it wouldn’t be much at all.
Patient 5	Patient diagnosed with asthma in teenage years and ended up in emergency room often due to losing job and insurance coverage. Patient reported that over-the-counter inhalers did not work well and described life with asthma “confining” due to avoiding exposure to the outdoors due to exacerbations. When asked how much patient could spend on breathing medications per month, patient reported \$20, if that. Before coming to CPCO, patient would go to emergency room if breathing was troublesome and use the inhaler received there. Once inhaler ran out, patient would go back to the emergency room. Patient reported going without prescribed inhaler a few times because CPCO could not access it and physician was not willing to substitute an alternative medication.



Appendix A: Patient Interview Questions

- Pulmonary disease history:
 - I see that you are taking a breathing medication(s). Please tell me why you were prescribed this medication.
 - Tell me about when you were first diagnosed with airway disease.
 - How has your breathing changed, if at all, since you were diagnosed?
 - Why do you think your breathing has gotten better/worse?
 - What is your life like with airway disease?
- Payer situation:
 - How did you get your breathing medications before coming to the Charitable Pharmacy?
 - Why could you no longer get your breathing medications in that way?
 - *If insurance:* how do you feel about having difficulty affording your medications even though you have insurance?
 - *If no insurance:* do you feel that getting your breathing medications would be different if you had insurance?
 - How much would you currently be able to spend per month on breathing medications?
- Perception of pulmonary health:
 - How often did you go without breathing medications before coming to the Charitable Pharmacy? If often, why?
 - How often were you hospitalized due to breathing issues prior to coming to the Charitable Pharmacy?
 - Since coming to Charitable Pharmacy, how often do you go without your breathing medications? If often, why?
 - How often have you been hospitalized due to breathing issues since coming to the Charitable Pharmacy?
 - Do you feel like your breathing is better or worse when you are able to get your breathing medication?
- Modifications to breathing regimen:
 - To your knowledge, has the Charitable Pharmacy ever had to ask your doctor to change your breathing medication? How do you feel about this?
 - Have you ever tried to make your breathing medication last longer so you would not run out? If so, tell us which medication and how you took it.
 - Do you take your breathing medications every day or only as needed? Why do you take them this way?
- Ongoing access:
 - If you got new prescriptions, where would you go first to get your medications?
 - What would you do if your breathing medications were not working?
 - Where would you go to ask a question about your breathing medications? Who would you ask?
 - Are you still getting your breathing medication from the Charitable Pharmacy? If not, why?