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PHARMACOTHERAPY



Quality improvement project to increase screening and referral for biologic therapy for patients with uncontrolled asthma

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ABSTRACT

Background: Asthma is a treatable chronic disease of airway inflammation with varying levels of control and severity. Biological therapy is an effective evidence-based treatment for patients with allergic and eosinophilic phenotypes of asthma who are classified as poorly controlled moderate to severe asthma. Yet, evidence-based treatments are infrequently used to support effective care of poorly controlled moderate and severe asthma. This quality improvement (QI) project aimed to increase the number of patients with uncontrolled moderate to severe asthma at an outpatient asthma center who are screened and referred for biologic therapy when appropriate.

Methods: A guideline-based biologic screening protocol was implemented using plan-do-study-act (PDSA) methodology allowing for a systematic approach for implementation, monitoring and making adjustments. A pre- and post-independent groups comparative design was utilized to evaluate screening and referral data.

Results: Screening improved significantly from pre- ($n=30$, 23.8%) to post-implementation ($n=17$, 70.8%), $p<0.001$; $\phi=.372$. Referrals to biologics also improved from 42.4% ($n=28$) to 93.3% ($n=14$), $p<0.001$; $\phi=.396$. Providers reported increased knowledge, confidence, and satisfaction with the asthma screening protocol at post-implementation.

Conclusions: The implementation of an asthma screening protocol for asthma patients in an ambulatory center is an effective way of increasing screening for eligibility for biologic therapy. Adhering to the standard of care based on evidence-based guidelines increased access to biologic therapy with a higher percentage of patients being referred for therapy.

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Introduction

Asthma is a chronic heterogeneous disease characterized by airway inflammation, bronchial hyperresponsiveness and reversible airway obstruction (1). As one of the most common chronic diseases, asthma affects more than 300 million people globally and over 19 million adults in the of the United States (US) (2). Among those diagnosed with asthma, a higher prevalence is found in women (9.8%) compared to men (6.1%) (3). When race is considered, a higher incidence is found among Blacks (9.7) than Whites (8.1%) and Hispanics (6.1%) nationally (3). Severe asthma, which affects 5% to 10% of adults, is a significant health problem requiring use of emergency care services resulting in increased healthcare utilization with 1.5 million emergency room visits, 7.3 million

physician office visits and 182,620 hospitalizations annually (3,4). In addition, it is associated with poorer health outcomes including increased morbidity, more frequent and longer hospitalizations, and the loss of over 15 million disability adjusted life years annually (3,5).

Advancement in the understanding of the pathophysiology of asthma over the past decade has led to the identification of inflammatory pathway endotypes T2-high (eosinophilic) and T2-low (non-eosinophilic) that are key biomarkers in classifying asthma (6). Phenotypes of asthma include allergic asthma which affects nearly half the population of asthmatics and is associated with atopy, allergic rhinitis, and elevated immunoglobulin E (IgE) levels (4). Others have what is known as eosinophilic asthma, which results in higher eosinophil levels in the blood and airways (1).

Conventional treatments with inhaled bronchodilators, antileukotrienes and inhaled corticosteroids are not as effective in treating T2 endotypes. Newer targeted asthma therapies called biologics which are made from human organisms are available for the treatment of moderate to severe asthma with allergic and eosinophilic phenotypes of asthma and has shown effectiveness in those who have failed treatment with the standards of care (7,8). By identifying specific biomarkers in the blood or sputum, providers can tailor treatment with biologics aimed at specific inflammatory pathways (6). The development of this focused and effective therapy addresses the gaps in the treatment of allergic and eosinophilic phenotypes resulting in moderate to severe asthma (4).

In 2018, New York State (NYS) had 1.6 million adults with asthma, the second highest numbers in the US (3). The Bronx, one of five boroughs in New York City (NYC), has 1.4 million predominantly African American and Hispanic residents with nearly 6.8% with current asthma (9). The higher prevalence of asthma in the Bronx compared to the rest of the state is due to economic factors, lack of access to specialty care, and increased exposure to environmental pollution and poor indoor air quality (9). In addition, known racial and ethnic health disparities such as obesity, socioeconomic status and genetic factors contribute to the disproportionately higher rate of asthma (10,11).

A retrospective chart review of adults seen from January 14, 2019, through September 30, 2019, found 126 patients with moderate to severe asthma that met Global Initiative for Asthma Guidelines (GINA) criteria for biologic screening. Of these patients: 1) 33.3% ($n=42$) had a discussion about biologic therapy with the provider, 2) 23.8% ($n=30$) were screened for biologic therapy, and 3) 52.4% ($n=66$) were eligible for biologic therapy. Of those eligible patients, 28 (42.4%) 42.4% ($n=28$) were referred for biologic therapy. In 2020, an internal audit review showed only 9.5% ($n=12$) of patients with uncontrolled asthma received biologic therapy at an outpatient asthma center in the Bronx which mostly treat adults with moderate to severe asthma. However, 67% ($n=84$) with uncontrolled moderate to severe asthma were not screened or referred for biologic therapy indicating the standard of care is not being met (12).

Asthma is a complex disease and the use of clinical practice guidelines (CPGs) like the Global Initiative for Asthma Guidelines (GINA) provide a standardized method of assessing and treating patients (13,14). CPGs are effective in directing care and improving

practice (15). However, the adoption and implementation of guidelines is a major barrier to managing severe asthma as various chronic disease studies show they are not always accepted, understood, or consistently used in practice by providers (16,17). One of the main reasons for the underuse of guidelines is the lack of familiarity or knowledge (7,18,19). Improving provider's knowledge of CPGs and the efficacy of a screening tool was vital to the implementation of the new intervention (19).

The purpose of this quality improvement (QI) project was to implement an asthma screening protocol utilized by providers caring for adults with allergic and eosinophilic phenotypes with uncontrolled moderate to severe asthma in an ambulatory setting to improve access to biologic therapy. The aims of the project were as follows:

1. Increase the number of patients screened (based on initial assessment, labs, and assessing severity and control) for biologic therapy using the Biologic Screening Protocol.
2. Increase the number of eligible patients who were offered a referral for biologic therapy.
3. Identify the barriers and facilitators of initiating biologic therapy screening at the Asthma Center post-implementation.
4. Evaluate provider perceptions and satisfaction with the implementation of a Biologic Screening Protocol.

Methods

A pre- and post-independent groups comparative design was used to assess baseline data. The effectiveness of using a Biologic Screening Protocol was assessed post-implementation. The IHI Plan-Do-Study-Act (PDSA) cycle methodology guided the initiative and provided a systematic approach to implementing the innovation, monitoring for improvements, and making adjustments as needed (20). The Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines was used as a guide to report the efforts and results of this QI project (21). The project has been formally evaluated using a QI checklist and determined not to be human subjects' research. The hospital's institutional review board did grant IRB approval for data collected for non-research purposes. The implementation of the QI project involved four PDSA cycles with each cycle lasting two weeks.

Setting and population

The site for this QI project is an asthma center located in a large academic medical center comprised of 15 member hospitals and more than 200 outpatient care sites located throughout New York. The center serves a mostly Black and Latino population in a low-income area. An interdisciplinary team consisting of physicians, nurses, nurse practitioner and patient care technicians (PCT) are onsite providing a comprehensive approach to caring for patients with asthma.

The QI project included a convenience sample of male and female adults, English and non-English speaking, age 18 years and older who were seen at the Asthma Center from May to July 2021. All patients screened for biologic therapy appropriateness included: 1) diagnosis of moderate to severe asthma as defined by the GINA criteria, 2) not well controlled on the current standards of care 3) adherent to treatment as assessed by providers through patient self-report, and 4) not currently on biologics. Excluded from the project were patients who 1) see the provider at their private practice or a different clinic and their asthma is not primarily managed at the Asthma Center, 2) are seeing the provider for the first time, 3) have already tried or currently on biologic therapy and, 4) who have a diagnosis of mild, intermittent, or well-controlled asthma or another primary respiratory diagnosis other than asthma.

Intervention

The Biologic Screening Protocol was developed by the nurse practitioner (NP) and center's Medical Director. Using the GINA guidelines as the basis, an easy-to-follow algorithm was designed (14). The screening process began with the patient care technician (PCT) or nurse obtaining a brief history, vital signs, and spirometry per the usual standards of care. The PCT or nurse attached the Biologic Screening Protocol to the patient's chart for the provider to complete during the visit (Figure 1). The Biologic Screening Protocol outlined criteria for biological therapy eligibility: 1) pulmonary function tests (PFT), 2) oral steroid use, 3) absolute eosinophil levels, IgE levels, 4) exacerbations per year, and 5) presence of perennial allergies. The protocol algorithm was followed by the provider during the patient visit to assess eligibility for biologic therapy (Figure 2).

The patient was seen by either the pulmonologist or allergist/immunologist as scheduled and assessed for asthma history, severity, control, and medication

optimization and adherence. If the provider determined that the patient did not have all the required PFTs and biomarker tests completed as outlined in the Biologic Screening Protocol, the specific tests needed were ordered for the patient and a follow-up appointment was made to review the results with the patient. If the patient had all the required tests, the patient was assessed for eligibility for biologic therapy. If the patient was determined eligible, biologic therapy as a treatment option was discussed with the patient. If the patient agreed to start biologic therapy a referral was made to clinic staff to obtain prior authorization and coordinate with the pharmacy. Providers discussed biologic treatment options at the next clinic visit with patients who chose not to start biological therapy at the initial screening visit. Patients who opted out of biological therapy continued with usual care (Figure 1).

PDSA cycle 1

The initial roll-out of the Biologic Screening Protocol occurred at an informal meeting with clinic staff which included nurses, PCTs and providers followed by a meeting with the faculty practice manager. The clinic staff received training on the Biologic Screening Protocol with detailed overview of all elements of the screening protocol tool and the plan for implementation (Figure 1). Staff were informed and showed the location of the blank screening protocol forms to be placed in the folder with their initial patient assessment given to the provider at the start of the visit. The educational sessions were repeated each week to ensure all staff were educated and information provided was consistent.

PDSA cycle 2

The NP had one-on-one discussions on a weekly basis with clinic staff to assess their knowledge and use of the screening protocol. The sessions revealed that several nurses and PCTs were unaware of the screening protocol and that the documents were being stored near the nurse's station on a wall shelf in a yellow labeled folder. Thus, to make the folder clearly identifiable, the folder was changed to a red labeled folder positioned at the top of the shelf making it easier for staff to see.

PDSA cycle 3

This cycle lasted for two weeks and included continued educational discussions with clinical staff.

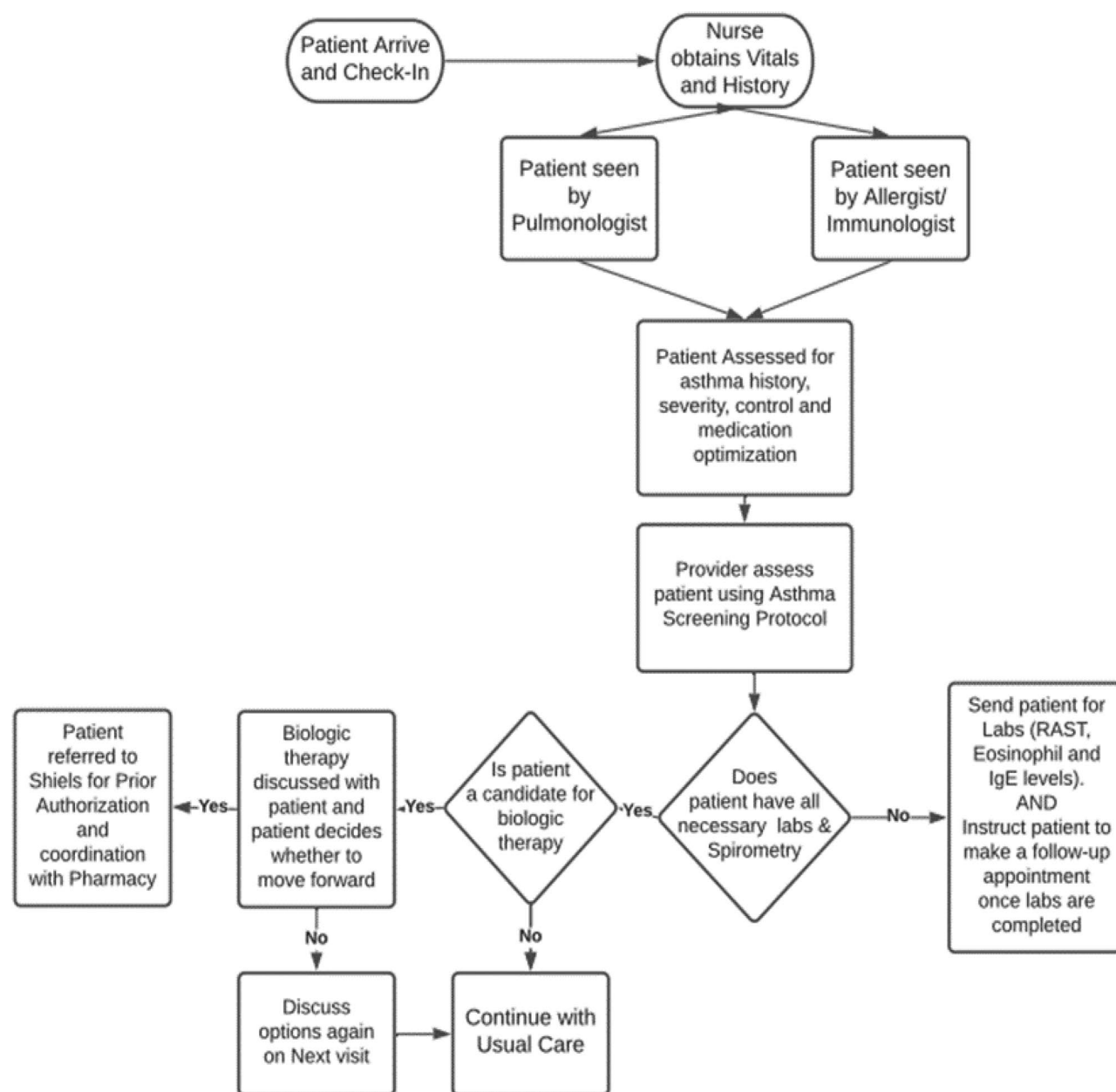


Figure 1. Biologic Screening Protocol.

Feedback from staff indicated greater awareness and knowledge of the protocol with no additional improvements warranted. Biologic Screening Protocol forms, chart reviews and discussions with providers revealed that there was a low patient visit rate. The target sample size post-implementation was forty-seven. However, after discussing with the providers and reviewing the patient visit schedule for the upcoming month, it was clear that this number was not going to be achieved. As a result, it was determined that the implementation of the protocol would continue an additional two weeks.

PDSA cycle 4

The final two weeks of the protocol implementation phase was completed without any additional adjustments or changes to the implementation process.

Data collection

Patient demographics of age, gender, race, and funding source were collected from the electronic health record (EHR). To assess fidelity and completion of the screening process the following items were verified

ASTHMA CENTER

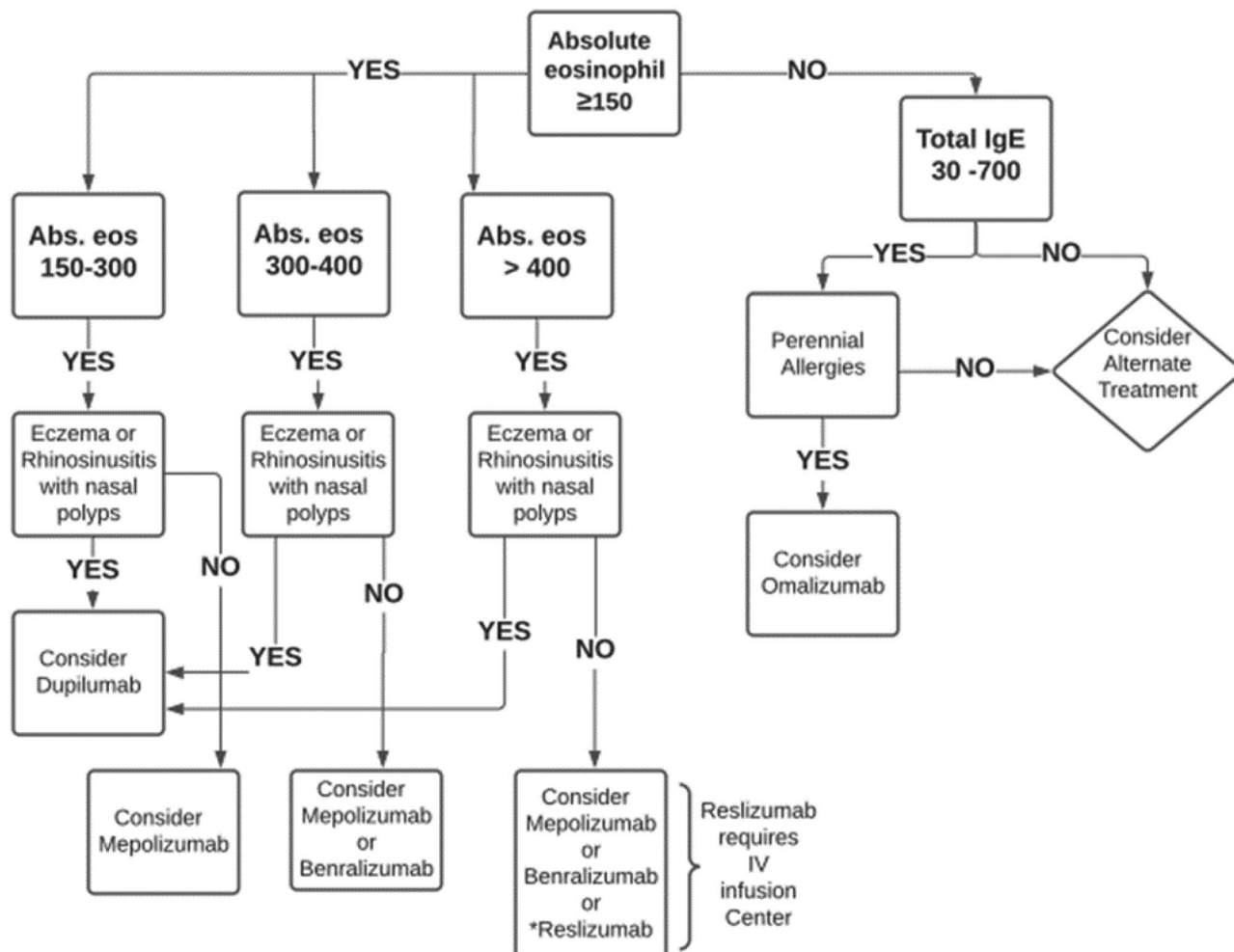
Biologic Screening Protocol

ADULTS ONLY
Approach to selection of biologic agents for add-on therapy for severe asthma

Name: _____
MRN: _____
PFTs with FEV1 < 80% and FEV1/FVC < LLN? Y ____ N ____
or
Peak Flow: average daily variability > 10% (over 1 week) Y ____ N ____
or
BD reversibility: FEV1 by >200ml AND >12% after BD: Y ____ N ____
Chronic Oral Steroids: Y ____ N ____
Absolute Eosinophil level off steroids: _____
IgE level: _____
Exacerbations per year: _____
Perennial Allergies: Y ____ N ____

DATE: _____

Provider: _____



These biologic agents are for use in patients with uncontrolled asthma despite regular use of a combination of medium-to-high dose inhaled glucocorticoid and long-acting beta-2 agonists and FEV1<80% predicted.

Figure 2. Biologic Screening Protocol Process Map.

as collected: biomarkers, current asthma medications and biologic eligibility indicators as outlined above. Screening was considered completed once a provider checked all the elements on the biologic screening protocol (Figure 2). The total number of referrals was collected from the EHR. Providers completed a survey identifying barriers and facilitators for initiating biologic therapy using a check all that apply format. See Table 1 for the elements included in the survey. A 5-point Likert scale survey data (strongly disagree – strongly agree) was created to illicit provider perceptions of and satisfaction with the screening process. The survey was administered via Qualtrics, a web-based survey tool.

Data analysis

Patient demographics, provider perceptions, provider satisfaction and barriers were described using descriptive statistics. Screening and referral rates were compared between pre and post implementation using Fisher's statistics (n, %). IBM SPSS version 27 was used to conduct statistical analysis with alpha set to 0.05.

Results

Patient demographics in the pre-implementation phase of the project were a mean age of 49 years, 84% female, 15.1% male and consisted of 53.7% Hispanic, 34.8% Black, 6.3% White and 5.0% Other. The patients were 73.4% on Medicaid or Medicare and 26.5% had private insurance. The post-implementation group mean age was 50 years, 84.5% female, 15.1% male, 7.8% Hispanic, 31.5% Black, 0.0% White and 10.5% Other. About 73.6% of the patients had Medicare or Medicaid while private insurers made up 26.5%.

In the pre-implementation phase 30 (23.8%) were screened compared to 17 (70.8%) in the post-implementation period, $p < 0.001$; $\phi = 0.372$ (moderate effect) showing a 47% increase in patients who were screened. Regarding referrals, 42.4% (28 out of 66) eligible (were referred in the pre-implementation period and 14 out of 15 eligible patients (93.3%) were referred in the post-implementation period, $p = < 0.001$; $\phi = 0.396$ (moderate effect) which was an 51% increase.

Providers recognized there are barriers to biologic therapy initiation. Both providers perceived

Table 1. Staff Survey Results Post-Implementation (N=2).

Post-implementation Survey items	n	%
Q1 – I am aware that there are barriers to initiating biologic therapy	2	100.0
Q2 – Which of the following do you perceive as barriers to initiating biologic therapy? (Check all that apply)		
Patient Focused		
Medication and copay costs	2	100.0
Patient lack of knowledge or understanding of biologic therapy	2	100.0
New patient – limited treatment and care history	1	50.0
Choosing the appropriate setting for the administration of medication	0	0.0
Patient's concern for the safety and/or efficacy of the medication	2	100.0
Patient's cultural beliefs or preferences	0	0.0
Missed or canceled appointments	1	50.0
Patient's lack of readiness or hesitation to start treatment	2	100.0
Q3 – Which of the following do you perceive as barriers to initiating biologic therapy? (Check all that apply)		
Provider Focused		
Provider's lack of knowledge or understanding of biologic therapy	1	50.0
Poor provider-patient communication	0	0.0
Difficulty in assessing asthma severity and/or control	1	50.0
Provider's preference for treatment	2	100.0
Q4 – Which of the following do you perceive as barriers to initiating biologic therapy? (Check all that apply)		
Process Focused		
Limited time for patient visit	0	0.0
Issues with patient insurance or difficulty obtaining prior authorization	2	100.0
Outdated biomarkers or labs	1	50.0
Unable to obtain necessary labs or tests to determine eligibility	0	0.0
Staffing issue	0	0.0
Q5 – Indicate which of the following you perceive as facilitators to initiating biologic therapy. (Check all that apply)		
Patient's trust	2	100.0
Shared decision making	1	50.0
Patient's readiness for treatment	2	100.0
Availability of a standardized screening protocol	1	50.0
Supportive and knowledgeable staff	0	0.0
Organizational leadership support	1	50.0
Ease of insurance prior authorization process	2	100.0
Setting options for biologic administration	0	0.0

medication co-pays, patient lack of knowledge, patient readiness, and safety concerns as patient barriers to initiating biologic therapy (100%). Provider preference (100%) was perceived as a barrier to initiating biological therapy. Barriers related to the process of initiating biologic therapy was primarily issues with patient insurance or difficulty obtaining prior authorization, patient trust, patient readiness for treatment, and ease of insurance prior authorization were perceived as facilitators to initiating biologic therapy (100% $n=2$). Shared decision-making with patients ($n=1$, 50%), a standardized screening protocol and organizational support ($n=1$, 50%) were perceived as facilitators by some of the providers (50% $n=1$). Table 2 contains the full survey results. Overall, 100% of the providers were satisfied and felt knowledgeable in using the Biologic Screening Protocol.

Discussion

The goal of this QI project was to increase the number of uncontrolled moderate to severe asthma patients who were screened for eligibility for biologic therapy with subsequent referral if nationally establish criteria were met (14). Patient demographics were representative of the country with a higher prevalence in women, Blacks and Hispanics (3). This demonstrates that the Asthma Center is treating patients who are more at risk for developing moderate to severe asthma and can greatly benefit from the use of biologic therapy. The implementation of the Biologic Screening Protocol led to a 47% increase in patients who were screened as well as a 51% increase in those referred for biologic therapy.

These results are consistent with what is seen in the literature that the use of a protocol can increase adherence to guidelines. A post-discharge evaluation and management protocol was used in a clinic to reduce readmission rates for heart failure patients and

successfully resulted in a 44.3% reduction in 30-day hospital readmission (22). The use of a guideline-based strategy fostered the use of standardized care in management of diabetes, like asthma, a difficult disease to manage (23).

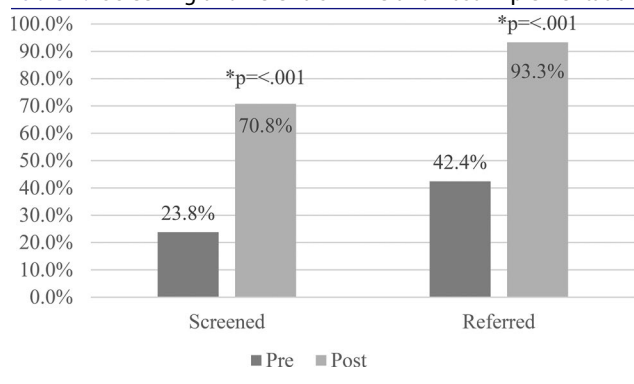
The pre-implementation strategies may have facilitated the use of the screening tool. For example, the design of the protocol with a clear flowchart for decision contributed to use by the providers. Adherence to protocols can vary but studies have shown that providers are more likely to use protocols that are simple, supported by clear evidence and do not require learning a new skill, or changing workflow (15). Maintaining practice routines was especially important for this project to obtain staff support and buy-in. Training of the providers prior to implementation of the screening tool facilitated the implementation. As part of the PDSA cycle weekly educational sessions were held to provide training to new staff. The training sessions offered an opportunity to seek clarification if needed. The post-implementation survey results showed that providers felt knowledgeable and confident and were satisfied with the Biologic Screening Protocol. Increasing provider's knowledge of evidence-based CPGs and the efficacy of screening tools was key to the implementation and utilization of the new protocol (19).

There were several limitations identified in the QI project. The Asthma Center operates from a single outpatient location and is only open one day a week thereby limiting the number of patients being treated and making it less generalizable to sites with multiple locations. A study that includes a more robust sample size would be beneficial.

Another limitation was the high number of patient no-shows due to systemic issues which led to a smaller sample size than originally planned. The high no-show rate has been attributed to the onset of summer when numbers are historically lower, the ongoing COVID-19 pandemic and the post-pandemic return to normalcy.

Multiple patients, provider and system focused barriers were identified but was solely from the providers perspective. A future project can include a patient survey which would provide another viewpoint and offer valuable information to address the identified barriers to initiating biologic therapy. This project did not look at the barriers to initiating therapy once the patient was determined to be eligible but acknowledges it as an important next step as a referral alone does not ensure treatment will start. A future study can follow up on patient continued use of the biologic and how this impacts hospitalizations.

Table 2. Screening and Referrals in Pre and Post Implementation.



Most of the patients had Medicaid or Medicare indicating that the cost of the medication could be a factor for starting biologic therapy which was acknowledged by providers as a barrier in the post-implementation survey. We recognize that the self-reporting of medication and treatment adherence as a limitation and suggest the use of a more formalized adherence tool be used to strengthen the assessment of the patient's control and severity of asthma.

There were other challenges faced during the implementation of this project. One limitation of this project which included staffing inconsistency and shortages due to the COVID-19 pandemic and the need for staff redeployment. Nursing shortages and changes in assignments led to more nurses being unfamiliar with the protocol causing an underuse. Lastly, it was difficult and very time consuming to retrieve information during chart reviews from the electronic medical record. The labs, notes and other documents are not in a centralized location but instead require navigation to multiple pages to obtain the data. The process of data retrieval and query can be time consuming and understanding system challenges and gathering resources and support should be explored.

Conclusions

This QI project has determined that more moderate to severe asthma patients can be screened and referred for biologic therapy when providers utilize an evidence-based screening tool that provides a clear decision-making pathway. Based on survey findings, adhering to evidence-based practice guidelines can minimize the variability in treatment between providers and reduce barriers to initiating therapy. Increasing providers knowledge and confidence in CPGs will encourage sustained use and help to maintain the standards of care. The implications for practice would be to extend this intervention to other practice areas and locations and educate more providers to increase access to biologic therapy.

Declaration of interest

There are no conflicts of interest related to the implementation of this project or writing of this article.

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