

Improvements in Cystic Fibrosis Quarterly Visits, Lung Function Tests, and Respiratory Cultures

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BACKGROUND: The Cystic Fibrosis (CF) Foundation recommends patients attend clinic ≥ 4 times per year with 4 respiratory cultures and 2 pulmonary function tests (PFTs). However, nationally only 57.4% of patients met these guidelines in 2012. We used a quality improvement program with a goal of 75% of our patients meeting this care guideline by 2012.

METHODS: A 2-stage program was started in 2011. Stage 1: education of patients/caregivers on importance of quarterly visits. Stage 2: quarterly tracking system of patient appointments. Data on clinic visits, respiratory cultures, and PFTs were collected from the CF registry from January 2009 through December 2013. Statistical process control charts were used to track improvements.

RESULTS: The average number of clinic visits increased significantly from 4.6 ± 2.3 in 2009 to 6.3 ± 4.6 in 2013 ($P < .0001$). The percentage of patients ages 6 through 18 completing a clinic visit, PFT, and respiratory culture per quarter increased significantly from 76.2% during 2009 to 86.4% in 2013. The percentage of patients completing ≥ 4 clinic visits with 4 respiratory cultures and 2 PFTs improved significantly from 47.5% in 2009 to 71.0% in 2013 ($P < .0001$).

CONCLUSIONS: A tracking system of patient appointments significantly improved adherence to the care guidelines better than education alone. The multiple-stage quality improvement program we implemented may be modifiable and able to be integrated in other CF centers or other multiple disciplinary chronic illness care centers.

Cystic fibrosis (CF) is an inherited disease that causes mucus plugging, infection and inflammation within the airways. The life expectancy has increased from the <1 year to almost 40 years of age over the last 60 years.¹ Quality improvement programs (QIPs) to advance the medical care of patients with CF are effective in improving outcomes and survival.² QIPs with published results include improving the treatment of inpatient pulmonary exacerbations,^{3,4} airway clearance techniques,⁴ quarterly visits,⁵ and nutritional outcomes.^{5,6} These

programs were supported by the CF Foundation through the Leadership and Learning Quality Improvement Collaborative.⁷

The CF Foundation also supports the development of evidence-based care guidelines. One of the guidelines recommends that patients age 6 to 17 years attend at least 4 clinic visits and receive 4 respiratory cultures and 2 pulmonary function tests (PFTs) per annum. These guidelines were based on published positive associations between increased frequency of clinic visits and higher lung function. This

abstract

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Dr Wooldridge conceptualized and designed the quality improvement program (QIP), completed analysis of the data, and drafted the initial manuscript; Ms Mason and Ms Brusatti completed the interventions employed during the QIP; Drs Albers and Noyes were involved in conceptualization and design of the QIP and completed patient education during the QIP; and all authors approved the final manuscript as submitted.

www.pediatrics.org/cgi/doi/10.1542/peds.2014-2979

DOI: 10.1542/peds.2014-2979

Accepted for publication Jun 8, 2015

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: This work was supported by an Accelerating the Rate of Improvement in CF care grant from the Cystic Fibrosis Foundation.

POTENTIAL CONFLICT OF INTEREST: Dr Albers has received grants and speaker fees from Novartis, speaker fees from Gilead, and a contract for the study of cystic fibrosis medication from Kalobios; the other authors have indicated they have no potential conflicts of interest to disclose.

association existed across all age groups and disease severity.⁸ The CF Foundation maintains an institutional review board (IRB)-approved patient registry that tracks CF care center adherence with the guidelines.⁹ In 2012, nationally only 57.4% of patients with CF met the guideline recommendations for clinic visits, respiratory cultures, and PFTs.¹ Ten years ago, this percentage was much lower at 24.6% indicating that CF care centers have successfully implemented changes. However, the 10 best performing CF centers in 2012 achieved a rate of 83.7%, which demonstrates that CF centers have continued potential for improvement.¹

Review of our CF center specific registry data revealed that we were a center with the possibility for improvement. In 2009 and 2010, only 40% of our patients met the care guidelines for 4 clinic visits, 4 respiratory cultures, and 2 PFTs per year. In 2011, we initiated a QIP to improve the frequency of quarterly visits for our patients with CF. Our goal was to increase the percentage of patients attending at least 4 clinic visits with 4 respiratory cultures and 2 PFTs to 75% by 2012.

METHODS

Settings

The QIP took place from January 2011 through December 2013 at Cardinal Glennon Children's Medical Center (CGCMC). CGCMC is a 195-bed, free-standing, tertiary care children's hospital located in a major metropolitan area. The hospital has ~8000 hospitalizations and ~150 000 outpatient visits per year. The insurance payer base of all patients receiving care at CGCMC is 65% Medicaid, 32% private insurance, and 3% other. The CF center is located within CGCMC with ~120 pediatric patients with CF receiving care. Three physicians, 2 nurses, 2 respiratory therapists, 1 social worker, and 1 dietician staff the center. A CF specific

clinic is held every Monday morning with up to 16 patients scheduled. Patients are also seen as sick visits during the other days of the workweek.

Sample

The source population included all patients with CF ≤ 18 years of age followed in clinic from January 2009 through December 2013. Patients ≥ 19 years of age were excluded due to the process of transitioning to the adult CF center. Patients with CF-related metabolic disease defined as per the CF Foundation practice guideline were excluded due to different clinical care guidelines.¹⁰ Quarter-years were defined as 3 consecutive month blocks within each year (for example, January, February, March = Quarter 1). Data from patients transferring care to/from the CF center were included starting in the quarter-year in which the patient received first care at the CGCMC.

Multifactorial Analysis

At the initiation of the QIP, the multidisciplinary CF care team met to discuss the factors, which could be contributing to patients not attending clinic once a quarter. The factors identified include weather affecting travel/road conditions, patient/caregiver transportation issues, lack of education/knowledge of impact of clinic visits, insurance/financial issues, work/school conflicts, difficulties with the clinic scheduling system, or psychosocial issues in the patient's home/family. The CF care team recognized that impacting/changing many of these factors would require intensive interventions. Based on this discussion, the team chose to focus on interventions related to education and scheduling.

The CF care team also discussed the completion of respiratory cultures and PFTs in the clinic. It was clear that the main factor affecting the completion of these tests was the recall of individual care team members. Therefore, the intervention

to improve the completion of respiratory cultures and PFTs focused on the clinic practices.

Scheduling Process at CGCMC

At the conclusion of a clinic visit, the physician, patient, and care provider discuss the recommended time to next appointment. This recommendation is printed on an after-visit summary and given to the patient. The patient/caregiver is encouraged to schedule the future appointment with a general scheduler at a desk located at the exit of the clinic lobby. Patients/caregivers can also call a hospital telephone number in which they speak directly with a general scheduling person and make the appointment. For sick visits, patients call directly to the pulmonary nurses' telephone line. The nurses then triage the patient, speak to the on-call physician, and schedule the patient as deemed appropriate.

Intervention for Clinic Visits

The continuous QIP began in 2011 and took place with 2 consecutive stages. The initial stage to improve patient attendance for quarterly visits addressed improving the knowledge/education of the patients and their families. A physician wrote an article in the biannual newsletter explaining the reasons for the recommendations of quarterly visits. This newsletter was sent to all patients' homes in January 2011. During clinic visits, physicians spoke to patients and their care providers about the recommendations and reasons for quarterly visits.

The second effort to improve patient adherence with quarterly visits involved a tracking process completed by the nurses. In January 2012, the nurses printed up a list of the current patients with CF. The nurses then recorded when each patient had a clinic appointment scheduled over the next 3 months. Each patient without a scheduled appointment received a telephone call

from the nurse. If the nurse talked directly to a caregiver, then she made the appointment for the patient. If the nurse reached a voice messaging system, then she left a message asking the patient or care provider to return her telephone call. The nurse made subsequent telephone calls on a weekly basis until she reached the patient or care provider and scheduled an appointment.

The CF care team met monthly to review the list of patients without a scheduled appointment despite 3 telephone calls from the nurse. The team developed individualized plans for each patient to facilitate scheduling an appointment. These plans, listed in order included (1) physician telephone call to the patient/care provider, (2) a physician/social worker letter mailed to the last known address, (3) decision by the team to stop refills for the patient's medications, and (4) decision by the team to involve child protective services because of concern for patient safety. In addition, at these meetings, the team reviewed available clinic slots and opened additional clinic slots as necessary to accommodate all patients.

Intervention for Respiratory Cultures

Patients needing a respiratory culture for the quarter were identified in the weekly preclinic review with all care team providers present. This list was given to the nurses on the day of clinic. As the nurse checked in the patient, the nurse would place a patient identification sticker on the computer screen in the patient's room. The sticker prompted the physicians when utilizing the electronic medical record system to obtain a respiratory culture from the patient.

Intervention for PFTs

All patients ≥ 5 years of age were designated as needing PFTs. After the nurse would triage the patient and place the patient in a clinic room, a respiratory therapist would escort

the patient to the PFT laboratory to complete the testing.

Measures

The percentage of completed clinic visits within each quarter-year was calculated as the number of patients seen in the CF clinic by a physician divided by the total number of patients followed at our CF center during the specific quarter. The percentage of completed respiratory cultures was defined as at least 1 respiratory (epiglottic, sputum, bronchoalveolar lavage fluid) culture completed per individual patient divided by the number of patients completing a clinic visit for each specific quarter. The percentage of completed PFTs was defined as at least 1 PFT completed by an individual patient divided by the number of patients completing a clinic visit for each specific quarter and ≥ 6 years of age. The percentage of patients meeting the CF care guideline of ≥ 6 years of age with at least 4 clinic visits, 4 respiratory cultures, and 2 PFTs per year was also calculated. (The national CF patient registry reports patients ages 7 through 17 years.¹)

Data Analysis

Center specific data were collected from the CF Foundation national patient registry from January 2009 through December 2013. The patient registry has St. Louis University IRB approval. Patient data are entered only with signed consent. All patients with CF receiving care at CGCMC are enrolled in the patient registry. The St. Louis University IRB determined that our project was a QI initiative and not human subjects' research.

The data were analyzed by using the commercially available statistical package JMP 10.0.2 and SAS 9.3 (SAS Institute, Inc, Cary, NC). The mean and SD of number of visits and age were calculated by year. The percent of subjects meeting the standard of care (4 clinic visits, 4 respiratory cultures, and 2 PFTs per year) was

also calculated by year. The differences by year were analyzed for the dependent variables of number of visits, age, and meeting the standard of care by using general linear and logistic mixed models adjusting for repeated measurements at the patient level. Posthoc contrasts were performed to determine if there were differences in any of the outcomes between the combined years of 2009 and 2010 compared with 2013.

The statistical process control (SPC) *P* control chart was used to determine if the percentage of each measure changed significantly from 2009 through 2013. The *P* chart has a central line and 2 limits. A lower control limit and upper control limit were calculated by using validated mathematical formulas at 3σ (~ 3 SDs), a risk level of 1%.¹¹ The control charts were generated by using JMP 10.0.2 (SAS Institute, Inc) with the *X*-axis being each quarter-year. Special causes indicate a significant change and are defined as (1) any point outside the control limits, (2) a run of 8 or more points all above or below the center line, (3) a trend of 6 or more points up or down, and (4) 2 out of 3 points near a control limit.¹¹ The SPC *P* control chart limits were recalculated after a special cause occurred.

RESULTS

Demographics

Between January 2009 and December 2013, 136 patients with CF completed 3241 clinic visits at our center. The number of patients with CF followed within each year increased from 102 in 2009 to 129 in 2013. The mean \pm SD age in years increased significantly over the course of the QIP, ranging from 7.9 ± 5.1 to 10.5 ± 5.5 in 2009 and 2013, respectively, $P < .0001$.

Clinic Visits

The mean \pm SD number of clinic visits per patient per year increased

significantly from 4.6 ± 2.3 in 2009 to 6.3 ± 4.6 in 2013 ($P < .0001$) with years 2009 and 2010 being statistically significantly lower than 2013 ($P < .0001$ for both; Table 1). Using traditional statistical analysis methods, the odds of individual patients completing 4 visits per year over time revealed an improving trend ($P = .11$). Using SPC control charts for analysis, the percentage of patients completing at least 1 clinic visit per quarter-year did not improve during the educational stage of the QIP process (Fig 1A). However, after the tracking process of the QIP was initiated in 2012, the percentage of patients attending at least 1 clinic visit per quarter significantly improved to 90% (Fig 1A).

From January 2012 through December 2013, individualized plans to facilitate scheduling an appointment were necessary for a total of 9 patients. All 9 patients received telephone calls from the physician to encourage scheduling an appointment. Six of those 9 patients then required a registered letter from the social worker/physician again encouraging scheduling an appointment plus informing patients whose future refills will not be given and child protective services may be contacted. Two of those 6 patients required denial of medication refills. And 1 of those 2 patients was reported to child protective services because of lack of follow-up in CF clinic.

Respiratory Cultures

In all patients attending a clinic visit per quarter, the initial mean percent of respiratory cultures obtained per quarter was 92.1% during 2009 and 2010. A significant increase to 96.2% occurred at the initiation of the QIP when physicians and nurses were prompted to obtain a culture (Fig 1B). This improvement was sustained through the length of the QIP.

Pulmonary Function Testing

For patients ages 6 through 18 years, 96.3% completed at least 1 PFT per

TABLE 1 Mean Number of Clinic Visits per Patient per Year

Year	Number of Subjects	Number of Visits		Age, Mean (SD)	Patients Completing 4 Visits, 4 Cultures, 2 PFT per Year, n (%)
		n	Mean (SD)		
2009	102	465	4.6 (2.3)	7.9 (5.1)	29 (44)
2010	110	516	4.7 (2.2)	7.9 (5.4)	24 (35)
2011	114	674	5.9 (3.9)	9.6 (5.3)	42 (52)
2012	124	771	6.2 (3.7)	9.6 (5.7)	52 (59)
2013	129	815	6.3 (4.6)	10.5 (5.5)	66 (71)
<i>P</i>			<.0001	<.0001	<.0001

Tests for differences between group means were linear/logistic mixed model for repeated measurements.

quarter from 2009 through 2013. There was no significant change identified in this measure during the QIP.

Combination of Clinic Visit, Respiratory Culture, and PFT per Quarter

The percentage of patients ages 6 through 18 completing a clinic visit, PFT, and respiratory culture per

quarter-year was 76.2% during 2009 and 2010 (Fig 2). A significant increase to 86.4% occurred in quarter 3/2011 after the education stage and before the tracking stage. This improvement was sustained through the length of the QIP.

CF Care Guidelines

The percentage of patients meeting the care guidelines of attending

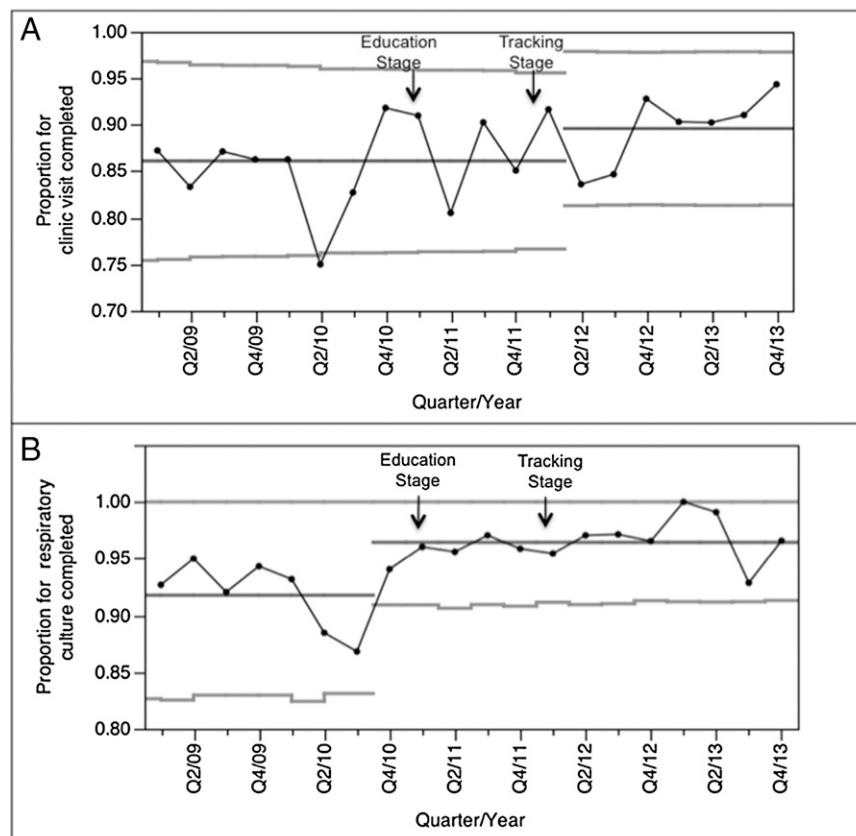


FIGURE 1

P chart showing (A) percentage of clinic patients per quarter-year who completed at least 1 clinic visit and (B) percentage of patients with at least 1 culture during each quarter-year. Light gray lines indicated upper and lower control limits. Control limits set at 3σ .

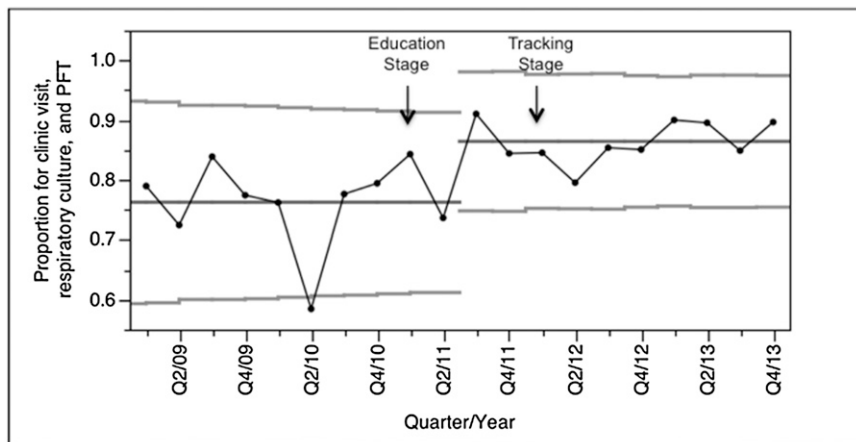


FIGURE 2

P chart showing percentage of patients completing at least 1 clinic visit, 1 respiratory culture, and 1 PFT per quarter/year. Light gray lines indicated upper and lower control limits. Control limits set at 3σ .

at least 4 clinic visits with 4 respiratory cultures and 2 PFTs per annum improved significantly during the course of the QIP from 47.5% in 2009 to 71.0% in 2013 ($P < .0001$; Table 1).

DISCUSSION

This QIP demonstrates that implementation of a tracking system significantly improves patient attendance for quarterly clinic visits. Education of patients and caregivers alone did not improve clinic visit adherence. In addition, prompting of physicians and staff to obtain respiratory cultures was effective in improving adherence for completion of this test.

This QIP is the first demonstrating successful implementation of all 3 components (clinic visit, respiratory culture, and PFT) of the CF care guidelines, despite the care guidelines being issued from the CF Foundation over 10 years ago. Decullier et al¹² reported on the experience in France of implementing similar care guidelines and how the average number of clinic visits increased from 3.7 to 5.0 per year. Unfortunately, the authors did not document the processes used by centers to achieve the improvement in clinic visits.

Another article revealed that multiple steps including restructuring the clinic schedule, insuring open slots for patients with CF, and standardizing the rescheduling process for missed appointments improved patient attendance of ≥ 4 times per year from 72% to 90%.⁵ This improvement was sustained over 7 years. However, the percentage of respiratory cultures and PFTs obtained was not measured as part of this QIP. The literature suggests that it is the combination of quarterly clinic visits with PFTs and a respiratory culture, which improve a patient's overall health.⁸

Regular clinic visits with respiratory cultures and PFTs are the foundation of improving the outcomes of patients with CF. Results from the Epidemiologic Study of CF demonstrated that across all age groups and severity of disease, patients with lung function in the upper quartile had more frequent clinic visits compared with patients with lung function in the lower quartile.⁸ In addition, the patients with lung function in the upper quartile independently had more frequent respiratory cultures and more frequent PFTs. The authors also report that CF centers with a higher mean forced expiratory volume in

1 second predicted for their patients used IV and oral antibiotics significantly more compared with CF centers with lower mean forced expiratory volume in 1 second predicted. These results suggest that pulmonary exacerbations are quickly identified and treated when patients are seen more frequently in clinic. The results further indicate the importance of quarterly clinic visits to improve the outcomes and survival of our patients with CF. In addition, other QI processes focusing on improving nutritional status and lung function will be unsuccessful if the patients do not attend clinic.

Berlinski et al⁵ speculated that the inclusion of nurses in the process to improve adherence with clinic visits is key to success. Our experience supports this speculation as our nurses completed the tracking of clinic appointments and made the majority of telephone calls to patients/caregivers. However, this reliance on nurses is also 1 of the limitations of the process because of the intensive time requirements of the nurses. They experienced frustrations with the number of telephone calls made to care providers and the care provider's limited availability to schedule appointments. For future steps, we are exploring the option of utilizing schedulers or medical secretaries versus nurses for the tracking system. However, the nurses have expressed concerns about a potential decline in adherence with clinic visits if an unknown scheduling person versus a known CF nurse contacts families. Another vital aspect of the tracking process was the support from the physicians, especially in difficult cases when protective services had to be contacted.

We found that family acceptance of care guidelines is also critical to successful implementation. We experienced only a small number of families who refused to attend clinic once a quarter despite being educated on the impact of clinic visits

on outcomes and receiving multiple telephone calls and letters. A clinic with a large numbers of families refusing will not be able to duplicate the success we report. We also did not address external barriers including lack of transportation, childcare issues for siblings, missed work and school, or long travel distances during the QIP.

Another limitation to the QIP may be the structure of the education process used. Literature from other medical specialties to improve clinic visits has demonstrated that exit-interviews can improve patient adherence with clinic visits.¹³ Exit-interviews consisted of asking patients if their questions and concerns were addressed, if they understood the information received, and if they agreed with the course of treatment. The education stage of our project did not include any of these components, which may have diminished the impact of the education stage of the process.

Perceptions and emotional state of the patient or care provider can also affect attendance to clinic visits. A qualitative design study exploring reasons for no-shows revealed 3 interconnected themes: (1) emotional barriers, (2) perceived disrespect of the patient's beliefs and time by the health care system, and (3) lack of understanding of the scheduling system.¹⁴ We did not measure or address these emotional states or perceptions during our QIP, which is another limitation of the QIP. Future QIPs, which address the 3 interconnected themes, present the opportunity to focus on patients who experience long-term struggles in clinic attendance.

CONCLUSIONS

We demonstrated a successful process improvement in patient

adherence with clinic visits and care guidelines. The process used for improvement is simple and prevents the need to overbook clinics. The multiple-stage QIP we implemented may be modifiable and able to be integrated in other CF centers or other multiple disciplinary chronic illness care centers.

ACKNOWLEDGMENTS

We thank Paula Buchanan, PhD, MPH, with the St. Louis University Center for Outcomes Research for reviewing and editing our statistical analysis.

ABBREVIATIONS

CF: cystic fibrosis
CGCMC: Cardinal Glennon
Children's Medical Center
IRB: institutional review board
PFT: pulmonary function test
QIP: quality improvement
programs
SPC: statistical process control

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Pediatrics 2015;136;1611

DOI: 10.1542/peds.2014-2979 originally published online November 16, 2015;

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The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://pediatrics.aappublications.org/content/136/6/1611>

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