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Implementation of Cystic Fibrosis Clinical Pathways Improved Physician Adherence to Care Guidelines

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Abstract

Introduction—There is significant variability in clinical outcomes, including growth and lung function, between the various cystic fibrosis (CF) centers. No specific or unique therapeutic practices have been identified to account for these differences. However, more uniform care within centers was associated with better outcomes. The objective of this study was to implement clinical pathways for diagnosis and treatment of nutritional failure and lung inflammation in order to achieve better health care provider adherence to center-specific, agreed-on practices.

Methods—Agreed-on clinical pathway treatment plans for both nutrition and lower airway inflammation were implemented on January 1, 2010. The primary outcome measure was to evaluate if patients' diagnoses and treatments were consistent with the agreed-on clinical pathways.

Results—The proportion of clinic visits from baseline to 18 months post-intervention where the provider completely followed nutrition clinical pathway increased from 57.72% to 79.49% ($p=0.049$) and the proportion for lower airway inflammation clinical pathway increased from 65.85% to 86.32% ($p=0.035$). The use of nutritional diagnosis and documentation of associated clinical pathway in the clinical plan increased from 16.26% to 61.54% and 56.10% to 94.87%, respectively. Similarly, diagnosis of lower airway inflammation and documentation related to their treatment plans increased from 1.63% to 43.59% and 30.08% to 87.18%, respectively.

Conclusion—Implementation of clinical pathways for nutrition and lower airway inflammation issues resulted in more uniform care of CF patients. Having objective criteria for diagnoses and agreed-on treatment plans for each of those diagnoses allowed for monitoring and individual feedback. Increases in utilization of correct diagnoses and discussion of specific therapeutic interventions in the clinic notes were associated with increased adherence to clinical pathways.

Keywords

cystic fibrosis; bronchoscopy; imaging; inflammation; nutrition; quality improvement

Introduction

In the last 50 years, clinical outcomes and survival for patients afflicted with cystic fibrosis (CF) has been one of continuous improvement. Recent CF Foundation Patient Registry data demonstrated substantial improvement in both pulmonary and nutritional outcomes across the entire care center network.¹ However, the processes of clinical care and outcomes between CF centers show significant variability.² No specific practices have been identified that are able to account for differences between centers. However, more uniform care within regional centers has been associated with better outcomes.³ This variability in care delivery and outcomes suggests an opportunity for further improvement based on current clinical science, evidence, and the use of clinical pathways. Clinical pathways, also known as care pathways or care maps, are one of the main tools used to improve quality and standardize care processes in healthcare. Implementation of quality improvement programs using such pathways has been shown to reduce treatment variability and lead to improved outcomes.⁴⁻⁷ However, there are many barriers to health care providers implementing clinical pathways including: 1) knowledge leading to the development of the care pathway; 2) acceptance of the pathway; and 3) adherence to recommending treatment plans consistent with the clinical pathway. This study focused on addressing these barriers with the primary goal of developing a model for successful implementation of clinical pathways at the University of Iowa's CF Care Center. The objective of this study was to implement clinical pathways for diagnosis and treatment of nutritional failure and lower airway inflammation in order to achieve better health care provider adherence to these center-specific, agreed-on practices.

Methods

The University of Iowa CF Center has operated within the Pediatric Allergy and Pulmonary Division under the same director since January 1977 through the duration of the data collection for this study in 2012. At the time of this quality improvement (QI) project, there were 6 pediatric pulmonologists and 4 advanced registered nurse practitioners (ARNP) providing care to 116 patients in the Pediatric CF Program. Although some patients mainly saw individual physicians, the general practice was a shared physician approach where any of the 6 pulmonologists might see a patient on a given clinic visit. Given this group-based rather than individual physician-based practice, utilization of agreed-on care guidelines and clinical pathways was important to help ensure continuity of care.

The standard of care practiced by all providers at the University of Iowa dating back to the mid 90's was to perform routine bronchoscopies and chest computerized tomography (CT) scans. The purpose of these tests was to see if there were objective measures of lung disease even with few or no symptoms. Therefore, these routine tests were generally performed only when the patient was well for at least a month and not during illnesses. These were used to guide clinical care and initiation of medications like dornase alfa and hypertonic saline, especially before lung functions could be obtained. Both bronchoscopy and chest CTs were performed roughly every 2 years, usually starting in the first year of life. Bronchoscopies were no longer performed if the patient produced sputum and chest CTs were no longer performed once bronchiectasis was first detected. Furthermore, if the bronchoscopy or CT would not change care regardless of the result, these routine studies also would not be

performed. Bronchoscopies and chest CTs could additionally be performed for other clinical reasons, such as failure to improve on standard therapies.

For this QI study, a stepwise approach was utilized to create agreed-on clinical pathways, as defined at this CF center. Our approach was divided into five stages: (1) health provider agreement on these pathways for a specific CF related issue (e.g. when to recommend enteral feeding); (2) input from the parent advisory board on the clinical pathways; (3) revision of the clinical pathways; (4) implementation of the these pathways; and (5) measurement of health care provider adherence to utilizing diagnoses and treatment plans consistent with the clinical pathways (Figure 1). This study was approved by the University of Iowa Institutional Review Board.

1. Health provider consensus on clinical pathways for a specific CF related issue

The members of the health care team at the University of Iowa met on a weekly basis to discuss CF care and CF related issues. During these weekly meetings, high priority patient care areas were selected from which to develop clinical pathways and included nutrition and lower airway inflammation. CF Foundation guidelines were reviewed for care in these specific areas, including data that served as the basis for those guidelines as well as other literature on the subjects. Through interactive discussions, a consensus was obtained for diagnoses and recommended clinical pathways for each specific diagnosis. All health care team members participated in development of these agreed-on care plans, including physicians, nurse practitioners, nurses, respiratory therapists, physical therapists, dieticians, and social workers.

2. Input from the parent advisory board on the clinical pathways

The data and rationale for the agreed-on clinical care pathways were presented to the advisory board in a manner that was understandable to the general public. Input was sought on the proposed clinical pathways, especially in terms of their practicality, likelihood of acceptance/compliance, and impact on patients/families.

3. Revision of the clinical pathways

Based on feedback from the parent advisory board, the CF care team revised the clinical pathways where appropriate and consistent with the CF Foundation's recommendations for standards-of-care for patients with CF. Revisions to the consensus also involved interactive discussions with the entire health care team.

4. Implementation of the clinical pathways

After coming to a revised consensus, the final nutrition and lower airway inflammation clinical pathways were formulated (Tables 1 & 2) and implemented on January 1, 2010. Because BAL and chest CTs were performed approximately every 2 years, we utilized the most recent results from these tests to calculate lung inflammation scores at each clinic visit. If no prior data for these tests were available, they did not contribute to the score. Post-implementation, healthcare providers were expected to use diagnoses and recommend treatment plans consistent with the clinical pathways at all clinic visits. For example, to be consistent with the clinical pathway for enteral feedings, all physicians at the center

previously agreed on the indications for when a patient would benefit from gastrostomy tube placement. This made it less likely that a patient truly needing this therapy could avoid having it recommended by choosing to see a particular physician, who put less emphasis on this recommendation. Furthermore, having more uniform recommendations from all of the health care providers (dietitians, nurse practitioners, and physicians) regarding the need for a gastrostomy tube made it more likely that the patient would accept this beneficial yet sometimes undesired treatment.

5. Measurement of health care provider adherence to utilizing treatment plans consistent with the clinical pathways

Chart reviews were utilized to determine: (1) if issues pertinent to the clinical pathway plans were documented in the clinic note (e.g. “patient had persistent poor weight gain”); (2) if the diagnoses used were consistent with those in the clinical pathway (e.g. at high risk for nutritional failure); and (3) if the medications/treatments were consistent with the agreed-on clinical pathways for that diagnosis (e.g. calorie boosting, dietary supplementation, and discussing the need for enteral feeds). Medical charts from July 2009 – June 2011 were reviewed to collect these data. Periodic quarterly feedback with provider-specific data for all physicians and nurse practitioners was used to help increase adherence to clinical pathways.

All data were dichotomous for each clinic visit and the proportion of clinic encounters consistent with the clinical pathways were calculated and compared over quarterly time-points. Run charts were created to document quarterly adherence to nutritional and lower airway inflammation clinical pathways. A generalized linear mixed model with a logit link was used to compare the healthcare provider adherence levels before and 18 months after implementation of the care pathways. All statistical analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC). Significance was defined as p values < 0.05 .

Results

A total of 111 patients receiving care at the University of Iowa CF Center were included in this analysis. From baseline (Q4 2009) to 18 months post-intervention (Q2 2011), the proportion of clinic visits where the provider completely followed the nutrition clinical pathway increased from 57.72% to 79.49% ($p=0.049$; OR = 2.98; 95% CI, 1.01–8.84). Similarly the proportion for lower airway inflammation clinical pathway increased from 65.85% to 86.32% ($p=0.035$; OR = 2.45; 95% CI, 1.07–5.61) (Figures 2b and 2d). The use of nutritional diagnosis and its discussion in the clinical plan increased from 16.26% to 61.54% and 56.10% to 94.87%, respectively (Figures 2a and 2b). Similarly, diagnosis of lower airway inflammation and its discussion increased from 1.63% to 43.59% and 30.08% to 87.18%, respectively (Figures 2c and 2d).

Discussion

Systematic implementation of nutrition and lower airway inflammation clinical pathways in our study was associated with increased physician adherence to center-specific, agreed-on clinical care practices. The study was also successful in addressing important barriers to health care providers implementing clinical pathways. This project not only increased the

knowledge and acceptance of the care guidelines but also gave a clear, individualized, and relatively objective process for managing the complexities of CF patient care. Additionally, it improved adherence and uniformity for recommending treatment plans that were consistent within this center. The use of diagnoses for both nutrition and lower airway inflammation showed steady improvement over the study period. The implementation of clinical pathways for nutrition as well as lower airway inflammation therapies and treatments started with moderate compliance and improved significantly over time. However, there was an initial slow increase in the adherence with the nutrition clinical pathways, which was thought to be a documentation issue rather than a true compliance issue (Figure 1b, Q3 2009 to Q2 2010 showed no significant improvement in following clinical pathways). We believed the problem was that the nutrition clinical pathway did not include medication interventions in contrast to lower airway inflammation, where adherence to the care pathway could be verified in the medication list. To address this issue, templates were built within the electronic medical record to allow for easier/standardized documentation of nutritional care pathway therapies such as recommended calorie boosting and/or oral supplements. Subsequent to that template intervention, discussion of and adherence with nutritional treatment plans consistent with clinical pathways increased.

Many of the methods and results of our study had similarities to previously published QI initiatives in CF. These included but were not limited to involvement of CF families, center-specific consensus on clinical management of CF, and standardization of care.^{7–11} Methods used in our QI project such as chart review to track adherence to center-specific care and periodic feedback to providers were also utilized in previous QI initiatives.^{7,9,12} Finally, some previous QI projects also focused on utilization of uniform pulmonary treatments.^{9,13,14} Our study is different from these studies in that it focused on both pulmonary and nutritional therapies. It also demonstrates a novel and comprehensive approach that included objective criteria for diagnoses and specific treatment plans that included not just medications, but other clinical practices.

This study has several limitations including that it was carried out at a single CF center, which could affect the generalizability of the results to other centers. However, being a single center study helped with feasibility, creating agreed-on clinical pathways, and providing feedback to our practitioners. Adherence rates in this study are similar to those observed by other CF QI initiatives.^{9,13,14} Another limitation is that we did not study the distribution of nutritional risk per quarter. We also did not directly assess the impact of improving prescribing adherence rates on pulmonary function outcomes, since we did not collect prescription data in our study. However, despite these limitations, there were improvements in clinical outcomes over the time frame of this study. For example, an overview of the annual center-specific reports from 2008 – 2012 generated by the CFF indicates that the FEV₁ for our center improved during the study period¹⁵. The mean FEV₁ percent predicted increased from 90% in 2008 to 96.2% in 2012, whereas the median FEV₁ percent predicted improved from 95.5% in 2008 to 98.4% in 2012 (Figure 3).¹⁵ Even though the national averages for lung function improved during this timeframe, the improvement at our center was higher than average. During the interval of the QI project, our CF center's ranking for median FEV₁% predicted increased from just above the national average to the 11th highest in the CF care network. Although the reasons for increases in lung function

during this study are multifactorial, this QI initiative may have contributed to this improvement. The increased use of some medications, such as ibuprofen, would not be expected to impact our center's median lung function in this 2 year time-frame. However, there was an increased use of other medications that have more immediate effects at our center during the study period, e.g., dornase alfa.¹⁵ The use of key CF treatments such as dornase alfa at our center increased from 26.5% in 2009 to 45.9% in 2011.¹⁵ Similarly, azithromycin and hypertonic saline use in patients 6 years and older increased from 84.1% to 96.1% and 32.7% to 49.4%, respectively.¹⁵ Additionally, having more uniform care alone can result in relatively rapid improvement in health care outcomes.⁴

In summary, utilizing objective criteria for nutrition and lower airway inflammation diagnoses and agreed-on clinical pathways increased physician adherence to center-specific, agreed-on care practices. The implementation of these care pathways with frequent healthcare provider feedback resulted in more uniform care of CF patients, which in turn, may have contributed to subsequent improvements in pulmonary outcomes.

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List of abbreviations

CF	cystic fibrosis
QI	quality improvement
OR	odds ratio
CI	confidence interval

References

1. Cystic Fibrosis Foundation. Patient Registry 2014 Annual Data Report. Bethesda, Maryland: Cystic Fibrosis Foundation; 2015.
2. Johnson C, Butler SM, Konstan MW, Morgan W, Wohl ME. Factors influencing outcomes in cystic fibrosis: a center-based analysis. *Chest*. 2003; 123(1):20–27. [PubMed: 12527598]
3. Quinton HB, O'Connor GT. Current issues in quality improvement in cystic fibrosis. *Clinics in chest medicine*. 2007; 28(2):459–472. [PubMed: 17467560]
4. Panella M, Marchisio S, Di Stanislao F. Reducing clinical variations with clinical pathways: do pathways work? *Int J Qual Health Care*. 2003; 15(6):509–521. [PubMed: 14660534]

5. Savant AP, O'Malley C, Bichl S, McColley SA. Improved patient safety through reduced airway infection rates in a paediatric cystic fibrosis programme after a quality improvement effort to enhance infection prevention and control measures. *BMJ Qual Saf.* 2014; 23(Suppl 1):i73–i80.
6. Siracusa CM, Weiland JL, Acton JD, Chima AK, Chini BA, Hoberman AJ, Wetzel JD, Amin RS, McPhail GL. The impact of transforming healthcare delivery on cystic fibrosis outcomes: a decade of quality improvement at Cincinnati Children's Hospital. *BMJ Qual Saf.* 2014; 23(Suppl 1):i56–i63.
7. Savant AP, Britton LJ, Petren K, McColley SA, Gutierrez HH. Sustained improvement in nutritional outcomes at two paediatric cystic fibrosis centres after quality improvement collaboratives. *BMJ Qual Saf.* 2014; 23(Suppl 1):i81–89.
8. Ramirez I, Filbrun A, Hasan A, Kidwell KM, Nasr SZ. Improving nutritional status in a pediatric cystic fibrosis center. *Pediatr Pulmonol.* 2015; 50(6):544–551. [PubMed: 25389061]
9. Kraynack NC, McBride JT. Improving care at cystic fibrosis centers through quality improvement. *Semin Respir Crit Care Med.* 2009; 30(5):547–558. [PubMed: 19760542]
10. Leonard A, Davis E, Rosenstein BJ, Zeitlin PL, Paranjape SM, Peeler D, Maynard C, Mogayzel PJ Jr. Description of a standardized nutrition classification plan and its relation to nutritional outcomes in children with cystic fibrosis. *J Pediatr Psychol.* 2010; 35(1):6–13. [PubMed: 19420226]
11. Diakakis GM, Peterson S, Sharma GD, Balk RA. Impact of frequent registered dietitian visits on body mass index percentiles. *Pediatric Pulmonology.* 2014; 49(S38)
12. Liou TG, Jensen JL, Allen SE, Brayshaw SJ, Brown MA, Chatfield B, Koenig J, McDonald C, Packer KA, Peet K, Radford P, Reineke LM, Otsuka K, Wagener JS, Young D, Marshall BC. Improving performance in the detection and management of cystic fibrosis-related diabetes in the Mountain West Cystic Fibrosis Consortium. *BMJ Open Diabetes Res Care.* 2016; 4(1):e000183.
13. Moore BM, Laguna TA, Liu M, McNamara JJ. Increased adherence to CFF practice guidelines for pulmonary medications correlates with improved FEV1. *Pediatr Pulmonol.* 2013; 48(8):747–753. [PubMed: 22997186]
14. McPhail GL, Weiland J, Acton JD, Ednick M, Chima A, VanDyke R, Fenchel MC, Amin RS, Seid M. Improving evidence-based care in cystic fibrosis through quality improvement. *Archives of pediatrics & adolescent medicine.* 2010; 164(10):957–960. [PubMed: 20921354]
15. Cystic Fibrosis Foundation. Center Specific Patient Registry Reports. Bethesda, Maryland: Cystic Fibrosis Foundation; 2012. 2013

Figure 1.

Timeline of the Development of Nutritional and Lower Airway Inflammation Clinical Pathways. These Dates Represent Milestones in the Consensus Process from Frequent Discussions.

Figure 2.

Chart Review of Healthcare Providers' Use of Clinical Pathways: (a) Compliance with Nutritional Clinical Pathway Diagnoses – (closed squares) represent the proportion of clinic visits in a quarter with correct nutritional diagnosis, (open circles) represent the proportion of clinic visits in a quarter with missing or incorrect nutritional diagnosis; (b) Compliance with Nutritional Clinical Pathway – (closed squares) represent the proportion of clinic visits in a quarter where the nutrition clinical pathway was completely followed, (open circles) represent the proportion of clinic visits in a quarter where nutrition was discussed in the clinical care plan; (c) Compliance with Lower Airway Inflammation Clinical Pathway Diagnoses – (closed squares) represent the proportion of clinic visits in a quarter with correct lower airway inflammation diagnosis, (open circles) represent the proportion of clinic visits in a quarter with missing or incorrect lower airway inflammation diagnosis; (d) Compliance with Lower Airway Inflammation Clinical Pathway – (closed squares) represent the proportion of clinic visits in a quarter where the lower airway inflammation clinical pathway was completely followed, (open circles) represent the proportion of clinic visits in a quarter where lower airway inflammation was discussed in the clinical care plan.

Figure 3. Median FEV₁ Percent Predicted for Patients with Cystic Fibrosis, 6 to 17 Years, from 2008–2012 – (closed circles) indicates median FEV₁ percent predicted at University of Iowa cystic fibrosis center, (open triangles) indicates median FEV₁ percent predicted at the ten best performing cystic fibrosis centers, (open squares) indicates median FEV₁ percent predicted for all cystic fibrosis centers in the United States. Reproduced with permission from the Cystic Fibrosis Foundation.¹⁵

Table 1

Nutrition Diagnoses and Associated Clinical Pathways

Diagnosis	BMI% ^a	Calorie Boosting	Supplements	Behavioral intervention ^b	Appetite Stimulants ^c	Enteral Feeds
Normal Growth	50	+/-				
At Low Risk for Nutritional Failure	25–50	++	+	+/-	+/- ^d	+/- ^d
At High Risk for Nutritional Failure	10–25	++	++	+	+	+ ^d
Nutritional Failure	<10	++	++	++	++	++

+/- = Consider; + = Strongly Consider; ++ = Recommended

^aFor patients < 2 years old, weight for length percentile was used

^bOnly considered if between 1–12 years of age

^cOnly considered if decreased appetite

^dOnly considered if weight/BMI% is declining

Table 2

Lung Inflammation Score, Diagnoses, and Associated Clinical Pathways

<u>Neutrophils in BAL (% of total count)</u>		<u>SCORE</u>
>50%		4
25–50%		2
>10 but <25%		1
<u>Chronic Cough (excluding when a “cold” is present)</u>		
Daily Productive cough (>75% of days in a year)		7
Productive cough >~25% of days in year		5
Any cough >50% of days in year		3
Any cough ~25–50% of days in year		2
Any cough ~10–25% of days in year		1
<u>Chest CT/Microbiology</u>		
In homogeneity of ventilation		1
Peribronchial thickening		1
Other signs suggestive of inflammation		1
Bronchiectasis &/or Chronic <i>P. aeruginosa</i> infection		7
<u>Grading of Inflammation Score</u>	<u>Treatment (additive)</u>	
0–1 No Lung Inflammation	None	
2–3 Mild Lung Inflammation	Azithromycin	
4–6 Moderate Lung Inflammation	Hypertonic saline &/or Pulmozyme	
7+ Severe Lung Inflammation	Ibuprofen or QOD steroids	

Abbreviations: BAL = bronchoalveolar lavage; CT = computerized tomography