abstract

OBJECTIVE: Despite guidelines recommending an annual oral glucose tolerance test (OGTT) for all patients with cystic fibrosis (CF) aged ≥10 years, screening rates for cystic fibrosis–related diabetes (CFRD) remained low at our center. The aim of this project was to implement an outpatient system to provide effective, evidence-based screening for CFRD at a pediatric CF program.

METHODS: Development of a system to improve outpatient screening for CFRD included structured education, communication with families, and processes for scheduling laboratory appointments. The primary outcome measure was the proportion of eligible patients seen at the clinic who received an OGTT by the subsequent clinic appointment. The proportion of patients without CFRD in our program who received an OGTT within the previous 12 months was also tracked longitudinally.

RESULTS: The outpatient screening rate for CFRD increased from 2% of eligible patients seen at the clinic during the 18 weeks before the start of our initiative to 78% during the 18 weeks after the start of our initiative (P < .001). The screening rate was also increased from the corresponding date range the previous year, when only 35% of eligible patients received an OGTT (P < .001). The overall percentage of patients without CFRD in our program who received an OGTT in the previous 12 months increased from 47% to 71% after implementation of our initiative (P = .003).

CONCLUSIONS: A systematic, quality improvement approach effectively increased the rate of outpatient screening for CFRD at a pediatric CF program. *Pediatrics* 2013;132:e512–e518

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KEY WORDS
cystic fibrosis, diabetes mellitus, glucose tolerance test, quality improvement, screening

ABBREVIATIONS
CF—cystic fibrosis
CFF—Cystic Fibrosis Foundation
CFRD—cystic fibrosis–related diabetes
EMR—electronic medical record
OGTT—oral glucose tolerance test
QI—quality improvement

Mr Kern conceptualized and designed the study; contributed substantially to the acquisition, analysis, and interpretation of data; drafted the initial manuscript; critically reviewed and revised the manuscript; and approved the final manuscript as submitted. Dr Prestridge conceptualized and designed the study; contributed substantially to the acquisition, analysis, and interpretation of data; critically reviewed and revised the manuscript; and approved the final manuscript as submitted.

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Cystic fibrosis–related diabetes (CFRD) is one of the most common comorbidities associated with cystic fibrosis (CF) and is estimated to occur in ∼20% of adolescents. The impact of CFRD is broad and has been associated with decreased lung function, increased pulmonary exacerbations, poor nutritional outcomes, and decreased survival. Previous studies have demonstrated the benefit of early administration of therapy for CFRD, thus stressing the importance of appropriate screening measures.

Annual screening for CFRD has been a longstanding recommendation in CF; however, it has not been easy to implement in clinical practice. The gold standard screening test of healthy outpatients is the oral glucose tolerance test (OGTT), recommended by the Cystic Fibrosis Foundation (CFF) annually for all patients with CF aged ≥10 years. However, the national average screening rate was only 31.5% in 2011, and there was considerable variation in care delivery. This poor performance may in part reflect the logistical difficulty of obtaining the OGTT (fasting is required for at least 8 hours before the time of testing). Therefore, the majority of patients with upcoming late-morning or afternoon clinic appointments must schedule testing at a separate time. The requirement for venipuncture as part of the OGTT may also present a barrier to screening, considering the distress often associated with blood draws in the pediatric population.

Due to the aforementioned logistical concerns, our program only routinely offered the OGTT to patients who were already scheduled for early-morning appointments and were simultaneously due for other blood work related to their CF care. Outside of this limited subset of patients, however, we lacked a standardized system for proactively contacting families to ensure the timely scheduling of fasting tests in the early morning. Consequently, despite an aggressive nutritional intervention program and heightened awareness of the importance of CFRD, our center’s annual OGTT screening rate failed to keep pace with the rising national average between 2009 and 2011 (Fig 1).

The study questions central to our initiative included: (1) How can we incorporate a wider and more effective screening effort into our existing preparation for CF clinic appointments? (2) How can we ensure that patients encouraged to receive an OGTT more reliably complete the screening? Our aim was to implement a standardized screening procedure for CFRD in all patients with CF aged ≥10 years who were not currently treated with insulin.

METHODS
Setting
Ann & Robert H. Lurie Children’s Hospital of Chicago (Lurie Children’s) is a freestanding academic and urban pediatric medical center. The Cystic Fibrosis Center at Lurie Children’s is composed of a multidisciplinary team that currently manages 182 patients. Our team members share a strong culture of quality improvement (QI), which facilitated our initiative’s development and success.

Improvement Team
The current QI initiative was designed as 1 component of a joint collaborative effort between our pediatric program and the Northwestern Memorial Hospital adult CF program addressing the screening, diagnosis, and treatment of CFRD. Specific improvement methods were developed independently by each program to meet the disparate needs of the pediatric and adult CF populations. At our site, the program’s co-director and a medical student who had previously worked with the program led the improvement team. All other team members, including physicians and administrative staff, provided frequent collaboration and feedback at weekly team meetings. The support and participation of all team members in this initiative were instrumental in allowing for the comprehensive screening of patients in our program.

Ethical Concerns
Our program’s initiative was determined to be QI work but was nonetheless approved by the Lurie Children’s...
institutional review board before implementation. To ensure patient safety, patients were not offered the OGTT if the primary physician deemed such efforts incongruent with their overall care plan. Diagnostic criteria were consistent with the CFF and American Diabetes Association clinical care guidelines for CFRD.

**Planning the Intervention**

In early June 2012, the full Lurie Children’s CF team was briefed on the initial QI plan. The CFRD Smart Change Compendium, developed by participants of the 2010–2011 Learning and Leadership Collaborative: CFRD, was consulted to gain insight into the experiences of other CF centers and to access resources shared across the CFF’s Care Center Network. Recommendations included in the compendium were then evaluated and adapted to meet the specific needs of our site.

Table 1 depicts key drivers that were believed to influence the effectiveness of CFRD screening at our program. The drivers and interventions illustrated were developed according to Plan-Do-Study-Act cycle methods used for improvement and continuous modification throughout the initiative.12

<table>
<thead>
<tr>
<th>TABLE 1 Key Drivers Outlining Interventions Used to Achieve the Desired Aim</th>
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<tbody>
<tr>
<td><strong>Key Drivers</strong></td>
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<tr>
<td>Encouragement and scheduling of OGTT before clinic</td>
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<td>Effective implementation of current OGTT</td>
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<td>Communication with families concerning future required OGTTs</td>
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<tr>
<td>Communication of OGTT results</td>
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<td>Follow-up with family to rectify unscheduled OGTTs after the clinic visit</td>
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The study aim was to increase the percentage of patients aged ≥10 years not taking insulin who receive an annual OGTT.
laboratory supply of glucose solution and families’ compliance with recommended OGTTs, we eliminated the practice of routinely offering walk-in OGTTs and instead requested that all families preschedule the test. Our clinical office assistants were trained to schedule the tests directly on the electronic medical record (EMR) system in lieu of requesting appointments from the laboratory.

**In-Clinic Interventions**

- Laboratory support: The staff leadership of the outpatient laboratories was consulted to formalize the system for conducting the OGTT, particularly within the context of routine CF clinic appointments. Process changes included more precise scheduling of blood draws in the EMR and laboratory documentation of the completion of oral glucose solution.
- Subsequent visit planning: A checklist of tests to be completed before or at the patient’s next clinic appointment, including the OGTT, was developed and incorporated into clinical processes. At the patient’s discharge from the clinic, the checklist was relayed to the family with instructions to provide the document to the scheduling staff at the checkout desk.
- Education: The educational sheet enclosed with the prediagnostic letter was also introduced routinely in the clinic to reinforce knowledge about the OGTT and CFRD. In-clinic education was later transitioned into a component of regular nutritional assessments to be offered at the discretion of the patient’s physician and dietitian.

**Postclinic Interventions**

- Results notification: If the screening test results were abnormal, the primary medical team placed telephone calls to discuss the results and next steps in care. In addition, standardized letters intended to convey the results of the OGTT to families were developed. Multiple templated versions of the letters were designed in the EMR to account for differing result classifications (normal, impaired, or CFRD), primary languages of families (English or Spanish), and patient ages (minor or adult). Once abnormal results were relayed by telephone or if a patient’s test results were normal, the letters were either mailed or posted onto the patient’s personal online health portal.
- Closing the loop: A back-office process was implemented to ensure that patients who did not receive a recommended test such as an OGTT were scheduled for these remaining needs. A clinical office assistant identified such patients by comparing scheduled appointments in the EMR with the physician’s assessment and plan after every clinic appointment. Any discrepancies between recommended and scheduled tests were addressed by telephone calls requesting families to make the necessary appointments.

**Planning the Study of the Intervention**

The primary outcome measure was the proportion of eligible patients seen in the clinic who received an OGTT by the subsequent clinic appointment. This parameter was calculated for each 2-week interval before and after the start of our initiative on June 15, 2012. As demonstrated, the screening rate improved dramatically during the postinitiative time period (June 15, 2012–October 18, 2012). Although the screening rate fluctuated, it remained substantially higher than during the preinitiative time period (February 20, 2012–June 14, 2012).

Table 2 compares the total proportion of eligible patients screened during the postinitiative time period with baseline time periods. Whereas only 1 (2%) of 46 eligible patients received an OGTT during the preinitiative time period, 45

To assess the performance of CFRD screening from a broader perspective, the proportion of all patients without CFRD in our program who received an OGTT in the past 12 months was tracked as a secondary outcome measure. Tracking of this measure was enabled through center-specific data on the CFF Patient Registry, a longitudinal, encounter-based database of multiple variables related to clinical status and treatment. Although the variable used in the Patient Registry is defined slightly differently than our primary outcome measure, it was nonetheless used to facilitate long-term monitoring that would ensure sustainability of our system.

**Data Analysis**

Screening rates were compared by using a 2-tailed Fisher’s exact test. Statistical analyses were performed by using Stata version 12.1 (StataCorp, College Station, TX). All results were considered statistically significant at $P < .05$.

**RESULTS**

Figure 2 displays the CFRD screening rate in 2-week intervals spanning the 18 weeks before and after the start of our initiative on June 15, 2012. As demonstrated, the screening rate improved dramatically during the postinitiative time period (June 15, 2012–October 18, 2012). Although the screening rate fluctuated, it remained substantially higher than during the preinitiative time period (February 20, 2012–June 14, 2012).

Table 2 compares the total proportion of eligible patients screened during the postinitiative time period with baseline time periods. Whereas only 1 (2%) of 46 eligible patients received an OGTT during the preinitiative time period, 45
(78%) of 58 eligible patients received an OGTT during the postinitiative time period, a statistically significant increase (P < .001). However, the possibility that seasonal variation could confound the effect was considered, as the time-consuming OGTT is less burdensome to complete in the summer months. Therefore, we compared the postinitiative screening rate with the corresponding date range the previous year (June 15, 2011–October 18, 2011). Table 2 shows that the postinitiative screening rate was more than twice the corresponding 2011 rate (17 of 48 [35% of eligible patients]), which was also a statistically significant difference (P < .001).

The quarterly data tracking shown in Table 3 enables a more global assessment of our CFRD screening program. As of June 2012, <50% of patients without a previous CFRD diagnosis were current with the recommended annual OGTT when measured at the end of any quarter. At the end of the quarter that followed the full implementation of our interventions (September 30, 2012), however, 71% of such patients had received an OGTT in the past 12 months, a significant increase from the most recent quarterly measurement before the implementation of our initiative (47% on March 31, 2012; P = .003). By the end of the calendar year 2012, 82% of eligible patients had been screened in the previous 12 months (Table 3). Of the 68 patients screened, 4 (6%) had an OGTT result consistent with CFRD, 16 (24%) had impaired glucose
tolerance, and 48 (71%) had normal glucose tolerance.

**DISCUSSION**

The need for QI efforts to address disparate performance in CFRD screening and management across CF centers has long been voiced in the literature. Therefore, the aim of this QI initiative was to improve our pediatric program’s adherence to CFF guidelines for CFRD. After the implementation of our interventions, the proportion of patients receiving OGGT increased significantly according to multiple measures used to evaluate our screening program. Based on the evidence, we believe that the observed improvement is directly attributable to our interventions. The apparent effectiveness of our interventions is consistent with successful past QI efforts by The Northern New England Cystic Fibrosis Consortium.

The fact that our medical student, who was not a full-time team member, played an integral role in the planning and piloting of our efforts may raise questions about the sustainability of our initiative. To help mollify this concern, a detailed center playbook for outpatient CFRD screening was introduced to the pediatric team at the beginning of August 2012. Individual meetings were held with key team members, who were given versions of the playbook designed for their specific roles. A 2-week transition period enabled the transfer of responsibilities previously held by the medical student to other team members. After the medical student’s departure in mid-August, we continued to monitor our data and have experienced sustained levels of screening. By the end of 2012, we had performed screening on 82% of our patients in the past 12 months. Our center continues to track the data to monitor for slips in our success. Due to the high rate of screening, we have transitioned to monthly data assessment for the upcoming calendar year. If successful, we will then increase to quarterly monitoring of the data.

The interventions that were used to target communication with families, education, and scheduling processes helped our program obtain elevated screening rates for CFRD. These interventions, however, are not just specific to CF; they are feasible to implement in any clinic for any screening test. Although we were fortunate to have a medical student who accelerated the rate of improvement by contributing dedicated time toward this effort, the entire process change and implementation were completed in only 10 weeks. In addition, our CF program staff were well-versed in QI methods, and thus performing small tests of change was commonplace for our team. After the medical student left, the screening process became routine for the staff and consumed minimal additional time, while continued monitoring required <1 hour per month to complete. Other sites may not have a dedicated individual to design and implement interventions in an accelerated timeframe or have a team that is as familiar with QI processes as ours was; however, the initiative could have been completed over a more extended period of time while still achieving the same results.

The QI methods adopted in this study confer some limitations. Specifically, the difficulty of definitively excluding external factors that may have contributed to the observed improvement in concert with our initiative constitutes a “history threat” to internal validity. However, the higher screening rate after our initiative relative to the corresponding date range the previous year should mitigate concern that the improvement is merely attributable to the initiative’s summertime implementation. External validity is also limited due to the initiative’s implementation at a single CF program, where the geographic or financial barriers to obtaining OGGT may not be representative of CF care at large. Other limitations stem from the shortcomings of our primary outcome measure: the proportion of eligible patients seen at the clinic who were screened before the subsequent clinic appointment. Because it was not possible to discern the pulmonary exacerbation status and thus the eligibility of patients who had rescheduled, canceled, or failed to appear at appointments, such appointments were excluded from screening rate calculations. However, this action may have inadvertently introduced self-selection bias, as families who reliably attend appointments may be more amenable to the recommendation for OGGT. The increase observed in our secondary outcome measure (ie, the total proportion of patients without CFRD screened in the past 12 months) therefore lends support to the effectiveness of our interventions in improving screening for CFRD.

### TABLE 3

Percentage of Patients Aged ≥10 Years Without CFRD Receiving OGGT in Previous 12 Months (Measured Quarterly)

<table>
<thead>
<tr>
<th>Date at End of Quarter</th>
<th>No. Screened</th>
<th>No. of Patients</th>
<th>Percent Screened</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/31/2011</td>
<td>23</td>
<td>70</td>
<td>33</td>
</tr>
<tr>
<td>6/30/2011</td>
<td>27</td>
<td>73</td>
<td>37</td>
</tr>
<tr>
<td>9/30/2011</td>
<td>35</td>
<td>74</td>
<td>47</td>
</tr>
<tr>
<td>12/31/2011</td>
<td>30</td>
<td>74</td>
<td>41</td>
</tr>
<tr>
<td>3/31/2012</td>
<td>35</td>
<td>74</td>
<td>47</td>
</tr>
<tr>
<td>6/30/2012</td>
<td>36</td>
<td>76</td>
<td>47</td>
</tr>
<tr>
<td>9/30/2012</td>
<td>55</td>
<td>77</td>
<td>71a</td>
</tr>
<tr>
<td>12/31/2012</td>
<td>68</td>
<td>83</td>
<td>82</td>
</tr>
</tbody>
</table>

*P = .003 comparing the quarter ending 3/31/2012 with the quarter ending 9/30/2012 (Fisher’s exact test).
CONCLUSIONS
This multifaceted strategy, specifically targeting education about CFRD and the OGTT, communication with families, and scheduling processes, was effective in improving the rate of screening for diabetes at our pediatric CF program. We encourage other QI teams, working both within and beyond CF care, to capitalize on such a strategy in their efforts to implement improvement plans. Future QI initiatives related to CFRD at our program will include developing a systematic process to screen inpatients hospitalized with CF exacerbations for CFRD and investigating the clinical utility of nonfasting tests proposed as alternatives to the standard OGTT.17–19

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