Reliable Individualized Monitoring Improves Cholesterol Control in Kidney Transplant Recipients

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KEY WORDS

cholesterol, dyslipidemia, kidney transplant, low-density lipoprotein cholesterol, reliable systems, quality improvement, cardiovascular disease, preventive cardiology

ARRREVIATIONS

CVD-cardiovascular disease

EMR-electronic medical record

KT-kidney transplantation

KTR-kidney transplant recipient

LDL—low-density lipoprotein cholesterol

QI-quality improvement

TLC—therapeutic lifestyle change

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abstract

OBJECTIVE: To develop and evaluate a system for reliable and efficient individualized risk-based monitoring of cholesterol and 11 other tests after kidney transplantation in children.

METHODS: We identified system components that drive reliable individualized monitoring and used quality improvement methods to develop and implement interventions, including (1) monitoring schedules individualized by dyslipidemia risk assigned to each patient, (2) automated previsit decision support from our electronic medical record, (3) standardized work flow and responsibility, and (4) automated forwarding of results to providers. We measured the proportion of patients due for cholesterol testing who had it performed within 1 week of their clinic visit and the proportion of patients in our population who achieved low-density lipoprotein (LDL) cholesterol control at baseline and for 2 years after improved monitoring.

RESULTS: The proportion of visits in which cholesterol monitoring was completed when indicated improved from 80% to 98% within 8 months and was sustained for more than 1 year. The number of patients with controlled LDL (<130 mg/dL, 3.3 mmol/L) improved from 44 (71%) of 62 at the start of our project to 58 (94%) of 62 (P = .002) at an average follow-up of 24 months.

CONCLUSIONS: Using quality improvement and health information technology, we achieved sustained, reliable and efficient personalized monitoring of cholesterol and 11 other tests. This approach enabled substantial improvement in LDL cholesterol control. Structured methods of system redesign that leverage information technology systems hold promise for rapidly achieving reliable individualized care in other settings. *Pediatrics* 2013;131:e1271—e1279

Cardiovascular disease (CVD) is the leading cause of mortality in adults who undergo kidney transplantation (KT) during childhood, with the risk of cardiac death up to 50-fold greater than in the general population. Accordingly, guidelines place pediatric KT recipients (KTRs) in the highest CVD risk category.^{2–4} Among other CVD risk factors, pediatric KTRs have a high prevalence of dyslipidemia,5 which is a strong predictor of atherosclerosis in children⁶ and may compound the CVD risk conferred by coronary artery media calcifications in children receiving dialysis before KT.7,8 Dyslipidemia in KTRs is multifactorial, including traditional risk factors (eg, genetic predisposition, obesity, high-fat diet) and those specific to kidney disease and transplantation (proteinuria, and antihypertensive and immunosuppressive medications, especially sirolimus9). Thus, guidelines recommend regular cholesterol monitoring and control through therapeutic lifestyle change (TLC)^{2-4,10-12} for all pediatric KTRs and through pharmacotherapy with 3-hydroxy-3-methyl-glutaryl-CoA reductase inhibitors (statins) for those > 10 years of age with low-density lipoprotein cholesterol (LDL) persistently >130 mg/dL (3.3 mmol/L) despite a trial of TLC.3,4,11

Dyslipidemia guidelines for pediatric KTRs have not been reliably implemented into clinical practice. At 8 Midwest Pediatric Nephrology Consortium centers, only 47% of adolescents with kidney disease or transplant had a cholesterol documented in their chart and, of those with high cholesterol, 44% were on medical therapy. Thus, the high cardiovascular risk for these patients in adulthood may be, in part, related to unreliable systems for preventive CVD care as children.

Evidence suggests that using structured quality improvement (QI) methods to redesign systems for reliable

chronic care delivery can improve clinical outcomes. 14,15 Moreover, removing unwanted variation in clinical practice may allow clinicians to better understand patient-specific variation. 16

In 2008, the KT program at our center started a QI initiative to use a new electronic medical record (EMR) to improve our system of monitoring cholesterol and 11 other tests according to individualized schedules. We hypothesized that reliable cholesterol monitoring, individualized by dyslipidemia risk, would lead to improved treatment and control of dyslipidemia in our population.

METHODS

Study Design

We used an interrupted time series design to assess the impact of structured QI methods and iterative plando-study-act cycles to test, refine, and reliably implement interventions to improve our system of cholesterol monitoring. 17–19 This study was approved by our center's institutional review board.

Setting

The KT program at our center performs 15 to 25 transplants yearly and follows 70 to 100 KTRs at any given time. Our multidisciplinary team includes nurse coordinators, clinic nurses, physicians, a renal dietician, a social worker, and a psychologist. Immunosuppression includes induction with basiliximab and methylprednisolone. Maintenance immunosuppression consists of prednisone, mycophenolate mofetil and tacrolimus. We dose prednisone initially at 1.5 to 2.0 mg/kg/d and wean over 6 months to a dosage of 0.1 mg/kg every 24 to 48 hours. We offer conversion from tacrolimus to sirolimus at 6 months after transplantation to standard- or low-immunologic-risk patients. Because of dyslipidemia risk, other comorbidities, and drug side effects, our practice before October 2008 was to monitor 23 different tests according to a complex algorithm individualized by time since transplant, current medications (eg, statins, sirolimus), and infection risk (Table 1). KTRs were seen by 1 of 9 pediatric nephrologists at 6 outpatient locations. The providers were notified of testing algorithms by e-mail dissemination of a 1-page spreadsheet listing all 23 tests and how often each should be monitored. Clinic documentation was performed in paper charts, whereas internal laboratory results were reported in an EMR. In October 2008, our division implemented a new, comprehensive EMR and we redesigned our process to be more efficient and reliable.

Planning the Intervention

A pediatric nephrology fellow (D.K.H.) and KT nurse coordinator (J.R.) co-led a multidisciplinary team composed of an EMR specialist, a computer analyst, the medical director of KT, and a QI consultant. The team first identified a set of system factors, termed key drivers, that we thought to be necessary for reliable individualized monitoring (Fig 1). These key drivers were informed by the Chronic Care Model^{20,21} and incorporated principles of reliability science.22 Our aim was to develop a system that would achieve cholesterol monitoring in at least 95% of patients due for a cholesterol test at the time of their clinic visit. We chose this goal based on our perception of patients' expectations and our belief that we could achieve this level of reliability²² through an intentionally redesigned process using human factors engineering principles.

We reviewed our current process to ensure proper monitoring and found that it relied on the specialized knowledge

 TABLE 1
 Posttransplant Monitoring (September 2008)

Tests Monitored at Every Visit

Urinalysis

Complete blood count

Renal profile

Calcium, magnesium, phosphorus

Glucose

Medication levels (tacrolimus, sirolimus, cyclosporine)

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Tests Not	Monitored	at Every	Visit

Test	Frequency		
Liver profile	(Not on statin) at 6 mo, 1 y, 2 y, and every 2 y		
	(On a statin) before statin, monthly for 3 mo, ther at 6 mo after statin and every 6 mo thereafter		
Creatine kinase (only if on statin)	See liver profile "on a statin"		
Uric acid	At 6 mo, 1 y, 2 y, and every 2 y		
Fasting lipid profile	(Not on sirolimus) At 6 mo, 1 y, 2 y, and every 2 y		
	(On sirolimus) every 6 mo		
Nuclear glomerular filtration rate	At 6 mo, 1 y, 2 y, and every 2 y		
Cystatin C	At 6 mo, 1 y, 2 y, and every 2 y		
Urine BK virus	At 1 mo, at 6 mo, at 1 y, and yearly		
Testosterone, LH, FSH (only if on sirolimus)	At time of sirolimus initiation, every 6 mo while on sirolimus		
Echocardiogram	At 1 y, 2 y, and every 2 y		
Transplant ultrasound	At 3 mo, 1 y, 2 y, and every 2 y		
EBV IgG & IgM, EBV quantitative PCR (only	At 1 mo, quarterly during the first 2 y, and yearly		
for EBV IgG-negative patients)	until converted		

EBV, Epstein-Barr virus; FSH, follicle stimulating hormone; Ig, immunoglobulin; LH, luteinizing hormone; PCR, polymerase chain reaction.

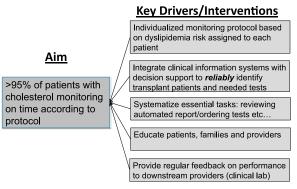


FIGURE 1Key driver diagram for improving cholesterol monitoring in pediatric kidney transplant recipients.

and diligence of our most experienced transplant nurse coordinator. Her process consisted of reviewing clinic rosters for the coming week to identify scheduled KTRs and reviewing medical records (both electronic and paper) to determine whether testing was indicated. Her primary intervention was to place "sticky notes" in patient charts reminding physicians to order indicated tests. Once a test was ordered, she

would contact the patient/family and provide necessary instructions. This process was time-consuming and unreliable because it did not happen if she was absent.

Improvement Activities

We, first, simplified our laboratory monitoring schedules. The pediatric nephrology fellow (D.K.H.) and medical director of KT (J.G.) reviewed all labo-

ratory tests and identified those that were monitored infrequently, rather than at every medical encounter (Table 1). We selected 12 tests, including fasting lipid profile, for personalized monitoring and developed 18 discrete individualized schedules based on evidence and published guidelines (Table 2).11 Cholesterol monitoring frequency was determined by dyslipidemia risk (Table 3). The highest-risk patients with dyslipidemia (on a statin <6 months) were monitored guarterly. Patients with moderate risk (<1year posttransplant, on sirolimus, or treated long term with a statin) were monitored semiannually. Lowest-risk patients (>1 year posttransplant and not on sirolimus or a statin) were monitored yearly.

Our second intervention was to develop a decision-support report automatically generated from our EMR to (1) identify all KTRs coming to clinic in the upcoming week, (2) assign 1 of the new 18 unique testing schedules to each patient according to dyslipidemia risk, and (3) report the most recent test results, whether additional testing was due, and the next due date for each test. This report was tested iteratively to refine it for accuracy and ease of use. Our head transplant nurse coordinator assessed accuracy by comparing the report with data gathered manually. The same nurse coordinator initially determined ease of use subjectively, then all nurse coordinators in our group trialed the report to ensure that any of them could reproducibly interpret it and order needed tests appropriately.

Subsequent interventions focused on developing reliable systems to use this report. We assigned a nurse to review the report weekly. We initially trialed entering reminders for indicated testing into the EMR, but quickly learned that providers did not always review this information. Educating physicians

TABLE 2 New Individualized Posttransplant Monitoring Schedule for 12 Tests (October 2008)

9		
Frequency		
(Not on statin) at 6 mo, 1 y, 2 y, and every 2 y		
(On a statin) before statin, every 3 mo ×2, a then every		
6 mo thereafter		
See liver profile "on a statin"		
At 6 mo, 1 y, 2 y, and every 2 y		
(Not on sirolimus) at 6 mo, 1 y, then yearly thereafter ^a		
(On sirolimus) at initiation, every 6 mo		
(On statin) at initiation, every 3 mo $ imes 2$, then every 6 mo $^{ ext{a}}$		
At 6 mo, 1 y, 2 y, and every 2 y		
At 6 mo, 1 y, 2 y, and every 2 y		
At 1 mo, at 6 mo, at 1 y, and yearly		
At time of sirolimus initiation, every 6 mo while on		
sirolimus		
At 1 y, 2 y, and every 2 y		
At 3 mo, 1 y, 2 y, and every 2 y		

^a Indicates a new frequency of monitoring. FSH, follicle stimulating hormone; LH, luteinizing hormone.

TABLE 3 Frequency of Cholesterol Monitoring by Dyslipidemia Risk

Risk	Low	Moderate	High
Criteria	 >1 y posttransplant No dyslipidemia Not on sirolimus or statin 	<1 y posttransplantOn sirolimusOn statin >6 mo	• On statin <6 mo
Cholesterol monitoring frequency	Yearly	Every 6 mo	Every 3 mo

about this process resulted in modest improvement. We then modified our process so that orders for indicated testing were pended in the EMR by the individual reviewing the report and forwarded to the responsible physician for signature before the patient would come to clinic. This same team member would then contact the patient and/or family and give any special instructions and required education (eg, come fasting for lipid profile). The EMR was configured to automatically forward laboratory results to the ordering physician after the patient's visit. If cholesterol results were abnormal, the patient was contacted by the provider or nurse to verify they had fasted.

There were no specific interventions focused on reliable therapy for dyslipidemia. As had been the practice before our interventions, treatment was at the discretion of the patient's nephrologist, according to published guidelines.³

Data Collection and Measures

Cholesterol Monitoring

We measured the proportion of visits for which indicated monitoring was performed within 1 week. We also monitored the total time per week allotted to ensuring testing was performed and the percentage of visits for which all indicated testing (in addition to cholesterol) was performed within 1 week. Internal laboratory results were available immediately in our EMR and external laboratory results were faxed to our center and entered into the EMR on the day received. This process did not change throughout our study. KT nurse coordinators collected data weekly as part of their standardized work flow. They recorded the number of indicated tests each week in a spreadsheet and then reviewed the EMR the following week to determine whether indicated testing was performed. Data collection was started at the time of EMR roll-out, before project initiation, and continued through September 2010 when we had sufficient belief that our system had experienced sustained improvement.

Control of Dyslipidemia

After implementing our monitoring system, we assessed whether monitoring, treatment, and control of dyslipidemia improved in our population. Our primary measure was the proportion of KTRs who had LDL < 130 mg/ dL (3.3 mmol/L) documented within the previous 12 months. We included the most recent LDL value of patients >7 months posttransplant (when cholesterol monitoring begins) and who had been seen within the previous year. Patients who transferred care or experienced graft loss were removed from the population at the time of event. Other measures included the proportion of patients with a lipid profile recorded in the previous 12 months and the percentage of KTRs aged ≥10 years with dyslipidemia who were on statin therapy. We defined dyslipidemia as LDL ≥130 mg/dL (3.3 mmol/L) or on statin therapy. For outcome measures, we recorded the most recent value for each patient and carried them forward for each subsequent time point until a new assessment was performed.16 We extracted data quarterly from our EMR using automated reports to create statistical process control charts¹⁷ from October 2008 through January 2012. We validated data by manual chart review.

Methods of Analysis

We plotted the percentage of visits where indicated cholesterol testing was performed over time on a run chart and applied run chart rules¹⁸ to detect improvements in the process. We evaluated population-based measures (control of dyslipidemia, treatment of dyslipidemia, and cholesterol monitoring; see previous section "Control of Dyslipidemia") using statistical

process control.¹⁷ Data from the base-line period (October 2008–April 2009, during improvement activities) were compared with data from July 2009 to January 2012. We identified data points outside the control limits (±3 SDs)¹⁷ as special cause variation (apparent improvement) and adjusted the centerline mean and control limits accordingly. We generated charts in Microsoft Excel (2007) by using templates developed at our center.

Because patients entered (new KTR) and exited (transfer or graft loss) our cohort over time, changes in case mix might have affected our time-series results. To account for this, we performed a before/after analysis of cholesterol control in a cohort of 62 patients who had fasting cholesterol measured at 2 time points: (1) within the year before our QI initiative, and (2) at least 6 months after the full implementation of our improvement bundle. By using SAS 9.2 statistical software (SAS Institute, Cary, NC) and McNemar's test for paired data, we compared the percentage of patients with LDL <130 mg/dL (3.3 mmol/L) at each time point. We considered P < .05 to be statistically significant.

RESULTS

Study Population

Seventy-eight patients met inclusion criteria at the start of our project in October 2008 and there were 69 by January 2012. Over this time span, 36 patients left the population (26 transitioned to adult care, 5 went on dialysis, 2 died, 2 were lost to follow-up, 1 moved) and 27 new patients entered it (24 new transplants, 3 transferred care). Demographics and clinical characteristics for patients at each time point and for the 62 patients in the before/after analysis are listed in Table 4. Patients were predominantly male and white and ranged from 3 to 26 years old. The most common underlying disorders

TABLE 4 Patient Demographics

	Oct. 2009	Jan. 2012	Before/After Cohort
n	78	69	62
Male, n (%)	52 (67)	43 (62)	39 (63)
Median years old (range)	18 (3-26)	18 (3–25)	16 (2-24)
Median years since transplant (range)	4.9 (0.7-14.4)	5.3 (0.6-16)	4.6 (0.6-13.8)
Race/Ethnicity, n (%)			
White non-Hispanic	60 (77)	52 (75)	45 (73)
Black non-Hispanic	16 (21)	13 (19)	15 (24)
Hispanic	0 (0)	1(1)	0 (0)
Other	2 (3)	3 (4)	2 (3)
Primary diagnosis			
Aplasia/Hypoplasia/Dysplasia	20 (26)	17 (25)	14 (23)
Obstructive/Reflux Nephropathy	13 (17)	11 (16)	9 (15)
FSGS	13 (17)	9 (13)	12 (19)
Chronic glomerulonephritis and nephrotic syndrome	10 (13)	7 (10)	10 (16)
Cystic disease	7 (9)	5 (7)	5 (8)
Other	15 (19)	20 (29)	12 (19)
On sirolimus, n (%)	37 (47)	38 (55)	
On statin, n (%)	15 (19)	26 (38)	

were aplasia/hypoplasia/dysplasia, followed by "other," obstructive/reflux, and focal segmental glomerulo-sclerosis.

Reliability of Cholesterol Monitoring

During the baseline period, cholesterol testing was performed correctly ~80% of the time (Fig 2). By January 2009, we had completely implemented our new process, and reliability of cholesterol monitoring started to improve. Thereafter, our new tracking process exposed a problem in the clinical laboratory: even when orders were entered and signed appropriately, the laboratory did not always process them appropriately. Accordingly, we initiated regular performance feedback to the clinical laboratory that resulted in improvement of their processes. By 8 months, the new process had achieved 98% reliability that was sustained for more than a year (Fig 2). The reliability of monitoring all other tests was similar (95%) for the same period. Within our entire population, the percentage of patients with cholesterol documented in the previous 12 months increased from 84% at the start of our project to 95% and has been sustained for nearly 2 years (Fig 3).

Treatment of Dyslipidemia

At the initiation of our project, 23 (28%) of 81 patients had dyslipidemia. Of these, 12 (52%) were on statin therapy. Over the next 3 years, statin prescriptions for patients with dyslipidemia increased to 23 (88%) of 26 patients (Fig 4A). Improved treatment of dyslipidemia was accompanied by an increase in the percentage of patients with LDL <130 mg/dL (3.3 mmol/L) in the previous 12 months, from 51 (65%) of 78 at baseline to 57 (83%) of 69 in January 2012 (Fig 4B).

Before/After Analysis

Sixty-two (95%) of 65 patients with a fasting cholesterol in the year before January 2009 also had another fasting lipid profile documented at least 6 months (June 2009) after sustained improvement in cholesterol monitoring. Before our interventions, 44 (71%) of 62 patients had an LDL <130 mg/dL (3.3 mmol/L), compared with 58 (94%) of 62 (P=.002) after a median follow-up of 24 months.

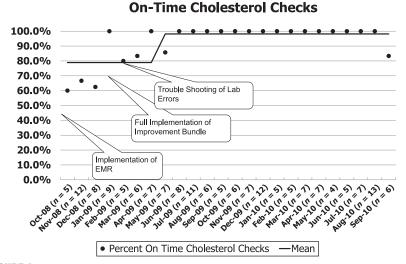


FIGURE 2
Annotated Run chart of our primary measure for improved cholesterol monitoring. Each point represents the percentage of visit where indicated cholesterol testing was performed. The line indicates the mean. The annotations mark interventions and external factors that may influence our system.

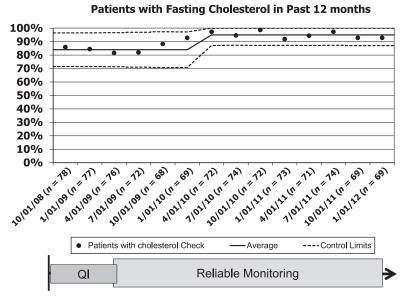


FIGURE 3
Statistical process control chart of the percentage of patients with a fasting cholesterol documented in the previous 12 months. Baseline median and 3-σ control limits were based on data from October 2008 through April 2009 and were readjusted when special cause was achieved.

DISCUSSION

This study demonstrates rapid achievement of efficient and reliable individualized laboratory screening by implementing components of the Chronic Care Model²⁰ using structured QI methodology. Our improved system requires less time and no longer relies on the specialized knowledge of an ex-

perienced nurse coordinator. Moreover, we observed associated improvement in treatment and control of dyslipidemia within the first year of reliable, risk-based monitoring.

The importance of screening for and controlling modifiable cardiovascular risk factors in KTRs is well recognized,^{2,3,11,12} including in the recent report from the

for Cardiovascular Health and Risk Reduction in Children and Adolescents at the National Heart, Lung and Blood Institute.4 Pediatric KTRs are among the patients at highest risk for CVD. with substantially increased cardiovascular mortality in adulthood.1 Yet, recent data indicate that only about 50% of adolescents with advanced kidney disease or after KT have even a single cholesterol test documented before transferring to an adult-focused provider and, of those with uncontrolled cholesterol, fewer than half were on statin therapy.¹³ This is consistent with other research findings that indicate preventive care is delivered less than half the time in the pediatric ambulatory setting²³ and that fewer than 40% of adult transplant patients have controlled LDL cholesterol, with indicated therapy prescribed in only about 60%.24 More than a decade ago, Wagner and colleagues²¹ identified the potential to improve outcomes for patients with chronic disease by developing new systems capable of delivering reliable evidence-based and individualized care. Their Chronic Care Model²⁰ called for planned care according to evidence-based guidelines supported by clinical information systems, decision support, and delivery system design. Unfortunately, with the exception of relatively few group practices, widespread reliable chronic disease management for both children and patients with kidney disease has yet to be achieved.23,24 Our study demonstrates the potential for such systems to achieve desired therapeutic targets in most patients.

Expert Panel on Integrated Guidelines

This QI initiative did not focus specifically on treating cholesterol, but, rather, on monitoring. Consequently, our measure of reliable monitoring is only one indicator of this system that has ultimately improved patient care. Other key drivers also affected this system. For

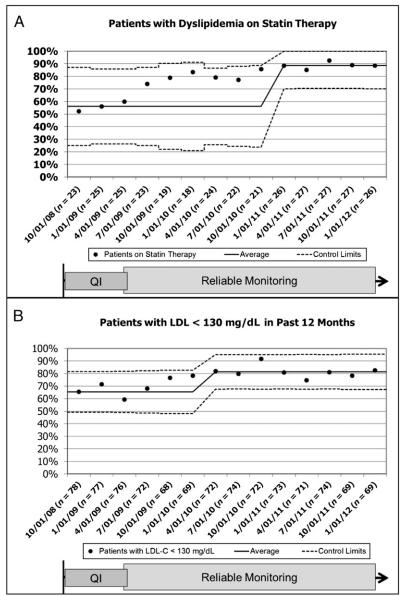


FIGURE 4 Statistical process control chart of (A) the percentage of dyslipidemic patients >10 years treated with a statin and (B) the percentage of patients in our cohort with LDL <130 mg/dL (3.3 mmol/l) documented in the previous 12 months. Data are limited to patients \ge 7 months out from kidney transplant. Baseline median and 3- σ control limits were based on data from 0ctober 2008 through April 2009 and were readjusted when special cause was achieved.

example, our use of health information technology enabled each patient to be assigned an individualized cholesterolmonitoring schedule determined by dyslipidemia risk. We configured the EMR to forward results automatically to responsible providers. Care delivery team design including assigned individual roles ensured that tests were ordered and forwarded to physicians

before the clinic visit. Education of patients, providers, and staff helped ensure that each knew his or her responsibility within the system. Ultimately, these interventions combine to create a system that has resulted in improved care and is now part of our routine.

There are several approaches for managing dyslipidemia²⁵ in high-risk

patients. Current guidelines^{2,3} recommend assessment by a trained dietician and a trial of TLC before initiating statin therapy. Additional interventions include minimizing dyslipidemia-causing medications, such as steroids²⁶ or sirolimus,9 and/or treating with statins.^{27,28} Despite the resulting substantial improvement in cholesterol control, our project did not focus on treating dyslipidemia, but, rather, on improving our process for monitoring this and other important risks. As such, treatment of dyslipidemia was at the discretion of the patient's physician, according to published guidelines.2 Thus, our results suggest that reliable monitoring and forwarding of results to clinicians can have substantial effects on treatment and control of dyslipidemia. Future efforts should focus on developing and testing more sophisticated risk-stratification (eg. proteinuria, other dyslipidemia-causing medications) and standardizing therapy for dyslipidemic patients, including dietary assessment and TLC. Such approaches should emphasize the essential role of trained dieticians as part of a multidisciplinary team.29

Our findings should be interpreted in light of their limitations. First, to most effectively demonstrate improvement in our process, we would have, ideally, collected several months of baseline cholesterol monitoring data before intervening. However, even without a large amount of baseline data, we decided to begin improvement because the initial data were consistent with our knowledge of the system's performance. Second, the time series analysis of cholesterol control in our population may have been affected by higher- or lower-risk patients entering or leaving the population over time. To account for this, we performed a before/after analysis on a discrete cohort of patients who had cholesterol testing both before and after our OI interventions. Finally, our project did not address patient behavior, such as medication adherence, clinic "no shows," and patients who had not been seen in more than 12 months. Accordingly, a small proportion of our population was not reached by our new system. Comprehensive chronic disease management will require selfmanagement support and strategies to enhance the patient interaction with our system, including specific interventions focused on adherence. Notwithstanding these limitations, our report adds to the small, but accumu-

lating, literature supporting the use of QI methods to drive improved clinical outcomes in pediatric patients with chronic illness.

CONCLUSIONS

We used QI methods to rapidly implement a series of changes that created a reliable system for individualized monitoring of cholesterol and 11 other tests in KTRs who are at exceedingly high risk for CVD in adulthood. This reliable, risk-based monitoring was followed by improved treatment and

control of dyslipidemia in our population. Our interventions were informed by the Chronic Care Model²⁰ and reliability science and hold promise for improving care and outcomes for patients with other chronic conditions.

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