Title: Quality of care in childhood-onset systemic lupus erythematosus: Report of an intervention to improve cardiovascular and bone health screening

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Key indexing terms: Pediatric systemic lupus erythematosus; cardiovascular diseases; bone density; prevention and control

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Financial support: None to report.

Conflict of interest: The authors report no commercial financial disclosures related to this work.

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Running Head: Improving cSLE health screening

Abstract

Objective: Initial benchmarking of childhood-onset systemic lupus erythematosus (cSLE) quality indicators revealed suboptimal performance across multiple centers. Our aim was to improve cardiovascular and bone health screenings at a tertiary treatment center for cSLE. This included annual measurements of vitamin D, lipid profiles, and bone mineral density testing via dual x-ray absorptiometry (DXA).

Methods: Quality improvement methodology was applied to design and implement a standardized pre-visit planning process to electronically pend orders for needed screenings prior to a scheduled clinic visit. Process outcomes were measured using statistical process control charts. Univariate analyses were completed to assess patient-level factors.

Results: During the study, 123 cSLE patients participated across 619 clinic visits. The percentage of patients with completed screenings improved from 54% to 92% for annual vitamin D, 55% to 84% for annual lipid profiles, and 57% to 78% for DXA, which was sustained for more than 1 year. Providers responded to a majority of abnormal results, and improvement in the average vitamin D level was observed over time. Higher levels of disease activity, damage, number of clinic visits, and screenings completed at baseline were observed in patients with all screenings completed at the end of the intervention.

Conclusion: Implementation of elements of the chronic illness care model for cSLE management improved performance of cardiovascular and bone health screenings, a step towards preventing long-term morbidity in cSLE. Our study also suggests that more patient interaction with the health system may promote successful completion of health maintenance screenings.

INTRODUCTION

Childhood-onset systemic lupus erythematosus (cSLE) is a chronic autoimmune disease with poor health outcomes and high rates of devastating disease complications, some which may be preventable. Compared to patients with adult-onset disease, patients with cSLE, defined as disease onset before 18 years, have significantly higher rates of active disease and irreversible organ damage(1) and a two-fold higher mortality rate(2). Since treatment of cSLE often entails chronic use of glucocorticoids, it is critical to minimize the associated cardiovascular and bone health toxicities, including vitamin D deficiency(3), hyperlipidemia(4), and decreased bone mass(5). Furthermore, intervention to prevent adverse sequelae is critically important during childhood due to vulnerability with growth, development, and bone mass accrual and potential for cumulative morbidity over time. There is evidence that improved quality of care in the rheumatology clinic is associated with improved clinical outcomes for adults with SLE(6, 7). To improve long-term morbidity and mortality in cSLE, dedicated work to define quality care and implement interventions to achieve care delivery standards is needed, followed by documented improvement of health outcomes.

To date, quality indicator measures that emphasize preventive processes of care, including comorbidity screenings, have been developed for cSLE(8). However, initial benchmarking at 7 international pediatric rheumatology centers revealed suboptimal performance and marked variation across the 26 quality indicators in clinical practice, especially for cardiovascular and bone health screenings(9). In other pediatric chronic conditions, standardization and reliable implementation of processes of care have led to significant improvements in clinical outcomes(10, 11). In a cohort of pediatric kidney transplant recipients, introducing pre-visit planning to reliably implement cholesterol monitoring led to a significant increase in the number of patients on statin therapy and with cholesterol values at goal(12). Therefore, by designing a reliable system to improve rates of preventive screenings for patients

with cSLE, earlier recognition and intervention on critical risk factors could have the potential to impact long-term health outcomes for this population.

The objective of this study was to design and implement an intervention to improve cardiovascular and bone health screenings in cSLE patients. Published quality indicators were adapted to track performance at our local center for completing vitamin D and lipid profiles annually and bone mineral density testing with dual x-ray absorptiometry (DXA) at least once. The specific aim of the intervention was to increase the percentage of cSLE clinic visits with completed cardiovascular and bone health screenings from baseline to greater than 80% over the period from August 2016 to December 2017. We hypothesized that use of quality improvement methods enables the design and implementation of a health system intervention to reliably improve the rate of comorbidity screenings, thereby improving the quality of care provided to our patients with cSLE.

MATERIALS AND METHODS

Context

This study took place in a pediatric rheumatology clinic at a large, Midwestern pediatric tertiary care center that actively follows around 120 cSLE patients, often into adulthood. Pediatric rheumatology clinical providers included 10 attending physicians, 2 with combined Internal Medicine-Pediatrics training, and 1 nurse practitioner with a mean of 15 years in practice (range 0.5-35). The electronic health record (EHR) was leveraged to identify patients through a disease registry function and to generate reports for screening completions and screening failures. Test results were later extracted from the EHR by both automated and manual review. The Institutional Review Board approved the study and waived requirement for consent (study ID 2018-1455).

Intervention

The intervention was structured following the Model for Improvement(13). We formed a team of key stakeholders from pediatric rheumatology, including the lead investigator (EAS), a

registered nurse, nurse coordinator, nursing director, QI divisional leaders, and the division director. The team hypothesized key system drivers necessary to achieve reliable health screening for cSLE patients in keeping with quality guidelines (Figure 1). The current clinic process for cSLE disease management using pre-visit planning was thoroughly reviewed, theoretical and known failures at each step of the process were identified, and a list of potential interventions was developed (Figure 2).

The intervention began in August 2016 with presentation of 6 months of baseline performance data to clinical providers, and feedback was solicited on potential process interventions. Through a series of iterative test cycles to refine process improvements, we focused our intervention on an existing pre-visit planning procedure. Prior to the intervention, the rheumatology nurse coordinator or registered nurse would use the EHR to identify cSLE patients scheduled for clinic one week in advance and review certain criteria that varied by provider. With the intervention, this pre-visit planning process was standardized so that for every patient, the EHR was reviewed for results of a serum 25-OH vitamin D level and serum lipid profile during the preceding 410 days (allowing for a 45-day margin past one year) and one prior DXA scan. If results were not found, electronic orders were pended in the EHR for review and/or sign off by the treating provider during the upcoming clinic visit. The pended orders were documented in a note and were visible in the EHR order entry function; however, a chart could still be closed without the provider taking action if the provider did not navigate to the order entry screen or sign the pended orders during the visit.

During the initial 6 months of the intervention, the lead investigator received a weekly patient-level automated report for visits completed the previous week with the most recent completion date for each of the 3 screenings. If screenings were due but had not been completed, chart review was performed and a reason was recorded. Through this analysis, additional interventions were implemented to increase the reliability and scope of the pre-visit planning procedure, including standardizing pre-visit planning documentation, updating an existing

electronic order-set, expanding capability for electronic entry of results on tests performed external to the institution to make them searchable for inclusion in compliance reports, and training clinic staff on these processes.

Measures

The study population was defined as patients scheduled in the pediatric rheumatology clinic with the ICD-10-CM diagnosis code of M32* for systemic lupus erythematosus used in at least two prior clinic visits in the pediatric rheumatology department and at least one month since diagnosis with no age exclusions. Patients were identified through a validated registry list in the EHR. The primary outcome measure was the percentage of cSLE clinic visits each month with cardiovascular and bone health screenings completed, including serum 25-OH vitamin D in the last 410 days, serum lipid profile in the last 410 days, and one prior DXA scan. We reviewed 6 months of baseline data starting in February 2016, and then began prospective collection in August 2016. We retrospectively measured the proportion of the population with screenings completed during the baseline period and intervention period. We also collected the results of the screening tests and whether an action was taken by the care provider in response to abnormal results, such as a new medication prescription, new referral, follow-up testing, or documentation of counseling the patient and/or family. For screenings that were not completed, we recorded a reason related to the clinic process that led to the failure of screening completion.

In a post-hoc analysis, we explored the association of patient-level measures with successful screening completion (yes/no). These patient-level measures were: 1) demographics including age, gender, and race, 2) clinical characteristics at the start of the intervention including disease duration in years, body mass index (BMI), SLE Disease Activity Index (SLEDAI)(14), and Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SDI)(15), and 3) health system factors including insurance status, number of clinic visits during the intervention period, if all screenings were completed at baseline, and if the patient's provider was a higher vs lower volume provider. To determine provider volume, the number of

patients per provider during the intervention period were calculated, and providers were divided into patient volume quartiles. Lower volume providers were in the first and second quartiles, and higher volume providers were in the third and fourth quartiles.

Analysis

The intervention was designed as an interrupted time series trial, in which data is longitudinally collected before and after intervention(13). The primary outcome measure was plotted over time on an attribute statistical process control chart, or "P-chart", that includes a mean centerline and upper and lower control limits calculated using the standard deviation(16). This allows for distinguishing common cause variation within the system and special cause variation reflecting a change to the system. Based on established rules, we sub-grouped the proportion of clinic visits in which screenings were completed before or by one week after the visit by month and adjusted the centerline and control limits to document special cause variation and improvement(16). The goal was for 80% of visits each month to have completed screenings to achieve first level process reliability(17), and we tracked each screening separately and together as a bundle. These charts were generated using a standard package from Microsoft Excel.

In addition, for patients with visits during both the baseline and intervention period, we compared the completion rates for each of the 3 screening tests using McNemar's test for paired observations. We calculated the percentage of patients with abnormal screening results during the intervention and the percentage of abnormal results where an action was taken by the provider. We also calculated the average monthly results over time.

In the post-hoc analysis, we divided patients into two groups based on whether all 3 screenings were completed by the end of the study or not and performed multiple univariate comparisons to identify differences in patient demographics, clinical characteristics, and health system factors between these two groups. Descriptive statistics were performed for each variable listed above using frequency and percentage for categorical variables and mean and standard deviation for continuous variables, respectively. Group differences in categorical variables were

analyzed using chi-squared tests or Fisher's exact tests for small cell values, and continuous variables were analyzed using t-tests. BMI was analyzed using Wilcoxon rank sum test. Statistical significance was set at $p \leq 0.05$ (two-tailed). Analyses were performed using R software(18).

RESULTS

During the 23-month study period, 123 individual patients were evaluated across 619 clinic encounters staffed by 11 pediatric rheumatology providers. Of these, 100 patients were seen during the baseline period from February 2016 through July 2016, 111 were seen during the intervention period from August 2016 through December 2017, and 88 were seen during both. The mean age for all patients was 19.5 years with 86% female and 52% Caucasian (Table 1). The number of visits per patient during the total study period ranged from 1 to 13 with a median of 5 visits per patient. The number of patients followed by each provider ranged from 1 to 42 with a median of 5 patients per provider. Five providers were considered higher volume and 6 were considered lower volume based on the quartile definition described above.

At baseline, the proportion of patients with completed screenings was 54% for vitamin D, 55% for lipid, 57% for DXA, and only 22% for the bundle of all 3 tests. On each of the statistical process control "P-charts" that tracked performance of each screening separately and as a bundle, a shift was observed in the proportion of clinic visits each month with screenings completed, which corresponded to the start of the pre-visit planning intervention (Figure 3). This improvement was sustained for over a year. By the end of the intervention, the proportion of patients with completed screenings was 92% for vitamin D, 84% for lipid, 78% for DXA, and 64% for the bundle. For the 88 patients (72% of total) seen during both the baseline and intervention period, there was a significant difference in the proportion with completed screenings for vitamin D ($\chi^2 = 29.3$, $p < 0.01$), lipids ($\chi^2 = 15.6$, $p < 0.01$), and DXA ($\chi^2 = 17.1$, $p < 0.01$). Improvement was observed across all providers.

During the intervention, 101 patients had vitamin D screenings completed, 88 had lipids completed, and 51 had a DXA scan (Table 2). A majority of patients had abnormal serum 25-OH vitamin D levels with 42 (42%) classified as insufficient (20-30 ng/mL) and 23 (23%) as deficient (< 20 ng/mL). In addition, a majority of patients had an abnormal total body z-score on DXA with 21 (41%) with z-score < -1.0 SD and 8 (16%) with z-score < -2.0. Although treatment algorithms were not part of the intervention, providers did respond to abnormal lab values in the majority of cases, including prescription of vitamin D supplementation and/or repeat testing for abnormal vitamin D, lifestyle modification counseling and referrals to physical fitness and/or nutrition programs for abnormal lipids, and prescription of vitamin D and/or calcium and lifestyle modification counseling for abnormal DXA z-scores. There was improvement over time in the mean+SD 25-OH vitamin D values collected each month from 27+12 ng/mL at baseline to 34.5+16 ng/mL at the end of the study period.

Reasons for screenings not completed during the intervention period were identified by review of the EHR and tracked using Pareto charts(16). The majority of vitamin D non-completions (5 of 9) occurred when pre-visit planning was not done, such as with urgent visits (i.e., scheduled outside of the regular pre-visit planning window). Six of 17 lipid non-completions were also due to urgent scheduling, and 5 of 17 due to a glitch discovered in releasing electronic orders in phlebotomy. For DXA scans, 7 of 23 non-completions occurred when providers did not sign the pended orders for various documented reasons such as lack of insurance, and an additional 7 of 23 were not done related to scheduling difficulties. The other reasons for non-completion across all 3 screenings included tests ordered external to our hospital system without documentation of results in the EHR, patients failing to present to the phlebotomy unit after the clinic visit despite instructions, and patients who receive lab draws during scheduled infusion visits due to a parallel but separate process used for infusion orders outside of the usual clinic workflow through which pended orders cannot be visualized.

Finally, multiple patient-level variables were compared in a post-hoc analysis between patients in the intervention group who had all 3 screenings completed (n=71, 64%) versus not all completed (n=40, 36%) at the end of the study period. Patients with all 3 screenings completed had higher SLEDAI scores, higher SDI scores, more clinic encounters, and were more likely to have had screenings completed prior to the intervention (Table 3). Differences were not observed in age, gender, race, disease duration, BMI, insurance status, or the provider's patient volume status.

DISCUSSION

This study is the first to our knowledge to demonstrate improvement in completing cardiovascular and bone health screenings for cSLE patients. We utilized rigorous quality improvement methodology to design and implement a health system intervention that improved performance for quality of care measures that were previously benchmarked as suboptimal(9). In addition to sustained improvement in screening completion, our study also demonstrated provider response to the majority of abnormal results without use of a treatment algorithm and improvement in vitamin D results over time. By developing a reliable system of care that emphasizes early risk-based monitoring and intervention, there is potential to significantly improve long-term comorbidity outcomes for cSLE patients.

The results of our baseline assessment of completed screenings were within the range of previously published benchmarks of cardiovascular and bone health quality indicators from an international sample of pediatric rheumatology centers(9), in addition to other single-center studies(18, 19). Through the application of quality improvement methods, we were able to demonstrate sustained improvement in these measures that resulted in a change to our routine provision of care for patients with cSLE within our local clinic. The use of an interrupted time series design and statistical process control charts for measurement allowed us to determine that our

intervention led to process improvement. Notably, this improvement was sustained for over a year, accounting for any potential seasonal effects.

The key feature in our intervention that led to improvement was utilizing a standardized system to review patient data ahead of scheduled clinic visits and prepare for identified needs during the clinic visit, a process referred to as pre-visit planning. Rooted in the elements of the Chronic Care Model(20), pre-visit planning is recognized as an important strategy to improve processes of care and outcomes for multiple chronic conditions, including in pediatrics(10, 12, 21). Interviews of young adults with cSLE have previously revealed that comprehensive and coordinated care was a top healthcare priority(22). However, active provision of non-visit care is resource intense and may be challenging to implement in certain clinical contexts. The pre-visit planning intervention implemented in this study required the time and knowledge of highly skilled staff to conduct the pre-visit chart review and pend orders for providers as well as sophisticated clinical information system capabilities of the existing EHR. While reliance on trained personnel is a limitation of the reported intervention, further automation is now being pursued since the system has proven stable(13). We did not explicitly measure time spent on pre-visit review as a balancing measure since tasks were incorporated into an existing process, but this is an important consideration for replication in other settings. Such a highly technology-based solution impacts the generalizability to care centers with limited EHR capability, but provides evidence for advocating for further investment in health information technology. Finally, while this process intervention limits the ability to comment on the distal impact on patient outcomes, by implementing a reliable risk assessment process and demonstrating documentation of provider response, we can infer an eventual downstream effect.

An interesting finding in our post-hoc analysis was that patients who had all screenings completed at the end of the study had more clinic visits during the intervention period compared to those who did not have all screenings completed. Previous studies in SLE have also reported an association between number of clinical visits and improved performance on quality indicator

measures(5). It may be that more clinic visits lead to more opportunities to place the order for needed screenings or to discuss and mitigate potential barriers to completing screenings. In considering less clinic visits in the group of patients with not all screenings completed, this may reflect the time constraints encountered when visits occur infrequently in cSLE. Infrequent appointments require catch-up on a large number of complex chronic illness care maintenance items in a constrained period of time (e.g., 30 minutes), and when such visits are made urgently, rather than preventively, the acute illness may supersede health maintenance concerns. This finding advocates for more emphasis on non-visit methods of care provision for patients with chronic conditions, such as a care manager or care-coordinator. Although the patients with completed screenings also had higher disease activity scores and damage indices at the start of the intervention which may account for the increased number of visits, this observation may suggest an increased vigilance for health maintenance in patients with more severe disease. Finally, this finding may indicate that patients who more readily engage with the health care system, whether due to severe disease or otherwise, are more likely to receive high quality care. If this hypothesis is true and especially if this impacts long-term outcomes, design of a behavioral intervention to target patient engagement in their health care would be of high value.

While the aim of this study was to design and implement a single-center intervention, there is considerable potential to spread the improvement to other centers. Use of pre-visit planning to identify and mitigate patient needs prior to the clinic visit is a well-accepted tool to improve care for patients with chronic conditions and would be amenable for testing across multiple centers to enhance the learning and potential impact of the intervention. A multi-center implementation network, Pediatric Rheumatology Care and Outcomes Improvement Network (PR-COIN), was established in 2011 to improve the care and outcomes for children with rheumatic conditions(23). A substantial effort through PR-COIN to date has focused on designing and implementing pre-visit planning strategies for patients with juvenile idiopathic arthritis (JIA). Since all pediatric rheumatology centers participating in PR-COIN care for patients with both JIA and cSLE, this

study demonstrates the utility of expansion of pre-visit planning to patients with cSLE. The established infrastructure of PR-COIN could facilitate the testing and spread of our cSLE comorbidity screening intervention at a multi-center level to impact more patient health outcomes.

In conclusion, we developed an intervention utilizing care coordination and health information technology that significantly improved the proportion of cSLE patients with completed cardiovascular and bone health comorbidity screenings. The design of our intervention could be applied to other categories of health maintenance monitoring both for cSLE and other chronic conditions. In addition, further investigation into the impact of patient engagement with the health care system on quality of care and health outcomes should be considered. This intervention serves as an initial step towards a comprehensive management approach to improve quality of care in cSLE. We assert that reliable completion of preventive screenings for patients with cSLE will ultimately lead to lower rates of comorbidities in adulthood and improve long-term outcomes for this high-risk population.

ACKNOWLEDGEMENTS

The authors acknowledge the efforts of Courtney Paffett, RN, BSN, CPN and Barbara Weyer, RN, MSN for their important contributions to the improvement work. We also acknowledge the participation of all pediatric rheumatology clinical providers and staff in the William S. Rowe Division of Rheumatology at Cincinnati Children's Hospital Medical Center. Finally, we acknowledge the analytic support provided by Amy M. Anneken, MS, as well as the contribution of multiple faculty and staff through the James M. Anderson Center for Health Systems Excellence's Intermediate Improvement Science Series course.

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FIGURE LEGENDS

Figure 1. Key driver diagram for improving cardiovascular and bone health screenings for cSLE.

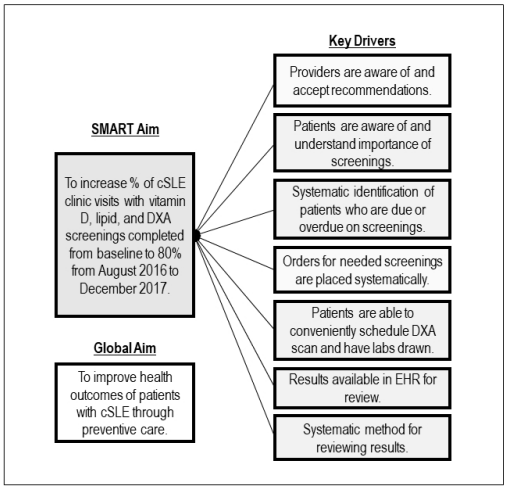
Figure 2. Simplified Failure Modes Effect Analysis (FMEA) for improving the reliability of performing cardiovascular and bone health screenings for cSLE. Interventions that were implemented are highlighted in bold.

Figure 3. Statistical process control “P-charts” showing the percentage of cSLE clinic visits with screenings completed for A) annual serum 25-OH vitamin D, B) annual serum lipid profile, C) one-time DXA scan, and D) the bundle of all 3 screenings.

Table 1. Patient demographic characteristics.

Table 2. Results of serum 25-OH vitamin D, serum lipid profiles, and DXA scan screenings completed during the intervention.

Table 3. Comparison of patients in the intervention with all 3 screenings completed versus not all completed at end of study.



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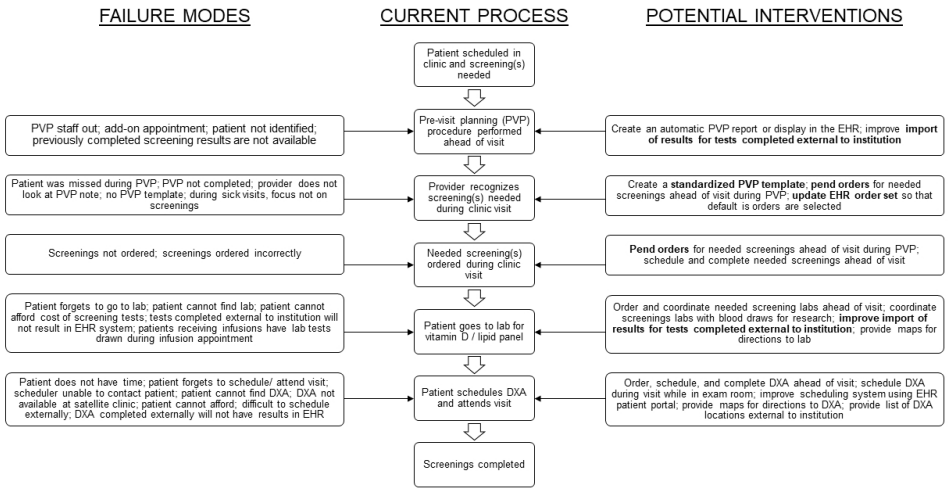

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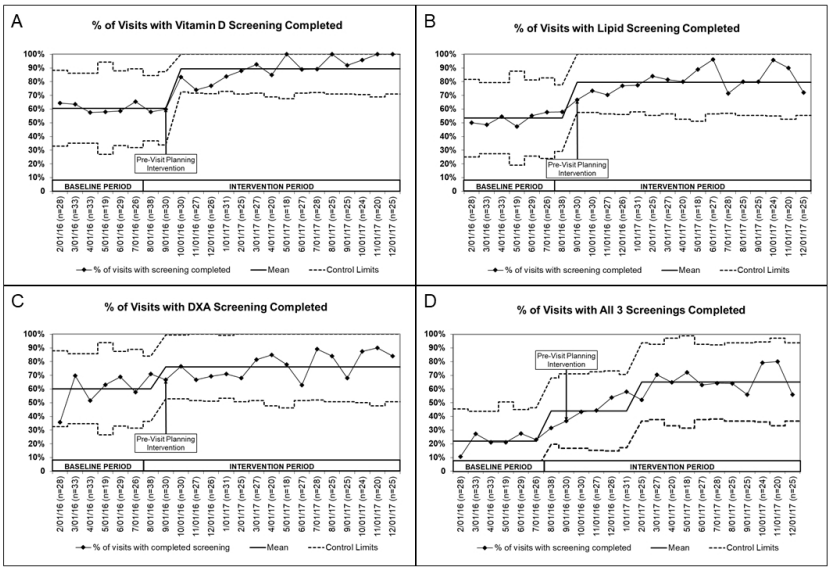

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338x190mm (96 x 96 DPI)

Table 1. Patient demographic characteristics.	
Total n	123
Age in years, Mean (SD)	19.5 (4)
Female, n (%)	106 (86%)
Race, n (%)	
Caucasian	64 (52%)
African American	48 (39%)
Asian	7 (6%)
Hispanic	2 (2%)
Other	2 (2%)

Table 2. Results of serum 25-OH vitamin D, serum lipid profiles, and DXA scan screenings completed during the intervention.

	25-OH Vitamin D	Total Cholesterol	LDL	DXA
Patients with screening completed, n	101	88	88	51
Average result, Mean (SD)	28 (12)	151 (40)	73 (33)	-0.7 (1.2)
Abnormal results, n (%)*	65 (64%)	10 (11%)	7 (8%)	29 (57%)
Action on abnormal result, n (%)	43 (66%)	6 (60%)	5 (71%)	22 (76%)

* Definitions for abnormal results: 25-OH vitamin D <30 ng/mL, total cholesterol > 200 mg/dL, LDL > 130 mg/dL, DXA total Body z-score < -1.0 SD.

Table 3. Comparison of patients in the intervention, n = 111, with all 3 screenings completed vs. not all completed at end of study.

	Group with All 3 Screenings Completed (n = 71)	Group with Not All Screenings Completed (n = 40)	p value
Demographic Characteristics			
Age in years, Mean (SD, range)	19.7 (4.1, 13-40)	19.0 (3.8, 12-28)	0.351
Female, n (%)	62 (87%)	33 (83%)	0.679
Caucasian, n (%)	37 (52%)	18 (45%)	0.602
Clinical Characteristics			
Disease Duration (years), Mean (SD)	4.7 (3.8)	4 (3.3)	0.317
BMI (kg/m^2), Mean (SD)	24.3 (4.9)	26.2 (7.8)	0.502
SLEDAI, Mean (SD)	4.04 (5.7)	2.08 (2.4)	0.013*
SDI, Mean (SD)	0.73 (1.2)	0.38 (0.56)	0.042*
Health System Characteristics			
Insurance Status, n (%)			0.687
Private	39 (55%)	19 (48%)	
Public	26 (37%)	18 (45%)	
None	6 (8%)	3 (8%)	
Clinic visits per patient, Mean (SD)	4.5 (2.7)	3.3 (2.4)	0.016*
All Screenings Complete at Baseline, n (%)	18/59 (31%)	3/28 (11%)	0.024*
Higher Volume Provider, n (%)	57 (80%)	34 (85%)	0.716

* Denotes significance. Comparisons for categorical variables were performed using chi-squared test except insurance status and all screenings complete at baseline used Fisher's exact test; comparisons for continuous variables were performed using student's t test; comparisons for BMI were performed using Wilcoxon rank sum test. Patients not followed during the baseline period were not included in the analysis of all screenings complete at baseline.