Routine Laboratory Testing Every 4 Versus Every 6 Weeks for Patients on Maintenance Hemodialysis: A Quality Improvement Project

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Rationale & Objective: Few data exist revealing how the frequency of routine blood work for patients on maintenance hemodialysis therapy affects patient outcomes and the costs of care. Our objective was to determine the effect of changing the frequency of blood work from 4- to 6-week intervals on the achievement of anemia and chronic kidney disease–mineral and bone disorder (CKD-MBD) targets.

Study Design: Retrospective interrupted time series from June 1, 2012, to December 31, 2015.

Setting & Participants: Tertiary hospital in Ontario, Canada, that provides maintenance hemodialysis therapy to 350 to 400 adult patients.

Quality Improvement Activities: Institution-wide switch of the interval for routine blood work from 4 to 6 weeks on March 24, 2014.

Outcomes: Achievement of recommended hemoglobin and phosphate level targets. Cost savings attributable to a change in frequency of blood work for hemoglobin, ferritin, iron saturation, calcium, and phosphate comparing 252-day periods under each testing frequency condition.

Analytical Approach: Statistical process control to analyze variation in the clinical outcomes.

Results: The proportion of patients who achieved hemoglobin (10-12 g/dL) and phosphate (2.5-4.6 mg/dL) targets remained stable (average of 60% and 46%, respectively), with no measurements beyond 3 standard deviations from the mean. The hemodialysis unit mortality rate also remained stable (average of 2% per month). Reducing blood work frequency to every 6 weeks was associated with a saving of $85 per patient-year, corresponding to a program-wide savings of $35,000.

Limitations: No case-mix adjustment due to use of aggregate hemodialysis unit data, and absence of data for hospitalizations and transfusions limiting assessment of the full cost of patient care.

Conclusions: After switching the frequency of routine blood work from 4- to 6-week intervals, performance on anemia and CKD-MBD targets did not change and the reduction in blood work was associated with laboratory cost savings. Reducing the frequency of blood work may represent an opportunity for hemodialysis providers to devote greater efforts toward other care elements that better improve patient outcomes.

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Patients treated using long-term dialysis therapy experience numerous complications, including anemia, chronic kidney disease–mineral and bone disorder (CKD-MBD), and electrolyte abnormalities. As a result of these complications and their associated treatments, regular surveillance blood work is an important component of care for patients on dialysis therapy. Although more frequent blood work allows for closer monitoring of patients, differences in laboratory testing volumes among institutions have not been associated with clinical outcomes in the general population.[1-3] Clinical practice guidelines for patients on dialysis therapy provide ungraded recommendations for blood work frequency, varying between 1 and 3 months for the management of anemia and phosphate levels.[4,5] Based on informal conversations with dialysis providers, the predominant practice in North America appears to be routine blood work at 4-week intervals. However, to our knowledge, no interval of routine blood work in patients on hemodialysis therapy has been studied in relation to clinical outcomes.

This lack of evidence and guideline variation on blood work monitoring for patients on dialysis therapy is particularly relevant given the Choosing Wisely initiative's international dialogue on unnecessary medical tests and treatments.[6] Unintended consequences of frequent blood work include iatrogenic anemia, increased patient anxiety, and greater health care costs. Moreover, the need to frequently review and respond to blood work results may come at the expense of health care providers addressing other relevant issues facing dialysis patients, including kidney transplantation assessment, volume control, and symptom relief.[7,8] Therefore, current routine blood work practices for patients on dialysis therapy require a thorough re-evaluation.

In this quality improvement study from an academic medical center in Ontario, Canada, we sought to compare clinical outcomes and laboratory costs after an institution-wide change from routine blood work at 4-week intervals to 6-week intervals in patients on hemodialysis therapy. Our objectives were to determine the association between blood work frequency and the achievement of recommended anemia and CKD-MBD targets, as well as quantify the cost savings from less frequent monitoring. We hypothesized that there would be no difference in anemia or CKD-MBD target performance between the 4- (high frequency) and 6-week (low frequency) blood work periods, and this effect would be sustained for more than 1 year after the change.

Methods

Study Design and Participants

We conducted a retrospective interrupted time series analysis of a regional hemodialysis program in Kingston, Ontario, Canada, from June 1, 2012, to December 31, 2015. Our hemodialysis program serves 350 to 400 patients in a catchment area of more than 500,000 residents. In addition to in-center hemodialysis and home hemodialysis, we also offer other renal replacement therapy options such as peritoneal dialysis and kidney transplantation. The hemodialysis program operates at Kingston Health Sciences Center, with responsibility for 7 satellite clinics in our region. Kingston Health Sciences Center is a 440-bed tertiary-care hospital fully affiliated with Queen's University.

We obtained annual characteristics for adult patients receiving in-center hemodialysis at Kingston Health Sciences Center from the Canadian Organ Replacement Register (CORR), an information system that manages data for all dialysis programs in Canada.[9] The hospital laboratory provided the total number of blood tests (routine and nonroutine), and we ascertained the achievement of clinical targets from our electronic medical record (NephroCare). Because we did not use patient-identifiable data, we did not obtain informed consent for this study. The ARECCI (A Project Ethics Community Consensus Initiative) screening tool deemed this project consistent with quality improvement at minimal risk to participants.[10] Formal research ethics board review was waived by Queen's University based on the Tri-Council Policy Statement for ethical human research.[11] This quality improvement project was approved by the clinical leadership of the Kingston Health Sciences Center hemodialysis program. We performed, analyzed, and reported this study in accordance with the SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines.[12]

Quality Improvement Intervention

At our center (which is similar to other Canadian centers), usual practice involves blood work rounds at which anemia and CKD-MBD parameters are assessed on a regular basis, approximately 2 to 7 days after being sent to the local laboratory. In response to a hospital-wide initiative to order blood tests more judiciously, our hemodialysis program elected to change routine blood work frequency from every 4 weeks to every 6 weeks on March 24, 2014. We chose 6 weeks because this was the lowest acceptable frequency referenced by clinical practice guidelines for anemia management.[13] This lower 6-week blood work frequency became standard practice throughout our entire regional hemodialysis program. Health care providers could still request additional blood work based on individual patient needs and circumstances.

Outcomes

The primary outcomes were achievement of hemoglobin (10-12 g/dL) and phosphate (2.5-4.6 mg/dL) targets as recommended by the College of Physicians and Surgeons of Ontario and the Canadian Society of Nephrology, which did not change during the study period.[14-16] Secondary outcomes included use of erythropoietin, achievement of calcium (8.8-10.2 mg/dL) and parathyroid hormone (PTH; 94-462 pg/mL) targets, and all-cause mortality. We measured outcomes until December 31, 2015, after which a change in local laboratory assays precluded the comparison of test results between periods.

To ensure that routine blood work at 6-week intervals rather than 4-week intervals did not result in additional nonroutine blood work, we captured all blood tests during the study period regardless of whether completed on a routine blood work day. We also performed a cost subanalysis that compared 4-week intervals during 252 days (July 15, 2013, to March 23, 2014) with 6-week intervals during 252 days (March 25, 2014, to December 1, 2014). The costs of individual tests were based on the Ontario Schedule of Benefits for Laboratory Services in Canadian dollars as follows: hemoglobin ($8.27), ferritin ($14.48), iron saturation ($17.58), serum calcium ($2.59), and serum phosphate ($2.59).[17]

Statistical Analysis

We used statistical process control charts to analyze variation over time in the achievement of anemia and CKD-MBD targets and all-cause mortality. Statistical process control charts combine chronologic analysis with tests of statistical significance, which allows them to evaluate the effectiveness and sustainability of a process over time.[18,19] The 4-week (high frequency) period occurred from June 1, 2012, to March 23, 2014 (661 days), and the 6-week (low frequency) period occurred from March 25, 2014, to December 31, 2015 (647 days). We divided all time periods into 4- or 6-week intervals, as appropriate to facilitate analysis, except for PTH, which was measured every 3 months throughout the entire study period. The null hypothesis was that target achievement and clinical outcomes would fluctuate randomly over time (common cause variation). The alternative hypothesis was that outcomes would display unnatural variation after the change to less frequent routine blood work (special cause variation).

To construct the statistical process control charts, we calculated mean performance during the entire study period and plotted control limits 3 standard deviations (SDs) from this mean using p-chart formulas that are based on the binomial distribution to detect special cause variation associated with the change in blood work frequency.[19] Special cause variation on statistical process control charts can also be represented by other patterns that depict nonrandom performance, including 8 or more continuous observations from the mean, 6 consecutive observations all in the same direction, or 2 of 3 successive points more than 2 SDs from the mean.[18,19] In return for a minor increase in false-positive results, these additional tests greatly increase the power of control charts to detect process improvements and deteriorations.[18] We used QI Macros (KnowWare) to construct the statistical process control charts.

Results

Patient Characteristics

Between 2012 and 2015, the number of prevalent hemodialysis patients increased from 344 to 422. This represented 697 patient-years from June 1, 2012, to March 23, 2014, and 766 patient-years from March 25, 2014, to December 21, 2015. Patient demographics and characteristics remained similar, with a trend in later years toward older patients and greater use of central venous catheters (Table 1). In 2012, mean age was 63.7 ± 15.7 (SD) years, 55.5% of patients were men, 44.5% used a central venous catheter, and 39.5% had diabetes listed as the primary cause of kidney failure. In 2015, mean age was 65.1 ± 15.5 years, 58.8% of patients were men, 46.9% used a central venous catheter, and 37.9% had diabetes listed as the primary cause of kidney failure. During the entire study period, our hemodialysis patient population ranged from 86.9% to 89.4% white and 4.8% to 6.2% aboriginal.

Clinical Outcomes

The proportion of patients who achieved the recommended clinical targets for hemoglobin and phosphate levels were stable during the entire study period, with no measurements outside the control limits (Figs 1 and 2). Mean target achievement was 60% and 46%, respectively. For hemoglobin targets, in late 2014/early 2015, two of 3 consecutive measurements were <2 SDs from the mean. However, performance quickly rebounded to previous levels of 60%. There was no evidence of special cause variation in phosphate targets.

During the study period, average use of erythropoietin was 78% (Fig S1). In early 2015, there was evidence of special cause variation with a decrease in erythropoietin use as demonstrated by 8 continuous observations below the mean.[19] Hemoglobin targets were stable during this period.

The proportions of patients who achieved the recommend calcium and PTH clinical targets were stable during the entire study period, with no measurements outside the control limits (Figs S2 and S3). Mean achievement of these targets was 48% and 55%, respectively. Mortality fluctuated widely while blood work was sampled every 4 weeks, with several points above the upper control limit and 8 continuous observations below the mean (Fig 3). The hemodialysis unit mortality rate remained stable after the change to less frequent blood work at 6-week intervals.

Table 1. Baseline Characteristics

	2012	2013	2014	2015
No. of prevalent patients	344	357	381	422
No. of incident patients	83	105	109	129
Age, y[a]	63.7 ± 15.7	64.4 ± 15.5	65.0 ± 15.1	65.1 ± 15.5
Male sex	55.5%	55.7%	57.2%	58.8%
Race				
White	86.9%	89.4%	89.0%	88.4%
Black	1.2%	0.8%	0.8%	0.5%
Asian	2.6%	2.5%	1.6%	1.7%
Aboriginal	6.1%	4.8%	5.2%	6.2%
Other	0.6%	0.6%	1.3%	1.3%
Unknown	2.6%	1.9%	2.1%	1.9%
Primary cause of kidney disease				
Glomerulonephritis	16.3%	14.6%	12.9%	11.8%
Diabetes	39.5%	38.7%	39.6%	37.9%
Renal vascular disease	14.5%	16.0%	14.4%	13.3%
Polycystic kidney disease	4.4%	5.0%	4.2%	4.0%
Other	18.6%	17.9%	17.8%	22.1%
Unknown	6.7%	7.8%	11.1%	10.9%
Hemodialysis access				
Central venous catheter	44.5%	42.6%	45.7%	46.9%
Arteriovenous graft	2.6%	3.1%	2.6%	1.4%
Arteriovenous fistula	52.9	54.3%	51.7%	51.7%

Note: Characteristics assessed yearly for the Canadian Organ Replacement Register on October 31.
[a]Mean ± standard deviation.

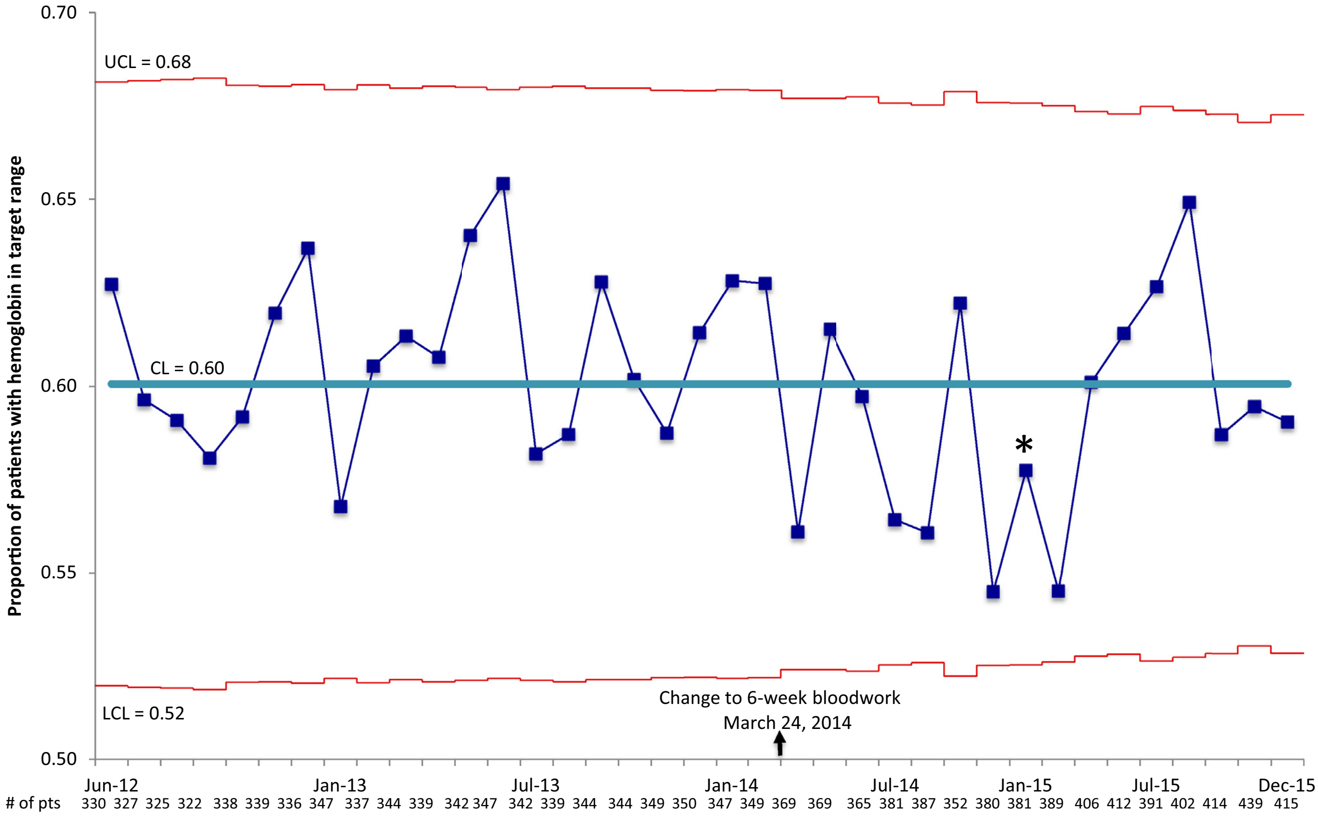

Figure 1. The proportion of patients (pts) with hemoglobin levels in the target range (10-12 g/dL) at a given interval. The change from 4- to 6-week blood work occurred on March 24, 2014. The mean upper (UCL) and lower control limits (LCL) are plotted 3 standard deviations (SDs) from the mean (CL). *Two of 3 consecutive measurements outside 2 SDs from the mean.

Numbers and Costs of Laboratory Testing

For the 252-day period in which we measured the number of tests and direct costs, we observed less testing and lower costs across all available laboratory types (Table 2). We performed 529 fewer hemoglobin tests (cost savings of $4,375), 575 fewer ferritin tests (cost savings of $8,326), 592 fewer iron saturation tests (cost savings of $10,407), 283 fewer calcium tests (cost savings of $733), and 439 fewer phosphate tests (cost savings of $1,137). On a yearly basis, the change to 6-week blood work would be expected to save our 400-patient hemodialysis unit ∼$6,000 in hemoglobin tests, $12,000 in ferritin tests, $15,000 in iron saturation tests, $1,000 in calcium tests, and $1,600 in phosphate tests.

Discussion

We demonstrated that a quality improvement intervention to reduce routine blood work frequency from 4-week intervals to 6-week intervals in patients receiving maintenance hemodialysis reduced blood draws without negatively affecting the achievement of recommended anemia and CKD-MBD targets. This effect was sustained for more than 18 months after the reduction in blood work frequency and was associated with a reduction in laboratory expenditures and no increase in all-cause mortality.

There is little evidence to inform the frequency of routine blood work monitoring for patients on hemodialysis therapy. The KDIGO (Kidney Disease: Improving Global Outcomes) anemia guideline recommends hemoglobin measurement at least monthly in patients with anemia and at least quarterly in patients without anemia.[4] The KDIGO guideline for CKD-MBD recommends serum calcium and phosphate measurement every 1 to 3 months, and PTH, every 3 to 6 months.[5] However, these guidelines acknowledge the lack of evidence for their recommendations, and accordingly, the strength of the recommendations are "not graded."[4] Sensibly, both documents support the individualization of blood work frequency based on trends and side effects. The predominant practice in North America appears to be routine blood work at 4-week intervals, as demonstrated by the standard of care at Dialysis Clinic Incorporated (D.E. Weiner, personal communication; September 2018), Satellite Healthcare (G.M. Chertow, personal communication; September 2018), and in Ontario, Canada (R.W., unpublished data from 67% of hemodialysis programs; 2018).

Our study illustrates that achievement of performance targets for anemia and CKD-MBD is possible despite less

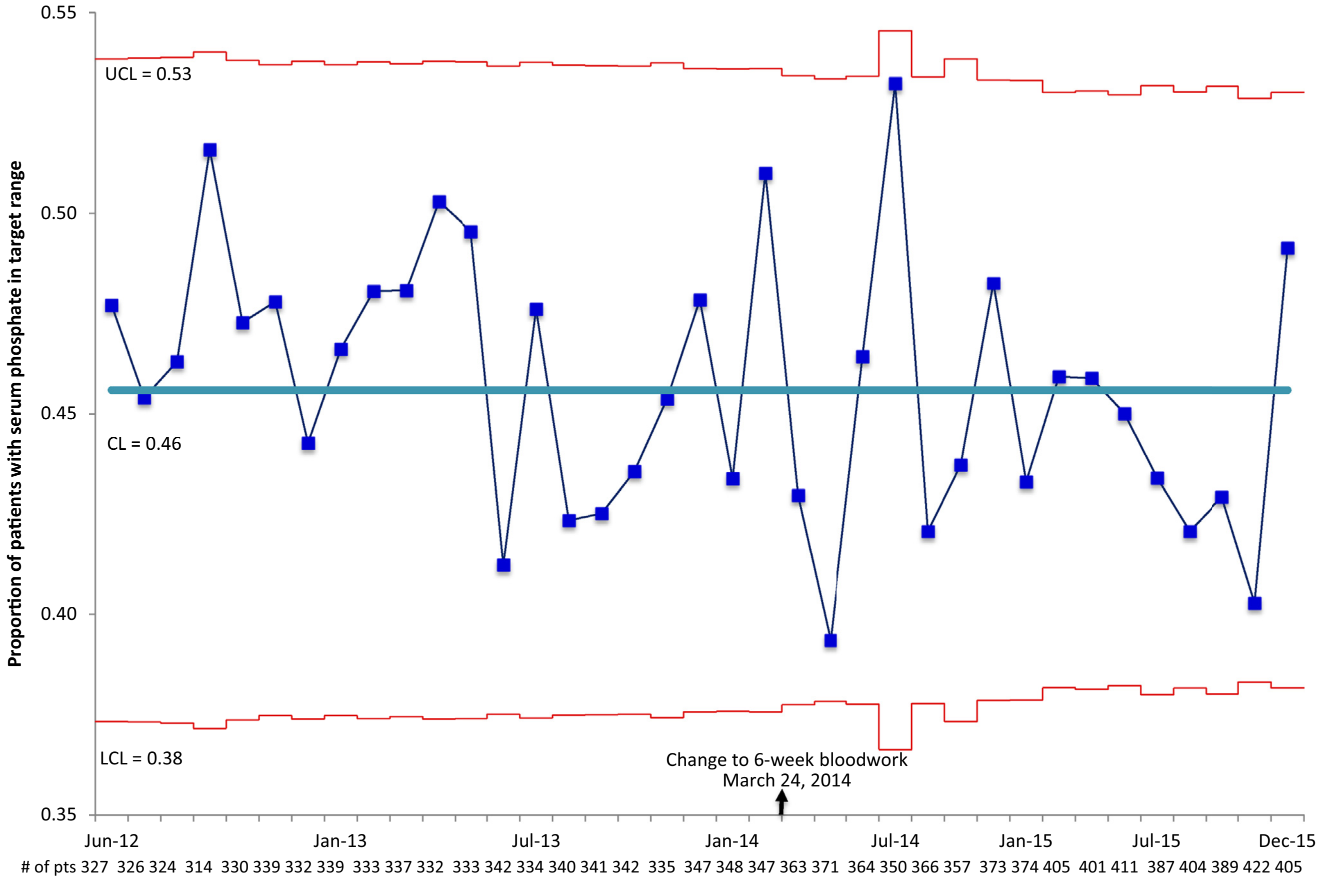

Figure 2. The proportion of patients (pts) with phosphate levels in the target range (2.5-4.6 mg/dL) at a given interval. The change from 4- to 6-week blood work occurred on March 24, 2014. The mean upper (UCL) and lower control limits (LCL) are plotted 3 standard deviations from the mean (CL).

frequent routine blood work. We observed similar hemoglobin levels (60% between 10 and 12 g/dL) and erythropoietin use (78%) in our hemodialysis unit as reported by the Canadian arm of DOPPS (Dialysis Outcomes and Practice Pattern Study),[20] as well as CKD-MBD parameters consistent with provincial data reported by CORR.[9]

Although there was a signal toward fewer patients reaching hemoglobin targets in late 2014/early 2015 (Fig 1), the statistical process control criterion by which we identified this variation is overly sensitive, suggesting a possible false positive.[18,19] Another possibility is seasonal variation in hemoglobin levels[21] or a reduction due to decreased holiday staffing and increased patient travel during the holiday period affecting quality of care. The false-positive interpretation is supported by hemoglobin targets returning to previous levels for a sustained 42 weeks.

Erythropoietin use decreased by 2% to 5% at the end of 2015 without an associated decrease in hemoglobin target achievement, which could be due to less iatrogenic anemia from fewer blood draws and the uptake of evidence that showed little benefit and possible harm with erythropoietin at higher hemoglobin levels.[22-24] We favor the latter explanation combined with improved erythropoietin stewardship given the small absolute change in erythropoietin use. However, we do not have access to erythropoietin dosages to confirm and we cannot definitively rule out other cointerventions or secular changes, such as blood transfusion practices.

Although we performed routine blood work less frequently, health care providers retained the flexibility to individualize testing based on patient circumstances. Nonetheless, we still observed fewer blood samples processed for hemoglobin, ferritin, iron saturation, calcium, and phosphate in the 6-week group (Table 2), which suggests that health care providers believed that the policy of measuring routine blood work every 6 weeks enabled them to adequately care for their patients with few instances that justified supplemental blood work. The cost savings of eliminating this potentially superfluous blood work totaled $85 per patient-year. When extrapolated to the Canadian hemodialysis population of approximately 20,000 patients,[9] the annual population-level savings amount to $1.7 million. This number may be a conservative estimate because many hemodialysis units include

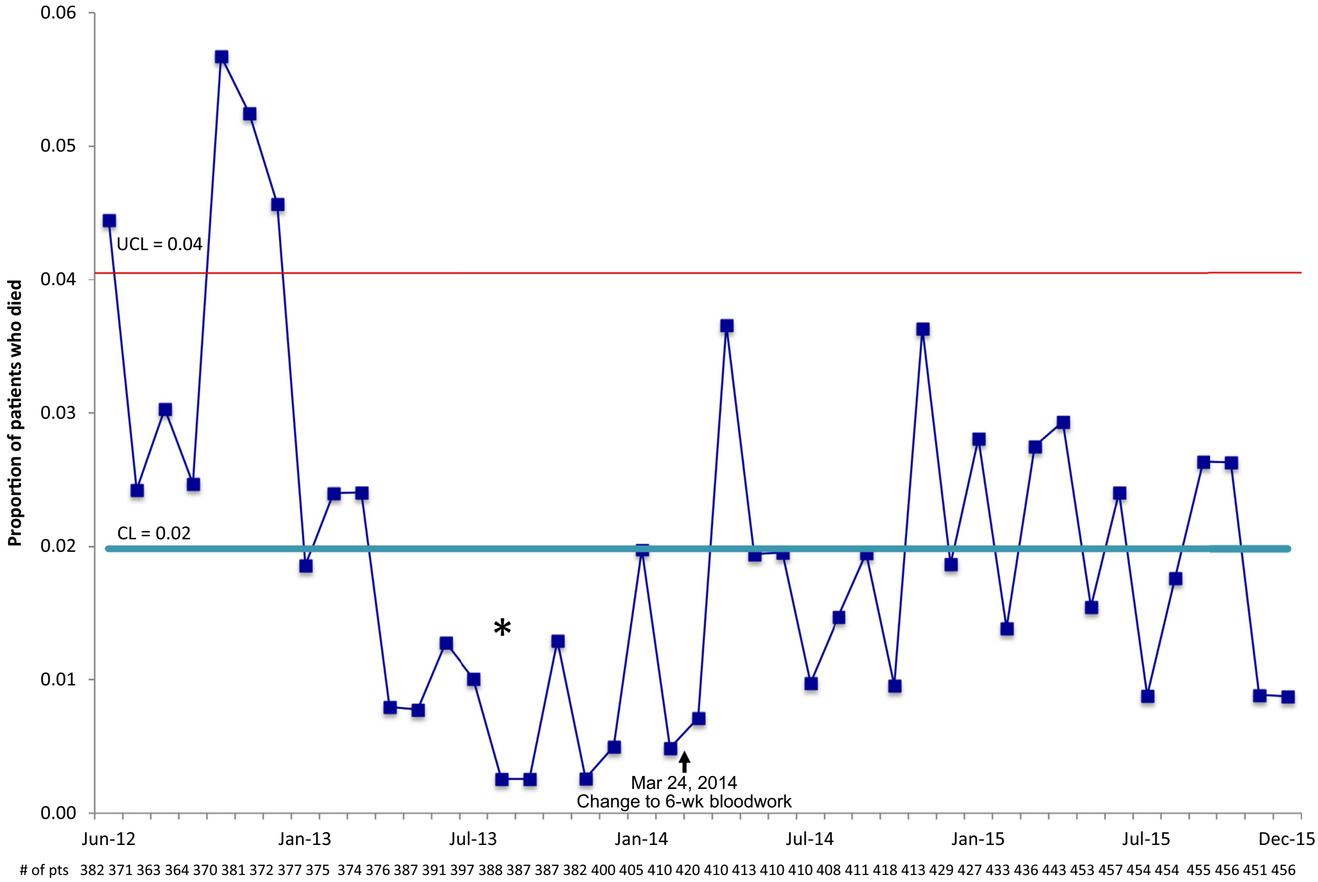

Figure 3. The hemodialysis unit mortality rate from June 1, 2012, to December 31, 2015, at a given interval. The change from 4- to 6-week blood work occurred on March 24, 2014. The upper control limit (UCL) is plotted 3 standard deviations from the mean (CL). *Eight or more continuous observations below the mean. Abbreviation: pts, patients.

additional tests as part of their routine blood work panel, such as electrolytes and serum albumin, and the estimates do not account for the cost of laboratory technicians and equipment maintenance. Most of the cost savings are related to a reduction in the most expensive tests (ie, ferritin and iron saturation), which suggests that the most expensive blood work may be a starting point from which other hemodialysis units can experiment with their own blood work de-escalation initiatives.

Health care cost is not the only motivation to re-examine current blood work practices. Frequent blood work occupies the time of physicians, nurses, pharmacists, and dieticians; therefore, there are opportunity costs to ordering more laboratory tests. Research on patient and caregiver priorities to improve hemodialysis care suggest that health care provider time may be redirected to other areas.[7,8] In one such multicenter study from Australia and Canada, biochemical outcomes (ie, calcium, phosphate, PTH, hemoglobin, and potassium) ranked lowest in importance to patients and caregivers; blood work was described as imperceptible measures of concern to physicians that are not necessarily experienced by patients.[7] Rather, patients prefer health care providers to focus on lifestyle and psychosocial concerns, such as fatigue, resilience, anxiety, depression, and cognition.[7,8]

The Institute for Healthcare Improvement Triple Aim of health system performance consists of patient outcomes, health care costs, and the patient experience. Our results demonstrated similar clinical outcomes at reduced costs for less frequent blood work, which suggests that nephrologists should consider recalibrating the time devoted to certain tasks in the hemodialysis unit so that at least one element of the Triple Aim is improved. Competing time demands is an important message of the Choosing Wisely initiative,[6] and reconsidering the time committed to routine tasks without clear benefit may represent an opportunity to spend more time on other elements of care that matter to patients, such as patient-reported outcomes and the patient experience.

This study has several strengths. Our role as a regional hemodialysis program allowed for the uniform care and close follow-up of 350 to 400 patients on hemodialysis therapy. All patients in our program transitioned from routine blood work at 4-week intervals to 6-week intervals at the same time, and hemodialysis units followed identical policies (eg, rounding schedules, nurse ratios, and allied

Table 2. Number and Costs (in Canadian Dollars) of Laboratory Testing

Laboratory Test	4-Week Blood Work	6-Week Blood Work
Time period assessed	8 blood draws over 252 days (Jul 15, 2013-Mar 23, 2014)	6 blood draws over 252 days (Mar 25, 2014-Dec 1, 2014)
Hemoglobin		
No. of tests	3,799	3,270
Cost	$31,418	$27,043
Ferritin		
No. of tests	2,959	2,384
Cost	$42,846	$34,520
Iron saturation		
No. of tests	2,975	2,383
Cost	$52,300	$41,893
Calcium		
No. of tests	3,262	2,979
Cost	$8,449	$7,716
Phosphate		
No. of tests	3,227	2,788
Cost	$8,358	$7,221

health staffing). Both features minimize the effect of cointerventions (eg, use of intravenous iron and calcitriol). We considered all blood tests completed over each interval, thereby accounting for health care provider preferences to order additional blood work outside of routine periods. Finally, we measured clinical performance for more than 18 months after the change to 6-week blood work intervals to ensure sustainability.

Our study also has limitations. First, the use of aggregate data from our hemodialysis unit meant that we could not adjust for patient case-mix. However, patient characteristics were similar from 2012 to 2015, with slightly older patients during the 6-week period which would strengthen our results.

Second, we measured the achievement of clinical targets rather than absolute laboratory values, so it is possible that less frequent blood work changed absolute values or increased variability. The latter point is noteworthy because increased hemoglobin level variability is associated with death, and it has been suggested that more frequent monitoring may decrease blood work variability.[25] However, targeting a range of values is consistent with current guidelines and clinical practice,[4,5] and the benefits of more frequent blood work on hemoglobin level variability and outcomes remain to be determined.

Third, we did not measure all possible routine laboratory tests (eg, potassium), clinical outcomes, and associated costs. We are reassured that there was no signal of increased mortality associated with less frequent blood work, but additional data for other clinical outcomes are needed to ensure that the reported cost-savings are not offset by an increase in other adverse events such as hospitalizations and blood transfusions.

Fourth, we changed to routine blood work at 6-week intervals based on the lowest acceptable frequency referenced by clinical practice guidelines.[13] It is possible that even less frequent routine blood work (eg, every 8-12 weeks) could yield similar results.

Fifth, we did not measure changes in patient behavior, which could be affected by routine blood work frequency or the awareness of an ongoing study. The latter is less likely given that the study design was both pragmatic and did not require informed consent.

Last, results are from a single Canadian hemodialysis program and may not be generalizable to other geographic or patient populations (eg, home hemodialysis). Programs may need to adapt our results based on their own routine blood work protocols and practice patterns, consistent with the principles of quality improvement.

Our retrospective interrupted time series analysis of a regional hemodialysis program in Ontario, Canada, found that the proportion of patients who achieved recommended hemoglobin and CKD-MBD targets did not change after switching the routine blood work frequency from every 4 weeks to 6 weeks. The effects were sustained for more than 18 months and saved our program $85 per patient-year in laboratory costs. At the national level, cost savings from less frequent blood work could approach millions of dollars annually, but our results would need to be confirmed in different centers and across multiple clinical outcomes and include a more robust economic analysis. In the meantime, hemodialysis programs should reexamine their own blood work practices while more research is conducted to generate high-quality evidence to guide optimal routine blood work frequencies.

Supplementary Material

Figure S1: The proportion of patients using erythropoietin at a given interval.

Figure S2: The proportion of patients with serum calcium in the target range at a given interval.

Figure S3: The proportion of patients with PTH in the target range at a given interval.

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