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Cost-Utility of Real-Time Potassium Monitoring in United States Patients Receiving Hemodialysis

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Introduction: Patients with kidney failure requiring hemodialysis are at high risk for hyperkalemia between treatments, which is associated with increased cardiovascular morbidity and mortality. Early detection of hyperkalemic events may be useful to prevent adverse outcomes and their associated costs. We performed a cost-utility analysis comparing an intervention where a real-time potassium monitoring device is administered in patients on hemodialysis in comparison to usual care.

Methods: We developed a cost-utility model with microsimulation from the perspective of the United States health care payer. Primary outcomes included the monthly cost-effectiveness threshold cost and break-even cost per patient attributable to the intervention and the incremental cost-effectiveness ratio comparing the intervention to usual care. A 25% reduction in hyperkalemic events was applied as a baseline device effectiveness estimate. Concurrent first and second order microsimulations were performed using 10%, 25%, and 50% effectiveness estimates as sensitivity analyses. Results are presented over a 10-year time horizon in 2022 United States dollars and a willingness-to-pay threshold of $100,000 per quality-adjusted life year (QALY) was considered.

Results: Over 10 years, threshold and break-even analysis yielded maximum monthly costs of $201.10 and $144.15 per patient, respectively. The intervention was associated with reduced mean costs ($6381.21) and increased mean QALYs (0.03) per patient; therefore, was considered dominant. In sensitivity analysis, the intervention was dominant in 99% of simulations performed at all effectiveness rates.

Conclusion: Implementing a real-time potassium monitoring device in patients on hemodialysis has the potential for cost savings and improved outcomes from the perspective of the United States health care payer.

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Hyperkalemia is defined as an elevated level of potassium (typically above 5.0–5.5 mEq/l) and is associated with increased cardiovascular morbidity and mortality.[1-3] Considering that the kidneys play an essential role in regulating potassium levels in the body, patients with kidney failure requiring hemodialysis are at high risk for hyperkalemia, given the intermittent nature of hemodialysis which typically takes place 3 times per week.

Estimates place the prevalence of hyperkalemia in the United States general population from 2.6% to 2.7%.[4] Among patients on hemodialysis, the prevalence of hyperkalemia is markedly higher, with estimates ranging from 50.2% to 52.8%.[2,4] Severe hyperkalemic events require immediate medical intervention due to an increased risk of potentially lethal cardiac arrythmias.[5-7] In 2020, there were 807,920 patients in the United States receiving life-sustaining dialysis.[8] The majority of these patients received thrice weekly intermittent hemodialysis, a procedure which carried a 190.1 per 1000 person-years adjusted all-cause mortality rate, of which 42.8% are attributed to arrhythmia or cardiac arrest.[8] Resource expenditure related to these events are significant, with inpatient visits being the primary cost driver (average $24,178 in 2015 United States dollars/stay).[9] Furthermore, history of hyperkalemia has been identified as a significant contributor to per-patient annual costs in United States

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Commercial and Medicare patients with kidney failure requiring dialysis, with the increase being as high as 57% compared to those without a history of hyperkalemia.[4,10] Interventions aimed at early detection and targeted interventions to avoid hyperkalemic events, severe outcomes, and their associated costs could help avoid adverse outcomes and emergency resource utilization.

Similar to a continuous glucose monitoring (CGM) device, wearable real-time potassium monitoring devices are currently being developed to allow both patients and care providers to actively monitor potassium levels.[11] In patients with diabetes, CGM has been shown to improve diabetes-related quality of life, enable patients to preemptively avoid dysglycemia, and to be cost-effective in comparison to intermittent monitoring.[12-17] Currently, in most in-center hemodialysis programs, predialysis potassium is measured at varying intervals.[18] Furthermore, patients are unable to self-monitor their potassium levels in the home setting and the range of potentially dangerous potassium levels in a patient on intermittent hemodialysis remains poorly characterized. As a result, avoiding major complications such as fatal arrhythmias leading to cardiac arrest can be difficult because symptoms may not present until potassium levels are well past the normal range.[19-21] A continuous potassium monitoring device may improve patient safety in this patient population suffering from a disproportionate rate of cardiovascular and all-cause mortality, contributing to reduced death due to lethal arrythmia and hospitalizations for acute hemodialysis sessions due to high serum potassium concentration.[1]

To inform the development and adoption of real-time self-monitoring of serum potassium levels, the goal of this study was to better understand how assumptions related to the costs and effectiveness of a proposed wearable device may affect estimates of cost-effectiveness of this strategy. As such, the objective of the study was to conduct a cost-utility analysis comparing a scenario with real-time potassium monitoring to usual care in patients on hemodialysis.

METHODS

We constructed a cost-utility model from the perspective of the United States health care system. A decision analytic Markov model using microsimulation was created with Treeage Pro 2022 (Williamstown, MA), simulating 10,000 three times per week facility-based hemodialysis patients in the United States. The analytic framework followed the guidelines from the Institute for Clinical and Economic Review value assessment framework.[22] Incremental costs and utilities were compared between the intervention and usual care scenarios. The intervention consisted of implementing a daily continuous real-time potassium monitoring device in patients on hemodialysis. Patients experiencing elevated potassium levels may alter their diet and lifestyle to avoid serious events, dose reduce or permanently discontinue medications that may contribute to hyperkalemia such as renin-angiotensin-aldosterone system inhibitors or mineralocorticoid receptor agonists; or may also benefit from treatments such as additional dialysis, dietary counselling, and/or medications such as diuretics (if they have residual kidney function) or potassium binders. The related costs of these treatments are considered in whole as part of the intervention and may vary from patient to patient depending upon their individualized needs.

Main outcomes were mean costs (presented in 2022 United States dollars) and utility (QALYs) per patient, and the monthly threshold cost defined as the maximum monthly cost attributable to the intervention where the health-payor would incur no additional expenses. Secondary outcomes included the number of hospitalizations and deaths post hyperkalemic event in each scenario. We presented relevant outcomes over a range of plausible intervention effectiveness rates (10%, 25%, and 50% reduction in hyperkalemic events). Unless otherwise specified, analyses assumed a 25% effectiveness rate.

This model used monthly cycles over a 10-year time horizon. Although the intervention may be implemented in shorter time frames, 10 years was chosen due to the chronic nature of the condition, which requires ongoing management. All future costs and utilities were discounted at 5% to conform with published guidelines.[23] Historical costs were inflated to 2022 United States dollars using the United States consumer price index (Supplementary Table S1).[24] Because patients may transition between states at different times within a cycle, this model used a half-cycle correction to account for state membership overestimation. An overview of the model can be found in Figure 1.

Primary cost assumptions in our model included the cost of maintenance hemodialysis, oral potassium binders (Patiromer was chosen due to public availability of costing estimates), and all-cause hospitalizations, defined as an emergency department visit with admission to the same hospital. The cost of maintenance dialysis was sourced from the United States Renal Data System[26] and the cost of an emergency department visit, including hospital admission was sourced from the Health Care Cost and Utilization Project for hyperpotassemia (ICD-9-CM diagnoses code 276.7).[25] We chose this source because it is from a nationally representative data source and is in line with other

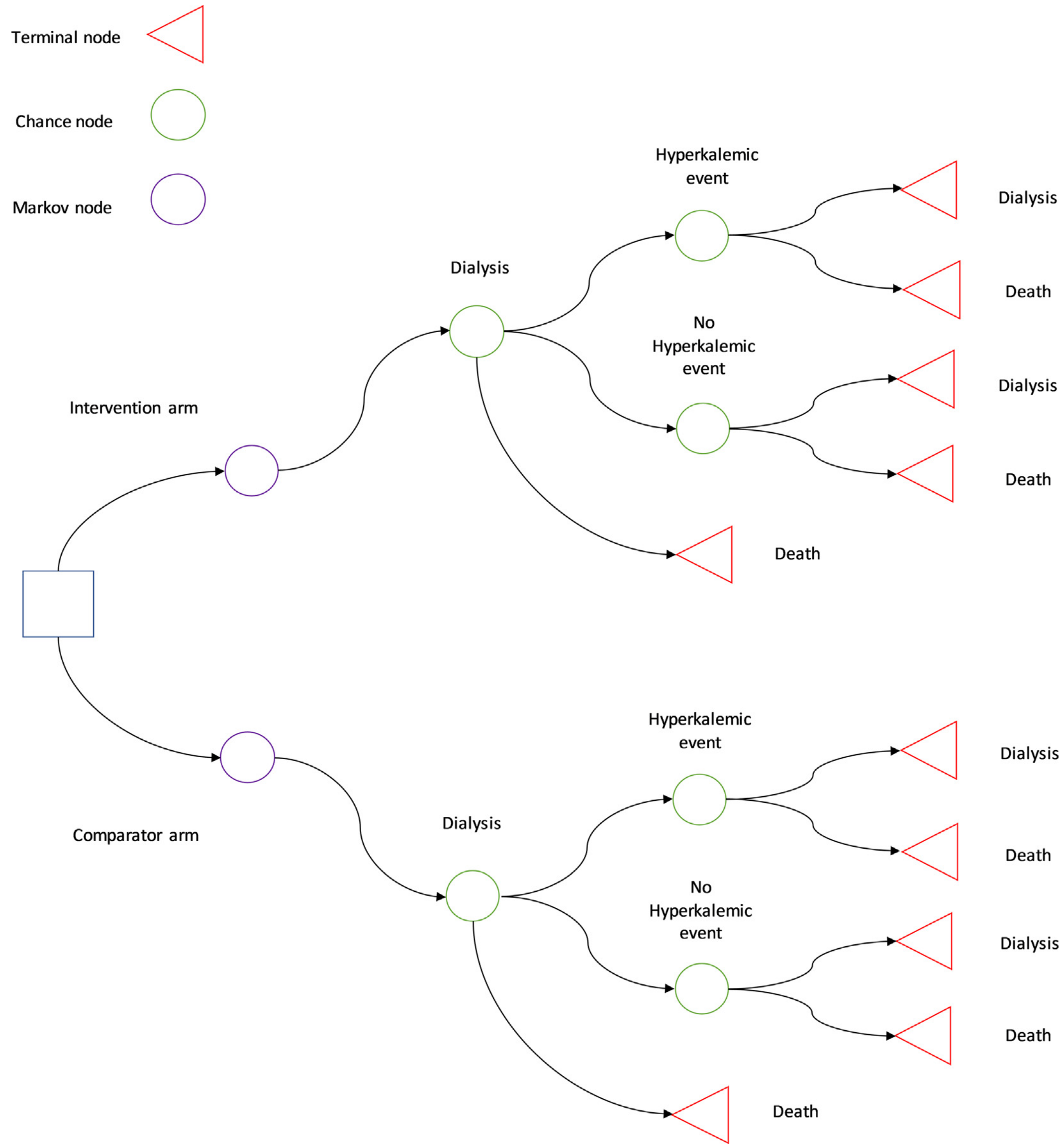

Figure 1. Model overview. Decision tree depicting patient transitions between health states in the intervention and usual care scenarios. All transition and event probabilities used in the model are found in Table 1 and Supplementary Materials S2 to S5.

published inpatient cost estimates.[35] The cost of an 8.4 g dose of oral Patiromer was sourced from the literature.[27,28] We assumed all patients experiencing potassium levels >6 mEq/l consumed 1 dose of Patiromer. No additional reduction in all-cause hospitalization associated with potassium binders was considered because this was encompassed in the data used to derive the applied hazard-ratio.[29] Potential intervention costs were evaluated in threshold analyses to determine points at which the intervention would (i) be cost-effective at a threshold of $100,000/QALY or (ii) be break-even.

All-cause hospitalization and mortality rates for hemodialysis patients were sourced from the United States Renal Data System[26,30] (Supplementary Tables S2 and S3). All-cause hospitalization and mortality rates post hyperkalemic event were derived by applying outcome-specific hazard ratios to regular rates in the United States hemodialysis population (Supplementary Tables S4 and S5).[26,29,30] Sourced hazard ratios (originally grouped by serum potassium level 5.1–5.5, 5.6–6.0, and >6 mEq/l) were meta-analyzed using Review Manager (RevMan) version 5.3 to determine 1 weighted value for the population (Supplementary Table S6). All rates were converted to monthly probabilities. The monthly prevalence of hyperkalemic events (defined as serum potassium >5.5 mEq/l) used was specific to the United States and was assumed to be identical each month.[31] Dialysis utility estimates were sourced from a published systematic review and meta-analysis.[32] Quality-of-life decrements (or disutility's) associated with hospitalization posthyperkalemic event were employed in this model and sourced from the literature.[33,34] Model inputs are presented in Table 1.

Table 1. Model inputs

Variable	Baseline point estimate	Distribution	Source
Costs			
Acute hyperkalemic event (ED + hospitalization) (2022 USD)	$36,679.79	Lognormal (Mean: 36,679.79, Median: 22,255.48)	25
Dialysis (annual) (2022 USD)	$108,597.79	Gamma (Alpha:16, Lambda: 0.000147)	26
Oral Patiromer (2022 USD)	$29.84		27,28
All-cause death			
Hazard ratio applied to regular ESRD all-cause mortality rate	1.2		29
Probability of all-cause mortality, hemodialysis patients	Item S4	Poisson	30
Probability of all-cause mortality, hemodialysis patients post hyperkalemic event	Item S5	Poisson	29,30
All-cause hospitalization			
Hazard ratio applied to regular ESRD all-cause hospitalization rate	1.17		29
Probability of all-cause hospitalization, hemodialysis patients	Item S2	Poisson	30
Probability of all-cause hospitalization, hemodialysis patients post hyperkalemic event	Item S3	Poisson	29,30
Other			
Probability of a hyperkalemic event, ≥5.5 mEq/l (monthly)	0.145		31
Dialysis utility	0.71	Normal (Mean: 0.71, SD: 0.04)	32
Disutility (hospitalization)	−0.024		33,34
CPI	Item S1		24
Baseline effectiveness rate (reduction in hyperkalemic events)	0.75		
Discount rate, costs	0.5	Uniform	23
Discount rate, utilities	0.5	Uniform	23

CPI, consumer price index; ED, emergency department; ESRD, end-stage renal disease; USD, United States dollar.

Ten thousand first order Monte Carlo simulations were assessed to determine event counts, including instances of hyperkalemic episodes requiring acute dialysis or hospitalization and death. Furthermore, 1000 first order Monte Carlo simulations were employed over 50 second order Monte Carlo simulations to assess variability in parameter estimates across plausible distributions taken from the literature and other publicly available sources (probabilistic sensitivity analysis). We employed threshold analysis to estimate the monthly cost attributable to the intervention to remain cost-effective. Furthermore, we performed break-even analyses to present the maximum monthly intervention cost where a health system would incur no additional expenses in comparison to the current standard of care. Univariate sensitivity analysis was undertaken on all cost inputs to determine influential costing parameters and presented as a tornado diagram. Scenario analysis was performed by increasing the baseline all-cause hospitalization rates post hyperkalemic event by 10% and 25% to evaluate the intervention in higher risk populations. Two-way sensitivity analysis was performed by altering the device effectiveness rate between 0% and 50% and the monthly intervention cost per patient between $0 and $1500. A willingness-to-pay threshold of $100,000 per QALY was considered. Study approval from a research ethics board was not sought because only aggregate or previously published data were used. Furthermore, to enhance interpretability we have included definitions of key terms in Supplementary Table S7.

Table 2. Ten-year mean cost per patient

	Reduction in hyperkalemic events		
Scenario	10%	25%	50%
Usual care, mean (SD)	$441,191.88 ($365,230.18)	$441,191.88 ($365,230.18)	$441,191.88 ($365,230.18)
Intervention, mean (SD)	$438,442.80 ($360,098.31)	$434,810.67 ($352,987.54)	$427,690.91 ($343,832.90)

Table 3. Ten-year mean quality-adjusted life years per patient

	Reduction in hyperkalemic events		
Scenario	10%	25%	50%
Usual care, mean (SD)	2.61 (2.07)	2.61 (2.07)	2.61 (2.07)
Intervention, mean (SD)	2.62 (2.07)	2.64 (2.08)	2.66 (2.09)

RESULTS

Costs

Total mean costs per patient is presented in Table 2. Over 10 years, the mean cost per patient in the usual care scenario was $441,191.88 (SD: $365,230.18). Assuming a 10%, 25%, and 50% reduction in hyperkalemic events, the 10-year mean costs per patient in the intervention scenario were $438,442.80 (SD: $360,098.31), $434,810.67 (SD: $352,987.54), and $427,690.91 (SD: $343,832.90), respectively, representing mean differences of $2,749.08, $6,381.21, and $13,500.97 per patient compared to the usual care scenario.

Quality of Life

The 10-year mean QALYs in the usual care scenario were 2.61 (SD: 2.07). In comparison, mean QALYs per patient in the intervention scenario were 2.62

Table 4. Monthly threshold cost per patient by effectiveness rate

Reduction in hyperkalemic events (%)	Monthly intervention cost ($)
10	82.68
25	201.10
50	413.06

Table 5. Event counts over 10-years, hyperkalemic events, all-cause hospitalization and all-cause death post hyperkalemic event

	Reduction in hyperkalemic events (%)	Usual care	Intervention	Difference	Total reduction in costs ($)
All-cause hospitalization post hyperkalemic event	10	27,339	24,669	−2670	−38,477,099.71
	25	27,339	20,723	−6616	−97,678,280.77
	50	27,339	13,948	−13,391	−197,300,590.41
	Reduction in hyperkalemic events (%)	**Usual care**	**Intervention**	**Difference**	**Total unadjusted yrs of life gained**
All-cause death post hyperkalemic event	10	3911	3532	−379	3.3
	25	3911	2955	−956	9.8
	50	3911	2012	−1899	16.80

(SD: 2.07), 2.64 (SD: 2.08) and 2.66 (SD: 2.09) when assuming a 10%, 25%, and 50% reduction in hyperkalemic events. These represented differences of 0.01, 0.03, and 0.05 mean QALYs per patient at 10%, 25%, and 50% device effectiveness rates respectively (Table 3).

Threshold and Break-Even Analysis

In threshold analysis, it was found that a monthly intervention cost of $201.10 per patient over 10 years was the maximum amount where the intervention remained cost-effective, assuming a 25% effectiveness rate. When considering 10% and 50%, the monthly threshold costs per patient were $82.68 and $413.06, respectively. Break-even analysis (i.e., willingness-to-pay threshold of $0/QALY) yielded a monthly intervention cost of $144.15 per patient over 10 years. Threshold analysis results by effectiveness rate can be found in Table 4.

Events

Total counts of all-cause hospitalizations and deaths post hyperkalemic event in 10,000 incident hemodialysis patients by device effectiveness rate and scenario are presented in Table 5. At a 25% device effectiveness rate, all-cause hospitalization and deaths post-hyperkalemic event were reduced by 6616 and 956 respectively over 10 years, translating to an overall reduction in costs of $97,678,280.77, and 9.8 additional unadjusted years of life gained.

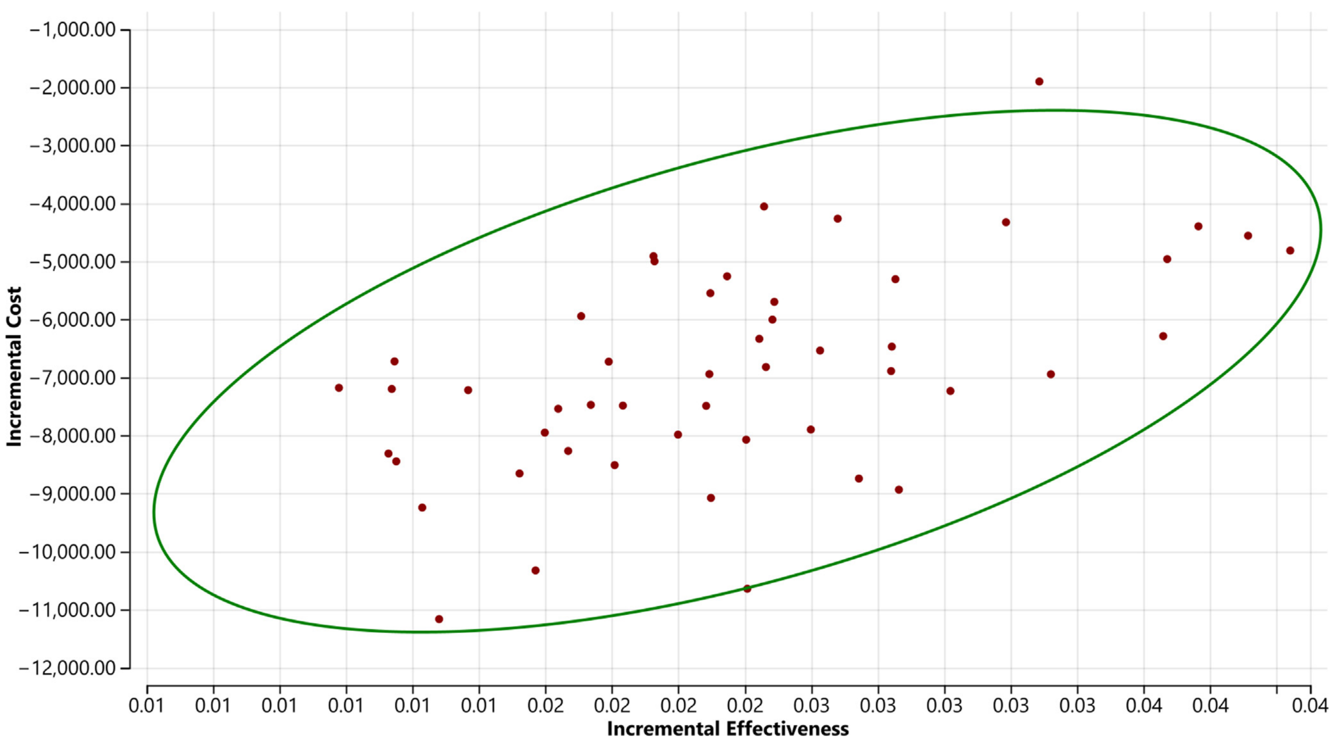

Figure 2. Incremental cost-effectiveness, intervention scenario versus usual care scenario (25% reduction in hyperkalemic events). Incremental cost-effectiveness in the base case scenario comparing the intervention to usual care. The y-axis represents the difference in the mean cost associated with the intervention, and the-x axis represents the difference in mean quality-adjusted life years associated with the intervention, translating to an incremental cost-effectiveness ratio. Each point represents the results of a simulation, and the circle is the associated 95% confidence interval around the mean incremental cost-effectiveness ratio estimate of all the simulations.

Table 6. Deterministic and probabilistic sensitivity analysis-costs and quality-adjusted life years

Scenario	Reduction in hyperkalemic events (%)	Cost ($)	QALYs
Usual care	10	454,047.25 (99,699.82)	2.63 (0.17)
	25	454,047.25 (99,699.82)	2.63 (0.17)
	50	454,047.25 (99,699.82)	2.63 (0.17)
Intervention	10	451,406.12 (99,884.21)	2.64 (0.17)
	25	447,150.73 (100,074.47)	2.65 (0.17)
	50	439,735.82 (100,434.42)	2.68 (0.17)

Outcomes are presented as Mean (SD).
QALY, quality-adjusted life year.

Sensitivity and Scenario Analyses

Concurrent deterministic and probabilistic sensitivity analysis yielded mean 10-year cost and QALYs per patient of $454,047.25 (SD: $99,699.82) and 2.63 (SD: 0.17) in the usual care scenario. Comparatively, mean costs and QALYs assuming a 25% device effectiveness rate were $447,150.73 (SD: $100,074.47) and 2.65 (SD: 0.17), respectively. The intervention remained dominant (lower cost, higher effectiveness) in 99.3% of all simulations (100% of simulations at 25% and 50% device effectiveness rates, and 98% of simulations at 10% effectiveness). Graphical representation of the Institute for Clinical and Economic Review distributions assuming a 25% effectiveness rate is presented in Figure 2. Complete results by device effectiveness are presented in Table 6.

Univariate sensitivity analysis identified dialysis as the most influential cost parameter in the model. When the cost of dialysis was altered by ± 25%, the 10-year mean cost per patient changed by approximately 22.8% and 23.3% in the usual care and intervention scenarios respectively. The intervention remained less costly per patient when either cost parameter was varied by ± 25%. Full results are presented in Table 7, Figure 3, and Figure 4. Two-way sensitivity analysis results are presented graphically in Figure 5. Results indicate adequate robustness, because they agree with main threshold analysis results in both direction and magnitude. As per Table 8, the intervention scenario remained dominant when all-cause hospitalization rates after hyperkalemic event were increased by both 10% and 25%.

DISCUSSION

Our microsimulation model provides a comprehensive cost-utility analysis associated with implementing a real-time potassium monitoring device in United States patients on hemodialysis. The intervention was determined to be dominant in all base-case and sensitivity analyses, contributing to increased certainty in the conclusions drawn. The monthly break-even cost point for the intervention to remain cost-effective was found to be $201.10 per patient over 10 years assuming a conservative 25% device effectiveness rate in reducing hyperkalemic events. When ignoring effectiveness (i.e., willingness-to-pay threshold = $0/QALY), the break-even monthly cost was $144.15 per patient. Given that no continuous potassium monitoring device has been implemented as a health intervention to our knowledge, effectiveness rate estimates related to a reduction in hyperkalemic events were unknown. We provided results over a range of estimates and our model concluded the intervention to be dominant at an effectiveness rate of 10% and above in all main and scenario analyses. Device, consumables, and interventions costs would have to be less than the monthly threshold cost to be considered cost-effective. Manufacturers of these technologies must take note of this willingness-to-pay threshold in their respective business model.

Hyperkalemia has been shown to negatively affect health-related quality of life in the chronic kidney disease (CKD) population.[36] One study found that patients with hyperkalemia in the United States had significant lower quality-of-life scores in 4 of the 5

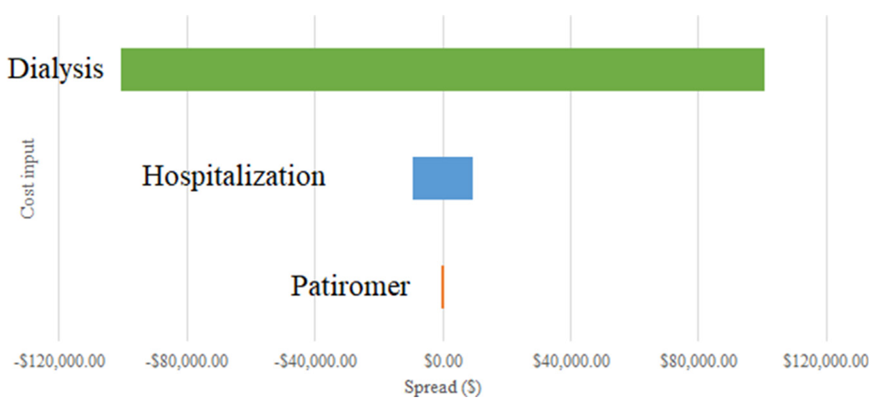

Figure 3. Tornado diagram, univariate sensitivity analysis-usual care. The difference in mean costs per patient when varying cost inputs (dialysis, hospitalization, and Patiromer) by ±25% in the usual-care scenario. Each bar represents by how much the mean cost per patient would change if that cost input were to increase or decrease by 25%, all else equal. Refer to Table 7 for a more detailed numerical output.

Table 7. Univariate sensitivity analysis

Scenario	Cost input	Mean	−25%	+25%	Spread
Usual care	Dialysis	441,191.88	340,446.63	541,937.13	201,490.50
	Hospitalization	441,191.88	431,654.68	450,729.08	19,074.40
	Patiromer	441,191.88	441,176.36	441,207.40	31.04
Intervention	Dialysis	434,810.67	333,312.10	536,309.23	202,997.14
	Hospitalization	434,810.67	427,618.27	442,003.06	14,384.79
	Patiromer	434,810.67	434,798.96	434,822.37	23.41

All values are given in USD ($).

domains of the Kidney Disease Quality of Life 36-item short form survey: burden of kidney disease in comparison to normokalemic patients.[36] Symptoms related to hyperkalemia include vomiting, weakness, diarrhea, fatigue, with the potential for neuromuscular and cardiac complications as well as increased risk of death in more severe cases.[2,37-39] Interventions aimed at reducing hyperkalemic events may produce positive externalities in the form of improved symptoms. Further research is required to understand the potential impact on patient health-related quality of life.

Hyperkalemia has been defined as a common CKD-specific ambulatory care sensitive condition, which refers to a condition where subsequent hospitalizations may not be required if properly managed in an outpatient setting.[40,41] Research has shown that an estimated 10% to 20% of patients with CKD will require hospitalization due to a CKD-specific ambulatory care sensitive condition at some point.[40-42] Similar to CGM, a continuous potassium monitoring device may improve outpatient management, thus reducing unneeded hospitalizations related to hyperkalemia. Furthermore, 1 study estimated that 14% of patients with CKD previously hospitalized for an ambulatory care sensitive condition accounted for 45.5% of the total CKD-specific ambulatory care sensitive condition hospitalizations.[42]

The relative difference in costs and QALYs between scenarios became more pronounced when all-cause hospitalization rates posthyperkalemic event was increased from 10% to 20%, suggesting an increased comparative attractiveness in higher risk populations. Health systems may choose to target patients at higher risk of experiencing hyperkalemia and/or severe outcomes post event to maximize benefit. This may include patients on medications known to promote hyperkalemia in patients with reduced estimated glomerular filtration rate such as renin-angiotensin-aldosterone system inhibitors and mineralocorticoid receptor agonists, individuals who schedule missing hemodialysis treatments for a variety of reasons, those without residual kidney function, or simply those with a history of severe hyperkalemic episodes.[29,43-45] It is important to note that for those who are nonadherent to dialysis, potassium restriction in their diet or taking potassium binding resins may not be as adherent to continuous self-monitoring; therefore, the results may not be as generalizable to this patient population. Nonetheless, our analysis indicates reduced mean costs and higher QALYs per patient when considering all patients on thrice weekly facility-based hemodialysis.

The majority (≥90%) of clinicians surveyed across Europe and North America agree that people at risk of hyperkalemia should be monitored closely with a strategy in place to manage potassium levels effectively.[46] Considering that CGM programs have been successfully implemented in health systems worldwide, patients, health care providers, and health care programs may be more willing to support or adopt the proposed intervention due to the prevailing evidence with respect to the efficacy, patient experiences, and cost-effectiveness of CGM programs.[17] Furthermore, this provides indirect evidence for the feasibility of implementing continuous potassium monitoring programs, given the similar presentation of an often asymptomatic potentially lethal biomarker that requires a relatively simple patient intervention to

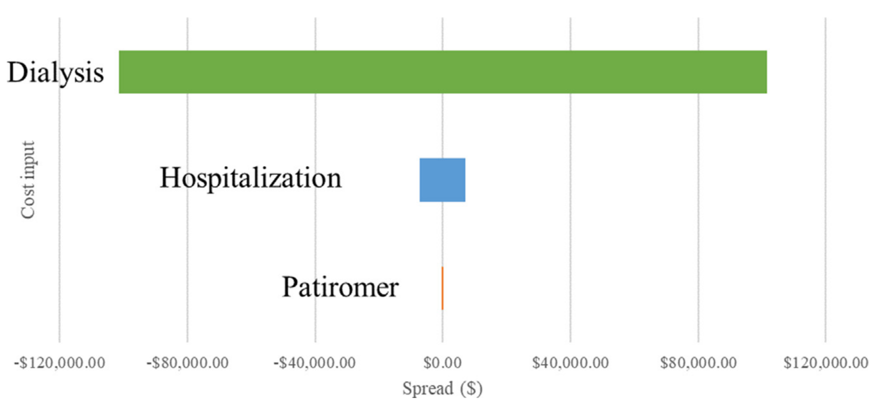

Figure 4. Tornado diagram, univariate sensitivity analysis-intervention. The difference in mean costs per patient when varying cost inputs (dialysis and hospitalization) by ±25% in the intervention scenario. Each bar represents by how much the mean cost per patient would change if that cost input were to increase or decrease by 25%, all else equal. Refer to Table 7 for a more detailed numerical output.

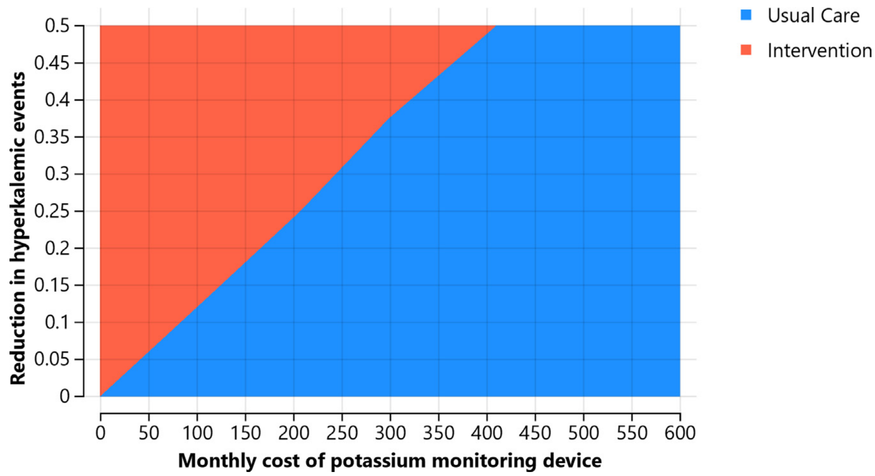

Figure 5. Two-way sensitivity analysis-device cost and intervention effectiveness rate. Cost-effectiveness threshold as both device effectiveness and the monthly intervention cost increase simultaneously at a willingness-to-pay threshold of $100,000 per quality-adjusted life-year. The line where the usual-care and intervention scenario meet represents the break-even cost at each level of device effectiveness between 0% and 50% when a health payer is willing to spend $100,000 to gain 1 additional quality-adjusted life-year.

prevent an adverse event or death. Details of already existent CGM programs can be drawn upon to provide a framework for the intervention, allowing for patient-population specific modifications.

The main strength of our model is that all main, sensitivity and scenario analyses are congruent, contributing to the robustness of the model and certainty in conclusions drawn. Our model also has several limitations. First, data were unavailable to determine indirect costs, such as those related to caregiver burden, patient travel, emergency transport services, and opportunity costs of missed employment. Second, hospital readmission probabilities were independent of previous admissions. This may not be representative of actual patient transitions because past hyperkalemia-related hospitalizations have been shown to significantly increase readmission rates.[45] Furthermore, this analysis does not account for program size. It may be burdensome to integrate systems in certain small areas, thus a personalized budget analysis may be warranted in such scenarios. Finally, the proposed intervention relies on patients taking active measures related to their diet and lifestyle to maintain adequate potassium levels as well as reacting with evidence-informed treatments such as potassium binders to avoid serious, potentially lethal outcomes, which may not be extrapolatable to patients with nonadherence.[47] We presented outcomes assuming varying levels of effectiveness rates, which may account for a portion of the reduced adherence; further research is warranted.

Table 8. Scenario analysis - 10-year mean cost and quality-adjusted life years per patient

Percent increase in all-cause hospitalization	Scenario	Cost ($)	QALYs
10	Usual Care	445,006.76 (371,651.85)	2.61 (2.06)
	Intervention	437,687.62 (357,493.61)	2.63 (2.08)
25	Usual Care	450,729.08 (381,776.50)	2.60 (2.06)
	Intervention	442,003.06 (364,604.92)	2.63 (2.07)

QALY, quality-adjusted life year.

In conclusion, we have developed a first-of-its-kind cost utility model that estimates the costs, as well as utilities and threshold cost associated with the implementation of a continuous potassium monitoring device compared to the current standard-of-care demonstrating that a real time potassium monitoring device offers excellent value for money in the high-risk use case of patients on thrice weekly hemodialysis for whom adverse cardiovascular and all-cause mortality outcomes remain unacceptably poor. Further study is needed to demonstrate real-world effectiveness of this device and use in other contexts such as late-stage CKD and heart failure.

DISCLOSURE

RJB reports personal fees from Klinrisk Inc. and Navdeep Medical Corporation outside of the reported work. TWF reports personal fees from Strategic Health Resources, Quanta Dialysis Technologies Ltd., Baxter Canada, ClinPredict Ltd., and Klinrisk Inc. outside of the reported work. PK is an advisor to Proton Intelligence Inc and reports stock ownership in Proton Intelligence Inc. He is Chief Medical Officer of Quanta Dialysis Technologies. NT reports grants, personal fees, and other from Tricida Inc; grants and personal fees from AstraZeneca Inc; grants from the Canadian Institutes for Health Research; grants from the Kidney Foundation of Canada; personal fees from Otsuka Inc; grants and personal fees from Janssen; grants and personal fees from Boehringer Ingelheim/Eli Lilly; personal fees from Renibus; grants and personal fees from Bayer; other from PulseData, personal fees from Roche; personal fees and other from ClinPredict Ltd.; and personal fees and other from Klinrisk Inc. outside of the reported work. DC reports grants from the Canadian Institutes of Health Canada, Research Manitoba/Boehringer Ingelheim, the Center for Medicinal Cannabis Research; and is funded by a KRESCENT New Investigator Award outside of the reported work. CR declared no competing interests.

ACKNOWLEDGMENTS

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DATA AVAILABILITY STATEMENT

All data supporting the findings of this study are openly available from publicly accessible sources.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Table S1. United States consumer price index (base year adjusted to 2012).

Table S2. All-cause hospitalization rates and probabilities, hemodialysis patients.

Table S3. All-cause mortality rates and probabilities, hemodialysis patients (transplant censored).

Table S4. All-cause hospitalization rates and probabilities, hemodialysis patients post hyperkalemic event.

Table S5. All-cause mortality rates and probabilities, hemodialysis patients (transplant censored) post hyperkalemic event.

Table S6. Hazard ratios for all-cause hospitalization and all-cause mortality

Table S7. Key term definitions

CHEERS 2022 Checklist.

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