At-Home Versus In-Clinic INR Monitoring: A Cost–Utility Analysis from The Home INR Study (THINRS)

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BACKGROUND: Effective management of patients using warfarin is resource-intensive, requiring frequent in-clinic testing of the international normalized ratio (INR). Patient self-testing (PST) using portable at-home INR monitoring devices has emerged as a convenient alternative. As revealed by The Home INR Study (THINRS), event rates for PST were not significantly different from those for in-clinic high-quality anticoagulation management (HQACM), and a cumulative gain in quality of life was observed for patients undergoing PST.

OBJECTIVE: To perform a cost–utility analysis of weekly PST versus monthly HQACM and to examine the sensitivity of these results to testing frequency.

PATIENTS/INTERVENTIONS: In this study, 2922 patients taking warfarin for atrial fibrillation or mechanical heart valve, and who demonstrated PST competence, were randomized to either weekly PST (n= 1465) or monthly in-clinic testing (n= 1457). In a sub-study, 234 additional patients were randomized to PST once every 4 weeks (n= 116) or PST twice weekly (n= 118). The endpoints were quality of life (measured by the Health Utilities Index), health care utilization, and costs over 2 years of follow-up.

RESULTS: PST and HQACM participants were similar with regard to gender, age, and $CHADS_2$ score. The total cost per patient over 2 years of follow-up was $32,484 for HQACM and $33,460 for weekly PST, representing a difference of $976. The incremental cost per quality-adjusted life year gained with PST once weekly was $5566 (95 % CI, −$11,490 to $25,142). The incremental cost-effectiveness ratio (ICER) was sensitive to testing frequency: weekly PST dominated PST twice weekly and once every 4 weeks. Compared to HQACM, weekly PST was associated with statistically significant and clinically meaningful improvements in quality of life. The ICER for weekly PST versus HQACM was well within accepted standards for cost-effectiveness, and was preferred over more or less frequent PST. These results were robust to sensitivity analyses of key assumptions.

CONCLUSION: Weekly PST is a cost-effective alternative to monthly HQACM and a preferred testing frequency compared to twice weekly or monthly PST.

KEY WORDS: anticoagulants; atrial fibrillation; heart valve; cost effectiveness; randomized trials.
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INTRODUCTION

Although anticoagulation with warfarin is effective in reducing the risk of thromboembolism in patients with atrial fibrillation or a mechanical heart valve,[1] management requires frequent monitoring of the international normalized ratio (INR) to ensure that an adequate yet safe dose is taken. Failure to maintain the INR in therapeutic range is associated with increased risk of hemorrhage or thromboembolism, depending on the direction of deviation. Although alternatives such as dabigatran offer similar efficacy and do not require frequent blood tests for the INR, warfarin remains the standard pharmacotherapy for patients with atrial fibrillation and a moderate to high risk of thrombosis.[2].

Given the necessity of frequent monitoring and dosing adjustments, the quality of anticoagulation management with warfarin has been shown to vary widely in clinical practice.[3] High-quality anticoagulation management (HQACM; management by a dedicated anticoagulation clinic)[4] is associated with greater time spent in therapeutic range and lower event rates compared to standard clinical practice.[5] However, conventional laboratory testing of INR, as performed in both HQACM and standard clinical practice, can be inconvenient for patients who must travel to a centralized location.[6,7] In some cases, this may limit the frequency of INR testing as well as access to anticoagulation treatment.

Systematic reviews have supported frequent home monitoring via patient self-testing (PST) of INR as a safe and effective alternative to standard in-clinic testing.[6,8–10] In 2012, the American College of Chest Physicians revised its clinical practice guidelines to incorporate the use of portable at-home INR testing devices.[11] The Home INR Study (THINRS), the largest randomized controlled trial of PST ($n=2922$) to date, found negligible differences in clinical outcomes between weekly PST and once-monthly in-clinic testing via HQACM.[7] In order to examine the effects of testing frequency, THINRS included a sub-study in which 234 additional patients were randomized to PST twice weekly ($n=118$) or once every 4 weeks ($n=116$).

The paper that reported the primary results of THINRS did not include a formal economic analysis; only the differences in mean costs and outcomes between all patients who underwent PST (regardless of frequency) and the HQACM group were reported.[7] These comparisons revealed a statistically significant improvement in quality-adjusted life years (QALYs), as measured by the Health Utilities Index Mark 3 (HUI),[12] for the PST group. Costs were somewhat higher in the PST group than in the HQACM group, but this difference was not statistically significant.

The main objective of this study was to conduct a cost utility analysis of weekly PST versus HQACM from the perspective of a health care system. Given that the THINRS test-frequency sub-study found that more frequent test frequency was associated with greater time spent in target INR range,[13] a secondary objective was to examine the cost–utility of different PST testing frequencies.

METHODS

Summary of THINRS Design

THINRS was a two-part prospective, randomized, open-label trial, which has been described previously.[7,14] Briefly, patients were eligible if they had atrial fibrillation, a mechanical heart valve, or both, and required chronic warfarin therapy for an indeterminate period. In part one, patients were trained to use a portable at-home INR monitoring device, and were evaluated 2 to 4 weeks later for PST competency.[14] Patients who demonstrated PST competency were eligible for part two of the study, which randomized patients to PST or HQACM. Patients gave separate written informed consent for the two parts of the study, and the research protocol was approved by the appropriate institutional review boards.

THINRS data were collected at 28 Veterans Affairs (VA) Medical Centers with anticoagulation clinics that met HQACM care guidelines, as defined by the Managing Anticoagulation Services Trial (MAST).[4] This required a centralized, specialized trained anticoagulation service staffed by nurses and/or pharmacists under the supervision of physicians who provide patient education, monitoring, coordination, and routine dosing decisions. All patients were followed for a minimum of 2 years (excluding dropouts and deaths), and could be followed until the end of the trial. After randomization, all patients had scheduled follow-up study visits every 3 months to collect interval information, including quality of life and use of non-VA health care.

Study Sample

The sample used for this analysis is different from that previously reported.[7] Figure 1 outlines the differences. Five HQACM and three weekly PST patients were excluded due to incomplete HUI data. The 118 patients randomized to undergo PST twice weekly and 116 patients randomized to undergo PST once every 4 weeks were excluded from the main analysis and were considered separately. The final sample for the main comparison included 1452 HQACM and 1228 weekly PST patients.

Data

Costs and utilization of VA care were obtained from centralized VA files; the costs were the actual VA production costs. The remaining costs were micro-costed from study data. Patient-completed study forms were used to capture data on non-VA health care utilization and patient travel costs. Mean VA costs for similar types of care were used to assign costs to all non-VA utilization. The IRS-allowed expense rate for travel for medical care was used to assign costs to patient travel. The staff time for training patients on performing PST, verifying PST competence, and monitoring PST were captured from

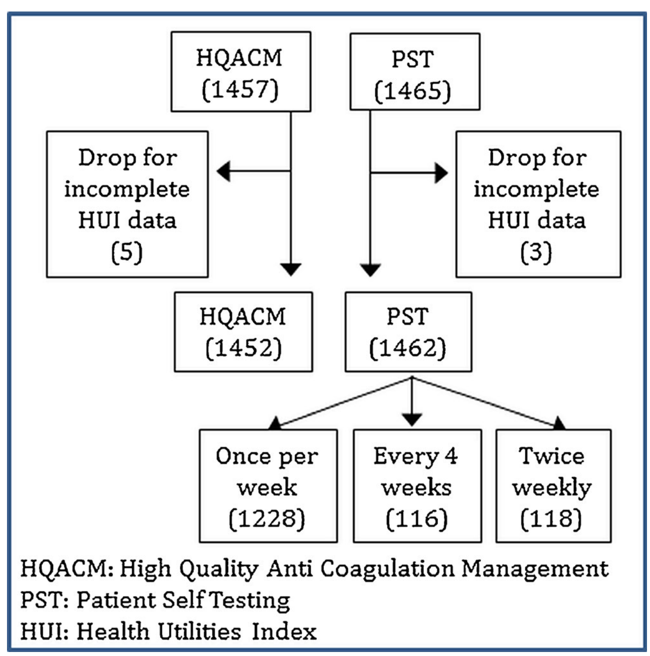

Figure 1 Participants, randomization, and numbers dropped for incomplete HUI data

study forms. Average VA labor costs for each type of labor were used to calculate the training and monitoring costs. The training costs were inflated to adjust for the fact that only 80 % of the patients in part one of the trial demonstrated competency.[15] The VA purchase price was used for the cost of the portable at-home INR monitor ($900) and for the test strips ($3.00 per strip). The overall Consumer Price Index was used to adjust all costs except the meters and test strips to April 2013 dollars.[16] Monitor and test strip prices were not adjusted for inflation, given observed price reductions over time, likely associated with the increased demand due to Medicare approval of the use of this technology. A recent check of a major online commercial retailer found monitors available for as low as $475.[17]

Quality of life was measured by the HUI, which was measured at baseline and at quarterly patient study visits.[12] The Duke Anticoagulation Satisfaction Scale (DASS) was also measured to assess patient satisfaction with their anticoagulation management, as this could be an important driver of potential utility differences.[18].

Cost–Utility Analysis

The gains in QALYs over the2-year period were calculated by summing the HUI using the method described by Fairclough, with deaths assigned an HUI of zero for the remainder of the period.[19] All costs and utilities were discounted at 3 %. The cost–utility analysis was conducted following the methods recommended by the US Public Health Service Task Force.[20,21] The analyses were conducted from the perspective of the health care system. Only direct costs were included in order to avoid double counting for indirect costs that are theoretically captured in the utility.

A conservative approach was adopted in assessing the cost-effectiveness of PST: all up-front costs of initiating PST were attributed to the first 2 years after randomization, and only the QALY differences for the first 2 years of follow-up for which data were available for all patients were included. This approach explicitly ignores any gains in QALYs that accrue after 2 years of follow-up and forces the full costs of the monitor and patient training to be amortized over 2 years. The time horizon was not extended beyond 2 years because complete follow-up data was available for only 2 years.

The statistical analyses (chi-square and Fisher tests for categorical variables and *t* test and Wilcoxon for continuous variables) were performed using SAS version 9.1.3 (SAS Institute Inc., Cary, NC). Because costs and all of the subcomponents of costs had skewed, ln(costs) were used for the *t* tests for cots. The incremental cost-effectiveness ratio (ICER) was defined as the difference in costs between PST and HQACM, divided by the difference in 2-year QALY between PST and HQACM. The bootstrapped cost-effectiveness regions using 1000 samples with replacement were calculated using Stata version 11 (StataCorp LP, College Station, TX) and the user-written program by Glick.[22,23].

Sensitivity analyses were conducted to test the effects of results to changes in cost differences, the HUI gains, the length of time that the meter costs were amortized, and changes in the cost of the meter and test supplies. While patient travel costs were not included in the direct costs for the main analyses, because such costs are typically considered an indirect cost, an additional analysis was conducted that included these as a direct non-medical cost. Analyses were also conducted that split the sample into patients with and without a mechanical heart valve, and by length of time on warfarin therapy at baseline.

RESULTS

Baseline Characteristics

The baseline characteristics of the 2914 patients in this analysis are reported in Table 1; the statistical comparisons are between HQACM and weekly PST only. Overall, all groups were similar at baseline. Differences between the HQACM and weekly PST groups that reached statistical significance were small and unlikely to be clinically meaningful; for example, the percentage of Hispanic/Latino participants in the HQACM and PST once-weekly groups was 6 and 8 %, respectively.

Costs and Health Utility

Mean health care utilization, costs, and quality of life for all groups are summarized in Table 2. The total cost per patient over 2 years of follow-up was similar between HQACM and weekly PST ($32,484 for HQACM vs. $33,460 for once-weekly PST), but larger for PST every 4 weeks and twice-weekly PST. While the mean differences in costs and the subcomponents of costs shown ion Table 2 were relatively small, all of the distributions of these costs were skewed, and most of the differences were statistically significant when the natural logarithms of costs were compared. The difference between HQACM and weekly PST was $975 (95 % CI, −$2074 to $4025; $p = 0.53$). The change from the $1249 difference reported previously[7] is due to the exclusion of the sub-study patients.

After the costs associated with home monitoring were excluded, the costs for the weekly PST patients were slightly lower than those for HQACM; the cost per patient of the meters, supplies, and monitoring averaged $1605. Consistent with the elimination of the monthly HQACM clinic visits, the only significant difference in utilization between HQACM and weekly PST was 21 fewer outpatient visits, for which the weekly PST patients incurred an average of $1230 less in costs. The other PST groups also had reduced outpatient visits.

Cost–Utility

The cumulative gain in HUI scores[19] was greatest for weekly PST (1.23) and lowest for HQACM (1.05), the difference between which was statistically significant (0.176; 95 % CI, 0.131 to 0.221; $P < 0.001$). At 2 years of follow-up,

Table 1 Baseline Characteristics

Characteristic	HQACM ($n=1452$)	Weekly PST ($n=1228$)	PST every 4 weeks ($n=116$)	PST twice weekly ($n=118$)	*P* value‡
Male gender, no. of patients (%)	1426 (98 %)	1207 (98 %)	114 (98 %)	117 (98 %)	0.87
Age, years					
Mean (SD)	67.4 (9.4)	66.6 (9.7)	66 (10.1)	67 (9.5)	0.07
Range	33–99	32–89	23–86	32–87	
Ethnicity, Hispanic/Latino, no. of patients (%)	90 (6 %)	101 (8 %)	3 (3 %)	4 (3 %)	0.04
Race*, no. of patients (%)					
White	1343 (92 %)	1139 (93 %)	105 (91 %)	101 (85 %)	0.80
Black	76 (5 %)	69 (6 %)	10 (9 %)	15 (13 %)	0.66
Highest level of education, no. of patients (%)					0.10
Grades 1–8	62 (4 %)	47 (4 %)	3 (3 %)	7 (6 %)	–
Grades 9–11	122 (8 %)	80 (7 %)	4 (3 %)	12 (10 %)	–
High school graduate	411 (28 %)	392 (32 %)	32 (28 %)	25 (21 %)	–
Some college but no degree	446 (31 %)	395 (32 %)	42 (36)	48 (40 %)	–
Undergraduate degree	296 (20 %)	217 (18 %)	22 (19 %)	22 (18 %)	–
Postgraduate degree	115 (8 %)	97 (8 %)	13 (11 %)	5 (4 %)	–
Number of household members	2.1 (1)	2.1 (1)	2.1 (1)	2.1 (1)	0.50
Transport to clinic, did not drive self, no. of patients (%)	229 (16 %)	182 (15 %)	21 (18 %)	24 (20 %)	0.50
Months of anticoagulation treatment, no. of patients (%)					0.56
<3	126 (9 %)	102 (8 %)	5 (4 %)	8 (7 %)	–
3 to 6	99 (7 %)	70 (6 %)	6 (5 %)	8 (7 %)	–
> 6 to 12	106 (7 %)	83 (7 %)	6 (5 %)	8 (7 %)	–
> 12	1121 (77 %)	973 (79 %)	99 (85 %)	95 (80 %)	–
Cardiac disorders, no. of patients (%)					
Atrial fibrillation	1216 (84 %)	1008 (82 %)	96 (83 %)	95 (80 %)	0.25
$CHADS_2$ score, no. of patients and % of those with atrial fibrillation only					0.48†
0	110 (5 %)	112 (5 %)	7 (8 %)	8 (9 %)	–
1	328 (16 %)	269 (13 %)	25 (29 %)	29 (33 %)	–
2	354 (17 %)	280 (14 %)	27 (31 %)	19 (22 %)	–
3	206 (10 %)	163 (8 %)	16 (18 %)	20 (23 %)	–
4	82 (4 %)	78 (4 %)	8 (9 %)	10 (11 %)	–
5	36 (2 %)	30 (1 %)	4 (5 %)	0 (0 %)	–
6	2 (0 %)	5 (0 %)	0 (0 %)	1 (1 %)	–
Mean	1. 94	1. 93	2.06	1.99	0.82
Mechanical heart valve	333 (23 %)	290 (24 %)	29 (25 %)	32 (27 %)	0.68
Aortic	256 (18 %)	234 (19 %)	19 (16 %)	25 (21 %)	0.34
Mitral	89 (6 %)	72 (6 %)	11 (9 %)	8 (7 %)	0.77
Other valve	0 (0 %)	0 (0 %)	0 (0 %)	0 (0 %)	–
Arrhythmia, not atrial fibrillation	159 (11 %)	136 (11 %)	8 (7 %)	14 (12 %)	0.92
Congestive heart failure	431 (30 %)	328 (27 %)	37 (32 %)	39 (33 %)	0.09
Angina	254 (17 %)	203 (17 %)	17 (15 %)	21 (18 %)	0.51
Diabetes mellitus, no. of patients (%)	491 (34 %)	393 (32 %)	41 (35 %)	37 (31 %)	0.32
Hypertension, no. of patients (%)	1006 (69 %)	864 (70 %)	88 (76 %)	89 (75 %)	0.55
Previous stroke, no. of patients (%)	140 (10 %)	117 (10 %)	9 (8 %)	10 (8 %)	0.92
Average weekly warfarin dose (mg)	36.1 (15.9)	36.6 (16.1)	40.2 (16.3)	39.1 (18.3)	0.56
Median	35	35	40	35	–
Range	5 - 112	5 – 122.5	14–90	3.2–135	–
Antiplatelet medication, no. of patients (%)					
Aspirin	390 (27 %)	325 (26 %)	31 (27 %)	41 (34 %)	0.81
Clopidogrel	20 (1 %)	20 (2 %)	3 (3 %)	1 (1 %)	0.59
Ticlopidine	1 (0 %)	0 (0 %)	0 (0 %)	0 (0 %)	1.00
Amiodarone	112 (8 %)	97 (8 %)	11 (9 %)	10 (8 %)	0.86

**Given subject could be tallied under more than one race category*
†Chi-square test for distribution by integer score (0 through 6)
‡ P values compare HQACM with weekly PST only
HQACM high-quality anticoagulation management, PST patient self-testing

satisfaction with anticoagulation as measured by DASS (lower value indicates higher satisfaction) had a test frequency gradient that was best for twice-weekly PST (45.3) and worst for HQACM (49.2). The difference in DASS scores between the weekly PST and HQACM groups was statistically significant (difference, −2.3; 95 % CI,−3.9 to−0.8; $P=0.003$).

The bootstrapped cost-effectiveness region for the incremental cost per QALY gained associated with once-weekly PST compared to HQACM was $5566 (95 % CI, $-11,490 to $25,142) (Fig. 2). All of the bootstrapped QALY differences were positive (once-weekly PST preferred to HQACM). Seventy-three percent of cases are located in the upper right quadrant, indicating that PST is more costly and more effective than conventional management. The remaining 27 % of cases are located in the lower right quadrant, indicating that weekly PST is dominant (i.e., less costly and more effective) compared to HQACM.

The cost–utility comparisons between the different study arms are reported in Table 3. The results are sensitive to test frequency; weekly PST strictly dominated PST once every 4 weeks and twice weekly (i.e., weekly PST was both less expensive and more effective).

Table 2 Mean per-patient costs and utilization

	HQACM *N* = 1452	Weekly PST *N* = 1228	PST every 4 weeks *N* = 116	PST twice weekly *N* = 118	*P* value†
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	
Grand total (2 years)	$32,484 ($39,010)	$33,460 ($41,389)	$41,596 ($49,624)	$40,700 ($56,675)	0.53
Annualized cost per person*	$16,242 ($19,505)	$16,730 ($20,694)	$20,798 ($24,812)	$20,350 ($28,338)	0.53
Cost without meter	–	$16,199 ($20,695)	$20,261 ($24,813)	$19,813 ($28,337)	–
Cost of meter	–	$900 ($0)	$900 ($0)	$900 ($0)	–
Cost of supplies	–	$408 ($148)	$122 ($53)	$674 ($322)	–
Cost of training, monitoring and assessment	–	$297 ($152)	$219 ($86)	$298 ($165)	–
Acute inpatient costs	$11,331 ($26,203)	$11,838 ($31,503)	$16,785 ($36,273)	$15,416 ($37,442)	0.65
Acute inpatient utilization (days)	5.59 (15 59)	6.15 (18.35)	7.59 (17.50)	7.98 (24.42)	0.40
Other inpatient cost	$1110 ($8143)	$811 ($6308)	$3054 ($10,082)	$4094 ($27,682)	0.28
Other inpatient utilization (days)	2.99 (30.32)	1.55 (13.56)	7.71 (22.71)	12.32 (85.01)	0.10
Outpatient cost	$16,458 ($16,937)	$15,228 ($13,952)	$17,256 ($17,025)	$16,943 ($19,226)	0.04
Outpatient visits	92.08 (57.51)	70.7 (50.7)	70.00 (52.84)	75.55 (76.62)	<0.001
Outpatient pharmacy cost	$3622 ($3728)	$3817 ($3702)	$4836 ($7046)	$4131 ($3922)	0.18
DASS score at 2 years*	49.2 (17.9)	46.9 (16.1)	47.2 (19.3)	45.3 (16.2)	0.003
2-year HUI	1.05 (0.62)	1.23 (0.56)	1.06 (0.63)	1.11 (0.61)	<0.001

**Not all patients had a DASS at 2 years. These data are for the 962 PST and 929 HQACM patients with a 2-year DASS*
†P values compare HQACM with weekly PST only
HQACM high-quality anticoagulation management, PST patient self-testing, DASS Duke Anticoagulation Satisfaction Scale

Sensitivity Analysis

To test the assumptions of the analyses, extensive sensitivity analyses were conducted, the results of which are reported in the online Appendix. The results were robust to large changes in QALY gains. The results were more sensitive to changes in costs, but increasing the cost differential by one standard deviation increased the ICER to only $14,381. If the meter costs are amortized over the 5 years that the Centers for Medicare and Medicaid Services use as the basis for reimbursement for home INR monitoring, the ICER decreases to $2477. Including patient travel costs as a non-medical direct cost decreases the ICER to $4914. The ICER was lower for patients with a mechanical heart value ($2753) than for those with atrial fibrillation only ($6641). The ICER was higher for patients who had been on warfarin for fewer than 12 months at baseline ($8584) than for those who had been on warfarin for greater than 12 months ($5041).

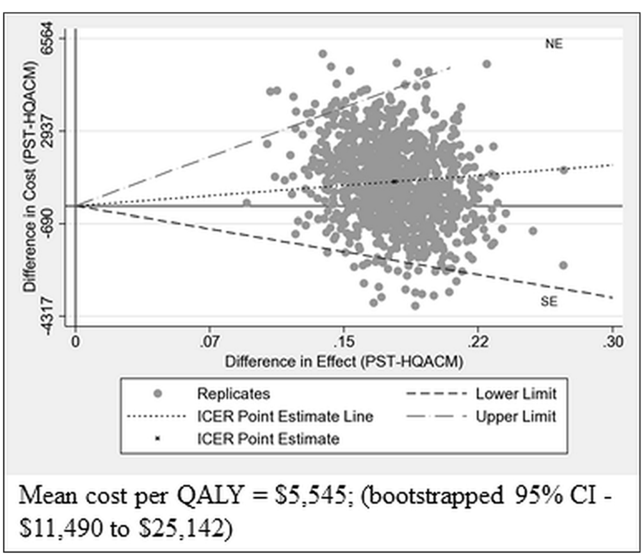

Figure 2 Bootstrapped scatterplot of the incremental cost-effectiveness ratio (ICER) for the weekly patient self-testing (PST) and monthly testing via high-quality anticoagulation management (HQACM) groups

DISCUSSION

The results of THINRS, the largest trial to date of point-of-care INR testing, found a negligible difference between PST and HQACM in preventing major clinical outcomes. However, THINRS showed that PST yielded modest improvements in time in therapeutic range, quality of life, and patient satisfaction with anticoagulation therapy.[6] The average gain in HUI (about 0.09 QALYs per year) for the once-weekly PST group is well above the recognized minimum value of 0.03 for a clinically meaningful difference.[24,25] This gain came at an additional cost of less than $1000, resulting in an ICER of $5566, which is well below the commonly accepted standard for cost-effectiveness of $50,000 per QALY.[26] In fact, given that approximately one quarter of the bootstrapped replications showed net cost savings, it is possible that this technology could save money while improving quality of life. Together, these results show that home INR monitoring is a cost-effective technology that should be considered for those who demonstrate PST competence.

The results were robust to sensitivity analyses for the key assumptions; the largest ICER from the sensitivity analyses was $14,381. The results are more sensitive to changes in costs than to changes in outcomes. Results varied somewhat for different subgroups, but remained cost-effective for all. Compared to weekly PST, no benefit in QALYs or cost was observed for more or less frequent PST, suggesting that weekly testing is a reasonable default frequency for PST.

Table 3 Cost Effectiveness by PST Frequency

	2-year total cost	Effectiveness (2-year quality-adjusted life years [QALYs])	Incremental cost vs. next less costly intervention	Incremental effectiveness vs. next less costly intervention	Incremental cost-effectiveness ratio (ICER)
HQACM	$32,484	1.051	–	–	–
PST weekly	$33,460	1.226	$974	0.175	$5566/QALY*
PST twice weekly	$40,700	1.112	$7240	−0.114	Dominated
PST every 4 weeks	$41,596	1.050	$896	−0.062	Dominated

*The upper 95 % confidence interval for ICER based on bootstrap is $25,142/QALY
HQACM high-quality anticoagulation management, PST patient self-testing

Given that the major clinical event rate did not differ significantly between groups, it is likely that the gains in QALYs for the weekly PST group were associated with the observed improvement in patient satisfaction with anticoagulation management (as measured by DASS), the reduction in clinic visits for INR monitoring, and perhaps an increased sense of patient empowerment and control.

It is notable that the ICER for PST versus HQACM is likely to be a conservative estimate. As noted above, in the main analysis, the full cost of the meter was amortized over 2 years and did not include patient travel costs or quality-of-life gains beyond 2 years. Sensitivity analyses showed that relaxing the two cost assumptions reduced the ICER to $1829. Sensitivity analyses that included changes in quality of life beyond 2 years were not conducted, as assumptions about such changes would have been conjecture. However, the sensitivity analyses that varied the changes in utilities as measured by HUI indicated that any changes would probably be modest. Also, while the cost of travel was considered in a sensitivity analysis, patient time was not. Patient time cost is usually considered a productivity cost and thus not included in a cost-effectiveness analysis, but some have argued that such costs are direct non-medical costs, and have advocated for of this class of patient time costs.[27] Had the time for patient travel or any other patient time costs that were not measured been included in the cost calculation, the ICER would have been even more attractive for PST.

The feature of this analysis that one might argue most substantially biases the results against PST is that only evidence from THINRS was included, in which no statistically significant benefit was seen in major events: stroke, major bleed, or death. Based on evidence that "usual care" is often suboptimal,[4] and that the control subjects were managed by anticoagulation clinics that met standards for high-quality management, it is reasonable to conjecture that this could have reduced events in the control subjects. A meta-analysis that pooled individual patient data, which included data from THINRS, suggests that PST may indeed reduce the incidence of major events. If PST actually does reduce major events, then the ICER would be even more attractive for PST, and possibly even dominant (i.e., offering better outcomes at lower costs).[9].

One limitation of this study is that all participants came from the VA population. While the care provided by the VA is reflective of mainstream US medical care, the patient population differs from the general population in several ways. Most notably, the VA population is predominately male and comprises relatively few minorities. Furthermore, VA patients tend to have more comorbid conditions and lower income, but similar educational achievement, compared to the general population. The age-adjusted education attainment of THINRS patients was actually somewhat higher than that of non-veterans.[28] However, it is unclear how these differences may have influenced results. Other data have shown that the overall VA warfarin prescription rate is consistent with North American norms.[29] One can only speculate whether a more broadly representative population would have experienced an even greater improvement in quality of life from PST over conventional in-clinic testing.

Anticoagulation with warfarin remains well established as an effective treatment for thromboembolism. One traditional challenge to its use has been the need for frequent patient visits for testing and dose adjustment. This study provides important evidence that the improvement in quality of life associated with self-testing can be achieved at a reasonable cost. These results support further efforts to expand the availability of technologies that engage patients in their care.

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Compliance with Ethical Standards:

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