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UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science

DOCTOR OF NURSING PRACTICE PORTFOLIO

by

Anisa Munshi, BSN

A portfolio presented to the

FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
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In partial fulfillment of the
requirements for the degree

DOCTOR OF NURSING PRACTICE
May 2015

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Clinical effectiveness of INR patient self-testing: Adults on warfarin therapy in private practice

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1825 words in text; 1 table and 2 figures.

Background: Warfarin is the most commonly prescribed oral anticoagulant for the prevention and treatment of venous thromboembolism. Due to its narrow therapeutic index, warfarin requires close monitoring of the international normalized ratio (INR) to ensure proper anticoagulation control and safety. INRs outside of this range are strongly associated with an increased risk of major bleeding, thromboembolic events, and death. Patient self-testing (PST) using a point-of-care device allows patients to monitor INR results at home. Evidence shows that PST improves the clinical outcomes of warfarin therapy compared to usual care, which includes laboratory INR monitoring. **Purpose:** To compare the clinical effectiveness of INR patient self-testing in adults on warfarin therapy versus usual care in an internal medicine practice. **Conclusions:** On average, PST achieved tighter anticoagulation control compared to usual care. PST provided more consistent and less variable INR results within the therapeutic range. These findings are clinically and statistically significant, suggesting the clinical efficacy of PST. **Clinical Implications:** These outcomes warrant the comparison of different INR meters, in terms of patient choice and satisfaction.

KEY WORDS: INR, warfarin, anticoagulation, patient self-testing, home monitoring, point-of-care device

Background

Warfarin is the most commonly prescribed oral anticoagulant for the prevention and treatment of venous thromboembolism associated with chronic atrial fibrillation and mechanical heart valves [1]. Due to its narrow therapeutic index, warfarin requires regular monitoring of the international normalized ratio (INR) to ensure proper anticoagulation control [2]. The INR therapeutic range for anticoagulation therapy is between 2.0 and 3.0, except for mechanical heart valves, which require an INR between 2.5 and 3.5. INRs outside of this range are strongly associated with an increased risk of major bleeding, thromboembolic events, and even death [3]. Laboratory monitoring of warfarin therapy, known as usual care, includes repeated venous punctures to obtain INR results and subsequent dose adjustments by the health care provider [4].

Using conventional measures, frequency of INR monitoring is problematic in ambulatory care. A research study showed that gaps in monitoring during warfarin therapy are associated with poor anticoagulation control and adverse events [5]. The data related gaps to non-adherence with INR monitoring and identified patient-level predictors, which included poverty, driving distance, dementia, depression, and nonwhite race. Another study evaluated patient non-adherence to standard INR testing and found that the rate of thromboembolic events was higher in the non-adherent group compared to the adherent group [6]. Non-adherence to INR monitoring is a common and significant barrier to proper anticoagulation control.

The option of patient self-testing (PST) using a point-of-care (POC) device has eliminated some of these barriers by enabling patients to test their INR levels at home via a fingerstick blood sample, compared to outpatient visits to a laboratory or clinic. The POC device communicates the INR result to the patient's provider wirelessly, through a secured website, and the provider adjusts the patient's warfarin dose accordingly. Another option of patient self-

management (PSM) is available, in which patients are trained to self-test and interpret the INR result for dose adjustment.

Systematic reviews have shown PST/PSM to be superior to usual care with fewer bleeding events and thromboembolic events, as well as reduced overall mortality [7-11]. Therefore, evidence-based clinical practice guidelines recommend PST/PSM to all suitable patients receiving oral anticoagulation therapy [3, 12]. In this study, PST alone was implemented and its effects analyzed.

Methods

Scope of the Problem

In January 2010, the clinical problem of non-therapeutic INRs in patients receiving warfarin therapy was identified at a private practice setting in the southwest region of the United States. The scope of the problem was appreciated after collecting INR results from contracted laboratories over a 15-month period and calculating the average INR per quarter, or every three months. Infrequent and inconsistent INR testing was the main factor contributing to non-therapeutic levels. Therefore, PST was proposed as a solution to the problem.

Patient Recruitment

The practice setting's providers offered PST to patients if they met the following inclusion criteria: indication for long-term warfarin therapy, such as chronic atrial fibrillation, mechanical heart valve, and/or history of deep vein thrombosis; taking warfarin for at least 6 months; and willingness to participate in PST. Exclusion criteria included inability to perform the test, due to factors such as poor coordination with hand tremor or poor visual acuity, and denial of health insurance coverage for the device and PST-related billing expenses.

Training

Providers referred eligible patients to the practice setting's nurse practitioner who provided hands-on device training during a 45- minute consultation appointment. At the end of the appointment, the nurse practitioner assessed the patient's competency via a return demonstration. At the conclusion of the visit, the nurse practitioner provided the patient with a meter reference manual as well as contact information if questions or problems occurred.

Online System

Once the POC device was received, all participating patients were instructed to test their INR level at least once a week for the first month, or until therapeutic, and biweekly thereafter. INR results were communicated to the provider via fax, phone call, and wirelessly through a secured online system. If the result was above or below the prescribed therapeutic range, the online system alerted the provider via phone call, requesting the provider to contact the patient within 24 hours for warfarin dose adjustment. Provider telephone support was available to the patients at all times.

Patients and providers were able to access the online system to view INR results. The system also stored patient information such as demographics, indication for therapy, insurance carrier information, provider, and past INR results. Information was only available to patients and providers through a password-protected website.

Data Collection

Patient data were collected and analyzed from January 2010 to September 2014. Patient data, including age, gender, indication for warfarin therapy, INR results, provider, and insurance carrier, were collected from electronic medical records. Regardless of each patient's start date, INR results were collected for at least six months before and after PST implementation. Using

Microsoft excel, INR results were organized by pre and post-PST implementation and the averages were calculated every three months (quarterly) for data concision. INR averages were analyzed using QI Macros software and X-bar-S control charts were created.

Results

Of the 36 patients recruited for this project from January 2010 to September 2014, eight patients were excluded due to PST noncompliance, no longer being patients of the practice, or death. A total of twenty-eight patients remained and were included in the analysis.

Table 1 Descriptive analysis

Group	# of observations	Mean	Min	Max
Males	28	0.54	0.00	1.00
Age	28	71.80	26.84	91.31
Lab INR measurements	25	8.96	1.00	33.00
Meter INR measurements	28	87.93	7.00	228.00

Table 1 provides descriptive information about the sample used in the analysis. Males made up 54% of the patients, and the average age of patients was 72 years (range 27 to 91 years). In laboratory monitoring, 25 out of 28 patients had their INRs measured an average of 9 times before receiving the meter for PST monitoring. During meter monitoring, all 28 patients measured their INRs 88 times, on average, which is significantly greater than laboratory monitoring frequency ($p<0.001$). Overall, PST increased the frequency of INR monitoring.

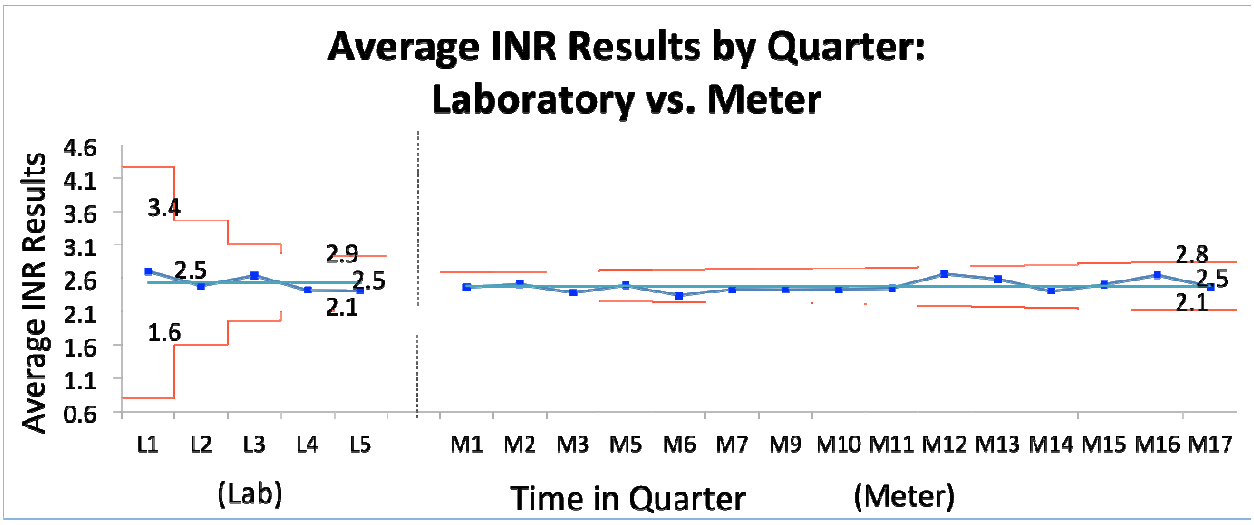

Fig. 1 X-bar-S Control Chart Displaying Process Control for Laboratory Versus Metered INR Monitoring

The X-bar-S control chart plots the process mean and process standard deviation for patients to help determine the stability of INR measurements over time. The X-bar-S control chart is reported in Figure 1 and serves as an indicator of whether PST provided an improved and consistent process over time compared to usual care. The dashed vertical line represents the point at which PST was implemented and metered monitoring began, separating the laboratory INR measurements from the metered INR measurements. In Figure 1, time (represented by the x-axis) is partitioned into quarters with an "L" preceding the quarter number if data were collected when patients were monitoring their INRs in a laboratory setting or an "M" preceding the quarter number if data were collected using metered monitoring to measure their INRs. The mean of INRs is represented by the middle turquoise line, which shows an INR mean measurement of approximately 2.5 in laboratory monitoring as compared with an INR mean measurement of approximately 2.4 in metered monitoring. The upper and lower control limits are calculated as three standard deviations above and below the mean, respectively. These limits are represented by two red lines indicating an upper limit of 3.4 and a lower limit of 1.6 in laboratory monitoring as compared with an upper limit of 2.8 and a lower limit of 2.1 in metered monitoring. The

narrowing of control limits towards the therapeutic range over time (from laboratory monitoring to metered monitoring) indicates that metered monitoring is associated with greater control of patients' INR measurements within a desirable range. In comparison, laboratory monitoring has a larger spread between its upper and lower control limits with variable results, suggesting a poorly controlled process. In sum, average INRs in PST using metered monitoring are better controlled than in usual care using laboratory monitoring. Overall, Figure 1 shows that metered monitoring is associated with a more stable process as compared with laboratory monitoring, with resulting INR measurements occurring within a more desirable range.

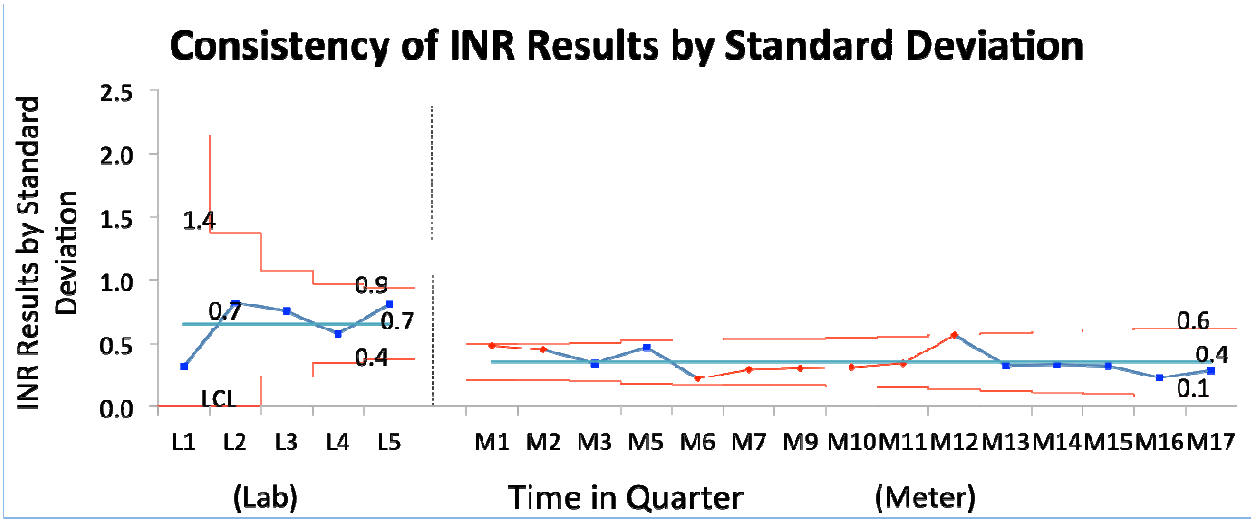

Fig. 2 X-bar-S Control Chart Displaying Process Consistency of Laboratory Versus Metered INR Monitoring

Figure 2 depicts the relative consistency of INR results by comparing the standard deviations of laboratory data with those for metered monitoring. In the laboratory monitoring phase, represented by quarters L1 to L5, there is more variation as seen by the larger upper and lower controls limits as compared with the metered monitoring phase, which is represented by quarters M1 to M17. After PST implementation, depicted by the dashed line, there is less variation in the metered monitoring phase as indicated by the narrower upper and lower control limits. The red points indicate statistical significance, which are seen immediately in quarters M1

and M2. The trend of red points seen in quarters M6 to M12, indicates consistent and statistically significant INR results. Although consistency slips in M3 to M5 and again after M13, metered monitoring still provides dramatically more consistent INR results compared to the INR results collected during laboratory monitoring.

Discussion

The results of this analysis provide insight to the quality of INR control in patients who self-test, as well as the clinical efficacy of warfarin therapy. Additionally, the data from the analysis allows a comparison of the quality of INR control between PST and usual care.

Since major adverse events and death could not be attributed to a confirmable cause in the data, no analysis on the rate of major thromboembolic or bleeding events could be completed. Thus, it is not possible to compare the rate of events in this data to the rate of newer oral anticoagulants reported in studies. Furthermore, this analysis is based on data collected in clinical practice, not in the controlled setting of a randomized controlled trial.

The mean frequency of INR testing was higher in PST using metered monitoring (88 times) than in usual care using laboratory monitoring (9 times). Testing frequency is strongly correlated with INR control. Therefore, PST was found to be more efficient in maintaining INR control and potentially reducing major adverse and fatal events, compared to usual care. Moreover, the frequency of critical INR values is an important indicator of the effectiveness of warfarin therapy. Critical INR values are defined as those below 1.5, carrying a major risk of a thromboembolic event, and those above 5.0, carrying a major risk for a bleeding event [13, 14]. In Figure 1, the frequency of near-critical values is observed in the laboratory (usual care) data set with the lower control limit of 1.6. There are no critical values seen in the metered (PST) data set as the lower and upper control limits are within therapeutic range, 2.1 and 2.8, respectively. This

suggests that PST is able to achieve tighter INR control within the defined therapeutic range of 2.0 to 3.0.

Conclusion

Overall, this project showed that PST was clinically more effective in INR monitoring than usual care in our internal medicine practice. PST achieved tight INR control within therapeutic range, improved therapeutic efficacy of warfarin, and enhanced treatment safety for patients. Thus, PST should be offered and recommended as a vital element of INR monitoring of long-term warfarin therapy.

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EFFECTIVENESS OF INR PATIENT SELF-TESTING: ADULTS ON WARFARIN THERAPY IN INTERNAL MEDICINE

PURPOSE:
To compare the clinical effectiveness of INR patient self-testing in adults on warfarin therapy versus usual care in an internal medicine practice.

BACKGROUND:
Warfarin is the most commonly prescribed oral anticoagulant for the prevention and treatment of venous thromboembolism. Due to its narrow therapeutic index, warfarin requires close monitoring of the international normalized ratio (INR) to ensure proper anticoagulation control and safety. INRs outside of this range are strongly associated with an increased risk of major bleeding, thromboembolic events and even death. Patient self-testing (PST) using a point-of-care device allows patients to monitor their INR results from home. Evidence shows that PST improves the clinical outcomes of warfarin therapy compared to usual care, which includes laboratory INR monitoring.

METHODS:

Included competent and motivated adult patients with AF and/or DVT taking warfarin therapy for at least 6 months. Excluded those unable to self-test or denied health insurance coverage for PST-related expenses. The clinic Nurse Practitioner provided hands-on meter training and set-up to eligible patients. Competency and willingness to participate were assessed. Age, gender, insurance carrier, provider, indication for warfarin therapy and INR results were collected from January 2010 to September 2014. Quarterly INR averages (every 3 months) were calculated for data concision using Microsoft Excel. Control charts were created using QI Macros to compare laboratory INR data (usual care) to meter INR data (PST).

OUTCOMES:
In laboratory (usual care) monitoring, control limits are wide and INR results are variable, no statistically significant INR averages resulted. In meter (PST) monitoring, control limits are narrow and INR results are tightly controlled, resulting in statistically significant INR averages.

CONCLUSIONS:
Compared to usual care, PST resulted in tighter control of patients' INR measurements within a desirable range. PST provides a consistent process as well as a higher frequency of INR testing. As recommended by evidence-based practice guidelines, PST should be offered to suitable patients.

Effectiveness of INR Patient Self-testing: Adults on Warfarin Therapy in Internal Medicine

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BACKGROUND

Warfarin

- Most commonly prescribed oral anticoagulant
- Prevents and treats venous thromboembolism associated with atrial fibrillation (AF) and deep vein thrombosis (DVT)
- Most implicated medication responsible for adverse events in the U.S.

INR Therapeutic Range

- The international normalized ratio (INR) is a blood test that monitors the therapeutic effect of warfarin
- INR therapeutic range for AF and DVT is 2.0 – 3.0
- Patients on warfarin only spend half of the time within therapeutic range
- INRs outside of therapeutic range are strongly associated with a risk of major bleeding, thromboembolic events and death

PRACTICE INNOVATION

Practice Setting Problem

- Non-therapeutic INRs due to infrequent and inconsistent laboratory monitoring (usual care)

Patient Self-Testing (PST)

- Allows patients to test their INR from home using a meter
- Systematic reviews show that PST is superior to usual care by an overall reduction of adverse events
- Evidence-based clinical practice guidelines recommend PST

OBJECTIVE

To compare the clinical effectiveness of INR patient self-testing in adults on warfarin therapy versus usual care in an internal medicine practice.

METHODS

Inclusion/Exclusion Criteria

- Included competent and motivated adult patients with AF and/or DVT taking warfarin therapy for at least 6 months
- Excluded those unable to self-test or denied health insurance coverage for PST-related expenses

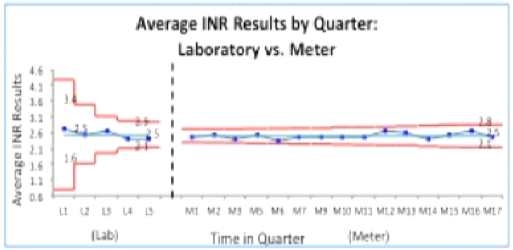
PST Training

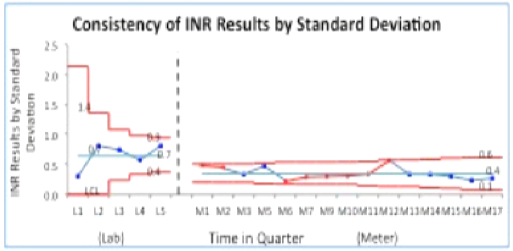
- Clinic Nurse Practitioner provided hands-on meter training and set-up to eligible patients
- Competency and willingness to participate were assessed

Data Collection & Analysis

- Age, gender, insurance carrier, provider, indication for warfarin therapy and INR results were collected from January 2010 to September 2014
- Quarterly INR averages (every 3 months) were calculated for data concision using Microsoft Excel
- Control charts were created using QI Macros to compare laboratory INR data (usual care) to meter INR data (PST)

RESULTS





RESULTS

Figure 1

- Laboratory (usual care) monitoring – control limits are wide and INR results are variable
- Meter (PST) monitoring – control limits are narrow and INR results are tightly controlled

Figure 2

- Meter (PST) monitoring – resulted in statistically significant INR averages and a running trend (red points)
- Laboratory (usual care) monitoring – no statistically significant INR averages resulted

CONCLUSION

- Compared to usual care, PST resulted in tighter control of patients' INR measurements within a desirable range
- PST provides a consistent process and a higher frequency of INR testing
- As recommended by evidence-based practice guidelines, PST should be offered to suitable patients

Stakeholders' Powerpoint

CLINICAL EFFECTIVENESS OF INR PATIENT SELF-TESTING: ADULTS ON WARFARIN THERAPY IN INTERNAL MEDICINE

Anisa Munshi, DNP-FNP, BSN-RN
Karen Macauley, PhD, DNP, FNP-BC, GNP-BC

BACKGROUND

- **Warfarin**
  - Prevents and treats venous thromboembolism associated with atrial fibrillation (AF), mechanical heart valves (MHV), and deep vein thrombosis (DVT)
- **INR Therapeutic Range**
  - INR is a blood test that monitors warfarin's therapeutic effect
  - Therapeutic range for AF & DVT is 2.0 – 3.0, and MHV is 2.5 – 3.5
  - This narrow therapeutic range requires frequent and consistent INR monitoring

SYNOPSIS OF EVIDENCE

- **Warfarin**
  - Most commonly prescribed oral anticoagulant
  - Most implicated medication responsible for adverse events in the U.S.
- **INR Therapeutic Range**
  - Patients spend only half of the time within therapeutic range
  - INRs outside of therapeutic range are strongly associated with a risk of major bleeding, thromboembolic events and death
- **Usual care**
  - Rate of thromboembolic events was higher in patients who were non-adherent to usual care
  - Gaps in INR monitoring during warfarin therapy are associated with poor anticoagulation control and adverse events

EVIDENCE-BASED INTERVENTION

- **Practice Setting Problem**
  - Non-therapeutic INRs due to infrequent and inconsistent laboratory monitoring (usual care)
- **Patient Self-Testing (PST)**
  - Allows patients to test their INR from home using a meter
  - Frequent INR measurements improves control of anticoagulation therapy
  - Systematic reviews show that PST is superior to usual care by an overall reduction of adverse events
  - Evidence-based clinical practice guidelines recommend PST instead of usual care

BENCHMARKS

- Baseline assessment
  - January 2010: INRs were in therapeutic range only 49% of the time
- Goal
  - Increase time spent within therapeutic range > 70%
  - Research shows that time spent within therapeutic range > 70% are associated with improved outcomes

PICO QUESTION

For adult patients on warfarin therapy, is INR patient self-testing more effective at maintaining INRs within therapeutic range than usual care in private practice?

PROJECT PLANNING PROCESS

- **Training**
  - Practice setting's nurse practitioner provided patients with hands-on meter training and set-up
  - Competency and willingness to participate were assessed
  - Reference materials were provided
- **Sample size**
  - 36 patients recruited
  - 28 patients remained
  - Indication: AF

Group	# of observations	Mean	Min	Max
Males	28	0.54	0.00	1.00
Age	28	71.80	26.84	91.31
Lab INR measurements	25	8.96	1.00	33.00
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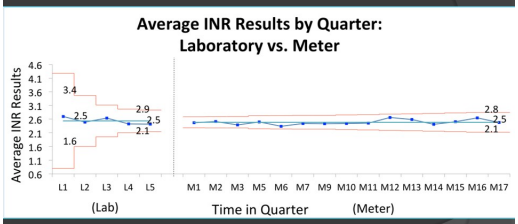
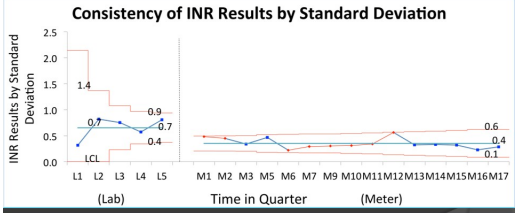
RESULTS



RESULTS (cont.)



COST/BENEFIT RATIO

- **Insurance Coverage**
  - Medicare and PPO provides coverage for PST-related costs
  - HMO does not
  - Some patients stopped participating in PST due to out-of-pocket expenses such as cost of strips, that were covered by Medicare
- **Limitations**
  - Transportation costs
  - Hospital costs related to adverse events associated with usual care vs. PST

CONCLUSION

- Compared to usual care, PST resulted in tighter control of patients' INR measurements within a desirable range

IMPLICATIONS FOR PRACTICE

- PST provides a consistent process and a higher frequency of INR testing
- As recommended by evidence-based practice guidelines, PST should be offered to suitable patients

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